



INFECTION CONTROL AUDIT (ICA) TOOL

GUIDELINES FOR HEALTHCARE PROFESSIONALS

(Version 1: January 2020)

الإدارة العامة لمكافحة عدوى المنشآت الصحية

General Directorate of Infection Prevention & Control

(GDIPC)

بِسْمِ اللَّهِ الرَّحْمَنِ الرَّحِيمِ

MESSAGE FROM GENERAL DIRECTOR

Compliance of healthcare facilities in implementing effective infection control measures is vital for patient, visitor and staff safety. One tool to assess the proper implementation infection control measures in clinical areas is the Infection Control Audit in a standardized methodology.

This manual serves as a guide for auditors to assess the facility in infection control. The manual consists of several standards and sub-standards that reflect current guidelines and good practice in infection prevention and control within a healthcare environment.

To ensure that IPC standards are met, as well as ensuring that the quality of the infection control practice within institutions are of a high standard, Ministry of Health conducts continuous auditing visits by qualified auditors.

The audit report and its recommendations help to ensure that practices improve their compliance to infection prevention and control according to current national guidelines and should serve as a useful reference point. Therefore, it is essential that this report and its recommendations is given consideration and that the action plan which outlines how the practice plan to address the issues highlighted is completed and returned appropriately as advised.

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TABLE OF CONTENTS

1. HOSPITAL LEADERSHIP SUPPORT	2
2. INFECTION CONTROL DEPARTMENT	7
3. INFECTION CONTROL COMMITTEE	15
4. INFECTION CONTROL PROGRAM	24
5. INFECTION CONTROL ANNUAL PLAN	34
6. INFECTION CONTROL MANUAL (IC POLICIES & PROCEDURES)	42
7. INFECTION CONTROL EDUCATION & TRAINING	47
8. HAND HYGIENE	50
9. PERSONAL PROTECTIVE EQUIPMENT (PPE)	64
10. ISOLATION PRECAUTIONS	73
11. ASEPTIC TECHNIQUE	86
12. MERS-COV	108
13. EMPLOYEE HEALTH PROGRAM	124
14. OUTBREAK MANAGEMENT	146
15. ANTIMICROBIAL RESISTANCE PROGRAM (AMR) /ANTIMICROBIAL STEWARDSHIP PROGRAM (ASP)	154
16. HOUSEKEEPING & HOSPITAL ENVIRONMENT	173
17. INFECTIOUS MEDICAL WASTE	182
18. MEDICAL DEPARTMENTAL STORES	198
19. CONSTRUCTION & RENOVATION	203
20. CLEANING / DISINFECTION OF MEDICAL EQUIPMENT	214
21. DISINFECTANTS & ANTISEPTICS SUPPLIES	217
22. SINGLE USE DEVICE (SUD)	219
23. HAIS SURVEILLANCE	220
24. STANDARD: PATIENT'S CARE BUNDLES FOR PREVENTION OF HAIS & MDROS	242
25. HAEMODIALYSIS UNIT (HD)	270
26. COMPOUND STERILE PREPARATION (CSP) IN THE PHARMACY	297
27. OPERATING ROOM (OR)	307
28. LABORATORY	315
29. DENTAL	325
30. DIETRY SERVICES	341
31. LAUNDRY	359
32. THE MORTUARY	367

1

HOSPITAL LEADERSHIP SUPPORT

1

Sub-standard – 1:01

Adequate resources are allocated to infection control Department (e.g., offices, internet access, IT support ...etc.) **(O,SI)**

Observation
(O)

Observe:

1. Availability of separate Infection control office with provision of all required resources. *(Computers, printers, reliable internet service etc.)*
2. The number of computers provided for the IC department and match with the number of Infection control preventionists working in the unit. *(Ideally, each ICP has a separate computer with internet connection. But if separate computer not provided for each ICP, would be considered fully compliant if it's not interfering with continuity of work)*

Staff Interview
(SI)

Interview:

1. IPC team if their requests and needs are always considered and provided by the leadership personnel and the high officials.
2. The staff about the speed and reliability of internet service and **backup plan** to ensure the continuity of work if there is no availability of internet service / system is down.
3. Randomly ask staff to access HESN website to check the speed & reliability of provided internet service.
4. Ask staff about IT support & troubleshooting time i.e. IT department has good response to them when needed.
5. Ask about access to **patients & lab data** (If hospital has electronic filing system)

2

Sub-standard – 1:02

Adequate infection control supplies are provided to HCWs for successful IC program (e.g., PPE, disinfectants ...etc.)(D,O,SI)

Document
(D)

Review the following:

1. Plan for continuous supply of PPE.
2. PPE checklist for monitoring consumption.
3. Electronic database / Excel spreadsheets as a mechanism of monitoring consumption of IC supply & to ensure adequacy.
4. The documented supply chain / flowchart describing mechanism of supply request from units.
5. Review if contingency / emergency plan is incorporated to address the shortage in outbreak situations in order to ensure continuous supply of PPE, disinfectants & other IC supply. *(E.g. Direct purchase, contract with neighboring hospitals, emergency stock not used in routine etc.*
(Rationale: In outbreak situations there is increased consumption of IC supply including PPE, hand sanitizers, disinfectants etc. so there should be a clear plan to address increased demand in such unforeseen situations).
6. Check the supply chain follow up in the hospital departments especially when the supplies reaching the PAR stock level. **(PAR: Periodic Automatic Replenishment.)**
*(PAR level is PAR level is the minimum quantity of an item stocked, which will be automatically
be automatically reordered, should the level fall below a preset level.)*

Observation
(O)

Observe:

- ❖ Observe the availability of infection control resources and supplies including **PPEs** *(Gowns - clean, sterile) gloves, (clean, sterile) face shields / eye goggles, Surgical masks, different sizes of N-95 masks, disinfectants, Hand rub dispensers, waste receptacles, sharp containers etc. in all units.*

(Randomly open the hand rub dispenser to check for availability of hand sanitizers & if date is valid or expired)

Staff Interview
(SI)

Interview:

1. Interview the IC team / supply in charge about the process of replenishment, maintenance and first-time request of supplies, when and where needed.
2. Investigate the shortage with the person in charge, when it is clearly observed.
3. Ask the staff about the mechanism how the stock will be requested what the alternate back is up if not available in main hospital store.

3

Sub-standard – 1:03

Infection control team is given full authority to implement the Infection Control (IC) policies & procedures. (D,SI)

Document
(D)

Review:

1. Statement of authority approved by the hospital director or hospital infection control committee.
2. This statement of authority is reviewed and authenticated by the administration of the institution at least every three years or sooner, as per policy.
3. All policies & procedures are established by infection control team.
4. Check for availability of authority statement or **MEMO** circulated by top administration office to all **units** stating authorization of IC team with regard to infection control practices.

The Director of the Infection Prevention and Control Program has the responsibility and authority to establish policies and procedures for the instruction of its personnel and for the overall supervision of infection prevention and control activities in its facilities.

Staff Interview
(SI)

Interview:

1. IC Team members if they have been given the appropriate attention & respect by the heads of other departments during daily rounds, training & education activities etc..
2. IC team regarding the authority to make decisions and to influence field implementation.
3. If the IPC department has been well understood and directly acted upon its comments, remarks, recommendations and commands.
4. Moreover, heads of the departments are continuously working on IPC improvements & corrective actions if any breach of IC practice has been communicated to them based on internal & external audit findings.
5. If HCWs simply obey, any order or command coming from the infection control personnel through any means, even if it is verbal command in matters related to infection control.

4

Sub-standard – 1:04

Hospital leaders support IC personnel supervision when some functions are outsourced (e.g. laundry or dietary services) (D,SI)

Review the following documents:

1: Contract of outsourced laundry service:

- Check for validity and accuracy of contract with clear description of policies of the related out sourced service. ***(Most common outsourced functions are laundry, dietary service and CSSD in some hospitals etc..)***
- For instance if Laundry service is outsourced, check the contract incorporating details of the collection & transportation of the soiled and clean linen including transportation carts, frequency of linen collection, processing of linen with temperature specifications & disinfectants to be used & frequency of inspection visits by hospital IC team etc..

2: Inspection visit checklists / tools:

- Review the checklist incorporating all details of IC measures in the relevant outsourced service (Laundry, kitchen etc.) based on the referenced guidelines (MOH, CDC etc..)
- Laundry checklist should contain important items like policies & procedures, direction of workflow, availability of hand hygiene facilities, washing cycles: high temperature wash cycle

(Water temperature is at a minimum of 71°C for 25 minutes: heat disinfection), low temperature wash cycle, (22°C C-50°C), sodium hypochlorite is added as a disinfectant during bleach wash cycle. Etc.

3: Inspection visit report & action plan:

- Review the last 03 visits reports for all outsourced functions.
- Check if the report was sent to the outsourced service team & they responded with corrective action plan based on the findings of visit report.

Inspection / Audit visit should be conducted to outsourced laundry unit at least once in each quarter by IC Team in collaboration with environmental health team

Document
(D)

Staff Interview
(SI)

Interview:

- ❖ IC team with regard to outsourced service hospital policy with its implementation (monitoring of outsourced service by the hospital i.e. process, frequency of visits, etc.)
- ❖ Inquire IC team about needed leadership support if any major breaches has been observed in the outsourced service in repeated visits with no corrective action.

(An example of leadership support would be: Hospital director/ CEO would consider change of laundry company or catering company if the quality of processed linen or food quality is not up to the mark even if they have to pay high price).

REFERENCES / WEB BASED RESOURCES:

- 1) *GCC Infection Prevention & Control Manual 3rd Edition 2018 – Statement of authority ICM - I - 03 Page # 07*
- 2) *Joint Commission International Accreditation Standards for Hospitals, JCI 5th edition, April 2014. PCI.4 (Leadership support)*
- 3) *Core components for infection control prevention and control programmes Geneva: World Health Organization; 2009 ([http:// www.who.int/csr/resources/publications/WHO_HSE_EPR_2009_1/en/index.html](http://www.who.int/csr/resources/publications/WHO_HSE_EPR_2009_1/en/index.html), accessed 18 October 2016).*

INFECTION CONTROL DEPARTMENT

1

Sub-standard – 2:01

For hospitals ≥ 150 beds: the director of IC department is a full timer personnel qualified in infection control through certification, training AND experience for two years at least. (PF,SI)

Review the following documents in PF:

❖ Assignment Letter / Job Description:

1. Verify if the Infection Director is working full time by reviewing assignment letter from executive leadership & job description to review roles and responsibilities of IC director as full time.
2. **Infection Control Director will be considered working as FULL TIME in the infection control department only if the below mentioned criteria is fulfilled:**
3. Available and accessible at all time and dedicate 100% of working hours to infection control departmental activities.
4. IC Directors **DO NOT** hold any additional administrative tasks (e.g. Medical Director, etc.)
5. **ID consultants and Physicians** would be considered **FULL TIME** only if they spend **3 out of 5 working days** OR dedicate **70% of working hours** to the Infection control departmental activities with no additional tasks.

❖ CV, certificates & training evidence:

1. The personal file of the IC director to check for educational background. **(Physician, nurse, microbiologist, public health Specialist etc.)**
2. Check degrees / certifications in infection Control **(Masters in Infection Control, CIC, and Diploma in infection Control etc.)**
3. Attendance in training activities **(local, national, international conferences, workshops, seminars & symposiums etc.)**
4. Calculate total duration of experience in infection control from date of joining as IC Director. **(For IC director 02 years' experience is required)**
5. Experience and training of the IC director should match the services provided by the department and the duties and responsibilities of the position.

PERSONAL FILE
(PF)

Comments:

- *It is not mandatory for Infection Control Director to be a physician. As long as he / she is qualified based on abovementioned credentials and working full time this substandard would be fully met.*
- *Full timer is the one who has no additional assigned duties / Clinics other than Infection control.*

Interview:

1. IC Director to assess his / her knowledge and skills about infection control.
2. Ask about his involvement in development / review of policies and procedures.
3. Ask about role in surveillance activities and implementation of IC measures to assess his orientation about all areas of hospital.
4. Ask how the time is split among data management, policy & procedure development, education, employee health, quality improvement, program development, consulting & managing potential outbreaks etc.
5. During the entire audit visit, knowledge & orientation of IC director about IC activities will be indirectly assessed.

2

Sub-standard – 2:02

For hospitals < 150 beds: the director of IC department is a full timer personnel qualified in infection control through certification, training OR experience for two years at least. (PF,SI)

- ❖ Sub-standards – 2:01 & Sub-standard – 2:02 have similar assessment modes.
- ❖ For IC director of hospitals with bed capacity 150 & below, certification **OR** Training **OR** experience of 02 years is acceptable for the position of IC director if working full time.

3

Sub-standard – 2:03

The director of IC program reports directly to the highest administrative authority (General director or medical director of the hospital). (D)

Review:

1. Hospital **organization chart** for the reporting authority of the IC program director.

(Organogram should clearly delineate that IC director is directly reporting directly to top management and not to assistants / assigned designees, quality director or any other administrative personnel.

2. Ask for any **Request Letter** from Infection Control Director & check its addressed to whom. *(As per substandard any letter from IC Director should be directly addressed to highest administrative authority.*

4

Sub-standard – 2:04

At least one full time IC practitioner is assigned for every 100 regular beds including medical departments, surgical departments, dental units ...etc. (D,SI)

Review the following documents:

1. IPC department organizational chart.
2. Document stating bed capacity of hospital including emergency beds, dialysis beds / chairs, dental chairs, day cases, and others).
3. Compare number of ICPs with bed capacity and calculate the required number of ICPs as follows:
 - ❖ 001 – 100 beds : 1 ICP is needed
 - ❖ 101 – 200 beds : 2 ICPs are needed
 - ❖ 201 – 300 beds : 3 ICPs are needed
 - ❖ 301 – 400 beds : 4 ICPs are needed
 - ❖ 401 – 500 beds : 5 ICPs are needed & so on
4. Work schedule of ICPs for last 3 months to check allocation of ICPs as per requirement in all areas of hospital according to the scope of services.

Interview:

5. Staff about work distribution & responsibilities in the IC department.
6. Ask about duration of rotation in each assigned unit and daily activities. *(E.g. Hand hygiene observations, surveillance activities, monitoring & evaluation, education & training etc.)*

Document
(D)

Staff Interview
(SI)

5

Sub-standard – 2:05

An additional one IC practitioner / 30 beds in critical care units e.g., ICU, PICU, ER, burn unit ...etc.. (at least one) (D,SI)

Document
(D)

Review:

1. Organizational chart / Organogram of IC Department.
2. Document showing bed capacity of each critical care unit. (ER, PICU, NICU etc.)
Where ventilation and hemodynamic monitoring are routinely performed.
3. Match the requirement of additional ICPs with bed capacity of each critical care unit as follows:
 - a. < 30 beds : No additional ICP is needed
 - b. 30 – 59 beds : 1 additional ICP is needed
 - c. 60 – 89 beds : 2 additional ICPs are needed
 - d. 90 – 119 beds : 3 additional ICPs are needed & so on
4. Work schedule of ICPs for last 3 months to check allocation of ICPs as per requirement.

Staff Interview
(SI)

Interview:

1. Staff about work distribution & responsibilities related to critical care units. *(Rule out additional assigned tasks other than assigned critical care unit (if any))*
2. Ask about duration of rotation in critical care units and daily activities in the assigned unit & how they are managing activities *(HAIs Surveillance, Training & education, monitoring and observations etc.)*

6

Sub-standard – 2:06**An additional one IC practitioner / 120 dialysis patients per day (at least one) (D,SI)**Document
(D)**Review:**

1. Organizational chart / Organogram of IC Department.
 2. Document showing number of dialysis beds / chairs in Hemodialysis unit.
 3. Number of dialysis sessions done per day.
 4. Match the requirement of additional ICPs with number of dialysis patients dialyzed each day.
- ❖ < 120 dialysis patients per day (1- 119 sessions) : No additional ICP is needed
 - ❖ 120 dialysis patients per day (120 & above) : An additional ICP is needed

Staff Interview
(SI)**Interview:**

1. ICP about distribution of work and responsibilities in the hemodialysis unit. (**Rule out additional assigned tasks other than dialysis unit (if any)**)
2. Ask about duration of rotation in the dialysis unit and number of dialysis sessions per day and how they are managing activities inside unit (**DE Surveillance, training & education, monitoring & evaluation etc.)**)

Comment (if any):**Example 1:****Bed capacity of Hospital "A" = 560 beds**

Adult ICU = 45 beds

PICU = 15 Beds

NICU = 30 beds

ER = 20 beds

Hemodialysis unit = 80 beds (Working in 02 shifts) 160 dialysis sessions per day

What is the required number of ICPs? *Refer to substandards 2.02, 2.03, & 2.04***Number of ICPs required = Total 09**

- 6 for every 100 beds
- 1 additional for adult ICU / 30 Beds
- 1 additional for NICU / 30 beds
- 1 additional for Hemodialysis unit / 120 dialysis sessions per day

Example 2:**Bed capacity of "hospital B" = 950 beds**

Adult ICU = 60 beds

Trauma ICU = 25 beds

PICU = 35 Beds

NICU = 42 beds

ER = 40 beds

Hemodialysis unit = 40 beds (Working in 02 shifts) 80 dialysis sessions per day

What is the required number of ICPs? *Refer to substandards 2.02, 2.03, & 2.04***Number of ICPs required = Total 15**

- 10 for every 100 beds
- 02 additional for adult ICU / 30 beds
- 01 additional for NICU / 30 beds
- 01 additional for PICU / 30 beds
- 01 additional for ER / 30 beds

Sub-standard – 2:07

Infection control practitioners are qualified in infection control through certification, training, or experience for one year at least. (PF,SI)

Review the following documents in PF:❖ **Assignment Letter / Job Description:**

1. Verify if the Infection Control Practitioners are working full time by reviewing assignment letter from executive leadership & job description to review roles and responsibilities of ICPs as full time.

❖ **CV, certificates & training evidence:**

1. The personal file of the ICPs to check for educational background *(Physician, nurse, microbiologist, medical technologist, public health Specialist etc.)*
2. Check degrees / certifications in infection Control *(Masters in infection Control, CIC, Diploma in infection Control etc.)*
3. Attendance in training activities *(local, national international conferences, workshops, seminars & symposiums etc.)*
4. Calculate total duration of experience in infection control from date of joining as IC Practitioner. *(For ICPs at least 1 year experience is required)*

PERSONAL FILE
(PF)

Interview:

1. IC Practitioners to assess his / her knowledge and skills about infection control.
2. Ask about their activities in daily IC rounds.
3. Ask about their role in surveillance activities and methodology of surveillance data collection, CDC-NHSN criteria etc.
4. During the entire audit visit knowledge & orientation of ICPs about IC activities can be easily assessed.

*The infection control Director & Infection Control Practitioners must have the knowledge and expertise in microbiology, epidemiology, sterilization and disinfection, infectious diseases, antiseptic usage, clinical practices and statistics. The Infection Perfectionists functions in pivotal roles as educator, investigator, researcher, patient advocate, agent of change, consultant, statistician, sanitarian, role model, coordinator, and diplomat.***

Staff Interview
(SI)

∞

Sub-standard – 2:08

Infection control practitioners have updated infection control skills and knowledge through continuous medical education program and attendance of IC scientific activities.

(PF,SI)

PERSONAL FILE
(PF)

Review:

1. Personal file to check for evidence of attendance in IC scientific activities. Either conferences, (*local, national international Infection Control conferences, workshops, seminars & symposiums etc.*) (Check for valid certificates).
2. Departmental continuous educational activities conducted inside the hospital. Check for schedule of CME activities, content delivered and attendance sheets to ensure 100% of Infection Control staff has attended with competency assessment.
 - ❖ *Professional development is essential to keeping infection preventionists up-to-date with the latest knowledge, skills & strategies for preventing infections.*
 - ❖ *Competence has been defined as essential knowledge, behaviors & skills that an individual possess and demonstrate in a specific discipline. It implies an expert level of knowledge and skill that is transferrable to the practice of Infection Prevention & Control. (Simply stated , It's the ability to put knowledge into action)*

Staff Interview
(SI)

Interview:

1. IC Practitioners to assess his / her knowledge and skills about infection control.
2. Ask about their activities in daily IC rounds.
3. Ask about their role in surveillance activities and methodology of surveillance data collection, CDC - NHSN criteria etc.
4. During the entire audit visit, knowledge & orientation of ICPs about IC activities can be easily assessed.

Infection Perfectionists must acquire skills & knowledge to critically review and understand the scientific evidence regarding infection prevention interventions & engage and educate a diverse group of stakeholders (e.g. Physicians, nurses, lab & radiology technicians, respiratory therapists, environmental services staff & administrators etc.

REFERENCES / WEB BASED RESOURCES:

1. APIC text of Infection Control & Epidemiology: Competency & certification of Infection Perfectionists
 - a. [http:// text.apic.org/toc/overview-of-infection-prevention-programs/competency-certification-of-infection - preventionists](http://text.apic.org/toc/overview-of-infection-prevention-programs/competency-certification-of-infection-preventionists)
2. APIC text of Infection Control & Epidemiology: Staffing
 - a. [http:// text.apic.org/toc/overview-of-infection-prevention-programs-staffing](http://text.apic.org/toc/overview-of-infection-prevention-programs-staffing)
3. APIC text of Infection Control & Epidemiology: Infection Prevention & Control Programs
 - a. [http:// text.apic.org/toc/overview-of-infection-prevention-programs/infection-prevention-control-programs-](http://text.apic.org/toc/overview-of-infection-prevention-programs/infection-prevention-control-programs-)
4. Joint Commission International Accreditation Standards for Hospitals, 5th edition, April 2014. PCI.1
5. Core components for infection control prevention and control programmes Geneva: World Health Organization; 2009 ([http:// www.who.int/csr/resources/publications/WHO_HSE_EPR_2009_1/en/index.html](http://www.who.int/csr/resources/publications/WHO_HSE_EPR_2009_1/en/index.html), accessed 18 October 2016).
6. APIC text of Infection Control & Epidemiology: Education & Training
 - a. [http:// text.apic.org/toc/overview-of-infection-prevention-programs / education-and-training](http://text.apic.org/toc/overview-of-infection-prevention-programs/education-and-training)

Sub-standard – 3:01

There is written approved terms of references for the infection control committee containing structure, rules, duties and members responsibilities. (D)

Review the terms of reference (TOR) of Infection Control Committee meeting and verify the following:

1. TOR are **valid and updated** (Check for dates)
2. **Approved** (Check for approvals by top administration)
3. **Structure** (Composition of IC committee with inclusion of membership from all relevant units)

The committee consists of multidisciplinary team members.

- Chairman : Hospital Director or Medical Director
- Deputy Chairman : Nominated by chairman
- Committee coordinator
- Committee secretary

Permanent Members : included but not limited to:

- Head of Infection Control Department
- Head of Nursing Department
- Head of Quality Management & Patient safety
- Head of Critical Care Departments (ICU, NICU, PICU, CCU etc.)
- Head of Obstetrics / Gynecology Department
- Head of Surgery Department
- Head of Operating Room (OR)
- Head of Laboratory (Microbiology)
- Head of Renal Dialysis unit / Nephrology
- Head of Pharmacy Department
- Head of Emergency Medicine (ER)
- Representative from Employee Health Clinic
- Head of Central Sterile Supply Department (CSSD)
- Head of Dietary services Department
- Head of Environmental health Department
- Head of Administrative & Financial department
- Infection Control Department Members



Guest Members:

Chairman & deputy can invite any hospital employee from different departments on an official basis when matters pertaining to their services e.g. Family & community Medicine, dental, supply & logistics etc.

- 1) **Purpose of multidisciplinary committee is :**
 - ❖ To provide oversight of the infection prevention and control program.
 - ❖ To coordinate, evaluate, and support the activities of the Infection Prevention and Control Program and to communicate with all departments of the healthcare facility to ensure the engagement and full support to the program by all stakeholders.
 - ❖ The ICC advocates for the program shall ensure all resources needed are available.
- 2) **Rules of operations including:**⁽³⁾
 - ❖ **Frequency of meetings:** (Quarterly or as scheduled in hospital, special meetings will be called by chair when circumstances dictate etc.)
 - ❖ **Agenda:** (All matters to be addressed by the committee should be brought to the attention of the chairperson, Infection Preventionists (IP), and/or the appropriate committee members.
 - ❖ Committee coordinator will prepare the agenda & chairman will sign agenda before distribution to all members)
 - ❖ **Attendance & Quorum:** Appointed members are expected to attend and participate in committee activities. 50 - 60% of committee members plus committee chairman/deputy chairman shall constitute quorum of regular & additional meetings.
 - ❖ **Minutes taking:** Proceedings of the meetings shall be recorded & prepared by the secretary / IC coordinator of committee and circulated to all members in a timely manner before next proceeding.
- 3) **Duties / Functions of IC Committee :**⁽²⁾

General functions of committee includes but not necessarily restricted to the following:

 - ❖ To ensure that hospital IC practices meets the requirement of accrediting bodies CBAHI etc.
 - ❖ Pursue opportunities to improve patient care and clinical performance.
 - ❖ Recommend practices to resolve identified infection control problems in care and performance.
 - ❖ Recommend corrective actions to governing bodies when necessary.
 - ❖ Establishes, reviews and approves the hospital infection prevention and control (IP&C) policies and procedures at least every three years.
 - ❖ Approve the type and scope of surveillance activities including stratified infection risk, focused infection studies, and prevalence and incidence studies.
 - ❖ Determine the amount of time required to conduct infection surveillance, prevention and control activities
 - ❖ Evaluates and revises on a continuous basis the procedures and mechanisms developed by the (IP&C) team to serve established standards and goals.
 - ❖ Brings to the attention of the (IP&C) any infection control related issues arising in different departments of the hospital and suggests solutions. *(For more details refer to 1,3)*



4) **Responsibilities of members & attendees:**

- ❖ Attend at least 75% of meetings having read all agenda & papers beforehand.
- ❖ Act as champions disseminating information and good practice as appropriate.
- ❖ Identify agenda items to be considered by chair of committee ahead of time.
- ❖ If unable to attend send apology to chair and secretary and send designee to attend on their behalf.
- ❖ Contribute to discussion and maintain confidences. *(For more details refer to 3)*

Sub-standard – 3:02

Meeting minutes written in a manner of task force tables with time limit for the actions needed and actions must be followed in the next meeting. (D)

Review the format of Meeting Minutes:

Check if the standard format is being followed for documenting committee meeting minutes:

- a) Meeting minutes of IC committee should incorporate Meeting number, Date, time, venue, Title, List of Attendees, absentees & apologies etc.
- b) It should include **Agenda / Items, Discussion & Findings, Actions / Recommendations, Responsible Person/s, Time frame & status.** (Open / Closed)
- c) Agenda would include **call to order, Review of previous meeting minutes, Infection control reports** (*Healthcare-Associated Infection Rates, Multi-Drug Resistant Organisms MRSA rates, any outbreaks, Hand hygiene compliance rate etc.*), **Departmental Infection control Issues & Solutions** e.g. *delayed release of culture results from microbiology lab etc.*, **Discussion of antibiogram, Employee health issues** (*e.g. Not all hospital employees attending the employee health clinic for annual medical checkup /Influenza vaccination refusals etc.*), inadequate IC supply, Issues related to isolation rooms, construction & renovation, outbreaks etc., **Adjournment and Closing remarks,**
- d) Status of last committee meetings recommendations to be reviewed. ***Closed issues to be considered as accomplishments. These accomplishments shall / can be submitted to the management as part of the committee's performance.***
- e) Issues that are not yet addressed / accomplished to be considered as pending issues. These pending issues shall be added as agenda in the ***old business*** to find solutions to close the issues. If not, it should be closed as 'abandoned', a new alternate solution need to be in place.
- f) Is still not resolved need to be escalated to executive committee.
- g) Issues discussed in IPC committee meetings are assigned to concerned representatives and should be traceable, timely followed, monitored and evaluated.
- h) Discussions, conclusions, recommendations, assignments, actions, and approvals are documented in the minutes of the committee meetings.
- i) Minutes are distributed to each Committee member and are forwarded to other appropriate staff.

Example:

- ❖ **Agenda / Items to be discussed:** Infection Control Surveillance statistics
- ❖ **Discussion:**
CLABSI rates in 3rd Quarter had retained high with average rate of 10.06
CAUTI rate for 3rd Quarter was 6.24
- ❖ **Recommendations /Actions:** Strict implementation of infection control measures during insertion / maintenance and daily necessity review to be intensely implemented and applied by the clinicians to able to reduce occurrence of HAI associated with CLABSI and CAUTI as the committee concluded.

- ❖ **Responsibilities:** Clinicians, nurses, ICPs
- ❖ **Time frame:** October - December 2019
- ❖ **Status:** Closed

Procedure:

- ❖ Committee members will identify agenda items for consideration by the chairman, coordinator / secretary at least 12 days before the meeting.
- ❖ All matters to be addressed by the committee should be brought to the attention of the chairperson, Infection Preventionists (IP), and / or the appropriate committee members.
- ❖ The committee chairman shall instruct to include these issues / recommendations in the next agenda for discussion.
- ❖ Committee coordinator will prepare the agenda.
- ❖ Chairman will sign the agenda before distributing to all members prior the time of the meeting.
- ❖ Chairman requests from members to discuss the new agenda, to update committee on previous agenda / matters and present report to the committee.
- ❖ Committee meets quarterly or as scheduled in the hospital.
- ❖ Discussions, conclusions, recommendations, assignments, actions, and approvals are documented in the minutes of the Committee meetings by IC coordinator / secretary.
- ❖ The minutes shall be approved & signed by chairperson of the Committee. i.e. Hospital Director, Medical Director.
- ❖ The minutes shall be distributed after to all committee members and forwarded to all relevant staff.
- ❖ Minutes of each committee meeting shall be maintained in a permanent separate file.
- ❖ Committee annual report on yearly performance to be developed and distributed.

3	<p>Sub-standard – 3:03 IC committee is chaired by the hospital director or the medical director. (D)</p>
4	<p>Sub-standard – 3:04 Membership of IC committee includes medical staff, nursing staff, microbiology, OR, CS SD, Pharmacy, dietary services, housekeeping, and other departments as needed. (D)</p>
Document (D)	<p>Review the following documents: <u>1: TOR, Meeting minutes & attendance sheets:</u></p> <ul style="list-style-type: none"> ❖ Check the meeting minutes with attendance sheets of last 03 committee meetings for purpose of verification. ❖ Review team composition with multidisciplinary involvement to verify if matching with composition / structure of IC committee members as described in Terms of Reference. <i>(Refer to composition under substandard 1)</i> ❖ Verify that the committee is chaired by hospital director or medical director (i.e., committee’s chairman name should be reflected in term of reference and meeting minutes. ❖ Issues discussed in IPC committee meetings are assigned to concerned representatives and should be traceable and timely closed.

5	<p>Sub-standard – 3:05 IC committee meets on a regular basis (at least quarterly).(D)</p>
Document (D)	<p>Review:</p> <ul style="list-style-type: none"> ❖ IC committee meetings minutes to verify if the committee is meeting on regular basis (at least each quarter) and when needed. (Review at least last 03 meeting minutes). The Chair can call special meetings when circumstances dictate. <ol style="list-style-type: none"> a) <i>Check the dates and attendance sheet to see the presence of 50% Quorum as mentioned in the TOR.</i> b) <i>50% of Committee members + Committee chairman / deputy chairman shall constitute a quorum of regular & additional meetings.</i> c) <i>If the Quorum is not met (i.e. attendance falls below 50% level of any meeting), the meeting will be rescheduled upon discretion of chairman.</i>

Sub-standard – 3:06

Functions of IC committee include but not limited to (revision and evaluation of the IC yearly plan, review and approval of IC policies & procedures, review of surveillance data,etc.) (D,SI)

Review the following:

- ❖ Review Infection Prevention and Control Committee term of reference (TOR) and meeting minutes to ensure incorporating functions as highlighted below.**
- ❖ Review the meeting minutes to check the content / issues discussed in past 03 meetings and check the status.

