NATIONAL INFECTION CONTROL GUIDELINES

2016

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Introduction

Healthcare associated infections (HAIs) are preventable through implementation of best infection prevention and control practices. This will facilitate the delivery of high quality health care for patients and a safe working environment for our healthcare workers.

These national guidelines are developed to provide a co-ordinated approach to the prevention and management of HAIs. The guidelines are based on the best available current evidence and built on existing international guidelines and reviews, as well as systematic reviews of the evidence. They provide a basis for healthcare workers and healthcare facilities to develop detailed protocols and processes for infection prevention and control specific to local settings.

The guidelines are for use by all working in healthcare—this includes healthcare workers, management and support staff.

The guidelines also provide recommendations that outline the critical aspects of infection prevention and control. The levels of risk may differ according to the different types of facility and therefore, some recommendations should be justified by risk assessment. When implementing these recommendations all healthcare facilities need to consider the risk of transmission of infection and implement according to their specific setting and circumstances.

Surveillance of Healthcare associated Infections

1. Introduction

Surveillance is the systematic, on-going collection, collation and analysis of data with timely dissemination of information to those who require it in order to take action. The actions usually relate to improvements in prevention or control of the condition. Surveillance for health care-associated infections is normally performed by trained infection prevention and control professionals or hospital epidemiologists.

Healthcare associated infections (HAIs) can result in significant costs to patients and the healthcare system. Surveillance provides information on the occurrence of unusually high rates of infection and trends over time. In turn, this is used to help implement prevention and control strategies within the organisation and to evaluate the impact of interventions on rates of infection. Surveillance is also useful in monitoring the effectiveness of the Infection Prevention and Control preventive programs.

2. Designing a surveillance program

It is not feasible to conduct facility-wide surveillance for all events; therefore surveillance is often targeted, with a focus on specific events, processes, organisms, medical devices or high-risk patient populations.

Healthcare-associated infections surveillance programs may focus on:

- specific sites of infection (e.g. bloodstream, surgical sites)

- specific populations (e.g., healthcare worker occupational exposure to blood and body substances)
- specific organisms or types of organisms (e.g. MDROs, *C.difficile*)
- specific locations in the healthcare facility or community (e.g. intensive care unit, community hospital, nursing home).

There are two types of measures commonly used in surveillance — process and outcome measures. Process measures are usually easier to measure, less ambiguous and more widely applicable than outcome indicators. They may be an adjunct to outcome measures. Alternatively, they can entirely replace outcome surveillance for practices or locations that have too few adverse outcomes for statistical analysis (e.g. small facilities where the number of patients at risk of infection may be too small to calculate valid infection rates). Examples of published process measures of high value include:

- Compliance to aseptic insertion and management of peripheral or central intravascular devices
- Healthcare workers' compliance with hand hygiene
- Compliance with surgical prophylaxis

Outcome measures monitors adverse events e.g. incidence of healthcare-associated MRSA bacteraemia.

a. Assess the population to be surveyed

As each health care setting serves different types of patients/residents who face varying levels of risk for different types of infections, an evaluation of the populations served by the hospital or long-term care home should be a first step in planning a surveillance system. This evaluation enables priorities for a surveillance system to be established. Resources for surveillance can be then targeted to the populations at risk for the outcomes of greatest importance, defined in these priority areas.

b. Select the outcomes for surveillance

Selection of the types of infections that will be surveyed should be undertaken in conjunction with an assessment of the population and identification of surveillance priorities as described above. Most Infection Prevention and Control programs have prioritized the types of infections for surveillance that have the most important impact on the populations that they serve. A hospital may select its surveillance outcomes based on other factors that are important to the facility.

Incidence rates are population-level measures where the <u>numerator</u> is the infection or event of interest and the <u>denominator</u> includes the group of persons in which the infection or event may occur during the time frame of interest, i.e., population at risk for nosocomial infection.

Where there are limited resources for surveillance, prevalence rates may be used for monitoring. This is the surveillance of all existing and new nosocomial infections in a health care setting either on a single day (point prevalence) or over a specified number of days (period prevalence). Data from each patient/resident is collected only once. A prevalence survey can provide a rapid, inexpensive way to estimate the *2016 Draft for Consultation*

global view and magnitude of health care-associated infections in a health care setting at a single point in time. It should also be noted that while a prevalence survey provides a picture of healthcare associated infections at a single point in time, this risk estimate can be affected by the context for infection at that time.

Indicators types may include the following:

A. Multiple drug resistant organisms (MDROs) [infections and/or colonizations)]

This will monitor the number of new MDRO cases, including infected and colonized cases over time. The MDRO of epidemiological interest may include MRSA, VRE and CP-CRE. This may be computed as:

No. of cases over specified time period (e.g. surveillance quarter) x 10,000

Total number patient/resident days in hospital or facility over time period

B. Device-associated infection (DAI) rates (e.g. CLABSI, VAP and CAUTI)

Classically, this monitors the device associated infections in ICU patients but CLABSI and CAUTI may also be monitored in patients in general ward setting. Formula:

No. of cases over specified time period (e.g. surveillance quarter) x 1000

Total number days that patients/residents were exposed to the device

C. Surgical site infection (SSI) rates

This may be used to monitor specific surgical procedures of interest. The NHSN SSI Risk Index is used in the data collection. Formula for reporting:

Total number days that patients/residents underwent the same operative procedure

in the same time period

c. Establish case definitions for infection

In any surveillance system, all elements of the data that are being collected need to be clearly defined, including the infection outcome, the '*at risk*' population and other risk factors for infection. A widely used international acceptable definition is that provided by the National Healthcare Safety Network (NHSN) system.

d. Collect the surveillance data

The goals and outcomes of the surveillance system and the case definitions established in the previous section will determine the data required by the surveillance program. HAIs are best expressed as rates, i.e., the proportion of cases as well as the number of persons at risk over a particular period of time. Three elements are required to generate these HAI rates:

- the number of cases (i.e., persons developing a particular infection);
- number of persons at risk (i.e., population at risk for development of that infection); and
- the time period involved.

Because health care settings will have differing priorities for surveillance and resources available to them, case finding may vary from facility to facility. The following procedures provide a guide that may be followed when collecting the data required for the surveillance program based on its objectives and available resources:

- i. Review and select sources of data/information for the numerator (number of cases) and denominator (number of persons and/or period of time at risk).
- ii. Assess the *sensitivity* and *specificity* of the data sources and maximize these two parameters.
- iii. Choose the most feasible surveillance system for the health care setting.
- iv. Implement the data collection system.
- v. Review the information to ensure the dataset is complete (e.g., ensure that a particular physician or service does not forget to report their cases).

e. Calculate and analyze surveillance rates

The steps in data collection described to this point have been focused at the level of the individual patient/resident. Calculating incidence rates involves compiling individual level patient/resident data and then aggregating it into a summary of the risk for developing a nosocomial infection within a population of patients over a specified time period.

f. Apply risk stratification methodology

Patients/residents served by differing health care settings have differing extrinsic risk factors, related to the treatments and procedures that they undergo, and intrinsic (or patient-related) risk factors for HAIs, including underlying disease condition and advanced age. Without adjustment for these factors, comparisons within the same health care setting or inter-facility comparisons may be invalid or misleading. Examples of risk stratification methods include use of patient days as a denominator, use of risk factors in the collection of SSI rates, monitoring Device Associated Infection_(DAI) rates by ICU types, etc. 2016 Draft for Consultation 10

g. Interpret infection rates

Infection Control professionals must be able to interpret HAI rates so that they can identify areas where improvements to infection prevention and control practices are needed to lower the rate of infection, or to evaluate where preventive interventions have been effective in reducing the risk of infection. Interpreting the meaning of a rate of infection requires a close working knowledge of how one's surveillance system operates and of the changing risks of infection in one's facility. It is recommended that health care facilities report rates using control charts as these help to distinguish random variation and special cause variation. It is also recommended that health care facilities compare their HAI rates against benchmarks, both internal and external.

h. Communicate and use surveillance information to improve practice

If surveillance data are not used to effect changes to infection prevention and control practices, then the surveillance system is not working. Communication of surveillance data and their use as an input to infection prevention and control practice constitutes the end goal of an effective surveillance system. A surveillance system that simply collects and houses data without communicating it to stakeholders stops short of attaining the main goal, that of improved infection prevention and control prevention and control practice and decreased rates of HAIs.

i. Evaluate the surveillance system

A final recommended practice is evaluation of the surveillance system, which entails a review of: 2016 Draft for Consultation

- how efficiently and effectively the surveillance system works (process evaluation); and
- how the information produced by a surveillance system is used to reduce the risk of HAI (outcome evaluation).

Standard Precautions

Chain of infection

The chain of infection represents the transmission of microorganisms and subsequent infection within a health care setting, with each link in the chain representing a factor related to the spread of microorganisms. Transmission does not take place unless all six of the elements in the chain of transmission are present. Transmission occurs when the agent in the reservoir exits the reservoir through a portal of exit, travels via a mode of transmission and gains entry through a portal of entry to a susceptible host. HCPs must assess the risk of exposure to blood, body fluids and non-intact skin and identify the strategies that will decrease exposure risk and prevent the transmission of microorganisms. This is based on the

- 1. client/patient/resident infection status (including colonization)
- 2. characteristics of the client/patient/resident
- 3. type of care activities to be performed
- 4. resources available for control
- 5. HCP's immune status

Risks are assessed for

- contamination of skin or clothing by microorganisms in the client/patient/resident environment
- exposure to blood, body fluids, secretions, excretions, tissues
- exposure to non-intact skin
- exposure to mucous membranes

• exposure to contaminated equipment or surfaces

Rationale for Standard Precautions

Standard Precautions are the minimum infection prevention practices that apply to all patient care, regardless of suspected or confirmed infection status of the patient, in any setting where healthcare is delivered. These practices are designed to both protect healthcare personnel (HCPs) and prevent HCPs from spreading infections among patients, especially those due to blood-borne pathogens. These Standard Precautions include:

- 1) hand hygiene,
- 2) use of personal protective equipment (e.g. gloves, gowns, masks),
- 3) safe injection practices,
- 4) safe handling of potentially contaminated equipment or surfaces in the patient environment, and
- 5) respiratory hygiene/cough etiquette.

Components in Standard Precautions

A. Hand Hygiene

The practice of good hand hygiene, either by use of alcohol-based hand rubs or handwashing with soap and water, is critical to reduce the risk of transmission of infections.

The use of soap and water is recommended when hands are visibly soiled (e.g. blood, body fluids), or after caring for patients with known or suspected infectious diarrhea (e.g. *Clostridium difficile*, norovirus). Otherwise, the preferred method of

hand decontamination is with an alcohol-based hand rub as recommended by the CDC and the World Health Organization (WHO) because of its enhanced activity against a broad spectrum of epidemiologically important pathogens. Additionally, it increases compliance with recommended hand hygiene practices as it requires less time in cleaning the hands (20-30 seconds versus 2 mins).

B. Personal Protective Equipment (PPE)

This refers to wearable equipment that is intended to protect HCPs from exposure to or contact with infectious agents. These include gloves, gowns, facemasks, respirators, goggles and face shields. The selection of PPE is based on the nature of the patient interaction and potential for exposure to blood, body fluids or infectious agents.

I. Gloves

Gloves must be worn when it is anticipated that the hands will be in contact with mucous membranes, non-intact skin, tissue, blood, body fluids, secretions, excretions, or equipment and environmental surfaces contaminated with the above. They are not required for routine health care activities in which contact is limited to intact skin of the client/patient/resident (e.g. taking blood pressure, bathing and dressing the client/patient/resident). Compliance with hand hygiene should always be the first consideration. Gloves are task-specific and single-use for the task. Sterile gloves are used in operating theatres and when performing sterile procedures such as central line insertions. Hand hygiene should be done before wearing and after removing gloves.

II. Mask, eye protection / face shield

A surgical mask is used by a HCP (in addition to eye protection) to protect the mucous membranes of the nose and mouth when it is anticipated that a procedure or care activity is likely to generate splashes or sprays of blood, body fluids, secretions or excretions, or within 2 metres of a coughing client/patient/resident. Masks are also required in operating theatres and when performing aseptic procedures (e.g. central line insertions, lumbar punctures, blood cultures, urinary catheter insertion). A mask should be placed on a coughing client/patient/resident when outside his/her room, if tolerated, to limit dissemination of infectious respiratory secretions (cough etiquette). It should discarded after each use; or changed every 4 hours or when soiled. Hand hygiene should be done before wearing and after removal of mask/eye protection/face shield.

Eye protection should also be worn for wound irrigation procedures if there is any risk of sprays or splashes. These may include:

- safety glasses
- safety goggles
- face shields
- visors attached to masks

A gown is worn when it is anticipated that a procedure or care activity is likely to generate splashes or sprays of blood, body fluids, secretions, or excretions. A sleeveless apron may be worn where full coverage is not required. They are removed and discarded immediately after each use, followed by hand hygiene to avoid transfer of micro-organisms to other patients or environment.

C. Safe injection practices

A sharps injury prevention program must be in place in all health care settings. This should include follow-up for exposure to blood-borne pathogens. Precautions are to be taken to prevent injuries when handling needles, scalpels and other sharp instruments, devices during procedures, cleaning process and disposal:

- Do not recap used needle.
- Dispose used needles and syringes as one unit.
- Do not remove, bend, manipulate or break a used needle by hand.
- Discard all sharps into an appropriate puncture-resistant sharp disposal container.
- Contaminated instruments should be placed in a puncture- resistant container when transporting to the reprocessing area.
- Refer to 'Management of blood and body fluids exposure' chapter.
- Treat all specimens as potentially infectious.
- Place them in appropriate containers and into a biohazard specimen bag to prevent potential spillage and transmission of pathogens.

In event of blood or body fluid spills: 2016 Draft for Consultation

- Pour chlorine based disinfectant (e.g. NaDCC granules or solution) over blood or body fluid spills. It should achieve 10,000ppm chlorine.
- Wear gloves and use paper towels to clean up blood and body fluids spills
- Dispose them into a biohazard bag and mop the area with institution recommended disinfectant

D. Medical Equipment Cleaning

All single-use medical equipment should preferably not re-used. Healthcare facilities should ensure that all reusable medical equipment (e.g. blood glucose meters and other point-of-care devices, surgical instruments, endoscopes) is cleaned and reprocessed appropriately prior to use on another patient. Reusable medical equipment must be cleaned and reprocessed (disinfection or sterilization) and maintained according to the manufacturer's instructions. HCPs must have access to and wear appropriate PPE when handling and reprocessing contaminated patient equipment.

E. Environmental Hygiene

Facilities should establish policies and procedures for routine cleaning and disinfection of environmental surfaces as part of their infection prevention plan. Cleaning refers to the removal of visible soil and organic contamination from a device or environmental surface using the physical action of scrubbing with a surfactant or detergent and water or appropriate chemical agents. Emphasis for cleaning and disinfection should be placed on surfaces that are most likely to

become contaminated with pathogens, including those in close proximity to the patient (e.g. bedrails) and frequently touched surfaces in the patient-care environment (e.g. doorknobs). Facility policies and procedures should also address prompt and appropriate cleaning and decontamination of spills of blood or other potentially infectious materials.

Environmental services staff should be trained and responsible for routine cleaning and disinfection of environmental surfaces. Cleaning procedures can be periodically monitored or assessed to ensure that they are consistently and correctly performed. HCPs should follow the manufacturer's recommendations for use of products selected for cleaning and disinfection (e.g. amount, dilution, contact time, safe use and disposal).

F. Linen

Used linen soiled with blood, body fluids, secretions and excretions should be handled, transported and processed in a manner that prevents skin and mucus membrane exposure. Contamination of clothing and transfer of micro-organisms to other patients and the environment should be avoided.

G. Respiratory hygiene / cough etiquette

Respiratory hygiene and cough etiquette involves using source control measures to prevent patients with respiratory infections from transmitting their infection to others. These include:

- Cover mouth and nose when coughing or sneezing
- Offer a surgical mask to patients or visitors who are coughing

- Use tissue to contain respiratory secretions and dispose them in a non-touch disposal bin (e.g. bin with foot pedal-operated lid)
- Perform hand hygiene after contact with respiratory secretions

At patient care areas, the HCP is required to ensure the following:

- Display posters on respiratory hygiene in appropriate language for the population served, and these should have instructions to patients and accompanying family members or friends
- Provide surgical masks and non-touch disposal bins for patient's or visitor's use

Recommendations

- 1. Standard Precautions should be part of the work culture of all health care settings and the daily practice of each HCP during the care of all clients/patients/residents at all times. [BII]
- 2. A risk assessment should be made by the HCP before each interaction with a client/patient/resident or their environment in order to determine which precautions are required to prevent transmission during the planned interaction. [BIII]
- 3. A comprehensive hand hygiene program should be established in all healthcare facilities.[AI]
- 4. Education in the proper use of PPE should be provided to all HCPs and other staff who have the potential to be exposed to blood and body fluids. [BII]
- 5. Gloves are to be worn when it is anticipated that the hands will be in contact with mucous membranes, non-intact skin, tissue, blood, body fluids, secretions, 2016 Draft for Consultation 20

excretions, or equipment and environmental surfaces contaminated with the above. [AII]

- 6. Gloves are not required for routine health care activities in which contact is limited to the intact skin of the client/patient/resident. [AIII]
- Hand hygiene should be done before putting on gloves for aseptic procedures.
 [AIII]
- Gowns are to be removed immediately after the task for which it has been used in a manner that prevents contamination of clothing or skin and prevents agitation of the gown. [BII]
- 9. A mask and eye protection are to be worn to protect the mucous membranes of the eyes, nose and mouth when it is anticipated that a procedure or care activity is likely to generate splashes or sprays of blood, body fluids, secretions or excretions. [AII]
- 10. Clients/patients/residents who visibly soil the environment or for whom appropriate hygiene cannot be maintained are to be placed in single rooms with dedicated toileting facilities. [AIII]
- 11.A sharps injury prevention program is to be implemented in all health care settings. [AII]

Droplet Precautions

Droplet Precautions when used in addition to Standard Precautions are intended to prevent transmission of pathogens spread through close respiratory or mucous membrane contact with respiratory secretions

Examples where Droplet Precautions are indicated include patients with the following infectious agents:

- 1. B. pertussis
- 2. Influenza virus
- 3. Adenovirus
- 4. Rhinovirus
- 5. N. meningitidis
- 6. Group A Streptococcus (for the first 24 hours of antimicrobial therapy).

Patient Placement

A single patient room is preferred for patients who require Droplet Precautions. When a single-patient room is not available, consultation with infection control personnel is recommended to assess the various risks associated with other patient placement options (e.g. cohorting, keeping the patient with an existing roommate). Spatial separation of > 1 m and drawing the curtain between patient beds is especially important for patients in multi-bed rooms with infections transmitted by the droplet route.

Signage

Droplet Precautions signage for the appropriate Personal Protective Equipment to be worn should be place before entering patient room to guide people on the precautions to be taken. Steps on appropriate PPE removal should also be displayed.

Personal Protective Equipment (PPE) / Hand Hygiene

Healthcare personnel should wear a surgical mask for close contact with an infectious patient; the mask is generally donned upon room entry. Patients on Droplet Precautions who must be transported outside of the room should wear a mask if tolerated and follow Respiratory Hygiene/Cough Etiquette. Staff should perform hand hygiene according to WHO 5 moments.

After leaving the patient-care environment and removing the surgical mask, staff must perform hand hygiene immediately. Refer to Hand Hygiene guidelines.

Environmental control

Patient-care items, bedside equipment and frequently touched surfaces are cleaned daily. Clean the environmental surfaces with hospital-approved disinfectants.

Patient - care equipment and linen

Where possible, dedicate the use of non-critical patient-care equipment and items such a stethoscope, sphygmomanometer or bedside commode to a single patient (or cohort of patients infected or colonised with the pathogen) to avoid sharing between patients.

If use of common equipment or items is unavoidable, then adequately clean and disinfect them before use on another patient.

Contaminated linen should be handled as little as possible to prevent gross microbial contamination of the air. All linen from the patient's isolation room should be handled as per hospital protocol.

Patient transport

Patient movement and transport from the room should be limited unless for essential purposes. If a patient needs to be transported out of the room, inform the receiving department of the need for Droplet Precautions. Staff involved in the patient's transfer should wear appropriate PPE during transportation. The patient should wear a surgical mask and follow Respiratory Hygiene /Cough Etiquette in order to minimise the dispersal of droplet nuclei during transportation.

Infection control precautions should be maintained to minimise the risk of transmission of micro-organisms to other patients and contamination of environmental surfaces or other equipment.

The linen on the trolley should be removed for washing after transfer of patient. Clean or wipe trolley/ wheelchair with hospital-approved disinfectant.

Communication

Infection Control staff should inform clinical staff via e-mail or phone call to update them on Droplet Precautions to be taken. The need for Droplet Precautions can be identified using coloured stickers in the patient case sheet, 'O slot' vision outside the patient room, OT chit, or electronic tagging to inform all healthcare on the precautions to be taken.

Recommendations

- In acute care setting and community hospitals, place patients who require Droplet Precautions in a single room with dedicated toilet and patient sink, when available. [All]
- 2. In long-term care and other residential settings, ensure residents who require Droplet Precautions remain in their room or bed space, if feasible. [AII]
- 3. In ambulatory settings, offer a surgical mask and hand hygiene to clients/patients at triage. Triage client/patient away from waiting area to a single room as soon as possible, or maintain a one-metre spatial separation. [AII]
- Wear a surgical mask and eye protection (when splashes to the eye /mucous membrane is contemplated) within 1 metre of a client/patient/resident on Droplet Precautions. [BII]
- 5. Provide a surgical mask to clients/patients/residents on Droplet Precautions for transport or ambulation outside of the room, if tolerated. [BIII]

Contact Precautions

Contact transmission is the most common route of transmission of infectious agents. It may be any of the following:

- a. *Direct contact*, which occurs through touching e.g. a person may transmit microorganisms to others by touching them.
- b. *Indirect contact*, which occurs when microorganisms are transferred via contaminated objects e.g. *C. difficile* might be transferred between patients, if a commode used by a patient with *C. difficile* is taken to another patient without cleaning and disinfecting the commode in between uses.

Contact Precautions is used in addition to Standard Precautions, to prevent transmission of infectious agents, including epidemiologically important microorganisms, which are spread by direct/indirect contact involving passive transfer of microorganisms to a susceptible host via an intermediate object, such as contaminated hands that are not washed between patients or contaminated instruments or other inanimate objects in the patient environment.

Examples where Contact Precautions apply include clients/patients/residents with

- 1. Clostridium difficile
- 2. Gastroenteritis
- 3. Undiagnosed diarrhea
- 4. Scabies
- 5. Pediculosis (Head Lice)

- 6. Zoster-limited (Shingles)
- 7. Undiagnosed rash
- 8. Multiply drug resistant organism e.g. MRSA, VRE, CP-CRE

Components of Contact Precautions

A. Patient Placement

Preferred accommodation in acute care for Contact Precautions is a single room with a dedicated toilet and patient sink. If single rooms are unavailable, clients / patients / residents may be cohorted with other clients/patients/residents who are infected with the same microorganism. In ILTCs, placement of residents requiring Contact Precautions should be reviewed on a case-by-case basis. Infection risk to other occupants of the room must be considered when selecting roommates.

B. Personal Protective Equipment

Where patients or residents are placed in isolation rooms, a disposable gown and gloves must be worn on entering the patient's isolation room. Gloves must be removed and hands cleaned on exit from the room.

For MDRO carriers who are nursed in a multi-bedded cubicle:

- Wear gloves and gown/ apron only when there is bodily contact (i.e. HCP's clothing will have direct contact with the patient) or potentially contaminated environmental surfaces or equipment in close proximity to the patient.
- Remove and discard gloves before removing gown / apron.

- Clean hands after removing each PPE.
- Where there is no bodily contact, hand hygiene is to be practised according to WHO 5 moments.
- Remove gown before leaving the patient-care environment and perform hand hygiene immediately. Refer to 'Hand Hygiene' chapter.

Environmental control

Clients/patients/residents care items, bedside equipment and frequently touched surfaces are to be cleaned daily. Clean the environmental surfaces with hospital-approved disinfectants e.g. in a cubicle or ICU with incidence of *Clostridium difficile* (e.g. one case or more in the cubicle or ICU), all surfaces should be decontaminated with a minimal dilution of sodium hypochlorite disinfectant of 1:10 (or 5,000 parts per million available chlorine); for MDRO patients in a cubicle, the environment is best cleaned with sodium hypochlorite disinfectant with 1000 ppm available chlorine.

Patient - care equipment and linen

Where possible, dedicate the use of non-critical patient-care equipment and items such a stethoscope, sphygmomanometer or bedside commode to a single client/patient/resident (or cohort of clients/patients/residents infected or colonised with the pathogen) to avoid sharing between clients/patients/residents. If use of common equipment or items is unavoidable, then adequately clean and disinfect them before use on another client/patient/resident. Contaminated linen should be handled as little as possible to prevent gross microbial contamination of the air. All

linen from the clients/patients/residents' isolation room should be handled as per facility protocol.

Clients/patients/residents transport

Clients/patients/residents movement and transport from the room should be limited unless for essential purposes. If clients/patients/residents need to be transported out of the room, inform the receiving department of the need for Contact Precautions. Staff who accompany the client/patient/resident during the transportation are to discard gown and gloves and perform hand hygiene before leaving the room. They need not put on gown / apron and gloves during transportation. This is to prevent environmental contamination that could occur through contaminated gloves and gowns/apron. Clients/patients/residents who are respiratory dispersers should wear a surgical mask en-route.

Infection control precautions should be maintained to minimise the risk of transmission of micro-organisms to other clients/patients/residents and contamination of environmental surfaces or other equipment. The linen trolley should be removed for washing after transfer of clients/patients/residents. Clean or wipe trolley/ wheelchair with hospital-approved disinfectant.

Communication

Infection Control staff should inform clinical staff via e-mail or phone call to update them on the Contact Precautions to be taken. The need for Contact Precautions can be identified using coloured stickers in patient case sheets, 'O slot' vision outside the patient room, OT chit, and electronic tagging to inform all HCPs on the precautions to be taken.

Recommendations

- In acute care settings and community hospitals, place patients who require strict Contact Precautions in a single room with dedicated toilet and patient sink when available. Where isolation rooms are not available, patients who require Contact Precautions may be cohorted in cubicles. [AII]
- 2. Do not wear the same gowns and gloves when going from patient-to-patient within the cohort and do not share patient care equipment. [AII]
- In long-term care and other residential settings, place residents who require Contact Precautions as determined on a case-by-case basis using a risk assessment. [BII]
- 4. In ambulatory settings, place patients who require Contact Precautions in an examination room or cubicle as soon as possible. [BII]
- In acute care settings and community hospitals where patients are in isolation rooms, for Contact Precautions wear gloves for all activities in the patient's room. Remove gloves and perform hand hygiene immediately on leaving the room or bed space. [AII]
- 6. In acute care settings and community hospitals, for Contact Precautions wear a gown for all direct intimate activities where skin or clothing will come in contact with the patient or the patient's environment. Otherwise, hand hygiene alone is adequate for non-intimate direct contact. When indicated, put on a gown on entry

to the patient's room or bed space. If used, remove gown and perform hand hygiene immediately on leaving the room or bed space. [BIII]

7. In non-acute settings, for Contact Precautions wear gloves and a gown for activities that involve direct intimate care. Remove gloves and gown, if worn, and perform hand hygiene immediately on leaving the room. [AII]

Airborne Infection Isolation Precautions

Airborne Precautions used in addition to Standard Precautions, are intended to reduce the risk of airborne transmission of infectious agents (< 5 µm in size). Minute infectious droplets may be generated by an infectious person during coughing, sneezing, talking or performing of procedures (e.g. Intubation). These droplets remain suspended in air for long periods of time.

Airborne transmission is further classified into obligate or preferential airborne transmission:

- Obligate airborne transmission occurs with pathogens that are transmitted only by deposition of droplet nuclei under natural conditions (e.g. pulmonary tuberculosis).
- Preferential airborne transmission occurs with pathogens that can initiate infection by multiple routes, but are predominantly transmitted by droplet nuclei (e.g. measles and chickenpox).

Patient Placement:

Place patient in an All Room and the room should meet the following ventilation standards:

- minimum 12 air changes per hour (ACH)
- inward directional airflow from adjacent spaces to the room with negative pressure differentials of > - 2.5 Pascal

• supply of clean air flowing first to the area of the room where staff or visitors are likely to be present, and then flowing across the bed area to the exhaust 2016 Draft for Consultation 32

- exhaust air directed to outside or HEPA-filtered, if recirculated
- room monitored on initiation of use and at least daily when in use
- door kept closed at all times when not required for entry and exit

If All room is not available, place patient in an adequately ventilated single room or transfer patient to a facility that has an All room available.

Aerosol-generating procedures

Aerosol-generating procedures associated with risk of pathogen transmission (e.g. Intubation, bronchoscopy) should be performed using appropriate PPE in an AIIR.

Personal Protective Equipment (PPE)

Airborne Precautions are used in addition to Standard Precautions for patients known or suspected of having airborne transmission illness.

National Institute for Occupational Safety and Health (NIOSH)-approved N95 or higher level respirators are used to prevent inhalation of small particles that may contain infectious agents transmitted via the airborne route. Healthcare personnel should wear a fit-tested NIOSH-approved N95 or higher level respirator for respiratory protection before entering the room of a patient who requires airborne precautions. Perform user-sealed check of N95 mask or respirator each time it is being donned to minimise leakage around the face piece. Avoid touching or fiddling with the mask once the mask is properly applied. Change the respirator if wet or soiled. Remove N95 mask or respirator correctly outside the patient room or in an

anteroom and ensure that the door of the patient room is closed. Discard respirator into appropriate waste bin and perform hand hygiene immediately.

Equipment /Consumables

Dedicated use of non-critical patient-care equipment and items such a stethoscope, sphygmomanometer and thermometer is recommended. If use of common equipment or items is unavoidable, ensure adequate cleaning and decontamination of the equipment or items after and between patient use. Contaminated linen should be handled as little as possible to prevent gross microbial contamination of the air and is to be managed as per hospital protocol.

Dishware and eating utensils

The combination of hot water and detergents used in dishwashers is sufficient to decontaminate dishware (e.g., dishes, glasses, cups) and eating utensils. Therefore, reusable dishware and utensils may be used for patients. Disposable dishes and eating utensils may be used if there are no adequate resources for cleaning dishes and utensils.

Environment cleaning

Daily environmental and surface cleaning of the isolation room with hospital approved disinfectant is recommended. Pay special attention to cleaning frequently touched surfaces.

Personnel Restriction

Whenever possible, susceptible healthcare personnel should not enter the rooms of patients known or suspected to have measles (rubeola), varicella (chickenpox), disseminated zoster, or smallpox.

Visitors

Patient with TB:

- Household contacts who have been exposed do not need to wear an N95 respirator.
- Visitors who are non-household contacts should be discouraged from visiting. They should be counselled about their risk and taught how to use an N95 respirator appropriately if they do visit.

Patient with varicella and measles:

- Household contacts who have been exposed do not need to wear N95 respirator. They should be assessed for presence of active infections before visiting.
- Visitors who are known to be immune or vaccinated do not need to wear an N95 respirator.
- Visitors who are non-household contacts, not immune or vaccinated and have no history of varicella and measles should not visit.

Patient transport

Patient movement and transport from the room should be limited unless for essential purposes. If a patient needs to be transported out of the room, inform the receiving department of the need for airborne precautions. Healthcare personnel should wear an N95 mask or respirator during transportation of patients. Patients should wear a surgical mask if tolerable and follow Respiratory Hygiene /Cough Etiquette in order to minimise the dispersal of droplet nuclei during transportation.

Communication

- Display an airborne precaution sign outside the isolation room to alert and guide healthcare personnel on the wearing of appropriate PPE.
- Indicate on investigation or procedure request forms (e.g. Radiology, Physiotherapy, operation etc) that the patient is on airborne infection isolation precautions to alert staff on the infection risk.
- Notify the receiving department or healthcare facility before transporting or transferring the patient to allow adequate preparation of infection control measures.

Recommendations

- 1. Wear an N95 respirator when entering an airborne infection isolation room. [AII]
- 2. Do not enter the room of a patient with measles, varicella or zoster unless immune. [AIII]
- 3. Provide a surgical mask to clients/patients/residents on Airborne Precautions during transport or activities outside their room, if tolerated. [BIII] 2016 Draft for Consultation
Wear an N95 respirator during transport of clients/patients/residents on Airborne Precautions. [CIII]

Protective Environment

Protective Environment (PE) is designed to accommodate patients with severely compromised immune system to minimize the risk of exposure to fungal spores in the air and reduce the risk of invasive environmental fungal infections.

Patient Placement.

Place allogeneic HSCT patients or patients with absolute neutrophil count <500 cells/mL in a PE room. No recommendation for placing patients undergoing solid organ transplantation or other immunocompromised patients in a PE.

Ventilation/Environmental Control

PE room should meet the following ventilation/environmental control standards:

- HEPA (high efficiency particulate air) filtration of incoming air, capable of removing 99.97% of particles ≥ 0.3 microns in diameter
- Directed room airflow with the filtered air supply on one side of the room. The air flow across the patient's bed and exhausted on the opposite side of the room.
- Minimum 12 air changes per hour (ACH)
- Positive room air pressure in relation to the corridor with pressure differentials of > +2.5 Pascal.
- Self-closing doors on all room exits

- Well-sealed room that prevent infiltration of outside air
 - Proper construction of windows, doors, intake ports and exhaust ports
 - Ceilings are smooth, free of fissures, open joints and crevices
 - Walls sealed above and below the ceiling
- Monitor room differential pressure on initiation of use and at least daily during when in use
- Door kept closed at all times when not required for entry and exit
- For patients who require both PE and airborne precautions (e.g., pulmonary or laryngeal tuberculosis, acute varicella-zoster), use an anteroom to ensure proper air-balance relative to the corridor and the PE room. Provide an independent exhaust of contaminated air to the outside. Place a HEPA filter in the exhaust duct if recirculated air.
- If anteroom is not available, place patient in an All room and use portable industrial-grade HEPA filters to enhance filtration of spores in the air.
- No carpeting in patient rooms or hallways.
- No upholstered furniture and furnishings. Use smooth and non-porous surfaces and finishes that can be scrubbed or easily cleaned.
- No fresh or dried flowers or potted plants.

Personal Protective Equipment (PPE)

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Implement Standard Precautions for patients who are on protective precautions. Gown, gloves and mask are NOT required for Healthcare Workers (HCWs) and visitors for routine entry into the room. Practice good hand hygiene according to WHO 5 moments for hand hygiene. Use appropriate PPE as indicated accordingly to standard precautions or for suspect or proven infections for which transmissionbased (contact, droplet, airborne) precautions are required.

Equipment /Consumable

Dedicate the use of non-critical patient-care equipment and items such a stethoscope, sphygmomanometer and thermometer. If use of common equipment or items is unavoidable, ensure adequate cleaning and decontaminating of the equipment or items after and between patients used. Check opened and unopened wound-dressing supplies (e.g., adhesive bandages, elastic adhesive tape) to detect mold contamination before using on patients to prevent subsequent cutaneous transmission. Discard all bandages and wound dressings that are expired, have damaged packaging, or are visually contaminated by construction debris or moisture.

Environment cleaning

- Avoid dusting methods that disperse dust.
- Daily wet-mopping of all horizontal surfaces including exhaust vent and windows sill using cloths moistened with hospital approved detergent or disinfectant.

 Prohibit exposures of patients to vacuum cleaning that could cause aerosolization of fungal spores. Use vacuum cleaner equipped with HEPA filters when vacuum cleaning is necessary. Closed doors to patient rooms when vacuuming the corridors.

Personnel Restriction

HCWs with diseases transmissible by air, droplet and direct contact (e.g., VZV, infectious gastroenteritis, HSV lesions of lips or fingers, and URIs) should be restricted from patient contact and temporarily reassigned to other duties. Healthcare facilities should have a policy regarding the immunizations of HCWs to prevent transmission of vaccine-preventable diseases to severely immunocompromised patients. HCWs with bloodborne viruses (e.g., HIV, hepatitis B or C viruses) need not be restricted from patient contact as long as they do not perform high risk procedures that could result in patient exposure to the HCW's blood or body fluids.

Visitors

Restrict visitors with communicable infectious diseases (e.g., Upper Respiratory Infections, flu-like illnesses and recent exposure to communicable diseases) from visiting severely immunocompromised patients. All visitors must be able to understand and follow appropriate hand hygiene before and after patient contact.

Patient transport

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Patient movement and transport from the room should be limited unless for diagnostic or therapeutic procedures that cannot be done in the room. Should severely immunocompromised patients (e.g. HSCT) required to leave the Protective Environment, they are advised to wear a high-efficiency respirator (e,g, N95 mask) if tolerable to prevent inhalation of fungal spores when there is construction, renovation or other dust-generating activities in and around the healthcare facility. There is no recommendation for fit-testing of patients who are using respirators. The use of masks or respirators by severely immunocompromised patients when they are outside of the PE for prevention of environmental fungal infections in the absence of construction or renovation has not been evaluated. Minimize the length of time that patients who require a PE are outside their rooms for essential purposes.

Communication

- Display a protective precaution signage outside the isolation room to alert healthcare personnel.
- Notify receiving department or healthcare facility before transporting or transferring patient to allow minimizing the length of time patients are outside the PE.

