INFECTION PREVENTION AND PATIENT SAFETY

REFERENCE MANUAL FOR SERVICE PROVIDERS AND MANAGERS IN HEALTHCARE FACILITIES OF ETHIOPIA

FEDERAL MINISTRY OF HEALTH

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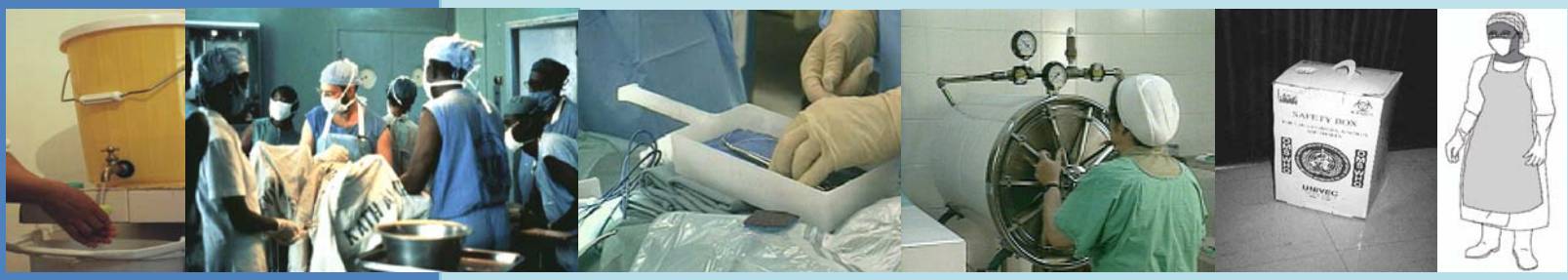


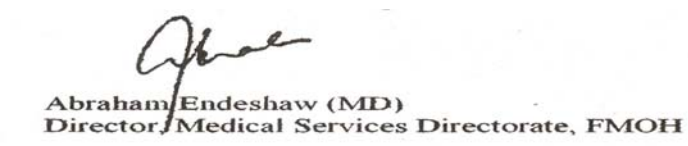
FOREWORD

In Ethiopia, effort being made to improve the healthcare provision to citizens is increasing in all aspects of health ranging from the basic family health to the chemotherapy for public threats like AIDS. Among multitude of initiatives currently underway, the protection of patients and healthcare workers from infections in health facilities has been given particular attention by the Federal Ministry of Health. It is known that infection prevention is a critical component of quality health services. In this respect, the Ministry is indeed scaling-up its activities related to health facility related infection prevention and patient safety and will make use of all opportunities to strengthen ongoing activities directed to it. As in many of its programs, the undertakings of the Ministry pertaining to this special goal largely depends on the current scientific evidences to establish optimal infection prevention and patient safety practices or processes in health facilities.

Globally, a significant proportion of healthcare providers and patients/clients acquire nosocomial (Healthcare facility-associated/acquired) infections. The situation tends to persist causing a real threat to healthcare providers and community at large and at times demand additional cost to the patient in particular and the healthcare system in general. Furthermore, with an inadequate practice of infection prevention and patient safety, healthcare providers and patients would be at an increased risk of acquiring most serious infections like HIV, HBV, HCV, multidrug-resistant TB and other emerging and re-emerging bacterial or viral infections. Fortunately, most nosocomial infections in healthcare facilities can be prevented with readily available, relatively inexpensive and simple strategies.

In Ethiopia, where many health care settings are resource constrained, the control of the risk of acquiring nosocomial infections is a bit challenging. Because, for the control measure or practice to kick into action, material, human power, training, policy, and guideline would certainly be necessary. Infection prevention and patient safety in healthcare settings is therefore, a broad and cross-cutting component of healthcare which involves every aspect of patient care, food hygiene, housekeeping, laundry service, healthcare waste management and a lot others.

This infection prevention and patient safety reference manual is intended to primarily serve healthcare providers and managers. This manual is believed to aid the target users by way of providing clear guidance in the provisions of standard infection prevention and patient safety practices in their respective setups. The material is developed by way of incorporating both indigenous experiences and internationally acclaimed standardized recommendations. It is composed of innovative and evidence based methods widely in use all over the world to reduce the incidence of nosocomial infections and the entailing overhead cost of an infection prevention and patient safety program. It is also anticipated that health bureaus, program managers, other stakeholders and interest groups would benefit from consulting this reference manual which embodies a wide spectrum of issues pertaining to prevent infections in different healthcare facilities. Finally, I wish to extend my heartily gratitude for all individuals and institutions that have contributed to the realization of this Reference Manual.



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LIST OF ACRONYMS

ABC	Abacavir
AIA	America Institute of Architecture
AIDS	Acquired Immunodeficiency Syndrome
ARC	AIDS resource center
ART MDT	Antiretroviral Treatment Multidisciplinary Team
ARV	Antiretroviral
AZT	Zidovudine
BPMH	Best Possible Medication History
BSI	Body substance Isolation
BSL	Biosafety level
CDC	Centers for Disease Control and Prevention
DDI	Didanosine
DHHS	Department of health and human service
DMPA	Depot Mediroxy Progesteron Acetate
d4T	Stavudine
EPI	Expanded Program of Immunization
EFV	Efavirenez
HAART	Highly active antiretroviral treatment
HBV	Hepatitis B virus
HCP	Healthcare providers
HBe Ag	Hepatitis Be antigen
HBs Ag	Hepatities B surface antigen
HAIs	Healthcare Associated Infections
HICPAC	Healthcare Infection Control Practices Advisory Committee
HCF	Healthcare Facility
HCP	Healthcare provider
HCWM	Healthcare Waste Management
HCV	Hepatitis C virus
HIV	Human Immunodeficiency Virus
HCW	Healthcare worker
HLD	High level disinfection
IP	Infection Prevention
IPC	Infection Prevention Committee
IUD	Intrauterine device
IAIS	Intra-Amniotic Infection Syndrome
LASA	Look-Alike Sound Alike
Lpr/r	Lopinavir/ritonavir
MDR TB	Multidrug Resistant Tuberculosis
MDT	Multidisciplinary Team
MoH	Ministry of Health
MRN	Medical Record Number
MSDs	Material safety data sheets
nPEP	non occupationnel Post Exposure prophylaxies
NVP	Nevirapine

PEP	Post-exposure prophylaxis
PLWHA	People Living With HIV/AIDS
PMTCT	Prevention of Mother-to-Child Transmission
PPE	Personal protective equipment
ppm	Parts Per Million
PS	Patient Safety
OHSO	Occupational Health and Safety Officer
QUAT	Quaternary ammonium compound
RNA	Ribonucleic acid
SSI	Surgical site infection
SHIV	Simian human immunodeficiency virus
SIV	Simian immunodeficiency virus
SUD	Single-use device
TDF	Tenofovir
TB	Tuberculosis
3TC	Lamivudine
TTI	Transfusion Transmissible Infection
TST	Time, Steam, Temperature
UP	Universal Precautions
VVM	Vaccine Vial Monitor
WHO	World Health Organization

RATIONALE OF THE MANUAL

Since the publication of the first National Infection Prevention Guideline in 2005, considerable progress has been exhibited in understanding and implementing evidence based IP practices in healthcare facilities. However, the recommended evidence based practices, keeps on modifying globally due to incoming scientific findings. In connection with that, it was observed that the existing national IP guideline lack updated information and is inadequate on some important topics. This surely calls for updating the guideline and designing a comprehensive Infection Prevention (IP) and Patient Safety (PS) Reference Manual for Healthcare Facilities in Ethiopia which will give an in depth information on IP and PS. Furthermore, it is anticipated that this manual would be instrumental as one among materials like the Ethiopian Hospital Reform Implementation Guidelines (EHRIG), The National Healthcare Waste Management Guideline and other similar documents

To that effect, great efforts have been put to come up with up-to-date information and practical interventions in the area of serious concerns. In this regard, all of the chapters incorporated in IP and PS have been revised. Furthermore, additional topics like: Tuberculosis (TB) Infection Prevention and Control, Safe Surgery, Medication Safety, Healthcare Risk Management, Client Education on relevant practices and Researches issues have been included as well. This manual purports primarily to provide the practitioners with most appropriate recommendations in the activities of IP and PS putting more emphasis to practices and procedures that could be applicable in the country.

As a document meant for macro level functions, the manual principally can serves as a standardized IP and PS Reference Manual for healthcare providers and managers in all government, private and non-governmental healthcare delivery systems. As an informative, relevant and user-friendly material, it would also be of a considerable resource to health educators, trainers, public health and medical officials. Moreover, it also could serves for pre-service education, group-based training or on the Job learning.

Cognizant of this, the Federal Ministry of Health revitalized the national IP and PS Advisory Technical Working Group (ATWG) in 2009 under the Medical Services Directorate. The group consequently identified the IP and PS gaps and took the initiative to review the existing IP and PS related documents and developed this manual.

BACKGROUND

Healthcare Associated Infections (HAIs) are major public health problems of the globe. According to a prevalence survey conducted on 55 hospitals in 14 developing countries, it was estimated that at any point in time, over 1.4 million patients worldwide will have infectious complications from hospitals (Tikhomirov, 1987). Currently, this rate is expected to be higher because of emerging diseases and HIV/AIDS pandemic (Tietjen L. *et al*., 2003).

HAIs are common healthcare problems of both developed and developing countries although there is big disparity of share of the burden. Developing countries have the lion's share of the magnitude and impact of the problem. It is estimated that, in developing countries of Africa, Latin America and Asia 5% to 10% of patients acquire one or more HAIs (Ibid.). Moreover, HAIs were found to range from as low as 1% in a few developed nations found in Europe and America to more than 40% in developing countries found in Asia, Latin America and Sub-Saharan African countries (Lynch *et al.*, 1997). Furthermore, the risk of acquiring HAIs coupled with adverse effects and medical errors is 2 two 20 times higher than that of the developed countries (FMOH, 2010). In Sub-Saharan countries, the problem associated with patient safety often gets blurred due to poor documentation. Nonetheless, prevalence studies on hospital-wide healthcare-associated infections in some African countries is reported to be of high infection rates (Mali 18.9%, Tanzania 14.8%, Algeria 9.8%) of patients undergoing surgery being the most frequently affected (FMOH, 2010). In addition to HAIs, developing countries are known to be hit hard by HIV/AIDS pandemic. Hence, poor IP and PS practices such as unsafe medical care could fuel up the transmission of HIV and other diseases in healthcare facilities (Gisselquist *et al*., 2002). The occurrences of HAIs in these setups worsen situations of an already poorly structured, staffed and managed healthcare system. No doubt, repercussions of these incidences in turn aggravate the prevailing shortage of human and material resources for the new demand competes with other priorities of public health (FMOH, 2010).

Healthcare Associated Infections (HAIs) range from mild upper respiratory tract infections to a complicated post operative wound infections. The commonest ones are infections of surgical wound, urinary tract and lower respiratory tract. Although all individuals exposed to HAIs are vulnerable to be infected, immune-compromised individuals like AIDS patients are more prone to these infections (WHO, 2002). Healthcare associated infections result usually in prolonged hospital stay, long term disability, increased resistance of microorganisms to antimicrobials, massive financial burdens to the clients, excessive mortality rate, high costs for the health systems and emotional stresses to the patients and their families (WHO, 2002).

Healthcare associated infections affect patients, healthcare workers, support staff, medical students and patient attendants in healthcare facilities. Healthcare workers are mostly affected while caring to patients, especially if the working environment is conducive for the transmission of infection from patients or colleagues. Studies showed that worldwide, a huge number of healthcare workers get infected with different micro-organisms every day while working (Tietjen L. *et al*., 2003). In USA, for an instance, more than 800,000 needle stick injuries to health workers are reported each year (Rogers, 1997). It is a foregone conclusion that situations like this definitely increases the chance of acquiring blood borne pathogens.

In Ethiopia, the magnitude of nosocomial infections is not known or not well studied. On the other hand, many other developing countries have taken a good notice that it is one among their most prominent problems of high rate of HAIs. Obviously, many health facilities have troubles with consistently running water for hygiene and sanitation, severe scarcity of essential supplies for infection prevention and absence of well structured surveillance system for program monitoring and evaluation. Above all, health professionals lack adequate knowledge and motivation to implement the recommended infection prevention and patient safety practices in the healthcare facilities (FMOH, 2010).

It is true that most of these HAIs, no matter what, can effectively be prevented using the readily available, relatively inexpensive, practical and scientifically proven infection prevention and patient safety practices if given the due attention .Hence, Infection Prevention and Patient Safety recommendations could easily be implemented given, everyone in the health service delivery system ranging from policy makers to healthcare providers collaborate reasonably well (WHO 2002; FMOH 2010).

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CHAPTER 1: INTRODUCTION TO INFECTION PREVENTION AND PATIENT SAFETY

KEY TOPICS TO BE DISCUSSED:

- The goal and basic principles of Infection Prevention and Patient Safety.
- Measures to be taken to stop the spread of disease at each part of transmission cycle.
- The role of infection prevention in reducing the level of risk.
- The role of the CDC isolation guidelines in preventing HAIs.
- Overview of Patient Safety.

The Infection prevention and Patient Safety principles described in this manual are intended for use in all types of medical and healthcare facilities ranging from specialized referral hospitals to health posts in both public and private health facilities found in the country. All healthcare workers, program managers and hospital administrators are expected to grasp the basic principles of Infection Prevention and Patient Safety and accordingly utilize the recommended processes and practices. The manual incorporated key points from isolation precaution guideline for hospitals and Patient Safety compiled by Center for Disease Control and Prevention (CDC (Siegel JD. *et al*., 2007).

The goal of Infection Prevention and Patient Safety is to make healthcare facilities safer places.

DEFINITIONS

Asepsis and Aseptic Technique - a combination of efforts made to prevent entry of microorganisms into any area of the body where they are likely to cause infection. The goal of asepsis is to reduce or eliminate the number of microorganisms on both animate (living) surfaces (skin and mucous membranes) and inanimate objects (surgical instruments and other items) to an infection free level.

Antisepsis - a process of reducing the number of microorganisms on the skin, mucous membranes or other body tissue by applying an antimicrobial (antiseptic) agent.

Decontamination - a process that makes inanimate objects safer for the staff to handle them before cleaning (i.e. inactivates HBV, HCV and HIV and reduces, but does not eliminate, the number of other contaminating microorganisms).

Cleaning - a process that physically removes all visible dust, soil blood or other body fluids from inanimate object as well as removing sufficient number of microorganisms to reduce risks for those who touch the skin or handle the object. (It consists of thorough washing with soap or detergent and water, rinsing with clean water and drying.)

High-Level Disinfection (HLD) - a process of eliminating all microorganisms except some bacterial endospores from inanimate objects by boiling, steaming or using chemical disinfectants.

Sterilization - a Process of eliminating all microorganisms (bacteria, viruses, fungi and parasites) including bacterial endospores from inanimate objects by high-pressure steam (autoclave), dry heat (oven), chemical sterilization or radiation.

Micro-Organisms - are causative agents of infections such as bacteria, viruses, fungi and parasites.

Colonization - the presence of pathogenic (illness or disease causing) organisms in a person or animal in abundance (i.e. they can be detected by cultures or other tests) usually without causing symptoms or clinical findings (i.e. they do not invade tissues, cause cellular changes or cause damages).In other words, it is the appearance or increased number of a particular invasive bacterial species in the resident micro flora.

Colonized Persons - can be a major source of transfer of pathogens to other persons. For instance, *Neisseria meningitides* colonizes nasal cavity and oropharynx with or without causing subsequent infections. *Entameba histolytica* can colonize the large bowel without any harm to the host but are often shade in the stool as infectious cysts which may cause dysentery.

Infection - is an invasion and multiplication of microorganisms in body tissues which may clinically be apparent or result in local cellular injury due to competitive metabolism, toxins, intracellular replication or antigen antibody response.

Disease - is any deviation from being healthy or interruption of the normal structure or function of any body part, organ, or system manifested by a characteristic set of symptoms and signs whose etiology, pathology, and prognosis may be known or unknown.

Infectious Microorganisms - are microorganisms capable of producing disease in the appropriate hosts.

Infection Prevention - is a systematic effort or process of placing barriers between a susceptible host (person lacking effective natural or acquired protection) and the microorganism.

Patient Safety - is an issue focusing at reduction or aversion of unsafe acts/circumstances within the healthcare system through the use of best practices leading to optimal patient outcomes.

Protective Barriers - are physical, mechanical or chemical processes that help to prevent the spread of infectious microorganisms from person to person (patient, healthcare client or health workers) and/or equipments, instruments and environmental surfaces to people.

Nosocomial Infection - is a term used interchangeably with "healthcare facility acquired infection" or "healthcare associated infections (HAIs)" and is defined as a situation in which patients coming to health institutions seeking treatments acquire an infection/s in healthcare facility afterwards other than diseases/health problems they had. Or,

- Infections acquired while a patients is under hospital (or any other health facility) care which are not present or incubating at time of admission. It is a time related criterion which refers to Infections occurring more than 48 hours after admission
- For this situation to definitely happen, an infection occurring in a patient at a hospital or other healthcare facility should not be present at the outset or should yet be in an incubatory stage at the time of admission. This situation, therefore, is inclusive of infections acquired in the hospital but appeared after discharge and occupational infections among the staff of the facility as well.

HOW RISKY IS WORKING IN HEALTHCARE FACILITIES

Healthcare personnel including the support staff (e.g. housekeeping, laundry staff and maintenance), who work in healthcare settings are at risk of exposure to serious potentially life-threatening infections such as HIV, HBV, HCV. Direct contact with blood and other body fluids is the most common or frequent risk healthcare workers encounter while caring for patients. Studies in the United States have shown that the risk of acquiring HBV after being stuck with a needle from an HBV+ client ranges 27 to 37%. In addition, the risk of acquiring HCV and HIV after being stuck with a needle from an infected person is 3 to 10% and 0.2% to 0.4% respectively (Gerberding, 1990; Gershon *et al*., 1995 & Landpher, 1994). Among these, the efficiency for transmission of hepatitis B is high. For example, an accidental splash in the eye of as little as 10^{-8ml} (0.00000001ml) of infected blood can transmit HBV to a susceptible host (Bond *et al*., 1982).

Each year, in United States, 800,000 sharp injuries are reported by healthcare workers (Rogers, 1997). However, it is anticipated that most healthcare workers do not report needle stick or other sharps injuries as often as they should. Hence, the number of needle stick injuries is under reported in most cases.

Similarly, a survey conducted in the year 2003 and 2004 on about 40 health facilities in Ethiopia, reported that 32% of the healthcare workers in these institutions sustained needle stick injuries in 12-months time.

THE DISEASE TRANSMISSION CYCLE

Microorganisms live everywhere in our environment. Humans normally carry them on their skin, upper respiratory, intestinal and genital tracts. Generally, micro organisms live in animals, plants, soil, air and water. Not all, but some among these microorganism are pathogenic (likely to cause disease) in varied degrees. When they get favorable conditions, most of these microorganisms may cause infections if transmitted to immune compromised people such as patients with AIDS (Burke, 1977).

Microorganisms can be classified as bacteria, virus, fungi and protozoa. Bacteria can again be further divided in to three categories: vegetative (e.g. *staphylococcus*), Mycobacteria (e.g. *tuberculosis)* and endospores (e.g. *tetanus*). Of all common infectious agents, endospores are the most difficult to kill due to their protective coating.[1]

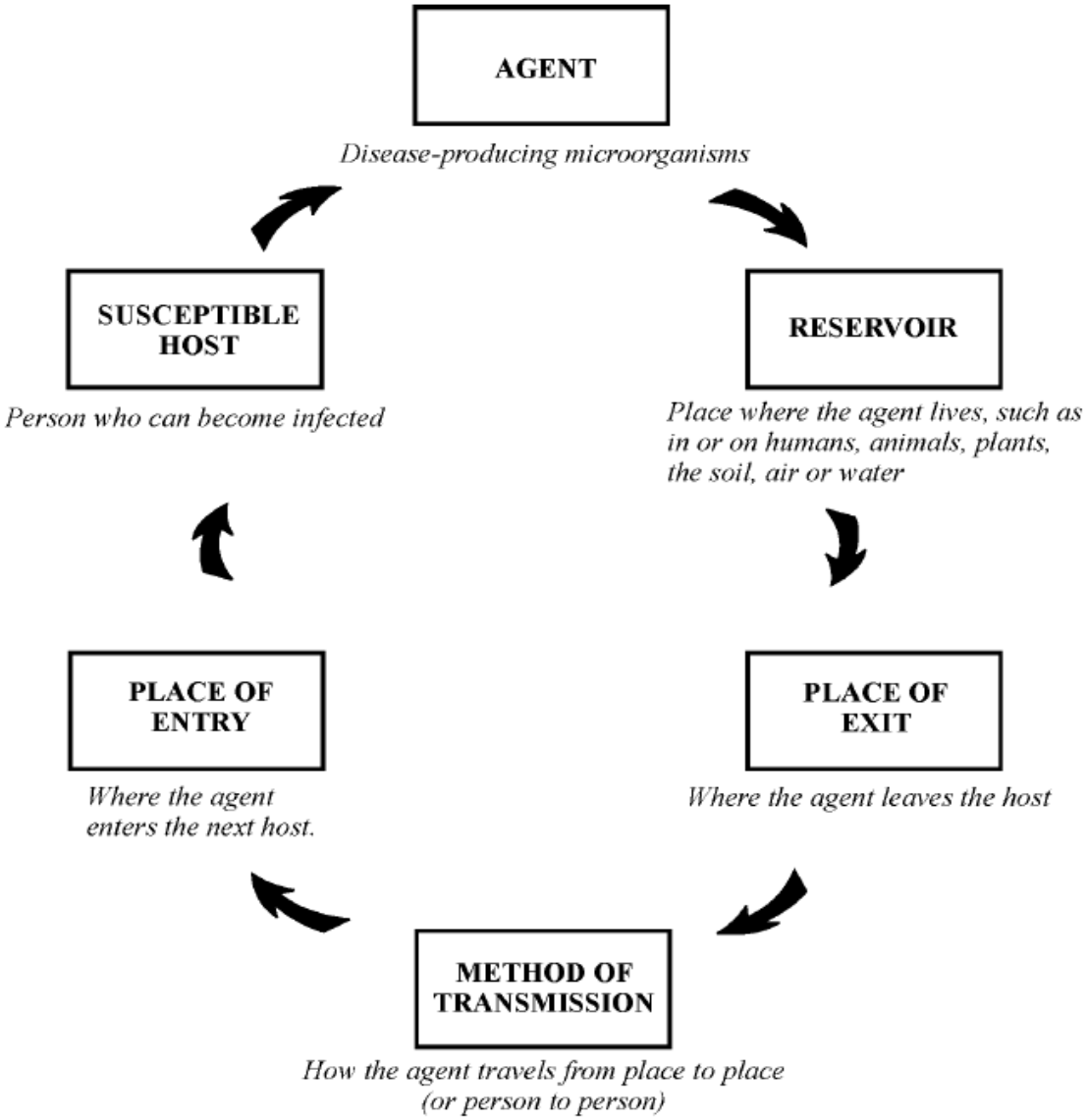
All humans are susceptible to infections due to some bacterial and most of the viral agents. The number (dose) of organisms necessary to produce infection in a susceptible host varies with the location. All of us touch materials which contain some organisms every day but suffer from no infection because organisms coming into contact with the intact skin are unlikely to cause such risk. Nonetheless, when these organisms come into contact with mucous membranes or non intact skin, the chance of risk of infection correspondingly increases. Infection risk increases

[1] Prions, which are protein-containing infectious agents present in brain , spinal column and eye tissue or patients with Creutzfeldt-Jakob disease and even harder to kill.

greatly when organisms come into contact with normally sterile body sites. In such cases, the introduction of only few organisms may produce disease.

For bacterial, viral and other infectious agents to successfully survive and spread, certain factors or conditions must be fulfilled. The essential factors in the transmission of disease-causing microorganisms from person to person are illustrated in **Figure 1.1** (APIC, 1983; WPRO/WHO, 1990).

Figure 1.1 The Disease Transmission Cycle



Adapted from: APIC 1983; WPRO/WHO 1990.

As shown in the above figure, an infectious disease needs certain conditions in order to spread (be transmitted) to others. These are:

Agent- is something (biological, chemical, physical, etc) that can cause illness. Most important among these are biological agents which include: bacteria, virus, fungus, parasite etc.

Host/Reservoir - reservoir of an agent is the habitat in which an infectious agent normally lives, grows, and multiplies. Reservoirs include humans, animals, and the environment. The reservoir may or may not be the source from which an agent is transferred to a host. For example, the reservoir of *Clostridium botulinum* is soil, but the source of most botulism infections is improperly canned food containing *C. botulinum* spores.

Human Reservoirs - many of the common infectious diseases have human reservoirs. Diseases which are transmitted from person to person without intermediaries include the sexually transmitted diseases, measles, mumps, streptococcal infection, most respiratory pathogens, and many others. Smallpox was eradicated after the last human case was identified and isolated because humans were the only reservoir for the smallpox virus. Two types of human reservoir exist:

- Persons with symptomatic illness
- Carriers

Portal of Exit - this is a gateway through which the agent leaves the host or reservoir. However, the agent must have the right environment for its survival until it gets an entry to infect another person/animal. For example, the bacteria that cause tuberculosis can survive in sputum for weeks, but fortunately could be killed by sunlight within few hours.

Mode of Transmission - an agent which exits and develops in its natural reservoir, can be transmitted in numerous ways to a susceptible host and get portal of entry. These modes of transmission are classified as:

- **Direct Transmission -** refers to an immediate transfer of the agent from a reservoir to a susceptible host through direct contact or droplet.
- **Direct Contact -** occurs through kissing, skin-to-skin contact, and sexual intercourse. Direct contact refers also to contact with soil or vegetation harboring infectious organisms. Infections such as mononucleosis ("kissing disease") and gonorrhea are contracted from direct contact to an infected person. Likewise, Hookworm infection is acquired through direct contact with contaminated soil.
- **Droplet Spread -** refers to a spray of a relatively large, short-range germ laden aerosols produced by sneezing and/or coughing (or even talking) of infected people. Droplet Spread is classified as direct because transmission is by direct spray over a few feet, before the droplets fall to the ground.
- **Indirect Transmission -** an agent is carried from a reservoir to the susceptible host by suspended air particles or by animate (vector) or inanimate (vehicle) intermediaries.
    - ✓ Airborne
    - ✓ Vehicle-borne
    - ✓ Vector borne
    - ✓ Mechanical
    - ✓ Biologic

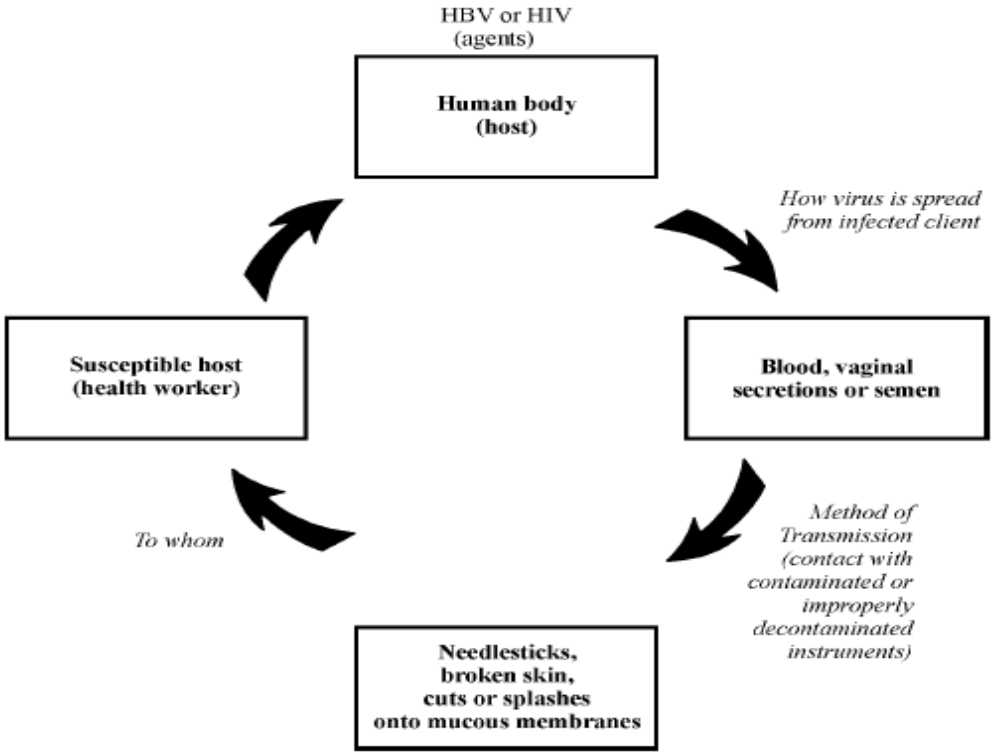
This manual deals primarily with preventing the spread of infectious diseases taking place in healthcare facilities from contacts with sources like air (airborne and droplets), blood or body fluids and contaminated foods or articles.

Portal of Entry - is the gate way through which an infectious agent enters in to the susceptible host. These portals of entry could be mouth, nose, skin etc.

Susceptible Host - is an organism (human or animal) which is liable to take up infectious agents/pathogens and harbors them. People are exposed to disease-causing agents every day but do not always get sick. An infectious agent/pathogen getting access or inhabiting in the host does not necessarily lead to infection or initiate illness due to the body's natural defense mechanisms and the immune system is normally at work to fight back against the invading agent. However, organisms which got access to a new host and reproduce there cause colonization which may later increase the likelihood of development of infections. The other reason why people do not get sick could be because of previous exposition to it through artificial or natural immunity (e.g. vaccinated for it or previously had the disease).

The following figure indicates the steps in the transmission of hepatitis B virus (HBV) and human immunodeficiency virus (HIV) from infected persons (e.g. a family planning client or pregnant woman attending an antenatal clinic) or patients getting treated in healthcare institutions. This spread of infection from Viruses occurs when the staffs (physician, nurse or housekeeping personnel) are exposed to the blood or body fluids of an infected person (e.g. needle stick injury).

Figure 1.2 Transmissions of HBV and HIV from Patients to Healthcare Workers



PREVENTING INFECTIOUS DISEASES

Understanding the Disease Transmission Cycle is Important If Healthcare Workers are to:

- Prevent transmission of microorganisms from patient to patient, from patient to the provider or vice versa during medical and surgical procedures;
- Teach others on the factors required for transmission to occur and most importantly.
- Teach others on how to break the disease transmission cycle;

Preventing the spread of infectious agents or proper infection prevention and patient safety practice requires removing one or more of the conditions necessary for transmission of the diseases from the host or reservoir to the susceptible host by:

- Reducing the number of microorganisms present (e.g. hand washing, cleaning of instruments);
- Killing, inhibiting or inactivating microorganisms (e.g. hand washing with a waterless alcohol preparation, decontamination);
- Creating barriers to prevent infectious agents from spreading (e.g. wearing gloves or personal protective equipment); or
- Reducing or eliminating risky practices (e.g. by using hands-free technique in the operation room, using disposable gloves and syringes etc).
- Making sure that people, especially healthcare workers, are immune or vaccinated; and
- Reducing adverse events (e.g. by improving data collection, epidemiological surveys of adverse events, training on prevention of adverse events.

SPAULDING CATEGORIES OF POTENTIAL INFECTION RISK

In 1968, Spaulding proposed three categories of potential infection risk to serve as the basis for selecting the prevention practices or processes to use (e.g. sterilization or medical instruments, gloves and other items) when caring for patients. This classification has passed the test of time and still serves as a good basis for setting priorities to any infection prevention program. The Spaulding categories are summarized below:

Critical - these items and practices affect normally sterile tissues or the blood system and represent the highest level of infection risk. Failure to manage sterility or where appropriate, high-level disinfection of items, is most likely to result in serious infections.

Semi-Critical - these items and practices rank second in importance and affect mucous membranes and small areas of non intact skin. Management needs are considerable and require knowledge and skills in: handling many invasive devices (e.g. gastrointestinal endoscopes and vaginal specula), performing decontamination, cleaning and high-level disinfection, and gloving for the staff who touch mucous membranes and non intact skin.

Non-Critical - this is a management of items and practices involving intact skin and represents the lowest level of risk. Poor management of non-critical items such as an overuse of examination gloves often consumes a major share of resources while providing only limited benefits.

The healthcare team should make decisions regarding infection prevention and patient safety practices for the final step in processing instrument and other items to be used based on the Spaulding classification given above. The following table indicates which final instrument processing is to be used.

Table 1.1 Final Processing for Surgical Instruments, Gloves and Other Items

TISSUE	FINAL PROCESSING	EXAMPLES
Intact mucous membranes or broken skin	**High-level disinfection** (HLD) destroys all microorganisms except some endospores.[a]	Uterine sounds, vaginal specula and plastic cannulae for suction curettage
Blood stream or tissue beneath the skin which normally is sterile	**Sterilization** destroys all microorganisms, including endospores.	Surgical instruments such as scalpels, trocars for insertion/removal of Norplant® implants and surgical gloves

[a] Bacterial endospores are forms of bacteria that are very difficult to kill because of their coating. Types of bacteria that make endospores include those causing tetanus (*Clostridium tetani*), gangrene (*Clostridium perfringens*) or anthrax (*Bacillus anthracis*).

Adapted from: Spaulding 1968.

NEW ISOLATION GUIDELINES AND RECOMMENDATIONS

Since CDC's first introduction of disease-specific category system of isolation precautions in 1979, many different policies and practices of preventing the spread of infections in hospitals have been recommended. Traditionally, barrier precautions (e.g. hand hygiene and gloves) have been used to reduce the risk of transmission of HCAIs to and from hospitalized patients. The emergence of blood borne diseases such as AIDS and hepatitis C in the 1980s coupled with the resurgence of tuberculosis, led to the introduction of Universal Precautions (UPs) of the 1985 for protecting healthcare workers from becoming infected with these agents and the like. From the moment these manuals were issued, healthcare facilities began to use them but it was recognized that this new strategy did not consider risks to patients from other potentially infective body fluids (e.g. semen, amniotic fluid, or mucous secretions).Universal precautions (UPs) did not also recognize that most people with HIV have no symptoms. Therefore, the guidelines had to be modified to include all persons and-patients/clients attending healthcare facilities regardless of whether or not they are infected (CDC, 1985).

At nearly the same time that UPs were being introduced, a new system of health worker and patient precautions was proposed as an alternative to the diagnosis-driven UPs (Lynch *et al.,* 1987). This approach called Body Substance Isolation (BSI), focused on protecting patients and health personnel from all moist and potentially infected body substances (secretions and excretions), not just blood. BSI was based primarily on the use of gloves. The health personnel were instructed to put on clean gloves just before touching mucous membranes or non-intact

skin, and before anticipated contact with moist body fluids (e.g. blood, semen, vaginal secretions, wound drainage, sputum, saliva, amniotic fluid, etc).

Other Issue Addressed By BSI Includes:

- Protective immunization of susceptible patients and staff against infectious diseases that are transmitted through airborne or droplets (measles, mumps, chicken pox and rubella), hepatitis A and B and tetanus or a booster dose; and
- Revised instructions to persons wishing to enter a patient's room or care for patients with infections transmitted by the airborne route (Lynch *et al*., 1990).

BSI quickly gained acceptance over UP because it was simple to learn and implement and it acknowledged that all patients, not just those diagnosed or with symptoms, may be infected and be risk to other patients or the staff. The disadvantages of BSI, on the other hand, includes the added cost of protective barrier equipment particularly gloves; difficulty in maintaining routine use of the protocol for all patients; uncertainty about precautions for patients in isolation rooms and the overuse of gloves to protect the staff at the expense of patients (Patterson *et al*., 1991).

Consequently, healthcare facilities and the staff in the 1990s were totally confused regarding what to do about patient and staff precaution guidelines. Even though many hospitals quickly began using some or all of the recommendations, there prevailed much local variation and confusion in the use and interpretation of both UPs and BSI. For example, some hospitals had implemented UPs while others had implemented BSI. Indeed, even hospitals and the staff considered to follow UPs were in reality using BSI and vice versa. There also existed variety of local interpretations and use of both UPs and BSI in effect producing variety of combinations. Moreover, there was a persisting lack of agreement on the role of hand washing when gloves were used. This confusion has coupled with the existing need to use additional precautions to prevent the spread of diseases through airborne, droplet and contact were major limitations of BSI (Rudnick *et al*., 1993).

Regarding these problems and concerns, simple merging of UP with BSI appears to be effective solution. Thus, center for disease control (CDC) and the Hospital infection control practices Advisory Committee (HICPAC) issued a system of isolation precautions in 1966 (Garner & HICPAC, 1996). What has emerged since then is a new system which provides a single set of isolation guidelines with logistically feasible recommendations for preventing many infections occurring in healthcare facilities through all known modes of transmission.

This System Involves A Two Level Approach:

- Standard Precautions and
- Transmission-based precautions

When these guidelines (Standard precautions and Transmission based precautions) were developed, they were designed in such a way that they meet the following criteria:

- Be epidemiologically sound.
- Recognize the pathogenecity of all body fluids, secretions and excretions (except sweat).

- Be as simple and user-friendly as possible.
- Use new terms to avoid confusion with existing system.

Later in 2007, the Guideline for Isolation Precautions developed information material on Preventing Transmission of Infectious Agents in Healthcare Settings by updating and expanding the 1996 Guideline for Isolation Precautions (Siegel JD. *et al*., HICPAC, 2007). The following developments led to revision of the previous guideline:

1. The transition of healthcare delivery from primarily acute care hospitals to other healthcare settings demanded a universally applied recommendation applicable to all healthcare settings rendering a wider range healthcare. The recommendations using common principles of infection control practice could be modified to reflect setting-specific needs. Accordingly, the revised guideline addresses the spectrum of healthcare delivery settings.
2. The emergence of new pathogens (e.g. SARS-CoV associated with the severe acute respiratory syndrome [SARS], Avian influenza in humans), redirected the concern for evolving known pathogens (e.g. *C. difficile, Noroviruses*, community associated MRSA [CA-MRSA]). Established a need to address a broader scope of issues than in previous isolation guidelines.
3. The first successful experience with Standard Precautions recommended in the 1996 guideline, has led to the reaffirmation of this approach as the foundation for preventing transmission of infectious agents in all healthcare settings. New additions to the recommendations for Standard Precautions are Respiratory Hygiene/Cough Etiquette and safe injection practices including the use of a mask when performing certain high-risk, prolonged procedures involving spinal canal punctures (e.g. myelography, epidural anesthesia).
4. The cumulative evidences that environmental controls decrease the risk of life threatening fungal infections in the most severely immune-compromised patients (allogeneic, hematopoietic, stem-cell transplant patients) calls for updating components of a Protective Environment.
5. Evidence on the fact that organizational characteristics (e.g. nurse staffing levels and composition, establishment of a safety culture) influence healthcare personnel's adherence to the recommended infection control practices and the presence of other important ways of preventing transmission of infectious agents, gave way to a new emphasis on the involvement of the administration in the development and support of infection control programs.
6. An ever increasing rate of incidence of HAIs due to multi drug-resistant organisms in all healthcare settings and the evolving knowledge of prevention of transmission about these organisms created a need for more specific recommendations on a practical and effective surveillance and control of these pathogens in various types of healthcare settings.

The New System Accomplished the Following:

- Incorporates the major features of both UPs and BSI into a single set of precautions called standard precautions designed to be used in treating all clients attending healthcare facilities regardless of their presumed diagnosis.

- Retains the recommendations that healthcare workers engaged in direct care especially like those working in surgical or obstetric units should be immune to *Rubella, Measles, Mumps, Varicella* (chicken pox) and *Hepatitis* A and B and receive tetanus toxoid as well.
- Reduces the old disease-specific isolation categories into three sets of precautions based on routes of transmission called Transmission-based precautions. (These guidelines apply to hospitalized patients or those in nursing home or other types of extended care facilities).
- List specific clinical syndromes in hospitalized adult and child patients who are highly susceptible for infection (i.e. the so called "empirical" use of transmission-based precautions).
- Isolation guidelines are important steps to reduce the risk of transmitting infections not only to and from patients and clients using healthcare services, but also to the healthcare personnel caring for them.

STANDARD PRECAUTIONS are designed for use in caring for all people-both clients and patients attending healthcare facilities (first level precautions). These apply to blood, all body fluids, secretions and excretions (except sweat), non-intact skin and mucous membranes. Since no one really knows what organisms do clients or patients have, it is necessary that standard precautions be used all the time.

TRANSMISSION-BASED PRECAUTIONS the second level precaution is intended for use in patients known or highly suspected of being infected or colonized with pathogens transmitted by:

- Air (tuberculosis, chicken pox, measles, etc).
- Droplet (flu, mumps and rubella); or
- Contact (hepatitis A or E and other enteric pathogens, herpes simplex and skin or eye infections)[2].

If there is any impending development of an infectious process in a patient without known diagnosis, implementing Transmission-Based Precautions should be based on the patient's signs and symptoms (empirical basis) up until a definitive diagnosis is made.

In all cases (whether they are being used alone or in combination), transmission based precautions must be used in conjunction with the Standard Precautions.

[2] Contact precautions also should be used for patients with wet or draining infections that may be contagious (e.g. draining abscesses, herpes zoster, impetigo, conjunctivitis, scabies, lice and wound infections)

OVERVIEW OF PATIENT SAFETY

‘‘….Prescribe Regimens for the good of my Patients according to my ability and my Judgment and never do harm to anyone…’’

Hippocratic Oath

Patient safety is a globally imperative issue; it has extensive implications for all WHO Member states, for all health service providers and patients. In the late 19th century, despite an increasing emphasis on the scientific basis of Medical practice in Europe and United Stated, data on adverse outcomes were hard to come by (Robert K, 2010). In late 20th century, however, reports on an ever increasing repeated anesthetic accident in the USA became a reason for the American Society of Anesthesiologists to establish the Anesthesia Patient Safety Foundation (APSF) in 1984. The APSF marked the first use of the term “Patient safety” in the name of professional reviewing organization. Likewise, in Australia, the Australian Patient safety foundation was founded in 1989 with the purpose of monitoring error of anesthesia. Both organizations were soon expanded as the magnitude of the medical error crisis becomes known.

As a matter of fact, subsequent reports indicate the importance of patient safety issues. For instance, in the United States, the full magnitude and impact of errors in healthcare was not appreciated until the 1990s when several reports brought attention to this issue (Thomas EJ *et al*., 2000; Brennan TA *et al*., 1991). A study done in July, 2004, concluded that there were over one million adverse events associated with Medicare hospitalizations from 2000 to 2002, resulting in up to 195,000 accidental deaths per year in American hospitals (Health Grades Quality Study, 2004). The experience has been similar in other countries too. In 2004, the Canadian Adverse Events study found that adverse events occurs in more than 7% of hospital admissions and estimated that 9,000 to 24,000 Canadians die annually after an avoidable medical error (Rose GB *et al*., 2004). Recent WHO data suggest that developing countries account for around 77% of all reported cases of countries is unusable or only partly usable, resulting in an increased risk of harm to patients and health workers (World Alliance for Patient Safety, 2004). These and other reports from New Zealand (New Zealand MOH, 2001), Denmark (Schioler T *et al*., 2001) and developing countries (World Alliance for Patient Safety, 2004) have led the WHO to estimate that one in ten persons receiving healthcare will suffer preventable harm.

Adverse events occur in all settings where healthcare is provided. Most of the current evidence comes from hospitals because risks associated with hospital treatment are higher but many such events occur in other lower healthcare settings. Every point in the process of care giving contains an inherent lack of safety. Adverse events may therefore be the result of problems in practice, products, procedures or systems. The current conceptual thinking on the safety of patients, shoulders the prime responsibility for adverse events on deficiencies on the system design, organization and operation rather than on individual practitioners or products. Because, counter measures based on changes in the system have evidently been far more productive than those targeting on behavior of individuals and their tendency to commit errors.

In 2002, WHO acknowledged that to tackle problems relating to patients’ safety internationally, a comprehensive multifaceted approach involving cultural change, system development and technical expertise would be necessary. In line with this, WHO launched the world alliance for

patients' safety on the 27th of October in 2000 with aiming to coordinate international actions and avoid duplication of effort in coping with this escalating problem.

Patients safety initiative of the WHO includes all of the three global health challenges namely: '**Clean care is safer care**', '**safe surgery**' and prevention of '**Anti microbial resistance'**. In an African context, patient safety key issues has been identified and ratified by African health Ministerial meeting in Yaoundé Cameron in 2007. These key patient safety issues are also the building blocks of any healthcare institutions. The implementation will not only improve the care but also enhance the morale and satisfaction of health workers. The key action areas are:

- Patient safety and health services and systems development
- National patient safety policy
- Knowledge and learning in patient safety
- Raising awareness of Patient safety
- Healthcare-associated infections
- Healthcare worker protection
- Healthcare waste management
- Safe surgical care
- Medication safety
- Patient safety partnerships
- Patient safety funding
- Patient safety surveillance and research

For the implementation purpose, six African hospitals were selected together with European hospitals which are willing to join hands to the endeavor geared into action. Ethiopia is one among the six countries selected for the implementation of Patient Safety program. Of the 12 key patient safety areas, Ethiopia has ratified the following five action areas:

- Healthcare Associated Infection Prevention
- Medication safety
- Safe surgery
- Research and surveillance
- Healthcare worker protection

In our context, four implementation sites namely University of Gondar Hospital, Hawassa University Hospital, Jimma University Hospital and Mekele University Hospital were selected as Patient safety implementation sites.

RECOMMENDED ACTIVITIES TO IMPPROVE IP AND PS PRACTICES:

- Use appropriate hand hygiene techniques including hand washing, hand antisepsis, antiseptic hand rub and surgical hand scrub (the most practical and important procedure for preventing cross-contamination, person to person or contaminated object to person).
- Wear Personal Protective Equipment (PPE) including gloves, masks, protective eye wear, face shields, fluid resistant gowns/aprons, shoes/boots and caps.
- Wear gloves (both hands) before touching anything wet (broken skin, mucous membranes, blood, body fluids, secretions or excretions), soiled instruments and contaminated waste materials, or before performing invasive procedures.
- Use other PPE's if splashes or spills of any blood, body fluids, secretions or excretions are anticipated.
- Use antiseptic agents for cleansing the skin or mucous membrane prior to invasive procedures/surgery, cleaning wounds, or performing hand rubs or surgical hand scrubs using an alcohol based antiseptic product.
- Use safe work practices such as not recapping or bending needles, safely passing sharp instruments and disposing or sharps in puncture proof containers at point of use.
- Process instruments and other items that come in contact with blood, body fluids, secretions and excretions (decontamination, cleaning and sterilization or high-level disinfection) and proper storing and handling of processed instruments.
- Routinely clean and disinfect the environment where patients are cared for (rooms, furniture and equipment).
- Safely dispose of infectious waste materials to protect those who handle them and prevent injury or spread of infection to the community.
- Proper handling of specimens (blood, tissue, excretions and secretions).
- Managing traffic flow and activity pattern in wards, procedure areas and operating theater.
- Follow proper isolation precautions for infectious patients or until ruled out if secretions or excretions cannot otherwise be contained.
- Manage safe and proper disposal of healthcare wastes (i.e. segregating waste at point of waste generation and then either incinerating, burying or burning contaminated waste).
- Report accidental exposure to blood and body fluids including needle stick injuries and proper management of accidental injuries.
- Minimize preoperative stay in the healthcare facility.
- Provide continuous supportive supervisions and monitoring of infection prevention practices and infection rates.
- Ensure rational use of prescription of drugs and maximize clinical effectiveness.
- Carry out Intensive sensitization campaigns and special training programs on the prevention of adverse events should be held on a regular basis for healthcare workers.
- Include PS in the curricula of health-related training institutions.
- Translate issues of patient charters or rights in local languages.

- Involve patients to raise their awareness on PS.
- Provide the staff with Vaccinations against HBV and other vaccine-preventable pathogens.
- Improve surgical outcomes for patients regardless of circumstance or environment, by improving the processes consistently in operating theatres.
- Establish Regulations to control the quality of medicines.
- Increase partnerships between patients, family members, health professionals and policy-makers to effect meaningful change in patient safety.
- Improve basic data collection and promotion of research projects will allow countries to know the real magnitude of the patient safety problem.
- Research priorities should include epidemiological surveys of adverse events.
- Provide regular reporting of all adverse events occurring in all healthcare facilities.

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CHAPTER 2: STANDARD PRECAUTIONS

KEY TOPICS TO BE DISCUSSED:

- The standard precautions
- Designing standard precautions
- The newly added elements of standard precautions
- Recommended preventive process and practices

BACKGROUND

The guidelines issued by CDC in 1996 involve a two-level approach namely Standard Precautions and Transmission based Precautions. Because most people with blood borne viral infections such as HIV and HBV do not have symptoms, nor can they easily be recognized as such, Standard Precautions are designed for the care of all persons-patients, clients and staff-regardless of whether or not they are actually infected. Standard Precautions combine the major features of Universal Precautions (UP) and Body Substance Isolation (BSI) and are based on the principle that all blood, body fluids, secretions, excretions except sweat, non-intact skin, and mucous membranes may contain transmissible infectious agents. Their implementation is meant to reduce the risk of transmitting micro organisms from known or unknown sources of infection (e.g. patients, contaminated objects, used needles and syringes, etc) within the healthcare system. Applying Standard Precautions has become the primary strategy to preventing HAIs in hospitalized patients.

The application of Standard Precautions during patient care is determined by the nature of the healthcare worker-patient interaction and the extent of anticipated blood, body fluid, or pathogen exposure. For some interactions (e.g. performing veni-puncture), only gloves may be needed; during other interactions (e.g. intubations), use of gloves, gown, and face shield or mask and goggles is necessary. Education and training on the principles and rationale of the recommended practices are critical elements of Standard Precautions to facilitate appropriate decision-making and promote compliance of healthcare workers facing new circumstances (Siegel JD. *et al*.; HICPAC, 2007). Standard Precautions aim also to create conducive situations where patients are reliably protected from healthcare workers carrying infectious agents on their hands or via equipment they used during patient care.

Over the years, the indications for use of certain isolation practices over others (e.g. clean gloves are more effective than gowns in preventing cross- contamination) have been re-confirmed through research (Leclaire *et al*., 1987). Whatsoever, healthcare administrators and staff will need to carefully review the recommendations contained in the Standard Precautions and implement them according to what is possible and applicable within their resource setting.

NEW ELEMENTS OF STANDARD PRECAUTIONS

Infection control problems that are identified in the course of outbreak investigations often indicate the need for adoption of new recommendations or reinforcement of the existing infection control recommendations to protect patients. Because such recommendations are

considered standards of care and may not be included in other guidelines, they are incorporated in Standard Precautions. Three such areas of practice that have been added are (Siegel JD *et al*.; HICPAC, 2007):

- Respiratory Hygiene/Cough Etiquette,
- Safe injection practices and
- Use of masks for insertion of catheters or injection of material into spinal or epidural spaces via lumbar puncture procedures (e.g. myelogram, spinal or epidural anesthesia).

As most elements of Standard Precautions evolve from Universal Precautions developed for protection of healthcare staff, protection of patients is also the center of focus in the standard precaution.

KEY COMPONENTS AND THEIR USE

The Key components of the Standard Precautions and their use are outlined in **Table 2.1** placing a physical, mechanical or chemical barriers between microorganisms and an individual-be it a woman coming for antenatal care, a hospitalized patient or just a healthcare worker, it is a highly effective means of preventing the spread of infections (i.e. the barrier serves to break the disease transmission cycle).

For example, the following actions create protective barriers for preventing infections in clients, patients and healthcare workers and provide the means for implementing the new Standard Precautions:

- **Consider Every Person (**patient or staff) as potentially infectious and susceptible to infection.
- **Wash Hands as** he most important procedure for preventing cross contamination (person to person or contaminated object to person).
- **Wear Gloves** in both hands before touching anything wet-broken skin, mucous membranes, blood or other body fluids, or soiled instruments and contaminated waste materials-or before performing invasive procedures.
- **Use Physical Barriers** like protective goggles, face masks and aprons if splashes and spills of any body fluids (secretions and excretions) are likely (e.g. cleaning instruments and other items).
- **Use Antiseptic Agents** for cleansing the skin or mucous membrane prior to surgery, cleaning wounds, or doing hand rubs or surgical hand scrubs with an alcohol-based antiseptic product.
- **Use Safe Work Practices** like: not recapping or bending needles, safely passing sharp instruments and suturing, when appropriate, with blunt needles.
- **Safely Dispose of Infectious Waste Materials** to protect those who handle them and prevent injury or spread of infection to the community.
- **Process Instruments, Gloves and Other Items** after use by first decontaminating and thoroughly cleaning them, then either sterilizing or high-level disinfecting them using the recommended procedures.

- **Respiratory Hygiene/Cough Etiquette** a strategy which is incorporated into infection control practices as a new component of Standard Precautions. The transmission of SARS-CoV in emergency departments by patients and their family members during the widespread SARS outbreaks in 2003 highlighted the need for vigilance and prompt implementation of infection control measures at the spot within a healthcare setting (e.g. reception and triage areas in emergency departments, outpatient clinics and physician offices).

The strategy targets patients, accompanying family members and friends with undiagnosed transmissible respiratory infections, and applies the procedure to any person with signs of illness like Cough, congestion, rhinorrhea, or increased production of respiratory secretions on arrival at the health facilities and afterwards. The term cough etiquette is derived from recommended source control measures for *M. tuberculosis.* The elements of Respiratory Hygiene/Cough Etiquette generally include:

- Education of healthcare facility staff, patients, and visitors;
- Posted signs, in language(s) appropriate to the population served, with instructions to patients and accompanying family members or friends;
- Source control measures (e.g. covering the mouth/nose with a tissue when coughing and prompt disposal of used tissues, using surgical masks on the coughing person when tolerated and appropriate);
- Hygiene of the hand after contact with respiratory secretions; and
- Spatial separation, ideally>3 feet, of persons with respiratory infections in common waiting areas when possible. Covering sneezes and coughs and placing masks on coughing patients are proven means of source containment that prevent infected persons from dispersing respiratory secretions into the air.

Table 2.1 Key Components of Standard Precautions

COMPONENT	SOME OF THE RECOMMENDATIONS
Hand hygiene (hand washing with soap and water or use an antiseptic hand rub)	▪ After touching blood, body fluids, secretions, Excretions and contaminated items; ▪ Immediately after removing gloves; ▪ Between patient contacts
Personal protective equipment (PPE)	
Gloves	▪ For contact with blood, body fluids, secretions/excretions or contaminated items; ▪ For contact with mucous membranes and non-intact skin
Gown/Apron	▪ Protect skin from blood or body fluid contact ▪ Prevent soiling of clothing during procedures that may involve contact with blood or any body fluids (secretions/excretions)
Linen	▪ Handle soiled linen to prevent touching of skin or mucous membranes ▪ Do not pre-rinse soiled linens in patient care areas

COMPONENT	SOME OF THE RECOMMENDATIONS
Mask, goggles and face shield*	Protect mucous membranes of eyes, nose and mouth when contact with blood and body fluids is likely or possible
Soiled patient-care equipment	▪ Handle soiled equipment in a manner to prevent contact with skin or mucous membranes and to prevent contamination of clothing or the environment ▪ Clean reusable equipment prior to reuse
Environmental control	Develop procedures for routine care, cleaning, and disinfection of equipment and environmental surfaces, especially frequently touched surfaces in Patient-care areas.
Textiles and laundry	Handle in a manner that prevents transfer of microorganisms to others and to the environment
Needles and other sharps	▪ Avoid recapping, bending, breaking, or hand-manipulate used needles; if recapping is required, use a one-handed scoop technique only; ▪ Avoid removing used needles from disposable syringes ▪ Place used sharps in puncture-resistant container at point of use
Patient resuscitation	Use mouthpiece, resuscitation bags or other ventilation devices to avoid mouth-to-mouth resuscitation
Patient placement	▪ Place patients who contaminate the environment or cannot maintain appropriate hygiene in private rooms ▪ Place patients on airborne, droplet, contact precautions in appropriate rooms
Respiratory hygiene/cough etiquette	▪ Instruct symptomatic persons to cover mouth/nose when sneezing/coughing or use tissue papers and dispose in no-touch receptacle; ▪ Observe hand hygiene after soiling of hands with respiratory secretions; ▪ Wear surgical mask if tolerated or maintain spatial separation, >3 feet if possible.

* During aerosol-generating processes in patients with suspected or confirmed infections transmitted by respiratory aerosols (e.g. SARS), a fit-tested N95 or higher respirator should be worn in addition to gloves, gown and face/eye protection.

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http://www.cdc.gov/ncidod/dhqp/pdf/isolation2007.pdf

CHAPTER 3: HAND HYGIENE

KEY TOPICS TO BE DISCUSSED:

- The significance of Hand hygiene
- Components of Hand hygiene; when and how to wash hands, use hand antisepsis**,** antiseptic hand rub and surgical hand scrub
- Common malpractices related with each types of practices of Hand hygiene
- The barriers in an appropriate Hand hygiene and strategies to improve it

BACKGROUND

Hand hygiene is a general term referring to any action of hand cleansing. It includes care of hands, nails and skin. Proper Hand hygiene and use of protective gloves be it for surgery in the operating room or handling contaminated materials in the household are key activities of minimizing the spread of disease and maintaining an infection-free environment.

Among various hygienic practices of the hands, the use of soap and water when hands are visibly soiled remains the commonest and most important. For hands which are free of dirt or debris, however, alternatives such as antiseptic hand-rubs which are faster to act, cheaper and easier to use, are increasingly gaining acceptance especially in setups where access to sinks and clean water is limited.[3] From the perspectives of infection prevention, both practices of hand washing and surgical hand scrubbing purport to prevent hand borne infections by removing dirt and/or debris and inhibiting or killing microorganisms on skin. The action is effective not only on the organisms acquired through contact with patients and the environment but also on some organisms permanently living in the deeper layers of the skin.

With the emergence of AIDS epidemic in the late 1980s, efforts put to prevent transmission of HIV and other blood borne viruses from patients to the staff re-invigorated all aspects of infection prevention. This situation has contributed to fast growing usage of Hand hygiene and glove in particular.

Studies indicate that failure to perform appropriate Hand hygiene is considered to be the leading cause of healthcare associated infections, the spread of multidrug resistant micro organisms and a significant contributor to outbreaks (Boyce & Pittet, 2002). Considering the hygienic guideline which has traditionally dealt with recommendations on the when and how to perform hand washing or surgical hand scrubs, the early procedures have undergone a rapid change in the past 15 years.

[3] If tap water is contaminated, use water that has been boiled for 10 minutes and filtered to remove particulate matter (if necessary), or use chlorinated water-water treated with a dilute bleach solution (sodium hypochlorite) to make the final concentration 0.001%

The First Step in this Process is Educating Healthcare Workers and Students About:

- The importance of Hand hygiene, how to correctly perform various hand washing and hand scrubbing procedures; and
- The evidence supporting the use of these procedures in reducing transmission of microorganisms and subsequent decrease in the frequency of healthcare associated infections.

Finally, it should not be forgotten that frequent hand washing reduces the spread of infection not only from the hands of health workers but also from everyone else's hands as well! For example, it is estimated that persuading people especially young children, to wash their hands with soap and clean water after going to the toilet, handling or changing a dirty baby, or before doing some other tasks (cleaning vegetables, fresh meat or fish) with potentially contaminated hands can reduce diarrheal diseases by 45%-saving the lives of millions of children annually (The Economist, 2002).

Interestingly enough, in a large study conducted in the US military found that when troops washed their hands five or more times daily, the number of sniffles, coughs and common "colds" dropped by 43%.

DEFINITIONS

Antiseptic or Antimicrobial Agent (Terms Used Interchangeably) - are chemicals that are applied on the skin or other living tissue to inhibit or kill microorganisms (both transient and resident) thereby reducing the total bacterial counts. Examples include alcohols (ethyl and isopropyl) dilute iodine solutions, Iodophors, Chlorhexidine and Triclosan. (**See Appendix B** for complete listing of uses, effectiveness, advantages and disadvantages of selected antiseptic agents).

Safe (Clean) Water - it is water that does not contain harmful chemical substances or microorganisms with a concentration that could cause illness in any form or just impurities that interfere with color, taste, transparency and odor. Drinking water must be physically microbiologically and chemically safe. Safe water is either natural or chemically treated and filtered water made safe to drink and use for other purposes (e.g. hand washing and medical instrument cleaning) because it meets specified public health standards. These standards include: zero levels of microorganisms, such as bacteria (e.g. *fecal coliform & Escherichia coli*), parasites (e.g. *Giardia lamblia*) and viruses (e.g. hepatitis A or E); low turbidity (cloudiness due to particulate matter and other contaminants); minimum levels of disinfectants, disinfectant by-products, inorganic, organic chemicals and radioactive materials. Clean water should at least be free of microorganisms and have low turbidity (clear, not cloudy).

Emollient - is an organic liquid such as Glycerol, Propylene glycol or Sorbitol when added to hand rubs and hand lotions soften the skin and help to prevent skin damage (cracking, drying, irritation and dermatitis) due to frequent hand washing with soap (with or without antiseptic agent) and water.

Hand Washing - a Process of mechanically removing soil and debris from the skin of the hands using plain soap and water.

Soaps and Detergents (**terms used interchangeably**) - are cleaning products (bar, liquid, leaflet or powder) that lower surface tension thereby helping to remove dirt, debris and transient microorganisms from hands. Plain soaps require friction (scrubbing) to mechanically remove microorganisms, whereas antiseptic (antimicrobial) soaps could kill or inhibit the growth of most microorganisms without doing so.

Transient and Resident (Normal) flora - refer to where bacteria and other microorganisms are located in the layers of the skin. Transient floras are acquired through contact with patients, healthcare workers or contaminated surfaces (e.g. examination tables, floors or toilets) during the course of the normal workday. These organisms live in the upper layers of the skin and can partially be removed by washing with plain soap and clean water. These are organisms most likely to cause nosocomial/healthcare associated infections (HAIs). Resident floras are found on body surfaces contagious to the outside environment, in the deeper layers of the skin and within hair follicles as well. These floras cannot be completely removed, even by vigorous washing and rinsing with plain soap and clean water. Fortunately, resident flora is often of little association with infections. The hands or fingernails of some health workers, however, can become colonized in the deep layers with organisms that cause infections, such as *S. aureus,* gram-negative bacilli or yeast.

Visibly Soiled Hands - are hands which are visibly dirty or those contaminated with blood or body fluids (urine, feces, sputum or vomit).

Waterless, Alcohol-Based Antiseptic Hand Rub or Antiseptic Hand Rubs - (terms used interchangeably) are fast acting antiseptic hand rubs that do not require the use of water to: remove transient flora, reduce resident microorganisms and protect the skin. Most of these antiseptics contain 60 to 90% alcohols, an emollient and often additional antiseptic (e.g. 2 to 4% Chlorexidine gluconate) which have residual actions (Larson *et al*., 2001).

HAND HYGIENE PRACTICES

Hand hygiene can be accomplished by:

- Hand washing
- Hand Antisepsis
- Antiseptic Hand rub
- Surgical Hand scrub

The decision of choosing which type of hand hygiene practice to use depends on:

- Intensity of contact with patient and/or blood and body fluids,
- The likelihood of microbial transmission,
- Patient's susceptibility to infection, and
- Procedures being performed

Hygiene is the single most important infection prevention procedure.

Hand hygiene significantly reduces the number of disease-causing microorganisms harboring on the hands and arms to result in minimization of cross-contamination (e.g. from health worker to patient). The indications for this hygiene are well known, but guidelines for best practices are still evolving and not yet established. For example, the choice of plain or antiseptic soap or use of an antiseptic hand rub depends on the degree of the risk of contacts with patients (e.g. routine medical procedure versus surgery) and availability the materials (Larson E. *et al*., 1995).

HANDWASHING

The purpose of hand washing with plain soap and water is to mechanically remove debris from the skin so as to reduce the number of transient microorganisms. This practice is as effective as washing with antimicrobial soaps (Pereira LJ *et al*., 1997). If the tap water is contaminated, however, hand washing with plain soap is effective only in removing dirt and debris. It is also notable that a plain soap causes much less skin irritation (Pereira LJ *et al*., 1997).

Time and Situations Needing Hand Washing:

- Immediately on arrival and departure from work (the health facility).
- Before and after examining (coming in direct contact with) a client/patient.
- Immediately after touching contaminated instruments or articles.
- Immediately after exposure/bare skin contact to mucous membranes, blood, body fluids, secretions or excretions.
- Before putting on gloves and after removing them.
- Whenever the hands become visibly soiled after nasal blowing or following a covered sneeze.
- Before eating or serving food.
- After visiting the toilet.

Note:

- Hands should be washed with soap and clean water (or an antiseptic hand rub) after removing gloves because the gloves may still have tiny holes or tears which let bacteria to rapidly multiply on the gloved hands due to the moist and warm environment within the glove (CDC, 1989; Korniewicz *et al*., 1990).
- If tap water is contaminated, use water that has been boiled for 10 minutes and filtered to remove particulate matter (if necessary) or use chlorinated water---water treated with a dilute bleach solution (sodium hypochlorite) to make the final concentration reach 0.001%.

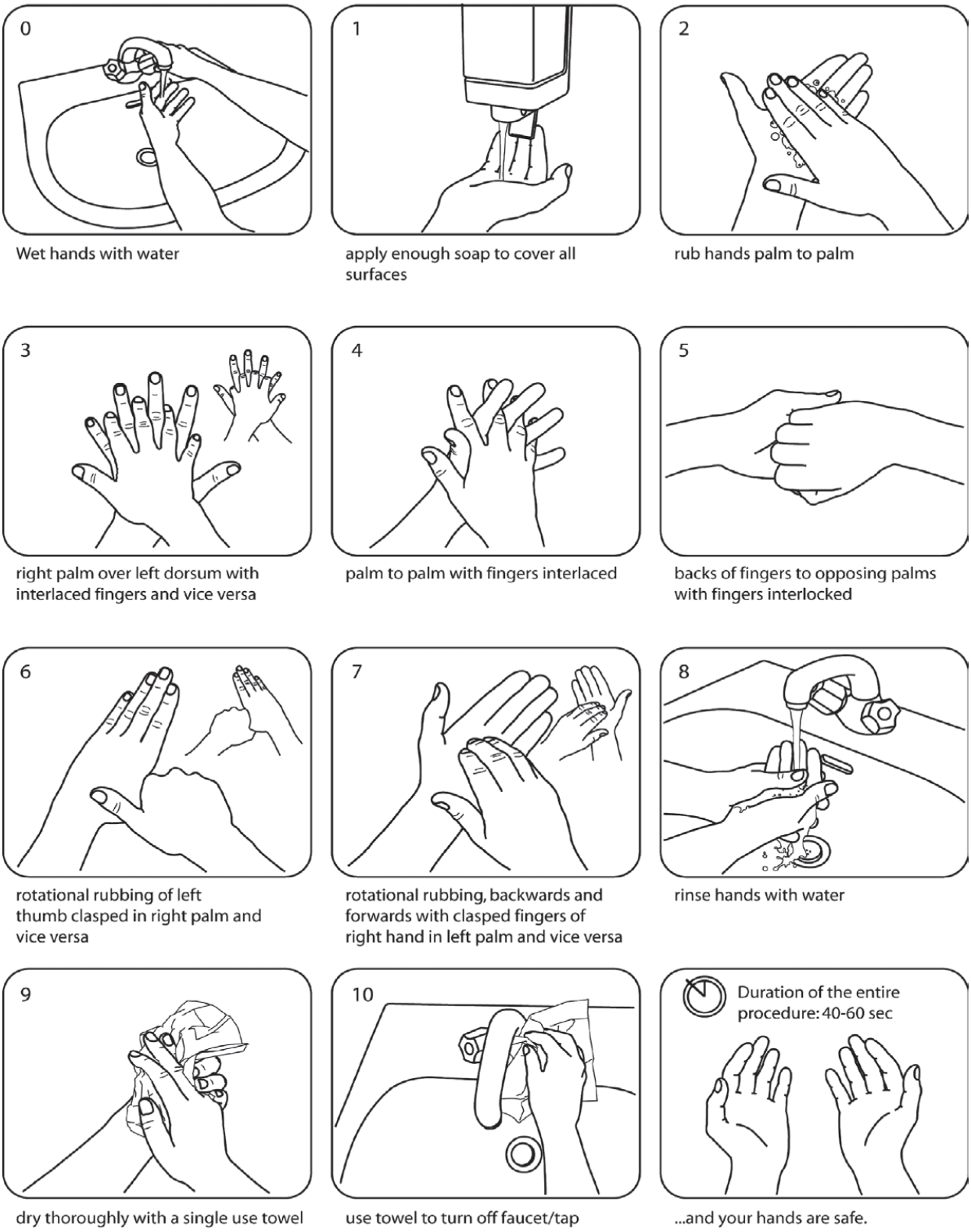
The Steps for Routine Hand Washing are:

- Wash hands with water thoroughly.
- Apply a plain soap (antiseptic agent is not necessary).
- Rub all areas of hands and fingers vigorously for 10 to 15 seconds, paying close attention to areas under fingernails and between fingers.
- Rinse hands thoroughly with clean water.
- Dry hands with personal dry clean towel or paper towel.
- Use a paper towel or a single use towel after drying hands to turn off the water for faucet handles are also contaminants. (**Figure 3.1,** illustrates the steps for hand washing).

Note:

When drying hands, the use common towels should be avoided. Shared towels are likely to harbor microorganisms and contaminate hands even after proper hand washing. Therefore, it is advisable to carry and use a small personal towel that could be replaced or cleaned daily when wet or visibly dirty.

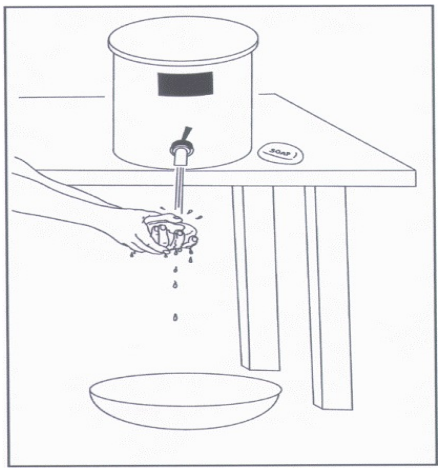
Figure 3.1 Hand washing Technique with Soap and Water



In settings where standing water is used for cleaning, the following procedure is recommended:

- If bar soap is used, provide small bars and soap racks which allows drainage.
- Use running water and avoid dipping hands into a basin containing standing water. Even if it is treated with antiseptic agents, such as Dettol or Savlon, microorganisms can survive and multiply in it (Rutala, 1996 WA, 1996).
- If liquid soap is being used, do not add soap to a partially empty liquid soap dispenser. This practice of "topping off'' dispensers may lead to contamination of the soap itself. Liquid soap dispenser should be thoroughly washed and dried before refilling it.
- A bucket with tap or a bucket with a pitcher or jug can be used if running water is not available from the tap. The used water should be collected in a basin and discarded in a latrine if a drain is not available.

Figure 3.2 Hand Washing Technique with Soap and Water Using Improvised Washing Bucket



HAND ANTISEPSIS

The purpose of hand antisepsis is to remove soil and debris to reduce both transient and resident flora on the hands. The technique for hand antisepsis is similar to hand washing except that it involves use of soap containing an antimicrobial agent (often Chlorhexidine, Iodophors or Triclosan) instead of plain soap or detergent. The antiseptic will continue to inhibit the growth of organisms present on the hands. Some of the commonly found medicated soaps with antimicrobial agent includes: Medicum, Life boy, Dettol, etc.

Hand Antisepsis should be Done Before:

- Examining or caring for highly susceptible patients (e.g. premature infants, elderly patients or those with advanced AIDS, etc.);
- Performing an invasive procedure such as placement of an intravascular device; and
- Leaving the room of patients on Contact Precautions (e.g. Hepatitis A or E), or those with drug resistant infections (e.g. Methicillin-resistant *S. aureus*).

Hand washing with medicated soaps or detergents repeatedly is more irritating to the skin than that of using antiseptic hand rubs. So if available, antiseptic hand rubs should be used instead (Larson E *et al*., 1990 & Larson E *et al*., 2001).

ANTISEPTIC HAND RUB

The purpose of antiseptic hand rub is to inhibit or kill transient and resident flora. Use of a waterless, alcohol-based hand rub product is more effective in killing these floras than the plain or medicated soap and water. Antiseptic hand rub is quicker and easier to perform and gives a greater initial reduction in hand flora (Girou E *et al*., 2002). These hand rubs also contain a small amount of an emollient such as Glycerin, Propylene glycol or Sorbitol that protects and softens skin. Further, it is less irritating to the skin than medicated soaps as well.

As shown below, an effective antiseptic hand rub solution is cheaper and simpler to prepare

Note:

A non-irritating antiseptic hand rub can be made by adding either Glycerine[a], Proplyene glycol or Sorbitol to alcohol (2ml. in 100ml. of 60 to 90% Ethyl or Isopropyl alcohol solution) (Larson, 1990 & Pierce, 1990). Use 5ml. (about one teaspoonful) for each application and continue rubbing the solution over the hands until they are dry (15 to 30 seconds).

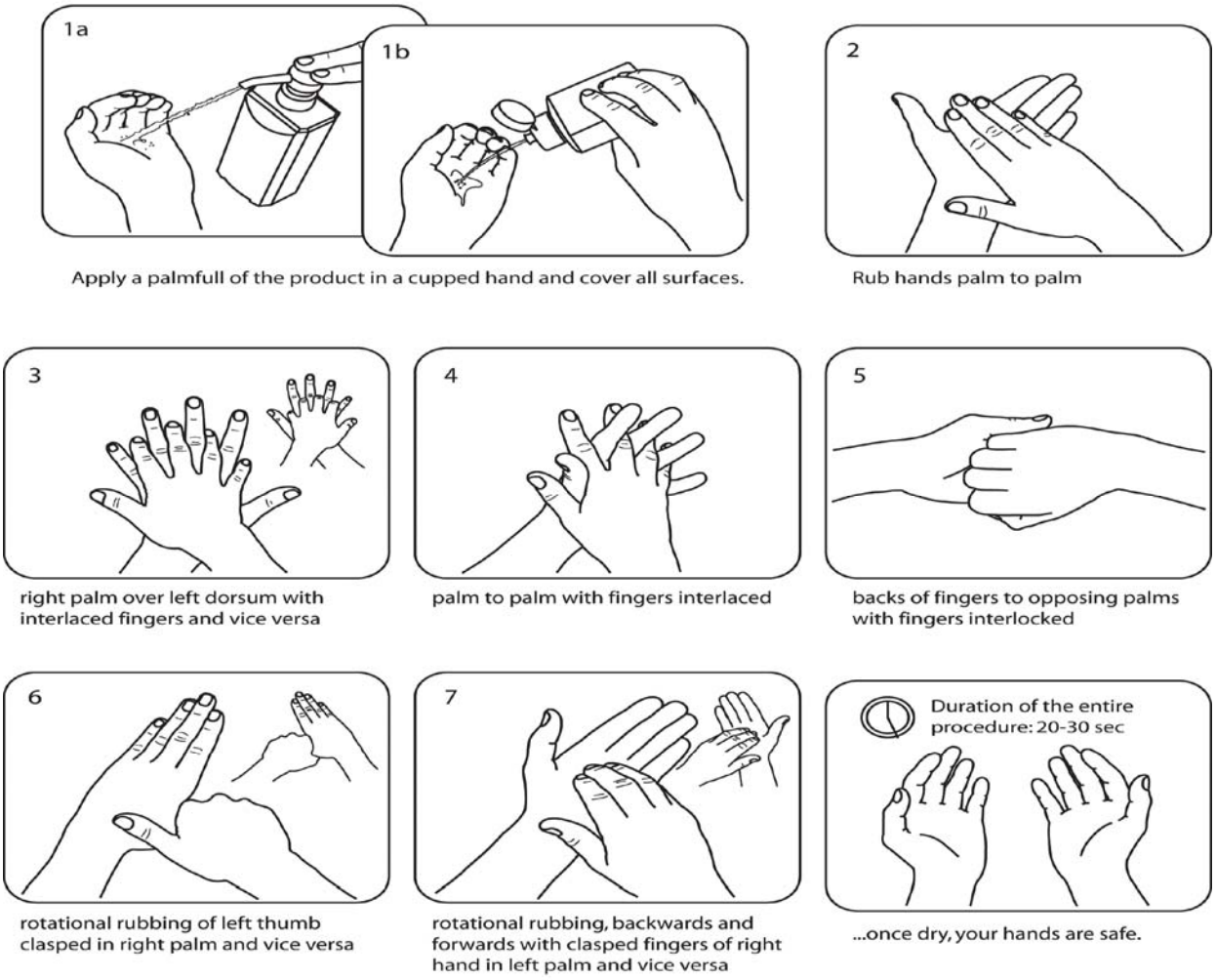
[a] Glycerin is often sold in cosmetic departments because it is used as a hand softener.

For a better effect, an adequate amount (5ml.) of antiseptic hand rub solution should be used.

The Technique Applied to Perform Antiseptic Hand Rub is:

- Apply enough alcohol-based hand rub (5ml.) to cover the entire surface of the hands and fingers. Rub the solutions vigorously on the hands especially between the fingers and under the nails until dry.
- Do not rinse hands after applying hand rub.

Figure 3.3 Hand Hygiene Technique with Alcohol-Based Formulation



WHO Guidelines on Hand Hygiene in Healthcare (advanced draft)/ Modified according to EN 1500

Alcohol based hand rubs do not remove soil or organic nature/materials. For better effects, therefore, hand washing with soap and water should be done first if hands are visibly soiled or contaminated with blood or body fluids. Besides, it is recommended that the washing should be done every 5 to 10 applications so as to reduce the "build up" of emollients on hands after repeated use of alcohol-based hand rubs. Finally, hand rubs containing alcohol only as the active ingredient, have limited residual effect (i.e. ability to prevent growth of bacteria after being applied) compared to those containing alcohol plus antiseptics such as Chlorhexidine.

SURGICAL HAND SCRUB

The aim of surgical hand scrub is to mechanically remove soil or debris along with transient organisms and to reduce resident flora prior to performing any surgical procedures and throughout. The ultimatum for the goal is prevention of wound contamination due to microorganisms from the hands and arms of the surgeon and assistants resulting from possible breakage or inadequacy of intactness/coverage of the gloves or gowns.

For many years, preoperative hand scrubbing protocols used to be carried out by way of at least 6 to 10 minute vigorous scrubbing with a brush or sponge, using soap containing an antiseptic agent (Chlorhexidine or Iodophor). This practice, however, has proved to be damaging to the skin and at times resulting in an increased shedding of bacteria from the hands (Dineen, 1966; Kikuchi, Numagami *et al*., 1999). Several studies suggest that neither a brush nor sponge is necessary to reduce bacterial counts on the hands of the surgical staff to an acceptable level. For example, a two-minutes hand washing with soap and clean water followed by application of 2 to 4% Chlorhexidine or 7.5 to 10% Povidone iodine was found to be as effective as a five-minute hand scrub with an antiseptic soap (Deshmukh *et al.,* 1996; Pereiraetal, 1997). As a result, the guidelines for performing the general surgical scrub technique have been made in such a way that it is less arduous and time consumptive to perform. The steps are as follows:

1. Remove all rings, watches and bracelets.
2. Wash hands thoroughly, especially between fingers and forearms up to the elbows with soap and water. (If a brush is used, it should be cleaned and either sterilized or reliably disinfected before being reused or shared with others. Sponges, if used, should be discarded).
3. Clean nails with a nail cleaner.
4. Rinse hands and forearms thoroughly with clean, running water.
5. Apply an antiseptic agent (e.g. 2 to 4% Chlorhexidine gluconate (CHG)) up on all surfaces of hands and forearms up to the elbows and rub hands and forearms vigorously for at least two minutes.
6. Rinse the hands and arms thoroughly, holding hands higher than the elbows (If tap water is contaminated, uses boiled and cooled water or chlorinated water and filter if necessary).
7. Keep hands up and away from the body; do not touch any surface or article; and dry hands and forearms with a sterile towel.
8. Put sterile or high-level disinfected surgical gloves on both hands.

Applying an antiseptic minimizes the number of microorganisms on hands under the gloves and the growth of flora from within during surgery. This is important because gloves may have in apparent holes or tears, or may be nicked during surgery.

Complete instructions on how to do a general surgical hand scrub are outlined in **Appendix A**

Note:

Skin damage caused by allergic reactions confers an ideal place for microorganisms to multiply and hence should be avoided. Health personnel with allergies to antiseptics may use plain soap followed by applying the waterless alcohol-based hand rub described above.

Alternatively, hand washing with plain soap and water followed by use of a waterless, alcohol-based hand rub containing Chlorhexidine has been known to significantly yield greater reduction of microbial counts on the hands, improve skin health, reduce the time needed and save resources (Larson E *et al*., 2001).

The Steps of Performing this Simpler and Shorter Surgical Hand Scrub Technique are:

- Remove rings, watches and bracelets.
- Wash hands thoroughly, especially between fingers and forearms up to the elbows with soap and water, clean nails with a nail cleaner (tooth prick or soft brush).
- Rinse hands and forearms with clean running water and dry thoroughly with a clean dry towel.
- Apply 5ml. of waterless alcohol-based hand rub/antiseptic; hand rub hands, fingers along with forearms and rub until it dries; repeat the application two more times for a total of at least two minutes using a total of about 15mls of the hand rub antiseptic.
- Keep hands up and away from the body; avoid touching any surface or article prior to putting sterile or reliably disinfected surgical gloves on both hands.
- Take great care not to contaminate the Glycerin meant to be used for the preparation of alcohol based hand rub for surgical scrub.

Before entering the operation theatre and starting surgical hand scrub preparation, one must:

- Keep nails short (less 3mm.).
- Avoid wearing artificial nails or nail polish.

IMPROVING PRACTICE OF HAND HYGIENE: WHAT WORKS

Hand washing has been considered one of the most important measures for reducing transmission of microorganisms and preventing infection for more than 150 years. For example, the study of Semmelweiss, (1861) and numerous others who have conducted researches on the issue demonstrated that it is possible to transmit infectious diseases from patient to patient through the hands of the healthcare workers. Equally well documented, is the fact that good Hand hygiene can prevent transmission of microorganisms and decrease the frequency of healthcare associated infections (Boyce JM *et al*., 1999; Larson E, 1995). The persisting problem, however, is maintaining adherence to the recommended hand washing practices among healthcare workers. In the US, for example, rate of compliance with hand washing among healthcare workers ranges from 25% to 50% only depending on the setting (i.e. better compliance in pediatric units than in general medical services). Key reasons given for not washing hands according to recommended guidelines include: lack of time, limited access to sinks and running water, irritations of the skin on the hands from frequent hand washing, overconfidence on the protective capacity of wearing gloves, lack of confidence on the effectiveness of hand washing to prevent infections, and misperception that peers and supervisors do not perform hand washing as recommended (**Table 3.1**). Moreover, it has been evident that the health professionals wrongly believe that they wash their hands more often than they should have (Tibballs, 1996)!

Over the years, nurses and physicians have diligently studied and written about this problem. Numerous reports have maintained that the effectiveness of hand washing and other related procedures along with uses of gloves are cost-effective ways to reduce infections. Despite this truth, compliance with the practice remained poor and the problem of HAIs infections transmitted through healthcare workers continues to increase globally. In the last few years, several strategies have been designed and tested to correct this situation and improve compliance. Those strategies lending to

most promising effects combine behavioral change activities such as continuing education, motivation and change of system, with role modeling or mentoring, and continuity of feedbacks to the staff. While the results to date have not been totally successful, improvements have still been demonstrated (i.e. reduced rates of HAIs) in several studies (Larson E *et al*., 2000; Pittet D *et al*., 2000). In the future, other innovative approaches like education of patients and their families about the importance of the health care staff's Hand hygiene is believed to be more helpful to bring about positive changes concerning the issue.