Functions include:**

- A. Review of the hospital infection prevention and control policies and procedures.
(Check if hospital infection prevention and control policies and procedures manual were approved and signed by the committee members who had discussed and revised thoroughly the manual.)
- B. Review of the reports of healthcare associated infections surveillance submitted regularly by the infection prevention and control team and suggestion of appropriate actions.
(Rate of HAI should be tracked and followed meticulously in the committee, AND the members are always suggesting and agreeing – upon the appropriate actions.)
- C. Revision of the yearly plan submitted by infection prevention and control team and suggestion of additions/changes if necessary.
(When IPC department submitted the annual plan, the members would recommend and advice if any additions, modifications and amendments are necessary and required.)
- D. Evaluates and revises on a continuous basis the procedures & the mechanisms developed by the infection prevention & control team to serve established standards and goals.
- E. Each member of the committee acts as an advocate of infection prevention & control in his department, trying to promote its principles, and ensures application of its rules. *(Refer for more functions to Reference 1,2)*

Interview:

- 1) At random members of Infection control Committee representatives during rounds (*ICU, OR, ER etc.*) to assess if they are aware and well informed with regard to the functions of infection control committee, frequency of meetings etc.
- 2) Ask how they are acting as an advocate of infection prevention & control in his / her department, trying to promote its principles, and ensures application of its rules. (*Encourage HCWs to comply with infection control policies and procedures in their Units.*)

Example:

High CLABSI rate in NICU was discussed as urgent issue in last infection control committee meetings by IC department. Causes and corrective actions were discussed with approval of CLABSI improvement project for NICU. Head / Representative from NICU & other team members in NICU should be well aware of PIP as implementations would be executed through them as per suggested solution in IC committee meeting.

- 3) As if committee representatives were aware about HAIs (CLABSI, CAUTI, VAP/VAE, SSI, and MDROs) & Hand hygiene trends projected in last committee meetings concerning their units and actions taken to reduce them. (*VAP/VAE rate in ICUs & implementation of care bundles, SSI rates and SSI bundle compliance etc.) Hand hygiene compliance rates etc.)*
- 4) Ask if they face any new issue related to infection control in their unit /area, how they are addressing it? *Must be communicated to chairperson or designee & brought to the attention of the infection prevention & control team any new infection control issues arising in different departments of the hospital with suggested solutions.*

REFERENCES / WEB BASED RESOURCES:

1. GCC Infection Prevention & Control Manual 3rd Edition 2018 – ICM - I - 02 Infection Control Committee Responsibilities: Page 5-6
2. Ministry of Health: Guidelines for Infection Control Committee.. تعميم لجنة مكافحة العدوى بالمستشفيات pdf (14-03-2019). Available online at www.gdipc.org.
3. <https://www.infectioncontroltoday.com/general-hais/infection-control-committee>
4. Core components for infection control prevention and control programmes. Geneva: World Health Organization; 2009 (http:// www.who.int/csr/resources/publications/WHO_HSE_EPR_2009_1/en/index.html, accessed 18 October 2016).

1

Sub-standard – 4:01

There is a program to reduce the risk of (HAIs) which involves patients, staff, trainees, volunteers, families and visitors. (D,SI)

Infection Control — is the discipline / process by which health care facilities develop and implement specific policies and procedures to prevent the spread of infections among health care staff and patients.

Nosocomial Infection (HAIs) — An infection contracted by a patient or staff member while in a hospital or health care facility (*not present or incubating on admission*)

- **An Infection Prevention and Control (IPC) programme** is the most important component of safe, high-quality health service delivery. IC program implemented in the hospital is critical not only to prevent HAIs but also to prepare for and respond to communicable diseases crises. ⁽⁴⁾
- IPC programme with a dedicated, trained team should be in place in each acute health care facility for the purpose of preventing HAI and combating AMR through IPC good practices. ⁽³⁾
- Purpose of IC program is to eliminate the risk of HAIs and work related infections within the healthcare facility through the implementation of established guidelines and policies.
- Hospital Acquired Infections are one of the most common complications or adverse events affecting patients and health care workers. They result in increased morbidity and mortality and impact on the capacity of health systems to function effectively. *HAI also increase health care costs and can result in the increased usage of antimicrobial agents, thereby fuelling the problem of AMR. In 2011, WHO reported that 7% of patients in developed and 10% in developing countries will acquire at least one HAI at any given time.* ⁽⁴⁾
- Each healthcare facility need to implement an efficient, comprehensive infection control program in order to ensure patients, staff & visitors safety.
- IC Teams need to incorporate a set of essential core components to help plan, organize and implement an IPC programme. ⁽⁴⁾
- These core components, together with their constituent elements, should be implemented in line with the priorities of the IPC programme and the resources available and adapted to both national and healthcare facility level. ⁽⁴⁾

Review:

Hospital's infection prevention & control program incorporating following core elements included but not limited to:

- **Introduction**
- **Goals, Mission & Vision of IC Program:** *Goals of the infection control program need to be incorporated into the mission statement of the facility. A mission statement should tell who you are, what you do, and should communicate a clear view of purpose and set a strategy for accomplishing the goals e.g. "Our mission is to promote a healthy and safe environment by preventing transmission of infectious agents among patients, staff and visitors"*
- **Organizational structure** of the IPC program (IPC staffing & responsibilities)
- **Infection Control Committee**
- **Scope of service** : *Activities performed by the Prevention and Control of Infection Department members fall within the current Prevention & Control of Infection standards and these include the following:*
 - ❖ **Surveillance** of Healthcare associated infections & Antimicrobial Resistance (AMR).²
 - ❖ IPC activities related to patients, visitors and health care workers' safety and the prevention of AMR transmission. (Hand hygiene program, respiratory protection program. Employee health Program etc.
 - ❖ Development or adaptation of **guidelines** and standardization of effective preventive practices (standard operating procedures) and their implementation.
 - ❖ Ensuring implementation of at least: - **standard precautions - transmission-based precautions** - appropriate selection and use of IPC supplies (*for example, personal protective equipment, hand hygiene products, antiseptics, etc.*) –
 - ❖ Assurance that patient care activities are undertaken in a **clean and hygienic environment** and supported by adequate infrastructures.
 - ❖ Maintaining effective **aseptic techniques** for health care practices.
 - ❖ **Reduce risks** associated with procedures, medication preparation and invasive devices
 - ❖ **Outbreak prevention and response**, including triage, screening, and risk assessment especially during community outbreaks of communicable diseases & communicable disease reporting.
 - ❖ **Health care worker education** and practical training.
 - ❖ **Education of patients, visitors and families** about prevention and control of infection procedures.
 - ❖ **Assessment and feedback** of compliance with IPC practices.
 - ❖ Assurance of continuous procurement of adequate **supplies** & equipments relevant for IPC practices.
 - ❖ **Environmental monitoring** (waste management, food service, water and air monitoring)

❖ **Monitoring and evaluation** of IPC programme (*Process & Outcome indicators*)

- **Additional Program Components / services:**

- ❖ Housekeeping services, CSSD services, laundry services, pharmacy services & FMS etc.
- ❖ Infection Control Risk Assessment & development of annual IC Plan
- ❖ Performance improvement projects

❖ **Aim of Infection prevention & control program is to ensure safety of patients, staff, trainees, volunteers, families and visitors by their involvement.**

Patients:

Patients are integrated within the infection control program through education. They are aware of their rights, concerns of their safety and standard precautions to be followed.

Some examples of how patients can contribute in reducing HAIs.

- *Patient must observe doctor or nurse whether they cleaned their hands? If not, ask them to wash their hands with soap and water or an alcohol-based hand rub (hand sanitizer) before they start working with you.*
- *Ask visitors to clean their hands every time they enter room. And ask them to follow any special instructions from your doctors and nurses.*
- *Clean their own hands often with soap and water or hand sanitizer, especially after using the bathroom.*
- *If they cough or sneeze, cover mouth and nose with a tissue and discard the tissue right away. Then clean your hands.*
- *If your treatment involves a medical device like a urinary catheter, ask the doctors and nurses why it's needed and when it will be removed. Report any symptoms you have to your doctors or nurses.*⁽⁷⁾

Staff & Trainees:

Hand hygiene, compliance with work practices, appropriate use of personal protective equipment, compliance with all infection control policies and procedure, reporting exposure to communicable illness & needle stick injury etc.

Visitors: Visitors & Families:

All visitors' areas are under infection control supervision.

- Visitors are educated on precautions to be taken while being in the surrounding of a patient, the importance of hand hygiene and the isolation precautions required in case of isolated patients.
- Visitors are also educated on the importance of not visiting patients while having a contagious disease.

- Infection control department is communicating with the follow up department to assure compliance with the correct visiting time in accordance with the hospital security plan.

Comments (if any):

- ❖ *Above-mentioned activities / program components are mentioned as brief only.*
- ❖ *Facilities need to have a detailed infection control program according to scope of hospital services.*

Interview:

- ❖ To check if staff in different hospital area and assess if they are oriented and aware about various infection control programs & their role in HAI reduction.
- ❖ Randomly selected staff to enumerate various infection control subprograms.
- ❖ Staff about role of hand hygiene in reducing burden of hospital acquired infections.
- ❖ Staff if they could identify the differences between transmissions based isolation precautions and required PE for each type. (Airborne, Droplet and Contact precautions)
- ❖ Importance of practicing care bundles for prevention of device associated HAIs, SSIs & MDROs. etc.

Comments (if any):

Staff Interview
(SI)

Sub-standard – 4:02

The program is applied to all areas of the hospital according to the scope of services.

(D,O,SI)

- ❖ **Scope of hospital services** is a structural measure that reflects whether a hospital has the resources—facilities, staff, and equipment—to treat and provide care for the medical conditions affecting potential patients.
- ❖ **Services directly related to patients:** includes emergency services, outpatient services, inpatient services, services in Intensive care units & operative rooms (OR) etc..
- ❖ **Supportive / auxiliary services:** CSSD, dietary services, pharmacy services, laundry, laboratory services, radiology services & housekeeping etc.
- ❖ **Each patient care & support service department** must have relevant infection control programs with detailed referenced policies & procedures fully applicable according to the services provided by the unit.

Review:

- ❖ IPC Policy and procedure for each individual program / department in an electronic system, manual or any written and printed documents.
Check if hospital has specific / relevant IC programs implemented according to the scope of services type of unit /department

For example, at least following policies & procedures related to specific program must be available in Intensive Care Unit:

- ❖ Standard & expanded infection control program (Isolation precautions etc.)
- ❖ Aseptic Technique
- ❖ Hand Hygiene program
- ❖ Respiratory Protection Program
- ❖ HAI surveillance Program including the prevention bundles.(Central line, Urinary catheter, Ventilator & MDROs bundles)
- ❖ Outbreak Management Program
- ❖ AMR Program
- ❖ Employee Health Program (*Post exposure Management & follow up etc.*)
- ❖ Waste Management & housekeeping Program
- ❖ Training & Education Program (In service) etc.

Observe:

If the HCWs are practicing and providing services in alignment with the IPC standards and measures related to their scope and mandate of their departments. e.g.

Practicing 5' moments of Hand Hygiene

- ❖ Selecting & using appropriate PPE according to type of isolation precautions
- ❖ Donning, fit tested - seal checked N95 with appropriate technique.
- ❖ Not recapping needles & safe sharp disposal
- ❖ Aseptic technique during medication preparation
- ❖ Appropriate signage / reminders posted in appropriate languages (Hand hygiene & PPE donning / doffing posters, etc.)
- ❖ Appropriate IPC education materials are posted (e.g. case definition & education about MERS – CoV, Cough etiquettes / Respiratory hygiene etc.)
- ❖ Hospital hygiene (*Floors, surfaces, cabinets etc.*)

Interview:

- ❖ If the HCWs could easily answer and respond to your questions regarding how to apply IPC services, practices and measures while they are working or handling the patients.
- ❖ Give them specific tasks to demonstrate according to the unit /area:
 - How to prepare & transport medication to the patients?? (*Assess hand hygiene, aseptic technique etc.*)
 - Ask about protocols of patient transportation under airborne isolation precautions??
 - Ask about elements of any care bundle (SSI, VAP, Central line etc. & their implementation; ***How will you perform oral care for ventilated patients??***)
 - Preoperative measures for prevention of surgical site infections?? etc.
 - Ask about steps of post exposure follow up & management of needle stick injuries etc. (*Assess implementation of employee health program*)

An ongoing program of theory and practice for continuing education is a major requirement and mandate. Therefore, education, reminders, and instructions on infection prevention and control practices and the principles of Standard Precautions are available for all categories of staff, patients, families and sitters through the IPC Department.¹

Sub-standard – 4:03

The IC program is based on current scientific knowledge, referenced practices guidelines and applicable national laws and regulations. (D,SI)

Review:**IC Program & check for references:**

- ❖ IC program should be based on scientific references.
- ❖ Each hospital / organization supports a comprehensive infection prevention and control program within the recommendations of the **World Health Organization (WHO)** and Centers for Disease Control and Prevention (**CDC**), standards of the JClA, and the guidelines of the **Ministry of Health (MOH)** & IC standards of local accrediting body.
- ❖ All relevant references must be kept in Infection control office and used as reference for updating, answering and facing any scientific debates.
- ❖ References would include **APIC, CDC, WHO, IHI, FDA, OSHA, GCC, MOH etc.**

1: Association for Professionals in Infection Control and Epidemiology (APIC):²

- ❖ The Association for Professionals in Infection Control and Epidemiology (APIC) is the leading professional association for infection preventionists (IPs) with more than 15,000 members.
- ❖ It was established in 1972 to provide education & science based information to strengthen & improve practice of infection Control by developing professional and practice standards, education & training programs, scientific journal etc.
- ❖ It established Certification Board of Infection control & epidemiology (**CBIC**) in 1982 to administer an infection Prevention & control certification Program (**CIC**)
- ❖ APIC is a major proponent of zero tolerant perspective for HAIs. This idea requires culture change for Healthcare workers where no infection is perceived as acceptable by any member of healthcare team.

2: Centers for Disease Control & Prevention (CDC):²

- ❖ The Centers for Disease Control and Prevention (CDC) is the leading national public health institute of the United States formed on July 1, 1946.
- ❖ It especially focuses its attention on infectious disease, food borne pathogens, environmental health, occupational safety and health, health promotion, injury prevention and educational activities designed to improve the health of citizens.
- ❖ In the 1960s, the Centers for Disease Control and Prevention (CDC) began recommending that hospitals conduct surveillance for the occurrence of nosocomial infections.

3: Food & Drug Administration (FDA):²

- ❖ FDA is responsible for implementing, monitoring & enforcing standards for the safety, efficacy & labeling of all drugs and biologicals for human use.
- ❖ Activities related to IC teams food, blood, & medical devices (especially single use devices) and antimicrobial products and chemical germicides used with medical devices.

4: Institute for healthcare improvement (IHI):²

- ❖ Independent not - for - profit organization helping to lead the improvement of healthcare throughout the world.
- ❖ IHI works to accelerate improvement by building the will for change, cultivating concepts for improving patient care, and helping healthcare systems put those ideas in action (*e.g. Healthcare bundles etc.*)

5: Joint Commission (JCIA):²

- ❖ Joint commission started publishing minimum infection prevention & control standards in 1953.
- ❖ JCIA standards are used by many institutions including hospitals, long term care facilities in order of establish a framework for an infection prevention program.

6: National Institute for occupational safety & health (NIOSH):²

- ❖ Established in 1970 & became part of CDC in 1973.
- ❖ Responsible to conduct laboratory and epidemiological research on occupational hazards.
- ❖ Decisions regarding type of devices used for employees protection (Respirators, sharp containers) are part of NIOSH mandate.

7: Occupational Safety & Health Administration (OSHA):²

- ❖ Began infection prevention & control activities in 1973 with publication of blood borne pathogens rules.
- ❖ OSHA standards focus on determining employee's health risks as a result of exposure to communicable diseases.

8: World Health Organization ("WHO"):

- ❖ World Health Organization (WHO) is a specialized agency of the United Nations that is concerned with international public health. It was established on 7 April 1948, and is headquartered in Geneva, Switzerland.
- ❖ Aim is to ensure health promotion via elimination & eradication of communicable diseases, Antimicrobial resistance, training of health workforce, & improve monitoring data & information. Etc.

9: Gulf Cooperation Council Center for Infection Control (GCC - CIC):

- ❖ GCC manual was designed to give up-to-date guidelines for the GCC States that provides evidence-based infection control practices for all healthcare settings.
- ❖ The consistent application of proper infection control principles and practices in all healthcare activities is necessary to achieve the goals of optimum patient safety and ensure best outcomes.⁽¹⁾

10: National References: (Ministry of health (MOH)

- ❖ Reference of national guidelines / MEMO pertaining to specific programs ***(National outbreak guidelines, national MERS –CoV guidelines, National guidelines for Hemodialysis & dental units etc.)***

Interview:

- ❖ IC team on how they developed their policies in comparison to the references, scientific facts and current regulations.
- ❖ They should give an example of how they used these scientific references. ***E.g. how they have developed policies & procedures for Antimicrobial resistance (AMR) program and how & which references they have incorporated.***

REFERENCES / WEB BASED RESOURCES:

- 4) *GCC Infection Prevention & Control Manual 3rd Edition 2018 – ICM - I - 04 INFECTION PREVENTION AND CONTROL PROGRAM: Page 8*
- 5) *APIC text of Infection Control & Epidemiology: Infection Prevention & control programs*
<http://text.apic.org/toc/overview-of-infection-prevention-programs/infection-prevention-and-control-programs>
- 6) *Core components for infection control prevention and control programmes. Geneva: World Health Organization; 2009 (http://www.who.int/csr/resources/publications/WHO_HSE_EPR_2009_1/en/index.html, accessed 18 October 2016).*
- 7) https://www.who.int/csr/resources/publications/AM_CoreCom_IPC.pdf
- 8) <https://apic.org/about-apic/about-apic-overview/>
- 9) <https://www.cdc.gov/hai/pdfs/guidelines/basic-infection-control-prevention-plan-2011.pdf>
- 10) <https://www.cdc.gov/>
- 11) <https://www.shea-online.org/index.php/practice-resources/patients>

1

Sub-standard – 5:01:

The annual plan is based on Infection Control Risk Assessment - ICRA (i.e., addresses processes, procedures and devices that are identified by the IC practitioners to be associated with risk of HAIs). (D,SI)

Annual IC Plan: *is a written, risk-based document with goals and measurable objectives, strategies and evaluation methods.*

Risk Assessment: *Risk assessment is a term used to describe the overall process or method to identify & evaluate risk factors that have the potential to cause harm to the patients, staff & visitors.*

Why to perform An Annual Risk Assessment?

Helps focus activities on essential tasks to reducing critical infection control risks:

- *Improves patient safety*
- *Improves staff safety*
- *Improves efficacy (desired results)*
- *Identifies training issues*
- *Understanding of disease transmission and prevention*
- *For implementing new interventions etc.*

Review the following:

- ❖ Infection Control Risk assessment (ICRA)
- ❖ Infection Control Annual Plan

(Match ICRA & Annual IC Plan with below described steps & protocols with examples)

Document
(D)

Steps Involved in risk Assessment:

Step 1: Annual Infection Control Program Review:

(Analyze & review data which is the basis of the annual risk assessment)

- *Data aggregation and analysis*
- *Healthcare-acquired infection trends (Identified infections with the highest probability and potential for harm (known risk, potential risk, contamination, exposures)*
- *Compliance with infection control standards*
- *Communicable diseases (prevalence rates, incidence rates)*
- *Identified environmental issues / concerns*
- *Identified organizational areas of weakness*

Step 2: Risk Assessment Grid / Tool:

PURPOSE :

- *Rank risks by score to determine organizational priorities*
- *Assist in determining where to focus with available resources*
- *Provides basis for developing the Infection Control Plan*
- *Identify gaps in infection prevention measures / processes*
- *Provide leadership and patient care providers with known and potential risks, which can directly affect patients, & Health care providers.*

Risk Assessment Scoring: A Numeric scoring system based upon probability of event occurring.

- *Multiply the ratings for each risk in the area of **probability, impact and organization preparedness = Risk Score***
- *Ranking risks by total score to help identify priorities*
- *Sort in order of risk*

*Priorities are used in the development of the **Infection Control Plan***

INFECTION CONTROL ANNUAL RISK ASSESSMENT																
HOSPITAL NAME:					REGION:			YEAR:		BED CAPACITY:						
Potential Risks	Probability of Occurrence					Risk/Impact (Health, Financial, Legal, Regulatory)					Current Systems/Preparedness					Score
	Expected	Likely	Maybe	Rare	Never	Life Threatening	Serious Loss	Prolonged Length of Stay	Moderate Clinical	Minimal Clinical	None	Poor	Fair	Good	Solid	
	4	3	2	1	0	4	3	2	1	0	5	4	3	2	1	
Failure of Prevention Activities																
▪ Lack of Hand Hygiene Compliance		3				4							3			36
▪ Lack of Resp Hygiene/Cough Etiquette																
▪ Lack of Supplies for Hand Hygiene																
Isolation Activities																
▪ Lack of Standard Precautions																
▪ Lack of Airborne Precautions	4					4					4					64
▪ Lack of Droplet Precautions																
▪ Lack of Contact Precautions																
▪ Lack of Supplies Necessary for Isolation																
HAI Surveillance																
▪ SSI	4					4							3			48
▪ VAP in ICUs																
▪ CLABSI in ICUs																
▪ Dialysis-Related Infections																
▪ CAUTI																
▪ Outbreak																
▪ Sentinel Event																
▪ Other-HAI																

STEP 3: THE ANNUAL INFECTION CONTROL PLAN:

Potential Risks / Problems	Goals / Objectives	Strategies / Interventions	Responsible persons	Timeframe	Method of Evaluation
<p>Procedure related risk:</p> <p>1: Surgical Site Infection</p> <p>Rationale:</p> <p>Surgical site infections are the most common healthcare associated infection, accounting for 31% of all HAIs among hospitalized patients. SSIs are a substantial</p>	<p>To ensure Patient Safety</p> <p>Overall SSI rate \leq 0.50%</p> <p>C-sec = Reduce by 50%</p> <p>Number of SSI / Expected SSI</p> <p>Fx = reduce by 50%</p> <p>Number of</p>	<p>Strict implementation of surgical bundle</p> <p>Provision of resources to implement bundle variables (prophylactic antibiotics, clippers etc.)</p> <p>Continuous Training & Education of OR staff</p> <p>Improve patients education on pre-operative showering</p>	<p>Surgical staff, surgeons, anesthesiologist</p> <p>Central Sterile Processing Staff</p> <p>Infection Control Team</p> <p>Patient Educators</p> <p>TQM staff</p>	<p>Annually January 1, 2020- December 31, 2020</p> <p>Daily/ Monthly /Quarterly follow up</p>	<p>SSI preventive Checklist monitoring (Daily/weekly rounds)</p> <p>SSI Rate (Monthly / Quarterly)</p> <p>SSI Bundle Compliance rate (Monthly/Quarterly)</p> <p>SSI rates per 100 operative procedures are calculated by dividing the number of SSIs with the number of specific operative procedures and multiplying the results by 100 SSI rate calculations are performed separately</p>

<p>cause of morbidity, prolonged hospitalization, and death.</p> <p>Procedures involving contact with a medical device or surgical instrument with a patient's sterile tissue or mucous membranes poses a major risk of introducing pathogens which can lead to infection. Failure to properly clean, disinfect or sterilize equipment may lead to SSIs.</p>	<p>SSI / Expected SSI</p> <p>100% compliance with elements of Surgical Bundle</p> <p>100% percent compliance with defined process for cleaning, disinfecting and sterilization of critical and semi-critical devices and instruments</p>	<p>post discharge wound care etc., Distribution of updated antibiotic policy</p> <p>Meticulous sterilization practices.</p>			<p>for different types of operative procedures and stratified by the basic risk index</p>
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Comment (if any):

Review the IC committee meeting minutes to confirm annual evaluation and approval of the IPC plan by the IPC committee,

Staff Interview (SI)

Interview:

- ❖ Infection Control Team about steps involved in risk assessment & components of ICRA.
- ❖ Ask how they will identify & grade according to probability of occurrence, Impact on patients, staff & visitors & Facility preparedness for that risk.
- ❖ Let them pretend any risk and conduct IC risk assessment for that specific risk.

2

Sub-standard – 5:02:

The plan includes goals for patient safety (e.g., standard precautions, transmission based isolation precautions, Healthcare bundles, and patient/family education). (D,SI)

Review the annual Plan & verify:

- ❖ If these components (**standard precautions, transmission based isolation precautions, Healthcare bundles, and patient / family education and alike**) are mentioned clearly in the plan in a detailed fashion, in which the objectives and activities are written along with the KPIs relevant to them.
- ❖ If there is any risk assessment for the patient safety data available, e.g. health care bundles are well – related to the HCAs rates.

Example: Isolation Activities:

Potential Risk: Lack of Airborne Precautions / AIIRs in the facility

Goals / Measurable Objectives: Provide adequate isolation facilities / AIIRs according to bed capacity 1 AIIR / 25 beds etc.

Strategies / Methods: 1: Send request / Follow up previous requests for provision of Negative pressure isolation rooms, HEPA filters & fixed monitors for continuous monitoring of negative pressure differentials & Air changes per hour etc. 2: Make clear guidelines on management of patients with airborne infections till availability of Airborne Infection Isolation Rooms (AIIRs)

Responsible Person (s): Higher Administration, Infection control Team for follow up, Directorate / Ministry (MOH hospitals only)

Timeframe: Annually January 1, 2020 - December 31, 2020 with specified timeframe for each activity

Monitoring / Evaluation: Assessment of the need for more airborne isolation rooms depending on the volume of patients in need for airborne isolation admitted to the hospital.

Document
(D)

Interview:

- ❖ IPC team to explain the rationale behind the existing annual plan.
- ❖ ICPs to enumerate goals for patient safety.
- ❖ If they could easily describe and explain the followings :
- ❖ How did they prepare / write the plan? (Mention the steps of the appropriate plan format, logical framework including the elements like risk priority, objectives, situation analysis, activities linked with time, place, persons and others...)
- ❖ How could monitor and evaluate the progress regarding **Key Performance Indicators (KPIs)** of patient safety?

Staff Interview
(SI)

3

Sub-standard – 5:03:

The plan includes goals for staff safety (e.g., staff immunization, post exposure management, and staff education). (D,SI)

Review the annual Plan & verify:

- ❖ If these components (e.g.: **staff immunization, post exposure management, and staff education**) are mentioned clearly in the plan in a detailed fashion, in which the objectives and activities are written along with the **KPIs** relevant to them.
- ❖ If there is any risk assessment for the staff safety data is present e.g. post exposure management are well – related to the incidents or reports of contracting infections. **Number of Needle stick injuries reported in 2019 etc.**

Example: Staff Safety

Potential Risk: *Declining influenza vaccination coverage among Health Care Workers*

Goals / Measurable Objectives: *100% influenza vaccination coverage among targeted health care workers.*

Strategies / Methods: *1: Staff Education & awareness regarding importance of influenza vaccination. 2: Availability of adequate vaccines & relevant IC supply. 3: Explore & address reasons for declining rate. 4: Disciplinary procedures for HCWs who are noncompliant with the vaccination policy.*

Responsible Person (s): *Employee Health Team, Infection control Team*

Timeframe: *Annually January 1, 2020 - December 31, 2020 with specified timeframe for each activity*

Monitoring / Evaluation: *Vaccination census & coverage rates in each quarter*

Document
(D)

Staff Interview
(SI)

Interview:

- ❖ IPC team to explain the rationale behind the existing annual plan.
- ❖ Staff to enumerate goals for staff safety.
- ❖ If they could easily describe and explain the followings :
- ❖ How did they prepare / write the plan? (Mention the steps of the appropriate plan format, logical framework including the elements like risk priority, objectives, situation analysis, activities linked with time, place, persons and others...)
- ❖ How could monitor and evaluate the progress regarding KPIs of staff safety?

4

Sub-standard – 5:04:

There is a system or a tool to monitor achievements of the annual plan's goals. (D,SI)

Review the following documents:

- 1) Annual Plan to check for presence of the **KPIs** column in the logical framework of the plan.
- 2) Any document written and approved to convince that mechanism of follow up and monitoring is established and functioning.
- 3) Metrics of required changes in targets and goals to reduce hospital acquired infections.
- 4) Monitoring and Evaluation processes, dashboards, indicators are clearly present in any form e.g. electronic or manual.

Purpose of Monitoring:¹

- ❖ *IPC programmes should be periodically evaluated to assess:*
 - *The extent to which the objectives are met, the goals accomplished.*
 - *Whether the activities are being performed according to requirements.*
 - *To identify aspects that may need improvement identified via standardized audits.*
- ❖ *Regular monitoring / evaluation of goals and timely feedback of health care practices according to IPC standards should be performed to prevent and control HAI and AMR at the health care facility level. Feedback should be provided to all audited persons and relevant staff.*

Document
(D)

Staff Interview
(SI)

Interview:

1. If the IPC personnel are well acquainted with the technique of how to develop a system of monitoring and evaluation in terms of setting **KPIs** according to the required goals.
2. If are they responding effectively and efficiently to any declining /decreasing rates and failure to achieve the previously – set goals.

REFERENCES / WEB BASED RESOURCES:

- 1) http://apicnyc.org/uploads/3/4/0/6/34063157/04_infection_prevention_plan_risk_assessment_and_isolation_recs_-_m_pavia_10-26-2018.pdf
- 2) http://www.cdc.gov/ncidod/dhqp/pdf/guidelines/Enviro_guide_03.pdf
- 3) [Core components for infection control prevention and control programmes. Geneva: World Health Organization; 2009 \(http:// www.who.int/csr/resources/publications/WHO_HSE_EPR_2009_1/en/index.html, accessed 18 October 2016\).](http://www.who.int/csr/resources/publications/WHO_HSE_EPR_2009_1/en/index.html)
- 4) <https://www.cdc.gov/hai/pdfs/guidelines/basic-infection-control-prevention-plan-2011.pdf>
- 5) <https://www.who.int/infection-prevention/tools/core-components/IPCAF-facility.PDF>
- 6) <https://www.who.int/infection-prevention/tools/core-components/facility-manual.pdf>

Sub-standard – 6:01:

Infection control policies & procedures are developed by IC department to be approved by IC committee (P&P are based on scientific references approved by MOH (GCC, CDC, WHO and APIC)). (D)

- ❖ *Evidence-based Policies & Procedures / guidelines should be developed and implemented for the purpose of reducing HAI and AMR. The education and training of relevant health care workers on the guidelines and the monitoring of adherence with guideline recommendations should be undertaken to achieve successful implementation.²*
- ❖ *Appropriate IPC expertise is necessary to write or adapt and adopt a guideline both at the national and health care facility level. Guidelines should be evidence-based and reference international or national standards. Adaptation to local conditions should be considered for the most effective uptake and implementation.²*

Document
(D)

Review:

- ❖ All Infection Control policies & procedures related to Infection Control.
- ❖ Review IC policies and procedures to make sure that they are developed by IC staff and approved by the IC committee.
- ❖ Verify in each policy that all IC policies and procedures are developed by infection Control department in collaboration with relevant medical staff, nursing staff and other internal and external stakeholders.
- ❖ *For example : Policies & Procedures related to Hemodialysis unit (HDU) should be developed in collaboration with head of HDU, nursing department, environmental health etc.*

❖ **Check for following in each P/P:**

- 1) **Validity** : All P/P should be valid (updated within 2 - 3 years and when indicated)
- 2) **Title of Policy**: “. Instead of “**Blood Spill**” would be “**Management of Blood & body fluid spills**”

Other examples as follows:

Old Title	Suggested improved Title
Outbreaks	<i>Management of Infectious Diseases Outbreak</i>
Dental Unit	<i>Infection Control Measures in Dental Settings</i>
Waste Management	<i>Management of Infectious Medical Waste</i>

- 3) **Content of policy:**
 - ❖ **Comprehensive**: Covers all aspects of infection control relevant to particular unit, program etc..
 - ❖ **Fully applicable**: All elements of the policy can be applied and comply with the hospital’s scope of services.
- 4) **References**: All P/P to be based on scientific references approved by MOH (GCC, CDC, WHO & APIC) *(Refer to substandard 4:03 for more details for each referencing body)*
- 5) **Signatories**: Signed from authorized personnel (i.e., owner of the policy / hospital director or medical director / concerned department head)
- 6) **Approvals**: Each policy & procedure should be discussed and approved by IC Committee *(Check for specific policy approval in the documented Infection control committee meeting minutes)*

- *Approval by IC committee is required for the infection control manual as a whole before distribution and for individual policy after major changes.*

2

Sub-standard – 6:02:

Infection control policies & procedures are organized in one manual that is well-distributed and available in all hospital areas. **(D,O,SI)**

- ❖ *Every facility should have an infection prevention manual compiling evidence-based practices for patient care.*
- ❖ *This manual should be developed and updated in a timely manner by the infection control team.*
- ❖ *It is to be reviewed and approved by infection control committee.*

Review:

Infection Control Manual & check for following:

- 5) IC Manual is updated as per hospital policy.
- 6) Nicely designed & appropriately indexed with table of contents **(Policy number, Title of Policy & Page numbers.)**
- 7) Divided into appropriate sections for ease of accessibility **(Administrative policies, Departmental policies & procedures, Isolation Procedures, Environmental health , support services etc.)**
- 8) IC Manual must be available in the infection control department **(Electronic + Printed version)**
- 9) The manual must be available in each department. **(Electronic or hard version)**

Importance of written documents is considered least not to encounter shut down of the electricity / system failure.