Recommendations

- 5. Place allogeneic hematopoietic stem cell transplant (HSCT) patients in a PE to reduce exposure to environmental fungi (e.g., *Aspergillus* sp), (BI)
- No published reports support the benefit of placing patients undergoing solid organ transplantation or other immunocompromised patients in a PE. (C)

- Use Standard Precautions as recommended for all patient interactions (AI)
- Implement transmission-based, droplet or contact precautions together with standard precautions when indicated (BI).
- Implement Airborne Precautions for patients who require a PE room and who also have an airborne infectious disease (e.g., pulmonary or laryngeal tuberculosis, acute varicella-zoster). (AI)
- 10. Ensure that the Protective Environment is designed to maintain positive pressure (BI)
- 11. For patients who require both PE and airborne precautions, use an anteroom to ensure proper air-balance relative to the corridor and the PE room. Provide an independent exhaust of contaminated air to the outside. Place a HEPA filter in the exhaust duct if recirculated air (BI).
- 12. If anteroom is not available, place patient in an AII room and use portable industrial-grade HEPA filters to enhance filtration of spores in the air (BII).
- 13. Avoid carpeting in hallways and patient rooms or areas (BI)
- 14. HCWs with diseases transmissible by air, droplet and direct contact (e.g., VZV, infectious gastroenteritis, HSV lesions of lips or fingers, and URIs) should be restricted from patient contact and temporarily reassigned to other duties (AI).
- 15. Minimize the length of time that patients who require a Protective Environment are outside their rooms for diagnostic or therapeutic procedures that cannot be done in the room (BI)

Hand Hygiene

Hand Hygiene is the most important and effective procedure to prevent and control the spread of hospital associated infections (HAIs). It is the responsibility of all health care to carry this out at the right moment during patient care. Effective hand hygiene kills or removes transient bacteria on the skin via any of the following two methods:

- a. Use of a 70 to 90% alcohol-based hand rub (ABHR) is the preferred method (when hands are not visibly soiled) for cleaning hands. Using easilyaccessible ABHR in health care settings takes less time than traditional hand washing and has been shown to be more effective than washing with soap (even using an antimicrobial soap) and water when hands are not visibly soiled.
- b. Hand washing with soap and running water must be performed when hands are visibly soiled. The effectiveness of alcohol is inhibited by the presence of organic material. The mechanical action of washing, rinsing and drying is the most important contributor to the removal of transient bacteria that might be present. If hands are visibly soiled and running water is not available, use a moistened towelette to remove the visible soil, followed by ABHR.

Indications for hand hygiene

This is simplified as the moments for Hand Hygiene by WHO, as these are considered the most fundamental times for the levels of hand hygiene to be undertaken during care delivery and daily routine.

A. Acute care and community hospital (Figure 1).



Moment 1	Before touching a patient	WHEN? Clean your hands before touching a patient when approaching him/her EXAMPLES: shaking hands, helping a patient to move around, clinical examination
Moment 2	Before clean/aseptic procedure	WHEN? Clean your hands immediately before any aseptic task EXAMPLES: oral/dental care, secretion aspiration, wound dressing, catheter insertion, preparation of food, medications
Moment 3	After body fluid exposure risk	WHEN? Clean your hands immediately after an exposure risk to body fluids (and after glove removal) EXAMPLES: oral/dental care, secretion aspiration, drawing and manipulating blood, clearing up urine, faeces, handling waste.

Moment 4	After touching a patient	WHEN? Clean your hands after touching a patient and her/his immediate surroundings, when leaving the patient's side EXAMPLES: shaking hands, helping a patient to move around, and clinical examination.	
Moment 5	After touching patient surroundings	WHEN? Clean your hands after touching any object or furniture in the patient's immediate surroundings, when leaving - even if the patient has not been touched EXAMPLES: changing bed linen, perfusion speed adjustment	

B. Intermediate and Long Term Care (ILTC) Facilities

In intermediate and long term care facilities, care of the incontinent resident is one of the most frequently performed actions with a high risk of hand contamination. The resident and the room environment represent the patient zone. The point/s of care is/are where the HCW touches the resident and the surroundings.

Your Moments for Hand Hygiene Health care in a residential home EANIASEPTIC CEDURE AFTER BEFORE TOUCHING TOUCHING A PATIENT A PATIENT FLUID EXPOSURE RISK Clean your hands before touching a patient. WHEN? BEFORE TOUCHING A PATIENT WHY? To protect the patient against harmful germs carried on your hands WHEN? Clean your hands immediately before performing a clean/aseptic procedure. BEFORE CLEAN/ ASEPTIC PROCEDURE 2 WHY? To protect the patient against harmful germs, including the patient's own, from entering his/her body. AFTER BODY FLUID EXPOSURE RISK WHEN? Clean your hands immediately after a procedure involving exposure risk to body fluids (and after glove removal). 3 WHY? To protect yourself and the environment from harmful patient germs. WHEN? Clean your hands after touching the patient at the end of the encounter or when the encounter is interrupted. AFTER TOUCHING A PATIENT WHY? To protect yourself and the environment from harmful patient germs.

Many of the activities in long-term care homes are shared activities and the approach to hand hygiene incorporates these shared activities:

- a) in the resident's room (entire room in a single room) or bed space (inside the privacy curtain in a multi-bed room), staff, volunteers and family members are to clean hands according to the four moments for hand hygiene
- b) in common areas where residents gather, to reduce the spread of organisms,
 residents, staff, volunteers and family members are to clean hands before
 beginning and after ending the activity; some residents may need help cleaning

their hands before they begin and after they end an activity 2016 Draft for Consultation

- c) if staff, volunteers or family members provide any **direct care** in areas where shared or group activities occur, the four moments for hand hygiene are to be followed
- d) hands of residents, staff, volunteers or family members are to be cleaned before assisting with meals or snacks
- e) if, during assisting with meals or snacks of one or more residents, there is exposure of the hands to saliva or mucous membranes, hands should be cleaned before continuing

Sequence of care

It is recommended that the HCW organises his work for better compliance in hand hygiene.

The following scenario is an example to help highlight the importance of work organisation and its influence in hand hygiene compliance.

Example 1

- 1. The HCW enters the resident's room and verbally greets him. The HCW performs hand hygiene (Moment 1)
- 2. He explains to the resident that he wants to change his diaper.
- The HCW takes the necessary material from the cabinet and dons disposable gloves.

- 4. He rolls down the bed linen to uncover the resident and removes and folds the used diaper and puts it in the waste bin.
- 5. The HCW cleans the resident using cellulose and a cleaning foam before putting on a clean diaper.
- 6. He puts the used cellulose in the waste bin and then removes and discards his gloves in the waste bin. **The HCW performs hand hygiene** (Moment 3)
- 7. The HCW installs the resident in a comfortable position in his bed and pulls up the bed covers. **The HCW performs hand hygiene** (Moment 4)
- 8. The HCW leaves the room.

Example 2

- 1. The patient arrives, places his belongings on the bedside table, and goes to wash his arm and to be weighed. The patient returns and lies down on the bed or sits in the armchair while the nurse arrives with the machine ready for use. She wears a gown, mask and goggles. **The nurse performs hand hygiene** (Moment 1)
- 2. The nurse measures the vital signs and temperature, asks for the weight result, checks the thrill of the fistula, helps to hook the patient to the machine, and places a protection under the patient's arm.
- The nurse records the data in the patient chart and puts it on top of the dialysis machine.
- 4. The nurse sets the machine. The nurse performs hand hygiene (Moment 2).
- 5. The nurse opens the administration set for puncture on the top of the bedside table, pours antiseptic, prepares the needle and some tubes for blood sampling, if

necessary, then fills syringes and adds compresses. **The nurse performs hand hygiene** (Moment 2).

- 6. The nurse dons sterile gloves and applies antiseptic on the puncture site (arterialvenous fistula site) using instruments.
- 7. The nurse inserts the first needle, rinses and fixes it to the port, connects the dialysis circuit, and repeats the procedure with the second needle.
- 8. The nurse adjusts the output of the machine.
- The nurse clears the puncture set and removes and discards gloves in the waste bin. The nurse performs hand hygiene (Moment 3).
- 10. The nurse checks again the vital signs and records them, and gives a book to the patient from his bag on the bedside table. **The nurse performs hand hygiene** (Moment 4).

Methods of hand hygiene

I. Routine patient care

Alcohol-based handrubs (ABHRs): (ABHRs) are the first choice for hand hygiene when hands are not visibly soiled. ABHRs are less time consuming to use than washing with soap and water. It takes 20-30 seconds for the entire procedure (Refer to Appendix 1).

Hand washing: This method takes about 40-60 seconds. It is an essential technique to ensure every part of your hands gets washed. Wet your hands with warm water under a running tap and apply soap (preferably liquid soap from a

pump dispenser). (Refer to Appendix 2).

II. Surgical hand rub

Surgical handrub should be performed with alcohol-based formulations. It is not necessary to wash hands before handrub unless hands are visibly soiled or dirty. The hands of the surgical team should be clean upon entering the operating theatre by washing with a non-medicated soap (Refer to Appendix 3).

Key points:

- Keep nails short and pay attention to them when washing your hands most microbes on hands come from beneath the fingernails.
- Do not wear artificial nails or nail polish.
- Remove all jewellery (rings, watches, bracelets) before entering the operating theatre.
- Wash hands and arms with a non-medicated soap before entering the operating theatre area or if hands are visibly soiled.

Hand Care

- Intact skin is a natural defense against infection therefore health care workers should cover all cuts and abrasions with a water-resistant dressing.
- The use of hand cream (moisturizer) is recommended as hands may become dry with constant hand washing.
- Do not use personal hand creams at work as it may counteract the antiseptic properties in the antiseptic preparation.

- Hand cream containing oil should be avoided as they may cause latex gloves to split.
- Provide alternative hand hygiene products for HCWs with confirmed allergies or adverse reactions to standard products used in the health-care setting.

Hand hygiene program

All healthcare facilities should allocate resources to plan and implement an ongoing program promoting excellent hand hygiene practices by staff, patients and visitors. A self-assessment on current hand hygiene activities is recommended using the WHO Hand Hygiene Self-Assessment Framework. It is also recommended that the WHO multimodal strategy be adopted. This strategy includes the following:

1. System change

System change is a vital component of the World Health organization (WHO) Multimodal Hand Hygiene Improvement Strategy for all health-care facilities. It refers to ensuring that the health-care facility has the necessary infrastructure in place to allow health-care workers to practice hand hygiene. According to WHO guidelines on hand hygiene in healthcare, compliance with hand hygiene is only possible if the healthcare setting ensures an adequate infrastructure and if a reliable and permanent supply of hand hygiene products at the right time and location is provided.

Tools for system change: 2016 Draft for Consultation

- Ward infrastructure survey
- Alcohol-based handrub planning and costing tool
- Guide to local production: WHO-recommended handrub formulations
- Soap/handrub consumption survey
- Protocol for evaluation of tolerability and acceptability of alcohol-based handrub in use or planned to be introduced
- Protocol for evaluation and comparison of tolerability and acceptability of different alcohol-based handrubs

Note: Tools can be obtained from World Health Organization website at www.who.int/gpsc/en

2. Training / Education

Education is an important and critical factor and represents one of the cornerstones for improvement of hand hygiene practices. All healthcare workers require training and education on the importance of hand hygiene, the indication on the 5 Moments of hand hygiene and the correct steps of hand hygiene. Clear and standardized message need to be conveyed to all healthcare workers to ensure consistency in hand hygiene. In addition, this is also to encourage behavioural and cultural change.

Tools for education and training:

• Slides for the hand hygiene coordinator

- Slides for education sessions for trainers, observers and healthcare workers
- Hand hygiene training films
- Slides accompanying the training films
- Hand hygiene technical reference manual
- Observation form
- Hand hygiene why, how and when brochure
- Glove use information leaflet
- Your 5 moments for hand hygiene poster
- Frequently asked questions
- Key scientific publications
- Sustaining improvement additional activities for consideration by healthcare facilities

Note: Tools can be obtained from World Health Organization website at www.who.int/gpsc/en

3. Evaluation and feedback

Evaluation and repeated monitoring of a range of indicators indicating hand hygiene practices and infrastructure including knowledge and perception of the problem of healthcare-associated infection and the importance of hand hygiene is an important aspect in improving hand hygiene. Continuous monitoring of any implementation that had been introduced is essential to assess the effectiveness of the strategy in improving hand hygiene in the institution. Tools for evaluation and feedback:

- Hand hygiene technical reference manual
- Observation tools: observation form and compliance calculation form
- Ward infrastructure survey
- Soap/handrub consumption survey
- Perception survey for healthcare workers
 - Perception survey for senior managers
 - Hand hygiene knowledge questionnaire for healthcare workers
 - Protocol for evaluation of tolerability and acceptability of alcohol-based handrub in use or planned to be introduced
 - Protocol for evaluation and comparison of tolerability and acceptability of different alcohol-based handrubs
 - Data entry analysis tool
 - Instructions for data entry and analysis
 - Data summary report framework

Note: 1. Tools can be obtained from World Health Organization website at www.who.int/gpsc/en

3. General recommendation for performing hand hygiene auditing (Refer to Appendix 4)

4. <u>Reminders in the workplace</u>

Reminders are important to remind and prompt all healthcare workers on the importance of hand hygiene and the WHO 5 Moments to hand hygiene. Patients and visitors are also informed of the standard of care that they should expect from their healthcare workers with regards to hand hygiene through these reminders. Reminders can be visual such as posters or audio such as via public announcements. Other initiatives can be in the form of patient educational leaflets, badges etc.

Tools for reminders in the workplace

- Your 5 Moments for hand hygiene poster
- How to handrub poster
- How to handwash poster
- Hand hygiene: when and how leaflet
- Save lives: clean your hands screensaver

Note: Tools can be obtained from World Health Organization website at <u>www.who.int/gpsc/en</u>

5. Institutional safety climate

This refers to creating an environment and perceptions that facilitate awareness about patient safety issues while guaranteeing consideration of hand hygiene improvement as a high priority at all levels:

- 1. Active participation at both the institutional and individual levels
- 2. Awareness of individual and institutional capacity to change and improve
- 3. Partnering with patients and patient organizations

Tools for institutional safety climate:

- Template to advocate hand hygiene to managers
- Template letter to communicate hand hygiene initiatives to managers
- Guidance on engaging patients and relatives
- Sustaining improvement additional activities for consideration by healthcare facilities
- Save lives: clean your hands promotional video

Note: Tools can be obtained from World Health Organization website at www.who.int/gpsc/en

Infrastructure considerations in facility design

The healthcare setting needs to ensure adequate infrastructure and a reliable supply of hand hygiene products at the right time and at the right location to achieve compliance with hand hygiene. Thus, facility design considerations are important in the initial implementation phase. A baseline survey needs to be carried out to identify any deficiencies in hand hygiene facilities and products. There is a need to look at the availability of a clean water supply, sink:bed ratio, soap, towel and alcohol-based handrubs.

In a study carried out by Kaplan and McGuckin, they showed a statistitical difference in handwashing rates in the medical ICU (76%) with a sink to bed ratio of 1:1, compared to the surgical ICU (51%) where the ratio was 4:1.

Evaluation of hand hygiene program

It is of utmost importance to evaluate the effectiveness of your institution's hand hygiene program in order to drive improvement and compliance. WHO has developed a 'Hand Hygiene Self-Assessment Framework' tool which uses a set of indicators that can then be scored to give a situation analysis of hand hygiene promotion and practices within an individual health-care facility. Repeated use of the Framework will allow documentation of progress with time.

Note: Tools can be obtained from World Health Organization website at www.who.int/gpsc/en

Recommendations

- 1. A multidisciplinary, multifaceted hand hygiene program must be developed and implemented in all health care settings [BI].
- 2. Hand hygiene agents are to be made available at point-of-care in all health care settings. [AI].

- Each health care setting must have written hand hygiene policies and procedures.[BIII]
- 4. Provide staff with hand moisturizing skin-care products (and encourage regular frequent use) to minimize the occurrence of irritant contact dermatitis associated with hand hygiene. [AI]
- 5. Wash hands with soap and water if there is visible soiling with dirt, blood, body fluids or other body substances. [AI] If hands are visibly soiled and running water is not available, use moistened towelettes to remove the visible soil, followed by alcohol- based hand rub.
- 6. Hand hygiene products must not interfere with glove integrity or with the action of other hand hygiene or hand care products. [AII]
- Before aseptic procedure, perform surgical hand antisepsis using either an antimicrobial soap or an alcohol-based surgical hand rub that ensures sustained antimicrobial activity, before donning sterile gloves. [BI]
- 8. The use of gloves does not replace the need for hand hygiene. [BI]
- 9. Hand hygiene should be performed after removal of gloves. [AII]
- 10. Educate health care providers about [AII]:
 - a. indications for hand hygiene
 - b. factors that influence hand hygiene
 - c. hand hygiene agents
 - d. hand hygiene techniques
 - e. hand care to promote skin integrity
- 11. Routinely monitor hand hygiene compliance with the provision of timely feedback by using a reliable, validated observer audit tool and training process. [AII]

- 12. Monitoring should assess compliance with each of the WHO moments to direct education and provide reliability. [BIII]
- 13. Results of hand hygiene compliance should be regularly reviewed by the Infection Control Committee [BIII]

Sterilization and Disinfection

General Principles

The goals of safe reprocessing of medical equipment/devices include:

- 1. preventing transmission of microorganisms to personnel and clients/patients/residents; and
- minimizing damage to medical equipment/devices from foreign material (e.g. blood, body fluids, saline and medications) or inappropriate handling.

Best practices in reprocessing medical equipment/devices must include the following:

- adequate review by all parties whenever new equipment/devices are being considered for purchase (e.g. reprocessing committee);
- a centralized area for reprocessing or an area that complies with the requirements for reprocessing;
- written policies and procedures for reprocessing each type of medical equipment/device;
- 4. training of all staff who performs reprocessing;
- 5. validation of cleanliness, sterility and function of the reprocessed equipment/device;
- 6. continual monitoring of reprocessing procedures to ensure their quality;
- a corporate strategy for dealing with single-use medical equipment/devices;

- 8. management and reporting of medical incidents;
- 9. management and reporting of safety-related accidents;
- 10. recall of improperly reprocessed devices; and
- 11.procedures to be followed in emergency situations (e.g. utilities shutdowns, compromised packaging, biological indicator (BI) testing failures).

Decisions related to reprocessing medical equipment/devices should be made by a multi-disciplinary Infection Control Committee that includes the individuals responsible for purchasing the equipment/device, reprocessing the equipment/device, maintaining the equipment/device, infection prevention and control, occupational health and safety, and the end-user of the equipment/device.

It is strongly recommended that, wherever possible, reprocessing should be performed in a centralized area that complies with the physical and human resource requirements for reprocessing.

When formulating written policies and procedures, the following steps in reprocessing must be included:

- 1. collection at point-of-use, containment and transport;
- 2. disassembly (if required);
- 3. inspection;

4. cleaning; 2016 Draft for Consultation

- disinfection/sterilization (including establishment of the level of reprocessing required for items, based on Spaulding's Classification and manufacturer's instructions);
- 6. rinsing (following disinfection);
- 7. drying/aeration;
- 8. reassembly and functional testing;
- 9. clean transportation; and
- 10. storage.

It is essential that an overall inventory of all reprocessing practices within the healthcare setting is done, including documentation as to where, how and by whom all equipment/devices are being reprocessed and whether current standards are being met, as set out in this document. All processes must continue to be audited on a regular basis (e.g. annually), with clear and known consequences resulting from non- compliance.

As new reprocessing technologies and processes become available, they must be evaluated against the same criteria as current methodologies. Verify that:

- a) the process is compatible with the equipment/device being reprocessed;
- b) the process is compatible with the cleaning products being used;
- c) environmental issues with the process have been considered (e.g. odors, toxic waste products, toxic vapors);

- d) occupational health issues with the process have been considered (e.g. is PPE or special ventilation required);
- e) staff education and training is available (provided by the manufacturer);
- f) the facility is able to provide the required preventive maintenance;
- g) the process can be monitored (e.g. there are physical, chemical and biologic monitors and indicators available);
- h) quarantine of non-implantable items in processed loads pending results of biological indicator (BI) testing (if load quarantine is not possible, evaluation of a Class 5 or 6 chemical indicator (CI) and specific cycle physical parameters may be used to justify the release of loads);

 quarantine of each load containing implantable devices pending results of BI testing.

Factors Affecting the Efficacy of the Reprocessing Procedure

Policies and procedures for disinfection and sterilization must include statements and information relating to factors that might affect the effectiveness of reprocessing. These procedures must be readily accessible to staff doing the reprocessing.

Many factors affect the efficacy of reprocessing, particularly when chemical reprocessing is used. These factors include:

a) Cleanliness of the surface of the equipment/device:

- i) many chemical disinfectants/sterilants are inactivated by organic material;
 cleaning must always precede decontamination;
- ii) the greater the bioburden, the more difficult it is to disinfect or sterilize the equipment/device.

b) Characteristics of equipment/device:

- i) long, narrow lumens and channels are difficult to clean;
- ii) materials such as rubber and plastic may require special treatment;
- iii) rough or porous surfaces may trap microorganisms (e.g. ridges, ribbing, grooves, and articulations);
- iv) hinges, cracks, coils, valves, joints, clamps, crevices on the equipment/device may impede successful disinfection/sterilization.

c) Type and concentration of the product:

 products used for disinfection and/or sterilization must be mixed according to the manufacturer's recommendations in order to achieve the correct dilution; if the concentration of the disinfectant is too low, the efficacy will be decreased; if the concentration is too high, the risk of damage to the instrument or toxic effects on the user increases;

- ii. dry equipment/devices after cleaning, before immersing in disinfectant, to prevent dilution of the disinfectant;
- iii. discard solutions on or before expiry date; diluted products are inherently unstable once mixed and the manufacturer's directions as to duration of use must be followed;
- iv. use chemical test strips for all high-level liquid disinfectants to assess their efficacy; during reuse, the concentration of active ingredients may decrease as dilution of the product occurs and organic impurities accumulate;
- v. use the appropriate disinfectant/sporicide for the task; infection prevention and control must approve disinfectants and their application; and
- vi. some microorganisms are more resistant to disinfectants/sporicides, and this must be taken into consideration when choosing the product/process.

d) Duration and temperature of exposure to the product:

- i. Spaulding's Classification (see use Table 1) for the level of disinfection/sterilization required for the intended of the use equipment/device and minimum exposure time to disinfectants/sterilants to achieve this level;
- ii. use manufacturer's recommendations for temperature and for exposure time required to achieve the desired level of disinfection/sterilization; do not exceed the manufacturer's maximum exposure time, as some chemicals may cause damage to the medical equipment/device if used for extended periods of time;

- iii. all surfaces of the article must be in direct contact with the disinfectant/sterilant; and
- iv. contact may be compromised by the complexity of the article and the ability of the disinfectant to penetrate lumens etc.

e) Physical and chemical properties of the reprocessing environment:

- i. water hardness can affect some disinfectants;
- ii. excessive humidity may compromise sterile wrappings and
- iii. the pH of the solution may be an important consideration, as extremes of acidity or alkalinity affect growth of microorganisms or alter the activity of disinfectants and sterilants.

Figure 1 - Decreasing order of resistance of microorganisms to disinfection and sterilization and the level of disinfection or sterilization (Reference: CDC Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008)

Resistant Level		Level / method of disinfection & sterilization
Resistant	Prions (Creutzfeldt-Jakob Disease)	Prion reprocessing
	Bacterial spores (<i>Bacillus atrophaeus</i>)	Sterilization
	Coccidia (Cryptosporidium)	

	Mycobacteria (M. tuberculosis, M.	
	terrae)	
	Nonlipid or small viruses (polio,	Intermediate
	coxsackie)	
	Fungi (Aspergillus, Candida)	
	Vegetative bacteria (S. aureus, P.	Low
	aeruginosa)	
Susceptible	Lipid or medium-sized viruses (HIV,	
	herpes, hepatitis B)	

Disassembly, Inspection and Cleaning of Reusable Medical Equipment/Devices

Reusable medical equipment/devices must be thoroughly cleaned before disinfection or sterilization. The process of cleaning physically removes contaminants from the equipment/device, rather than killing microorganisms. If an item is not cleaned, soil (e.g. blood, body fluids, dirt) can protect the microorganisms from the action of the disinfection or sterilization process making it ineffective, as well as inactivate the disinfectant or sterilant so that it does not work. Disinfectants that become overloaded with soil can become contaminated and may become a source for transmission of microorganisms. Cleaning is always essential prior to disinfected or sterilization. An item that has not been cleaned cannot be adequately disinfected or sterilized. Gross soil (e.g. faeces, sputum, blood) shall be removed immediately at point-of-use. If cleaning cannot be done immediately, the medical equipment/device must be submerged in tepid water and detergent or enzymatic cleaner to prevent organic matter from drying on it. This does not eliminate the chance of transmission of infectious agents to healthcare workers. Personnel who perform such task should wear appropriate protective equipment and follow safe work practice according to Standard Precautions.

Factors that affect the ability to effectively clean medical equipment/devices must be considered prior to cleaning. Policies and procedures for cleaning medical equipment/devices shall be based on the manufacturer's instructions and must be developed in consultation with Infection Prevention and Control, Occupational Health and Safety, Biomedical Engineering and Environmental Services. Full PPE shall be worn for handling and cleaning contaminated equipment/devices. Once medical equipment/devices have been received in the reprocessing area/department, they must be disassembled, sorted and soaked:

a) **Disassembly** – facilitates access of the cleaning agent, disinfectant and/or sterilant to device surfaces:

 equipment/devices shall be disassembled prior to cleaning if there is one or more removable part, unless otherwise recommended by the manufacturer; and ii. follow the manufacturer's recommendations when disassembling medical equipment/devices prior to washing.

b) **Sorting –** keeps medical equipment/devices that belong to a set together and streamlines the cleaning process:

- sort equipment/devices into groups of like products requiring the same processes;
- ii. segregate sharps and/or delicate equipment/devices to prevent injury to personnel and damage to the equipment/device.

c) **Soaking** – prevents soil from drying on equipment/devices and makes them easier to clean:

- i. soak equipment/device in a hospital approved instrument soaking solution;
- ii. do not use saline as a soaking solution as it damages some medical equipment/devices;
- iii. use detergent-based products, including those containing enzymes, as part of the soaking process;
- iv. ensure that detergents (including enzymatic cleaners) are appropriate to the equipment/device being cleaned (products used must be approved by the equipment/device manufacturer); and
- v. avoid prolonged soaking (e.g. overnight) of equipment/devices.

B. Cleaning

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Cleaning may be done manually or using mechanical cleaning machines (e.g. washer-disinfector, ultrasonic washer, washer-sterilizer) after gross soil has been removed. Automated machines may increase productivity, improve cleaning effectiveness and decrease staff exposure to blood and body fluids. Manual cleaning may be required for delicate or intricate items. The equipment/device manufacturer's cleaning instructions shall be followed, including specifications for detergent type, water temperature and cleaning methods. The following procedures are included in the cleaning process:

a) Physical Removal of Organic Materials

- i. completely submerge immersible items during the cleaning process to minimize aerosolization of microorganisms and assist in cleaning;
- ii. minimize the production of aerosols when cleaning non-immersible equipment/devices;
- iii. remove gross soil using tools such as brushes and cloths;

b) Manual Cleaning

- i. any brushing required should be done under water
- ii. clean equipment/devices that have lumens with a brush, according to the manufacturer's instructions, then manually or mechanically flush with a detergent solution and rinse;
- iii. check equipment/devices with lumens for obstructions and leakage;

c) Mechanical Cleaning

Whenever possible, clean equipment/devices by mechanical means:

- i. any brushing required should be done underwater;
- ii. use mechanical washers in accordance with the manufacturer's instructions;
- iii. manually clean heavily soiled equipment/devices before mechanical cleaning;
- iv. ensure that the equipment/device to be cleaned is compatible with the mechanical
- v. cleaning equipment and chemical solutions that are being used;
- vi. ultrasonic washers are strongly recommended for any semi-critical or critical medical equipment/device that has joints, crevices, lumens or other areas that are difficult to clean:
 - the manufacturer's instructions must be followed for use and routine cleaning and maintenance of the ultrasonic washer
 - equipment/devices shall be completely immersed in the washing solution
 - after cleaning, equipment/devices shall be rinsed thoroughly prior to further reprocessing
 - the ultrasonic washing solution should be changed at least daily or more frequently if it becomes visibly soiled or if the manufacturer's instructions specify more frequent changes
- vii. washer-disinfectors are strongly recommended for medical equipment/devices that can withstand mechanical cleaning, to achieve the required exposure for cleaning and to reduce potential risk to personnel:
 - the manufacturer's instructions must be followed for the use and routine maintenance, cleaning and calibration of the washer-disinfector
 - washer-disinfectors may be used for low-level disinfection
 - washer-disinfectors are not to be used for high-level disinfection

d) Care of Cleaning Tools

- inspect brushes and other cleaning equipment for damage after each use, and discard if necessary;
- ii. clean, disinfect, dry and store tools used to assist in cleaning (e.g. brushes, cloths).

e) Rinsing

Rinsing following cleaning is necessary, as residual detergent may neutralize the disinfectant:

- i. rinse all equipment/devices thoroughly after cleaning with water to remove residues which might react with the disinfectant/sterilant;
- ii. perform the final rinse for equipment/devices containing lumens with commercially
- iii. prepared sterile, pyrogen-free water (note: distilled water is not necessarily sterile or pyrogen-free).

f) Drying

Drying is an important step that prevents dilution of chemical disinfectants which may render

them ineffective and prevents microbial growth:

- i. follow the manufacturer's instructions for drying of the equipment/device;
- equipment/devices may be air-dried or dried by hand with a clean, lint-free towel;
- iii. dry lumens with compressed air that has been filtered and dried;
- iv. dry stainless steel equipment/devices immediately after rinsing to prevent spotting.

C. Post-Cleaning

Once medical equipment/devices have been reprocessed, there must be a process to ensure that they can be differentiated from equipment/devices which have not been reprocessed. Sterilized items may be identified using external chemical indicators (CIs), such as autoclave tape, which changes color during sterilization. Equipment/devices which receive high-level disinfection should also be labeled, tagged or color-coded to indicate that they have been reprocessed.

The following procedures must be included following the cleaning process:

a) Reassembly and Inspection

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- visually inspect all equipment/devices once the cleaning process has been completed and prior to terminal disinfection/sterilization to ensure cleanliness and integrity of the equipment/device (e.g. cracks, defects, adhesive failures, missing parts);
- ii. repeat the cleaning on any item that is not clean;
- iii. do not reassemble equipment/device prior to disinfection/sterilization;
- iv. if the equipment/device manufacturer's instructions specify reassembly at this stage in the reprocessing, it shall take place in a clean area and be performed in accordance with the manufacturer's instructions.

b) Lubrication

- i. follow the manufacturer's guidelines for lubrication;
- ii. equipment/devices requiring lubrication shall be lubricated prior to sterilization;
- iii. Iubricants shall be compatible with the device and with the sterilization process;
- iv. discard lubricants on expiry date or when visibly soiled or contaminated.

c) Wrapping

i. equipment/devices that are to be sterilized require wrapping prior to sterilization (except for intermediate use steam sterilisation);

 ii. container and materials used for wrapping shall be prepared in a manner that will allow adequate air removal, steam penetration and evacuation to all surfaces.

d) Practice audits

- i. cleaning processes must be audited on a regular basis;
- ii. a quality improvement process must be in place to deal with any irregularities/concerns resulting from the audit.

Policies and Procedures

Every healthcare facility must establish its own policies and procedures to ensure appropriate sterilization and disinfection processes. Completed policies and procedures should be reviewed by an individual with infection prevention and control expertise (e.g. facility's infection prevention and control professionals, public health staff with certification in infection prevention and control). Review of reprocessing policies and procedures must take place at least annually.

Reprocessing policies and procedures shall include the following:

- a) responsibilities of management and staff;
- b) qualifications, education and training for staff involved in reprocessing;
- c) infection prevention and control activities;

d) worker health and safety activities; 2016 Draft for Consultation

- e) preventive maintenance requirements with documentation of actions;
- f) written protocols for each component of the cleaning, disinfection and/or sterilization processes that are based on the manufacturer's recommendations and established guidelines for the intended use of the product;

g) provision for annual review of policies and procedures with updating as required;

- h) documentation and maintenance of records for each process;
- i) ongoing audits of competency and procedures (who, when, how);
- j) management and reporting to administration or appropriate regulatory body of incidents where healthcare workers and patient safety may have been compromised;
- k) procedures for the recall and reprocessing of improperly reprocessed medical requirements for internal or external subcontractors, if applicable written a protocol that prevents the release of loads containing implantable devices pending results of BI testing equipment/devices.

Education and Training

The manager and all supervisors involved in reprocessing must, as a minimum, have completed a recognized qualification/certification course in reprocessing practices. A plan must be in place for each person involved in reprocessing to obtain this qualification. It is the supervisor's responsibility to ensure that:

- any individual involved in the cleaning, disinfection and/or sterilization of medical equipment/devices is properly trained and their practice audited on a regular basis to verify that standards are met;
- b) training includes information on cleaning, disinfection and sterilization, occupational health and safety issues, and infection prevention and control;
- c) orientation and continuing education is provided and documented for all personnel involved in reprocessing of medical equipment/devices; and
- d) feedback is provided to reprocessing staff in a timely manner.

The policies of the health care setting specify the requirements for, and frequency of, education and training as well as competency assessment for all personnel involved in the reprocessing of medical equipment/devices and will ensure that:

a) all staffs who are primarily involved in reprocessing obtain and maintain certification;

- b) any individual involved in any aspect of reprocessing obtains education, orientation and training specific to the medical equipment/device to be reprocessed (e.g. dental hygienists, radiation technologists, nurses in longterm care, nurses in physician offices);
- c) there is a process in place to ensure continued competency, including continuing education;

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 d) supervisory staff must be competent through education, training and experience in the reprocessing of reusable medical equipment/devices.

All staff involved in reprocessing of medical equipment/devices must be supervised and shall be qualified through education in a formally recognized course for sterilization technology, training and experience in the functions they perform shall be provided at regular intervals and periodic competency assessment all orientation, training and continuing education is documented.

Environmental Requirements for Reprocessing Areas

A. Physical Space

There must be a centralized area for reprocessing medical equipment/devices. Reprocessing performed outside the centralized area must be kept to a minimum and must be approved by the Infection Control Committee or those accountable for safe reprocessing practices and must conform to the requirements for reprocessing space. In smaller settings, such as clinics or offices in the community, this refers to any segregated area where reprocessing of equipment/devices takes place, away from clients/patients/residents and clean areas.

The central processing area(s) ideally should be divided into at least three areas: decontamination, packaging, and sterilization and storage. Physical barriers should separate the decontamination area from the other sections to contain contamination

on used items. 2016 Draft for Consultation In the decontamination area, reusable contaminated supplies (and possibly disposable items that are reused) are received, sorted, and decontaminated. The recommended airflow pattern should contain contaminates within the decontamination area and minimize the flow of contaminates to the clean areas.

The American Institute of Architects recommends negative pressure and no fewer than six air exchanges per hour in the decontamination area (AAMI recommends 10 air changes per hour) and 10 air changes per hour with positive pressure in the sterilizer equipment room.

The environment where cleaning/decontamination is performed must:

- a) have adequate space for the cleaning process and storage of necessary equipment and supplies;
- b) be distinctly separate from areas where clean/disinfected/sterile equipment/devices are handled or stored;
- c) have easy access to hand hygiene facilities;
- d) have surfaces that can be easily cleaned and disinfected;
- e) have slip-proof flooring that can withstand wet mopping and hospital-grade cleaning and disinfecting products;

f) have restricted access from other areas in the setting and ensure one-way
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movement by staff.

Decontamination work areas shall be physically separated from clean and other work areas by walls or partitions to control traffic flow and to contain contaminants generated during the stages of cleaning. Walls or partitions should be cleaned regularly and be constructed of materials that can withstand cleaning and disinfection.

Decontamination sinks:

- a) shall be designed and arranged to facilitate soaking, washing and rinsing of equipment/devices with minimal movement or delay between steps;
- b) should be adjacent to waterproof counter tops and a backsplash;
- c) shall not have an overflow;

d) should be at a height that allows workers to use them without bending or straining;

- e) should be large enough to accommodate trays or baskets of instruments;
- f) should be deep enough to allow complete immersion of larger devices and instruments so that aerosols are not generated during cleaning; and
- g) should be equipped with water ports for the flushing of instruments with lumens, if appropriate.

The packaging area is for inspecting, assembling, and packaging clean, but not sterile, material.

The sterile storage area should be a limited access area with a controlled temperature (may be as high as 24°C) and relative humidity (30-60% in all works areas except sterile storage, where the relative humidity should not exceed 70%).

The floors and walls should be constructed of materials capable of withstanding chemical agents used for cleaning or disinfecting. Ceilings and wall surfaces should be constructed of non-shedding materials.

Hand hygiene facilities should be located in all personnel support areas and at all entrances to, and exits from, the decontamination area. Hand hygiene facilities should include:

- a) accessible hand washing sinks with hands-free controls, soap dispensers and paper towels; and/or
- b) alcohol-based hand-rub (ABHR).

See Table 1 in Appendix 5 for recommended design parameters.

Occupational exposure limits such as ceiling exposure value (CEV) for chemical agents (e.g. glutaraldehyde, ethylene oxide) are to be complied with in accordance to local environmental law. A CEV is the maximum airborne concentration of a chemical agent to which a worker is exposed at any time. If control measures are not available during reprocessing involving a chemical agent, air sampling may be required to ensure that the regulated limit has not been exceeded for the chemical being used. (Reference: CDC Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008)

The health care setting must have air changes; temperature and humidity appropriate to the process/product being used. In health care settings where there are dedicated central reprocessing areas, negative pressure airflow must be maintained in soiled areas and positive pressure airflow must be maintained in clean areas and be monitored.

C. Water Quality

The health care setting should be aware of the quality of its water supply and develop policies to address known problems. There should be written reprocessing contingency plans in place that address loss of potable water, boil water advisories and other situations where the water supply becomes compromised.

D. Environmental Cleaning in Sterile Processing Departments

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The housekeeping department should consult with the management of the sterile processing department and infection prevention and control to establish policies and procedures for cleaning practices and cleaning frequency. As a minimum:

- a) the facility shall have written cleaning procedures with clearly defined responsibilities for all areas in the facility where decontamination is performed;
- b) all work areas, stands, tables, countertops, sinks and equipment surfaces shall be cleaned with hospital approved agents and disinfected at least daily;
- c) floors shall be cleaned at least daily;
- d) if a spill occurs, the affected area shall be cleaned immediately;

e) sinks shall be cleaned each shift at a minimum and more frequently as necessary;

- f) sinks used for cleaning endoscopes and respiratory equipment shall be cleaned between each use;
- g) the sequence of cleaning shall be from clean areas to soiled areas, from high areas to low areas (i.e., top of walls to floor) and from least contaminated to most contaminated;

h) cleaning staff shall not move back and forth between clean and soiled areas;
and

 cleaning equipment used in the decontamination area shall not be used in any other area.

Occupational Health and Safety for Reprocessing

An Occupational Health and Safety review is recommended for all protocols for reprocessing medical equipment/devices to verify that staff safety measures are followed and are in compliance with the Workplace Safety and Health Act. This review will verify that:

- a) sharps are handled appropriately
- b) local exhaust ventilation systems adequately protect staff from toxic vapors
- c) chemicals are labeled, stored and handled appropriately, and Safety Data Sheets (SDS) are readily available
- an eyewash fountain is installed to prevent a potential hazard to the eye due to contact with a biological or chemical agent; and
- e) personal protective equipment such as elbow length impervious gloves (insulated if using a steam autoclave) for unloading the autoclave is present and complies with regulatory requirements. Procedures must be in place for immediate response to staff exposure to blood and body fluids or injury from sharp objects. All staff working in reprocessing must be immune to Hepatitis B or receive Hepatitis B immunization.