Table 3.1 Why Healthcare Professionals Do not Wash Their Hands

Belief that:

- Handwashing between every patient encounter is unnecessary
- Handwashing does not affect clinical outcome
- Handwashing is unnecessary when gloves are worn
- Routine or frequent handwashing is unnecessary
- Frequent handwashing interrupts efficient patient care
- Frequent handwashing damages skin and causes cracking, dryness, irritation and dermatitis
- Handwashing damages nails and nail polish
- Handwashing facilities are not conveniently placed or well designed
- Handwashing is inconvenient
- Handwashing takes too much time

Failure of supervisors and managers to:

- Establish a handwashing policy
- Involve administrators in handwashing policy
- Effectively communicate handwashing policy
- Demonstrate handwashing policy through actions
- Enforce handwashing policy

Adapted from: Alvarado 2000.

Hand hygiene is the primary measure especially proven to be effective in preventing healthcare associated infections and the spread of antimicrobial resistance. However, it has been observed that healthcare workers encounter difficulties in complying with the recommended indications of the practices at different levels.

Although bringing about change of behavior in this area is a real challenge, there still are certain steps that increase the chances of success. These include:

- Widely disseminate current guidelines on hand hygiene practices, evidences supporting their effectiveness in preventing disease and the need for health workers to adhere to the guidelines.
- Involve healthcare facility administrators in promoting and enforcing the guidelines by convincing them of the cost benefits of hand washing and other related hygiene practices.

- Use successful educational techniques including role modeling (especially by supervisors), mentoring, monitoring and receiving positive feedback.
- Use performance improvement approaches targeted to all healthcare staff, not just physicians and nurses, to promote compliance.
- Consider the need of the staff for convenient and effective options for hygiene practice of the hands which make compliance a lot easier.

A promising instance on how to make compliance easier is by way of providing staff with small, individual-use containers of an antiseptic hand rub. Development of this product stems from the observation that improper hand washing techniques and low compliance has made the current recommendations ineffective. Use of an affordable antiseptic hand rub simple to prepare, however, minimizes many of the factors limiting better use of recommended guidelines for Hand hygiene. In addition to that, these hand rubs which are more effective than that of washing hands with plain or medicated soaps, can be made much more available for no sink or running water needed; requiring less time to use; and causing little or no irritation of the skin (less drying, cracking or chapping). As a consequence, antiseptic hand-rubs may soon replace hand washing with plain or medicated soap and water as a primary procedure for improving compliance (Larson E *et al*., 2000; Pittet D *et al*., 2000). Interestingly, the only large-scale, hospital-based programs that have reported to sustain improvement from adherence to recommended procedures and the use of antiseptic hand rubs, have ascribed it to a reduced infection rates incorporated (Larson E *et al*., 2000; Pitte D *et al*., 2000). It must be recognized, however, that making a hand-rub available to staff without ongoing educational and motivational activities may not result in long-lasting improvement in the practices. Just installing dispensers of a rapid acting antiseptic hand rub, for example, is not sufficient (Muto *et al*., 2000).

The second example focuses on encouraging the staff to use hand-care products (moisturizing lotions and creams) that help prevent skin irritation and contact dermatitis associated with frequent hand washing, especially with a soap or detergent containing an antiseptic agent. The staffs were highly satisfied not only with the results but also with the study (McCormick *et al.,* 2000) which improved skin conditions due to use of a hand lotion leading to a 50% increase of frequency of hand washing!

Recognizing the possibly confusing guidelines on Hand hygiene and advocating for their improvement is also what is expected of teachers and supervisors to demonstrate their commitment. This obviously helps health workers to meet the criteria both for correct practices and providing appropriate patient care. In summary, although improving compliance with the guidelines has so far been difficult, some programs and institutions are beginning to be successful. The key to success appears to hinge on multi-factorial interventions involving behavior change, creative education, monitoring and feedback and above all, exemplary supervisors serving as role models and the support of administration. In connection with that, it would be sound to conclude that Hand hygiene needs to generally be regarded as a quality indicator for optimal safety of patients.

OTHER ISSUES AND CONSIDERATIONS RELATED TO HAND HYGIENE

Glove Use

Since the emergence of AIDS epidemic in1987, the use of gloves by all types of healthcare staff increased dramatically in connection with an effort to prevent transmission of HIV and other blood borne viruses. Although the effectiveness of gloves in preventing contamination of health workers' hands has repeatedly been confirmed and considerably capitalized (Tenorio *et al.,* 2001), preventing gross contamination of hands is considered important too. On the other hand, it is true that hand washing-even with an antiseptic agent, may not remove all potential pathogens when hands are heavily contaminated. Studies showed that gloves, in fact, by no means confer complete protection against contamination of the hands. For example, it was known that bacteria from patients could be recovered in about 30% of the staffs who wear gloves during patient care (Kotilainen *et al*., 1989). Such findings have misled some health workers to doubting the efficacy of the practices under any circumstances, resulting in poor or rare use of hand washing.

In the same line, it has been known that oral surgeons wearing gloves and other protective devices have become infected with hepatitis B, presumably due to contamination via small defects in the gloves or possibly contaminations of their hands during glove removal (Reingold *et al.,* 1988). Moreover, mal practices such as wearing the same pair of gloves and washing gloved hands for each patient or caring movement from dirty to a clean body site could no longer be a safe practice. Doebbeling and his colleagues (1988), recovered significant amounts of bacteria on the hands of the staff not changing gloves between patients but just washing their gloved hands. The overall merits entwined with the use of gloves in hygiene practices of the hands do not seem to be clear for the staff. For example, some studies have reported that staffs who wear gloves were less likely to wash their hands, while others have found out the opposite. Given the generally poor compliance with the practices, every effort must be put to reinforce the message that gloves do not replace the practice in Hand hygiene. In certain circumstances, however, gloves should be used in addition to keeping Hand hygiene

Wearing gloves do not replace the need for Hand hygiene

Hand Lotions and Hand Creams

To minimize contact dermatitis related to frequent hand washing (>30 times per shift) using harsh detergents and frequent exposures to antiseptic agents, (60 to 90% Alcohol is found to be less irritating to the skin than any other antiseptic or non- antiseptic detergent). Healthcare workers may instead use hand lotions, creams and moisturizing skin care products. Several studies have shown that regular use (at least twice per day) of such products can help prevent and treat contact dermatitis (McCormic *et al.,* 2000). Such products can help prevent and treat contact dermatitis but these products should be water based and without fragrance. In addition to that, moisturizers can prevent drying and damage to the skin and loss of skin fats as well. There is also biological evidence that emollient such as Glycerol and Sorption (with or without antiseptics) may decrease cross contamination because they reduce the shedding of bacteria from the skin up to 4 hours. Whenever CHG product is being used, the lotion needs to be compatible if at all the activity of the CHG could not be diminished). By contrast, oil based barrier products

like those containing petroleum jelly (Vaseline or lanolin), should not be used for these damage latex rubber gloves.

Lesions and Skin Breaks

Cuticles, hands, and forearms should be free from lesions (dermatitis or eczema) and skin breaks. Cuts and abrasions should be covered with waterproof dressings. If this is not possible, the surgical staff with skin lesions should not operate until the lesions have healed.

Finger Nails

Research has shown that the area around the base of nails contains the highest microbial count on the hands (McGinley, Larson & Leydon; 1988). Several recent studies have indicated that long nails may serve as a reservoir for gram-negative bacilli (*P. aeruginosa*), yeast and other pathogens (Heddermick *et al*., 2000). Moreover, long nails, natural or artificial, tend to puncture gloves more easily (Olsen *et al*., 1993). Thus, it is recommended that nails be kept moderately short- not extend more than 3mm (or 1/8 inch) beyond the fingertip.

Artificial Nails

Artificial nails (nail wraps, nail tips, acrylic lengtheners, etc) worn by healthcare workers can contribute to healthcare associated infections (Hedderwick *et al*., 2000). Besides, on the ground that there is evidence on their functioning as a reservoir for pathogenic gram-negative bacilli, the use of artificial nails by health workers should be restricted. This restriction should be imposed unto the surgical team members in particular, and those working in specialty areas like ICUs dealing with neonates and patients highly susceptible to infection, or patients having infections with resistant organisms (Moolenaar *et al*., 2000).

Nail Polish

Although there could not be apparent reasons forwarded restrictions on wearing nail polish, it is suggested that surgical team members and those staff working in specialty areas could wear freshly applied, clear nail polish only. At this junction, however, it is stressed that chipped nail polish supports the growth of large number of organisms on fingernails compared to freshly polish or natural nails. Another point to make is that dark colored nail polish may cover up the dirt and debris under fingernails impeding quick notice and removal thus serves as good hiding place for organisms (Baumgardner *et al*., 1993).

Jewelry

Although several studies have shown that the skin under rings is more heavily colonized than comparable areas of skin on fingers without it (Jacobson *et al.,* 1985). Yet, it is not so far known or affirmed whether wearing of rings gives way to a greater transmission of pathogens. Nonetheless, it is still sound enough to suggest surgical team members not wear rings since it may be more difficult to put on surgical gloves without tearing them.

Note: The indications for hygiene practice of the hands are well known, but guidelines for best practices continue to evolve. Current recommendations for health care workers are:

- When skin is damaged or frequent hand washing is required, a mild soap (without antiseptic agent) should be used to remove soil and debris.
- If antimicrobial action is desired (e.g. before an invasive procedure or contact with highly susceptible patients such those with AIDS or newborns) and hands are not visibly dirty, an antiseptic hand rub should be used rather than washing hands with medicated antiseptic soap.
- In high-risk areas such as the operating room, neonatal ICU or transplant units, hand scrub protocols that use soft brushes or sponges for a shorter time (at least two minutes) should replace harsh scrubbing by hard brushes for 6 to10 minutes.
- The staff who frequently wash their hands (30 times or more per shift), should be provided with hand lotions and creams helpful to reduce irritation of the skin.

MONITORING COMPLIANCE WITH HAND HYGIENE

Monitoring the practices of Hand hygiene is an important activity directed towards assessing baseline compliance by healthcare workers, to evaluate the impact of promotional interventions and channel feedbacks to healthcare workers. Monitoring can also be instrumental in the investigations of infection outbreaks in assessing the potential role of the ongoing practices and also in determining the extent to which infection can be decreased depending on the different rates of compliance. The extent of compliance with Hand hygiene can be evaluated directly or indirectly. A direct method includes observation, patient assessment or self-reports. Indirect methods, on the other hand, include monitoring consumption of products, such as soap or hand-rub, and electronic monitoring of the use of hand wash basins. Direct methods are necessary to determine the compliance rates precisely. A direct method, according to the definitions for hand hygiene indications, consists of a count of the number of episodes in the hygiene practice performed by healthcare workers divided by the number of opportunities for the practices. Performance feedback on the behavior of Hand hygiene is critical to improve compliance with the recommended practices among healthcare workers.

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CHAPTER 4: PERSONAL PROTECTIVE EQUIPMENT

KEY TOPICS TO BE DISCUSSED:

- Items of personal protective equipment
- When and why gloves should be worn
- Common malpractices related with use of gloves
- Effective personal protective equipment
- Types and respective uses of drapes

BACKGROUND

Healthcare workers are confronted each day with the difficult question of working safely (risk-free environment) within a potentially hazardous environment health care facilities. Today, the most common occupational risk the healthcare personnel face is due to contact with blood and body fluids during routine works like cleaning, instrument processing and patient care. This exposure to pathogens increases risk of getting serious infection and possible death. Health workers in some occupational settings such as surgery and delivery rooms, have a higher risk of exposure to pathogens than those in all other departments combined (Gershon & Vlahov, 1992; Gershon & Zirkin, 1995). Ongoing research has identified several psychosocial and organizational factors that may contribute to lack of compliance by healthcare staff. The most important of these factors are:

- Poor safety conditions for the staff working in hospitals and clinics, and
- Conflict of interest between providing the best patient care and protecting oneself from exposure (Gershon, 1996).

Protective barriers and clothing are now commonly referred to as personal protective equipment (PPE). The use of PPE is ages old and has been reasonably helpful to protect clients from microorganisms present on the medical staff and others working in the healthcare setting. Lately, with the emergence of HIV/AIDS, HBV, HCV and resurgence of tuberculosis in many countries including Ethiopia, PPE now grew to be more important for protecting the healthcare providers than ever.

The basic principle behind wearing personal protective equipment is to get physical barrier/protection of healthcare providers and patients/clients from pathogenic microorganisms. Personal protective equipment includes: gloves, masks/respirators, eyewear (face shields, goggles or glasses), caps, gowns, aprons and other items. In many countries, caps, masks, gowns and drapes are made of clothes or papers. The most effective barriers, however, are made of treated fabrics or synthetic materials that do not allow water or other liquids (blood or body fluids) to penetrate them. These fluid-resistant materials are not, however, widely available because they are expensive. Lightweight cotton clothes (with a thread count of $140/inch^2$) are materials most commonly used for surgical clothing (masks, caps and gowns) and drapes in many countries. Unfortunately, lightweight cotton does not provide an effective barrier because moisture can pass through it easily, allowing contamination.

Denims, canvas and heavy twill, on the other hand, are too dense to allow steam penetration (i.e. they cannot be sterilized); and hard to wash and take too long to dry as well. When fabric is used, it should be white or light colored showing dirt and contamination more easily. Caps, masks or drapes made from paper should never be reused for there is no way to properly clean them. The simple rule: 'If you can't wash it, don't reuse it.' is valuable. To be effective, PPE must be used correctly. For example, surgical gowns and drapes have proved to be preventive for impending wound infection only when dry. When wet, however, clothes act as a wick or sponge to draw bacteria from the skin or equipment up through the fabric that can then contaminate a surgical wound (**Figure 4.1**)

Figure 4.1 Bacterial Transfers Though Fabric

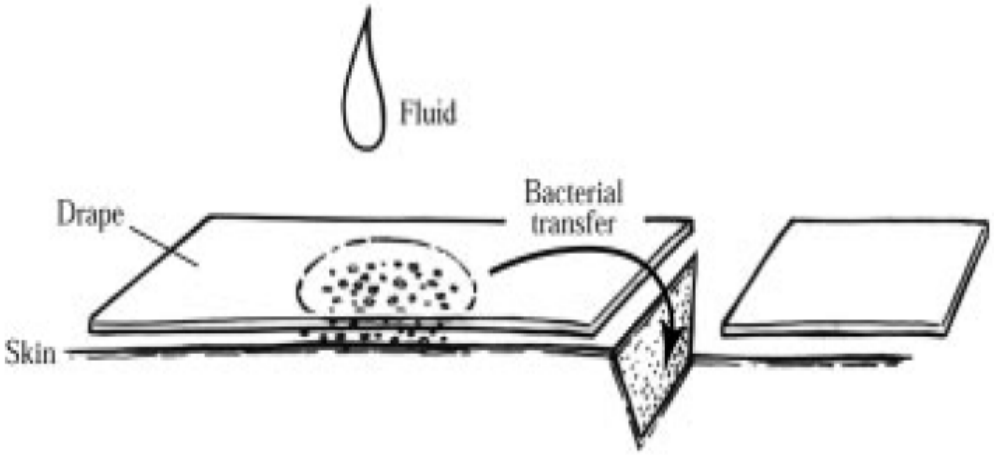


Table 4.1 Below describes how personal protective equipment blocks the spread of microorganisms. This will help health workers in healthcare facilities make decisions about using personal protective equipment.

Table 4.1 How Personal Protective Equipment Blocks the Spread of Microorganisms

WHERE MICROORGANISMS ARE FOUND	HOW MICROORGANISMS ARE SPREAD	BARRIERS TO STOP THE SPREAD OF MICROORGANISMS	WHO THE BARRERS PROTECT
Healthcare Staff			
Hair and scalp	Shedding skin or hair	Cap	Patient
Nose and mouth	Coughing, talking	Mask (water resistant)	Patient
Body and skin	Shedding skin or hair	Scrub suit, cover gowns	Patient
Hands	Touching	Gloves, hand washing or waterless antiseptic	Patient
Patient			
Mucous membrane and non-intact skin	Touching	Gloves	Patient and staff
Blood and body fluids	Splashing or spraying	Gloves, eyewear, mask, drapes, and apron	Staff
	Touching (contact)	Instrument processing	Patient
	Accidental exposure with contaminated needles and scalpel blades	Protective footwear, decontamination and disposal; use of a Safe or Neutral Zone during surgery	Staff
	Infectious waste	Utility gloves, plastic bags and proper disposal	Staff
Unprepared skin	Touching	Skin preparation, drapes, gloves	Patient
Clinic or hospital environment	Touching	Gloves, hand washing Dressing	Staff and their families

Table 4.2 Types of Personal Protective Equipment

TYPE OF PPE	MUST BE USED FOR	PRIMARILY PROTECTS
Caps, Gowns/Scrub Suits, Masks, Aprons, Drapes	Invasive procedures where tissue beneath the skin is exposed	Service provider and client
Closed boots or shoes (open sandals are not acceptable)	Situation involving sharp instruments or where contact with blood and/or body fluids is likely	Service provider
Goggles or glasses, Masks, Apron, or Mackintosh	Situation where splashing or blood, body fluids, secretions or excretions is likely	Service provider
Mackintosh or Apron	Situation where splashing or spillage of blood, body fluids, secretions or excretions is likely	Service provider
Masks	Situation which call for airborne or droplet transmission precautions	Service providers and client
Sterile Drapes	Major or minor surgical procedures	Client

As a rule, hospital administrators, supervisors and healthcare workers need to be aware not only of the benefits and limitations of specific PPE, but also of the actual role PPE play in preventing infection so that they can use them effectively and efficiently.

GLOVES

Healthcare Workers Wear Gloves for the Following Three Reasons:

1. To reduce the risk of acquiring bacterial infections to the staff from patients.
2. To guard the staff against transmitting their skin flora to patients.
3. To reduce contamination of the hands of the staff by microorganisms transmissible from one patient to another (cross-contamination). It is appropriate to stress that gloves were primarily worn only by staff caring for patients infected with certain virulent pathogens or patients with high risk of hepatitis B**.**

Since 1987, the year of the emergence of AIDS epidemic, a dramatic increase was evidently observed in the use of gloves pervades among all types of healthcare staff. This effect is attributable to the growing concern of this new phenomenon and reaction to prevent transmission of HIV along with other blood borne and body fluid viruses from patients to the staff. As a result, disposable examination and surgical gloves which are items of personal protective equipment presently became so pervasive in healthcare settings and among health care providers.

Note:

Practice of hand hygiene, coupled with the use of protective gloves, is a key component in minimizing the spread of diseases and maintaining an infection-free environment. In addition to that, clear understanding of the parameters to opt to either sterile or high-level disinfected gloves is important. Judicious use of these options can reduce costs and at times maintain safety both for the patients and the staff.

TYPES OF GLOVES

Surgical Glove - should be used when performing invasive medical or surgical procedures.

Clean Examination Gloves - provide protection to healthcare workers when performing many of their routine duties. These gloves can be used whenever contact with mucous membrane and non-intact skin is to made (e.g. during medical examinations and procedures such as pelvic examination).

Utility or Heavy-Duty Household Gloves - should be worn when processing instruments, equipment and other items, for handling and disposing contaminated waste, and when cleaning contaminated surfaces. Double gloving of either new examination gloves or reprocessed surgical gloves provide some protection in case utility gloves are not available.

> **Note:**
> The use of high-level disinfected surgical gloves when performing surgical or invasive procedures, is the only acceptable alternative on condition that sterile surgical gloves are not available

The best surgical gloves are made of latex rubber because of the rubber's natural elasticity, sensitivity, durability and a comfortable fit. An increasing problem of latex allergy now a day created a demand for a search of another material causing little or no such problem. Consequently, a new synthetic rubber-like material called "Nitrile," which has properties similar to latex, has been developed to make better gloves. These new fabric of gloves are less likely to cause allergic reactions in the user. In many countries, the only type of examination gloves usually available is made up of vinyl, a synthetic material that is less expensive than latex rubber. Even though Vinyl is cheaper, it is inelastic (does not stretch like latex) making these gloves loose-fitting and easy to tear. To conclude, better quality examination gloves, so far, are made from latex or Nitrile and they can be found in medical supply stores in most countries. Utility gloves which are made of thick rubber are more intractable and sensitive deliberately meant for maximal protection by way of acting as a barrier.

Making decision on which type of examination glove is best for a task (if a choice is available) largely depends on the degree of risk from the exposure (low or high risk) to a potentially pathogen laden blood or body fluids; the length of the procedure to be carried out; and the possibility the development of allergy to latex or, rarely, to Nitrile.

Vinyl examination gloves are the cheapest of the three types of gloves currently available. They are good for short tasks involving minimal stress on the glove and low risk of exposure. They are loose-fitting (baggy), have limited elasticity and tear easily. The recommended usage is during a brief suctioning of endotracheal secretions, emptying emesis basins and the removal of an IV line. Nonetheless, if they are the only type of examination glove available and the risk of exposure to blood and body fluids is high, frequent changing or double gloving should be considered.

Natural rubber latex examination gloves provide the best protection. Hence, they are the most appropriate for surgical procedures and tasks involving moderate to high risk such as exposure to blood or body fluids. At this junction, it should be well taken up that these gloves should avoided

if the staff have known or suspected allergy to latex or for prolonged) contact (>1 hour) with high-level disinfectants such as Glutaraldehyde (for it may cause loss of effectiveness due to breakdown of latex).

Nitrile examination gloves are best for the staff with latex allergy and may be used for activities involving moderate to high risk. Nitrile gloves have many of the characteristics of latex but a better resistance to oil-based products. In this sense, the staff with known allergy to Nitrile or latex compounds should not use these gloves.

Note:

When using latex rubber gloves, avoid use of hand cream or lotions that contain mineral oil, petroleum jelly (Vaseline) or lanolin to protect your hands, because they may cause the gloves to break down within minutes.

WHEN TO WEAR GLOVES

Although the effectiveness of gloves in preventing contamination of the healthcare workers' hands has been repeatedly confirmed (Tenorio *et al*., 2001), wearing gloves does not replace the need for hand washing. The truth is that even the best quality latex surgical gloves may have small and unnoticeable defects; they may be torn during use; and the hands can become contaminated during removal (Bagg *et al.,* 1990; Davis, 2001).

Depending on the situation, surgical gloves, clean examination or utility gloves should be worn by all staff where:

- There is a chance of hands coming in contact with blood or other body fluids, mucous membranes or none intact skin;
- They perform invasive medical procedures (e.g. inserting vascular devices such as peripheral venous lines); or
- They handle contaminated waste items or touch contaminated surfaces.

Note:

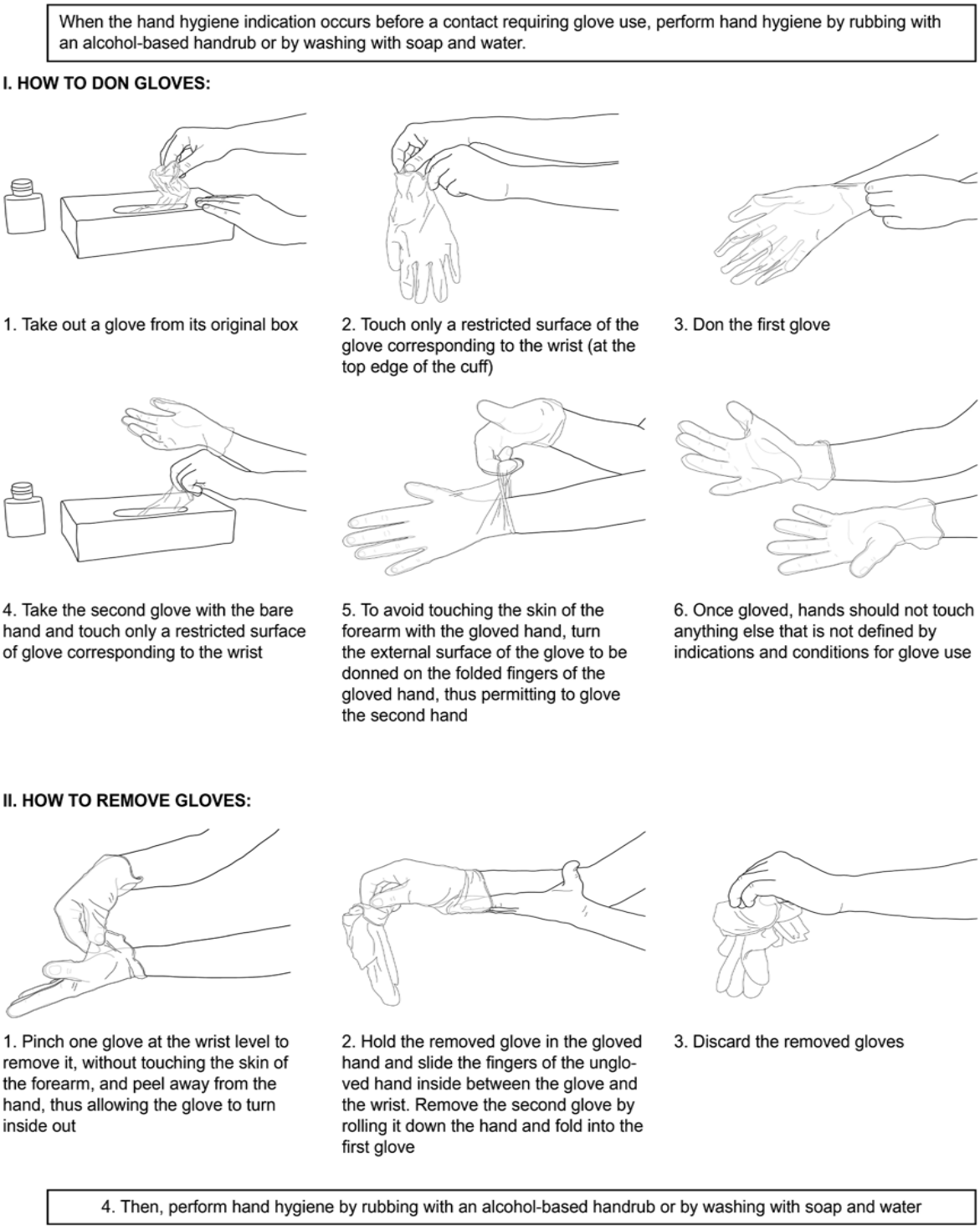
A separate pair of gloves must be used for each client to avoid cross-contamination or when moving from one site to another site on the same patient (i.e. from respiratory care to a dressing change).

It is preferable to use new and single use (disposable) gloves only.

REMOVING, DISCARDING AND REPROCESSING GLOVES

- If gloves are to be discarded, briefly immerse them in 0.5% Chlorine solution, remove and dispose them in a container for contaminated waste.
- If gloves are to be re-processed and reused, immerse them in a 0.5% Chlorine solution briefly, remove gloves by inverting them and then soak them in the 0.5% Chlorine solution for 10 minutes before cleaning and processing them for reuse.

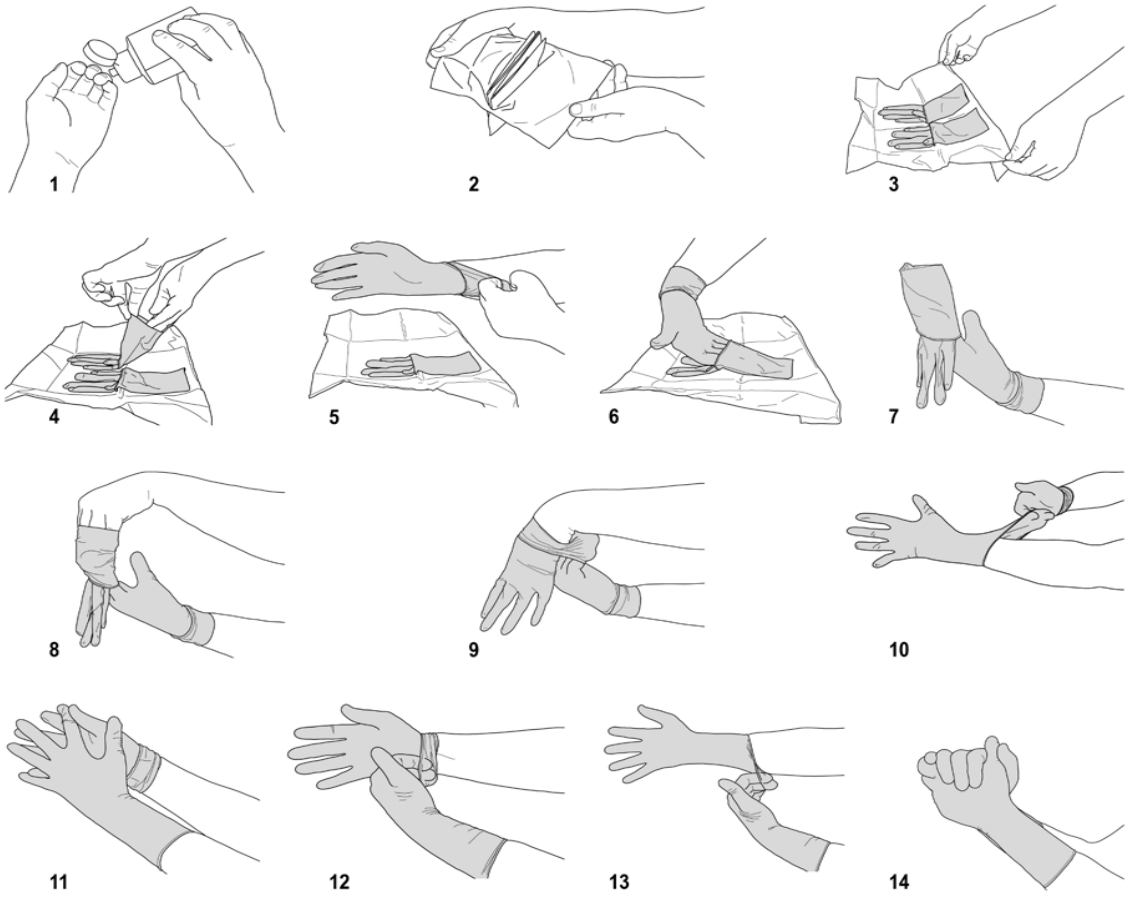
Figure 4.2 How to don and remove examination gloves



The purpose of donning and removing sterile gloves as indicated in **Figure 4.3** is to ensure maximum asepsis for patients and protect the healthcare workers from the patient's body fluid. In the correct usage of gloves-an instrument to achieve this double goal, the skin of the

healthcare worker remains exclusively in contact with the inner surface of the glove and has no contact with the outer surface. Any error in the performance of this technique leads to a lack of asepsis requiring a change of glove.

Figure 4.3 How to don and remove Sterile Gloves



1. Perform hand hygiene before an "aseptic procedure'' by hand rubbing or hand washing.
2. Check the package for intactness. Open the first non-sterile packaging by peeling it completely off the heat seal (cover) to expose the second sterile wrapper, but without touching it.
3. Place the second sterile package on a clean and dry surface without touching the surface. Open the package and fold it towards the bottom so as to unfold the paper and keep it open.
4. Using the thumb and index finger of one hand, carefully grasp the folded cuff edge of the glove.
5. Slip the other hand into the glove in a single movement, keeping the folded cuff at the wrist level.

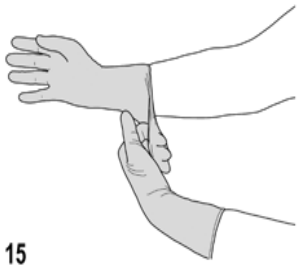
6-7. Pick up the second glove by sliding the fingers of the gloved hand underneath the cuff of the glove.

8-10. In a single movement, slip the second glove on to the ungloved hand while avoiding any contact/resting of the gloved hand on surface other than the glove to be donned (contact/resting constitutes a lack of asepsis and requires a change of glove).

11. If necessary, after donning both gloves, adjust the fingers and inter-digital spaces until the gloves fit comfortably.

12-13. Unfold the cuff of the first gloved hand by gently slipping the fingers of the other hand inside the fold, making sure that any contact with the outer surface of the glove is avoided (lack of asepsis requiring a change of gloves).

14. The hands are gloved and must touch exclusively sterile devices or the previously-disinfected patient's body area.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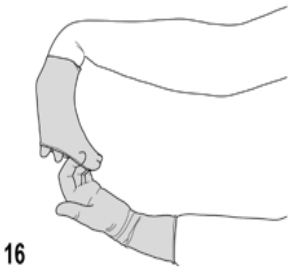
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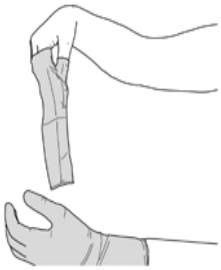
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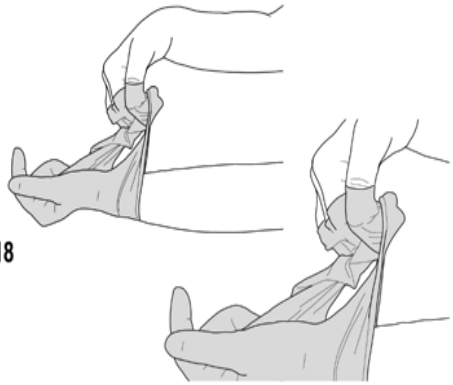
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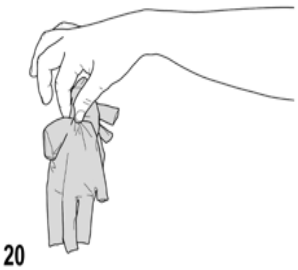
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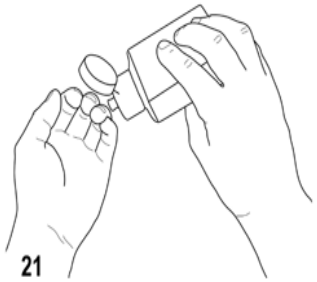
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15-17. Remove the first glove by peeling it back with the fingers of the opposite hand. Remove the glove by rolling it inside out to the second finger joint (do not remove completely).

18. Remove the other glove by turning its outer edge on the fingers of the partially ungloved hand.
19. Remove the glove by turning it inside out entirely (ball forming) to ensure that the skin of the health-care worker is always and exclusively in contact with the inner surface of the glove.
20. Discard gloves.
21. Perform hand hygiene after glove removal according to the recommended indication.

Donning surgical sterile gloves at the time of a surgical intervention follows the same sequences except that:

- It is preceded by a surgical hand preparation.
- Donning of the gloves is performed after putting on the sterile surgical gown.
- The opening of the first packaging (non-sterile) is done by an assistant.
- The second packaging (sterile) is placed on a sterile surface and then used for the intervention.
- Gloves should cover the wrists of the sterile gown.

WHAT TYPE OF GLOVES TO USE

- Sterile surgical gloves should be used when performing surgical or invasive procedures.
- High-level disinfected surgical gloves are the only acceptable alternatives to be used in surgical or invasive procedures only if sterile surgical gloves are not available.
- Disposable clean examination gloves are chosen (High-level disinfected reusable gloves are acceptable) in situations where contact with mucous membrane and non-intact skin is involved (e.g. performing medical examinations and procedures such as pelvic examination).
- Clean, heavy duty household (utility) gloves should be used for cleaning instruments, equipment, contaminated surfaces, and when handling or disposing of contaminated waste. Double gloving using either new examination gloves or reprocessed surgical gloves confer some protection in case utility gloves are not available. The following table provides guidelines on uses of gloves in common medical and surgical procedures.

Table 4.3 Glove Requirements for Common Medical and Surgical Procedures

TASK/ACTIVITY	ARE GLOVES NEEDED?	PREFERRED GLOVES[a]	ACCEPTABLE GLOVES
Blood pressure check	No		
Temperature check	No		
Injection	No		
Blood drawing	Yes	Exam[b]	HLD Surgical[d]
Endotracheal suctioning	Yes	Exam	HLD surgical
IV. insertion and removal	Yes	Exam[b]	HLD Surgical[d]
Pelvic examination (not for women in labor)	Yes	Exam	HLD Surgical[d]
Physical exam (intact skin)	No		
Rectal exam	Yes	Exam	HLD Surgical
IUD. insertion (loaded in sterile package and inserted using no-touch technique)	Yes	Exam	HLD Surgical[d]
IUD. removal (using no-touch technique)	Yes	Exam	HLD Surgical[d]
Manual vacuum aspiration (using no-touch technique)	Yes	Exam	HLD Surgical[d]
Norplant implants insertion and removal	Yes	Sterile Surgical[c]	HLD Surgical[d]
Vaginal delivery	Yes	Sterile Surgical[c]	HLD Surgical[d]
Cesarean section or laparotomy	Yes	Sterile Surgical[c]	HLD Surgical[d]
Vasectomy or laparoscopy	Yes	Sterile Surgical[c]	HLD Surgical[d]
Handling and cleaning instruments	Yes	Utility	Exam or HLD Surgical[d]
Handling contaminated waste	Yes	Utility	Exam or HLD Surgical[d]
Cleaning blood or body fluid spills	Yes	Utility	Exam or HLD Surgical[d]

[a] Although sterile gloves may be used for any surgical procedure, they are not always required. In some cases, examination or HLD surgical gloves are equally safe and less expensive.
[b] This includes new gloves, "never used'' twice even in the care for an individual or bulk-packaged examination gloves (as long as boxes are stored properly).
[c] When sterilization equipment (autoclave) is not available, high-level disinfection is the only acceptable alternative.
[d] Reprocessed surgical gloves.
Adapted from: Tietjen, Cronin, & McIntosh 1992.

General guidelines for wearing gloves are given in **Table 4.4**

Table 4.4 Glove Wearing Guidelines

PROCEDURES	TYPE OF GLOVES	COMMENTS
Any time there may be contact with mucous membranes and broken or non-intact skin	Examination gloves (recommended) Sterilized or high-level disinfected surgical gloves (acceptable)	Single use disposable gloves High-level disinfected reusable surgical gloves are acceptable if disposable examination gloves are not available
All procedures involving contact with any tissue underneath the skin For example, starting an IV. line,	Sterile surgical gloves (recommended) Sterilized reusable surgical gloves (acceptable) High-level disinfected reusable surgical gloves (acceptable only if there are no sterile gloves)	Single use disposable sterile surgical gloves Sterilized reusable surgical gloves are acceptable if disposable sterile surgical gloves are not available When sterilization equipment is not available, high-level disinfection is the only acceptable alternative
Handling and cleaning used instruments Cleaning contaminated surfaces Handling or disposing or disposing or contaminated waste	Heavy duty household (utility) gloves (recommended) Double gloving with reprocessed surgical or new examination gloves are acceptable	Heavy duty utility gloves: These are reusable, but must be decontaminated and cleaned between use When utility gloves are not available, double gloving with reprocessed surgical gloves or new examination gloves provide some protection
Gloves are not required if there is no contact with mucous membranes, blood, body fluids, secretions, or excretions (e.g. checking's of blood pressure, temperature, etc. or giving IM injections) Gloves should not be worn unless they are necessary. Rational use of gloves in turn, ensures availability in times of real need (i.e. use sterile gloves for necessary purpose only-they are expensive irrespective of who is paying for it)		NO GLOVES REQUIRED

WHEN TO USE DOUBLE GLOVES

The transmission of HBV and HCV from surgeon to patient and vice versa is known to have occurred even in the absence of incorrect application of the technique and apparent problems of intactness of the gloves (Davis, 2001). Even the best quality, new latex rubber surgical gloves

may leak up to 4% of the time[4]. Moreover, it was found that latex gloves gradually become weaker and lose their intactness especially when exposed to fat on surfaces of wounds.

Although double gloving is of little benefit in preventing exposure to blood in case of needle sticks or other similar injuries, it may decrease the risk of blood-hand contact. A recent study, for instance, showed that surgeons wearing single gloves had a blood-hand contact rate of 14% while those wearing double gloves had only a rate of 5% (Tokars *et al*., 1995; Tokars *et al*., 1992). As recommended in this study, the following are reasonable guidelines for when to use double gloves:

- The procedure involves coming in contact with large amounts of blood or other body fluids (e.g. vaginal deliveries and cesarean sections).
- Orthopedic procedures in which sharp bone fragments, wire sutures and other sharp edged materials are likely to be encountered.
- Surgical procedures lasting more than 30 minutes. (Most surgeons, these days use double glove routinely).

When double gloving, the first glove should be a half size larger than normally worn gloves. The second pair, however, should be the correct size as this will help prevent the hand from cramping. Whether or not the surgeon, assistant or nurse should double glove must be considered carefully especially in setups where gloves are reused and the risk of contracting blood borne pathogens such as HIV, is high (**>5% prevalence**).

In general, for short time surgical procedures (30 minutes or less) and those involving minimal exposure to blood or mucous secretions (e.g. laparoscopy or mini-laparotomy), double gloving is probably not necessary.

Surgical gloves can be reused but it should be done with great care for the probability of presence of in apparent holes or perforations in any type of reprocessed glove is higher than in new gloves.

WHEN TO USE ELBOW LENGTH GLOVES

Elbow length gloves should be used during vaginal deliveries and cesarean sections where the chance of coming in contact with blood is 25% and 35% respectively. Elbow length gloves are also recommended to be used during performing procedures like manual removal of placenta and any other procedure where contact with a large volume of blood or body fluids is likely. This kind of glove is generally meant to give protection to the hands including the forearms.

When readymade elbow length gloves are not available, an effective alternative material (as described below) can easily be made from previously used surgical latex gloves that have been re-processed (decontaminated, cleaned and dried, through the two methods of either sterilization or high-level disinfection).

[4] The acceptable "leak rate for new surgical and examination gloves designated by regulatory agencies is up to 4% (Davis 2001)

1. Cut one or more fingers depending on the size of your hands completely off. Do the same for the other pair of the glove shown just below to allow all of the fingers slip into the gloves (**see Figure 4.4**)

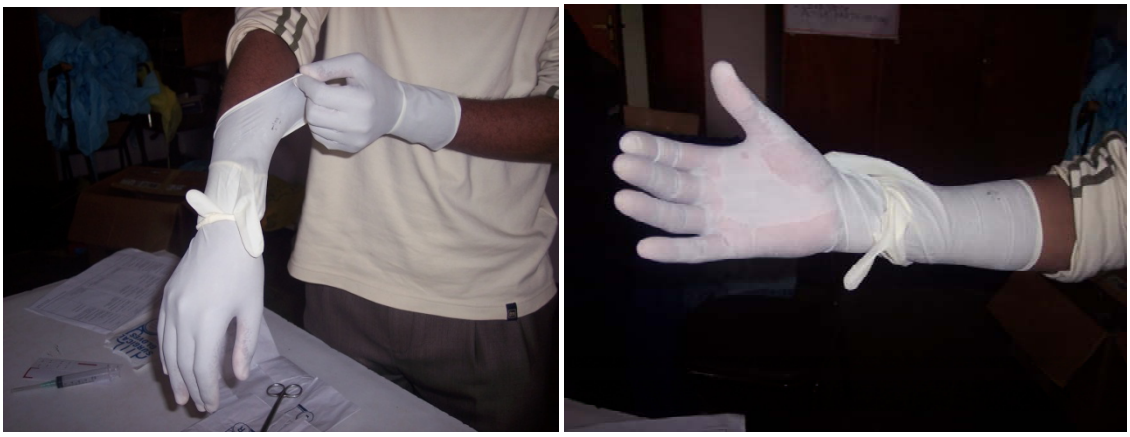
Figure 4.4 Cutting the Four Fingers off a Glove

2. Sterilize or HLD 2 to 3 pairs of cut-off (fingerless) gloves according to the recommended process for each method and store the gloves after final processing in a sterile or high-level disinfected container until needed.

How to Use

- Perform surgical hand scrub.
- Put on the intact sterile or HLD surgical gloves to completely cover up the distal end of the fingerless gloves. (**See Figure 4.4**).
- Put the fingerless sterile or HLD gloves and pull them up to the forearms.

Figure 4.5 Putting Surgical Gloves on Both Hands



SOME DOS AND DON'TS ABOUT GLOVES

- Do wear the correct size gloves, particularly the surgical gloves. A poorly fitting glove can limit your ability to perform the task and may get damaged easily.
- Do change surgical gloves periodically (every 45 minutes) during long cases as the protective effect of latex gloves decreases with time and in apparent tears may occur.
- Do keep fingernails trimmed moderately short (less than 3mm beyond the finger tip) to reduce the risk of tears.
- Do pull gloves up over cuffs of gown (if worn) to protect the wrists.
- Do use water-soluble hand lotions and moisturizers often to prevent hands from drying, and cracking due to frequent hand washing and gloving.
- Don't use oil-based hand lotions or creams, because they will damage latex surgical and examination gloves.
- Don't use latex gloves if you or the patients have an allergy to latex.
- Don't store gloves in areas where there are extremes of temperature (e.g. direct sunlight, near the heater, air conditioner, ultraviolet light, and X-ray machine). These conditions may damage the gloves (cause breakdown of the material they are made of), thus reducing their effectiveness as a barrier.
- Don't reprocess gloves that are cracked or have detectable holes/tears.
- Don't reprocess examination gloves for reuse.

ALLERGIC REACTIONS TO GLOVES

Allergic reactions to latex rubber gloves are being increasingly reported among healthcare workers of all types including housekeepers, laboratory workers and dentists. If possible, non latex (Nitrile) or low-allergen latex gloves should be used if allergy is suspected (Allergic reactions to Nitrile also occur, less frequently though). Furthermore, wearing powder-free gloves is recommended (Powdered gloves may result in more reactions because the powder from the gloves carries the latex particles in the air). If at all this is not possible, wearing clothes or vinyl gloves beneath latex gloves may help to prevent skin sensitization. It will not, however, prevent possible sensitivity of the mucous membranes of the eyes and nose if these gloves are powdered (Garner & HICPAC, 1996).

People with sensitivity do have symptoms like skin rashes, runny nose and itchy eyes that may persist or get progressively worse (i.e., cause breathing problems such as asthma). An allergic reaction following the use of latex can develop within a month. Reactions generally take long time (3 to 5 years) to develop even in susceptible people and may not develop for as long as 15 years (Baumann, 1992). No matter what, there still exists no therapy or desensitization for latex allergy. Therefore, the only option is to avoid contact with it.

OTHER PERSONAL PROTECTIVE EQUIPMENT (PPE)

CAPS are used to keep the hair and scalp covered so that flakes of the skin and hair are not shed up on the wound during surgery. Caps meant to be reliably protective should be large enough to cover all of the hair on the scalp.

MASKS should be large enough to cover the nose, the lower part of the face, the jaw and all of the facial hair. They are worn in an attempt to retain/confine moist droplets expelled as health workers or surgical staff speaks, cough or sneeze. Equally important, is its protective function against accidental splashes of blood or other contaminated body fluids on the health workers' nose or mouth. This preventive function, however, would not be effective unless the masks are made of fluid-resistant materials.

When removing, one should handle the masks by the strings do it with great care as the center of the mask is the most contaminated site of all other parts (Rothrock, McEwen & Smith, 2003).

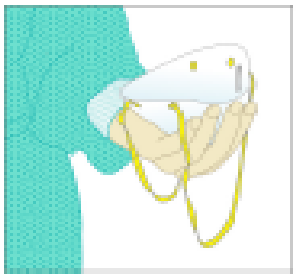
RESPIRATORS are special types of masks called particulate respirators worn by healthcare personnel for protection against inhalation exposure to airborne infectious agents that are < 5μm. These include infectious droplet nuclei from patients with *Micobacterium tuberculosis*, *Variola virus* [smallpox], SARS-CoV), and dust particles containing infectious particles such as spores of environmental fungi (e.g. *Aspergillus* sp.). Respirators should be worn when filtering inhaled air is deemed important. These articles contain multiple layers of filter material and fit into the face tightly allowing no air leaks around the mask when breathing. The N95 disposable particulate and air purifying respirator is the type used most commonly by healthcare personnel. Other respirators used include N-99 and N-100 particulate respirators; powered air-purifying respirators with high efficiency filters; and non-powered full-face piece electrometric negative pressure respirators (Siegel JD. *et al*.; HICPAC, 2007).

Figure 4.6 Types of Masks

Surgical Mask

Respirator (95)

Figure 4.7 Safe Donning and Removing of Respirator



1. Cup the respirator in your hand with the nosepiece at your fingertips allowing the headbands to hang freely below your hand.

2. Position the respirator under your chin with the nosepiece up

3. Pull the top strap over your head resting it high at the back of your head. Pull the bottom strap over your head and position it around the neck below the ears

4. Place fingertips of both hands at the top of the metal nosepiece. Then mould the nosepiece (using two fingers of each hand) to the shape of your nose. Pinching the nosepiece using one hand may result in less effective respirator performance

5. Cover the front of the respirator with both hands, being careful not to disturb the position of the respirator

5A. <u>Positive seal check</u>

- ✓ Exhale sharply. a positive pressure inside the respirator normally yields no leakage. If there is leakage, adjust the position and/or tension straps and re-test the seal.
- ✓ Repeat the steps until respirator is sealed properly

5B. <u>Negative seal check</u>

- ✓ Inhale deeply. If no leakage, negative pressure will make respirator cling to your face.
- ✓ Leakage results from the negative pressure in the respirator due to entry of air through the gaps in the seal.

6. To remove the respirator, first pull upward and outward the strap of the respirator that is over your head then the one which is immediately above your ear. Do not touch the front part of the respirator, because it is contaminated.

EYEWEAR protects the staff during accidental splash of blood or other body fluid by covering the eyes. Eyewear includes clear plastic goggles, safety goggles and face shields. Prescription glasses are also acceptable as long as the eyes are protected (top and sides). Masks and eyewear should be worn when performing any task where an accidental splash into the face could occur (e.g. performing cesarean section, vaginal delivery or cleaning instruments) when giving care to patients with droplet precautions. If face shields are not available, goggles or glasses and mask can be used together.

Figure 4.8 Eye Wears

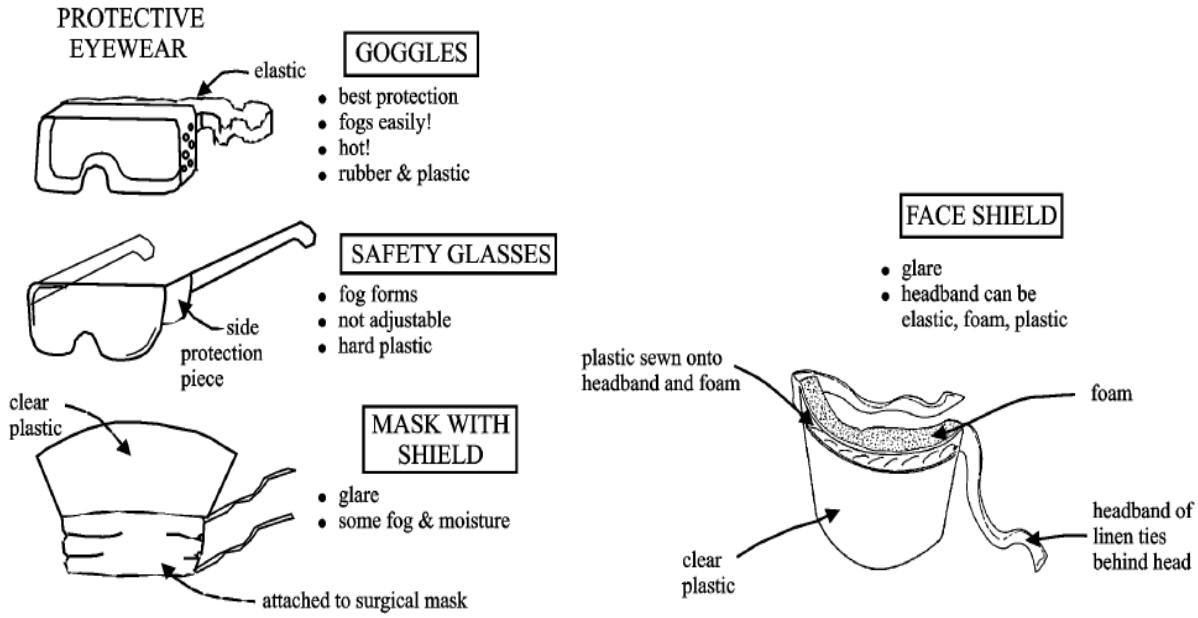


Figure 4.9 Safe Donning and Removing of Eye Wears

GOGGLES/FACE SHIELD

- Outside of goggles or face shield are contaminated!
- To remove, handle by "clean" head band or ear pieces
- Place in designated receptacle for reprocessing or in waste container

SCRUB SUITS OR COVER GOWNS are worn over the casual dresses underneath, or just replace the normal/casual clothing's. The main use of cover gowns is to protect the healthcare workers' clothing. Scrub suits usually consist of drawstring pants and a shirt. A V-shaped neck shirt must not be too long to allow the wearer's shoulders to slide off or expose men's chest hair.

SURGICAL GOWNS were first used to protect patients from microorganisms present on the abdomen and arms of the healthcare staff during surgery. Lightweight cloth gowns generally available in Ethiopia are believed to offer little protection. As a consequence, the healthcare staff either wear a plastic apron before putting on the surgical gowns or, take shower or bathe soon after the end of the procedure (this is especially true in case of large spills). When surgical gowns are worn, sleeves should either taper gently toward the wrists or end with elastic lace around the wrists. Large and loose fitting (hanging) sleeves favor accidental contamination. Correspondingly, the cuffs of the surgical gloves should completely cover the end of the sleeves. Below, safe donning and removing of gown is illustrated in Figure 4.10

Figure 4.10 Safe Donning and Removing of Gown

GOWN

- Fully cover torso from neck to knees, arms to end of wrist, and wrap around the back
- Fasten in back at neck and waist

- Gown front and sleeves are contaminated!
- Unfasten neck, then waist ties
- Remove gown using a peeling motion; pull gown from each shoulder toward the same hand
- Gown will turn inside out
- Hold removed gown away from body, roll into a bundle and discard into waste or linen receptacle

MACKINTOSH OR PLASTIC APRON is used to protect clothing or surfaces from contamination. Aprons which are made of rubber or plastic provide with a waterproof barrier along the front of the personnel's body. Thus, it should also be worn during cleaning and procedures with likelihood of splashes or spillage of blood, body fluids, secretions or excretions (e.g. when conducting deliveries).

Aprons keep contaminated fluids off the healthcare worker's clothing's and skin. In surgery, wearing a clean plastic apron over the scrub suit will not only help to guard the surgeon or assistants against exposure to blood or body fluids (e.g. amniotic fluid), but also prevents the surgeon's or assistant's abdominal skin from being a source of contamination to the patient.

FOOTWEAR is worn to protect the feet from injury by sharp or heavy items or fluids that may accidentally spill over, drip, or even pour out upon them. For this reason, sandals, "thongs" or shoes made of soft materials are not acceptable. Rubber boots or leather shoes are acceptable but they must be kept clean and free of contamination from blood or other body fluid spills. Shoe covers are unnecessary if clean and sturdy shoes are available for dedicated use only in the surgical area.

To wash hands before and after donning and removing PPE

THE ROLE OF DRAPES

Drapes are usually made of hemmed linen squares and have varying sizes and purposes.

There are four types of drapes: towel drapes, drapes or lap sheets, site drapes, and pack wrapper drapes.

Sterile drapes, made of cloth can be placed around a prepared surgical incision to create a work area. Cloth drapes allow moisture to soak through and can help to spread of organisms from the skin into the incision even after surgical cleansing with an antiseptic agent. Thus, neither gloved hands nor sterile or high-level disinfected instruments and other items should touch drapes once they are in place. Using towel drapes to create a working area around the incision limits the skin area which needs cleaning and reminds the surgical team not to touch other areas.

Using Drapes for Surgical Procedure

Using sterile towel drapes to create a work area around the incision limits the amount of skin that needs to be cleaned and prepared with antiseptic solution prior to placing the drapes. Although this area is often called the "sterile field," it is only briefly sterile. This is true beyond doubt in that once a sterile drape touches the patient's skin; the 'field' gets less sterile for cloth drapes do not serve as an effective barrier any more. For better effects, clean and dry towel drapes can be used if sterile towel drapes are not available. The following guidelines for draping are designed to reduce overuse of costly sterile items and to avoid unnecessary draping. There are the following simple rules:

- All drapes should be applied around a completely dry, widely prepared skin.

- If sterile drapes are used, sterile or HLD surgical gloves should be worn when placing the drapes (when putting drapes in place, care must be taken not to touch the patient's body with gloved hands).
- Drapes should be handled as little as possible and should never be shaken or flapped. Drapes should always be held above the area to be draped, and need to be discarded if they fall below this area.

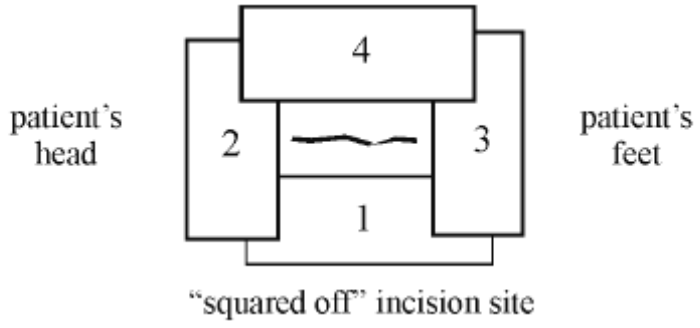
For Minor Surgical Procedure:

- Use a site drape if the open skin required around the incision is not bigger than five centimeter.
- Place the hole in the drape over the prepared incision site and do not move it once it has touched the skin.
- If the site being draped is not sterile, put on a sterile or HLD gloves after placing the drape on the patient to avoid contaminating the gloves.

For Major Surgical Procedure:

- Use large drapes or lap sheets to cover the patient's body. These drapes do not need to be sterile because they will not be near the incision site. They should be clean and dry.
- After preparing the skin, place the sterile towel drapes to square off the incision site.
- Begin by placing the drape on the area closest to you to decrease the chance of contamination.
- Holding one side of the drape, allows the other side to touch the abdominal skin about two inches away from the proposed incision site. Gently drop the rest of the drape onto the abdomen. Once in place, the drape should never be moved closer to the incision. It can, however, be pulled away from it.

Figure 4.11 Squaring off a Work Area



- Place three additional drapes (2, 3 and 4) to square off the work area as shown in **Figure 4.11** above.
- Use non-perforating towel clips to secure the corners of the towel drapes.

During Procedure

- Do not use the patient's body or the draped area for placing instruments.
- Keep all instruments on the instrument stand covered with a sterile towel or drape.
- Do not lean against or on the table during surgery.
- If a drape is torn or cut during a procedure, it should be covered with a new drape. Do not, however, place new drape on top of a drape that has become wet. There is no evidence that this is effective in creating a barrier. (OR Manager! 990b).

Note:

- Once a sterile drape touches the patient's skin, it is no longer sterile.
- Sterile cloth drapes do not replace good aseptic technique.

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CHAPTER 5: SURGICAL ANTISEPSIS

KEY TOPICS TO BE DISCUSSED:

- Causes of wound infections
- The safest and most effective antiseptics
- Use antiseptics and performing surgical antisepsis.
- Ways of preventing the contamination of antiseptics.
- Ways of performing skin and mucus preparation prior to procedures.

BACKGROUND

Before the work of Joseph Lister and others in the 1860s, surgical patients commonly developed postoperative fever followed by purulent drainage from their incisions, suffered from sepsis and often lose their lives. The introduction of the principles of antisepsis by Lister and the acceptance of Pasteur's germ theory in the late nineteenth century led to a marked decrease in wound infection rates. These discoveries also radically changed surgery from an activity associated with infection and death to one of the health interventions which prevents sufferings and prolong lives**.**

Despite improvements in operating room practices, instrument sterilization methods, better surgical technique and the best efforts of practitioners to prevent infection, surgical site infections (SSIs) remained a major cause of nosocomial infections (healthcare associated) and the rates of the problem are increasing globally (Alvarado, 2000). Sadly, in poor nations where resources are limited, even basic life-saving operations such as appendectomies and cesarean sections are entwined with high infection rate and mortality. Hence, postoperative wound infection remained a leading cause of healthcare associated infections especially in developing countries.

The great majority of postoperative incisional or superficial wound infections are caused by microorganisms normally found on the patient's skin or the mucous membranes adjacent to the surgical site and less often from other sites, the surgeon or the assistants. Among surgical patients, SSIs are the most common HAIs, accounting for about a third of all such infections. On average, having an SSI increases a patient's hospital stay by 7 to 10 days, with organ/space and deep incisional SSIs accounting for the longest stays and highest costs. Organisms associated with SSIs vary with the type of procedure and the anatomic location of the operation. *Staphylcoccus aureus* (coagulase negative staphylococci), *enterococcus species* and *Escherichia coli* are the three most frequently isolated pathogens. An increasing number of SSIs are caused by antimicrobial-resistant pathogens. Likewise, the incidence of fungal SSIs has risen significantly in the last decade in part because of the dramatic increase in the number of HIV/AIDS patients. In these countries where SSI rates are higher, therefore, it makes sense to focus on preventing the problems entailed in those frequently performed procedures. For most SSIs, the source of the pathogens comes from the patient's skin, mucous membranes or bowel and rarely from another infected site in the body (endogenous sources).

Exogenous sources of SSI pathogens are occasionally responsible. These include:

- Organisms from members of the surgical team (e.g. hands, nose or other body parts);
- Contaminated surfaces in the operating room and even the atmospheric air; and
- Contaminated instruments, surgical gloves or other items used in the surgery.

Exogenous organisms are primarily *aerobic staphylococci* or *streptococci species* (with the exception of *tetanus endospores*). Although fungi are widely present in the environment, they rarely cause SSIs. **Table 5.1** List the most widely accepted patient and operative characteristics that may increase the risk of SSI.

Table 5.1 Patient and Operation Characteristics that May Influence the Risk of Developing a Surgical Site Infection

PATIENT
▪ Malnutrition ▪ Diabetes (uncontrolled) and presence of other chronic diseases ▪ Smoking or use of other tobacco products (should be stopped at least 30 days before elective surgery) ▪ Obesity ▪ Age ▪ Coexistent infections at a remote body site ▪ Colonization with microorganisms ▪ Altered immune response (HIV/AIDS and chronic corticosteroid use) ▪ Length of preoperative stay
OPERATION
▪ Preoperative shaving of the operation site ▪ Increased length of surgical procedures (estimated that infection rate nearly doubles with each hour of surgery) ▪ Antimicrobial prophylaxis ▪ Operating room ventilation ▪ Instrument processing (cleaning, HLD or sterilization) ▪ Foreign material in the surgical site ▪ Surgical drains ▪ Prolonged preoperative hospitalization ▪ Surgical techniques ➢ Poor homeostasis ➢ Failure to obliterate dead space ➢ Tissue trauma
Adapted from: SHEA, APIC, CDC and SIS 1990

The likelihood of a potential infection depends on several factors, but the most important ones are:

- The number of bacteria entering the wound;
- The type and virulence (ability to cause infection) of the bacteria;
- The host defense mechanisms (e.g. effectiveness of inflammatory response and status of the immune system); and
- External factors like the duration of stay in the hospital before surgery or the duration of the operation lasting for more than 4 hours.

Although the skin cannot be sterilized, applying an antiseptic solution to it minimizes the number of microorganisms around the surgical site that could otherwise contaminate the surgical wound and cause infection. Thus, surgical antisepsis plays an important role in limiting the type and number of microorganisms transferred into the wound during surgery, but not necessarily a determinant one in preventing postoperative wound infections.

DEFINITIONS

Antiseptic or Antimicrobial Agents - (terms used interchangeably) are Chemicals that are applied to the skin or other living tissue to inhibit or kill microorganisms (both transient and resident) thereby reducing the total bacterial count. Examples include Alcohols (Ethyl and Isopropyl), Iodine solutions, Iodophors, Chlorhexidine and Triclosan.

Antisepsis - is a technical process of reducing the number of microorganisms on the skin, mucous membranes or other body tissues by applying an antimicrobial (antiseptic) agent.

Organ/Space SSI - is any part of the body other than the incised body wall parts that were opened or handled during an operation.

Surgical Site Infections (SSI) - is an infection resulting either from an incision or organ/space infection occurring within 30 days after an operation or within a year if an implant is present. Incisional SSIs in turn are also further divided into two: superficial (which involves skin and subcutaneous tissue only)[5] and deep (which involves the deeper soft tissues fascia and muscle layers).[6]

Disinfectants - are chemicals that destroy or inactivate microorganisms on an inanimate object, such as instruments or surfaces.

[5] Does not include stitch abscess, infection of episiotomy or newborn circumcision, or infected burn wound. Specific criteria are used for identifying these infections and reporting them

[6] For confirmation of all SSIs, clinical findings (sign and symptoms of infection) and/or laboratory test results (organisms isolated from aseptically obtained culture) are required.

SELECTION OF ANTISEPTICS

A plain soap and clean water physically remove dirt and others like transient microorganisms from the skin. Antiseptic solutions which are stronger than plain soaps kill or inhibit almost all transient and many resident microorganisms including most vegetative bacteria and many viruses. Antiseptics are designed to remove as many microorganisms as possible without damaging or irritating the skin or mucous membrane on which they are applied. Some antiseptic solutions have a residual effect, a situation in which killing the actions the antiseptics continue for some time after application to skin or mucous membranes. Many chemicals are used to make safe antiseptics. **Table 5.2** lists these recommended antiseptic solutions, their microbiologic activity and potential uses. (The grading system used in this table is excellent, good, fair, and none). Among the most frequently used antiseptics is Chlorhexidine gluconate which is also an ingredient in Hibitane®, Hibiscrub®, and Iodophors such as Betadine® and Wescodyne®. Not listed in **Table 5.2**, is Savlon® which contains Chlorhexidine and available throughout the world. Because, it is abundantly found in the market in the form of concentrated solution is usually diluted with water when ready for use. In many countries, the concentration widely used is less than 1% which is too low to be effective. Despite the proper intent, antiseptics are sometimes used as disinfectants (e.g. Savlon or Dettol®) for processing instruments and other inanimate objects. These antiseptics, however, do not have the same killing power as chemical disinfectants (e.g. Glutaraldehydes, Hypochlorite and Peroxides) and should not be used for this purpose (Rutala, 1996). On dealing with choices of antiseptics, the desired characteristics (e.g. absorption and persistence) along with evidence of the product's safety, efficacy, acceptability to staff and, most importantly, cost should be considered (Boyce and Pittet, 2002; Larson, 1995; Rutala, 1996). In brief, the following recommended antiseptic solutions are generally available around the world:

- Alcohol based solutions of Iodine and Chlorhexidine.
- Alcohols (60 to 90%) (Ethyl, Isopropyl or "Methylated spirit").
- Chlorhexidine gluconate (2 to 4%) (Hibiclens®, Hibiscrub®, Hibitane®).
- Chlorhexidine gluconate and Cetrimide, various concentrations at least 2% e.g. (Savlon®).
- Iodine (3%); aqueous iodine and alcohol-containing (tincture of iodine) products.
- Iodophors (7.5 to 10%), various concentrations (Betadine® or Wescodyne®).
- Chloroxylenol (0.5 to 4%) (Para-chloro-metaxylenol or PCMX) various concentrations (Dettol®).
- Triclosan (0.2 to 2%).

Do not dilute Savlon® or Dettol® available in the market.

Table 5.2 Antiseptic Solutions: Microbiologic Activities and Potential Uses

GROUP	ACTIVITY AGAINST BACTERIA						RELATIVE SPEED OF ACTION	AFFECTED BY ORGANIC MATTER	USES		Comments
	Gram Pos.	Most Gram Neg.	TB	Virus	Fungi	Endo spores			Surgical Scrub	Skin Prep	
Alcohols (60-90% ethyl or isopropyl)	Good	Good	Good	Good	Good	None	Fast	Moderate	Yes	Yes	Not for use on mucous membranes; not good for physical cleaning of skin, no persistent activity
Chlorhexidine [1] (2-4%) (Hibitane, Hibiscrub)	Good	Good	Fair	Good	Fair	None	Inter-mediate	Slight	Yes	Yes	Has good and persistent effect but the undesirable effects of toxicity to ears and eyes
Iodine Preparation (3%) (Water or alcohol based)	Good	Good	Good	Good	Good	Poor	Fast	Marked	No	Yes	Not for use on mucous membranes or open wounds; Can burn skin .So remove after several minutes
Iodophors (7.5-10%) (Betadine®)	Good	Good	Good	Good	Good	None	Inter-mediate	Moderate	Yes	Yes	Can be used on mucous membranes. Waiting for 2 minutes after applying is necessary for better effects.
Para-chloro-metaxynelol (PCMX) (0.5-4%)	Fair	Good	Poor	Fair	Poor	Unknown	Slow	Minimal	No	Yes	Penetrates the skin and should not be used on newborns' skin for fear of harming them.
Triclosan (0.2-2%)	Good	Good	Fair	Good	Poor	Unknown	Inter-mediate	Minimal	Yes	No	Acceptability on hands varies

[1] Note: Savlon®, which contains Chlorhexidine, is not listed here because the concentration of Chlorhexidine varies in different countries ranging from less than 1% to 4%. Some of these agents such as Iodine or Chlorhexidine are combined with alcohol to form tinctures and are available as such.

Adapted from: *Larson 1988*; *Olmsted 1996*.

ADVANTAGE AND LIMITATION OF COMMONLY USED ANTISEPTICS

ALCOHOL SOLUTIONS (ETHYL OR ISOPROPYL)

Ethyl and Isopropyl alcohol (60 to 90%) are relatively cheaper, easily available and at times, excellent antiseptics. Their rapid killing action makes them very effective in reducing the number of microorganisms on the skin, even under gloves. Alcohols are effective against all hepatitis viruses and HIV. However, they should not be used on mucous membranes (e.g. for vaginal preparation) for Alcohols dry and irritate them even to further promote the growth of microorganisms.

Alcohols are among the safest known antiseptics. A 60 to 70% solution of Ethyl or Isopropyl alcohol is effective, less drying to the skin and less costly than those with higher concentrations. The characteristic merit of, Ethyl alcohol‘s being less drying, outweighs the use of isopropyl alcohol. Therefore, Ethyl alcohol is chosen over Isopropyl alcohol for frequent use on skin (Larson, 1995).

Note:

In many countries, alcohols are available as “industrial methylated spirit,” or Ethyl alcohol denatured with a small amount of wood (Methyl alcohol) (Harpin & Rutter, 1982). Because Methyl alcohol is the least effective of the alcohols, it should not be used alone. Prior to using it in mixture, one must be sure that the ethyl alcohol has the adequate strength (60 to 90%) in a locally available “spirit.”

Advantages

- These solutions rapidly kill all fungi and bacteria including mycobacteria; isopropyl alcohol kills most viruses, including HBV, HCV and HIV; ethyl alcohol kills all viruses.
- They are effective in the rapid reduction of microorganisms on the skin and protect against re-growth of organisms, even under gloves, for several hours even though Alcohols have no persistent killing effect,
- They are relatively cheaper and widely available throughout the world.

Limitation

- They need emollient (e.g. Glycerin or Propylene glycol) to prevent drying of skin (Ethyl alcohol may be less drying than Isopropyl).
- They are easily inactivated by organic materials.
- They are flammable (requires storage in cool, well-ventilated areas).[7]
- They damage rubber (latex) over time.
- They are not good cleaning agents.

[7] Residual alcohol on hands or skin may be ignited by static electricity, so allow hands to dry thoroughly after using antiseptic hand rub

CHLORHEXIDINE GLUCONATE (CHG)

Chlorhexidine gluconate (CHG) is an excellent antiseptic. It remains active against microorganisms on the skin many hours after use (referred as residual effect) and is safe even for use on newborn infants. Due to the threat of inactivation by a concomitant use of soaps, CHG's residual antimicrobial activity is dependent upon its concentration availed in the market. Chlorhexidine with 2 to 4 % of concentration is the recommended. The new 2% aqueous formulations and 1% Chlorhexidine in a waterless, alcohol-based antiseptic hand rub are also effective (Larson, 1995).

Advantages

- Broad spectrum of antimicrobial action.
- Persistent action on the skin (chemically active for at least 6 hours).[8]
- Chemical protection (the number of microorganisms inhibited) increases with repeated use.
- Minimally affected by organic material.
- Several products are commercially available most commonly in the form of detergent base or as a waterless alcohol-based antiseptic hand rub.

Limitation

- Expensive and not always available.
- Action is reduced or neutralized by natural soaps and substances present in hard tap water and some hand creams.
- Not effective against Tubercle bacillus and only fairly active against fungi.
- Cannot be used above pH of 8 because it decomposes.
- Contact with eyes could cause conjunctivitis.

IODINE AND IODOPHOR SOLUTIONS

Iodine solutions with 3% concentration are very effective and are available both as an aqueous (Lugol) and tincture solutions (Iodine in 70% alcohol). Iodophors with 7.5 to 10% are solutions of iodine mixed with a carrier a complexing agent like Polyvinyl pyrrolidone (Povidone) that releases a small amount of iodine. Povidone-iodine is the most common Iodophor available globally.

The amount of "free" iodine present determines the level of antimicrobial activity of Iodophors (e.g. 10% Povidone-iodine contains 1% available iodine, yielding a "free" iodine concentration of 1 ppm [0.0001%] (Anderson, 1989). Iodophors have a broad spectrum of activity. Thus they kill vegetative bacteria, mycobacterium, viruses and fungi. For an optimal effect, however, they require up to 2 minutes of contact time to release free iodine which is chemically active form. Once the free iodine is released, it elicits a rapid killing action. Besides, Iodophors are generally

[8] For maximum effectiveness and residual activity, Chlorhexidine should be used on a regular basis(at least daily)

nontoxic and nonirritating to skin and mucous membranes unless there is some allergy to it. (Larson, 1995). Commercially available Iodophors manufactured for antisepsis should not be diluted (Betadine or Wescodyne) as this increases the concentration of free iodine that can be released and increase the degree of skin irritation.

Note:

Iodophors manufactured for use as antiseptic are not effective for disinfecting inorganic objects and surfaces have significantly less treatability to iodine than to other chemical disinfectants.

Advantages

- Broad spectrum of antimicrobial action.
- Aqueous iodine preparations are less costly, widely available, and effective.
- Are non-irritating to skin or mucous membranes (unless the person is allergic to iodine), making them ideal for vaginal use (e.g. before IUD insertion).
- Aqueous solutions up to 3% concentration do not stain the skin.

Limitation

- Slow to intermediate antimicrobial action.
- Have little residual effect.
- Are rapidly inactivated by organic materials such as blood or sputum.
- May cause skin irritation and staining (true in the case of tincture or aqueous iodine) and must be removed from skin after drying. (Use alcohol to remove the stain is advisable).
- May cause hypothyroidism in newborn infants if of the free iodine is absorbed through skin and mucous membranes. So, its usage must be limited (Newman, 1989).
- Allergic reactions to Iodine and Iodophors can occur so patients should be checked for history of allergy (Iodine and shellfish).

Note:

Iodine (aqueous or tincture) must never be used on mucous membranes because of its rapid absorption and irritation to the epithelium.

CHLOROHEXYLENOL

Chlorohexylenol (para-chloro-metaxylenol or PCMX) is a halogenated derivative of Xylenol widely available in concentration of 0.5 to 4%. Chlorohexylenol destroys microorganisms by breaking down the cell wall. It has low germicidal action (Favero, 1985) compared to alcohols, Iodine or Iodophors and is less effective in decreasing skin flora than both CHG and Iodophors (Sheena & Stiles, 1982). Because of its capacity to penetrate the skin and possibility of turning to be toxic on its application to some areas of the body, it should not be used on newborns. To avoid some harm, therefore, one should avoid using commercial products with Chlorohexylenol concentrations above 4%.

In expensive commercial preparations such as Dettol, the antiseptic and disinfectant activity is due primarily to the alcohol content, not the Chlorohexylenol. An alcohol solution with 60 to 90% concentration is equally effective and much less costly.

Advantages

- Broad spectrum of activity.
- Only minimally affected by organic materials.
- Residual effect persisting for several hours.
- Minimally affected by organic matter.

Limitation

- Inactivated by soaps (nonionic surfactants) making it less useful for skin preparation.
- Rapid absorption and potential toxicity (That is why it should not be used on newborns).

TRICLOSAN

Triclosan is a colorless substance often serving as an ingredient in soaps which are considered antimicrobial agents. Concentrations from 0.2 to 2.0% have moderate antimicrobial activity against *gram-positive cocci, mycobateria* and yeast but not *gram-negative bacilli*, especially *P. aeruginosa* (Larson, 1995). Although there are growing concerns of the resistance to this agent is developing more readily than to other antiseptic agents, resistance to skin flora has not so far been observed in long-term clinical studies.

Advantages

- Broad spectrum of activity.
- Excellent persistence.
- Minimally affected by organic matter.

Limitation

- Not effective against *P. aeruginosa* or other gram-negative bacilli.
- Bacteriostatic (only inhibits growth).

PRODUCTS THAT SHOULD NOT BE USED AS ANTISEPTICS:

HEXACHLOROPHENE (HCP)

Hexachlorophene (3%) is active against gram-positive cocci such as staphylococcus, but has little or no action against gram-negative bacteria, viruses, *Mycobacterium tuberculosis* and fungi. It is slow acting and a single wash with it does not reduce skin flora. Hexachlorophene also has neurotoxic side effects and can penetrate the skin of premature infants. Lest it should do some harm, it is not to be used on broken skin or mucous membranes. When used intermittently, bacteria may grow back in a large number between uses (rebound growth), all of which limits its use (Larson, 1995).

ZEPHIRAN® (BENZALKONIUM CHLORIDE)

Zephiran is commonly used in many parts of the world as an antiseptic, but it has several distinct disadvantages too. To mention just few, the antiseptic:

- Has repeatedly been shown to become contaminated by *Pseudomonas* species and other common bacteria (Block, 1991).
- Is easily inactivated by cotton gauze and other organic material and are incompatible with soap (Block, 1991).
- Takes at least 10 minutes to kill HIV, the virus causing AIDS (Angle, 1992). By contrast, 0.5% chlorine solution kills HIV in less than 1 minute.

MERCURY LAUREL OR OTHER MERCURY- CONTAINING COMPOUNDS

Although, it is often sold as antiseptics, chemicals containing mercury should be avoided because of their high toxicity (Block, 1991):

- Skin exposure to low levels of mercury causes blister formation and contact dermatitis.
- Inhalation or ingestion of low levels of mercury affects the central nervous system (numbness, speech impairment, deafness) and those with higher doses (200 mg) are fatal.
- Skin contact alone can result in absorption of measurable amounts of mercury.
- Pregnant women exposed to small doses may not show toxic effects themselves. The fetus, however, may be harmed because mercury is a potent teratogen (causes birth defects, including cleft palate, cerebral palsy and other central nervous system abnormalities).

USE OF ANTISEPTICS

I. HAND HYGIENE

Antimicrobial soaps or detergents are not more effective than are plain soaps and clean water in reducing the risk of infection when used for routine hand washing provided that the water quality is satisfactory (Pereira, Lee & Wade, 1997). Water containing large amount of particulate matter (makes the water cloudy) or which is contaminated (high bacteria count) should not be used for performing a surgical hand scrub[9]. On the other angle, antimicrobial soaps are costly and more irritating to the skin than plain soaps. Detailed instructions for performing a surgical hand scrub using either an antiseptic solution or antiseptic hand rub are presented in **Chapter 3 and Appendix A**.

[9] If the tap water is cloudy, most of the particulates (debris and organic material) can be removed by filtering through four layers of moderately woven cotton clothes such as cheese clothes or old sari material, before boiling or treating with dilute Chlorine (Sodium hypochlorite) solution (Colwell *et al*., 2003; Huq *et al.,* 1996).

II. SKIN PREPARATION PRIOR TO SURGICAL PROCEDURES

Applying an antiseptic solution minimizes the number of microorganisms around the surgical wound that may contaminate and cause infection.

Instructions

STEP 1 Do not shave hair around the operative site. Shaving increases the risk of infection 5 to10 fold because the tiny nicks in the skin provide an ideal setting for microorganisms to grow and multiply (Nichols, 1991; Seropian & Reynolds, 1971). If the hair must be cut, trim the hair close to the skin surface with scissors immediately before surgery.

STEP 2 Ask the patient about previous allergic reactions (e.g. to iodine preparations) before selecting an antiseptic solution.

STEP 3 Gently wash it with soap and clean water and dry the area before applying the antiseptic if the skin or external genital area is visibly soiled,

Select the antiseptic solution from the following recommended products:

- Alcohol-based solutions (tinctures) of Iodine or Chlorhexidine.
- Alcohols (60 to 90% ethyl, isopropyl or "methylated spirit").
- Chlorhexidine (2 to 4%) (Hibiclens®, Hibiscrub®, Hibitane®).
- Chlorhexidine and Cetrimide, various concentrations at least 2% (e.g. Savlon®).
- Iodine (3%); aqueous iodine and alcohol-containing (tincture of iodine) products.
- Iodophors (7.5 to 10%), various concentrations (Betadine® or Wescodyne®).
- Chloroxylenol (0.5 to 4%) (Para-chloro-metaxylenol or PCMX) various concentrations (Dettol®).

STEP 4 Using dry, high-level disinfected forceps and new cotton or gauze squares soaked in antiseptic to thoroughly cleanse the skin.[3]Cleanse from the operative site outward for several centimeters. (A circular motion from the center out helps to prevent recontamination of the operative site with local skin bacteria).

Do not allow the antiseptic to pool underneath the client's body for this can irritate or burn the skin

STEP 5 Allow the antiseptic enough time for better effect before beginning the procedure. For example, when an Iodophor is used, allow 2 minutes or wait until the skin is visibly dry before proceeding, because free iodine the active agent, is released only slowly.

Generally, always allow the antiseptic enough time to dry. Equally important, is that care must be taken not to allow the applied antiseptic to pool underneath the patient's body for fear that it can irritate the skin.

III. SKIN PREPARATION FOR INJECTIONS

According to WHO and its Safe Injection Global Network (SIGN), "swabbing of clean skin with an antiseptic solution prior to giving an injection is unnecessary," because, no infections were noted in controlled trials. Interestingly enough, a review of microbiologic studies did not suggest that wiping the skin with an antiseptic before giving an intra-dermal, subcutaneous or intramuscular injection reduce the risk of infection (Hutin *et al*., 2001). If the injection site is visibly soiled, wash the site with soap and water and dry it with a clean towel and then give the injection.[10]

Patients receiving injections regularly (e.g. using DMPA for contraception) should be taught to wash the injection site (arm or buttocks) with soap and clean water just before coming to the clinic or receiving the injection at their home.

IV. CERVICAL OR VAGINAL PREPARATION

For cervical and vaginal antisepsis, prior to inserting a uterine elevator for mini laparotomy or doing an endometrial biopsy, select an aqueous (water based) antiseptic such as an Iodophor (Povidone-iodine) or Chlorhexidine 2 to 4% (e.g. Hibiclens or Savlon when properly prepared). The use of Alcohols or Alcohol-containing preparations such as Dettol is not advisable. Alcohols are found to be not indicated here for they are easily flammable, cause dryness and irritations of the mucous membranes. This, in turn, promotes the growth of microorganisms. Further, hexachlorophene (pHisoHex®) is neurotoxic (Larson, 1988) and should not be used on mucous membranes such as the vaginal mucosa, because it is readily absorbed there (Larson, 1995).

INSTRUCTION FOR CERVICAL OR VAGINAL PREPARATION

STEP 1 Ask the patient about previous allergic reactions (e.g. to Iodine preparations) before selecting an antiseptic solution.

STEP 2 If the external genital area is visibly soiled, gently wash it with soap and clean water and dry the area before applying the antiseptic.

STEP 3 After inserting the speculum, apply antiseptic solution liberally to the cervix and vagina (two times). It is not necessary to prepare the external genital area with antiseptic solution if it appears clean.

STEP 4 If Iodophor is used, allow time (2 minutes) before proceeding.