Observe:

- Availability & accessibility of policy and procedure documents in each department.
- ❖ Healthcare workers are familiar with the policy and procedure and know how to access the system whenever needed.

Document
(D)

Observation
(O)

Interview:

1. **Staff about availability of Infection Control Manual (Electronic and/ or Manual)**
2. **Staff to enumerate infection control policy and procedures (P/P) applicable for their department.**

For example in ICU: Staff must mention

- ❖ P/P for standard precautions
 - ❖ P/P for Transmission based precautions
 - ❖ P/P for Aseptic technique
 - ❖ P/P for Patient's Care Bundles for Prevention of HAIs & MDROs
 - ❖ P/P for Cleaning & disinfection of Medical Equipments
 - ❖ P/P for Housekeeping Services
 - ❖ P/P for Management of infectious Waste etc.
3. **Randomly ask any staff to access policies & procedures for Prevention of central line associated Blood stream infections incorporating Central line care bundles.**
 4. **Ask staff what alternate they have if the system is down (For hospitals relying electronic versions of IC Manual only)**

Sub-standard – 6:03:

Infection control policies & procedures are revised periodically by the infection control department every 2-3 years, or when required. (D)

Review:

- ❖ Main policy stating the periodic revision of each policies and procedures. **(2 OR 3 years)**
- ❖ Any relevant document stating P/P will undergo revisions every **2 OR 3 years** & when required. *For example if new guidelines from ministry or new updates are available.*
- ❖ Match the revision dates mentioned on the policies with the periodic revision policy for purpose of verification.

Comment (if any):

- *Policies and procedures exceeding the revision dates will be considered (Not met)*
- *Each hospital should start revision process ahead of time in order to avoid delay.*
- *Any new guidelines / updates released from Ministry of Health need to be incorporated in the policies within 2 months maximum.*

REFERENCES / WEB BASED RESOURCES:

- 12) *GCC Infection Prevention & Control Manual 3rd Edition 2018 – ICM - I - 06 INFECTION PREVENTION AND CONTROL CORE COMPONENTS: Page 10*
- 13) *Core components for infection control prevention and control programmes. Geneva: World Health Organization; 2009 ([http:// www.who.int/csr/resources/publications/WHO_HSE_EPR_2009_1/en/index.html](http://www.who.int/csr/resources/publications/WHO_HSE_EPR_2009_1/en/index.html), accessed 18 October 2016).*
- 14) *APIC text of Infection Control & Epidemiology: Infection Prevention & control programs*
[http:// text.apic.org/toc/overview-of-infection-prevention-programs/infection-prevention-and-control-programs](http://text.apic.org/toc/overview-of-infection-prevention-programs/infection-prevention-and-control-programs)
- 15) https://www.who.int/csr/resources/publications/AM_CoreCom_IPC.pdf
- 16) <https://apic.org/about-apic/about-apic-overview/>
- 17) <https://www.cdc.gov/>
- 18) <https://www.who.int/infection-prevention/tools/core-components/facility-manual.pdf>

7

INFECTION CONTROL EDUCATION & TRAINING

1

Sub-standard – 7:01:

Annual infection control training program based on need assessment and include basic and specialized infection control training. (D,SI)

Review:

- ❖ Annual infection control training plan that is not routinely including the same programs and topics but updated annually based on need assessment and staff interests and include lectures and practical training. Plus, any updates to annual plan as raising particular infection rate e.g. increased VAP rate in ICUs necessitates urgent training program including all personnel involved in ventilator insertion and care.
- ❖ Educational program also should include basic program for all staff, plus specialized program for different staff categories as specialized program for staff working in OR and surgery department, ICUs, AKU, etc....
- ❖ Educational program courses and training workshops shall cover all kinds of IPC personnel of different specialties and categories (trainee, volunteers, new employees, lab, OR, etc...).

Document
(D)

Staff Interview
(SI)

Ask:

- ❖ Interview with the IC staff about Justification for programs included in the annual training plan and methods used for need assessment either survey, group discussion, personal interview, analysis of internal reports, etc.

2

Sub-standard – 7:02:

IC department provides continuous education and training (formal & on- job training) for HCWs on infection control with competency assessment. (D,PF,SI)

Review:

- ❖ Training file includes documentation of already done training activities including schedule, list of attendees, competency testing.

Document
(D)

Personal File
(PF)

Review:

Random selection of a number of personal files to review the certificates of pre-employment training and competency together with any documented specific training certificates.

Staff Interview
(SI)

Ask:

- ❖ Ask the staff about Last IC course or on job training they attend.
- ❖ Ask the staff about KAP acquired from attending this course.

3

Sub-standard – 7:03:

IC department provides orientation and training on basics of infection control for newly hired staff before or maximum within 1 month of joining the work. (D,SI)

Document
(D)

Review:

Randomly request a sample from personal files of a newly hired staff in order to look for their IPC training attendance and competencies.

Staff Interview
(SI)

Ask

- ❖ Ask the staff if they have been received formal or on job training upon hiring The HCWs are able to nominate and identify the title and components of any training program that they had been previously attended.
- ❖ The employee to describe and explain any types of IPC services and practices e.g. ask about the difference between standard and transmission – based precautions.

4

Sub-standard – 7:04:

IC department provides education on infection control for patients, families and visitors. (D,SI)

Document
(D)

Review:

- ❖ If there is any document that is designated and formulated to help in the education of the patients and visitors, e.g. plans and Posters, Brochures...
- ❖ The educational programs designated for visitors and patients, if they are really valid, fruitful and productive (you can check one of the patient programs directed - for example – to the isolation services and practices.

Visitor Interview

Ask:

- ❖ One of the visitors, who are in the isolation department, if received any precautions before allowed to visit the isolated relative,
- ❖ If So, Ask the visitor if he can tell you about these precautions and how can he practice it correctly. e.g. could he/her easily know and do hand hygiene, wear PPE and etc...

1

Sub-standard – 8:01

There are written infection prevention policies and procedures for hand hygiene, including types, indications, supplies, techniques and monitoring. (D)

Hand hygiene is a critical component of patient & staff safety. Effective patient safety and infection prevention programs require that healthcare personnel must be familiar with hand hygiene recommendations and consistently adhere to them.⁽¹⁾

Review:

*Policies & Procedures for Hand Hygiene which should be **comprehensive** incorporating all aspects of hand hygiene program as follows:*

1) Types of hand hygiene:

Hand hygiene is a general term referring to hand washing, antiseptic hand rub, or surgical hand antisepsis

- ❖ **Hand washing** – washing hands with plain or antimicrobial soap and water.
- ❖ **Hand rubbing** – Applying an antiseptic hand rub to reduce or inhibit the growth of microorganisms without the need for an exogenous source of water and requiring no rinsing or drying with towels or other devices.
- ❖ **Surgical hand antisepsis** – An antiseptic hand wash or antiseptic hand rub performed preoperatively by surgical personnel to eliminate transient and reduce resident flora.

2) Indications:

- ❖ **Five moments of hand hygiene:** before touching a patient, before clean/aseptic procedures, after body fluid exposure risk, after touching a patient, after touching patient's surroundings.
- ❖ **Hand wash with water and soap:** When hands are visibly soiled, potential exposure to spore forming organism (*Clostridium difficile*, *Bacillus anthracis*), before eating and after using a restroom etc.

NB:

- *Waterless, alcohol-based hand rubs are now the preferred products for routine hand hygiene in healthcare settings, unless hands are visibly soiled.*
- *Use only soap and water when dealing with spore forming bacteria (e.g., *Clostridium difficile*) and /or when hands are visibly soiled.*
- *Artificial fingernails or nail extenders are prohibited for those having direct contact with patients at high risk areas (e.g. Intensive care units, OR etc.)*

3) Supplies: ¹**1: Plain (non-antimicrobial) soap:**

- *These soaps are detergent-based and will remove lipids, adhering dirt, and organic matter*
- *They have no antimicrobial activity. Such soaps can remove transient flora from the skin*

2: Antimicrobial soap:

- These soaps are detergent-based and will remove lipids, adhering dirt, and organic matter. They have antimicrobial activity.

They can remove transient and resident flora from the skin. (Examples: Alcohol, chlorhexidine, chlorine, Quaternary ammonium compounds etc.)

3: Alcohols

Alcohol-based hand rub is a solution that contains 60% to 95% alcohol and is designed to be applied to hands to reduce the number of viable microorganism on the hands.

Although ethyl alcohol and isopropyl alcohol are both effective against bacteria, fungi, and viruses, isopropyl alcohol has slightly greater activity against bacteria & ethyl alcohol has greater activity against viruses.¹

4) Techniques:

(Technique should be well described in the policy apart from visual illustrations :

- Hand washing with soap and water:
- Hand rubbing with alcohol
- Surgical Hand Antisepsis

5) Monitoring for adherence:

Hospitals should incorporate details of Hand hygiene monitoring protocols in the policy:

CDC & WHO guidelines require monitoring of health care providers adherence to recommended hand hygiene practices with feedback about performance.¹

- ❖ Direct observation of sample of hand hygiene opportunities and calculate the **rate of adherence (Number of hand hygiene episodes performed / Number of hand hygiene opportunities) by ward or service.**
- ❖ Assess the quality of hand hygiene adherence (**time spent per hand hygiene episode, whether soap was used during hand washing, etc..**)
- ❖ **Monitor the volume** of specific hand hygiene products.
- ❖ Could be **automated systems** that have potential to monitor all patient care episodes & provide **“just in time”** reminders to staff who has forgotten to perform hand hygiene.

Other domains of Policies & procedures:

P/P for Hand Hygiene should be :

- 6) **Fully applicable:** all elements of the policy can be applied and comply with the hospital's scope of services
- 7) **Based on scientific references** approved by MOH (**GCC, CDC, WHO & APIC**)
- 8) **Signed** from authorized personnel (i.e., owner of the policy / hospital director or Medical director / concerned department)
- 9) **Approved** by IC committee
- 10) **Valid** (updated within 2 - 3 years and when indicated).

The WHO and CDC guidelines recommend that healthcare workers be provided with a readily available alcohol-based hand rub product. Data suggest that this recommendation will increase the frequency of healthcare worker hand hygiene and result in decreased incidence of dermatitis caused by the drying effects of soap and water and abrasive towels.

2

Sub-standard – 8:02

Hand washing facilities and supplies are available & easily accessible (sinks with hot & cold water / plain and antimicrobial soap/ towels), one for every 2-4 beds in the critical care areas and at least one per patient's room. (O)

Observe the following:

- ❖ Hospital wide hand washing facilities that meet the needs of the hospital and are clean and in good repair.
- ❖ Check the availability of hand washing facilities in patients' rooms.
- ❖ Check the availability of hand washing facilities inside critical care units. (*ICU, CCU, NICU, PICU, ER, HDU etc.*)
(Observe the number of hand washing sinks if meeting the requirement as mentioned in the substandard (1 per every 2 - 4 beds)
- ❖ Observe availability of water supply (hot and cold) for hand washing (*Place hands under the water tap if hands free operation or open the tap to check for hot & cold water supply*)
- ❖ Observe whether hand washing facilities are conveniently placed and their ease of accessibility to staff.
- ❖ Observe the availability of following supplies:

1: Plain (non-antimicrobial) soap

2: Antimicrobial soap

3: Paper Towels for drying

Drying practice is a critical factor to determine the level of bacterial residue. Paper towels should be used & pat the skin dry rather than rub it to avoid cracking (skin excoriation may lead to bacteria colonizing the skin) & Do not reuse or share hand drying towels⁽³⁾

Observation
(O)

3

Sub-standard – 8:03

Alcohol based hand rub dispensers are available in adequate numbers (one dispenser per patient's bed, one at every nursing station and at any service areas). (O)

Observation
(O)

Observe:

- ❖ Hospital wide hand rub dispensers as per requirements mentioned in the substandard above. *(one dispenser per patient's bed, one at every nursing station and at any service areas)*
- ❖ Dispensers are conveniently mounted and accessible at the point of care:
 - a. *At the entrance to each patient room.*
 - b. *Examination room*
 - c. *Treatment rooms, and similar areas etc.¹*
- *The dispensers should not be installed over or directly adjacent to electrical outlets and switches.*
- *Randomly open any dispenser to check if hand sanitizer is available & not expired.*

4

Sub-standard – 8:04

Hand hygiene compliance rates are regularly monitored, Results are discussed in IC committee meetings for corrective actions. (D)

Document
(D)

Review the following documents:

1. Hand Hygiene Compliance reports:

- ❖ Review trended data overtime that compares the hand hygiene compliance rate over the months and compare different staff categories & units.

2. Infection Control Committee Meeting Minutes:

- ❖ Review the last 3 committee meeting minutes & verify if hand hygiene trends are presented & discussed.
- ❖ Check for suggestive correction actions if hand hygiene compliance is low.

Corrective Actions would include:

- *Continuous education & training of HCWs*
- *Continuous monitoring & observation*
- *Performance feedback on compliance*
- *Ensuring availability of supplies for hand hygiene in adequate amount and appropriate places. Convenient and acceptable hand hygiene products & dispensers.¹*
- *Disciplinary action for any breach in practices*
- *Administrative support*
- *Performance Improvement Project for hand hygiene*
- *Motivational & incentive programs etc.*

Document
(D)

Hand Hygiene remains a foundation of patient safety and infection prevention. Yet achieving and maintaining adherence remains a challenge.

Education alone seldom leads to adequate adherence to hand hygiene in healthcare. Multimodal multidisciplinary strategies are more like to lead to change and improve hand hygiene practices. Complex dynamic of behavioral change requires a combination of education, motivation & system change.¹

5

Sub-standard – 8:05

Reporting of Hand Hygiene Compliance Rates is active and ongoing (i.e., reliable data is passed through regional coordinator to the central body of national hand hygiene program in timely manner). (D)

Document
(D)

Review;

- ❖ Monthly hand hygiene reports submitted to regional hand hygiene coordinator via electronic system. *(Review last 3 months to ensure quality and frequency of submission hand hygiene data.*

(Take feedback from hand hygiene coordinator can be taken regarding quality & frequency of data reporting if visit is planned for a specific MOH hospital.

NB: As per quality requirements, hand hygiene compliance rate above 80% is not acceptable by central body of national hand hygiene program. (Cut off limit is 80%)

Comment (if any):

This substandard is applicable for Ministry of health hospitals only who are reporting monthly Hand hygiene data via electronic system.

6

Sub-standard – 8:06

Visual alerts for Hand Hygiene are available (WHO 5 moments - how to hand wash - how to hand rub) and HCWs are knowledgeable about it. (O, SI)

Observation
(O)

Observe:

- ❖ Visual education tools / Visual alerts for staff reminders at workplaces are posted at appropriate places.
 - **WHO 5 moments for hand hygiene at (nursing stations, procedure rooms, OPD clinics etc.**
 - **How to hand wash poster at each hand washing sink**
 - **How to hand rub poster beside each hand hygiene dispenser,**

Staff Interview
(SI)

Interview:

- ❖ At random the staff belonging to different categories (Doctors, nurses, technicians, respiratory therapists etc.) if they are aware and have good knowledge about 5' moments and steps of hand hygiene.
 - a. Ask to enumerate steps for hand washing and hand rubbing.
 - b. Ask about the WHO five moments of hand hygiene by giving different situation /scenario

Example of Opportunities of hand hygiene in the dialysis unit. (5 Moments):

1. **Before touching a patient :**

- Before entering the station to provide care to a patient.
- Before contact with vascular access site.
- Before adjusting or removing cannulas.

2: **Before aseptic procedures :**

- Before cannulation or accessing catheter.
- Before performing catheter site care.
- Before parenteral medication preparation.
- Before administering infusions or IV medications

3: **Following body fluid exposure risk:**

- Following exposure to any blood or body fluids.
- Following contact with other contaminated fluids (e.g., spent dialysate).
- After handling used dialyzers, blood tubing, or priming buckets.
- After performing wound care or dressing changes.

4: **After touching a patient:**

- When leaving the station after performing patient care.
- After removing gloves.

5. **After touching patient surroundings:**

- When leaving the station after touching dialysis machine or other items within the dialysis station.
- After removing gloves.

Staff Interview
(SI)

- *After using chair side computers for charting.*

2: Hand rub technique:

Hand cleansing with an alcohol-based hand rub can be accomplished by applying alcohol-based hand rub into palm and briskly rubbing over all surfaces and under nails until dry.

- *Apply a 3-5ml of the product in a cupped hand and cover all surfaces*
- *Rub hands palm to palm*
- *Right palm over left dorsum with interlaced fingers and vice versa*
- *Palm to palm with fingers interlaced*
- *Back of fingers to opposing palms with fingers interlocked*
- *Rotational rubbing of left thumb clasped in right palm and vice versa*
- *Rotational rubbing, backwards and forwards with clasped fingers of right hand in left palm and vice versa*
- *Duration of the entire procedure: **20-30 seconds** once dry, your hands are safe.*

3: Hand washing technique:

Hand washing with plain or antimicrobial soap includes following steps:

- *Wet hands with water*
- *Apply enough soap to cover all surfaces*
- *Rub hands together vigorously for at least 15 seconds, generating friction on all surfaces of the hands and fingers*
- *Rub hands palm to palm*
- *Right palm over left dorsum with interlaced finger and vice versa*
- *Palm to palm with finger interlaced*
- *Backs of fingers to opposing palms with fingers interlocked*
- *Rotational rubbing of left thumb clasped in right palm and vice versa*
- *Rotational rubbing, backwards and forwards with clasped fingers of right hand in left palm and vice versa,(to remove debris from under the fingernails*
- *Rinse hands with water*
- *Dry thoroughly with a single-use towel*
- *Use towel to turn off faucet/tap*
- *Duration of the entire procedure: **40-60 seconds** and your hands are safe*

7

Sub-standard – 8:07

HCWs (8 - 10) are performing hand hygiene properly (appropriate technique and recommended duration). (O, SI)

Observation
(O)

Observe:

- ❖ During visit in all patient care areas the practice of staff, whether they are compliant with hand hygiene practices or not.
- ❖ Staff if they are following the recommended duration, steps and technique of hand rubbing & hand washing.

You may find staff providing care for patients in many units like ER, ICU, HDU, wards etc. or coming out of Isolation room in IUC, ER etc.. Keep watching their practice to get an idea of real compliance.

Staff Interview
(SI)

Interview:

- ❖ Randomly select different categories of healthcare workers (**HCWs**) and ask them to simulate hand hygiene. (Focus on technique, steps & duration). (*For duration, she must have timer to calculate exact duration of 20 – 30 seconds & hand washing for 40-60 seconds.*)
- ❖ Interview at least 8 - 10 different categories to get an average about their performance.
 - **Doctors**
 - **Nurses**
 - **Lab technicians**
 - **Respiratory therapists**
 - **Housekeeping / Waste collection Staff**
 - **Cover these categories in all units. (ER, ICU, OR, HDU, Endoscopy, Pharmacy, laboratory, Dental, kitchen. Laundry, Mortuary etc.**

Interview staff by giving a scenario:

Example: 1

*You have to give medication to patient ABC admitted in the medical ward with **MRSA**. After removing your gown and gloves how will you clean your hands.*

Answer: She must opt for hand rubbing with alcohol based hand sanitizer unless her hands are visibly soiled

Example: 2

Patient XYZ is admitted in ICU under contact isolation precautions. Diagnosis is Clostridium Difficile. You are assigned as primary nurse. After dealing with the patient how will you clean your hands?

Answer: She must opt for hand washing with soap & water because C- diff spores cannot be killed by alcohol based hand sanitizers.

Sub-standard – 8:08:

Reporting of hand hygiene self-assessment to “WHO” & “GDIPC” is active and ongoing using “WHO” hand hygiene self-Assessment framework (HHS). **(D,SI)**

- ❖ *Hand hygiene self-assessment framework is a systematic tool with which to obtain a situation analysis of hand hygiene promotion. Health-care facilities can track their progress in hand hygiene resources, promotion, and activities, plan their actions and aim for improvement and sustainability through the use of the WHO Hand Hygiene Self-Assessment Framework.*
- ❖ *The Hand Hygiene Self-Assessment Framework is divided into five components and 27 indicators. The five components reflect the five elements of the WHO Multimodal Hand Hygiene Improvement Strategy and the indicators have been selected to represent the key elements of each component.*

Review the following documents:

- ❖ The last hand hygiene self-assessment report submitted to “**World Health Organization**” and “**GDIPC**”.
- ❖ Check for completeness of self-assessment document incorporating all five components.
- ❖ For **GDIPC**, reporting is via electronic online system once per year.
- ❖ For **World Health Organization “WHO”** reporting is once per year.

Interview:

- ❖ IC team members how frequently they are submitting Hand Hygiene Self-Assessment Framework to GDICP & “WHO”
- ❖ Ask about components and major indicators of each components.
- ❖ Ask how the tool works and how is the interpretation done.

Components & Indicators of HHS framework :

1) System Change:

Indicators:

- *How easily available is alcohol-based hand rub in your health-care facility?*
- *What is the sink: bed ratio? etc.*

2) Training and Education:

Indicators:

- *How frequently do health-care workers receive training regarding hand hygiene in your facility?*
- *Is a process in place to confirm that all health-care workers complete this training?*
- *Is a system in place for training and validation of hand hygiene compliance observers? etc.*

3) Evaluation and Feedback:

Indicators:

- *Are regular (at least annual) ward-based audits undertaken to assess the availability of hand rub, soap, single use towels and other hand hygiene resources?*
- *Direct & Indirect Monitoring of Hand Hygiene Compliance*
- *Is immediate feedback given to health-care workers at the end of each hand hygiene compliance observation session?*
- *Systematic feedback is regular (at least 6 monthly).*
- *Feedback of data related to hand hygiene indicators with demonstration of trends over time.*

4) Reminders in the Workplace:

Indicators:

- *Are the following posters (or locally produced equivalent with similar content) displayed?*
- *How frequently does a systematic audit of all posters for evidence of damage occur, with replacement as required?*

5) Institutional Safety Climate for Hand Hygiene:

Indicators:

- *Hand hygiene team is dedicated to the promotion and implementation of optimal hand hygiene practice in your facility:*
- *Facility leadership made a clear commitment to support hand hygiene improvement? (e.g. a written or verbal commitment to hand hygiene promotion received by the majority of health-care workers)etc.*

Available @

https://www.who.int/gpsc/country_work/hhsa_framework_October_2010.pdf?ua=1

Sub-standard – 8:09

“WHO” hand hygiene improvement strategy tools are applied to improve the quality of hand hygiene. (D, O, SI)

- ❖ *Successful and sustained hand hygiene improvement is achieved by implementing multiple actions to tackle different obstacles and behavioral barriers. Based on the evidence and recommendations from the WHO Guidelines on Hand Hygiene in Health Care, a number of components make up an effective multimodal strategy for hand hygiene.*
- ❖ *The WHO multimodal hand hygiene improvement strategy has been proposed to translate into practice the WHO recommendations on hand hygiene and is accompanied by a wide range of practical tools (implementation toolkit) ready to use for implementation.*

The key components of the “WHO” Multimodal Hand Hygiene Improvement strategy are:

1) System change:

Ensuring that the necessary infrastructure is in place to allow health-care workers to practice hand hygiene. This includes two essential elements:

- *Access to a safe, continuous water supply as well as to soap and towels*
- *Readily accessible alcohol-based hand rub at the point of care*

2) Training / Education:

Providing regular training on the importance of hand hygiene, based on the “My 5 Moments for Hand Hygiene” approach, and the correct procedures for hand rubbing and hand washing, to all health-care workers.

3) Evaluation and feedback:

Monitoring hand hygiene practices and infrastructure, along with related perceptions and knowledge among health-care workers, while providing performance and results feedback to staff.

4) Reminders in the workplace:

Prompting and reminding health-care workers about the importance of hand hygiene and about the appropriate indications and procedures for performing it.

5) Institutional safety climate:

Creating an environment and the perceptions that facilitate awareness-raising about patient safety issues while guaranteeing consideration of hand hygiene improvement as a high priority at all level.

(Refer to WHO guidelines for more details

https://www.who.int/apsc/5may/Guide_to_Implementation.pdf)

Review:

Various Hand hygiene improvement strategy tools in the infection control department:

- ❖ Tools for System Change (*Ward Infrastructure Survey, Alcohol-based Hand rub Planning and Costing Tool, etc.*)
- ❖ Tools for Training / Education (*Slides for the Hand Hygiene Co-coordinator, Slides for Education Sessions for Trainers, Observers and Health-Care Workers, Hand Hygiene Training Videos, Observation Form etc.*)
- ❖ Tools for Evaluation and Feedback (*Hand Hygiene Technical Reference Manual, Observation Tools: Observation Form and Compliance Calculation Form etc.*)
- ❖ Tools for Reminders in the Workplace *Your 5 Moments for Hand Hygiene Poster, How to Hand wash Poster, How to Hand rub Poster*
- ❖ Tools for Institutional Safety Climate. *Template Letter to Advocate Hand Hygiene to Managers, Template Letter to Communicate Hand Hygiene Initiatives to Managers*

Observe:

In different patient care areas :

“WHO” Education tools for reminders at workplace :

- *Your 5 Moments for Hand Hygiene Poster*
- *Hand Hygiene: When and How Leaflet*
- *SAVE LIVES: Clean Your Hands Screensaver*
- *How to Hand rub Poster*
- *How to Hand wash Poster*
- *Glove Use Information Leaflet*
- *Hand hygiene information leaflets etc.*

Interview:

- ❖ Infection control team member about the **“WHO” multimodal hand hygiene improvement strategy tools.**
- ❖ Ask how they are using and implementing the various tools used for improving hand hygiene.
- ❖ Randomly ask how they are implementing WHO tools for hand hygiene observations. (ER, HDU, Wards, ICU, NICU etc.) Using **“WHO” observation forms.**

REFERENCES / WEB BASED RESOURCES:

1. APIC text of Infection Control & Epidemiology: Hand Hygiene
<http://text.apic.org/toc/basic-principles-of-infection-prevention-practice-/hand-hygiene>
2. Centre for disease Prevention & Control (CDC) Hand Hygiene. CDC website 2013
(Available at <https://www.cdc.gov/handhygiene/index.html>)
3. WHO Guidelines on Hand Hygiene in Healthcare 2009 (World Alliance for Patient Safety).
4. GCC Infection Prevention & Control Manual 3rd Edition 2018 – ICM - II – 04 Hand Hygiene : (Page 19 – 27)
5. WHO Guidelines on Hand Hygiene in Health Care : Clean care is safe care
<https://www.who.int/gpsc/5may/tools/9789241597906/en/>
6. Patrick M and Wicklin S. Implementing AORN recommended practices for hand hygiene. AORN Journal, 2012; 95:4.
7. Centers for Disease Control (CDC). Guideline for Hand Hygiene in Health-Care Settings.
<https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5116a1.htm>
8. Interventions to improve hand hygiene compliance in patient care: Available at
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6483670/>
9. A Guide to the Implementation of the WHO Multimodal Hand Hygiene Improvement Strategy
https://www.who.int/gpsc/5may/Guide_to_Implementation.pdf
10. WHO Hand Hygiene Self-Assessment Framework
https://www.who.int/gpsc/5may/hhsa_framework/en/

Sub-standard – 9:01

There are written infection prevention policies and procedures for PPE including types, indications, donning, doffing, disposal and safety. (D)

Personal Protective Equipment (PPE) is used to create a barrier between HCWs and patients, body substances, or surfaces. Appropriate PPE (gloves/gowns/plastic aprons/eye protection) should be used to prevent skin, eyes, mucous membrane, airways and clothing exposure. Components of PPE can be used alone or in combination based on the degree and risk of exposure in order to achieve desired level of protection.

Review:

*Policies & Procedures for Personal Protective Equipment use which should be **comprehensive** incorporating major domains as follows:*

✓ **Types of PPE:****a) Gloves:**

Gloves should be worn when there is contact with blood or body fluids, non-intact skin or mucous membrane, by touching surfaces / equipment contaminated with body fluids.

Types of gloves:

- a. Sterile gloves*
- b. Non-sterile gloves*
- c. Heavy duty gloves*

(Glove material – vinyl, latex, nitrile etc.)

b) Gowns / Plastic Aprons:

Gowns / Aprons should be worn if more extensive blood or body fluids splashing of clothing are likely and during procedures that may generate splashes or aerosolization of body substances and cause the soiling of clothes.

Types of gowns:

- a. Sterile gowns*
- b. Non-sterile gowns*

c) Mask & Respirators (N - 95)

Types of Masks:

- a. **Standard surgical masks (Protects mouth & nose)**
- b. **PPE for respiratory Protection: (Respirators (N- 95 masks) protects respiratory tract form airborne infectious agents e.g. mycobacterium Tuberculosis etc.)**
 - **High-efficiency particulate respirators (N- 95 , N 99 etc.)**
 - **Powered Air Purifying Respirators (PAPRs)**

- Surgical mask should be worn (with protective eye/face wear) if splashing or aerosolization of blood or body fluids is expected.
- Masks should fully cover the nose and mouth and prevent fluid penetration. Masks should fit snugly over the nose and mouth.
- Change mask between patients and sooner if mask becomes wet, moist or torn.
- Wear an N95 mask when indicated to enter an airborne isolation room, and remove it only when outside of the room.³

d) Protective Eye / Face wear:

- Eye/face wear should be worn if required for combined protection from eye/face contamination by aerosolized body substances.
- Wash and disinfect visibly soiled reusable face shields or protective eyewear prior to reuse, according to hospital policy.
- Protective eyewear / face wear are not to be worn after leaving the patient room or procedure area.

✓ **Indication of PPE use:** ³

PPE is indicated to be used based on risk assessment as part of standard precautions & Transmission based precautions.

(All isolation precautions must be used together with Standard Precautions)

- ❖ **Contact:** Appropriate PPE – Gown & Gloves
- ❖ **Droplet:** Appropriate PPE - Surgical mask, Gloves, and Gown
- ❖ **Airborne:** N95 mask / respirator before entering the room.

✓ **Sequence of donning and doffing of PPEs:** ³

(with eyewear, e.g., goggles or face shield) before entering and leaving a patient's room:

Donning: PPEs should be donned in this order.

Hand hygiene, gown, surgical mask, goggles/face shield then gloves.

Doffing: PPEs should be doffed in this order:

Gloves, hand hygiene, goggles/face shield, gown, hand hygiene, surgical mask then hand hygiene.

e) Mask & Respirators (N - 95)

Types of Masks:

- a. **Standard surgical masks (Protects mouth & nose)**
- b. **PPE for respiratory Protection: (Respirators (N- 95 masks) protects respiratory tract form airborne infectious agents e.g. mycobacterium Tuberculosis etc.)**

- **High-efficiency particulate respirators (N- 95, N 99 etc.)**
- **Powered Air Purifying Respirators (PAPRs)**

- *Surgical mask should be worn (with protective eye/face wear) if splashing or aerosolization of blood or body fluids is expected.*
- *Masks should fully cover the nose and mouth and prevent fluid penetration. Masks should fit snugly over the nose and mouth.*
- *Change mask between patients and sooner if mask becomes wet, moist or torn.*
- *Wear an N95 mask when indicated to enter an airborne isolation room, and remove it only when outside of the room.³*

f) **Protective Eye / Face wear:**

- *Eye/face wear should be worn if required for combined protection from eye/face contamination by aerosolized body substances.*
- *Wash and disinfect visibly soiled reusable face shields or protective eyewear prior to reuse, according to hospital policy.*
- *Protective eyewear / face wear are not to be worn after leaving the patient room or procedure area.*

✓ **Indication of PPE use:** ³

PPE is indicated to be used based on risk assessment as part of standard precautions & Transmission based precautions.

(All isolation precautions must be used together with Standard Precautions)

- ❖ **Contact:** Appropriate PPE – Gown & Gloves
- ❖ **Droplet:** Appropriate PPE - Surgical mask, Gloves, and Gown
- ❖ **Airborne:** N95 mask / respirator before entering the room.