A. Routine Practices

Routine practices must be part of all staff education and training to prevent exposure

to body substances. Routine practices in reprocessing areas include:

- a policy that prohibits eating/drinking, storage of food, smoking, application of cosmetics or and handling contact lenses in the reprocessing area;
- b) no storage of personal effects, including food and drink, in the reprocessing area;
- c) hand hygiene facilities located at all entrances to, and exits from, reprocessing areas and faucets;
- should be supplied with foot-, wrist- or knee-operated handles or electronic sensors
- e) hands are cleaned before beginning work, before breaks and upon completion of work; after removing gloves; and whenever hands are contaminated with body substances if there is visible soil on the hands, hand hygiene is performed with soap and water; if there is no visible soil on the hands, staff may use either soap and water or an alcohol- based hand rub (ABHR)
- f) hand and arm jewelry or artificial nails are not worn; and
- g) provision for, and wearing of, appropriate PPE for all reprocessing activities;
- h) dedicated staff for the decontamination area.

B. Personal Protective Equipment (PPE)

Standard precautions are to be complied by all staffs. Staff involved in reprocessing must be trained in the correct use, wearing, limitations and indications for PPE:

a) PPE worn for cleaning and handling contaminated equipment/devices includes gloves appropriate to the task, face protection (full face shield OR fluid-impervious face mask and protective eyewear) and impermeable gown or waterproof apron;

b) when choosing gloves, the following points need to be considered:

- i) gloves must be long enough to cover wrists and forearms;
- ii) gloves must be of sufficient weight to be highly tear-resistant;
- iii) gloves must allow adequate dexterity of the fingers;
- iv) disposable gloves are recommended; if reusable gloves are used, they must be decontaminated daily, inspected for tears and holes.
- c) PPE is removed on completion of the task for which it was indicated and before leaving the reprocessing area;
- d) staff must be trained in management of a blood or body fluid spill and
- e) where there is the risk of exposure to biological and/or chemical agents, eye wash stations must be provided and staff must be trained in their use.

C. Safe Handling of Sharps

Procedures shall be in place to prevent injuries from sharp objects. When working with sharps, staff in the decontamination area shall:

- a) place disposable sharp objects in puncture-resistant containers;
- b) take care when handling glass and other fragile objects;
- c) discard chipped or broken glass devices or arrange to have them repaired;

- d) not recap used needles or other sharps unless using a recapping device; and
- e) not manually bend or break needles.

D. Work Restrictions

Reprocessing staff are subject to some work restrictions:

- a) staff who have respiratory problems (e.g. asthma) should be assessed by Occupational Health and Safety staff prior to working with chemical disinfectants or cleaning agents; and
- b) staffs who have exudative lesions or weeping dermatitis shall refrain from handling client/patient/resident care equipment until the condition is resolved.

Transportation and Handling of Contaminated Medical Equipment / Devices

Soiled medical equipment/devices must be handled in a manner that reduces the risk of exposure and/or injury to personnel and clients/patients/residents, or contamination of environmental surfaces:

- a) closed carts or covered containers designed to prevent the spill of liquids, with easily cleanable surfaces, shall be used for handling and transporting soiled medical equipment/devices;
- b) soiled equipment/devices shall be transported by direct routes, that avoid high-traffic, clean/sterile storage and client/patient/resident care areas, to areas where cleaning will be done;

- c) containers or carts used to transport soiled medical equipment/devices shall be cleaned after each use; and
- d) disposable sharps shall be disposed of in an appropriate puncture-resistant sharps container at point-of-use, prior to transportation.

Disinfection of Reusable Medical Equipment/Devices

Disinfection is the inactivation of disease-producing microorganisms. Disinfection does not destroy bacterial spores or prions. Disinfection of medical equipment/devices falls into two major categories – low-level disinfection and high-level disinfection.

A. Low-Level Disinfection (LLD)

Low-level disinfection eliminates vegetative ('live') bacteria, some fungi and enveloped viruses. LLD is used for non-critical medical equipment/devices and some environmental surfaces. Low-level disinfectants include 3% hydrogen peroxide, 0.5% accelerated hydrogen peroxide, some quaternary ammonium compounds (QUATS), phenolics and diluted sodium hypochlorite (e.g. bleach) solutions.

LLD is performed after the equipment/device is thoroughly cleaned; rinsed and excess rinse water is removed. The container used for disinfection must be washed, rinsed and dried when the solution is changed. Non-critical medical equipment/devices require decontamination using a low-level disinfectant.

B. High-Level Disinfection (HLD)

High-level disinfection eliminates vegetative bacteria, enveloped viruses, fungi, mycobacteria (e.g. Tuberculosis) and non-enveloped viruses. HLD is used for semicritical medical equipment/devices. High level disinfectants include 2% glutaraldehyde, 6% hydrogen peroxide, 0.2% peracetic acid, 7% accelerated hydrogen peroxide and 0.55% ortho-phthalaldehyde (OPA). Refer to Table 2 in Appendix 5 for contact time required for high level disinfection. Pasteurization also achieves high-level disinfection. HLD is performed after the equipment/device is thoroughly cleaned, rinsed and excess rinse water is removed. Semi-critical medical equipment/devices require decontamination using, at a minimum, high-level disinfection. Sterilization is preferred.

C. Methods of Disinfection for Semi-critical Medical Equipment/Devices

There are two major methods of disinfection used in health care settings – liquid chemicals and pasteurization.

1. Liquid Chemical Disinfection

When selecting a disinfectant for reprocessing medical equipment/devices in the health care setting, consider:

a) efficacy for the intended use;

b) compatibility with the equipment/device and surfaces to be disinfected; 2016 Draft for Consultation

- c) compatibility with detergents, cleaning agents and disinfection and/or sterilization processes;
- d) the intended end use of the equipment/devices to be disinfected;
- e) the method for monitoring the product concentration;
- f) recommendations for rinsing (e.g. water quality, volume, time);
- g) safety for use, with minimal toxic and irritating effects to/for staff; and
- h) environmental safety and biodegradability.

The manufacturer's recommendations for chemical disinfectants must be followed pertaining to:

a) usage - disinfectant manufacturers must supply recommended usage for the disinfectant to ensure that it is compatible with the medical equipment/devices on which it will be used;

b) contact time (NOTE: where the manufacturer recommends a shorter contact time with a particular product than is required to achieve the desired level of disinfection/sterilization, an infection prevention and control professional must be consulted for advice);

c) shelf life;

d) storage;

- e) appropriate dilution; and
- f) required PPE.

The process of high-level disinfection requires monitoring and auditing:

- a) chemical test strips should be used to determine whether an effective concentration of active ingredients is present, despite repeated use and dilution:
 - the frequency of testing should be based on how frequently the solutions are used (i.e., test daily if used daily);
 - ii) chemical test strips must be checked each time a new package/bottle is opened to verify they are accurate, using positive (e.g. full strength disinfectant solution) and negative (e.g. tap water) controls; see manufacturer's recommendations for appropriate controls;
 - iii) test strips must not be considered a way of extending the use of a disinfectant solution beyond the expiration date;
- b) a permanent record of processing shall be completed and retained according to the policy of the facility; this record shall include, but not be limited to:
 - i. the identification of the equipment/device to be disinfected;
 - ii. ii) date and time of the clinical procedure;
 - iii. iii) concentration and contact time of the disinfectant used in each process;
 - iv. results of each inspection (and, for endoscopes, each leak test);
 - v. result of each testing of the disinfectant; and
 - vi. the name of the person completing the reprocessing.
- c) disinfection practices shall be audited on a regular basis and a quality improvement process must be in place to deal with any irregularities/concerns resulting from the audit;
- d) prepared solutions shall not be topped up with fresh solution;

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- e) if manual disinfection is performed, the container used for disinfection shall be kept covered during use and washed, rinsed and dried when the solution is changed; and
- f) rinsing of medical equipment/devices following chemical disinfection requires three separate rinses, using sterile water, and the rinse solutions must be changed after each process.

2. Pasteurization

Pasteurization is a process of hot water disinfection (minimum 71°C for 30 minutes), which is accomplished through the use of automated pasteurizers or washer disinfectors. Semi-critical medical equipment/devices suitable for pasteurization include equipment for respiratory therapy and anesthesia.

Advantages of pasteurization include:

- a) no toxicity;
- b) rapid disinfection cycle; and
- c) moderate cost of machinery and upkeep.

Disadvantages of pasteurization include:

- a) may cause splash burns;
- b) difficulty validating the effectiveness of the process; and

c) pasteurizers and related equipment can become contaminated without a good preventive maintenance program and careful monitoring of processes.

The manufacturer's instructions for installation, operation and ongoing maintenance of pasteurizing equipment must be followed to ensure that the machine does not become contaminated:

- a) the process must be monitored with mechanical temperature gauges and timing mechanisms for each load, with a paper printout record; pasteurizing equipment must have, or be retrofitted for, mechanical paper printout;
- b) water temperature within the pasteurizer should be verified weekly by manually measuring the cycle water temperature;
- c) cycle time should be verified manually and recorded daily;
- calibration of pasteurization equipment will be performed according to the manufacturer's recommendations;
- e) daily cleaning of pasteurizing equipment is required following the manufacturer's

recommendations; and

- following pasteurization, medical equipment/devices should be inspected for wear, cracks or soil:
 - i. damaged equipment/devices shall be handled according to facility procedures; and
 - ii. ii) soiled equipment/devices shall be reprocessed.

Following pasteurization, medical equipment/devices shall be handled in a manner that prevents contamination. Equipment/devices shall be transported directly from the pasteurizer to a clean area for drying, assembly and packaging. Medical equipment/devices shall be thoroughly dried in a drying cabinet that is equipped with a high efficiency particulate air (HEPA) filter and is used exclusively for the drying of pasteurized equipment/devices. A preventive maintenance program for drying cabinets must be implemented and documented. Printed records of each cycle (i.e., temperature, time) shall be retained in accordance with the health care setting's requirements.

Selection of Product/Process for Reprocessing

The reprocessing method and products required for medical equipment/devices will depend on the intended use of the equipment/device and the potential risk of infection involved in the use of the equipment/device. The process and products used for cleaning, disinfection and/or sterilization of medical equipment/devices must be compatible with the equipment/devices:

- a) compatibility of the equipment/device to be reprocessed to detergents, cleaning agents and disinfection/sterilization processes is determined by the manufacturer of the equipment/device; and
- b) the manufacturer must provide written information regarding the safe and appropriate reprocessing of the medical equipment/device.

A. Reprocessing Process

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The classification system developed by Spaulding divides medical equipment/devices into three categories, based on the potential risk of infection involved in their use:

Classification	Definition	Level of Processing/ Reprocessing	Examples
Critical	Equipment/device that enters sterile tissues, including vascular system	Cleaning followed by sterilization	Surgical instruments, biopsy instruments
Semi-critical	Equipment/device that comes into contact with non- intact skin or mucous membranes but do not penetrate them	Cleaning followed by high-level disinfection (as a minimum). Sterilization is preferred	Respiratory therapy equipment, anesthesia equipment, tonometer
Non-critical	Equipment/device that touches only intact skin and not mucous membranes, or does not directly touch the patient	Cleaning followed by low-level disinfection	ECG machines, oximeter, bedpans, urinals, commodes, blood pressure cuffs, crutches, computers, bed rails, bedside tables, patient furniture and floors

Table 1: Spaulding's Classification of Medical Equipment/Devices andRequired Level of Processing/Reprocessing

All medical equipment/devices that will be purchased and/or will be reprocessed

must have written device specific manufacturer's cleaning, disinfection and 2016 Draft for Consultation 96

sterilization instruction. If disassembly or reassembly is required, detailed instructions with pictures must be included. It is recommended that hospitals or healthcare facilities follow the written, updated instruction (e.g. Instructions for Use [IFU], Product Insert) provided by the device manufacturers on how their devices should be cleaned, disinfected or sterilized. To achieve this, staff training must be provided on these processes before the medical equipment/device is placed into circulation.

B. Reprocessing Products

Products used for any/all stages in reprocessing (i.e., cleaning, disinfection, sterilization) must be:

- a) appropriate to the level of reprocessing that is required for the use of the medical equipment/device;
- b) approved by the committee responsible for product selection, by an individual with reprocessing expertise and by an individual with infection prevention and control expertise (e.g. facility's infection prevention and control professionals, public health staff with training in infection prevention and control, regional infection control network).

Reprocessing Endoscopy Equipment/Devices

Critical Endoscope: Endoscopes usd in the examination of critical spaces, such as joints and sterile cavities. Many of these endoscopes are rigid with no lumen. Examples of critical endoscopes are arthroscopes and laparoscopes. 2016 Draft for Consultation 97 **Semi-critical Endoscope:** Fibreoptic or video endoscopes used in the examination of the hollow viscera. These endoscopes generally invade only semi-critical spaces, although some of their components might enter tissues or other critical spaces. Examples of semi-critical endoscopes are laryngoscopes, nasopharyngeal endoscopes, transesophageal probes, colonoscopes, gastroscopes, duodenoscopes, sigmoidoscopes and enteroscopes. Due to the complexity of their design, flexible fibreoptic and video endoscopes require special cleaning and handling.

A. Education and Training

Individuals responsible for reprocessing endoscopes require training and must meet the health care setting's written endoscope processing competency requirements, which include ongoing education and training:

- a) staff assigned to reprocess endoscopes must receive device-specific reprocessing instructions to ensure proper cleaning and high-level disinfection or sterilization;
- b) competency testing of personnel reprocessing endoscopes shall be performed at least annually and
- c) temporary personnel shall not be allowed to reprocess endoscopes until competency has been established.

B. Physical Space

The area used to reprocess endoscopes must include:

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- 1. adequate space for the storage and holding of clean and soiled materials that is separate from other activities and controlled to prohibit public contact;
- dedicated processing room(s) for cleaning and decontaminating instruments that are physically separated from clean areas, client/patient/resident care areas and procedure rooms;
- within processing/decontamination rooms, utility sink(s) appropriate to the volume of work and method of decontamination;
- 4. dedicated hand hygiene sink(s);
- 5. eye-washing facilities;
- 6. sufficient cleanable counter space to handle the volume of work;
- space and utility connections for automatic endoscope reprocessor(s) (AER), if used;
- ventilation system that will remove toxic vapors generated by, or emitted from, cleaning or disinfecting agents;
 - i. the vapor concentration of the chemical disinfectant used shall not exceed allowable limits (e.g. 0.05 ppm for glutaraldehyde);
 - ii. air-exchange equipment (e.g. ventilation system, exhaust hoods) should be used to minimize the exposure of all persons to potentially toxic vapors;
 - iii. in-use disinfectant solutions must be maintained in closed, covered,labeled containers at all times; and
 - air quality should be monitored on a scheduled basis to ensure control of vapors;
- negative pressure ventilation and a minimum air exchange rate to 10 per hour for processing/decontamination area

10. adequate space for the storage and holding of materials/equipment that is separate from other activities, has adequate positive pressure ventilation and is controlled to prohibit public contact.

C. Cleaning Procedures

Each health care setting in which endoscopic procedures are performed shall have written detailed procedures for the cleaning and handling of endoscopes. Endoscopic cleaning shall take place immediately following completion of the clinical procedure, as soiled residue in endoscope lumens dries rapidly, becoming very difficult to remove.

Immediately following completion of the endoscopy procedure:

- a) flush and wipe the endoscope at point-of-use;
- b) use a freshly prepared enzymatic cleaning solution; and
- c) place the endoscope and accessories in a covered, leak proof container and transport to the designated decontamination area.

The following steps must be included in the cleaning procedure:

- 1. follow the manufacturer's recommendations for cleaning and cleaning products;
- 2. perform leak testing after each use, prior to cleaning:
 - i. verify the potency and integrity of the endoscope sheath through leak testing, performed prior to, and during, immersion of the endoscope;
 - ii. perform the leak test according to the manufacturer's instructions;

- iii. an endoscope that fails the dry leak test should not undergo the immersion leak test;
- soak and manually clean all immersible endoscope components with water and a recommended cleaning agent prior to automated or further manual disinfection or sterilization;
- disconnect and disassemble endoscope components (e.g. air/water and suction valves) as far as possible and completely immerse the endoscope and components in enzymatic cleaner;
- flush and brush all channels and lumens of the endoscope while submerged to remove debris and minimize aerosols;
- ensure that brushes used for cleaning lumens are of an appropriate size, inspected before and after use, and discarded or cleaned, high-level disinfected and dried following use;
- consider irrigation adaptors or manifolds that may be recommended by the manufacturer to facilitate cleaning;
- thoroughly rinse endoscope and all components with clean filtered water prior to disinfection/sterilization and remove excess rinse water;
- 9. identify damaged endoscopes and immediately remove from service;
- 10. discard enzymatic cleaner after each use; and
- 11. discard disposable cleaning items or thoroughly clean and high-level disinfect/sterilize non-disposable items between uses.

D. Endoscope Disinfection and Sterilization

Procedures for disinfection and sterilization of endoscopes must ensure that a minimum of high-level disinfection is used for all endoscopes and their accessories, excluding biopsy forceps and brushes (which require sterilization). The following steps must be included in the disinfection/sterilization procedure:

- 1. choose a disinfectant that is compatible with the endoscope;
- monitor the efficacy of the disinfectant before each use with test strips available from the product manufacturer;
- 3. maintain a written log of monitoring test results;
- 4. do not use disinfectants past their expiry date;
- carefully follow the manufacturer's directions regarding the ambient temperature and duration of contact for the disinfectant (e.g. 2% glutaraldehyde for 20 minutes at 20°C);
- completely immerse the endoscope and endoscope components in the high-level disinfectant/sterilant and ensure all channels are perfused; and
- following disinfection, rinse the endoscope and flush the channels with bacteriafree or sterile water.

E. Drying and Storage of Endoscopes

Steps in the final drying of semi-critical endoscopes include:

- a) initial flushing of all channels with medical or filtered air;
- b) flushing all channels with 70% isopropyl alcohol to aid in the drying process; and
- c) second flushing of the channels with medical or filtered air.

Storage procedures must include the following:

a) remove caps, valves and other detachable components during storage and reassemble just before use; store close to the endoscope in a manner that minimizes contamination;

b) store semi-critical endoscopes by hanging vertically in a well-ventilated area in a manner that minimizes contamination or damage;

c) store endoscopes that have been sterilized in their sterilization containers;

d) do not allow endoscopes to coil, touch the floor or bottom of the cabinet while handing, or be stored in their cases;

e) ensure that endoscope storage cabinets are constructed of non-porous material that can be cleaned;

f) clean and disinfect endoscope storage cabinets at least weekly.

Colonoscopes have a maximum shelf life of 7 days, if stored dry. There are no recommendations regarding shelf life of other types of endoscopes.

F. Accessories

Endoscopic accessories (e.g. biopsy forceps and brushes) that break the mucosal barrier must be sterilized after each use:

a) because of the difficulty cleaning biopsy forceps/brushes, it is strongly recommended that disposable items be used; and

b) if reusable biopsy forceps/brushes are used, they must be meticulously cleaned prior to sterilization.

G. Automated Endoscope Reprocessor (AER)

To achieve consistency in endoscope reprocessing, it is recommended that automated endoscope reprocessor (AER) be used. The following must be included in the procedure:

a) follow the manufacturer's instructions for use of the AER;

b) ensure that the endoscope and endoscope components to be reprocessed are compatible with

the AER used;

c) ensure that channel connectors and caps for both the AER and the endoscope are compatible;

d) place brushes and instruments used to clean the endoscope in the AER for disinfection;

e) do not open or stop the AER once started; if an AER cycle is interrupted, highlevel disinfection cannot be assured;

f) implement and document preventive maintenance program(s) for the AER(s).

H. Equipment Used for Cleaning

The water bottle and its connecting tube, used for cleaning the endoscope lens and irrigation during the procedure, should receive high-level disinfection or sterilization at least daily. Sterile water shall be used to fill the water bottle.

I. Record-keeping

An accurate, permanent record of endoscope use and reprocessing will assist in tracking endoscopes and clients/patients/residents in the event of a recall or follow-up:

- a) for each procedure, document the client/patient/resident's name and record number, the date and time of the procedure, the type of procedure, the endoscopist, and the serial number or other identifier of both the endoscope and the AER (if used) to assist in outbreak investigation;
- b) record the endoscope number in the patient record; and
- c) retain records according to the policy of the facility.

Sterilization of Reusable Medical Equipment/Devices

Sterilization is the elimination of all disease-producing microorganisms, including spores (e.g. *Clostridium* and *Bacillus* species) and prions. The latter is not susceptible to routine sterilization. Sterilization is used on critical medical equipment/devices and, whenever possible, semi-critical medical equipment/devices.

For equipment/devices that cannot withstand heat sterilization, some examples of sterilants include:

a) 6% hydrogen peroxide;

b) 2% glutaraldehyde (> 10 hours);

c) hydrogen peroxide gas plasma;

d) 0.2% peracetic acid;

e) 7% accelerated hydrogen peroxide; and

f) 100% ethylene oxide.

Refer to Table 2 in Appendix 5 for contact time for sterilization.

A. Sterilization Process

Medical equipment/devices that have contact with sterile body tissues or fluids are considered critical items. All critical medical equipment/devices must be sterilized, because microbial contamination could result in disease transmission. Critical items include surgical instruments, implants, foot care equipment, endoscopes that enter sterile cavities and spaces, colposcopy equipment, biopsy forceps and brushes, eye equipment and dental equipment. Semi-critical medical equipment/devices have contact with non-intact skin or mucous membranes but do not penetrate them. Whenever possible, semi-critical medical equipment/devices should be sterilized. When sterilization is not possible, semicritical equipment/devices shall be cleaned, followed by high-level disinfection. Health care settings shall have written policies and procedures for sterilization of medical equipment/devices processes that:

- a) ensure that the sterilization processes follow the principles of infection prevention and control;
- b) ensure that manufacturer's instructions for installation, operation, cleaning and preventive maintenance of the equipment are followed;
- c) include clearly defined responsibilities;
- d) include cleaning, decontamination, drying, inspection, lubrication, disassembly, wrapping, sealing and labeling;
- e) include a thorough evaluation of all sterilization processes before being put into service, and at regular intervals thereafter.

The floors and walls should be constructed of materials capable of withstanding chemical agents used for cleaning or disinfecting. Ceilings and wall surfaces should be constructed of non-shedding materials.

B. New Sterilizers

Input from a professional with infection prevention and control expertise must be obtained prior to the purchase of a new sterilizer. There must be good 2016 Draft for Consultation 107

communication between the health care setting and the manufacturer of the sterilizer to ensure that:

- a) manufacturers of sterilizers provide specific, written instructions on installation and use of their equipment;
- b) storage and transportation practices maintain sterility to the point of use; and
- c) manufacturers of sterilizers specific which medical are as to equipment/devices can be sterilized in their machines and the recommended sterilization methods.

Sterilizers must be subjected to rigorous testing and monitoring on installation and following disruptions to their normal activity:

- a) autoclaves must be installed according to the manufacturer's instructions;
- b) tabletop steam sterilizers are recommended for office settings;
- c) following installation of a new sterilizer, the sterilizer must pass at least three consecutive cycles with the appropriate challenges (i.e., biological, chemical) placed in an empty sterilizer, as well as at least one cycle challenged with a full test load, before the sterilizer can be put into routine service;
- d) for sterilizers of the dynamic air removal type (vacuum), three consecutive air removal tests shall be conducted in an empty sterilizer with the air detection test pack (e.g. Bowie-Dick)
- e) a sterilizer shall not be approved for use if the biological indicator (BI) yields a positive result on any of the tests;
- f) sterilizers must be monitored with a test load and be fully re-qualified in the following circumstances:

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- i. after major repairs to an existing sterilizer;
- ii. when there has been construction, relocation or other environmental changes in the area;
- iii. after unexplained sterility failures;
- iv. after changes in steam and/or ethylene oxide supply or delivery; and
- v. after repairs or modification to the emission control system.

C. Monitors and Indicators

Physical, biological and chemical monitoring is done to verify the effectiveness of sterilizers and the sterilization process. Monitoring is done when a sterilizer is first installed before it is put into general use and to assess routine performance thereafter. Performance monitoring using all three types of indicators/monitors must be completed in all sterilizers to ensure that effective sterilization has been achieved.

1. Physical Monitors

A physical monitor is a device that monitors the physical parameters of a sterilizer, such as time, temperature and pressure that are measured during the sterilization cycle and recorded (as a printout or electronic record) on completion of each cycle.

2. Biological Indicators (BI)

A biological indicator is a test system containing viable microorganisms (e.g. sporeladen strips or vials) providing a defined resistance to a specified sterilization process. The BI is generally contained inside a process challenge device (PCD) that simulates the in-use challenges presented by packaged devices. Once sterilized, a BI is incubated to see if the microorganism will grow, which indicates a failure of the sterilizer.

The manufacturer's instructions regarding the type of BI to be used in a particular sterilizer should be followed. The recommended test microorganisms generally used as BIs are:

a) Geobacillus stearothermophilus (formerly Bacillus stearothermophilus) spores for sterilizers that use steam, hydrogen peroxide gas plasma or peracetic acid, as well as IUSS sterilizers; and

b) *Bacillus atrophaeus* (formerly *Bacillus subtilis*) spores for sterilizers that use dry heat or ethylene oxide.

The BI is incubated according to the manufacturer's instructions. Most BIs require up to 48 hours of incubation before the test is complete. Recently, however, rapid readout biological indicators have become available that provide BI results in one hour. These indicators detect enzymes of *Geobacillus stearothermophilus* (the test organism for steam sterilizers) by reading a fluorescent product produced by the enzymatic breakdown of a non-fluorescent substrate. Studies have shown that the sensitivity of rapid-readout tests for steam sterilization (1 hour for 132°C gravity sterilizers, 3 hours for 121°C gravity and 132°C vacuum sterilizers) parallels that of the conventional sterilization-specific BIs.

3. Chemical Indicators (CI)

A chemical indicator is a system that responds to a change in one or more predefined process variables with a chemical or physical change. There are six classes of chemical indicators (see Table 2, 'International Classes of Steam Chemical Indicators').

Chemical indicators do not necessarily indicate that a device is sterile and do not replace the need to use a BI, but do indicate that the package has been processed through a sterilization cycle.

Table 2: International Classes of Steam Chemical Indicators

Class	Definition type	Use	Examples
	Process indicator to differentiate processed from non-processed items	To indicate that item has been directly exposed to sterilization process, usually applied outside of packages	Indicator tapes, indicator labels, load cards
II	Indicator for use in specific tests	To evaluate sterilizer performance	Bowie-Dick test
	Single variable indicator to indicate when a stated value has been reached e.g. temperature at specific location in chamber	For pack control monitoring but not as useful as Class IV or V indicators; for exposure control monitoring	Temperature tubes
IV	Multi-variable indicator that reacts to 2 or more critical variables in sterilization cycle	For pack control	Paper strips
V	Integrating indicator that reacts to all critical variables in the sterilization process (time, temperature, presence of steam) and has stated values that correlate to a BI at 3 time/temperature	For pack control or as additional monitoring tool to release loads that do not contain implants	

Class	Definition type	Use	Examples
	relationships		
VI	Emulating indicator that reacts to all critical variables (time, temperature, presence of steam) for specified sterilization cycle (e.g. 10 min, 18 min, 40 min)		

4. Process Challenge Device (PCD)

A process challenge device is a test device intended to provide a challenge to the sterilization process that is equal to, or greater than, the challenge posed by the most difficult item routinely processed. Examples include BI test packs which also contain a chemical indicator, or CI test packs which contain a Class 5 integrating indicator or an enzyme-only indicator. During routine monitoring of sterilizers, the BI and/or CI is usually placed within a PCD and placed in the sterilizer. A PCD can be commercially manufactured or prepared in-house.

D. Routine Monitoring of Sterilizers

Routine monitoring verifies that the sterilization process is working as expected and that medical equipment/devices achieve sterility. Routine monitoring of sterilizers involves the assessment of physical parameters of the sterilizer cycle, chemical indicators and biological indicators. All monitoring must comply with the manufacturer's instructions. *2016 Draft for Consultation* 113

The following are included in routine monitoring:

- a) record and initial results of physical, chemical and biological parameters;
- b) document daily operation of the sterilizer:
 - review physical monitoring parameters for each operation (e.g. printed or electronic records);
 - ii. ii) note any malfunction and take appropriate action to ensure that the product either has been properly treated or is returned for reprocessing;
- c) test filter systems for leakage;
- validate gas sterilization units for such factors as gas concentration, temperature, and relative humidity;
- e) conduct three consecutive tests with the air detection test pack (Bowie-Dick) for sterilizers of the dynamic air removal type; and
- f) monitor dry heat sterilization with each cycle due to differences in penetration with different items.

When using sterilization indicators:

- a) indicator shall be used according to the indicator manufacturer's instructions;
- b) indicator shall be used only for the sterilizer type and cycle for which it was designed and validated;
- c) indicator shall be interpreted only by qualified staff who have been trained to do so;
- d) indicator shall not be used beyond the expiration date; and
- e) indicator shall be stored in accordance with the manufacturer's instructions.

The following requirements apply to chemical monitoring:

- a) an internal chemical indicator shall be placed inside each package, container or bundle that is undergoing sterilization in the area judged to be least accessible to steam penetration or to the sterilizing agent; this may not necessarily be at the centre of the package; the class of indicator chosen is based on the parameters being measured and the degree of precision that is needed;
- b) each package or container to be sterilized shall have an externally visible
 Class I chemical indicator, which is examined immediately after sterilization to
 make sure that the item has been exposed to the sterilization process; and
- c) for dynamic air removal-type sterilizers, an air removal test with a Class II chemical indicator shall be performed every day the sterilizer is used.

The following requirements apply to biological monitoring:

- a) a biological indicator shall be used to test the sterilizer each day that it is used and with each type of cycle that is used that day; except for steam sterilizer which should be done weekly;
- b) a biological indicator shall be included in every load that is to be sterilized with ethylene oxide;
- c) a biological indicator shall be included in every load containing implantable devices;
- d) items in the processed load should not be released until the results of the BI test are available; if quarantine pending BI results is not possible, evaluation

of a Class 5 or 6 chemical indicator and the specific cycle physical parameters may be used to justify the release of routine loads; and

e) implantable devices should be quarantined until the results of the BI test are available.

Immediate Use Steam Sterilization (IUSS)

IUSS shall only be used in emergency situations and shall not be used for implantable equipment/devices or on complete sets or trays of instruments. Sterilization is a process, not an event. Operative scheduling and lack of instrumentation do not qualify as reasons to use IUSS. Effective sterilization is impaired if all the necessary parameters of the process are not met. These include, but are not limited to, the following:

- decontamination and sterilization areas must meet the requirements for processing space and shall not be located in the operative procedure room or near any potential source of contamination, such as
- 2. sinks, hoppers, linen or trash disposal areas;
- a record for each piece of equipment/device being subjected to IUSS that includes the name of the client/patient/resident, procedure, physician/practitioner and equipment/device used; the client/patient/resident record should also reflect this information;
- 4. if, in an emergency situation, a IUSS sterilizer is used, a biological monitor must be included at least once daily and with each type of cycle and every load configuration (i.e., open tray, rigid IUSS container, single wrapper) that will be used that day;

- 5. the load printout must be signed to verify that the required time, temperature and pressure have been achieved;
- 6. records must be retained according to the facility's policy;
- 7. there must be a procedure for notification of the client/patient/resident in the event of a recall (e.g. positive biological indicator); and
- records should be reviewed on a regular basis to correct issues relating to overuse of IUSS.

Unacceptable Methods of Disinfection/Sterilization

The following methods of disinfection/sterilization are **NOT** recommended:

A. Boiling

The use of boiling water to clean instruments and utensils is not an effective means of sterilization. Boiling water is inadequate for the destruction of bacterial spores and some viruses.

B. Ultraviolet Irradiation

The germicidal effectiveness of ultraviolet (UV) radiation is influenced by organic matter, wavelength, type of suspension, temperature, type of microorganism and UV intensity, which is affected by distance and dirty tubes. The application of UV light in the health care setting is limited to the destruction of airborne organisms (e.g. ventilation ducts) or inactivation of microorganisms located on surfaces (e.g. 2016 Draft for Consultation 117

laboratory hoods). It is not an acceptable method of disinfection/sterilization for medical equipment/devices.

C. Glass Bead Sterilization

Glass bead sterilizers use small glass beads and high temperature for brief exposure times to inactivate microorganisms. Glass bead sterilizers are difficult to monitor for effectiveness, have inconsistent heating resulting in cold spots, and often have trapped air which affects the sterilization process. The U.S. Food and Drug Administration has determined that a risk of infection exists with this equipment because of their potential failure to sterilize dental instruments and has required their commercial distribution cease until the device has received FDA clearance. Glass bead sterilization is not an acceptable method of sterilization for medical equipment/devices.

D. Chemiclave

Unsaturated chemical-vapor sterilization ('chemiclave') involves heating a chemical solution of primarily alcohol with 0.23% formaldehyde in a closed pressurized chamber. Because of the environmental risks associated with formaldehyde, this method of sterilization is discouraged. If used, it must be closely monitored and local regulations for hazardous waste disposal must be followed and air sampling for toxic vapors may be indicated.

E. Microwave Oven Sterilization

Microwave ovens are unreliable and difficult to monitor for effective sterilization. Home microwaves have been shown to inactivate bacteria, viruses, mycobacteria and some spores, however there may not be even distribution of microwave energy over the entire device. More research and testing is required to validate the use of microwave ovens for sterilization. The use of microwave ovens for sterilization of medical equipment/devices is not currently acceptable.

Continued Monitoring and System Failures Recalls

Improper reprocessing includes, but is not limited to, the following situations:

- a) the load contains a positive BI;
- b) an incorrect reprocessing method was used on the equipment/device;
- c) print-outs on reprocessing equipment indicate failure to reach correct parameters (e.g. temperature, pressure, exposure time);
- d) CI or monitoring tape has not changed colour; and
- e) there is doubt about the sterility of medical equipment/devices.

A written procedure must be established for the recall and reprocessing of improperly reprocessed medical equipment/devices. All equipment/devices in each processed load must be recorded to enable tracking in the event of a recall. The recall procedure should include:

1. designation of department and staff responsible for executing the recall;

- identification of the medical equipment/devices to be recalled1; if recall is due to a failed BI, the recall shall include the medical devices in the failed load as well as all other devices processed in the sterilizer since the last successfully sterilized load;
- 3. assessment of client/patient/resident risk;
- 4. procedure for subsequent notification of physicians, patients, other facilities and/or regulatory bodies, if indicated; and
- 5. involvement of the facility's risk manager, if applicable.

Health care settings shall have a process for receiving and disseminating medical device alerts and recalls originating from manufacturers or government agencies.

Single-Use Medical Equipment/Devices

Health care settings must have written policies regarding single-use medical equipment and devices. Critical and semi-critical medical equipment/devices labeled as single-use must not be reprocessed and re-used unless the reprocessing is done according to institutional policy.

Health care settings that wish to have their single-use medical equipment/devices reprocessed should ensure that the facilities and procedures have been certified by a regulatory authority or an accredited quality system auditor to ensure the cleanliness, sterility, safety and functionality of the reprocessed equipment/devices.

In order to have critical or semi-critical medical equipment/devices reprocessed by one of these facilities, there must be processes for:

- 1. tracking and labeling equipment/devices;
- 2. recalling improperly reprocessed medical equipment/devices;
- 3. assuring proof of sterility or high-level disinfection;
- 4. testing for pyrogens;
- 5. maintenance of equipment/device functionality and integrity;
- 6. quality assurance and quality control;
- 7. reporting adverse events; and
- 8. provision of good manufacturing procedures.

Whereas reusable medical equipment/devices are sold with instructions for proper cleaning and sterilization, no such instructions exist for single-use medical equipment/devices. Furthermore, manufacturers often have not provided data to determine whether the equipment/device can be thoroughly cleaned, whether the materials can withstand heat or chemical sterilization, or whether delicate mechanical and electrical components will continue to function after one or more reprocessing cycles. In circumstances where the manufacturer does not approve of reuse, the facility will bear the brunt of legal responsibility in establishing when and under what conditions reuse of medical equipment/devices presents no increased risk to patients and that a reasonable standard of care was adhered to in the reuse of the equipment/device. This would involve written policies, extensive testing of reprocessing protocols and strict adherence to quality assurance investigations. This

is a detailed and expensive process and should only be undertaken if there is a compelling reason to do so.

Equipment/Devices with Small Lumens

Reusable equipment/devices with small lumens or other characteristics that make them difficult to clean effectively can put patients at risk, as they cannot be cleaned effectively or be adequately checked for cleanliness during reprocessing. This includes items, such as catheters, drains, fine cannulae (excluding endoscopy equipment). These items should be designated single-use and not be reprocessed and re-used, even if designated as reusable by the manufacturer.

Equipment/Devices in Home Health Care

Equipment/devices owned by the client that are re-used in their home must be adequately cleaned prior to reuse. Home health care agencies may consider reusing single-use semicritical medical equipment/devices for a single client in their home when reuse is safe and the cost of replacing the equipment/device is prohibitive for the client.

Prion-Contaminated Medical Instruments and Environment (excluding vCJD)

Dried films of tissue are more resistant to prion inactivation by steam sterilization than are tissues that have been kept moist. Instruments should be kept moist (either wet by immersion in water or a detergent with prionicidal activity or, if not possible, 2016 Draft for Consultation 122 by use of a wet cloth draped over the instruments or use of a transport gel or foam) after use and during storage or transport prior to decontamination in central processing departments. Instruments should be decontaminated as soon as possible after use. Decontaminate instruments in a mechanical washer (e.g. washer-disinfector) with a detergent (preferably a detergent that has been shown to have prionicidal activity).

After the device is clean, it should be sterilized by either autoclaving (i.e. steam sterilization) or using a combination of sodium hydroxide and autoclaving, using one of the four options below:

- 1. Autoclave at 134[°]C for 18 minutes in a prevacuum sterilizer.
- 2. Autoclave at 132[°]C for 1 hour in a gravity displacement sterilizer.
- Immerse in 1 N NaOH (1 N NaOH is a solution of 40 g NaOH in 1 L water) for 1 hour; remove and rinse in water, then transfer to an open pan and autoclave (121^oC gravity displacement sterilizer or 134^oC porous or prevacuum sterilizer) for 1 hour.
- 4. Immerse in 1 N NaOH for 1 hour and heat in a gravity displacement sterilizer at 121^oC for 30 minutes, then clean and subject to routine sterilization.