STORING AND DISPENSING ANTISEPTICS

All antiseptics can become contaminated by microorganisms which can then cause subsequent infection when used for hand washing or skin preparation. Microorganisms contaminating antiseptic solutions include *Staphylococcus epidermidis* and *aureus*, *gram-negative bacilli, Pseudomonas aeruginosa,* and some *endospores.* Contaminated antiseptics can cause subsequent

[10] Patients receiving injections regularly (e.g. using DMPA for contraception) should be taught to wash the injection site (arm or buttocks) with soap and clean water just prior to coming to the clinic or receiving the injection at their home.

infection when used for hand washing or preparing a client's skin. The following can prevent contamination of antiseptic solutions:

- Use antiseptics in small quantities at a time.
  - If antiseptics are provided in large containers, pour a small quantity at a time into a reusable container for daily use.
  - Avoid "topping off" antiseptic dispenser.
- Make sure the correct name of the solution is on the container (labeled correctly) each time you refill it. Reusable containers should also be labeled with the date each time they are washed, dried and refilled.
- Never soak and store gauze or cotton wool in any antiseptic because this promotes contamination.
- Prepare fresh solutions regularly. (Solutions are at increased risk if becoming contaminated after a week of storage).
- Wash reusable antiseptic containers thoroughly with soap and clean water, rinse with boiled water if available and drip dry before refilling.
- Concentrated antiseptic solutions should be stored in a cool and dark place, not in places exposing to excessive heat and direct sunlight (e.g. upper shelves in a tin-roofed building).

Always follow the manufacturer's instructions for diluting an antiseptic solution.

PREVENTING INFECTIONS RELATED TO USE OF INTRAVASCULAR DEVICES

Most infections related to intravascular devices are caused by contamination of the catheter (or needle) with organisms from the patient's skin or the health worker's hands during insertion. Catheter insertions could possibly find way to germs directly in to the bloodstream. Once the catheter gets inside, pathogens can be transferred into the bloodstream in four ways:

1. By traveling along the catheter-tissue interface,
2. Through contamination of the hub,
3. Through contaminated infusion fluid, and
4. Through the bloodstream from another site of infection.

The risk of infection associated with the use of intravascular devices can be reduced by following recommended techniques pertaining to the procedure (e.g. the use of aseptic technique) and a good management of the device in place.

REDUCING THE RISK OF NOSOCOMIAL INFECTIONS ASSOCIATED WITH THE USE OF INTRAVASCULAR DEVICES:

Hand Hygiene and Gloves

- Wash hands before touching any of the IV set components. (If hands are visibly clean, you can disinfect them with an antiseptic hand rub made from 60 to 90% Ethyl or Isopropyl alcohol and an emollient, such as Glycerin).
- Clean examination gloves or reprocessed high-level disinfected surgical gloves should be put on just before touching the insertion site or the hub of the needle or catheter.
- Wash hands or use a waterless alcohol-based antiseptic hand rub after removing gloves.

Site Care and Dressings:

- If the site for inserting the catheter is visibly dirty, wash it with soap and clean water and dry it before applying the skin antiseptic.
- Use 2% Chlorhexidine, 10% Povidone-Iodine (PVI) or 60 to 90% alcohol for skin preparation. If PVI is used, it should be at towed to dry after being applied or wait at least 2 minutes before insertion.
- Applying antimicrobial ointment around the insertion site does not reduce the risk of infection.
- Transparent and adherent dressings allow inspection of the site; act as tape to hold the catheter or needle; and may be more comfortable; nonetheless, their use is not well founded in that there is no evidence whether they reduce risk of infection as compared to that of sterile or clean gauze or surgical tape. Besides, they are expensive.
- Dressings can be left in place for up to 72 hours if they are kept dry. So they should be changed immediately if they get wet, soiled or loose.
- Gauze and tape dressings need to be changed if an inspection of the site is necessary.
- The catheter or needle site should be gently palpated daily for tenderness.
- The insertion site should be inspected if the patient develops tenderness or fever without an obvious cause.

Peripheral Catheters (Venous and Arterial)

Site Selection and Rotation

- For adults, hand veins are preferred to arm veins, whereas arm veins are chosen over leg and foot veins. Because, needles and catheters inserted in the veins on the leg and foot veins are more likely to get inflamed at the insertion site or develop phlebitis.
- Rotating sites within 72 to 96 hours will reduce chance of development of phlebitis and local infection.
- If only short-term (less than 48 hours) IV infusion is planned, straight or butterfly needles are appropriate for they are less irritating than plastic catheters and have lower rates of infection.

- Due to the likely consequence of infiltration during the use of straight and butterfly needles, they should not be used with solutions that could cause tissue necrosis.

Central Venous Catheters-Site Care and Dressings

- If the site for inserting the catheter is visibly dirty, wash it with soap and clean water and dry it before applying the skin antiseptic.
- Insertion should be done using full barrier precautions (sterile or high-level disinfected gloves, gown, mask and full body drape site drape) in a procedure area, not at the bedside.
- Use 2 to 4% Chlorhexidine gluconate with Alcohol, 10% PVI or 60 to 90% Alcohol for skin preparation.

Changing Fluids and Infusion (Administration) Sets

- Change infusion bottles or plastic bags with parenteral solutions every 24 hours.
- Change infusion bottles or plastic bags with lipid emulsion given alone within 12 hours.
- Change infusion bottles or plastic bags with parenteral solutions every 24 hours.
- Change infusion bottles or plastic bags with lipid emulsion given alone within 12 hours.

Note:

- Do not insert unattached needle or catheter into a vein and allow blood to drip out on the patient's hand, forearm, the bed or floor!
- The tourniquet should be washed with soap and water, rinsed and dried whenever it is visibly soiled and wiped with 0.5% Chlorine solution or 60 to 90% alcohol between patients.
- Carefully write the date and time of placement of the IV line and needle size on the dressing.

PREVENTING CATHETER-RELATED URINARY TRACT INFECTIONS

Placement of an indwelling catheter should be performed only when other methods of emptying the bladder are not effective. Hence, it is particularly important to limit the duration as much as possible. The accepted indications for catheterization are:

- Short-term (days) management of incontinence (the inability to control urination) or retention (the inability to pass urine) not manageable by other methods.
- Measurement of urine output over several days in critically ill patients.
- Instill medications through it.
- Treatment of urinary outlet obstruction (blockage of the tube leading from the bladder to the outside, the urethra)
- Postoperative management of surgical patients with impaired bladder function (the most common routine use).

Other methods for management of urinary tract problems include: intermittent catheterization using a reusable "red rubber" straight catheter, condom catheters for male patients, adult diaper pads, and bladder retraining

Indwelling catheters should not be used for long-term management of incontinence.

Tips for Preventing Infections in Catheterized Patients:

- Remove the catheter as soon as possible.
- The catheter collection system should remain closed and not be opened.
- Warn the patient against pulling on the catheter.
- Urine flow through the catheter should be checked several times a day to ensure that the catheter is not blocked.
- Avoid raising the collection bag above the level of the bladder.
- If it becomes necessary to raise the bag above the level of the patient's bladder during transfer of the patient to a bed or stretcher, clamp the tubing.
- Before the patient stands up, drain all urine from the tubing into the bag.
- The urine drainage (collection) bags should be emptied aseptically; do not touch the tip of the emptying tube to the side of the collection vessel, do not permit the tip to touch the urine in the vessel.
- If the drainage tubing becomes disconnected, do not touch the ends of the catheter or tubing. Wipe the ends of the catheter and tubing with an antiseptic solution before reconnecting them.
- Wash the head of the penis and urethral opening (men) or the tissue around the urethral opening (women) after a bowel movement or if the patient is incontinent.
- If frequent irrigation is required, the catheter should be changed.

Note:

- Applying antiseptics (e.g. Iodophor solution such as Betadine) or topical antibiotics to the perineal area (the urethral area for women and the head of the penis in men) does not reduce the risk of catheter-associated urinary tract infections.
- Whenever a patient has an indwelling catheter, infections due to gram-negative septicemia can occur as well. So a daily checking for possible signs of infection back or flank pain, cloudy urine or fever is necessary.

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CHAPTER 6: SAFE SURGERY AND SAFE PRACTICE IN THE OPERATION ROOM

KEY TOPICS TO BE DISCUSSED:

- The proven safe surgical care standards.
- The operating room and associated risks for patients and the staff.
- Instruments as a cause of most injuries in the operating room.
- Avoiding injuries from sharps and designing a safe operation room.

SAFE SURGERY

Surgical care has been an essential component of healthcare everywhere for over a century. As the incidences of traumatic injuries, cancers and cardiovascular disease continue to raise, the impact of surgical intervention on public health systems will grow. Surgery is often the only therapy to alleviate disabilities and reduce the risk for death from common conditions. Each year, millions of people undergo surgical treatment due to traumatic injuries, pregnancy-related complications and malignancies. Annually, major operations are performed for about 234 million across the world. This means, roughly one operation is done per every 25 people a situation which obviously indicates that the safety of care is of great public health importance. Contrary to the fact that surgical procedures are intended to save lives, it is embarrassing to often vigil unsafe surgical interventions causing substantial harm instead. Mortality from general anesthesia alone is reported to be as high as one in 150 people in parts of sub-Saharan Africa. Infections and other postoperative morbidities are also a serious problems prevailing around the world. Moreover, given the previously estimated rates of major complication and death following in-patient surgery, we have postulated that even using conservative estimate of Seven million patients suffer from complications of surgery half of which were preventable. Given the ubiquity of surgery, these facts have significantly negative impacts on the professional carrier and the service too.

Safe surgery is a surgery culminating in no harm and/or exposure to any avoidable risk on the patient and/or the provider.

The WHO Surgical Safety Checklist (**refer Appendix B**) has improved compliance with standards and decreased complications from surgery in eight pilot hospitals selected for evaluation. In different health care institutions ranging from small district hospitals to large medical centers in diverse geographical settings, the use of a 19-item checklist was found to noticeably reduce the complications and mortality associated with a variety of surgical procedures by 30%. For instance, the rate of major inpatient complications dropped from 11% to 7%, and the in-patient death rate following major operations dropped from 1.5% to 0.8%. Interestingly enough, the effect was of similar magnitude in both high and low/middle income countries. The checklist has been designed to be simple to use and applicable in many settings. Currently, it is actively being used and so pervasive in operating rooms around the world.

Monitoring and evaluation of outcomes is an essential component of surgical care. In this regard, many facilities and departments are already engaged in this process. Additional data collection,

in this case, is neither recommended nor encouraged if such a system is already in place and proves useful to the clinicians and staff as a means of improving the quality of care. However, in hospitals where results of surgical care are not routinely tracked and postoperative complications are not recorded, or where surveillance mechanisms have not been sufficient to identify poor practices, WHO highly recommends that a monitoring system be established. As a means of surgical surveillance at hospital and practitioner levels, death on the day of surgery and postoperative in-hospital deaths should be collected systematically by facilities and clinicians. When combined with operative volume, such information provides departments of surgery with day-of-surgery and postoperative in-hospital mortality rates. Mortality rates can help surgeons identify safety shortfalls and provides guidance to clinicians for improvements in care. Besides, for those facilities with the capacity to do so, surgical site infection rates and the Surgical Apgar Score are also important outcome measures. In addition to deaths and complications, process measures can also be incorporated into the evaluation system to identify safety lapses and areas for improvement. Improved compliance has been associated with better outcomes and may identify weaknesses in the system of care delivery.

The Safe Surgery Checklist is now in use in Ethiopia in few hospitals by a few surgeons. It is being promoted but not consistently used by the members of the Society of Surgeons or Anesthesiologists. As far as monitoring and evaluation of surgical care is concerned, postoperative complications were to be recorded on the Surgery report, however they are not always recorded or routinely tracked in the facility report, nor are surveillance mechanisms sufficient to identify poor practices in place.

THE SAFE SURGERY GUIDELINES WILL FOCUS ON TWO MAIN POINTS:

1. The implementation of the safe surgery checklist.
2. The monitoring and evaluation of surgical outcomes.

THE IMPLEMENTATION OF THE SAFE SURGERY CHECKLIST

The Checklist involves the coordination of the operating team: the surgeons, anesthetist and nurses to discuss key safety checks prior to specific phases of peri-operative care: a “Sign In” prior to induction of anesthesia, a “Time Out” prior to skin incision, and a “Sign Out” before the team leaves the operating room. Many of the checks are already being practiced routinely in some institutions, but strangely few operating teams accomplish them all consistently even in the most advanced settings.

Surgical care is complex and involves dozens of steps which must be optimized for individual patients. In order to minimize unnecessary loss of life and serious complications, operating team formulated 10 basic essential objectives which are congruent to safe surgery guidelines of the WHO.

In any surgical case:

1. The team will operate on the correct patient at the correct site.
2. The team will use methods known to prevent harm from administration of anesthetics, while protecting the patient from pain.

3. The team will recognize and effectively prepare for life threatening loss of airway or respiratory function.
4. The team will recognize and effectively prepare for risk of high blood loss.
5. The team will avoid inducing an allergic or adverse drug reaction for which the patient is known to be at significant risk.
6. The team will consistently use methods known to minimize the risk for surgical site infection.
7. The team will prevent inadvertent retention of instruments and sponges in surgical wounds.
8. The team will secure and accurately identify all surgical specimens.
9. The team will effectively communicate and exchange critical information for the safe conduct of the operation.
10. Hospitals and public health systems will establish routine surveillance of surgical capacity, volume and results

THE MONITORING AND EVALUATION OF SURGICAL OUTCOMES

The monthly facility report should include data on:

1. Death on the day of surgery must be recorded by the facility and the clinician.
2. Postoperative in-hospital deaths must be recorded by facility and clinician.
3. The frequency of compliance with:

    - Marking of the operative site by the surgeon.
    - Performance of an anesthesia safety check of the machine and medications.
    - Use of pulse oximetry throughout administration of anesthesia in all cases.
    - Objective evaluation of the airway.
    - Use of sterility indicators to ensure adequacy of sterility Practices.
    - Administration of prophylactic antibiotics within an hour before skin incision (if indicated).
    - Verbal confirmation of patient, site and procedure immediately before incision with all team members present.
    - Preoperative team briefing to discuss clinical concerns, operative plan, and other critical issues.
    - Post-operative team debriefing to discuss problems during the case and concerns for recovery and management of the patient.

SAFE PRACTICES IN THE OPERATING ROOM

In the past decade, awareness of the risk of exposure to blood and body fluids containing HIV, HBV and most recently HCV have created a new era in surgical infection prevention practices. Just as patients must be protected from wound contamination and infections, providers should also be protected from intra-operative injuries and exposure to patients' blood and other body

fluids. The operating room is clearly one of the most hazardous environments in the healthcare delivery system. By definition, surgery is invasive. So, occasionally instruments designed to penetrate patients' tissue could accidentally inflict harm/injure the provider as well. Bleeding (only reasonable amount) is unavoidable thus blood is likely to be seen everywhere. Speed is quite essential in this setup for emergency situations can occur any time and interrupt routines. One can imagine that preventing injuries and exposures (to infectious agents) to oneself under these circumstances is indeed challenging.

The science of safety in the surgical unit in a large specialty hospital or a freestanding primary healthcare clinic, has not kept up with the urgent need for prevention strategies. Even so, most of the recommendations in this chapter have been found to be worthwhile and deserve consideration.

Preventing infections following an operation is a complex process that begins in the operating room by preparing and maintaining a safe environment for performing the surgery. Surgical aseptic techniques are designed to create such an environment by controlling the four main sources of infectious organisms: the patient, surgical staff, the equipment and the operating room environment. Although the patient is often the source of surgical infections, the other three sources are important and should not be overlooked.

Specific techniques required to establish and maintain surgical asepsis for making the surgical environment safer include:

- **Patient considerations** - skin cleaning pre-operatively, skin antisepsis and wound covering.
- **Surgical staff considerations** - hand hygiene (hand washing and/or hand rub and hand rubbing with waterless, alcohol-based antiseptic agents); use and removal of gloves and gowns.
- **Equipment and room preparation considerations** - traffic flow and activity patterns, housekeeping practices and decontamination, cleaning and either sterilization or high-level disinfection of instruments, gloves and other items.
- **Environmental considerations** - maintaining an aseptic operating field and using safer operating practices and techniques.

For reasons of convenience, the traffic, the flow, equipment processing and room preparation requirements are to be discussed in other chapters. The focus of this chapter will be on improving the surgical environment (operating room) especially the practices and techniques that make surgery safer for both the patient and staff (**refer Appendix C**)

DEFINITIONS

Antisepsis - process of reducing the number of microorganisms on the skin, mucous membranes or other body tissue by applying an antimicrobial (antiseptic) agent.

Asepsis and aseptic technique - combination of efforts made to prevent entry of microorganisms into any area of the body where they are likely to cause infection. The goal of

asepsis is to reduce to a safe level or eliminate the number of microorganisms on both animate (living) surfaces (skin and tissue) and inanimate objects (surgical instruments and other items).
Surgical asepsis - preparation and maintenance of a relatively germ free or a reduced (safe) number of microorganisms and hence infection during an operation by controlling four main sources of infectious organisms: the patient, personnel, equipment and the environment.

THE SURGICAL ENVIRONMENT

The operating room has special characteristics that increase the chance of accidents. The staff often uses and passes sharp instruments without looking at the instrument or letting the other person know what they are doing. The workspace is too confined for some members of the team to be able to see what is going on in the operative field. Moreover, there is a real need for speed and the added stress of anxiety, fatigue, frustration and even anger. As are other mishaps, the exposure to blood is often abrupt and happens without being noticed, usually not until the gloves are removed. In some instances, blood enters into the eyes of the operating person further increasing the risk of infection with blood borne pathogens.

INSTRUMENTS CAUSING INJURIES

In hospitals, the vast majority of injuries from sharp edged materials occur in the operating room. Most frequently occurring among these are scalpel and suture-needle injuries. Many other sharp edged instruments can also cause direct physical injuries or indirectly inflict harm by tearing gloves to result in exposure to blood. Below are a few more surgical instruments and articles which are important:

- Hypodermic needles
- Wire sutures
- Laparoscopy and surgical drain trocars
- Orthopedic drill bits, screws, pins, wires and saws
- Needle point cautery tips
- Skin hooks and towel clips
- Sharp-pointed scissors and sharp-tipped mosquito forceps
- Dissecting forceps
- Sharp-toothed tenaculi
- Broken Medication ampoules
- Spinal needles
- Sharp bone edges and bone fragments

WHEN DO INJURIES OCCUR?

Most often, scalpel injuries occur when:

- Putting on and taking off the disposable blade.
- Passing the scalpel hand to hand between team members.

- Cutting (e.g. in using fingers to hold or spread tissue or cutting toward the fingers of the surgeon or assistant).
- Using the scalpel (before and after): leaving it on the operative field, dropping it on your own or the assistant's foot, and reaching for scalpels sliding off the drapes.
- Placing the scalpel in an over-filled sharps container or a poorly located container.

Most often, suture needle injuries occur when:

- Loading or repositioning it in the needle holder.
- Passing the needle hand to hand between team members.
- Suturing: using fingers to hold tissue or to guide the needle, sewing toward the surgeon or assistant and holding back other tissues by the surgeon or assistant.
- Tying with the needle still attached or left on the operative field.
- Using the needle (before and after): leaving it on the operative field, dropping it on your own or the assistant's foot, and reaching for suture needles or needles loaded in the needle holder sliding off the drapes.
- Placing needles in an over-filled sharps container or a poorly located container.

Almost all of these injuries can easily be avoided with simple measures suggested below:

- Use a small Mayo forceps (not fingers) when holding the scalpel blade, when putting it on or taking it off or loading the suture needle. (Alternatively, use disposable scalpels with a permanent blade that cannot be removed).
- Always use tissue forceps, not fingers, to hold tissue when using a scalpel or suturing.
- Use a "hands-free" technique to pass or transfer sharps (scalpel, needles and sharp-tipped scissors) by establishing a Safe or Neutral Zone in the operative field (see below).
- Always remove sharpened materials from the field immediately after use.
- Make sure that containers for sharp material are replaced when they are only three-quarters full and place containers as close to where sharp materials are being used as conveniently possible (i.e. within arm's reach).

THE "HANDS-FREE" TECHNIQUE FOR PASSING SURGICAL INSTRUMENTS

A safer method of passing sharp instruments (scalpels, suture needles and sharp scissors) during surgery called the "Hands-Free" technique has recently been recommended. This technique for keeping sharp edged materials away, is cheap, simple to use, and ensures that the surgeon, assistant or scrub nurse never touch the same instrument at the same time (Bessinger, 1988; Fox, 1992). Instruments passed with the hands-free technique (other than those listed above) include anything sharp enough to puncture a glove (e.g. trocars, sharp-tipped mosquito forceps and loaded needle holders). Using the hands-free technique, the assistant or scrub nurse places a sterile or high level disinfected kidney basin or other suitable small container on the operative field between her/himself and the surgeon. The container is designated as the Safe or Neutral Zone in which sharpen materials are placed before and immediately after use. Various items, such as basins, mats or trays, including part of a sterile instrument stand or a designated area on

the operative field, have been used as the safe zone. To avoid dulling of scalpel blades, use a plastic container or place a sterile cloth in a metal container. For example, the assistant or scrub nurse alerts the surgeon that a sharp instrument has been placed in or on the Safe Zone, with the handle pointing toward the surgeon, by saying "scalpel" or "sharp" while placing it there. The surgeon then picks up the instrument and returns it to the container after use, this time with the handle pointing away from her/him.

Another way to do this is to have the assistant or scrub nurse place the instrument in a container and pass it to the surgeon. The surgeon picks up the instrument out of the container which is left on the field until the surgeon returns the instrument to it. The assistant or scrub nurse, in turn, lifts up the container and returns it to the Mayo stand.

DESIGNING SAFER OPERATIONS

- Using the least dangerous instrument or device that will effectively accomplish the task, while at the same time minimizing risks to the patient and surgical team, should be a goal of any operation.
- Simple things such as a brief pre-operative discussion on how sharp materials should be held by the surgeon, assistant or scrub nurse can be very helpful. Still another is the need for the surgical team to review how to make each step in the operation safer-- starting from securing the towel drapes around the proposed incision with non perforating towel clips to using blunt-tipped needles for closure of all layers except the skin (CDC, 1997; Dauleh *et al*., 1994). Other examples of instruments that protect the surgical team without sacrificing patients' safety or staff performance are shown in Table 6.1. In addition to that, the use of hand-held straight suture needles to close skin incisions is especially dangerous with a reported injury rate of 17%, much higher than those with curved needles carried in a needle holder (Davis, 2001).
- Anesthesiologists, radiologists and others who close small incisions after placement of vascular catheters or cut-downs should be made aware of this hazard.

The risk associated with assisting or being the scrub nurse in surgery may be reduced by anticipating (preferably knowing) the needs of the surgeon for each step of the operation in advance. Where procedures are short (30 minutes or less) and/or surgical steps are straightforward such as D & C or cesarean section, this can be accomplished by developing checklists that lay out each step (or task) of the operation in the order of performance (i.e. from skin incision to closure). Reviewing the checklist with the surgical team just before starting the case and pointing out where deviations may be necessary will make the proceedings of the planned surgery be smooth and less risky. An additional advantage of this review is that it can help protect patients from possible further injuries or increased blood loss.

Table 6.1 Reducing the Risk of Exposure

FUNCTION	SAFER	LESS SAFE	LEAST SAFE[1]
Skin incision	cautery	disposable scalpel	scalpel with removable blade
Cutting	scissors, blunt tip or cautery probe	scissors, sharp tip	scalpel
Hemostasis	blunt suture needles staples or cautery	sharp suture needles	wire sutures
Sponging with gauze while using a scalpel	surgeon does sponging; assistant only retracts	assistant sponges but only by request	assistant sponges spontaneously (no communication)
Retraction	blunt retractor	sharp retractor	fingers or hands
Sharps transfer	Neutral Zone	hand-to-hand (communication)	hand to hand (no communication)
Surgical gloves	double gloving	single pair of gloves or double gloving with reprocessed gloves	single pair of reprocessed gloves,
Closing peritoneum (small, 2–3 cm incision)	do not close	purse-string closure using tissue forceps to grasp needle	purse-string closure using fingers to grasp needle

[1] Should be avoided if at all possible.

BLUNT NEEDLES FOR SUTURING

The range of "bluntness" in commercially available blunt-tipped needles varies. Their bluntness range from minimal (no extra effort needed to use them) to very blunt (does not penetrate tissue such as fascia and requires conscious effort). Minimally blunt needles can be used for closure of all layers from fascia to skin**.** Intermediate blunt needles, on the other hand, require some additional conscious effort to close fascia, but are safer to use. Very blunt needles are seldom used except when operating deep in the pelvis where the needle must be retrieved with fingers. The technique for using blunt needles is as follows:

STEP 1 Use a strong needle holder and lock it fully.

STEP 2 Position the needle in the mid-curve, rather than three-quarters of the way back to prevent slippage or bending the needle. (This usually is not necessary when using minimally blunt needles).

STEP 3 Grasp and hold the tissue to be sutured with a tissue forceps to make it easier for the needle to go through the tissue being sutured. In general, the blunter the tip, the more important it is to follow these three steps.

MAKING THE SURGICAL ENVIRONMENT SAFER

The responsibility for making today's operating rooms safer, extends beyond concern for the well-being of the patient to all healthcare staff forming the surgical team. The approaches to making operations safer outlined in this chapter are simple, practical and have been documented over a 10-year period. The key to success is to apply the principles and practices in an integrated and consistent manner with daily attention to details and support at all levels of the healthcare system.

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CHAPTER 7: MEDICATION SAFETY

KEY TOPICS TO BE DISCUSSED:

- The international standards of safe medication practices.
- The frame work for medication reconciliation.
- The frame work for medication management.
- The frame work for lookalike and sound alike medications.

BACKGROUND

Errors are common when medications are procured, prescribed, dispensed, administered, and monitored. Most important among these phases at which too many errors occur are phases of prescribing and administering medications. The impact of these errors is significant in many nations. To just substantiate this fact, an instance in the US America could be a good one. In this country, erroneous medication is estimated to harm about 1.5 million people and kill several thousand each year costing the nation at least US$ 3.5 billion annually. Other industrialized countries around the world similarly experienced that adverse effects from medications are one of the leading cause of injury and death in their healthcare systems. No doubt, the repercussion of such errors in resource poor countries like Ethiopia is so huge and unbearable for the service is not yet developed and the coverage is so small. In some other countries, up to 67% of patients have history of one or more errors in their medical prescription. About 46% of these errors, it was observed, occurred when new orders are written on admission or discharge of patients. As a remedial measure against this scenario, medication reconciliation process has been designed to prevent medication errors at patients' transition points.

Confusingly numerous names of drugs are also one of the most common causes of medication errors and issues of concern. With tens of thousands of drugs currently on the market including non-proprietary (generic) and proprietary (brand or trademarked) names, the potential for error due to confusing drug names is considerable. Because, most of these names of drugs look and/or sound alike. Although they are marketed under the same or similar-sounding brand names, some medicines may contain different active ingredients in different countries. Furthermore, the same drug marketed by more than one company may have more than one brand name. Other factors still contributing to this confusion are illegible handwriting, incomplete knowledge of drug names, newly available products, similar packaging or labeling, similar clinical use, similar strengths, dosage forms, frequency of administration. What worsens the problem still, is the failure of manufacturers and regulatory authorities to recognize the potential for error and to conduct rigorous risk assessments both for nonproprietary and brand names, prior to approving new product names. Previously, medication safety issue is centered on adverse drug reactions due to side effects of correct medication. Currently, however, issues of medication safety grew broader and include errors which are not side effects of drugs, i.e. wrong drug, wrong route, and wrong dose.

Note:

Even though the risk of poly-pharmacy is so prevalent in the practices of prescribing medications, it is underplayed in this material and not addressed in detail. Instead, we stress on the key solution the medication reconciliation process which provides opportunities to reconsider the appropriateness of a patient's medications over time in accordance with the changes in patient's condition or other in coming drug prescription.

MEDICATION RECONCILIATION

Medication reconciliation is a process designed to prevent errors on medication at patient transition points. Another critical factor upon which medication reconciliation depends is the appropriateness of the medications prescribed in relation to the patient's illness and underlying conditions.

It includes:

- Creating the most complete and accurate list possible or "Best Possible Medication History" (BPMH) of all medications the patient is currently taking (also called the "home" medication list).
- Comparing the list against the admission, transfer, and/or discharge orders when writing medication orders; identifying and bringing any discrepancies to the attention of the prescribing health professional; and if appropriate, making changes to the orders while ensuring the changes are documented.
- Updating the list as new orders are written to reflect all of the patient's current medications.
- Communicating the list to the next provider of care whenever the patient is transferred or discharged.
- Providing the patient with the list at the time of discharge.

Effectively engaging the patient along with the family in medication reconciliation is a key strategy for targeting and preventing errors during prescription and administration and there by prevent or reduces harm to patients. To be optimally effective, encourage patients in particular to participate and provide them with the tools to do so. Educating patients about safe use of medications and provide access to reliable, relevant, and understandable information about their medications should also be emphasized.

The patient needs to be encouraged to exercise his/her rights of being fully informed about all medications prescribed to him by multiple caregivers. The care givers on the other side need to help enhance and maintain the transfer of information on medications and advise patients to put all their medications in a bag and bring it with them whenever they go to health care institutions or visit a doctor.

Encourage patients, family, and caregivers to keep and maintain an accurate list of all medications, including prescribed and non prescribed medications, herbal and nutritional supplements, history of immunization, and any allergic or adverse reactions to medications. These lists of medications should be updated and reviewed with the patient/family/caregiver at each care encounter. Patients should be taught about the risks of medications both individually and in groups with special focus at patients on multiple medications prescribed by multiple caregivers.

The reconciliation of medications comprises comparison of the patient's medication list with the medications being ordered to identify: omissions, duplications, inconsistencies (between the patient's medications and the clinical conditions), dosing errors and potential interactions within

specified time frames (e.g. within 24 hours of admission; shorter time frames for high-risk drugs, potentially serious dosage variances, and/or upcoming administration times). A process for updating the list as new orders are written reflects all of the patient's current medications including any self-administered medications patients brought to the organization.

On discharge, the process seeking to ensure patients' safety updates patient's medication list to include all new, continuing, and previously discontinued "home" medications that are to be resumed following discharge. The list should be communicated to the next provider(s) of care and also be provided to the patient as part of the discharge instructions. Medications not to be continued should ideally be discarded by patients.

ESTABLISH A FRAMEWORK FOR MEDICATION MANAGEMENT

Setting Policy

Clear assignment of roles and responsibilities for all steps in the medication reconciliation process should be given to qualified individuals within a context of shared accountability. The list of possible assignee may include the patient's primary care provider, other physicians, nurses, pharmacists and other clinicians. The qualifications of the responsible individuals should be determined by the health-care organization within the limits of applicable law and regulation. There should be access to relevant information and advice from the pharmacist at each step of the reconciliation process as much as possible.

Make sure that health-care organizations have clear policies and procedures in place that require:

1. The patient's current medication list is presented consistently and located conspicuously (for example, the patient's chart), so that it is easily accessible to clinicians who are writing drug prescriptions.
2. The use of the home medication list as a reference when ordering medications at the time of treatment in a clinic or emergency unit or upon admission to an inpatient service.
3. The provision of the current medication list to the receiving caregiver(s) at each care transition point (admission, transfer, discharge, outpatient visit). This includes Prescribed and non-prescribed (over-the-counter) medications, vitamins, nutritional supplements, potentially interactive food items, herbal preparations, recreational drugs, their dosage, frequency, route, and timing of last dose, etc, as appropriate.

Incorporate training on procedures for reconciling medications into the educational curricula, orientation, and continuing professional development for health-care professionals.

Whenever possible,

1. Validate the home medication list with the patient,
2. Determine the patient's actual level of compliance with prescribed dosing and
3. The source(s) of the patient's medications.

As deemed necessary, involve the patient's community pharmacist(s) or primary care provider(s) in collecting and validating the home medication information.

Looking Forward:

- Develop a standardized card/form for the patient to incorporate details of the patient's current list of medications.
- Consider use of technological support and electronic medical records to facilitate the medication reconciliation process.

Procedural Standards

Ordered medications are not to be carried out unless all of the elements listed below are present. If an element is missing, the physician who issued the order should be called to complete the order.

Date and time - refers to when the order was written.

Full name of the medication - either the chemical or generic name can be used without abbreviations.

Dosages specify - the amount of medicine to be given. Abbreviations are discouraged.

Concentration - if the medication is to be diluted in IV fluid, the amount and type of diluents/s ordered.

Duration - if the medication is to be given over a period of time as in the case of IV Administrations, the duration of the infusion ordered should be recorded by the physician. Nurses should then translate and document the duration of infusion into number of (micro) drops per minute.

Time and frequency - the time of day and how often a medication is to be given, as ordered by the physician. The nurse who transcribes the order will identify the specific time that the medication is to be given by following a standardized schedule.

Route - for medications that can be given in several ways, the route of administration needs to be clearly written.

Physician Signature - is to be clearly written immediately following the order.

Once medications are received by the dispensing nurse, there should be a checking at every step of:

- Patient identification
- Labeling of name on medication containers, dosage and timing
- Any adverse effects amidst the course of medication

EXPLAIN THE FRAMEWORK FOR MANAGEMENT OF LOOK-ALIKE/SOUND-ALIKE MEDICATIONS

To reduce one of the most common causes of errors in medication, facilities should actively identify impeding mistakes in the use of medications and manage risks associated with look-alike sound alike (LASA) medications by:

A. Annually reviewing the LASA medications used in their facility.

B. Implementing clinical protocols which:
- Minimizes the use of verbal and telephone orders.
- Emphasizes on the need to carefully read the label each time a medication is accessed and again prior to administration, rather than relying on visual recognition, location, or other less specific cues.
- Emphasizes on the need to check the purpose of the medication on the prescription/order and, prior to administering the medication, check for an active diagnosis that matches the purpose/indication.
- Includes both the nonproprietary name and the brand name of medications on the orders and labels with the nonproprietary (generic) name put more proximate and in larger font size than that of the brand name.

C. Developing strategies to avoid confusion or misinterpretation caused by illegible prescription or medication orders including those that: require the printing of drug names and dosages. Emphasize on drug name differences using methods such as “tall man” lettering.

D. Storing problem medications in separate locations or in non-alphabetical order (by bin number, on shelves, or in automated dispensing devices).

E. Using techniques such as boldface and color differences to reduce the confusion associated with the use of LASA names on labels, storage bins and shelves, computer screens, automated dispensing devices, and medication administration records.

F. Developing strategies to involve patients and their caregivers in reducing risks through:
- Providing patients and their caregivers with written information on medications including indications, nonproprietary and brand names, and potential medication side effects.
- Developing strategies to accommodate patients with sight impairment, language differences, and limited knowledge of healthcare.
- Seek the pharmacist’s review of dispensed medications with the patient’s clinical condition to confirm indications and expected appearance, especially when dispensing a drug known to have a problematic name.

G. Ensuring that all steps in the medication management process are carried out by qualified and competent individuals.

In line with medication management situations including self administration and family/care giver administration, it advisable to:

- Encourage patients, families, and caregivers to learn the nonproprietary name as the key identifier of their medication products.
- Instruct patients to alert caregivers whenever a medicine appears to vary in any way from what is usually taken or administered.

There are many challenges to successfully implement such programs in all settings medications are used. Successful implementation requires leadership support; active involvement of the physician, nursing, and pharmacist; effective implementation teams; and collaborative learning sessions.

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CHAPTER 8: SAFE INJECTION PRACTICE

KEY TOPICS TO BE DISCUSSED:

- Injection safety and its related problems
- The risks and impacts associated with unsafe injection practices
- The best practices in injection safety
- Injection devices and their safety features

BACKGROUND

WHO estimates that in developing and transitional member States, 16 billion healthcare injections are administered each year i.e. an average of 3.4 injections per person yearly. Concurrently, it is also estimated that at least 50 % of all injections are unsafe. This fact along with reports indicating inappropriate use of injections, suggests that injections are overused as a means of administering medications. In addition to being overused, of course, injections may also be administered through unsafe procedures and cause infections.

Improper use of syringes, needles, and medication vials during routine healthcare procedures such as administering injections have resulted in more than 40 outbreaks in both hospital and non-hospital settings with transmission of blood borne viruses, including hepatitis C virus. A mathematical model developed by WHO suggests that in the year 2000, reuse of injection devices in developing and transitional member states, is estimated to have caused 22 million new infections with Hepatitis B virus (one-third of all such infections); two million new infections with hepatitis C virus (40% of all such infections); and 260,000 new HIV infections (5% of all such infections). The infections acquired in the year 2000 alone, are known to have caused an estimated nine million years of life lost (adjusted for disability) between year 2000 and 2030.

Injection safety baseline studies conducted by MOH and MMIS in 2004 and 2005 revealed that injection practices are unsafe: exposing patients, health workers and the community to transmission of HIV and other blood borne infections. According to the findings, about 74% of injections were unsafe, about 72% of health facilities practiced unsafe disposal and the prevalence rate of needle stick injury was 30 to 35%. Still another, shortage and inconsistent supply of injection safety materials was also common. It is also reported that almost half (45%) of the community members have a tendency of preferring injections to other preparations.

Evidence shows that death and disability associated with unsafe injections are highly preventable. Communication with patients about prescribed medications and improving prescriptions through monitoring of providers have effectively decreased injection overuse. Secondly, interventions to make single-use syringes regularly available in each healthcare facility effectively prevent the reuse of injection devices and bad consequences likely to develop afterwards.

DEFINITIONS

Safe Injection - is the one that is given using appropriate equipment, without harming the recipient, exposing the provider to any avoidable risk and t in any waste that is dangerous to the community.

Needles-tick injury - are punctures of the skin caused by an injection needle.

Sharps injury an injury caused by puncture of the skin by a sharp objects/instruments including an injection needle.

Auto-disable (A-D) syringes - a specially modified plastic syringe with a fixed needle, which is automatically disabled after a single use.

Safety device/Sharps engineered sharps injury protections (ESIPS) - a non-needle sharp or needle device used for withdrawing body fluids, accessing a vein, artery, or administering medications or other fluids, with a built-in safety feature or mechanism that effectively reduces the risk of an exposure incident (OSHA).

Safety (Sharps) box - a puncture/liquid-proof container designed to hold used sharps safely during collection, disposal and destruction.

Safety syringe - is a modified disposable plastic syringe designed so that the healthcare worker can disable it in such a way that the needle is protected and cannot be re-used.

INTRODUCTION TO INJECTION SAFETY

- A safe injection, as has already been briefly defined, does not harm the recipient, expose the provider to any avoidable risk and result in any waste that is dangerous to the community.
- Unsafe injection practice, on the contrary, is the one that could harm the recipient, and/or the provider and/or may result in waste that is dangerous to the community.
- Injection safety is;
    - An integral component of infection prevention and control,
    - An element of Standard Precautions,
    - Key element of patient and healthcare workers safety,
    - Supported by infection prevention and control policies and procedures such as hygiene of the hand , housekeeping, waste management,

COMMON REASONS FOR PRESCRIBING AND PROVIDING UNNECESSARY AND/OR UNSAFE INJECTIONS:

1. Inadequate dissemination/promotion and use of standard treatment guidelines.
2. Prescriber's predilections to injections. Lack of knowledge on the dangers of injections, wrong perception that injections are more effective than oral medications, give more rapid relief, are more potent are some factors influencing for an over use of injections. Other known factors are: financial incentive for prescribing injections and the fear that patients will go elsewhere if therapy is given otherwise or Perceived belief that patients prefer injections.

3. Informal providers giving injections.

MAGNITUDE OF UNSAFE INJECTION:

- Each year, 16 billion injections are given in developing and transitional countries.
- Most of the injections are therapeutic (90 to 95%); while few (5 to 10%) are given for immunization.
- The great majority (70%) of these injections are unnecessary given when oral medications could have been prescribed.
- A study of 40 health facilities using a combined survey/observation method found that about 74% of the injections were unsafe. The fact that Ethiopian patients generally prefer injections to other forms of medications further increases the risk of disease transmission;
- Injection providers (about 47%) are known to believe that oral medications are less effective than injections for the treatment of fever caused by minor illness.

RISK AND IMPACTS OF UNSAFE INJECTION

Table 8.1 Conditions Causing Risks to Community, Patients/Clients and Providers

Community	Patient/client	Providers
▪ Unsafe waste disposal system of health facilities ▪ Receiving injections from informal injectors ▪ Leaving sharps in accessible place to the public, especially children ▪ Sharing needles and syringe ▪ Reusing needles and syringes	▪ Use of injections when there are other suitable alternatives ▪ Applying pressure to bleeding sites with dirty material or finger ▪ Drug administered at incorrect anatomical site. For example, ▪ Infants vaccinated at the buttocks rather than anterior-lateral thigh ▪ Giving large boluses of intramuscular injections ▪ Injecting a nerve ▪ Use of unsterile syringes and needles (or use of "new" but damaged compromised package) ▪ Re-use of syringe and needles ▪ Use of opened multi-use vials stored beyond recommended time (contaminated drug use) ▪ Using wrong diluents or wrong amount ▪ Use of expired drugs ▪ Syringes are loaded with different medications	▪ Shortage or absence of appropriate injection and safety devices ▪ Carrying used needles before disposal ▪ Placing needle on a surface prior to disposal ▪ Recapping needles (either one or two hand) ▪ Manually detaching needles from syringes ▪ Manipulating used sharps (cleaning, bending, breaking or cutting hypodermic needle) ▪ Passing on sharps from one health worker to another ▪ Sharps are found in unexpected places like linen

	▪ Loading syringe with multiple doses ▪ Drugs and vaccines are stored in the same refrigerator ▪ Accidental switching of drugs ▪ Health workers not following aseptic techniques ▪ Patient/client moves during administration of injection ▪ Sharps are found in unexpected places like linen ▪ Self-medication	▪ Overfilling of sharps' containers ▪ Using a syringe on an agitated patient without assistant or patient/client moves during administration of injection

1. Risks Associated with Unsafe Injection Practices

- Adverse effects are often caused by an unsafe injection. This is an incidence which harms a person receiving healthcare caused by poor injection practices rather than the underlying disease which caused the patient to seek treatment. Adverse events caused by an unsafe injection includes:

  - **Transmission of blood born infections - occurs due to** inoculation of infectious agents into the patient's body. There are about 40 blood borne pathogens that could be transmitted via injection. Among these, HBV, HCV, HIV/AIDS are the commonest and with grave implications.
  - **Injection abscesses -** these are inflammatory conditions ranges from the initial signs of inflammation to big swellings occurring from suppurative processes.
  - **Paralysis** following the damage of a nerve as a result of injection of a drug into a nerve and trauma.
  - **Drug/allergic reactions shock -** a life threatening condition characterized by sudden collapse of the circulatory system due to immunological response to the injected drug, or other local or systemic allergic reactions.

2. Impacts of Unsafe Injection

2.1 **Health Impacts** un safe injections have always been known to negatively affect people's health not only patients but also on care providers .The health problems could range from simple to deadly ones.(**refer Table 8.2**).

Table 8.2 Proportion of Infections and Total Burden of Disease Caused by Unsafe Injection Practices Annually, 2000.

Infections	Estimated Burden of Infections Due to Unsafe Injection Practices	Estimated Proportion of Infections Due to Unsafe Injection Practices
Hepatitis B	22 million new cases	32%
Hepatitis C	2 million new cases	40%
HIV/AIDS	260,000 new cases	5%
Deaths in 2000 due to unsafe injection practices in the past, 501,000 deaths		

*Source: WHO. **"Safety of Injections. Global Facts and Figures,"** PP 1-2.*

2.2 **Socio-Economic** each year, the annual global burden of indirect medical costs due to hepatitis B, hepatitis C and HIV/AIDS is estimated to be US$ 535 million.

2.3 **Psycho-Social** impact includes**:** Stigma, discrimination and social isolation following infections like HIV, Stress associated with HIV, burden on family & the community (unproductive, children will be orphans, etc), risk of transmitting infections to family and the community. The Psycho-Social impacts **c**an be seen at an individual, family, community and country level.

BEST PRACTICES IN INJECTION SAFETY

1. **Elimination of Unnecessary Injection** the results of a survey conducted through interview of patients showed that 76.2% of the prescriptions had at least one injection. The study was conducted in four regions of Ethiopia. The most commonly prescribed medications include antibiotics, analgesics, antispasmodics and vitamins. All of these medications were just as effective if they were given by mouth. Many inject able medications have an oral equivalent that are equally strong, effective and much safer. Therefore, unnecessary injections should be reduced through:

    A. **Promoting Rational Prescribing** injections should only be used during life threatening conditions, mal-absorption syndromes or inability to swallow.
    B. **Educating the patients** encourage patients to accept oral medications; and explain the risks associated with injections when possible to limit the use only when necessary.

2. Administer Injections Safely

Make sure that the 'right' things/ways are fulfilled when administering injections (refer Table 8.3)

Table 8.3 Right Ways to Give Safe Injection

Rights	Standards Always check and verify all 'rights'	Method of Verification
1. Right Patient	What is the name on the prescription? Is this the right patient?	Ask patient/guardian, etc. to repeat name
2. Right Drug	Is the name of the drug on the prescription the same as the injection you are about to administer?	Verify name of drug on prescription with injection to be administered If you are unsure verify with physician or pharmacist
3. Right Formulation	Could the medication be given orally instead of as an injection?	Discuss with patient available choices
4. Right Injection Equipment	Use only sterile, non-reusable syringes, dental cartridge, etc	Check to ensure that syringe/needle package is unbroken
5. Right Dosage	Check dosage against patient's age, weight and the pharmacokinetics of the drug	Read the pharmaceutical recommendations of the drug If unsure, verify with the physician/prescriber
6. Right Time	Follow the specific dose interval	Be mindful of the action of the drug and why the time interval should be followed. Explain the importance of this to the patient
7. Right Route	Be sure to use the correct route of administration (intra-muscular, intravenous, intra-dermal or subcutaneous)	Observe the direction of the prescriber Check prescription or other related records
8. Right Storage	Right temperature, Vaccine Vial Monitor (VVM) shake test	Check cold chain issues including Vaccine Vial Monitor
9. Right Method of Disposal	Do not recap needle. Dispose of used syringe and needle immediately after use in appropriate safety box **Or** Use the needle cutter and safety box	Check the safety box for correct method of disposal

Standards for Administering Injections (Refer Table 8.3)

- Prepare a well-laid up tray including emergency drugs for management or possible drug reaction.
- Wash hands with soap and water. Alcohol could be used as a secondary step after soap and water except for EPI injection.
- Dry up hands. You can use small paper towels or any single use towels.
- Check for the integrity of the vial/ampoule for the following expiry date, breach, leaks, particles or any contamination.
- Make sure that the right dose, formulation and route are used for the right patient or client.
- For medications that need to be reconstituted, (power forms) it should be done according to the manufacturer's instruction and use the correct diluents.
- Draw the right dose as prescribed, including expelling the air using right injection equipments.
- Ensure aseptic technique while giving the injection.
- Administer the drug at the correct site.
- Dispose the used syringes and needles immediately into the sharp's container. (Never give used syringes and needles to patients or clients to carry home even if they came with the equipment).
- A patient should be kept in the room for at least 5 minutes after the injection has been given and be observed for any possible adverse effect or events.
- Thank the patient or the client.
- Record the date and time of injection administered.

THE ROLE OF PRESCRIBERS AND PROVIDERS IN INJECTION SAFETY

Eliminating unnecessary injections represents the highest priority to injection safety. Therefore injections should only be used in:

- Life threatening conditions
- Mal-absorption syndromes or
- Inability to swallow

Prescribers and service providers should also:

- Encourage patients to accept oral medications when possible. Injections should be given only when necessary.
- Explain the risks associated with injections
- Explain to patients the need to take oral drugs as prescribed and review these instructions with them.
- Inform patients the potential side effects of medications that is being prescribed
- Explore why patients prefer injections

PRINCIPLES OF SAFE INJECTION PRACTICES

The practices of safety which have been determined through scientific evidences or expert consensus, is designed to most effectively protect patients, providers and communities. The plans could generally divide in to four major areas of intervention (**refer to Table 8.4**):

1. Use Sterile Injection Equipment

Primarily, a single use syringe and needle for each injection is recommended (Auto-disable syringes are mandatory for all immunization injections). For curative and other purpose injections, syringes with reuse prevention devices and safety features are recommended. Where these ones are not available, standard disposable syringes can be used. Because several studies showed that unsafe injection practices such as using the same needle, syringe or both for more than one injection or improperly processed syringes and needles, are responsible for the transmission of HIV, HBV and HIV (Drucker *et al.,* 2001; Simonsen *et al*., 1999). Therefore, after each use, the assembled needle and syringes should be placed in containers for disposal of sharps.

Make sure that the syringe and needle are sealed and inspect packaging for breaches in barrier integrity. Therefore, it needs reconstituting each unit of medication separately to practice single use syringe and needle or sterile equipment.

2. Prevent Contamination of Injection Equipment and Medication

- Prepare each injection in a clean designated area where blood or body fluid contamination is unlikely.
- Use single dose vials rather than multi-dose vials.
- If multi-dose vials must be used, always pierce the septum with a sterile needle and avoid leaving the needle in place in the stopper of the vial.
- Select pop-open ampoules rather than ampoules that require use of a metal file to open.
- If you are using an ampoule that requires a metal file to open, protect fingers with a clean barrier (e.g. small gauze pad) when opening the ampoule.
- Inspect medicaments and discard those with visible contamination or breaches of integrity (e.g. cracks, leaks).
- Follow product-specific recommendation for use, storage and handling.
- Swabbing of a new vial tops or ampoules with an antiseptic or disinfect is unnecessary. If swabbing with an antiseptic is selected for use, use a clean, single use swab and maintain product specific recommendation contact time. Do not use cotton balls stored wet in a multi-use container.
- Swabbing of clean skin before giving an injection is unnecessary. Wash skin visibly soiled or dirty with soap and water. If swabbing with an antiseptic is selected for use, use a clean, single use swab and maintain product specific recommendation contact time. Do not use cotton balls stored wet in a multi-use container.
- Discard a needle that has touched any non-sterile surface.

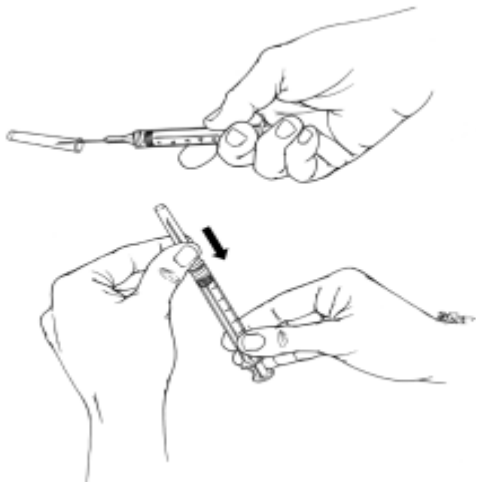
3. Prevent Injuries to the Provider

Hypodermic needles (hollow bore needles) cause most of the injuries to healthcare workers at all level. However, physicians and nurses are often stuck by hypodermic needles during procedures while the cleaning staffs are most often stuck by needles when washing soiled instruments. Still others like the housekeeping staffs are equally exposed to being stuck by needles when disposing infectious waste material.

Before administering an injection or any skin piercing procedure, make sure that precautions are taken depending on the types of procedure being carried out.

- Anticipate and take measures to prevent sudden patient movement during and after injection.
- Do not recap, bend or break needles prior to disposal of single use needles and syringes after giving injections. However, if there is a need to recap a needle due to various reasons, needles must be recapped using the "one-handed" recap method as follows:
    - First, place the needle cap on a firm and flat surface, and then remove the hand.
    - Next, with one hand holding the syringe, use the needle to "scoop" up the cap (**Figure 8.1**).
    - With the cap now covering the needle tip, turn the syringe upright (vertical) so the needle and syringe are pointing toward the ceiling.
    - Finally, using the forefinger and thumb of your other hand, grasp the cap just above its open end (**Figure 8.1**) and push the cap firmly down onto the hub (the place where the needle joins the syringe under the cap).

Figure 8.1 One Handed Recap Method



- Decontaminate the needle and syringes prior to disposal.
- Do not disassemble the needle and syringe after use.
- All used syringes and needles or any other sharps should be discarded at the point of use in an enclosed sharps container which is puncture and leak proof and s sealed before being completely full.

- During injection, disposable gloves are indicated only if excessive bleeding anticipated.

4. Prevent Access to Used Needles and Syringes

- Seal sharp containers for transport to a secure area in preparation for disposal. After closing and sealing sharps containers, never open, empty or reuse them.
- Manage/dispose sharps waste in an efficient, safe and environment-friendly way to protect people from voluntary or accidental exposure to used injection equipment.
- Disposal of used syringes, needles and sharp containers.
- The following guiding principles should be used for disposal of syringes, needles, and sharps containers.
- Dispose all sharps in a safety box immediately after injection.
- If the syringe is a retractable one, make sure to engage the retraction feature before disposing of the syringe.
- Collect used syringes and needles at the point of use in an enclosed sharps container (safety box) that is puncture and leak-proof.
- Do not use boxes that are open, overflowing or punctured. Get a new one instead.
- Seal safety boxes before they are completely full. Do not overfill them.
- Dispose of the sharps and sharp containers by burning, burying or encapsulation.
- Always put on a heavy duty gloves when handling sharps containers.

Table 8.4 Best Practices for Administering Injection

- **Select safe medicines**
  - Proper handling of medicines including keeping it in a clean environment.
  - Label them clearly
  - Observe proper storage conditions, including temperature and humidity (as recommended by manufacturer)
  - Check expiry dates
- **Use of sterile equipment**
  - Use needle and syringe from sealed package
  - Use syringes with re-use prevention features
- **Avoid contamination (Adhere to principales of Aseptic Technique)**
  - Wash hands
  - Prepare on clean surface
  - Do not touch part of needle that will come in contact with patient's tissue and avoid recapping. If recap is necessary, apply one hand technique.
  - Do not leave the needle in the rubber cap of the vial

- **Re-constitute drugs or vaccines safely**
  - Use new sterile syringe and needle for each reconstitution
  - Use the correct diluents/water for injection
  - Reconstitute according to the manufacturers' specifications
- **Disposal of injection wastes and sharps properly**
  - Immediate disposal of needle and syringe in puncture- and leak-proof container
- **Disseminate public health education and information.**

INJECTION DEVICES AND THEIR SAFETY FEATURES

Syringes and needles are the major devices needed to provide injection and the following are used as standard types of syringes in healthcare facilities (**refer table 8.5**):

1. Auto disable syringe.
2. Manually retractable.
3. Automatically retractable.
4. Standard Disposable.

Both private and public health facilities should use the above listed syringe and needles to provide any type of injections. After injections syringe and needles should be disposed in to safety boxes.

Table 8.5 Types of Injection Devices: Advantages and Disadvantages

Type of Device	Advantages	Disadvantages
Auto-disable syringes	▪ Cannot be reused ▪ They save time for healthcare workers from the burden of sterilization ▪ Eliminate the patient-to-patient disease transmission caused by the use of contaminated syringes and needles	▪ More expensive than standard disposable (but are still affordable) ▪ Have no safety features ▪ Need collection and disposal system
Manually retractable	▪ Cannot be reused ▪ Safety feature: needle retracts inside barrel ▪ They save time for healthcare workers from the burden of sterilization ▪ Eliminate the patient-to-patient disease transmission caused by the use of contaminated syringes and needles	▪ Not automatic; relies on good will of healthcare worker ▪ More costly
Automatically retractable	▪ Cannot be reused. Automatic ▪ Safety feature: needle retracts inside barrel ▪ It saves time for healthcare workers from the burden of sterilization ▪ Eliminate the patient-to-patient disease transmission caused by the use of contaminated syringes and needles	▪ Most costly

Type of Device	Advantages	Disadvantages
Standard disposable	▪ Cheap ▪ Available on local market. ▪ They save time for healthcare workers from the burden of sterilization ▪ Eliminate the patient-to-patient disease transmission caused by the use of contaminated syringes and needles	▪ Can be reused without sterilization ▪ Have no safety features ▪ Need sharps container or needle remover ▪ Carry a high risk of infections
Re-usable syringes	▪ Cheapest solution ▪ Few disposals	▪ Can be re-used without sterilization ▪ Maintenance of equipment required

Special Note:

- All patients undergoing an injection should be educated/counseled before injection is given e.g. on the type of drug, side effects, possible adverse effects/events following the administration of the injection and total number of doses to be given by injection.
- Self-injecting patients such as diabetic patients should be properly informed about their medications and how to ensure safety or injection. In case a patient needs to take the injection equipment home, he/she should be counseled on the storage, disposal and sterility of their drugs and equipment.

SAFETY TIPS FOR USING A NEEDLE AND SYRINGE FOR MULTIPLE INJECTIONS IN THE OPERATING ROOM

- If a hypodermic needle must be used for multiple injections during a surgical procedure, the options below could be used for preventing accidents between uses. These are:
  - Roll a sterile towel into a tube shape.
  - Stick the needle into the towel between uses.

HOW TO WITHDRAW MEDICATION FROM A STERILE MULTI-DOSE BOTTLE

- Wipe the top of the bottle with a cotton swab soaked in 60 to 90% alcohol or other locally available disinfectant. Allow it to dry.
- If a new disposable needle and syringe is to be used, open the sterile pack.
- If a sterile or high-level disinfected syringe is to be used, remove it from the covered container using dry, sterile or high-level disinfected forceps.
- Attach the needle to the syringe.
- Remove the needle cap and insert the needle tip until it touches the bottom of the bottle.
- After filling the syringe, withdraw both the needle and syringe from the bottle. Multi dose bottles already opened should be stored in a separate, covered container to avoid

contamination. Also, mark the date of the first withdrawal to discard if unused after 30 days or if contaminated at any time.

- Do not leave a needle inserted in the rubber stopper of a multi-dose bottle. This practice provides a direct route for microorganisms including HIV to enter the bottle and contaminate the fluid between each use.

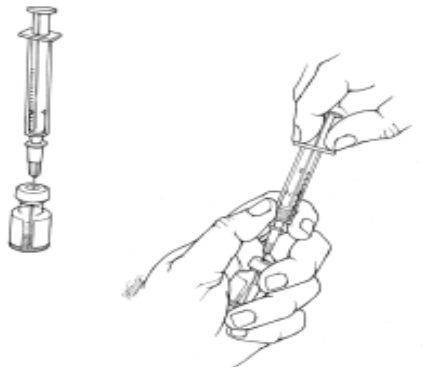
HOW TO WITHDRAW MEDICATION USING AN AUTO DISABLE SYRINGE

Intending to improve injection safety, WHO recommended several years ago that all immunizations be given using auto disable syringes. Since then, these syringes have been widely used in both campaign and routine immunization settings. Although there are many types of auto-disable syringes, they are all similar in that they only permit the syringe to be filled and be emptied at once. In 2002, USAID began providing the Solo Shot FXTM auto-disable syringe for use in giving the injectable contraceptive DMPA (Depo Provera). The Solo Shot FX syringe is a single-use, disposable syringe with a metal clip that locks the plunger after a single use (i.e. it cannot be pulled back a second time). The syringe is packed with a detachable needle which cannot be attached to any other type of syringes in a sterile package. Although auto-disable syringes and needles are similar to conventional ones, most health workers will need to practice in order to correctly fill them and avoid wasting medication, syringes and needles (i.e. if air is drawn up into the syringe instead of the prescribed amount of medication, the syringe cannot be refilled).

As time goes on, it is anticipated that the use of auto-disable syringes for giving other purposes of injections will increase; therefore, clinicians need to be familiar with using auto-disable syringes. The following instructions are specific for the Solo Shot FX syringe and needle:

- Open the sterile pack containing the needle and syringe and attach the needle firmly.
- Remove the needle cap and insert the needle tip until it touches the bottom of the bottle as shown in **Figure 8.2** (to avoid drawing air into the syringe, the needle tip should stay below the fluid level in the bottle).
- While holding the bottle with one hand, slowly pull back on the plunger of the syringe and draw up fluid to just above the fill line make (**Figure 8.2**). For the solo shot FX syringes used with DMPA, the "fill line" mark is at 1ml.

Figure 8.2 Withdrawing Medication Using an Auto-Disable Syringe (Solo shot FX ™)



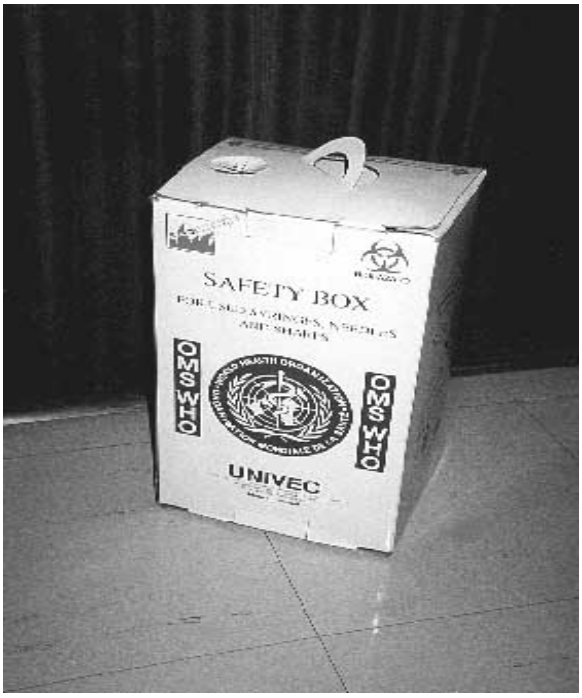
Withdraw the needle and syringe from the bottle and hold the syringe upright (needle pointing to the ceiling) to see if any air is in the syringe. If there are air bubbles, slowly push the plunger in, but only until the "fill line" mark is reached.

Check that the fluid level in the syringe is at or slightly above the "fill line" mark. If it is below the fill line mark, there may not be enough medication to be effective and the injection should not be administered. In this situation, either inject the medication back into the single dose bottle and draw up the medication again using a new auto-disable syringe and needle, or discard the partially filled syringe and use a new bottle and auto-disable syringe and needle.

SAFETY DEVICE: SAFETY BOXES

Safety box is a puncture and leak-resistant container for disposal of sharps including hypodermic needles, needles from IV bags, lancets, scalpels and suture needles. Other operating room-specific sharps requiring similar disposal include: surgical drain trocars, needle point cautery tips, wire sutures, orthopedic drill bits and a range of hollow injection. There are special needles used by radiologists and anesthesiologists for various medical invasive procedures as well. Disposal of these items after use requires careful planning and action on the part of the healthcare team to avoid injury to the housekeeping and maintenance staff that ultimately will be removing them. Safety box is very advantageous to immediately confine contaminated sharps or waste and prevent reuse. Proper use of safety box is also capable of preventing needle-stick injuries to healthcare workers and community. It should be noted that a safety box is capable of meeting its intended objectives, if health professionals and waste handlers are using it properly starting from the time of assembling up to the final disposal. Materials that should not be contained are the following: latex gloves, IV bags or extension tubes, dressing materials (like adhesive tape and gauze), compresses, cotton pads, empty vials and ampoule broken thermometers. In the US and other developed countries, a whole industrial development has grown up to meet the increasing demand for sharps containers. Today, sharps containers of all sizes and shapes are available, either disposable or reusable. Most manufactured containers are designed to be wall mounted or attached to a surface and come with special mounting brackets. A few of them, however, are still designed to be freestanding (ECRI, 1993). In most developing countries, these manufactured items are quite a luxury. As a result, health workers throughout the world have cleverly developed sharps containers from readily available "throw away" items such as metal food containers made of aluminum, tin or heavy plastic (e.g. cooking oil bottles and cans). Heavy duty cardboard boxes and even the used plastic drinking water bottles with caps that liter the streets and country side. Although some of these resources could be safer to use than others, they all provide a no-cost and sustainable source of disposable sharps containers for use in small clinics, polyclinics and district-level hospitals with limited budgets. Rather than discouraging practitioners from using these items in favor of manufactured products, they should be helped in developing better and safer containers from existing materials (e.g. advised on which items are more appropriate to use).

Figure 8.3 Standard Safety Box



SHARPS CONTAINERS-DOS AND DON'TS:

- Do put sharps containers as close to the point of use as possible, ideally within arm's reach.
- Do attach containers to walls or other surfaces if at all possible.
- Do mark them clearly so that people will not unknowingly use them as for discarding other items.
- Do place them at a convenient height so staff can use and replace them easily.
- Do mark the fill line at the three quarters full level.
- Don't shake a container to settle its contents and make room for more sharps.
- Don't place containers in high traffic areas where people could bump into them or be stuck by someone carrying sharps to be disposed of.
- Don't place containers on the floor or anywhere they could be knocked over or easily reached by a child.
- Don't place containers near light switches, overhead fans or thermostat controls where people might accidentally put their hand into them.

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CHAPTER 9: HEALTHCARE WASTE MANAGEMENT

KEY TOPICS TO BE DISCUSSED:

- Background and definition,
- Types of waste,
- Key waste management steps,
- Prevention and control of healthcare associated infection risk.

BACKGROUND

Safe management of Healthcare Waste (HCW) is a key issue to control and reduce HAIs in both public and private healthcare facilities (HCF) and to ensure that the environment outside is well protected. Healthcare Waste Management (HCWM) should be part of the overall management system of a HCF and reflect the quality of the services provided by the facilities.

Most wastes (80% to 85%) generated from HCFs can be treated as regular solid municipal wastes due to the fact that it is believed to be non-infectious and risk-free. About 15% to 20% of these wastes from HCFs, however, can be dangerous and require special attention. These ones are referred as 'risk waste' of which 1% of risk waste is sharps waste. The commonest risky waste in HCFs includes sharps and other wastes which are pathological, biological, chemical and pharmaceutical. In the absence of waste segregation, however, all wastes generated in HCFs can be considered as infectious and hazardous.

DEFINITION

Healthcare waste management refers to all activities involved in the containment, collection, storage, transport, treatment, and disposal of waste produced at healthcare facilities.

TYPES OF HEALTHCARE WASTES

Healthcare waste includes all wastes generated by healthcare establishments, research facilities and laboratories. But it also includes the waste originating from "minor" or "scattered" sources such as that produced in the course of healthcare undertaken in the hoe (dialysis, insulin injections, etc).

Healthcare wastes can generally be classified as high and low risk wastes depending on the level of the risk they cause on the health provider, patient and community.

I. High Risk Wastes

- Infectious waste
- Anatomical waste
- Sharps wastes (used or unused)
- Chemical waste
- Pharmaceutical waste
- Radioactive wastes
- Pressurized containers

- **Infectious waste:**
  - Blood, blood products & other body fluids or items contaminated with similar fluids.
  - Culture and stock of infectious agents from laboratory & items contaminated with such agents.
  - Isolation wastes from highly infectious patients (including food residue).
  - Discarded live and attenuated vaccines.
  - Waste, bedding, bandages, surgical dressings, & other contaminated material infected with human pathogens.
- **Anatomical waste:**
  - Human tissues, body parts and fetus.
  - Biopsies, autopsies, carcasses, organs and tissues infected with human pathogens.
- **Sharps waste (used or unused):**
  - Syringes, needles, scalpel blades, suture needles, razors, IV sets needles.
- **Chemical waste:**
  - Formaldehyde, photographic chemicals, solvents, organic & inorganic chemicals.
- **Pharmaceutical waste:**
  - Outdated medications and residuals of drugs used in chemotherapy.
  - Items contaminated by or containing pharmaceutical bottles/boxes.
- **Radioactive waste:**
  - Contamination with radioactive isotopes.
- **Genotoxic waste:**
  - Cystostatic drugs.
  - Vomitus, urine, or faeces from patients treated with cytotoxic drugs, chemicals & radioactive material.
- **Pressurized containers:**
  - Explosion of cylinders containing gases or aerosols.
- **Waste with high contents of heavy metals:**
  - Batteries, broken thermometers, blood pressure gauges, etc.

II. Low Risk Wastes

- **Non infectious wastes**

  - Commercial wastes are non-contaminated wastes which pose no risk of infections to persons who handle them. These include: paper, trash, boxes, bottles, plastic containers, leftover foods and food products.

KEY STEPS IN HEALTHCARE WASTE MANAGEMENT

Little is understood hitherto on why HCW should be managed in a different way than the other categories of wastes such as residential wastes, municipal wastes, etc. and particularly why HCW should be segregated on the spot from where it is generated. The key steps in the management of healthcare waste are the following:

A. Waste Minimization/Containment

Waste minimization is the first and the best way to reduce healthcare waste quantities and costs, and to reduce environmental impacts on air pollution and landfill capacity.

Effective waste minimization practice requires that all purchases of material and supplies be made with waste reduction in mind stressing that materials and supplies should be purchased with intent of producing little or no waste. For instance, advocating for oral medications than injectables would help to minimize the amount of sharp wastes that could be generated at a given facility. Likewise, practicing good ordering, good stock and inventory management at all level is helpful to minimize the volume of expired or unusable medicines and supplies.

B. Segregation

Waste segregation is separating waste by type at the place where it is generated. Waste should be separated by the person generating the waste right away according to its type and placed in a bin with an appropriate colored bin liner or a sharps container. Waste handlers should never sort through waste after it has already been placed in the bin. In the absence of waste segregation practice, all waste streams need to be considered infectious/hazardous and requires treatment and such practices in general increases the total waste management cost for treatment and disposal.

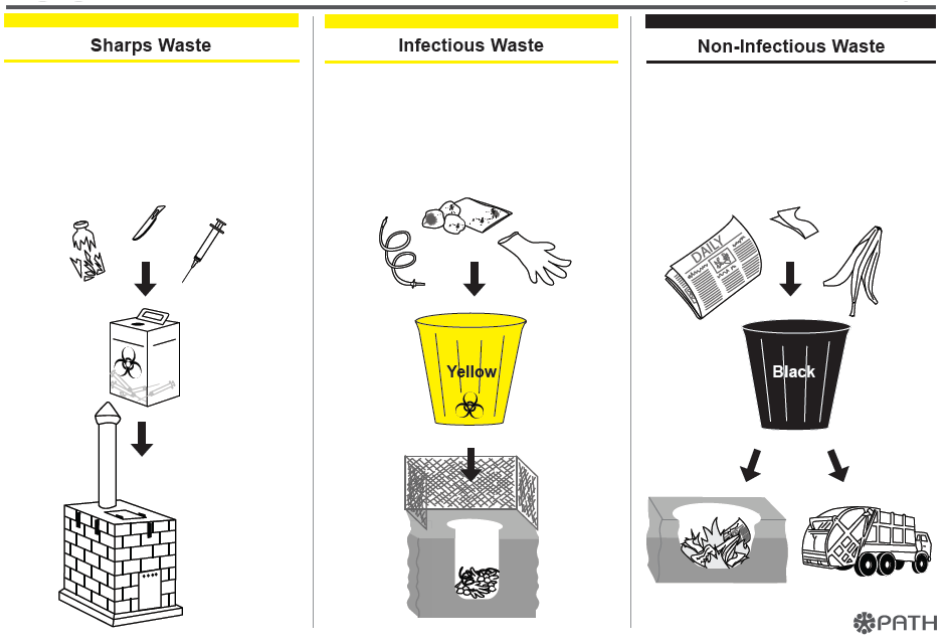
Sealing and labeling of all waste containers should be done to allow an instant recognition of the contents:

- **Noninfectious (Black color code)** presents no risk. Examples: paper, packaging materials, office supplies, drink containers, hand towels, boxes, glass, plastic bottles, and food.
- **Infectious (Yellow color code)** contaminated with human blood and has the ability to spread disease. Examples include: gauze, cotton, dressings, laboratory cultures, IV fluid lines, blood bags, gloves, anatomical waste, and pharmaceutical waste.
- **Sharps waste** (**Safety box, needle remover, or other puncture-resistant and leak-resistant sharps containers**) has the potential to puncture the skin and cause disease.

Examples include: needles, needle of IV set scalpels, knives, blades, lancets, and broken glass. Syringes and needles should be discarded without recapping.

The color-coding system aims at ensuring immediate and non-equivocal identification and segregation of the hazards associated with the type of healthcare waste that is handled or treated. It is very important that both providers and waste handlers understand the color-coding system and handle waste accordingly. In addition to the useful aspects of segregation in minimizing risks of infection and injury, the other one is that some items can be reprocessed and made into other plastic products, e.g. buckets or benches (recycling).

Figure 9.1 Segregation of Medical Waste



C. Waste Handling, Collection and Storage

- **Waste Handling** is a term referring to the activities of waste collection and storage. Workers handling wastes should always wear protective clothing when on their duty (working on healthcare wastes). The clothing includes: apron, heavy duty gloves, footwear, goggles/glasses, and masks. The clothing worn should be taken off when work with wastes is completed. Hands should always be washed with soap and running water after removal of gloves. To be kept in a good condition, protective clothing must be cleaned after each use and be kept at the healthcare facility. Protective clothing must never bet taken home.
- **Waste Collection** is removing waste bags from the service point and taking it to storage or disposal area. It also includes quantification of waste by volume and labeling as to its source, and recording.
- **Waste Storing** is placing waste in a secure place until it can be disposed. The ideal storage area should be designated (for waste only), secure (only authorized persons should have access), kept clean, dry and pest free. The designated central storage facility

shall be located within the premise of the health facility and close to the treatment unit but away from food storage or food preparation areas. Healthcare waste should be stored for not longer than 2 to 3 days, depending on weather conditions. However, in the case of safety boxes, the filled box can be stored in a locked room for up to one week at lower-level healthcare facilities where there is no incinerator. The disposal of organic waste should be carried out daily. Segregation must be maintained throughout until final disposal. Never store infectious waste in patient's rooms, function room or any public access area. Do not mix infectious waste with non-infectious general waste. Close all waste containers and describe the contents on a label.

D. Waste Transportation

Waste transportation is a movement of waste from one place to another. Waste transportation can be either on-site or off-site.

On-site on moving waste from one point to another within the healthcare facility, the following are recommended practices for on-site transportation:

- Waste should be moved in a designated trolley or wheel barrel.
- The trolley should be easy to load and unload, cleaned regularly
- If possible, yellow bags of hazardous healthcare waste and black bags of non-risk healthcare waste shall be collected on separate trolleys that should be painted or marked with the corresponding colors and washed regularly.
- The collection route should be the most direct one from the collection point to the central storage.
- The collection waste should not be left unattended even temporarily, or taken anywhere other than the designated central storage.
- Containers should be covered with lids during storage and transport.

Off-site Transporting waste outside the health facility. The basic recommendations for safe off-site transportation of waste include:

- Bins/bags/safety boxes must be kept upright, secured, dry (i.e. protected against rain), and out of direct contact with other supplies.
- The person responsible for waste disposal must be aware of the schedule for pickup and delivery of waste.
- It is preferable if the vehicle is designated for waste transport only.
- It is preferable if the vehicle has a cover.
- The vehicle must be cleaned and sanitized at the end of each day.

E. Treatment and Disposal

Healthcare waste is treated to render it non-hazardous. Non-infectious waste does not need to be treated. The most appropriate one among all of the existing technologies for the treatment and disposal of healthcare waste should be applied. The choice, however, should be made without losing sight of reliability, affordability, and sustainability of the technology in accordance with the technical, human and financial resources of a particular healthcare facility. This technology

should also minimize the immediate public health risks associated with healthcare waste management with the lowest impact on the environment. All waste disposal methods must be agreed upon by key line ministries and stakeholders.

Best health care waste treatment and disposal options at HCF level by decreasing order of importance and applicability

- **Sharps Wastes**
  - Incineration using properly built brick incinerator.
  - Transport to off-site incinerators, if there is centralized treatment service.
  - On-site burial.
- **Infectious Wastes**
  - On-site burial.
  - On site incineration provided that the incinerator is standard and capable of destroying such wastes.
  - Transport of offsite treatment/disposal site, if there is the service.
- **Non-Risk Waste**
  - Collection by municipal truck for landfill disposal.
  - On-site secured burning.

SOME OF THE COMMON DISPOSAL METHODS ARE:

1. Secured Burial Pit:

- Waste is placed into a pit (2 to 3 meters wide, 2.5 meters deep & at least 1.5 meters above the water table) and covered with earth
- The pit should be at least 50 meters away from any waster source, be fenced to restrict unauthorized access and located away from public areas.
- The site should have proper drainage, be located downhill from any wells, be free of any standing water, and be in an area that does not flood.
- Keep waste covered with a 10.30cm layer of soil every time waste is added to the pit.
- When the level of waste reaches to within 30.50cm of the surface of the ground, fill the pit with soil and dig another pit.
- Protected burial pits are acceptable and perhaps the most appropriate- disposal option for infectious wastes in rural healthcare facilities.
- Only contaminated and hazardous waste needs to be buried.
- Expired vaccines drugs should be encapsulated and buried, not burned.

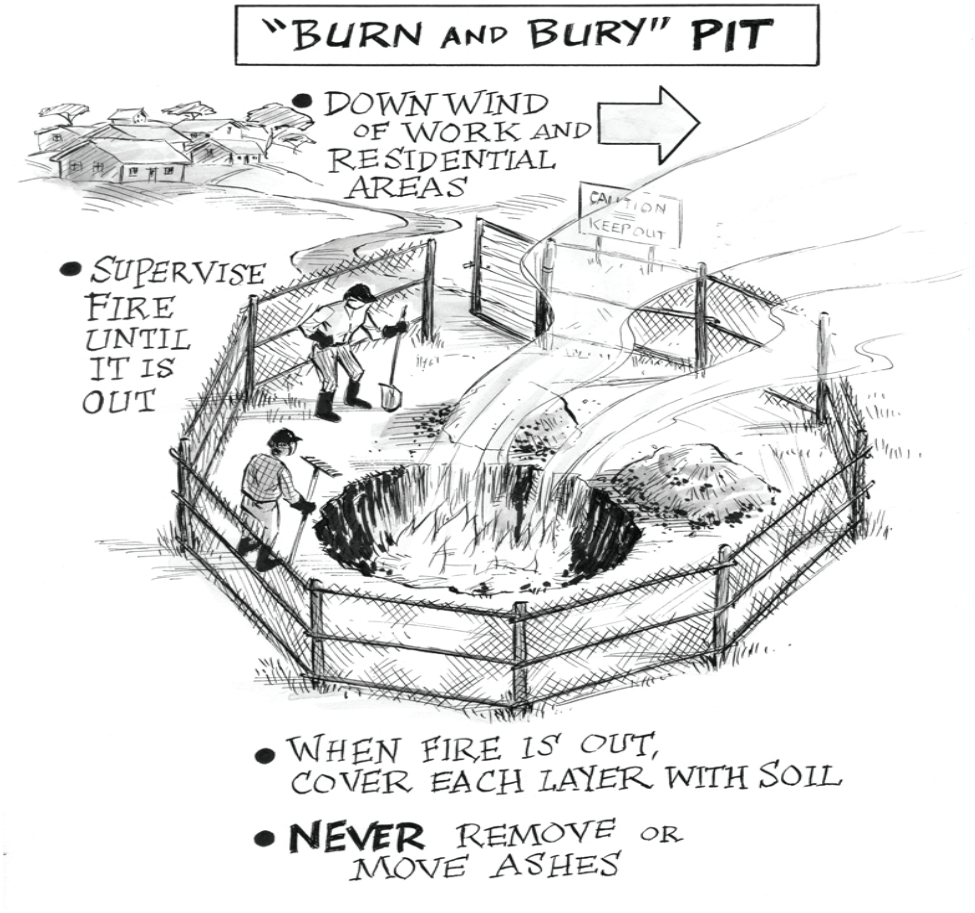
Figure 9.2: Making the Burial Pit Area Secured

2. Secured Burning and Burying of the Ash :

- Waste is placed into a pit and burned on a regular basis (at least once a week, according to volume of waste and size of pit). Waste must be burned thoroughly and ashes must be covered with soil.
- Pits should be dug 1.2 meters wide and to the depth of 2.5 meters, and at least 1.5 meters above water table. The pit should be fenced to restrict unauthorized access. The burn pit must be located away from public areas, and smoke from the burning waste must not affect the surrounding area. The pit should not be dug around water shed areas either.
- Open burning (outside of a pit, on the ground) should not be practiced.

- Use a regular community disposal site for the general waste. This will conserve both time and other resources.
- Treat the ash as general waste. Bury or otherwise opt to disposal of it in a designated area.
- Medical waste may not burn easily, especially if it is wet. Add kerosene to make the fire hot enough to burn all wastes. Be sure to add some kerosene before starting the fire. Adding kerosene after the fire has started might cause an explosion.

Figure 9.3: Secured Burning and Burying



3. Incineration:

Incineration is high temperature burning. It reduces the volume of the waste and eliminates pathogens. Large scale incinerators that can reach very high temperatures are preferred to small scale lower temperature incinerators. Incineration produces fewer pollutants than open-air burning and is chosen over the other on condition that a good quality incinerator and a well trained operator are available. For an incinerator to be used properly, it must have the following:

- Clear procedure of operation which should be posted near the incinerator.
- Trained operator.

- Reliable segregation system in which only infectious and non-polluting materials are incinerated.
- Reliable transport system to take waste to the incinerator.
- Ash pit to safely dump the incineration ash.
- Regular maintenance and repair.
- Adequate supply of fuel.

Recommended type of Incinerator

Pyrolytic incinerator: The pyrolytic incinerators comprises of a double pyrolytic chamber and a post combustion chamber. It is a very efficient method of treatment for infectious and hazardous HCW producing a temperature of as high as 900-1200°C in the combustion process using an excess amount of air to minimize smoke and odors. This kind of incinerator is required in Ethiopia for big health facilities such as national/central specialized hospitals and research institutes. Governmental and private hospitals located in the city of Addis Ababa and regional specialized hospitals in the country are recommended to have a pyrolytic incinerator.

Single chamber brick incinerator: Single chamber brick incinerator may be built by constructing a closed area with brick or concrete walls and is already in use in many health facilities including hospitals and health centers. If properly managed, the efficiency of this type of incinerator may reach 80–90% and result in destruction of 99% of microorganisms and a dramatic reduction in the volume and weight of waste. Some of the pitfalls of single chamber brick incinerator are that many chemical and pharmaceutical residues will persist if temperatures do not exceed 200°C and the process will cause massive emission of smoke, fly ash and potentially toxic gases. Despite these limitations, this kind of incinerators remains to be affordable, simple to operate and maintenance cost is minimal. These incinerators can satisfy the minimum requirements for safe treatment of infectious HCW produced in primary and/or general hospitals, health centers and private higher clinics and therefore, recommended for use in Ethiopia. Small size single chamber brick incinerator or drum incinerator can also be used in health posts, medium and lower private clinics as these units also produce infectious wastes resulting from injections (immunization) and injuries.

When Using Incinerator:

- Keep the incinerator clean. Remove ash from ash chamber and grate and do not store waste in incinerator.
- Some incinerators need to be preheated by burning general or non-medical waste (e.g. paper) and supplemented with kerosene or diesel fuel as may be necessary. This process takes 20 to 30 minutes before the incinerator reaches the recommended temperature for incinerating healthcare waste (800^0C in the burning chamber).
- Safety boxes and infectious waste should be loaded at a rate that maintains a constant and good, but not fierce fire in the gate.

- PVC plastics (like blood bags and IV lines); large amounts of reactive chemical waste, silver salts and photographic or radiographic wastes (x-ray materials); wastes with high mercury (such as broken mercury thermometers); Cadmium content batteries; aerosol cans or pressurized gas containers and glass vials must not be incinerated.

Note that Syringes are not PVC plastic!

Special Situation

Blood and other cultures and stocks of infectious agents from laboratory work should be sterilized by steam sterilization at the earliest, prior to disposal. However, in the absence of steam sterilization, facilities can decontaminate the waste in 0.5% chlorine solution to decrease /avoid any possible risks.

Open Site of Waste should be Avoided Because They:

- Pose infection risks and fire hazards
- Produce foul odor
- Attract insects
- Are unsightly

PREVENTION AND CONTROL OF HEALTHCARE ASSOCIATED INFECTION RISK

Healthcare waste management guidelines should include provision for a continuous monitoring of workers' health and safety to ensure that correct handling, treatment, storage, and disposal procedures are being followed. Essential occupational health and safety measures to prevent and control healthcare associated risks include the following:

- Proper training of workers.
- Provision of equipment and clothing for personal protection.
- Establishment of an effective occupational health program that includes immunization, PPE treatment and medical surveillance.