✓ **Sequence of donning and doffing of PPEs:** ³

(with eyewear, e.g., goggles or face shield) before entering and leaving a patient's room:

Donning: PPEs should be donned in this order.

Hand hygiene, gown, surgical mask, goggles/face shield then gloves.

Doffing: PPEs should be doffed in this order:

Gloves, hand hygiene, goggles/face shield, gown, hand hygiene, surgical mask then hand hygiene.

✓ **Disposal of PPEs:** ³

a) Single-use PPE disposal:

- ❖ All PPEs are doffed inside the patient's room except N95 respirator which is removed outside AIR after closure of the door of patient's room in a specified waste receptacle as per hospital waste disposal policy.

b) Reusable PPE:

- ❖ Manufacturer's instructions must be followed for safe reuse of PPE. e.g Reuse of N-95 mask, eye goggles etc.
- ❖ Reusable heavy-duty gloves and boots (individual use) should be cleaned & disinfected after use and allowed to dry.

✓ **Safety :** ³

PPE should be used with extreme safety in order to avoid risk of acquiring infection & contamination. e.g:

- ❖ Keep gloved hands away from face
- ❖ Avoid touching or adjusting other PPE
- ❖ Remove gloves if they become torn; perform hand hygiene before donning new gloves
- ❖ Limit surfaces and items to be touched etc.
- ❖ Before leaving the patient's room or cubicle, PPE must be removed and discarded

Other domains of Policies & procedures:

P/P for PPE use should be :

Fully applicable: all elements of the policy can be applied and comply with the hospital's scope of services

Based on scientific references approved by MOH (***GCC, CDC, WHO & APIC***)

Signed from authorized personnel (i.e., owner of the policy / hospital director or Medical director / concerned department)

Approved by IC committee

2

Sub-standard – 9:02

Sub-standard - PPE is available in all patients care areas in adequate amounts and proper qualities. (D, O, SI)

Document
(D)

Review:

- ❖ PPE checklist for each unit / isolation room / wards and others patient care area
- ❖ PPE checklist should include minimal quantity of each type of PPE with daily monitoring.

Observation
(O)

Observe:

- ❖ **Availability of various types of PPE in all patient care areas:**
 - *Different sizes & types of gloves*
 - *Different sizes and type of N - 95 masks*
 - *Surgical masks*
 - *Gowns / Aprons*
 - *Protective eye/face wear (Goggles , face shields)*
 - *Powered air purifying respirators (PAPRs) for bearded staff etc.*
- ❖ **Assess the quality:**
 - *Yellow gowns: Check if fluid resistant and of thick material*
 - *Gloves: Check if good quality or loose at wrists*

(Quality can be assessed while HCWs are donning PPE)

Staff Interview
(SI)

Interview:

- ❖ Head nurse in all units about the availability of all types & sizes of PPE.
- ❖ Ask if she is satisfied with the quality of PPE provided.
- ❖ Ask about the process /mechanism of ensuring PPE availability at all time in all circumstances.

3

Sub-standard – 9:03

PPE is used according to the standard and/or transmission-based precautions through regular training on proper usage, and safety measures by infection control practitioners. (O, SI)

Observe:

- ❖ In different patient care if the health care workers are adhering with PPE policy. HCWs should use PPE judiciously based on specific indication & risk assessment. There should be no overuse or misuse of PPE.

Example:

During visit in various hospital units observe staff practice:

- ❖ *If patient is under **contact isolation** which PPE they are using, where they are doffing PPE & assess the sequence & technique while doffing PPE.*
- ❖ ***You may observe staff moving with PPE (Mask & gowns) & using computers with gloved hands.***
- ❖ *Open waste receptacles at random in isolation rooms to check if they are doffing PPE at appropriate places. (You may observe N - 95 mask inside isolation room waste receptacle)*

Comment (if any):

All PPE are doffed inside the patient's room except N95 respirator which is removed outside AIIR after closure of the door of patient's room.

Observation
(O)

Interview:

- ❖ Staff in different categories (Doctors, nurses, housekeeping, respiratory therapist etc.) about the required PPE in different situations.
- ❖ Ask about PPE used for contact, droplet, & airborne precautions.
- ❖ Ask about the training received from IC department on PPE use.

Ask them to simulate donning & doffing by giving different scenario and assess PPE selection, technique & steps of donning & doffing etc.

Example 1: Targeted HCW (Nurses, doctors)

How will you prepare yourself while entering patient's room under droplet isolation precautions: (Influenza A -H1N1 etc.) (Standard + Droplet)

Answer must be: Gloves, Gown, & surgical mask (Staff may select sterile gloves instead of clean gloves & may don N-95 mask instead of ordinary surgical mask etc.)

Example 2: Targeted HCW ((Nurses, doctors)

Patient is highly suspected for MERS-CoV and is in critical condition requiring CPR. As part of team how will you protect yourself before entering the isolation room??

Answer must be : Gloves, Gown, & N- 95 respirator, face /eye protection (Standard + Contact + Airborne)

Rationale: Critically ill suspected MERS – CoV patients requires Airborne precautions. Moreover CPR is an aerosol generating procedure so staff must consider full protection.

Example 3: Targeted HCW (Nurses, doctors)

Patient xyz is under contact isolation precautions due to Hospital Onset - MRSA (Methicillin Resistant Staphylococcus Aurous). What is the required PPE to be doffed before entering patient's room?((Standard + Contact)

Answer must be : Gloves & Gown with standard precautions (Staff may add surgical mask without any indication)

4

Document
(D)

Sub-standard – 9:04

N95 respirator fit testing is conducted for all HCWs every 2 years or when required. (D, SI)

Review:

- ❖ Policies & procedures for N - 95 fit test
- ❖ *(Could be a separate policy or part of policy. Policy must incorporate type of fit testing (Qualitative/Quantitative, Frequency of fit test, indication for use, alternate for bearded staff and those who failed repeated fit test etc.)*
- ❖ Records of N – 95 respirator fit test (electronic data base / manual) and match with the total number of staff.
- ❖ Check the percentage of fit test coverage.
- ❖ Check sample of fit test ID provided to the staff.

Staff Interview
(SI)

Interview:

- ❖ IC team regarding frequency of repeating fit test & which technique they have adopted for fit testing.
- ❖ Ask about % of staff coverage for N -95 fit test.
- ❖ Check fit test ID of any staff at random during visit and check for dates. Ask him / her for size and last fit test conducted.
- ❖ *Healthcare workers are required to have a respirator fit test at least once every 2 years and if weight fluctuates or facial/dental alterations occur.⁹*
- ❖ *A fit test only qualifies the specific brand/make/model of a respirator with which an acceptable fit testing result was achieved and therefore users should only wear the specific brand, model, and size he or she wore during a successful fit test.*
- ❖ *Each time a respirator is donned, a seal check must be performed using the procedures recommended by the manufacturer of the respirator.*
- ❖ *For healthcare workers who have facial hair that comes between the sealing surface of the face piece and the face of the wearer a Powered Air Purifying Respirator (PAPR) should be used instead.*

REFERENCES / WEB BASED RESOURCES:

11. APIC text of Infection Control & Epidemiology: Standard precautions
[http:// text.apic.org/toc/basic-principles-of-infection-prevention-practice-/standard – precautions](http://text.apic.org/toc/basic-principles-of-infection-prevention-practice-/standard-precautions)
12. Association for Professionals in Infection Control (APIC) and Epidemiology, Inc. (2014). Chapter 29: Isolation Precautions. In APIC Text of infection control and epidemiology (4th ed.)
13. Guidance for the Selection and Use of Personal Protective Equipment (PPE) in Healthcare Settings Available at <https://www.cdc.gov/HAI/pdfs/ppe/PPEslides6-29-04.pdf>
14. <https://www.cdc.gov/niosh/npptl/respirators/>
15. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4791533/>
16. <https://www.cdc.gov/infectioncontrol/guidelines/isolation/index.html>
17. <https://wwwn.cdc.gov/PPEInfo/>
18. https://www.cdc.gov/hai/prevent/ppe_train.html
19. Middle East Respiratory Syndrome Coronavirus; Guidelines For Healthcare Professionals Version 5.1 MAY 21, 2018

1

Sub-standard – 10:01

There are written policies and procedures for standard and transmission based precautions, including types, duration of isolation, patient transport, and visitors control. (D, SI)

Document
(D)**Review the policy, which should be:**

- 3) Comprehensive: it covers all standard and transmission based precautions, including types, duration of isolation, patient transport, and visitor's control.
- 4) Fully applicable: all elements of the policy can be applied and comply with the hospital's scope of services
- 5) Based on scientific references approved by MOH (GCC, CDC, WHO & APIC)
- 6) Signed from authorized personnel (i.e., owner of the policy / hospital director or hospital director / concerned department)
- 7) Approved by IC committee.
- 8) Valid (updated within 2 - 3 years and when indicated)

Staff Interview
(SI)**Ask HCWs about:**

1. Policy and procedure regarding to standard and transmission based precautions to measure their awareness about it.
2. In case of transporting of any patient with infectious diseases, what they will do with him to protect other from infection?

2

Sub-standard – 10:02

There is a clinical hand washing facility with hands free operation inside the patient's room or in the anteroom if available. (O)

Observation
(O)**Observe all isolation rooms in the hospital to insure that:**

- 1) It should contain hand-washing facility with hand free operation.
- 2) It should contain private toilet and shower.

3

Sub-standard – 10:03

Patient's room is provided with private toilet and shower (for isolation room in ICU, NICU, CCU toilet and shower are optional). (O)

Observation
(O)

Observe all isolation rooms in the hospital to insure that:

- 1) It should contain private toilet and shower.

4

Sub-standard – 10:04

PPE and alcoholic hand rub solution are available outside the patient's room at the corridor or in the anteroom (if provided). (O)

Observation
(O)

Observe all isolation rooms in the hospital to insure that:

- 1) PPE and hand hygiene supplies are available outside the PT's room at the corridor or in the anteroom if available.

5

Sub-standard – 10:05

All PPE are doffed inside the patient's room except N95 respirator which is removed outside AIIR after closure of the door of patient's room. (O,SI)

Observe all isolation rooms in the hospital to insure that:

All PPE are doffed inside the patient's room except N95 respirator which is removed outside AIIR after closure of the door of patient's room.

Staff Interview
(SI)

Ask HCWs about:

- 1) In case of caring of isolated PT, where are the HCWs should remove the PPE which include some time N95.

6

Sub-standard – 10:06

Visitors receive proper instructions from assigned personnel before entering into an isolation room, and they comply with recommended PPE. (O,SI)

Observation
(O)

Observe all isolation rooms in the hospital to insure that:

- 1) Presence clear signs with Arabic& English language that used to educate and guide the visitor about type of isolation and the precaution that should be taken before visit the isolated patient.
- 2) That educational signs should be attached to isolation rooms.

Staff Interview
(SI)

Ask HCWs about:

- 1) What is the proper way that to be used to educate the visitors of isolated patient to prevent them from infection?

7

Sub-standard – 10:07

A logbook is used for HCWs and visitors who had entered the isolation room, when needed. (D,SI)

Document
(D)

- 1) Make sure of presence of log book in each isolation room for HCWs and visitors who had entered the isolation room for example in case of mers-Cov patient.

Staff Interview
(SI)

Ask HCWs about:

- 1) Log book that used for HCWs and visitors who had entered the isolation room.
- 2) What is the purpose of that log book to ensure their awareness about It.

8

Sub-standard – 10:08

Non-critical patient-care equipment are single use or dedicated to one patient. (O,SI)

Observation
(O)

Observe the units which have isolation room to ensure that:

- 1) Are they use single item for isolated patient or not, such as BP devices, thermometer and food utensils?

Staff Interview
(SI)

Ask HCWs about:

- 1) Items or equipment that used for isolated patient, is it single use or not?

9

Sub-standard – 10:09

The signs used to indicate categories of isolation precautions are Clear and visible for HCWs and visitors, Bilingual (in Arabic & English., Color coded and compatible with diagnosis (Examples: contact: green, airborne: blue, and droplet: pink or red) (it is preferable to use the GDIPC approved isolation signs). (O,SI)

Observation
(O)

Observe all the units which have isolation room to ensure that:

presence of The signs used to indicate categories of isolation precautions are:

- (1) Clear and visible for HCWs and visitors
- (2) Bilingual (in Arabic & English.
- (3) Color coded and compatible with diagnosis (Examples: contact: green, airborne: blue, and droplet: pink or red).
- (4) The used signs are those approved from GDIPC. especially in MOH hospitals

Comment (if any): Color coded is according to policy of the hospital sometimes.

Staff Interview
(SI)

Ask HCWs about:

- 1) The signs used to indicate categories of isolation precautions?
- 2) Sign's Color and coded that used in their hospital.

10

Sub-standard – 10:10

Sputum specimens for tuberculosis are collected in AIIR (Airborne Infection Isolation Room) or well-ventilated place. (O,SI)

Observation
(O)

Observe all patient care unites to ensure that:

- 1) It should have AIIR to be used in case of collecting if sputum specimens for TB.

Staff Interview
(SI)

Ask HCWS about:

- 1) In case of TB sputum sample, where are patients should take it?

11

Sub-standard – 10:11

The receiving unit or facility is informed about the required isolation precautions and availability of appropriate PPE is ensured. (D, SI)

Document
(D)

Review the isolated patient medical record to ensure that:

- 1) Presence of infection control form or note to emphasize the required isolation precautions and information about appropriate PPE.

Staff Interview
(SI)

Ask HCWs about :

- 1) The policy and forms for transferring of isolated patient to another unit or hospital.

12

Sub-standard – 10:12

The transfer of patient under isolation precautions is restricted to medically necessary purposes, Isolation transportation cards must be used are consistent with the patient diagnosis , color coded and are posted in Arabic and English, and indicating the type of precautions required for staff (it is preferable to use the GDIPC approved isolation transportation cards) and selecting, low traffic time & route.. (O, SI)

Observation
(O)

Observe all patient services areas to ensure that :

- 1) Proper way for in case of transferring of isolated patient for example selected elevator and using transportation isolation cards.

Staff Interview
(SI)

Ask HCWs to ensure that:

- 1) Policy of transferring of isolated patient.
- 2) Transferring Time and way of isolated patient to ensure avoidance crowding and admixture him with others.
- 3) Availability and awareness of the approved transportation cards.

13

Sub-standard – 10:13

For transport patient under contact isolation precautions:

• Contain and cover all skin lesions and infected or colonized areas of the patient's body with clean bandages and clean linens. (O, SI)

Observation
(O)

- 1) Visit any patient with skin lesion under contact isolation and observe that lesion is covered with proper dressing or not?

Staff Interview
(SI)

Ask HCWs about:

- 1) Proper way to be taken with any isolated patient with skin lesion before transporting him.

14

Sub-standard – 10:14

For transport patient under droplet/airborne isolation precautions

- Instruct the patient to wear a surgical mask and follow respiratory hygiene and cough etiquette.
- Cover exposed skin lesions with clean bandages and/or clean linens. (D, SI)

15

Sub-standard – 10:15

HCWs who are transferring the patient under droplet/airborne isolation precautions do not need to wear respiratory protection during transport if the patient is masked and all skin lesions are covered. (D, SI)

16

Sub-standard – 10:16

There is screening policy for newly admitted or transferred patients to all critical care units (e.g., ICU, Cardiac CCU, NICU...) to identify those who require isolation precautions. (D, SI)

Review the screening policy of new admitted or transferred patient to all critical care units and it should be:

- 1) Comprehensive: it covers all infectious diseases and MDROs, blood born disease ...ect in critical care unit.
- 2) Fully applicable: all elements of the policy can be applied and comply with the hospital's scope of services.
- 3) Based on scientific references approved by MOH (GCC, CDC, WHO & APIC)
- 4) Signed from authorized personnel (i.e., owner of the policy / hospital director or hospital director /head critical care unit)
- 5) Approved by IC committee.
- 6) Valid (updated within 2 - 3 years and when indicated)

Document
(D)

Staff Interview
(SI)

Ask HCWs in critical care unit about:

- 1) Screening Policy of new admitted or transferred patient to critical care unit to ensure their awareness about it.

17

Sub-standard – 10:17

Portable chest x-ray is available for usage in isolation room when needed. (O, SI)

Observation
(O)

Observe the radiology department to ensure :

- 1) Presence of Portable chest x-ray is available for usage in isolation room when needed.

Staff Interview
(SI)

Ask HCWS in patient services area including the radiology department about presence of Presence of Portable chest x-ray in case of isolated patient when needed.

18

Sub-standard – 10:18

There is at least one AIIR for every 25 beds in general wards. (O)

Observation
(O)

Observe each general ward to ensure that:

- 1) Bed capacity of each ward.
- 2) Number of AIIRs.

19

Sub-standard – 10:19

At least one AIIR for each 8 beds in the ICU /PICU departments. (O)

Observation
(O)

Observe each critical area to ensure that:

- 2) Bed capacity of each ICU / PICU.
- 3) Number of AIIRs.

20

Sub-standard – 10:20

At least one AIIR for each 12 beds in the emergency room. (O)

Observation
(O)

Observe emergency room to ensure that:

- 1) Bed capacity of ER.
- 2) Number of AIIRs.

21

Sub-standard – 10:21

one AIIR in the NICU department as a minimum. (O)

Observation
(O)

Observe NICU to ensure that:

- 1) Availability of one AIIR or more.

22	<p>Sub-standard – 10:22</p> <p>AllIRs fulfill all MOH specifications for standard isolation rooms + windows are sealed and fixed (i.e., could not be opened/ (openings in walls and ceiling are sealed and airtight / doors are properly designed and well-sealed. (O)</p>
Observation (O)	<p>Observe each AIIRs in the hospital to ensure that:</p> <ol style="list-style-type: none"> 1. All AIIRs are fit to all MOH specifications for standard isolation rooms. 2. No windows can be opened. 3. Walls and ceiling should be sealed 4. All doors should be designed properly and well-sealed.

23	<p>Sub-standard – 10:23</p> <p>Airborne Infection Isolation Rooms (AIIRs) are under negative pressure (minimum -2.5 Pascal) with air totally exhausted to outside (100%) through High-Efficiency Particulate Air (HEPA) filters. The exhaust air ducts are independent of the building exhaust air system. (D)</p>
Document (D)	<p>Review the documentations that prove that all AIIRs in each unit are under monitoring for last 3 months to ensure that:</p> <ol style="list-style-type: none"> 1) Continuous monitoring of negative pressure to ensure that AIIRs are (-2.5) all the time. 2) Totally air exhausted to outside (100%) through High-Efficiency Particulate Air (HEPA) filters. 3) The exhaust air ducts are independent of the building exhaust air system. <p>Comment (if any): <u>You can call maintenance engineers to provide you with all document you want.</u></p>

24	<p>Sub-standard – 10:24</p> <p>There is 100% fresh air supply (i.e. return of air is not permitted) from central AC or concealed separate unit. All components of AIIR ventilation unit (supply & exhaust) are connected to emergency power supply to maintain air pressurization in the event of power failure. (D,O)</p>
Document (D)	<p>Review the documentation regarding to AIIRs to ensure that:</p> <ol style="list-style-type: none"> 1) The policy of AIIRs should contain with fresh air supply method as recommended. 2) Call maintenance engineers to provide you with document prove that fresh air supply to AIIRs as recommended and under their responsibility.

Observation
(O)

Observe each AIIRs in hospital to ensure that:

- 1) There is 100% fresh air supply from central AC or concealed separate unit.
- 2) All components of AIIR ventilation unit (supply & exhaust) are connected to emergency power supply to maintain air pressurization in the event of power failure.

Comment (if any): You can call maintenance engineers to help you to see central AC above the ceiling and explain it to you.

25

Sub-standard – 10:25

There is a fixed monitor outside the patient room in the corridor to continuously monitor the pressure difference between the patient room and corridor, with activation of audiovisual alarm when the ventilation system failed. (O)

Observation
(O)

Observe each AIIRs in the hospital to ensure that:

1. Fixed monitor outside each AIIRs in the corridor to monitor the pressure difference between the room and corridor.
2. It should be with audiovisual alarm when ventilation system failed.
3. Test the monitor to ensure that alarm is working or no, by keeping the door of AIIRs open for few seconds.

26

Sub-standard – 10:26

There is evidence of regular monitoring of negative pressure difference of AIIRs

- Daily when in use (i.e., a patient is isolated inside).
- Weekly when not in use (i.e., no patient is isolated).
- Monthly check by biomedical personals. (D)

Document
(D)

Review each document regarding to AIIRs to ensure:

1. Clear policy for regular monitoring of negative pressure difference of AIIRs.
2. All documents that prove of regular monitoring of negative pressure difference of AIIRs for at least last 3 months:
 - Daily when in use (i.e., a patient is isolated inside).
 - Weekly when not in use (i.e., no patient is isolated).
 - Monthly check by biomedical personals
3. Review all document that prove the biomedical personals are monitor an AIIRs monthly.

Observation
(O)

Observe each AIIRs in all hospital to ensure that:

1. Which AIIRs are occupied with patient or not to ensure the policy regarding to regular monitoring of negative pressure difference of AIIRs is applied or not.
 - If it is occupied, observe daily monitoring.
 - If it is unoccupied, observe weekly monitoring ...ect

27

Sub-standard – 10:27

HEPA filter is changed on a regular basis and according to manufacturer's recommendations. (D)

Document
(D)

Review all documents that prove the maintenance and changing of HEPA filter (as recommended) of each AIIRs in the hospital

28

Sub-standard – 10:28

There is evidence that air exchange of AIIR is ≥ 12 air changes per hour (≥ 12 ACH) with regular monitoring (at least quarterly). (D)

Document
(D)

Review all document that prove the air exchange of AIIRs is ≥ 12 air changes per hour (≥ 12 ACH) monitored at least quarterly.

29

ub-standard – 10:29

AIRs are used only for isolation of suspected or confirmed cases with airborne infectious diseases. (D,O,SI)

Document
(D)

Review the policy of AIRs to ensure that:

- 1) AIRs are used only for isolation of suspected or confirmed cases with airborne infectious diseases.

Observation
(O)

Observe each AIRS in the hospital to ensure that:

- 1) It is prohibited to use an AIRs for any patient other than suspected or confirmed cases with airborne infectious diseases. (observe each AIRs that occupied with patient by review the diagnosis in the medical record)

Staff Interview
(SI)

Ask HCWs in the patient services areas about:

1. How many AIRs they have?
2. What is it used for?
3. Are they occupied it with non-infectious diseases patients?

1

Sub-standard – 11:01

There is a written policy and procedures for clean, aseptic and sterile techniques. (D)

Review the policy, which should be:

- 9) Comprehensive and well descriptive: it covers all aspects of clean, aseptic and sterile techniques, including (but not limited to):
 - Proper preparation, dilution and/or preservation of medications in designated areas which are physically separated from patients' treatment areas
 - Essential safe practices for invasive procedures (required devices and supplies, antisepsis and recommended PPE & procedures)
 - Safe practices required for inserting peripheral venous catheter (i.e., fixing, dressing, labeling and replacement of peripheral venous catheters).
 - Recommended aseptic techniques and safe practices for preparation and use of:
 - a) Single-dose medication vials or single-use ampules
 - b) Multi-dose medication vials
 - c) Single-use devices (e.g., syringes, needles ...etc..)
 - d) Single-patient devices (e.g., cartridge devices as insulin pen)
 - e) Reusable (multi-use) devices
 - f) IV solution bottles
 - g) IV sets (including secondary sets and add-on devices)
 - h) Ventilation circuits
 - i) Humidifiers, nebulizers and other aerosol generating system
 - Necessary safe practices for urinary catheterization and handling collecting urine bags (required supplies, antisepsis and recommended PPE & procedures)
 - Safe practices required for spinal/epidural space catheterization or injection (required supplies, antisepsis and recommended PPE & procedures)
- 10) Fully applicable: all elements of the policy can be applied and comply with the hospital's scope of services
- 11) Based on scientific references approved by MOH (GCC, CDC, WHO & APIC)
- 12) Signed from authorized personnel (i.e., owner of the policy / hospital director or medical director / concerned department)
- 13) Approved by IC committee*
- 14) Valid (updated within 2 - 3 years and when indicated)

Document
(D)

Comment (if any):

- Approval by IC committee is required for the infection control manual as a whole before distribution and also for individual policy after major changes.

2

Sub-standard – 11:02

Separate clean area is available and maintained for preparation of medications (i.e., away from patients' treatment areas). (O – SI)

Observation
(O)

Observe patient's care areas that should be separated and away from clean area specified for preparation of medications:

- 1) Check the availability of the dedicated medication preparation areas which are physically separated from patients' treatment areas.
- 2) Observe medication preparation area(s) which should be provided with :
 - Controlled ventilation with monitor for recording the temperature and humidity (temperature ranges from 22 °C to 24 °C / relative humidity up to 70%)
 - At least, one hand washing sink that is equipped with hot & cold water / plain and antimicrobial soap / towels
 - At least, one alcohol based hand rub dispenser.
- 3) Observe if any patient requires medication during the visit, and where and how the responsible nurse is preparing this treatment.

Medication preparation area is the place for preparing and preservation of the multi-dose medications, while single dose medications can be taken to patients' care areas for single use purposes and any remaining doses should be discarded immediately (i.e., single-dose vials cannot be stored for future use even on the same patient)

Staff Interview
(SI)

Ask HCWs:

- 1) Where is the area specified for medication preparation?
or
- 2) Where and how are you preparing medications (e.g. getting a dose from multi-dose vials and preparing supplies for dressing change)?
- 3) Where you prepare medications? Especially if there is no available separated clean area
- 4) Where is the area specified for transient storing of lab specimen?
- 5) Where is the area specified for keeping used patient equipment before sending to CSSD?
- 6) Where is the area specified for transient storage of other used patient supplies?

Comment (if any):

Instead of direct questions, indirect ones or scenarios are advisable

3

Sub-standard – 11:03

For invasive procedures, sterile devices and supplies are used after patient's skin antisepsis (e.g., sterile syringes, needles and medications are used after skin antisepsis with approved antiseptic wipes). **(O – SI)**

Observation
(O)

Visit medical stores and medication preparation areas:

- 1) Observe if sterile devices and supplies required for invasive procedures (e.g., sterile syringes, needles, sterile medications, skin antiseptics, antiseptic wipes ...etc..) are available in adequate amounts in the medical stores or not?
- 2) Check if sterile devices and supplies required for invasive procedures (e.g., sterile syringes, needles, sterile medications, skin antiseptics, antiseptic wipes ...etc..) are available in adequate amounts in the medication preparation areas or not?

If amounts of these devices and supplies are inadequate, it is more likely to utilize unsterile items, ignore skin antisepsis, reuse single-use supplies ...etc..

- 3) Observe medical stores and medication preparation areas for the presence of opened sterile devices and supplies (e.g., opened syringes, needles, wound dressings, specific procedure kits, single-use medications ...etc..) which are kept to be used later on for invasive procedures.

This practices are prohibited even if these devices and items are used for the same patient (whether labeled with patient's name or not / whether labeled with date & time of the first use or not)

Ask HCWs:

Instead of direct questions, indirect ones or scenarios are advisable, Examples:

- 1) What are the types of devices and supplies required for a specific invasive procedure (e.g., IM injection, peripheral venous catheter insertion, wound dressing, foley's catheter insertion ...etc..)?
To assess their awareness about sterile devices and supplies that should be used for invasive procedure and importance of patient's procedure site antiseptics
- 2) How to properly apply patient's procedure site antiseptics for different invasive procedures?
- 3) What are the recommended safe practices for reusing syringes, needles, wound dressings or specific procedure's kits (regarding correct storage for future reuse / proper technique and labeling with date & time)
- 4) What are the precautions that should be strictly followed while storing a remaining dose in a prefilled syringe or single-use medication bottle for future use on the same patient? (regarding correct storage for future reuse / proper technique and labeling with date & time / discarding when indicated or after expiration of reuse life)
- 5) How you deal with opened unused sterile devices or items (e.g., syringes, needles or wound dressing kits) after treatment session or patient discharge?
- 6) How you deal with unused sterile devices or items (i.e. unused items with intact original wrap), that are brought to patient's care area?

- **Answer:**

- Only sterile devices and supplies are used for invasive procedures after patient's skin antiseptics (e.g., sterile syringes, sterile needles, sterile medications, sterile wound dressings, specific procedure kits, skin antiseptics, antiseptic wipes ...etc..)
- Sterile single-use devices or items (sterile syringes, needles, wound dressing kits, single-use medications ...etc..) are exclusively used for a single invasive procedure in a single patient. It should not be stored for future reuse even on the same patient (whether labeled with patient's name or not / whether labeled with date & time of the first use or not)
- Supplies are brought to patient's care area only when needed and after treatment session or patient discharge, all remaining single-use items are discarded while reusable ones are sent to CSSD for reprocessing (even unused items with intact original wrap).

4

Sub-standard – 11:04

A peripheral venous catheter is properly fixed, with a clearly written date of insertion, and to reduce risk of infection and phlebitis, it is replaced - if still needed - as follows:

- In adults: peripheral venous catheter is not replaced more frequently than every 72 to 96 hours
- In children: peripheral venous catheter is replaced only when clinically indicated. (O – SI)

Observation
(O)

Visit number of patients to observe fixed peripheral venous catheters & assess if:

- 1) Peripheral venous catheters are fixed properly (preferably with transparent sterile dressings)
- 2) Data of insertion are clearly written (date, time and responsible HCW)
- 3) Ask patient about the insertion time of peripheral venous catheter to insure that HCWs strictly follow the peripheral venous catheter related policy
- 4) Any peripheral venous catheter that is conflicting with the recommended duration for the replacement in adults (i.e., observe how frequent they are changing peripheral venous catheters in adult & children)
- 5) Peripheral venous catheter's insertion site is inspected each shift to be removed if signs of inflammation, infiltration, extravasation, signs of infection, occlusion or blockage are present, or if the PVC is no longer needed for therapy.
- 6) There is any sign that indicates replacement of peripheral venous catheter (e.g., signs of inflammation, infiltration, extravasation, signs of infection, occlusion, blockage ... etc..)

Ask HCWs:

Instead of direct questions, indirect ones or scenarios are advisable, Examples:

- 1) What are the recommended safe practices for inserting peripheral venous catheter (focused on fixing, dressing, labeling and replacement of peripheral venous catheters)?
- 2) How frequent should you inspect peripheral venous catheters for signs that indicate replacement (e.g., signs of inflammation, infiltration, extravasation, signs of infection, occlusion, blockage ... etc..)
- 3) What are the different indications for replacement of peripheral venous catheters (i.e., in adults and children)?

To assess their awareness about indications for replacement of peripheral venous catheters either time related or clinically based

- 4) How you manage a peripheral venous catheter if signs of infiltration or extravasation are observed?
- 5) How you manage a peripheral venous catheter if signs of occlusion or blockage are observed?
- 6) How you manage a peripheral venous catheter if signs of inflammation or infection are observed?

- **Answer:**

- Peripheral venous catheter should be fixed properly (preferably with transparent sterile dressings)
- Date of insertion should be clearly written (date, time and responsible HCW)
- Peripheral venous catheter's insertion site is inspected each shift to be removed if signs of inflammation, infiltration, extravasation, signs of infection, occlusion or blockage are present, or if the PVC is no longer needed for therapy.
- In adults, peripheral venous catheter is not replaced more frequently than every 72 to 96 hours
- In children, peripheral venous catheter is replaced only when clinically indicated.

5

Sub-standard – 11:05

Preparation & dilution of medications are only done by ready-made single-dose sterile solutions. (O – SI)

Visit medical stores and medication preparation areas:

- 1) Check if ready-made single-dose sterile solutions' bottles of appropriate sizes are available in adequate amounts in the medical stores or not?
- 2) Observe if ready-made single-dose sterile solutions' bottles of appropriate sizes are available in adequate amounts in the medication preparation areas or not?

If amounts of these items are inadequate or there is shortage of supplies, it is more likely to use large IV solution bottles for preparation & dilution of medications

- 3) Check if there is an opened large IV solution bottle in any medication preparation area specified for preparation & dilution of medications? Large IV solution bottle should not be used for preparation & dilution of medications even for the same patient (whether labeled with patient's name or not / whether labeled with date & time of the first use or not)

Ask HCWs:

Instead of direct questions, indirect ones or scenarios are advisable, Examples:

- 7) What are the types of sterile solutions that are used for preparation and dilution of different medications?
- 8) What are the recommended safe practices for using IV solution bottle in preparation and dilution of different medications (regarding correct storage for future reuse / proper technique and labeling with date & time / discarding when indicated or after expiration of reuse life)
- 9) What are the precautions that should be strictly followed while using IV solution bottle in dilution and preparation of different medications for the same patient?
- 10) How can you safely keep any remaining amounts after using ready-made single-dose sterile solutions' bottles for preparation and dilution of different medications?