Devices that are impossible to clean are to be discarded. IUSS should not be used for reprocessing instruments. Items that permit only low-temperature sterilization (e.g. sterilization with ethylene oxide) are to be discarded. No recommendation can be made regarding the use of low-temperature technologies that have shown prionicidal activity, such as a specific type of hydrogen peroxide gas plasma and vaporized hydrogen peroxide, as current data is limited.

Contaminated items (e.g. medical devices used for brain biopsy before diagnosis) that have not been processed according to these recommendations are to be recalled and appropriately reprocessed. To minimize patient exposure to neurosurgical instruments later determined to have been used on a patient with CJD, sterilization guidelines as above for neurosurgical instruments are to be used on patients undergoing brain biopsy when a specific lesion (e.g. a suspected tumour or abscess) has not been demonstrated (by computed tomography or magnetic resonance imaging). Alternatively, disposable neurosurgical instruments may be used.

Non-critical environmental surfaces contaminated with high-risk tissues (e.g. a laboratory surface in contact with brain tissue of a CJD-infected person) should be cleaned with a detergent and then spot decontaminate these surfaces with a 1: 5 to 1:10 dilution of sodium hypochlorite (ie. bleach; a 1:5 dilution of 5.25%–6.15% sodium hypochlorite provides 10,500–12,300 ppm chlorine), ideally for a contact time of at least 15 minutes. To minimize environmental contamination, disposable plastic-backed cover sheets on work surfaces may be used.

Non-critical equipment that has been contaminated with high-risk tissue should be cleaned and then disinfected using a 1:5 to 1:10 dilution of sodium hypochlorite or 2016 Draft for Consultation 124

1N NaOH, depending on material compatibility. All contaminated surfaces should be exposed to the disinfectant.

Storage and Use of Reprocessed Medical Equipment/Devices

The shelf life of a sterile package is event-related rather than time-related. Eventrelated shelf life is based on the concept that items that have been properly decontaminated, wrapped, sterilized, stored and handled will remain sterile indefinitely, unless the integrity of the package is compromised (i.e. open, wet, dirty).

A. Sterile Storage Areas

The sterile storage area should be located adjacent to the sterilization area, preferably in a separate, enclosed, limited-access area. See Table 1 in Appendix 5 for recommended design parameters. Requirements for this area include:

- a) containers used for storage of clean equipment/devices should be moistureresistant and cleanable (i.e. cardboard boxes must not be used);
- b) equipment/devices are stored in a clean, dry, dust-free area (closed shelves), not at floor level, and at least one meter away from debris, drains, moisture and vermin to prevent contamination;
- c) equipment/devices are stored in an area where they are not subject to tampering by unauthorized persons;
- d) equipment/devices are transported in a manner that avoids contamination or damage to the equipment/device; and

 e) supplies and materials not used for reprocessing will not be stored in sterile processing areas.

B. Maintaining Sterility

Health care settings must have procedures for storage and handling of clean and sterile medical equipment/devices that include:

- a) medical equipment/devices purchased as sterile must be used before the expiration date, if one is given;
- b) reprocessed medical equipment/devices shall be stored in a clean, dry location in a manner that minimizes contamination or damage;
- c) sterility must be maintained until used;
- d) sterile packages that lose their integrity shall be re-sterilized prior to use; and
- e) equipment/devices must be handled in a manner that prevents recontamination of the item.

C. Using Sterile Equipment/Devices

At point-of-use, upon opening the reprocessed medical equipment/device, a check must be made for integrity of the packaging and the equipment/device. Those performing this inspection must be provided with education that includes:

- a) validating results of chemical tape and internal monitors, if present;
- b) visually inspecting the equipment/device for discoloration or soil; if present, the item is removed from service and reprocessed;
- c) checking for defective equipment/devices and removing them from use;

- d) checking for dampness or wetness (e.g. high humidity); if present, reprocessing may be required;
- e) reassembly of equipment/device if required.

Recommendations

- 1. It is strongly recommended that, wherever possible, reprocessing should be performed in a centralized area that complies with the physical and human resource requirements for reprocessing. [BIII]
- The chemical disinfectant used for disinfecting medical equipment/devices must be compatible with both the equipment/device manufacturer's instructions for disinfection and the cleaning products involved in the reprocessing of the equipment/device. [BIII]
- 3. The health care setting must have written policies regarding single-use medical equipment/devices. [AIII]
- 4. Critical and semi-critical medical equipment/devices labeled as single-use must not be reprocessed and re-used unless the reprocessing is done by a licensed reprocessor. [All]
- 5. It is strongly recommended that catheters, drains and other medical equipment/devices with small lumens (excluding endoscopy equipment) be designated single-use and not be reprocessed and re-used, even if designated as reusable by the manufacturer. [AII]

- 6. Home health care agencies may consider re-using single-use semicritical medical equipment/devices for a single client in their home when reuse is safe and the cost of replacing the equipment/device is prohibitive for the client. [AIII]
- 7. After a device that has been used on a CJD person has been cleaned, it should be sterilized by either autoclaving (i.e., steam sterilization) or using a combination of sodium hydroxide and autoclaving, using one of the four options below [BI]:
 - i. Autoclave at 134[°]C for 18 minutes in a prevacuum sterilizer.
 - ii. Autoclave at 132^oC for 1 hour in a gravity displacement sterilizer.
 - iii. Immerse in 1 N NaOH (1 N NaOH is a solution of 40 g NaOH in 1 L water) for 1 hour; remove and rinse in water, then transfer to an open pan and autoclave (121^oC gravity displacement sterilizer or 134^oC porous or prevacuum sterilizer) for 1 hour.
 - iv. Immerse in 1 N NaOH for 1 hour and heat in a gravity displacement sterilizer at 121°C for 30 minutes, then clean and subject to routine sterilization.
- The following methods are not acceptable for achieving disinfection/sterilization:
 [BIII]
 - a. boiling
 - b. ultraviolet light
 - c. glass bead sterilization
 - d. microwave ovens
 - e. chemiclave sterilization

Prevention of Healthcare associated Pneumonia

A. Introduction

a. Definition

Pneumonia is an inflammatory process of the lung parenchyma caused by a microbial agent. Pneumonia is usually classified according to its site of origin. This delineation helps guide antimicrobial therapy decisions as the causative organisms are likely to be different. Hospital-acquired pneumonia (HAP) is defined as pneumonia that occurs 48 hours or more after hospital admission that was not present at the time of admission. Healthcare-associated pneumonia (HCAP) includes patients who have recently been hospitalized within 90 days of the infection, resided in a nursing home or long-term care facility, or received parenteral antimicrobial therapy, chemotherapy, or wound care within 30 days of pneumonia. Ventilator-associated pneumonia (VAP) refers to hospital-acquired pneumonia that develops in patients who have been intubated and have received mechanical ventilation for at least 48 hours. The National Healthcare Safety Network defines VAP as any pneumonia that develops after the patient has been intubated, regardless of the time elapsed. The term HAP is often used to represent both VAP and HCAP.

b. Pathogenesis

In general, it is believed that the colonization of the upper respiratory tract precedes the development of healthcare-associated pneumonia. For pneumonia 2016 Draft for Consultation 130

to develop, pathogenic microorganisms must reach the distal lung and then multiply, overcoming host defences at each step. These host defences include filtration and humidification of air in the upper airways, epiglottic and cough reflexes, ciliary transport by respiratory epithelium, phagocytes and opsonins in the distal lung, and systemic cell-mediated and humoral immunity.

The probable sources of colonization are postulated to be:

1) endogenous sources including the stomach and intestines (uncommon), and upper respiratory tract, and,

2) exogenous sources from either another patient or healthcare provider (HCP) which most probably occurs via hands of HCP which enables direct inoculation of micro-organisms into the tracheobronchial tree during the manipulation of ventilator circuits or tubes.

The environment (air, water, sink, faucets, respiratory care equipment, and fomites) and tube-feeding formulas are other sources reported to be associated with outbreaks of HAP.

Of all the plausible routes, micro-aspiration of oropharyngeal organisms to the lower respiratory tract is believed to be the most important route for HAP and community-acquired pneumonia. Persons with abnormal swallowing, such as those who have depressed consciousness, respiratory tract instrumentation and/or mechanically assisted ventilation, gastrointestinal tract instrumentation or diseases, or who have just undergone surgery, especially thoracic and/or abdominal surgery, are particularly likely to aspirate. In patients receiving mechanical ventilation, aspiration of oropharyngeal pathogens, or leakage of bacteria-containing secretions around the endotracheal tube cuff, is believed to 2016 Draft for Consultation

be the primary routes of bacterial entry into the lower respiratory tract. Similarly, in nursing homes, silent aspiration is said to be the most important cause of pneumonia in the elderly population.

c. Risk factors

Risk factors for the development of HAP can be differentiated into modifiable and non-modifiable conditions. Modifiable risk factors are obvious targets for improved management. These include:

1) intubation and mechanical ventilation,

- 2) supine patient positioning,
- 3) enteral nutrition,
- 4) oropharyngeal colonization,
- 5) stress bleeding prophylaxis,
- 6) exposure to transfusion of blood products,
- 7) poor glucose control, and,
- 8) exposure to antibiotics.

Non-modifiable factors reported are mostly patient-related: 1) male sex, 2) preexisting pulmonary disease, 3) multiple organ system failure, 4) presence of underlying morbidity and impairment of the local and systemic host defences, 5) other host factors such as extremes of age; malnutrition; prior episode of a largevolume aspiration; depressed level of consciousness; and severe trauma. In addition to the abovementioned factors, independent predictors of nursing homeassociated pneumonia (NHAP) have included poor functional status; presence of

a nasogastric tube; swallowing difficulties; occurrence of an unusual event associated with altered mental alertness.

The risk factors for HAP, VAP and HCAP with multidrug-resistant organisms (MDRO) are: 1) history of antimicrobial therapy in preceding 90 days, 2) current hospitalization of 5 days or longer, 3) high prevalence of antibiotic resistance in the community or in the specific healthcare institution, and, 4) presence of the abovementioned risk factors for HCAP.

d. Epidemiology

HAP carries a crude mortality rate of 30 to 70% with an estimated attributable mortality rate to pneumonia between 27% and 50%. In USA, the exact incidence of HAP is usually between 5 and 15 cases per 1,000 hospital admissions depending on the case definition and study population. Incidence of HAP increases by 6 to 21 fold in mechanically ventilated patients, rendering VAP as the most common nosocomial infection in critically ill patients. Development of a VAP was associated with an increase of more than USD\$ 40,000 in mean hospital charges per patient. Patients with late onset of HAP and VAP are more likely to be infected with MDRO and have higher crude mortality rates than patients with early onset disease. In long term care facilities (LTCF), pneumonia is the first or second most common nosocomial infection and accounts for 13 –

48% of all nursing home-associated infections. The case-fatality rate of NHAP is reported to be from 6% to 23%.

Bacteria cause most cases of HAP, VAP and HCAP and many infections are polymicrobial. Aerobic gram-negative bacilli and gram-positive cocci are the most common pathogens associated with HAP, VAP and HCAP. These include Pseudomonas aeruginosa, Klebsiella pneumoniae, Acinetobacter baumannii and Staphylococcus aureus. However, it is important to note that the causative agents can vary depending on the length of time the patient has spent in the ICU (Intensive Care Unit) and/or received mechanical ventilation. In addition, the lack of reports of the association of HAP due to anaerobic bacteria or viruses is partly because anaerobic bacterial and viral cultures were not performed routinely in reporting facilities. The rates of Legionella pneumophilla also vary some considerably between hospitals and disease occurs more commonly with serogroup 1 when the water supply was colonized or when there was on-going construction. Legionella spp. and Chlamydia pneumonia have caused outbreaks in LTCF. Outbreaks of influenza and respiratory syncytial virus were reported sporadically especially in nursing homes and the risk of infection can be substantially reduced with widespread effective infection control, vaccination and use of anti-influenza agents. The prevalence of MDRO varies by patient population, hospital, and type of ICU and this underscores the importance of HAP surveillance in individual institutions.

The bacterial etiology of non-HAP (NHAP) is inconclusive primarily because definitive etiologic diagnosis usually is not rigorously pursued. *Streptococcus pneumonia, Haemophilus influenza, Staphylococcus aureus* and *Moraxella catarrhalis* are said to be the most common causative agents. There is a lack of reports on the NHAP in Singapore. However, a retrospective descriptive study on patients with severe community-acquired pneumonia reported similar findings. Gram-negative organisms were responsible for 47% of the patients recruited in the study and the most common bacteria identified were *Klebsiella pneumoniae, Haemophilus influenza* and *Streptococcus pneumoniae*.

B. General Recommendations for All healthcare Settings

Increasing complexity of patient, client, and resident care and the increasing severity of illness of patients and clients in all healthcare settings necessitate increasing awareness of the appropriate infection prevention and control measures and how to apply them. Continuing education should be provided to all HCWs and HCPs consistent with their work environment (e.g., patient care, administration, engineering services, housekeeping) and responsibility level within the facility and/or organization regarding the following:

- routine practices and additional precautions for preventing the transmission of infections in health care
- epidemiology of HAP, specific to the work setting
- modes of transmission of specific microbial agents responsible for HAP

- specific measures and procedures to prevent and control healthcareassociated pneumonia
- the importance of compliance with infection control practices and procedures to prevent and control healthcare-associated pneumonia.

Recommendations

- Healthcare facilities and organizations providing patient/resident/client care should have policies and procedures for the prevention of healthcare-associated pneumonia. [AII]
- 2. Continuing education should be provided to all HCWs and HCPs on infection control principles in the prevention of transmission of healthcare associated infections as well as the prevention of HAP. [AII]

C. Recommendations for Acute Care Facilities and Community Hospitals

Mechanical ventilation is the primary risk factor for the development of pneumonia in acute care settings. The key prevention strategies therefore focus on three main issues namely aspiration, colonization of the aerodigestive tract and contamination of respiratory care equipment. With these strategies there should be ongoing quality improvement programs including infection surveillance for outcome measures, direct observation and audit for compliance and educate healthcare personnel who care for patients undergoing ventilation.

1. Prevent aspiration

- a. Intubation and mechanical ventilation should be avoided whenever possible. The risk of aspiration around an artificial airway can be reduced by noninvasive positive pressure ventilation, using either a full face mask or a nasal mask.
- b. Nurse the ventilated patient in semi-recumbent position between 30 40 degrees, especially during feeding and transportation, unless there is a contraindication.
- c. Decrease the duration of intubation by assessing the patient's readiness for weaning and the appropriateness of spontaneous breathing trials on a daily basis.
 - 3.1 Avoid continuous use of paralytics.
 - 3.2 Avoid over-sedation
 - 3.3 Interrupt or lighten sedations daily at an appropriate time
- d. Ensure gastric tube is in the proper position every time before feeding.
- e. The rate of tube feeding should be carefully monitored according to the individual's tolerance by auscultating for bowel sounds and measuring the abdominal girth frequently to prevent gastric over-distention.
- f. For long term ventilated patients, the use of gastrostomy tube feeding can lower the risk of aspiration.

2. Prevent colonization of the aerodigestive tract

a. Consistent and thorough hand hygiene is the most effective means of preventing colonization / infection caused by exogenous microorganisms. All healthcare workers should diligently observe the five moments of hand hygiene. Gloves should be worn if contact with respiratory secretions or contaminated objects are anticipated, and appropriate hand hygiene should be performed before and after glove use.

- b. Provide oral care to ventilated patients such as 0.12% Chlorhexidine antiseptic oral rinse at regular interval.
- c. The use of stress ulcer prophylaxis to prevent peptic ulcers for ventilated patients can reduce gastric acidity which can result in greater gastric colonization with pathogenic bacteria and should be used judiciously.

3. Prevent contamination of respiratory care equipment

- a. Practice Standard Precautions during respiratory care.
- b. Maintain aseptic technique when performing intubation procedures. Mask and gloves should be worn.
- c. Use the oral route for insertion of the endotracheal tube if there is no contraindication.
- d. Perform endotracheal suctioning only when indicated. Measure the depth of suction catheter insertion beforehand and carry out suctioning procedures using aseptic technique.
- e. Saline instillation to loosen sputum for suction should be avoided. If there is a need to do so, single dose sterile solution should be used.
- f. Whenever possible, use steam sterilization or high level disinfection for reprocessing respiratory equipment.
- g. Sterile water should be used to rinse reusable respiratory equipment.

- h. All respiratory care items should be stored in a clean area away from exposure to dust, excess heat or moisture.
- i. The humidifier on the ventilatorshould be positioned below the bed level to prevent condensation from draining towards the patients.
- Condensate from ventilator circuits should be removed before repositioning the patient. During condensate removal the ventilator circuit should be kept closed.
- k. Change the ventilator circuit only when visibly soiled or malfunctioning.

Prevention of VAP

I. Elevation of head of bed

A semi-recumbent position with head elevated to $30-45^{\circ}$ reduces the potential for aspiration and increases capacity of the lungs for breathing. Drakulovic et al in 1998 conducted a randomized controlled trial of 86 mechanically ventilated patients. Patients were randomly assigned to semi recumbent or supine position. Results showed suspected cases of VAP in 34% of patients in the supine position and 8% in the semi-recumbent position (p=0.003). Confirmed cases of pneumonia were 23% and 5% respectively (p=0.018).

Recommendation

 Whenever possible, the head of bed is routinely elevated and measured to be at least 30-45 degrees [BI]

II. Daily 'sedation vacations' and assessment for readiness to extubate

Daily review of sedation with the aim to lighten it helps to prepare patient for readiness to extubate. It becomes easier to wean off the ventilator as the patient is more alert and able to cough and control secretions. Early extubation also decreases the time spent on mechanical ventilation and directly reduces the risk of VAP. In a randomized controlled trial by Kress et al, 128 mechanically ventilated adult patients irrespective of clinical condition and clinician discretion, were randomized to receive daily interruption of sedation. This resulted in a significant reduction in mechanical ventilation time from 7.3 to 4.9 days (P=0.004).

Sedation vacations are not without risk. Careful assessment and graduated lightening of sedation should be practiced to prevent self-extubation, keep the patient comfortable with minimal pain and anxiety while allowing return of self-breathing and synchrony with the ventilator and avoid episodes of desaturation.

Recommendation

III. In patients mechanically ventilated for >48 hours, a daily sedation vacation and assessment for readiness-to-extubate is undertaken (AI)

Daily oral care with chlorhexidine

The recommended chlorhexidine solution strength used is 0.12%. In mechanically ventilated patients, dental plaque occurs because of the lack of mechanical chewing and absence of saliva production. The existence of these 2016 Draft for Consultation 140

plaques serve as significant reservoirs for potential respiratory pathogens that cause VAP. Good oral care prevents this.

Chlorhexidine antiseptic has proven to inhibit the development of dental plaque formation and gingivitis. A study in 1996 by DeRiso and colleagues demonstrated that the use of 0.12% chlorhexidine oral rinse reduces nosocomial respiratory tract infections in cardiac surgery patients.

Chan and colleagues in 2007 reported in a meta-analysis, the evaluation of eleven studies for the effect of oral decontamination on the incidence of ventilator-associated pneumonia and mortality in mechanically ventilated adults. Results concluded that oral decontamination using chlorhexidine is associated with a lower risk of ventilator-associated pneumonia in mechanically ventilated patients.

Recommendation

 Oral decontamination with chlorhexidine twice a day is recommended for the prevention of VAP (AI)

IV. Route of Endotracheal Intubation

While the causality between sinusitis and VAP has not been firmly established, aspiration of infected secretions from nasal sinuses would, intuitively, predispose to the development of VAP.

In a prospective randomized study (n=300), Holzapfel et al demonstrated that orotracheal intubation is associated with lower VAP rates as compared to nasotracheal intubation (RR 0.52; 95% confidence interval 0.24- 1.13). 2016 Draft for Consultation 141 This study, together with 4 other trials showed a decreased incidence of sinusitis with orotracheal intubation. Of note, patients who do not develop sinusitis have a lower incidence of VAP.

Recommendation

1. Where possible, orotracheal intubation should be used in preference to nasotracheal intubation (AI).

V. Systematic search for maxillary sinusitis

Maxillary nosocomial sinusitis as a complication of endotracheal intubation has been reported. The incidence of infectious sinusitis is estimated at 20% after 8 days of mechanical ventilation in patients orotracheally or nasotracheally intubated. Clinical signs are not specific. Sinusitis is usually searched for in patients with unexplained fever and is diagnosed by sinus radiograph or sinus CT scan.

Reported risk factors for sinusitis include head trauma, prior high dose steroids, sedation, nasotracheal intubation, nasogastric tubes and duration of endotracheal and gastric intubation.

No recommendation can be made for the systematic search for maxillary sinusitis because of insufficient evidence. There is only one randomised controlled trial that demonstrated that a systematic search for maxillary sinusitis in patients who are intubated by the nasotracheal route may decrease the incidence of VAP.

VI. Frequency of ventilator circuit changes

The relation between the frequency of ventilator tubing change and the incidence of ventilator associated pneumonia has been investigated by several groups¹⁻⁵. No benefit in terms of reducing infection has been demonstrated by routinely changing ventilator circuits. Randomized trials have found that when circuits were changed when visibly soiled or mechanically defective, they were associated with rates of VAP similar to or modestly lower than rates occurring with regularly scheduled changes.

Handling and disposing of the condensate that forms on the inspiratory phase tubing of ventilator circuits poses a risk of pneumonia in patients undergoing mechanical ventilation with humidification. This condensate rapidly becomes colonized with flora and if not appropriately drained. Contaminated fluid may be accidentally washed directly into the patient's trachea when the tubing is manipulated.

Decontaminate hands with soap and water (if hands are visibly soiled) or with an alcohol-based hand rub after performing the procedure or handling the fluid (IA).

Recommendations

- The ventilator circuit should only be changed when defective or physically soiled (AI).
- Breathing-circuit-tubing condensate in the tubing of a mechanical ventilator is to be drained periodically. Precautions are to be taken not to allow condensate to drain toward the patient (BI)⁷.

3. Gloves are to worn when performing the previous procedures and/or when handling the fluid (BI).

VII. Type of airway humidification

When the upper airway is bypassed, humidification during mechanical ventilation is necessary to prevent hypothermia, inspissation of airway secretions, destruction of airway epithelial cells and atelectasis. This may be accomplished using a heat and moisture exchanger (HME) or heated humidifier. HMEs operate passively by storing heat and moisture from the patient's exhaled gas and releasing it to the inhaled gas. Heated humidifiers operate actively to increase the heat and water vapour content of inspired gas.

No recommendations can be made for the preferential use of either HMEs or heated humidifiers to prevent pneumonia in patients receiving mechanically assisted ventilation. Use of heat and moisture exchangers may be associated with a slight decrease in incidence of VAP compared with heated humidifiers.

Heat and moisture exchangers are contraindicated in patients with hemoptysis or who require high minute ventilation. Cost considerations favour the use of heat and moisture exchangers.

No recommendations can be made for the preferential use of either HMEs or heated humidifiers to prevent pneumonia in patients receiving mechanically assisted ventilation.

Recommendation
No recommendation can be made or the use of HMEs over heated humidifiers in the prevention of VAP (BI).

VIII. Frequency of change of airway humidification

Manufacturers state that HME should be changed every 24 hours but there is no clinical data to support this recommendation.

Studies have suggested that the same HME can be safely left in place for longer than 24 hours without adverse patient outcomes. Infrequent changes to heat and moisture exchangers may be associated with a slightly decreased incidence of VAP. Reduction in the frequency of humidifier changes might be considered as a cost-reduction measure.

Recommendations

- 1. Change a HME that is in use on a patient when it malfunctions or becomes visibly soiled (BII). Do not change more frequently than every 48 hours a HME that is in use on a patient (BII).
- 2. Do not change routinely the breathing circuit attached to a HME while it is use on a patient in the absence of gross contamination or malfunction (BII).

IX. Type of endotracheal suctioning system (Open vs Closed)

Endotracheal suctioning is an essential part of care for patients requiring mechanical ventilation, to keep the airways free from bronchial secretions, thereby guaranteeing good ventilation and oxygenation. There are 2 types of 2016 Draft for Consultation

suction systems. In the conventional open system, endotracheal suctioning requires opening of the respiratory circuit, which is usually performed by disconnecting the patient from the ventilator and introducing a single-use sterile suctioning catheter into the endotracheal tube. The closed suction system, which was developed in the 1980s, removes the necessity of disconnecting the patient from the respiratory circuit and employs multiuse suction catheters. Suctioning is performed without barrier precautions, because a plastic envelope protects the catheter.

The potential benefits of the closed system, compared with the open system, are:

- a) There is no loss of positive end expiratory pressure and lung volume,
- b) Reduce exogenous contamination of the inside of the endotracheal tube,
- c) Decrease contamination of the environment or of the hands of healthcare workers from respiratory microorganisms.

The main concerns about closed systems are an increase in colonization inside the suction catheter during the multiple uses in 24 hours. There is autocontamination of a larger number of microorganisms into the trachea each time suctioning is performed.

Although the literature reports several advantages for the closed suction system, reviews did not show differences between the two systems in the main outcomes studied. These outcomes were ventilator-associated pneumonia and mortality.

The Centers for Disease Control and Prevention do not establish recommendations about the type of endotracheal suction systems that should be used and the frequency of changing catheters in closed suction systems.

Does the type of endotracheal suctioning system (open or closed) affect the incidence of VAP?

There were 2 trials that concluded the type of suctioning system has no effect on the incidence of VAP. Another 2 studies compared an open endotracheal suctioning system to a closed system. One study reported significantly less environmental contamination with closed suctioning than with open suctioning. Accordingly, the patient usually contaminates the catheter, rather than vice versa. Use of closed suctioning has been recommended as part of a VAP prevention program. Another study, however, reported a 3.5 times greater risk of VAP in patients randomized to receive open suctioning than those receiving closed suctioning. As ventilator circuits do not need to be changed at regular intervals for infection control purposes, this might suggest that in-line suction catheters also do not need to be changed at regular intervals for infectional study reported no change in VAP rate when in-line suction catheters were changed on a weekly rather than daily basis.

Although the available evidence is not conclusive that closed suctioning decreases the risk of VAP, there is no high-level evidence that use of closed suction catheters increases the risk of VAP. The type of endotracheal suctioning system (open or closed) has no effect on duration of ventilation. Safety considerations (patient and healthcare worker such as exposure to aerosols) support the use of a closed system.

Recommendation

There is no recommendation for the routine use of closed endotracheal suctioning for the reduction of VAP (AI).

X. Frequency of change of endotracheal suctioning system

When closed suction catheters are used, scheduled daily changes or unscheduled changes of the suctioning system have no effect on the incidence of VAP.

Recommendation

In-line catheters for closed endotracheal suction systems should only be changed when defective or soiled (BI)

XI. Subglottic Secretion Drainage (SSD)

Aspiration of oropharyngeal secretions containing bacterial pathogens into the lower respiratory tract is the most important process in the pathogenesis of VAP.

SSD is designed to minimize the pooling and subsequent leakage of secretions around the cuff of the endotracheal tube (ETT).

A randomized, controlled, multicenter study involving 333 patients demonstrated a significant reduction of VAP in the treatment arm (intermittent SSD) as compared to

control group (RR 0.42; 95% confidence interval 0.10- 0.63). The beneficial effects of SSD was seen both in early and late onset VAP patients.

Similarly, a recent meta-analysis with a total of 2442 randomized patients showed a reduction of VAP rates in the SSD arm (RR 0.55; 95% confidence interval 0.46-0.66). The use of SSD was also associated with decreased length of mechanical ventilator days (-1.08 days; 95% confidence interval -2.04 to -0.12), shortened ICU length of stay (-1.52 days; 95% confidence interval -2.94 to -0.11) and increased time to the first episode of VAP (2.66 days; 95% confidence interval 1.06- 4.26).

Subglottic- suction ETTs are, however, more expensive than standard ETTs and are more likely to benefit patients who need prolonged mechanical ventilation. Various studies analyzing the cost effectiveness of such tubes on VAP modeling showed an overall cost savings per episode of VAP prevented with SSD despite a higher acquisition cost.

Recommendation

Use of SSD is recommended in patients who are expected to require mechanical ventilation for more than 72 hours (AI).

XII. Timing of Tracheostomy

Tracheostomy has several advantages in patients who require prolonged intubation and mechanical ventilation. It affords better patient comfort, facilitates oral hygiene and secretion management while reducing anatomical dead space and airway resistance. Early tracheostomy (usually within 7 days of laryngeal intubation) has been postulated to prevent VAP, this is however controversial with some studies showing benefit and some none.

A prospective randomized trial (n=120) reported early tracheostomy (within 2 days of intubation) was associated with reduced incidence of pneumonia, length of ICU stay and ventilator days when compared to the late group (14-16 days).¹ In contrast, Blot et al found no difference in VAP rates, duration of mechanical ventilation and ICU stay between early tracheostomy (within 4 days) versus prolonged endotracheal intubation.

In a randomized controlled multicenter trial, early when compared to late tracheostomy did not result in any significant improvement in the incidence of VAP.

Similarly, the authors of a recent meta-analysis (seven trials, 1044 patients) comparing important outcomes in ventilated patients who received early versus late tracheostomy concluded that early tracheostomy did not reduce incidence of VAP (RR 0.94; 95% confidence interval 0.77-1.15). The timing of tracheostomy was also not associated with reduced duration of mechanical ventilation nor shortened ICU stay.

Importantly, though, it is noted that the trials till date have significant methodological limitations and heterogeneity. Caution should be taken while interpreting these pooled results. The yet to be published results of the TracMan trial may, in the future, provide a clearer indication on the role of early

tracheostomy in critically ill patients. 2016 Draft for Consultation

Recommendation

Early tracheostomy is not recommended routinely for the prevention of VAP (AI).

XIII. The VAP Bundle

The Institute of Health Improvement (IHI) Ventilator Bundle¹ is a series of evidence based interventions that when implemented together will achieve significant outcomes of reducing VAP in patients on mechanical ventilation.

The components of the VAP Bundle are:

- 1) Elevation of head of bed
- 2) Daily 'sedation vacations' and assessment for readiness to extubate
- 3) Peptic Ulcer Disease prophylaxis
- 4) Deep Venous Thrombosis prophylaxis
- 5) Daily oral care with chlorhexidine

It is controversial whether all the components of the VAP bundle contribute equally to the prevention of VAP. As discussed, there is reasonably good evidence for elevation of the head of bed, sedation vacations and daily oral care. Prophylaxis against peptic ulcers and deep vein thrombosis represents good practice in all mechanically-ventilated patients as these complications are relatively common. However, these interventions have not been individually shown to reduce VAP, nor is there a good biologic rationale to believe so. Nevertheless, when the VAP bundle is implemented as a whole, before-and-after studies seem to suggest that VAP rates 2016 Draft for Consultation 151 are reduced. For example, in a recent publication by AI-Tawfiq et al, implementation of the IHI VAP bundle resulted in a reduction of VAP from 9.3 per 1000 ventilator days to 2.3 per 1000 ventilator days.

D. Recommendations for ILTCs

I. General preventive measures

Swallowing should be assessed in residents/clients who are at risk of aspiration. A modified barium swallow should be used for this assessment if indicated. HCWs should be educated to identify residents/clients who may be at risk of, or who have dysphagia. An appropriate diet and liquid consistency should be provided to residents/clients with swallowing disorders. Positioning issues, i.e., hyperextended neck, that prevent spontaneous clearing of secretions and increase the risk of aspiration, should be addressed, if possible. The resident/client should be in an upright position (elevate the head of the bed to 30°-45° degrees) during meals or tube feeds and for at least one hour after eating. The use of anti-cholinergic and/or sedative-hypnotic medications should be minimized. Drug use should be monitored to ensure that it is consistent with standards, and residents/clients should be routinely evaluated for tardive dyskinesia and other movement disorders. Attention should be given to oral hygiene and dental care, especially in residents/clients with oral dryness (xerostomia). Residents/clients should have routine dental evaluations, and staff should be aware of dental hygiene techniques. Residents/clients with xerostomia should be treated as follows: medication modification, optimized hydration status, artificial saliva or water as oral lubricants, mechanical stimulants (e.g., sugarless gum), gustatory stimulants (e.g., sugarless lemon drops), systemic salivary

stimulants (pilocarpine), close dental monitoring, and fluoride treatment for decay. Residents/clients who are at risk of salivary gland dysfunction (i.e., medications causing xerostomia, Sjogren's syndrome, radiation-induced dysfunction, dehydration, infection, gland occlusion) should be identified. Feeding, gastrostomy, and jejunostomy tubes have not been shown to prevent pneumonia in residents/clients at risk of aspiration.

II. Respiratory care equipment

If there is any risk that equipment may be shared by another resident (e.g., equipment is reprocessed in a central area), it must be subjected to high-level disinfection at a minimum.

III. Tracheostomy Care

Aseptic technique should be used for a tracheostomy less than one month old. A clean technique rather than aseptic technique may be used if the tracheostomy is more than one month old. The healed tracheostomy site should be cleansed as needed but at least twice daily with equal parts 3% hydrogen peroxide and water, or according to the resident's established routine. Clean gloves should be worn for contact with the tracheostomy tube. Tracheostomy ties and dressings should be changed when they are soiled.

IV. Suctioning

A clean technique may be used for suctioning the trachea. Suctioning should be performed using "no touch" technique while wearing gloves on both hands. Although fresh gloves should be used for each suctioning, sterile gloves are not needed. Sterile water should be used for suctioning and clearing the catheter during and after suctioning.

In the long-term care setting, suction catheters may be cleaned, reprocessed, and reused on the same resident as long as the structural integrity or function of the catheter is not changed in the process and they are stored in a manner to keep them dry and free from contamination. If the suction catheter is reused without reprocessing, it should be replaced with a new, sterile catheter every 8-24 hours. Between uses, suction catheters and cannulas should be mechanically cleaned to remove secretions. Before reuse, the catheter should be flushed with sterile water. Suction collection canisters that are reused should be emptied when full or at least daily and cleaned with soap and water. The system with tubing should be disinfected at least weekly with a 1:10 bleach solution.

V. Tracheostomy cannula care

Tracheostomy inner cannulas should be cleaned as necessary with soap and water using a clean pipe cleaner or small bottle brushe to clear the inner lumens. If dedicated for sole use by a resident, inner cannulas should be disinfected as necessary by one of the following methods:

1) soak in 3% hydrogen peroxide (30 minutes), wash in hot soapy water, rinse, and air dry;

2) soak in 70% isopropyl alcohol (five minutes) and rinse thoroughly with tap water; or

3) boil metal cannula for 15 minutes and dry thoroughly.

VI. Ventilator and Equipment Care

I. Ventilator circuits

When changed, circuits should be taken apart, washed with soap and water, and scrubbed with a brush if necessary to remove secretions or other foreign material. All parts of the circuit, including tubing, connectors, nebulizer or humidifier, and exhalation valve, should undergo high-level disinfection at a minimum and be thoroughly dried before reuse.

II. Large volume nebulizers and medication delivery devices

Nebulizers and the circuits used to deliver mist to the patient should be taken apart, cleaned, and disinfected every 24 hours. Sterile solutions should be used with aerosol delivery devices. Fresh, previously unopened sterile solutions must be used for the preparation of medication. After each treatment, nebulizers should be rinsed and dried.

III. Oxygen delivery equipment and humidification

If a pre-filled humidifier is used, it may be used down to the minimum effective fluid level and then discarded. If the humidifier is reusable, it should be emptied and rinsed well and the water replaced daily. Sterile water is not required. Humidifiers should not be "topped up" with water. The humidifier should be cleaned and disinfected after 72 hours (three days) of use. Oxygen therapy tubing and cannulas may be cleaned with a white vinegar solution of one teaspoon per quart of water or saline solution.

IV. Room humidifiers

Aerosol-producing humidifiers should not be used. Wick-type humidifiers can be used if humidity is desired.

V. Nasal and mask CPAP devices

As devices are for single patient use, they should cleaned as necessary according to the manufacturer's recommendations.

Prospective surveillance for respiratory and influenza-like illnesses should be established in every ILTC. HCWs who have direct contact with residents should receive annual influenza immunization as a standard of care for influenza prevention. All ILTCs should have a written plan for managing a viral respiratory tract infection outbreak.

Infection control measures during a viral respiratory tract infection outbreak include:

- Consideration should be given to maintaining two metres spatial separation from other residents and from visitors
- Participation in group activities may need to be adjusted or restricted while the resident is symptomatic.
- c. Symptomatic residents should be confined to their rooms if possible. Restrict cases (ill residents) to their room until five days after the onset of acute illness or until symptoms have completely resolved (whichever is shorter).
- d. In addition to routine precautions, Contact and Droplet precautions should be applied during the outbreak.
- e. All unvaccinated residents should be given influenza vaccination immediately when an influenza outbreak occurs, unless contraindications exist.
- f. In an influenza outbreak, unvaccinated HCWs who are not taking antiviral prophylaxis should be excluded from direct resident care.
- g. Unvaccinated HCWs who receive prophylaxis should also be immediately vaccinated for influenza unless contraindications exist and may continue work without restrictions.

Recommendations

- 1. All ILTCs should have a written plan for managing a viral respiratory tract infection outbreak [C]
- 2. Consideration should be given to maintaining two metres spatial separation from other residents and from visitors in an outbreak situation. [BIII]

E. Recommendations for Ambulatory Care

Waiting areas in ambulatory care centres should have appropriate space, traffic flow, and ventilation. If possible, separate waiting rooms or areas for well-child visits and for children with acute respiratory symptoms should be considered, especially during community outbreaks. Immunocompromised clients who may be at increased risk of droplet-spread viral RTIs should be identified and contact with other clients/patients in the waiting room minimized.

Patients with signs and symptoms of respiratory infection should be placed in a separate examination room as soon as possible. Symptoms should be evaluated and, if required, additional precautions should be applied prior to full diagnostic work-up.

Recommendation

1 Patients with signs and symptoms of respiratory infection should be placed in a separate examination room as soon as possible. [BIII]

F. Recommendations for Home Care

Clients with symptoms of potentially transmissible respiratory infections should be managed according to Infection Control Guidelines: Routine Practices and 2016 Draft for Consultation 157 Additional Precautions for Preventing the Transmission of Infection in Health Care. HCWs, volunteers, and family members in home care should receive appropriate vaccinations.