To protect workers, the following guidelines should be followed at the central store, food, laundry, other services and offices of workers:

- Desks and countertops should be free of sharp and other HCW.
- Needles and other sharp instruments should be discarded in designated puncture-resistant containers and not in trash cans or plastic bags.
- There should be no recapping of needles. Besides, rules for safe disposal and collection of sharp instruments or other hazardous materials should be reviewed regularly.
- Workers should examine and handle soiled linens and/or similar items as if they contained hazardous items.

- Workers should receive periodic instruction to keep them aware of the specific hazards of HCW of HCFs.
- Worker should follow instructions issued by the infection control and patient safety personnel for reporting infections.
- Workers should take appropriate measures to limit further contagion from HCWs by practicing universal precautions of self-protection from exposure to infectious wastes.

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CHAPTER 10: PROCESSING INSTRUMENTS

KEY TOPICS TO BE DISCUSSED:

- The steps of processing instruments
- Decontamination
- The rationale for decontamination before cleaning
- Preparing chlorine solution for decontamination
- Decontaminating soiled instruments and other items
- Significance of cleaning and checking for cleanliness of an object
- Cleaning soiled instruments and other items
- Sterilization
- Common methods of sterilization
- The basic steps for steam, dry heat and chemical sterilization
- Monitoring sterilization procedures
- Storing sterile items
- High level disinfection (HLD)
- Common methods of sterilization
- The basic steps for HLD by boiling, steaming and chemical methods
- Storing HLD items

BACKGROUND

As the prime concern of safety procedures is to protect both patients and the staff from infection, the transmission of infection from medical devices/and/or equipment contaminated with patients' body or their body fluids is the focal area of intervention in health facilities. Instruments which are reused without being properly processed and made safe are one of the causes of infections in developing countries. Healthcare workers are increasingly at risk of becoming infected with serious blood borne viruses such as HBV, HCV and HIV. Some research findings showed that there are 8 to 16 million new infections of Hepatitis B annually due to unsterile injections in developing countries. On the other hand, it was found that HIV survives in needles and syringes for more than 4 weeks at room temperature (Abdala *et al*., 1999; Rich *et al*., 1998). Thus, the greatest risk results from the staff's in direct contact with these life threatening infections while they perform or assist with surgical procedures (physicians, nurses and midwives); process surgical instruments and equipment (staff); perform housekeeping and waste management tasks; including disposal of infectious waste items.

The basic infection prevention processes recommended to reduce disease transmission from soiled instruments; surgical gloves and other reusable items; by way of decontamination, cleaning and either sterilization or high-level disinfection (HLD). Regardless of the type of the operative procedures, the steps in processing surgical instruments and other items are the same. (**Illustrated in Figure10.1**)

In the effort put to create an infection-free environment, it is important that the rationale for each of the recommended infection prevention processes, and their limitations, be clearly understood by clinic staff at all levels from healthcare providers to cleaning and maintenance. Infection prevention principles require that all reused medical equipment should be properly processed before reusing them to avert infections related to medical equipments. Processing these reusable instruments is not knowledge and technology intensive. Rather, they need only simple and basic trainings on how to process them after procedures.

After completing an operation or invasive medical procedure or while still wearing gloves, the physician or assistant should dispose of contaminated objects (gauze or cotton and other waste items) in a plastic bag or leak proof covered container. Next, disposable sharps (e.g. scalpel blades and suture needles) should be placed in a sharps container. Finally, all instruments and reusable items such as surgical gloves, syringes and suction cannula, whether or not they were used in the operation, should be decontaminated by soaking for 10 minutes in a disinfectant (e.g. 0.5% chlorine solution). This step is especially important if these items are to be cleaned by hand (Nyström, 1981).

Following decontamination, the instruments and reusable items should be thoroughly cleaned with soap and water and be completely rinsed and dried. Surgical instruments and those items that come in contact with the blood stream or touch normally sterile tissue beneath the skin (critical items) should be sterilized to destroy all microorganisms including bacterial endospores. (When sterilization is not feasible or equipment not available, however, HLD by boiling, steaming or soaking in a chemical disinfectant is the only acceptable alternative). Instruments and other items touching mucous membranes or broken skin only (semi critical items), however, need to be high-level disinfected.

DEFINITIONS

Cleaning - a process that physically removes all visible dust, soil, blood or other body fluids from inanimate objects as well as removing sufficient numbers of microorganisms to reduce risks for those who touch the skin or handle the object. It consists of thoroughly washing with soap or detergent and water rinsing with clean water and drying. (If tap water is contaminated, use water boiled for 10 minutes and filtered to remove particulate matter (if necessary) or chlorinated water (water treated with a dilute bleach solution sodium hypochlorite to make the final concentration 0.001%).

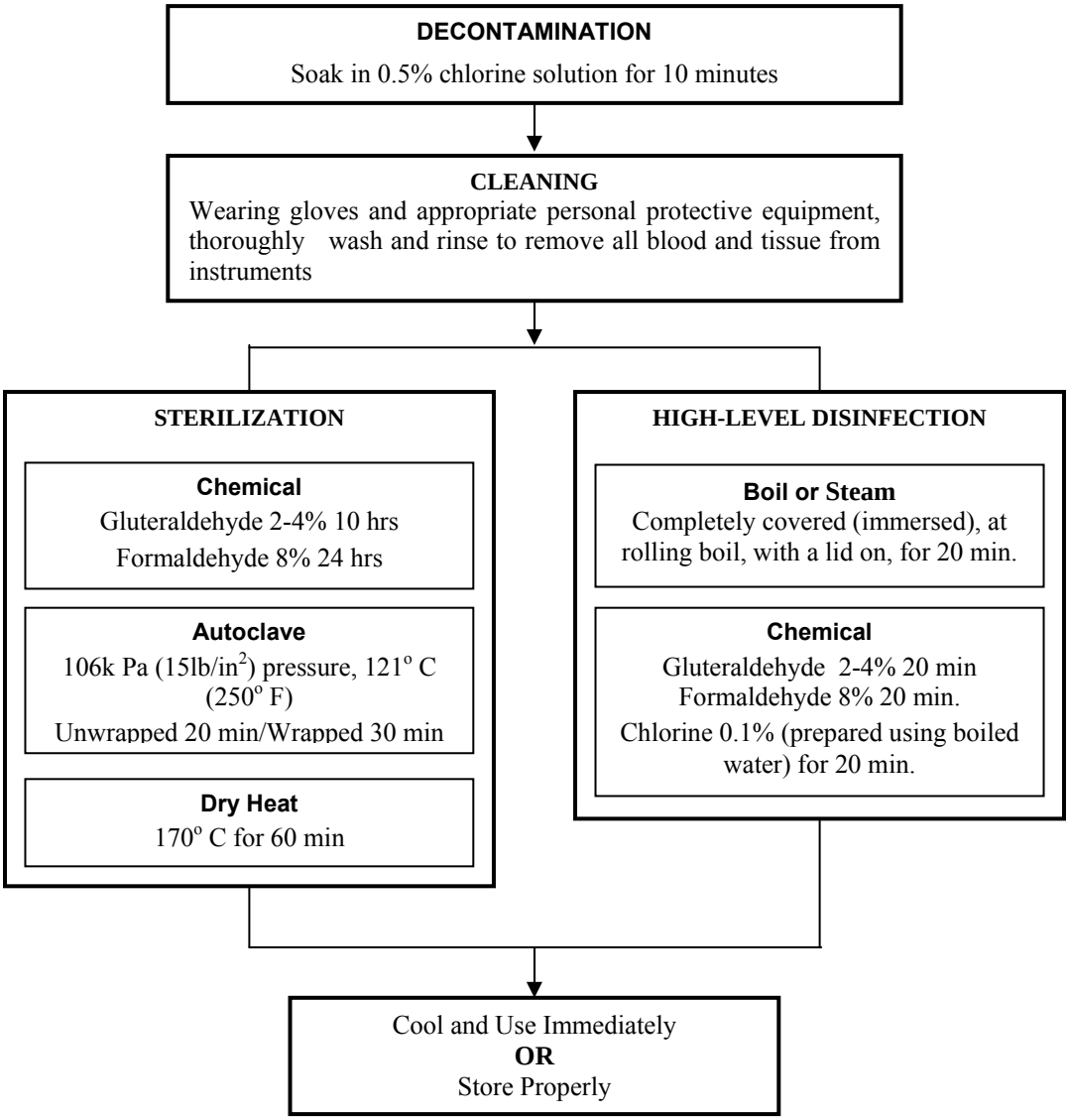
Decontamination - a process that makes inanimate objects safer to be handled by the staff before cleaning (i.e. inactivates HBV, HCV and HIV, it reduces the number of other microorganisms but does not eliminate them).

High-level Disinfection (HLD) - is a process that eliminates all microorganisms except some bacterial endospores from inanimate objects by boiling, steaming or the use of chemical disinfectants.

Sterilization - a process that eliminates all microorganisms (bacteria, viruses, fungi and parasites) including bacterial endospores from inanimate objects by high-pressure steam (autoclave), dry heat (oven), chemical sterilization or radiation.

Figure 10.1 Key Steps in Processing Contaminated Instruments, Gloves and Other Items

In all steps, special attention should be given to proper handling of the instruments and other items to minimize the risk of accidental injury or exposure to blood and other body fluids of the housekeeping staff and to attain high quality end result.



GUIDELINES FOR PROCESSING ITEMS

Each item, be it soiled metal instruments or pair of surgical gloves; requires special handling and processing in order to:

- Minimize the risk of accidental injury or exposure to blood or body fluid to the cleaning and housekeeping staff; and
- Provide a high quality end product (i.e. sterile or high-level disinfected instruments and other items). Specific guidelines for processing instruments, surgical gloves, equipment and other items used to provide healthcare services are summarized in **Table 10.9**.

In this table, the first column lists the items to be processed. The next two columns describe how to decontaminate and clean each item. In the last two columns, the conditions for sterilization or high-level disinfection are presented. If correctly performed, these processes provide excellent barriers preventing the spread of infection from medical instruments, surgical gloves and other items to keep patients and healthcare personnel safe.

COMMONLY USED CHEMICAL DISINFECTANTS

Disinfectants are chemicals that destroy or inactivate microorganisms. The most commonly used chemical disinfectants in healthcare settings are:

- Alcohols.
- Chlorine and chlorine releasing compounds.
    - Sodium hyporchlorite (Chlorine bleach).
    - Calcium hypochlorite or chlorinated lime.
    - Sodium dichloroisocyanurate.
- Formaldehyde.
- Gluteraldhyde.
- Iodine and Iodophor solutions.

ALCOHOLS

Ethyl and isopropyl (2-propyl) alcohol (60 to 90%) are excellent disinfectants which are relatively cheaper and commonly available. Their rapid action and absence of chemical residue make them ideal for disinfection of many medical items. The activity of both alcohols, however, drops sharply when diluted below 50%. To attain better results, therefore, the optimal concentration of the solution should be kept between 60 to 90% with water (volume/volume).

Advantages

- Rapidly kill all fungi and bacteria including Mycobacteria; Isopropyl alcohol kills most viruses including HBV and HIV while Ethyl alcohol kills all viruses; both are also tuberculocidal (Rutala, 1996).
- Rapid killing action.

- Not corrosive to metal.
- Less costly in comparison with other disinfectants.
- Useful for soaking rubber or latex items occasionally.
- Leave no chemical residue and therefore do not require rinsing.

Limitation

- Evaporate rapidly making extended contact time difficult unless the items are immersed.
- Do not penetrate organic material and are easily inactivated.
- Are flammable.
- May swell or harden rubber and plastic materials if used repeatedly or for prolonged periods of time.
- Damage shellac mounting of lenses in endoscopes.

Considerations for Use

- They are primarily used as antiseptic and as a low or intermediate-level disinfectant (wiping oral and rectal thermometers and disinfecting external surfaces of equipment-stethoscopes, cryoprobe tips, ultrasound probes, Ambu bags or anatomic models).
- Should be stored in a cool and well-ventilated places for they are flammable.

CHLORINE AND CHLORINE RELEASING COMPOUNDS

Hypochlorites are the most widely used chemicals among Chlorine disinfectants and are available in liquid (sodium hypochlorite) and solid (Calcium hypochlorite and Sodium dichloroisocyanurate) forms. Chlorine-releasing compounds available in powder (Calcium hypochlorite or Chlorinated lime) or tablet form (Sodium dichloroisocyanurate). Chlorine solutions and compounds are high-level disinfectants because they inactivate all bacteria, viruses, fungi, parasites and some spores (Russell *et al*., 1982). Besides, they are fast-acting, very effective against HBV, HCV and HIV/AIDS, relatively cheaper and readily available. They are extremely useful for decontaminating soiled surgical instruments, gloves and other items as well as large surfaces such as examination tables (Shapshak *et al*., 1993). Chlorine solution should be stored in closed brown bottles (Rutala *et al*., 1998).

SODIUM HYPORCHLORITE (CHLORINE BLEACH)

Advantages

- Usually is the least expensive and most readily available disinfectant of all disinfectants.
- Easy to prepare and use.
- Quickly inactivates all viruses including HBV, HCV and HIV, and kill tubercle bacillus as well as killing.
- Very useful for decontaminating soiled surgical instruments, gloves and other items and objects with large surface areas. (HLD takes 20 minutes, but decontamination takes as short as 60 seconds to kill HIV!)

Limitation

- Inactivated by organic matter. Chloramine-T, an alternative compound that releases chlorine, is not inactivated by organic matter to the same extent as Hypochlorites (WHO, 1988).
- Loses potency on standing if left in open container (replace at least daily).
- May corrode metal instruments (with prolonged exposure i.e. >20 minutes to concentrations greater than 0.5%).

Note:

- To minimize corrosion, solutions should not be prepared or be kept in metal containers (use plastic containers when possible);
- Electrolytic corrosion occurs when two or more dissimilar metals are placed in water or salt solutions especially if the items come into contact with each other. To avoid this type of corrosion, steel and aluminum instruments should be immersed in separate trays. Also, if metal trays or pans (e.g. stainless steel) are used, a plastic mat or gauze pad should be placed on the bottom of the tray to prevent metal-to-metal contact during soaking. This is especially important when metal instruments are soaked for prolonged periods (12 to 24 hours) for chemical sterilization. So in brief,
- Exposure time should not exceed 20 minutes; and
- Metal items should be thoroughly rinsed with water and dried after being decontaminated or immersed in clean water for up to an hour before washing.

CALCIUM HYPOCHLORITE OR CHLORINATED LIME

Calcium hypochlorite and chlorinated lime are available in powder form.

- Calcium hypochlorite contains approximately 70% available chlorine.
- Chlorinated lime contains approximately 35% available chlorine.

The availability of pre-diluted chlorinated lime solutions can be confusing and should be avoided as much as possible:

Advantages

- Both compounds decompose more slowly than sodium hypochlorite, but they should still be protected by storing away from heat and light.

Limitation

- Inactivated by organic matter.
- Like all chlorine compounds, it may corrode metal with prolonged exposure (>20 minutes) to concentrations greater than 0.5% unless thoroughly rinsed.

- More difficult to prepare diluted solutions due to poor solubility of the compound in alkaline water (pH >8) and amount of non dissolvable particulate matter in most such products.

SODIUM DICHLOROISOCYANURATE

Sodium dichloroisocyanurate (NaDCC) forms Hypochlorous acid when dissolved in water. It is available as a powder or tablet. The powder NaDCC has about 60% available chlorine; the tablet NaDCC, on the other hand, contains 1.5 g available chlorine per tablet.

Advantages

- NaDCC does not decompose as quickly as sodium or calcium hypochlorite.
- Tablets are easy to use for measuring.

Limitation

- More expensive than sodium or calcium Hypchlorite.
- Like all chlorine compounds, they may corrode metals with prolonged exposure (>20 minutes) to it when the concentration is greater than 0.5% unless thoroughly rinsed.

FORMALDEHYDE

- Formaldehyde in both liquid and gaseous forms can be used for a chemical sterilization, as well as a high-level disinfectant (Taylor, Barbeito & Gremillion 1969; Tulis, 1973). A commercially available solution of Formaldehyde (Formalin) which contains 35 to 40% formaldehyde by weight should be diluted with boiled water (1:5) to a final solution containing about 8% Formaldehyde. Despite its limitation, formaldehyde continues to be used in many countries because both liquid and solid forms (Para formaldehyde) are very cheap and readily available. Thus, its use in hospitals and clinics persisted for many years. Switching over to a less toxic compounds such as Glutaraldehydes or other newer high-level disinfectants, is strongly recommended but difficult to implement because of the high cost of these alternatives.

Advantages

- Not readily inactivated by organic materials.
- Can be used for up to 14 days.
- Can safely be used on surgical endoscopes (laparoscopes) because 8% formaldehyde will not corrode metal or damage instruments lenses, plastics or rubber.

Limitation

- Causes skin irritation.
- Is a Potential carcinogen.
- Irritates the skin, eyes and respiratory tract, even at low concentrations.
- For sterilization, 24 hours soaking in 8% formaldehyde solution kill all microorganisms, including bacterial endospores.

This compound produces a dangerous gas (bis-chloromethyl-ether) when mixed with chlorine.

Glutaraldehydes are widely used for chemical sterilization and HLD of medical instruments. Aqueous solutions are acidic (pH < 7) and are activated only when made alkaline. There are many types of Glutaraldehydes available worldwide. The most commonly used antiseptic is an alkaline-stabilized 2% Glutaraldehyde available commercially as Cidex® or Cidex 7®. These chemicals which are derivatives of Formaldehyde are also irritating and their fumes are very unpleasant. Therefore, they should be used only in well-ventilated rooms. Due to the fact that the stability and activity of Glutaraldehydes vary considerably depending on how they are prepared and stored, the manufacturers' directions must be followed carefully.

Do not dilute this chemical unless specified in the manufacturer's instructions

Advantages

- Not readily inactivated by organic materials.
- Can generally be used for up to 14 to 28 days.
- Can safely be used on surgical endoscopes (laparoscopes) for they will not corrode metal or damage lenses instruments (endoscopes), plastics or rubber.

Limitation

- Can cause skin irritation or dermatitis with chronic exposure.
- Vapors are irritating to mucous membranes (eye, nose and mouth) and respiratory tract.
- Works best at room temperature (20 to 25^0C or 68 to 77^0F).
- Is costly.

IODINE AND IODOPHOR SOLUTIONS

Iodine solutions (1 to 3% aqueous or tincture) and Iodophor (Iodine complexes with an organic material) have been used primarily as antiseptics.

Note:

For many years, Iodophor s manufactured for use as antiseptics proved to be ineffective for disinfecting inorganic objects and surfaces. Usually, antiseptics have significantly less Iodine (Rutala, 1996). Whatever the case may be, it is good to make sure that labels are checked.

Iodophors are not high-level disinfectants because conclusive evidence is lacking on their effectiveness against bacterial endospores and some fungi. For an instance, Pseudomonas species, a group of gram-negative bacteria, have been known to multiply in Iodophors (Favero, 1985; Rutala, 1993). These solutions are generally nontoxic and nonirritating to skin and mucous membranes. Iodophors must be properly diluted to be effective. Interestingly enough, correctly

diluted Iodophors have more active killing power than the full strength Iodophors due to the decreased availability of "free" Iodine in the latter.

Advantages

- They do not cause deterioration or softening of plastic items if they are kept dry between soakings.
- Diluted solutions of Iodine and Iodophors are nontoxic and nonirritating (unless there is known allergy to it).
- Can be used for disinfection of blood culture bottles and medical equipment such as thermometers.

Limitation

- It is an oxidizing agent (causes rust) and should be used only for high-quality stainless steel equipment or plastic materials.
- Like Alcohol and Chlorine, Iodine and Iodophors are inactivated by organic materials; therefore, only previously cleaned instruments should be placed in Iodine or Iodophor solutions.

Note:
To effectively avoid inactivation, medical articles/equipment should first be thoroughly rinsed with sterile water or boiled and filtered (if necessary) water at least three times after soaking.

Allergic reactions can also occur to the staff handling Iodine solutions and Iodophors. Therefore, they are:

- Primarily used as antiseptic for skin and mucous membranes (aqueous preparations only).
- Used for decontamination when the commercial preparation with aqueous solutions is available, but must be made fresh on daily basis.

In addition to that, they can safely be used on surgical endoscopes (laparoscopes) because 8% Formaldehyde will not corrode metal or damage lenses instruments, plastics or rubber.

DECONTAMINATION

It has been more than two decades, since it was confirmed that decontamination markedly reduces the level of microbial contamination of surgical instruments. For example, a study by Nyström (1981) showed that 75% of previously soiled instruments had fewer than 10 microorganisms and 98% had fewer than 100 after being decontaminated prior to cleaning. Because of this finding and similar others, it was strongly recommended that if instruments and other items are to be cleaned by hand, they should first be decontaminated to minimize the risk of infection following accidental injury to cleaning staff as well as to reduce microbial contamination of their hands. In instrument processing, therefore, decontamination is the first step in handling used instruments and gloves. So, immediately after use, all instruments should be placed in an approved disinfectant such as 0.5% Chlorine solution for 10 minutes to inactivate HBV, HCV and HIV and reduce the number

of microorganisms. But remember that this step does not eliminate them all (AORN, 1990; ASHCSP, 1986).

Decontamination is one of the highly effective IP measures that can minimize the risk of transmission of these viruses to healthcare workers, especially the cleaning and housekeeping staff when they handle soiled medical instruments, surgical gloves or other items.

These measures are also important steps in breaking the infection transmission cycle for patients (**see Chapter 1)**. Both processes are easy to do and are cost effective ways of ensuring that patients and staff are at a lower risk of becoming infected from contaminated instruments and other inanimate objects.

As presented in **Figure 10.1**, decontamination is the first step in processing soiled surgical instruments, surgical gloves and other items. It is important, to decontaminate these items before cleaning by placing them in a 0.5% Chlorine solution for 10 minutes. This very step rapidly inactivates HBV, HCV and HIV and makes the items safer to be handled by personnel who clean them (ibid.).

The formula for making a diluted chlorine solution from any concentrated hypochlorite solution is shown in **Table 10.1**.

Table 10.1 Formula for Making a Dilute Solution from a Concentrated Solution

- Check concentration (% concentrate) of the chlorine product you are using.
- Determine total parts water needed using **Table 10-1** or the formula below.

$$\textit{Total Parts (TP) water} = \left[\frac{\%\ \textit{Concentrate}}{\%\ \textit{Dilute}}\right] - 1$$

- Mix 1 part concentrated bleach with the total parts water required.

Example: Make a dilute solution (0.5%) from 5% concentrated solution

STEP 1: Calculate TP water: $\left[\frac{5.0\%}{0.5\%}\right] - 1 = 10 - 1 = 9$

STEP 2: Take 1 part concentrated solution and add to 9 parts water.

The formula for making a dilute solution from a powder of any percent available chlorine is shown in **Table 10.2**.

Table 10.2 Formula for Making Chlorine Solutions from Dry Powders

- Check concentration (% concentrate) of the powder you are using.
- Determine grams bleach needed using **Table 10-2** or the formula below.

$$\textit{Grams/Liter} = \left[\frac{\%\ \textit{Dilute}}{\%\ \textit{Concentrate}}\right] x\ 1000$$

- Mix measured amount of bleach powder with 1 liter of water.

Example: Make a dilute chlorine-releasing solution (0.5%) from a concentrated powder (35%).

STEP 1: Calculate grams/liter: $\left[\frac{0.5\%}{35\%}\right] x\ 1000 = 14.2\ g / L$

STEP 2: Add 14.2 grams (≈14 g) to 1 liter of water.

WHO (1989) recommends, 0.5% Chlorine solution for decontaminating instruments and surfaces before cleaning because potable (clean) tap water is not often available for making the solution. Further, the potentially high load of microorganisms and/or other organic material (blood or other body fluids) on soiled items, using a 0.5% solution for decontamination provides a wider margin of safety (Tietjen & McIntosh, 1989). For HLD, a chlorine solution (0.1%) can be prepared by providing boiled and filtered (if necessary) water used for dilution so as to clean and rinse the items thoroughly. The following table describes how to make 0.1% and 0.5% chlorine solutions using commercially available liquid bleach products.

Table 10.3 Preparing Dilute Chlorine Solutions form Liquid Bleach (Sodium Hypochlorite solution) for Decontamination and HLD

TYPE OR BRAND OF BLEACH (BY COUNTRY)	CHLORINE	PARTS WATER TO 1 PART BLEACH[a]	
	% available	0.5%	0.1%[b]
8 °chlorum[c]	2.4%	4	23
JIK (Kenya), Robin Bleach (Nepal)	3.5%	6	34
12 °chlorum	3.6%	6	35
Household bleach (USA, Indonesia), ACE (Turkey), Eau de Javal (France)	5%	9	49
(15 °chlorum), Lejía (Peru)			
Blanquedor, Cloro (Mexico)	6%	11	59
Lavandina (Bolivia)	8%	15	79
Chloros (UK)	10%	19	99
Chloros (UK), Extrait de Javel (France)	15%	29	149
(48 °chlorum[c])			

[a] Read as one part (e.g., cup or glass) concentrated bleach to x parts water (e.g., JIK [0.5% solution]—mix 1 cup bleach with 6 cups water for a total of 7 cups).
[b] Use boiled water when preparing a 0.1% chlorine solution for HLD because tap water contains microscopic organic matter that inactivates chlorine.
[c] In some countries, the concentration of sodium hypochlorite is expressed in chlorometric degrees (°chlorum); one °chlorum is approximately equivalent to 0.3% available chlorine.

Adapted from: WHO 1989.

The approximate amount (grams) needed to make 0.1% and 0.5% Chlorine releasing solutions from several commercially available chlorine-releasing compounds (dry powders) are listed in Table 10.4.

Table 10.4 Preparing Dilute Chlorine Solutions from Dry Powders

AVAILABLE CHLORINE REQUIRED	0.5%	0.1%[b]
Calcium hypochlorite (70% available chlorine)	7.1 g/L[a]	1.4 g/L
Calcium hypochlorite (35% available chlorine)	14.2 g/L	2.8 g/L
NaDCC[c] (60% available chlorine)	8.3 g/L	1.5 g/L
Chloramine **tablets**[d] (1 g of available chlorine per tablet)	20 g/L (20 tablets/liter) [d]	4 g/L (4 tablets/liter) [d]
NaDCC-based **tablets** (1.5 g of available chlorine per tablet)	4 tablets/liter	1 tablet/liter

[a] For dry powders, read x grams per liter (example: Calcium hypochlorite—7.1 grams mixed with 1 liter water).
[b] Use boiled water when preparing a 0.1% chlorine solution for HLD because tap water contains microscopic organic matter that inactivates chlorine.
[c] Sodium dichloroisocyanurate
[d] Chloramine releases chlorine at a slower rate than does hypochlorite. Before using the solution, be sure the tablet is completely dissolved.

Adapted from: World Health Organization (WHO) 1989.

TIPS ON DECONTAMINATION

The objective of decontamination is to protect individuals who handle surgical instruments and other items which have been in contact with pathogen laden blood or body fluids of patients with serious diseases.

Use a plastic container for decontamination to guard medical instruments against:

- Dulling of sharps (e.g. scissors) due to contact with metal containers; and
- Rusting of instruments due to a chemical reaction (electrolysis) possibly occurring between two different metals (i.e. the instrument and container) when soaked into water.

Do not soak metal instruments that are electro plated (i.e. which are not 100% stainless steel) even in plain water for more than an hour for fear that they rust.

As indicated in the above two formulas, a 0.5% Chlorine solution (Barkina) can be made from a readily available liquid or powder chlorine. Liquid chlorine is available under different brand names and in different concentration as listed in **Table 10.4** and **10.5**. In Ethiopia, for example, "Ghion" and "Sedex" are the most commonly and widely used liquid bleaches which contain 5% Chlorine solution.

After decontamination, instruments should be rinsed immediately with cool water to remove visible organic material before being thoroughly cleaned. Some healthcare facilities, for an instance, keep two buckets ready in the procedure areas or operating rooms: one filled with 0.5% Chlorine solution, and the other with water. So doing, helps to soak the instruments into the

water after soaking them in the chlorine solution for 10 minutes. Although this surely helps to prevent corrosion, leaving the instruments in plain water for more than an hour could let them rust.

Note:
The aim of decontamination is to protect individuals who handle surgical instruments and other items which have been in contact with blood or body fluids possibly carrying pathogens, from patients with serious diseases.

Some Ways to Achieve Satisfactory Decontamination:

- Due to their low cost and abundance, chlorine solutions prepared from liquid or powdered bleach are recommended.
- Freshly diluted solutions must be prepared whenever the solution looks like needing to be changed (e.g. when it becomes cloudy or heavily contaminated with blood or other body fluids). Otherwise, the organic matter destroys the chlorine.
- Freshly diluted solutions must be prepared daily for Chlorine solutions gradually lose strength.
- Clear water should be used to make the solution to guard organic matter against destroying the chlorine.
- Use plastic containers for mixing and storing bleach solutions as metal containers can be corroded rapidly and affect the solution.
- Prepare the solution in well ventilated areas because they give off chlorine.
- Label the container with 0.5% Chlorine decontamination solution and note the day and time of its preparation.
- Since 0.5% Chlorine solution is caustic, avoid its direct contact with skin and eyes.
- Use plastic and non-corrosive container for decontamination. This keeps sharp instruments from getting dull due to contact with metal containers. It also prevents rusting of instruments due to chemical reaction (electrolysis) taking place between two different metals when put into water.
- Do not soak metal instruments that are not electroplated (i.e. not 100% stainless steel) even in plain water for more than an hour because rusting will occur.
- Do not mix Chlorine solutions with either formaldehyde or with ammonia-based solutions as toxic gas may be produced.

Decontaminating Hypodermic Needles, Syringes, and Large Surfaces

- Hypodermic needles and syringes made ready for disposal should be decontaminated and placed in a puncture-resistant sharp container.
- Large surfaces such as tables for pelvic examination, operation, or delivery, which may have come into contact with blood and body fluid, should be decontaminated using 0.5% Chlorine solution.

Decontaminating Used Instruments and Other Items

1. Keep surgical or examination gloves after completing the procedure.
2. Place all instruments in 0.5% Chlorine solution for 10 minutes immediately after completing the procedure.
3. Decontaminate any surface contaminated during a procedure by wiping them with a cloth soaked in 0.5% chlorine solution.
4. Immerse gloved hands in 0.5% Chlorine solution.
5. Remove gloves by turning inside out. During their disposal, place them in a leak proof containing or heavy-duty plastic container.
6. If reusing gloves, soak in 0.5% Chlorine solution for 10 minutes to decontaminate it.
7. Remove instruments from 0.5% Chlorine solution after 10 minutes and immediately rinse them with cool water to remove residual Chlorine before cleaning them thoroughly.
8. Two buckets can be used in the procedure areas or operating rooms-one filled with 0.5% chlorine solution and the other, with water. Subsequently, instruments can be placed in the water after 10 minutes to help prevent possible corrosion.
9. Once instruments and other items have been decontaminated, they can safely be further processed. This step consists of cleaning and finally activity of either sterilization or high-level disinfection.

CLEANING

After decontamination of soiled instruments or gloves in 0.5% Chlorine solution for 10 minutes, they must be cleaned to remove organic materials or chemical residue. Cleaning is a process of physically removing infectious agents and other organic matters on which they live and thrive but does not necessarily destroy infectious agents. This is important because dried organic material can entrap microorganisms including endospores in a residue that protects them against sterilization or disinfection. In like manner, organic matter can also partially inactivate some high-level disinfectants diminishing their effective (AORN, 1992; Rutala *et al*., 1998). It is an essential pre-requisite to ensure effective disinfection or sterilization by reducing the number of microorganisms, especially endospores causing tetanus usually found on soiled instruments and equipment. Neither sterilization nor high level disinfection could be effective without prior cleaning (Porter, 1987).

Cleaning using hand soap (bar) or the powdered one is not advisable because the fatty acids in them react with the minerals in hard water leaving a residue or scum (insoluble calcium salt) which is difficult to remove. Using liquid soap, however, is better in that it mixes easily with water than bar or powdered soaps. It can also break fats and grease very easily making the cleaning process easier and more effective. The water we use for cleaning purpose should be a tap water which is not contaminated. If this is not possible, one may optionally use water boiled for 10 minutes and filtered to remove particulate matter (if necessary), or chlorinated water-water treated with a dilute bleach solution (sodium hypochlorite) to make the final concentration 0.001%.

It is not advisable to use abrasive cleaners (e.g. Vim® or Comet®) or steel wool because these products can scratch or pit metal or stainless steel. These scratches then become a good hiding place for micro organisms and make cleaning more difficult hence increasing the chance of rusting.

Note:

Many cleaning products contain ammonia which can interact with bleach and cause the formation of toxic fumes. Check the label of any cleaning product to see if it contains ammonia. (Sometimes you can be alerted about it if you come across to pungent smell of ammonia when opening the container).

Table 10.5 Effectiveness of Methods of Processing Instruments

METHOD	EFFECTIVENESS (kill or remove microorganisms)	END POINT
Decontamination	Kills HBV and HIV and some microorganisms	10 minute soak
Cleaning (water only)	Up to 50%	Until visibly clean
Cleaning (soap and rinsing with water)	Up to 80%	Until visibly clean
High-Level Disinfection	95% (does not inactivate some endospores)	Boiling, steaming or chemical for 20 minutes
Sterilization	100%	High-pressure steam, dry heat or chemical for the recommended time

As shown in Table 10.5, most microorganisms (up to 80%) in blood and other organic material are removed during the cleaning process. Moreover, a study showed that following the standard cleaning, most non lumen surgical instruments are found to contain less than 100 colony-forming units (CFU) consisting of relatively non pathogenic microorganisms (Rutala *et al*., 1998). This study confirmed that thorough cleaning is more effective than was previously assumed and documented the importance of cleaning in producing the desired safe outcome of surgery.

Once an item is washed, it needs also to be rinsed and usually dried. Thorough rinsing with clean water removes any soap residue that can interfere with sterilization or HLD. After rinsing, items should be dried especially if they will be sterilized or high-level disinfected using chemical disinfectants. It should be noted that water possibly remaining on the surgical articles/equipment (e.g. surgical instruments), if not dried well, dilutes the solution and may hamper the process.

Steps of Cleaning are:

- Wear gloves while cleaning instruments and equipment (thick household gloves or utility gloves work well). If they are torn or damaged, they should be discarded; otherwise, they should be cleaned and left to dry for re-use in the following day. Even when wearing heavy-duty utility gloves, care should be taken to prevent needle sticks or cuts when washing sharps.
- Put on protective eyewear (plastic visors, face shields, goggles or glasses, protective shoes) and a plastic apron, if available, while cleaning instruments and equipment to minimize the risk of splashing contaminated fluids into the eyes and onto the body.
- Use a soft brush or old tooth brush, detergent and water, scrub instruments and other items vigorously to completely remove all blood, other body fluids, tissue and other foreign matters. Hold items under the surface of the water while scrubbing and cleaning to avoid splashing. Disassemble instruments and other items with multiple parts and be sure to brush in the grooves, teeth, and joints of items which could host and stick organic materials upon it.
- Rinse items thoroughly with clean water to remove all detergent. Any detergent left on the items can reduce the effectiveness of further chemical processing.
- Allow items to air dry (or dry them with a clean towel).

Note:
Instruments that will further be processed with chemical solutions must dry completely to avoid diluting the chemicals; however, items to be treated with high level disinfection by boiling or steaming do not need to be dried first.

Finally, if instruments are to be sterilized, they should be packaged or individually wrapped after cleaning.

Items that cannot be cleaned thoroughly should not be reused, but be discarded after

STERILIZATION

Sterilization is a process in which the destruction of all micro-organisms including bacterial endospores takes place. This can be achieved by either physical or chemical methods necessary especially for medical devices penetrating sterile body sites or having direct contact with the blood (Spaulding, 1939).

The proper sterilization of medical devices, surgical instruments, supplies and equipment utilized in direct patient care and/or surgery is very critical in the modern healthcare delivery system and of great impact on patients' safety. Sterilization in health facilities can be achieved by high pressure steam (autoclaves), dry heat (oven), chemical sterilants (Glutaraldehyde or formaldehyde solutions) or physical agents (radiation).

Note:
Rinsing an item with Alcohol and then igniting it with a match (flaming) is sometimes categorized as a method of sterilization, it is not effective though.

Essentials of Sterilization Process:

1. The sterilants and sterilizing equipment must be validated and appropriate in design and operation to correctly integrate key yardsticks like: time, temperature, contact, pressure (for steam sterilization) and right sterilants (for chemical sterilization) to be as effective as they should be.
2. Instruments must be thoroughly cleaned to reduce dirt in order to guarantee effectiveness of the sterilization process. The higher the dirt the greater the challenge to the sterilization process. Therefore, it could be said that the effective sterilization is entwined with an effective removal of the dirt before making it ready for sterilization.
3. There must be close and adequate contact between the chemical sterilant and all surfaces and crevices of the device to be sterilized.

The Effectiveness of any Sterilization Method is also dependent Upon Four Other Factors:

1. The type of micro-organism present.
2. The number of micro-organisms present.
3. The amount and type of organic material that protects the micro-organisms. Blood or tissue remaining on poorly cleaned instruments acts as a shield to microorganisms during the sterilization process.
4. The number of cracks and scratches on an instrument that might harbor micro-organisms.

Note:
Sterilization is a process, not a single event; therefore, all phases and steps in the process must be carried out correctly.

METHOD OF HEAT STERILIZATION

I. High Pressure Steam Sterilization (Autoclaves)
II. Dry-heat sterilization (oven)

Standard Conditions for Heat Sterilization

Steam sterilization (Gravity): In the usual practice, the temperature in steaming process should be 121^0C (250^0F) and its pressure,106 kPa (15 lbs/in^2) the time being 20 minutes for unwrapped items; and 30 minutes for wrapped items. As an alternative, it could be set at a higher temperature of 132^0C (270^0F) with the pressure of 30lbs/in^2; and the duration being 15 minutes for wrapped items. What ever the case may be, one should allow all items to dry before removing them from the sterilizer.

Note: Pressure settings (kPa or lbs/in^2) may vary slightly depending on the sterilizer used. When possible, follow manufacturers' recommendations.

Dry heat:

- Heat treatment in 170^0C (340^0F) for an hour (total cycle time-placing instruments in the oven for an hour, and then cooling for 2 to 2.5 hours), or
- Heat treatment in 160^0C (320^0F) for 2 hours (total cycle time is from 3 to 3.5 hours).

Remember:

- **Exposure time begins only after the sterilizer has reached the target temperature.**
- **Do not overload the sterilizer (Leave at least 7.5 cm [3 inches] between the items and walls of sterilizer). Overloading alters heat convection and increases the time required to sterilize.**

Source: Perkins 1983

I. HIGH PRESSURE STEAM STERILIZATION (AUTOCLAVES)

Is an effective method of sterilization but is the most difficult of all types to carry out correctly (Gruendemann & Mangum, 2001). Despite its being difficult, it is generally considered the method of choice for sterilizing instruments and other items used in healthcare facilities. In settings where electricity is a problem, instruments can be sterilized in a non electric steam sterilizer using kerosene or other fuel as a heat source.

The two Rationale of Steam Sterilization:

- Saturated steam is an extremely effective carrier of thermal energy that makes it many times more effective in conveying the necessary energy to the items to be sterilized than dry air.
- Steam is an effective sterilant in that they can soften any resistant and protective outer layer of the micro-organisms allowing coagulation of the inner sensitive portion of the micro-organisms.

Advantages

- Most commonly used effective method of sterilization.
- Sterilization cycle time is shorter in steam sterilization than in any other type of sterilization.

Limitation

- Requires a continuous source of heat (wood fuel, kerosene or electricity).
- Requires equipment (steam sterilizer) which needs to be expertly maintained to keep it in working condition.
- Requires strict adherence to time, temperature and pressure settings.
- Difficult to produce dry packs because breaks in procedure are common (e.g. not allowing items to dry before removing, especially in hot, humid climates).
- Repeated sterilization cycles can cause pitting and dulling of cutting edges of instruments (i.e. scissors).
- Plastic items cannot withstand high temperatures.

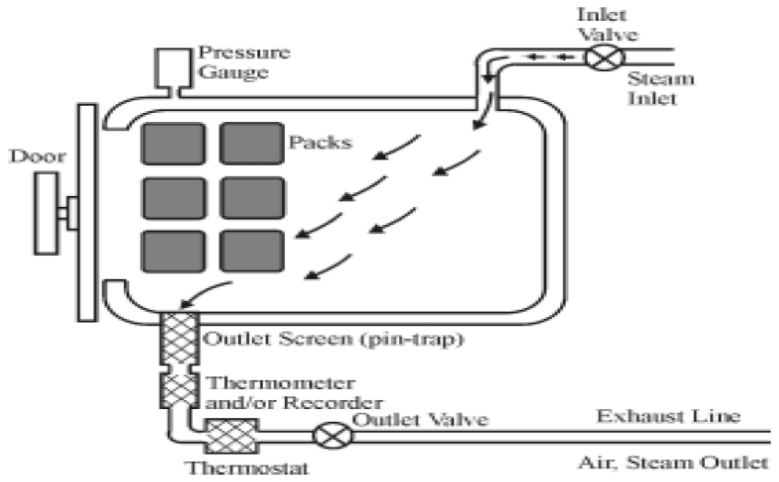
There are three types of high-pressure steam sterilizers:

- Gravity displacement
- Prevacuum
- Flash

Gravity Displacement Sterilizers:

Table-top models are relatively simple to operate and these are essentially horizontal pressure cookers. A pool of water in the bottom of the sterilizer is heated until it turns into steam using a power source of electricity or kerosene. The steam then rises to the top of the chamber because it is lighter than the cool air in the chamber. As more and more steam is produced, the cool air is forced out of the chamber through the drain near the bottom of the chamber. When the steam pushes all the cool air out, steam enters the drain, triggering thermally (heat) regulated valve to close. Once the valve is closed, the steam continues to build up pressure until the operating temperature (normally 121^0C/250^0F) is reached. The timer can now be activated and be counted down. At the end of the cycle (normally 20 minutes for unwrapped items and 30 minutes for wrapped items), the relief valve is opens to allow the steam to escape. Usually the steam passes through the water reservoir where it condenses back to water and thus does not enter the room. After the pressure on the gauge reads zero, the door can be opened 12 to 14cm (5 to 6 inches). Items inside it should be left to cool for 30 minutes. If steam is still present (and the chamber is quite warm), condensation of the moist air may cause wetness of the items or packs if they are placed on a cool or cold surface.

Figure 10.2 Simplified Diagram of a Gravity Displacement Steam Sterilizer



PREVACUUM STERILIZERS

These sterilizers are similar to the gravity displacement sterilizers except that they have a vacuum pump system to remove the air in the chamber before the steam is let in. This step reduces the total cycle time. Most prevacuum sterilizers are operated at the same temperature (121^0C/250^0F) as gravity displacement sterilizers. A special type of vacuum sterilizer called a high speed vacuum sterilizer, however, is operated at a higher temperature (134^0C/275^oF). The vacuum system not only shortens the cycle time, but also reduces the chance of creation of air pockets. Because a prevacuum sterilizer is more complex to operate, it is necessary to monitor its functioning closely and maintain it on regular basis

FLASH STERILIZERS

These are small table-top prevacuum sterilizers usually located in operating rooms or adjacent to them. They operate at a higher temperature (134^0C/275^0F) and thus have a shorter cycle time. Due to their small size, their use is normally limited to sterilization of unwrapped surgical instruments for emergency purposes (e.g. dropped instruments, etc). Hence, most healthcare facilities often use gravity displacement sterilizers. In most countries, High-speed vacuum and flash sterilizers are usually found only in large referral hospitals (Webb, 1986).

OPERATION

Instructions for operating on the steam sterilizers (autoclaves) and its routine maintenance should be included in the basic training of healthcare staff. A steam sterilizer will reliably sterilize items only when kept in good working condition and operated correctly. Sterilization by steam requires four conditions: adequate contact, sufficient temperature, proper time and sufficient moisture. Even if these conditions are all necessary for sterilization to take place, sterilization failures in clinics and hospitals are most often caused by lack of steam contact or failure to attain adequate temperature (Webb, 1986).

CONTACT

The most frequent reason for sterilization failure is the lack of contact between the steam and the microorganisms. This failure may be related to human error or mechanical malfunction. Frequent causes of steam contact failure include the following:

- Failure to clean the object being sterilized adequately.
- Instruments which are closed, locked or stacked.
- Packages wrapped too tightly.
- Packs which are over staffed.
- Wrong position of container.
- Clogged strainer.
- Other mechanical problems

TEMPERATURE

The next most important factor in steam sterilization is temperature. The most commonly used temperature for steam sterilization is 121^0C (250^0F). When an object at room temperature is placed in a sterilizer, the steam transmits thermal energy to the object until the object reaches the same temperature as the steam. Under normal circumstances, this equilibrium occurs within a few minutes. If the steam is unsaturated (too dry) or if the steam is prevented from reaching all parts of the object, the temperature may never reach the level required for sterilization. The only way to be certain that the sterilizer is working correctly is, to make sure that the temperature at all points inside the load has reached the full operating temperature of 121^0C (250^0F).

TIMING

Just as it takes a certain amount of time to cook food, sterilization/killing micro-organisms/does need time to do the work. In both cases, the hotter the temperature, the less time is required. Sterilization time is measured in D-values. A D-value is the amount of time required to kill 90% of the microorganisms present. Different microorganisms are killed in different scales/measures of time. In other words, each kind of microorganism has a different set of D-values corresponding with certain measure/level of temperature.

MOISTURE

Last, but surely not least, is the moisture requirement. Adequate moisture content of the sterilizer atmosphere is mandatory for effective sterilization by steam.

Adequate moisture content implies that the steam must be “saturated” having a relative humidity of 100%. When any cool object is placed in the sterilizer, the steam at the surface of the object cools and becomes supersaturated. Water begins to condense on the surface of the object. This condensation produces two immediate effects:

- The volume of gas in the sterilizer chamber decreases as the steam (water vapor) changes to liquid state and more steam is drawn into the chamber and hence comes in to an increased contact with the articles being sterilized.
- Very large amount of thermal energy is transferred to the object raising the temperature of the article significantly. The amount of heat released is best explained by comparing the calories required to change the temperature of steam against the calories absorbed when water is converted to water vapor (steam).

If the steam is not saturated (less than 100% relative humidity), two problems will soon develop which individually or together interfere with the adequacy of the sterilization process:

- Articles in the sterilizer will remain dry and the microorganisms present cannot be killed as readily as under wet conditions (Water vapor softens the capsules of microorganisms making them more vulnerable to destruction by heat).
- Articles in the sterilizer will remain "cool" much longer especially if they are wrapped. Again using the home kitchen as an example, if a kettle of beans is placed in an oven (dry heat), it may take hours for them to be cooked. On the other hand, if they are placed in a pressure cooker (saturated steam) they will cook them much more quickly. Saturated steam is a much better "carrier" of thermal energy than dry air.

In summary**,** saturation of the steam is vital to sterilizer operation because water vapor is the best carrier of thermal energy which at times make the microorganisms more vulnerable to destruction by heat (Webb, 1986).

HEAT STERILIZATION FOR PRION DISEASE

Prion diseases, such as Creutzfeldt-Jakob disease (CJD), are a group of degenerative brain diseases that have received much attention during the past few years. They occur in animals (dogs, cows and primates) as well as humans and are rapidly fatal once symptoms develop. In humans, CJD remains rare with an incidence of less than one per million in the general population (Holman *et al.,* 1996). Creutzfeldt-Jakob disease (CJD) poses a unique infection prevention problem because prions which are protein-containing infectious agents can survive recommended heat or high-pressure steam sterilization processes. In addition to that, chemical disinfectants including sterilants like Gluteraldehyde and Formaldehyde are not strong enough to eliminate the infectivity of Prions by way of treating contaminated instruments and other items. Therefore, surgical instruments and other critical devices contaminated with high-risk tissue (i.e. brain, spinal cord and eye tissue) from patients with known or suspected CJD require special treatment (Rutala & Weber, 2001).

On caring for patients with known or suspected CJD and the subsequent handling and processing contaminant articles, (instruments/equipment/devices) the following are suggested:

- The risk of transmission of prions from patients or noncritical items (e.g. dishes or bedpans) to health workers is low. So, only Standard Precautions are needed for patients with known or suspected CJD.

- During surgery, put a minimum number of instruments on the operative field and monitor which instruments were used. This reduces the number of instruments requiring special handling and processing.

After Surgery:

- Avoid handling contaminated instruments.
- Disposable items and personal protective equipment worn by the surgical team should be placed in a plastic bag and incinerated.
- Following surgery, noncritical items such as the operating table, Mayo stand and other environmental surfaces can be decontaminated by wiping them with a cloth soaked with 0.5% chlorine solution.
- Heat-resistant instruments and other devices should first be decontaminated by placing them in a gravity displacement sterilizer at 121^0 C (250^0 F) for an hour, or in a prevacuum sterilizer at 134^oC (275^oF) for 18 minutes. Nonetheless, devices and instruments that are not heat- resistant or difficult to clean should be incinerated.

Do not soak or wash instruments used for CJD patients in dilute bleach (0.5% Chlorine) solution

- After decontamination, clean and sterilize the instruments using the recommended processes.
- Alternatively, after surgery, soak contaminated instruments and other devices in sodium hydroxide (NaoH) for an hour, then clean and sterilize those using recommended processes (Abrutyn *et al.,* 1998; Fishman *et al.,* 2002).

WHO suggested that contaminated instruments be steam sterilized while they are still soaked in Sodium hydroxide (NaoH). This practice, however, is no longer recommended because of the additional risk of damage to the sterilizer and exposure of health workers to chemical toxicity. In addition to that, Sodium hydroxide (NaoH) is caustic and must be neutralized right after use and before its disposal by diluting with large amounts of tap water or addition of an acid such as Hydrochloric acid.

- Biopsy tissues and surgical specimens should be placed in a formalin for about 48 hours; then in formic acid for an hour; and finally, back into fresh formalin for 48 hours (Abrutyn *et al.,* 1998).

EFFECTIVE STERILIZATION DEPENDS ON CORRECTLY FOLLOWING PROCEDURES OF THE PROCESS.

These include:

- Routine maintenance,
- Preparing items to be sterilized,
- Packaging and wrapping,
- Loading,

- Operating, and
- Unloading the sterilizer.

It is only when all these procedures are strictly undertaken that items would certainly be sterilized.

Routine Maintenance

Although there are many brands of steam sterilizers, routine maintenance practices are generally the same regardless of the make or type. For routine maintenance:

- The outlet screen (or pin-trap) should be removed daily and cleaned using a mild soap and brush under running water.
- The chamber should be cleaned daily using a soft cloth, or for large sterilizers, a long-handled mop which is used only for this purpose. Do not use abrasives or steel wool because they may scratch the stainless steel surface and increase the occurrence of corrosion.
- All door gaskets should be cleaned daily with a lint-free cloth and checked for defects. Defective rubber gaskets should be replaced.
- The carriage (loading cart used to hold the packs placed in a sterilizer) should be cleaned daily using a mild soap and lint-free cloth. (The wheels of the loading cart also should be cleaned at this time, removing any string or other debris).
- The exhaust line (or chamber drain) should be flushed weekly. This will keep the drain free of substances that might hinder air or steam removal from the chamber. Before flushing the exhaust line, check the maintenance instructions because Trisodium phosphate solution (a special type of soap) is often recommended (DHEW, 1975; Webb 1986). This can be prepared by adding one ounce of Trisodium phosphate to one liter (one quart) hot water. If this chemical is not available, the exhaust line can be flushed with hot water containing a mild soap solution. To do this, one should first remove the screen. Then pour one liter (one quart) of the solution down the drain using a funnel. Complete the process by pouring a liter of hot water to rinse out the soap and replace the screen. Usually, high-pressure steam sterilizers (autoclaves) also contain specific instructions on the operations and the routine maintenance. Managers should make copies of these instructions to avail it for the service of the staff. If replacement copies are needed, they can be obtained by writing to the individual manufacturer (normally the address can be found on the autoclave) or the donor agency providing with the equipment.

Preparing Items for Steam Sterilization

All instruments and other items should be decontaminated and thoroughly cleaned and dried before being sterilized. In some cases, it is not necessary to completely dry the items (needles or the like which have small openings) being sterilized for the small amount of water left inside these openings help in the steam sterilization process. For such items, flushing them with distilled or boiled water just prior to packaging for steam sterilization should be done after

cleaning. Finally, all jointed instruments should be open (or be unlocked) and disassembled. Reusable cloth items should be laundered and dried after use or prior to sterilization in order to:

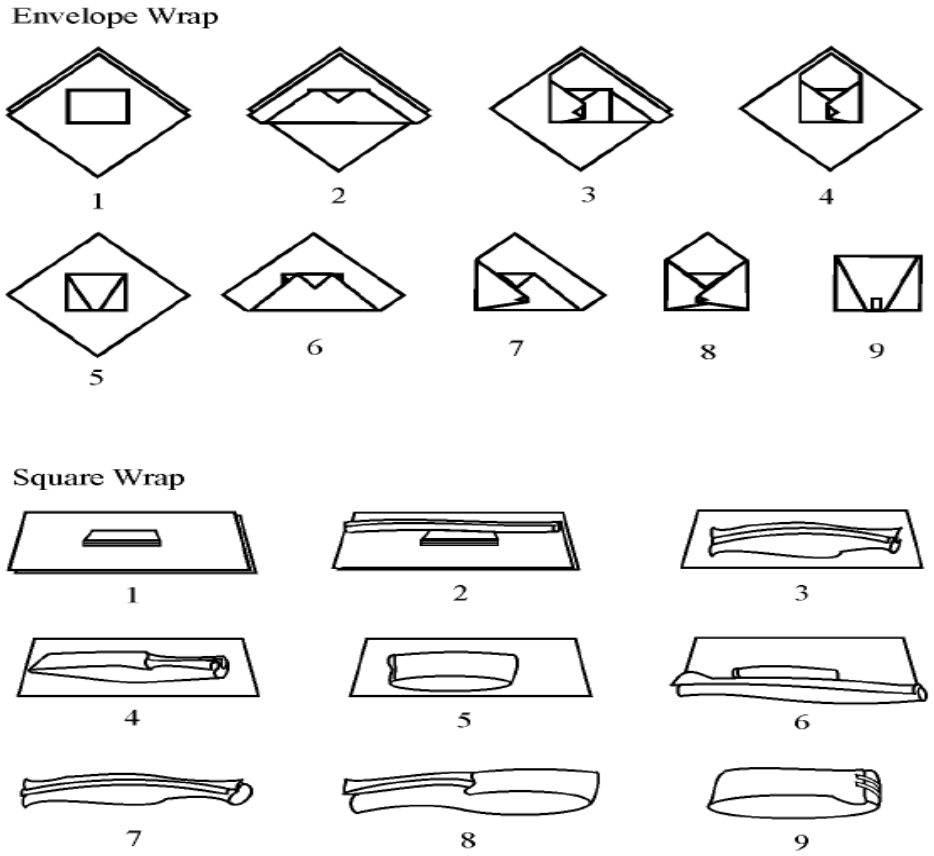
- Remove organic matter, and
- Prolong the life of the cloth by restoring the fabric's normal moisture (water) content.

Packing and Wrapping

Wrapping items to be sterilized permit sterile items to be handled and stored without being contaminated (**See Figure 10.3** for typical wrapping techniques). Materials used for wrappers should:

- Allow air removal and steam penetration
- Act as a barrier to microorganisms and fluids
- Resist tears and punctures and be free of holes
- Be nontoxic and low-lint
- Not be costly

Figure 10.3 Typical Wrapping Techniques



Types of materials that can be used as wrappers include:

- **Muslin cloth (140 thread count) -** use two double thicknesses wraps (four layers in all) as this is the least effective of all materials used for wrapping. Use for both steam and dry heat sterilization.
- **Paper -** double wrapping (two layers) is recommended. Use it for steam sterilization only and avoid reuse.

Tips for wrapping

- At least two layers of wrapping should always be used to reduce the possibility of contaminating the contents during unwrapping.
- Do not wrap packages too tightly. If they are wrapped too tightly, air can become trapped at the center of the packages preventing the temperature from getting high enough to kill all the microorganisms. Also, wrapping with strings or rubber bands or tying linen too tightly can prevent steam from reaching all surfaces.
- The outer wrapper of the pack can be loosely secured using linen ties. Packs can be secured with linen ties made from the same cloth. Hemmed strips of about ½ inch wide and of varied lengths. One or two of such strips can be used for each package. Because they can fit to almost any size of package, they eliminate the need for an expensive and hard-to-remove indicator tape.
- Do not wrap items in any waterproof material such as plastic or canvas for steam sterilization as the steam cannot penetrate the material and leave the item unsterilized.
- Wrappers should not be reused if they are torn, stained with oils or have hard or gummy deposits.

Note:

To aid the prevention of dulling of the sharp points and cutting edges, wrap the sharp edges and needle points in gauze before sterilizing. Repair (sharpen) or replace instruments as needed.

Loading and Unloading

Objectives

- To load items into the autoclave in such a way that it allows passage of the most steam through the load.
- To unload the steam autoclave so as to maintain the sterility of the items processed through a sterilizing cycle.

General Principles

- When loading, leave sufficient space for steam to circulate freely and avoid overloading.
- Place all packs (linen, gloves, etc) on edge and place canisters, utensils and treatment trays on their sides.
- Place instrument sets in trays having mesh or perforated bottoms flat on the shelves.

- In combination loads of cloth (or paper) packs and instruments trays, place linens on top shelves and trays on lower shelves. This prevents any condensation (moisture) which forms on cool metal when steam initially contacts with the item from dripping onto linen packs (DHEW, 1975).
- Surgical gloves should be sterilized by themselves or placed on the top shelves.
- Nested packs should be positioned in the same direction to help prevent air pockets so that the condensation can drain and the steam can circulate freely.
- Shelves (metal wire) or a loading cart must be used to ensure proper loading. It is preferable to use the cart that comes with the sterilizer. **See Figure 10.4, 10.5** and **Table 10.6** and **10.7**.

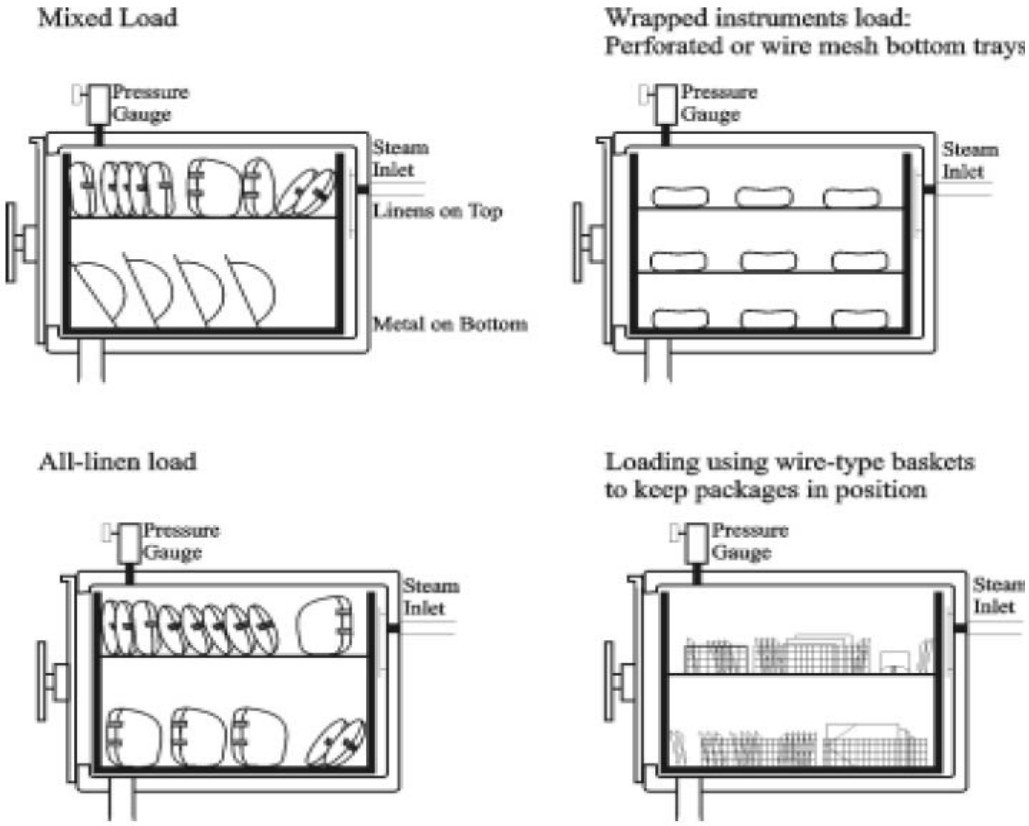
Note:

If an item goes in wet, it will come out wet. All items (instruments, basins and glassware) must be dry before being loaded into the sterilizer. This helps prevent "wet packs". The sterilizer is capable of drying items that have become moist during a properly loaded and operated sterilization process, but it still cannot remove excess moisture.

Metals and Glassware

- Instrument sets should not exceed 8kg (18 lbs). Basin sets should not exceed 3kg (7 lbs). This is done for reasons of limiting the amount of condensation which forms when steam contacts cool metal. Using these limits ensures that the items will dry during the sterilization cycle.
- Solid containers should be placed on their sides to allow airflow out of them. If air is trapped in a solid container, it will prevent the steam from contacting the inner surface and prevent sterilization.

Figure 10.4 Loading Steam Sterilizer



Source: AAMI 1990.

Linens

- Linen packs should not be too large and heavy (not more that 5kg or 12 pounds) to secure better steam penetration of the pack in 30 minutes (the time allowed for sterilizing wrapped items).
- Packs containing sheets, table covers and towels are most impenetrable and difficult to reach each fiber for the steam. Such packs must be placed on the edge of the shelf to insure better steam penetration.

Liquids

- Liquids must be sterilized by themselves.
- The amount of liquid in the bottle, not the size of the container, determines the time required for sterilization.
- Use only Borosilicate heat-resistant glass (Pyrex®).
- Use only automatic self-sealing caps for closure.

Table 10.6 Loading the Steam Sterilizer Using Loading Carts or Shelves

ESSENTIAL STEPS	KEY POINTS
Place all items on a shelf. Use either a loading cart or shelves in the sterilizer.	Never place items (wrapped or unwrapped) on the floor of the sterilizer. Items placed on the floor could block discharge of air from the sterilizer, or allow air and moisture to be trapped in pockets, resulting in sterilization failure and "wet packs."
Items must not touch chamber walls.	Packs touching the chamber walls can be scorched or contents damaged due to excessive heat of the metal walls.
Always allow 7–8 cm (3 inches) of space between top-most package and top of chamber.	This allows displacement of air and free flow of steam.
Place all fabric packs on the edge (folds perpendicular to shelf); and when loading two layers on one shelf, place the upper layer crosswise to the bottom layer.	It is easier for steam to flow down through the folds to penetrate each fiber than through flat, compressed surfaces.
Place all bottles, solid metal and glass containers of dry materials on their sides with lids held loosely in place.	Air will drain out and steam will take its place.
Place treatment trays and utensils on the edge, tipped slightly forward.	This prevents pooling of condensation and facilitates drying.
Place instrument trays (mesh or perforated bottom only) flat on shelves. If instruments have been placed in a solid tray or on a Mayo tray, the tray must be placed on the edge and tipped slightly forward.	This helps maintain an orderly arrangement of contents and reduces damage caused by "dumping" all the instruments into bottom of tray if instrument tray is placed on its side. This also facilitates drying.
Solutions must be sterilized by themselves, and placed on the shelves not touching each other.	There is always a possibility that solutions will explode. If instruments and other items are in the steam sterilizer, they will be contaminated and they may be damaged.
Use a wire basket to hold glove packages upright. Never place packages on top of each other.	If gloves are stacked, the compression at the bottom of the pile will prevent access of steam to the gloves.
Use only the upper shelves for gloves. Place glove packages loosely on edge with thumbs up, well away from the walls of the chamber. **Never** place them on the bottom shelf of the chamber.	Residual air gravitates to the lower part of the chamber and will increase the rate of deterioration of the rubber.
Do not compress packages or overload the chamber.	When placing packages on shelves, put hand between them to be sure packages are not compressed and give least possible resistance to steam throughout the load.

Adapted from: Tomlinson et al 1996.

Combination Loads

- In loads which combine linens (fabrics) and metal items, place linens on top shelves and metal items below. This prevents condensation from dripping onto the linen packs, causing them to absorb the excess moisture.
- When a load is made up of wrapped and unwrapped items requiring different times to ensure sterilization, the longest required time **(**i.e. 30 minutes) must be used.

The fundamental rule in loading the sterilizer is to prepare all items and arrange the load in such a manner as to encounter the least possible resistance to the passage of steam through the load (i.e. from the top of the chamber toward the bottom).

Unloading Tips

- Allow instrument packs to dry completely before removal (takes 30 minutes).
- Place sterile trays and packs on surfaces padded with paper or fabric (avoid placing warm packs on cold metal surfaces so as to prevent condensation).
- Store when packs reach room temperature (usually takes about an hour).
- Sterilized packs and articles should be handled gently and used as reasonably as possible.

If a pack is dropped, turns to be moist or comes into contact with moisture, it must be considered contaminated.

Table 10.7 Unloading the Steam Sterilizer

ESSENTIAL STEPS	KEY POINTS
After the sterilizing cycle has been completed and the chamber pressure gauge reaches "0," open the door 12–14 cm (5–6 inches).	Always keep the door between you and the sterilizer when opening the door.
Wait 30 minutes before unloading the sterilizer.	This allows residual moisture to dry and the load to cool.
Unloading Using a Loading Cart	
Remove the loading cart from the sterilizer and place it where there is no open window or fan in close proximity.	Do not place freshly sterilized packages, especially those not completely cooled, in front of an open window or a fan because there may be residual humidity in the packages, and dust and dirt could be forced through the wrappers, contaminating the contents. If there are water droplets or visible moisture on the outside of the wrapper or package, or on the tape used to secure it, the package is contaminated. It must be reprocessed before use.
Look at, but do not handle, the outside of the package to test for dryness.	
When the packs reach room temperature, remove packs from the loading cart and place on storage shelves. They may be dispensed or placed in sterile storage.	It may take 1 hour or longer for packs to reach room temperature. Avoid unnecessary handling.
Unloading Using Shelves (loading cart not used)	
Remove packages from the sterilizer shelves.	Avoid unnecessary handling.
Look at outside of the wrappers for dryness..	If there are water droplets or visible moisture (water stains) on the outside surfaces of packages, or on the tape used to secure it, the package is contaminated. It must be reprocessed before use.
Place packs on a surface well padded with paper or fabric, away from open windows or the front of a fan.	In order to prevent condensation from forming, do not place on a cool or cold surface. Do not place freshly sterilized packages, especially those not completely cooled, in front of an open window or a fan because there may be residual humidity in the packages, and dust and dirt could be forced through the wrappers, contaminating the contents. If there are water droplets or visible moisture on the outside of the wrapper or package, or on the tape used to secure it, the package is contaminated. It must be reprocessed before use.
When packages have cooled to room temperature, they may be dispensed or placed in sterile storage.	It may take 1 hour or longer for packs to reach room temperature. Avoid unnecessary handling.

Adapted from: Tomlinson et al 1996.

STEAM STERILIZING LIQUIDS

Sterile water can be prepared only by steam sterilization.

Instructions

- All liquids should be in heat-resistant glass (Pyrex) closed with automatic self-sealing caps.
- Load steam sterilizer with liquids only.
- Wait until thermometer indicator shows 121^0C (250^0F) and 106 kPa (15lbs/in$_2$).
- Time the sterilization using a clock. The amount (volume) of solution in the bottle determines the sterilization time, not the size of the bottle:

75	to 200	ml	20 minutes
200	to 500	ml	25 minutes
500	to 1000	ml	30 minutes
1000	to 1500	ml	35 minutes
1500	to 2000	ml	40 minutes

Note:
If bottles of solutions with different volumes are sterilized in the same load, use the sterilization time recommended for the bottle containing the largest volume of liquid.

- When the sterilization cycle has ended, release the pressure slowly, taking not less than 15 minutes, until the chamber pressure is at "0." Turn operating valve off and open the door only 1cm (½ inch). (Suddenly opening the door all the way after a sterilization cycle could cause liquids to boil over or bottles to burst). Wait an additional 30 minutes for the chamber to cool before removing the load.

INSTRUCTIONS OF OPERATING A STEAM STERILIZER

STEP 1 Decontaminate, clean and dry all instruments and other items to be sterilized.

STEP 2 All jointed instruments should be in an open or unlock position, while instruments composed of more than one part or sliding parts should be disassembled.

STEP 3 Instruments should not be held tightly together by rubber bands or any other means that will prevent steam contact with all surfaces.

STEP 4 Arrange packs in the chamber to allow free circulation and penetration of steam to all surfaces.

STEP 5 When using a steam sterilizer, it is best to wrap clean instruments or other clean items in a double thickness of muslin or newsprint. (Unwrapped instruments must be used immediately after removal from the sterilizer, unless they are kept in a covered, sterile container.)

If using a pressure cooker or kerosene-powered (non electric) gravity displacement steam sterilizer, bring the water to a boil (mind that it should not boil dry) and let the steam escape

from the pressure valve (this should be done always); then turn down the heat, but keep the steam coming out of the pressure valve.

STEP 6 Sterilize at 121^0C (250^0F) for 30 minutes for wrapped items and 20 minutes for unwrapped items; set time of the clock.

STEP 7 Wait 20 to 30 minutes (or until the pressure gauge reads zero) to permit the sterilizer to cool sufficiently. Then open the lid or door to allow steam to escape. Allow instrument packs to dry completely before removal which may take up to 30 minutes (Wet packs act like a wick drawing in bacteria, viruses and fungi from the environment). Wrapped instrument packs are considered unacceptable if there are water droplets or visible moisture on the package exterior when they are removed from the steam sterilizer chamber. If using rigid containers (e.g. drums), close the gaskets.

STEP 8 To prevent condensation when removing the packs from the chamber, place sterile trays and packs on a surface padded with paper or fabric.

STEP 9 After sterilizing, items wrapped in cloth or papers are considered sterile as long as the pack remains clean, dry (including no water stains) and intact. Unwrapped items must be used immediately or stored in covered sterile containers.

- Maintain a steam sterilizer log including heat begun, correct temperature and pressure achieved, heat turned down, and heat turned off.
- Each load should be monitored with mechanical (time, temperature and pressure) and chemical (internal and external chemical test strips) indicators.
- Autoclave should be tested daily with an air-removal test to ensure proper removal of air.

If steam escapes from the safety valve or under the lid, the autoclave is not working correctly. Rather, it is merely steaming items at low-pressure (which may be equivalent to HLD, not sterilization). Then, what is to be done?

- If steam escapes from the safety valve instead of the pressure valve, the pressure valve must be cleaned and inspected.
- If steam escapes from under the lid, the gasket (rubber ring) must be cleaned and dried or replaced.

DRY HEAT STERILIZATION METHOD

Dry heat sterilization is caused by hot air that destroys micro-organisms through oxidation that causes slow destruction of the micro-organisms protein. Dry heat sterilization methods have limited value because it is difficult to maintain the same temperature throughout the process. Moreover, dry heat sterilization takes longer than steam sterilization, because the moisture in the steam sterilization process significantly speeds up the penetration of heat and shortens the time needed to kill microorganism. When available, dry heat is a practical means by which needles and other sharp instruments are sterilized. Dry-heat sterilization can be achieved with a simple oven as long as a thermometer is used to verify the temperature inside the oven. Dry heat sterilization is accomplished by thermal (heat) conduction. Initially, heat is absorbed by the exterior surface of an item and then

passed to the next layer. Eventually, the entire object reaches the temperature needed for sterilization.

> **Note:**
> Just as with steam sterilization, thorough cleaning of the object prior to dry heat sterilization is critical. If an instrument is not properly cleaned, effective sterilization cannot be ensured regardless of how long the instrument is heated.

Advantages

- An effective method as dry heat by conduction reaches all surfaces of instruments, even for instruments that cannot be disassembled.
- Protective of sharps or instruments with a cutting edge (fewer problems with dulling of cutting edges).
- Leaves no chemical residue.
- Eliminates "wet pack" problems in humid climates.

Limitation

- Plastic and rubber items cannot be dry-heat sterilized because temperatures used (160 to 170^0C) are too high for these materials.
- Dry heat penetrates materials slowly and unevenly.
- Requires oven and continuous source of electricity.

INSTRUCTIONS FOR OPERATING ON DRY HEAT OVEN

To ensure correct operation, consult specific operating instructions supplied by the oven's manufacturer.

STEP 1 Decontaminate, clean and dry all instruments and other items to be sterilized.

STEP 2 If desired, wrap instruments in aluminum foil or place in a metal container with a tight-fitting closed lid. Wrapping helps prevent recontamination prior to use. Hypodermic or suture needles should be placed in glass tubes with cotton stoppers.

> **When using dry heat to sterilize instruments wrapped in cloth, be sure that temperature does not exceed 170^0C/340^0F**

STEP 3 Place loose (unwrapped) instruments in metal containers or on trays in the oven and heat them to the desired temperature.

STEP 4 After the desired temperature is reached, begin timing. The following temperature/time ratios are recommended (APIC 2002):

170^0C (340^0F) 60 minutes
160^0C (320^0F) 120 minutes
150^0C (300^0F) 150 minutes
140^0C (285^0F) 180 minutes
121^0C (250^0F) overnight

Note:

Use dry heat only for items that can withstand a temperature of 170^0C (340^0F) (Perkins, 1983). Needles and other instruments with cutting edges should be sterilized at lower temperatures (160^0C [320^0F]) because higher temperatures can destroy the sharpness of cutting edges (Ibid).

Depending on the temperature selected, the total cycle time (preheating, sterilization time and cool down) will range from about 2.5 hours at 170^0C to more than 8 hours at 121^0C.

STEP 5 After cooling, remove packs and/or metal containers and store.

Loose items should be removed with sterile forceps/pickups and used immediately or placed in a sterile container with a tight-fitting lid until the time of use.

II. CHEMICAL STERILIZATION

Chemical sterilization is an alternative to high-pressure steam or dry-heat sterilization and often called "cold sterilization". If objects need to be sterilized and when the availing methods like high-pressure steam or dry-heat sterilization would damage them or equipment are not available (or operational), they can be chemically sterilized.

Some high-level disinfectants will kill endospores after prolonged (10 to 24 hours) exposure. Common disinfectants that can be used for chemical sterilization include Glutaraldehydes and Formaldehyde. Sterilization takes place by soaking for at least 10 hours in 2 to 4% Glutaraldehyde solution or at least 24 hours in 8% Formaldehyde. Glutaraldehydes such as Cidex, are often in short supply and very expensive, but they are the only practical sterilants for some instruments such as laparoscopes which cannot be heated. Both Glutaraldehydes and Formaldehyde require special handling and leave a residue on treated instruments; therefore, rinsing with sterile water is essential if the item must be kept sterile. If they are not rinsed off, this residue can interfere (cause sticking) with the sliding parts of the laparoscope and cloud the lens.

Although Formaldehyde is less expensive than Glutaraldehydes, it is more irritating to the skin, eyes and respiratory tract and classified as a potential carcinogen (Rutala, 1996). When using Glutaraldehydes or Formaldehyde, wear gloves to avoid skin contact; wear eyewear to protect from splashes; limit exposure time; and use both chemicals only in well ventilated areas (Clark, 1983).

As items are unwrapped after chemical sterilization, they should be transported and stored in a covered sterile container. (**Table 10.8** provides guidelines for preparing and using Glutaraldehydes and Formaldehyde solutions).

Note:

Do not dilute formaldehyde with chlorinated water because so doing can produce a dangerous gas (bischloromethyl-ether).

Advantages

- They are not readily inactivated by organic materials.
- They can be used for items that will not tolerate heat sterilization such as laparoscopes.
- Formaldehyde solutions can be used for up to 14 days (replace sooner if cloudy) but some Glutaraldehydes can be used for up to 28 days (Check the manufacturers' instructions). Although manufacturers provide guidelines for dilution and the appropriate duration for the use of the solution, many of their claims have not been validated (Gurevich *et al.,* 1990). Chemical strip tests can be used to determine the effectiveness of a solution. If these are not available or practical, use the solution only for the minimum recommended time and change it if it is diluted by wet instruments or is visibly cloudy.

Limitation

- Glutaraldehydes and formaldehyde are chemicals that cause skin irritation; therefore, all equipment soaked in either solution must be thoroughly rinsed with sterile water after soaking.
- Because Glutaraldehydes work best at room temperature, chemical sterilization cannot be assured in cold environments (in temperatures less than 20^0C/68^0F), even with prolonged soaking.
- Glutaraldehydes are expensive.
- Vapors from Formaldehyde (classified as a potential carcinogen) and to a lesser degree from Glutaraldehydes, are irritating to the skin, eyes and respiratory tract. Therefore, one should wear gloves and eyewear, limit exposure time and use both chemicals only in well-ventilated areas.
- Formaldehyde cannot be mixed with Chlorine or chlorinated water because a dangerous gas (bis-chloromethyl-ether) can be produced.

INSTRUCTIONS ON THE USE OF CHEMICAL STERILIZATION

STEP 1 Decontaminate, clean and dry all instruments and other items to be sterilized.

STEP 2 Completely submerge items in a clean container filled with the chemical solution and place the lid on the container.

STEP 3 Allow items to soak:

- 10 hours in a Glutaraldehyde (check specific product instructions), or
- At least 24 hours in 8% Formaldehyde.

STEP 4 Remove objects from the solution with sterile forceps; rinse all surfaces three times in sterile water; and air dry them. Ideally, three separate (sequential) rinse containers should be used.

STEP 5 Store objects in a sterile container with a tight-fitting lid if they will not be used immediately.

MONITORING STERILIZATION PROCEDURES

Sterilization procedures can be monitored routinely using a combination of biological, chemical and mechanical indicators as parameters. Different sterilization processes have different monitoring requirement.

Biological Indicators

Monitoring the sterilization process with reliable biological indicators at regular intervals is strongly recommended. Measurements should be performed with a biological indicator that employs spores of established resistance in a known population. The biological indicator types and minimum recommended intervals should be:

- **Steam Sterilizers** - a highly resistant but relatively harmless (nonpathogenic) microorganism called *Bacillus stearothermophilus* is used to test steam sterilizers. As used in hospitals and clinics to test sterilizers, this microorganism has a D-value of about 2 minutes at 121^0C (250^0F). In other words, it would take 2 minutes at 121^0C (250^0F) to kill 90% of the test microorganisms present. Through research, mathematical calculation and intelligent "guesses", authorities have generally agreed that for normal hospital sterilization, about six *Bacillus stearothermophilus* D-values (or about 12 minutes) should be sufficient to kill essentially all pathogenic microorganisms and give a large margin of safety. For reasons of the absence of internal temperature sensing devices such as temperature-specific chemical indicators in many countries, extra time is recommended as an added safety margin. Thus, twenty minutes for unwrapped and 30 minutes for wrapped packs are considered sufficient to kill most microorganisms. This biological indicator should be done weekly and as deemed necessary.
- **Dry-Heat Sterilizers** - *Bacillus subtilis*, is used as an indicator on weekly basis and as deemed necessary. Similar to *Bacillus stearothermophilus,* the recommended time and temperature is found to be effective in the sterilization of the instruments.
- **Chemical Indicators** - chemical indicators include indicator tape or labels which monitor time, temperature and pressure for steam sterilization and for dry-heat sterilization. These indicators should be used on the inside and outside of each package or container.
- **External Indicators** - are used to verify whether the items have been exposed to the correct conditions of the sterilization process and the specific pack has been sterilized.
- **Internal Indicators** - are placed inside a pack or container in the area most difficult for the sterilization agent to reach (i.e. the middle of a linen pack). This is the indicator that tells if the item has been sterilized. Chemical indicators like heat sensitive tape or glass vials containing pellets that melt at certain temperatures and duration do not imply achieved/successful sterilization. They do, however, indicate whether mechanical or procedural problems have occurred in the sterilization process.
- **Mechanical Indicators** - Mechanical indicators for sterilizers provide a visible record of the time, temperature and pressure for the sterilization cycle. This is usually a printout or graph from the sterilizer or it can be a log of time, temperature and pressure kept by the person responsible for the sterilization process that day.

Storage

All sterile items should be stored appropriately to protect them from dust, dirt, moisture, animals and insects. The storage area should be located next to the place of sterilization or connected to it in a separately enclosed area with limited access that is used just to store sterile and clean patient care supplies. In smaller clinics, this area may be just a room close to the Central Supplies Department or in the Operating Room.

Instructions for Storing Sterile Items

1. Keep the storage area clean, dry, dust-free and lint-free.
2. Control temperature and humidity (approximate temperature 24^{o}C and relative humidity <70%) when possible.
3. Packs and containers with sterile (or high-level disinfected) items should be stored 20 to 25cm off the floor, 45 to 50cm from the ceiling and 15 to 20cm from an outside wall.
4. Do not use cardboard boxes for storage because cardboard boxes shed dust and debris and may harbor insects.
5. Date and rotate the supplies (first in/first out). This process serves as a reminder, but does not guarantee sterility of the packs.
6. Distribute sterile and high-level disinfected items from this area.

Shelf Life

- The shelf life of an item (how long items can be considered sterile) after sterilization is event-related. An item remains sterile until something causes the package or container to become contaminated as time goes on since sterilization is not the determining factor.
- To make sure items remain sterile until you need them, prevent events that can contaminate sterile packs and protect them by placing them in plastic covers (thick polyethylene bags). An event can be a tear or worn-out area in the wrapping, the package becoming wet or anything else that will enable microorganism to enter the package becoming wet or anything else that will enable microorganism to enter the package or container.
- Before using any sterile item, look at the package to make sure that the wrapping is intact and the seal is unbroken, clean and dry (as well as having not water stains).
- If the quality of wrapping clothes is poor and plastic bags are not available, limiting the shelf life is a reasonable option to resort to and secure the sterility of the instruments.

The Shelf Life of Sterilization Depends on the Following Factors:

- Quality of the wrapper or container.
- Number of times a package is handled before use.
- Number of people who have handled the package.
- Whether the package is stored on open or closed shelves.
- Condition of storage area (e.g. humidity and cleanliness).

- Use of plastic dust cover and method of sealing (AORN, 1992).
- Frequent or improper handling or storage.

Note:
- To make sure items remain sterile until you need them;
- Prevent events that can contaminate sterile packs, and
- Protect them by placing in plastic cover (bags).

In some healthcare facilities, where replacement of supplies is limited and the cloth used for wrapping is of poor quality, time as a limiting factor also serves as safety margin. If plastic covers (bags) are unavailable for the sterilized items, limiting the shelf life to a specific length of time (e.g. one month) may be reasonable decisions as long as the pack remains dry and intact.

OTHER STERILIZATION METHODS

Gas Sterilization - one of the first uses of Formaldehyde gas was to fumigate rooms a practice which has long been proven to be ineffective and unnecessary (Schmidt, 1899). Due to the irritating nature of its vapor to the skin, eyes, respiratory tract and its carcinogenic effects, the use of formaldehyde in this form should be limited.

Ethylene oxide (ETO) - is the other gas which is most frequently used in the United States and several other countries for sterilization of heat and moisture sensitive surgical instruments such as plastic devices and delicate instruments. Sterilization using ETO, however, is a more complicated (requires a 2 hour exposure time and a long aeration period) and costly process than either steam or dry-heat sterilization because items that are sterilized by ETO needed to be aerated (exposed to the outside), so that the residual ETO gas can diffuse out of the packages and items. This can take longer leading to complete cycle times of 24 hours or more (Steel man, 1992). Moreover, it requires sophisticated equipment and skilled staff specially trained for its safe use-making it impractical for use in many countries (Gruendemann & Mangum, 2001). ETO is also hazardous to healthcare workers, patients and the environment.