- **Answer:**

- Only ready-made single-dose sterile solutions' bottles are used for preparation & dilution of different medications
- Ready-made single-dose sterile solution's bottle is exclusively used in preparation & dilution of medication for a single procedure/injection in a single patient. It should not be stored for reuse even on the same patient (whether labeled with patient's name or not / whether labeled with date & time of the first use or not)
- IV solution bottle should not be used for preparation & dilution of medications even for the same patient (whether labeled with patient's name or not / whether labeled with date & time of the first use or not)

Observation
(O)

Staff Interview
(SI)

6

Sub-standard – 11:06

Single-dose or single-use vial is used for a single procedure/injection in a single patient (i.e., single-dose or single-use vial is not stored for future use even on the same patient). (O – SI)

Visit medical stores, medication preparation areas and patient's care areas:

- 4) Check if single-dose or single-use vial is used for a single procedure/injection in a single patient or not?
- Observe if single-dose vials are available in adequate amounts (It is more likely to reuse these items if amounts are inadequate or there is shortage of supplies)
- Observe if these items are kept with remaining doses (single-dose vial should not be kept opened with any remaining dose whether labeled with any patient's name or not to avoid its reuse or storing for future use even on the same patient)

Examples:

- While checking the medication refrigerator, you find opened single-use vial labeled with patient's name & medical record number. This means it is stored for future use on the same patient.
- While checking the medication refrigerator, you find opened single-use vial without patient's name or medical record number. This means it is more likely to be reused by multiple patients.

Ask HCWs:

Instead of direct questions, indirect ones or scenarios are advisable,

Examples:

- 11) What are the best practices recommended for use of single-dose vials regarding number of patients; keeping remaining doses for future reuse and safe reuse life?
- 12) What are the precautions that should be strictly followed while storing a remaining dose in a single-use vial for future use on the same patient?
- 13) How can you safely inject multiple patients from one single-use medication vial?
- 14) How you deal with single-use vial after taking a small dose and patient discharge?

- Answer:

- Single-dose or single-use vial is used exclusively for only a single procedure/injection in a single patient. It should not be kept opened with any remaining dose whether labeled with any patient's name or not to avoid its reuse or storing for future use even on the same patient

Observation
(O)

Staff Interview
(SI)

7

Sub-standard – 11:07

Needles and syringes including prefilled syringes, and vacutainer holders are used for a single procedure/injection. (O – SI)

Observation
(O)

Visit medical stores, medication preparation areas and patient's care areas:

- 1) Check if needles, syringes including prefilled syringes, and vacutainer holders are used only for a single procedure/injection or not?
 - Observe if these items are available in adequate amounts (It is more likely to reuse these items if amounts are inadequate or there is shortage of supplies)
 - Observe if these items are kept sterile and with their original intact wrap (they should not be kept opened or labeled with any patient's name to avoid their reuse or storing for future use even on the same patient)

Examples:

- While checking the medication refrigerator, you find opened prefilled syringe labeled with patient's name & medical record number. This means it is stored for future use on the same patient.
- While checking the medication refrigerator, you find opened prefilled syringe without patient's name or medical record number. This means it is more likely to be reused by multiple patients.

Staff Interview
(SI)

Ask HCWs:

Instead of direct questions, indirect ones or scenarios are advisable,

Examples:

- 15) What are the best practices recommended for use of needles, syringes including prefilled syringes, and vacutainer holders regarding number of patients; keeping them for reuse and safe reuse life?
- 16) What are the precautions that should be strictly followed while storing a remaining dose in a prefilled syringe for future use on the same patient?
- 17) How can you safely inject multiple patients from one syringe filled with large dose of medication?
- 18) How you deal with vacutainer holder after taking samples and patient discharge?
 - **Answer:**
 - Needles, syringes including prefilled syringes, and vacutainer holders are used exclusively for only one procedure/injection. They should not be kept opened or labeled with any patient's name to avoid their reuse or storing for future use even on the same patient.

8

Sub-standard – 11:08

Cartridge devices such as insulin pens are used for only one patient. (O – SI)

Observation
(O)

Visit medication preparation areas:

- 5) Check if cartridge devices such as insulin pens are used or not (e.g., presence of insulin pens in the medication refrigerator)?
 - Open the refrigerator, if cartridge devices such as insulin pens are present, and HCWs claim that each device is exclusively allocated only for one patient:
Check that any used cartridge device is labeled with following data:
 - Patient's name & medical record number to be used exclusively for only one patient
 - Date of the first use to be discarded after expiration of the reuse life recommended by the manufacturer.
 - Check the refrigerator, if you find used cartridge device such as insulin pen without patient's name or medical record number, this means it is used for multiple patients.

Staff Interview
(SI)

Ask staff members:

- 1) Are cartridge devices such as insulin pens are used?
If yes:
 - 2) Is cartridge device as insulin pen exclusively used for only one patient?
If yes:
 - 3) What are essential data required to be recorded on cartridge device?
 - Answer:
 - Patient's name & medical record number to be used exclusively for only one patient.
 - Date of the first use to be discarded after expiration of the reuse life recommended by the manufacturer.
- Instead of direct questions, indirect ones or scenarios are advisable, Examples:**
- 4) What are the best practices recommended for use of cartridge devices regarding number of patients; keeping them while in use and reuse life?
 - 5) What are the precautions that should be strictly followed while using a cartridge device such as insulin pen for multiple patients?
 - 6) How can you safely inject a dose from a cartridge device such as insulin pen that is used for multiple patients?
 - 7) How you deal with insulin pen after patient discharge?
 - Answer:
 - Cartridge devices such as insulin pens are used exclusively for only one patient. It should be labeled with patient's name, medical record number and date of the first use to avoid its use for multiple patients and after expiration of the reuse life recommended by the manufacturer.

9

Sub-standard – 11:09

Supplies are brought to patient’s care area only when needed and after patient discharge, all remaining single-use items are discarded while reusable ones are sent to CSSD for reprocessing (even unused items with intact original wrap). (O – SI)

Observe the attitude of the staff members in different patient’s care areas (especially critical care areas, e.g., ER) towards:

- 1) Supplies and single-use medications that are taken to patient’s care areas (i.e., for any procedure, are only required or necessary amount of supplies and medications brought to patient’s care areas or not?)
- 2) Remaining unused supplies and medications taken to patient's care areas after termination of treatment session, completion of the procedure or patient discharge (i.e., are all remaining single-use items discarded while reusable ones sent to CSSD or not? even items with intact original wrap)

Supplies and single-use medications that are brought to patient’s care area only when needed

After termination of treatment session, completion of the procedure or patient discharge:

- All remaining single-use items are discarded, even unused ones with intact original wrap (i.e., they cannot be used on other patients or returned to clean areas, such as medical stores or medication preparation areas)
- All reusable items are sent for reprocessing, even unused ones with intact original wrap.

Example: Observe an ER nurse who wants to insert peripheral venous catheter:

- Is he/she brought supplies that are only needed for the procedure or extra supplies are taken there?
- If there are extra supplies, does he/she discard all unused single –use items and sent reusable ones to CSSD after patient discharge or not?

Observation
(O)

Comment (if any):

For successful observation, it is advisable to assess this standard during initiation & termination of different procedures or treatment sessions (e.g., HCWs bring and prepare medications and supplies before initiation of the procedures)

Ask staff members:

Instead of direct questions, indirect ones or scenarios are advisable, Examples:

- 1) What to do with extra supplies or single-use medications that are taken to patient's care area without being used during the procedure or the treatment session (items are still unused with intact original wrap)?
- 2) How you safely handle or disinfect unused extra supplies and medications that are taken to patient's care area during the procedure or the treatment session before being used for other patients?
- 3) In emergency situations, what are the rules that should be considered before returning unused extra supplies or medications that are taken to patient's care area to the central preparation area?

Answer:

- Remaining disposable supplies or single-use medications are discarded, even unused ones with intact original wrap (i.e., they cannot be used on other patients or returned to clean areas, such as medical stores or central preparation areas)
- All reusable items are sent for reprocessing, even unused ones with intact original wrap.

10

Sub-standard – 11:10

Whenever possible, multi-dose vial is used for a single patient, with recorded patient's name and date of the first use (when it has been accessed for the first time), and discarded after 28 days unless the manufacturer specifies a different shorter or a longer date (i.e., reuse life). (O – SI)

Sub-standard – 11:11

11

If multi-dose vial is used for more than one patient, it is exclusively kept and accessed in the area specified for preparation of medications (i.e., away from patients' treatment areas). (O – SI)

Observation
(O)

Visit medication preparation areas:

2) Check if multi-dose vials are used or not (presence of multi-dose vials to be used instead of single-dose vials)?

- If multi-dose vials are present, and HCWs claim that each multi-dose vial is exclusively allocated only for one patient (or whenever possible, used for one patient):

Observe to ensure that the following data are recorded on used vials:

- Date of the first use (when it has been accessed for the first time) to be discarded after 28 days unless the manufacturer specifies a different shorter or a longer date (i.e., reuse life).
- Patient's name & medical record number to be used exclusively for only one patient (or whenever possible, used for one patient)

- If multi-dose vials are present, and used for multiple patients:

Observe to ensure that:

- Date of the first use is recorded on used vial, to be discarded after 28 days unless the manufacturer specifies a different shorter or a longer date (i.e., reuse life).
- Multi-dose vials are exclusively kept and accessed in the medications preparation areas (i.e., multi-dose vials used for more than one patient are never taken to patients' treatment areas)

Visit patients' care areas:

1) Check if multi-dose vials are used instead of single-dose vials and present in patients' care areas?

- If multi-dose vials are present in patients' care areas:

Observe to ensure that the following information are recorded on used vials:

- Date of the first use is recorded on used vial, to be discarded after 28 days unless the manufacturer specifies a different shorter or a longer date (i.e., reuse life).
- Patient's name & medical record number is recorded on used vial to be used exclusively for only this patient (i.e., multi-dose vial is never kept in patients' treatment areas without patient's name & medical record number to avoid its use for multiple patients)

Ask HCWs:

- 1) Are multi-dose vials available and used instead of single-dose vials?
If yes:
- 2) Is multi-dose vial exclusively used for only one patient (or whenever possible, used for one patient)?
If yes:
- 3) What are essential data required to be recorded on multi-dose vials?
 - **Answer:**
 - Date of the first use (when it has been accessed for the first time) to be discarded after 28 days unless the manufacturer specifies a different shorter or a longer date (i.e., reuse life).
 - Patient's name & medical record number to be used exclusively for only one patient (or whenever possible, used for one patient)
 - If no, and multi-dose vials are used for multiple patients:
- 4) What are the precautions that required to be strictly followed while using multi-dose vials?
 - **Answer:**
 - Date of the first use is recorded on used vial, to be discarded after 28 days unless the manufacturer specifies a different shorter or a longer date (i.e., reuse life).
 - Multi-dose vials are exclusively kept and accessed in the medications preparation areas (i.e., multi-dose vials used for more than one patient are never taken to patients' treatment areas)
 - If multi-dose vial is present or kept in patients' treatment areas, patient's name & medical record number is recorded on used vial to avoid its use for multiple patients
- 5) To demonstrate how they can safely obtain a dose from a multi-dose vial that is used for multiple patients (i.e., required supplies, correct storage while in use, proper technique with labeling with date & time and discarding when indicated).

Ask HCWs about:

- 6) The best practices for use of multi-dose vials regarding number of patients, keeping vials while in use and reuse life

12

Sub-standard – 11:12

The self-sealed rubber cap of a medication vial or an IV solution bottle is disinfected with approved antiseptic wipes (e.g., alcohol wipes) prior to any access. **(O – SI)**

13

Sub-standard – 11:13

IV solution bottles are only accessed through the self-sealed rubber cap after being disinfected. **(O – SI)**

Observation
(O)

Visit medication preparation areas and/or patients' care areas:

- 1) Observe for availability of supplies required for disinfecting self-sealed rubber caps of medication vials or IV solution bottles prior to access (e.g., approved antiseptic alcohol wipes).
- 2) Observe to ensure that prior to any access to medication vial or IV solution bottle, its self-sealed rubber cap is disinfected with approved alcohol antiseptic wipes.
- 3) Check that IV solution bottles are only accessed through their self-sealed rubber caps after being disinfected.

Staff Interview
(SI)

Ask HCWs:

- 1) How can you safely get an access to the contents of a medication vial or an IV solution bottle?
or
- 2) What are precautions required while handling medication vials or IV solution bottles to prevent contamination?
- **Answer:**
 - Sterile devices are only used to access medication vials and IV solution bottles with strict adherence to aseptic techniques
 - Prior to any access to a medication vial or an IV solution bottle, its self-sealed rubber cap is disinfected with approved alcohol antiseptic wipe (i.e., vigorously scrub the self-sealed rubber cap with antiseptic wipe for 10 – 15 seconds / never touch the access site after the application of antiseptic / wait the access site to dry before being penetrated with sterile device)
 - Exclusively, IV solution bottles should be accessed through their self-sealed rubber caps after being disinfected.
- 3) To demonstrate how they can safely obtain a dose from a medication vial or get an access to an IV solution bottle (i.e., required supplies, right access through self-sealed rubber cap, proper technique with labeling with date & time when required, and changing IV solution bottle or discarding medication vial when indicated).

14

Sub-standard – 11:14

IV sets (including secondary sets and add-on devices) that are continually used to infuse crystalloid solutions (hypotonic, isotonic, or hypertonic), are replaced at least every 7 days, but not more frequently than 96-hour intervals. (O – SI)

15

Sub-standard – 11:15

IV sets that are used to administer blood, blood products, lipid emulsions, or dextrose/amino acid TPN solutions are replaced within 24 hours of initiating the infusion. (O – SI)

Visit patients' care areas:

- 1) In patients who are not receiving blood, blood products, lipid emulsions, or dextrose/amino acid TPN solutions (i.e., infusion of crystalloid solutions: hypotonic, isotonic, or hypertonic solutions), check that IV administration sets (including secondary sets and add-on devices) are continuously connected and replaced no more frequently than at 96 hour intervals, but at least every 7 days.

Rationale: Extending the duration of use permits considerable cost savings to hospitals without significant increase in the risk of healthcare-associated BSI with peripheral IVs

- 2) In patients who are receiving blood, blood products, lipid emulsions, or dextrose/amino acid TPN solutions, check that IV delivery systems are continuously connected and changed within 24 hours of initiating the infusion.
- 3) Observe that IV administration sets are labelled with dates & times of initiating treatment (e.g., dates & times of initiating infusion of crystalloid solutions (hypotonic, isotonic, or hypertonic solutions) or administration of blood, blood products, lipid emulsions or TPN solutions).

Notes:

- If possible, coordinate IV tubing changes with IV solution changes.
- If an epidemic of infusion-associated BSI is suspected, it may be prudent and practical to change IV administration sets within 24 hours of initiating the infusion.

Observation
(O)

Ask HCWs:

- 4) How frequent you should routinely replace IV administration sets that are continuously connected (including secondary sets and add-on devices)
or
- 5) What are the maximum periods allowed for the use IV delivery systems that are continuously connected?
 - **Answer:**
 - In patients who are not receiving blood, blood products, lipid emulsions, or TPN solutions (i.e., infusion of crystalloid solutions: hypotonic, isotonic, or hypertonic solutions), continuously connected IV delivery systems (including secondary sets and add-on devices) are replaced no more frequently than at 96 hour intervals, but at least every 7 days.
 - In patients who are receiving blood, blood products, lipid emulsions, or TPN solutions, continuously connected IV administration sets are changed within 24 hours of initiating the infusion.
 - If an epidemic of infusion-associated BSI is suspected, change IV administration sets within 24 hours of initiating the infusion.
- 6) What are the maximum period allowed for the use IV delivery system if an epidemic of infusion-associated BSI is suspected?
 - **Answer:**
 - In these circumstances, it may be prudent and practical to change IV administration set within 24 hours of initiating the infusion.
- 7) To demonstrate how they should prepare for infusion of crystalloid solutions (hypotonic, isotonic, or hypertonic solutions) or administration of blood, blood products, lipid emulsions or TPN solutions (i.e., required supplies, proper technique with labeling with date & time of initiating infusion or treatment and frequency of change of IV tubing and IV solution).

16

Sub-standard – 11:16

For a ventilated patient, ventilation circuit is only changed when visibly soiled or mechanically malfunctioning. (D – SI)

Document
(D)

Review the following documents:

- 1) Documented evidence that demonstrate proper application of this sub-standard:
 - Specific policy for change of ventilation circuits in the ventilated patients (Multidisciplinary policy approved from medical department, respiratory therapy department and nursing department)
 - Documents that record events of changing ventilation circuits in the ventilated patients with indications for replacement (either hard copies or soft copies / either individual patient's file, unit's records or respiratory therapist logs)

Staff Interview
(SI)

Ask HCWs (nurses – RT):

- 1) How frequent you should routinely change ventilation circuit in a ventilated patient, (what is the maximum period allowed to prevent VAP)?
 - **Answer:** For a ventilated patient, ventilation circuit is not routinely changed. Only changed when:
 - It is visibly soiled.
 - It is damaged, disrupted or mechanically malfunctioning

17

Sub-standard – 11:17

Sterile solutions are used in nebulizers, humidifiers, or any aerosol generating system and changed between patients and every 24 hours for the same patient unless the manufacturer of ready-made sterile solutions specifies different dates. (O – SI)

Observation
(O)

Visit patients' care areas to:

- 4) Observe for availability of supplies required for filling nebulizers, humidifiers, and any aerosol generating system (e.g., ready-made single-use bottles of sterile saline or sterile water / prefilled humidifiers with sterile solutions).
- 5) Check that only ready-made single-use bottles of sterile solutions are used to fill nebulizers, humidifiers, and any aerosol generating system (the use of prefilled humidifiers with sterile solutions is preferable).
- 6) Notice if sterile solutions used in nebulizers, humidifiers, and any aerosol generating system are changed between patients and every 24 hours for the same patient.
Observe to ensure that when humidifier or nebulizer is in use, it is labelled with date & time of initiating treatment (e.g., date & time of filling the humidifier or nebulizer with sterile solution).
- 7) Always follow instructions of the ready-made sterile solutions manufacturer when different dates for change are specified (e.g., the use of some prefilled humidifiers may extend for 1 month).

Staff Interview
(SI)

Ask HCWs:

- 8) What are the supplies required for using or filling nebulizers, humidifiers, and any aerosol generating system
- **Answer:** only ready-made single-use bottles of sterile saline or sterile water / prefilled humidifiers with sterile solutions.
- 9) How frequent you should routinely change sterile solutions used in nebulizers, humidifiers, and any aerosol generating system (what are the maximum periods allowed)?
- **Answer:** Sterile solutions used to fill nebulizers, humidifiers, and any aerosol generating system should be changed:
 - In-between patients (after each patient).
 - Every 24 hours for the same patient.
 - As specified by the ready-made sterile solutions manufacturer (e.g., the use of some prefilled humidifiers may extend for 1 month)
- 10) To demonstrate how they should prepare for and perform inhalation therapy using nebulizers, humidifiers, and any aerosol generating system (i.e., required supplies, proper technique with labeling with date & time of initiating treatment and frequency of change of sterile solutions)

18

Sub-standard – 11:18

A sterile urine bag is continuously connected to urinary catheter and evacuated with proper technique and appropriate PPE. (O – SI)

Observation
(O)

Visit patients' care areas to:

- 1) Observe for availability of all supplies required for strict adherence to aseptic technique while inserting the urinary catheter.
- 2) Check if aseptic technique is strictly applied while inserting the urinary catheter with maintenance of closed drainage system?
- 3) Notice if the closed drainage system of urinary catheterization is maintained at all times?
- 4) Observe for availability of urinary catheter systems with pre-connected, sealed catheter-tubing junctions (if applicable).
- 5) Check if the urinary catheter and collecting tube is always kept un-kinked to maintain unobstructed urine flow.
- 6) Check if the collecting urine bag is always kept below the level of the bladder and elevated from floor.
- 7) Observe emptying of the collecting urine bag: it should be performed regularly using proper technique (aseptic technique with proper PPE: gloves and gown as appropriate / clean separate collecting container for each patient / without splashing or contact of the drainage spigot with the nonsterile collecting container).
- 8) Check to ensure that urinary catheters and drainage bags are not changed on routine basis (change is only based on clinical indications such as breaks in aseptic technique, infection, obstruction, leakage, disconnection, or if the closed system is compromised).

Ask HCWs:

- 1) How frequent you should routinely change indwelling catheters or drainage bags?
 - **Answer:** urinary catheters and drainage bags are not changed on routine basis (change is only based on clinical indications such as breaks in aseptic technique, infection, obstruction, leakage, disconnection, or if the closed system is compromised).
- 2) How you should perform evacuation of the drainage urine bags?
 - **Answer:** emptying the collecting bag is regularly done using aseptic technique with proper PPE: gloves and gown as appropriate / clean separate collecting container for each patient / avoiding splashing and contact of the drainage spigot with the nonsterile collecting container
- 3) What is the proper PPE that should be worn during manipulation of the urinary catheters and collecting systems?
 - **Answer:** gloves and gown as appropriate
- 4) To demonstrate how they should prepare for and perform an urinary catheter insertion (i.e., required supplies, PPE and proper technique that should be followed during the urinary catheter insertion)
- 5) To demonstrate how they should prepare for and perform evacuation of the collecting urine bag (i.e., required supplies, PPE and proper technique that should be followed for regular emptying of urine bag)

19

Sub-standard – 11:19

HCW wears mask during insertion of a catheter or injection into spinal or epidural space. (O – SI)

Observation
(O)

Visit patients' care areas to:

- 1) Check if invasive procedures into spinal or epidural spaces are applicable in this unit(s) or not?
- 2) Observe for availability of all supplies required for strict adherence to aseptic technique while performing invasive procedures into spinal or epidural spaces (e.g., antiseptic wipes, sterile gloves, sterile drapes, and **surgical mask**)
- 3) Check if aseptic technique including wearing of a surgical mask is strictly applied while performing invasive procedures into spinal or epidural spaces (i.e., inserting catheter or injection into spinal or epidural space)?

Staff Interview
(SI)

Ask HCWs:

- 1) What are the best practices that should be applied while performing invasive procedures into spinal or epidural spaces (i.e., inserting catheter or injection into spinal or epidural space)?
- Answer should include wearing of a surgical mask.
- 2) To demonstrate how they should prepare for invasive procedures into spinal or epidural spaces (i.e., required supplies, PPE and steps for inserting catheter or injection into spinal or epidural space)
- Answer should include wearing of a surgical mask.

1

Sub-standard – 12:01

There is a written policy and procedure for suspected or confirmed MERS-CoV patients based on updated MOH guidelines. **(D)**

Middle East Respiratory Syndrome (MERS) is a viral respiratory disease caused by a novel coronavirus (Middle East Respiratory Syndrome Coronavirus, or MERS-CoV) that was first identified in Saudi Arabia in 2012. Typical MERS-CoV symptoms include fever, cough and shortness of breath. Pneumonia is common, but not always present. Approximately 35% of reported patients with MERS-CoV have died. Ministry of Health guidelines provides on managing MERS-CoV infection based on the best available scientific evidence including guidance on MERS-CoV surveillance activities in the healthcare setting and in the community, guidance on the infection control precautions for suspected and confirmed MERS-CoV cases, Standardizing the clinical management of MERS-CoV patients & to provide guidance for rational use of resources including laboratory testing etc..

Each hospital need to have clear policies and procedures for suspected or confirmed MERS-CoV cases adopted from MOH guidelines (Version 5.1 - 2018, tailored according to hospital situation.

Review:

*Policies & Procedures for MERS – CoV should be **comprehensive** incorporating following important domains⁽¹⁾*

- ❖ Case definition of suspected and confirmed case
- ❖ Description of respiratory pathway / Designated respiratory triage area with clear flowchart (**Visual triage station with scoring grid, Respiratory assessment room, Respiratory waiting area, Isolation room, etc.**)
- ❖ Transmission based Precautions
- ❖ Patient Placement
- ❖ Patient Transportation
- ❖ Personal Protective Equipment (PPE) For Healthcare workers
- ❖ Environmental Cleaning /Disinfection & Handling waste and linen
- ❖ IC Precaution for Aerosol-Generating Procedures (AGPs)
- ❖ Management of exposure to MERS- CoV in health care facilities
 - **Healthcare workers exposed to a MERS-CoV case**
 - **Patients exposed to a MERS-CoV case**

Document
(D)

- ❖ MERS – CoV outbreak Management
- ❖ Patient Transportation & prehospital Emergency Medical Services
- ❖ Duration of isolation Precautions for MERS – CoV infection
- ❖ Home Isolation instructions for eligible patients
- ❖ Laboratory Diagnosis (Specimen shipment protocols: Sample collection, packaging and shipping)
- ❖ General outlines of Management
- ❖ Managing bodies of deceased MERS – CoV cases etc.
- ❖ Appendices:
 - *Appendix A: Pneumonia Severity Index (PSI) scoring*
 - *Appendix B Visual triage checklist*
 - *Appendix C Algorithm for Managing Suspected MERS-CoV Patients*
 - *Appendix D MERS-CoV Surveillance Forms*
 - *Appendix E Guidelines for MERS-CoV Sample Collection, Packaging and Shipment*
 - *Others (as needed by hospital)*

Other domains of Policies & procedures:

P/P for MERS - CoV should be :

- **Fully applicable**: all elements of the policy can be applied and comply with the hospital's scope of services
- **Based on scientific references** approved by MOH
- **Signed** from authorized personnel (i.e., owner of the policy / hospital director or Medical director / concerned department)
- **Approved** by IC committee
- **Valid** : updated based on latest guidelines released from MOH.

2

Sub-standard – 12:02

HCWs have received continuous job-specific infection control training on MERS-CoV and competency testing. (D,PF,SI)

Document
(D)

Review the following documents:

- ❖ MERS-CoV specific training schedule / calendar
- ❖ Attendance sheet of training activities conducted for MERS - CoV
- ❖ MERS CoV specific competency form

Personal File
(PF)

Review the randomly selected Personal files of HCWs and check the following:

- ❖ Evidence of MERS CoV specific training activities (*in service, local, national certificates of attendance in MERS – CoV specific conferences, workshops, seminars etc.*)
- ❖ Evidence of MERS- CoV competency assessment

Staff Interview
(SI)

Interview:

- ❖ Healthcare workers at random when did they last receive training on MERS CoV guidelines.
- ❖ Assess the knowledge by asking relevant questions related to their unit etc.
 - a) *What are signs and symptoms and mode of transmission of MERS – CoV??*
 - b) *What is the type of precaution required for stable and critically ill MERS patients???*
 - c) *What are Aerosol generating procedures??*
 - d) *What are Post exposure management & follow up protocols for HCWs??*
- *Professional development of Healthcare workers is an important component of practice.¹*
- *In order to ensure and sustain the competencies of healthcare workers (HCWs) in infection control practices training and education is of utmost importance to limit the chances of infectious disease transmission among HCWs, patients, sitters, and visitors.²*
- *All HCWs need to be properly informed, trained and provided with the required knowledge and skills on infection control best practices relevant to their specific job.*
- *Competency is defined as the proven ability to use knowledge and skills on personal, social, and/ or methodological capabilities in work and study situations, especially in professional practices and professional development.*

Comment (if any):

Efficient training of HCW assigned for the Respiratory triage is likely to improve the reliability of process.

3

Sub-standard – 12:03

Written reminders for updated definitions of suspected cases of MERS-CoV are available in the emergency department & staff are quite familiar with these definitions. **(O,SI)**

Observation
(O)**Observe:**

- ❖ Updated written case definition reminders in Emergency department and hemodialysis unit. **(Case definition posters, personal cards etc.)**
- ❖ Observe if posted at convenient locations. **(Nursing stations, respiratory assessment rooms etc. for education & as a reminder for ER & HDU physicians to apply criteria for suspected case definitions for all patients directed from visual triage station with score 4 & above.**

Staff Interview
(SI)**Interview:**

- ❖ ER & HDU physicians & other relevant staff regarding updated case definition of **MERS- CoV**.
- ❖ Ask when they last received orientation / training about latest **MERS- CoV** guidelines including case definition.

Answer must include age categorization, Clinical presentation of suspected case categories (I – IV) including Severity Scores for Community-Acquired Pneumonia (CURB 65) & epidemiological link.

See case definition below

4. CASE DEFINITION**4.1 SUSPECTED CASE¹**

Age	Clinical Presentation	Epidemiologic Link
Adults	I. Severe pneumonia (severity score ≥ 3 points) (Appendix A) or ARDS (based on clinical or radiological evidence)	Not required
Adults ²	II. Unexplained deterioration ³ of a chronic condition of patients with congestive heart failure or chronic kidney disease on hemodialysis	Not required
Children and adults	III. Acute febrile illness ($T \geq 38^{\circ}C$) with/without respiratory symptoms OR IV. Gastrointestinal symptoms (diarrhea or vomiting), AND leukopenia ($WBC \leq 3.5 \times 10^9/L$) or thrombocytopenia (platelets $< 150 \times 10^9/L$)	Within 14 days before symptom onset: 1. Exposure ⁴ to a confirmed case of MERS-CoV infection OR 2. Visit to a healthcare facility where MERS-CoV patients(s) has recently (within 2 weeks) been identified/treated OR 3. Contact with dromedary camels ⁵ or consumption of camel products (e.g. raw meat, unpasteurized milk, urine)

Sub-standard – 12:04

There is a designated triage areas “FOR RESPIRATORY TRIAGE” in ER and Hemodialysis unit (and employee health clinic only in case of MERS - CoV outbreaks) for suspected MERS-CoV cases that is physically separated from other areas. (O)

To prevent the transmission of respiratory infections in the healthcare settings, including MERS-CoV and influenza, all healthcare facilities should have designated triage area for suspected MERS-CoV cases that is physically separated from other areas. ⁽¹⁾

Observe the availability of designated triage area in the following units: (Should be the first area to be reached by ER & dialysis patients before they get in contact with staff or other patients.)

1: Emergency Rooms & Hemodialysis Units:

❖ Visual Triage:

Visual Triage must be available at the entry point of the healthcare facility (i.e. emergency room entrance, dialysis unit entrance) for effective capturing & early identification of all individuals passing through the entrance with ARI symptoms. ***(Required equipments at Visual triage includes Respiratory scoring forms. Surgical mask, hand hygiene sanitizer, posters etc.) ⁽¹⁾***

❖ Respiratory Triage Clinic / Assessment room :

Designated Respiratory Triage Clinic / Isolation room) is available. Identified ARI patients should be isolated and evaluated immediately in an area separate from other patients separate ideally a separate room ⁽¹⁾.

- ***Suspected cases score ≥ 4 are escorted / directed safely to Respiratory Triage Clinic / Isolation room.***
- ***If fulfilling criteria for suspected MERS – CoV patients should be transferred to negative pressure room or single room with HEPA filter for further management. (MERS – CoV testing etc.)*****

❖ Respiratory Waiting Area:

Dedicated waiting area for the ARI patients with fixed chairs & spatial separation of at least 1.2 meter between each ARI patient and others need to be available.⁽¹⁾

- ***If ARI patients cannot be evaluated immediately, they should wait in a waiting area dedicated for the ARI patients.¹***

❖ Airborne Infection Isolation Room / Single room with HEPA filter:

Suspected Patients are transferred to AIIR / Single isolation room with HEPA filters for necessary chest x-ray and swabbing. (When needed).

Patient Placement:

- ***Patient fulfilling criteria for suspected /confirmed cases who are not critically ill should be placed in single patient rooms in an area that is clearly segregated from other patient-care areas using HEPA filter.***
- ***Critically ill patients with suspected or confirmed MERS-CoV infection should be placed in Airborne Infection Isolation Rooms (Negative Pressure Rooms), if available. When negative pressure rooms are not available, the patients***

should be placed in adequately ventilated private rooms with a portable HEPA filter.(1)

2: Employee health Clinic (EHC):

- ❖ Designated triage area need to be available in EHC during **MERS – CoV** outbreaks situations only.
- ❖ During outbreaks due to varying number of staff exposures ER capacity would be inadequate to provide post exposure management services for all exposed health care workers.