I. Tracheostomy Care

Aseptic technique should be used for a tracheostomy that is less than one month old. A clean technique rather than aseptic technique may be used if the tracheostomy is more than one month old. The healed tracheostomy site should be cleansed as needed but at least twice daily with 3% hydrogen peroxide. Clean gloves should be worn for contact with the tracheostomy tube. Tracheostomy ties and dressings should be changed when they are soiled.

II. Suctioning

A clean technique may be used for suctioning the trachea. Suctioning should be performed using "no touch" technique or while wearing gloves on both hands. Although new gloves should be used for each suctioning, sterile gloves are not needed. Recently boiled or sterile distilled water should be used for clearing the catheter during and after suctioning, followed by suctioning of air through the device to dry the internal surface. The outer surface may be wiped with alcohol or hydrogen peroxide. The catheter should be allowed to air dry and then stored in a clean dry area. In the home care setting, suction catheters may be cleaned, reprocessed, and reused as long as the structural integrity or function of the catheter is not changed in the process and they are stored in a manner to keep them dry and free from contamination. If the suction catheter is reused without reprocessing, it should be replaced with a new, sterile catheter every 8-24 hours.

to remove secretions before disinfection. Before reuse, the catheter should be flushed with sterile water.

Suction catheters may be processed for reuse according to one of the following methods:

1) clean with soapy water, rinse, and boil catheters for 20 min;

- flush with sterile water and place in 3% hydrogen peroxide; flush with sterile water before use;
- 3) flush with 3% hydrogen peroxide, place in boiling, soapy water and let sit overnight; rinse with hot tap water; suction boiling water through catheter; air dry; wipe outside of catheter with alcohol and store in plastic bag.

After processing for reuse, suction catheters should be stored in a manner to keep them dry and to avoid contamination. Suction collection canisters should be emptied when full or at least daily and cleaned with soap and water. The system with tubing should be disinfected at least weekly with a 1:3 vinegar solution, a 1:10 bleach solution, or a phenolic solution.

III. Tracheostomy cannula care

Tracheostomy inner cannulas should be cleaned as necessary with soap and water using a clean pipe cleaner or small bottle brush to clean the inner lumen.

Inner cannulas should be disinfected as necessary by one of the following methods:

1) soak in 3% hydrogen peroxide (30 min) and wash in hot soapy water; rinse; and air dry;

- 2) soak in 70% isopropyl alcohol (five minutes) and rinse thoroughly with tap water; or
- 3) boil metal cannula in water for 15 minutes and dry thoroughly.

IV. Ventilator and Equipment Care

1) Ventilator circuits

When changed, circuits should be taken apart, washed with soap and water, and scrubbed with a brush, if necessary, to remove secretions or other foreign material, then rinsed until all soap is gone. All parts of the circuit, including tubing, connectors, nebulizer, or humidifier and exhalation valve, should be soaked in a disinfectant solution recommended for home use (e.g., bleach, 70% alcohol, 3% hydrogen peroxide) according to the manufacturer's instructions and thoroughly rinsed and dried before they are reused. Drain off as much water as possible and hang tubing to dry.

2) Large volume nebulizers and medication delivery devices

Nebulizers and the circuits used to deliver mist to the patient should be taken apart, cleaned, and disinfected every 24 hours. Sterile solutions should be used with aerosol delivery devices. Fresh, previously unopened sterile solutions should be used for the preparation of medications.

After each treatment, nebulizers should be cleaned with soap and water, and disinfected by one of the following methods:

- 1) boil in water for five minutes; or
- 2) immerse in one of the following:

- i. 1:50 dilution of 5.25% to 6.15% sodium hypochlorite(household bleach) for three minutes,
- ii. 70% to 90% ethyl or isopropyl alcohol for five minutes or
- iii. 3% hydrogen peroxide for 30 minutes;
- rinse with sterile water (or, as an alternative, 70% to 90% ethyl or isopropyl alcohol); air dry all equipment.

A standard cycle dishwasher may also be used if the water temperature is 70° or higher.

3) Oxygen delivery equipment and humidification

If a pre-filled humidifier is used, it may be used down to the minimum effective level and then discarded. If the humidifier is reusable, it should be emptied, rinsed well, and replace the water daily. Sterile water is not necessary. Humidifiers should never be "topped up" with water. The humidifier should be cleaned and disinfected after 72 hours (three days) of use. Oxygen therapy tubing and cannulas may be cleaned with a white vinegar solution of one teaspoon per quart of water or saline solution.

4) Room humidifiers

Aerosol-producing humidifiers should not be used. Wick-type humidifiers can be used if humidity is desired.

5) Nasal and mask CPAP devices

As devices are for single patient use, CPAP masks, devices, and circuits should be cleaned as necessary following the manufacturer's recommendations.

Prevention of Intravascular Catheter-related Infections

Introduction

a. Definition

The term catheter-related bloodstream infection (CRBSI) has been used interchangeably with central line-associated bloodstream infection (CLABSI). While CRBSI is mostly used for diagnosing and treatment purpose, CLABSI is a term used by CDC's National Healthcare Safety Network (NHSN) for surveillance. In general, a CLABSI is a primary BSI in a patient that had a central line within the 48-hour period before the development of the BSI and is not a BSI related to a secondary source. It is important to note that the CLABSI surveillance definition may overestimate the true incidence of CRBSI as some secondary sources may not be easily recognized.

By placing the emphasis in microbiologic confirmation, Crnich and Maki proposed a set of criteria for the definitions for IV catheter-associated infection (Table 1) which is believed to be a set of more rigorous working definitions for IV catheterassociated infections.

Table 1Proposed Definitions for Intravascular Catheter-Associated
Colonization, Local Infection, and Bloodstream Infection Based on
Microbiologic Confirmation of the Intravascular Catheter as the
Source

Terminology	Definition
IV catheter colonization	 A positive semi-quantitative^a (or quantitative^b) culture of the implanted portion or portions of the catheter; and, absence of signs of local or systemic infection.

Local IV catheter infection	 i. A positive semi-quantitative^a (or quantitative^b) culture of the removed catheter or a positive microscopic examination or culture of pus or thrombus from the cannulated vessel; and, ii. clinical evidence of infection of the insertion site (i.e., erythema, induration, or purulence) but; iii. absence of systemic signs of infection and negative blood cultures, if done.
	If the catheter is <u>removed</u> :
IV catheter- associated BSI	 A positive semi-quantitative^a (or quantitative^b) culture of the catheter or a positive culture of the catheter hub or infusate (or positive microscopic examination or culture of pus or thrombus from the cannulated vessel) <i>and</i> one or more positive blood cultures, ideally percutaneously drawn, concordant for the same species, ideally by molecular subtyping methods; and, clinical and microbiologic data disclose no other clear-cut source for the BSI.
	If the catheter is <u>retained</u> :
	 i. If quantitative blood cultures are available, cultures drawn both from the catheter and a peripheral vein (or another catheter) are both positive and show a marked step-up in quantitative positivity (≥ fivefold) in the catheter-drawn culture; and, ii. clinical and microbiologic data disclose no other clear-cut source for the BSI,
	OR,
	 i. If automated monitoring of incubating blood cultures is available, blood cultures drawn concomitantly from the catheter and a peripheral vein (or another catheter) show both are positive, but the catheter-drawn blood culture turns positive more than 2 hours before the peripherally drawn culture; and, ii. clinical and microbiologic data disclose no other clear-cut source for the BSI

^aRoll plate of cannula segment(s) >15 colony-forming units (cfu).

^bSonication culture of cannula segment(s) $\geq 10^3$ cfu.

BSI, bloodstream infection; IV, intravascular.

Adapted from Crnich CJ, Maki DG. The role of intravascular devices in sepsis. *Curr Infect Dis Rep* 2001;3(6):497–506.

Despite the challenge of identifying the source of a patient's signs of sepsis, patients with abrupt onset of signs and symptoms of sepsis without any other identifiable source should prompt suspicion of an IV catheter-associated infection. If purulence is seen in combination with signs and symptoms of sepsis, it is highly likely the patient has an IV catheter-associated BSI, implying the necessary removal of IV catheter. In addition, recovery of certain microorganisms in multiple blood cultures, such as staphylococci, *Corynebacterium* or *Bacillus species*, or *Candida* or *Malassezia* species strongly suggests infection of the IV catheter.

b. Pathogenesis

The pathogenesis of IV catheter-associated infections involves complex interactions between the invading microorganism(s), the catheter and the infusate, and the host. For microorganisms to cause an IV catheter-associated infection, they must first gain access to the extraluminal or intraluminal surface of the catheter, where they can adhere, produce, and subsequently form a layer of biofilm. This biofilm acts as a solid enclave, in which microbial organisms can embed themselves, allowing various microorganisms to withstand host defence mechanisms (i.e., engulfment and killing by polymorphonuclear leukocytes).

Four identified routes for catheter contamination are:

- transcutaneous migration of endogenous or extrinsic organism(s) at the insertion site into the extraluminal surface of the catheter with colonization of the catheter tip;
- direct contamination of the catheter or catheter hub by contact with healthcare provider's hands or contaminated disinfectant, fluids or devices;
- 3. haematogenous seeding from distant, unrelated sites of infection; and
- 4. contaminated infusate, the most frequent cause of epidemic CRBSI.

Figure 1 illustrates the potential sources of contamination of IV catheters. The longer the duration a catheter remains in place, the higher likelihood of a break in asepsis takes place leading to contamination of the hub of a catheter. Therefore, while short-term catheters are most frequently colonized via the transcutaneous route, longer-term catheters become colonized via hub contamination.

Fig 1 Potential sources of infection of a percutaneous IV catheter



(From Crnich CJ, Maki DG. The promise of novel technology for the prevention of intravascular device-related bloodstream infection. I. Pathogenesis and short-term devices. *Clin Infect Dis* 2002;34(9):1232–1242.)

c. Risk factors

Factors associated with increased risk of IV catheter-associated BSI include:

- patient-related factors: prolonged hospitalization, severity of illness, underlying severe immunosuppression such as neutropenia, prematurity, acquired immunodeficiency syndrome, trauma wound or huge loss of skin integrity (Burns Intensive Care Unit patients), and bone marrow transplantation;
- catheter-related factors: central venous catheter (CVC), multi-lumen, hyperalimentation (total parenteral nutrition), the conditions under which the catheter was inserted (breach in asepsis), site of insertion (femoral site) and maintenance (breach in asepsis, excessive manipulation),
- institutional factors including academic affiliation of the institution and bed size, the behavioural patterns of healthcare providers.

d. Epidemiology

While peripheral venous catheters are rarely associated with BSI with point incidence rate of 0.5 infections per 1000 catheter-days, CVCs account for almost 90% of CRBSI. The incidence of CLABSI in short-term use, non-cuffed CVCs and surgically implanted cuffed Hickman lines are 2.7 and 1.6 infections per 1000 catheter-days respectively. CLABSIs have been associated with extended hospitalization and increased healthcare costs, ranging from USD \$7,288 to \$29,156 per episode. However, most studies have not found CLABSI to be an

independent risk factor for mortality. Reports on CLABSI attributed by peripherally inserted central venous catheters (PICC) are rare but PICC used for parenteral nutrition has a higher infection rate than PICC used for other indications.

An analysis of 159 prospective studies reported that skin microorganisms form the largest proportion of IV catheter-associated BSIs: Coagulase-negative staphylococci 31%; Staphylococcus aureus 18%; and, Corynebacterium spp. 5%. Additionally, enteric gram-negative bacilli account for third largest proportion (14%) and Candida spp. 6% of the BSI. It is important to note that fungal pathogens are becoming important organisms associated with BSI in patients receiving parenteral nutrition fluids. The data from 2008 NHSN Annual Update indicate that multidrug-resistant organisms are commonly implicated in CLABSIs. According to the report, more than 50% of Staphylococcus aureus are MRSA Staphylococcus aureus), (methicillin-resistant and vancomycin-resistant enterococci forms 36.4% of enterococci. The report also indicates the emergence of gram-negative microorganisms with more than 20% of Pseudomonas aeruginosa are resistant to carbapenems groups.

1 Education and surveillance

Appropriate education, training, and competency assessment resources are needed for all staff responsible for the insertion and maintenance of CVCs. The following factors can affect the success of any improvement initiative that is designed to reduce or eliminate healthcare–associated infections (HAIs), including CLABSIs:

a. Leadership 2016 Draft for Consultation

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- b. Culture of safety
- c. Multidisciplinary teams and teamwork
- d. Accountability of health care personnel
- e. Empowerment
- f. Resource availability
- g. Data collection and feedback of CLABSI rates
- h. Policies and procedures
- i. Involvement of patients and families

The safety culture in any health care setting should hold that everyone is accountable for following evidence-based CLABSI prevention practices, and organization leaders must clearly communicate that department or unit leaders are accountable for the CLABSIs that occur in their patients.

Surveillance for health care–associated infections (HAIs), including CLABSIs, is an essential component in any infection prevention and control program, a necessary first step in defining the nature and magnitude of the problem. Surveillance involves systematically collecting, analyzing, interpreting, and disseminating data to members of the health care team as a means to facilitate improvement in patient outcomes.

- 2 Care of Specific Catheters
- I. Central venous catheters (CVCs) including peripherally inserted central venous catheters (PICCs), haemodialysis and pulmonary artery catheters

1. CLABSI Insertion Bundle

a. Hand hygiene 2016 Draft for Consultation

Hand hygiene, combined with aseptic techniques before catheter insertion and during subsequent catheter care, reduces the risk of IV catheterassociated BSI significantly. Hence, surgical hand hygiene should be performed prior to the handling of the catheter or its administration set, either with alcohol-based handrub preparation or handwash with antiseptic soap (e.g. 4%CHG).

b. Maximum barrier precautions

Maximal sterile barrier (MSB) precautions require the CVC inserter to wear a mask and cap, a sterile gown, and sterile gloves and to use a large (head-to-toe) sterile drape over the patient during the placement of a CVC or exchange of a catheter over a guidewire.

c. Chlorhexidine skin preparation

Use of 2% chlorhexidine with 70% isopsropyl alcohol preparation has been reported to be effective in preventing CRBSIs. If there is a contraindication to chlorhexidine, tincture of iodine, an iodophor, or 70% alcohol can be used as alternatives. No recommendation can be made for the safety or efficacy of chlorhexidine in infants aged <2 months. The antiseptic used should be allowed to have sufficient contact time with the skin according to the manufacturer's recommendation prior to placing the dressing. After the antiseptic has been applied to the site, further palpation of the insertion site should be avoided, unless aseptic technique is maintained.

d. Optimal site selection

Data derived from several observational studies of CVC insertions suggest that the greatest risk of infection in adults is associated with use of the femoral 2016 Draft for Consultation 169 vein as the insertion site, and the lowest risk is associated with subclavian site insertions, with an intermediate level of risk associated with internal jugular vein insertions for non-tunneled CVCs. The risk of infection with peripherally inserted central catheters that are placed in the internal jugular or subclavian veins in hospitalized patients is similar to the risk with CVCs.

ii. CLABSI Maintenance Bundle

a. Hand hygiene

Hand hygiene reduces the risk of IV catheter-associated BSI significantly. Hand hygiene is to be performed before and after accessing, replacing, repairing, or dressing the catheter.

b. Cleaning and changing the needleless access device aseptically

Strict adherence to disinfection and maintenance recommendations is important, so as to minimize the incidence of catheter-related bloodstream infections (see section 6).

c. Proper dressing change technique

Dressing of catheters that are associated with higher risk of CRBSIs (including arterial catheters, all types of CVCs and PICCs) should be changed under aseptic technique using sterile gloves. In contrast, clean gloves (donned using a "no-touch" technique), could be used when changing the dressing of peripheral IV catheters, and care must be taken to avoid recontamination of the access site.

There are two major types of dressing materials recommended for dressing of IV catheter site: sterile gauze and tape, or sterile transparent, semipermeable,

polyurethane film dressing. It is recommended that both types of dressing could be used for peripheral IVs and short-term CVCs. Conversely, polyurethane dressings are not recommended for use on arterial catheters. In addition, gauze dressing is recommended in diaphoretic patients or when the catheter site is bleeding or oozing. There is abundance of evidence on the clinical effectiveness of the use of chlorhexidine-impregnated sponge dressing in reducing CRBSI in adult patients and paediatrics with short-term CVCs. However, the use of chlorhexidine dressing in neonates with low birth weight (<1000 g) and extremely premature infants is not advised due to the risk of dermatotoxicity. Additional studies are required before chlorhexidine dressing can be recommended for routine use with long-term CVCs. Therefore, if the institutional CLABSI rate is above benchmark despite comprehensive preventive strategies, a chlorhexidine-impregnated sponge dressing is recommended for temporary short-term catheters in patients older than 2 months of age.

The dressing regimes vary according to the type of dressing material used and patient's condition. The HICPAC/CDC guidelines recommend replacing the dressing on short-term CVCs every two days for gauze dressing and at least every 7 days for transparent dressings. Exception should be made for paediatric patients where the risk of the catheter dislodgement may outweigh the benefit of dressing changing. For tunnelled or implanted CVCs, the dressing should be replaced no more frequently than weekly, until the site is healed. Apart from the regime, replace the dressing if it becomes damped, loosened or visibly soiled. The catheter site should be monitored for signs of local infection. This is done by visually monitor the dressing or by palpation through the intact dressing on regular basis. The dressing should be removed for thorough examination if the patient manifests signs and symptoms suggesting CRBSI. Patients should be advised to monitor and report to their healthcare providers if they observe any changes in their catheter site or new discomfort. They should be informed not to submerge the catheter site in water. Showering is permitted if care could be taken to prevent the catheter site from contamination (e.g., cover the dressing and the connecting device with an impermeable cover during the shower). In addition, the HICPAC/CDC guidelines recommend using a 2% chlorhexidine wash for daily skin cleansing (bed sponging or shower) to further reduce the risk of CRBSI.

Topical antibiotic ointment or creams are not recommended for the care of insertion site, because of their potential in promoting fungal infections and antimicrobial resistance. Nevertheless, catheter rupture had been reported in a patient after application of mupirocin ointment to the insertion site of peritoneal catheter suggesting the importance of ensuring the exit site care is compatible with the catheter material. CDC recommends using povidone iodine ointment or triple antibiotic ointment (bacitracin / gramicidin / polymyxin B) at the hemodialysis catheter exit site after catheter insertion and at each hemodialysis session and emphasizes the importance of ensuring the compatibility of the ointment with the catheter material (http: www.cdc.gov/dialysis/prevention-tools/core-interventions.html#sites).

d. Standardize tubing change

Replace tubing used to administer blood, blood products, or fat emulsions within 24 hours of initiating the infusion. Replace tubing used to administer propofol infusions every 6 or 12 hours, when the vial is changed, per the manufacturer's recommendation.

e. Daily review of catheter necessity

A meta-analysis by Cook and colleagues found no significant benefit of routine replacement of short-term CVCs. In addition, studies have showed that routine replacement of CVC without clinical indication does not reduce the risk of CRBSI. The Cochrane review in 2013 also found no conclusive evidence of benefit in routine changing of peripheral IV catheters every 72 to 96 hours. These reports suggest that daily assessment of the catheter necessity and replacement based on clinical assessment a more cost-effective approach in preventing CRBSI. Institute for Healthcare Improvement (IHI) provides a detailed approach on conducting daily review of catheter necessity and recommends daily review for the intensive care population as it may not be appropriate for long-term CVCs. All IV catheters should be removed as soon as it is no longer required.

3 Care of administration sets

Several studies in both local and overseas settings report that IV administration sets do not need to be replaced more frequently than every 96 hours. Adding on, the HICPAC/CDC guidelines recommend the replacement to be done at least every 7 days, unless CRBSI is suspected or when infusing blood, blood products, or lipid emulsion

s. Effort must be made to keep all components of the administration sets sterile and asepsis must be maintained in accessing to the IV system. When there is a suspected infusion-associated BSI, it is prudent to change administration sets within 24 hours of initiating the infusion. Similarly, administration sets used to administer blood, blood products, or lipid emulsions should be changed within 24 hours of initiating the infusion. A report of an outbreak of BSI involving sixty two patients indicate that the source, propofol, a lipid-based medication, could be a good medium for bacterial growth when it is left at room temperature. It is recommended in the HICPAC/CDC guidelines that the administration sets used to administer propofol infusions should be replaced every 6 to 12 hours.

When a pressure monitoring is used, the transducer should be replaced at every 96 hours. This includes other components of the system (the tubing, continuous-flush device, and flush solution). With the reported lower incidence of bacterial contamination of the arterial system, a closed system with continuous flush is preferred to an open system for the maintenance of the patency of the system. Beck-Sague and Jarvis reported eight outbreaks of nosocomial BSIs which were traced to contamination of transducer used for arterial pressure monitoring. If the use of disposable transducer is not feasible, reusable transducer is to be sterilized according to the manufacturer's recommendation.

Recommendations

 Perform hand hygiene before and after palpating catheter insertion sites as well as before and after inserting, replacing, accessing, repairing or dressing an IV catheter. Palpation of the insertion site should not be performed after the application of antiseptic, unless aseptic technique is maintained. [BI]
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- 2. Maintain aseptic technique for the insertion and care of intravascular devices. [BI]
- 3. Wear clean gloves for insertion and care of peripheral IV catheters if access site is not touched after the application of skin antiseptics. [CI]
- 4. Wear sterile gloves for the insertion of arterial, central and midline catheters. [AI]
- 5. Wear either clean or sterile gloves when changing the dressing on intravascular catheters. [CI]
- Prepare clean skin with an antiseptic (70% alcohol, tincture of iodine, an iodophor or alcohol/chlorhexidine gluconate) before peripheral venous catheter insertion.
 [BI]
- 7. Prepare clean skin with a >0.5% chlorhexidine preparation with alcohol before CVC and peripheral arterial catheter insertion and during dressing changes. If there is a contradiction to chlorhexidine, tincture of iodine, an iodophor, or 70% alcohol can be used as alternatives. [AI]
- 8. Antiseptics should be allowed to dry according to the manufacturer's recommendation prior to placing the catheter. [BI]
- Use either sterile gauze or sterile transparent, semipermeable dressing to cover the catheter site. [AI]
- Replace catheter site dressing if the dressing becomes damp, loosened or visibly soiled. [BI]
- 11. Do not use topical antibiotic ointment or creams on insertion sites, except for dialysis catheters, because of their potential to promote fungal infections and antimicrobial resistance. [BI]
- 12. Do not submerge the catheter or catheter site in water. Showering should be permitted if precautions can be taken to reduce the likelihood of introducing organisms into the catheter (e.g., use of an impermeable cover). [BI]
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- 13. Replace dressings used on short-term CVC sites at least every 7 days for transparent dressings, except in those paediatric patients in which the risk for dislodging the catheter may outweigh the benefit of changing the dressing. [BII]
- 14. Ensure that catheter site care is compatible with the catheter material. [BI]
- 15. Use a sterile sleeve for all pulmonary artery catheters. [BI]
- 16. Use a chlorhexidine-impregnated sponge dressing for temporary short-term catheters in patients older than 2 months if the CLABSI rate is not decreasing despite adherence to basic prevention measures. [BI]
- 17. Monitor the catheter sites visually when changing the dressing or by palpation through an intact dressing on a regular basis, depending on the clinical situation of the patient. If patients have tenderness at the insertion site, fever without obvious source, or other manifestations suggesting local or bloodstream infection, the dressing should be removed to allow thorough examination of the site. [BI]
- 18. Use povidone iodine antiseptic ointment or bacitracin/gramicidin/polymyxin B ointment at the hemodialysis catheter exit site after catheter insertion and at the end of each dialysis session only if the ointment does not interact with the material of the hemodialysis catheter per manufacturer's recommendation. [BI]
- 19. In patients not receiving blood, blood products or fat emulsions, replace administration sets that are continuously used, including secondary sets and addon devices, no more frequently than at 96-hour intervals, but at least every 7 days. [AI]
- 20. Replace tubing used to administer blood, blood products, or fat emulsions within 24 hours of initiating the infusion. [BI]

- 21. Replace tubing used to administer propofol infusions every 6 or 12 hours, when the vial is changed, per the manufacturer's recommendation. [AI]
- 22. Use disposable, rather than reusable, transducer assemblies when possible. [BI]
- 23. Replace disposable or reusable transducers at 96-hour intervals. Replace other components of the system (including the tubing, continuous-flush device, and flush solution) at the time the transducer is replaced. [BI]
- 24. Keep all components of the pressure monitoring system (including calibration devices and flush solution) sterile. [AI]
- 25. Do not administer dextrose-containing solutions or parenteral nutrition fluids through the pressure monitoring circuit. [AI]
- 26. Sterilize reusable transducers according to the manufacturers' instructions if the use of disposable transducers is not feasible. [AI]

4 Care of Infusate, IV medication and Admixture

Lipid-containing solutions are to complete infusion within 24 hours of hanging the solution; whilst lipid emulsions alone will need to be completed within 12 hours, and maximum within 24 hours. Single-dose vial of parenteral additive and medications are recommended as far as possible. Diaphragms of the multidose vials are to be disinfected with 70% alcohol before insertion. Any unopened parenteral fluid or admixture that has visible turbidity, containing particulate matter or container with leaks or cracks are to be saved, and reported to Infection Control for investigation. Routine culture of parenteral fluids, as a check on sterility for infection preventive measure is not recommended. It is recommended that a distinctive supplementary label be attached to each admixed parenteral fluid given; this should have information on the additive and dosage, the date and 2016 Draft for Consultation 177

time of compounding, the expiration time and signature of the person who did the compounding.

5 Needleless Intravascular Catheter Systems

Needleless connectors are originally designed with the aim to reduce the risk of needlestick injuries among healthcare providers during the care of IV catheter. The most common types of needleless connectors include split septum connector and mechanical valve device. In most hospitals and healthcare settings in the majority of developed world, these devices are used routinely to protect staff. This is especially so in Singapore with a high prevalence of blood borne pathogens in our patient population. However, there are a variety of needleless connector types, and some have been associated with an increase in central venous catheter-related bloodstream infections, especially with use of the mechanical valve devices. It is thus vital that care be taken in the selection and use of needleless connectors. Strict adherence to disinfection and maintenance recommendations is important, so as to minimize the incidence of catheter-related bloodstream infections. The choice of disinfectant used to disinfect the connector prior to the access of the IV system and the duration of disinfection are also important factors in the development of CRBSI.

To reduce the risk of CRBSI associated with the use of needleless connector, the following are recommended:

 disinfect or scrub the access port immediately prior to each use with an appropriate antiseptic (chlorhexidine, povidone iodine, an iodophor, or 70% alcohol);

access the port only with sterile devices;
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- ensure that all components of the needleless system are compatible to minimize leaks and breaks in the system;
- change needleless connector according to the manufacturer's recommendations or no more frequently than every 72 hours;
- 5) change the needleless components at least as frequently as the administration set; and,
- use of needleless system with a split septum valve is preferred over some mechanical valves.

Recommendations

- Needleless connectors with mechanical valves should not be routinely used before a thorough assessment of risks, benefits and education regarding proper use. Split septum connectors should be preferentially used over needleless connectors with mechanical valves until more clinical data becomes available.
 [BII]
- Positive-pressure needleless connectors with mechanical valves should not be routinely used before a thorough assessment of risks, benefits and education regarding proper use. [BII]
- 3. Zero fluid displacement connector are should be used if possible, over positiveand negative-pressure needleless connectors. ([BII]
- There is insufficient clinical evidence to make recommendations for the use of antiseptic barrier caps and silver-coated needleless connectors, and further clinical evaluation is required. [CIII]
- 5. Infection control personnel should be involved in the selection of needleless connectors. [CIII]

- 6. When any product changes are made, education should be provided to all users, and rates of infection and occlusion should be monitored to detect any increase in incidence of catheter-related bloodstream infection. [CIII]
- 7. Needleless connectors must be disinfected before accessing the catheter. [BIII]
- 8. Chlorhexidine/alcohol or povidone-iodine should be preferentially used over isopropyl alcohol for disinfection of needleless connectors. [BI]
- Catheter access ports should be disinfected with 5 to 15 seconds of vigorous scrubbing with alcohol or chlorhexidine. [BII]
- There is insufficient evidence to support the regular change of end caps of needleless connectors to minimize catheter associated bloodstream infection.
 [BIII]
- 11. Needleless connectors should be changed at least as frequently as the administration set. There no benefit to changing these more frequently than every 72 hours. [BIII)]
- 12. Needleless connectors with mechanical valves may not be recommended for use on central venous catheters in patients on home infusion therapy or in long-term care facilities in view of possible increased risks of catheter related blood stream infection. [BII]
Prevention of Catheter associated Urinary Tract Infections

Introduction

A. Epidemiology

Urinary tract infections (UTIs) remain the commonest nosocomial infection worldwide. UTIs have been estimated to cause about 32% of healthcare-associated infections (HAIs) in the acute care setting in the United States (US). Of these, approximately 75% are associated with a urinary catheter. The sheer number of urinary catheters in use leads to the significance of CAUTI in the healthcare system even though their impact on morbidity and mortality is relatively limited.

The problem of CAUTI extends globally, and also outside of the acute cares setting. UTIs have been found to be the commonest cause of HAIs among residents of long-term care facilities, accounting for 40% of HAIs in an Irish prevalence study. In a surveillance study conducted by the International Nosocomial Infection Control Consortium in Latin America, Asia, Africa, and Europe, Rosenthal *et al.* found CAUTIs to be a significant problem in developing countries, with a rate of 6.3 CAUTI per 1,000 urinary catheter-days. This was in contrast to a rate of 3.3 per 1,000 catheter-days in comparable US ICUs. There are no published local epidemiology data from Singapore but small case series suggest that the majority of extremely drug resistant gram-negative organisms have a urinary tract origin.

B. Definition

Symptomatic UTI (SUTI) is defined as a case fulfilling all the following criteria:

- Patient had an indwelling urinary catheter that had been in place for > 2days on the date of event (day of device placement = Day 1) AND was either:
 - Still present on the date of event, OR
 - Removed the day before the date of event

2. Patient has at least **one** of the following signs or symptoms:

	Catheter is in place- still		Catheter is not in place- recently
	present on the date of event		removed on the day of or the
•	fever (>38.0°C)		day before the date of event
•	suprapubic tenderness*	•	fever (>38.0°C)
•	costovertebral angle pain or	•	suprapubic tenderness*
	tenderness*	•	costovertebral angle pain or
			tenderness*
		•	urinary urgency*
		•	urinary frequency*
		•	dysuria*

*With no other recognized cause

 Patient has a urine culture with no more than two species of organisms, at least one of which is a bacteria of ≥100,000 cfu/ml. All elements of the UTI criterion must occur during the Infection Window Period.

Symptomatic UTI (SUTI) is defined as a case fulfilling all the criteria below:

- Patient had an indwelling urinary catheter that had been in place for > 2days on the date of event (day of device placement = Day 1) AND was either:
 - i) Still present on the date of event, OR
 - ii) Removed the day before the date of event
- 2. Patient has at least **one** of the following signs or symptoms:
 - fever (>38.0°C)
 - suprapubic tenderness*
 - costovertebral angle pain or tenderness*
 - urinary urgency*
 - urinary frequency*

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- dysuria*
- Patient has a urine culture with no more than two species of organisms, at least one of which is a bacteria of ≥105 CFU/ml. All elements of the UTI criterion must occur during the Infection Window Period

Notes:

- a) An indwelling urinary catheter in place would constitute "other recognized cause" for patient complaints of "frequency" "urgency" or "dysuria" and therefore these cannot be used as symptoms when catheter is in place.
- b) Fever and hypothermia are non-specific symptoms of infection and cannot be excluded from UTI determination because they are clinically deemed due to another recognized cause.

Symptomatic UTI in patients 1 year of age or less is defined as a case fulfilling all the criteria below:

- 1. Patient is ≤ 1 year of age (with or without an indwelling urinary catheter)
- 2. Patient has at least **one** of the following signs or symptoms:
 - fever (>38.0°C)
 - hypothermia (<36.0°C)
 - apnea*
 - bradycardia*
 - lethargy*
 - vomiting*
 - suprapubic tenderness*
- Patient has a urine culture with no more than two species of organisms, at least one of which is a bacteria of ≥10⁵ cfu/ml. All elements of the SUTI criterion must occur during the Infection Window Period

Asymptomatic Bacteremic Urinary Tract Infection (ABUTI) is defined as a case fulfilling all the criteria below:

- Patient with* or without an indwelling urinary catheter has no signs or symptoms of SUTI 1 or 2 according to age (Note: Patients >65 years of age with a non-catheterassociated ABUTI may have a fever and still meet the ABUTI criterion)
- Patient has a urine culture with no more than two species of organisms, at least one of which is a bacteria of ≥10⁵ cfu/ml
- Patient has a positive blood culture with at least one matching bacteria to the urine culture, or meets LCBI criterion 2 (without fever) and matching common commensal(s) in the urine. All elements of the ABUTI criterion must occur during the Infection Window Period

*Patient had an indwelling urinary catheter in place for >2 calendar days, with day of device placement being Day 1, and catheter was in place on the date of event or the day before.

C. Pathogenesis

The presence of a urethral catheter will bypass or inhibit natural host defenses, predisposing patients to CAUTIs. This is further exacerbated by the development of biofilm on the urinary catheters, which provides a favorable environment for bacterial proliferation & invasion.

Bacteria may be introduced into the urinary tract via several routes, such as:

- i. Inoculation at the time of catheter insertion, especially in patients who have had inadequate disinfection of the urethra opening prior to catheterization.
- ii. Via intraluminal ascent in the urinary catheter after contamination of the urinary catheter and/or bag (such as via breaks in aseptic practice during the opening of urinary drainage bag taps, or disconnection of catheters from urinary bags).

iii. Via the extraluminal route of ascent, along the external surface of the urinary catheter and the urethra. The risk of developing bacteriuria hence correlates with duration of catheterization.

D. Risk factors

Risk factors for CAUTI are broadly divided into host factors, bacterial factors and catheter factors. Prospective observational studies which did multivariable analyses identified the major risk factors for CAUTI, which include:

- Duration of catheterization
- Female gender
- Anatomical or functional abnormalities of the urinary tract
- Insertion of the catheter outside the operating theatre
- Diabetes mellitus
- Poor catheterization technique or breaks in aseptic technique

2. Conducting a CAUTI Risk Assessment

CAUTI risk assessment should be performed to guide the development of a surveillance, prevention, and control plan that is based on facility-specific data and conditions.

Baseline CAUTI Risk Assessment must be conducted to determine the demographics of those patients or residents who have the highest utilization of indwelling urinary catheters.

Surveillance data collected by Infection Control Personnel for the CAUTI Risk Assessment will help to provide information needed to identify whether CAUTI is increasing, decreasing or remaining the same in the facility. The following steps may be used for conducting a CAUTI Risk Assessment:

Step 1: Assess whether an effective organization program exists

Step 2: Assess population at risk

Step 3: Assess baseline outcome data

Step 4: Determine financial impact

Examples of Baseline CAUTI Risk Assessment Tool are found in Figure 1 and 2. A Data

Collection sheet (Figure 3) can be use at baseline, during and after program implementation.

A point prevalence study may be use to provide baseline data to complete the risk assessment, monitor trend in care practices and identify outliers per unit, shift, or service.

The point prevalence survey questions may those in example shown in Table 1.

Table 1	Example of point prevalence survey questions
---------	--

NO.	CRITERIA	YES	NO
1	Is there a Foley catheter in use?		
2	Is this the type of catheter normally used in this facility?		
3	Is a closed system being maintained?		
4	Is the Foley inserted using a pre-connected tray		
5	Is the Foley secured to the patient's body to prevent urethra tension?		
6	Is the bag below the level of the patient's bladder?		
7	Is the tubing from the catheter to the bag free of dependent loops?		
8	Is the tubing secured to the bed or chair to prevent pulling on the entire system?		
9	Is the bag hanging free without touching the floor?		
10	Does the patient have an individual measuring device marked with his / her name and room number?		

The denominator for this survey is the number of patients who have urinary catheters during the surveillance period on the unit / population being survey.

Once the hospital-specific CAUTI risk assessment baseline is established, CAUTI rates can be compared over time to determine if there are trends within patient populations and/or departments. Evaluation of the CAUTI risk assessment will influence plans for control of CAUTI in the facility e.g. it may be decided that the CAUTI surveillance, prevention and control plan will target symptomatic CAUTI (i.e. exclude asymptomatic bacteriuria).

Recommendation

 Perform a CAUTI risk assessment and implement an organization-wide program to identify and remove catheters that are no longer necessary using one or more methods documented to be effective (B II).

Figure 1

Baseline CAUTI risk assessment tool: This can help to identify the population at risk in the facility.

UNIT	MEDICAL	SURGICAL	MICU	SICU	ORTHO
Structure					
Number of beds					
Nurse Staffing Ratio					
Number of different physicians					
Does the hospital or unit have any policies or standard operating procedures relating to indwelling urinary catheter use					
Do they use any templates or reminders related to use of indwelling urinary catheters					
Processes					
Where are indwelling urinary catheters placed for patients on this unit					

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What personnel insert indwelling urinary catheters on this unit			
Outcome			
5 day count on number of indwelling urinary catheters / number of patients			
CAUTI / UTI rates for this unit			

Figure 2

Baseline CAUTI risk assessment tool: This can be used to assess whether an

effective organization program exists.

	CRITERIA	(HOSPITAL WIDE)	(UNIT	NO
1 G		-	BASED)	
	Guidelines on appropriate indications for urinary catheter use			
2 G	Guidelines on proper techniques for urinary catheter insertion			
	Guidelines on proper techniques for urinary catheter naintenance			
4 S	System of documenting urinary catheter insertions			
5 S	System of documenting urinary removals			
6 p	Regular in-service training for appropriate healthcare personnel on techniques and procedures for urinary catheter nsertion, maintenance and removal			
	Readily available supplies necessary for aseptic urinary nsertion			
	Policies or guidelines for use of a bladder scanner prior to nsertion of a catheter for urinary retention			

Unit	1		1.10.000000000	0.11	1 D 1	0.11.1	0
Date			Urinary	Cathe	eter Data	a Collect	ion Sheet
Phase		1					
Room/bed	Patient #		Urinary Catheter present	Indicated?	Indication		
		No =					1
After 1	IP nentation mplementation mability		Non-Indicate Indicated = Evaluated or the baseline implementat phases	1 A A A A A A A A A A A A A A A A A A A	Perioperative use in Perioperative use in Perioperative and sacral icospice/comfort/ pa tequired immobiliza- tequired immobiliza- tequi	ation for trauma or so urinary catheter on a inary Catheters Re pring OUTSIDE Inten- ut a sacral or perinea	= 2 nt patients = 3 urgery = 5 dmission = 6 sasons: sive care = 7 il pressure sore = 8 from intensive care, dementia, and

3. CAUTI Insertion Bundle

A. Verification of need prior to insertion

The most important measure to prevent CAUTI is to limit the use of urinary catheters to carefully selected patients and leave them in place as long as indications for catheterization persist.