Because ETO is moderately toxic when inhaled, regular exposure to low levels (greater than one part per million) may produce harmful effects in humans. Moreover, the gas is irritating to the eyes and mucous membranes. Likewise, the residual ETO on instruments can cause skin injuries and inflammatory reactions in patients. Above all, because of the toxicity of this gas and category as a potential carcinogen as well as mutagen, the disposal of it is difficult (Ibid.).

Ultraviolet Light Sterilization

Ultraviolet (UV) light has been used to help disinfect the air for more than 50 years (Morris, 1972). However, UV irradiation has very limited energy; UV light does not penetrate dust, mucous or water. Therefore, despite the manufacturers' claims, it cannot be used to sterilize water. Theoretically, an intense UV light can be both bactericidal and veridical; practically, however, it was found out that only limited disinfection of instruments could be achieved. For surfaces that cannot be reached by the UV rays (e.g. inside the barrel of a needle or laparoscope), any microorganisms present will not be killed (Ibid). For these and other issues, UV radiation is neither practical nor effective method in most situations (Riley & Nardell, 1989).

OTHER CHEMICAL STERILANTS:

- **Paracetic acid (Peroxyacetic acid) -** the acid is rapidly acting and effective against all micro organisms. Unlike other similar compounds, its activity will not be impeded by organic matters on items to be sterilized and it decomposes into safe products. When diluted, it is very unstable and must be used with a specially designed automatic sterilizer (APIC, 2002). It is usually used for sterilizing different types of endoscopes and other heat-sensitive instruments.
- **Para formaldehyde -** this solid polymer of formaldehyde may be vaporized by dry heat in an enclosed area to sterilize objects (Taylor *et al.,* 1969). This technique, called "self-sterilization" (Tulis, 1973), may be suitable for sterilizing endoscopes and other heat-sensitive instruments.
- **Gas plasma sterilization (hydrogen peroxide based) -** this method can sterilize items in less than an hour and has no harmful by products. It does not penetrate well, however, and cannot be used on paper or linen. A specialized sterilizer is required for performing gas plasma sterilization (Taurasi, 1997).

HIGH-LEVEL DISINFECTION

Although sterilization is the safest and most effective method for the final processing of instruments, the sterilization equipment are often either not available or not suitable (Rutala, 1996). In these cases, HLD is the only acceptable alternative to resort to. The HLD process destroys all microorganisms (including vegetative bacteria, tuberculosis, yeasts and viruses) except some bacterial endospores.

High-level disinfection can be achieved by:

- Boiling in water,
- Steaming (moist heat) or
- Soaking instruments in chemical disinfectants (chemical disinfection).

To be effective, all steps in performing each method must be monitored carefully. Essentially all vegetative forms of bacteria are killed by moist heat at temperatures of 60 to75^0C within 10 minutes (Salle, 1973). *Hepatitis B* virus, which is one of the most difficult viruses to kill, is inactivated in 10 minutes when heated to 80^0C (Kobayashi *et al.,* 1984; Russell *et al.,* 1982). Even though many types of spores can be killed when boiled at 99.5^0C for 15 to 20 minutes (Williams & Zimmerman, 1951), *Clostridium tetani* spores are quite heat-resistant and can survive even boiling for up to 90 minutes (Spaulding, 1939).

The highest temperature that boiling water or low-pressure steam will reach is 100^0C (212^0F) at sea level. Because the boiling point of water is 1.1^0C lower for each 1,000 feet in altitude, it is best to boil or steam items to be high-level disinfected for a minimum of 20 minutes. This provides a margin of safety for variations in altitudes up to 5,500 meters (18,000 ft) and at the same time eliminates the risk of infection from some, but not all endospores.

Boiling Versus Steaming

In both boiling and steaming, moist heat is used to kill microorganisms. Steaming has several distinct advantages over boiling for the final processing of surgical gloves and other items such as plastic cannula and syringes. It is less destructive but more cost-effective for it uses much less fuel than boiling. For example, only about a liter of water is needed to steam gloves or instruments, whereas 4 to 5 liters are required for boiling. Besides, it is free from discoloration of instruments resulting from calcium or other heavy metals contained in some tap water for the steam contains only pure water molecules. Finally, although boiling and steaming gloves are equally easy to do, drying boiled gloves is not practical because it is difficult to prevent contamination while they are being dried in the open air. If steaming is instead opted to, they remain in the closed steamer pan which results in little or no contamination of gloves.

The major limitation of steaming is that if the steamers available locally are small, they can practically be used only for a small number of items (e.g. one set of instruments or 15 to 20 pairs of surgical gloves) per tray or pan. For steaming to be effective, the bottom pan must contain enough water to continue boiling throughout the steaming process. By contrast, large boiling pots are easier to use for metal instruments and do not need to be monitored the entire time to be sure that the process is being done correctly.

Both boiling and steaming share some advantages and limitations over chemical high-level disinfection which is the only other method of HLD.

Advantages

- Inexpensive procedures.
- Easily taught to healthcare workers.
- Require no special chemicals or dilutions and leave no chemical residue.
- Heat sources (boilers or rice cookers) are commonly available.

Limitation

- Length of processing time must be carefully measured (i.e. start timing only after the steam begins to escape or water has reached a rolling boil). Once timing starts, no additional items or water can be added.
- Objects cannot be packaged prior to HLD; therefore, there is a greater chance of contamination if items are to be stored.
- Requires a fuel source that may be unreliable.

HIGH-LEVEL DISINFECTION BY BOILING

Boiling in water is an effective and practical way to high-level disinfect instruments and other items. Although boiling instruments in water for 20 minutes will kill all vegetative forms of bacteria, viruses (including HBV, HCV and HIV), yeasts and fungi; it will not kill all endospores reliably.

INSTRUCTIONS FOR HLD BY BOILING

STEP 1 Decontaminate and clean all instruments along with other items to be high level disinfected.

STEP 2 If possible, completely immerse items in the water. Adjust the water level so that there is at least 2.5cm (1 inch) of water above the instruments. Further, make sure that all bowls and containers to be boiled are full of water. For example, one needs to empty bowls that turned bottom side up and float on the surface containing air pockets.

> **Note:**
> A study documented that the interior temperature of a plastic cannula floating on the surface of boiling water reaches a temperature of 96 to 98^0c in less than a minute. Therefore, for items that float (e.g. syringes, plastic MVA cannula or rubber items), it is not necessary that they be fully covered by the water to achieve HLD if the pot is covered with a lid (IPAS, 1993).

STEP 3 Close-lid over pan and bring water to a gentle rolling boil. Boiling too vigorously wastes fuel, rapidly evaporates the water and may damage delicate [or sharp] instruments or other items. Hence, a gentle rolling boil is sufficient and will prevent instruments or other items from being bounced around and possibly damaged by striking other instruments or the side walls of the boiling pot.

STEP 4 Start timer. In the HLD log, note time on the clock and record the time when rolling boil begins.

STEP 5 Boil all items for 20 minutes.

Tips on Boiling

- Always boil for 20 minutes in a pot with a lid.
- Start timing when the water begins to boil.
- Metal instruments should be completely covered with water during boiling.
- Do not add anything to the pot after timing begins.

STEP 6 After boiling for 20 minutes and remove objects with previously high-level disinfected forceps. Never leave boiled instruments in the water that has stopped boiling. Because, as the water cools and the steam condense, air and dust particles are drawn down into the container and may contaminate those instruments (Perkins, 1983).

STEP 7 Use instruments and other items immediately or else, pick them up with high-level disinfected forceps or gloves and place objects in a high-level disinfected container with a tight-fitting cover. If any pooled water remains in the bottom of the container, remove the already dried items and place them in another high-level disinfected container that is dry and can be tightly covered.

PROTECTING THE LIFE OF INSTRUMENTS THAT ARE FREQUENTLY BOILED

Lime deposits may form on metal instruments that are frequently boiled. This scale formation caused by lime salts in the water, is difficult to avoid. Following the steps below, however, can minimize the problem of lime deposits. These steps are:

STEP 1 Boil the water for 10 minutes at the beginning of each day before use (This precipitates much of the lime salt in the water on to the walls of the boiling pot before objects are added).

STEP 2 Use the same water throughout the day adding enough water only to keep the surface at least an inch above the instruments to be high-level disinfected (Frequent draining and replacing the water; and boiling too vigorously, increase the risk of lime deposits on instruments).

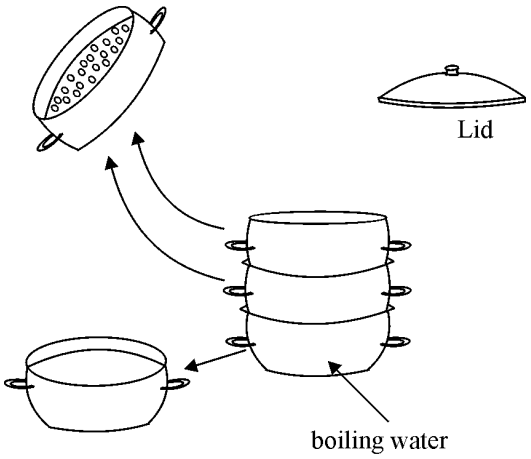
STEP 3 Drain and clean the boiler or pot at the end of each day to remove lime deposits.

HIGH-LEVEL DISINFECTION BY STEAMING

Steaming surgical gloves has been used as the final step in processing gloves for many years in Indonesia and other parts of Southeast Asia. A study conducted on the practice later, confirmed the effectiveness of this process of making gloves ready for re-use (Macintosh *et al*., 1994).
The steamer used in the study (**Figure 12.1**) consists of:

- A bottom pan (approximately 31cm in diameter) for boiling water;
- One, two or three circular pans with multiple 0.5cm (diameter) holes in their bottoms to permit the passage of steam through them and water back down to the bottom pan; and
- A lid that fits on the top pan.

Figure 10.5 Steamer Used for HLD



Two types of tests were conducted to determine whether surgical gloves and other items could be high-level disinfected using this process. In the first set of experiments, a thermocouple was placed inside a glove in each of the three pans and the rate and extent of the temperature change was recorded. As shown in Figure 10.5, when 5 to 15 pairs of surgical gloves were placed in

each of the three pans, the temperature reached 96 to 98^0C in less than 4 minutes in the bottom and middle pans and within 6 minutes in the upper pan. Thereafter, the temperature remained constant throughout the remaining 20 minutes. In the second set of experiments, batches of new surgical gloves were contaminated with *Staphylococcus epidermidis*, *Staphylococcus aureus*, *Pseudomonas aeruginosa* and *Candida albicans* as well as *Bacillus subtilis* (heat-sensitive) and *Bacillus stearothermophilus* (heat-resistant) endospores. Next, the gloves were placed in each of the three pans and steamed for 20 minutes. After this, the gloves were removed from the pans and incubated for 24 hours in sterile media and then were placed on blood agar. In all cases (6, 15 and 30 gloves per pan), there was no growth of any microorganisms or *B. subtilis* endospores within 24 hours. As was expected, only a reduction in the number of *B. stearothermophilus* (heat-resistant) endospores occurred, nothing more than that.

INSTRUCTIONS FOR HLD BY STEAMING

After instruments and other items have been decontaminated and thoroughly cleaned, they are ready for HLD by steaming.

STEP 1 Place instruments, plastic MVA cannula and other items in one of the steamer pans with holes in its bottom (**Figure 10.5**). To make removal from the pan easier, do not overfill the pan.

STEP 2 Repeat this process up until three steamer pans have been filled. Stack the filled steamer pans on top of a bottom pan containing water for boiling. A second empty pan without holes should be placed on the counter next to the heat source (**see Step 7)**

Make sure that there is sufficient water in the bottom of the pan for the entire 20 minutes of steaming.

STEP 3 Place a lid on the top pan and bring the water to a full rolling boil.
It should be noted that when water only simmers, very little steam is formed and the temperature may not get high enough to kill microorganisms.

STEP 4 When steam begins to come out between the pans and the lid, start the timer or note the time on a clock and record the time in the HLD log.

STEP 5 Steam items for 20 minutes.

STEP 6 Remove the top steamer pan and put the lid on the pan that was below it (the pan now on top). Gently shake excess water from the pan just removed.

STEP 7 Put the pan just removed onto the empty pan (**see Step 3**). Repeat until all pans are restacked on this empty pan and cover the top pan with the lid. This step allows the items to cool and dry without becoming contaminated.

STEP 8 Allow items to dry in the air while in the steamer pans (1 to 2 hours) before using.

STEP 9 Using a high-level disinfected forceps; transfer the dry items to a dry, high-level disinfected container with a tight-fitting cover. Instruments and other items can also be stored in the stacked and covered steamer pans as long as a bottom pan (with no holes) is used.

HIGH-LEVEL DISINFECTION USING CHEMICALS

Although a number of disinfectants are commercially available in most countries, four disinfectants-Chlorine, Glutaraldehydes, Formaldehyde and Peroxide-are routinely used as high-level disinfectants. (**Table 10.8** provides guidelines for preparing and using these disinfectants). These chemicals can achieve high-level disinfection if the items being disinfected are thoroughly cleaned before immersion. A high-level disinfectant should be selected for use based on the characteristics of the items to be disinfected, the physical area (i.e. whether it is well ventilated) and the skills of personnel available to do the procedure.

The Major Advantages and Limitation of These High-Level Disinfectants are:

- **Chlorine solutions -** are fast acting, very effective against HBV, HCV and HIV/AIDS, relatively cheaper and readily available (CDC, 1987; WHO, 1989). A major disadvantage is that concentrated Chlorine solutions (>0.5%) can corrode metals; however, stainless steel and plated instruments can safely be high-level disinfected in 0.1% chlorine solution by soaking in a plastic container for about 20 minutes. Using the lower chlorine concentration (0.1%) is just as effective and will extend the useful life of the instrument. For HLD, the 0.1% chlorine solution should be made using boiled water which has been filtered if the tap water is cloudy. Prior to soaking, the items should be thoroughly cleaned, rinsed and dried. Problems from discoloration can be decreased if items are rinsed with boiled water and dried promptly. Discoloration of metal items which occurs when calcium (not sodium) hypochlorite powders are used is often confused with corrosion (rusting). The problem in this case, is simple. So, just wiping up the discolored items with a cloth soaked with vinegar (dilute acetic acid) will quickly remove the discoloration. Although Chlorine solutions for HLD may deteriorate if left standing uncovered or stored in a clear (transparent) container, fresh solutions for HLD need to be made only if the solution is visibly cloudy. **Tables 10.4** and **10.5** describe how to make 0.1% chlorine solutions from commercially available liquid bleach products and dry powders, respectively.

- **Formaldehyde -** (8%), which is relatively cheaper and readily available, is an effective high-level disinfectant (HLD). As mentioned previously, however, its vapors are very irritating and classified as a potentially carcinogenic. It is also imperative that care must be taken to protect both the staff and patients from the fumes when mixing and using formaldehyde solutions. Do not dilute with chlorinated water for fear that a dangerous gas (bis-chloromethyl-ether) can be produced. The staff should avoid skin contact, protect eyes from splashes, limit exposure time and use these solutions only in a well-ventilated area.

- **Glutaraldehyde -** is less irritating than is formaldehyde, but the staff and clients still need to be protected from the fumes when mixing and using these solutions. The staff should wear gloves and protective eyewear to avoid skin contact; protect eyes from splashes; limit exposure time; and use them only in a well-ventilated area.
    - Because both Glutaraldehyde and formaldehyde (formalin) solutions leave a residue, instruments must be rinsed thoroughly with boiled water three times after chemical HLD to remove any residue and prevent skin irritation.

- **Hydrogen Peroxide -** (H_2O_2), which must be diluted to a 6% solution, is often available locally and is relatively cheaper than any other chemical disinfectants. The 3% hydrogen peroxide solutions used as antiseptics, however, should not be used as a disinfectant. The major limitation of this compound is that it is highly corrosive and should not be used to disinfect copper, aluminum, zinc or brass. Lest it should lose its potency rapidly when exposed to heat and light, it should be stored in a cool and dark place. WHO does not recommend using H_2O_2 in hot (tropical) climates because of its instability in the presence of heat and light (WHO, 1989).

- **Alcohols and Iodophors -** although Alcohols and Iodophors are relatively cheaper and readily available, they are no longer classified as high-level disinfectants. Alcohols do not kill some viruses and are not sporicidal either. Further, it has been found that Pseudomonas species can even multiply in Iodophors (Favero, 1985; Rutala, 1993). Thus, these chemicals should be used only when the high-level disinfectants listed above are not available or appropriate.

KEY STEPS IN CHEMICAL HIGH-LEVEL DISINFECTION

How to Prepare an HLD Container

- Decontaminate instruments and other items that may have been contaminated with blood and body fluids and thoroughly clean and dry them before placing them in the disinfectant solution.
- Completely immerse all items in the high-level disinfectant.
- Soak them for 20 minutes.
- Remove items using high-level disinfected or sterile forceps or gloves.
- Rinse well with boiled and filtered (if necessary) water three times and air dry.
- Use promptly or store in a dry, high-level disinfected and covered container.

Adapted from: Tietjen and McIntosh 1989.

- For small containers, boil water in the covered container for 20 minutes; then pour out the water which can be used for other purposes; replace the cover; and allow the container to dry.
- For large containers, fill a plastic container with 0.5% chlorine solution and immerse the cover in chlorine solution as well. Then soak them for 20 minutes. Thereafter, rinse the cover and the inside of the container three times with boiled water and allow them to dry in the air. Note that large metal containers cannot be HLD using chemicals.

Storage of Disinfectants

- Chemical disinfectants should be stored in a cool and dark area.
- Never store chemicals in direct sunlight or in excessive heat (e.g. upper shelves in a tin-roofed building).

Disposal of Used Chemical Containers

- **Glass containers** - may be washed with soap, rinsed, dried and reused. Alternatively, thoroughly rinse them (at least two times) with water and dispose of by burying.[5]
- **Plastic containers** - used for toxic substances such as Glutaraldehydes or Formaldehyde should be rinsed (at least three times) with water and disposed of by burning.

Disposal of Used Chemicals

Wastes should carefully be poured down into a utility sink drain or a flushable toilet and then rinsed or flushed with water. Liquid wastes can also be poured into a latrine. The activity, however, should be done without losing sight of precaution to avoid splashing. Rinse the toilet or sink carefully and thoroughly with water to remove residual wastes.

PRODUCTS NOT TO BE USED AS DISINFECTANTS

Many antiseptic solutions are incorrectly used as disinfectants. Although antiseptics (sometimes called "skin disinfectants'') are adequate for cleansing skin before surgical procedures, they are not appropriate for disinfecting surgical instruments and gloves. These antiseptics do not reliably destroy bacteria, virus or endospores. For example, Savlon (Chlorhexidine gluconate with or without Cetrimide), which is readily available worldwide, is often mistakenly used as a disinfectant.

Antiseptics that should not be Used as Disinfectants are:

- Acridine derivatives (e.g. gentian or crystal violet)
- Cetrimide (e.g. Cetavlon®)
- Chlorhexidine gluconate and cetrimide in various concentrations (e.g. Savlon)
- Chlorhexidine gluconate (e.g. Hibiscrub®, Hibitane®)
- Chlorinated lime and Boric acid (e.g. Eusol®)
- Chloroxylenol in alcohol (e.g. Dettol®)
- Hexachlorophene (e.g. PhisoHex®)
- Mercury compounds

Mercury Solutions - (such as mercury laurel) can cause birth defects and are too toxic to use as either disinfectants or antiseptics although it is known to posses functions of low-level disinfectants (Block, 1991). Other products frequently used to disinfect equipment are 1 to 2% Phenol (e.g. Phenol®), 5% Carbolic acid (Lysol®) and Benzalkonium chloride, and Quaternary ammonium compound (Zephiran®). These are low-level disinfectants and should only be used to decontaminate environmental surfaces (e.g. floors or walls).

Table 10.8 Preparing and Using Chemical Disinfectants

Disinfectant (common solution or brand)	**Effective Concentration**	**How to Dilute**	**Skin Irritant**	**Eye Irritant**	**Respiratory Irritant**	**Corrosive**	**Leaves Residue**	**Time Needed for HLD**	**Time Needed for Sterilization**	**Activated Shelf Life**[a]
CHEMICALS FOR STERILIZATION OR HIGH-LEVEL DISINFECTION										
Chlorine	0.1%	Dilution procedures vary[b]	Yes (with prolonged contact)	Yes	Yes	Yes[c]	Yes	20 minutes	Do not use	Change every 14 days, sooner if cloudy.
Formaldehyde (35B40%)	8%	1 part 35B40% solution to 4 parts boiled water	Yes	Yes	Yes	No	Yes	20 minutes	24 hours	Change every 14 days, sooner if cloudy.
Glutaraldehyde(Cidex7)	Varies (2–4%)	Add activator	Yes	Yes (vapors)	Yes	No	Yes	20 minutes at 25EC[d]	10 hours for Cidex7	Change every 14–28 days; sooner if cloudy.
Hydrogen Peroxide (30%)	6%	1 part 30% solution to 4 parts boiled water	Yes	Yes	No	Yes	No	20 minutes	Do not use	Change daily; sooner if cloudy.
CHEMICALS FOR DISINFECTION (alcohols and Iodophors are not high-level disinfectants)										
Alcohol (ethyl or isopropyl)	60B90%	Use full strength	Yes (can dry skin)	Yes	No	No	No	Do not use	Do not use	If container (bottle) kept closed, use until empty.
Iodophors (10% povidone-iodine) (PVI)	Approximately 2.5%	1 part 10% PVI to 3 parts water	No	Yes	No	Yes	Yes	Do not use	Do not use	If container (bottle) kept closed, use until empty.

[a] All chemical disinfectants are heat and light sensitive and should be stored away from direct sunlight and in a cool place (<40EC).
[b] See Tables 10.1 and 10.2 for instructions on preparing chlorine solutions.
[c] Only corrosive with prolonged (>20 minutes) contact at concentrations >0.5% if not rinsed immediately with boiled water.
[d] Different commercial preparations of Cidex and other glutaraldehydes are effective at lower temperatures (20°C) and for longer activated shelf life. Always check manufacturers' instructions.

Adapted from: Rutala 1996.

Table 10.9 Guidelines for Processing Instruments, Surgical Gloves and Other Items

INSTRUMENTS OR OTHER ITEMS	DECONTAMINATION *First step in handling used items; it reduces risk of HBV, HCV and HIV viruses.*	CLEANING *Removes all visible blood, body fluids and dirt.*	STERILIZATION[a] *Destroys all microorganisms, including endospores.*	HIGH-LEVEL DISINFECTION[b] *Destroys all viruses, bacteria, parasites, fungi and **some** endospores.*
Airways (plastic)	Soak in a 0.5% chlorine solution for 10 minutes prior to cleaning. Rinse and wash immediately.	Wash with soap and water. Rinse with clean water, air or towel dry.	Not necessary	Not necessary
Ambu bags and CPR face masks	Wipe exposed surfaces with gauze pad soaked in 60B90% alcohol or 0.5% chlorine; rinse immediately.	Wash with soap and water. Rinse with clean water, air or towel dry.	Not necessary	Not necessary
Aprons (heavy plastic or rubber)	Wipe with 0.5% chlorine solution. Rinse with clean water. Between each procedure or each time they are taken off.	Wash with liquid soap and water. Rinse with clean water, air or towel dry at the end of the day or when visibly soiled.	Not necessary	Not necessary
Bed pans, urinals or emesis basins	Not necessary.	Using a brush, wash with disinfectant solution (soap and 0.5% chlorine). Rinse with clean water.	Not necessary	Not necessary
Blood pressure cuff	If contaminated with blood or body fluids, wipe with gauze pad or cloth soaked with 0.5% chlorine solution.	If soiled, wash with soap and water. Rinse with clean water, air or towel dry.	Not necessary	Not necessary
Diaphragms or fitting rings (used for sizing with clients)	Soak in 0.5% chlorine solution for 10 minutes prior to cleaning. Rinse or wash immediately.	Wash with soap and water. Rinse with clean water. Air or towel dry.	Not necessary but can be autoclaved at 121°C (250°F) 106 kPa (15 lbs/in^2) for 20 minutes (unwrapped).	Steam or boil for 20 minutes. Chemically high-level disinfect by soaking in 8% formaldehyde, or a 2 to 4% Glutaraldehyde for 20 minutes. Rinse well in water that has been **boiled**.
Exam or operating room tables or other large surface areas (carts and stretchers)	Wipe off with 0.5% chlorine solution.	Wash with soap and water if organic material remains after decontamination.	Not necessary	Not necessary

Table 10.9 Guidelines for Processing Instruments, Surgical Gloves and Other Items (Continued---)

INSTRUMENTS OR OTHER ITEMS	DECONTAMINATION *First step in handling used items; it reduces risk of HBV, HCV and HIV viruses.*	CLEANING *Removes all visible blood, body fluids and dirt.*	STERILIZATION [a] *Destroys all microorganisms, including endospores.*	HIGH-LEVEL DISINFECTION[b] *Destroys all viruses, bacteria, parasites, fungi and **some** endospores.*
Footwear (rubber shoes or boots)	Wipe with 0.5% chlorine solution. Rinse with clean water. At the end of the day or when visibly soiled.	Wash with liquid soap and water. Rinse with clean water, air or towel dry at the end of the day or when visibly soiled.	Not necessary	Not necessary
Hypodermic needles and syringes (glass or plastic)	While holding needle under the surface of 0.5% chlorine solution, fill assembled needle and syringe with solution and soak for 10 minutes prior to cleaning. Rinse by flushing three times with clean water.	Disassemble, and then wash with soap and water. Rinse with clean water, air or towel dry syringes (only air dry needles).	Preferable (glass only): Dry heat for 2 hours after reaching 160°C (320°F) (glass syringes only), or Autoclave at 121°C (250°F) and 106 kPa (15 lbs/in^2) for 20 minutes (30 minutes if wrapped).	Acceptable (glass or plastic): Steam or boil for 20 minutes. (Chemical HLD is not recommended because chemical residue may remain even after repeated rinsing with boiled water. These residues may interfere with the action of drugs being injected.)
IUDs and inserters (never reuse)	Not appropriate	Not appropriate	Not recommended. Most IUDs and inserters come in sterile packages. Discard if package seal is broken.	Not recommended
Laparoscopes	Wipe exposed surfaces with gauze pad soaked in 60B90% alcohol; rinse immediately.	Disassemble, then using a brush wash with soap and water. Rinse with clean water, towel dry.	Sterilize daily using chemical sterilization. Soak in: a Glutaraldehyde (usually 2%) for 10 hours, or 8% formaldehyde for 24 hours. Rinse with **sterile** water or water which has been boiled for 20 minutes three times.	Between cases, soak for 20 minutes in: a Glutaraldehyde (usually 2 to 4%), or 8% formaldehyde, or 0.1% chlorine solution with boiled and filtered (if necessary) water. Rinse three times with water that has been **boiled** for 20 minutes.
PPE (caps, masks, cover gowns)[d]	Not necessary. (Laundry staff should wear plastic aprons, gloves and protective foot and eyewear when handling soiled linen.)	Wash with soap and hot water. Rinse with clean water, air or machine dry. Wrap for reuse.	Not necessary	Not necessary

Table 10.9 Guidelines for Processing Instruments, Surgical Gloves & Other Items (Continued---)

INSTRUMENTS OR OTHER ITEMS	**DECONTAMINATION** *First step in handling used items; it reduces risk of HBV, HCV and HIV viruses.*	**CLEANING** *Removes all visible blood, body fluids and dirt.*	**STERILIZATION**[a] *Destroys all microorganisms, including endospores.*	**HIGH-LEVEL DISINFECTION**[b] *Destroys all viruses, bacteria, parasites, fungi and **some** endospores.*
Stethoscopes	Wipe with gauze pad soaked in 60–90% alcohol.	If soiled, wash with soap and water. Rinse with clean water, air or towel dry.	Not necessary	Not necessary
Storage containers for instruments (metal or plastic)	Soak in 0.5% chlorine solution for 10 minutes prior to cleaning. Rinse or wash immediately	Wash with soap and water. Rinse with clean water, air or towel dry.	Dry heat for 1 hour after reaching 170°C (340°F), or Autoclave at 121°C (250°F) and 106 kPa (15 lbs/in^2) for 20 minutes (30 minutes if wrapped).	Boil container and lid for 20 minutes. If container is too large: Fill container with 0.5% chlorine solution and soak for 20 minutes. Rinse with water that has been **boiled** for 20 minutes and air dry before use.
Suction bulbs (rubber)	Soak in a 0.5% chlorine solution for 10 minutes prior to cleaning. Rinse and wash immediately.	Wash with soap and water. Rinse with clean water, air or towel dry.	Not necessary	Not necessary
Suction cannula (plastic) for manual vacuum aspiration (MVA)	Soak in 0.5% chlorine solution for 10 minutes prior to cleaning. Rinse or wash immediately.	Pass soapy water through cannula three times, removing all particles.	Not recommended. (Heat from autoclaving or dry-heat ovens will damage cannula.)	Steam or boil for 20 minutes.
Suction catheters (rubber or plastic)	Soak in 0.5% chlorine solution for 10 minutes prior to cleaning. Rinse or wash immediately.	Pass soapy water through catheter three times. Rinse three times with clean water (inside and outside).	Not recommended. (Heat from autoclaving or dry-heat ovens will damage plastic catheters; rubber catheters can be autoclaved.)	Steam or boil for 20 minutes. (Chemical HLD is not recommended because chemical residue may remain even after repeated rinsing with boiled water.)
Surgical gloves	Soak in 0.5% chlorine solution for 10 minutes prior to cleaning. Rinse or wash immediately.	Wash with soap and water. Rinse with clean water and check for holes. If to be sterilized, dry inside and out (air or towel dry) and package.	If used for surgery: Autoclave at 121°C (250°F), and 106 kPa (15 lbs/in^2) for 20 minutes. Do not use for 24B48 hours.	Steam for 20 minutes and allow to dry in steamer.

Table 10.9 Guidelines for Processing Instruments, Surgical Gloves & Other Items (Continued---)

INSTRUMENTS OR OTHER ITEMS	DECONTAMINATION *First step in handling used items; it reduces risk of HBV, HCV and HIV viruses.*	CLEANING *Removes all visible blood, body fluids and dirt.*	STERILIZATION[a] *Destroys all microorganisms, including endospores.*	HIGH-LEVEL DISINFECTION[b] *Destroys all viruses, bacteria, parasites, fungi and **some** endospores.*
Surgical gowns, linen drapes and wrappers[d]	Not necessary. (Laundry staff should wear plastic aprons, gloves and protective foot and eyewear, when handling soiled linen.)	Wash with soap and hot water. Rinse with clean water, air or machine dry.	Autoclave at 120°C/250°F and 106 kPa (15 lbs/in^2) for 30 minutes.	Not practical
Surgical instruments (metal)	Soak in 0.5% chlorine solution for 10 minutes prior to cleaning. Rinse or wash immediately	Using a brush, wash with soap and water. Rinse with clean water. If to be sterilized, air or towel dry and wrap in packs or individually.	Preferable: Dry heat for 1 hour after reaching 170°C (340°F)[e], or Autoclave at 121°C (250°F) and 106 kPa (15 lbs/in^2) for 20 minutes (30 minutes if wrapped). For sharp instruments: Dry heat for 2 hours after reaching 160°C (320°F).[e]	Acceptable: Steam or boil for 20 minutes. Chemically high-level disinfect by soaking for 20 minutes. Rinse well with boiled water and air dry before use or storage.
Thermometers (glass)	Not necessary	Wipe with disinfectant solution (soap and 0.5% chlorine). Rinse with clean water, air or towel dry.	Not necessary	Not necessary
Transfer forceps (chittle) and container (metal)	Soak in 0.5% chlorine solution for 10 minutes prior to cleaning. Rinse or wash immediately (Reprocess per shift or when contaminated.)	Using a brush, wash with soap and water. Rinse with clean water. If to be sterilized, air or towel dry.	Preferable: Dry heat for 1 hour after reaching 170°C (340°F)[e], or Autoclave at 121°C (250°F) and 106 kPa (15 lbs/in^2) for 20 minutes (30 minutes if wrapped).	Acceptable: Steam or boil for 20 minutes. Chemically high-level disinfect by soaking for 20 minutes. Rinse well with boiled water and air dry before use.
Urinary catheters (rubber and straight metal)	Soak in 0.5% chlorine solution for 10 minutes prior to cleaning. Rinse or wash immediately	Using a brush, wash with soap and water. Rinse three times with clean water (inside and outside).	Preferable (metal only): Dry heat for 2 hours after reaching 160°C (320°F), or Autoclave at 121°C (250°F) and 106 kPa (15 lbs/in^2) for 20 minutes (30 minutes if wrapped).	Acceptable (rubber or metal): Steam or boil for 20 minutes.

Table 10-9 Guidelines for Processing Instruments, Surgical Gloves & Other Items (Continued---)

INSTRUMENTS OR OTHER ITEMS	DECONTAMINATION *First step in handling used items; it reduces risk of HBV, HCV and HIV viruses.*	CLEANING *Removes all visible blood, body fluids and dirt.*	STERILIZATION[a] *Destroys all microorganisms, including endospores.*	HIGH-LEVEL DISINFECTION[b] *Destroys all viruses, bacteria, parasites, fungi and **some** endospores.*
Ventilator tubing or circuits	Not necessary	Using a brush, wash with soap and water. Rinse with clean water and air dry.	Not possible using an autoclave or dry heat oven.	***Acceptable*** Steam or boil for 20 minutes. Air dry before use.

[a] If unwrapped, use immediately; if wrapped, reprocess if package becomes damaged or contaminated.
[b] If sterilization (dry-heat or autoclave) is not available, these items can be high-level disinfected either by boiling, steaming or soaking in a chemical disinfectant.
[c] Avoid prolonged exposure (> 20 minutes) to chlorine solution (> 0.5%) to minimize corrosion (rusting) of instruments and deterioration of rubber or cloth products.
[d] Paper or plastic gowns, caps or masks. Place in a plastic bag or leak proof, covered waste container for disposal.
[e] Instruments with cutting edges or needles should **not** be sterilized at temperatures above 160^0C to avoid dulling.

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CHAPTER 11: PROCESSING LINEN AND LAUNDRY

KEY TOPICS TO BE DISCUSSED:

- Minimum requirements for standard Laundry
- Monitoring and routine maintenance issues
- Importance of careful handling and processing of soiled linen
- The use of Personal protective equipment
- Ways of Collecting and transporting soiled linen
- Ways of sorting, washing, and drying soiled linen
- Ways of storing, transporting, distributing clean linen

BACKGROUND

Although soiled linen may contain large numbers of microorganisms, there is little risk to health workers during linen processing. If work related infection occurs, it so happens often due to healthcare workers' not using gloves or other personal protective equipment or washing their hands during or after collecting, transporting and sorting soiled items. At this junction, therefore, no special precautions would be necessary regardless of the patient's diagnosis if the standard precautions are taken in all situations.

DEFINITIONS

Detergent is a cleaning agent that makes no antimicrobial claims on the label. Detergents (liquid or powder) are composed of a hydrophilic (water-seeking) component and a lipophilic (fat-seeking) component. These detergents can be divided into four types: anionic, cationic, amphoteric, and nonionic detergents.

Linens cloth items used in healthcare facilities by housekeeping staff (bedding and towels), cleaning staff (cleaning cloths, gowns and caps), and surgical personnel (caps, masks, scrub suits, surgical gowns, drapes and wrappers) as well as the staff of specialty units such as ICUs and other units performing invasive medical procedures (e.g. anesthesiology, radiology or cardiology).

Occupational Injury or Infection is an injury or infection acquired by the healthcare staff while performing their normal duties.

Soaps and Detergents (Terms used Interchangeably) cleaning products (bar, liquid, leaflet or powder) that lower surface tension thereby helping remove dirt, debris and transient microorganisms on the hands. Plain soaps require friction (scrubbing) to mechanically remove microorganisms while antiseptic (antimicrobial) soaps kill or inhibit growth of most microorganisms.

Soiled or Contaminated Linen is a cloth item coming from multiple sources within the hospital or clinic that has been collected and brought to the laundry for processing. All items, regardless of whether or not they are visibly dirty or have been used in a surgical procedure, must be

washed and dried. Even though the sterile towel drapes contained in a surgical pack have not been used, they must be laundered before being sterilized.

Sorting is a process of inspecting and removing foreign and in some cases dangerous objects (e.g. sharps or broken glass) from soiled linen before washing. This step is extremely important because soiled linen from the operating room or clinic has occasionally been found containing sharps (e.g. scalpels, sharp-tipped scissors, hypodermic and suture needles and towel clips).

MINIMUM REQUIREMENTS FOR STANDARD LAUNDRY

- Maintain the receiving area for contaminated textiles at negative pressure compared with the clean areas of the laundry in accordance with AIA construction standards in effect during the time of facility construction.
- Ensure that laundry areas have hand washing facilities and products and appropriate PPE available for workers.
- Use and maintain laundry equipment according to manufacturers' instructions.
- Do not leave damp textiles or fabrics in machines overnight.
- Disinfection of washing and drying machines in residential care is not needed as long as gross soil is removed from items before washing. So, proper washing and drying procedures are sufficient.

Periodic Monitoring

- Monitoring/inspection of the laundry unit on weekly basis (cleanness, functionality, availability of all necessary detergent, water and all activities including collection, storage, efficiency and recording/information of the unit).
- Include the laundry activity in weekly, monthly, quarterly and yearly plan and report accordingly.
- Use microbiologic sampling during outbreak investigations if epidemiologic evidence indicates a role for health-care textiles and clothing in disease transmission.

Maintenance Issue of Laundry

- Use and maintain laundry equipment according to manufacturers' instruction.
- Make sure that spare parts are available for parts which can easily be damaged and needing replacements on regular basis.
- Train the laundry staffs on users' maintenance and assign focal person for managing the machine and reporting.

Types of Personal Protective Equipment to use in Laundry

Utility gloves, plastic or rubber apron, protective eyewear and closed shoes that protect feet from dropped items and spilled blood and body fluids should always be used when collecting and handling, transporting, sorting, hand washing soiled linen or loading it in automatic washers.

Note:

If utility gloves are not available, putting on two pairs of examination or reprocessed surgical gloves (double gloving) provide some protection for the staff responsible for collecting, transporting and sorting soiled linen and other items.

PROCESSING LINEN

Processing linen consists of all the steps required to collect, transport and sort soiled linen as well as to launder (wash, dry and fold or pack), store and distribute it. Safely processing linen from multiple sources is a complex process.

Staff assigned to collecting, transporting and sorting soiled linen need to especially be careful. They should wear thick utility or heavy-duty household gloves to minimize the risk of accidental injury from a needle stick or other sharp object including broken glass. Staff responsible for washing soiled items should wear utility gloves, protective eyewear and plastic or rubber aprons.

PRINCIPLES AND KEY STEPS IN PROCESSING LINEN:

- Housekeeping and laundry personnel should wear gloves and other personal protective equipment as indicated when collecting, handling, transporting, sorting and washing soiled linen.
- When collecting and transporting soiled linen, handle it as little as possible and with minimum contact to avoid accidental injury and spreading of microorganisms.
- Consider all cloth items (e.g. surgical drapes, gowns, wrappers) used during a procedure as infectious. Even if there is no visible contamination, the item must be laundered.
- Carry soiled linen in covered containers or plastic bags to prevent spills and splashes, and confine the soiled linen to designated areas (interim storage area) until transported to the laundry.
- Carefully sort all linen in the laundry area before washing. Do not presort or wash linen at the point of use.

Do not presorts or wash linen at the point of use.

COLLECTING, TRANSPORTING AND SORTING SOILED LINEN

Collecting and Transporting after invasive medical or surgical procedures or when changing linen in patient rooms:

- Collect used linen in cloth or plastic bags or containers with lids. If linen is heavily contaminated with blood or body fluids, carefully roll the contaminated area into the center of the linen and place in a leak proof bag or container with a lid.
- Cloth bags are adequate for the majority of the patient care linen. They require the same processing as their contents.
- Handle soiled linen as little as possible and do not shake it off. This helps to prevent spreading microorganisms to the environment, personnel and other patients.
- It is not necessary to double-bag or use additional precautions for used linen from patients in isolation.
- Do not sort and wash soiled linens in patient care areas.
- Collect and remove soiled linen after each procedure on daily basis or as deemed necessary including patient rooms.

- Transport collected soiled linen in closed leak proof bags or containers with lids or covered carts to the processing area daily or as needed.
- Transport soiled linen and clean linen separately. If there are separate carts or containers available for soiled and clean linen, they should be labeled accordingly. If not, thoroughly clean the containers or carts used to transport soiled linen before using them to transport clean linen.

Sorting Soiled Linen

- Safe sorting of linen is extremely important. Sorting must be carefully performed because soiled linen (large drapes and towel drapes) from the operating room or other areas of procedure could sometimes contain sharps (e.g. scalpels, sharp-tipped scissors, hypodermic and suture needles and sharp-tipped towel clips).
- The processing area for soiled linen must be separate from other areas used for folding and storing clean linen, patient care and food preparation.
- Maintain adequate ventilation and physical barriers between the clean and soiled linen areas.
- Always wear protective eyewear, utility gloves, appropriate footwear and plastic or rubber apron while handling soiled linen.
- Be cautious about scalpels, sharp tipped scissors, and hypodermic and suture needles.
- Wash hands after removing the gloves. Although infrequent infection is related to sorting, they have been attributed to failure of hand washing and proper use of PPE (McDonald, 2002).

Laundering Linen

- All linen items including bed sheets, surgical drapes, masks, gowns should be thoroughly washed before re-use. Decontamination of linen prior to washing is not necessary unless linen is heavily soiled and/or it is to be hand washed.
- The workers should not carry wet and soiled linen close to their body even though they are wearing a plastic or rubber apron.
- The storage time for soiled linen before washing is related to practical issues such as available space and aesthetics, not to infection prevention practices.

Hand Washing Linen

- Wash heavily soiled linen separately from non-soiled linen.
- Wash the entire item in water with soap to remove all spoilage, even if not visible.
- Use warm water and add bleach to aid cleaning and bactericidal action. Also add some sour (mild acetic acid) to prevent yellowing of linen, if available.
    - Use warm water if available.
    - Presoak heavily soiled lined with soap and bleach (0.5% chlorine) for 10 minutes.

Non soiled linen should not be presoaked in bleach and soap. Instead, it should be washed with soap and water until visibly clean. Then add bleach e.g. 2ml of bleach (5% chlorine solution) for 1 liters of water) and wash keep further cleaning and disinfection.

- Add sour (a mild acetic acid) to prevent yellowing of linen, if desirable.
- Check items for cleanliness and rewash if it is still dirty or stained.
- Rinse linen with clean water.

Presoaking in soap, water and bleach is necessary only for heavily soiled linen.

Machine Washing

- Do not overload the machine.
- Wash heavily soiled linen separately from non-soiled linen.
- A pre-wash rinse cycle of 15 minutes will remove remaining gross spillage.
- Adjust the temperature and time cycle of the machine according to manufacturer's instruction and the type of soap or other washing products being used. Both cold and hot water washing cycles that include bleach reduce bacterial counts in the linen.
- Follow manufacturer's instruction for operating on the machine.
- In cold water washes, chemicals such as bleach must be added (2ml of household bleach for every liter of water) with detergent to facilitate disinfection.
- A high temperature (hot- water washing)[11] wash must be performed (> 70 ^{0}C) if cold water detergent with bleach are not used.

Note:
Lower temperature or cold water washing are satisfactory if the cleaning products (type of soap or detergent , amount of bleach and other additive) are appropriate and used in proper concentration. Using cold water also saves energy.

- During the rinse cycle, souring agent should be added to the rinse cycle to reduce alkalinity and prevent yellowing. This decreases the likelihood of skin irritation and further reduces the number of bacteria present.
- Air dry or machine dry before further processing. Linen should be dried as soon as possible after washing to prevent the re-growth of any bacteria not killed by the washing procedure.
- Heavily soiled linen may need one more cycle if not found visibly clean at the end of first cycle.

Drying, Checking and Folding Linen

- Linen can be machine or air dried in direct sunlight, if possible, keeping the fabric off the ground away from dust and moisture.
- After the linen dries, check for holes and threadbare areas. If damaged, either discard or repair before re-use.
- The linen that is not going to be sterilized should be ironed and folded. If surgical drapes are to be sterilized, however, avoid ironing them for it dries out the material making autoclaving more difficult.

Ironing especially using a steam iron will destroy pathogens.

STORING, TRANSPORTING AND DISTRIBUTING CLEAN LINEN

Storing Clean Linen:

- Keep clean linen in a clean and closed storage area.
- Use physical barriers to separate folding and storage rooms from soiled areas.
- Keep the shelves clean. Besides, Items put on the shelf must be stored at least 4 to 6 inches off the floor and should be covered when transported from the store to other areas.

Handle stored linen as little as possible

Transporting Clean Linen:

- Clean and soiled linen should be transported separately.
- Containers or carts used to transport soiled linen should be thoroughly cleaned before using being used for transporting clean linen.
- Clean linen must be wrapped or covered during transport to avoid contamination.
- Linen to be sterilized must be appropriately wrapped before being sent to the sterile processing department.

Distributing Clean Linen

- Protect clean linen until it is distributed.
- Do not leave extra linen in patient's area.
- Handle clean linen as little as possible.
- Avoid shaking off clean linen for it releases dust and lint into the room.
- Clean soiled mattresses before putting clean linen on them.

Sterilization is the preferred end process for surgical gowns, linen drapes and wrappers.

Table 11.1 Guidelines for Processing Linen and Personal Protective Equipment (PPE)

ITEM	DECONTAMINATION	CLEANING	HIGH-LEVEL DISINFECTION	STERILIZATIC
Protective eyewear (plastic goggles and face shields)	Wipe with 0.5% chlorine solution. Rinse with clean water. After each procedure or when is visibly soiled.	Wash with liquid soap and water. Rinse with clean water, then air or towel dry.[2] After each procedure or when visibly soiled.	Not necessary	Not necessary
Linens (caps, masks, scrubsuits or covergowns)	Not necessary. (Laundry staff should wear plastic aprons, gloves, and protective foot and eyewear when handling soiled items.)	Wash with liquid soap and water, removing all dirt particles. Rinse with clean water, air or machine dry.[2] Air-dried attire can be ironed before use.	Not necessary	Not necessary
Aprons (heavy plastic or rubber)	Wipe with 0.5% chlorine solution. Rinse with clean water. Between each procedure or each time they are taken off.	Wash with liquid soap and water. Rinse with clean water, air or towel dry at the end of the day or when visibly soiled.[2]	Not necessary	Not necessary
Footwear (rubber shoes or boots)	Wipe with 0.5% chlorine solution. Rinse with clean water. At the end of the day or when visibly soiled.	Wash with liquid soap and water. Rinse with clean water, air or towel dry at the end of the day or when visibly soiled.[2]	Not necessary	Not necessary
Surgical gowns, linen drapes and wrappers	Not necessary. (Laundry staff should wear plastic aprons, gloves and protective foot and eyewear when handling soiled items.)	Wash with liquid soap and water, removing all particles. Rinse with clean water, air or machine dry.[2]	Not practical	Preferred
Paper or disposable plastic items	Place in plastic bag or leakproof, covered waste container for disposal.			

2. If tap water is contaminated, use water that has been boiled for 10 minutes and filtered to remove particulate matter (if necessary) or use chlorinated water- water treated with a dilute bleach solution (sodium hypochlorite) to make the final concentration 0.001%.

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CHAPTER 12: TRAFFIC FLOW AND ACTIVITY PATTERN

KEY TOPICS TO BE DISCUSSED:

- The significance of regulating traffic flow and defining activity patterns in hospitals and clinics.
- Designing traffic flow and activity patterns in procedures: instrument processing and surgical areas.
- The traffic flow requirements for different areas.

BACKGROUND

Regulating the flow of visitors, patients and the staff plays a central role in preventing disease transmission in healthcare facilities. This is so for the number of microorganisms in a designated area tends to be related to that of the number of people present and their activity. Microbial contamination is found to be high in areas such as waiting rooms and places where soiled surgical instruments and other equipment are initially processed. Microbial contamination is minimized by reducing the number of people coming to the area and defining the activities taking place there.

An important objective of infection prevention is to minimize the level of microbial contamination in areas where patient care and instrument processing take place. Such areas include: procedure areas, surgical units, and work areas (where instruments are processed).

These include dirty and clean areas where soiled instruments, equipments and other items are first cleaned and then processed and stored. It is important to direct activity patterns and traffic flow in the above-mentioned areas to keep contaminated areas separate from areas where procedures take place.

- **Procedure areas** - are settings where patients are examined and procedures (e.g. pelvic examinations, wound care management, blood drawing, immunizations, IUD insertions and removals, and normal childbirth) are carried out.
- **Surgical units** - are settings where major and minor operations are performed. The surgical unit also includes preoperative and recovery rooms as well as several other areas.
- **Work areas** - are settings where instruments are being processed. These include dirty and clean areas where soiled instruments, equipment and other items are first cleaned and either high-level disinfected or sterilized and then stored.

It is important to direct activity patterns and traffic flow in these areas to keep contaminated areas separate from areas where procedures take place.

Activities such as waste disposal, instrument processing and cleaning procedure areas should be carefully planned and organized to minimize the risk of infection to patients and healthcare workers. Equally important, is designing and implementing traffic flow patterns that prevent soiled instruments and other items from coming across to the cleaned, high-level-disinfected or sterilized items.

Traffic flow is also related with separating people who have or are likely to have communicable diseases from those who are at risk (susceptible). These people pose a great risk to susceptible patients and healthcare workers simply by availing themselves in the same room; therefore, it is necessary to identify and remove them quickly.

DEFINITIONS

At point of use - equipment, instruments and supply items are at the place where needed (e.g. sharps containers are placed within an arm's reach of where injections are being given).

Environmental Controls - standards specifying procedures to be followed on: the routine care, cleaning and disinfection of environmental surfaces, beds, bedrails, bedside equipment and other frequently touched surfaces.

Operating Room - is an area or space where surgical procedures are performed.

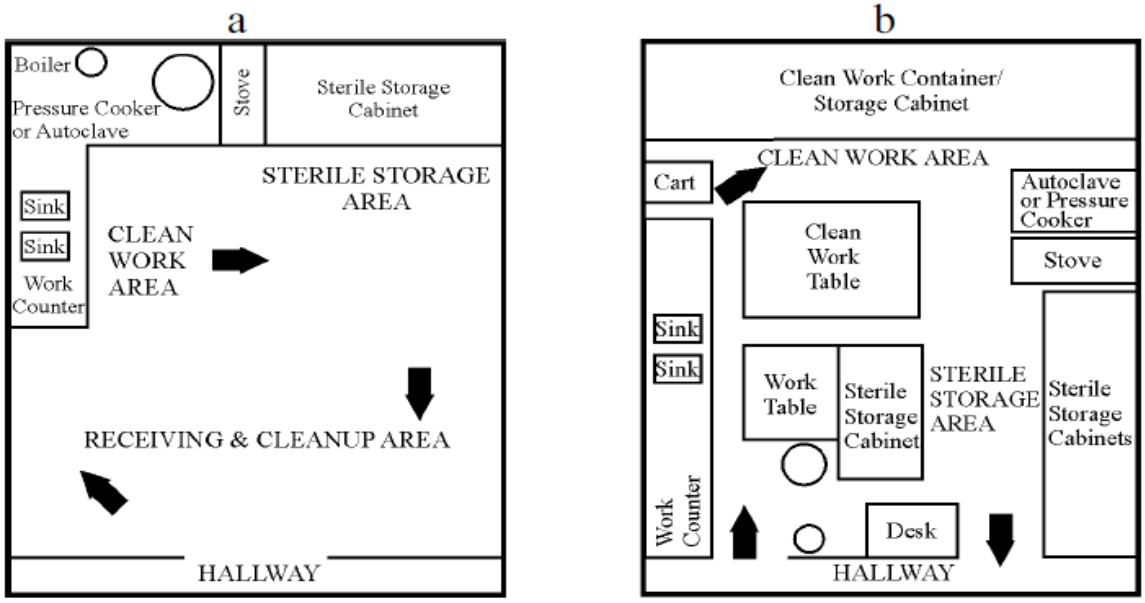
Surgical Unit - is a whole surgical area including: lockers and dressing rooms; preoperative and recovery rooms; peripheral support areas including storage space for sterile and high-level disinfected items; other consumable supplies and corridors leading to restricted areas; the operating room(s), scrub sink areas and the nursing station.

SPACE AND EQUIPMENT REQUIREMENTS

Healthcare facilities vary in the types of services they provide. For example, a rural clinic may offer only a few procedures (e.g. IUD insertion and removal, immunizations, antenatal care and minor surgery for suturing wounds). Larger facilities (including district and referral hospitals) provide major and minor general surgical procedures in addition to ambulatory procedures. Regardless of the size of the facility, however, the specific space and equipment requirements to perform a particular procedure do not generally vary.

In clinics where only minor procedures are performed, a procedure room with a hand washing sink is required for examining clients and performing procedures. A separate room with at least one sink for cleaning and an area for processing instruments and other items is also desirable (**Figure 12.1a**). Ideally, the processing area should include more than one room (e.g. a dirty room for receiving dirty instruments and a clean room for final processing and storage). If only a single room is available (**Figure 12.1a**), soiled equipment should be received and cleaned in an area of the room distant enough from areas where equipment are high-level disinfected or sterilized and then stored.

Figure 12.1a and b Floor Plans for Instrument Cleaning, High-Level Disinfecting and Sterilizing Areas in a Clinic and Larger Facility



Design for small clinic with minimal service space available

Design for larger facility or where volume is greater

Source: SEARO/WHO 1988.

Although the space requirements for performing various minor surgical procedures may not be different, it may still be quite different to some extent depending on the classification of the procedure (semi critical or critical), the instrument processing requirements (high-level disinfection or sterilization). Inserting or removing an IUD, for example, is classified as a semi critical procedure not normally sterile, or can be made so if necessary (Spaulding, 1968). In contrast, inserting a laparoscope into the abdomen is classified as a critical procedure because tissues that are normally sterile are being touched. For the former, either sterile or high-level disinfected instruments are acceptable, but for the latter, the preferred final processing is sterilization. To sum up, it should be noted that sterile metal instruments with laparoscopy, calls for an additional separate area for final processing (high-pressure sterilization by autoclaving). (**Figure 12.1b**). This is especially important if the volume of services is high (five or more procedures per day).

The space, equipment and need for well-defined traffic flow and activity patterns become progressively more complex as the type of surgical procedure changes from general surgery and obstetrics to open heart surgery. As a guide, the space requirements for the types of surgery typically performed at district hospitals are roughly the same as that of a busy surgical center or polyclinic.

These include:

- Changing room and scrub area for the clinic staff.
- Preoperative area where clients are examined and evaluated prior to surgery.
- Operating room.
- Recovery area for observation of patients after surgery (may be combined with the preoperative area).
- Processing area for cleaning and sterilizing or high-level disinfecting instruments and other items.
- Space for storing sterile packs and/or high-level disinfected containers of instruments and other items.

MINIMIZING MICROBIAL CONTAMINATION

The recommended infection prevention practices for minimizing microbial contamination of specific areas in healthcare facilities are briefly described below.

Procedure Area

- Limit traffic to authorized staff and patients at all times.
- Permit only the patient and staff (performing and assisting) in the procedure room (family members should be limited with obstetrical procedures).
- Patients can wear their own clean clothing.
- Staff should wear attire and personal protective equipment (PPE) according to procedures performed.
- Have a covered container filled with a 0.5% Chlorine solution for immediate decontamination of instruments and other items once they are no longer needed.

TRAFFIC FLOW AND ACTIVITY PATTERNS

- Have a leak proof and covered waste container for disposal of contaminated waste items (cotton, gauze, dressings) right after use.
- Have a puncture-resistant container for safe disposal of sharps (e.g. used suture needles, hypodermic needles and syringes, and disposable scalpel blades) right after use.
- Have storage space in procedure rooms for clean, high-level disinfected and sterile supplies (Storage shelves should be enclosed to minimize dust and debris collecting on stored items).

SURGICAL UNIT - the surgical unit is often divided into four designated areas defined by the activities performed in each unrestricted area: **transition zone**, **semi restricted** and **restricted area**. Environmental controls and use of surgical attire increase as one move from unrestricted to restricted areas. Moreover, staff with respiratory or skin infections and/uncovered open sores should not be allowed in the surgical unit.

Post signs in each area to clearly indicate the appropriate environmental control and surgical attire required.

Unrestricted Area Note

This area is the entrance from the main corridor and is isolated from other areas of the surgical unit. This is the point through which the staff, patients and materials enter the surgical unit.

Transition Zone

This area consists primarily of dressing rooms and lockers. It is where the staff put on surgical attire that allows them to move from unrestricted to semi-restricted or restricted areas in the surgical unit. Thus, only authorized staff should enter this area.

Semi-Restricted Area

This is the peripheral support area of the surgical unit and includes preoperative and recovery rooms; storage space for sterile and high-level disinfected items; and corridors leading to the restricted area. This is an area where support activities (e.g. instrument processing and storage) for the operating room are carried out. So,

- Limit traffic to authorized staff and patients every time.
- Have a work area for processing of clean instruments.
- Have storage space for clean, sterile or high-level disinfected supplies with enclosed shelves to minimize dust and debris collecting on stored items.

Flip flops or sandals should not be worn as they provide no protection from dropped sharps.

- Have doors limiting access to the restricted area of the surgical unit.
- Staff working in this area should wear surgical attire and a cap.
- Staff should wear clean and closed shoes that will protect their feet from fluids and dropped items.

Restricted Area

This designated area consists of the operating room(s) and scrub sink areas.

Never store instruments and other items in the operating room.

- Limit traffic to authorized staff and patients at all times.
- Keep the door closed at all times, except during movement of the staff, patients, supplies and equipment.

- Scrubbed staff must wear full surgical attire and cover head and facial hair with a cap and mask.
- Staff should wear clean and closed shoes that will protect their feet from fluids and dropped items.
- Masks are required when sterile supplies are open and when the scrubbed staffs are operating.
- Patients entering the surgical unit should wear clean gowns or be covered with clean linen and have their hair covered.
- Patients do not need to wear masks during transport (unless they seek airborne precautions).

Operating Room(s)

- The operating room should be enclosed to minimize dust and eliminate flies; however, central air conditioning is necessary (If windows are the only ventilation, provide tight-fitting screens).
- The operating room should be located away from areas of the hospital or healthcare facility that are heavily staffed with frequent movements of the staff and patients.

BEFORE SURGICAL PROCEDURES:

- Place a clean and covered container filled with a 0.5% Chlorine solution or other locally available and approved disinfectant for immediate decontamination of instruments and other items once they are no longer needed.
- Place a plastic bag or leak proof-covered waste container for contaminated waste items (cotton gauze and old dressings).
- Place a puncture-resistant container for the safe disposal of sharps (e.g. suture needles, hypodermic needles and syringes, and disposable scalpel blades) at the point of use but without contaminating the sterile field.
- Place a leak proof and covered waste container for soiled linen away from sterile items.
- Organize tables, Mayo and ring stands side by side in an area away from the traffic patterns and at least 45cm (18 inches) from walls, cabinets and other non-sterile surfaces.
- Place a clean sheet, a lift sheet and arm board covers on the operating room bed.
- Check and set up suction, oxygen and anesthesia equipment.
- Place supplies and packages that are ready to open on the tables, not on the floor.
- Mayo stand and other non sterile surfaces that are to be used during the procedure should be covered with a sterile towel or cloth.

DURING SURGICAL PROCEDURES:

- Limit the number of staff entering the operating room only to those necessary to perform procedures and to patients (family members as deemed necessary). Make the surgical team self-sufficient so that outside help is not required.

- Keep the doors closed at all times, except during movement of the staff, patients, supplies and equipment.
- Keep the number of people and their movement to a minimum; because, the numbers of microorganisms is directly proportional to an increase with people's activity.
- Keep talking to the minimum in the presence of a sterile field.
- Scrubbed staff should wear full surgical attire including:
    - A clean scrub suit covering the bare arm (one or two pieces); if a two piece pantsuit is worn, the top of the scrub suit should be tucked into the pants;
    - A clean surgical cap that covers the head;
    - Clean, closed shoes that protect the feet from fluids or dropped items; and
    - Sterile (or high-level disinfected) surgical gloves, protective eyewear and a mask covering the mouth, nose and any facial hair.
- Scrubbed staff should keep their arms and hands within the operative field at all times and touch only sterile items or areas. Non-scrubbed staff should wear surgical attire including:
    - Long sleeved jackets banded at the wrist and that are closed during use;
    - A clean surgical cap that covers the head;
    - Clean, closed shoes that protect the feet from fluids or dropped items; and
    - A mask covering the mouth, nose and any facial hair.
- Non-scrubbed staff should stay at the periphery of the operating room, keeping their distance from sterile areas. They should not lean or reach over the operative field.
- Clean accidental spills or contaminated debris in areas outside the surgical field with a 0.5% Chlorine solution as promptly as possible (a non-scrubbed staff member wearing utility gloves should do this).

After surgical procedures, non-scrubbed staff wearing utility gloves should:

- Collect all waste and remove it from the room in closed leak proof containers.
- Close and remove puncture-resistant containers when they are three quarters full.
- Remove covered containers with a 0.5% chlorine solution with instruments and surgical gloves from the room.
- Remove soiled linen in closed leak proof containers.
- Remove waste, soiled linen, soiled instruments and equipment and supplies that have been opened but not used, in an enclosed cart or in a leak proof and covered waste container. (Be sure that these items do not reenter the restricted area).

Work Area - according to the size and type of the healthcare facility, the work area for processing instruments (e.g. the Central Supply Department or CSD) may be: part of the surgical unit; or just connected to it; or an independent area somewhere away from it.

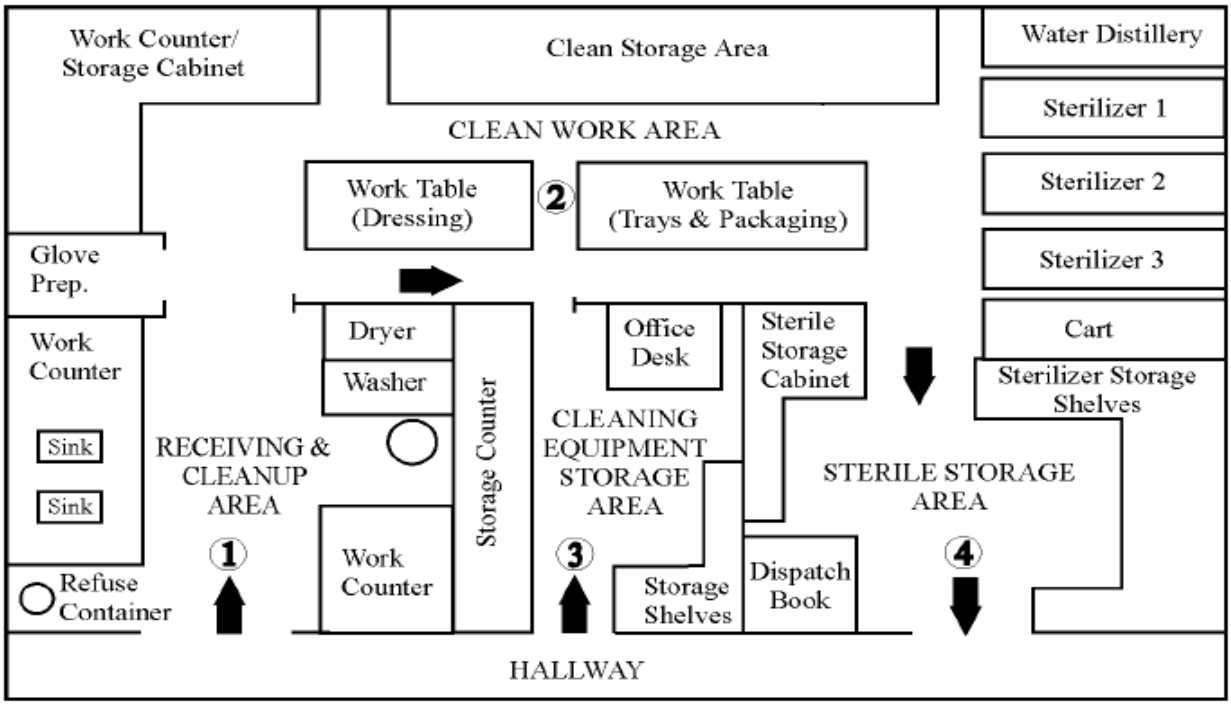
This is the area where instruments, surgical gloves and equipment are processed and where the staff should be specially trained in handling, processing and storing instruments, equipment and other clean, sterile or high-level disinfected items. The CSD is considered a semi-restricted area; hence all the recommendations for traffic patterns and proper attire described above should be followed.

Permit only authorized personnel to enter this area.

A CSD consists of four areas, as shown in **Figure 12.2.** These areas are:

1. The "dirty" receiving/cleanup area,
2. The "clean" work area,
3. The cleaning equipment storage area, and
4. The sterile or high-level disinfected storage area.

Figure 12.2 Floor Plan for a Central Supply Department in a Hospital



Following surgery, decontaminate instruments, surgical gloves and other items by placing them in a plastic container filled with a 0.5% chlorine solution at the point of use. Cover the container and transport it to the CSD or designated instrument and equipment processing area. Alternatively, place soiled instruments in their original sterile wrap and transport them to the CSD where they can be immediately decontaminated before further processing.

Separate the "dirty" receiving/cleanup area (1) from the "clean" work area (2) with a physical barrier (wall and door). If this is not possible, use a screen or paint a red line on the floor to designate separation between areas.

Note:
Develop flow patterns to help ensure that contaminated items never come in contact with clean, disinfected or sterile items.

The function and equipment requirements for the four areas of a typical CSD are summarized below.

"Dirty" Receiving/Cleanup Area (1)

In this area, soiled items are received, disassembled, washed, rinsed and dried. Congruently, the Staff in the receiving/cleanup area should wear plastic aprons, utility gloves and safety goggles or face shields to protect themselves from spills and splashes. The "dirty" receiving/cleanup area should have:

- A receiving counter. If it is not possible to decontaminate instruments and other items in procedure or operating rooms, a decontamination counter is needed for this step.
- Two sinks if possible (one for cleaning and one for rinsing) with a clean water supply; and
- A clean equipment counter for drying.

"Clean" Work Area (2)

In the clean work area, cleaned items are:

- Inspected for flaws or damage;
- Packaged (if indicated) and either sterilized or high-level disinfected; and
- Sent for storage as packaged or air dried and placed in a sterile or high level disinfected container.

The clean work area should have:

- A large work table;
- Shelves for holding clean and packaged items; and
- A high-pressure steam sterilizer, a dry-heat oven, a steamer or a boiler.

Staff entering the clean work area should wear clean cover gowns.

Clean Equipment Storage Area (3)

Store: clean the equipment in this area. The staff of CSD should also enter the department through this area. Equip the area with:

- Shelves (preferably enclosed) for storing clean equipment, and
- An office or desk for record keeping.

Sterile or High-Level Disinfected Storage Area (4)

Store sterilized packs and covered sterile or high-level disinfected containers in this area. This area should be separated from the central sterile supply area:

- Limit access to the storage area and/or store items in closed cabinets or shelves. (Shelves or cabinets had better be closed as they protect packs and containers from dust and debris. Open shelves are acceptable only if the area has limited access and if housekeeping and ventilation practices are controlled).
- Keep the storage area clean, dry, dust-free and lint-free by following a regular housekeeping schedule.
- Packs and containers with sterile or high-level disinfected items should be stored 20 to 25 cm (8 to 10 inches) off the floor, 45 to 50cm (18 to 20 inches) from the ceiling and 15 to 20cm (6 to 8 inches) from an outside wall.
- Do not use cardboard boxes for storage. (Cardboard boxes shed dust and debris and may harbor insects).
- Date and rotate the supplies (first in, first out). This process serves as a reminder that the package is susceptible to contamination and conserves storage space, but it does not guarantee sterility.
- Packs will remain sterile as long as the integrity of the package is maintained.
- Sterile or high-level disinfected containers remain so up until they are opened.
- Dispense sterile and high-level disinfected articles from this area.

SHELF LIFE (Belkin, 1997a; Belkin, 1997b)

- The shelf life of a packaged sterile item is event-related and not time related.
- An event can compromise the integrity and effectiveness of the package.
- Events that can compromise or destroy package sterility include multiple handling, loss of package integrity, moisture penetration and airborne contamination.
- Sterility is lost when the package has tears in the wrapper, has become wet, has been dropped on the floor, has dust on it or is not sealed.
- The shelf life of a sterile package will depend on: the quality of packing; conditions during storage and transport; and the amount of handling prior to use.
- Sealing sterile packs in plastic bags can help prevent damage and contamination.

- Most contaminating events are related to excessive or improper handling of the packages. The ideal number of times an item should be handled is three:
    1. When removing it from the sterilizer cart and placing on a storage shelf,
    2. When transporting it to the place where it is to be used, and
    3. When selecting it to be opened for use.

HANDLING AND TRANSPORTING INSTRUMENTS AND OTHER ITEMS

- Keep clean and high-level disinfected or sterile instruments and other items separate from soiled equipment and waste items. Do not transport or store these items together.
- Transport high-level disinfected and sterile instruments and other items to the procedure or operating room in a closed cart or container with a cover to prevent contamination.
- Remove supplies from all shipping cartons and boxes before bringing such supplies into the procedure room, the operating room or the clean work area of the CSD. (Shipping boxes shed dust and harbor insects that may contaminate these areas).
- Transport soiled supplies and instruments to the receiving/cleanup area of the CSD in leak proof and covered waste containers.
- Transport contaminated waste to the disposal site in leak proof and covered waste containers.

Note:
If supplies are being delivered to the surgical area; one person standing outside should pass them through the door to a person inside the operating room.

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CHAPTER 13: HOUSE KEEPING

KEY TOPICS TO BE DISCUSSED:

- Significance of housekeeping in hospitals and clinics.
- General principles of cleaning
- Ways of preparing disinfectant cleaning solutions.
- When and how to clean low and high risk areas.
- Cleaning spills of blood or other body fluids.
- Cleaning the housekeeping equipment.

BACKGROUND

Accumulation of dust, soil and microbial contaminants on environmental surfaces is both unsightly and potential source of HAIs. Effective and efficient cleaning methods and schedules are, therefore, necessary to maintain a clean and healthy environment in healthcare settings (Chou, 2002).

Housekeeping practices in the healthcare facilities address the general cleaning of hospitals and clinics including: the floors, walls, various type of equipment, tables and other surfaces. Housekeeping activities are not expensive and technology intensive in most cases. The purpose of general housekeeping is to:

- Reduce the number of microorganisms that may come in contact with patients, visitors, staff and the community; and
- Provide a clean and pleasant atmosphere for patients and staff.

Most of the areas in hospitals and clinics like waiting rooms and administrative offices are normally of low-risk for they can be cleaned using only soap and water. In high-risk areas where heavy contamination is expected, sources of contaminations such as toilets and latrines; and blood or body fluid spills can be handled by disinfectants like 0.5% Chlorine or 1% Phenol which should be added to the cleaning solution (SEARO, 1988). Using a disinfectant in addition to soap and water is also recommended in other high-risk areas such as operating rooms, pre- and postoperative recovery areas and intensive care units (ICUs).

In connection with this, patient rooms especially those items that might be touched bare handedly by patients and the staff should be cleaned using a disinfectant solution to minimize the risk of infection. For an instance, a study in the area (McFarland *et al.,* 1989) found that when patients who did not have *Clostridium difficile* were admitted to a room previously occupied by a patient with these bacteria, the risk of infection from the bacteria for these new patients is known to increase in many folds-even in the context of correct use of precautions to prevent cross-contamination. If the purpose of housekeeping as stated above is to be achieved, it is important that housekeeping staff be trained to perform their assigned tasks and are supervised on a regular basis. As part of their training, it is important that the housekeeping staff:

- Understand the risk of exposure to contaminated items and surfaces when performing environmental cleaning procedures; and
- Follow recommended policies and guidelines including the use of appropriate personal protective equipment (PPE).

Housekeeping is a very simple activity which is based on the above simple practical principles but its impact in preventing a range of health facility acquired infections is very tremendous.

DEFINITIONS

Cleaning Solution - any combination of soap (or detergent) and water, with or without a chemical disinfectant used to wash or wipe down environmental surfaces such as floors, chairs, bench tops, walls and ceilings.

Disinfectants – is a chemicals that destroy or inactivate microorganisms. Disinfectants are classified as low, intermediate or high-level depending on their ability to kill or immobilize some (low or intermediate-level) or all (high-level) microorganisms (but not all spores). Phenols, chlorine or chlorine-containing compounds and QUATs are classes of disinfectants frequently used to clean non critical surfaces such as floors, walls and furniture.

Disinfectant Cleaning Solution - is a product that is a combination of detergent (soap) and a chemical disinfectant. It is true, that not all detergents and disinfectants are compatible. But, there still are range of several combinations such as alkaline detergents with chlorine compounds, alkaline detergents with quaternary ammonium compounds (QUATs) or other nonionic surfactants, and acid detergents with Iodophors which are available commercially or can be prepared.

Environmental Controls - activities of keeping **s**tandards specifying procedures to be followed for the routine care, cleaning and disinfection of environmental surfaces, beds, bedrails, bedside equipment and other frequently touched surfaces .

Environmental Hygiene - is a process of maintaining a clean, healthy and pleasant working environment.

Sanitizer - a chemical that reduces the number of bacterial contaminants on inanimate objects to safe levels based on public health requirements (i.e. a chemical that kills 99.999% of the specific test bacteria in 30 seconds under the conditions of the test).

Soaps and **Detergents (terms used interchangeably) -** are cleaning products (bar, liquid, leaflet or powder) that lower surface tension thereby helping remove dirt, debris and transient microorganisms from hands. Plain soaps require friction (scrubbing) to mechanically remove microorganisms; while antiseptic (antimicrobial) soaps kill or inhibit the growth of most microorganisms.

Sterilants - these are Chemicals used to destroy all forms of microorganisms including endospores. Most sterilants are also high-level disinfectants when used for a shorter period of time. These chemicals are to be applied only on inanimate objects (e.g. surgical instruments) that are used in semi-critical and critical areas (e.g. surgery). It should be noted that they are not meant to be used for cleaning environmental surfaces.

Surfactant - an agent that reduces the surface tension of water or the tension at the interface between water and another liquid; and a wetting agent found in many sterilants and disinfectants.

Type of Detergents - commercial cleaning products (liquid or powder) that are composed of two components-hydrophilic (water-seeking) and lipophilic (fat-seeking) components and it can generally be divided into four types: anionic, cationic, amphoteric and nonionic detergents.

Encapsulation- is filling a container with cement or clay, which, after hardening, can be disposed of safely in a landfill.

GENERAL PRINCIPLES FOR CLEANING

- Scrubbing (frictional cleaning) is the best way to physically remove dirt, debris and microorganisms.
- Cleaning is required prior to any disinfection process because dirt, debris and other materials can decrease the effectiveness of many chemical disinfectants.
- Cleaning products should be selected on the basis of their use, efficacy, safety and cost.
- Cleaning should always progress from the least soiled areas to the most soiled areas and from high to low areas so that the dirtiest areas and debris falling on the floor will be cleaned up last.
- Dry sweeping, mopping and dusting should be avoided to prevent dust, debris and microorganisms from getting into the air and landing on clean surfaces. Airborne fungal spores are especially important as they can cause fatal infections in immune-suppressed patients (AORN *et al.,* 1991).
- Instructions for mixing (dilution) should strictly be followed when using disinfectants. (Too much or too little water may reduce the effectiveness of disinfectants).
- Cleaning methods and written cleaning schedules should be based on the type of the surface, the amount and the extent of the soil present and the purpose of the area.
- Routine cleaning is necessary to maintain the standard of cleanliness. Also, schedules and procedures should be consistent and posted.

HOW TO SELECT CLEANING PRODUCTS

There are different types of cleaning products which are used for different purposes. The housekeeping staff in particular and health facility staff in general, have to get a clear idea on how to select a cleaning product and for what purpose. There are some basic facts which should be remembered before making selections of the products. An ideal cleaning product should accomplish the following:

- Suspending fats in water (suspended fat in water).
- Saponifiction of fat (make fats water-soluble).
- Surfaction (decreasing surface tension of water and allowing greater penetration of the agent into the dirt or soil).
- Dispersion (break up of soil into small particles).
- Protein destruction (break up proteins).

- Softening the water by removing calcium and magnesium from it.

The Main Guiding Principles for Resource Limited Areas are:

- Unnecessarily expensive products should not be selected.
- What is selected and bought should be based on evidence (not to be left to chance).
- The right product should be for the right purpose.

In conclusion, it is believed that the selection of disinfectants and other cleaning products should be based on the following factors:

- Intended use of the product/s.
- Efficacy of the product/s.
- Acceptability of the product/s.
- Environment friendly.
- Safety of the product/s.
- Cost-effectiveness of the product/s.

PERSONAL PROTECTIVE EQUIPMENT FOR HOUSEKEEPING

The housekeeping staff in health facilities deals with dirt, soils and other materials that expose them to risks of infections and other health hazards. To avoid this hazardous exposure, they have to be equipped with the relevant personal protective equipment.

Some of personal protective equipment for housekeeping purposes are:

- Gloves preferably the household utility ones
- Protective shoes
- Plastic or rubber apron
- Masks
- Protective eye wears
- The housekeeping staffs should use the above mentioned PPEs for

    - Handling disinfectant cleaning solutions
    - Cleaning patient care areas
    - Cleaning heavily contaminated areas
    - Handling soiled linens
    - Handling soiled items and instruments
    - Handling or disposing of wastes
    - When spills or splashes are expected

HOW TO PREPARE A DISINFECTANT CLEANING SOLUTION

The disinfectant cleaning solutions contain both disinfectants for decontamination and detergents (soap) for cleaning. When we use Chlorine solution, we should be very cautious. Although chlorine-containing solutions (sodium hypochlorite) are excellent and inexpensive disinfectants, they should not be mixed with cleaning solutions containing an acid (e.g. phosphoric acid) like Ammonia or Ammonium chloride (NH_2Cl).So doing will release chlorine gas and other by-products that can result in temporary illness (nausea, tearing, headache or shortness of breath) of the staff inhaling fumes in a poorly ventilated area (CDC, 1991). To find out if a cleaning solution contains ammonia, first check the label. If it is not mentioned among the ingredients, you may still be able to detect ammonia when opening the product by its pungent and burning smell. If one is exposed to Chlorine gas or Ammonium chloride or other unpleasant (noxious) gases with strong odors, the subject should immediately leave the room or the area until it becomes completely ventilated.

STEP 1 Prepare a 0.5% Chlorine solution from liquid concentrates (**see Table 10.1**) for directions) or from Chlorine powder compounds (**see Table 10.2**). Alternative disinfectants that can be used include 1 to 2% Phenols or 5% Carbolic acid.

STEP 2 Add enough detergent to the 0.5% Chlorine solution or another disinfectant to make a mild and soapy cleaning solution.

CLEANING METHODS

Cleaning should start with the least soiled area and extend to the most soiled area and from high to low surfaces. Common methods of cleaning are briefly described below:

Wet Mopping Method-(Preferable for Floor Cleaning)

Single-Bucket (Basin) Technique - one bucket of cleaning solution is used here. The solution, however, needs to be changed when dirty. (The killing power of the cleaning product decreases with the increased load of soil and organic material present).

Double-Bucket Technique - two different buckets are used here---one containing a cleaning solution and the other containing water for rinsing. The mop is always rinsed and wrung out before it is dipped into the cleaning solution. The double-bucket technique extends the life of the cleaning solution (fewer changes are required) saving both labor and material costs.

Triple-Bucket Technique - the third bucket is used for wringing out the mop before rinsing which extends the life of the rinse water.

Flooding Followed by Wet Vacuuming Method

- It is preferable for surgical suits.
- It eliminates mopping and minimizes the spread of micro-organisms.
- It increases the contact time of the disinfectant and the area to be cleaned.
- Preferably, it should be done at night when the traffic flow of the facility is low.

Dusting

- Should be used for cleaning walls, ceilings, doors, windows, furniture and other environmental surfaces.
- Clean clothes or mops are made wet with cleaning solution contained in a basin or bucket. The double-bucket system minimizes the contamination of the cleaning solution.
- Dry dusting should be avoided and dust cloths should not be shaken either for fear of spreading of micro-organisms.
- Should be performed in a systematic way using a starting point as a reference to endure that all surfaces have been reached.
- Check for a stain that may indicate possible leaks when doing high dusting, (ceiling tiles and walls). Leaking holes or cracks should be repaired as soon as possible because moist ceiling provide a reservoir for fungal growth.

Dry Vacuuming

* This is recommended only for cleaning carpets.

SCHEDULES AND PROCEDURES FOR SPECIFIC AREAS

In health facilities, housekeeping activities should be scheduled. Housekeeping schedule should be planned, written and closely followed. Cleaning schedules should be developed according to the need of each area.

Walls, Windows, Ceilings and Doors, including Door Handles - these should be cleaned at the spot when visibly dirty with a damp cloth, detergent and water. In general, routine damp dusting is adequate for these areas (disinfection is unnecessary). These surfaces are seldom heavily contaminated with microorganisms as long as the surfaces remain dry and intact (Russellet *et al.,* 1982).

Chairs, Lamps, Tables, Tabletops, Beds, Handrails, Grab Bars, Lights, Tops of Doors and Counters - these items should be wiped daily and whenever visibly soiled with a damp cloth containing disinfectant cleaning solution. A disinfectant should be used when contaminations from blood or other body fluid spills are present.

Non-Critical Equipment - (e.g. stethoscopes and blood pressure cuffs) these ones can just be wiped daily and whenever visibly soiled with a damp cloth with detergent and water. If the equipment is visibly soiled with blood or other body fluids or when the patient is under contact precautions, however, it should be cleaned and disinfected before it is reused.

Floors - floors usually cleaned (daily and as needed) with a wet mop, detergent and water. A disinfectant should be used during an actual or potential contamination from sources like blood or other body fluid spills as described below.

Sinks - scrub frequently (daily or more often as needed) with a separate mop, cloth or brush is using a disinfectant cleaning solution. Following this, it needs to be rinsed with water.

Toilets and Latrines - scrub them frequently (daily and more often as needed) with a separate mop, cloth or brush and a disinfectant cleaning solution.

Patient Rooms - they should be cleaned daily and right after patient is discharged using the processes described above. The same cleaning process applies to rooms of patients who are under isolation precautions. Any cleaning equipment used in the rooms of patients under isolation precautions should be cleaned and disinfected before being used in another room.

Procedure Rooms - wipe horizontal surfaces, equipment and furniture used for the procedures, with a disinfectant cleaning solution after each procedure and whenever visibly soiled. Clean blood or other body fluid spills as described below.

Examination Rooms - wipe horizontal surfaces with a disinfectant cleaning solution after each procedure and whenever visibly soiled. Linen or paper on the examination table should be changed and laid out for each patient. Clean blood or other body fluid spills as described below.

Laboratory - wipe countertops with a disinfectant cleaning solution after each shift and whenever visibly soiled. Clean blood or other body fluid spills as described below.

Curtains - change and clean curtains according to the routine schedule and when visibly soiled.

Carpets - vacuuming daily carpets in patient rooms or weekly in offices or conference rooms.

Soiled Linen - collect soiled linen daily (or more often as needed) put them in closed and leak proof containers.

Waste - collect waste from all areas at least daily (or more frequently as needed) and avoid overflowing.

Waste Containers - clean contaminated waste containers each time following emptying. Clean no contaminated waste containers when visibly soiled and at least once a week. Use a disinfectant cleaning solution and scrub to remove soil and organic material.