5

Sub-standard – 12:05

Respiratory triage for MERS-CoV is activated in ER and hemodialysis unit according to updated MOH MERS-CoV guidelines. **(O,SI)**

Observation
(O)

- ❖ *All patients attending hemodialysis units and all emergency room attendees (except those with immediately life-threatening conditions) must be triaged at the entrance using predefined scoring.* ⁽¹⁾
- ❖ *Respiratory triage station should be placed at the entry point of the healthcare facility (i.e. emergency room entrance, dialysis unit entrance) or other designated areas and attended by a trained nurse or nurse assistant.* ⁽¹⁾

Observe:

- ❖ Availability of **Respiratory** triage stations at the entry point of all areas specified above. **(Emergency room entrance, dialysis unit entrance etc.)**
- ❖ Visual triage is active and updated predefined scoring grid is available. **(Manual / Electronic)**
- ❖ How staff is interviewing the patients (If possible to observe real scenario) & if she / he is bilingual (Arabic + English)

Staff Interview
(SI)

Interview:

1: ER:

- ❖ Ask staff assigned at the respiratory triage station for how long respiratory triage is functional / activated throughout the day. **(Answer should be 24/7)**
- ❖ Ask about her role at the respiratory triage station.
- ❖ Ask if he /she has any back up if she has to leave the station for some time (During lunch break etc.)

2: In Hemodialysis Unit:

- ❖ **Assigned and trained HCW should be available in the Respiratory triage area before starting each dialysis session.**

6

Sub-standard – 12:06

Patients who have acute respiratory symptoms are instructed to wear surgical masks and placed in a dedicated separated waiting area with distance between them according to updated MOH MERS-CoV guidelines. **(O,SI)**

Respiratory Waiting Area: Dedicated waiting area for the ARI patients with spatial separation of at least 1.2 meter between each ARI patient and others need to be available.⁽¹⁾

Observe:

- ❖ How the respiratory triage nurse is dealing with patients with acute respiratory symptoms and their companions. **(Instruction should include perform hand hygiene & wear surgical mask)**
- ❖ If alcohol-based hand sanitizer, surgical masks are available at the visual triage desk or not.
- ❖ How she is directing the patients to the dedicated respiratory waiting area.
- ❖ Dedicated respiratory waiting area for ARI patients if fulfills MOH requirements.
 - Estimate the distance between chairs in the waiting area. **(spatial separation of at least 1.2 meter between each ARI patient and others according to MOH MERS – CoV guidelines)**
 - Observe if **alcohol-based hand sanitizer**, paper towels, MERS **education material**, education material on cough etiquette /respiratory hygiene & hand hygiene etc. is posted.

Interview:

- ❖ Staff at the visual triage station about the instructions to be given to the patients with ARI symptoms and their companions. **(Identified ARI patients should be asked to perform hand hygiene and wear a surgical mask.)**
- ❖ Ask staff what would be the next patient destination if score is 4 & above and how she will manage situation if she face 2 or more patients at the same time. **(Answer : Patient A will be directed to respiratory assessment room & remaining patients will wait in dedicated waiting area for ARI patients)**

Comment (if any):

If ARI patients cannot be evaluated immediately, they should wait in a waiting area dedicated for the ARI patients.¹

Observation
(O)

Staff Interview
(SI)

7

Sub-standard – 12:07

Bilingual visual signs for patients and visitors on recommended Hand Hygiene & Respiratory Hygiene/Cough Etiquette practices are posted in the emergency department and outpatients and inpatient areas .(O)

Observe:

- ❖ If Visual alerts (in appropriate languages **Arabic, English**) are posted at the entrance of healthcare facilities (e.g., emergency rooms, inpatients and outpatient areas).
(Posters, banners, electronic screens etc.) Containing information regarding hand hygiene & Respiratory Hygiene/Cough Etiquette practices.
- ❖ Check if these visual alters are posted at convenient locations / places where information can be easily seen and read by the patients & visitors in order to alert them.
- ❖ **Messages in the visual alerts include the following:**
 - **Cover your mouth and nose with a tissue when coughing or sneezing.**
 - **Dispose of the tissue in the nearest waste receptacle immediately after use.**
 - **How to wear surgical mask & Perform hand hygiene (e.g., hand washing with non-antimicrobial soap and water, alcohol-based hand sanitizer, or antiseptic hand wash) after having contact with respiratory secretions and contaminated objects or materials.**

Observation
(O)

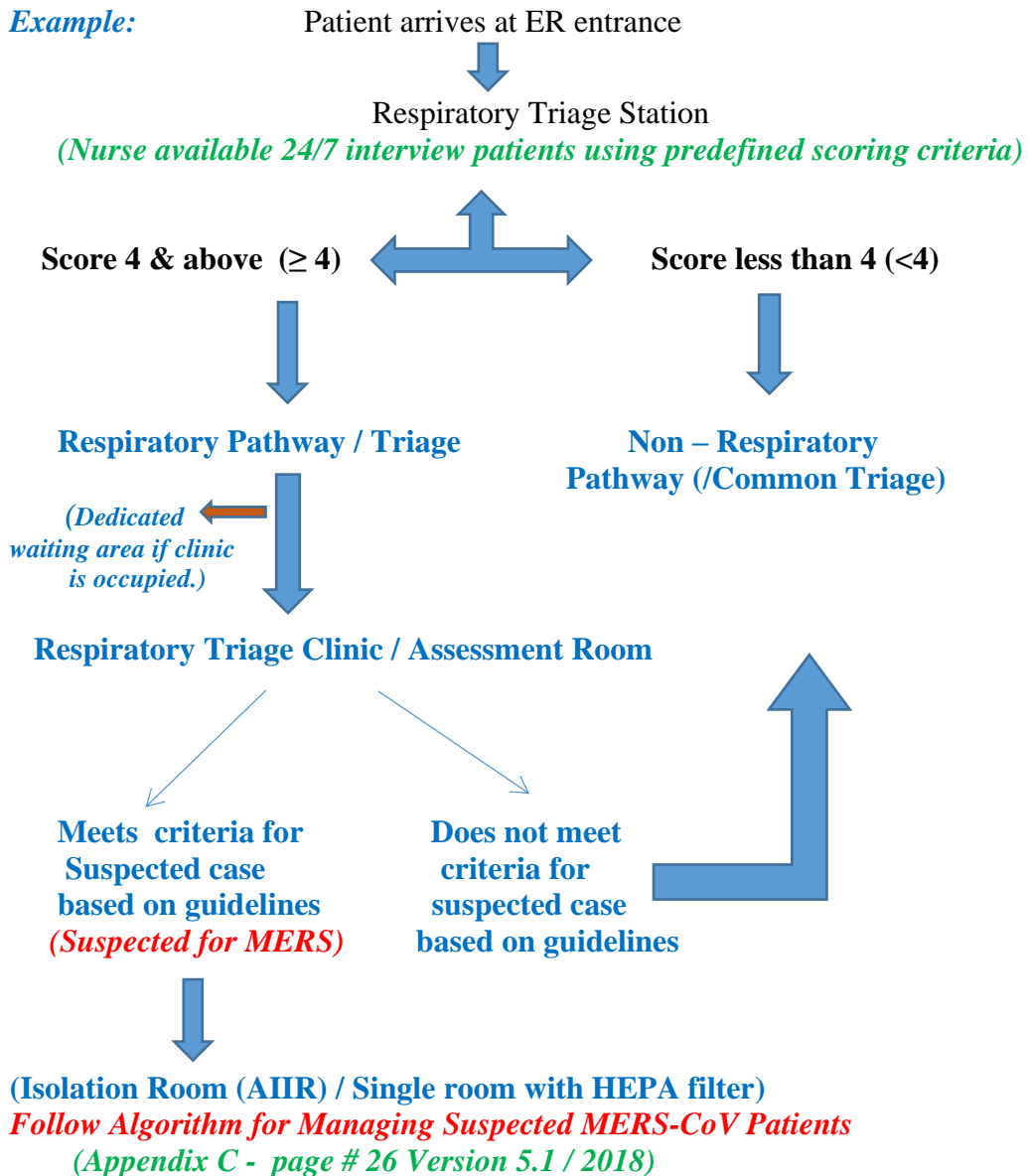
Sub-standard – 12:08

There is a protocol for early detection, management, and transfer of respiratory illness patients, “Flow Chart” must be available and present on well seen place in ER& HDU.

(D,SI)

Review :

- ❖ Flowchart for suspected or confirmed MERS –CoV cases based on updated MOH guidelines.
- ❖ Flowchart should clearly describe respiratory pathway from initial checkpoint at ER / HDU entrance.

Example:

Interview:

- ❖ IC team about how they developed the flowchart. *(Must be based on MERS – Guidelines)*
- ❖ Staff in ER about the flowchart and match with the hospital situation.
- ❖ Flowchart must be available & posted in ER & HDU for suspected MERS – CoV & all staff must be very well oriented about the protocols / steps to be followed based on hospital flowchart.

Comment (if any):

HDU must have their own flowchart describing the respiratory pathway for suspected hemodialysis patients.

Sub-standard – 12:09

Hospital has log for HCWs who contact with a confirmed case to record the presence of fever, symptoms of acute respiratory illness, diarrhea, vomiting or nausea before starting their shift. **(D,SI)**

According to MERS – CoV guidelines from Ministry of health, all healthcare facilities should identify and trace all health care workers who had protected (proper use of PPE) or unprotected (without wearing PPE or PPE used improperly) exposure to patients with suspected, or confirmed MERS-CoV infection. Asymptomatic healthcare workers WITH protected exposure OR unprotected low risk exposure (more than 1.5 meters of the patient). (Refer to MERS guidelines)

Healthcare workers shall be assessed daily for 14 days post exposure for the development of symptoms through the activation of log.

Review :

- ❖ Log with line listing of all contacts exposed to confirmed case recording the signs & symptoms for the duration of 14 days. **(Applicable for Hospitals previously reported MERS CoV cases and 14 days monitoring was done)**
- ❖ Sample of log sheet is attached below.

Interview:

- ❖ Staff about the post exposure management & follow up to a confirmed positive MERS- CoV case.
- ❖ Ask her if she has low risk unprotected exposure, for how long she / he should be under observation & how the monitoring will be done.

(Answer should be 14 days post exposure with daily monitoring via activation of logbook before starting shift)

Comment (if any): *See below the line list form*

Appendix C

Line Listing Record for Exposed Healthcare Workers Contacts: (Form 4)

Page # 42

Appendix D (count..)

Middle East Respiratory Syndrome Coronavirus;
Guidelines for Healthcare Professionals - April 2018 - v 5.1

MERS-CoV Outbreak

Line Listing Record for Healthcare Workers Contacts: (Form 4)

Facility: _____

Facility Contact: _____

Personal Data						Daily Progress Use Legend: SF=Symptoms Free; F=Fever; C=Cough; N/V=Nausea/Vomiting; BA= Body Aches; H=Headache Died=Death HOS=Hospitalization, Test=MERS-CoV tested														
Record name once and do not remove name from line list						Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8	Day 9	Day 10	Day 11	Day 12	Day 13	Day 14	
Name (To be typed in English and Arabic)	ID/ iqama number	Age/ Sex	Nationality	Exposure risk (High or Low)		DDV/ MNU/ Y	DDV/ MNU/ Y	DDV/ MNU/ Y	DDV/ MNU/ Y	DDV/ MNU/ Y	DDV/ MNU/ Y	DDV/ MNU/ Y	DDV/ MNU/ Y	DDV/ MNU/ Y	DDV/ MNU/ Y	DDV/ MNU/ Y	DDV/ MNU/ Y	DDV/ MNU/ Y	DDV/ MNU/ Y	
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10

Sub-standard – 12:10

Nasopharyngeal swabbing of suspected or re-swabbing for confirmed patients is performed by trained HCW personnel, there must be schedule for duty covering 24 hours for the trained assigned HCWs for nasopharyngeal swabbing. **(D,SI)**

Document
(D)

Review:

- ❖ List of health care workers (Doctors, nurses etc.) who have received training on appropriate technique of nasopharyngeal swab from patients from infection control department. (Manual or electronic evidence)
- ❖ Check of schedule for duty covering 24 hours for the trained assigned HCWs for nasopharyngeal swabbing.

Nasopharyngeal Swabs (NS Specimen Collection) :

Health caring facilities must assign and train personnel to perform nasopharyngeal swabbing.

Ensure that HCWs who collect specimens should be properly trained on the technique and wear PPE appropriate for aerosol generating procedures.

Staff Interview
(SI)

Interview:

- ❖ Concerned staff (doctors, nurses etc.) in ER, ICU about last training on nasopharyngeal swab technique.
- ❖ Randomly ask staff to simulate technique of nasopharyngeal sample collection for MERS – CoV testing..

APPENDIX - E

Guidelines for MERS-CoV Sample Collection, Packaging and Shipping

Technique of sample collection:

***Nasopharyngeal swabs:** Insert a swab into the nostril parallel to the hard palate. Leave the swab in place for a few seconds to absorb secretions. Swab both nasopharyngeal areas.*

***Nasopharyngeal and Oropharyngeal swabs (NP/OP swabs) MUST BE TAKEN TOGETHER.** Use only synthetic fiber swabs with plastic shafts. Do not use calcium alginate swabs or swabs with wooden shafts, as they may contain substances that inactivate some viruses and inhibit PCR testing. Place swabs immediately into sterile tubes containing 2-3 ml of viral transport media. NP/OP specimens MUST BE combined, placing both swabs in the same vial. Refrigerate specimen at 2-8°C up to 48 hours; if exceeding 48 hours, freeze at - 70°C and ship on dry ice.*

***Oropharyngeal swabs:** Swab the posterior pharynx, avoiding the tongue.*

11

Sub-standard – 12:11

HCWs perform aerosol generating procedures (AGP) on any suspected or confirmed MERS-CoV cases in a negative pressure room or single room with a portable HEPA filter using proper PPE (e.g., N95 mask, eye protection, gloves, and gown). (O,SI)

An aerosol-generating procedure (AGP) is defined as any medical procedure that can induce the production of aerosols of various sizes, including small (< 5 microns)

Particles. AGPs includes bronchoscopy, sputum induction, intubation and extubation, cardiopulmonary resuscitation, open suctioning of airways, Ambu bagging, nebulization therapy, high frequency oscillation ventilation and Bilevel Positive Airway Pressure ventilation – BiPAP

As per MERS – CoV guidelines:

Precautions to be observed when performing aerosol- generating procedures, which may be associated with an increased risk of infection transmission:

- ❖ *Perform procedures in a negative pressure room or single room with HEPA filter*
- ❖ *Limit the number of persons present in the room to the absolute minimum required for the patient's care and support.*
- ❖ *Wear N95 masks: Every healthcare worker should wear a fit-tested seal check N95 mask (or an alternative respirator if fit testing failed) Wear eye protection (i.e. goggles or a face shield).*
- ❖ *Wear a clean, non-sterile, long-sleeved gown and gloves (some of procedures require sterile gloves*
- ❖ *Wear an impermeable apron for some procedures with expected high fluid volumes that might penetrate the gown.*
- ❖ *Perform hand hygiene before and after contact with the patient and his or her surroundings and after PPE removal.*

Observe :

HCWs performing any aerosol generating Procedure (**AGPs**) like CPR, intubation, extubation, suctioning etc. for any suspected or confirmed MERS- CoV cases. **(If possible to observe the real situation / scenario)**

- ❖ Type of PPE used by HCWs while preparing for AGPs.
- ❖ If AGPs are performed in negative pressure room / single room with HEPA filter.

Interview:

- ❖ HCWs (*Doctors / nurses*) at random about what is meant by term Aerosol Generating Procedures **AGPs** and if they can enumerate different aerosol generating Procedures (**AGPs.**)
- ❖ HCWs about type of precautions to be take & / PPE to be worn while performing **AGPs.**
- ❖ HCWs where **AGPs** to be performed for any suspected or confirmed MERS –CoV patient.

Alternatively they can be interviewed by giving a scenario.

Scenario:

Observation
(O)

Staff Interview
(SI)

*Patient XYZ was directed to Respiratory assessment room from visual triage with score 8. After applying criteria for suspected MERS – CoV based on guidelines patient fulfilled criteria IV. You decide to take Nasopharyngeal swab for the patient.
Where are you going to perform the procedure and what type of precautions will be taken before entering the patient's room?*

REFERENCES / WEB BASED RESOURCES:

- 1) Middle East Respiratory Syndrome Coronavirus ; Guidelines for Healthcare Professionals :*Version 5.1 May 21, 2018 : Ministry of health Guidelines*
- 2) “WHO” Middle East Respiratory Syndrome Coronavirus (MERS-CoV) : *Monthly summary*
<https://www.who.int/emergencies/mers-cov/en/>
- 3) “CDC” Middle East Respiratory Syndrome Coronavirus (MERS-CoV)
<https://www.cdc.gov/coronavirus/mers/index.html>
- 4) Interim Infection Prevention and Control Recommendations for Hospitalized Patients with Middle East Respiratory Syndrome Coronavirus (MERS-CoV)
<https://www.cdc.gov/coronavirus/mers/infection-prevention-control.html>
- 5) Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Middle East Respiratory Syndrome Coronavirus (MERS-CoV). Centers for Disease Control and prevention (CDC). *Available at: <http://www.cdc.gov/coronavirus/mers/guidelines-lab-biosafety.html>*
- 6) Assiri A, McGeer A, Perl TM, Price CS, Al Rabeeah AA, Cummings DA, Alabdullatif ZN, Assad M, Almulhim A, Makhdoom H, et al. Hospital outbreak of Middle East respiratory syndrome coronavirus. **N Engl J Med.** 2013;369(5):407-16.
- 7) Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Patients Under Investigation (PUIs) for the Middle East Respiratory Syndrome Coronavirus (MERS-CoV) – Version 2. *Centers for Disease Control and prevention (CDC). 9 January 2014. Available at: <http://www.cdc.gov/coronavirus/mers/guidelines-clinical-specimens.htm>*
- 8) IP Competency Task Force. APIC Competency model for the Infection Preventionists: A conceptual approach to guide current and future practice.” APIC 2010-2011.

NEJM Procedure: Collection of Nasopharyngeal Specimens with the Swab Technique:
<http://www.youtube.com/watch?v=DVJNWefmHjE> <https://youtu.be/CcyLv67U8-Y>

1

Sub-standard – 13:01

There is a written policies and procedures for employees' health related issues (i.e., pre-employment counseling and screening, immunization, post exposure management and work restriction). (D)

Review the policy, which should be:

- ❖ Comprehensive: it covers all aspects of infection control regarding employee's health program, including (but not limited to):
 - Pre-employment counseling & baseline screening
 - Determining of immune status & administering appropriate vaccines
 - Reporting, follow up and management of needlestick or sharp injuries and blood or body fluid exposures.
 - Reporting, follow up and management of exposure to open pulmonary TB, MERS-CoV, chicken pox, measles, mumps, and rubella
 - Work restrictions.
 - Employee health related education & training programs
 - BICSL license & N95 fit testing
- ❖ Fully applicable: all elements of the policy can be applied and comply with the hospital's scope of services
- ❖ Based on scientific references approved by MOH (GCC, CDC, WHO & APIC)
- ❖ Signed from authorized personnel (i.e., owner of the policy / hospital director or medical director / concerned department)
- ❖ Approved by IC committee*
- ❖ Valid (updated within 2 - 3 years and when indicated)

Document
(D)

Comments:

- Approval by IC committee is required for the infection control manual as a whole before distribution and also for individual policy after major changes

2

Sub-standard – 13:02

There is a special clinic for employees' health that provides pre-employment counseling and screening, immunization, post exposure management and work restriction. (O - SI)

Observation
(O)

Observe the employee health clinic to ensure that:

- 1) It is a dedicated clinic that covers all activities of employee health program:
 - Pre-employment counseling & baseline screening
 - Determining of immune status & administering appropriate vaccines
 - Reporting, follow up and management of needlestick or sharp injuries and blood or body fluid exposures.
 - Reporting, follow up and management of exposure to open pulmonary TB, MERS-CoV, chicken pox, measles, mumps, and rubella
 - Work restrictions.
 - Employee health related education & training programs
 - BICSL license & N95 fit testing
- 2) The clinic has a definite time and assigned staff (either full-time or part-time)

Staff Interview
(SI)

Ask assigned staff of the employee health clinic about activities of the clinic:

- 1) How do you determine the immune status of newly hired staff against hepatitis B, measles, mumps, rubella and varicella to administer appropriate vaccine(s)?
- 2) How do you report, follow up and manage a physician with unprotected exposure to a case of confirmed MERS-CoV infection?
- 3) How do you manage a HCW who has been exposed to a case of chicken pox?
- 4) What are you going to do after being informed that a laundry employee has been exposed to needlestick injury today?
- 5) How do you report, manage and follow up a nurse who has been exposed patient's blood during surgery?
- 6) What are the components of BICSL license and how do you calculate coverage rate?
- 7) How do you send reports and data through EPINet, HESN or other approved reporting system (if applicable)?
- 8) How can you apply work restrictions on a nurse who has been exposed to a case of measles (if applicable)?
- 9)

Comment (if any):

- **Instead of direct questions, indirect ones or scenarios are advisable.**

3

Sub-standard – 13:03

All employees have a baseline screening for hepatitis B, hepatitis C, HIV and tuberculosis (TB). **(D - MR)**

4

Sub-standard – 13:04

The immune status of newly hired staff against hepatitis B, measles, mumps, rubella and varicella are determined by documented vaccination, serological evidence of immunity, or documented clinical / laboratory evidence of disease with lifelong immunity). Appropriate vaccine(s) is administered to those who are susceptible. **(D - MR - SI)**

Document
(D)

Review the following documents:

- 2) Plan & written protocol for screening any newly hired employee for hepatitis B, hepatitis C, HIV and tuberculosis (TB).
- 3) Screening data
- 4) Plan & written protocol for identifying susceptible staff based on documented vaccination, serological evidence of immunity, or documented clinical / laboratory evidence of the disease.
- 5) Vaccination programs for susceptible HCWs
- 6) Vaccination activities / Lists of target groups for different vaccines & coverage rates.

Medical Record
(MR)

Randomly review 3 - 4 HCWs' medical records:

Examples: medical director, head of ICU department, ER nurse, surgeon, lab.

Technician, respiratory therapist ... etc.

- 1) Check for evidence of baseline screening for hepatitis B, hepatitis C, HIV and tuberculosis (TB)
- 2) Check for evidence of immunity regarding hepatitis B, measles, mumps, rubella and varicella:
 - Documented vaccination
 - Serological evidence of immunity
 - Documented clinical / laboratory evidence of the disease
- 3) Check for evidence of administration of appropriate vaccine(s) to those who are susceptible.

Ask assigned staff of the employee health clinic:

- 1) How do you identify susceptible staff regarding hepatitis B, measles, mumps, rubella and varicella to administer appropriate vaccine(s)?
- 2) How can you establish required vaccination programs for susceptible HCWs?
- 3) How do you correctly prepare lists of target groups & calculate coverage rates for different vaccines?
- 4) How can you properly document different vaccination activities?

Comment (if any):

- Instead of direct questions, indirect ones or scenarios are advisable.

***Level of immunity is defined as:**

- 1) **Hepatitis B virus:** evidence of immunity by level of HBsAb > 10 m IU/ ml
- 2) **Measles:** Presumptive evidence of immunity is written documentation of vaccination with two doses of MMR vaccine administered at least 28 days apart, laboratory evidence of immunity, laboratory confirmation of disease.
- 3) **Mumps:** presumptive evidence of immunity if they have written documentation of vaccination with two doses of MMR vaccine administered at least 28 days apart, laboratory evidence of immunity, laboratory confirmation of disease.
- 4) **Rubella:** Personnel should have documentation of one dose of live rubella vaccine on or after their first birthdays or laboratory evidence of immunity to rubella.
- 5) **Varicella** HCP are considered to have immunity if they have laboratory evidence of immunity, an evidence of clinical diagnosed or verified varicella or zoster, or documentation of age-appropriate vaccination.

5

Sub-standard – 13:05

The influenza vaccine is administered annually to targeted HCWs as per MOH recommendations. (D - MR - SI)

Document
(D)

Review the following documents:

- 1) Lists of target groups for annual influenza vaccination
- 2) Annual report of the employee health clinic that includes overall coverage rate of annual influenza vaccination

Medical Record
(MR)

Randomly review 3 - 4 employee medical records:

Examples: **medical director, head of ICU department, ER nurse, surgeon, lab. Technician, respiratory therapist, one of housekeeping staff, ... etc..**

- 1) Check for evidence of annual influenza vaccination
- 2) Check for evidence valid BICSL license (if applicable)

Staff Interview
(SI)

Ask 3 - 4 HCWs about being vaccinated with the annual influenza vaccine:

- 1) What is the last vaccine you get and when?
- 2) Show me your card of BICSL license (if applicable, it should be valid license)

Comment:

- Instead of direct questions, indirect ones or scenarios are advisable.

6

Sub-standard – 13:06

Newly hired staff are screened for tuberculosis upon contracting with Purified Protein Derivative based Tuberculin Skin Test (PPD-based TST). The test is repeated annually for those who are non-reactive and PPD-based TST conversion rates are monitored and calculated. (D - MR - SI)

Document
(D)

Review the following documents:

- 1) Overall coverage rate for baseline PPD-based Tuberculin Skin Testing of hospital's staff.
- 2) Lists of target groups (non-reactive HCWs) for annual PPD-based TST
- 3) Annual report of the employee health clinic that includes coverage rate of annual PPD-based TST & conversion rate

Medical Record
(MR)

Randomly review 3 - 4 employee medical records:

Examples: head of medical department, ER nurse, physician, lab. Technician, respiratory therapist, one of housekeeping staff, one of kitchen staff (butcher, or pastry cooker), one of waste personnel ... etc..

- 3) Check for evidence of the baseline PPD-based TST (if applicable)
- 4) If HCW is non-reactive, check for evidence of annual PPD-based TST

Staff Interview
(SI)

Ask assigned staff of the employee health clinic:

- 1) How do you correctly prepare lists for target groups for baseline and annual PPD-based TST?
 - 2) Do you have to include HCWs who have a history of receiving BCG vaccine in baseline PPD testing?
 - 3) Do you have to include HCWs with documented previous PPD-based TST positive reaction?
 - 4) How do you administer and read PPD-based TST?
 - 5) How do you properly interpret results of PPD-based TST?
 - 6) How can you calculate PPD-based TST conversion rates?
- **Instead of direct questions, indirect ones or scenarios are advisable.**

Comment (if any):

- A Purified Protein Derivative based Tuberculin Skin Test (PPD-based TST) should be administered, read, and interpreted by trained personnel.
- Intradermal method (Mantoux) is used to administer the PPD-based TST. Tine tests should not be used.
- Baseline screening should be conducted at the time of hire. Those individuals who have a history of having received the BCG vaccination should be included unless they have documentation of a previous positive reaction.

- A two-step TST should be performed when the initial TST is negative and there is no documented negative TST during the preceding 12 months.
- Interpretation of the TST depends on measured TST induration in millimeters, the person's risk for being infected with *M. tuberculosis*, and risk for progression to active TB if infected.

Purpose of Testing	Tuberculin Skin Test
Baseline	<ul style="list-style-type: none"> • ≥ 10 mm is considered a positive result (either first or second step)
Serial testing without known exposure	<ul style="list-style-type: none"> • Increase of ≥ 10 mm is considered a positive result (TST conversion)
Known exposure (close contact)	<ul style="list-style-type: none"> • ≥ 5 mm is considered a positive result in persons who have a baseline TST result of 0 mm • An increase of ≥ 10 mm is considered a positive result in persons with a negative baseline TST result or previous follow-up screening TST result of ≥ 0 mm

- If personnel have a positive TST, a chest radiograph should be done promptly to check for active disease. A history of exposure should be obtained to determine if infection is occupational or community-associated.
- The person should be instructed to report symptoms that are suggestive of TB as chest radiographs do not need to be repeated unless the person is symptomatic.
- A recent converter should be referred to a healthcare provider for consideration of preventive therapy.
- **PPD-based TST conversion:** a 10-mm or greater increase in the size of the TST induration during a 2-year period in a person with a documented negative (<10 mm) baseline two-step TST result
- **The conversion rate:** is the percentage of persons whose test result has converted within a specified period.
(i.e., to calculate a conversion rate, divide the number of conversions among HCWs in the setting in a specified period (numerator) by the number of personnel who received tests in the setting over the same period and multiply by 100).
- If there has been unprotected exposure of workers to TB, TSTs should be administered at the time of the exposure and repeated at 12 weeks post-exposure to look for possible converters. Chest radiographs are performed only on those with prior positive TST and who are currently symptomatic (consider retesting immunocompromised personnel at least every 6 months)
- Personnel who have laryngeal or pulmonary TB are excluded from work until they are receiving adequate therapy, the cough has resolved, and there have been three consecutive sputum smears negative for acid-fast bacilli. The employee health clinic should obtain periodic documentation from the healthcare provider. If treatment is discontinued, the person needs to be promptly evaluated for infectiousness.

7

Sub-standard – 13:07

There is an implemented system for reporting, follow up, and management of sharp or needlestick injuries and blood/body fluid exposures. (D - MR - SI)

8

Sub-standard – 13:08

Reporting through electronic system is active and ongoing (i.e., reliable reports of sharp or needlestick injuries and blood/body fluid exposures are sent to GDIPC through EPINet, HESN or other approved reporting system in a timely manner). (D - SI)

Document
(D)

Review the following documents:

- 1) Fulfilled EPINeT forms (or other equivalent forms) during the last 3 - 6 months for HCWs who had exposed to sharp/needlestick injuries or blood/body fluid
- 2) Evidence of regular reliable reporting (i.e., ongoing & active reporting in timely manner).
- 3) Annual report of the employee health clinic that includes sharp/needlestick injuries & blood/body fluid exposures rates

Medical Record
(MR)

Review medical records of the last 2-3 HCWs who had exposed to sharp/needlestick injuries or blood/body fluid for:

- 1) Documented evidence of follow up and management:
 - Post Exposure Prophylaxis (PEP)
 - Vaccination against Hepatitis B virus
 - Hepatitis B immune globulin (HBIG) to susceptible HCWs
 - Follow up serological testing
 - Counselling & treating diseased HCWs, ... etc..

Ask 3 - 4 of hospital's staff of different categories:

Examples: ER nurse, surgeon, lab. Technician, respiratory therapist, one of the waste handling team, one of housekeeping staff, laundry personnel ... etc.

- 1) What are you going to do if you have exposed a sharp or needlestick injury?
- 2) Do you have to squeeze the site of injury and apply powerful antiseptics locally?
- 3) What are you going to do for reporting this incident?

Ask assigned staff of the employee health clinic:

- 1) How do you evaluate both the exposed employee and the source patient?
 - 2) How can you properly apply post-exposure follow up & management plan for HBV, HCV or HIV?
 - 3) How can you report, manage and follow up a nurse who had exposed to sharp injury from unknown source?
 - 4) How can you report, manage and follow up a lab. technician who had exposed to needlestick injury from a patient +ve for HBV & HIV?
 - 5) When do you get your last training program regarding EPINet, HESN or other approved reporting system
 - 6) Show me how you can report a case of sharp/needlestick injury or blood/body fluid exposure to GDIPC through EPINet, HESN or other approved reporting system
 - 7) How do you properly interpret changes in sharp/needlestick injuries & blood/body fluid exposure rates?
- **Instead of direct questions, indirect ones or scenarios are advisable.**

Comments:

Expected answer of hospital's staff:

- I do not squeeze the site of injury and no need to apply antiseptics locally.
- I just wash affected area with soap and running water (for eye exposure I wash with saline or running water)
- I contact employee health clinic to report the incident and fill up EPINet or other equivalent form, then I join a special protocol for post-exposure follow up & management

9

Sub-standard – 13:09

There is an implemented system for reporting, follow up and management of exposure to open pulmonary TB, MERS-CoV, chicken pox, measles, mumps, and rubella. (D - SI)

Document
(D)

Review the following documents:

- 1) Last 2 - 3 fulfilled forms for exposure (lists of HCWs who had exposed to MERS-CoV, open pulmonary TB, chicken pox, measles, mumps or rubella, with classification into low or high risk / protected or non-protected exposure).
- 2) Isolation room's logs that record HCWs who had exposed to the above mentioned diseases
- 3) Evidence of reliable reporting of exposures to GDIPC when indicated (e.g., exposure to MERS-CoV confirmed cases, exposures during chicken pox or measles outbreaks, ... etc..).
- 4) Annual report of the employee health clinic that includes exposure incidents to MERS-CoV, open pulmonary TB, chicken pox, measles, mumps and rubella

Staff Interview
(SI)

Ask assigned staff of the employee health clinic:

- 1) How can you properly apply post-exposure reporting, follow up & management plan for MERS-CoV, open pulmonary TB, chicken pox, measles, mumps and rubella?
- 2) How do you report, manage and follow up a physician who had exposed to a patient confirmed for MERS-Co?
- 3) How can you report, manage and follow up a respiratory therapist who had exposed to a case of open pulmonary TB?
- 4) How do you report, manage and follow up exposures during chicken pox outbreak?
- 5) How can you report, manage and follow up a nurse who had exposed to a patient +ve for measles

Comments:

- Instead of direct questions, indirect ones or scenarios are advisable.