Prior to catheterization, consideration should be given to alternative management methods (e.g. condoms or intermittent catheterization). Urinary catheters should only be used when necessary and should be removed as soon as possible to avoid potential complications such as infection, bacteraemia, urethritis, urethral stricture, hematuria and bladder perforation. Studies have shown that indwelling catheters are frequently used when not indicated or, if indicated, remain in situ longer than necessary. Various studies have demonstrated that the presence of the urinary catheter is inappropriate in 21 – 54% of catheterized patients.

Indications for catheterization

- To relieve clinically significant urinary retention or bladder outlet obstruction (temporary relief or longer term drainage if medical therapy not effective and surgical correction not indicated).
- To assist the healing of an open sacral sore or perianal wound.
- To monitor accurately the urine output in critically ill patients.
- During prolonged surgical procedures with general or spinal anaesthesia, selected urological and gynaecological procedures.
- For patients requiring prolonged immobilization e.g. potentially unstable thoracic or lumbar spine, multiple traumatic injuries such as pelvic fractures.
- For urinary incontinence e.g. comfort in a terminally ill patient.

B. Insert urinary catheter using aseptic technique

There are few data on the optimal level of sterility required to insert an indwelling urinary catheter. Tambyah et al found that patients catheterized in the operating room had a lower incidence of early community acquired bacteriuria (CA-bacteriuria) than those catheterized in the ward to in the emergency department (RR 0.5; 95%Cl 0.2-1.0; P=.03). This suggests that augmented barrier precautions at the time of catheter insertion may reduce the risk off early CA-bacteriuria. Shapiro at al also showed that catheter insertion outside of the operating room is associated with a higher risk of CA-bacteriuria.

However in a prospective trial conducted in the operating room, 156 patients who were undergoing pre-operative urethral catheterization were randomly allocated to sterile or clean/non-sterile technique (hands washed with soap and tap water, non-sterile gloves, cleaning external genitalia with tap water only and holding the catheter within its plastic sheath). There was no statistically significant difference between the 2 groups with respect to the incidence of CA-bacteriuria but the sterile method was twice as expensive. However the use of the aseptic technique was preferred at insertion of urethral catheter although further study is warranted.

Health care workers (HCWs) performing urethral catheterization should be trained and have been assessed and documented as competent on the technical aspects and application of the principles of the aseptic technique to minimise the risk of infection. Standard precautions must be applied by all HCWs when inserting and caring for urinary catheters with particular reference to hand hygiene, personal protective equipment (PPE) and management of waste. Aseptic technique refers to the practices that help to reduce the risk of post-procedure infection in patients by decreasing the likelihood of microorganisms entering the body during the clinical procedure. Sterile equipment and aseptic technique must be used during insertion and intermittent urinary catheters in healthcare settings. Antiseptic hand hygiene must be performed immediately before donning sterile gloves prior to insertion of a urinary catheter and after removal of PPE. For catheter insertion, a disposable plastic apron and sterile gloves will usually be sufficient.

Meatal cleaning and environmental disinfection

As infection can occur extraluminally (via the external surface of the catheter) when the catheter is inserted, the urethral meatus should be carefully cleaned prior to catheterization. The use of antiseptic solution versus sterile saline for meatal preparation prior to catheter insertion remains unresolved. Before the procedure, the environmental surfaces involved should be effectively cleaned and disinfected. HCWs should use sterile gloves and a drape to create a sterile field. All inclusive sterile catheter packs should be used where available.

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Insertion procedure for indwelling urethral catheterization

Urethral catheterization can cause bruising and trauma to the urethral mucosa which then acts as an entry point doe microorganisms into the blood and lymphatic system. It is recommended that an appropriate lubricant or anaesthetic gel from a single-used container should be applied to the urethral meatus and catheter surface prior to the insertion of the catheter to minimize urethral trauma or infection. Once the catheter is inserted, urine is allowed to drain before the balloon is inflated. The indwelling catheter should be connected to a closed sterile drainage bag which is placed below the level of the bladder to facilitate drainage.

When a catheter is inserted, the following information should be documented in the patient's record:

- Indication for catheter insertion
- Date and time of catheter insertion
- Type and size of catheter used
- Any complications encountered
- Name of HCW who inserted the catheter

Recommendations

- 1. Indwelling catheters should be placed only when they are indicated (AIII)
- Institutions should develop a list of appropriate indications for inserting indwelling urinary catheters, educate staff about such indications and periodically assess adherence to the institution-specific guidelines (AIII)
- 3. Institutions should require a physician's order in the chart before an indwelling catheter is

- 4. Indwelling urethral catheters should be inserted using aseptic technique and sterile equipment (BIII).
- 5. Only properly trained persons (HCWs) who have correct technique of aseptic catheter insertion and maintenance are given this responsibility (BI).
- Further research is needed on the use of antiseptic solution versus sterile saline for meatal cleaning prior to catheter insertion (No recommendation – unresolved issue).
- 4. CAUTI Maintenance Bundle

As with most device-associated infections, the removal of the device is the primary approach to prevention of the infection. There is a growing body of evidence, as well as general consensus among infection control practitioners, to support the reduction of urinary catheter use as well as limiting its duration. Where catheterization is indicated, strict adherence to catheter care maintenance practices is recommended, although the evidence for most of the measures is not very conclusive due to the difficulty in conducting randomized controlled clinical trials.

Key features in the maintenance bundle include:

- A. Daily review of urinary catheter
- B. Check the catheter has been continuously connected to the drainage system
- C. Ensure patients are aware of their role in preventing urinary tract infection perform routine daily meatal hygiene
- D. Regularly empty urinary drainage bags as separate procedures, each into a clean container
- E. Unobstructed flow maintained
- F. Perform hand hygiene and don gloves and apron prior to each catheter care procedure; on procedure completion, remove gloves and apron and perform hand hygiene again

Avoiding and minimizing duration of urinary catheterization remains the key strategy in the prevention of CAUTIs, as continued urethral catheterization is associated with a 3 - 10% daily incidence of bacteriuria. Unfortunately, unnecessary urinary catheter use remains prevalent, and physicians are often unaware of the presence of urinary catheters in their patients.

Various reminder systems to review the continuation of catheterization have been shown to be efficacious and cost-effective, and <u>must</u> be implemented where possible according to what works best in the institution or facility.

These may include:

- Nurse generated daily verbal reminders or reminder stickers to physicians to review appropriateness of continuing catheterization.
- Computer generated reminders to review indications for continuing catheterization.
- Prewritten or computer-generated 'stop orders', whereby a catheter was removed by default after a set time period or when certain clinical criteria are met. Nurse-led, protocol driven review systems have also been found to be effective.

Recommendations

- Establish a daily reminder system to review the continuation of urinary catheterization (AI)
- 2. Maintain a sterile, continuously closed drainage system (BIII).
- Maintain unobstructed urine flow. Keep the collecting bag below the level of the bladder at all times; do not place the bag on the floor. Keep catheter and collecting tube free from kinking (BIII).
- Empty the collecting bag regularly using a separate collecting container for each patient.
 Avoid touching the draining spigot to the collecting container (BIII).

5. Employ routine hygiene; cleaning the meatal area with antiseptic solutions is unnecessary (BIII).

Prevention of Surgical Site Infections

Introduction

Surgical site infections (SSIs) are an important source of healthcare-associated infections (HAIs) in which wound infection occurs after an invasive (surgical) procedure. It is the most common HAI and accounts for 20% of all HAIs in inpatients. It is a high burden on both patients and hospitals in terms of morbidity, mortality, prolonged length of hospital stay and additional cost. The incidence of SSIs is dependent on the surgical procedure, the surveillance criteria used, and the quality of the data collection in particular post-discharge surveillance in this era of same-day surgery. The most commonly isolated organisms are *Staphylococcus aureus*, coagulase-negative *Staphylococcus* spp, *Enterococcus* spp. *Klebsiella pneumoniae* and *Escherichia coli*.

Definition

SSIs are defined as infections occurring up to 30 days after surgery (or up to 90 days after surgery in patients receiving implants where day 1 is the date of procedure) and affecting either the incision or deep tissue at the operation site. Definitions are in accordance with the Centers for Disease Control and Prevention National Nosocomial Infections Surveillance (NNIS) System and the National Healthcare Safety Network (NHSN) definitions for SSI (see Fig 1).

Figure 1 Centers for Disease Control and Prevention's National Healthcare Safety Network classification for surgical site infection (SSI)



Pathogenesis

Most SSIs are believed to be acquired at the time of surgery. However, there is currently no data on the actual proportion acquired in the operating theatre versus post-operative care. The commonest source of pathogens for most SSIs is the endogenous flora of the patient's skin, mucous membranes or hollow viscera as the exposed tissues are at risk of contamination when mucous membranes or skin is incised. Exogenous sources of SSI pathogens include members of the surgical team, the operating room environment including air, and all surgical instruments and materials brought to the sterile field during an operation.

Risk Factors

Risk of SSI if no antibiotic surgical prophylaxis is given is estimated to be as follows:

- a. Clean surgical wound classification e.g. inguinal hernia repair: <5%
- b. Clean contaminated wound classification e.g. cholecystectomy with no bile spillage: 5-10%
- c. Contaminated wound classification e.g. appendicectomy: 15-25%

 d. Dirty wound classification e.g. sigmoid colectomy (Hartman's procedure) for fecal peritonitis: 25-40%

Patent-related risk factors for SSI include existing infection, existing *Staphylococcus aureus* carriers, low serum albumin concentration, older age, obesity, smoking, diabetes mellitus, immunosuppressive medications and ischemia secondary to vascular disease or irradiation. Surgical risk factors for SSI include prolonged procedures, inadequacy in surgical scrub and inadequacy in antiseptic preparation of the skin. Physiological risk factors for SSI include trauma, shock, hypothermia, hypoxia and hyperglycaemia. Therefore, prevention of SSI requires multimodal interventions i.e. targeting several risk factors at the same time.

Infection Control Measures

A. Pre-operative measures

- 1. Preparation of patient
 - a. Whenever possible, identify and treat all infections remote to the surgical site before elective operation. Postpone elective operations until the infection has resolved.
 - b. Adequately control serum blood glucose levels in all diabetic patients particularly avoid hyperglycemia peri-operatively. Reduce glycosylated hemoglobin A1c levels to <7% before surgery, if possible. For patients undergoing cardiac surgery, maintain the postoperative blood glucose level at less than 11.1 mmol/L.

- c. Encourage tobacco cessation. At minimum, advise patients to abstain for at least 30 days before elective operation from smoking cigarettes, or any other form of tobacco.
- d. Unless contraindicated, patients should be instructed or assisted to perform two preoperative shampoo and baths or showers the night before and on the morning of the surgery with chlorhexidine gluconate (CHG), or equivalent, before surgery to reduce the number of microorganisms on the skin and reduce the risk of subsequent contamination of the surgical wound. Conditioners and other hair care products should not be used after performing preoperative shampoos with CHG.
- e. Caution should be exercised to avoid CHG contact with the eyes, the inside of the ears, the meninges, or other mucous membranes. If CHG solution gets into the eye, immediately rinse the area with copious amounts of running water for at least 15 minutes and seek medical attention. CHG should not be used on the head if the patient's tympanic membrane is not intact. CHG should not be used on patients for whom it is contraindicated, including patients with a known hypersensitivity to CHG or any other ingredient in the product.
- f. Do not remove hair preoperatively unless the hair at or around the incision site will interfere with the operation. If hair is to be removed, remove immediately just before the operation preferably with electric clippers with a single-use head. Alternatively, a depilatory agent could be used if testing has been performed without tissue irritation.

- g. Do not routinely use nasal decontamination alone with topical antimicrobial agents aimed at eliminating *Staphylococcus aureus* to reduce the risk of surgical site infection.
- h. Skin preparation prior to operation:
 - Thoroughly wash and clean at and around the incision site to remove gross contamination before performing antiseptic skin preparation.
 - ii. Use an alcohol containing antiseptic agent for skin preparation.
 - iii. Apply preoperative skin preparation in concentric circles moving towards the periphery. The prepared area must be large enough to extend the incision or create new incisions or drain sites, if necessary.
- 2. Theatre wear

It is good practice to discard all used theatre wear prior to leaving the operating area to prevent healthcare workers, patients and visitors being exposed to the risk of contamination. However, there is no direct evidence that this practice has any effect on the incidence of SSI. Staff should not leave the operating theatre suite wearing non-sterile theatre wear as this is important in the maintenance of theatre discipline which is important in minimising the risk of SSI.

- a. Patients:
 - i. Patients may be given theatre wear that is appropriate for the procedure and that provides easy access to the operative site and areas for placing devices, e.g., intravenous cannulae.
- b. Healthcare personnels (HCPs) in all areas:
 - i. Wear dedicated non-sterile attire.

- ii. Staff should keep their movements in and out of the operating area to a minimum.
- c. HCPs at semi-restricted and restricted areas of the surgical or invasive procedure setting:
 - i. Wear clean surgical attire, including shoes, head covering, surgical masks, and identification badges.
 - ii. Head cover or cap should cover the hair on the head and face fully when entering the operating room.
 - iii. Surgical mask should cover the mouth and nose fully when entering operating room if an operation is about to begin or already under way, or if sterile instruments or equipment are exposed. Wear the mask throughout the operation.
 - iv. Scrubbed team members are required to put on sterile gloves after donning a sterile gown. Use surgical gowns that are effective barriers to liquid penetration.
- 3. Hand decontamination

In certain circumstances artificial nails and jewellery may conceal underlying soiling and impair hand decontamination. Hence, it is advisable that the operating team should remove hand jewellery, artificial nails before operations. Hand decontamination prior to surgery is required to minimise the risk that either the resident flora of microorganisms that normally colonise the skin or transient organisms acquired by touch contaminate the surgical wound. While transient microorganisms are readily removed by soap and water, scrubbing with antiseptics such as alcohol or detergent solutions containing chlorhexidine and povidone-iodine may be required to eliminate microorganisms that reside in deep 2016 Draft for Consultation 201

crevices and hair follicles. Although alcohol rapidly kills microorganisms, it does not physically remove organic material and it should, therefore, not be used when the hands are visibly soiled.

The operating team must decontaminate their hands many times a day. However, the regimen chosen should not damage the skin. Hence, handrubbing may be preferred compared to traditional hand scrubbing.

- a. HCPs should not wear artificial fingernails, arm or hand jewellery in the perioperative environment.
- b. HCPs should keep natural finger nails short. HCPs should follow a standardized procedure for hand hygiene. A surgical hand cleansing should be performed by staff before donning sterile gloves for surgical or other invasive procedures. HCPs should use either an antimicrobial surgical scrub agent intended for surgical hand antisepsis or an alcohol-based antiseptic surgical hand rub with documented persistent and cumulative activity that has met US Food and Drug Administration (FDA) regulatory requirements (or appropriate local health authority, e.g., Health Science Authority, Singapore) for surgical hand antisepsis.
- c. The operating team should wash their hands prior to the first operation on the list using an aqueous antiseptic surgical solution (according to the manufacturer's instruction), with a single-use brush or pick for the nails, and ensure that hands and nails are visibly clean. This is followed by preoperative surgical scrub, or a rinse-free alcohol-based surgical hand antisepsis (refer to manufacturer's recommendations on duration).

- d. After performing a preoperative surgical scrub or alcohol-based surgical hand antisepsis, keep hands up and away from the body (elbows in flexed position) so that water runs from the tips of the fingers toward the elbows.
 Dry hands with a sterile towel and don a sterile gown and gloves.
- e. Before subsequent operations, hands should be washed using either an alcoholic hand rub or an antiseptic surgical solution. If hands are soiled then they should be washed again with an antiseptic surgical solution.
- 4. Management of infected or colonized surgical personnel
 - a. Educate and encourage surgical personnel who have signs and symptoms of a transmissible infectious illness to report conditions promptly to their supervisory and occupational health service personnel.
 - b. Surgical personnel who have draining skin lesions should be excluded from duty until infection has been ruled out or resolved.
 - c. Do not routinely exclude surgical personnel who are colonized with organisms such as *S. aureus* (nose, hands, or other body site) or group A *Streptococcus*, unless such personnel have been linked epidemiologically to dissemination of the organism in the healthcare setting.
- 5. Antibiotic prophylaxis and mechanical bowel preparation
 - a. Administer an antibiotic prophylaxis only when indicated, and select it based on its efficacy against the most common pathogens causing SSI for a specific operation and published recommendations. Do not use antibiotic prophylaxis routinely for uncomplicated clean surgeries without prosthetic implants.

- b. Inform patients before the operation, whenever possible, if they will need antibiotic prophylaxis, and afterwards if they have been given antibiotics during their operation.
- c. Before giving antibiotic prophylaxis, consider the timing and pharmacokinetics (for e.g., the serum half-life) and necessary infusion time of the antibiotic. Give a repeat dose of antibiotic prophylaxis when the operation is longer than the half-life of the antibiotic given.
- d. Administer by the intravenous route the initial dose of prophylactic antimicrobial agent, within one hour before incision to maximize tissue concentration. Vancomycin and fluoroquinolones can be given 2 hours before incision. However, do not routinely use vancomycin to reduce the risk of surgical site infection.
- e. Stop prophylaxis within 24 hours after non-cardiac surgeries; and within 48 hours for cardiac surgeries.
- f. Before elective colorectal operations in addition to the above, mechanically prepare the colon by use of enemas and cathartic agents. Administer nonabsorbable oral antimicrobial agents in divided doses on the day before the operation. Do not use mechanical bowel preparation routinely to prevention of surgical site infection.
- g. Give antibiotic treatment (in addition to prophylaxis) to a patient having surgery on dirty or infected wounds.
- h. Consider screening for MRSA carriage and decolonization with nasal mupirocin ointment or octenidine nasal gel and chlorhexidine / octenidine body washes before elective surgery such as cardiac and implant surgery.

B. Intra-operative measures

- 1. Ventilation and movement of staff
 - a. Follow the recommendations of the Facility Guidelines Institute (FGI Guidelines for Healthcare Facilities) or local authorities on the ventilation requirements of an operating room.
 - b. Do not routinely use ultraviolet radiation in the operating room to prevent surgical site infection.
 - c. Keep operating room doors closed except as needed for passage of equipment, personnel and patients. Limit the number of people entering the operating room to necessary personnel only.
 - d. The traffic in the operating room should be minimized. Scrubbed personnel should remain close to the sterile field.
- 2. Sterile gown, gloves and drapes

Surgical attire is intended to function as a barrier between the surgical field and the potential sources of microorganisms in the environment, skin of the patient or the staff involved in the operation. It also performs an additional function of protecting the operator from exposure to blood or body fluids. The extent to which the materials used for gowns and drapes act as a barrier depends on the closeness of the weave and water-resistant properties.

Use of gloves is part of the aseptic surgical ritual to reduce the risk of introducing infection. They protect the operating team's hands and also protect the team from viral transmission from patients' body fluids (hepatitis and HIV) during surgery. The use of two pairs of gloves has also been suggested as a means of reducing glove puncture and hence potential contamination of the surgical wound by microorganisms from the operator's skin.

There is no difference between reusable and disposable drapes and gowns in terms of SSI incidence. Although the use of reusable or disposable drapes and gowns is not an issue with regard to reducing risk of SSI, disposable drapes and gowns can be considered when the patient is at risk of or is infected with blood borne pathogens such as HIV.

- a. The operating team should wear sterile gowns or sterile procedure attire in the operating theatre during the operation or procedure.
- b. Change scrub suits that are visibly soiled, contaminated, and/or penetrated by blood or other potentially infectious materials.
- c. Consider wearing two pairs of sterile gloves when there is a high risk of glove perforation as the consequences of contamination may be serious (e.g., operating on a patient who is a hepatitis C carrier or known to have a high viral load of any blood borne virus).
- d. Sterile drapes should be used to establish a sterile field and should be placed on the patient, furniture, and equipment to effectively prevent cross contamination. Once the sterile field is established, shifting or moving of the sterile drape should be avoided.
- e. Use sterile drapes that are effective barriers to liquid penetration.
- f. Do not use non-iodophor-impregnated incise drapes routinely for surgery as they may increase the risk of surgical site infection. If an incise drape is required, consider using an iodophor-impregnated drape unless the patient has an iodine allergy.

- 3. Asepsis and surgical technique
 - a. Adhere to standard principles of asepsis for all procedures including placement of intravascular devices, spinal or epidural anaesthesia catheters, and when dispensing and administering intravenous drugs.
 - b. Assemble sterile equipment and solutions immediately prior to use.
 - c. Handle tissue gently, maintain effective hemostasis (see item 4d), minimize devitalized tissue and foreign bodies, and eradicate dead space at the surgical site.
 - d. Maintaining effective hemostasis:
 - i. Maintain patient normothermia and prevent 'inadvertent perioperative hypothermia'.
 - ii. Maintain optimal oxygenation during surgery and ensure that anappropriate haemoglobin saturation is maintained during surgery and recovery.
 - iii. Maintain adequate perfusion during surgery.
 - e. Do not use intra-operative skin re-disinfection or topical antimicrobials in abdominal surgery to reduce the risk of surgical site infection.
 - f. At the end of the operation, cover surgical incisions with an appropriate interactive dressing such as semi-permeable film membrane with our without an absorbent.
 - g. Use delayed primary skin closure or leave an incision open to heal by second intention if the surgeon considers the surgical site to be heavily contaminated.

- h. If drainage is necessary, use a closed suction drain. Place a drain through a separate incision distant from the operative incision. Remove the drain as soon as possible.
- i. There is no formal recommendation on the duration of operation although it is known that longer surgeries are associated with higher risks for SSI. Sterilize all surgical equipment according to published guidelines. Minimize the use of immediate-use steam sterilization.
- 4. Use impervious plastic wound protectors for gastrointestinal and biliary tract surgery.

C. Post-operative measures

The main purposes of surgical dressings are to allow appropriate assessment of the wound postoperatively, to absorb exudates, to ease pain and to provide protection for newly forming tissue. They maintain an optimal moist wound environment without causing maceration of the surrounding skin as the dressing material is permeable to moisture and gas. Some dressings allow early bathing or showering of the rest of the patient in the first few postoperative days, which is part of early mobilisation. It is generally accepted good clinical practice to cover the wound with an appropriate interactive dressing for a period of 48 hours unless otherwise clinically indicated, for example, if there is excess wound leakage or haemorrhage.

1. Changing dressings

To prevent microorganisms on hands, surfaces and equipment from being introduce into the wound, aseptic non-touch dressing technique should be employed for the management of post-operative wound.

2. Postoperative cleansing

The most appropriate and preferred cleansing solution is sterile normal saline because it is non-toxic and the isotonic solution does not damage healing tissues. The objective is to remove excess wound exudate or any mobile slough and wound debris.

3. Topical antimicrobial agents for wound healing by primary intention

Primary intention healing is healing of a wound where the wound edges heal directly touching each other. This result in a small line of scar tissue, which is the goal whenever a wound is sutured closed. To reduce the risk of surgical site infection, do not use topical antimicrobial agents for surgical wounds that are healing by primary intention.

4. Dressings for wound healing by secondary intention

Do not use Eusol and gauze, or moist cotton gauze or mercuric antiseptic solutions to manage surgical wounds that are healing by secondary intention.

Use an appropriate interactive dressing to manage surgical wounds that are healing by secondary intention.

5. Antibiotic treatment of surgical site infection and treatment failure

Antibiotic treatment is not routinely recommended for all SSIs. For minor infections pus can be drained by removal of sutures and application of antisepsis. When surgical site infection is suspected, patient should be given an antibiotic

that covers the likely organisms. In choosing an antibiotic, one should consider the results of microbiological sensitivity tests and local sensitivity patterns.

6. Debridement

Debridement is the process of removing necrotic material or slough within the wound margin. The slough acts as a medium for bacterial proliferation therefore delaying the healing process. Currently there are a number of accepted methods available for wound debridement, including sharp debridement, hydrocolloid dressings and hydrogels. The promotion of wound healing is enhanced by appropriately timed dressing changes which allow granulation of tissue.

7. Specialist wound care services

To improve overall management of surgical wounds, a structured approach to wound care including preoperative assessments to identify individuals with potential wound healing problems should be developed. This can be achieved by providing specialist wound care services, enhanced education to health care professionals, patients and carers, and sharing of clinical expertise.

Recommendations

- 1. Do not remove hair unless hair will interfere with the operation. If hair removal is necessary, remove outside the OT by clipping. Do not use razors. (All)
- 2. Encourage smoking cessation within 30 days of procedure. B(I)
- 3. Control serum blood glucose levels for all surgical patients, including patients without diabetes. For patients with diabetes mellitus, reduce glycosylated hemoglobin A1c levels to less than 7% before surgery, if possible. (AI)

- 4. Use a dual agent for patient skin preparation containing alcohol, unless contraindications exist. (AI)
- 5. Administer surgical prophylaxis only when indicated, within 1 hour of incision to maximize tissue concentration. (AI)
- 6. Stop surgical prophylactic agents within 24 hours after the procedure for all procedures except cardiothoracic surgery where 48 hours is acceptable. (BII)
- 7. Sterilize all surgical equipment according to published guidelines. Minimize the use of immediate-use steam sterilization. (All)
- 8. Optimize tissue oxygenation by administering supplemental oxygen during and immediately following surgical procedures involving mechanical ventilation. (BI)
- 9. Use impervious plastic wound protectors for gastrointestinal and biliary tract surgery. (BI)

SSI Bundle

Application of the SSI Bundle is recommended to prevent SSI i.e. all the following components applied as a package:

- 1. If at all possible avoid hair removal; if hair removal is necessary, avoid the use of razors
- Ensure prophylactic antibiotics are prescribed as per local antibiotic policy for the specific operation category and administered within 60 minutes prior to the operation.
- 3. Ensure the patient's body temperature was normal throughout the operation (excludes cardiac patients).
- 4. Ensure the patient's blood glucose level was normal throughout the operation (diabetic patients only).

5. Use an alcohol-containing antiseptic agent for preoperative skin preparation

1. Hair removal

The removal of hair may be necessary to give adequate view or access to the operative site. It is known that micro-abrasions of the skin may be caused by shaving with razors. This then may support bacterial multiplication especially if shaving had been done several hours prior to surgery. The increased number of skin colonisers at the operative site may then facilitate contamination of the wound leading to consequent SSI. Hence, where hair removal is required, it is recommended to do so using clippers or depilatory cream on the table at the operating theatre, just prior to surgery.

2. Surgical prophylaxis

The objective of administration of surgical prophylaxis is to achieve high tissue levels of antimicrobials at the time of skin incision. Hence, the optimal time for administration of preoperative doses is within 60 minutes before surgical incision. The exception lies with vancomycin prophylaxis, where vancomycin administration is initiated as slow infusion over 1 hour when patient is called to operating theatre. Traditionally, for caesarean section, surgical prophylaxis is given after cord clamping. However, recent evidences now support the practice of surgical prophylaxis be administered before surgical incision. This has been endorsed by ACOG and AAP.

Adequate dosing is important and adjustments by body weight needs to be made for obese patients. For all patients, intraoperative re-dosing is needed to ensure adequate serum and tissue concentrations of the antimicrobial if the duration of the procedure exceeds two half-lives of the drug or there is excessive blood loss during the procedure e.g. re-dosing of cefazolin after every 4 hours of the procedure.

In view of the relationship of antimicrobial utilization and development of antimicrobial resistance, surgical prophylaxis is therefore, not recommended as a routine for clean non-prosthetic uncomplicated surgery. Where warranted, a single dose or continuation for less than 24 hours is recommended for surgical prophylaxis when administered.

3. Intraoperative body temperature

The medical literature indicates that patients undergoing colorectal surgery may have a decreased risk of SSI if they are not allowed to become hypothermic during the perioperative period. Anesthesia, anxiety, wet skin preparations, and skin exposure in cold operating rooms can cause patients to become clinically hypothermic during surgery. Hence, it is recommended that perioperative normothermia (temperature of 35.5[°]C or more) is maintained in surgical patients who have anesthesia duration of at least 60 minutes. The rationale is that even mild degrees of hypothermia may increase SSI rates. Hypothermia may directly impair neutrophil function or impair it indirectly by triggering subcutaneous vasoconstriction and subsequent tissue hypoxia. In addition, hypothermia may increase blood loss, leading to wound hematomas or need for transfusion, both of which can increase rates of SSI. Some randomized controlled trials have shown the benefits of both preoperative and intraoperative warming to reduce SSI rates and to reduce intraoperative blood loss although others have not shown a similar 2016 Draft for Consultation 213

benefit.

4. Perioperative blood glucose control for cardiac surgery

Elevated blood glucose levels may increase patient's susceptibility to SSI. There have been several large cohort studies in cardiac surgery, which indicate that tight postoperative blood glucose control can reduce the risk of surgical site infections, and the serious complication of sternal incision infection in particular. It is recommended that blood glucose control of 10 mmol/L or lower is achieved in cardiac surgery patients in the time frame of 18–24 hours after anesthesia end time. It should be noted that intensive postoperative glucose levels of less than 6.2 mmol/L have not been shown to reduce the risk of SSI and may actually lead to higher rates of adverse outcomes, including stroke and death.

5. Pre-operative skin preparation for patient

Skin cleansing with antiseptics is done with the objective to reduce the number of microorganisms on the skin around the incision. Alcohol-based solutions have the advantage of being both microbicidal and dry rapidly. Hence, it is recommended that skin cleansing at the surgical site be done with an aqueous or alcohol-based antiseptic preparation - povidone-iodine or 2% CHG with 70% IPA are most suitable. If diathermy is to be used, the antiseptic skin preparations should be dried by evaporation and pooling of alcohol-based preparations be avoided to prevent development of fire on the table.

Since the development of the SSI Bundle by the Institute of Health Improvement in December 2006, it has been implemented nationally in the US through the Surgical Care Improvement Project (SCIP). Data from SCIP (September 2010) indicated significant reduction in SSI following implementation using the model for 2016 Draft for Consultation 214

improvement approach. This model has two parts:

A. Three fundamental questions that guide improvement teams:

i. What are we trying to accomplish?

ii. How will we know if a change is an improvement?

iii. What changes can we make that will result in an improvement?

B. The Plan-Do-Study-Act (PDSA) cycle to conduct small-scale tests of change in real work settings i.e. by planning a test, trying it, observing the results, and acting on what is learned.

After testing a change on a small scale, learning from each test, and refining the change through several PDSA cycles, the multidisciplinary quality improvement team can then implement the change on a broader scale e.g. hospital-wide. To track progress of implementation of changes, it is recommended that both process and outcome measures be tracked over time e.g.

- 1. Prophylactic Antibiotic Received Within One Hour Prior to Surgical Incision
- 2. Prophylactic Antibiotic Selection for Surgical Patients
- 3. Prophylactic Antibiotics Discontinued Within 24 Hours after Surgery End Time
- 4. Cardiac Surgery Patients with Controlled 6 AM Postoperative Serum Glucose
- 5. Surgery Patients with Appropriate Hair Removal
- 6. Colorectal Surgery Patients with Immediate Postoperative Normothermia
- 7. Percent of Clean Surgery Patients with Surgical Infection

Enhanced SSI Bundle

An enhanced SSI Bundle is recommended for hip and knee arthroplasty and to be 2016 Draft for Consultation 215

implemented in addition to the SSI Bundle described earlier. The additional interventions are:

- 1. Use an alcohol-containing antiseptic agent for preoperative skin preparation
- Instruct patients to bathe or shower with chlorhexidine gluconate (CHG) or octenidine soap for at least 3 days before surgery
- 3. Screen patients for *Staphylococcus aureus* (SA) and decolonize SA carriers with five days of intranasal mupirocin or octenidine nasal gel AND bathing or showering with chlorhexidine gluconate or octenidine soap for at least 3 days before surgery

Preoperative skin preparation

Adequate preoperative skin preparation to prevent entry of skin flora into the surgical incision is an important basic infection prevention practice. Preoperative skin preparation of the operative site involves use of an antiseptic agent with long-acting antimicrobial activity, such as chlorhexidine gluconate (CHG) and iodophors. The combination of a long-acting agent (either an iodophor or CHG) is better than povidone- iodine alone for preventing SSI. There is insufficient evidence to support recommending the use of one combination agent over another. Two types of preoperative skin preparations that combine alcohol (which has an immediate and dramatic killing effect on skin bacteria) with long-acting antimicrobial agents appear to be more effective at preventing SSI than povidone-iodine (an iodophor) alone:

A. CHG plus alcohol

B. lodophor plus alcohol 2016 Draft for Consultation
Pre-operative antiseptic showers

The microbial flora on the skin comprises transient microorganisms that are easily removed by washing with soap, and resident flora that normally live in the skin appendages such as hair follicles. The resident flora is generally not pathogenic but is not so readily removed by soap although antiseptics can reduce its numbers.

A Cochrane review on its effect on SSI prevention showed no clear benefit and its role in SSI prevention is still uncertain. Given that there is limited scientific evidence to guide recommendations, individual physicians may wish to consider intervening with CHG or octenidine soap bath or showers for at least 3 days before surgery after discussing the risks and benefit with the patient. Where MRSA is of high prevalence, this may be an additional adjunct measure towards reducing SSI associated with MRSA.

Implementation of the Enhanced SSI Bundle is best done using the model of improvement described earlier for implementation of the SSI Bundle. For best results, it is recommended that one carefully consider the current practices in the hospital for each intervention and then move on to develop a coordinated strategy to sequence implementation of the 3 interventions, since each intervention requires changes in different systems. The success of implementation of the interventions is best tracked using process and outcome measures over time for both the SSI Bundle and Enhanced SSI Bundle. Examples of additional measures to be tracked are:

1. Percentage of patients undergoing hip or knee replacement surgery with skin antisepsis at the surgical site using an alcohol-containing preoperative

skin antisepsis agent

- Percentage of patients undergoing elective hip or knee replacement surgery who have bathed or showered with CHG or octenidine soap or wipes for at least 3 days prior to surgery
- Percentage of patients undergoing hip and knee replacement surgery who have had preoperative nasal swabs to screen for *Staphylococcus aureus* / MRSA / both

Preoperative Methicillin-Resistant *Staphylococcus aureus* (MRSA) Screening

Introduction

Staphylococcus aureus remains a common cause of healthcare-associated infections (HAI), particularly for SSI, where it can be associated with severe outcomes including mortality. The risk of HAI is up to 6 times higher among *Staphylococcus aureus* carriers, and the source of the infection has been shown to be endogenous in greater than 80%. This problem is particularly important for methicillin-resistant *Staphylococcus aureus* (MRSA) carriage and infections, in view of the additional costs of treatment, and the limited antibiotic treatment options available.

Preoperative screening and decolonisation for MRSA carriers have remained a controversial issue, and an active area of research.

Recommendations

- Patients may be screened prior to or during admission for nasal carriage of Staphylococcus aureus with culture-based or polymerase-chain-reaction (PCR) methods. (AI). PCR based tests will need to be validated in the local context in view of the emergence of novel strains of MRSA.
- A MRSA screening programme which consists of active universal surveillance pre-operatively, followed by decolonization of carriers may be implemented. However, it is recommended that a system exists to monitor mupirocin

resistance. It may be cost and resource effective in view of the higher costs associated with healthcare-associated MRSA infections. (BII)

- 3. Nasal carriers of *Staphylococcus aureus* should undergo decolonisation of nasal and extranasal sites with 5 days of twice daily intranasal application of 2% mupirocin ointment or octenidine nasal gel and daily total-body wash with chlorhexidine gluconate soap or octenidine.(AI)
- 4. Preoperative nasal decolonisation of *Staphylococcus aureus* carriers and prophylaxis of MRSA carriers with a glycopeptide antibiotic may be performed for patients undergoing cardiac operations or total joint replacement procedures, so as to prevent SSI. This recommendation may be extended to all types of thoracic surgery. (AI)

Management of Blood and Body Fluids Exposure

1. Epidemiology of sharps injuries & Blood and Body Fluid

The estimated annual incidence of needlestick injuries (NIs) is 384,000 in the United States, 100,000 in the United Kingdom, 700,000 in Germany, 29,719 in France, 28,200 in Italy, and 21,815 in Spain. The data from the EPINet system suggested that at an average hospital, there will be 30 NIs injuries per 100 beds per year. The reporting rate varies among job categories and disciplines and surgeons had the lowest reporting rate (<30%) in the United States. On the other hand, more than 25% of the exposures occurred in operating rooms and within inpatient units, approximately one-third of exposures occurred in ICUs.

NIs carry a huge impact to healthcare industries in both aspects of safety and economic burden. The United Kingdom reported a rate of 1.43 known hepatitis C virus or human immunodeficiency virus (HIV) transmissions to healthcare workers per annum. Among susceptible healthcare workers, in the absence of post-exposure prophylaxis, the risk of Hepatitis B virus (HBV) infection after a NI is 37% to 62% if the source patient is hepatitis B e antigen (HBeAg) positive and 23% to 37% if the patient is HBeAg negative. The economic burden of NIs varies from country to country; for instance, annual costs are estimated at €7 million in Italy and \$118 million to \$591 million in the United States.

The majority of reported NIs involved hollow-bore needles (55-62%), and recapping was the most common behavior associated with NI. Overall, more than half of percutaneous injuries involving hollow-bore needles were potentially preventable through safer work practices or technologies. The US General 2016 Draft for Consultation 221

Accounting Office estimates that 29% of NIs that occur in hospitals could be prevented through the adoption of safety-engineered needles or needle-free devices. A report from UK reported that the greatest reductions in NIs were achieved by blunt suture needles and safety cannulae. In conclusion, findings on the incidence and economic burden of NIs indicate the need for safetyengineered needles or needle-free technology, along with increased education regarding safer practices in the work environment.