SCHEDULE AND PROCEDURES FOR THE OPERATING ROOM

- At the beginning of each day, all flat (horizontal) surfaces (table, chairs, etc.) should be wiped with a clean, lint-free and moist cloth to remove dust and lint that may have collected overnight.
- Total cleaning is not necessary between each case for surgical procedures.
- Total cleaning or terminal cleaning (mopping floors and scrubbing all surfaces from top to bottom) of the operating room should be done at the end of each day.

Note:
Do not dry mop or sweep the operating room. (This causes dust, debris and microorganisms to become airborne and contaminate clean surfaces).

TOTAL CLEANING

STEP 1 Move covered decontamination buckets to the central supply or processing room. A clean bucket containing a fresh 0.5% Chlorine solution or other locally available and approved disinfectants should be provided at the beginning of each day and after each case.

STEP 2 Remove covered contaminated waste container and replace it with a clean container. Arrange for burning (incineration) or burial as soon as possible.

STEP 3 Close and remove sharps containers when three quarters full.

STEP 4 Remove soiled linen in closed leak proof containers.

STEP 5 Soak a cloth in disinfectant cleaning solution and wipe down all surfaces, including counters, tabletops, sinks, lights, etc. Wash from top to bottom so that any debris that falls on the floor will be cleaned up last.

Note:
All areas of the surgical suite, scrub sinks, scrub or utility areas, hallways and equipment should be totally cleaned regardless of their being used during the 24- hour surgery period.

- **Walls and Ceilings** - wipe them with a damp cloth with detergent and water as needed for visible soil.

Note:
If walls and ceilings are deteriorating or damp, cover them up with clean plastic sheets during procedures.

- **Chairs, Lamps, Sink Tabletops and Counters** - wipe them with a damp cloth with disinfectant cleaning solution.
- **Operating Room Lamp** - wipe them with a damp cloth with disinfectant cleaning solution.

Note:
The double or triple bucket method is recommended for the cleaning of the operating room and other areas of the surgical suite.

- **Operating Room Table** - wipe it with a 0.5% Chlorine solution (or other approved disinfectant) to decontaminate. Then clean top, sides, base, legs and any accessories (e.g. leg stirrups) with a damp cloth and disinfectant cleaning solution.
- **Floors** - clean with a wet mop using a disinfectant cleaning solution.
- **Vents** (heating or air conditioning) - wipe them with a damp cloth with soap and water. When carrying out , the following is advised :

    - **Spills** - clean spills with a 0.5% chlorine solution or other locally available and approved disinfectants (see below).
    - **Operating Room Bed** - wipe all surfaces and mattress pads with a disinfectant cleaning solution.
    - **Instrument Tables (Trolley and Mayo stand) and other Flat Surfaces** - wipe all flat surfaces that have come in to an immediate contact with a patient or body fluids with a disinfectant cleaning solution.

- **Center of Operating Room Surrounding the Operating Room Bed** - mop it with a disinfectant cleaning solution (if visibly soiled).
- **Waste** - collect and remove all waste from the operating room in closed leak proof containers.
- **Sharps Containers** - close and remove containers from the operating room when they are three quarters full.
- **Containers with a 0.5% Chlorine Solution for Decontamination** - remove covered containers with instruments from the operating room and replace them with clean containers with a fresh 0.5% chlorine solution.
- **Soiled linen** - remove soiled linen in leak proof, covered waste containers.

Note:

- Cleaning the filters in air conditioners regularly will help them run more efficiently and decrease the growth of molds.
- Because all patients are considered potentially susceptible and at times infectious, standard precautions are to be used and no additional measures are necessary even if a client is known to have an infection.

HOW TO CLEAN SPILLS OF BLOOD AND OTHER BODY FLUIDS

Clean spills of blood, body fluids and other potentially infectious fluids immediately:

- For small spills, remove visible material using a cloth soaked in a 0.5% Chlorine solution, then wipe clean with a disinfectant cleaning solution while wearing utility or examination gloves.
- For large spills, flood the area with a 0.5% Chlorine solution and mop up the solution and then clean as usual with detergent and water while wearing gloves.

HOW TO MANAGE SPILLS OF MERCURY FROM BROKEN THERMOMETER AND BLOOD PRESSURE EQUIPMENT:

- Put examination gloves on both hands,
- Collect all droplets of mercury with a spoon.
- Place in a small, closed container for disposal (possibly encapsulation and burial of the waste away from water resource area) or reuse,
- Wash or clean the area with a chlorine solution,
- Remove used gloves carefully and wash hands properly,

HOW TO CLEAN SOILED AND CONTAMINATED CLEANING EQUIPMENT

STEP 1 Decontaminate cleaning equipment that has been contaminated with blood or body fluids by soaking it for 10 minutes in a 0.5% Chlorine solution or other locally available and approved disinfectants.

STEP 2 Wash cleaning buckets, cloths, brushes, mops and the like with detergent and water daily or right away if visibly dirty.

STEP 3 Rinse them in clean water.

STEP 4 Dry them completely before reuse. (Wet clothes and mop heads are heavily contaminated with microorganisms).

FUMIGATION AND THE USE OF UV LIGHT

The use of Formaldehyde gas for killing microorganisms and to disinfect the air was practiced before the turn of the century (Morris, 1972). One of the first uses of Formaldehyde gas was to fumigate rooms. Moreover, formaldehyde vapors are irritating to the skin, eyes and respiratory tract. It is also categorized as a potential carcinogen making its use very limited. This is therefore, generally believed to be ineffective since long (Schmidt, 1899).

UV irradiation, on the other hand, has long been proved that its power is too limited to penetrate dust, mucous or water. Therefore, despite manufacturers' claims, it cannot be used to sterilize water. Although intense UV light can theoretically be both bactericidal and viricidal, in practice only limited disinfection of instruments is known to be achieved through it. This is because the UV rays can kill only those microorganisms that are directly struck by UV light beams.

Other disadvantages of UV:

- It requires a reliable source of electricity.
- It is not effective in areas of high relative humidity.
- UV bulbs require frequent cleaning to remain effective.
- Exposure to UV rays can burn the skin and eyes.

As a consequence, UV irradiation is neither practical nor effective method in most situations (Riley & Nardell, 1989). Hence, scrubbing objects with a disinfectant cleaning is a safer, quicker and more effective way to reduce microbial contamination on these surfaces.

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CHAPTER 14: CLINICAL LABORATORY SERVICES

KEY TOPICS TO BE DISCUSSED:

- Special risks of exposure to laboratory staff.
- Occurrence of exposures or accidental injuries.
- Criteria for classifications of laboratories Bio-safety and infection prevention practices in clinical laboratories.

BACKGROUND

The sources of laboratory hazards could be physical, chemical or biological agents. Hazards which arise from physical agents such as flames, hot water or broken glasses are referred to as physical hazards. On the other hand, laboratory chemicals can be corrosive, explosive, or poisonous and can be source of laboratory risk if not handled and used properly. The commonest laboratory hazards arise from biological materials and microorganisms.

Laboratory-acquired infections are healthcare associated infections resulting from the performance of laboratory activities by staff regardless of how they occurred. Laboratory workers who handle blood or potentially infectious body fluids are at some risk of accidental injury or exposure. Most at risk among them, however, are the staff working in clinical laboratories or research units isolating or handling pathogenic microorganisms (e.g. vaccine development).

Prior to the emergence of HIV/AIDS and the re-emergence of multi-drug resistant tuberculosis in the 1990s, little progress was made in reducing laboratory acquired infections. In the US, for instance, the annual incidence of such infections was about 3 per 1000 laboratory workers (Grist & Emslie, 1991). Lately, however, interest in bio-safety efforts not only began to be renewed afresh, but also gave way to an increasing compliance among health workers. In contrast, the situation is quite different in developing countries. For example, a recent research reports indicated that among 44 clinical laboratories in Karachi-Pakistan, only two (4.5%) laboratories use gloves and only seven (16%) use disinfectants. Moreover, only seven laboratories (16%) have access to an incinerator (Mujeeb *et al*., 2003).

The bio-safety recommendations cover: safe work practices, laboratory design, use of appropriate personal protective equipment (**as described in Chapter 4**) and waste management (**as described in Chapter 9**) of this reference manual. Adherence to these bio-safety guidelines can reduce the risk of exposure and subsequent laboratory-acquired infections (Harding *et al*., 1995).

SAFE LABORATORY PRACTICE

Requirements for safe laboratory practice include:

- Appropriate laboratory design (superstructure, furniture and space).
- Adequate light, water, sewage, ventilation and electrical facilities.

- Waste disposal facilities.
- Appropriate storage of facilities.
- Use of safety devices and bio-safety cabinets.
- Restricted access to laboratories

The bio-safety guidelines described in this chapter are designed for the prevention of laboratory-acquired infections in general hospital settings. They are aimed at containing the bio-hazardous agents and educating laboratory workers about the occupational risks.

Bio-safety level (BSL) Guidelines - is a combination of primary and secondary containment and safety guidelines designed for use in microbiology laboratories and bacteriology research units functioning at four levels (BSL-1 to BSL-4) of increasing risk:

- **BSL-1** is the lowest level of containment and microbiologic safety guidelines and is entirely based on standard laboratory practices. These guidelines are recommended for those working with microorganisms such as *Bacillus subtilis* that are not known to cause infections in healthy adults.

Gloves should be pulled over the cuffs of gowns to protect the wrists.

- **BSL-2** is generally applied in bacteriology laboratories working with agents (e.g. Salmonella species) associated with human diseases of varying severity. When standard microbiologic practices are applied, the agents may be handled on open benches especially if primary barriers such as facemasks, gowns and examination gloves, are used when appropriate. The use of biologic safety cabinets (BSCs) and safety centrifuges may be necessary.

Gloves should be pulled over the cuffs of gowns to protect the wrists.

- **BSL-3** is aimed at containing hazardous microorganisms primarily transmitted by airborne route (aerosols and droplets) such as *tuberculosis* or *varicella* (chicken pox). Laboratory staff working in these situations must be trained on the use of appropriate equipment including suitable ventilation systems and the use of BSCs.
- **BSL-4** is designed for use where agents causing life-threatening or untreatable diseases such as hemorrhagic fever viruses potentially affecting the laboratory staff via the airborne route are present. Trained workers using level III BSCs or wearing full-body, air-supported positive pressure suits must perform all procedures in these laboratories. Besides, the facility itself must be totally isolated from other laboratories and have specialized ventilation and waste management systems.

Biological Safety Cabinets (BSCs) - these are devices that provide protection for the staff the agent being processed and the environment. The complexity ranges from level I (general research cabinets for use with low to moderate-risk microorganisms) to level III (totally enclosed cabinets with gas-tight construction that provide maximum protection to workers and the environment).

LABORATORY-ACQUIRED INFECTIONS

Laboratory infections from pathogenic organisms occur through different means. The most common are the following:

- **Inhalation -** mixing, grinding or blending an infectious agent or flaming a transfer loop can generate aerosols (airborne droplets) possibly inhaled by unprotected workers. Pathogens can be inhaled when snap-closing specimen containers, dispensing or pipetting infectious fluids, or centrifuging infectious material in open buckets. Infectious aerosols can also be formed and inhaled following breakages or spill over of infectious fluids. Breakages in centrifuges can particularly be hazardous if the centrifuge is opened before the aerosols have settled.
- **Ingestion -** workers may be exposed through:
    - Unconscious hand-to-mouth contacts;
    - Placing contaminated articles (pencils) or fingers (when biting fingernails) in the mouth;
    - Eating, drinking or smoking in the laboratory or failing to use proper hygiene of hand (neglecting to wash hands or to use a waterless, alcohol-based antiseptic hand rub before and after eating); or
    - Mouth pipetting (13% of accidental laboratory-acquired infections are associated with this practice).
- **Puncture Wounds -** accidental injury with sharps (scalpel blades and contaminated broken glassware); or needles (suture needles and pricking needles) are the leading causes of laboratory-acquired infections. A puncture wound does not usually result in excessive bleeding; the wound created also closes quickly on its own.
- **Contamination of Skin and Mucous Membranes -** splashes and sprays of contaminated fluids onto mucous membranes of the mouth; nasal cavity and conjunctivae of the eyes; and hand-to-face actions can lead to the transmission of pathogenic organisms.
- **Infected Laboratory Animals -** these are potential sources of biohazards. They transmit infection by making cuts and scratches or by producing infective aerosols during laboratory experiments.

FACTORS CONTRIBUTING TO LABORATORY ACCIDENTS

A number of factors contribute to various laboratory accidents. Some of these factors are intrinsic i.e. associated with the individual practitioner and the majorities are extrinsic factors.

These factors include:

- Poor training.
- Lack of concentration.
- Carelessness and negligence.
- Overwork and fatigue-emergency conditions.
- Untidy and noisy working environment.

- Lack of adequate protective equipment.
- Poor waste disposal system.
- Hot and humid climatic conditions.
- Hurrying to finish work on time.
- Poor design of laboratories.

RECOMMENDED INFECTION PREVENTION PRACTICES FOR LABORATORY WORKERS

Laboratory workers in hospitals and clinics handling blood products, potentially contaminated body fluids or specimens containing pathogenic microorganisms, need to be aware of the potential hazards of these infectious agents and materials. Correspondingly, they need to know how to protect themselves, fellow workers, and the environment in general.

Most hospital or clinic laboratories are defined as BSL-1 or BSL-2 units. Prevention of occupationally-acquired infections in these laboratories consists of staff conscientiously using the basic practices prescribed for all healthcare workers namely Hand hygiene (hand washing or use of an antiseptic hand rub). Similar to the other health care staff, Lab workers are to practice them before and after eating or contact with infectious materials, and the use of protective gloves, facemasks and gowns. Due to the fact that the infectious agents Lab workers may encounter are classified as low or moderate risk, special containment practices are not required (i.e. these agents are not a significant risk to the environment and can be disposed of as any other infectious hospital waste).

For the staff working in bacteriology laboratories or microbiologic research units (BSL-3 or 4), containment of hazardous agents to protect the environment is an added requirement for the safe handling of these infectious agents. As described above, the requirements of BSCs and other PPE (e.g. full-body, air-supported positive pressure suits) largely depends on the type of organisms being handled and the staff must be fully trained in their use.

GENERAL BIO-SAFETY AND INFECTION PREVENTION GUIDELINES

- Wear new examination gloves when handling blood, body fluids and/or specimens containing pathogenic microorganisms.
- No eating, drinking or smoking is permitted in the laboratory.
- Food should not be stored in refrigerators used for clinical or research specimens.
- No mouth pipetting is permitted; use proper mechanical devices instead (e.g. suction bulbs).
- Do not open centrifuges while still in motion.
- Always cover the end of blood collection tubes with a cloth or paper towel or point them away from anyone's face when opening.
- Decontaminate working surfaces daily or when contaminated (e.g. after spills, with a 0.5% Chlorine solution).

- Wear protective face shields or masks and goggles if splashes and sprays of blood, body fluids, or fluids containing infectious agents are possible.
- Wear heavy-duty or utility gloves when cleaning laboratory glassware.
- Use puncture-resistant and leak proof containers for sharps.
- Place infectious waste materials in plastic bags or containers.
- Immunization against highly infectious agents such as HBV.

Blood Drawing (Phlebotomy)

The Center for Disease Control and Prevention (CDC) considers blood drawing (phlebotomy) to be one of the highest-risk sharps procedures. This perspective is based on the fact that the commonly used needles are large bore (18 to 22 gauges) and some amount of blood would be left in the needle after use. In a 1999 (EPIN), 21% of 1,993 sharps injuries reported in the US, were associated with blood drawing (venous or arterial blood samples and finger/heel sticks). According to the findings, over 80% of the needle sticks occurs during drawing venous blood using either a vacuum-tube blood collection needle, disposable syringe/needle or butterfly needle.

Each blood sample drawn or handled in the laboratory carries the risk of exposure to HIV and other infectious agents. Microorganisms in the blood or other potentially infectious materials that can transmit disease include Hepatitis B, Hepatitis C, HIV, tuberculosis and others.

When collecting a blood specimen (phlebotomy), make sure that you:

- Wear examination gloves.
- Have assistance when patients might be uncooperative (children, mentally impaired, etc).
- Have assistance for holding children when doing heel sticks.

If Exposed to Blood-borne Pathogens (e.g. due to needle-stick)

- Take immediate measures (**as explained in chapter 16**).
- Report it to the supervisor immediately.
- Complete 'Exposure Report'.
- Evaluate the source patient.
- Consult with local senior management regarding possible treatment and follow-up (PEP).

Post Exposure Prophylaxis (PEP)

- Is an antiretroviral medication which may reduce the risk of HIV sero-conversion in exposed individuals. The medication for this purpose is taken for about four weeks.
- Must be taken as soon as possible after exposure preferably within two hours and usually no later than 72 hours after exposure if an optimal effect is to be attained.
- The exposed individual will begin the PEP medications until HIV status of source patient is clarified.

- PEP is indicated when:
    - The source patient is known to be HIV positive.
    - The source patient is at high risk for HIV.
    - The HIV status of the source patient is unknown
- PEP is not indicated for:
    - Low risk exposures or
    - Persons already HIV infected

Note:

- PEP drugs can have major side effects; therefore, indications for PEP drugs are determined on a case by case basis.
- PEP is fully explained in Chapter 16

In general, laboratory workers should be aware of the various biohazards and exposure risks to protect themselves and their environment. All kinds of biological specimens like blood and body fluids are potentially infectious and must be handled with great care. Besides, microbiological cultures, retained specimens, control specimens or sera and infected laboratory animals are source of laboratory infections. It is, therefore, imperative that workers in this setup comply with the recommended infection prevention practices in: handling and processing specimens; sharps and other laboratory materials; and the use of protective equipment and hand washing which are essential for reducing occupational exposure and risk.

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CHAPTER 15: BLOOD SAFETY

KEY TOPICS TO BE DISCUSSED:

- Components of blood bank and transfusion services.
- Blood donor selection criteria and informed consent.
- Steps in the collection of blood from donors.
- Different blood components and testing for infectious diseases.
- Prevention of transmissible infections from transfusions and protection of healthcare workers.

BACKGROUND

Blood safety refers to all procedures undertaken to render blood safe for utilization in a patient. These procedures include: preparing national policies/strategies and guidelines; meticulous selection of voluntary non-remunerated donors (VNRDs); aseptic blood collection from the donor; ABO and Rhesus factor grouping of the donated blood; and screening for Transfusion Transmissible Infections (TTIs) of public health importance (HIV, Hepatitis B, Hepatitis C, Syphilis). Blood safety also encompasses the organized storage (according to blood groups and shelf life) of the useable donations at the appropriate temperature. This again depends on the proper distribution before their expiry dates, proper transportation under ideal conditions, appropriate use at the clinical level and all that it entails from the time of reception at the hospital to transfusion including post transfusion care of the patient. The staffs working in blood banks and transfusion services are at risk of accidental injury or exposure to contaminated blood or blood products.

DEFINITION

Blood Bank is a facility or a unit in a hospital that performs the collection, processing, storage and distribution of human blood or blood products.

Clinically Significant Antibody an antibody capable of producing an adverse reaction to transfused blood or blood product obtained from a donor (allergenic antibody) or recipient (autologous antibody).

Closed System for Obtaining Blood a system in which the blood is kept free from being exposed to the air or outside elements during collection and processing, including separation of components (e.g. platelets) if required prior to transfusion. It is the safest way to collect process and store blood.

Donor-Patient is a person whose blood is collected for possible transfusion to another person (allogenic transfusion).

Donor-Recipient is a person whose own blood is collected for possible transfusion to her/him self (autologous transfusion).

Look back System a process of identifying persons who have received blood transfusions from donors who are subsequently found to have infections with HCV or HIV (and often HBV) and notifying them if appropriate.

Recipient Transfusion Reaction is an adverse reaction to infusing blood or blood products into a patient (recipient). It may occur at any time during the transfusion but often happens shortly afterwards. The reaction may be mild or severe and rarely--fatal. The reactions are categorized as allergic (from mild itching and hives to serious breathing problems) and hemolytic (destruction of red cells) characterized by fever, chills, rapid heart rate (tachycardia), hyperventilation, fainting and, rarely, cardiac arrest. Interestingly, delayed reactions are also known to occur several days or weeks after the transfusion. This situation is believed to result due to serum sickness (antigen-antibody reaction).

Transfusion Service is a service taking place in a facility or hospital unit incorporating activities like storage, pre-transfusion testing, cross-matching, and infusion of blood or blood products to intended patients (recipients).

Unit of Blood is a sterile plastic bag in which a fixed volume of blood is collected in a suitable amount of anticoagulant. (The collection system should be a closed one usually consisting of a sterile hypodermic needle connected to it by tubing to a collection bag or bottle with a sterile port or two for insertion of a sterile blood administration set).

BLOOD BANK AND TRANSFUSION SERVICES INVOLVE:

- Selecting donors and making sure that they have given an informed consent,
- Collecting blood from screened donors,
- Testing for blood components, antibodies and infectious diseases,
- Storing and transporting blood,
- Pre-transfusion testing of patient's blood, and
- Transfusing patients.

Donor Selection and Informed Consent

Effective blood transfusion begins with collection of safe blood from healthy blood donors. In Ethiopia, 60 to 65% of blood donors are family members and/or replacement donors (Ethiopia Red Cross Society, 2008 data). These donors have been identified and reported as unsafe for they carry very high risk of TTIs. Thus, it is advisable if each blood bank or transfusion service has a pool of regular and non-remunerated donors for safer blood.

- Obtain complete medical history and physical examination of each donor (this should include any medical problems, behaviors, or events that put a person at risk of being infected and transmitting a serious disease to the person receiving the transfusion).
- Prior to collection of blood, the elements of the donation process should be explained to the potential donor in a simple and easy to understand language.
- Explain about the risks of veni-puncture and the potential adverse responses to drawing 400 to 500 ml. of blood.
- Explain the laboratory tests that will be performed and how exactly the donor will be informed about the test results including any other medical abnormalities.

- Perform the routine laboratory test including Hemoglobin or Hematocrit and screening for HIV, HBV, HCV, syphilis, and malaria.
- Complete a written informed consent form that should be filled for each donor.

Blood Collection

1. Make sure that the following items are available:
   - Blood collection set consisting of sterile plastic bag containing a sufficient amount of anticoagulant for the quantity of blood to be collected.
   - IV tubing and large gauge hypodermic needles.
   - Pair of sterile or HLD surgical gloves.
   - Clean tourniquet or blood pressure cuff.
   - Antiseptic solution and sterile or clean gauze squares or cotton swabs.
   - Surgical tape.
   - Towel to place under patient's hand or forearm.
   - Basin of clean warm water.
   - Soap
   - Clean dry towel to wash patient's arm if visibly soiled.
   - Plastic bag or leak proof covered waste container for disposal of contaminated items.
   - Puncture-resistant sharps container.
2. Explain the procedure to the donor.
3. Identify the best vein for inserting the IV needle (a prominent, large and firm vein).
4. Put the tourniquet or blood pressure cuff on the upper arm about 9cms above the antecubital space to confirm that the vein is visible and then release the tourniquet or cuff.
5. If the veni-puncture site is visibly soiled, first wash it with soap and clean water and dry with a clean cloth or ask the donor to wash the forearm.
6. Wash hands and dry them with a clean towel or air dry (alternatively use alcohol hand rub 5ml and rub both hands vigorously until dry).
7. Place the donor's arm on a clean towel and cleanse an area about 3cm in diameter with an antiseptic solution. Use a circular motion outward from the proposed needle insertion site over the vein. (If using Povidone Iodine or other Iodophors, allow two minutes for antiseptic to take full effect).
8. Do not touch the area after applying the antiseptic solution.
9. Put the tourniquet or blood pressure cuff on the upper arm again; raise the pressure up to 40 to 60mm of mercury while collecting the blood.
10. Put sterile or HLD surgical gloves on both hands.
11. Insert the hypodermic needle into the vein without touching the skin if possible, release the tourniquet or cuff and then secure the needle by placing a short piece of tape across the blood collection tubing below the area cleansed with antiseptic.

12. When the required amount of blood has been obtained, remove the needle without touching the barrel or tip of the needle and place it in a puncture resistant sharps container.
13. Cover the insertion site with 2 x 2cm. gauze square, apply pressure until bleeding stops and secure the gauze square using 1 or 2 pieces of surgical tape.
14. Prior to removing gloves, place any blood-contaminated waste items in a plastic bag or leak proof and covered waste container.
15. Wash hands or use an antiseptic hand rub as above.
16. Let the donor remain resting on a bed or in the donor chair for several minutes.
17. Provide the donor with something to drink and eat.
18. Tell the donor to drink more fluid during the next 24 hours and avoid alcohol or smoking up until more food has been eaten. Ask the donor to lie down if there is dizziness or nauseating sensation.

To Avoid Contamination of Collected Blood:

- Maintain appropriate storage conditions (stored at 1 to 6^{o}C and monitoring temperature every four hours).
- Test the blood unit without entering the closed collection system.
- Infuse or discard the blood unit within a short period once the closed system has been opened.

Blood Component and Infectious Disease Testing:

- ABO blood group and Rhesus factor type.
- Blood from donor with history of transfusions or pregnancy should be tested for unexpected antibodies to red cell antibodies using methods to demonstrate clinically significant antibodies.
- Human immunodeficiency virus by testing for antibodies to HIV 1 and 2. As per the national policy on HIV/AIDS for Ethiopia and the national blood transfusion services strategy, all donated blood shall be screened prior to transfusion. In remote areas where testing facilities are limited, simple and/or rapid HIV tests shall be made available. Blood donors shall be informed about the tests which will be carried out on the donated blood. In the case of a donor wanting to know his/her HIV sero-status, he/she shall be referred to the appropriate health facilities for counseling and testing.
- Syphilis by screening with Rapid Plasma Reagent (RPR) test.
- Hepatitis B and Hepatitis C virus by testing for Hepatitis B surface antigen

Blood Storage and Short Distance Transport:

- Blood units must be stored in a refrigerator at a temperature ranging from 1 to 6^{o}C.
- There must be a system to monitor temperatures continuously and record them at least every 4 hours.

Steps of Discarding Blood Exposed to Higher Temperature:

- Wear examination or utility gloves and protective eyewear.
- Pour content down a utility sink or drain onto a flushable toilet or latrine.
- Place empty blood bags and tubing in a leak-proof container.
- Burn or bury them for disposal

Pre-transfusion Testing and Cross-Matching

- Test a sample of recipient blood using the same methods and recommended infection prevention practices used to test donor blood.
- Repeat testing of the donor blood to confirm the ABO group and Rhesus factor.
- Cross-match the red cells of selected donor against the serum or plasma of the recipient to be sure that there are no ABO and Rhesus factor incompatibility.

Transfusion of Blood or Blood Components

Indications for blood transfusion are:

- Actively bleeding patients and
- Patients with chronic or symptomatic anemia.
- The generally accepted Hemoglobin level for transfusing patients with acute blood loss is 7gm%; those patients having a level of 6 gm%, almost always require transfusion but those with a level of ≥10 gm% rarely need it.

Transfusing Patients

Before starting the transfusion:

- Explain the procedure to the patient if he/she is conscious.
- Correctly identify the blood product and the patient: confirm patient's name, check compatibility information attached to the blood bag and expiry date, check the ABO and Rhesus factor status of the patient on the patient chart, double check blood or type of blood product with the physician's order and check blood for clots.
- Record baseline pulse and blood pressure.
- Ask the patient or relatives to report chills, headaches, itching or rash immediately.
- Once the transfusion has started, take patient's pulse, blood pressure every 5 minutes for the first 15 minutes and hourly thereafter, observe the patient for flushing, itching, difficulty in breathing, hives (clear fluid filled lesions on the skin) or other rash when checking for the vital signs.

PREVENTING COMPLICATIONS AND HEALTHCARE ASSOCIATED INFECTION

To prevent complications and associated infections in patients:

- Avoid unnecessary transfusions.

- Screen donated blood for serious transfusion transmissible infections (HIV, HBV, HCV, and syphilis).
- Collect donor blood aseptically into a closed system to minimize contamination and accomplish all steps of processing the blood within this system.
- Store blood and blood products at the right temperature and make sure that the unit is within the expiry date.
- Follow all steps to ensure that donor and patient blood are compatible in terms of ABO, Rhesus factor and cross matching.
- Verify all of the necessary information regarding the blood to be donated and the intended recipient to secure correct matching.
- Use aseptic techniques to establish the peripheral IV Line for giving the transfusion.
- Monitor patient's vital signs regularly and check for any adverse reactions.
- Stop transfusion immediately when adverse reactions are noticed.

PROTECTING HEALTHCARE WORKERS

Wear gloves while collecting, testing and transfusing blood. Handle the sharps carefully and dispose immediately in a puncture resistant container. Wear personal protective equipment at all times.

Improving performance and compliance with recommended policies and guidelines can be significantly enhanced if there are:

- Consistent supports from the hospital administrators and the Hospital Transfusion Committee to improve the quality of services,
- Supervisors regularly provide positive feedback, rewards and suggestions for improvement,
- Physicians, other senior staff and faculty role model the practices and behaviors by actively supporting the policies and guidelines.

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CHAPRER 16: POST EXPOSURE PROPHYLAXIS TO HIVAND HBV

KEY TOPICS TO BE DISCUSSED:

- Definitions of terms used in PEP service delivery.
- Risk of acquiring HIV, HBV and HCV infection from occupational and non occupational exposures.
- Benefits of giving PEP service to reduce acquisition of HIV infection after potential exposures.
- Recommended steps in giving PEP service.
- Special considerations of PEP in non occupational exposures.
- Doing follow up of people obtaining PEP service.
- Documenting, monitoring and evaluating PEP services in health care facilities

BACKGROUND

HIV, HBV and HCV are the primary infectious agents that can be transmitted via exposure to bodily fluids. In addition to percutaneous injury, contact of mucous membranes or non-intact skin with blood, fluids containing blood, tissue or other potentially infectious bodily fluids pose an infectious risk. Potentially infectious body fluids include semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, peritoneal fluid, pericardial fluid amniotic fluid, pus, etc. In this case, body fluids like feces, nasal secretions, saliva, sputum, sweat, tears, urine, and vomits are not considered infectious unless they contain blood.

DEFINITIONS

Post-Exposure Prophylaxis (PEP) - is generally understood as a medical measure taken to prevent the transmission of blood-borne pathogens following a potential exposure to these pathogens. In the context of HIV, PEP refers to the set of services that are provided to manage the specific aspects of exposure to HIV and to help prevent HIV infection in a person exposed to the risk of getting infected by HIV. These services comprise: first aid, counseling (including the assessment of risk of exposure to the infection), HIV testing, and depending on the outcome of the exposure assessment, prescription of antiretroviral drugs for 28 days with appropriate support and follow-up (WHO/ILO guidelines on PEP, 2007).

Occupational Exposure - is exposure of individuals to HIV and other blood borne pathogens occurring in the course of their work. This exposure should not be assumed to be directed solely to health care workers but also to other workers like emergency rescue staff, waste-disposal workers, law enforcement personnel and fire-fighters. Because, these staff are also likely be exposed to health risk from pathogens in blood and other potentially infectious body fluids while doing their work.

Non-Occupational Exposure - is an exposure to HIV and other blood borne pathogens outside the work setting. This term predominantly refers to potential exposure through sexual assault. Other forms of potential non-occupational exposure include those arising from needle-sharing

among injecting drug users, consensual sex, needle sticks in the community, fights or playground incidents resulting in bleeding by an HIV-infected child and mass causalities like road traffic accidents, etc.

Exposed Person - is the person who is potentially at risk of acquiring HIV infection (and or infection from other pathogens) through exposure to blood or body fluids in his or her occupation or in another non-occupational situation.

Source Person - is the person who is (either identified or not identified as) the possible source of contamination through potentially infectious blood or body fluid. If the serostatus of the source person is unknown, he or she may be asked to provide informed consent to HIV testing. The source person may be: a patient if a healthcare worker is the one who is exposed (in occupational exposures) or a perpetrator if it is a case of sexual assault.

I. HIV Post Exposure Prophylaxis

A. OCCUPATIONAL EXPOSURE TO HIV

Each day, thousands of people around the world experience accidental exposure to blood and other body fluids or tissues while performing their work duties. Hence, it could be said that healthcare workers are especially vulnerable for infections. The risk of acquiring HIV after a mucous membrane exposure to blood is approximately 0.09 % while the acquisition through a percutaneous exposure is approximately 0.3% (Cardo DM *et al.,* 1997). The risk of acquiring HIV percutaneous is associated with deeper injuries, visibly bloody devices, and more advanced disease (likely due to a higher viral load) in the source patient. Hollow bore needle exposures have higher risk of transmission than that of solid bore needle exposures.

The use of post exposure prophylaxis against HIV infection dates back to the early 1990s for both direct and indirect evidence suggested that the treatment with ARVs soon after exposure to HIV decreases the risk of transmission. Animal studies have demonstrated mixed results on the efficacy of PEP (Black RJ, 1997). In macaques, PMPA (Tenofovir) blocked simian immunodeficiency virus (SIV) infection after intravenous challenge if administered within 24 hours of exposure and continued for 28 days. PMPA was not as effective if initiated 48 or 72 hours post exposure or if continued for only 3 or 10 days (Tsai CC *et al.*, 1998). Two macaque studies of combination antiretroviral therapy (Zidovudine, Lamivudine, & Indinavir) initiated 4 hours after simian/human immunodeficiency virus (SHIV) challenge and continued for 28 days, did not protect against infection but did result in reduced viral load among the animals infected (Le Grand R *et al.,* 2000).

In a macaque study designed to model non occupational PEP (nPEP) for mucosal HIV exposure, all animals administered PMPA for 28 days, beginning 12 hours (four animals) or 36 hours (four animals) after vaginal HIV-2 exposure, were protected. Three of the four animals treated 72 hours after exposure were also protected; the fourth animal had delayed seroconversion and maintained a low viral load after treatment (Otten RA *et al*., 2000). Therefore, these findings are consistent with those of macaque studies on the biology of vaginal SIV transmission. After a traumatic vaginal inoculation, lamina propria cells of the cervico-vaginal sub-epithelium were found to be infected first, virus was present in draining lymph nodes within 2 days and disseminated to the blood stream by 5 days (Spira AI, *et al*., 1997). Similarly, in another study,

SIV-RNA was detected in dendritic cells from the vaginal epithelium within an hour of intra-vaginal viral exposure and SIV-infected cells were detected in the lymph nodes within 18 hours. These data indicate a small window of opportunity during which it might be possible to interrupt either the initial infection of cells in the cervico-vaginal mucosa or the dissemination of local infection by the prompt administration of antiretroviral medications.

Perinatal clinical trials have also shown significant reduction in mother to child HIV transmissions as a result of antiretroviral therapy of varying composition and duration given to the mother and the new born (Sperling RS *et al.*, 1996; Shaffer N, *et al.,* 1999; Guay LA *et al*., 1997).

A retrospective case-control study demonstrated that PEP with AZT for 4 weeks was associated with an 81% reduction in transmission of HIV in humans. In that study, approximately 70% of patients received AZT within 4 hours of the exposure (Cardo DM, 1997). It is not known how long after an exposure PEP would turn to be ineffective. However, the data from animal studies mentioned above, suggest that PEP is effective when initiated within 72 hours of exposure. Taking the evidences mentioned above in to consideration, most international guidelines recommend PEP drugs to be started for exposed persons (based on the indication) as early as possible preferably within 2 hours of exposure but giving PEP drugs after 72 hours of exposure is not generally advisable. Measures that should be taken on initial management of exposure exposed persons are put on **Appendix D-1**.

Drug of Choice for PEP

With a lower risk of transmission for HIV, a two drug PEP regimen is recommended. After higher risk exposures, however, an expanded (three drug) regimen is recommended. The 2008 Ethiopian guideline for management of opportunistic infections and ART, recommended AZT/3TC and d4T/3TC as preferred 2 drug combinations with the addition of Efaverenz or Lopinavir/ritonavir (kaletra) when the expanded regimen is indicated (Ethiopian health reform documentation guideline, May 2010). TDF can also be used as a substitute to AZT and d4T as it is recommended by CDC and WHO guidelines. In the meantime, TDF is recommended as a first line drug for ART in the 2008 Ethiopian ART guideline. Lopinavir/ritonavir has many significant drug interactions. Hence, the exposed patient's medication list should be carefully reviewed prior to prescribing PEP. In places and situations, where Lopinavir/ritonavir (kaletra) is not available, Efavirenz can be used as an alternative to these drugs and hence regarded as the third drug in the expanded regimen. At this junction, it should be noted that Efavirenz is contra-indicated in pregnancy due to its teratogenicity. The use of drugs like ABC and NVP is contraindicated for PEP purpose. Still important to note, is that the use of drug combinations like d4T and DDI is contra indicated.

Table 16.1 Recommended PEP Regimens

Recommended PEP regimen
Two drug : ZDV/3TC* or d4T/3TC ** or TDF/3TC
Three drug : ZDV/3TC or d4T/3TC or TDF/3TC plus LPV/RTV *** or EFV

* ZDV/3TC = Combivir
** d4T/3TC = Stavudine & Lamivudine
*** LPV /RTV = Kaletra

The PEP drug recommendations for percutaneous injury and mucous membrane or non-intact skin exposure are found in **Table 16.2 and 16.3**.

Table 16.2 Recommended HIV Post Exposure Prophylaxes (PEP) for Percutaneous Injuries

Status code (SC)	Exposure code (EC)	
	EC 2	EC 3
SC 1	Recommend basic 2-drug PEP	Recommend expanded 3-drug PEP
SC 2	Recommend expanded 3-drug PEP	Recommend expanded 3-drug PEP
SC unknown	Generally, no PEP is warranted; however, consider basic 2-drug PEP for source with HIV risk factors.	Generally, no PEP is warranted; however consider basic 2-drug PEP for source with HIV risk factors
HIV-Negative	No PEP warranted	No PEP warranted.

Table 16.3 Recommended HIV Post Exposure Prophylaxes for Mucous Membrane Exposures and Non-intact Skin Exposures

Status code	Exposure code	
	EC 1	EC 2
SC 1	Consider basic 2-drug PEP	Recommend basic 2-drug PEP
SC 2	Recommend basic 2-drug PEP	Recommend expanded 3-drug PEP
SC unknown	Generally, no PEP warranted. If PEP is offered & administered and the source is later determined to be HIV-negative, PEP should be discontinued.	Generally, no PEP warranted; however consider basic 2-drug PEP for source with HIV risk factors.
HIV-Negative	No PEP warranted	No PEP warranted.

Adapted from Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HIV and Recommendations for Post exposure Prophylaxis. MMWR Recomm Rep 2005; 54 (No RR-9): 1-17 & MMWR 1998; 47(No. RR-7): 1-33.

Note:

Tables 16.2 and **16.3** are included in PEP decision making tools put as **Appendix D-10**. Clinicians should use this decision making tool as job aid while managing patients with HIV exposure.

Adherence

Compliance rates of 95% or greater are required to actually maximize the benefits of antiretroviral therapy. Although parallel data are not available for PEP, the magnitude of the positive effects of high levels of adherence to prescribed practices is generally assumed to be similar.

Incremental Dosing and Follow Up in the ART Clinic

Dispensing PEP drugs for three to five days should be chemotherapy for people getting the PEP service immediately after the eligibility for the patient is decided. The pharmacist working with in the case team should count and dispense the prescribed amount of PEP drugs. The person getting the PEP service should report to the ART clinic on the next working day for follow up, continued health education, counseling and support. In the ART clinic the PEP client is expected to have a minimum of six scheduled visits to complete the follow up on PEP.

On the first ART clinic visit which should be conducted in the first two to three days of exposure, Health professionals prescribe additional PEP drugs enough for the patient to take them for the next two weeks and come back at the day of finishing the medication. Besides, the client should be told to come to ART clinic even before the day of the appointment if he needs further counseling or if he cannot tolerate the drugs in the meantime. Service in the ART clinics should be accessible to patients who are on follow up for PEP services in every working day in regular working hour's i.e. 8:00 AM to 5:00 PM.

The second follow up visit to the ART clinic will be after two weeks. The ART clinician assesses adherence to treatment, drug side effects and prescribes additional PEP drugs for two weeks and appoints the patient after two weeks.

The third follow up visit will be four weeks after the patient started PEP. The patient needs to come for the third follow up visit. On this visit, the ART clinician verifies PEP drug treatment completion and gives the patient additional counseling on preventing further exposures and on the importance of having follow up visits.

The patient also needs to be appointed for HIV testing at 6 weeks (fourth visit), 3 months (fifth visit) and 6 months (sixth visit) after exposure. The testing procedure and counseling should be performed according to the national PITC protocol. The follow up of HIV testing should be done in the ART clinic (point of care testing) to address issues related with confidentiality.

Clients who have already started PEP but did not come to the ART clinic on the follow up appointment date, can be traced by giving a telephone call (or physically for those in the same health facility, if possible) to remind them to come to follow up visit. The Service given at each follow up visit should be documented on Potential exposure and PEP follow up forms (**Appendix D-6**) which should be attached to the chart of every patient who reports exposure.

Healthcare providers giving the PEP service should also inform clients about ARC hot line-952 and Warm line-932 accesses to information on HIV/AIDS rendering services of relevant IEC and counseling on PEP. The hot line gives information on HIV/AIDS to the general public. In this service, Health professionals, Psychologists and sociologists can be accessed by clients every day from 8:00 AM in the morning to 12:00 PM mid night. On the other hand, using Warm line-932 (intended to give information for health professionals), healthcare professionals can discuss with experienced health professionals to get professional advice and information on clinical management of HIV/AIDS including PEP and other related information. The health professionals can be accessed on working days from 8:30 AM to 5:30 PM. To facilitate counseling and informed decision making for HIV post exposure prophylaxis, the list of information items to be given for clients on PEP service is summarized in **Appendix D-3**.

Antiretroviral Side Effects and Toxicity

Initial concerns about severe side effects and toxicities of ARVs when used for PEP purposes have been ameliorated by experience with health-care workers who have taken PEP. Among 492 health-care workers reported in the occupational PEP registry, 63% of them took at least three medications. Overall, 76% of workers who received PEP and had 6 weeks of follow-up reported certain symptoms (i.e. nausea [57%] and fatigue or malaise [38%]). Only 8% of these workers had laboratory abnormalities few of which were serious and all of which were resolved promptly at the end of antiretroviral treatment (Wang SA, *et al*., 2000). Six (1.3%) of them reported severe adverse events and four stopped taking PEP because of side effects. Of the 68 workers who stopped taking PEP despite exposure to a source person known to be HIV-positive, 29 (43%) stopped taking PEP because of side effects. This indicates that Patients given PEP drugs should be counseled on side effects of ARVs. The steps in the clinical management of HIV PEP are summarized in **Appendix D-2**.

Considerations for Pregnant Women and Women of Childbearing Potential

Because of its potential teratogenicity, Efavirenz should not be used in any nPEP (non occupational PEP) regimen during pregnancy or among women of childbearing age at risk of becoming pregnant during the course of antiretroviral prophylaxis. A protease inhibitor or nucleoside reverse transcriptase inhibitor-based regimen should be considered in these circumstances. When Efavirenz is prescribed to women of childbearing potential, they should be instructed about the need to avoid pregnancy. The effect of Efavirenz on hormonal contraception is unknown. Therefore; women using such contraception should be informed of the need to use an additional method (e.g. barrier contraception).

Children

Potential HIV exposures in children occur most often by accident (e.g. needle sticks, in the community, fights, or playground incidents resulting in bleeding by an HIV-infected child) or by sexual abuse or assaults (Nourse CB *et al*., 1997). Young children who cannot swallow capsules or tablets needs to be benefitted by other alternative preparations appropriate for pediatric dosing (**Appendix D-4**). Adherence to the prescribed medications will depend on the involvement of parents or guardians, and support provided to them.

B. NON OCCUPATIONAL EXPOSURE TO HIV

The risk of HIV transmission per-contact from sexual exposure varies according to the nature of the exposure. The estimated risk is 1 to 30% with receptive anal intercourse; 0.1 to 10.0% with insertive anal intercourse and receptive vaginal intercourse; and 0.1 to 1.0% with insertive vaginal intercourse (CDC DHHS guideline on PEP, 2005; Powers KA *et al*., 2008; Boily MC *et al*., 2009). As compared to other forms of intercourse, oral intercourse is considered to pose a lower risk of HIV transmission although good risk estimates are lacking and there are case reports of HIV infections in persons in whom the only reported risk factor was oral intercourse (Lifson AR *et al*., 1990). The risks of sexual transmission are difficult to quantify: Thus, a range of reports on the risks per-contact transmission is derived from observational studies. The risk is again much influenced by many factors: the presence or absence of concomitant genital ulcer disease, other concurrent diseases, cervical or anal dysplasia, status of circumcision, the viral load in the genital compartment, and the degree of virulence of the virus. In line with this, the estimated risk of transmission associated with sharing needles for injection-drug use is observed to approximately be 0.67% per needle-sharing contact (Kaplan EH *et al*., 1995).

The 2007 HIV/AIDS policy of Federal democratic republic of Ethiopia states that PEP service should be made accessible to people who have experienced occupational exposures as well as to rape survivors. Data from transmission models, perinatal clinical trials, studies of healthcare workers receiving prophylaxis after occupational exposures, and observational studies, indicate that nPEP might reduce the risk for HIV infection after non occupational exposures. In a high-risk HIV incidence cohort in Brazil (Harrison LH, *et al*., 2000), nPEP instruction and 4-day starter packs of Zidovudine and Lamivudine were administered to about 200 homosexual and bisexual men. Men who began taking nPEP after a self-identified high-risk exposure were evaluated within 96 hours. In this case, seroincidence was 0.7 per 100 person-years (one seroconversion) among men who took nPEP and 4.1 per 100 person-years among men who did not take nPEP (11 seroconversions). In a study of sexual assault survivors in Sao Paolo, Brazil, women who sought care within 72 hours after exposure were treated for 28 days with Zidovudine and Lamivudine (for those without mucosal trauma) or Zidovudine, Lamivudine, and Indinavir (for those with mucosal trauma or those subjected to unprotected anal sex) for 28 days. Women victims were not treated if they sought care 72 hours or more after assault; if the assailant was HIV-negative; if a condom was used; and no mucosal trauma was seen. Of the 180 women treated, none was seroconverted. On the other hand, of 145 women not treated, four (2.7%) were seroconverted (Drezett J, 2002). Although these studies demonstrate that nPEP might reduce the risk for infection after sexual HIV exposures, participants were not randomly assigned for the sample sizes were too small to anticipate statistically significant conclusions.

In a study conducted in British Columbia, no seroconversions were observed among the 590 persons who completed a course of nPEP (Braitstein P *et al.,* 2001). In registries from four countries (Australia, France, Switzerland & the United States) including approximately 2,000 non occupational exposure case reports, no confirmed seroconversions have been attributed to a failure of nPEP in approximately 350 nPEP-treated persons reported to have been exposed to HIV-infected sources. However, this absence of seroconversions might not be attributed to the receipt of nPEP but rather, to the low per-act risk for infection and incomplete follow-up in the registries.

EVALUATION OF PERSONS SEEKING CARE AFTER POTENTIAL NON-OCCUPATIONAL EXPOSURE TO HIV

When deciding whether to recommend the initiation of nPEP, the clinician should assess and carefully weigh the following factors (see Table 16.4):

Table 16.4 Elements of assessment to determine whether nPEP is indicated

Risk Behavior*: **Did exposure to potentially HIV-infected blood or body fluid occur?** Was the exposure an isolated or episodic event, or result of habitual behavior?
Degree of Transmission Risk Based on Type of Exposure: What was the route of exposure? Are factors present that are known to further increase transmission risk?
Exposure Source: Is the source known to be HIV infected? ** If HIV status of the source is unknown, what is the likelihood of the source being HIV infected

* *Assessment* of *t*he behavioral factors and circumstances that led to HIV exposure includes: emotional, psychological and social factors that contribute to risk behavior such as depression, history of sexual abuse, and drug and alcohol use.

**If the source is known to be HIV infected, information about his/her CD4 count, viral load, ARV medication history, and history of ARV drug resistance should be obtained when possible to assist in selection of a PEP regimen.

In addition, evaluation, of sexual assault includes: Detailed medical history with details of sexual assault and a complete physical examination with a focus on genital examination: examining and documenting any change noticed on each of external and internal genital examination in a step wise fashion. Vaginal examination (speculum and digital) is rarely indicated in cases of sexual assault. The indications include: active bleeding not localized on external genitalia evaluation; vaginal discharge that is copious and needs to be localized and other similar conditions. If

forensic evidence and lab investigations are sought, vaginal swap for spermatozoa could be considered. This should be obtained with cotton tipped applicator from the interior of the vaginal wall (FMoH of Ethiopia, National guideline for survivors of sexual assault in Ethiopia, 2009).

Genital trauma is present in the majority of sexual assault survivors, with anal trauma present in just over half. Absence of visible trauma does not indicate that an assault did not occur; micro-abrasions are common and the appearance of manifestations may be delayed. Oral trauma may also occur during sexual assault with potential exposure to blood or semen from the alleged assailant, which would carry a potential risk for HIV exposure. Bites or trauma may be inflicted during an assault and are indications for prophylaxis if there is contact with blood or semen from the alleged assailant.

On the task of determination of the HIV status of the potentially exposed person, the timing and characteristics of the most recent exposure; the frequency of exposures to HIV; the HIV status of the source; and the likelihood of concomitant infection with other pathogens or negative health consequences of the exposure should all be well taken up and carefully reviewed.

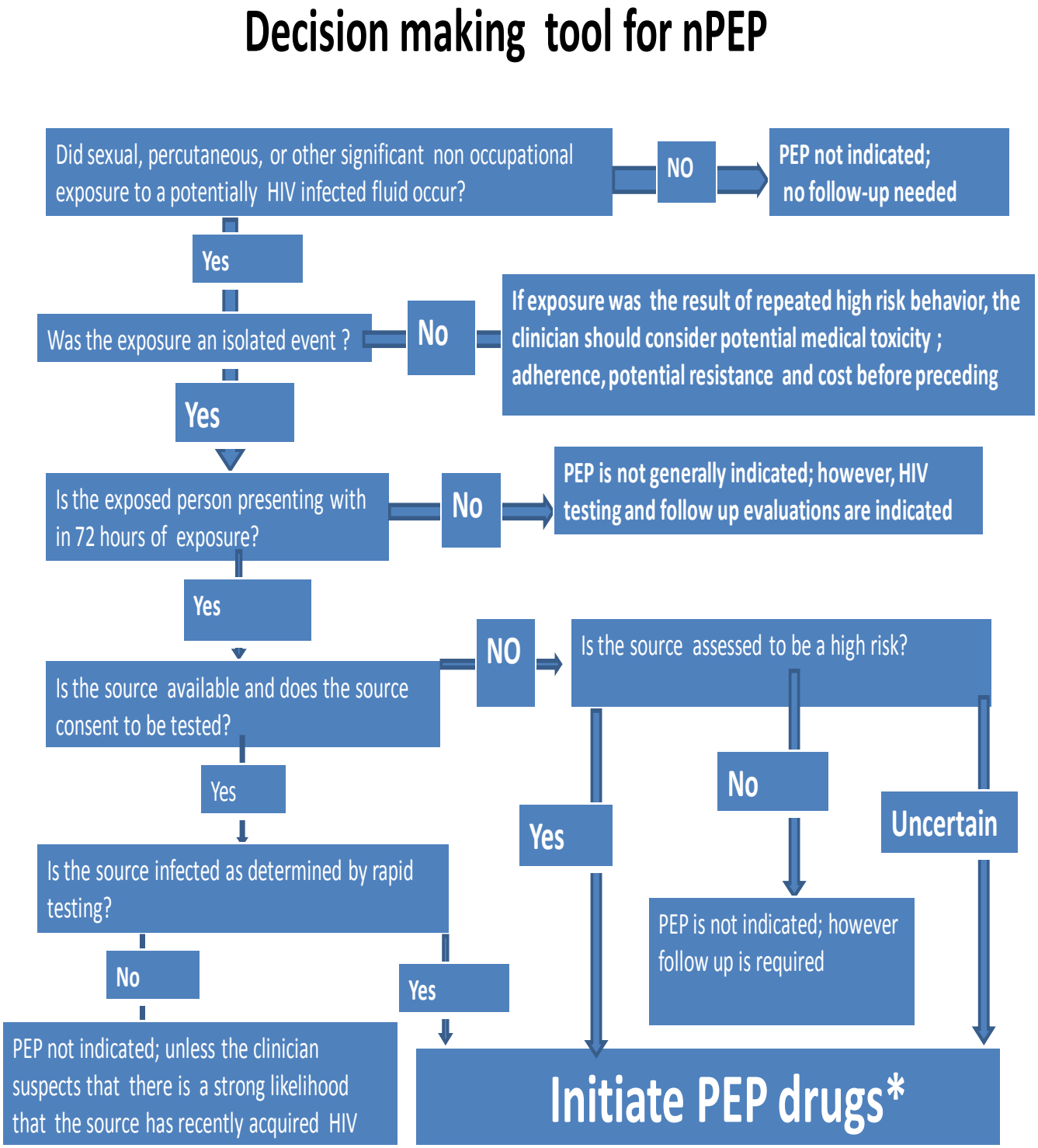
Currently available data pertaining to the issue, indicates that nPEP is less likely to be effective, if initiated longer than72 hours after HIV exposure. If initiation of nPEP is delayed, the likelihood of benefit might not outweigh the risks inherent in taking antiretroviral medications. However, in the case of ongoing sexual assault that occurs over a number of hours or days, the 72-hour time limit should be applied to the most recent potential exposure.

Therefore, clinicians should recommend HIV nPEP to survivors when significant exposure may have occurred, as defined by direct contact of the vagina, anus, or mouth with the semen or blood of the alleged assailant, with or without physical injury, tissue damage, or presence of blood at the site of the assault. Non-occupational PEP should also be offered in cases when broken skin or mucous membranes of the survivor have been in contact with blood or semen of the alleged assailant. Similarly, nPEP should be offered in cases of bites that result in visible blood.

HIV Status of Source

If possible, source persons should be tested for HIV. If the risk associated with the exposure is considered substantial, however, nPEP can be started pending determination of the HIV status of the source and then stopped if the source is determined to be none infected.

Figure 16.1 Algorithm for Evaluation and Treatment of Possible non Occupational HIV Exposures



a See Tables 16.4 and 16.5
b Decisions should be individualized, weighing the likelihood of transmission against the potential benefits and risks of treatment.
c In cases of sexual assault, the decision to initiate PEP is based on whether a significant exposure has occurred during the assault rather than on the risk behavior of the alleged assailant.
d If the source is known to be HIV infected, information about his/her CD4 count, viral load, ARV medication history, and history of ARV drug resistance should be obtained when possible to assist in selection of a PEP regimen.21
e The two regimens listed are essentially the same regimen because lamivudine and emtricitabine are interchangeable. The zidovudine + Truvada option has been added to increase access to the recommended PEP regimen and allow faster initiation of PEP, when indicated, based on the institution's availability of medications.
f If a sexual assault survivor is too distraught to engage in a discussion about the drug regimen or make a decision about whether to initiate treatment at the initial assessment, the clinician should offer a first dose of medication and make arrangements for a follow-up appointment within 24 hours to further discuss the indications for PEP.

CDC and DHHS (USA) guidelines recommend three PEP drug regimens for non occupational exposures. Classifying sexual exposures with risk of transmissions as high and a low risk as in the case of occupational exposures is very complicated. No evidence indicates that a three-drug HAART regimen is more likely to be effective than a two-drug regimen. The recommendation for a three-drug HAART regimen is based on the assumption that the maximal suppression of viral replication afforded by HAART (the goal in treating HIV-infected persons) will provide the best chance of preventing infection in a person who has been exposed. However, clinicians and patients who are concerned about potential adherence and toxicity issues associated with a three-drug HAART regimen might consider the use of a two-drug regimen (i.e., a combination of two reverse transcriptase inhibitors). Regardless of the regimen chosen, the exposed person should be counseled about the potential associated side effects and adverse events that require immediate medical attention. The use of medications to treat symptoms (e.g. antiemetic or ant motility agents) might improve adherence in certain instances.

Patients who have been sexually assaulted will benefit from supportive services to improve adherence to nPEP and from psychological and other support as required. All sexually assaulted patients should be tested for STIs and be provided with prophylaxis for sexually transmitted infections if needed (CDC STI guidelines, 2002). On the other hand, women who might become pregnant should be offered emergency contraception (Trussel K *et al*., 1997)**.**

Because of the emotional, social, and potential financial consequences of possible HIV infection, clinicians should handle nPEP evaluations with the highest level of confidentiality.

Bite injuries represent another potential means of transmitting HIV. However, HIV transmission by this route has rarely been reported (Wahn V *et al.,* 1986; Lancet, 1987; Vidmar L *et al.,* 1993). Transmission might theoretically occur through biting or receiving a bite from an HIV-infected person. Biting of an HIV-infected person resulting in a break in the skin exposes the oral mucous membranes to infected blood. This again implies that being bitten by an HIV-infected person exposes non intact skin to saliva. Saliva contaminated with infected blood poses a substantial exposure risk. However, saliva not contaminated with blood contains HIV in much lower titers and constitutes negligible exposure risk (Richman KM *et al.,* 1993).

Determining the degree of risk of HIV transmission is an important factor in guiding the patient and clinician in making a decision concerning nPEP. Non-occupational PEP should not be prescribed when there is negligible or low risk of HIV transmission. Table16.3 lists types of exposures that do not warrant nPEP and those that should prompt consideration of nPEP.

Table 16.5: Considerations of nPEP According to the type of risk exposure

Types of exposures that do not warrant nPEP	Types of exposures that should prompt considerations of nPEP
• Human bites not involved with blood • Exposure to sharps and needles not in contact with an HIV infected or at risk person • Mutual masturbation without skin break • Oral-anal contact • Receptive penile–oral contact without ejaculation • Insertive penile-oral contact • Oral-vaginal contact without blood exposure	• Unprotected receptive and insertive vaginal or anal intercourse with a source that is HIV-infected or at risk for HIV infection • Unprotected receptive penile-oral contact with ejaculation with a source that is HIV infected or at risk of HIV infection • • Oral-vaginal contact with blood exposure • • Needle sharing with a source known to be HIV infected or at risk for HIV infection • Injuries with exposure to blood from a source known to be HIV infected or at risk for HIV infection (including needle sticks, human bites and accidents)
This risk estimate considers many factors, including source viral load, presence of STDs and presence of ejaculates. It is prudent to recommend nPEP for receptive oral sex with ejaculation although discussion about the conflicting data should occur	

The recommendation for nPEP should be communicated simply and clearly to the patient, considering his/her emotional state and ability to comprehend the nature of ARV treatment. If a sexual assault survivor is too distraught to engage in a discussion about the drug regimen or make a decision about whether to initiate treatment at the initial assessment, the clinician should offer a first dose of medication and make arrangements for a follow-up appointment within 24 hours to further discuss the indications for nPEP. Other aspects of PEP service and follow up of patients who started PEP after non occupational exposure is practically similar to that of occupational exposure.

Note:
Provision of PEP service for people reporting unanticipated sexual intercourse with out condoms, condom breaks or sharing of needles in settings of intravenous drug use, is not generally recommended. Furthermore, it should not also be given especially in cases of chronic exposure because of concerns that this might negatively affect the general endeavors of prevention of HIV, gives way for unacceptable burden on health care facilities and the healthcare system including its consequence on logistics related to ARV drugs. The use of PEP in chronic exposures due to repeated high risk behavior, also poses significant risk of developing drug resistant HIV strains. Non-occupational PEP should not also be used as a pre-exposure prophylactic measure to prevent HIV transmission in a woman wishing to become pregnant with an HIV-infected male partner, or as prophylaxis for any person who plans to engage in high-risk behavior.

Clinicians should refer patients to mental health and/or substance use programs as necessary and should consider the need for intensive risk-reduction counseling services

II. EXPOSURE TO HEPATITIS B VIRUS

HBV infection is a well recognized occupational risk for HCP (Mast EE *et al.,* 1993). The risk of HBV infection is primarily related to the degree of contact with blood in the work place and also to *hepatitis B e antigen* (HBeAg) status of the source person. In studies of HCP who sustained injuries from needles contaminated with blood containing HBV, the risk of developing clinical hepatitis, if the blood was both hepatitis B surface antigen (HBsAg) and HBeAg-positive was 22% to 31%; the risk of developing serologic evidence of HBV infection was 37% to 62%. By comparison, the risk of developing clinical hepatitis from a needle contaminated with HBsAg-positive, HBeAg-negative blood was 1% to 6%, while the risk of developing serologic evidence of HBV infection was 23% to 37% (Werner BG *et al.*, 1982).

Blood contains the highest HBV titers of all body fluids and is the most important vehicle of transmission in the healthcare setting. HBsAg is also found in several other body fluids, including breast milk, bile, cerebrospinal fluid, feces, nasopharyngeal washings, saliva, semen, sweat, and synovial fluid (Bond WW *et al.,* 1977). However, the concentration of HBsAg in body fluids can be 100 to 1000 fold higher than the concentration of infectious HBV particles. Despite the presence of HBsAg, most body fluids are not efficient vehicles of transmission because they contain low quantities of infectious HBV.

In serologic studies conducted in the United States during the 1970s, HCP had a prevalence of HBV infection approximately 10 times higher than the general population (Segal HE *et al*., 1976; Denes AE *et al.,* 1978; Dienstag JL *et al.,* 1982). Because of the high risk of HBV infection among HCP, routine pre-exposure vaccination of HCP against hepatitis B and the use of standard precautions to prevent exposure to blood and other potentially infectious body fluids have been recommended in the US since the early 1980s. Since the beginning of the practice according to the recommendations, a sharp decline has been observed in the incidence of HBV infection among HCP in United States.

The effectiveness of hepatitis B immune globulin (HBIG) and/or hepatitis B vaccine in various post exposure settings has been evaluated by prospective studies. For perinatal exposure to an HBsAg, HBeAg-positive mother, a regimen combining HBIG and initiation of the hepatitis B vaccine series at birth is 85% to 95% effective in preventing HBV infection (Beasley RP *et al*., 1983; Stevens CE *et al.,* 1985). Regimens involving either multiple doses of HBIG alone or hepatitis B vaccine series alone are 70% to 75% effective in preventing HBV infection (Beasley RP *et al*., 1983). In the occupational setting, multiple doses of HBIG initiated within a week following percutaneous exposure to HBsAg-positive blood provide an estimated 75% protection from HBV infection (Grady GF *et al.,* 1978; Seeff LB, 1977; Prince AM *et al.*, 1975). Although the post exposure efficacy of the combination of HBIG and hepatitis B vaccine series has not been evaluated in the occupational setting, the increased efficacy of this regimen observed in the perinatal setting compared with HBIG alone, seems to reflect its applicability to the occupational setting as well. Because persons requiring PEP in the occupational setting are generally at continued risk for HBV exposure, they should receive the hepatitis B vaccine series.

Hepatitis B vaccine should always be administered by the intramuscular route in the deltoid muscle with a needle 1 to 1.5 inches long. This vaccine can be administered at the same time other vaccines are given for it has no interference with antibody response to other vaccines (Coursaget P *et al*., 1986). If the vaccination series is interrupted after the first dose, the second dose should be administered as soon as possible. The second and third doses should be separated by an interval of at least 2 months. If only the third dose is delayed, it should be administered when convenient. HCP who have contact with patients or blood and are at ongoing risk for percutaneous injuries should be tested 1.2 months after completion of the 3 dose vaccination series for anti-HBs. Persons who do not respond to the primary vaccine series (i.e. anti-HBs <10 mIU/mL) should complete a second 3 dose vaccine series or be evaluated to determine if they are HBsAg-positive.

Revaccinated persons should be retested at the completion of the second vaccine series. Persons who do not respond to an initial 3 dose vaccine series have a 30% to 50% chance of responding to a second 3 dose series (Hadler SC *et al*., 1986). Persons who have proved to be HBsAg-positive should be counseled regarding how to prevent HBV transmission to others and regarding the need for medical evaluation. Non responders to the vaccination who are HBsAg-negative should be considered susceptible to HBV infection and should be counseled regarding precautions to prevent HBV infection and the need to obtain HBIG prophylaxis for any known or probable parentral exposure to HBsAg-positive blood.

Booster doses of hepatitis B vaccine are not necessary and periodic serologic testing to monitor antibody concentrations after completion of the vaccine series is not recommended. Any blood or body fluid exposure sustained by an unvaccinated and susceptible person should lead to the initiation of the hepatitis B vaccine series (CDC guidelines on PEP for HBV and HCV exposures 2001).

The recommended post exposure prophylaxis for exposure to hepatitis B virus is attached as **Appendix D-5**.

It is recommended that healthcare workers should be vaccinated for HBV.

III. EXPOSURE TO HEPATITIS C VIRUS

The risk of HCV transmission from a percutaneous exposure is approximately 1.8% (Alter MJ, 1997; Lanphear *et al.,* BP 1994; Puro V *et al.,* 1995; Mitsui T *et al*., 1992). HCV is rarely transmitted from mucous membrane exposure to blood and it has never been documented as occurring as a consequence of a blood exposure to intact or non-intact skin. Therefore, there is no known PEP to HCV exposure. Nonetheless, a 2001 NEJM study found that treatment of patients with acute HCV with interferon alpha-2b led to resolution of HCV viremia in 98% of patients.

The CDC recommends follow-up testing for an exposure to HCV with anti-HCV antibody testing within 4 to 6 months. So it is resolved that a positive antibody test should prompt HCV viral load and liver function tests. Once exposure is confirmed, the management and follow up of non occupational HCV exposure is similar to that of the occupational exposure.

DOCUMENTATION OF PEP SERVICE GIVEN

Each person with occupational HIV exposure should report the incidence to his immediate supervisor. Initial PEP management should be given with in the case team and the exposed person is referred to the ART clinic for further follow up. Documentation of exposure and management given should be done by using potential HIV exposure documentation and follow up form (**Appendix D-6)** which would be attached with the patient chart. The person who gives PEP service should be trained on PEP service delivery (or a training with a PEP management component) for he/she is responsible for completing the potential HIV exposure documentation and follow up form (**Appendix D-6**), attach it with the patient chart and utilize the PEP decision-making tools (job aid) to determine indications for PEP and decide on the use of two or three drug regimens.

If PEP is not indicated, the PEP trained service provider (preferably case team leader) will file the completed Potential HIV exposure documentation and follow up form (**Appendix D-6**) with the patient chart and indicate to the exposed person that no further follow-up is needed. The incident and the service given should also be documented on service register in the service outlet.

Note:

An authorized PEP focal person will collect data on HIV exposures and PEP uptakes from each case team from the service register in each service outlets.

If PEP is indicated, the exposed person will be given appointment to visit the ART clinic on the next working day. The PEP's focal person will daily follow the number of: people who reported exposure to HIV, persons who started on PEP starter dose and people who came to ART clinic for follow up. If there are people who fail to come to follow up after taking the PEP starter dose the focal person will do telephone tracking (or physical tracking) in the case of occupational exposure to ensure follow up. The focal person can get the names and medical record number (MRN) of clients who got service for HIV exposure from the register put on the service outlet. The telephone number of the people who got PEP service exposure can be accessed from potential HIV exposure documentation and follow up form which is put in the patient card.

In the ART clinic, the persons getting PEP service will have a minimum of six follow up visits and each time the patient comes for visit, HIV exposure documentation and follow up form which is attached with the patient's chart and the PEP register (**Appendix D-7)** placed in the ART clinic are updated. Documentation and reporting of PEP service given for non occupational exposure will be similar to that of occupational exposure.

MONITORING & EVALUATION OF PEP SERVICE IN HEALTH FACILITIES

The PEP's focal person in the health facilities is expected to regularly (best daily) monitor the availability of inputs (as listed below) and supplies necessary to provide PEP services. The quality of PEP services in each case team depends on the efficiency of referral linkages for patients who started PEP drugs; the completeness of HIV exposure documentation; and follow up form and PEP registries in the ART clinic. The PEP's focal person should be an active member of the health facility, ART multidisciplinary team, infection prevention committees and participate in meetings with the MDT and IP committees at least monthly.

While the initial data documentation will be handled in the respective case teams, PEP program monitoring and evaluation will be managed by Healthcare facilities MDT and Infection Prevention & Control Committee (IPC). The PEP's focal person is expected to collect data on all HIV exposures and PEP services given preferably on daily bases and compile a monthly report based on the reporting form.

After data collection, the PEP's focal person will use the data to work with health facility ART, MDT and IP committees to improve occupational safety and PEP service delivery in the health facility. Then program evaluation questions should be discussed and answered using the inputs from Health Facility MDT and IPC Committee members before summary evaluation is given to medical director on a quarterly basis. Problems or inconsistencies with service provision, reporting, ART availability, etc., should be addressed immediately by the PEP's focal person and the committees.

1. Inputs Required for PEP Service

1.1 All Service Outlets

- The required IP supplies and health facility infrastructure must be made available in every service outlet as mentioned in other sections of this chapter.

1.2 PEP Outlets

- HCWs trained on PEP management assigned during both regular and non-regular working hours
- The recommended PEP drugs, potential exposure and PEP service follow up form and other job aids should be available in each case team. As listed in **Appendix D-9**. Check list of inputs required for standard PEP service delivery in health care facilities.

1.3 ART Clinic

- The PEP register should be available in the ART clinic and preferably this should be the primary place of operation for the PEP focal person.

2. Monitoring the Process

The health facility management will monitor the process of the PEP program implementation as follows:

- The availability of all input materials for giving comprehensive PEP service.
- The continuous availability of PEP services both at regular and non-regular working in each case team.
- The adherence of HCWs to the national PEP guideline or implementation guideline.
- The presence of regular (monthly) health facility MDT and IP committee meetings.
- The minutes of MDT and IP committees.
- Reporting system for the MDT and IP committees to the health facility management.
- The implementation of operational (action) plans developed for PEP following MDT and IP committee meetings.

3. **Out Put**

The health facility management will also be responsible for following PEP program outputs:

- The number of occupational and non-occupational exposures reported in the health facility.
- From non occupational exposures, the number of cases of sexual violence and other non occupational cases disaggregated.
- The age, sex, and occupation (including case team) of workers reporting an exposure.
- The number of people that started PEP treatment.
- The number of people that completed the PEP treatment.
- The number of people that received 6 weeks, 3 months or 6 month post-exposure HIV test.

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CHAPTER 17: ISOLATION PRECAUTIONS FOR HEALTHCARE FACILITIES

KEY TOPICS TO BE DISCUSSED:

- Reasons for the Transmission-Based Precautions.
- Purposes of transmission-Based Precautions.
- What Recommended preventive processes and practices for each route of infection transmission.
- Ways of effectively using Transmission-Based Precautions.

BACKGROUND

Although the spread of infectious disease in hospitals has been recognized for many years, understanding on how to prevent these infections and implementing the successful remedial policies and practices have so far been not easy. Isolation guidelines involve a two level approach: Standard Precautions, which apply to all clients and patients attending healthcare facilities on the one hand, and Transmission-Based Precautions which apply primarily to hospitalized patients on the other (Garner & HICPAC, 1996). Actually, either approach is too interlinked to be used in separation. Thus, the relatively specific approach-transmission-based precautions must be used in conjunction with the Standard Precautions.

TRANSMISSION BASED PRECAUTIONS

Transmission-Based Precautions are for patients who are known or suspected to be infected or colonized with infectious agents including certain epidemiologically important pathogens which require additional control measures to effectively prevent transmission. Since the infective agent is not often known at the time of admission to a healthcare facility, Transmission-Based Precautions are used empirically according to the clinical syndrome and the likely etiologic agents at the time. Later, the course of management would be modified when the pathogen is identified or a transmissible infectious etiology is ruled out.

THERE ARE THREE MAJOR ROUTES OF TRANSMISSION OF INFECTIOUS DISEASES:

- Airborne
- Droplet
- Contact.

Note:
For some diseases that have multiple routes of transmission, more than one Transmission-Based Precautions category may be used.

When used either individually or in combination, each routes of transmission based precautions are always used in addition to Standard Precautions. When Transmission-Based Precautions are indicated, efforts must be made to counteract possible adverse effects on patients (i.e. anxiety, depression and other mood disturbances, perceptions of stigma, reduced contact with clinical

staff, and increase in preventable adverse events in order to improve acceptance by the patients and adherence by Healthcare workers).

AIRBORNE PRECAUTIONS

Airborne Precautions prevent transmission of infectious agents that remain infectious over long distances (particles which are 5μm or less in size and can remain in the air for several hours and be widely dispersed). These precautions are effective in preventing infections like Tuberculosis, Chicken pox and measles. They are recommended for patients with either known or suspected infections that could be transmitted by airborne route. The precautions include:

Patient Placement

- Patients should be placed in airborne infection isolation room (AIIR). An AIIR is a single-patient room that is equipped with special air handling and ventilation capacity (i.e. a facility which could create negative pressure relative to the surrounding area, 12 air exchanges per hour for new construction and renovation and 6 air exchanges per hour for existing facilities, air exhausted directly to the outside, etc). In a setting where resources are limited, the air in the room should be exhausted to the outside using a fan or other filtration system keeping the door closed all the time.
    - If private room not available, place patients in a room with patient having active infection with the same disease, but with no other infection (cohorting).
    - The staff on duty should check all visitors for susceptibility before allowing them to visit.

Respiratory Protection

- Wear a respirator (N95 or equivalent mask or at least a surgical mask if respirator not available).
- In case of chickenpox or measles, no mask is needed for immune persons but susceptible persons should not be allowed to enter the room.
- Remove respirator or surgical mask after leaving the room and place in a plastic bag or waste container with tight-fitting lid.
- Patient Transport.
- Limit transport of patient to essential purposes only.
- During transport, patient must wear a surgical mask.
- Notify the area receiving the patient.
- In areas where TB is prevalent, it is important to devise a mechanism to quickly assess patients with suspected TB and put them under airborne precautions.

DROPLET PRECAUTIONS

These precautions reduce the risks of transmission of pathogens spread wholly or partly by droplets larger than 5μm in size (e.g. *H. influenza* & *N. Meningitides*, *M. pneumonia*, flu,

mumps, and rubella viruses). Other conditions include Diphtheria, Pertussis, Pneumonic Plague and *S. pharyngitis*.

The droplet precautions are simpler than airborne precautions as particles remain in the air for a short time and travel only a few feet:

- Patient placement.
- Private room, door may be left open.
- If private room is not available, place the patient in a room with patient having active infection with the same disease, not with other infection.
- If neither option is available, maintain over 3 feet spatial separation between patient beds and drawing the curtain between patient beds is especially necessary for patients in multi-bed.
- Respiratory protection.
- Wear mask if within a meter (3 feet) of patient.
- Patient transport.
- Limit transport of patient to essential purposes only.
- During transport, patients must wear surgical mask.
- Notify area receiving patients

CONTACT PRECAUTIONS

Contact precautions are indicated for patients infected or colonized with enteric pathogens, herpes simplex and hemorrhagic fever viruses and multidrug resistant bacteria. Chicken pox is spread both by the airborne and contact routes at different stages of illness. Contact precautions should be implemented for patient with wet or draining infection that may be contagious (e.g. draining abscesses, herpes zoster, impetigo, conjunctivitis, scabies, lice and wound infection).

Use the above approach in addition to Standard Precautions for patients known or suspected to be infected or colonized with microorganisms transmitted by direct contact with the patient or indirect contact with environmental surfaces or patient care items.

Patient Placement

A single patient room is preferred to others for patients who desire it; the door may be left open in this case. If private room is not available, place the patient in a room with patient having active infection with the same microorganism, not with other infections (cohorting).In multi-patient rooms, more than 3 feet spatial separation between patient beds is advised to reduce the opportunities for inadvertent sharing of items between the infected/colonized patient and other patients.

Gloving

- Wear clean, non sterile examination gloves or reprocessed surgical gloves when entering room.

- Change gloves after contact with infectious materials (or moving from one site to another).
- Remove gloves before leaving patient room.

Hand washing

- Wash hands with antimicrobial agent, or use alcohol hand rub before entering room and after removing gloves (if patient has *C. difficile* diarRhesus factorea need to wash hands with soap and water after removing gloves).
- Do not touch potentially contaminated surfaces or items before leaving the room.

Gowns and protective apron

- Wear clean, non sterile gown when entering patient room if patient contact is anticipated or patient is incontinent, has diarrhea, an ileostomy, colostomy or wound drainage not contained by dressing.
- Remove gown after leaving the room. Do not allow clothing to touch the potentially contaminated surfaces or items before leaving the room.

Patient Transport

- Limit transport of patients to essential purposes only.
- During transport, ensure precautions that are maintained to minimize risk of transmission of organisms (i.e. cover patient with clean linen not what was used on patients' bed).

Patient care equipment

- Reserve non-critical patient care equipment for use with a single patient if possible, otherwise process as per guidelines.
- Clean and disinfect any equipment shared among infected and non-infected patients after each use.

EMPIRICAL USE OF TRANSMISSION-BASED PRECAUTIONS

If there is any question of an infectious process in a patient without known diagnosis, implementing Transmission-Based Precautions should be considered depending on the patient's sign and symptoms until a definitive diagnosis is made later.

A complete listing of clinical syndromes or conditions warranting the empirical use of Transmission- based precautions is presented in **Table 17.1**. See also **Appendix E** for Types and duration of precautions recommended for selected infections and conditions.

Table 17.1 Clinical Syndromes or Conditions to be Considered for "Empirical Use" of Transmission-Based Precautions

CLINICAL SYNDROME OR CONDITION[a]	POTENTIAL PATHOGENS[b]	EMPIRICAL PRECAUTIONS
Diarrhea		
Acute diarrhea with a likely infectious cause in an incontinent or diapered patient	Enteric pathogens[c]	Contact
diarrhea in an adult with a history of recent antibiotic use	*Clostridium difficile*	Contact
Meningitis	*Neisseria meningitidis*	Droplet
Rash or exanthems, generalized, etiology unknown		
Petechial/echymotic with fever	*Neisseria meningitidis*	Droplet
Vesicular	*Varicella* (chicken pox)	Airborne and Contact
Maculopapular with coryza and fever	Rubeola (measles)	Airborne
Respiratory infections		
Cough/fever/upper lobe pulmonary infiltrate in an HIV-negative patient or a patient at low risk for HIV infection	*Mycobacterium tuberculosis*	Airborne
Cough/fever/pulmonary infiltrate in any lung location in an HIV-infected patient or a patient at high risk for HIV infection	*Mycobacterium tuberculosis*	Airborne
Paroxysmal or severe persistent cough during periods of pertussis activity	Bordetella pertussis	Droplet
Respiratory infections, particularly bronchiolitis and croup, in infants and young children	Respiratory syncytial or parainfluenza virus	Contact
Risk of multidrug-resistant microorganisms		
History of infection or colonization with multidrug-resistant organisms[d]	Resistant bacteria[d]	Contact
Skin, wound or urinary tract infection in a patient with a recent hospital or nursing home stay in a facility where multidrug-resistant organisms are prevalent	Resistant bacteria[d]	Contact

CLINICAL SYNDROME OR CONDITION[a]	POTENTIAL PATHOGENS[b]	EMPIRICAL PRECAUTIONS
CLINICAL SYNDROME OR CONDITION[a]	**POTENTIAL PATHOGENS[b]**	**EMPIRICAL PRECAUTIONS**
Skin or wound infection	*Staphylococcus aureus,* group A streptococcus	Contact

[a] Patients with the syndromes or conditions listed below may present with atypical signs or symptoms (e.g. *Pertussis* in neonates and adults may not have paroxysmal or severe cough). The clinician's index of suspicion should be guided by the prevalence of specific conditions in the community, as well as clinical judgment.

[b] The organisms listed under the column "Potential Pathogens" are not intended to represent the complete, or even most likely, diagnoses, but rather possible etiologic agents that require additional precautions beyond Standard Precautions until they can be ruled out.

[c] These pathogens include entero-hemorrhagic *Escherichia coli* O157:H7, *Shigella,* hepatitis A and rotavirus.

[d] Resistant bacteria judged by the infection control program, based on current state, regional or national recommendations, to be of special clinical or epidemiological significance.

Adapted from: Garner and HICPAC 1996.

RESPIRATORY HYGIENE/COUGH ETIQUETTE

The following measures taken to contain respiratory secretions are recommended for all individuals (staff, patients and visitors) with signs/symptoms of a respiratory infection.

- Cover the nose/mouth when coughing or sneezing; attempt to confine the coughed up/sneeze droplets on to the sleeve are better than on the hands.
- Use tissue paper to contain respiratory secretions and dispose of the tissue in the nearest waste container after use;
- Perform hand hygiene (e.g. hand washing with non-antimicrobial soap and water, waterless, alcohol-based antiseptic hand rub, or antiseptic hand wash) after having contact with respiratory secretions and contaminated objects/materials.

Health care facilities should ensure the availability of materials for adhering to respiratory hygiene/cough etiquette in waiting and service provision areas for patients and visitors:

- Provide tissue papers and avoid touching waste containers for tissue disposal.
- Provide conveniently located dispensers of alcohol-based hand rub where sinks are available, ensure that supplies for hand washing (i.e. soap and disposable towels) are consistently available.
- Provide masks for anyone who is coughing (patients and visitors).

When possible, encourage persons in common waiting areas who are coughing to sit at least 3 feet (or a meter) away from others.
Post visual alerts at the entrance to and inside the outpatient facilities (e.g. emergency departments, physician offices, outpatient clinics) with instructions to patients and persons accompanying them to practice respiratory hygiene/cough etiquette and inform a staff member of their symptoms as soon as possible. Generally, a person having a cough should be provided with a mask.

Message to Give Patients and Visitors

Serious respiratory illnesses like influenza, respiratory Syncytial virus (RSV), Whooping cough, and SARS are spread by:

- Coughing or sneezing.
- Unclean hands.

To help stop the spread of germs,

- Cover your mouth and nose with a tissue when you cough or sneeze.
- If you don't have a tissue, cough or sneeze into your upper sleeve, not your hands.
- Put your used tissue in the waste container.

Clean your hands after coughing or sneezing

- Wash with soap and water, or
- Clean with alcohol-based hand rub.

N.B You may be asked to put on a surgical mask to protect others.

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CHAPTER 18: TUBERCULOSIS (TB) INFECTION PREVENTION AND CONTROL

KEY TOPICS TO BE DISCUSSED:

- Ways of the spread of TB in the Healthcare facilities.
- Rationale for the primacy of the prevention of TB at healthcare facilities.
- Ways of minimizing the risk of transmission of TB transmission in healthcare facilities.

BACKGROUND

Healthcare workers are at increased risk of TB infection and disease compared to the general population. TB is the most common opportunistic infection and a leading cause of death in persons living with HIV/AIDS (PLWHA). Between 30% and 40% of PLWHA living in high burden TB settings, will develop TB in their lifetime. Ethiopia, ranking 7th among the 22 high morbidity burdened countries with TB infection, is reporting a huge number of TB cases annually. In 2008/9, for instance, the country had reported about 148,924 people with all forms of TB. According to the data from FMoH, TB is the third most important cause of hospital admission. The emergence of MDR TB and TB/HIV co-infection calls for the implementation of adequate infection prevention measures in healthcare settings.

WHO has recommended specific interventions to prevent TB and thereby reduce burden due to TB infection especially in countries with high prevalence of both TB and HIV. These interventions include 3 'I's": **Intensified Case Finding**, **Infection Control of TB**, and **Isoniazid Preventive Therapy**-even with the limitations and constraints of current diagnostic technologies. Case finding promotes early start of tuberculosis treatment which reduces HIV-related tuberculosis infection and death and simultaneously contributes to infection control by reducing transmission of tuberculosis in communities and health facilities. Isoniazid preventive therapy treats latent tuberculosis infection thereby reducing progression to active disease and simultaneously prevents newly engendering infections from becoming established. These interventions have been promoted by WHO since 2008. Since then, it has been endorsed by Ministries of Health in many countries with the development of official national guidelines mirroring the recommendations of WHO. A lot of work has to be done at the ground level to implement these recommendations and guidelines. A key missing piece has been a local champion to guide the implementation at the facility level.