10

Sub-standard – 13:10

The Employee health clinic team regularly monitors different types of staff exposure and recommend corrective actions to prevent recurrence, e.g., devices with safety mechanisms (self-sheathing needles-retractable needles and scalpels ... etc..). (D - SI)

Document
(D)

Review the following documents:

- 1) Annual report of the employee health clinic that includes rates of different exposures (or changes in exposure rates with or without corrective interventions)
- 2) Documented evidence of corrective intervention:
 - Change in specific policy to replace a risky procedure with a less risky procedure
 - Replacing a risky device or equipment with a device or equipment that has more advanced safety features
 - Comparing exposure rates before & after corrective actions or prevention strategies.
- 3) IC committee meeting minutes that discuss and interpret rates of different exposures (or changes in exposure rates) classified by department, occupational category, device-based ... etc..
- 4) Documented evidence of feedback that is provided to HCWs involved in corrective interventions or prevention strategies.

Staff Interview
(SI)

Ask HCWs involved in corrective interventions or prevention strategies about:

- 1) Rates of different exposures (or changes in exposure rates) classified by department, occupational category, device-based ... etc..
- 2) Continuous communication & feedback (e.g., exposure rates before & after application of the corrective action or the prevention strategy).
- 3) Change in the policy that replaces the risky procedure with the less risky procedure (if any)
- 4) Replacing the risky device or equipment with the device or equipment that has more advanced safety features (if any)

Comments:

- Instead of direct questions, indirect ones or scenarios are advisable.

11

Sub-standard – 13:11

Updated medical records (or copies) are available for all personnel of supportive services (i.e., kitchen, laundry, housekeeping, waste management ...etc.) **(D - MR)**

Document
(D)

Review the following documents:

- 1) Documented evidence of listing all of the hospital's staff with job categories including personnel in supportive services (i.e., kitchen, laundry, housekeeping, waste management ...etc.)

Medical Record
(MR)

Randomly review 3 - 4 original medical records (or copies) of personnel of supportive services:

Examples: **one of housekeeping staff, one of kitchen staff (butcher, or pastry cooker), one of waste personnel, laundry supervisor ... etc..**

- 1) Check for evidence of baseline screening (if applicable)
- 2) Check for evidence of immunity or administration of appropriate vaccine(s) to those who are susceptible
- 3) Check for evidence of post exposure follow up and management (if applicable)
- 4) Work restrictions
- 5)

12

Sub-standard – 13:12

The screening, immunization, and post exposure management data are kept in staff medical records. **(MR)**

Medical Record
(MR)

Randomly review 3 - 4 employee medical records:

Examples: **head of medical department, ER nurse, physician, lab. Technician, respiratory therapist, one of housekeeping staff, one of waste personnel ... etc..**

- 1) Check for evidence of baseline screening (if applicable)
- 2) Check for evidence of immunity or administration of appropriate vaccine(s) to those who are susceptible
- 3) Check for evidence of post exposure follow up and management (if applicable)
- 4) Work restrictions
- 5)

13

Sub-standard – 13:13

There are regular training activities for employee health program. **(D - PF - SI)**

Review documented evidence of training activities for employee health program:

Document
(D)

- 1) Annual report of the employee health clinic that includes yearly educational and training plan
- 2) Lists of target groups
- 1) Components or elements of the educational activities and training program, such as:
 - PPE
 - Respiratory protection & N95 fit testing
 - Sharp & needlestick injuries (risks & prevention)
 - Post exposure management & follow up
 - Recommended vaccines
 - Work restriction
- 3) Trainees' Attendance sheets
- 4) Records of educational and training activities with calculation of coverage rates

Personal Files
(PF)

Randomly review 3 - 4 personal files (original files or copies) for availability of:

- 2) BICSL license
- 3) Attended educational and training activities, such as:
 - PPE
 - Respiratory protection & N95 fit testing
 - Sharp & needlestick injuries (risks & prevention)
 - Post exposure management & follow up
 - Recommended vaccines
 - Work restriction

Ask 3 - 4 of hospital's staff of different categories:

Examples: ER nurse, surgeon, lab. technician, respiratory therapist, one of the waste handling team, one of housekeeping staff, laundry personnel ... etc.

- 1) What are the PPE required for caring a patient under airborne precautions? show me how you can don & remove them safely and in proper sequence.
- 2) What are you going to do if you have exposed a sharp or needlestick injury?
- 3) Do you have to squeeze the site of injury and apply powerful antiseptics locally?
- 4) What are you going to do for reporting this incident?
- 5) What are the medical conditions or diseases that should be reported to the employee health clinic to decide exclusion from work? & how do you report them?

Comments:

- Instead of direct questions, indirect ones or scenarios are advisable.

14

Sub-standard – 13:14

Exposed health care workers are isolated when needed (either home isolation in staff accommodation or identified rooms in the hospital for HCWs isolation). (O - SI)

Observation
(O)

Observation:

- 1) Observe the availability of allocated room(s) in staff accommodation for home isolation. Room(s) should be:
 - Adequately ventilated with separate air conditioning system
 - With separate Facilities (e.g., private bathroom(s))
- 2) If home isolation in staff accommodation is not attainable, check the rooms that are identified in the hospital for home isolation of HCWs when required

Comment:

- **Home isolation:** isolation that is applied on clinically stable HCWs without comorbidity that requires hospital admission as patients.

Staff Interview
(SI)

Ask 3 - 4 of hospital's staff about home isolation in staff accommodation:

- 1) What is meant by home isolation in staff accommodation?
- 2) How many rooms are assigned in your accommodation for home isolation? Do you know them?
- 3) How do you deal with HCWs under home isolation in your accommodation?
- 4) What are facilities that can be shared safely with HCWs under home isolation in your accommodation?

Answers:

- **Home isolation:** isolation that is applied on clinically stable HCWs without comorbidity that requires hospital admission as patients.
- When dealing with HCWs under home isolation, staff should apply recommended infection control precautions that match the required type(s) of isolation (e.g., contact isolation precautions)
- Facilities cannot be shared safely with HCWs under home isolation

Comments:

- Instead of direct questions, indirect ones or scenarios are advisable.

15

Sub-standard – 13:15

Approved MOH policies for work restriction are strictly applied. (D - SI)

Review documented evidence of application of work restriction as per an approved MOH policies:

Document
(D)

- 5) Annual report of the employee health clinic that includes yearly educational and training plan
- 6) Lists of target groups
- 4) Components or elements of the educational activities and training program, such as:
 - PPE
 - Respiratory protection & N95 fit testing
 - Sharp & needlestick injuries (risks & prevention)
 - Post exposure management & follow up
 - Recommended vaccines
 - Work restriction
- 7) Trainees' Attendance sheets
- 8) Records of educational and training activities with calculation of coverage rates

Document
(D)

Review the following documents:

- 1) Check for approved work restriction policy and related procedures for hospital's staff to outline infections or conditions that require exclusion from work
- 2) Fulfilled work restriction forms (or other relevant forms) during the last 3 - 6 months for HCWs who were restricted from work

Review the following documents:

- 1) Documented evidence of application of work restriction policy:
 - Medical sickness reports, which were fulfilled during the last 3 - 6 months for HCWs who were suffering from infections or conditions that require work restriction
 - Evaluation of their infections or conditions in employee's clinic, ER or medical department
 - Investigation & treatment reports
 - Check how HCW is allowed to join back after recovery

Comment:

- Review files of HCWs who were restricted from work in the last 3 - 6 months to see whether protocols were properly applied or not (the evidence should specify restriction condition, interventions, management and duration of restriction)

Ask assigned staff of the employee health clinic about application of work restriction plan:

Examples:

- 1) How do you report, manage and follow up a physician who was exposed to a patient confirmed for MERS-Co without PPE for more than 10 minutes?
- 2) How can you manage and follow up a susceptible nurse who had exposed to a patient +ve for measles?
- 3) How can you manage and follow up a respiratory therapist who had open pulmonary TB?
- 4) How do you manage and follow up a surgeon who had staphylococcus aureus infection (active draining skin lesions)?

Comments:

- Instead of direct questions, indirect ones or scenarios are advisable.

See appendix for work restriction plan

Suggested Work Restrictions for HCW Exposed to or Infected With Infectious Diseases of Importance in Healthcare Settings, in the Absence of National or Local Regulations

Disease/Problem	Work Restriction	Duration	Category
Conjunctivitis	Restrict from patient contact and contact with the patient's environment	Until discharge ceases	II
Cytomegalovirus infections	No restriction		II
Diarrheal diseases - Acute stage (diarrhea with other symptoms) - Convalescent stage, <i>Salmonella</i> spp.	Restrict from patient contact, contact with the patient's environment, or food handling Restrict from care of high-risk patients	Until symptoms resolve Until symptoms resolve; consult with local and state health authorities regarding need for negative stool cultures	IB IB
Diphtheria	Exclude from duty	Until antimicrobial therapy completed and two cultures obtained 24 hours apart are negative	IB
Enteroviral infections	Restrict from care of infants, neonates, and immunocompromised patients and their environments	Until symptoms resolve	II
Hepatitis A	Restrict from patient contact, contact with patient's environment, and food handling	Until 7 days after onset of jaundice	IB

<p>Hepatitis B</p> <ul style="list-style-type: none"> - Personnel with acute or chronic Hepatitis B surface antigenemia who do not perform exposure-prone procedures - Personnel with acute or chronic Hepatitis B e antigenemia who perform exposure-prone procedures 	<p>No restriction*; refer to state regulations; Standard Precautions should always be observed</p> <p>Do not perform exposure-prone invasive procedures until counsel from an expert review panel has been sought; panel should review and recommend procedures the worker can perform, taking into account specific procedure as well as skill and technique of worker; refer to state regulations</p>	<p>Until Hepatitis B e antigen is negative</p>	<p>II</p> <p>II</p>
<p>Hepatitis C</p>	<p>No recommendation</p>	<p>Until lesions heal</p>	<p>Unresolved issue</p>
<p>Herpes simplex</p> <p>Genital</p> <p>Hands (herpetic whitlow)</p> <p>Orofacial</p>	<p>No restriction</p> <p>Restrict from patient contact and contact with the patient's environment</p> <p>Evaluate for need to restrict from care of high-risk patients</p>		<p>II</p> <p>IA</p> <p>II</p>
<p>Human Immunodeficiency Virus (HIV)</p>	<p>Do not perform exposure-prone invasive procedures until counsel from an expert review panel has been sought; panel should review and recommend procedures the worker can perform, taking into account specific procedure as well as skill and technique of the worker; Standard Precautions should always be observed; refer to state regulations</p>		<p>II</p>

Measles - Active - Postexposure (susceptible personnel)	Exclude from duty	Until 7 days after the rash appears	IA
	Exclude from duty	From 5th day after first exposure through 21st day after last exposure and/or 4 days after rash appears	IB
Meningococcal infections	Exclude from duty	Until 24 hours after start of effective therapy	IA
Mumps - Active - Postexposure (susceptible personnel)	Exclude from duty	Until 9 days after onset of parotitis	IB
	Exclude from duty	From 9th day after first exposure through 26th day after last exposure or until 9 days after onset of parotitis	II
Pediculosis	Restrict from patient contact	Until treated and observed to be free of adult and immature lice	IB
Pertussis - Active - Postexposure (asymptomatic personnel) -	Exclude from duty	From beginning of catarrhal stage through third week after onset of paroxysms or until 5 days after start of effective antimicrobial therapy	IB
	No restriction, prophylaxis recommended		II
	Exclude from duty		IB

- Postexposure (symptomatic personnel)		Until 5 days after start of effective antimicrobial therapy	
Rubella	Exclude from duty	Until 5 days after rash appears	IA
- Active			
- Postexposure (susceptible personnel)	Exclude from duty	From 7th day after first exposure through 21st day after last exposure	IB
Scabies	Restrict from patient contact	Until cleared by medical evaluation	IB
<i>Staphylococcus aureus</i> infection	Restrict from contact with patients and patients' environment or food handling	Until lesions have resolved	IB
- Active, draining skin lesions			
- Carrier state	No restriction, unless personnel are epidemiologically linked to transmission of the organism		IB
Streptococcal infection, group A	Restrict from patient care, contact with patient's environment, or food handling	Until 24 hours after adequate treatment started	IB
Tuberculosis	Exclude from duty	Until proved noninfectious	IA
- Active disease			
- PPD converter	No restriction		IA
Varicella	Exclude from duty	Until all lesions dry and crust	IA
- Active			

- Postexposure (susceptible personnel)	Exclude from duty	From 10th day after first exposure through 21st day (28th day if VZIG given) after last exposure	IA
Zoster - Localized, in healthy person - Generalized or localized in immunosuppressed person - Postexposure (susceptible personnel)	Cover lesions; restrict from care of high-risk patient [†] Restrict from patient contact Restrict from patient contact	Until all lesions dry and crust Until all lesions dry and crust From 10th day after first exposure through 21st day (28th day if VZIG given) after last exposure or, if varicella occurs, until all lesions dry and crust	II IB IA
Viral respiratory infections, acute febrile	Consider excluding from the care of high-risk patients [‡] or contact with their environment during community outbreak of RSV and influenza	Until acute symptoms resolve	IB

*Unless epidemiologically linked to transmission of infection.

[†]Those susceptible to varicella and who are at increased risk of complications of varicella, such as neonates and immunocompromised persons of any age.

[‡]High-risk patients as defined by the ACIP for complications of influenza.

From Centers for Disease Control and Prevention. Guidelines for infection control in the healthcare worker, 1998. *Am J Infect Control* 1998; 26:289–354.

1

Sub-standard –14:01

There is a written policy and procedure for outbreak management (i.e., determination, investigation and control of outbreaks of HAIs) according to updated GDIPC outbreak guidelines. (D)

DOCUMENT

- *Disease outbreak is generally defined as "the occurrence of cases of disease in excess of what would normally be expected in a defined community, geographical area or season".*
- *In hospital settings, outbreak should be suspected when Healthcare Associated Infections (HAI's) occur above the background rate or when unusual microbe or adverse event is recognized.*
- *Outbreak in healthcare facilities are often multifactorial including breaches in infection control or clinical practices, contaminated devices, infected or colonized patient and /or healthcare worker.*
- *The aim of an outbreak investigation is to identify possible contributing factors, prevent further disease transmission, identify populations at risk of a disease, and prevent similar occurrences in the future and to evaluate the effectiveness of infection control measures. (Refer to Outbreak MOH guidelines for more details , although there is no approved endemic rate/ background rate in KSA for HAI's outbreak because the calculation of endemic rate need 5 years data*
- *Each hospital should have clear policies and procedures for managing infectious diseases outbreaks in the hospital, including early identification, initiation of appropriate control/containment measures to prevent the spread, and assignment of roles and responsibilities etc.. P&P shall guide staff for investigation and control of outbreaks of infectious diseases.*

Review:

Policies & Procedures for Outbreak Management which should be **comprehensive** incorporating all aspects of Outbreak Management program as follows:

1) Outbreak determination / detection / Identification /Recognition:

- ❖ *Outbreak management in healthcare facilities begin with the timely identification of an outbreak.³*
- ❖ *Different sources could be utilized to identify an existence of an outbreak: Notifications and routine surveillance. Laboratory services notification. informal reports from hospital clinicians, the regional epidemiology unit.³*
- ❖ *Surveillance for HAIs & adverse events can be a great aid in recognition of outbreaks in healthcare settings because it provides both baseline and ongoing monitoring.*

2) Outbreak Investigations:

Generally, Primary components / steps of outbreak investigation includes the following:

- 1) *Confirming existence of an outbreak*
- 2) *Alerting key partners about investigation*
- 3) *Performing a literature review*
- 4) *Establishing a preliminary case definition*
- 5) *Developing a methodology for case finding*
- 6) *Preparing an initial line list and epidemic curve*
- 7) *Form a tentative hypothesis*
- 8) *Evaluate hypothesis*
- 9) *Institute initial control measures*
- 10) *Monitor, Evaluate and Refine the control measures*
- 11) *Prepare and disseminate a final report*

3) Control of HAIs Outbreak :

- ❖ *The primary goal is control of the outbreak and prevention of additional cases. In general, control measures are usually directed against one or more segments in the chain of transmission (**agent, source, mode of transmission, portal of entry, or host**) that are susceptible to intervention.*
- ❖ *For some diseases, the most appropriate intervention may be directed at controlling or eliminating the agent at its source.*
- ❖ *Control measures include, but not limited to:*
 - **Strict hand hygiene compliance**
 - **Isolation / Cohorting**
 - **Staff training and education**
 - **Thorough environmental cleaning and so on.**

4: Policies and procedures should also incorporate:

- Common Healthcare Associated infection (HAI) Outbreak definitions, (e.g Multi-drug Resistant Organism (MDRO) Clostridium difficile infection (CDI), Candida species etc.)
- Common MDROs definitions e.g Methicillin resistant Staphylococcus Aureus, (MRSA) Vancomycin resistant Enterococcus (VRE),pp. Cabapenum Resistant Enterobacteriaceae (CRE) MDR Acinetobacter etc. ⁵

Compositiion of Outbreak Management & Roles and responsibilities of different stakeholders including:

Role of infection control department, Role of each member of outbreak management team, role of laboratory & role of environmental health office etc.

Other domains of Policies & procedures:

P/P for Outbreak Mangement should be :

- 11) **Fully applicable:** all elements of the policy can be applied and comply with the hospital's scope of services
- 12) **Based on scientific references** approved by MOH (**GCC, CDC, WHO & APIC**)
- 13) **Signed** from authorized personnel (i.e., owner of the policy / hospital director or Medical director / concerned department)
- 14) **Approved** by IC committee
- 15) **Valid** (updated within 2 - 3 years and when indicated.

2

Sub-standard –14:02

There is a defined outbreak management team approved from high authority.(D)

Each healthcare facility is required to establish an outbreak management team with clear roles and responsibilities of each member during any unforeseen situation based on MOH guidelines.

Review:

- ❖ Document enlisting the members of outbreak management team.(OMT)
- ❖ Check for approval of OMT by Hospital director / CEO.
- ❖ Members of outbreak management team includes but not limited to the following: ⁴
 - **Medical Director**
 - **Infection Control head**
 - **Microbiologist(preferable to be Clinical Microbiologist if available)**
 - **Infectious Disease consultant (if available)**
 - **Occupational Health Physician. (if available)**
 - **Head of the nursing department**
 - **Head of concerned department**
 - **Environmental health officer (In the case of suspected food poisoning)**
 - **Supportive services and supplies**
 - **Hospital Epidemiologist (if available)**

****Additional members to be added according to the nature of the outbreak.**

Comment (if any): *Refer to outbreak MOH guidelines for more details.*

Document
(D)

3

Sub-standard –14: 03

The outbreak management team members are qualified, trained, having experience and skills to detect and deal with outbreaks with regular meeting every 6 months to review the surveillance, laboratory data, bundles results and antibiogram. (PF,SI)

Review:

- ❖ Personal file to check for basic qualification of outbreak management team.
- ❖ Randomly review PF of outbreak management team members and verify if they have received / attended any outbreak specific training activities. (*Workshops, symposiums, conferences, webinars etc. – local / National / International.*)
- ❖ Check relevant certificates / evidence of attendance in personal file.

PERSONAL FILE
(PF)

Interview:

Interview infection control team, relevant members of outbreak management team during the hospital tour about:

- ❖ Their roles and responsibility in the management of the outbreak (e.g. how they respond to the outbreak? What control measures need to be taken? etc..)
- ❖ The last outbreak they have been involved in **(If any)**
- ❖ How to detect and confirm the presence of true outbreak through results of surveillance, laboratory, bundles, antibiogram ...etc.
 - How they will confirm the existence of an outbreak?
 - If they are receiving and analyzing critical results from the lab on a daily basis?
 - Interpretation of surveillance data for timely detection?
- ❖ Ask about steps of outbreak management??

Assess skills and expertise about outbreak management by giving a scenario:

Example: Unit head NICU etc.

There were increased number of MDR - Acinetobacter baumannii cases (more than 2 cases) reported from Neonatal ICU of your hospital. An outbreak was declared in the unit. IC team has already started Outbreak investigation. As part of outbreak management team, what role you will play to contain / control further transmission in your unit??

Answer for more details review outbreak MOH

guideline.(definition , role and responsibilities , detection , investigation and management ,.....)

Monitoring / observation of adherence to infection control practices in order to prevent further transmission. **(strict adherence to hand hygiene, use of dedicated equipments, rigorous environmental cleaning, , contact isolation/cohorting. early detection & reporting of new cases in liaison with lab, dedicated staff assignments, judicious antimicrobial use etc.**

- **Acinetobacter baumannii is a Gram-negative bacillus that can cause infections in the blood, urinary tract, and lungs (pneumonia), or in wounds in other parts of the body. It can also “colonize” or live in a patient without causing infections or symptoms, especially in respiratory secretions (sputum) or open wounds.**
- **Acinetobacter can live for long periods of time on environmental surfaces and shared equipment if they are not properly cleaned. The germs can spread from one person to another through contact with these contaminated surfaces or equipment or though person to person spread, often via contaminated hands.**

4

Sub-standard –14:04

Infection control practitioners receive immediate notification from hospital laboratory regarding critical values. (i.e., MDROs results, positive cultures...), and updated log book for these critical values is available in IC department. (D ,SI)

Document
(D)

Review the following:

- ❖ Notification system(electronic, phone, paper)
- ❖ critical results received from the laboratory (**Manual / electronic**)
- ❖ A log book / electronic file in the infection Control Department showing the critical lab results received form hospital laboratory. (*All type of MDROs : (Pseudomonas, Acinetobacter, E coli, klebsiella etc.), Clostridium difficile, blood borne pathogens ; Hepatitis B,C & HIV etc.*)

Staff Interview
(SI)

Ask:

- ❖ Infection Perfectionists regarding immediate notification from hospital laboratory. (**Phone call, email, notification form etc.**)
- ❖ What is their role and immediate action when they receive the result??
- ❖ The senior microbiologist regarding immediate notification from hospital laboratory. (**Phone call, email, notification form etc.**)

5

Sub-standard –14 :05

There is monthly report of HAI's outbreaks including ZERO report. (D)

Document
(D)

Review

- ❖ A document of monthly zero reporting of outbreaks in any unit / location within the healthcare facility. *(Review the last three months zero reporting evidence) (Zero reporting document & critical value results will help validate the non-outbreak status.)*

Comment (if any):

- *This substandard is applicable for MOH hospitals only.*
- *Information about specific MOH hospital regarding adherence to outbreak guidelines can be taken form outbreak program coordinator.*

6

Sub-standard –14:06

In case of an outbreak, infection control department in the hospital actively notifies IC team in the cluster (if applicable), IC regional directorate and GDIPC outbreak team at the same time. (D,SI)

Document
(D)

Review:

- ❖ **Outbreak notification form according to guidelines** as evidence of reporting outbreaks to the **IC team in the cluster (if applicable), IC regional directorate and GDIPC outbreak team at the same time.** *(Electronic excel sheet : sample attached)***
- ❖ Check email that was by IC team and match with the date outbreak was declared. *(IC team in the cluster(if applicable) , IC regional directorate and GDIPC outbreak team should be notified within 24 hours)*

Staff Interview
(SI)

Interview:

- ❖ Infection Control Team about reporting protocols in case of outbreaks.
- ❖ Ask about the used reporting forms &Assess if they are familiarized with contents of these forms.

Comment (if any):

- *This substandard is applicable only for MOH hospitals including clusters*
- *This is mandatory for hospitals to timely notify cluster (if applicable) Regional Directorates and GDIPC about the outbreak.*

7

Sub-standard –14:07

In case of an outbreak, the meeting minutes should include Investigation and control measures of outbreaks with written/documented action plan are led by director of IC department. (D,SI)

Document
(D)

Staff Interview
(SI)

Review the following:

- ❖ The last outbreak report (*If there was any outbreak in the past*)
- ❖ Verify if the report includes are necessary steps of outbreak investigation.
- ❖ Review the control measures if complete and applicable to the type of outbreak.
- ❖ The **detailed** action plan including all actions which have been taken to control the outbreak (*planning, organizing, coordination and controlling*)
- ❖ Action plan led by Infection Control director should specify goals/objectives, strategies / actions taken / responsible person and time frame.

Interview:

- ❖ IC director about his / her role in managing the outbreak and how the action plan was developed for the last outbreak? (*If any*)

REFERENCES / WEB BASED RESOURCES:

- 1) Association for Professionals in Infection Control (APIC) and Epidemiology, Inc. (2014). Chapter Outbreak Investigations. *In APIC Text of infection control and epidemiology (4th edition)*
- 2) GCC Infection Prevention & Control Manual 3rd Edition 2018 – ICM - VII – 01 *Management of infectious diseases outbreaks.: (Page 190 – 192)*
- 3) Ministry of health *MOH guidelines on the Management of Outbreaks in Healthcare Facilities, 2nd Edition 2018*
- 4) Outbreak Investigations in Healthcare Settings <https://www.cdc.gov/hai/outbreaks/index.html>
- 5) Diseases and Organisms in Healthcare Settings <https://www.cdc.gov/hai/organisms/organisms.html>
- 6) *Principles of Epidemiology* in Public Health Practice, 3^d edition, *Centers for Disease Control and Prevention (CDC), 2016.*
- 7) *Outbreak Investigation in Healthcare Settings*
<http://ndhealth.gov/disease/hai/Docs/WebEx/OutbreakWebinar.pdf>

ANTIMICROBIAL RESISTANCE PROGRAM (AMR) / ANTIMICROBIAL STEWARDSHIP PROGRAM (ASP)

1

Sub-standard –15:01

There is a written policy and procedure for *Antimicrobial Resistance Program (AMR) /Antimicrobial Stewardship Program (ASP)*. (D)

- *Antimicrobial Stewardship Program (ASP) refers to a systematic approach to optimizing antimicrobial therapy through a variety of structures and interventions to prevent emergency of antimicrobial resistance.*
- *ASP promotes not only limiting inappropriate use but also optimizing antimicrobial selection, dosing, route, and duration of therapy to maximize clinical cure or prevention of infection.*

Review:

Policies & Procedures for *Antimicrobial Stewardship Program (ASP)* which should be **comprehensive** incorporating all core elements of ASP as follows: ⁽¹⁾

- **Key Terminologies:**
Antimicrobial Stewardship Program (ASP), Antibio gram, Antimicrobial Stewardship Committee (ASC), Antimicrobial Stewardship Team (AST), Clinical Pathway / Guidelines etc.
- **Purpose:**
 - *To standardize the processes of antimicrobial use in the hospital in an effective and efficient way.*
 - *To deliver high-quality care consistently using evidence-based practices and functions in accordance with the national guidelines. etc.*
- **Applicability:**
 - *For all clinicians, health administrators, and personnel involved with the proper utilization of antimicrobials in hospitals and affiliated facilities.*

Clear policies and procedures need to be adopted from core component of ASP (CDC – WHO) according to hospitals scope of services: ^(1,2)

1: Hospital Leadership Commitment:

- ❖ Hospital leadership commitment is of utmost importance to emphasize the necessity of antimicrobial stewardship programs for dedication of necessary human, financial and information technology resources.

2: Accountability & Responsibility:

- ❖ A leader or co-leaders, such as a physician and pharmacist, to be appointed who will be responsible for program management and outcomes. **(Multidisciplinary AMS leadership committee in place with clear terms of reference)**
- ❖ Multidisciplinary **Antimicrobial Stewardship Team (AST)**
- ❖ Other health professionals identified and involved in **ASP activities**

*For small facilities **ASP champion could be appointed.** ***

Larger facilities have achieved success by hiring full-time staff to develop and manage stewardship programs while smaller facilities report other arrangements, including use of part-time or even off-site expertise, sometimes referred to as telestewardship ⁽¹⁾

3: Pharmacy Expertise:

- ❖ A clinical pharmacist to be appointed ideally as the co-leader of the stewardship program, to lead implementation efforts to improve antibiotic use & to reflect the importance of pharmacy engagement for leading implementation efforts to improve antibiotic use.

4: AMS Actions:

Priority Interventions to Improve Antibiotic Use:

- ❖ **Prospective audit and feedback (sometimes called post-prescription review):**
 - This is an external review of antibiotic therapy by an expert in antibiotic use, accompanied by suggestions to optimize use, at some point after the agent has been prescribed
- ❖ **Pre-authorization System for Restricted Antimicrobials:**
 - Each hospital has to have restricted antimicrobial policy where specific antimicrobials would be restricted by specific physicians in each hospital.
 - Preauthorization requires prescribers to gain approval prior to the use of certain antibiotics. This can help optimize initial empiric therapy because it allows for expert input on antibiotic selection and dosing, which can be lifesaving in serious infections, like sepsis. It can also prevent unnecessary initiation of antibiotics.
- ❖ **Facility-specific treatment guidelines / Antibiotic guidelines and the associated clinical pathways/protocols:**
 - Greatly enhance the effectiveness of both prospective audit and feedback and preauthorization by establishing clear recommendations for optimal antibiotic use at the hospital.
 - Guidelines are means to standardize clinical practice and avoid misuse and overuse of antimicrobial therapy. They serve as tool guiding prescribers who lack competencies for antimicrobial prescription.

- *Use of antimicrobial order forms with optimal timing and duration can assist pharmacist to automatic discontinuation when the predefined duration is completed.*

❖ **Prescribing Physicians:**

- *During continuation of treatment, the prescribing physician will monitor antimicrobial drug levels as required by the hospital policy and ensure daily consideration of **de-escalation**, **intravenous - oral switch** or **stopping antimicrobials** (based on clinical picture and laboratory results).*

❖ **ASP Point-of-care (POC) interventions:**

AST will provide direct feedback to the prescriber and an opportunity to educate clinicians on appropriate prescribing. This includes but not limited to:

- *Reviewing appropriateness of choice of antimicrobial and eliminating dual therapy.*
- *Directed therapy based on microbiological studies.*
- *Dose optimization*
- *Parenteral-to-oral conversion*
- *Therapeutic drug monitoring*
- *Automatic stop orders*
- *Appropriateness of time of initiation of antibiotic therapy with respect to time of surgery for prophylactic use and with respect to time of cultures for therapeutic use. etc.*

5: Tracking / Monitoring & Surveillance:¹

- *Monitoring appropriateness of antibiotic use at the unit and/or facility-wide level through audits or PPS (Point Prevalence Studies)*
- *Tracking the types and acceptance of recommendations from prospective audit and feedback interventions, which can identify areas where more education or additional focused interventions might be useful.*
- *Monitoring of preauthorization interventions by tracking agents that are being requested for certain conditions and ensuring that preauthorization is not creating delays in therapy.*
- *Monitoring adherence to facility-specific treatment guidelines. If feasible, consider tracking adherence by each prescriber. Etc.*
- *Measurement is critical to identify opportunities for improvement and assess the impact of improvement efforts*
 - *Evaluation of process (Are policies and guidelines being followed as expected?)*
 - *Evaluation of outcome (Have interventions improved antibiotic use and patient outcomes?)*

6: Reporting & Feedback:¹

- *Antibiotic stewardship programs should provide regular updates to prescribers, pharmacists, nurses, and leadership on process and outcome measures that address both national and local issues, including antibiotic resistance.*
- *Regular evaluation and sharing of health-care facility data on antibiotic use with prescribers*
- *Regular evaluation and sharing of health-care facility resistance rates with prescribers etc.*

7: Education¹

- Basic training in optimal antibiotic use for health-care professionals
- Continued training in optimal antibiotic use for health-care professionals etc.