2. Sharps prevention program

A. Develop Organizational Capacity

Each healthcare institution should have personnel responsible for the Sharps Prevention Program. It is recommended that the Infection Control Team/Department work in close collaboration with the following to achieve the goal of injury reduction or elimination:

- a. Occupational Health and Safety
- b. Staff Clinic
- c. Quality Improvement
- d. Materials Management/Product Evaluation

B. Assess Program Operation Processes

a. Assessing the Culture of Safety

A baseline assessment should include:

- i. Organization leadership's commitment to safety
- ii. Strategies used to report injuries and to identify and remove injury

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hazards

- iii. Feedback systems to improve safety awareness
- iv. Methods to promote individual accountability for safety.
- b. Assessing Procedures for Sharps Injury Reporting

All healthcare facilities will need to have procedure for sharps injury reporting and documenting employee needle- sticks and other percutaneous injuries. This need to be assessed to determine these procedures are adequate for data collection and analysis and determine the data sources that can be used to assess improvements in injury reporting.

- c. Assessing Methods for the Analysis and Use of Sharps Injury Data Data on sharps injuries need to be analyzed and interpreted so they will be meaningful for prevention planning. This part of the assessment determines how these data are compiled and used in the organization.
- d. Assessing the Process for Identifying, Selecting, and Implementing Engineered Sharps Injury Prevention Devices
 This baseline assessment considers who is involved and how decisions are made. As with other program functions, it is important to determine the data sources (e.g., product evaluation committee reports, lists of manufacturers contacted, device lists) that can be used to measure process improvement. A similar process assessment of methods for identifying and implementing other prevention interventions (e.g., changes in work practices, policies, and procedures) also could be included in this baseline assessment.

e. Assessing Programs for the Education and Training of Healthcare Personnel on Sharps Injury Prevention

All healthcare facilities should have a plan for providing employee education and training on blood-borne pathogen prevention at the time of hire, as well as on an annual basis. The implementation of a sharps injury prevention program is an opportune time to reassess the quality of these efforts and to identify other education and training opportunities. As with other processes, it is necessary to identify the data (e.g., staff development reports, curriculum changes, and training) that can be used to assess improvements in educating and training healthcare personnel.

C. Prepare a Baseline Profile of Sharps Injuries and Prevention Activities

The next step is to develop a baseline profile of injury risks in the institution. This information, along with the information gathered from the baseline assessment, will be used to develop an action plan for better prevention of sharps injuries. The following questions may be asked in the profiling:

- i. What occupational groups most frequently sustain sharps injuries?
- ii. Where do sharps injuries most frequently occur?
- iii. What devices are most commonly involved in sharps injuries?
- iv. What circumstances or procedures contribute to sharps injuries?
- v. What sharps injuries pose an increased risk for blood-borne virus transmission?
- vi. Has the organization taken steps to limit the unnecessary use of needles by healthcare personnel? If so, how has this been done?

- What devices with engineered sharps injury prevention features vii. have been implemented?
- Is there a list of recommended work practices to prevent sharps viii. injuries?
- What communication tools have been used to promote safe sharps ix. handling techniques?
- Is there a policy/procedure for determining the appropriate location х. of sharps containers?
- xi. Who is responsible for removing/replacing sharps containers?

D. Determine Intervention Priorities

Baseline information on sharps injuries, along with the weaknesses identified in the assessment of program operation processes should be used to determine priority areas.

The following approaches can be used alone or in combination to create a list of initial priorities for intervention:

- i. Determine priorities based on injuries that pose the greatest risk for blood borne virus transmission (e.g., focus initially on preventing injuries associated with vascular access)
- ii. Determine priorities based on the frequency of injury with a particular device (e.g., focus on injuries associated with hypodermic or suture needles)
- iii. Determine priorities based on a specific problem contributing to a high frequency of injuries (e.g., focus on sharps handling and/or disposal)

In general, priority is given to those areas that will have the greatest impact on 2016 Draft for Consultation 225

improving the overall operation of the program.

E. Develop and Implement Action Plans

Two action plans are recommended:

a. Establish an action plan for reducing injuries

i.Set targets for injury reduction

ii.Specify which interventions will be used

iii.Identify indicators of performance improvement

iv.Establish time lines and define responsibility

- b. Establish an action plan for performance improvement
 - i. List priorities for improvement, as identified in the baseline assessment
 - ii. Specify which interventions will be used
 - iii. Identify performance improvement measures
 - iv. Establish time lines and define responsibilities

F. Monitor Program Performance

It is recommended that this be monitored regularly. The following steps may be used:

- a. Develop a checklist of activities
- b. Create and monitor a time line for implementation
- c. Schedule periodic reviews for assessing performance improvements

3. Selection of sharps injury prevention devices

This step gives healthcare facilities a systematic way to determine and document which devices will best meet their needs. In general, the selected devices must be acceptable for clinical care and provide optimal protection against injuries.

Organize a product selection and product evaluation team. The team should comprise the following members:

- users from relevant clinical departments with insight into products used by their staff members and can identify departmental representatives to help with product selection and evaluation
- ii. Infection control staff, who can help identify potential infection risks or protective effects associated with particular devices;
- iii. Materials management staff (purchasing agents) have information about vendors and manufacturers (e.g., reliability, service record, in-service support) and can be involved with product purchasing;
- iv. Central service staff often know what devices are used in different settings in a facility and can identify supply and distribution issues; and
- v. Industrial hygiene staff (if available) can assess ergonomic and environmental use issues.

4. Post-exposure management and prophylaxis for HIV, HBV & HCV

Hepatitis B virus (HBV), hepatitis C virus (HCV) and the human immunodeficiency virus (HIV) constitute well-recognized occupational risks for healthcare workers (HCWs). Avoiding occupational blood exposure by the adherence to principles of standard precautions through the use of appropriate work practices and personal protective equipment is a cornerstone for preventing transmission of these blood-borne pathogens (BBP) in the health-care setting. Occupational exposure is serious and every effort should be taken to prevent its occurrence. However, accidents may still happen and if so, risk assessment and counseling constitutes the basis of post exposure management. Appropriate post exposure prophylaxis (PEP) should be provided using a case-by-case evaluation approach.

What are occupational injuries?

Occupational injuries may be divided into:

- (a) Percutaneous exposure (from needles, instruments, bone fragments, human bite which penetrates the skin layer, etc.);
- (b) Exposure via broken skin (exposed skin that is chapped, abraded, or afflicted with dermatitis etc.) with blood, tissue, or other body fluids that are potentially infectious; and
- (c) Exposure via mucous membranes including the eye.

Transmission of HIV through human bites are reported rarely, but not after an occupational exposure. Human bites, however, are associated with a significant risk for bacterial infection, including *Eikenella corrodens*, *Streptococcus anginosus* and *Staphylococcus aureus*, among many others. Tetanus immunization or booster should be considered after a bite exposure.

Exposures for which PEP is indicated

• Break in the skin by a sharp object (including hollow-bore, solid-bore, and cutting needles or broken glassware) that is contaminated with blood, visibly

bloody fluid, or other potentially infectious material, or sharp objects had been in the source patient's blood vessel.

- Bite from a patient with visible bleeding (in the mouth) and which causes bleeding in the exposed worker.
- Splash of blood, visibly bloody fluid, or other potentially infectious material to a mucosal surface (mouth, nose, or eyes).

First Aid

- Following any exposure, the wound should be washed <u>immediately</u> and <u>thoroughly</u> with soap and water. Alcohol, hydrogen peroxide, Betadine or other chemical cleansers are best avoided. Wound should not be squeezed or sucked.
- 2. For mucosal contact e.g. spillage into the conjunctivae, the exposed area should be <u>immediately flushed</u> with plenty of clean running water.
- 3. The exposed HCW should then seek <u>immediate</u> medical advice for proper wound care and post-exposure management.

The following information should be recorded in the exposed worker's confidential medical record:

 details about the source patient (e.g. name, NRIC No, diagnosis and any relevant

information)

- date, time and place of the exposure
- details of the procedure being performed
- use of protective equipment at the time of the exposure

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- the type, severity, and amount of fluid to which the worker was exposed
- 5. The health care worker should be tested for HIV antibody, HCV, HBV antigen and antibody
- 6. The source patient's blood (if available) should be tested for HIV, HCV & HBV.

Reporting

All institutions should have a mechanism in place for reporting and managing of sharp injuries and mucosal exposure in the occupational setting. HCWs must know the reporting process to facilitate quick and smooth flow so as to allow the attending physician to evaluate the risk of exposure and provide prompt appropriate postexposure treatment.

In addition, a surveillance system of exposure events should be available to avoid similar incidents from occurring in the future.

Evaluation of Risk for Occupational Exposure

The risk of transmission of HBV and HCV from an occupational exposure is significantly greater than the risk of HIV transmission.

Source	Risk	
HBV		
HBeAg+	22.0% - 30.0%	
HBeAg-	1.0% - 6.0%	

Table 1Risk of transmission

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HCV+	1.8%
HIV+	0.3%

Table 2 Risk in relation to exposure

Type of Exposure (Others)	Risk
Biting	Negligible
Spitting	Negligible
Throwing body fluids (including semen or	Negligible
saliva)	

After percutaneous exposures, factors that might increase the risk of HIV transmission are:

- Source patient was suffering from early or late stages of HIV infection with high viral load.
- Visible blood on a device.
- Procedure involved placement in a vein or artery.
- Injuries were deep.
- Injury was with a hollow-bore needle.

Counseling

Until the risk of infection is ruled out, advice should be given to the exposed staff to refrain from donating blood, plasma, organs, tissue or semen. The use of condom during sexual intercourse should also be advised. A place for psycho-social support is clearly indicated.

I. Post Exposure Management to HIV

When an occupational exposure to HIV source patient occurs, it should be considered as an urgent medical concern. PEP should be initiated as soon as possible, ideally within 24 hours of the exposure.

A first dose of PEP should be offered to the exposed worker while the evaluation is underway i.e. the determination of HIV status of the source patient. Initiating PEP should be the first priority and should not be delayed to await expert consultation.

PEP regimens* should include 3 (or more) antiretroviral drugs given for a period of 4 weeks

Table 3Post-Exposure Prophylaxis (PEP) Against HIV Infection for HCWExposed to Blood and /or Body Fluids

Exposure	Source patient HIV (+)	Source Patient Unknown	Considerations
Mucous membrane or skin, integrity compromised		No treatment	Skin integrity is compromised if there is evidence of chapped skin, dermatitis, abrasion or open wound
Small (few drops or short duration)	High titer Source patient has advanced AIDS, primary HIV infection, high or increasing viral load or low CD4 count – consider prophylaxis with PEP Regimen		
Exposure	Source patient HIV (+)	Source Patient Unknown	Considerations

Large (several drops, major blood splash and/or longer duration i.e. more than several minutes)	Low titer Source patient asymptomatic and high CD4 count – recommend prophylaxis with PEP regimen	If there is a possible risk for HIV exposure, consider prophylaxis with PEP regimen	
	High titer Source patient has advanced AIDS, primary HIV infection, high or increasing viral load or low CD4 count – recommend prophylaxis with PEP regimen		
Intact skin	PEP not needed unless there is high exposure to blood e.g. extensive area of skin exposed or prolonged contact with blood	No treatment	
Percutaneous exposure	Low titer Source patient asymptomatic and high CD4 count – recommend prophylaxis with PEP regimen	If there is a possible risk for HIV exposure, consider prophylaxis with PEP regimen	Combination of factors e.g. large bore hollow needle and deep puncture contribute to an increased risk for transmission if source patient is HIV positive
Less severe e.g. solid needle, superficial scratch	High titer Source patient has advanced AIDS, primary HIV infection, high or increasing viral load or low CD4 count – recommend prophylaxis with PEP regimen		
More severe e.g. large-bore hollow needle, deep puncture, visible blood on device, or needle used in source patient's artery or vein	Low or high titer Recommend prophylaxis with PEP regimen		

Regimen for HIV PEP Following Occupational Exposure

When there is a significant risk exposure which requires PEP, the following threedrug regimen is recommended as a preferred initial PEP regimen:

Raltegravir (Isentress; RAL) 400 mg PO twice daily Plus Truvada (Tenofovir DF [Viread; TDF] 300 mg + Emtricitabine [Emtriva; FTIC] 200 mg) 1 PO once daily

Alternatives can be considered where there is a potential for HIV resistance, toxicity risks, clinician preference, or constraints on the availability of particular agents OR when the initial or subsequent PEP regimen is not well tolerated (see Table 4).

Table 4 Alternative Regimens for HIV Post-Exposure prophylaxis

(Source: US Public Health Service Guideline Infection Control and

Hospital Epidemiology 2013; 34(9): 875-92)

May combine 1 drug from left column with 1 pair of nucleoside/nucleotide reverse transcriptase inhibitors from right column Raltegravir (Isentress; RAL) Tenofovir DF (Viread; TDF) + emtricitabine (Emtriva; FTC); available as Truvada Darunavir (Prezista; DRV) + ritonavir Tenofovir DF (Viread; TDF) + lamivudine (Norvir; RTV) (Epivir; 3TC) Etravirine (Intelence; ETR) Zidovudine (Retrovir; ZDV; AZT) + lamivudine (Epivir; 3TC); available as Combivir Rilpivirine (Edurant; RPV) Zidovudine (Retrovir; ZDV; AZT) + emtricitabine (Emtriva; FTC) Atazanavir (Reyataz; ATV) + ritonavir (Norvir; RTV) Lopinavir/ritonavir (Kaletra; LPV/RTV) The following alternative is a complete fixed-dose combination regimen, and no additional antiretrovirals are needed: Stribild (elvitegravir, cobicistat. tenofovir DF, emtricitabine)

Duration of PEP Regimen

• When the source patient is confirmed to be HIV-negative, clinicians should discontinue the PEP regimen even before its completion.

Follow-up appointments

- 1. Follow-up appointments should begin within 72 hours of HIV exposure and should include follow-up HIV testing, monitoring for drug toxicity, and counseling
- 2. HIV testing at baseline and at 6 weeks, 12 weeks, and 6 months after exposure.
- 3. HIV testing should generally continue for 6 months after exposure.
- 4. The follow-up period for exposed HCW can be shortened to 4 months (from 6) if the clinician is certain that a 4th generation combination HIV p24 antigen/antibody test is used.

Expert Consultation

There are several scenarios where expert consultation is recommended:

- a. Source patient is known to harbour drug-resistant HIV
- b. Pregnant or breast-feeding exposed HCW
- c. Severe illness in exposed HCW
- d. Delayed > 72 hours report of exposure
- e. Severe needlestick injury from unknown source

II. Management of accidental exposure to HBV

The management of an incident of accidental exposure to HBV involves proper risk assessment, counseling and post exposure prophylaxis that is tailored to the needs/status of individual healthcare worker (refer to Table 5)

Recommendation for PEP for HBV exposures:

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- Both the source patient's HBsAg status and the exposed worker's vaccination status should be considered.
- Both HBIG (if required) and the first dose of the hepatitis B vaccine should be ideally administered within 24 hours of exposure.
- Even if the risk of exposure to HBV is not deemed significant, HBV vaccination should still be advised for all non-HBV-immune exposed workers.
- The three-dose HBV vaccine series is given at 0, 1 to 2 months, and 6 months.

Table 5 Post-Exposure Prophylaxis (PEP) Against Hepatitis B for HCW

Immune Status of HCW	Source Patient HBsAg (+)	Source Patient HBsAg (-)	Source Not Tested Or Unknown
<u>Unvaccinated</u>	One dose HBIG and start one series of HB vaccination	Start HB vaccine series	Start HB vaccine series
Previously vaccinated			
Known responder (anti-HBs <u>></u> 10 mIU/mI)	No treatment	No treatment	
Known non- responder	One dose HBIG and start one series of HB vaccine	No treatment	If known high risk source, treat as if source were HBsAg (+)
Antibody response unknown	Check anti-HBs: If \geq 10 mIU/mI, no treatment* If < 10 mIU/mI, one dose HBIG and vaccine booster	No treatment	Check anti-HBs: If \geq 10 mIU/mI, no treatment If < 10 mIU/mI, one dose HBIG and vaccine booster

Exposed to Blood and/or Body Fluids

HBIG - Hepatitis B immunoglobulin

HB - Hepatitis B

- HBsAg anti-hepatitis B surface antigen
- HCW Healthcare worker

III. Hepatitis C Virus Post-Exposure Management

Currently, prophylaxis of HCV is neither available nor recommended although early identification of infection following exposure is recommended to be accompanied by referral to an infectious disease doctor or a specialist experienced in treating HCV.

HCW should be tested for HCV antibody and liver enzyme levels (alanine aminotransferase or ALT) as soon as possible after the exposure (baseline) and at 3-6 months after the exposure.

Table 6Hepatitis C Post-Exposure Management According to BaselineTest Results

Clinical Scenario	Follow-Up
Source patient is HCV-antibody negative	No further testing or follow-up is necessary for source patient or the exposed worker
Source patient is unavailable or refuses testing	Exposed worker: Follow-up HCV antibody and at 3 and 6 months
Source patient is HCV-antibody positive and HCV RNA negative	Manage the exposed worker as if the source patient has chronic hepatitis C
Source patient is positive for both HCV antibody and HCV RNA and Exposed worker is HCV-antibody negative	Exposed worker to be referred to specialist experienced in treating HCV infection

Post-Exposure Follow-Up for HCV

For individuals exposed to hepatitis C-infected source patients, regular follow-up with HCV RNA testing is recommended in addition to HCV antibody testing.

Construction and Renovation

I. Introduction

Immunosuppressed patients face health risks as a result of construction work that happens in healthcare buildings. Much data has been published with regards to the risks and its relations to the demolition, construction and maintenance activities that take place, due to its seriousness on patients.

Building works are a recognised source for healthcare associated infections caused by *Aspergillus* sp. Construction and renovation activities (e.g. drilling, cutting, removing walls, ceiling tiles and floor coverings) create tremendous amounts of dust or debris that disrupts air flow patterns. The dust particles remain suspended in the air (aerosolised) and act as transmitters of fungal spores or bacteria. This can be detrimental to high-risk patients, in that it may cause them to develop serious opportunistic infections.

During excavation, contaminants like dust particles carrying fungi were drawn into the HVAC of a facility adjacent to another building that was imploded. The contaminated air continued to infiltrate others high risk patient's unit causing serious opportunistic infections and deaths. In addition, excavation allows the release of microorganisms from the soil. These microorganisms eventually enter and contaminate the air, cooling towers, and water systems.

Another impact that can happen during construction is that air-handling duct is modified or perhaps simply shut down to accomplish the work during project. When the system is re-pressurised, there is a nearly instantaneous change in pressure 2016 Draft for Consultation 240

within the duct work, which will dislodge fungal spore-laden dust and allow it to become airborne.

It is common for a hospital's water supply to be temporarily disrupted, be it accidentally or intentionally, during construction projects. It is important to ensure that water systems shut down be flushed and decontaminated before they are returned to service. This is essential since the water systems may contain stagnant water and/or scale and corrosion that had been loosened by drilling or vibration. In such cases, *Legionella* bacteria may be carried in the water supply and if delivered to patient's care units, could lead to compromises in patients' safety. Damaged pipes can give rise to leaks and resultantly, dampness and/or floods the surrounding work spaces. If areas affected are not promptly cleaned and dried, mold can grow on materials like gypsum wallboard, ceiling tile or spray-applied fire-proofing.

A. Challenges

The numerous risks posed during construction and renovation works are especially so in vicinities with vulnerable patients. However, many hospitals still constantly undergo expansions, renovations and constructions in order to respond to changes in healthcare delivery, emerging technology, and to update aged infrastructure. Renovation is also an effort to meet the demands of increased patient activity, changing needs, to provide better service and remain financially viable. Therefore, it is important for Infection Control personnel to identify the infection risks involved and plan for ways to minimize these risks. To successfully meet these challenges, the Infection Control personnel must collaborate with engineers, nurse managers, administrators, architects and physicians before, during and after the construction projects. The priority is to reduce/eliminate the airborne dust which may contain fungal spores before it reaches areas with immuno-suppressed patients. It is also crucial for the Infection Control personnel to ensure that the risk assessment and prevention plan complies with infection control guidelines, ministries' regulations and accrediting agencies like the Joint Commissioner International.

B. Healthcare associated infections related to construction and renovation

A review of the literature of healthcare associated infections for the 20-year period (1978-1998) revealed many nosocomial outbreaks to be related to construction and renovation projects. Majority of the infections were caused by construction or renovation projects which happened within or adjacent to healthcare facilities. Others were due to the malfunctioning or improperly maintained ventilation systems during the period when healthcare facilities were undergoing construction or renovation. The reported construction-related nosocomial infections are primarily caused by fungi / mould (e.g. *Aspergillus, Penicillium, Candida, Zygomycetes, Fusarium*), and also, to a lesser extent, by bacteria (e.g. *Legionella, Bacillus, Nocardia, Mycobacteria*).

1. Fungi/ Mould

The most common etiological agent is *Aspergillus*. In particular, *A. fumigatus, A. flavus, A. niger* and *A. terreus* have been repeatedly documented in outbreaks. Amongst these, *A fumigatus* is considered the most pathogenic and is responsible for more than 90% of all *Aspergillus* infections. Fungi occur naturally.

They form an essential part of biological ecosystems and are found ubiquitously 2016 Draft for Consultation 242

in soil, water and decaying vegetation. Therefore, it is impossible to avoid it in our everyday living. The immune systems of healthy humans are able to recognise these fungi as being foreign to the body, thereby expelling them in very natural ways. However, for a human whose immune system is not functioning properly (either as a result of an underlying condition or as a result of medical treatment), the fungi is not as readily expelled. In these latter cases, the fungi will colonise, grow, multiply and invade after it enters the body.

Fungal spores (conidia) proliferate on dead organic debris. They are also capable of remaining viable for months in dry locations. During construction and renovation, when floors, walls, or ceilings are penetrated, spores can be dispersed together with dust or dirt particles. Since Aspergillus spores are small (2.5um-3.5 um) and settle very slowly (0.03 cm per second), they can remain suspended in the air for prolonged periods. This increases the likelihood of it contaminating environmental surfaces or being inhaled in by humans through breathing. The inhalation of spores poses a problem to patients with poor immune systems. The inhaled spores rapidly colonise the bronchial tree within the lungs, thereby causing pneumonia. In addition, these spores may also spread to the other organs of immunosuppressed / vulnerable patients. Some of the known infections caused by inhalation of spores/conidia are allergic aspergillosis, aspergilloma (hyphae ball), and invasive aspergillosis. In immunosuppressed patients, these infections are often fatal. The death rate for patients who have become colonised with aspergillus or have developed invasive aspergillosis is said to be between 40% and 90%. This is in spite of its recognition and treatment. Because of the high mortality rate of vulnerable patients due to invasive 2016 Draft for Consultation

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Aspergillosis, it becomes essential to minimise risks. When demolition or construction activities are taking place, it is necessary that immuno-suppressed / vulnerable patients are especially protected.

2. Legionella species

Legionellosis is an environment-related, acute respiratory infection caused by the Gram-negative Legionella bacteria, of which the most pathogenic is Legionella pneumophila. The infection is usually acquired due to the inhalation of aerosols contaminated with the pathogenic Legionella bacteria. Such contaminated aerosols are generated in man-made water systems, such as air-conditioning cooling towers, evaporative condensers, heated potable water systems, heating and air conditioning systems, whirlpool spas, and decorative fountains which have not been properly maintained. Other modes of transmission such as the aspiration of contaminated water are also possible.

There are 2 distinct clinical manifestations of legionellosis. Pontiac fever is a selflimited infection whereby a person experiences some flu-like symptoms, whereas the more severe form with pneumonia is known as Legionnaires' disease.

Legionnaires outbreaks are frequently associated with construction and renovation projects. This is because, during such projects, water supplies are usually turned off or not used for a period of time, allowing water to stagnate and Legionella bacteria to grow. Legionella contamination of the potable water may occur as pipes are re-pressurized. During construction activities, the introduction of contaminated soil into the plumbing system may also increase the amount of 2016 Draft for Consultation 244

Legionella bacteria in the pipes. Scale and biofilm within the tanks, pipes and fixtures contribute to this problem by providing *Legionella* with food and protection. The hot-water system may be a perfect breeding ground for *Legionella*. *Legionella* grows best in water temperatures of between 35°C to 46°C. Numerous cases of *Legionella* outbreaks have been associated with excavation. Some experts believe that excavation causes *Legionella* to be released from the soil and then to enter cooling towers, air intakes, water pipes and was inhaled by people nearby. Dust and dirt can also potentially provide a nutrient rich food source for existing *Legionella* in cooling towers or domestic water systems.

The occurrence of a nosocomial infection caused by *Legionella* depends on several factors. These include the resistance of the host, exposure of the host to a contaminated source, and the level of contamination of the source. Patients receiving high dose steroids are at a particular risk with *Legionella* from the water supply. Legionnaires' disease can be difficult to diagnose if it is not suspected because specialized laboratory methods and culture media are required. Thus, preventive measures to decrease the transmission of *Legionella* should be implemented whenever construction or renovation activities which disrupt health care facilities' water supply are being planned.

C. Risk factors for healthcare associated infections related to construction and renovation

Any patient exposed to construction activities or soil excavation may be at an increased risk of acquiring a construction-related nosocomial infection. However, certain patients are at an increased risk of construction-related nosocomial infections due to their underlying medical conditions. Comorbidity is one of the best predictors of the development of invasive aspergillosis or Legionnaires' disease.

Risk factors for fungal infections

- 1. Exposure to construction activities
- 2. Immunosuppressive conditions (e.g. bone marrow or solid organ transplantation; graft versus-host disease requiring treatment; prolonged neutropenia or granulocytopenia because of cytotoxic chemotherapy; prolonged use of antibiotics to treat fevers or previous infections; and steroid therapy or other immunosuppressive therapy)
- 3. AIDS, congenital immunodeficiencies
- 4. Dialysis, renal failure
- 5. Diabetic ketoacidosis
- 6. Mechanical ventilation
- 7. Smoking
- 8. Age of the patient (e.g. neonates and very old patients have a greater risk)

Risk factors for Legionnaires' Disease

- Exposure to soil excavation during construction and malfunction of plumbing systems
- 2. Immunosuppressive conditions (e.g. bone marrow or organ transplantation; graft-versus-host disease requiring treatment; and steroid therapy)

- 3. Advanced age
- 4. Chronic pulmonary disease
- 5. Smoking
- 6. Excessive use of alcohol
- 7. Surgery
- 8. Diabetes
- 9. Neoplastic disease
- 10. Renal failure
- 11. Cardiac failure

II. Preventive measures

A. Pre-designing and consultation phase

1. Multidisciplinary team

Pre-design planning is the most important time for construction and renovation in health care facilities. Appropriate infection prevention and control measures must be employed throughout construction and renovation projects in healthcare facilities to reduce health risk. This requires collaboration among a multidisciplinary team of architects, engineers, and facility staff, infection control personnel, safety officer, representatives from environmental services, administration and staff from specialized areas concerned with or impacted by the project. It is important for the Infection Control Personnel to play an active role in all phases of the project.

The multidisciplinary team would be involved in developing appropriate risk management planning for the project. This includes detailed project-specific control risk plans based on the risk assessments. It provides a strategic, 2016 Draft for Consultation 247

proactive design to mitigate environmental sources of microbes and to prevent infectious hazards through architectural design. It also consists of control measures to mitigate potential contamination during actual construction or renovation (e.g. dust barriers). This will be the document the Project Architect and Consultant Engineers will use to design protective systems and procedures for the duration of the project. Infection control policy specifically for construction and maintenance works should be available. The key functions and responsibilities of this team are to:

- a. Coordinate members' input in developing a comprehensive project management plan
- b. Conduct a risk assessment of the project to determine potential hazards to susceptible patients
- c. Prevent unnecessary exposures of patients, visitors, and staff to infectious agents
- d. Oversee all infection control aspects of construction activities
- e. Establish site-specific infection control protocols for specialised areas
- f. Provide education about the infection control impact of construction to staff and construction workers
- g. Ensure compliance with technical standards, contract provisions, and regulations
- h. Establish a mechanism to address and correct problems quickly
- Develop contingency plans for power failures, water supply disruptions, fires, short or long term delays (due to industrial action or material's delays) and emergency response

- j. Provide a water damage management plan (including drying protocols) for handling water intrusion from floods, leaks, and condensation
- k. Develop a plan for maintenance on the site during construction as well as afterwards

2. Risk Assessment

Risk assessment is the most crucial step in identifying potential hazards and the type of containment measures necessary for a safe environment. It should be carried out during the preplanning stage as part of a robust risk management programme.

At a minimum, the risk profile should:

- i. identify the location of high-risk patients within the site,
- ii. identify ventilation system types and their potential impact; determine air monitoring requirements, methodology and frequency and
- iii. take air samples to establish baseline values and identify possible contaminants and their locations (e.g. ceiling dust, service shafts, sprayed-on fire retardants and bird droppings)

For external projects, the following may be considered:

- a. Determine the location of air intakes in relation to any projects.
- b. Find out whether the ventilation system will function correctly with the pressure drop from excess contaminants collecting on the air intake system.
- c. Find out the need to increase preventative maintenance of the ventilation system to ensure proper functioning during external demolition or excavation.
- d. Locate any infiltration points pre-construction such as windows and doors.

- e. Determine whether the project requires penetration of existing walls and if so, how the occupants will be affected.
- f. Determine how environmental issues affect the project such as prevailing winds, outdoor temperatures.

For internal projects, factors to consider include:

- a. Investigate whether the project requires utility outages, and if so, the effect on occupants by outages.
- b. Determine the outage's effect on ventilation upstream and downstream.
- c. Determine whether ventilation requirements for special care areas can be achieved during shut.
- d. Decide whether to use recirculated air, and if so, how contaminants from the construction site will be trapped so that they are not dispersed into the general circulation.
- e. Determine where sensitive patient care areas are located under the project site.
- f. Investigate whether the construction activities produce vibrations, if so specify type.
- g. Investigate whether the vibrations create problems for facility operations e.g. surgery

3. Planning

At the beginning of the planning stage, it is necessary for the Infection Control precautions to be integrated into all documentation. It is important that the dust and infection control principles developed during the pre-design stage are integrated at the initial stages of design development. It is also important

that the pre-design team brief the design team and submit the findings of the survey and risk profile. It is important to address the following items:

- a. Determine the extent and locations of dust barriers. Ensure barriers are properly sealed right up to the slab, not just the ceiling, and to the floor and around all services to prevent air leakage. The barriers should be as air tight as possible.
- b. Establish locations for negative pressure HEPA filter units to create a negative pressure for the site. If an exhaust can be ducted to the outside and no air intakes are in the vicinity, subject to risk assessment, a HEPA filter may not be required and a simple temporary duct and fan used.
 - c. If the site is close to a high-risk area determine locations for HEPA filter clean air units outside the site access points.
 - d. Determine type of barrier required. This would depend on the duration of the job, light duty or temporary or the jobs only taking hours through to a framed and sheeted wall for long duration job. Remember to consider the risk level when choosing the barrier type.
 - e. Determine the location of the nearest smoke or firewalls. The use of these can reduce the amount of above ceiling barrier required.
 - f. Document sealing of windows, upgrading of air filter elements to a higher efficiency, and a higher frequency of air filter replacement if exterior work is required. The extent of this will be determined by how dusty the activity is.

- g. Develop and document a demolition strategy and include the method of removing the debris safely. Consider that external chutes have a stack effect that can potentially draw dust back up from the bin presenting potential dangers.
- Develop and document construction personnel traffic routes, taking into account high-risk patient locations. Construction workers tend to leave doors open and leave openings in barriers.
- Determine and document locations remote from the construction site that can be used for dirty/dusty work.
- j. Develop and document material handling, material transport and materials, storage, taking into account high-risk patient locations.
- k. Check locations above and below the site if penetrations are required.
 Develop strategies for the protection of high-risk patients during these events.
- I. Develop comprehensive dust and infection control specification clauses specific to the project. Ensure appropriate penalties are included for repeated breaches of infection control clauses. As *Aspergillus* sp thrive on water-damaged plasterboard, a clause should state that all gypsum plasterboard be protected from water damage. If wetted it must be replaced if not totally dry within 72 hours.

4. Education and Training of Construction Workers

This is necessary and it is recommended that it be done before work begins. The curriculum should address the following:

a. Why and how to adhere to infection control measures

b. Potential environmental risks e.g. fungal contamination for plumbers 2016 Draft for Consultation
- c. Use of particulate respirators or other PPE
- d. Risk prevention for safety issues e.g. noxious fumes or asbestos
- e. How to seek help and report exposures
- f. Training before site entry

These educational sessions should be documented.

B. Construction Phase

Attention to detail in the planning stages will ensure correct processes are in place for the construction phase. The risk to patients from construction and maintenance activities is greatly reduced when a formalized approach to risk management is conducted in conjunction with sound infection control procedures. Things can go wrong during construction stage. Hence, constant vigilance is required to ensure processes are in place and adhered to.

For external projects, the objective is to keep dust out of functioning facilities through the following manner:

- i. Water mist the soil or wall before excavation or demolition
- ii. Wet dust surfaces of truck or equipment path
- iii. Keep windows and doors closed as much as possible
- iv. Keep the facility air pressure positive to the outside
- v. Ensure sufficient air supply and exhaust
- vi. Regular filter maintenance to ensure intake of clean air

For internal projects done in facilities amidst patient care areas, the objective is to <u>keep dust in</u> within the work area through the following manner:

i. Hoarding

ii. Negative pressure within the worksite 2016 Draft for Consultation

- iii. Site cleanliness and waste management
- iv. Traffic control
- v. Additional measures for patient protection
- vi. Monitoring for compliance
- vii. Post-procedure clean up

Refer to Appendix 1 for detailed precautionary measures to be taken according to type of project work. In general, negative pressure is to be maintained within the area of work. This may be achieved with the use of HEPA filter placed within the work area. The HEPA filter captures particulates whilst creating negative pressure at the site in relative to adjacent areas. The filters are to be sealed and bagged securely at point of use before disposal.

Hoarding or physical control barriers minimize dust migration to adjacent areas. The types of hoarding to be used depend on the duration and extensiveness of the project. They must be <u>dust-tight</u> and be intact until all dust generating work is complete, walls and ceiling closed, sanding done, and area cleaned. Hoarding material varies:

- Plastic sheets hoarding: these may be used for projects with minimal dust generation. They should be sealed at full ceiling height with a minimum of 60cm overlapping flaps for access to entry
- b. Plaster board hoarding: these may be used for projects with moderate to high level dust generation. They are rigid, dust-proof fire-rated barrier walls (plywood, drywall) and the caulked seams should be tightly sealed

- c. Calcium silicate hoarding: these are cheaper than metal hoarding, easier to construct / amend, durable withstanding exposure to sun and rain. However, they are less lasting than metal hoarding
- d. Metal hoarding: these are the best hoarding type as it withstands long term exposure to sun and rain. However, they are costly and may be technically difficult to erect

All hoarding should be carefully and securely taped with heavy-duty tape materials. All junctures are to be taped:

- 1. Between ceiling tiles and hoarding
- 2. Between juncture of door frames
- 3. In between the gaps of hoarding materials
- 4. Between hoarding and floor

When hoarding extends through interstitial space, ensure all holes, pipes, conduits and punctures are tightly sealed.

1. Audit / Inspection rounds

It is highly recommended that regular audits be done to ensure that infection control measures are in place. The key factors to check on are:

- a. Integrity of hoarding and efficacy
- b. Negative pressure maintenance in renovation work area
- c. Environmental cleanliness i.e. dust control

The frequency of audits to be done is highly dependent on type of work. It is recommended that audits be done at least daily when work activity results in significant dust generation e.g. when demolition work is being conducted.

2. Air Monitoring

Serial fungal air sampling may be done to monitor risk for healthcare associated *Aspergillus* infections. Cumulative data is used to establish indoor and outdoor background levels of fungi for a particular site. There are no standards for the interpretation of fungal counts. Hence, it is usually used to monitor levels over time to correlate with construction / renovation activities and effectiveness of control measures. It is recommended that the following readings be collected at time of fungal air monitoring to assist in the interpretation of results:

- i. Wind direction
- ii. Air velocity
- iii. Temperature
- iv. Relative humidity

The air samplers used for fungal monitoring should be a slit or sieve impactor sampler that is capable of collecting large volumes of air in short periods of time to detect low numbers of fungal spores.

i. Indication for Air Sampling

- a. To monitor levels of contamination prior to occupancy of special controlled environment e.g. to determine efficiency of HEPA filters.
- b. To correlate outbreaks of invasive aspergillosis with hospital construction or demolition work

- c. To identify potential sources of nosocomial aspergillosis when a case has been identified.
- d. To predict environmental spore contamination from outside sources.
- e. To identify defects/breakdown in hospital ventilation systems

Air sampling is only recommended for commissioning and re-commissioning of operating rooms and clean rooms. It may be useful during construction where immunocompromised patients may be impacted, during cluster of infection investigation. Air sampling only measures indoor air quality at a single point of time. There are varieties of factors affecting sampling results. These include:

- a. indoor traffic,
- b. visitors coming into the facility,
- c. temperature,
- d. time of day or year,
- e. relative humidity,
- f. relative concentration of particles or organisms and
- g. performance of the air handling system components.

All results need to be compared to results from other defined areas with similar conditions, or time periods in order to be meaningful.

ii. Active Sampling Procedure for fungi and bacteria

The main principle of active sampling of air is to sample the air for the enumeration of bacteria and fungi. As part of a construction program or as an aid to investigation into infection clusters, air sampling is conducted at an interval determined by the Infection Control Committee, to determine fungi including

Aspergillus fumigatus spore loads or bacteria. It generally only provides usable 2016 Draft for Consultation 257

readings when a baseline level of counts is available to compare the latest results with. When commencing a sampling program, baseline sampling must be undertaken to establish both background levels and historical records. Historical records are essential to allow sessional variations in spore count to be taken into account. Active airborne sampling should be considered as part of a building risk management program. Cumulative data is used to establish indoor and outdoor background levels of filamentous fungi for a particular site. This will enable establishment of risk profiles for particular locations in and around the hospital.

iii. Location of Sampling

Sampling height is 1.2 metres for room hygiene, with other samples taken for exploratory purposes that are near suspected to the potential sources of contamination. Multiple air sampling over a period of time is preferred to a single sample.

iv. Interpretation of air sampling results

Sampling results are highly variable due the factors already outlined. It depends upon the season, outdoor spore levels can commonly exceed 1,000 CFU/m³ but can be as high as 10,000 CFU/m³ total spore count. *A. fumigatus* levels in outdoor air averages 1–15 CFU/m³. Indoor spore levels below 100 CFU/m³ total spore count are considered to be inconsequential in areas not housing an at risk population. In outbreaks involving at risk patients, aspergillosis cases have occurred when fungal spore concentrations in protective environment ambient air ranged as low as 0.9–2.2 colony-forming units per cubic meter (CFU/m³) of air.