DEFINITIONS

Control - a process of measure used to minimize the risk of spreading TB in a given population.

Droplet Nuclei - airborne are particles that carry *Mycobacterium tuberculosis*. Droplet nuclei are generated from people having pulmonary or laryngeal TB disease and are aborted byway of coughing, sneezing, shouting or singing. The particles are approximately 1-5μm; normal air currents can keep them airborne for a long time and let them spread throughout a room or building. Droplets are generally greater than 5μm in diameter. Droplets settle faster than droplet nuclei and do not reach the alveoli when inhaled.

Infection Control Assessment - an assessment of the implementation of managerial activities (including risk assessment); administrative and environmental controls; and respiratory protective equipment in a setting and context of local epidemiological, climatic and socioeconomic activities.

Infectious Case - smear-positive cases are the most infectious and likely to transmit TB infection to others. Nonetheless, it should also be noted that smear-negative but culture-positive cases can transmit TB.

Laboratory Bio-Safety - an infection control measures related specifically to laboratory environment dealing with the relative risk of exposure to biological agents, hazardous chemicals and laboratory procedures.

Measures - these include the set of managerial activities, administrative controls, environmental controls and personal protective equipment for TB control.

Mechanical Ventilation - ventilation created using an air supply or an exhaust fan to force air exchange and to drive airflow. Such ventilation works by generating negative or positive pressure in the room to drive air changes. To be effective, all doors and windows must be kept closed with controlled air leakage into or out of the room.

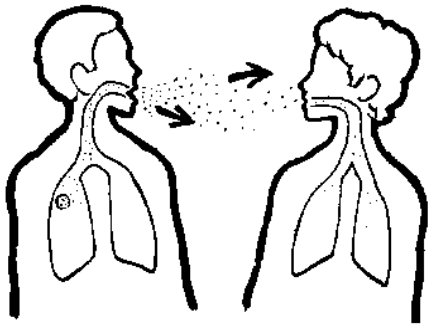
Natural Ventilation - ventilation created by the use of external natural forces such as wind and temperature. Control of airflow direction cannot be achieved by simple natural ventilation. Rather, it depends on sufficient wind speed or direction or temperature differential.

Triage - a system in the context of TB infection control devised to identify people with TB symptoms based on cough. Triage is used in fast-tracked TB diagnosis and further separation when necessary.

PATHOGENESIS AND TRANSMISSION OF TB

TB is caused by *M tuberculosis.* People who have TB disease in their lungs can release tiny particles containing *M. tuberculosis* into the air during coughing, sneezing and speaking. These particles are called droplet nuclei. They are invisible to the naked eye. Droplet nuclei can remain airborne in room air for many hours until they are removed by natural or mechanical ventilation. For TB infection to spread there must be a source-a person with TB disease who produces *M. tuberculosis*, and an exposed person to inhale droplet nuclei containing the bacteria. Although TB is not usually spread by a brief contact, anyone who shares air with a person with TB disease of the lungs in an infectious stage is at risk of inhaling it. A person who inhales one or more of the droplet nuclei can become infected with *M. tuberculosis*. The source of TB infection is a person with active pulmonary TB. Patients with smear-positive pulmonary TB shed TB bacilli in the community.

Figure 18.1 How far droplets of TB Travel



Tb Infection Control Strategies

There are three levels of infection control (IC) measures: administrative (managerial), environmental, and personal respiratory protection. Administrative controls are the most important since environmental controls and personal respiratory protection will not work in the absence of solid administrative control measures. Each level operates at a different point in the transmission process:

- Administrative controls reduce HCW and patient exposure.
- Environmental controls reduce the concentration of infectious droplet nuclei.
- Personal respiratory protection protects HCWs in areas where the concentration of droplet nuclei cannot be adequately reduced by administrative and environmental controls.

1st Priority	**Administrative Controls**
2nd Priority	**Environmental control**
3rd Priority	**Personal protective measures**

ADMINISTRATIVE (MANAGERIAL) CONTROLS

The first and most important level of control is the use of administrative control measures to prevent droplet nuclei from being generated and thus reducing the exposure of HCWs and patients to *M. tuberculosis*. Ideally, if the risk of exposure can be eliminated, no further controls are needed. Unfortunately, the risk cannot usually be eliminated but can significantly be reduced with proper administrative measures. Important administrative measures include: early diagnosis of potentially infectious TB patients; prompt separation or isolation of infectious TB patients; and prompt initiation of appropriate anti-tuberculosis treatment. Other important measures include: an assessment of the risk of transmission in the facility; the development of an IC plan that details in writing the measures that should be taken in a given facility; and adequate training of HCWs to implement the plan. In general, the IC plan should include: identification of risk areas and assessment of TB among HCWs (where feasible), HIV prevalence in the patient population (where feasible), HCW training needs, area-specific infection control recommendations, time-line and budget (e.g. material and personnel costs). Further, it is necessary that an individual be assigned responsible and authorized to monitor the implementation of the IC plan.

Table 18.1 Management of Patients to Prevent Transmission of TB in Community and Healthcare Settings

Seven Steps for Patient Management to prevent transmission of TB in the Community and healthcare settings		
Step	**Action**	**Description**
1.	Screen	Early identification and detection of patients with suspected or confirmed TB disease is the first step in the protocol. This can be achieved by assigning a staff member in a health facility and trained community health workers to screen patients for prolonged duration of cough and take immediate action. Patients with cough of more than two weeks duration, or who report being under investigation or treatment for TB*, should not be allowed to wait in the line with other patients. Instead, they should be managed as outlined below.
2.	Educate	Educating the above-mentioned persons identified through screening, in cough etiquette and respiratory hygiene. This includes instructing them to cover their noses and mouths when coughing or sneezing, and when possible providing facemasks, handkerchiefs or tissues to assist them in covering their mouths. Respiratory hygiene includes proper disposal of tissues and masks. Patients and their families should also be educated on the signs and symptoms of TB disease.
3.	Separate into special waiting areas	Triaging symptomatic patients to the front of the line for the services they are seeking (e.g. voluntary HIV counseling and testing, medication refills) to quickly provide care and reduce the amount of time others are exposed to these patients, is recommended. Patients who are identified as TB suspects or cases by the screening questions should be directed to another separate waiting room away from other patients and be asked to wait in a separate well-ventilated waiting area and are provided with a surgical mask or tissues to cover up their mouths and noses while waiting.
4.	Triage and provision of the needed services	In an integrated service delivery setting, if possible, the patients should receive the necessary healthcare services they are accessing before TB investigation**.** Patients in special groups (known HIV positive very young and old) should be given priority in care. There fore, triaging symptomatic patients to the front of the line for the services should be done. In an integrated service delivery setting, known HIV patients should be separated from smear positive TB patients. Known HIV positive clients in the community should be frequently be monitored for TB and referred promptly.
5.	Investigate for TB or Refer	TB diagnostic tests should be done onsite, if this is not possible, the facility should have an established link with a TB diagnostic and treatment site to which symptomatic patients can be referred.

ENVIRONMENTAL CONTROL MEASURES

Since the exposure to infectious droplet nuclei cannot usually be eliminated, various environmental control methods can instead be used in high-risk areas to reduce the concentration of droplet nuclei in the air. Such measures include maximizing natural ventilation and controlling the direction of airflow. Environmental controls are second line defense to prevent the spread of TB in high risk settings. It is thus important to recognize that if work practice or administrative controls are inadequate, environmental controls will not eliminate the risk. Environmental controls include:

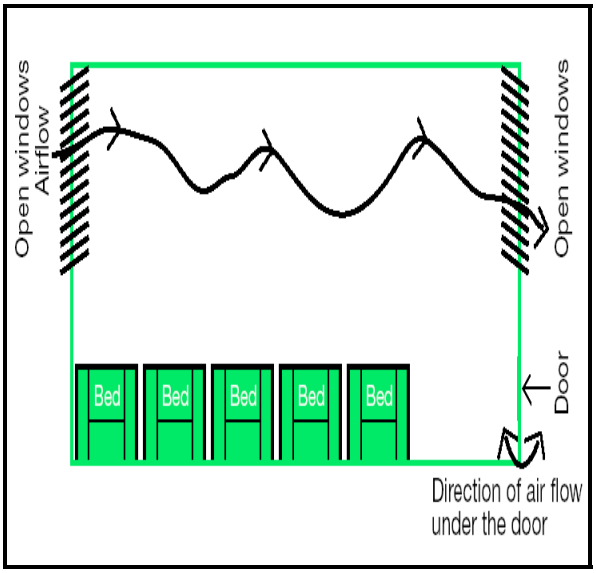
- Ventilation (natural and mechanical),
- Filtration, and
- Ultraviolet germicidal irradiation.

Many environmental control measures are technologically complex and expensive and hence are practical only in referral hospitals. Although these control measures are technologically complex and require expensive resources not available in most situations, controlled natural ventilation can still be used to reduce the risk of spreading *M. tuberculosis* (e.g. opening windows to increase natural ventilation and use of fans to control the direction of air flow) in resource-limited settings.

Natural Ventilation

Natural ventilation refers to fresh air that enters and leaves a room or an area through openings such as open doors and/or windows. Control occurs when openings are deliberately secured open to maintain air flow. Unrestricted openings (that cannot be closed) on opposite sides of a room provide the most effective natural ventilation. When fresh air enters a room it dilutes the concentration of particles in room air such as droplet nuclei containing *M. tuberculosis*.

Figure 18.2 The Direction of Air Flow



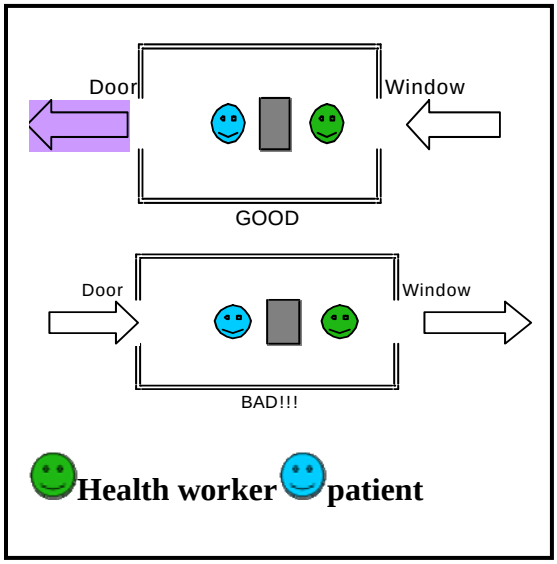


Figure 18.3 Proposed Alternative to Maximizes Natural Ventilation in Waiting Area of an Outpatient Clinic

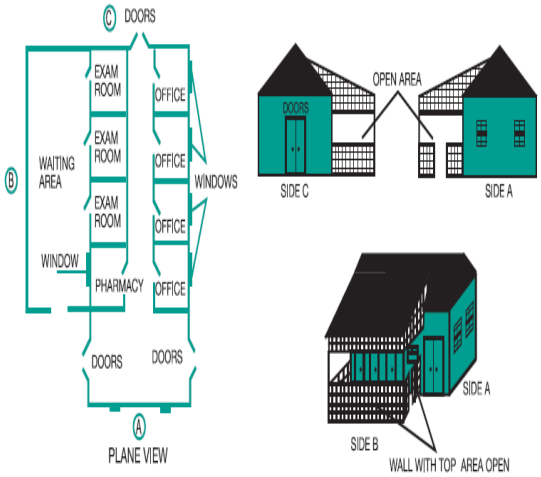
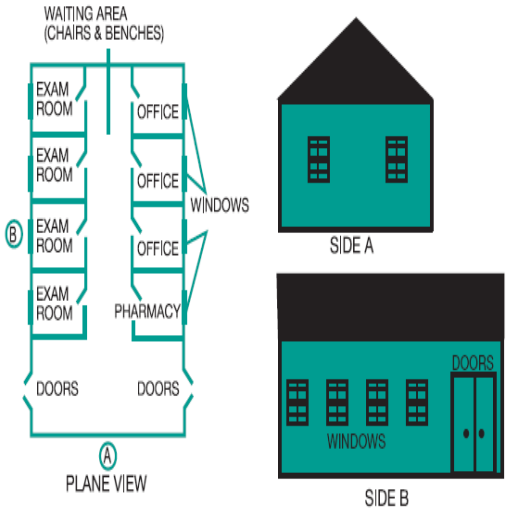


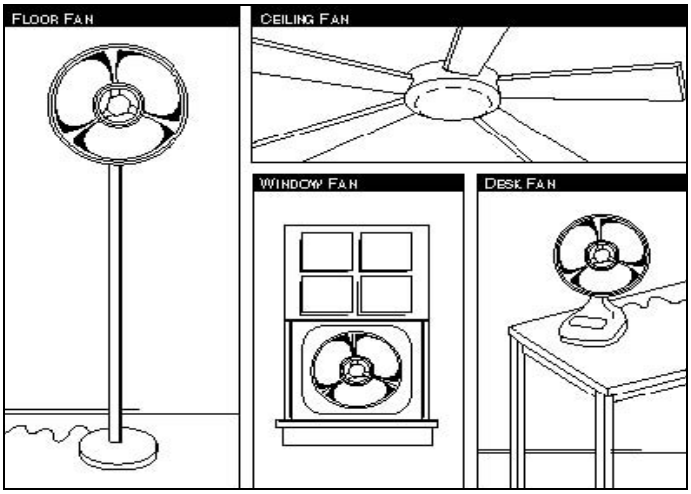
Figure 18.4 Poorly Ventilated Waiting Areas in an Outpatient TB Clinic



Mechanical Ventilation

In situations where natural ventilation is not feasible or is inadequate, mechanical ventilation can be used to reduce the concentration of infectious droplet nuclei in selected areas or rooms of the healthcare facility (e.g. patient rooms, waiting rooms, or examination rooms). It is also important to use equipment with sufficient power to facilitate air entry into and exhaust from the room or area.

Figure 18.5 Means of Mechanical Ventilation



Propeller fans include:

- Ceiling fans,
- Desk top small fans or those which can be posited on other surfaces,
- Fans that stand on the floor, and
- Fans mounted in a window opening.

Personal Respiratory Protection

The third recommended control measure is the protection of the HCW from inhaling infectious droplets through the use of personal respiratory protective devices which are designed to fit over the mouth and nose and filter out infectious TB particles. The type of surgical masks (cloth, paper) commonly used by HCWs do not filter out infectious droplet nuclei although they may be of some use if placed on patients to prevent the generation of such nuclei. Personal respiratory protective devices for HCWs that can adequately filter out infectious particles are more expensive than surgical masks which are the least effective of the three IC measures. Thus, they should not supplant more effective and less expensive IC measures. Rather, they should be used only in specialized settings (usually at the referral level) when all other IC measures have been fully implemented.

Respirators have very tiny pores and tight seal around the entire edge to be worn by health workers. Surgical masks on the other hand, have very large pores, no tight seal around and are to be worn by patients, not by health workers (**Refer to Figure 4.6**).

Laboratory Safety

- AFB smears preparation/sputum collection.
- Preparation of liquid suspension of MTB.
- Bio safety.
- Personal respiratory device in Lab.

TB INFECTION CONTROL PLAN

More people living with HIV are now attending health-care and community facilities than ever. These People are particularly vulnerable to developing TB disease if they become infected with *Mybacterium tuberculosis (M. Tb,* the germ that can causes TB) resulting from exposures in Health facilities. People with undiagnosed, untreated and potentially contagious TB are often so pervasive in HIV care settings.

Similarly, healthcare workers and other staff are also at particularly high risk of TB infection because of frequent exposure to patients with infectious and transmittable TB disease. Furthermore, healthcare workers and staff may themselves be immune-suppressed due to HIV infection and be at higher risk of developing TB disease once infected.

In accordance with the situation, each facility should have a written TB infection control plan/protocol of what is to be done and how to prevent TB infection in the facility. The protocol might include the following prompt recognition of TB, cough hygiene, separation, prompt provision of services, investigation for TB, and fast track of patients with suspected or confirmed TB disease.

The plan should designate a staff member as the infection control officer responsible to ensure that TB infection control procedures are implemented in the facility and correct any inappropriate practices or failure to adhere to institutional policies.

PREVENTION AND CONTROL OF MDR AND XDR TUBERCULOSIS

Drug-resistant tuberculosis poses a major threat to existing control programs since treatment is less effective, more complex, and far more costly than that of drug-susceptible Tuberculosis. Outbreaks of MDR and extensively drug-resistant (XDR) tuberculosis have emphasized the need for effective infection-control measures which are absent in most high-burden settings.

Efforts to address the epidemic of MDR and XDR tuberculosis have to prevent both acquired and primary resistance. Prevention of acquired resistance relies on early case finding and effective treatment by way of directly observed therapy, short course (DOTS) and Stop TB strategies aiming to improve treatment cure and completion rates and reduces failure and default. As compared to the former strategy, the prevention of transmission of drug-resistant strains focuses not only early identification and initiation of treatment but also infection control.

Transmission of tuberculosis occurs when droplet nuclei aerosolized by patients with infectious pulmonary tuberculosis are inhaled by another individual. Probability of infection depends on the site affected by the disease, the bacillary burden in the infectious patient, duration and proximity of contact, surrounding air volume and the speed of replacement of air through ventilation. The principles are the same for drug-susceptible and drug-resistant strains.

The mainstay of prevention of drug-resistant tuberculosis transmission is airborne infection control which strives to reduce aerosol production, sterilize bacterial load and prevent inhalation of droplet nuclei. A set of infection-control measures has been defined to support development of infection-control programs which includes: national and regional planning; facility design,

construction and renovation; administrative, environmental and personal control measures; necessary advocacy and communication steps; and monitoring and assessment. Drug resistance does not substantially change the basic infection-control strategies that are recommended, but does increase urgency.

Few resources have been devoted to the creation or implementation of infection-control policies or programs although the implementation of low technological and readily available measures (e.g. limitation of hospital admissions, natural ventilation, active case finding) could have a substantial effect in curbing transmission immediately and blunting the epidemic trajectory. Most of the researches on the transmission of drug-resistant strains have focused at institutional settings and vulnerable populations. In these settings, infection control has to include protection of clinical and laboratory healthcare workers whose rates of MDR and XDR tuberculosis are several times higher than in the general population.

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CHAPTER 19: FOOD AND WATER SAFETY

KEY TOPIC TO BE DISCUSSED:

Prevention of food and water born diseases occurrence among patients hospitalized in healthcare settings.

BACKGROUND

Healthcare associated diarrhea is a common problem in hospitals, children's care facilities and nursing homes (Lynch *et al.,* 1997). Outbreaks in healthcare facilities among patient hospitalized have mostly been associated with unsafe food and water. Variety of organisms including *Salmonella*, *Shigella*, *C. difficile*, *V. cholerea*, *C. albicans*, Staph. *aureus*, *cryptosporidium*, *rotavirus* and other *enteroviruses* are responsible for contamination of food and water. Factors that increase risk of water and food borne diseases in healthcare facilities include the fact that they serve food for more hours, serve food for ill and immune-compromised patients, transporting and distributing food at a greater distance and prepare naso-gastric feeding and special diets. In general, the staff are often transient, poorly trained in food handling and engage in unsafe practices involving the storage, preparation and handling of raw meat, chicken, fish and fresh eggs as well as some vegetables. Further, the quality of drinking water in countries with limited resources is often poor and unsafe again contributing to poor quality food services.

MANAGING FOOD AND WATER SERVICES

Planning, implementing and monitoring food and water service in healthcare facilities are of great value in preventing food and water contamination which at times leads to infection prevention among the hospitalized patients from such causes.

PRINCIPLE OF FOOD SAFETY

All activities in the food service department should be monitored regularly to be sure that safety standards are being followed. These include:

- **Temperature** should be kept above $60^{o}C/140^{o}F$ or below $7^{o}C/45^{o}F$. The temperature pertinent for the right storage of food should be maintained and checked periodically. Warm and perishable foods should be cooled before being stored.
- **Cooking** should be complete and standardized. Besides, frozen food items should be thawed before cooking to avoid the presence of cold spots in the interior.
- **Personal Health and Hygiene of Food Service Staff** this is of great importance and the staff engaging in food service should be supervised by a knowledgeable person. Hand hygiene plays crucial role in preventing healthcare associated diarrhea and other related health problems. The staff should report any gastrointestinal problems or skin lesions especially on hands. They need to know how to inspect properly; prepare and store the foods they handle; how to clean and operate equipment they use such as slices; and blenders and dishwashers if they are available and waste management.

- **Educate or Assist** the hospitalized patients and care takers should be trained and assisted on hand washing during critical times (before preparing food, before eating, after toilet).

- **Medical Checkup** of food handlers should be done quarterly. The check up for diseases transmitted through contaminated food, water or air should be carried out on regular basis. Cleanliness of the kitchen has to be done on daily basis monitored and verified in order to avoid contamination of food during cooking.
- **Ensure Equipment Cleaning and Disinfection** equipment especially like cutting boards used for preparing raw meat, fish or poultry. Utensils used for serving food and cups for drinking has to be properly washed or sanitized.
- **Purchase** raw food from known vendors that meet local inspection standards if possible. Foods prepared at home should not be shared with other hospitalized patients.
- **Transportation and Storage of Row and Cooked Food** purchased row food has to be transported to the healthcare facilities with transportation free from biological and chemical contaminants. Storage of row and cooked food should be separate and done in line with the recommended temperature for each type of food to be stored (for example easily perishable and cereals). In brief, the whole process including food handling has to be monitored daily.
- **Water Safety Principle** Identify the quality of water source used by the healthcare facility: biological quality of the source (Total *Coliform* and *E.coli* count based on WHO guideline value or country water quality standard if available). If it is feasible, examine the chemical quality as well. Infected patients should be restricted from using communal baths
- **Collection, Transportation, Storage and Handling of Water** healthcare facilities has to collect, transport, store and handle water with precaution to avoid risk of contamination (i.e. use properly washed/sanitized container to collect and store water, separate container for drinking and other purpose by clearly writing on the container which is for which.
- **Making Water Collected from Unsafe Source Safe** for hospitalized patients, water boiled for 1 to 5 minutes is considered safe to drink while water boiled for 20 minutes is labeled as high-level disinfected and hence even safer. Alternatively, water can be disinfected and made safe for drinking by adding a small amount of sodium hypochlorite. The formula for preparing 0.001% of Chlorine solution is given in these guidelines.
- **Monitoring/Inspection** the quality of water used by healthcare facilities including the sources, collection, and storage should be inspected regularly. The microbial water quality of the source should also be monitored quarterly.

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CHAPTER 20: HEALTHCARE RISK MANAGEMENT

KEY TOPICS TO BE DISCUSSED:

- Doing assessment of hazards and serious errors that might cause harm to patients and/or healthcare workers.
- Possible interventions to prevent or minimize possible risks.

BACKGROUND

Although each institution has specific risk factor, there are risks that are universal. These risks have been assessed at an international level in such a way that it addresses particular needs of each facility. These include:

- Informed consent.
- Prevention of falling accident
- Credentialing
- Event reporting
- Environmental safety
- Government regulations and standards
- Infection control
- Occupational safety and health of the staff
- Security
- Medication safety
- Fire safety
- Medical device-related incidents

The issues of infection control and medication safety are to be treated in chapters to follow. The focus here therefore, is only on:

1. Event reporting
2. Informed consent
3. Environmental safety
4. Occupational safety and health of the Staff

*** To clarify the process of assessment of hazards and possible errors that might cause harm to patients and or healthcare workers, the following parameters should be considered:**

1. Event Reporting

According to the guidelines on adverse event reporting of WHO, an event is defined as any deviation from the usual medical care that causes an injury to the patient or poses a risk of harm. It could include errors, preventable adverse events and hazards. An adverse event is defined as an injury related to medical management in contrast to complications of disease. Medical

management, on the other side, includes all aspects of care, including diagnosis and treatment, failure to diagnose or treat, and the systems and equipment used to deliver care. Adverse events may be preventable or non- preventable. It could be said that, in the overall endeavor to improve safety of patients and professionals, one of the most frustrating experiences is the apparent failure of healthcare systems to learn from their mistakes. Often, neither healthcare providers nor healthcare organizations advise others when mishaps occur or do they share what is learn from studies rarely conducted. As a consequence, mistakes recur frequently in many settings giving way to persistent harms to patients and health workers from preventable errors.

2. Informed Consent

Most of the time, healthcare workers tend to perform procedures on patients (for patient's benefit) without preceding explanation about the procedure to be undertaken or benefits or risks anticipated. It is sometimes assumed that the patient would not understand a medical explanation or will just trust an expert's judgment. This assumption eliminates the possibility of obtaining inputs from the patient like important personal or family medical history or concerns and questions. Further, the stress likely to develop upon patients and possible anxiety of the family stems from not being well informed, can cause any adverse effect in over all activity and raise questions that engender distrust. To sum up, it should be well taken up that every patient has the right to receive an understandable explanation and answers to questions about healthcare activities concerning him/her.

3. Environmental Safety

The hospital environment should always strive to be as hazard free as possible. It is true at the same time, that there are materials (equipment, articles, machines, etc) required for various reasons in the hospital site which could turn hazardous and activities coined with some possible harm. All these, must be handled as safely as possible.

4. Occupational Health

The hospital employees are occupationally at risk. Thus, they are likely to suffer from physical harms, diseases/infections, and emotional injures. It is a legal requirement that the health facility provides treatment for injuries experienced at work. As in most programs, the training to prevent injury is much more effective in and maintaining a healthy workforce and protecting them from incoming injuries than treating them after an injury. Loss of workers due to injury is significant enough in settings even in settings where trained healthcare workers are too low. Still important, is foreseeing the additional cost of paying compensation and medical expenses on hiring someone else to cover the duties left unfulfilled for it is too much for facilities to bear.

TIPS ON SPECIFIC TECHNIQUES OF HANDLING EACH PARAMETER

1. EVENT REPORTING

Reports could be made by the doctor, nurse, or other provider within the hospital or healthcare organization or by a responsible body to a broader audience through a system-wide, regional, or national reporting system. Most believe that an effective reporting system is the cornerstone of

safe practice and a measure of progress towards developing a culture of safety in healthcare institutions. Because, reporting can help to identify hazards and risks and provide information as to where the system is breaking down and help to rectify errors or plan for changes of the system to reduce the likelihood of injury to future patients. Generally, the following is advised

1. Adverse event reporting and learning systems should have the improvement of patient safety through the identification of errors and hazards which may warrant further analysis and investigation as their main objective in order to identify underlying systems factors. The principle purports not to penalize individuals but to let them learn from errors and improve the healthcare system from making the same mistake.
2. When designing adverse event reporting and learning systems, the responsible parties should clearly set out:
    - The objectives of the system.
    - Who should report (all health workers and patients are entitled to report).
    - What gets reported (anything can be reported).
    - Mechanisms for receiving reports and managing the data.
    - Sources of expertise for analysis.
    - The response to reports (Feed back to the reports is critical in continuity of reporting.
    - Methods for classifying and making sense of reported events.
    - Ways to disseminate findings.
    - Technical infrastructure and data security.
3. Healthcare workers and organizations should be encouraged to report a wide range of safety information and events.
4. Healthcare workers who report adverse events, near misses and other safety concerns should not be punished as a result of reporting.
5. Reporting systems should be independent of any authority with power to punish the reporter.
6. The identities of reporters should not normally be disclosed to third parties.
7. Reported events should be analyzed in a timely way.
8. Reported events should be analyzed by experts who understand the clinical circumstances and care processes involved and who are trained to recognize underlying systems causes.
9. The entity that receives reports should be capable of making and disseminating recommendations. Participating organizations should agree to implement recommendations wherever possible.
10. Recommendations for preventative strategies should be rapidly disseminated, especially when serious hazards are identified.

2. INFORMED CONSENT

The patients' participation in their healthcare settings can be improved by their level of understanding and approval of specific interventions. This enhances their cooperation and collaboration in their own cares, decreases their stress and often promotes an improved healing process. The explanation to the patient or qualified representative about risks and benefits of the process for all planned procedures and surgeries is mandatory. Documentation by way of a consent form signed by the patient or qualified representative and provision of entailed explanations will be parts of the permanent medical record to be confirmed prior to the beginning of the procedure or surgery.

3. ENVIRONMENTAL SAFETY

The following are some of the list of safety precautions to reduce risk:

HAZARDOUS MATERIALS

- Material safety data sheets (MSDSs) should be available for all chemicals found at the hospital.
- The hospital should ensure that reasonable stocks of personal protective equipment are made ready at all times (gloves, masks, eye protection, protective clothing, etc).

Fire Risk

- Hospitals should have a fire safety plan that addresses both prevention of fires and response to them.

Injury Hazards

- Wet floors, spills, broken glass, etc should be clearly labeled.
- All public areas should be kept clean and free of large objects.
- Stairwells and corridors should be kept clear and should not be used as storage areas.
- When cleaning is conducted only half of the area of corridors and stairwells should be wet cleaned at a time to always have a dry and safe path available for use.
- Major Incident Planning and Management (when the numbers or type of casualties overwhelm or threaten to overwhelm normal services, special arrangements are needed to deal with them) should be there and function well for an incident poses a serious threat to the health of the community or the hospital itself letting it to suffer serious internal disruption.
- Make sure that the hospital is capable of responding to major incidents of any scale in such a manner that it:
    - Delivers optimum care and assistance to victims,
    - Minimizes the consequential disruption to healthcare services.
    - Brings about a speedy return to normal levels of activity.
    - Having a set of expertise available at all time in a given short notice.
    - Having developed a set of core processes to handle the uncertainty and unpredictability of whatever happens.

- **To summarize the points made so far,**
  - ✓ Each hospital should assign an Occupational Health and Safety Officer (OHSO) who is accountable to the human resource Case Team leader.
  - ✓ All employees should undergo a health screening prior to employment at the hospital. (Should be done in conformity with the national policy).
  - ✓ Voluntary counseling and testing for HIV should be encouraged and made available to all workers.
  - ✓ Maintenance of immunity from risk of exposures and possible transmission of vaccine-preventable diseases such as TB, hepatitis B, influenza, measles, mumps, rubella, and varicella, through immunizations.
  - ✓ Work place injury treatment of any worker who sustains accident, injury or disease as a direct result of their employment, is entitled to receive free general and special medical treatment.
  - ✓ Trainings, providing information and implementation of educational activities aimed to raise the awareness and strengthen decision-making skills of workers related to exposures of infections and other hazards.

Professional Competence is a standardized requirement for an individual to properly perform a specific job. It encompasses a combination of knowledge, skills and behavior utilized to improve performance. To concluded, competence is the state or quality of being adequately skillful or well qualified implying an ability to perform a specific roles with the given reasonable time. For instance, Clinical competency includes chains of knowledge, skill and organizing findings in to a diagnosis followed by suggested treatment. A person possesses competence as long as skills, abilities, and knowledge that constitute competence are there enabling the person to perform certain tasks effectively in the context of working environment. Therefore, it should be well understood that even if knowledge, skill, or ability are there, competence could still be so low and/or be lacking for what is needed to do a job well changes in time and situations.

Clinical Effectiveness is the measure of the extent to which specific clinical interventions do what they are intended to do. (i.e. maintain and improve the health of patients securing the greatest possible health gain from the available resources). It is the right person doing the right thing (in the context of healthcare activities) as confirmed by continuous evaluation. Doing every job the right way needs skill and competence. At the same time, the time when the job is done and the setting of the service delivered also make difference in the achievement of the right result. Clinical effectiveness is thinking critically about achieving the desired result and making a congruent change to the practice.

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CHAPTER 21: CLIENT EDUCATION ON INFECTION PREVENTION AND PATIENT SAFETY

KEY TOPICS TO BE DISCUSSED:

- Client Education on IP and PS.
- An overview of research finding on Client Education on IP and PS and successful approaches.
- The significance of Client Education on IP and PS in healthcare facilities.
- Considerations for effective implementation of Patient Education on IP and PS.

BACKGROUND

Patient participation is increasingly recognized as a key component in the redesign of healthcare processes and is advocated as a means to improve and maintain patient safety. Patient participation is a complex concept which arises from the widespread consumer movement of the 1960s that affirmed the consumer's right to safety, be informed, choose, and be heard. During the past few years, the notion of patient participation grew with time to be recognized as a key component in the redesign of healthcare processes and began to be successfully applied to some aspects of patient care notably, the decision-making process and the treatment of chronic illness. Patient empowerment is a new concept in healthcare and has now been expanded to the domain of patient safety. According to the US-IHI report, in developing countries, client education has been influenced significantly on health quality and safety with a focus on increasing the public awareness of medical errors and national efforts to actively engage patients in their care.

In Ethiopia, as in most developing countries, the issue of patient rights for information and knowledge is becoming an essential part of policy consideration. There are increasing number of facilities that display posters with patient rights and other related issues posted in patient wards and other appropriate places. The issue of patient participation in healthcare, however, is still a new concept in most of the health facilities. The clients and the public at large, it could be said, are still neither informed nor involved. At present the FMoH has recognized that issues of IP and Patient Safety are high priority for the next 5 years. An emphasis on patient education is an essential component just like the infrastructure, supplies and improvement of skill and knowledge of health service providers.

DEFINITION

Even though the term can have different meanings and interpretations, Patient Education is defined as a systematized process of transfer of knowledge, skills, and attitude which empowers the patient, family care giver and community to actively participate in the promotion and maintenance of safe healthcare facility environment.

WHO defines empowerment as “a process through which people gain greater control over decisions and actions affecting their health” and should be seen both as an individual and a community process.

Four components have been reported as being fundamental to the process of patient/client empowerment:

1. Patient's understanding of his/her own role;
2. Patient's acquisition of sufficient knowledge on their ability to collaborate involve with their healthcare provider;
3. Patient's knowledge and skills; and
4. The presence of facilitating environment.

Based on these four components, empowerment can be defined as a process in which patients understand their role, are given knowledge and skills by their health-care providers to perform tasks cognizant of the community's socio-cultural differences and encourages patient participation.

Although there are many unanswered questions on how to approach patient involvement in this part of the guidelines, the WHO and World Alliance for Patient Safety are actively highlighting the role that patients and their families could play in the improvement of healthcare. Action strategies are being developed with a strong emphasis on working in partnership with healthcare authorities, partners and professionals.

They are the basis of infection control precautions which are to be used as a minimal expectation in the care of all patients. For example, Hand hygiene is a major component of standard precautions and one of the most effective methods to prevent transmission of pathogens associated with healthcare. In addition to that, the use of personal protective equipment should be guided by risk assessment and the extent of contact anticipated with blood and body fluids, or pathogens. Supplementary to the practices carried out by health workers when providing care, all individuals (including patients and visitors) should comply with infection control practices in health care settings. The control of spread of pathogens from the source is the key to avoid transmission. Among source control measures, those like respiratory hygiene/cough etiquette developed during the severe acute respiratory syndrome (SARS) outbreak, have now been considered part of standard precautions.

Worldwide escalation of the use of standard precautions would reduce unnecessary risks associated with healthcare promotion of an institutional safety climate helps to improve conformity with recommended measures. Thus, subsequent risk reduction, provision of adequate staff and supplies, together with leadership and education of health workers, patients and visitors are critical for an enhanced safety climate in healthcare settings.

Healthcare associated infection is a major issue in patient safety. Hand hygiene is one of the primary measures to prevent healthcare associated infection and limit the spread of antimicrobial resistance. However, for Hand hygiene to be promoted and practiced, patient participation is quite an important element of the strategy. Studies undertaken on the effects of patient education, confirmed that health education is a dependable instrument to increase staff adherence with hand washing. Given that support from healthcare workers is crucial for success, the first and most important step is to enlist their full and enthusiastic support. A major educational campaign using

articulate patients when possible may be needed to convince physicians and nurses of the value of patient participation.

The objective is to help healthcare workers recognize the contribution of patients and their families to the healing process and to be receptive to patient input. This campaign must be designed to take into account the numerous healthcare providers related obstacles to patient participation (e.g. perception of lack of time and their level of training in the patient-care giver relationship). Once healthcare workers are "on board," educational programs for patients must be offered so that they have the knowledge required to participate.

The strategy also emphasizes that while educating patients, the healthcare provider needs to understand the legitimacy and relevance of their involvement and be convinced of their effectiveness. So doing, is not simple in that numerous patient-related factors known to influence patient participation must be addressed and overcome. Although they are not modifiable, socio-demographic factors (e.g. age, disease severity, and ethnicity) must also be taken into account. When both the healthcare worker's and the patient's support are secured, positive feedback will emerge from the patients and contribute to the safety of healthcare.

COMPONENTS OF EFFECTIVE PATIENT EDUCATION PROGRAMS

1. Have clear policies and procedures in place that guide proper implementation of patient education and empowerment.
2. Have a clear assignment of roles and responsibilities for all steps in patient education process to qualified individuals within a context of shared accountability. The list is inclusive of the patient's primary care provider, other physicians, nurses, pharmacists and other clinicians. The qualifications of the responsible individuals should be determined by the healthcare organization within the limits of applicable law and regulation.
3. Incorporate training on procedures and basic principle for patient education into the educational curricula, orientation and continuing professional development activities for healthcare professionals.
4. Develop and include an evaluation component that includes using both qualitative and quantitative measures to determine not only what works, but under what conditions and within which organizational context the program works.

A program in which there is some evidence of empowering of patients and HCWs are usually part of the multifaceted approach and it includes one or all of the following: educational tools, motivation tools, and role modeling.

For example, education on Hand hygiene on admission to the hospital could be designed is such a way that it encompasses the above three components. With respect to Hand hygiene, educational program for patient/staff empowerment and improvements can be categorized as: educational (including Internet), motivational (reminders/posters), and role modeling within the context of a multimodal approach.

Example of Educational Program

Example 1

- In addressing infection prevention through Hand hygiene, it is very important that the administration ensure they have clear policies and procedures in place which require:
    - provision of education on the Hand hygiene on admission of the patient to the hospital,
    - Display reminders of Hand hygiene in a consistent and conspicuous location (for example, the patient's sink) so that it is easily accessible to patients and their family care givers.
- Information on Hand hygiene for patients can be designed in the form of **printed matter**, **an oral demonstration, or audiovisual means.** Hand hygiene and other educational reminders should be displayed in a consistent and highly noticeable location.

Example 2

The steps of patient participation orientation management in the hospital following surgery are:

- Wash your hands carefully after handling any type of soiled material. This is especially important after you have gone to the bathroom.
- Since you are part of your healthcare team, do not be afraid to remind doctors and nurses about washing their hands before working with you.
- If you have an intravenous catheter, keep the skin around the dressing clean and dry. Tell your nurse promptly if the dressing works loose or gets wet.
- Likewise, if you have a dressing on the wound, let your nurse know promptly if it works, gets loose or wet.
- If you have any type of catheter or drainage tube, let your nurse know promptly if it becomes loose or dislodged.
- Carefully follow your doctor's instructions regarding breathing treatments and getting out of bed. Don't be afraid to ask for help, advice, or sufficient pain medications!
- If possible, ask your friends and relatives not to visit you if they themselves feel ill.

The Six Key principles that allow patients to be more actively involved in their own care:

1. Share vital information with all caregivers, including all medicines, allergies, and ailments.
2. Ask questions about health problems and care.
3. Ask for help from family and friends.
4. Express your concerns.
5. Alert caregivers if your symptoms change.
6. Pay close attention to instructions.

Advised techniques for patient Educators (HCWs/community workers):

1. **Slow down** communication can be improved by speaking slowly and by spending just a small amount of additional time with each patient. This will help foster a patient-centered approach to the clinician-patient interaction.
2. **Use plain, non-medical languages explain things to patients** as you would explain them to your grandmother.
3. **Show or draw pictures** visual images can improve the patient's recall of ideas.
4. **Limit the amount of information provided and repeat it**. Information is best remembered when it is given in small pieces that are pertinent to the tasks at hand. Repetition further enhances recall.
5. **Use of the "teach-back" technique** re-confirms that patients really understood learning items taught before by asking them to repeat back your instructions.
6. **Create a shame-free environment** make patients feel comfortable to ask questions. Include other supporters of patients (patient's family or friends) to promote understanding. In spite of the fact that a great deal of attention focuses on written materials suitable for low literacy audiences, non-written materials can also be effective patient education tools. These non-written materials include graphic illustrations such as pictures, pictographs, and models, along with audiotapes, videotapes, and various forms of computer-assisted learning applications. Studies in the area tend to be supportive of the use of this alternative and are stressing on the effectiveness of these non-written modalities and their supremacy over written materials for patients with limited literacy.

Reminders and Motivational Messages

Patient empowerment models often include visual reminders for both the HCW and the patient. These visual reminders usually include small badges or stickers worn by patients with a message such as "did you wash/sanitize your hands?" If the message is framed correctly, posters can serve as a visual reminder and encouragement for both the patient and the HCW to participate in hygiene practices of the hands. Educational videos, posters, brochures, and visual reminders targeting on the education of HCWs and patients were evaluated in three long-term care facilities as part of a comprehensive program of Hand hygiene. This combination of HCW education and patient empowerment resulted in an aggregate increase in the compliance with Hand hygiene to bring about 52% and 32% of decrement in infections.

Role modeling

Role modeling in which the HCW's behavior towards Hand hygiene or other positive behavior is influenced by either peers or superiors has been observed to influence compliance and motivation of the patient to be empowered.

Graphic illustrations (pictures, pictographs, models)

Research has shown that using pictures including cartoons or pictographs with verbal explanations and use of models can greatly increase patient's understanding and retention of information. In a recent study, the mean correct recall of information was found to be 85% with

pictographs and 14% without it. Another study found that patients receiving wound care instructions with cartoons were able to answer questions correctly 46% of the time when tested three days later compared to only 6% of patients who received only written instructions and answered questions correctly.

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CHAPTER 22: RESEARCH IN PATIENT SAFETY AND PREVENTION OF HEALTHCARE ASSOCIATED INFECTION

KEY TOPICS TO BE DISCUSSED:

- Establishing research on priority issues
- Microbiological survey of drug resistance and other healthcare associated infections.
- Establishing and improving the basic data collection systems, skills and promotion of research projects.
- Establishing effective methods to provide reporting of all adverse events occurring in all heath care facilities.

BACKGROUND

In 2006, Patient Safety of the WHO set up an international expert working group to identify a global agenda for patient safety research. Its aim was to provide general guidance to research commissioners and fund institutions engaged in new researches on priority areas so as to significantly contribute to improve patient safety and Infection prevention practices. In the mid-2007, lists of priority areas were delivered after a rigorous literature review, assessment and consensus building. The expert group stressed the importance of priority setting to respond to pressing local needs for knowledge. Therefore, the group recommended that countries use the global priorities as a starting point but expand them and set their own priorities.

LIST OF ASPECTS OF THE HUMAN FACTOR DEFINITIONS:

The Culture of Safety in an organization can be defined as the product of individual and group values, attitudes, perceptions, competencies and patterns of behavior that determine the commitment along with the style and proficiency of an organization's health and safety management.

Managerial leadership can be defined as the process of influencing people towards achievement of organizational goals.

Communication can be defined as the transfer of information, ideas, or feelings.

Teamwork can be defined as a dynamic process involving two or more people engaged in the activities necessary to complete a task.

Team leadership is defined by the team leader who is the person appointed, elected or informally chosen to direct and coordinate the work of others in a group.

Situation Awareness refers to an individual's perception of the elements in the environment within the volume of time and space, the comprehension of their meaning and the projection of their status in the near future.

Decision-Making is the process of reaching a judgment or choosing an option sometimes called a course of action to meet the needs of a given situation.

Stress is defined as the adverse reaction people develop to encounter an excessive pressure or other types of demand placed upon them.

Fatigue is defined as the state of tiredness associated with long hours of work, prolonged periods without sleep, or requirements to work at times that are out of sync with the body's biological or circadian rhythm.

Work Environment is defined as a set of circumstances or a situation that could harm a person's interest, such as their health or welfare.

RESEARCH PRIORITIES FOR DEVELOPING COUNTRIES

The group concluded that the highest priority for research in developing countries is to facilitate the design and testing of locally effective and affordable solutions to patient safety and IP problems. Therefore, the group favored supporting applied and evaluative research as the top priority. This implies the need of assessing the effectiveness, cost-effectiveness and feasibility of existing solutions often identified and designed in most developed contexts to specific settings in developing countries. This message also applies to the analysis of any risk-reducing strategies. The key message is that research in developing countries should be linked to actions for improvement and development.

Other high priorities included some of the patient safety and IP issues responsible for most of the burden of death and disability related to unsafe care in developing countries such as counterfeit and substandard drugs; inadequate competency; training and skills; inadequate knowledge and knowledge transfer; substandard maternal and newborn care; health-care-associated infections inadequate understanding of the extent and nature of unsafe care; and unsafe injection and blood transfusion practices.

In Ethiopia, several studies are conducted each year by medical and nursing students and by post graduate program candidates. Although the topics and findings in some of these studies are relevant to patient safety and IP, the collection, logging or registration and distribution of these studies for consideration by national and international policy makers is limited.

Note:

Establish Research priorities which should include epidemiological surveys of adverse events, optimal and standardized injection and blood transfusion practices, safer maternal and newborn care, patient safety solutions, and microbiological and clinical assessment of drug resistance and rational drug use in the improvements of infection control.

The first step in research is choosing a topic. Patient safety indicators primarily target the outcomes that are relevant for patient safety. The literature review undertaken by WHO patient safety in 2008, kicked into action by formulating patient safety indicators for data-poor hospitals. This shows that it focused primarily on the main patient safety outcomes. The goal of the review was to identify the relevance of each of the patient's safety outcomes in terms of the frequency of occurrence and the severity of harm produced. Besides, it also attempts to identify and select the main contributing factors (structural or process factors) leading to the occurrence of such patient safety issues.

Following the review, experts evaluated the domains identified in the undertaking in relation to relevant and potential precursors for improvement. This effort finally came up with the following list of nine interest areas:

1. Healthcare-Associated Infections (HAIs)
2. Maternal care
3. Adverse drug events
4. Adverse events in devices
5. Unsafe injections
6. Unsafe blood products
7. Misdiagnosis
8. Surgical and anesthetic errors
9. Falls (falling accidents)

By contrast, the Research Priority Setting Working Group had ranked 20 Research priority areas as follows:

1. Identifications, design and testing of locally effective and affordable solutions
2. Cost-effectiveness of risk-reducing strategies
3. Counterfeit and substandard drugs
4. Inadequate competence, training and skills
5. Maternal and newborn care
6. Healthcare-associated infections
7. Extent and nature of the problem of patient safety (across the continuum)
8. Lack of appropriate knowledge and its transfer
9. Unsafe injection practices
10. Unsafe blood transfusion practices
11. Misdiagnosis
12. Unsafe blood products
13. Poor safety culture and blame-oriented processes
14. Shaping the agenda by burden of disease
15. Lack of communication & coordination (including communication across organizations, discontinuity and hand-over)
16. Inadequate regulations
17. Latent organizational failures
18. Adverse drug events due to drugs and medication errors
19. Lack of adequate reporting on patient safety
20. Inadequate safety indicators

Establishment or improvement of basic data collection and promotion of research projects which allows valid information on the real magnitude of the patient safety and IP problem is the key for any useful research on patient safety and IP.

The next step would be choosing the indicators. This step would first involve identification of the main contributing factors to the selected patient safety issues. These factors are process and structure elements of the care delivery process. They can be classified into two: hospital-wide factors and theme/outcome specific factors. The hospital-wide factors are cross-cutting for many if not all patient safety outcomes, where as the theme/diagnosis specific factors may focus more on a single type of patient outcome. Thus the process culminates in a list of relevant contributing factors based on these criteria.

The selected outcomes and contributing factors are then the basis for identifying the indicators. For each selected outcome domain and contributing factor, an inventory of candidate measures will be produced. The indicators to be drawn from the literature and other related measurement programs should seriously consider the feasibility and the method of the data collection.

Note:

It is advisable to establish effective methods to provide regular reporting of all adverse events and other patient safety issues occurring in all healthcare facilities.

REPORTING

The aim of this activity can be to produce an institutional report, less often a full research paper, or even a peer reviewed article for international publication. The format and process will be determined by the institution being submitted to and the overall aim. Please refer the chapter on documentation of adverse events.

Facility reports to the federal ministry of health should reflect patient safety events, issues, outcomes and effective solutions found concomitantly. All researches conducted should be accessible for reference through a central hospital library list which can be forwarded to a website or national library archive for medical research documents.

TRANSLATING RESEARCH FINDINGS INTO PRACTICE

The final step in the research cycle is to better understand how research findings can be translated into practice. This is especially important in developing countries and transitional economies where resources are scarce and research infrastructures are often limited. Solutions that are successful in one country may serve as an inspiration for the development of solutions in another. Unless the research study is accessible by the staff and other groups, the benefits may be lost not only to the hospital down the road but around the world.

Accessibility to studies done in all facets of healthcare and the assessment of the quality of the study will allow an effective base upon which to evaluate the relevance of practices and possible new and better solutions to healthcare problems. Review of the research done should be

periodically and systematically undertaken by policy making; implementing and regulating bodies to assure that best practices are being promoted institutionally, regionally and nationally.

Examples of Preliminary Research Questions

Adverse Events Due to Errors in Medications/Drugs

Research questions:

- What is the prevalence/incidence of the risk factors for adverse events due to drugs and medication errors in different population groups and settings?
- What are the minimum system and skill needs for effective reporting of errors in medications in both inpatient and outpatient settings?
- What strategies are effective for detecting and preventing errors in medications in both inpatient and outpatient settings?

Adverse Events Associated With Medical Devices

Research questions:

- What is the frequency of reporting's and lack of reporting on adverse events associated with medical devices?
- What is/are the principal cause/s and the potential solutions to reduce these events or mitigate the harm they cause?
- What is the impact of adverse events associated with medical devices on patient safety?
- Do medical device surveillance systems improve the use, maintenance and development of medical devices?

Extent and Nature of the Problem in Patient Safety

Research questions:

- What is the incidence and prevalence of patient safety problems in various health-care settings?
- What is the burden of unsafe care of the general population in terms of morbidity and mortality?
- What is the burden of unsafe care on special populations, such as the elderly, minorities and children?

Healthcare-Associated Infections

Research questions:

- What is/are the epidemiology and risk factors for healthcare associated infections in hospitals?
- What is the availability and cost of commercial hand rub products and how does that affect hand hygiene promotion strategies?

- What strategies are effective in optimizing participation in infection control practices?
- Are there effective practiced plans in place for control of epidemic outbreaks of healthcare-associated infections?
- Does the use of new practices (e.g. silver-coated catheters) reduce the incidence of healthcare-associated infections?

Inadequate Competence, Training and Skills

Research questions:

- Are healthcare professionals adequately trained in assessing and dealing with patients with reported adverse events or medical errors?
- Is patient safety a specific topic in the core curricula of physicians, nurses and health managers?
- What kinds of continuing medical education programs are most effective to ensure that physicians and nurses retain competency in patient safety?

Identification, Design and Testing of Locally Effective and Affordable Solutions

Research questions:

- What are the costs and benefits of adapting already established guidelines as opposed to designing new solutions?
- What mechanisms are needed to ensure that specific solutions are valid, effective and responsive to changing needs and sustainable and measurable over time?
- What solutions for preventing common adverse events are effective in low-resource situations?

Unsafe Injection Practices

Research questions:

- What are the epidemiology and burden of diseases transmitted through unsafe injections?
- To what extent is unsafe injection attributable to lack of safe equipment?
- What educational strategies are most effective in improving injection practices?

Involvement of Patients in Setting the Research Agenda

Research questions:

- How can patients optimally and meaningfully be engaged in awareness raising, promotion and research?
- What resources and support are needed to effectively engage patients and their family members in strategies for improving patient safety?
- How can patients be effectively empowered to take active roles in program planning and evaluation?

Lack of Consideration of Human Factors in Design and Operation of Procedures

Research questions:

- How cost-effective would it be to redesign procedures in order to account for human factors?
- Which procedures could benefit most from being redesigned?
- How important is the impact of lack of consideration of human factors on safety?

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CHAPTER 23: MANAGING INFECTION PREVENTION AND PATIENT SAFETY ACTIVITIES

KEY TOPICS TO BE DISCUSSED:

- Established organizing principles of IP and PS program management.
- Responsible working groups involved in managing IP and PS programs and purposes served.
- Basic IP and PS supportive supervision.
- Managing changes in introductions of recommended IP and PS practices and processes.
- Supportive supervision tools used in Ethiopia

BACKGROUND

Proper management of infection prevention and patient safety programs at various levels of implementation has paramount importance for the success and fulfillment of basic strategic objectives. Programs for preventing the spread of infectious diseases by any route and overall patient safety in healthcare facilities are based on understanding the scope of the problem, prioritizing activities and effectively using available resources and scientific standards. Due to the fact that available resources are invariably limited, careful planning, implementing and monitoring activities on a regular basis are all essential be it in a primary healthcare unit or high level tertiary hospital. A proper supportive supervision for performance improvement and change management is also critical for IP and PS activities management. In many countries, including Ethiopia, functioning infection surveillance systems are lacking, laboratory backup to identify the cause of nosocomial infections is inadequate, and treatment options are limited. Thus, infection prevention and patient safety are not only the most cost-effective option of mitigating morbidity burden but also the only realistic method to limit the spread of disease and insure patient safety within healthcare facilities. Unfortunately, it is the hardest of the three elements (surveillance, control and prevention) to implement because it requires staff at all levels to take an active role in preventing the spread of infections to patients, fellow workers and themselves. Fortunately, most nosocomial infections in healthcare facilities can be prevented with readily available, relatively inexpensive strategies. And for some of the most serious infections, namely, AIDS, hepatitis C and multidrug-resistant tuberculosis, prevention is all we can do To make this happen, healthcare administrators, clinic managers and staff at all levels of the healthcare system must be totally committed to support and use recommended infection prevention and Patient Safety practices. Efforts to prevent patients from acquiring an infection or bad outcome (e.g. phlebitis following intravenous infusions) while in a hospital, require that healthcare workers implement recommended infection prevention and Patient Safety practices.

DEVELOPING SUCCESSFUL IP AND PS PROGRAMS:

Helping healthcare facilities become safer places in which to work or be cared for is largely about changing behavior. Education is not enough. To change unsatisfactory performance by staff (e.g., lack of compliance with hand washing guidelines) requires management reinforcement if the behavior change is going to be sustained (Lynch et al 1997). It is the

responsibility of administrators and managers, working in conjunction with key staff serving on operating room safety or infection prevention and Patient Safety committees, to:

- Set standards for performance, mentor staff and regularly monitor staff performance; and
- Help staff at all levels "buy in" to using common sense when performing their assigned duties, as well as using appropriate personal protective equipment at all times.

In addition, there needs to be:

- Consistent support by hospital administrators and managers of safety efforts (e.g., identified deficiencies corrected, dangerous practices eliminated and staff actively encouraged to seek inexpensive, doable solutions).
- Supervisors who regularly provide feedback and reward appropriate behavior (e.g., hand washing between patient contacts).
- Role models, especially physicians and other senior staff and faculty,
- who actively support recommended infection prevention and Patient Safety practices and demonstrate appropriate behavior (Lipscomb and Rosenstock 1997).

ORGANIZING PRINCIPLES OF IP AND PS PROGRAM

Below are the three recommended organizing principles for managing IP/PS programs:

1. Establishing the relative importance of problems using their level of significance according to Spaulding's categories of potential infection risk. These are:

    - Critical
    - Semi-critical
    - Non critical

Such kind of potential risk categorization provides a good basis for determining relative importance and setting priorities (e.g. the most serious and frequent problems and infections involve management in the critical area and, therefore, deserve the most attention and resources).

2. Identifying and analyzing reasons for poor or incorrect implementation/performance.

    - The second principle correctly identifying why performance is not up to the standard, at this point, it usually comes up with three possible reasons. The performance is poor because the staff:
    - Do not know how to do the task correctly or why they need to do it;
    - Do not have the correct (adequate) protective and patient safety equipment; or
    - Lack motivation.

In most cases, more than one reason is involved. Understanding how these reasons contribute to performance deficits increases the potential for corrective action to be successful.

3. Costing the issues (i.e. estimating the cost and benefits of various IP and PS intervention activities). The third and the final principle are estimating the cost-benefit of the corrective

actions. In many settings, this is the most difficult task to implement because the data on which estimates are to be based is often lacking. However it is highly recommended to use national and locally available data sources for this decision making.

RESPONSIBLE BODIES IN THE MANAGEMENT OF IP AND PS ACTIVITIES

For the management of infection prevention and patient safety to be effective, an appropriate structures need to be established and strengthened at different levels. Hence, a national infection prevention and patient safety advisory committee consisting of experts in this area of interest should be established and spearhead the federal level program design and management. The IP and PS program management structure should be cascaded to regional and district level health offices with the aim of overseeing program implementation in their respective geographic distinctions. Since healthcare facilities are the ultimate point of service delivery, establishment and strengthening of facility-based (institutional) infection prevention and patient safety committees is vital. Guiding and supporting the use of recommended practices and to review and resolve related problems that may arise is the key responsibility of the committee. This working group or committee should include representatives from a variety of patient care areas (e.g. surgery, central services, housekeeping, laboratory, purchasing and administration) and include one or more health professionals. In small health facilities where these functions often overlap, however, the group may consist of only two or three individuals. Awareness creation amongst health facility managers and administrators on infection prevention and patient safety to enhance their understanding and subsequent decision making needs much emphasis. Healthcare facility managers in turn, should ensure that the different units and disciplines within the facility clearly understand and execute their roles and responsibilities. Regional health bureaus should make periodic supportive supervisions to facilities so as to assist materially and technically to fill up gaps and advance efforts to achievement the national IP and PS performance standards.

With infection prevention and patient safety, as with any clinical area, numerous situations arise calling for tough decisions to be made weighing up the advantages of a certain procedures against the possible risks to the patient or healthcare worker. These decisions must be practical and consistent and as much as possible and most of all should be based on scientific evidence.
Throughout this manual, evidence is presented to help managers make a better, more informed decisions and recommendations regarding frequently encountered problems. In making these decisions, managers must often strike a balance between the importance of the problem and the provision of acceptable levels of safety for specific healthcare tasks.

Basic guidance and activities that help managers to implement successful IP/PS program rollout;

- Have written policies, guidelines and procedures established to handle situations in which patients or staffs are exposed to the risk of infection and clinical malpractices.
- Conduct staff orientation before new policies, recommendations or procedures are started and provide follow-up training when management reinforcement is needed.
- Ensure the availability of adequate supplies, equipment and facilities before starting-up to meet the desired set of standards. Conduct regular reviews to ensure the adequacy of the recommended changes or practices to solve emerging problems and to address staff concerns.

Finally, effective and regular communication at all levels is the key to developing the support needed for a successful program.

TRAINING AND STAFF DEVELOPMENT

Prevention of infections and safety of patients primarily involve education linked to behavior change interventions. Staffs need to have not only correct information regarding risks and know how to avoid risks, but also appropriate risk-averting capability and sound patient management behavior recommended. In addition to that, personal concerns linked to the risk-taking behavior and tendency to mismanage patients need to be addressed. Healthcare workers are often willing to change bad attitudes and work habits when they understand the rationale and significance of new safety procedures. Nonetheless, this positive behavioral change and compliance shortly attained often starts to decline again in a few days or weeks. Thus, in order to ensure continued compliance, management reinforcement as well as a monitoring system that sums up results to overall performance indicators is necessary. Healthcare workers of all levels (e.g. Lab technicians, nurses, physicians, housekeepers and cleaners) need to know why infection prevention and patient safety is important.

The training should be standardized in terms of content, modality and time. All trainings and domestically operating procedures should be in line with the national strategic framework and this guideline. To attain long-term effects, the initial training should be followed up and monitoring should be targeted towards identifying and solving specific problems related to the introduction the new processes or procedures.

General reminders regarding the importance of maintaining an infection-free environment for safer delivery of services should be repeatedly emphasized as well.

SUPPORTIVE SUPERVISION AND REVIEW MEETING

Regular supportive supervision and periodic evaluation of the implementations on infection prevention and safety of patients at various levels is a critical element of the IP and PS program management. Supportive supervision to be held at a hospital level can fully employ the operational standards for IP in hospital are enlisted in the Ethiopian Hospital Implementation guidelines as follows:

1. Hospital Management supports improvement efforts in infection prevention by ensuring that operational and technical capacity; and financial and human resources required to adhere to infection prevention guidelines are available.
2. A designated group and/or individual(s) are in place to effectively implement and monitor infection prevention and control activities.
3. The hospital has an operational plan for the implementation of infection prevention activities. The plan follows national guidelines and includes guidance on the practices, procedures and materials for infection prevention.
4. Standard practices to prevent, control and reduce risk of hospital acquired infections are in place.

5. The hospital has an adequate plan to address transmission based precautions for the staff, patients, caregivers and visitors.
6. The hospital ensures that equipment, supplies and facilities/infrastructure necessary for infection prevention and control are available.
7. All hospital staff are trained using standard infection prevention training materials.
8. The hospital provides health education to patients, caregivers and visitors, as appropriate on: infections and preventive activities and control practices.

Program review will provide inputs as to how the overall program is operating as compared to the national IP and PS indicators. Responsible entities at national, regional and local level should plan and exercise supportive supervision and review meetings in their respective settings. Facility level managers and technical committee members should spearhead the routine implementation of IP and PS activities and are supposed to actively collaborate in all supportive supervision and review meetings pertinent to their respective facilities.

Many IP and PS improvement initiatives come to facilities by different stakeholders. All these initiatives need change management. Introducing interventions to improve performance and quality of healthcare services involves change, but unfortunately people are not always comfortable with it. It is, therefore, not enough to just design an intervention without taking anticipated adverse situations into account. The best ideas can fail because the people who are supposed to implement them are resistant to change. To improve performance and services, one must know how to manage the change process.

People may resist change because they feel:

- Threatened by the change
- Excluded
- Unhappy
- Isolated

It is difficult to eliminate resistance to change completely and permanently, but you can minimize it by take steps listed below:

- Develop common goal
- Involve stakeholders
- Communicate
- Involve all staff
- Anticipate and negotiate
- Monitor
- Demonstrate commitment and consistency

MONITORING INFECTION PREVENTION AND PATIENT SAFETY PRACTICES

Regular monitoring of infection prevention and patient safety practices and processes is important, not only to assess their effectiveness but also to determine areas of demand for more training or review for different staff member. Keeping records of infections and patient

mismanagement occurring in facilities has now a day become the best way to monitor the effectiveness of infection prevention and patient safety practices. Supervisors and managers at all level should always use a standardized monitoring and evaluation tools to guide all their monitoring and evaluation activities (see **Appendix F** for sample IP Monitoring and Surveillance Form).

In the broadest sense, infection-monitoring (surveillance) activities are designed to guide corrective action based on accurate information or provide the rationale for not acting when only selective or biased information is available. The activity regards the strengthening of record and report systems of IP and PS activities as a requirement. At national level, continuous monitoring and evaluation of IP and PS activities of the healthcare facilities should be established and for that indicators for assuring or improving the quality of IP and PS practice in general should be developed and used for periodic evaluation of the status of IP and PS related quality. The Ethiopian Hospital Implementation Guidelines listed the following indicators as monitoring tool to assess the effectiveness/outcomes of implementation of recommended IP and PS practices in a given facility.

Table 23.1 Infection Prevention and Patient Safety Indictors

No	Indicators	Formula	Frequency	Comment
1	Healthcare Acquire infections	total number of patients with an infection arising > 48 hours after admission during reporting period/ total number of admissions during reporting period x 100	Quarterly	
2	a) Number of occupational exposures reported in hospital, categorized by type of exposure b) Number of on- occupational exposures reported in hospital, categorized by type of exposure	a) Total number of occupational exposures during reporting period, categorized by types of exposure b) Total number of non-occupational exposures during reporting period, categorized by type	Quarterly	
3	The number of people that started PEP treatment	Total number of people started on PEP treatment during the reporting period	Quarterly	
4	% of people that completed that PEP treatment	Total number of people that completed PEP treatment during the reporting period/ total number of people who should have completed PEP treatment during the reporting period x 100	Quarterly	
5	a) Number of days when incinerator was not working	a) Total number of days that the incinerator was not working during the reporting period b) Total number of days that the	Quarterly	

	b) % of total days	incinerators was not working during the reporting period / total number of days in reporting period x 100		
	Inpatient satisfaction survey: % of respondents who answered 'always' or 'usually' to the question "during this health facility stay", how often was the room you were sleeping in kept clean?	Total number of inpatient who respond 'always or usually' to the list question/ Total number of inpatients respondents x 100	Biannual	
	Outpatient satisfaction survey: % of respondents who answered 'agree' or 'strongly agree' to the question "the out patient department was clean"	Total number of outpatients who respond 'agree' or 'strongly agree' to the listed questions /total number of out patients responded x 100	Biannual	

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APPENDIX A: GENERAL SURGICAL HAND SCRUB SUPPLIES

The supplies needed for a surgical hand scrub include:

- Plain or antiseptic (preferred) soap (Larson, 1988).
- Antiseptic agent (Povidone-Iodine or Chlorhexidine is less irritating to skin).
- Running water (When no running water is available, use a bucket with a tap which can be turned off when lathering the hands and turned on again when rinsing, or a bucket and pitcher).
- Soft stick with pointed end or brush for cleaning underneath the fingernails. (These items must be cleaned and preferably high-level disinfected after each use).
- Soft brush or sponge for cleaning the skin (These items must be cleaned after each use). Avoid using stiff brushes as these can damage the skin, especially if surgical hand scrub is done several times a day.
- Towels (sterile towels should be provided in the operating room.)

PROCEDURE

The surgeon, the scrub nurse or the technician should wear a short-sleeved shirt or blouse when performing a surgical hand scrub because it requires scrubbing to the elbows (Sorensen & Luckman, 1979).

Procedure	Rationale
1. Remove all jewelry.	1. Jewelry harbors microorganisms, is difficult to clean and makes putting on gloves more difficult (Salisbury, 1997).
2. Hold hands above the level of the elbow and wet hands thoroughly. Apply soap, and clean under each fingernail using the stick or brush.	2. Water should flow from area of least contamination (hands) to highest contamination (arms). Washing removes many organisms. Fingernails should not extend beyond the tip of the finger more than 3 mm (or 1/8 inch). Long fingernails can puncture gloves and allow bacteria to grow easily underneath them.
3. Beginning at the fingertips, lather with a soft brush or sponge, using a circular motion. Wash between all fingers. Move from fingertips to the elbow of one arm and repeat for the second arm.	3. Friction and lather raise the number of microorganisms. Moving from area of least contamination to area of highest contamination decreases the possibility of spreading contamination.
4. Wash using a soft brush or sponge for at least 2 minutes.	4. If a brush is used, it should be decontaminated and either high-level disinfected or sterilized before reuse, if used, should be discarded.

Procedure	Rationale
5. Rinse each hand and arm separately, fingertips first, holding hands above the level of elbows. Do not let rinse water flow over clean area.	5. Water should flow from area of least contamination to an area of highest contamination to decrease the possibility of contamination.
6. Apply antiseptic agent and vigorously rub all surfaces of hands, fingers and forearms for at least 2 minutes.	6. Use sufficient antiseptics to cover hands, fingers and forearms.
7. Repeat #5 using clean water 2.	7. See #5.
8. Use a separate sterile or clean cloth towel for each hand to wipe from the fingertips to the elbow and then discard the towel.	8. Moving from area of least contamination to area of highest contamination decreases the possibility of spreading contamination.
9. While waiting to put on sterile or high-level disinfected surgical gloves, hold hands above the level of the waist and do not touch anything	9. Contact with soiled objects contaminates clean hands. The area below the level of the waist is considered unclean

Note:

If scrubbed hands touch any contaminated surface or object before gloving, Steps 3 through 9 must be repeated.

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APPENDIX B: SAFE SURGERY CHECKLIST (WHO, 2000)

Surgical Safety Checklist

World Health Organization | Patient Safety

Before induction of anaesthesia
(with at least nurse and anaesthetist)

Has the patient confirmed his/her identity, site, procedure, and consent?
- ☐ Yes

Is the site marked?
- ☐ Yes
- ☐ Not applicable

Is the anaesthesia machine and medication check complete?
- ☐ Yes

Is the pulse oximeter on the patient and functioning?
- ☐ Yes

Does the patient have a:

Known allergy?
- ☐ No
- ☐ Yes

Difficult airway or aspiration risk?
- ☐ No
- ☐ Yes, and equipment/assistance available

Risk of >500ml blood loss (7ml/kg in children)?
- ☐ No
- ☐ Yes, and two IVs/central access and fluids planned

Before skin incision
(with nurse, anaesthetist and surgeon)

- ☐ **Confirm all team members have introduced themselves by name and role.**
- ☐ **Confirm the patient's name, procedure, and where the incision will be made.**

Has antibiotic prophylaxis been given within the last 60 minutes?
- ☐ Yes
- ☐ Not applicable

Anticipated Critical Events

To Surgeon:
- ☐ What are the critical or non-routine steps?
- ☐ How long will the case take?
- ☐ What is the anticipated blood loss?

To Anaesthetist:
- ☐ Are there any patient-specific concerns?

To Nursing Team:
- ☐ Has sterility (including indicator results) been confirmed?
- ☐ Are there equipment issues or any concerns?

Is essential imaging displayed?
- ☐ Yes
- ☐ Not applicable

Before patient leaves operating room
(with nurse, anaesthetist and surgeon)

Nurse Verbally Confirms:
- ☐ The name of the procedure
- ☐ Completion of instrument, sponge and needle counts
- ☐ Specimen labelling (read specimen labels aloud, including patient name)
- ☐ Whether there are any equipment problems to be addressed

To Surgeon, Anaesthetist and Nurse:
- ☐ What are the key concerns for recovery and management of this patient?

This checklist is not intended to be comprehensive. Additions and modifications to fit local practice are encouraged.

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APPENDIX C: GENERAL SAFETY CHECKLIST FOR SURGICAL TEAM

Absolute prerequisites

- ❑ Complete the hepatitis B vaccination series.
- ❑ Use Standard Precautions with all patients.

Personal protective equipment—appropriate choices

- ❑ Wear fluid-resistant head wear where appropriate.
- ❑ Use adequate eye and face protection.
- ❑ Use appropriate neck protection (consider recently shaved skin as nonintact).
- ❑ Wear fluid-resistant or fluid-impervious gowns, as appropriate to expected exposure risk (if available).
- ❑ Choose gloves appropriately (use double gloving, see below).
- ❑ Wear appropriate footwear (shoes not open toed or flip flops).

Personal protective equipment—appropriate use

- ❑ Remove gloves carefully to avoid blood splatter.
- ❑ Wash hands with soap and clean water or use antiseptic handscrub after removing gloves.
- ❑ Remove eye protection last.
- ❑ Remove contaminated personal protective equipment (PPE) before leaving the room.
- ❑ Carefully remove and discard mask following every procedure.

Safety techniques

- ❑ Wear examination gloves when handling surgical specimens.
- ❑ Wear eye protection if container is opened or splashing is anticipated.
- ❑ Apply dressings and handle drains or packs wearing clean new examination gloves.
- ❑ Avoid touching any surface with contaminated gloves.

Safety strategies

- ❑ Have extra PPE readily available should replacements be needed.
- ❑ Position sharps disposal containers at point of use.
- ❑ Have a plan for sharps management.
- ❑ Make sure all team members know the plan.
- ❑ Modify the plan as needed.
- ❑ Focus attention on sharps in use; be aware and alert.
- ❑ Alert other OR team members to possible hazards.
- ❑ Discourage unauthorized entry into the room.
- ❑ Keep extraneous conversation to a minimum.
- ❑ Store a tube of blood preoperatively on all surgical patients to be held in the laboratory for possible HIV testing should an exposure occur.
- ❑ A signed consent for HIV testing, in case of an exposure, should be obtained preoperatively to avoid delay in post-exposure followup.

Personal preparation

- ❑ Prepare your body and mind to function effectively and efficiently.
- ❑ Get enough sleep before surgery. If you are working a long shift on obstetrics or trauma service, nap if and when you can.
- ❑ Avoid caffeine, which increases hand tremor.
- ❑ Avoid alcohol or other substances that impair perception, judgment or reflexes.
- ❑ Promote general good health. Exercise regularly and have an annual physical.
- ❑ Avoid behaviors that increase nonoccupational risk of exposure to bloodborne viruses, such as unsafe sex.

SAFE ASSISTING AND OPERATING CHECKLIST

- ❑ Use forceps to put scalpel blade on handle.
- ❑ Avoid handling suture needles manually.
- ❑ Never hold a scalpel, loaded needle holder, or any other sharp in the same hand simultaneously with another instrument.
- ❑ Scalpels, loaded needle holders, and other sharps should be held in the hand only during cutting, suturing, or for other specific tasks. At all other times, sharps should be placed off the operative field.
- ❑ Properly employ a Safe Zone for the safe passing of sharps.
- ❑ Use verbal warnings to announce transfer of sharps.
- ❑ Before tying, either remove the needle from the suture and park the needle safely, or protect the needle point with the needle holder.
- ❑ Avoid finger contact with tissue being sutured or cut.
- ❑ Use retractors rather than manual retracting whenever possible.
- ❑ Avoid reflex sponging of tissue, which may not be anticipated by the surgeon, when a sharp is in use.
- ❑ Keep eyes on all sharps in use until they are returned to the Safe Zone.
- ❑ Pass long laparoscopic instruments, such as needle tip cautery and sharp-pointed scissors, handle first and tip down.
- ❑ Replace the shield onto the tip of a drain trocar with an instrument, not the fingers, before pulling the trocar out of the exit wound.
- ❑ When doing repeat injections with hypodermic needle and syringe, stick needle in rolled, sterile towel when not in use.
- ❑ Remove scalpel blade using forceps; place in sharps container.

OPERATING ROOM SAFETY CHECKLIST

(Post at scrub sinks or at OR doors)

PERSONAL PROTECTIVE EQUIPMENT

- ❑ Head wear that covers scalp hair
- ❑ Eye and face protection in place
- ❑ Appropriate gown
- ❑ Impervious boots
- ❑ Double gloves or glove liners as indicated
- ❑ Waterproof drapes (if available)

WORK PRACTICE CONTROLS

- ❑ Safe Zone selected and deployed
- ❑ Surgeon( ) right-handed ( ) left-handed
- ❑ Assistant ( ) right-handed ( ) left-handed
- ❑ Appropriate suture needle selection (blunt if applicable)
- ❑ Appropriate retractor selection (blunt if applicable)
- ❑ Disposable scalpels (if available)
- ❑ Smoke evacuation equipment available and functioning (operative laparoscopy)

SHARPS MANAGEMENT

- ❑ Sharps disposal container

DELIVERY ROOM SAFETY CHECKLIST

(Post at scrub sinks or at OR doors)

PERSONAL PROTECTIVE EQUIPMENT

- ❑ Head wear that covers scalp hair
- ❑ Eye and face protection in place
- ❑ Appropriate gown
- ❑ Impervious boots/shoe covers
- ❑ Double gloves, extended cuff gloves (gauntlet) or glove liners as indicated
- ❑ Waterproof drapes (if available)

WORK PRACTICE CONTROLS

- ❑ SAFE Zone (cesarean section)
- ❑ Surgeon ( ) right-handed ( ) left-handed
- ❑ Assistant ( ) right-handed ( ) left-handed
- ❑ Appropriate suture needle selection (blunt if applicable for episiotomy)
- ❑ Appropriate retractor selection (blunt if applicable for cesarean section)

SHARPS MANAGEMENT

- ❑ Sharps disposal container

MINIMALLY INVASIVE SURGERY SAFETY CHECKLIST

- ❑ Pass trocars, needles, and other short-length sharps through a Safe Zone.
- ❑ Pass long laparoscopic instruments that don't fit in the Safe Zone, such as needle-tip cautery and sharp-pointed scissors, handle first and tip down.
- ❑ Place long-pointed cautery needles, hollow-bore needles or other long sharps into sleeve ports, on request only, using two hands—preferably one person's hands—and then angle the handle toward the surgeon's waiting hand.
- ❑ Blunt-tipped suture needles may be used effectively during laparoscopic hysterectomy and are considered a safer option for patient and surgeon.
- ❑ Avoid sprayback; use trocar valves to protect anesthesia personnel as well as the surgical team members.
- ❑ Aspirate all gas, fluid, and blood from the abdomen prior to closing.

SAFE SHARPS DISPOSAL CHECKLIST

- ❑ Choose containers with built-in safety features, such as "see-through" (translucent) boxes with a readily apparent three fourths and full level lines.
- ❑ Lids should allow the sharp to enter the container by gravity alone, without the need for additional manipulation.
- ❑ Install containers close to the point of use ideally within arm's reach.
- ❑ Mount containers at a convenient height for use and service, in plain sight and free from obstructions.
- ❑ Do not leave containers freestanding on the floor on their side.
- ❑ Do not shake containers to avoid spillage or sharps sticking out.
- ❑ Schedule staff training and education for proper use of sharps containers.
- ❑ Assign responsibility for maintenance and service of sharps containers.

APPENDIX D-1: INITIAL MANAGEMENT OF A PERSON REPORTING EXPOSURE TO POTENTIALLY INFECTIOUS BODY FLUIDS

The initial management should aim at reducing time of contact with the source person's blood, body fluids or tissues and to clean and decontaminate the site of the exposure.

If the skin is broken following an injury with a used needle or sharp instrument, the following is recommended:

- Do not squeeze or rub the injury site.
- Wash the site immediately using soap or a mild disinfectant solution (like Chlorhexidine Gluconate solution or 70 to 80% alcohol solution) not irritating to the skin. If running water is not available, clean the site with a gel or other hand-cleaning solution or whatever is customarily available.
- Do not use strong solutions, such as bleach or Iodine to clean the site as these may irritate the wound and make the injury worse.

After a splash of blood or body fluids, the following is recommended.

After a splash contacts with unbroken skin, do the following:

- Wash the area immediately.
- If, running water is not available, clean the area with a gel or other hand rub solution or whatever is customarily available.
- Do not use strong disinfectants.

After a splash contacts with the eye, do the following:

- Irrigate the exposed eye immediately with water or normal saline.
- Sit in a chair, tilt the head back and have a colleague gently pour water or normal saline over the eye pulling the eyelids up and down to make sure the eye is cleaned thoroughly.
- If contact lenses are worn, leave these in place while irrigating the eye as they form a barrier over the eye and will help protect it. Once the eye has been cleaned, remove the contact lenses and clean them in the normal manner. This will make them safe to wear again.
- Do not use soap or disinfectant on the eye.

After a splash contacts with the mouth, do the following:

- Spit the fluid out immediately.
- Rinse the mouth thoroughly using water or saline, and spit again. Repeat this process several times.
- Do not use soap or disinfectant in the mouth.

APPENDIX D-2: SUMMARY OF STEPS IN CLINICAL MANAGEMENT OF HIV POST-EXPOSURE PROPHYLAXIS

Item	Recommended action and notes
Person reports Exposure	First aid, assess the type and severity of exposure, use decision making tools to assess the exposure and decide eligibility for PEP Fill the Potential HIV exposure documentation and PEP follow up form **(Appendix D.6).** This form should be filled for every exposure despite the eligibility for PEP
Eligibility	Eligible if the following four criteria are fulfilled: Exposure within 72 hours Exposed individual not known to be infected with HIV Significant exposure Person who was the source of exposure is HIV infected or has unknown HIV status
Informed consent for post-exposure Prophylaxis,	Information about risks and benefits of PEP Health education and counseling on adherence; side effects; risk reduction; trauma or mental health problems; and social support and safety (both occupational and non occupational) Consent may be given verbally Base line HIV testing of the exposed person Give IEC materials with local language
Additional laboratory evaluations	Rapid HIV test of the source person, if feasible and based on informed consent and standard operating procedures, also consider testing the source patient for HBV and HCV (if available) Pregnancy testing of exposed person if there the person is female in reproductive age group Hemoglobin (for zidovudine-containing PEP regimens) Hepatitis B and C screening if available
Medicine	Medicine Two nucleoside-analogue reverse-transcriptase inhibitors + /- boosted protease inhibitor Give doses of ARVs enough for 3 to 5 days (starter packs)
Time to initiation	The initial dose of antiretroviral medicines should be given as soon as possible but not later than 72 hours after exposure
Duration of therapy	28 days
Link to ART clinic and subsequent follow up there	The person started on PEP need to be informed report to the ART clinic in the next working day for further follow up. The exposed person should have a minimum of 6 visits to the ART clinic up to the sixth month HIV testing. In the ART clinic: Assess and manage side effects, Assess and support adherence Give continued health education and counseling on side effects; on the importance of treatment completion with good adherence, risk reduction; trauma or mental health problems; and social support and safety (both occupational and non occupational) in the first ART clinic visit, at 2 weeks and at 4 weeks. Do Follow-up HIV testing 6 weeks, 3 months and 6 months after exposure
Referral	Intra facility and inter facility referrals as appropriate
Record-keeping	Maintain accurate and confidential records

APPENDIX D-3: FACILITATING INFORMED PATIENT DECISION MAKING FOR HIV POST-EXPOSURE PROPHYLAXIS

In the process of giving health education and counseling for HIV post-exposure prophylaxis, people who have been exposed to HIV must be made fully aware of the following:

- The risk of acquiring HIV infection from the specific exposure;
- About the efficacy of PEP;
- The importance of taking a HIV test and of receiving appropriate post-test counseling before starting PEP drugs;
- The possibility that they might already be infected with HIV will need to be assessed if they have not already had an HIV test;
- People already living with HIV should be referred to the ART clinic for treatment of their infection, and if they had started PEP, the medicine should be stopped when the diagnosis is confirmed;
- The importance of adhering to medicine;
- The duration of the course of medicine (four weeks);
- The common side effects that may be experienced while taking PEP medicine and possible drug interactions.
- Exposed persons should be advised to avoid blood or tissue donations, breastfeeding, or pregnancy to prevent secondary transmission, especially during the first 6 to 12 weeks post exposure.
- PEP medicine can be taken during pregnancy and may protect the mother from getting HIV infection after exposure;
- That continuing to breastfeed while taking PEP is safe although the risk of transmitting HIV through breastfeeding is higher at the early stage of infection if the women get infected by HIV while breastfeeding; appropriate counseling.
- Discuss safe alternatives to breastfeeding if they are acceptable, feasible, affordable and sustainable; and
- Exclusive breastfeeding is strongly recommended whenever alternatives are not possible.
- Information provided as part of the informed consent process should be appropriate to the person's age, literacy skills and level of education and should take into account the context of the exposure.
- The consenting person must be able to understand the risks and benefits of the proposed intervention (PEP).