Investigators have also suggested limits of 15 CFU/m³ for total spore counts of fungal organisms and <0.1 CFU/m³ for *Aspergillus fumigatus* and other potentially opportunistic fungi in HEPA filtered areas with at least 12 ACH and positive air pressure. There has been no reported correlation of these values with the incidence of healthcare-associated fungal infection rates. Other investigators suggest specialised areas with HEPA filtered supply air systems with an air change rate of at least 15 air changes per hour should achieve a concentration of 0.03CFU/m³ of *A. fumigatus* for BMT and laminar flow suites should achieve a concentration of 0 CFU/m³ of A. fumigatus. Total indoor spore counts in these areas should not exceed 15 CFU/m³.

Hand-over and Pre-Occupation Stage

After hand-over it is the hospitals responsibility to ensure the area complies with hospital cleanliness standards for occupation. The hospital should thoroughly clean and decontaminate all surfaces including walls, ceilings, and windows as well as in high-risk area ventilation systems, service cavities and ceiling spaces.

If air sampling and particle counts are being conducted, sufficient time must be allocated for culturing. It is advisable to implement a program of air sampling in high risk areas for a period of time after hand-over and occupation. Once all these tasks have been completed, re-certify HEPA filters and laminar / clean flow systems where installed.

There is limited literature or published guidelines on post-construction inspection and commissioning. The recommendations listed below are largely referred from the recommendation by Bartley and Olmsted and applies to newly constructed facility. A checklist should be developed during planning stage and agreed upon by all key stakeholders in the project team including Infection Control and contractors to ensure a systematic assessment of all important aspects during post-construction inspection and commissioning. In general, the inspection should include, but are not limited to, the following:

- airflow, pressures, filters, location of air intakes and vents are meeting the pre-set requirement
- drains to the sanitary sewer system are connected and functioning

The inspection should be carried out according to the type and the phase of the project.

Two weeks before moving into new facility:

- 1. Use processing packs to check steam, gas sterilizers (applicable to newly constructed Supplies Sterilization and Processing Room).
- Verify correct water temperatures. Verify the quality of water with microbiological testing and check that the parameters are within acceptable range.
- Complete written schedules and procedures for routine maintenance of equipment, cooling towers, and suction machines (central and portable); establish documentation.
- 4. Determine transportation systems.
- 5. Walk through the facility with local health department representative and facility management personnel to ensure compliance with national guidelines.

One week before moving into new facility:

- Evaluate heat, ventilation, air-conditioning (HVAC) supplying special areas, such as operating rooms and interventional cardiology rooms. Objective evidence should be requested from contractor that HVAC is providing air exchanges and filtration as designed, before owner acceptance. Assess methods for determining effectiveness of particulate matter removal, whether it should be particle, bacterial or fungal spore counts monitoring.
- Evaluate laminar air hoods for effective operation; ensure functioning according to manufacturer specifications. Ensure a maintenance contract has been arranged and testing accomplished.
- 3. Ensure that there is adequate number of hand hygiene facilities (handwashing basins, paper towel dispensers, alcohol-based handrub holders). Ensure that the hand hygiene facilities are designed according to the requirement (including the type of basin and tabletop, location, functionality of the dispensers).
- 4. Verify that sinks in critical patient-care areas have properly functioning fixtures.
- 5. Open all faucets simultaneously to test drain effectiveness. Assess the water flow to ensure acceptable flow rate and to observe for the presence of water stagnation at the tip of the faucet. This is particularly important if sensoroperated faucets are used.
- 6. Check that aerators are not on designated faucets.

- Check floor drains, and ensure that traps have water seals to prevent sewer gases from entering rooms.
- 8. Check that there is adequate number of puncture-resistant containers and waste bins. The containers and bins should be installed according to the requirement. The location of the containers and bins should be aligned with the work process of the users, and the height of the puncture-resistant containers is at eye level.
- 9. Check that carpeting is not used in high-traffic zones in patient care areas or where spills are anticipated (e.g., burn therapy units, operating rooms, laboratories, and intensive care units) or in patient rooms in areas housing immuno-compromised patients (e.g., protective environment areas).
- 10. Ensure that contractors have completed their own cleaning and disinfecting; ensure housekeeping department has completed facility follow-up cleaning.
- 11. Ensure registered pest control and management are functioning and checked.
- 12. Infection Control should be prepared to intensify surveillance for HAIs and monitoring of infection control practice.

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Glossary

Action level: concentration of a regulated substance (e.g. ethylene oxide, formaldehyde) within the employee breathing zone

Adequately ventilated single room: A single room with \geq 12 air changes per hour (ACH) without controlled direction of air flow.

Airborne infection isolation room (AIIR): AIIR is also known as negative pressure isolation room. An AIIR is a single-occupancy patient-care room used to isolate persons with a suspected or confirmed airborne infection. It is a room with \geq 12 air changes per hour (ACH) and controlled direction of air flow with negative differential pressure of > -2.5 Pascal.

Air changes per hour (ACH): Refer to volume of air moved in one hour. One air change per hour in a room, home, or building means that all the air in that environment will be replaced in one hour

Anteroom: A small room leading from a corridor into patient or isolation room. Anteroom is used to further support the appropriate air-balance relative to the corridor. It is designed to provide an "air-lock" between the adjacent area and the patient or isolation room.

Antibiotic Resistant Organisms: Resistant organisms were defined as those organisms that were resistant to gentamicin and vancomycin or multiple-drug-resistant Gram-negative bacteria as well as methicillin-resistant *Staphylococcus aureus*.

Antiseptic: substance that prevents or arrests the growth or action of microorganisms by inhibiting their activity or by destroying them. The term is used especially for preparations applied topically to living tissue.

Asepsis: prevention of contact with microorganisms.

Autoclave: device that sterilizes instruments or other objects using steam under pressure. The length of time required for sterilization depends on temperature, vacuum, and pressure.

Bactericide: agent that kills bacteria.

Benchmark: A validated measure that may be used for comparison provided data are collected in the same way as that of the benchmark data. Benchmarks are used to compare HAI rates to data that use the same definitions for infection and are appropriately adjusted for patient risk factors so that meaningful comparisons can be made. Comparing HAI rates to a validated benchmark will indicate whether the rates are below or above the recognized average.

Bioburden: number and types of viable microorganisms with which an item is contaminated; also called *bioload* or *microbial load*.

Biofilm: accumulated mass of bacteria and extracellular material that is tightly adhered to a surface and cannot be easily removed.

Biologic indicator: device for monitoring the sterilization process. The device consists of a standardized, viable population of microorganisms (usually bacterial spores) known to be resistant to the sterilization process being monitored. Biologic indicators are intended to demonstrate whether conditions were adequate to achieve

sterilization. A negative biologic indicator does not prove that all items in the load are sterile or that they were all exposed to adequate sterilization conditions.

Bleach: Household bleach (5.25% or 6.00%–6.15% sodium hypochlorite depending on manufacturer) usually diluted in water at 1:10 or 1:100. Approximate dilutions are 1.5 cups of bleach in a gallon of water for a 1:10 dilution (~6,000 ppm) and 0.25 cup of bleach in a gallon of water for a 1:100 dilution (~600 ppm).

Bleach Solution	Dilution	Chlorine (ppm)
5.25-6.15%	None	52,500-61,500
	1:10	5,250-6,150
	1:100	525-615
	1:1000	53-62

Bloodborne pathogen: Pathogenic microorganisms that are transmitted via human blood and cause disease in humans. They include, but are not limited to, hepatitis B virus (HBV) and human immunodeficiency virus (HIV). Although a number of pathogens can be transmitted percutaneously, HIV-1 remains the most common

Bowie-Dick test: diagnostic test of a sterilizer's ability to remove air from the chamber of a prevacuum steam sterilizer. The air-removal or Bowie-Dick test is not a test for sterilization.

Ceiling limit: concentration of an airborne chemical contaminant that should not be exceeded during any part of the workday. If instantaneous monitoring is not feasible, the ceiling must be assessed as a 15-minute time-weighted average exposure.

Central processing or **Central service department**: the department within a health-care facility that processes, issues, and controls professional supplies and equipment, both sterile and non-sterile, for some or all patient-care areas of the facility.

Challenge test pack: pack used in installation, qualification, and ongoing quality assurance testing of health-care facility sterilizers.

Chemical indicator: device for monitoring a sterilization process. The device is designed to respond with a characteristic chemical or physical change to one or more of the physical conditions within the sterilizing chamber. Chemical indicators are intended to detect potential sterilization failures that could result from incorrect packaging, incorrect loading of the sterilizer, or malfunctions of the sterilizer. The "pass" response of a chemical indicator does not prove the item accompanied by the indicator is necessarily sterile. The Association for the Advancement of Medical Instrumentation has defined five classes of chemical indicators: Class 1 (process indicator); Class 2 (Bowie-Dick test indicator); Class 3 (single-parameter indicator); Class 4 (multi-parameter indicator); and Class 5 (integrating indicator).

Cleaning: removal, usually with detergent and water or enzyme cleaner and water, of adherent visible soil, blood, protein substances, microorganisms and other debris from the surfaces, crevices, serrations, joints, and lumens of instruments, devices, and equipment by a manual or mechanical process that prepares the items for safe handling and/or further decontamination.

Contact time: time a disinfectant is in direct contact with the surface or item to be disinfected. For surface disinfection, this period is framed by the application to the surface until complete drying has occurred.

Container system, rigid container: sterilization containment device designed to hold medical devices for sterilization, storage, transportation, and aseptic presentation of contents.

Contaminated: state of having actual or potential contact with microorganisms. As used in health care, the term generally refers to the presence of microorganisms that could produce disease or infection.

Cough etiquette: Terms used to describe infection prevention measures to decrease the transmission of respiratory illness (e.g. influenza and cold viruses).

Decontamination: "the use of physical or chemical means to remove, inactivate, or destroy bloodborne pathogens on a surface or item to the point where they are no longer capable of transmitting infectious particles and the surface or item is rendered safe for handling, use, or disposal" In health-care facilities, the term generally refers to all pathogenic organisms.

Decontamination area: area of a health-care facility designated for collection, retention, and cleaning of soiled and/or contaminated items.

Denominator: Represents the population at risk.

Detergent: cleaning agent that makes no antimicrobial claims on the label. They comprise a hydrophilic component and a lipo-philic component and can be divided into four types: anionic, cationic, amphoteric, and non-ionic detergents.

Disinfectant: usually a chemical agent (but sometimes a physical agent) that destroys disease-causing pathogens or other harmful microorganisms but might not kill bacterial spores. It refers to substances applied to inanimate objects.

Disinfection: thermal or chemical destruction of pathogenic and other types of microorganisms. Disinfection is less lethal than sterilization because it destroys most recognized pathogenic microorganisms but not necessarily all microbial forms (e.g. bacterial spores).

D value: time or radiation dose required to inactivate 90% of a population of the test microorganism under stated exposure conditions.

Endemic: The constant presence of a disease or infectious agent within a certain area.

Endoscope: an instrument that allows examination and treatment of the interior of the body canals and hollow organs.

Enzyme cleaner: a solution used before disinfecting instruments to improve removal of organic material (e.g. proteases to assist in removing protein).

Exposure time: period in a sterilization process during which items are exposed to the sterilant at the specified sterilization parameters. For example, in a steam sterilization process, exposure time is the period during which items are exposed to saturated steam at the specified temperature.

Fungicide: agent that destroys fungi (including yeasts) and/or fungal spores pathogenic to humans or other animals in the inanimate environment.

Germicide: agent that destroys microorganisms, especially pathogenic organisms. 2016 Draft for Consultation

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Hand hygiene: is the hygiene practices related to the administration of medicine and medical care that prevents or minimizes disease and the spreading of disease

Hand washing: The physical removal of microorganisms from the hands using soap (plain or antimicrobial) and running water.

Health Care-associated Infection (HAI): Infection acquired during the delivery of health care within a particular health care facility.

Health Care Facility: A set of physical infrastructure elements supporting the delivery of health-related services. A health care facility does not include a client/patient/resident's home or physician offices where health care may be provided.

Health Care Setting: Any location where health care is provided, including settings where emergency care is provided, hospitals, complex continuing care, rehabilitation hospitals, long-term care homes, mental health facilities, outpatient clinics, community health centres and clinics, physician offices, dental offices, offices of allied health professionals, public health clinics and home health care.

Hematopoietic stem cell transplantation (HSCT): Any transplantation of blood-or bone marrow-derived hematopoietic stem cells, regardless of donor type (e.g., allogeneic or autologous) or cell source (e.g., bone marrow, peripheral blood, or placental/umbilical cord blood); associated with periods of severe immunosuppression that vary with the source of the cells, the intensity of chemotherapy required, and the presence of graft versus host disease (MMWR 2000; 49: RR-10).

High-level disinfectant: agent capable of killing bacterial spores when used in sufficient concentration under suitable conditions. It therefore is expected to kill all other microorganisms.

Hospital disinfectant: disinfectant registered for use in hospitals, clinics, dental offices, and any other medical-related facility.

Hospital-wide Surveillance: All care areas are continuously and prospectively surveyed for all conditions or events of interest.

Implantable device: "device that is placed into a surgically or naturally formed cavity of the human body if it is intended to remain there for a period of 30 days or more"

Immunocompromised patients: Those patients whose immune mechanisms are deficient because of immunologic disorders (e.g., human immunodeficiency virus [HIV] infection, congenital immune deficiency syndrome, chronic diseases such as diabetes, cancer, emphysema, and cardiac failure) or immunosuppressive therapy (e.g., radiation, cytotoxic chemotherapy, anti-rejection medication, and steroids). Immunocompromised patients who are identified as high-risk patients have the greatest risk of infection caused by airborne or waterborne microorganisms. Patients in this subset include those who are severely neutropenic for prolonged periods of time (i.e., an absolute neutrophil count [ANC] of <500 cells/mL), allogeneic HSCT patients, and those who have received intensive chemotherapy (e.g., childhood acute myelogenous leukemia patients).

Immediate use steam sterilization (IUSS): process designed for the steam sterilization of unwrapped patient-care items for immediate use (or placed in a specially designed, covered, rigid container to allow for rapid penetration of steam).

Incidence Density: The measurement of new cases of infection (incidence) based on the time at risk in the patient population (e.g., length of stay in hospital, length of exposure to a device). An incidence density rate expresses the risk of infection in 'person time', or the amount of time that a person spends at risk.

Incidence Rate: A measurement of new cases of disease occurring within a population over a given period of time. The numerator is the number of new cases detected and the denominator is the initial population at risk for developing the particular infection or event during a given time frame.

Infection Risk: The probability that a patient/resident will acquire an infection based on the characteristics of the individual, the inherent risks associated with a procedure, or other factors that might put the individual at risk for a health careassociated infection.

Intermediate-level disinfectant: agent that destroys all vegetative bacteria, including tubercle bacilli, lipid and some nonlipid viruses, and fungi, but not bacterial spores.

Limited disinfectant: disinfectant registered for use against a specific major group of organisms (gram-negative or gram-positive bacteria). Efficacy has been demonstrated in laboratory tests against either *Salmonella choleraesuis* or *Staphylococcus aureus* bacteria.

Long-Term Care (LTC): A broad range of personal care, support and health services provided to people who have limitations that prevent them from full participation in the activities of daily living. The people who use long-term care services are usually the elderly, people with disabilities and people who have a chronic or prolonged illness.

Low-level disinfectant: agent that destroys all vegetative bacteria (except tubercle bacilli), lipid viruses, some nonlipid viruses, and some fungi, but not bacterial spores.

Mechanical indicator: devices that monitor the sterilization process (e.g. graphs, gauges, printouts).

Medical device: instrument, apparatus, material, or other article, whether used alone or in combination, including software necessary for its application, intended by the manufacturer to be used for human beings for diagnosis, prevention, monitoring treatment, or alleviation of disease.

Micro-organism: A microscopic organism which includes bacteria, viruses, fungi,algae and protozoa.

Minimum effective concentration (MEC): the minimum concentration of a liquid chemical germicide needed to achieve the claimed microbicidal activity as determined by dose-response testing. Sometimes used interchangeably with *minimum recommended concentration*.

Mycobacteria: bacteria with a thick, waxy coat that makes them more resistant to chemical germicides than other types of vegetative bacteria.

National Healthcare Safety Network (NHSN): A project of the Centers for Disease Control and Prevention that provides aggregate data compiled since 1992 from 300 U.S. acute care settings. NHSN HAI rates may be used for benchmarking acute care HAI rates, provided that the same standardized definitions for infection are used.

NHSN results are stratified by patient risk index. More information is available at: http://www.cdc.gov/nhsn/.

NHSN SSI Risk Index: A score used to predict a patient's risk of acquiring a surgical site infection. The risk index score, ranging from 0 to 3, indicates the number of infection risk factors present. One point is scored for each of the following: a) a patient with an American Society of Anesthesiologists' (ASA) physical status classification score of 3, 4, or 5; b) an operation classified as contaminated or dirty/infected; and c) an operation lasting greater than *T* hours, where *T* is the recommended average operation length of time assigned to the operation being performed.

Numerator: Each event/infection that occurs during the surveillance period.

One-step disinfection process: simultaneous cleaning and disinfection of a noncritical surface or item.

Outbreak: For the purposes of this document, an outbreak is an increase in the number of cases above the number normally occurring in a particular health care setting over a defined period of time.

Outcome surveillance: Surveillance used to measure client/patient/resident outcomes (changes in the client/patient/resident's health status that can be attributed to preceding care and service). An example of outcome surveillance related to infection prevention and control is surveillance of HAI rates. Outcome surveillance reflects the efficacy of the infection prevention and control program in protecting clients/patients/residents, health care providers and visitors from health care-associated infections while decreasing costs from infections.

Parametric release: declaration that a product is sterile on the basis of physical and/or chemical process data rather than on sample testing or biologic indicator results.

Parts per million (ppm): common measurement for concentrations by volume of trace contaminant gases in the air (or chemicals in a liquid); 1 volume of contaminated gas per 1 million volumes of contaminated air equal 1 ppm. Parts per million = μ g/mL or mg/L.

Pasteurization: process developed by Louis Pasteur of heating milk, wine, or other liquids to 65–77°C (or the equivalent) for approximately 30 minutes to kill or markedly reduce the number of pathogenic and spoilage organisms other than bacterial spores.

Patient/resident: Any person receiving care within a hospital or long-term care home.

Permissible exposure limit (PEL): time-weighted average maximum concentration of an air contaminant to which a worker can be exposed, according to OSHA standards. Usually calculated over 8 hours, with exposure considered over a 40-hour work week.

Personal protective equipment (PPE): specialized clothing or equipment worn by staff for protection against a hazard.

Protective Environment (PE): PE is a specialized patient-care area, usually in a hospital, with a positive airflow relative to the corridor (i.e., air flows from the room to the outside adjacent space). The combination of HEPA filtration, high numbers of air changes per hour (>12 ACH), and minimal leakage of air into the room creates an 2016 Draft for Consultation 319

environment that can safely accommodate patients who have undergone allogeneic hematopoietic stem cell transplant (HSCT) or patients with absolute neutrophil count <500 cells/mL.

Prions: transmissible pathogenic agents that cause a variety of neurodegenerative diseases of humans and animals, including sheep and goats, bovine spongiform encephalopathy in cattle, and Creutzfeldt-Jakob Disease (CJD) in humans. They are unlike any other infectious pathogens because they are composed of an abnormal conformational isoform of a normal cellular protein, the prion protein (PrP). Prions are extremely resistant to inactivation by sterilization processes and disinfecting agents.

Process challenge device (PCD): item designed to simulate product to be sterilized and to constitute a defined challenge to the sterilization process and used to assess the effective performance of the process. A PCD is a challenge test pack or test tray that contains a biologic indicator, a Class 5 integrating indicator, or an enzyme-only indicator.

Recommended exposure limit (REL): occupational exposure limit recommended by NIOSH as being protective of worker health and safety over a working lifetime. It is frequently expressed as a 40-hour time-weighted-average exposure for up to 10 hours per day during a 40-work week.

Reprocess: method to ensure proper disinfection or sterilization; can include: cleaning, inspection, wrapping, sterilizing, and storing.

Risk Stratification: This refers to a process to control for differences in the underlying risk factors for infection. Risk stratification involves calculating separate

rates for patients/residents with similar susceptibilities to health care-associated infections, or those in the same category of risk (e.g., surgeon-specific infection rates).

Severely Immunocompromised Patient: Patients who have undergone allogeneic hematopoietic stem cell transplant (HSCT) or absolute neutrophil count [ANC] of <500 cells/mL.

Shelf life: length of time an undiluted or use dilution of a product can remain active and effective. Also refers to the length of time a sterilized product (e.g. sterile instrument set) is expected to remain sterile.

Spaulding classification: strategy for reprocessing contaminated medical devices. The system classifies a medical device as critical, semi-critical, or non-critical on the basis of risk to patient safety from contamination on a device. The system also established three levels of germicidal activity (sterilization, high-level disinfection, and low-level disinfection) for strategies with the three classes of medical devices (critical, semi-critical, and non-critical).

Spore: 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 disinfectant and sterilant activity and drying conditions (specifically in the genera *Bacillus* and *Clostridium*).

Spore strip: paper strip impregnated with a known population of spores that meets the definition of biological indicators.

Steam quality: steam characteristic reflecting the dryness fraction (weight of dry steam in a mixture of dry saturated steam and entrained water) and the level of

noncondensable gas (air or other gas that will not condense under the conditions of temperature and pressure used during the sterilization process). The dryness fraction (i.e., the proportion of completely dry steam in the steam being considered) should not fall below 97%.

Steam sterilization: sterilization process that uses saturated steam under pressure for a specified exposure time and at a specified temperature, as the sterilizing agent.

Steam sterilization, dynamic air removal type: one of two types of sterilization cycles in which air is removed from the chamber and the load by a series of pressure and vacuum excursions (prevacuum cycle) or by a series of steam flushes and pressure pulses above atmospheric pressure (steam-flush-pressure-pulse cycle).

Sterile or **Sterility**: state of being free from all living microorganisms. In practice, usually described as a probability function, e.g. as the probability of a microorganism surviving sterilization being one in one million.

Sterility assurance level (SAL): probability of a viable microorganism being present on a product unit after sterilization. Usually expressed as 10–6; a SAL of 10-6 means \leq 1/1 million chance that a single viable microorganism is present on a sterilized item. A SAL of 10-6 generally is accepted as appropriate for items intended to contact compromised tissue (i.e., tissue that has lost the integrity of the natural body barriers). The sterilizer manufacturer is responsible for ensuring the sterilizer can achieve the desired SAL. The user is responsible for monitoring the performance of the sterilizer to ensure it is operating in conformance to the manufacturer's recommendations. **Sterilization**: validated process used to render a product free of all forms of viable microorganisms. In a sterilization process, the presence of microorganisms on any individual item can be expressed in terms of probability. Although this probability can be reduced to a very low number, it can never be reduced to zero.

Sterilization area: area of a health-care facility designed to house sterilization equipment, such as steam ethylene oxide, hydrogen peroxide gas plasma, or ozone sterilizers.

Sterilizer: apparatus used to sterilize medical devices, equipment, or supplies by direct exposure to the sterilizing agent.

Sterilizer, gravity-displacement type: type of steam sterilizer in which incoming steam displaces residual air through a port or drain in or near the bottom (usually) of the sterilizer chamber. Typical operating temperatures are 121–123°C and 132–135°C.

Sterilizer, prevacuum type: type of steam sterilizer that depends on one or more pressure and vacuum excursions at the beginning of the cycle to remove air. This method of operation results in shorter cycle times for wrapped items because of the rapid removal of air from the chamber and the load by the vacuum system and because of the usually higher operating temperature (132–135°C; 141–144°C). This type of sterilizer generally provides for shorter exposure time and accelerated drying of fabric loads by pulling a further vacuum at the end of the sterilizing cycle.

Sterilizer, steam-flush pressure-pulse type: type of sterilizer in which a repeated sequence consisting of a steam flush and a pressure pulse removes air from the sterilizing chamber and processed materials using steam at above atmospheric *2016 Draft for Consultation* 323

pressure (no vacuum is required). Like a prevacuum sterilizer, a steam-flush pressure-pulse sterilizer rapidly removes air from the sterilizing chamber and wrapped items; however, the system is not susceptible to air leaks because air is removed with the sterilizing chamber pressure at above atmospheric pressure. Typical operating temperatures are 121–123°C, 132–135°C, and 141–144°C).

Surveillance: The systematic, on-going collection, collation and analysis of data with timely dissemination of information to those who require it in order to take action.

Tabletop steam sterilizer: a compact gravity-displacement steam sterilizer that has a chamber volume of not more than 0.06 cubic meter and that generates its own steam when distilled or deionized water is added.

Targeted Surveillance: Surveillance that is focused on certain health care setting areas (e.g., intensive care unit), patient populations (e.g., surgical patients) and/or infection types (e.g., bloodstream infections, indwelling catheter-associated urinary tract infections), that have been identified as a priority within the health care setting.

Vegetative bacteria: bacteria that are devoid of spores and usually can be readily inactivated by many types of germicides.
Strength of Each Recommendation:

for use
for use

- **B** Moderate evidence to support a recommendation for use
- **C** Insufficient evidence to support a recommendation for or against use
- **D** Moderate evidence to support a recommendation against use
- **E** Good evidence to support a recommendation against use

Quality of evidence for each recommendation:

- I Evidence from at least one properly randomized, controlled trial
- II Evidence from at least one well-designed clinical trial without randomization, from cohort or case-controlled analytic studies, preferably from more than one centre, from multiple time series, or from dramatic results in uncontrolled experiments
- III Evidence from opinions of respected authorities on the basis of clinical experience, descriptive studies, or reports of expert committees

Appendix 1Hand Hygiene Technique with Alcohol-basedFormulation



Appendix 2 Hand Hygiene Technique with Soap and Water



Appendix 3 Surgical Handrub Technique

2

The handrubbing technique for surgical hand preparation must be performed on perfectly clean, dry hands. On arrival in the operating theatre and after having donned theatre clothing (cap/hat/bonnet and mask), hands must be washed with soap and water.

After the operation when removing gloves, hands must be rubbed with an alcohol-based formulation or washed with soap and water if any residual talc or biological fluids are present (e.g. the glove is punctured).

Surgical procedures may be carried out one after the other without the need for handwashing, provided that the handrubbing technique for surgical hand preparation is followed (Images 1 to 17).



Put approximately 5ml (3 doses) of alcohol-based handrub in the palm of your left hand, using the elbow of your other arm to operate the dispenser



Dip the fingertips of your right hand in the handrub to decontaminate under the nails (5 seconds)



Images 3–7: Smear the handrub on the right forearm up to the elbow. Ensure that the whole skin area is covered by using circular movements around the forearm until the handrub has fully evaporated (10-15 seconds)

3



See legend for Image 3



See legend for Image 3



See legend for Image 3

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Put approximately 5ml (3 doses) of alcohol-based handrub in the palm of your right hand, using the elbow of your other arm to operate the dispenser



Dip the fingertips of your left hand in the handrub to decontaminate under the nails (5 seconds)



Smear the handrub on the left forearm up to the elbow. Ensure that the whole skin area is covered by using circular movements around the forearm until the handrub has fully evaporated (10-15 seconds)

10



Put approximately 5ml (3 doses) of alcohol-based handrub in the palm of your left hand, using the elbow of your other arm to operate the distributor. Rub both hands at the same time up to the wrists, and ensure that all the steps represented in Images 12-17 are followed (20-30 seconds)



Cover the whole surface of the hands up to the wrist with alcohol-based handrub, rubbing palm against palm with a rotating movement



Rub the back of the fingers by holding them in the palm of the other hand with a sideways back and forth movement the wrist, moving the right palm back and forth, and vice-versa



Rub the thumb of the left hand by rotating it in the clasped palm of the right hand and vice versa



When the hands are dry, sterile surgical clothing and gloves can be donned

Repeat the above-illustrated sequence (average duration, 60 sec) according to the number of times corresponding to the total duration recommended by the manufacturer for surgical hand preparation with an alcohol-based handrub.

Appendix 4General Recommendation for PerformingHand Hygiene Auditing

General recommendation for performing hand hygiene auditing

- The session should last no more than 20 minutes (± 10 minutes according to the observed activity
- The observer may observe up to three health-care workers simultaneously, if the density of hand hygiene opportunities permits.
- Auditing should be unannounced and anonymous.
- Stratification of healthcare workers to be audited is based on the proportion of the institution workforce (representative in term of professional categories and setting); for example, if the nurses make-up 60% of the hospital workforce, you will need to audit 120 opportunities out of 200 opportunities (if set target is 200 opportunities) under the nurses category.

Professional categories:	According to the following classification:				
1. Nurse / midwife	1.1 nurse, 1.2 midwife, 1.3 student.				
2. Medical doctor					
3. Ancillary	3.1 healthcare assistant, 3.2 patient care assistant, 3.3 environmental services, 3.4 porter				
4. Allied health	d 4.1 therapist (physiotherapist, occupational therapist, audiologist, speech therapist), 4.2 technician (radiologist, cardiology technician, operating room technician, laboratory technician, etc), 4.3 other (dietician, dentist, social worker and any other health-related professional involved in patient care)				
Opportunity:	defined by one indication at least				
Indication:	reason(s) that motivate(s) hand hygiene action				
	before touching a patient	after body fluid exposure risk			
	before clean/aseptic procedure	after touching a patient			

		after surround	touching lings	patient
Hand hygiene action:	response to the hand hygiene indic action by performing handrub or h missing handrub or handwash	() ·		•

- The observation period is defined as the time window during which compliance is measured in a certain setting; for example, on a monthly basis (based on the institution needs).
- Understanding the five moments with care sequence:

The sequence of healthcare actions delivered to a single patient or to several patients can lead to a number of hand hygiene indications occurring simultaneously. This does not mean that each indication requires a separate hand hygiene action. One hand hygiene action is justified by the indication that immediately precedes or follows a sequence of two or more contacts; a single hand hygiene action is enough to prevent all risk of microbial transmission.

A single hand hygiene action is required with two indications



• Compliance with hand hygiene is the ratio of the number of performed actions to the number of opportunities and is expressed by the following formula:

Compliance (%) = Performed actions divided by opportunities X 100

Appendix 5 Recommended Design Parameters

Table 1Design parameters (ANSI/ASHRAE/ASHE standard 170-2008)

Location	Pressure relationsh ip to adjacent areas	Minimum outdoor ACH	Minimum total ACH	All room air exhauste d directly to outdoors	Air recirculat ed by means of room units	Relative humidity (%)	Temperat ure (⁰ C)
Decontami nation room	Negative	2	6	Yes	No	No requireme nt	22-26
Clean workroom	Positive	2	4	No requireme nt	No	No requireme nt	22-26
Sterile storage	Positive	2	4	No requireme nt	No requireme nt	Maximum 60	22-26
Sterilizer equipment room	Negative	No requireme nt	10	Yes	No	No requireme nt	No requireme nt

Table 2High-level chemical disinfectants or sterilants (Reference: CDC
Guideline for Disinfection and Sterilization in Healthcare Facilities,
2008)

	High level disinfection claim	Sterilization claim
Hydrogen peroxide 7.5%	30 mins at 20°C	6 hours at 20°C
Peracetic acid 0.2%	NA	12 mins at 50-56°C
Glutaradehyde ≥2%	20-90 mins at 20-25°C	10 hours at 20-25°C
Ortho-phthalaldehyde 0.55% (OPA)	5 mins at 20°C, 5 mins at 25°C in AER	None
Hydrogen peroxide / peracetic acid (7.35% / 0.23%)	15 mins at 20°C	3 hours at 20°C

Appendix 6 Infection Prevention Risk Assessment Matrix of Precautions for Construction and Renovation

Step One:

Using the following table, identify the Type of Construction Project Activity (Type A-

D)

	Inspection and Non-Invasive Activities			
	Includes, but is not limited to:			
ΤΥΡΕ Α	 removal of ceiling tiles for visual inspection limited to one tile per 50 square feet 			
	 painting (but not sanding) wall covering, electrical trim work, minor plumbing, and activities which do not generate dust or require cutting of walls or access to ceilings other than for visual inspection 			
	Small scale, short duration activities which create minimal dust			
TYPE B	Includes, but is not limited to:			
	 installation of telephone and computer cabling 			
	 access to chase spaces cutting of walls or ceiling where dust migration can be controlled 			
	Work that generates a moderate to high level of dust or requires demolition of any fixed building components or assemblies			
	Includes, but is not limited to:			
TYPE C	 sanding of walls for painting or wall covering 			
	 removal of floorcoverings, ceiling tiles, and casework new wall construction 			
	 minor duct work or electrical work above ceilings 			
	 major cabling activities 			
	 any activity which cannot be completed within a single workshift 			
	Major demolition and construction projects			
TYPE D	Includes, but is not limited to:			
	 activities which require consecutive work shifts requires heavy demolition or removal of a complete cabling system new construction 			

Step Two:

Using the following table, *identify* the Patient Risk Groups that will be affected. If more than one risk group will be affected, select the higher risk group:

LOW RISK	MEDIUM RISK	HIGH RISK	HIGHEST RISK
 Office areas 	 Cardiology Echocardiography Endoscopy Nuclear Medicine Physical Therapy Radiology/MRI Respiratory Therapy Dental Office 	 CCU Emergency Room Labor & Delivery Laboratories (specimen) Newborn Nursery Outpatient Surgery Paediatrics Pharmacy Post Anaesthesia Care Unit Surgical Units 	 Any area caring for immunocompromise d patients Burn Unit Cardiac Catheterization Lab Central Sterile Supply Intensive Care Units Medical Unit Negative pressure isolation rooms Oncology Operating rooms including C-section rooms

INFECTION PREVENTION RISK GROUPS

Step Three: Match the

- Patient Risk Group (Low, Medium, High, Highest) with the planned...
- Construction Project Type (A, B, C, D) on the following matrix, to find the...
- Class of Precautions (I, II, III or IV) or level of infection prevention activities required.

Class I-IV or Color-Coded Precautions are delineated on the following page.

IC Matrix - Class of Precautions: Construction Project by Patient Risk

	CO	NSTRUCTION	PROJECT TY	(PE
PATIENT RISK GROUP	TYPE	TYPE	TYPE	TYPE
	A	B	C	D

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LOW Risk Group	I	II	II	III/IV
MEDIUM Risk Group	I	II		IV
HIGH Risk Group	I	II	III/IV	IV
HIGHEST Risk Group	II	III/IV	III/IV	IV

	1. Execute work by methods to minimize raising dust from construction
CLASSI	operations.
CL	2. Immediately replace a ceiling tile displaced for visual inspection.
	1. Provide active means to prevent airborne dust from dispersing into
	atmosphere.
	2. Water mist work surfaces to control dust while cutting.
s=	3. Seal unused doors with duct tape.
CLASS II	4. Block off and seal air vents.
	5. Place dust mat at entrance and exit of work area.
	6. Remove or isolate HVAC system in areas where work is being
	performed.

	1.	Remove or isolate HVAC system in area where work is being done to
		prevent contamination of duct system.
	2.	Complete all critical barriers i.e., sheetrock, plywood, plastic, to seal
		area from non-work area or implement control cube method (cart with
		plastic covering and sealed connection to work site with HEPA vacuum
CLASS III		for vacuuming prior to exit) before construction begins.
CLA	3.	Maintain negative air pressure within work site utilizing HEPA equipped
		air filtration units.
	4.	Contain construction waste before transport in tightly covered
		containers.
	5.	Cover transport receptacles or carts. Tape covering unless solid lid.
	5.	Cover transport receptacies or carts. Tape covering unless solid lid.

	1.	Isolate HVAC system in area where work is being done to prevent
		contamination of duct system.
	2.	Complete all critical barriers i.e. sheetrock, plywood, plastic, to seal area
		from non work area or implement control cube method (cart with plastic
		covering and sealed connection to work site with HEPA vacuum for
		vacuuming prior to exit) before construction begins.
	3.	Maintain negative air pressure within work site utilizing HEPA equipped
		air filtration units.
>	4.	Seal holes, pipes, conduits, and punctures appropriately.
CLASS IV	5	Construct anteroom and require all personnel to pass through this room
CLA		so they can be vacuumed using a HEPA vacuum cleaner before leaving
		work site or they can wear cloth or paper coveralls that are removed
		each time they leave the work site.
	6.	All personnel entering work site are required to wear shoe covers. Shoe
		covers must be changed each time the worker exits the work area.
	7.	Do not remove barriers from work area until completed project is
		inspected by the owner's Safety Department and infection prevention
		Department and thoroughly cleaned by the owner's Environmental
		Services Department.
		covers must be changed each time the worker exits the work area. Do not remove barriers from work area until completed project inspected by the owner's Safety Department and infection preventio Department and thoroughly cleaned by the owner's Environmenta

Step 4: Identify the areas	surrounding the project area,	assessing potential impact

Unit Below	Unit Above	Lateral	Lateral	Behind	Front
Risk Group					

Step 5: Identify specific site of activity, e.g., patient rooms, medication room, etc.

Step 6: Identify issues related to: ventilation, plumbing, electrical in terms of the occurrence of probable outages.

Step 7: Identify containment measures, using prior assessment. What types of barriers? (e.g., solids wall barriers); will HEPA filtration be required?

(Note: Renovation/construction area shall be isolated from the occupied areas during construction and shall be negative with respect to surrounding areas)

Step 8: Consider potential risk of water damage. Is there a risk due to compromising structural integrity? (e.g., wall, ceiling, roof)

Step 9: Work hours: Can or will the work be done during non-patient care hours?

Step 10: Do plans allow for adequate number of isolation/negative airflow rooms? 2016 Draft for Consultation

Step 11: Do the plans allow for the required number and type of handwashing sinks?

Step 12: Does the infection prevention staff agree with the minimum number of sinks for this project? (Verify against AIA Guidelines for types and area.)

Step 13: Does the infection prevention staff agree with the plans relative to clean and soiled utility rooms?

Step 14: Plan to discuss the following containment issues with the project team, e.g., traffic flow, housekeeping, debris removal (how and when).

Appendix: Identify and communicate the responsibility for project monitoring that includes infection prevention concerns and risks. The ICRA may be modified throughout the project. Revisions must be communicated to the Project Manager.

Steps 1-3 Adapted with permission V. Kennedy, B. Barnard, St Luke Episcopal Hospital. Houston TX; C Fine, CA Steps 4-14 Adapted with permission Fairview University Medical Center, Minneapolis MN. Forms modified and provided courtesy of J. Bartley, ECS, Inc., Beverly Hills MI 2002 2016 Draft for Consultation 339

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