APPENDIX D-4: PEDIATRICS PEP DOSES

	Pediatric PEP dose	
1. Two drug PEP:		
A.	**AZT + 3TC**	
B.	**D4T + 3TC (if HB is < 7gm/dl)**	
2. Three drug PEP:		
A.	**AZT + 3TC + LVP/r**	
B	**D4T + 3TC + LPV/r [if HB < & 7 gm/dl]**	
	DOSE	**Formulation**
1. AZT	**0-4 wks: 4 mg/kg/dose PO BID**	**Syrup: 10mg/ml**
	4wks-12yrs: 180-240mg/m2/dose PO BID	**Capsules: 100mg**
	>/=13yrs: 300mg PO BID	**Tablet: 300mg** **Combvir(AZT/3TC): 300mg/150mg**
2. 3TC	**0-4wks: 2mg/kg/dose PO BID**	**Syrup: 10mg/ml**
	>/=4wks: 4mg/kg/dose PO BID	**Tablet: 150mg**
	≥13 yrs: 150 mg PO BID	**Combvir(AZT/3TC): 300mg/150mg**
3. D4T	**< 30 Kg: 1mg/kg/dose PO BID**	**Syrup: 1mg/ml**
	>/= 30mg: 30mg PO BID	**Capsules: 15mg, 30mg**
4. LPV/r	**LPV: 230mg/m2/dose +**	**Syrup: LPV/r=400mg/100mg in 5ml** **LPV/r = 80mg/ml/2omg/ml**
	r: 57.5mg/m2/dose PO BID	**Capsule: LPV/r=133.3/33.3**

APPENDIX D-5: RECOMMENDED POST-EXPOSURE PROPHYLAXIS FOR EXPOSURE TO HEPATITIS B VIRUS

Vaccination and antibody response status of exposed workers*	**Treatment**		
	Source HBsAg positive	**Source HBsAg negative**	**Source unknown not available for testing**
Unvaccinated	HBIG§ x 1 and initiate HB vaccine series	Initiate HB vaccine series	Initiate HB vaccine series
Previously vaccinated			
Known responder**	No treatment	No treatment	No treatment
Non responder†	HBIG x 1 and initiate revaccination source, or HBIG x 2 §§	No treatment	If known high risk treat as if source were HbsAg positive
Antibody response unknown	Test exposed person for HBsab 1. If adequate**, no treatment is necessary 2. If inadequate, administer HBIG x 1 vaccine booster	No treatment	Test exposed person for HBsab 1. If adequate**, no treatment is necessary 2. If inadequate†, administer vaccine and booster and recheck titer in 1 to 2 months

APPENDIX D-6: POST EXPOSURE PROPHYLAXIS FOLLOW UP CARD LEGEND

Facility Name: Write the name of the hospital or health center. **Date:** Date clients' exposure reported in Ethiopian calendar (dd/mm/yyyy. **Medical Record Number/Card Number:** A number given by the facility main chart room. For HMIS sites, this number is medical record number and for the other sites it is card number. **Patient Name:** Write patient full name. **Age:** Write age of the client in years **Sex:** Put a check mark on F for female and on M for Male. **Occupation:** Occupation of the exposed client (e.g. Nurse, physician, teacher, etc). **Address:** This information is helpful for tracking patients. Write the full address of the client in the spaces provided **Visits:** A follow up visits in the ART clinic. First the baseline information on the heading portion will be completed by the health worker who first encountered the exposed cases. The visits days/weeks are estimated from the first date the exposed person appears to the health facility. E.g. first visit is 1-3 days after initial presentation of the exposed case to the health facility. Write the **number of hours elapsed between time of exposure and time of reporting** in hours

Date of Visit

Enter date of visit in Ethiopian Calendar in dd/mm/yyyy format

HIV status of source case

Put a check mark on **Reactive** or **Non-Reactive** if the HIV status of the source case is known. If Unknown select **Unknown**

Circumstance of injury:

a) Trying to secure intravenous line
b) Needle stick injury during surgery
c) Needle stick while disposing of waste
d) Amniotic fluid splash during delivery
e) Splash with body cavity fluids during procedure
f) Other (specify: Cut injury with a surgical blade while doing a surgical procedure

Exposure code:

Occupational Exposure Code
Mucous Membrane
EC1= Few drops and short duration
EC2= Several drops /long duration/ major blood splash
Percutaneous
EC2= Solid and Superficial scratch
EC3= Hollow needle deep puncture

Source code

SC negative: HIV Negative
SC1: HIV positive; Asymptomatic/High CD4
SC2: HIV positive: Advanced disease/patient on antiretroviral therapy/primary infection/low CD4
SC unknown: HIV status unknown or source **unknown**

Exposure status

c) Hollow needle deep prick
d) Hollow needle superficial prick
e) Solid needle deep prick
f) Solid needle scratch
g) Splash to the conjunctivae
h) Splash to the oral cavity
i) Splash to intact skin
j) Splash to broken skin
k) Other (specify) cut injury with a surgical blades etc.....

Exposure type: Non-Occupational

1. Sexual assault
2. Pediatric exposures
3. Non HCW care givers
4. Unanticipated high risk exposure (consensual sexual activity)
5. Condom tears
6. Road traffic accident
7. Other (specify) e.g. Community fight, bite

Adherence grading

APPENDIX D-6: POST EXPOSURE PROPHYLAXIS FOLLOW UP CARD LEGEND (CONTINUED---)

<table>
<tr><td rowspan="8"></td><td rowspan="2">General counseling on PEP includes
▪ The risk of acquiring HIV infection due exposure
▪ The efficacy of PEP
▪ The importance of having a base line and follow up HIV test
▪ The importance of adherence to PEP drugs
▪ Advice to avoid secondary transmission to other people in case the exposed person becomes HIV positive due to exposure</td><td>Adherence</td><td>% of missed/mon</td><td># of missed dose per month</td></tr>
<tr><td>G(good)</td><td>>95%</td><td>≤ 3 doses</td></tr>
<tr><td rowspan="6">Counseling on:
▪ The risk of acquiring HIV infection due exposure
▪ The efficacy of PEP
▪ The importance of having a base line and follow up HIV test
▪ The importance of adherence to PEP drugs;
▪ The duration of the course of medicine (four weeks);
▪ The common side effects of PEP drugs
▪ Advice to avoid secondary transmission to other people in case</td><td>F(fair)</td><td>85-94%</td><td>5-8 dose</td></tr>
<tr><td>P(poor)</td><td><85%</td><td>≥ 9 doses</td></tr>
<tr><td colspan="3">Types of regimen given:</td></tr>
<tr><td colspan="3">d4T/3TC or AZT/3TC (CBV) or TDF/3TC
d4T/3TC/LPV/r
AZT/3TC/LPV/r
TDF/3TC/LPV/r
AZT/3TC/EFV</td></tr>
<tr><td colspan="3">Drug side effects</td></tr>
<tr><td colspan="3">1. Nauea
2. Dirrhea
3. Fatigue
4. Headache
5.Numbness/tingling
6. Rash
7. Anemia
8. Abdominal pain
9. Jaundice
10. Fat changes
11. Dizzy, anxiety, night mare
12. Other(specify)</td></tr>
<tr><td colspan="4">Remark: one may use the table to show any other additional information (e.g. linkage to HIV care or other support, tracking, lost dead etc)</td></tr>
</table>

Post Exposure Prophylaxis Follow up Card:

Patient Name: **Age:** **Sex:** □ **M** □ **F** **Occupation**

Address: Region: **Sub-city/Woreda**:
Kebele: **House #** **Tel:**

Exposure status:(a-i) Other specify: **Circumstance of injury:** Select a letter from the lists(a-e)

other(specify): Number of hours elapsed after exposure: hrs

HIV status of source case: □ **Reactive** □**Non-Reactive** □ **Unknown, If Reactive, Source code** □ **1** □ **2** **Exposure code:** □ **1** □ **2** □ **3**

Baseline HIV status of exposed person: □ Reactive □ Non-Reactive □ Not done **If female, pregnancy test:** □ Positive □ Negative

For Non-occupational exposure: □**Sexual violence/rape** □ **Other(specify)**

PEP Eligibility: □ **Eligible** □ **Not Eligible** **Type of PEP regimen provided :**

Visits		**Follow up information**				
			Fill the pt and service status as indicated	Measures taken in e.g. cases of poor adherence and drug side effect, additional PEP drugs prescribed for 2 weeks, linkages to other services etc.	**Next Appointment date**	**Remark (tracking of clients lost to follow up, etc)**
Visits in the ART clinic		Baseline info complete (Y/N)				
		General counseling on PEP(Y/N)				
	1st Visit (2-3 days)	Adherence (G/F/P)				
		Drug side effects (1-12)				
	2nd visit (2 weeks)	Adherence (G/F/P)				
		Drug side effects (1-12)				
		General counseling on PEP				
	3rd visit (4 weeks)	Adherence (G/F/P)				
		Drug side effects (1-12)				
		Treatment completed(Yes/No)				
		Reinforce counseling on PEP				
	4th visit (6weeks)	General counseling on PEP				
		HIV test result(N/NR)				
	5th visit (3 month)	HIV test result(N/NR)				
		General counseling on PEP				
	6th visit (6 month)	HIV test result(N/NR)				
		General counseling on PEP				

APPENDIX D-7: OCCUPATIONAL AND NON-OCCUPATIONAL HIV POST EXPOSURE PROPHYLAXIS REGISTER

Instructions for PEP register:

Serial Number (SN): A number assigned to patients on the register (e.g. 1, 2, 3, etc)

MRN/Card Number: A number given by the facility main chart room. For HMIS sites, this number is medical record number and for the other sites it is card number.

Date: Use Ethiopian Calendar and a format of DD/MM/YYYY to register when patient is enrolled in PEP service

Age: Enter client's age in year

Sex: Enter 'M' for male and 'F' for Female

Occupation: Enter Client current Occupation (e.g. health worker, teacher, daily laborer, etc)

Department/case team: Enter the Department or case team in which the client works (e.g. ANC, OPD, etc) for occupational exposures

Non-occupational Exposure: Put a check mark "√" under the Non-Occup-sexual assault/rape column if the client is exposed due to sexual assault/rape. Specify if the client is exposed to other non-occupational reasons under 'other-Non-Occup' column.

Occupational exposure: Put a check mark "√" under the 'Occup column' if the patient is exposed occupationally

Exposure Code/type: Put the exposure code types among the lists provided under the foot note of the PEP register. E.g. If a client is exposed to few drops of blood for short duration of time, write "EC1" under the 'Exposure code/type' column.

Source patient HIV Status code: Put the source patient HIV status code listed under the foot note of the PEP register under 'source patient HIV status code' column. E.g. If a client is exposed to a patient whose HIV status is negative after testing then write 'SC negative' under the 'source patient HIV status code' column

PEP Eligibility: If the client is eligible for PEP Write 'Eligible' otherwise write 'Not eligible'

Drug regimen provided: Put the PEP drug regimen provided to the client among the drug regimen listed under the foot note of PEP register. E.g. if a client is prescribed "AZT/3TC (CBV)" put 'AZT/3TC (CBV' under the 'drug regimen column'.

Treatment completed: Put 'Yes' if completed, 'No' if not completed the treatment under 'treatment completed' column

HIV status of exposed Person: Write 'R' for reactive) or 'NR' for non reactive depending or 'Unknown' for unknown status on the patient's HIV status at base line, 6 weeks, 3month, and 6 month

*** Remark:** Use the 'remark column' to document events like lost, stopped, linkage to HIV care and other (specify) as applicable

APPENDIX D-7: OCCUPATIONAL AND NON-OCCUPATIONAL HIV POST EXPOSURE PROPHYLAXIS REGISTERS (CONTINUED---)

SN	MRN/Card Number	Date	Age	sex	Occupation	Case team/Department	Non-occupational exposure		Occupational exposure(√)	Exposure Code/ type	Source patient HIV statu code	PEP Eligibility (Eligible/Not Eligible)	Drug regimen Provided	Treatment completed(Y/N)	HIV status of Exposed person(R or NR)				Remark
							Rape/Sexual assault(√)	Other Non occupational(specify)							Base line	6w	3m	6m	

Occupational exposure code

Mucus membrane

EC1=Few drops and short duration

EC2=Several drops /long duration/ major blood splash

Non-occupational exposure

- Sexual assult
- Pediatric exposure
- Un-anticipated high risk exposure
- Community fight
- Road traffic accident
- Other(specify)

Percutaneous

- EC2= Solid and superficial scracthes
- EC3=Hollow needle deep puncture

Drug Regimen Code

d4T/3TC or AZT/3TC (CBV) or TDF/3TC
d4T/3TC/LPV/r
AZT/3TC/LPV/r
TDF/3TC/LPV/r
AZT/3TC/EFV

HIV status code of the source

SC negative: HIV Negative

SC1: HIV positive; Asymptomatic/High CD4

SC2: HIV positive: Advanced disease/patient on antiretroviral therapy/primary infection/low CD4

SC unknown: HIV status unknown or source unknown

Remark

Lost
Dead
Stopped
Other (Specify)

APPENDIX D-8: PEP FACILITY ASSESSMENT FORM

1. (STI/(1/2)

Facility Completed by: _____

Date of Visit (Ethiopian Date) day [4] month [5] year [6] Checked by: _____

A. Set up of PEP Service

1. **Is there a PEP Service (both for occupational and non-occupational exposures) in the facility?**

   □ **Yes** □ **No**

2. **Is the PEP service in 24 hours available?**

   □ **Yes** □ **No**

3. **Are PEP drugs accessible 24 hours where?**

   □ **Emergency case team** □ **L &D case team**

   □ **In Patient case team** □ **OPD case team**

   □ **Others specify** _____

4. **Is there follow up of patients on PEP in the ART clinic**

   □ **Yes** □ **No**

5. **Are the staffs in the health facility aware of PEP service?**

   □ **Yes** □ **No**

B. Human Resource

1. **Number of staff trained in trainings that includes PEP (ART, IMAI/IMNCI, IP, STI/PEP)**

   MD___ Nurse___ HO____ HA/Junior Nurse___ Other____

2. **At least one PEP trained personnel assigned in each case team on duty hours to give PEP service (as an additional responsibility)**

   MD___ Nurse___ HO_____ Junior Nurse/HA_____

3. **At least one PIHCT trained personnel assigned in each case team on duty hours to give CT service for PEP purpose (as additional responsibility)**

   MD___ Nurse___ HO_____ Junior Nurse/HA _____

4. **Is there PEP Focal Person?**

   □ **Yes** □ **No**

5. **Is the PEP focal person a member of the MDT committee and IP committee?**

   □ **Yes** □ **No**

6. **Does PEP focal person regularly (weekly) follow, if the PEP service is given according to the standard management?**

   □ **Yes** □ **No**

C. Materials available in the PEP service outlets:

1. **Do the PEP service outlets have standard reference materials? (Check box when available)**

   - **National infection prevention and patient safety**
   - **Reference manual** □
   - **National PITC guideline** □
   - **PITC protocol** □
   - **PITC cue card** □
   - **Decision making tool for PEP wall charts** □
   - **Others specify** _____

2. **Standard IEC materials available in PEP service areas for**

   - **HIV** □ **Yes** □ **No**
   - **PITC** □ **Yes** □ **No**
   - **ART** □ **Yes** □ **No**
   - **PEP** □ **Yes** □ **No**

D. Equipment/Supplies/Furniture available in the facility:

1. **Is there adequate supply and appropriate use of personal protective equipments in every service outlet of the hospital?**

   □ **Yes**

   □ **No, specify** _____

2. **Is there clean water supply in the rooms?**

   □ **Yes** □ **No**

3. **Are the recommended ARVs for PEP available in PEP service delivery areas at least one pack from each?**

   □ **Yes** □ **No**

4. **Are condoms available in the service outlets?**

   □ **Yes** □ **No**

5. **Is there a penile model to demonstrate about condom use?**

   □ **Yes** □ **No**

6. **Are HIV test kits available in the PEP service outlets?**

   □ **Yes** □ **No**

7. **Are pregnancy test kits available in the PEP service outlets?**

   □ **Yes** □ **No**

8. **Safety boxes available in every service outlet for safe disposal of sharps**

□ Yes □ No

8. Does the Health facility have a mechanism for incorporating the IP and MDT reports (which includes PEP)

9. In the pharmacy, are enough stock of recommended ARV drugs for PEP available?

□ Yes specify _____ □ No

E. Standard M&E Tools

Are the following formats available in the ART clinic?

1. Potential HIV exposure documentation and follow up form

□ Yes □ No

2. PEP register

□ Yes □ No

3. Intra facility referral?

□ Yes □ No
□ Yes □ No

4. Service outlet HMIS register (in facilities that have not started the HMIS)

□ Yes □ No

F. Service Practice

1. Do healthcare workers follow IP protocol (like using appropriate personal protective equipments, safe disposal of sharps….)

□ Yes □ No □ sometimes

2. Is HIV testing and counseling (base line and follow up at 3 & 6 months) done for patients who take PEP?

□ Yes □ No □ sometimes

3. Adherence counseling and follow up of side effects done for PEP patients according to the standard

□ Yes □ No □ sometimes

4. Completing of PEP drugs is followed and documented in the PEP register.

□ Yes □ No □ sometimes

5. HIV testing of source patient (if required for decision making) done after taking consent.

□ Yes □ No □ sometimes

6. Do the health facility MDT and IP committees use PEP data generated in hospital to improve PEP service delivery and IP practice of the facility in general?

□ Yes □ No □ sometimes

7. Do health facility MDT and IP committees have monthly meetings and monitor the PEP service delivery and IP practice of health facilities

In to a final report that is given to the CEO and MD at least quarterly?

COMMENTS, RECOMMENDATIONS & FOLLOW-UP

Follow-up - Describe actions since last visit:

Comments about this visit

Recommended actions, persons responsible, time frame

APPENDIX D-9: CHECKLIST FOR PEP AT SITE LEVEL PEP SERVICE DELIVERY

The below mentioned human resources, materials and supplies need to be 24 hours available in each case of health facilities

1. Healthcare provider who is trained on PEP service delivery
2. National infection prevention and patient safety reference manual
3. National PITC guideline
4. PITC protocol
5. PITC cue card
6. Decision making tool for PEP wall charts
7. IEC materials on HIV, PITC, ART and PEP
8. Potential HIV exposure documentation and follow up form
9. PEP register
10. ARVs (recommended PEP drugs available in EOPD)
11. Condoms
12. Penile models
13. Gloves
14. Syringe with needle
15. Lancet
16. Safety box
17. Soap and water supply
18. HIV test kits
19. Pregnancy test kit
20. Post pill

APPENDIX D-10: DECISION MAKING TOOLS FOR PEP

Classify the client

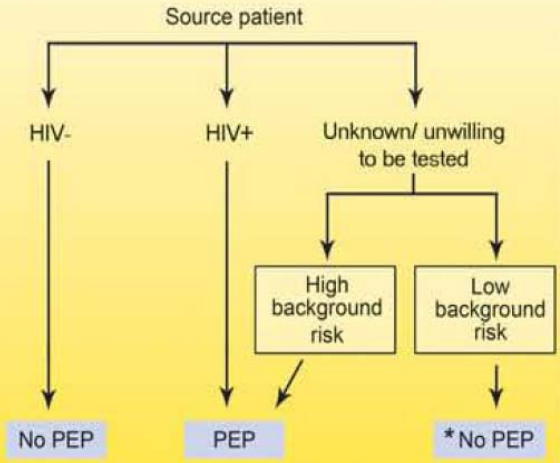
1. Determine the Status Code (SC)

- *Risk assessment of the source patient - choose **SC1**, **SC2**, or **SC unknown***

2. Determine the Exposure Code (EC)

- *Risk assessment of the exposure - choose **EC1**, **EC2**, or **EC3***

Decision tree to evaluate need for PEP



** CDC recommendation: usually PEP unnecessary; consider use if source patient is high risk*

NB: If HCW is HIV+, s/he sould not take PEP, but should be referred to ART clinic for continued care. If HIV status of HCW is unknown or previously negative(-), PEP may or may not be indicated depending on source risk assessment.

Determining HIV Status Code of the source (SC)

HIV Negative → *No PEP*

HIV Positive
- → *Asymptomatic / Viral load < 1500 copies/mL = HIV **SC1***
- → *Symptomatic HIV infection, AIDS, Acute seroconversion, patient on antiretroviral therapy, Viral load > 1500 copies/mL = HIV **SC2***

HIV status unknown or source unknown = HIV SC unknown

Determining the Exposure Code (EC)

Exposure on mucous membrane or broken skin

↓

Estimate volume

↓

*Few drops, short duration = **EC1***
*Several drops/ long duration/ major blood splash = **EC2***

Exposure on intact skin → No PEP

Percutaneous exposure → Determine severity →
- *Solid, superficial injury = **EC2***
- *Hollow needle deep puncture = **EC3***

Recommended HIV PEP for percutaneous injuries

Status code	Exposure code	
	EC 2	EC 3
SC1	Basic 2-drug PEP	Expanded 3-drug PEP
SC2	Expanded 3-drug PEP	Expanded 3-drug PEP
SC unknown	No PEP warranted Consider basic 2-drug PEP for source with HIV risk factors	No PEP warranted Consider basic 2-drug PEP for source with HIV risk factors
HIV-Negative	No PEP warranted	No PEP warranted

Recommended HIV PEP for mucous membrane exposures and nonintact skin exposures

Status code	Exposure code	
	EC 1	EC 2
SC 1	Consider basic 2-drug PEP	Basic 2-drug PEP
SC 2	Basic 2-drug PEP	Expanded 3-drug PEP
SC unknown	No PEP warranted. If PEP is given and the source is later determined to be HIV-negative, PEP should be stopped.	No PEP warranted Consider basic 2-drug PEP for source with HIV risk factors
HIV-Negative	No PEP warranted	No PEP warranted

APPENDIX D-10: DECISION MAKING TOOLS FOR PEP (CONTINUED---)

Recommended antiretroviral drugs for PEP use in Ethiopia	
2-drug PEP	3-drug PEP
ZDV/3TC or d4T (30)/3TC	ZDV/3TC or d4T (30)/3TC + LPV/r
ZDV/3TC = Combivir *d4T = Stavudine* *LPV/r = Kaletra*	

Dosages for Pediatric PEP			
	Two drug PEP	a) ZDV + 3TC	b) d4T + 3TC (if Hb < 7 gm/dL)
	Three drug PEP	a) ZDV + 3TC + LPV/r	b) d4T + 3TC + LPV/r (if Hb < 7 gm/dL)
	Dosage		Formulation
ZDV (AZT)	0-4 wks: 4 mg/kg/dose PO BID 4 wks – 12yrs: 180-240mg/m^2/dose PO BID ≥ 13yrs: 300mg PO BID		Syrup: 10mg/ml Capsules: 100mg Tablets: 300mg Combivir (AZT/3TC): 300mg/150mg
3TC	0-4wks: 2mg/kg/dose PO BID 4wks – 12yrs: 4mg/kg/dose PO BID ≥ 13yrs: 150mg PO BID		Syrup: 10mg/ml Tablet: 150mg Combivir (AZT/3TC): 300mg/150mg
d4T	< 30 Kg: 1mg/kg/dose PO BID ≥ 30 Kg: 30mg PO BID		Syrup: 1mg/ml Capsules: 15mg, 30mg
LPV/r	LPV: 230 mg/m^2/dose + r: 57.5 mg/m^2/dose } PO BID *Max: LPV/r 400mg/ 100mg PO BID		Syrup: LPV/r=400mg/100mg in 5ml or LPV/r = 80mg/ml/ 20 mg/ml Capsules: LPV/r=133.3mg/33.3mg Tablet: LPV/r = 200mg/50mg
	r = ritonavir		
	BSA (m^2) = $\sqrt{\text{ht (cm) x wt (kg) / 3600}}$		

APPENDIX E: TYPE AND DURATION OF PRECAUTIONS RECOMMENDED FOR SELECTED INFECTIONS AND CONDITIONS

Appendix E. Introduction

The mode(s) and risk of transmission for each specific disease agent included in **Appendix E**. were reviewed.

Principle sources consulted for the development of disease-specific recommendations for **Appendix E.** included infectious disease manuals and textbooks 833, 1043, 1044. The published literature was sought for evidence of person-to-person transmission in healthcare and non-healthcare settings with a focus on reported outbreaks that would assist in developing recommendations for all settings where healthcare is delivered. Criteria used to assign Transmission-Based Precautions categories follow:

- A Transmission-Based Precautions category was assigned if there was strong evidence for person-to-person transmission via droplet, contact, or airborne routes in healthcare or non-healthcare settings and/or if patient factors (e.g. diapered infants, diarrhea, draining wounds) increased the risk of transmission.
- Transmission-Based Precautions category assignments reflect the predominant mode(s) of transmission.
- If there was no evidence for person-to-person transmission by droplet, contact or airborne routes, Standard Precautions were assigned.
- If there was a low risk for person-to-person transmission and no evidence of healthcare-associated transmission, Standard Precautions were assigned.
- Standard Precautions were assigned for blood borne pathogens (e.g. hepatitis B and C viruses, human immunodeficiency virus) as per CDC recommendations for Universal Precautions issued in 1988. Subsequent experience has confirmed the efficacy of Standard Precautions to prevent exposure to infected blood and body fluid.

Additional information relevant to use of precautions was added in the comments column to assist the caregiver in decision-making. Citations were added as needed to support a change in or provide additional evidence for recommendations for a specific disease and for new infectious agents (e.g. SARS-CoV, avian influenza).

Infection/Condition	Precautions		
	Type *	Duration †	Comments
			with powder on them (http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5135a3.htm) **Hand hygiene:** Handwashing for 30-60 seconds with soap and water or 2% chlorhexidene gluconate after spore contact (alcohol handrubs inactive against spores [983]. **Post-exposure prophylaxis following environmental exposure**: 60 days of antimicrobials (either doxycycline, ciprofloxacin, or levofloxacin) and post-exposure vaccine under IND
Antibiotic-associated colitis (see *Clostridium difficile*)			
Arthropod-borne viral encephalitides (eastern, western, Venezuelan equine encephalomyelitis; St Louis, California encephalitis; West Nile Virus) and viral fevers (dengue, yellow fever, Colorado tick fever)	S		Not transmitted from person to person except rarely by transfusion, and for West Nile virus by organ transplant, breastmilk or transplacentally [530, 1047]. Install screens in windows and doors in endemic areas Use DEET-containing mosquito repellants and clothing to cover extremities
Ascariasis	S		Not transmitted from person to person
Aspergillosis	S		Contact Precautions and Airborne Precautions if massive soft tissue infection with copious drainage and repeated irrigations required [154].
Avian influenza (see influenza, avian below)			
Babesiosis	S		Not transmitted from person to person except rarely by transfusion,
Blastomycosis, North American, cutaneous or pulmonary	S		Not transmitted from person to person
Botulism	S		Not transmitted from person to person
Bronchiolitis (see respiratory infections in infants and young children)	C	DI	Use mask according to Standard Precautions.
Brucellosis (undulant, Malta, Mediterranean fever)	S		Not transmitted from person to person except rarely via banked spermatozoa and sexual contact [1048, 1049]. Provid antimicrobial prophylaxis following laboratory exposure [1050].
Campylobacter gastroenteritis (see gastroenteritis)			
Candidiasis, all forms including mucocutaneous	S		
Cat-scratch fever (benign inoculation lymphoreticulosis)	S		Not transmitted from person to person
Cellulitis	S		

Infection/Condition	Precautions		
	Type *	Duration †	Comments
Chancroid (soft chancre) (*H. ducreyi*)	S		Transmitted sexually from person to person
Chickenpox (see varicella)			
Chlamydia trachomatis			
Conjunctivitis	S		
Genital (lymphogranuloma venereum)	S		
Pneumonia (infants ≤ 3 mos. of age))	S		
Chlamydia pneumoniae	S		Outbreaks in institutionalized populations reported, rarely [1051, 1052]
Cholera (see gastroenteritis)			
Closed-cavity infection			
Open drain in place; limited or minor drainage	S		Contact Precautions if there is copious uncontained drainage
No drain or closed drainage system in place	S		
Clostridium			
C. botulinum	S		Not transmitted from person to person
C. difficile (see Gastroenteritis, *C. difficile)*	C	DI	
C. perfringens			
Food poisoning	S		Not transmitted from person to person
Gas gangrene	S		Transmission from person to person rare; one outbreak in a surgical setting reported [1053]. Use Contact Precautions if wound drainage is extensive.
Coccidioidomycosis (valley fever)			
Draining lesions	S		Not transmitted from person to person except under extraordinary circumstances because the infectious arthroconidial form of *Coccidioides immitis* is not produced in humans [1054].
Pneumonia	S		Not transmitted from person to person except under extraordinary circumstances, (e.g., inhalation of aerosolized tissue phase endospores during necropsy, transplantation of infected lung) because the infectious arthroconidial form of *Coccidioides immitis* is not produced in humans [1054, 1055].
Colorado tick fever	S		Not transmitted from person to person
Congenital rubella	C	Until 1 yr of age	Standard Precautions if nasopharyngeal and urine cultures repeatedly neg. after 3 mos. of age

Infection/Condition	Precautions		
	Type *	Duration †	Comments
Conjunctivitis			
Acute bacterial	S		
Chlamydia	S		
Gonococcal	S		
Acute viral (acute hemorrhagic)	C	DI	Adenovirus most common; enterovirus 70 [1056], Coxsackie virus A24 [1057]) also associated with community outbreaks. Highly contagious; outbreaks in eye clinics, pediatric and neonatal settings, institutional settings reported. Eye clinics should follow Standard Precautions when handling patients with conjunctivitis. Routine use of infection control measures in the handling of instruments and equipment will prevent the occurrence of outbreaks in this and other settings. [460, 814, 1058, 1059 461, 1060]
Corona virus associated with SARS (SARS-CoV) (see severe acute respiratory syndrome)			
Coxsackie virus disease (see enteroviral infection)			
Creutzfeldt-Jakob disease CJD, vCJD	S		Use disposable instruments or special sterilization/disinfection for surfaces, objects contaminated with neural tissue if CJD or vCJD suspected and has not been R/O; No special burial procedures [1061]
Croup (see respiratory infections in infants and young children)			
Crimean-Congo Fever (see Viral Hemorrhagic Fever)	S		
Cryptococcosis	S		Not transmitted from person to person, except rarely via tissue and corneal transplant [1062, 1063]
Cryptosporidiosis (see gastroenteritis)			
Cysticercosis	S		Not transmitted from person to person
Cytomegalovirus infection, including in neonates and immunosuppressed patients	S		No additional precautions for pregnant HCWs
Decubitus ulcer (see Pressure ulcer)			
Dengue fever	S		Not transmitted from person to person
Diarrhea, acute-infective etiology suspected (see gastroenteritis)			
Diphtheria			

Infection/Condition	Precautions		
	Type *	Duration †	Comments
Cutaneous	C	CN	Until 2 cultures taken 24 hrs. apart negative
Pharyngeal	D	CN	Until 2 cultures taken 24 hrs. apart negative
Ebola virus (see viral hemorrhagic fevers)			
Echinococcosis (hydatidosis)	S		Not transmitted from person to person
Echovirus (see enteroviral infection)			
Encephalitis or encephalomyelitis (see specific etiologic agents)			
Endometritis (endomyometritis)	S		
Enterobiasis (pinworm disease, oxyuriasis)	S		
Enterococcus species (see multidrug-resistant organisms if epidemiologically significant or vancomycin resistant)			
Enterocolitis, *C. difficile* (see *C. difficile*, gastroenteritis)			
Enteroviral infections (i.e., Group A and B Coxsackie viruses and Echo viruses) (excludes polio virus)	S		Use Contact Precautions for diapered or incontinent children for duration of illness and to control institutional outbreaks
Epiglottitis, due to *Haemophilus influenzae* type b	D	U 24 hrs	See specific disease agents for epiglottitis due to other etiologies)
Epstein-Barr virus infection, including infectious mononucleosis	S		
Erythema infectiosum (also see Parvovirus B19)			
Escherichia coli gastroenteritis (see gastroenteritis)			
Food poisoning			
Botulism	S		Not transmitted from person to person
C. perfringens or welchii	S		Not transmitted from person to person
Staphylococcal	S		Not transmitted from person to person
Furunculosis, staphylococcal	S		Contact if drainage not controlled. Follow institutional policies if MRSA
Infants and young children	C	DI	
Gangrene (gas gangrene)	S		Not transmitted from person to person
Gastroenteritis	S		Use Contact Precautions for diapered or incontinent persons for the duration of illness or to control institutional outbreaks for gastroenteritis caused by all of the agents below
Adenovirus	S		Use Contact Precautions for diapered or incontinent persons for the duration of illness or to control institutional outbreaks
Campylobacter species	S		Use Contact Precautions for diapered or incontinent persons for the duration of illness or to control institutional outbreaks

Infection/Condition	Precautions		
	Type *	Duration †	Comments
Cholera *(Vibrio cholerae)*	S		Use Contact Precautions for diapered or incontinent persons for the duration of illness or to control institutional outbreaks
C. difficile	C	DI	Discontinue antibiotics if appropriate. Do not share electronic thermometers [853, 854]; ensure consistent environmental cleaning and disinfection. Hypochlorite solutions may be required for cleaning if transmission continues [847]. Handwashing with soap and water preferred because of the absence of sporicidal activity of alcohol in waterless antiseptic handrubs [983].
Cryptosporidium species	S		Use Contact Precautions for diapered or incontinent persons for the duration of illness or to control institutional outbreaks
E. coli			
Enteropathogenic O157:H7 and other shiga toxin-producing Strains	S		Use Contact Precautions for diapered or incontinent persons for the duration of illness or to control institutional outbreaks
Other species	S		Use Contact Precautions for diapered or incontinent persons for the duration of illness or to control institutional outbreaks
Giardia lamblia	S		Use Contact Precautions for diapered or incontinent persons for the duration of illness or to control institutional outbreaks
Noroviruses	S		Use Contact Precautions for diapered or incontinent persons for the duration of illness or to control institutional outbreaks. Persons who clean areas heavily contaminated with feces or vomitus may benefit from wearing masks since virus can be aerosolized from these body substances [142, 147 148]; ensure consistent environmental cleaning and disinfection with focus on restrooms even when apparently unsoiled [273, 1064]). Hypochlorite solutions may be required when there is continued transmission [290-292]. Alcohol is less active, but there is no evidence that alcohol antiseptic handrubs are not effective for hand decontamination [294]. Cohorting of affected patients to separate airspaces and toilet facilities may help interrupt transmission during outbreaks.
Rotavirus	C	DI	Ensure consistent environmental cleaning and disinfection and frequent removal of soiled diapers. Prolonged shedding may occur in both immunocompetent and immunocompromised children and the

Infection/Condition	Precautions		
	Type *	Duration †	Comments
			elderly [932, 933].
Salmonella species (including *S. typhi*)	S		Use Contact Precautions for diapered or incontinent persons for the duration of illness or to control institutional outbreaks
Shigella species (Bacillary dysentery)	S		Use Contact Precautions for diapered or incontinent persons for the duration of illness or to control institutional outbreaks
Vibrio parahaemolyticus	S		Use Contact Precautions for diapered or incontinent persons for the duration of illness or to control institutional outbreaks
Viral (if not covered elsewhere)	S		Use Contact Precautions for diapered or incontinent persons for the duration of illness or to control institutional outbreaks
Yersinia enterocolitica	S		Use Contact Precautions for diapered or incontinent persons for the duration of illness or to control institutional outbreaks
German measles (see rubella; see congenital rubella)			
Giardiasis (see gastroenteritis)			
Gonococcal ophthalmia neonatorum (gonorrheal ophthalmia, acute conjunctivitis of newborn)	S		
Gonorrhea	S		
Granuloma inguinale (Donovanosis, granuloma venereum)	S		
Guillain-Barré' syndrome	S		Not an infectious condition
Haemophilus influenzae (see disease-specific recommendations)			
Hand, foot, and mouth disease (see enteroviral infection)			
Hansen's Disease (see Leprosy)			
Hantavirus pulmonary syndrome	S		Not transmitted from person to person
Helicobacter pylori	S		
Hepatitis, viral			
Type A	S		Provide hepatitis A vaccine post-exposure as recommended [1065]
Diapered or incontinent patients	C		Maintain Contact Precautions in infants and children <3 years of age for duration of hospitalization; for children 3-14 yrs. of age for 2 weeks after onset of symptoms; >14 yrs. of age for 1 week after onset of symptoms [833, 1066, 1067].
Type B-HBsAg positive; acute or chronic	S		See specific recommendations for care of patients in hemodialysis centers [778]

Infection/Condition	Precautions		
	Type *	Duration †	Comments
Type C and other unspecified non-A, non-B	S		See specific recommendations for care of patients in hemodialysis centers [778]
Type D (seen only with hepatitis B)	S		
Type E	S		Use Contact Precautions for diapered or incontinent individuals for the duration of illness [1068]
Type G	S		
Herpangina (see enteroviral infection)			
Hookworm	S		
Herpes simplex (*Herpesvirus hominis*)			
Encephalitis	S		
Mucocutaneous, disseminated or primary, severe	C	Until lesions dry and crusted	
Mucocutaneous, recurrent (skin, oral, genital)	S		
Neonatal	C	Until lesions dry and crusted	Also, for asymptomatic, exposed infants delivered vaginally or by C-section and if mother has active infection and membranes have been ruptured for more than 4 to 6 hrs until infant surface cultures obtained at 24-36 hrs. of age negative after 48 hrs incubation [1069, 1070]
Herpes zoster (varicella-zoster) (shingles)			
Disseminated disease in any patient Localized disease in immunocompromised patient until disseminated infection ruled out	A,C	DI	Susceptible HCWs should not enter room if immune caregivers are available; no recommendation for protection of immune HCWs; no recommendation for type of protection, i.e. surgical mask or respirator; for susceptible HCWs.
Localized in patient with intact immune system with lesions that can be contained/covered	S	DI	Susceptible HCWs should not provide direct patient care when other immune caregivers are available.
Histoplasmosis	S		Not transmitted from person to person
Human immunodeficiency virus (HIV)	S		Post-exposure chemoprophylaxis for some blood exposures [866].
Human metapneumovirus	C	DI	HAI reported [1071], but route of transmission not established [923]. Assumed to be Contact transmission as for RSV since the viruses are closely related and have similar clinical manifestations and epidemiology. Wear masks according to Standard Precautions..
Impetigo	C	U 24 hrs	

Infection/Condition	Precautions		
	Type *	Duration †	Comments
Infectious mononucleosis	S		
Influenza			
Human (seasonal influenza)	D	5 days except DI in immuno compromised persons	Single patient room when available or cohort; avoid placement with high-risk patients; mask patient when transported out of room; chemoprophylaxis/vaccine to control/prevent outbreaks [511]. Use gown and gloves according to Standard Precautions may be especially important in pediatric settings. Duration of precautions for immunocompromised patients cannot be defined; prolonged duration of viral shedding (i.e. for several weeks) has been observed; implications for transmission are unknown [930].
Avian (e.g., H5N1, H7, H9 strains))			See www.cdc.gov/flu/avian/professional/infect-control.htm for current avian influenza guidance.
Pandemic influenza (also a human influenza virus)	D	5 days from onset of symptoms	See http://www.pandemicflu.gov for current pandemic influenza guidance.
Kawasaki syndrome	S		Not an infectious condition
Lassa fever (see viral hemorrhagic fevers)			
Legionnaires' disease	S		Not transmitted from person to person
Leprosy	S		
Leptospirosis	S		Not transmitted from person to person
Lice			http://www.cdc.gov/ncidod/dpd/parasites/lice/default.htm
Head (pediculosis)	C	U 4 hrs	
Body	S		Transmitted person to person through infested clothing. Wear gown and gloves when removing clothing; bag and wash clothes according to CDC guidance above
Pubic	S		Transmitted person to person through sexual contact
Listeriosis (listeria monocytogenes)	S		Person-to-person transmission rare; cross-transmission in neonatal settings reported [1072, 1073 1074, 1075]
Lyme disease	S		Not transmitted from person to person
Lymphocytic choriomeningitis	S		Not transmitted from person to person

Infection/Condition	Precautions		
	Type *	Duration †	Comments
Lymphogranuloma venereum	S		
Malaria	S		Not transmitted from person to person except through transfusion rarely and through a failure to follow Standard Precautions during patient care [1076-1079]. Install screens in windows and doors in endemic areas. Use DEET-containing mosquito repellants and clothing to cover extremities
Marburg virus disease (see viral hemorrhagic fevers)			
Measles (rubeola)	A	4 days after onset of rash; DI in immune compromised	Susceptible HCWs should not enter room if immune care providers are available; no recommendation for face protection for immune HCW; no recommendation for type of face protection for susceptible HCWs, i.e., mask or respirator [1027, 1028]. For exposed susceptibles, post-exposure vaccine within 72 hrs. or immune globulin within 6 days when available [17, 1032, 1034]. Place exposed susceptible patients on Airborne Precautions and exclude susceptible healthcare personnel from duty from day 5 after first exposure to day 21 after last exposure, regardless of post-exposure vaccine [17].
Melioidosis, all forms	S		Not transmitted from person to person
Meningitis			
Aseptic (nonbacterial or viral; also see enteroviral infections)	S		Contact for infants and young children
Bacterial, gram-negative enteric, in neonates	S		
Fungal	S		
Haemophilus influenzae, type b known or suspected	D	U 24 hrs	
Listeria monocytogenes (See Listeriosis)	S		
Neisseria meningitidis (meningococcal) known or suspected	D	U 24 hrs	See meningococcal disease below
Streptococcus pneumoniae	S		
M. tuberculosis	S		Concurrent, active pulmonary disease or draining cutaneous lesions may necessitate addition of Contact and/or Airborne Precautions; For children, airborne precautions until active tuberculosis ruled out in visiting family members (see tuberculosis below) [42]
Other diagnosed bacterial	S		
Meningococcal disease: sepsis, pneumonia, meningitis	D	U 24 hrs	Postexposure chemoprophylaxis for household contacts, HCWs

Infection/Condition	Precautions		
	Type *	Duration †	Comments
			exposed to respiratory secretions; postexposure vaccine only to control outbreaks [15, 17].
Molluscum contagiosum	S		
Monkeypox	A,C	A-Until monkeypox confirmed and smallpox excluded C-Until lesions crusted	Use See www.cdc.gov/ncidod/monkeypox for most current recommendations. Transmission in hospital settings unlikely [269]. Pre- and post-exposure smallpox vaccine recommended for exposed HCWs
Mucormycosis	S		
Multidrug-resistant organisms (MDROs), infection or colonization (e.g., MRSA, VRE, VISA/VRSA, ESBLs, resistant *S. pneumoniae*)	S/C		MDROs judged by the infection control program, based on local, state, regional, or national recommendations, to be of clinical and epidemiologic significance. Contact Precautions recommended in settings with evidence of ongoing transmission, acute care settings with increased risk for transmission or wounds that cannot be contained by dressings. See recommendations for management options in Management of Multidrug-Resistant Organisms In Healthcare Settings, 2006 [870]. Contact state health department for guidance regarding new or emerging MDRO.
Mumps (infectious parotitis)	D	U 9 days	After onset of swelling; susceptible HCWs should not provide care if immune caregivers are available. Note: (Recent assessment of outbreaks in healthy 18-24 year olds has indicated that salivary viral shedding occurred early in the course of illness and that 5 days of isolation after onset of parotitis may be appropriate in community settings; however the implications for healthcare personnel and high-risk patient populations remain to be clarified.)
Mycobacteria, nontuberculosis (atypical)			Not transmitted person-to-person
Pulmonary	S		
Wound	S		
Mycoplasma pneumonia	D	DI	

Infection/Condition	Precautions		
	Type *	Duration †	Comments
Necrotizing enterocolitis	S		Contact Precautions when cases clustered temporally [1080-1083].
Nocardiosis, draining lesions, or other presentations	S		Not transmitted person-to-person
Norovirus (see gastroenteritis)			
Norwalk agent gastroenteritis (see gastroenteritis)			
Orf	S		
Parainfluenza virus infection, respiratory in infants and young children	C	DI	Viral shedding may be prolonged in immunosuppressed patients [1009, 1010]. Reliability of antigen testing to determine when to remove patients with prolonged hospitalizations from Contact Precautions uncertain.
Parvovirus B19 (Erythema infectiosum)	D		Maintain precautions for duration of hospitalization when chronic disease occurs in an immunocompromised patient. For patients with transient aplastic crisis or red-cell crisis, maintain precautions for 7 days. Duration of precautions for immunosuppressed patients with persistently positive PCR not defined, but transmission has occurred [929].
Pediculosis (lice)	C	U 24 hrs after treatment	
Pertussis (whooping cough)	D	U 5 days	Single patient room preferred. Cohorting an option. Post-exposure chemoprophylaxis for household contacts and HCWs with prolonged exposure to respiratory secretions [863]. Recommendations for Tdap vaccine in adults under development.
Pinworm infection (Enterobiasis)	S		
Plague *(Yersinia pestis)*			
Bubonic	S		
Pneumonic	D	U 48 hrs	Antimicrobial prophylaxis for exposed HCW [207].
Pneumonia			
Adenovirus	D, C	DI	Outbreaks in pediatric and institutional settings reported [376, 1084-1086]. In immunocompromised hosts, extend duration of Droplet and Contact Precautions due to prolonged shedding of virus [931]
Bacterial not listed elsewhere (including gram-negative bacterial)	S		
B. cepacia in patients with CF, including respiratory tract colonization	C	Unknown	Avoid exposure to other persons with CF; private room preferred. Criteria for D/C precautions not established. See CF Foundation

Infection/Condition	Precautions		
	Type *	Duration †	Comments
			guideline [20]
B. cepacia in patients without CF(see Multidrug-resistant organisms)			
Chlamydia	S		
Fungal	S		
Haemophilus influenzae, type b			
Adults	S		
Infants and children	D	U 24 hrs	
Legionella spp.	S		
Meningococcal	D	U 24 hrs	See meningococcal disease above
Multidrug-resistant bacterial (see multidrug-resistant organisms)			
Mycoplasma (primary atypical pneumonia)	D	DI	
Pneumococcal pneumonia	S		Use Droplet Precautions if evidence of transmission within a patient care unit or facility [196-198, 1087]
Pneumocystis jiroveci (*Pneumocystis carinii*)	S		Avoid placement in the same room with an immunocompromised patient.
Staphylococcus aureus	S		For MRSA, see MDROs
Streptococcus, group A			
Adults	D	U 24 hrs	See streptococcal disease (group A streptococcus) below Contact precautions if skin lesions present
Infants and young children	D	U 24 hrs	Contact Precautions if skin lesions present
Varicella-zoster (See Varicella-Zoster)			
Viral			
Adults	S		
Infants and young children (see respiratory infectious disease, acute, or specific viral agent)			
Poliomyelitis	C	DI	
Pressure ulcer (decubitus ulcer, pressure sore) infected			
Major	C	DI	If no dressing or containment of drainage; until drainage stops or can be contained by dressing
Minor or limited	S		If dressing covers and contains drainage

Infection/Condition	Precautions		
	Type *	Duration †	Comments
Prion disease (See Creutzfeld-Jacob Disease)			
Psittacosis (ornithosis) (*Chlamydia psittaci*)	S		Not transmitted from person to person
Q fever	S		
Rabies	S		Person to person transmission rare; transmission via corneal, tissue and organ transplants has been reported [539, 1088]. If patient has bitten another individual or saliva has contaminated an open wound or mucous membrane, wash exposed area thoroughly and administer postexposure prophylaxis. [1089]
Rat-bite fever (*Streptobacillus moniliformis* disease, *Spirillum minus* disease)	S		Not transmitted from person to person
Relapsing fever	S		Not transmitted from person to person
Resistant bacterial infection or colonization (see multidrug-resistant organisms)			
Respiratory infectious disease, acute (if not covered elsewhere)			
Adults	S		
Infants and young children	C	DI	Also see syndromes or conditions listed in Table 2
Respiratory syncytial virus infection, in infants, young children and immunocompromised adults	C	DI	Wear mask according to Standard Precautions [24] CB [116, 117]. In immunocompromised patients, extend the duration of Contact Precautions due to prolonged shedding [928]). Reliability of antigen testing to determine when to remove patients with prolonged hospitalizations from Contact Precautions uncertain.
Reye's syndrome	S		Not an infectious condition
Rheumatic fever	S		Not an infectious condition
Rhinovirus	D	DI	Droplet most important route of transmission [104, 1090]. Outbreaks have occurred in NICUs and LTCFs [413, 1091, 1092]. Add Contact Precautions if copious moist secretions and close contact likely to occur (e.g., young infants) [111, 833].
Rickettsial fevers, tickborne (Rocky Mountain spotted fever, tickborne typhus fever)	S		Not transmitted from person to person except through transfusion, rarely
Rickettsialpox (vesicular rickettsiosis)	S		Not transmitted from person to person
Ringworm (dermatophytosis, dermatomycosis, tinea)	S		Rarely, outbreaks have occurred in healthcare settings, (e.g., NICU

Infection/Condition	Precautions		
	Type *	Duration †	Comments
			[1093], rehabilitation hospital [1094]. Use Contact Precautions for outbreak.
Ritter's disease (staphylococcal scalded skin syndrome)	C	DI	See staphylococcal disease, scalded skin syndrome below
Rocky Mountain spotted fever	S		Not transmitted from person to person except through transfusion, rarely
Roseola infantum (exanthem subitum; caused by HHV-6)	S		
Rotavirus infection (see gastroenteritis)			
Rubella (German measles) (also see congenital rubella)	D	U 7 days after onset of rash	Susceptible HCWs should not enter room if immune caregivers are available. No recommendation for wearing face protection (e.g., a surgical mask) if immune. Pregnant women who are not immune should not care for these patients [17, 33]. Administer vaccine within three days of exposure to non-pregnant susceptible individuals. Place exposed susceptible patients on Droplet Precautions; exclude susceptible healthcare personnel from duty from day 5 after first exposure to day 21 after last exposure, regardless of post-exposure vaccine.
Rubeola (see measles)			
Salmonellosis (see gastroenteritis)			
Scabies	C	U 24	
Scalded skin syndrome, staphylococcal	C	DI	See staphylococcal disease, scalded skin syndrome below)
Schistosomiasis (bilharziasis)	S		
Severe acute respiratory syndrome (SARS)	A, D,C	DI plus 10 days after resolution of fever, provided respiratory symptoms are absent or improving	Airborne Precautions preferred; D if AIIR unavailable. N95 or higher respiratory protection; surgical mask if N95 unavailable; eye protection (goggles, face shield); aerosol-generating procedures and "supershedders" highest risk for transmission via small droplet nuclei and large droplets [93, 94, 96].Vigilant environmental disinfection (see www.cdc.gov/ncidod/sars)
Shigellosis (see gastroenteritis)			
Smallpox (variola; see vaccinia for management of vaccinated persons)	A,C	DI	Until all scabs have crusted and separated (3-4 weeks). Non-vaccinated HCWs should not provide care when immune HCWs are available; N95 or higher respiratory protection for susceptible and

Infection/Condition	Precautions		
	Type *	Duration †	Comments
			successfully vaccinated individuals; postexposure vaccine within 4 days of exposure protective [108, 129, 1038-1040].
Sporotrichosis	S		
Spirillum minor disease (rat-bite fever)	S		Not transmitted from person to person
Staphylococcal disease (*S aureus*)			
Skin, wound, or burn			
Major	C	DI	No dressing or dressing does not contain drainage adequately
Minor or limited	S		Dressing covers and contains drainage adequately
Enterocolitis	S		Use Contact Precautions for diapered or incontinent children for duration of illness
Multidrug-resistant (see multidrug-resistant organisms)			
Pneumonia	S		
Scalded skin syndrome	C	DI	Consider healthcare personnel as potential source of nursery, NICU outbreak [1095].
Toxic shock syndrome	S		
Streptobacillus moniliformis disease (rat-bite fever)	S		Not transmitted from person to person
Streptococcal disease (group A streptococcus)			
Skin, wound, or burn			
Major	C,D	U 24 hrs	No dressing or dressing does not contain drainage adequately
Minor or limited	S		Dressing covers and contains drainage adequately
Endometritis (puerperal sepsis)	S		
Pharyngitis in infants and young children	D	U 24 hrs	
Pneumonia	D	U 24 hrs	
Scarlet fever in infants and young children	D	U 24 hrs	
Serious invasive disease	D	U24 hrs	Outbreaks of serious invasive disease have occurred secondary to transmission among patients and healthcare personnel [162, 972, 1096-1098] Contact Precautions for draining wound as above; follow rec. for antimicrobial prophylaxis in selected conditions [160].
Streptococcal disease (group B streptococcus), neonatal	S		
Streptococcal disease (not group A or B) unless covered elsewhere	S		
Multidrug-resistant (see multidrug-resistant organisms)			

Infection/Condition	Precautions		
	Type *	Duration †	Comments
Strongyloidiasis	S		
Syphilis			
Latent (tertiary) and seropositivity without lesions	S		
Skin and mucous membrane, including congenital, primary, Secondary	S		
Tapeworm disease			
Hymenolepis nana	S		Not transmitted from person to person
Taenia solium (pork)	S		
Other	S		
Tetanus	S		Not transmitted from person to person
Tinea (e.g., dermatophytosis, dermatomycosis, ringworm)	S		Rare episodes of person-to-person transmission
Toxoplasmosis	S		Transmission from person to person is rare; vertical transmission from mother to child, transmission through organs and blood transfusion rare
Toxic shock syndrome (staphylococcal disease, streptococcal disease)	S		Droplet Precautions for the first 24 hours after implementation of antibiotic therapy if Group A streptococcus is a likely etiology
Trachoma, acute	S		
Transmissible spongiform encephalopathy (see Creutzfeld-Jacob disease, CJD, vCJD)			
Trench mouth (Vincent's angina)	S		
Trichinosis	S		
Trichomoniasis	S		
Trichuriasis (whipworm disease)	S		
Tuberculosis *(M. tuberculosis)*			
Extrapulmonary, draining lesion)	A,C		Discontinue precautions only when patient is improving clinically, and drainage has ceased or there are three consecutive negative cultures of continued drainage [1025, 1026]. Examine for evidence of active pulmonary tuberculosis.
Extrapulmonary, no draining lesion, meningitis	S		Examine for evidence of pulmonary tuberculosis. For infants and children, use Airborne Precautions until active pulmonary tuberculosis in visiting family members ruled out [42]

Infection/Condition	Precautions		
	Type *	Duration †	Comments
Pulmonary or laryngeal disease, confirmed	A		Discontinue precautions only when patient on effective therapy is improving clinically and has three consecutive sputum smears negative for acid-fast bacilli collected on separate days(MMWR 2005; 54: RR-17 http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5417a1.htm?s_cid=rr5417a1_e) [12].
Pulmonary or laryngeal disease, suspected	A		Discontinue precautions only when the likelihood of infectious TB disease is deemed negligible, and either 1) there is another diagnosis that explains the clinical syndrome or 2) the results of three sputum smears for AFB are negative. Each of the three sputum specimens should be collected 8-24 hours apart, and at least one should be an early morning specimen
Skin-test positive with no evidence of current active disease	S		
Tularemia			
Draining lesion	S		Not transmitted from person to person
Pulmonary	S		Not transmitted from person to person
Typhoid (*Salmonella typhi*) fever (see gastroenteritis)			
Typhus			
Rickettsia prowazekii (Epidemic or Louse-borne typhus)	S		Transmitted from person to person through close personal or clothing contact
Rickettsia typhi	S		Not transmitted from person to person
Urinary tract infection (including pyelonephritis), with or without urinary catheter	S		
Vaccinia (vaccination site, adverse events following vaccination) *			Only vaccinated HCWs have contact with active vaccination sites and care for persons with adverse vaccinia events; if unvaccinated, only HCWs without contraindications to vaccine may provide care.
Vaccination site care (including autoinoculated areas)	S		Vaccination recommended for vaccinators; for newly vaccinated HCWs: semi-permeable dressing over gauze until scab separates, with dressing change as fluid accumulates, ~3-5 days; gloves, hand hygiene for dressing change; vaccinated HCW or HCW without contraindication to vaccine for dressing changes [205, 221, 225].
Eczema vaccinatum	C	Until lesions dry	For contact with virus-containing lesions and exudative material

Infection/Condition	Precautions		
	Type *	Duration †	Comments
Fetal vaccinia	C	and crusted, scabs separated	
Generalized vaccinia	C		
Progressive vaccinia	C		
Postvaccinia encephalitis	S		
Blepharitis or conjunctivitis	S/C		Use Contact Precautions if there is copious drainage
Iritis or keratitis	S		
Vaccinia-associated erythema multiforme (Stevens Johnson Syndrome)	S		Not an infectious condition
Secondary bacterial infection (e.g., S. aureus, group A beta hemolytic streptococcus	S/C		Follow organism-specific (strep, staph most frequent) recommendations and consider magnitude of drainage
Varicella Zoster	A,C	Until lesions dry and crusted	Susceptible HCWs should not enter room if immune caregivers are available; no recommendation for face protection of immune HCWs; no recommendation for type of protection, i.e. surgical mask or respirator for susceptible HCWs. In immunocompromised host with varicella pneumonia, prolong duration of precautions for duration of illness. Post-exposure prophylaxis: provide post-exposure vaccine ASAP but within 120 hours; for susceptible exposed persons for whom vaccine is contraindicated (immunocompromised persons, pregnant women, newborns whose mother's varicella onset is ≤5days before delivery or within 48 hrs after delivery) provide VZIG, when available, within 96 hours; if unavailable, use IVIG, Use Airborne Precautions for exposed susceptible persons and exclude exposed susceptible healthcare workers beginning 8 days after first exposure until 21 days after last exposure or 28 if received VZIG, regardless of postexposure vaccination. [1036].
Variola (see smallpox)			
Vibrio parahaemolyticus (see gastroenteritis)			
Vincent's angina (trench mouth)	S		
Viral hemorrhagic fevers due to Lassa, Ebola, Marburg, Crimean-Congo fever viruses	S, D, C	DI	Single-patient room preferred. Emphasize: 1) use of sharps safety devices and safe work practices, 2) hand hygiene; 3) barrier protection against blood and body fluids upon entry into room (single gloves and fluid-resistant or impermeable gown, face/eye protection with masks,

Infection/Condition	Precautions		
	Type *	Duration †	Comments
			goggles or face shields); and 4) appropriate waste handling. Use N95 or higher respirators when performing aerosol-generating procedures. Largest viral load in final stages of illness when hemorrhage may occur; additional PPE, including double gloves, leg and shoe coverings may be used, especially in resource-limited settings where options for cleaning and laundry are limited. Notify public health officials immediately if Ebola is suspected [212, 314, 740, 772] Also see Table 3 for Ebola as a bioterrorism agent
Viral respiratory diseases (not covered elsewhere)			
Adults	S		
Infants and young children (see respiratory infectious disease, acute)			
Whooping cough (see pertussis)			
Wound infections			
Major	C	DI	No dressing or dressing does not contain drainage adequately
Minor or limited	S		Dressing covers and contains drainage adequately
Yersinia enterocolitica gastroenteritis (see gastroenteritis)			
Zoster (varicella-zoster) (see herpes zoster)			
Zygomycosis (phycomycosis, mucormycosis)	S		Not transmitted person-to-person

APPENDIX F: MONITORING AND SURVEILLANCE FORMS: SAMPLE INFECTION PREVENTION CHECKLIST TO ASSESS EACH CASE TEAM/UNIT

Case Team or Unit _____

Date of Assessment _____

OBSERVATION	RESPONSE (circle one) (N/A= Not applicable)		
Hand Hygiene (Provider)			
Hands are thoroughly washed immediately:			
1. Before and after each patient contact?	Yes	No	N/A
2. Before handling and putting on gloves?	Yes	No	N/A
3. After handing objects which might be contaminated?	Yes	No	N/A
4. After contact with blood or mucous membranes?	Yes	No	N/A
5. After removing gloves?	Yes	No	N/A
6. Is soap or antiseptic hand rub available at sinks and toilets?	Yes	No	N/A
7. Is there antiseptic hand rub available for use before and after contact with each patient contact?	Yes	No	N/A
Environmental Hygiene			
8. Sheets and blankets are clean and changed regularly?	Yes	No	N/A
9. Patients are wearing clean pajamas or gowns?	Yes	No	N/A
10. Mosquito nets (if necessary) are being used and are clean?	Yes	No	N/A
11. Staff are separating and disposing of ward waste properly?	Yes	No	N/A
Linens Processing			
12. Soiled linens are handled, stored and transported properly?	Yes	No	N/A
13. Is there a separate room for sorting soiled linens?	Yes	No	N/A
14. Is there a separate room for sorting clean linens?	Yes	No	N/A
15. Is there a separate room for storing clean linens?	Yes	No	N/A
16. Are separate carts designated and used for transporting contaminated/soiled linens and clean linens?	Yes	No	N/A

OBSERVATION	RESPONSE (circle one) (N/A= Not applicable)		
Housekeeping			
17. Are sinks in patient care areas clean, disinfected, tidy and functioning? ……...	Yes	No	N/A
18. Are ceilings, walls and floors in patient care areas clean? …….……....	Yes	No	N/A
19. Is lighting adequate in patient care areas? ……..…….....	Yes	No	N/A
20. Are patient rooms well ventilated? …….	Yes	No	N/A
Transmission based precautions			
21. Are isolation rooms available for highly contagious patients? ……...	Yes	No	N/A
Waste Disposal			
22. The hospital has an operating incinerator? …….….	Yes	No	N/A
23. Are separate (preferably color coded) bins/containers used for segregating waste into infectious, noninfectious and sharps waste? ..... ……..…..	Yes	No	N/A
24. Are infectious and sharps waste disposed by burning or burying? …….	Yes	No	N/A
25. The hospital has a properly constructed placenta pit? ……...…….	Yes	No	N/A
Observation of Single-use Needles, Scalpel Blades and other Sharp Objects			
26. Needles, scalpel blades and other sharp objects are disposed of immediately after use? ……..….	Yes	No	N/A
27. Needles, scalpel blades and other sharp objects are disposed of in a puncture resistant container? ……..	Yes	No	N/A
28. All sharps containers are removed when they are ¾ full and taken to the incinerator or the approved waste burial site? …….……..……..……	Yes	No	N/A
Decontamination and Cleaning			
29. Blood spills are cleaned by flooding with a disinfectant and then wiped up? ……	Yes	No	N/A
30. Instruments are decontaminated in a 0.5% chlorine solution immediately after use for 10 minutes? ……	Yes	No	N/A
31. Instruments are thoroughly cleaned, rinsed and dry before sterilization or HLD use of labeled plastic buckets for decontamination?……..…..……..……..……..……	Yes	No	N/A

OBSERVATION	RESPONSE (circle one) (N/A= Not applicable)		
Sterilization			
32. What method of sterilization is used?			
▪ High-pressure steam (if **YES**, go to # 2) …….....	Yes	No	N/A
▪ Dry heat (if YES, go to #3) ……...……...……..	Yes	No	N/A
33. When steam sterilizing, is the high – pressure steamer operating:			
▪ At 1210C (250^{o}F) …….	Yes	No	N/A
▪ At a pressure of 106 KPa, 15 Ib /in2 …….…...	Yes	No	N/A
▪ For at least 20 minutes for unwrapped items; 30 minutes for wrapped …….…….…..	Yes	No	N/A
34. When using dry heat, are the instruments kept:			
▪ At 170oC (340^{o}F) for sharps…….……..…..	Yes	No	N/A
▪ At the required temperature (170^{o}) for at least 1 hour, or ……	Yes	No	N/A
▪ At 160oC for 2 hours ……..…….....……..…...	Yes	No	N/A
High Level Disinfection			
35. What method of high-level disinfection is used?			
▪ Boiling (if **YES**, go to # 40) ……...…….	Yes	No	N/A
▪ Steaming (if **YES**, go to # 41) ……..……...	Yes	No	N/A
▪ Chemical disinfectants (if **YES**, go to # 42)……...……..	Yes	No	N/A
36. When boiling, are the instruments:			
▪ Boiled for at least 20 minutes once boiling begins, and ……..……	Yes	No	N/A
▪ Nothing is added after timing begins ……...……	Yes	No	N/A
37. When steaming, are the instruments:			
▪ Steamed for at least 20 minutes once boiling begins, and……..……....	Yes	No	N/A
▪ Nothing is added after timing begins .....……..…….…….……	Yes	No	N/A

OBSERVATION	RESPONSE (circle one) (N/A= Not applicable)		
38. when chemical high-level disinfectants are used:			
▪ Is an appropriate chemical used? ……	Yes	No	N/A
▪ Are items completely submerged? ……	Yes	No	N/A
▪ Are instruments soaked for at least 20 minutes? ……	Yes	No	N/A
▪ Are instruments rinsed with sterile/boiled water? ……	Yes	No	N/A
Worker's Health and Safety			
1. Has training on occupational hazards and safety measures been given in the last year? …… …….	Yes	No	N/A
2. Personal protective clothing and equipment is available (i.e. goggles, boots, aprons etc) ……	Yes	No	N/A
3. Is PIHCT/VCT service available 24 hours a day? ……	Yes	No	N/A
4. Is there a "Post Exposure Prophylaxis" (PEP) protocol in place and posted for all staff to see? …….	Yes	No	N/A
5. Does the hospital provide immunizations for common communicable diseases? ……	Yes	No	N/A

Case Team Leader

Name _____

Signature _____

Evaluator

Name _____

Signature _____

GLOSSARY

Airborne transmission	Transfer of particles 5μm or less in size into the air, either as airborne droplets or dust particles containing the infectious microorganism; can be produced by coughing, sneezing, talking or procedures such as bronchoscopy or suctioning; can remain in the air for up to several hours; and can be spread widely within a room or over longer distances. Special air handling and ventilation are needed to prevent airborne transmission.
Animate	Property of having life or being alive (e.g. human tissue or organs).
Antisepsis	Process of reducing the number of microorganisms on skin, mucous membranes or other body tissue by applying an antimicrobial (antiseptic) agent.
Antiseptic or antimicrobial agent (terms used interchangeably)	Chemicals that are applied to the skin or other living tissue to inhibit or kill microorganisms (both transient and resident) thereby reducing the total bacterial counts.
Antiseptic hand rub or waterless, alcohol-based antiseptic hand rub (terms used interchangeably)	Fast acting antiseptic hand rubs that do not require use of water to remove transient flora, reduce resident microorganisms and protect the skin. Most contain 60 to 90% Alcohol, an emollient and often an additional antiseptic (e.g. 2 to 4% Chlorhexidine gluconate) that has residual action.
Asepsis and aseptic technique	Combination of efforts made to prevent entry of microorganisms into any area of the body where they are likely to cause infection. The goal of asepsis is to reduce to a safe level or eliminate the number of microorganisms on both animate (living) surfaces (skin and tissue) and inanimate objects (surgical instruments and other items).
Bactericide	Agent that kills bacteria.
Bio-safety level (BSL) guidelines	Combination of primary and secondary containment and safety guidelines designed for use in microbiology laboratories and bacteriology research units functioning at four levels (BSL-1 to BSL-4) of increasing risk.
Biological safety cabinets (BSCs)	Devices that provide protection for personnel, the agent being processed and the environment. They range in complexity from level I (general research cabinets for use with low- to moderate-risk microorganisms) to level III (totally enclosed cabinets with gas-tight construction that provide maximum protection to workers and the environment).

Clean water	Natural or chemically treated and filtered water that is safe to drink and use for other purposes (e.g. hand washing and medical instrument cleaning) because it meets specified public health standards. These standards include: zero levels of microorganisms, such as bacteria (e.g. fecal coliform and *Escherichia coli*), parasites (e.g. *Giardia lamblia*) and viruses (e.g. hepatitis A or E); low turbidity (cloudiness due to particulate matter and other contaminants); and minimum levels of disinfectants, disinfectant by-products, inorganic and organic chemicals and radioactive materials. At minimum clean water should be free of microorganisms and have low turbidity (is clear, not cloudy).
Cleaning	Process that physically removes all visible dust, soil, blood or other body fluids from inanimate objects as well as removing sufficient numbers of microorganisms to reduce risks for those who touch the skin or handle the object.
Cleaning solution	Any combination of soap (or detergent) and water used to wash or wipe down environmental surfaces such as floors, walls, ceilings and furniture.
Clinically significant antibody	Antibody capable of producing an adverse reaction to transfused blood or blood product obtained from a donor (allergenic antibody) or recipient (autologous antibody).
Closed system for obtaining blood	System in which the blood is not exposed to air or outside elements during collection, processing-including separation of components (e.g. platelets) if required prior to transfusion and storage. It is the safest way to collect process and store blood.
Colonization	Pathogenic (illness or disease-causing) organisms are present in a person (i.e. they can be detected by cultures or other tests) but are not causing symptoms or clinical findings (i.e. no cellular changes or damage).
Contact time	Amount of time a disinfectant is in direct contact with the surface or item to be disinfected. For surface disinfection, this time period is framed by the application to the surface until complete drying has occurred.
Contact transmission	Infectious agent (bacteria, virus or parasite) transmitted directly or indirectly from one infected or colonized person to a susceptible host (patient), often on the contaminated hands of a health worker.
Contaminated	State of having been actually or potentially in contact with microorganisms. As used in healthcare, the term generally refers to the presence of microorganisms that could be capable of producing disease or infection.

Corrosion	Action of chemical solutions, such as those containing salt (sodium chloride) or commercial bleach (sodium hypochlorite at concentrations above 0.5%), to cause metal instruments to be gradually eaten away (rusted) with prolonged contact (i.e. more than 1 hour).
Critical medical device (or item)	Devices that penetrate skin or invade normally sterile parts of the body (e.g. central venous catheters). These items contact blood and require sterilization.
Culture	Growth of microorganisms in or on a nutrient medium; to grow microorganisms in or on such a medium.
Decontamination	Process that makes inanimate objects **safer** to be handled by staff **before** cleaning (i.e. inactivates HBV, HCV and HIV and reduces, but does not eliminate, the number of other contaminating microorganisms).
Detergents and soaps (terms used interchangeably)	Cleaning products (bar, liquid, leaflet or powder) that lower surface tension, thereby helping remove dirt and debris and transient microorganisms from hands. **Plain** soaps require friction (scrubbing) to mechanically remove microorganisms while **antiseptic** (antimicrobial) soaps also kill or inhibit growth of most microorganisms.
Disinfectant	Chemical that destroys or inactivates microorganisms. Disinfectants are classified as low-, intermediate, or high-level depending on their ability to kill or immobilize some (low- or intermediate-level) or all (high-level) microorganisms (but not all spores). Phenols, chlorine or chlorine-containing compounds and quaternary ammonium compounds (QUATs) are classes of disinfectants frequently used to clean noncritical surfaces such as floors, walls and furniture.
Disinfectant cleaning solution	Products that are a combination of a detergent (soap) and a chemical disinfectant. Not all detergents and disinfectants are compatible. Several combinations are available commercially or can be prepared, such as alkaline detergents with chlorine compounds, alkaline detergents with QUATs or other nonionic surfactants, and acid detergents with Iodophors.
Droplet transmission	Contact of the mucous membranes of the nose, mouth or conjunctivae of the eye with infectious particles larger than 5µm in size and can be produced by coughing, sneezing, talking or procedures such as bronchoscopy or suctioning. Droplet transmission requires close contact between the source and the susceptible person because particles remain airborne briefly and travel only about 3 feet (1 meter) or less.

Dry heat sterilization	Oven that sterilizes metal instruments, glass syringes and bottles and other items by dry heat. Plastic and rubber items cannot be dry-heat sterilized because temperatures used (160 to 170°C) are too high for these materials.
Encapsulation	Filling a sharps container that is three-quarters full with cement or clay, which after hardening, can be disposed of safely in a landfill.
Endemic illness or disease	Infectious disease, such as cholera or AIDS, which is continuously present at some level (prevalence) in a particular country or region.
Endometritis	Acute postpartum infection of the lining (endometrium) of the uterus with extension into the smooth muscle wall (myometrium). Clinical features include fever, usually developing on the first or second postpartum day, uterine tenderness, lower abdominal pain, foul-smelling vaginal discharge (lochia) and signs of peritonitis in women who have had a cesarean section.
Endospore or spore (terms used interchangeably)	Relatively water-poor round or elliptical resting cell consisting of condensed cytoplasm and nucleus surrounded by an impervious cell wall or coat. Spores are relatively resistant to disinfectants and sterilants, specifically the bacillus and clostridium species.
Environmental controls	Standards specifying procedures to be followed for the routine care, cleaning and disinfection of environmental surfaces, beds, bedrails, bedside equipment and other frequently touched surfaces.
Epidemic	Rapid spread of an infectious disease, such as cholera, among many individuals in a hospital or community at the same time.
Episiotomy	Surgical cut made in the perineum (usually at the 6 o'clock position) just prior to delivery. The purpose is to facilitate delivery of the presenting part and minimize the risk of injury to the perineal area. Episiotomies are, however, associated with increased bleeding, may extend resulting in increased tearing (3^{rd} or 4^{th} degree perineal laceration), frequently become infected and, most importantly, usually not necessary.
Exposure time	Period of time during a sterilization process in which items are exposed to the sterilant at the specified sterilization parameters. In a steam sterilization process, exposure time is the period during which items are exposed to saturated steam at the specified temperature.
Hand washing	Process of mechanically removing soil and debris from the skin of hands using plain soap and water.

Hazard	Intrinsic potential property or ability of any agent, equipment, material or process that can cause harm.
High-level disinfection (HLD)	Process that eliminates all microorganisms except some bacterial endospores from inanimate objects by boiling, steaming or the use of chemical disinfectants.
Hospital-acquired infection or nosocomial (terms used interchangeably)	Infection that is neither present nor incubating at the time the patient came to the hospital. (Nosocomial refers to the association between care and the subsequent onset of infection. It is a time-related criterion that does not imply a cause and effect relationship.)
Incineration	Controlled burning of solid, liquid or gaseous combustible (burnable) wastes to produce gases and residues containing little or no burnable material.
Infectious microorganisms	Microorganisms capable of producing disease in appropriate hosts.
Infectious waste	The part of medical waste that is capable of causing infectious diseases.
Intermediate-level disinfectant	Agent that destroys all vegetative bacteria, including tubercle bacilli, lipid and some non-lipid viruses, and fungus spores, but not bacterial spores.
Intra-amniotic infection syndrome (IAIS) (also referred to as amnionitis or chorioamnionitis)	Acute clinically detectable infection in the uterus and its contents (fetus, placenta and amniotic fluid) during pregnancy.
Invasive group B streptococcal sepsis	Newborn infection characterized by bacteremia, pneumonia, meningitis and death in up to 25% of infants with the infection. It occurs most commonly following IAIS. Other sites of infection include newborn skin infections (cellulitis) and infections in bones (osteomyelitis).
Laboratory-acquired infection	Nosocomial infection resulting from the performance of laboratory activities by staff, regardless of how it occurred.
Linens	Cloth items used in healthcare facilities by housekeeping staff (bedding and towels), cleaning staff (cleaning cloths, gowns and caps) and surgical personnel (caps, masks, scrub suits, surgical gowns, drapes and wrappers). Also used by staff working in specialty units such as intensive care (ICUs) and other units performing invasive medical procedures (e.g. anesthesiology, radiology, or cardiology).

Low-level disinfectant	Agent that destroys all vegetative bacteria (except tubercle bacilli), lipid viruses, some non-lipid viruses, and some fungus, but not bacterial spores.
Mechanical indicator	Automated devices that monitor the sterilization process (e.g. graphs, gauges, printouts).
Microorganisms	Causative agents of infection. They include bacteria, viruses, fungi and parasites. For infection prevention purposes, bacteria can be further divided into three categories: vegetative (e.g. staphylococcus), mycobacteria (e.g. tuberculosis) and endospores (e.g. tetanus). Of all the common infectious agents, endospores are the most difficult to kill due to their protective coating.
Municipal waste	General waste for collection by municipalities (e.g. local city or town authorities) generated mainly by households, commercial activities and street sweeping.
Mycobacteria	Bacteria with a thick, waxy coat that makes them more resistant to chemical disinfectants than other types of vegetative bacteria.
Noncritical medical device (or item)	Devices that normally make contact with the patient's intact skin (e.g. blood pressure cuff, oxygen masks). These devices require low to intermediate-level disinfection, and reuse carries little risk.
Nonionic	Neutral (neither positively nor negatively charged) particle or substance.
Non-lipid viruses	Viruses consist of a core of nucleic acid is surrounded by a coat of protein. Non-lipid viruses are generally viewed as more resilient to inactivation than lipid viruses. Non-lipid viruses are also referred to as non-enveloped or hydrophilic (water-seeking) viruses.
Nosocomial or hospital-acquired infection (terms used interchangeably)	Infection that is neither present nor incubating at the time the patient came to the hospital. (Nosocomial refers to the association between care and the subsequent onset of infection. It is a time-related criterion that does not imply a cause and effect relationship.)
Nosocomial diarrhea	On at least 2 consecutive days having at least three loose or watery stools with the onset more than 72 hours after admission to the hospital (or more days than the incubation period if the agent is known).
Nosocomial infection in newborns	Infection occurring after birth but excluding those infections known to have been transmitted across the placenta such as congenital syphilis, cytomegalovirus, rubella, varicella (chicken pox) and the protozoan parasite, *Toxoplasmosis gondii*.

Nosocomial infection in obstetrical patients	Infection that is neither present nor incubating at the time the patient is admitted to the hospital. Most urinary tract infections and endometritis are nosocomial even though the causative organism may be endogenous (i.e. present in the maternal lower genital tract prior to delivery).
Occupational injury or infection	Injury or infection acquired by healthcare staff while performing their normal duties.
Operating room	Area or space where surgical procedures are performed.
Organ/Space SSI	Any part of the body other than the incised body wall parts that were opened or handled during an operation.
Parts per million (ppm)	Concentrations of trace contaminant gases in the air (or chemicals in a liquid) are commonly measured in parts per million (ppm) by volume. To convert percent concentration to ppm and vice versa, use this formula: ppm = percent (%) x 10,000.
Personal protective equipment (PPE)	Specialized clothing or equipment (e.g. gloves, face mask or plastic apron) worn by an employee for protection against exposure to blood or body fluids or other hazards. Uniforms, pants, and shirts not designed to function as protection against a hazard are not considered to be PPE.
Phlebitis	Area of swelling, redness, warmth and tenderness of the skin around the site where the intravascular catheter comes out of the skin (the exit site). If phlebitis is associated with other signs of infection, such as fever and pus coming from the exit site, it is classified as a clinical exit site infection.
Protective barrier	Physical, mechanical or chemical process that helps prevent the spread of infectious microorganisms from person to person (patient, healthcare client or health worker), and from equipment, instruments and environmental surfaces to people.
QUAT	Abbreviated form of the term quaternary ammonium compound; a surface-active, water-soluble, low-level disinfecting substance that has four carbon atoms linked to a nitrogen atom through chemical (covalent) bonds.
Reprocessing	Decontaminating, disassembling (if necessary), cleaning, inspecting, testing, packaging, relabeling, and sterilizing or high-level disinfecting single-use devices (SUDs) after they have been used on a patient for their intended purpose. Reprocessing also is performed on SUDs that were removed from the package (or container) but not used on a patient or whose expiration date has passed.

Resident flora	Microorganisms that live in the deeper layers of the skin, as well as within hair follicles, and cannot be completely removed, even by vigorous washing and rinsing with plain soap and clean water.
Re-sterilization	Repeat application of a terminal process designed to remove or destroy all viable forms of microbial life, including bacterial spores, to an acceptable sterility assurance level. This process is performed on devices whose expiration date has passed or that has been opened and may or may not have been used on a patient.
Safe Zone (also Neutral Zone)	Device or designated area of the sterile field in which sharps are placed, accessed, returned, and retrieved to avoid hand-to-hand transfer of sharps between personnel.
Sanitary landfill	Engineered method of disposing of solid waste on land in a manner that protects the environment (e.g. by spreading the waste in thin layers, compacting it to the smallest practical volume and then covering it with soil at the end of each working day).
Scavenging	Manual sorting of solid waste at landfills and removal of usable material.
Segregation	Systematic separation of solid waste into designated categories.
Semicritical medical device (or item)	Devices that come in contact with mucous membranes or non-intact skin during use (e.g. endoscopes, respiratory equipment). These devices require high-level disinfection if sterilization is not practical, and reuse carries a greater risk for cross-contamination than noncritical items.
Septic pelvic thrombophlebitis	Thrombosis (blockage) of the deep pelvic veins due to inflammation and blood clots. It is uncommon (approximately 1 in 2000 deliveries). Predisposing factors include cesarean section after long labor (>24 hours), premature rupture of membranes, difficult delivery (forceps or vaginal extraction), anemia and malnutrition.
Sharps	Suture needles, scalpel blades, scissors, wire sutures, broken glass or any object that can cause a puncture or cut.
Soaps and detergents (terms used interchangeably)	Cleaning products (bar, liquid, leaflet or powder) that lower surface tension, thereby helping remove dirt, debris and transient microorganisms from hands. Plain soaps require friction (scrubbing) to mechanically remove microorganisms while antiseptic (antimicrobial) soaps also kill or inhibit growth of most microorganisms.

Soiled or contaminated linen	Linen from multiple sources within the hospital or clinic that has been collected and brought to the laundry for processing. All items, regardless of whether or not they are visibly dirty or have been used in a surgical procedure, must be washed and dried.
Sorting	Process of inspecting and removing foreign, and in some cases dangerous, objects (e.g. sharps or broken glass), from soiled linen before washing. This step is extremely important because soiled linen from the operating room or clinic occasionally contains sharps (e.g. scalpels, sharp-tipped scissors, hypodermic and suture needles and towel clips).
Spaulding classification	Strategy for reprocessing contaminated medical devices. The system classifies medical devices as critical, semi-critical, or noncritical based upon the risk from contamination on a device to patient safety.
Spore or endospores (terms used interchangeably)	Relatively water-poor round or elliptical resting cell consisting of condensed cytoplasm and nucleus surrounded by an impervious cell wall or coat. Spores are relatively resistant to disinfectants and sterilants, specifically the bacillus and clostridium species.
Steam sterilization	Sterilization process that uses saturated steam under pressure, for a specified exposure time and at a specific temperature, as the sterilizing agent.
Sterilants	Chemicals used to destroy all forms of microorganisms, including endospores. Most sterilants are also high-level disinfectants when used for a shorter period of time. Sterilants are only used on inanimate objects (e.g. surgical instruments) that are used in semi-critical and critical areas (e.g. surgery). Sterilants are not meant to be used for cleaning environmental surfaces.
Sterile or sterility	State of being free from all living microorganisms. In practice, usually described as a probability function (e.g. the probability of a microorganism surviving sterilization as being one in a million).
Sterilization	Process that eliminates all microorganisms (bacteria, viruses, fungi and parasites) including bacterial endospores from inanimate objects by high-pressure steam (autoclave), dry heat (oven), chemical sterilants or radiation.
Sterilizer	Apparatus used to sterilize medical instruments, surgical gloves, equipment or supplies by direct exposure to the sterilizing agent (autoclave or dry-heat oven).

Surfactant	Agent that reduces the surface tension of water or the tension at the interface between water and another liquid; a wetting agent found in many sterilants and disinfectants.
Surgical asepsis	Preparation and maintenance of a reduced (safe) level of microorganisms during an operation by controlling four main sources of infectious organisms: the patient, personnel, equipment and the environment.
Surgical site infections (SSI)	Either an incisional or organ/space infection occurring within 30 days after an operation or within a year if an implant is present. Incisional SSIs are further divided into superficial incisional (only involves skin and subcutaneous tissue) and deep incisional (involves deeper soft tissue, including fascia and muscle layers).
Surgical unit	Whole surgical area including lockers and dressing rooms, preoperative and recovery rooms, peripheral support areas including storage space for sterile and high-level disinfected items and other consumable supplies, corridors leading to restricted areas, the operating room(s), scrub sink areas and the nursing station.
Surveillance	Systematic collection of relevant data on patient care, the orderly analysis of the data and the prompt reporting of the data to those who need it. Active surveillance consists of collecting information directly from patients or staff, while passive surveillance includes examining reports, laboratory information and data from other sources.
Transfusion service	Facility or hospital unit that provides storage, pre-transfusion testing and cross-matching, and infusion of blood or blood products to intended patients (recipients).
Transient flora	Microorganisms acquired through contact with patients, other healthcare workers or contaminated surfaces (e.g. examination tables, floors or toilets) during the course of the normal workday. These organisms live in the upper layers of the skin and are partially removed by washing with plain soap and clean water.
Unit of blood	Sterile plastic bag in which a fixed volume of blood is collected in a suitable amount of anticoagulant.
Urticarial reaction	Allergic reaction consisting of itching (pruritis), hives, skin rash and/or similar allergic condition occurring during or following a transfusion of blood or blood products.
Vegetative bacteria	Bacteria that are devoid of spores and usually can be readily inactivated by many types of germicides.

Visibly soiled hands	Hands showing visible dirt or are visibly contaminated with blood or body fluids (urine, feces, sputum or vomit).
Waste management	All activities, administrative and operational (including transportation activities), involved in the handling, treatment, conditioning, storage and disposal of waste.
Waterless, alcohol-based antiseptic hand rub or antiseptic hand rub (terms used interchangeably)	Fast acting antiseptic hand rubs that do not require use of water to remove transient flora, reduce resident microorganisms and protect the skin. Most contain 60 to 90% Alcohol, an emollient and often an additional antiseptic (e.g. 2 to 4% Chlorhexidine gluconate) that has residual action.