Education is a key component of comprehensive efforts to improve hospital antibiotic use; however, education alone is not an effective stewardship intervention. Education is most effective when paired with interventions and measurement of outcomes. Case-based education can be especially powerful, so prospective audit with feedback and preauthorization are both good methods to provide education on antibiotic use.

8: Supplemental Antimicrobial Stewardship Strategies:

- Combination empirical therapy and de-escalation strategy
- Antimicrobial dose optimization
- Antimicrobial Order Form (AOF)
- Conversion from IV to PO therapy
- Surveillance of antimicrobial resistance
- Health-care facility access to IT services to support AMS activities
- Computer Surveillance and Decision Support

Other domains of Policies & procedures:

P/P for Antimicrobial Stewardship Program (ASP) should be :

- ❖ **Fully applicable**: all elements of the policy can be applied and comply with the hospital's scope of services
- ❖ **Based on scientific references** approved by MOH (**GCC, CDC, WHO & APIC**)
- ❖ **Signed** from authorized personnel (i.e., owner of the policy / hospital director or Medical director / concerned department)
- ❖ **Approved** by IC committee
- ❖ **Valid** (updated within 2 - 3 years and when indicated).

Comments (If any):

- ❖ ***Above-mentioned strategies / components of Antimicrobial stewardship program (ASP) are described as a guide for hospitals to establish policies and procedures for Antimicrobial stewardship program (ASP) in their respective facilities based on CDC, WHO & national antimicrobial stewardship Program.***
(Ref: CDC - The Core Elements of Hospital Antibiotic Stewardship Programs: 2019)

2

Sub-standard –15: 02

There is a multidisciplinary Antimicrobial Resistance Program (AMR) / Antimicrobial Stewardship Program (ASP) Committee with approved terms of reference (TOR) stating structure, rules, duties and responsibilities of all stakeholders. (D)

- ❖ *An Antimicrobial Stewardship Committee (ASC) is a standing committee responsible for reviewing all Drug Formulary management requests related to antimicrobial agents; wherein the composition includes physicians and pharmacists specialized in the field of infectious diseases.*
- ❖ *Antimicrobial Stewardship Committee (ASC) can be either stand-alone or embedded in another existing committee structure (e.g. drug and therapeutics committee, pharmacy committee etc..)*

Review:

Terms of reference of Antimicrobial Stewardship Committee (ASC) and verify the following:

- 1) *TOR are valid and updated (Check for dates)*
- 2) *Approved (Check for approvals by top administration)*
- 3) *Structure of Antimicrobial Stewardship Committee (ASC) would include but not limited to:*
 - ❖ *A dedicated AMS leader / co leaders identified for the health-care facility.*
 - *Consultant, Infectious Diseases*
 - *Clinical Pharmacists*
 - ❖ *Multidisciplinary Antimicrobial Stewardship Team (AST) with roles and responsibilities of each member:*
 - *Infection Control Preventionists / Coordinator*
 - *Representative from the Microbiology Department*
 - *Representative from nursing department*
 - *Representative from critical care units*
 - *Members from infectious diseases department*
 - *Representative from OR*
 - *Representative from surgical department*
 - *Clinicians & other members as needed*

Document
(D)

- **Rules of operations of ASC meetings:**
 - a) **Frequency of ASC meetings:**
 - TOR should specify frequency of **Antimicrobial Stewardship Committee (ASC) meetings.**
 - A **Antimicrobial stewardship Committee (ASC)** shall meet on a regular basis (at least biannually or as scheduled in the hospital).
 - b) **Agenda of ASC meetings**
 - c) **Attendance & Quorum**
 - d) **Minutes taking etc.**
- **Duties / Functions of Antimicrobial Stewardship Committee (ASC):**
 - 1) **Consultant, Infectious Diseases will serve as Team Leader/ co leader and perform the following: e.g.**
 - a. Provide expert advice, educate prescribers, and play a major role in the development and implementation of antimicrobial policy and prescription guidelines.
 - b. Use antimicrobial stewardship as clinical outcome measures and quality improve
 - 2) **Clinical Pharmacist will perform the following:**
 - a. Review antimicrobial orders in accordance with the Antimicrobial Guidelines and provide timely feedback (where applicable) to the prescriber.
 - b. Work with and educate ward pharmacists to identify potential patients for stewardship interventions (e.g. de-escalation, IV to oral switch etc..).
 - c. Ensure dose optimization is carried out especially for complex antimicrobials and complex clinical scenarios
 - d. Attends rounds with the AST etc.
 - 3) **Infection Control Preventionists / Coordinator will perform the following:**
 - a. Prepares surveillance and audit reports
 - b. Obtain and timely provision of data as required by the Program
 - c. Ensures complete filling of the forms (whenever applicable)
 - d. Provide help in organizing the administrative and educational activities etc.
 - 4) **Clinical Microbiologist will perform the following:**
 - a. Provision of timely and accurate reporting of culture and antimicrobial susceptibility data
 - b. Prepare antibiogram on bi-annual basis (every 6 months)
 - c. Work closely with the attending clinician, infectious diseases specialist and antimicrobial pharmacist in the management of patients with infections. etc.

3	<p>Sub-standard –15: 03</p> <p>Antimicrobial Resistance Program (AMR) / Antimicrobial Stewardship Program (ASP) is chaired by a physician and pharmacist to co-lead the program (the ASP committee meets on a regular basis, at least biannually) (D)</p>
4	<p>Sub-standard –15: 04</p> <p>Membership of the AMR / ASP Committee includes clinicians, pharmacy, microbiologist(s), IC practitioner(s), and head of critical care units, infectious diseases department, OR, surgical department, nursing department, etc. (If applicable).(D)</p>
Document (D)	<p>Review the following documents:</p> <p><u>1: Terms of reference (TOR), Meeting minutes & attendance sheets:</u></p> <ul style="list-style-type: none"> ❖ Check the meeting minutes with attendance sheets of last 03 committee meetings for purpose of verification. ❖ Review team composition with multidisciplinary involvement to verify if matching with composition / structure of Antimicrobial Stewardship Committee (ASC) members as described in Terms of Reference. <i>(Refer to composition under substandard 2)</i> ❖ Verify leadership of Antimicrobial Stewardship Committee (ASC) as reflected in term of reference and meeting minutes. (ID, Clinical pharmacist) ❖ Issues discussed in Antimicrobial Stewardship Committee (ASC) meetings are assigned to concerned representatives and should be traceable and timely closed.

Sub-standard –15: 05

Hospital leaders support AMR / ASP by necessary human, financial and information technology resources. **(D,SI)**

- *Support from the senior leadership of the hospital is critical to the success of antibiotic stewardship programs in order to get the resources needed to accomplish its goals. ⁽¹⁾*

Review documents which confirm hospital leaders support to improve Antimicrobial Stewardship Program (ASP):

❖ Human Resource Support:

- Employing experienced staff for AMR program (e.g., clinical pharmacist, microbiologist, infectious diseases consultant, clinicians, nursing staff and others as needed for **ASP...**)
- Check time allocation for stewardship program leader (s) to manage the program and conduct daily stewardship interventions & ensuring that staff from key support departments have sufficient time to contribute to stewardship activities.

(Review specific evidence to confirm; ASP specific schedules / Rota etc.)

- Outlining stewardship-related duties in job descriptions and annual performance reviews for program leads and key support staff. ⁽¹⁾

❖ Financial support:

- Allocating funds to support training and education for program leaders and hospital staff. ***(e.g. attendance in stewardship training courses and meetings)*** etc.
- Making formal statements of support for efforts to improve and monitor antibiotic use.
- Direct purchase of supply needed for Antimicrobial Stewardship Program (ASP). ***(Necessary Antibiotics etc.)***
- Dedicated, sustainable and budgeted financial support for AMS activities in the action plan ***(e.g. support for salary, training and information technology (IT) support)***. ⁽²⁾

❖ IT Support:

- ❖ Building up & implementing special IT system for improving antibiotics dispensing according to specific responsibilities and strict rules, approved by ***Antimicrobial Stewardship Committee.***
- ❖ As required by the Antimicrobial Stewardship Team (**AST**), IT to provide access to the Hospital Information System (HIS) electronic medical record (EMR), software and hardware support, as well as, support in maintaining electronic files, records, etc.

Interview:

- ❖ Infection Control Practitioners and one of ASP committee members (e.g., pharmacist, microbiologist, ID consultant regarding leadership support and commitment for Antimicrobial Stewardship Program (ASP) activities.
- ❖ How does the hospital director react towards requirements or problems faced by the Antimicrobial Stewardship Team **(AST)**?

(They should give specific examples of human, financial and IT support. (Considered and timely provided /met whenever needed)

Sub-standard –15: 06

There is an effective and efficient system implemented for monitoring and tracking of antibiotic prescription and resistance patterns. **(D,SI)**

- ❖ *Measurement of antibiotic stewardship interventions may involve evaluation of both processes and outcomes. For example, a program will need to evaluate if policies and guidelines are being followed as expected with desired change in antibiotic use?? (Processes) and if interventions have improved patient outcomes and unintended consequences of antibiotic use?? (Outcomes).*

Review the relevant documents to confirm if there is effective tracking & monitoring system:

- ❖ **Monitoring appropriateness of antibiotic use at the unit and/or facility-wide level through audits or PPS (Point Prevalence Survey)**
 - ❖ *The Antimicrobial Stewardship Team (AST) undertakes audits or PPSs, at the unit and/or health-care facility level, to assess the appropriateness of infection management and antibiotic prescription (e.g. indication, agent, dose and duration of antibiotic therapy in specific infectious conditions such as pneumonia or surgical prophylaxis) according to policy/guidance.*
- ❖ **Monitoring compliance of antibiotic stewardship interventions by the Antimicrobial Stewardship Committee (ASC).**
 - ❖ *The Antimicrobial Stewardship Committee (ASC) monitors compliance with one or more of the specific interventions put in place by the AMS team (e.g. **indication captured in the medical record for all patients on antibiotics**).*
- ❖ **Monitoring of antibiotic susceptibility and resistance rates for a range of key indicator bacteria:**
 - *The Antimicrobial Stewardship Team (AST) monitors antibiotic susceptibility and resistance rates for a range of key indicator bacteria at the health-care facility-wide level*
 - *Monitoring resistance at the patient level (i.e. what percent of patients develop resistant super-infections). etc.*
- ❖ **Monitoring quantity and types of antibiotic use (purchased / prescribed / dispensed) at the unit and/or facility-wide level.**
 - *Documents that evaluate trends for antibiotics prescription which should be based on updated antibiotics resistance pattern of the facility specific antibiogram. (**Appropriateness of antimicrobial start (choice, dose, duration, route etc.)**)*

Interview:

- ❖ Infection control preventionists, IDs, pharmacist etc. & other key members of Antimicrobial Stewardship Team (AST) during visit of various units (ICU, Surgical wards etc.) about the mechanism of monitoring and tracking antibiotic prescriptions in order to ensure appropriate antibiotic prescribing. **(e.g. indication, agent, dose and duration of antibiotic therapy in specific infectious conditions such as pneumonia or surgical prophylaxis) according to policy/guideline.)**
- ❖ Ask about the Antimicrobials resistance pattern in the last 6 months and the recommended trend for empirical antibiotics prescription.

7

Sub-standard –15: 07

There is implementation of restriction policy for certain antibiotics (colistin, vancomycin, Tygacycline, carbapenems etc.). (D,SI)

Document
(D)

Review the following documents:

- ❖ Restriction policy for specific antibiotics (***Pre-authorization System for Restricted Antimicrobials***)
- ❖ List of restricted antibiotics.
 1. Each hospital has to have ***restricted antimicrobial policy*** where specific antimicrobials would be ***restricted*** by specific physicians in each hospital.³
 2. If a physician is not privilege to prescribe an antibiotic, he has to go over required steps to obtain authorization.
 3. At initiation of treatment, the prescribing physician will provide a ***clinical rationale*** for antimicrobial initiation.
 4. The prescribing physician will send the ***appropriate specimens to diagnostic microbiology*** before the administration of antimicrobials.
 5. The prescribing physician will select the antimicrobial according to the hospital ***Antimicrobial Guidelines.***
 6. When prescribing ***restricted antimicrobial***, the prescribing physician has to communicate with the ***AST*** in a timely manner to obtain the authorization. (***For details refer to GCC Manual Page # 240***)

Comment (if any):

The health-care facility must have a formulary with a list of antibiotics approved for use in the facility and specifies a list of restricted antibiotics that require approval by the designated AMS team member (or infectious disease physician if available, physician or AMS champion) when used and/or are only permitted for specific conditions, e.g. the WATCH and RESERVE groups of antibiotics.²

Staff Interview
(SI)

Interview:

- ❖ Clinicians, nurses, IC Team or other relevant staff (*from critical care units, infectious diseases department, OR and surgical & other departments*) if they are aware about ***restricted antibiotic policy.***
- ❖ Ask prescribing physicians about mechanism to take authorization before prescribing restricted antibiotics.
- ❖ Ask staff at random to enumerate few restricted antibiotics (***colistin, Vancomycin, Tygacycline, carbapenems, etc.***).

8

Sub-standard –15 : 08

The antibiogram is prepared by hospital microbiologist at least every 6 months and data are reported to GDIPC annually (hospital ≥ 150 beds). If the hospital < 150 bed consult and prepare antibiogram with reference regional hospital / laboratory. (D)

- ❖ *Antibiogram summarizes the cumulative proportions of pathogenic organisms that are susceptible to particular antimicrobials. This provides a profile of the susceptibilities of specific pathogenic bacteria to antimicrobial agents as tested in routine clinical microbiology practice.*
- ❖ *An antibiogram is a useful tool for the infection preventionists to determine the status of strategies in place to reduce multidrug resistant organisms & monitor trends emerging in the drug resistance.*
- ❖ *Data should be analyzed when at least 30 isolates are tested for a given pathogen, and only the first isolate should be included from patients with multiple positive cultures,*

Document
(D)

Review the following documents:

- 1) Last 2 - 3 antibiogram reports (to review dates / updated detailed results of facility specific antibiotics, resistance trends / patterns).
- 2) Copies of last 2 - 3 official antibiogram reports that are directed to IC regional directorate using the approved template.
- 3) Copies of last 2 - 3 official antibiogram reports that are directed to GDIPC - MOH. *(To be sent annually to GDIPC)*

9

Sub-standard –15: 09

The antibiogram is regularly discussed by AMR / ASP Committee (at least every 6 months) & action plan and interventions to improve the use of antimicrobials are developed. (D)

Review the following documents:

- 1) Minutes of last 2-3 ASP committee meetings to review antibiogram reports and discussion of members about its consequences.
- 2) Documents that show corrective interventions and action plan to improve the antibiotic use *(e.g., modification of antibiotics prescription based on updated antibiotics resistance pattern of the antibiogram / restriction policy and restricted antibiotics / direct purchase of necessary antibiotics ... etc..)*

Document
(D)

10

Sub-standard –15 : 10

The antibiogram (the antibiotic use and resistance) is regularly shared with doctors, nurses and other relevant staff after analysis, interpretation and taking interventions. (D,SI)

- ❖ *Antibiotic stewardship programs should provide regular updates to prescribers, pharmacists, nurses, and leadership on process and outcome measures that address both national and local issues, including antibiotic resistance.*

Review:

- Report containing **antibiogram (the antibiotic use and resistance) with** analysis and interpretation of antibiotic use and resistance patterns to all concerned stakeholders (**doctors, nurses and other relevant staff etc.**)
(Check for evidence to confirm is report was shared (Manual / Electronic))

Report should include: ²

- Regular evaluation and sharing of health-care facility data on antibiotic use:
Data quantity of antibiotics purchased/prescribed/dispensed are reviewed and analyzed, and key findings are shared with prescribers along with specific action points.
- Regular evaluation and sharing of health-care facility resistance rates:
The facility reports on antibiotic susceptibility rates are reviewed, and analyses and key findings are shared with prescribers along with specific action points.
- Evaluation of appropriateness of data on antibiotic use:
Findings from audits/reviews of the quality/appropriateness of antibiotic use are communicated directly to prescribers along with specific action points.
- Health-care facility antibiogram for key antibiotics informed by data on antibiotic use and resistance

The health-care facility aggregate antibiogram is developed and regularly updated based on a review and analysis of facility antibiotic use and antibiotic-resistant bacteria. The antibiogram may help to inform updates of clinical guidelines.

Document
(D)

Staff Interview
(SI)

Interview:

- Staff in all relevant areas (**ICU, NICU, ER, Surgical & medical wards etc.**) if they have received any report containing information about antibiotic use and resistance patterns.
- Ask if latest antibiogram is shared and available in critical care units for prescribers.etc.

11

Sub-standard –15: 11

Education about antimicrobial resistance and optimal prescription of antimicrobials are provided repeatedly (at least biannually). **(D,SI)**

- ❖ *Education is a key component of comprehensive efforts to improve hospital antibiotic use & is most effective when paired with interventions and measurement of outcomes. Education need to be provided to prescribers, pharmacists, nurses, and patients about adverse reactions from antibiotics, antibiotic resistance, and optimal prescribing.¹*
- ❖ *Education could be provided by adopting multiple strategies:*

Passive • *Printed educational materials • Clinical practice guidelines • Formal lectures • Seminars, conferences • Educational courses • Reminders • e-learning etc.*

Active • *Discussion groups, journal clubs • prospective Audit and feedback • case scenarios, interactive educational workshops etc.*

Review the following documents:

- ❖ Plan of educational program about **antimicrobial resistance** and optimal prescription of antimicrobials.
- ❖ Check if relevant scientific education material related to **antimicrobial stewardship** is available and with distributed (*Booklets, leaflets, brochures, ASP toolkits etc.*)
- ❖ Attendance sheets of lectures or workshops related to the antibiotics guidelines and AMR stewardship program.
- ❖ Documents for target groups and calculation of coverage rates for different Units / groups.

Document
(D)

Interview:

- ❖ Staff in all relevant areas (*ICU, NICU, ER, Surgical & medical wards etc.*) if they have received any training on:
 - *Optimal prescribing principles, adverse reactions from antibiotics, and antibiotic resistance?*
 - *Ask clinicians if they have received training during prospective **audit and feedback process** by Antimicrobial Stewardship Team (AST) (sometimes called “handshake stewardship”)?*
 - *Date and topics of the last educational program that has been attended by them.*

Staff Interview
(SI)

Antimicrobial Resistance/Antibiotic Stewardship for all standards (staff interview/ documents)

What is Antibiotic Resistance?

Antibiotics are medicines used to prevent and treat bacterial infections. Antibiotic resistance occurs when the medicines used to treat infections caused by bacteria no longer work.

What is Antimicrobial Resistance?

Antimicrobial resistance is resistance to medicine used to treat all types of infections, including bacteria, fungi and parasites. When microorganisms (i.e. bacteria, fungi, viruses, and protozoa) develop antimicrobial resistance they are sometimes referred to as "superbugs".

When the medicines become ineffective, infections will persist in the body which increases the risk of spreading the infection to others.

What is Antimicrobial Stewardship?

Per the [Infectious Diseases Society of America](#): "Antimicrobial stewardship refers to coordinated interventions designed to improve and measure the appropriate use of antimicrobials by promoting the selection of the optimal antimicrobial drug regimen, dose, duration of therapy, and route of administration. Antimicrobial stewards seek to achieve optimal clinical outcomes related to antimicrobial use, minimize toxicity and other adverse events, reduce the costs of health care for infections, and limit the selection for antimicrobial resistant strains."

Core Elements of Antimicrobial Stewardship

- Leadership Commitment
- Accountability
- Drug Expertise
- Key Support
- Take Action through Policy and Practice Change to Improve Antibiotic Use
- Tracking and Reporting Antibiotic Use and Outcome

The AMR program is based on the five WHO-AMR:

- The role of antibiotics and the current challenges – improving awareness and understanding of antimicrobial resistance
(prepare MDROs training course biannual- lectures, videos, or consult AMR Regional Coordinator)
- Strengthening knowledge and evidence through monitoring & surveillance (Antiprogram **Report preparation with consultation of regional reference lab and AMR Regional Coordinator**)
- Interventions to tackle AMR

(Infection control guidelines- infection control policy and procedure, hand hygiene, environmental cleaning, isolation, patient referral to other hospital)

- Optimizing the use of antimicrobial medicines in human and animal health/if the hospital not implement the Stewardship program review if they are using the national antibiotic guideline especially in ER department for empiric therapy and there is restriction policy for certain antibiotics
- Policy-regulation-governance and the economic case for global sustainable investment to tackle AMR/ (review the implementation Antibiotic policy – research, hospital antibiotic consumption)

AMR Hospital Team < 150 beds:

- head of the hospital / medical directors
- Head of infection control /Team
- Head of the departments
- Microbiology doctor / SUPERVISOR
- head nurse
- Head of the pharmacy
- ID consultant if available
- Regional AMR coordinator if available

Meeting: every 6 months with document meeting minutes

WEB BASED RESOURCES:

1. Centers for Disease Control and Prevention. Core Elements of Hospital Antibiotic Stewardship Program. <http://www.cdc.gov/getsmart/healthcare/implementation/core-elements.html>
2. A [WHO](#) Practical Toolkit for Antimicrobial Stewardship Programmes in Health-Care Facilities in low – and Middle –Income countries
<https://apps.who.int/iris/bitstream/handle/10665/329404/9789241515481-eng.pdf>
3. GCC Infection Prevention & Control Manual 3rd Edition 2018 – [ICM - VII – 08 Antimicrobial Stewardship Program: \(Page 19 – 27\)](#)
4. Antimicrobial Resistance Committee, National Antimicrobial Guidelines for Community and Hospital Acquired Infections in Adults; Ministry of Health- General Administration of Pharmaceutical Care,
Revised 2018. <https://www.moh.gov.sa/en/CCC/healthp/regulations/Documents/National%20Antimicrobial%20%20Guidelines.pdf>
5. APIC text of Infection Control & Epidemiology: Infection Prevention & control programs
6. <http://text.apic.org/toc/microbiology-and-risk-factors-for-transmission/antimicrobial-and-resistance>
7. World Health Organization. Antimicrobial Resistance Factsheet. Sept 2016.
<http://www.who.int/mediacentre/factsheets/fs194/en/#>

World Health Organization. Global Action Plan on Antimicrobial Resistance. WHO. Geneva (CH): 2015. Available from: http://www.who.int/drugresistance/global_action_plan/en/

Sub-standard –16: 01**There is a written policy and procedures for hospital environment & housekeeping (D)****Review**

- 1) Comprehensive: policy must include the following:
 - 1.1. Cleaning protocol,
 - 1.2. Methods of cleaning
 - 1.3. Types of cleaning (Regular and Terminal)
 - 1.4. Frequency of cleaning of each area in the hospital according to risk assessment
 - 1.5. List of approved disinfectant used in the hospital
 - 1.6. Method of use of disinfectants and its preparation with clear description according to the manufacturer instructions (dilution, contact time, MSDS safety data sheet)
 - 1.7. Cleaning schedule with assigned responsibilities
 - 1.8. Curtain changing policy
 - 1.9. Environmental sampling
- 2) Updated according to national and international references (OSHA, CDC, MOH, GCC)
- 3) Valid (2 – 3 years) or If there is any update in the guidelines

2

Sub-standard –16: 02

There is a written policy and procedures for pest control (regular schedule and pest threshold / pesticides list / time and place of exposure). (D)(SI)

Document
(D)

Review the policy that should be:

- 1) Comprehensive and include the following:
 - 1.1. Describe a clear procedure for pest control in the hospital
 - 1.2. Timing and schedule for pesticides
 - 1.3. List of approved chemicals used *
- 2) Monitoring must be conducted from Infection Prevention and Control Department
- 3) Updated according to national and international references (CDC, MOH, GCC)
- 4) Valid (2 – 3 years) or If there is any update in the guidelines
- 5) Review the contract with the contractor for pest control regarding the date expiration of the current contract.
- 6) Review the log book for the pesticide company visits to the hospital and if it meets with the required schedule.

Comment (if any): *approval must be obtained from infection Prevention and Control

Department

Staff Interview
(SI)

Ask the pest control staff:

- 7) How they conduct Pest control activities in an area / procedure (routine or as needed)
- 8) List of pesticides they use and how they use it?

3

Sub-standard –16: 03

There is a written policy and procedure for management of blood/body fluids spills.

(D)(SI)

Document
(D)

Review the policy which should be-:

- 3) Comprehensive: the policy should include the following:
 - 1.1. The role and responsibility of housekeeper and nurses in management of blood/body fluid spills
 - 1.2. Described procedure / steps how to deal with spills (large, small) according to amount and type.
- 4) Updated according to national and international references (OSHA, CDC, MOH, GCC)
- 5) Valid (2 – 3 years) or If there is any update in the guidelines

Staff Interview
(SI)

Ask

- 6) Nursing staff what is the steps for management of blood/body fluid spills (ask a nurse to simulate the procedure)
- 7) Housekeeper staff: what is their role in blood/body fluid spills
- 8) Availability of spill kit in different clinical departments.
- 9) Chemicals used / and their concentration (this question mostly directed to ICPs)

Sub-standard –16: 04

4

Each unit has a schedule of cleaning/ disinfection activities log that records responsible worker, used agents, methods of cleaning and the environmental surfaces intended to be cleaned **(D)(SI)**

Document
(D)

Review

- 1) Schedule of unit cleaning and disinfection
- 2) Schedule must include the frequency, the used disinfectant and the responsible staff:
 - 1.1. Nursing staff for medical equipment
 - 1.2. Housekeeper for other environmental surfaces
 - 1.3. Radiology technicians for portable X-ray
 - 1.4. Respiratory therapist for respiratory therapy equipment. Etc..

Staff Interview
(SI)

Ask

- 3) Nursing staff about the method and how frequent they disinfect medical equipment (ask a nurse to simulate the procedure of cleaning and disinfection of patient monitor)
- 4) Ask the housekeeper how frequent they do routine cleaning of patient room.
- 5) Nursing staff about used disinfectant in disinfection and cleaning of regular room and isolation room

Sub-standard –16: 05

5

Cleaning agents and disinfectants are consistent with hospital's policies and MOH specifications and used in the correct method (e.g., dilution and contact time... etc.)
(O)(SI)

Observe

- 4) Process of cleaning (from high to low surfaces, from clean to dirty areas and if they allow the contact time)
- 5) A daily and terminal cleaning process
- 6) Housekeeper cleaning cart (All equipment and disinfectants needed are available e.g. mops, disinfectants, small measuring containers and microfiber cloths ...)
- 7) Presence of assigned equipment and cart for isolation rooms
- 8) phenolic disinfectant in the patient care areas is prohibited

Observation
(O)

Ask the housekeeper:

- 9) What disinfectants you are using for environmental surfaces cleaning in regular room, isolation room and bathrooms?
- 10) Who is responsible about disinfectant preparation and dilutions and How you prepare different solutions?
- 11) Describe how you will clean the patient room? The housekeeper may perform the cleaning process in front of you
- 12) What is the contact time for different disinfectants?

Staff Interview
(SI)

6

Sub-standard –16: 06

There are separate clean and dirty utility rooms in each patient care area. (O)(D)

Observation
(O)

Observe

- 1) Designated/labeled room for clean and dirty utility equipment/materials
- 2) Rooms dedicated only for its usage (observe that no dirty/used items are stored in clean utility room)

7

Sub-standard –16: 07

Allocated staff for housekeeping are trained on hand hygiene, use of PPE, methods of cleaning, and proper and safe mixing of chemicals. Only experienced or well-trained housekeeping staff are allowed in critical care areas (O,D,SI)

Document
(D)

Review

- 1) Attendance sheets for housekeeper infection control training about infection control standards (HH, PPEs, environmental cleaning and disinfection, preparation of cleaning solutions ...)
- 2) Approved documented special training for housekeepers working in critical areas e.g. OR, ICUs ...etc..

Observation
(O)

Observe

- 3) How they conduct HH, PPEs and mixing of the solutions
- 4) How they use equipment in a regular room / isolation room
- 5) Type of PPEs used during cleaning process

Staff Interview
(SI)

Ask

- 6) How frequent you receive infection control training?
- 7) What topics covered in the training?
- 8) How you prepare solutions used in regular /isolation rooms?

8

Sub-standard –16: 08

Hospital environment, lockers and cabinets are regularly cleaned, dry and dust free.
(O)(D)

Document
(D)

Review

- 1) Cleaning schedule located in the area with date and time

Observation
(O)

Observe

- 2) Observe any presence of dirty/dusty surfaces. You may use wet wipe to wipe a surface that you suspect it's not clean
- 3) Open lockers or cabinets and check for its cleanliness from inside

9

Sub-standard –16: 09

Bedside curtains are clean, free of stains and changed regularly & when visibly contaminated (O,D,SI)

Document
(D)

Review

- 1) Log sheet for curtain changing according to risk classification of the areas

Observation
(O)

Observe

- 2) Curtains in patient rooms for any dirt or stain

Ask

- 3) The staff how frequent they change the curtains / indications
- 4) Frequency of changing in isolation rooms (after patient discharge or referral)
- 5) Availability of replacement stocks of the clean curtains in the clean utility room.

10	<p>Sub-standard –16: 10</p> <p>Terminal cleaning process is done properly when indicated by using updated detailed checklist. (O,D,SI)</p>
11	<p>Sub-standard –16: 11</p> <p>Terminal cleaning process after discontinuation of isolation is supervised by the in-charge nurse, and in case of an outbreak by infection control practitioner (O,D,SI)</p>
Document (D)	<p>Review</p> <ol style="list-style-type: none"> 1) Terminal cleaning checklist (must include all the items present in the assigned area) 2) Last terminal cleaning checklist which should be signed by the nurse in-charge or infection preventionist
Observation (O)	<p>Observe</p> <ol style="list-style-type: none"> 3) Process of terminal cleaning if possible 4) The hard point that hard to be reach (if clean) 5) Terminal cleaning in OR
Staff Interview (SI)	<p>Ask</p> <ol style="list-style-type: none"> 6) When they conduct terminal cleaning? 7) Steps for proper terminal cleaning 8) If they use a dedicated checklist 9) The nurse in-charge how she will supervise the process of terminal cleaning

12

Sub-standard –16: 12

Biological spill kits are available in all patient care units and HCWs are capable of using them properly. (O,SI)

Observation
(O)

Observe

- 1) Availability of the Biological spill kits in the area with its content.
- 2) Clear instruction how to use
- 3) Demonstrate how to use the kit

Staff Interview
(SI)

Ask

- 4) Indication when to use the kit
- 5) The staff how to deal with Biological spill kits. You may ask a nurse to simulate the management of blood spill.

13

Sub-standard –16: 13

Random, undirected environmental microbiological cultures (for air, water, or environmental surfaces) are not recommended routinely. Only directed microbiologic sampling is conducted when indicated and approved by the regional IC team. (D,SI)

Document
(D)

Review within the infection control department:

- 1) The last environmental sampling done, it's indications and results (if available)

Staff Interview
(SI)

Ask the infection control practitioners:

- 2) When it's indicated to take environmental samples? (answer should be during an outbreak or after construction and renovation)

1

Sub-standard -01

There is a written policy and procedures that covers infectious waste management (Types of medical waste, sorting, collection, transport, storage, PPE, etc..) (D)

- ❖ *Infectious waste should always be segregated, collected, transported and stored in a safe manner with consideration of the risk, occupational safety rules and should be in accordance with local regulations.*
- ❖ *Staff should be knowledgeable about the risks and safety operating procedures of the waste they are handling.*
- ❖ *The risk of acquiring an infection from medical waste is extremely remote.*
- ❖ *No waste disposal worker or member of the general public has ever acquired an infection from medical waste.*
- ❖ *Medical wastes require careful disposal and containment before collection and consolidation for treatment. Strict adherence to safety measures should be ensured in order to protect the workers who generate medical wastes and who manage the wastes from point of generation to disposal.*
- ❖ *Infectious waste has been specifically defined as any infectious waste to be capable of causing infection, a susceptible host must be exposed to a pathogen in the waste and must have a portal of entry, and the pathogen must be of sufficient virulence and quantity*

If Medical waste is not properly managed and disposed of, it can result in injury by contaminated sharps and infection with Blood borne pathogens

Careful handling, sorting, and appropriate disposal of waste from these settings is important to prevent transmission of infection.

Review:

Policies & Procedures for **management of infectious waste** which should be **comprehensive** incorporating all aspects of waste **management program** as follows:

A) Types of infectious waste

Infectious waste is categorized as:

- **Blood and blood products:**

Bulk blood, blood-tinged suctioned fluids, excretions, secretions are considered infectious waste.

- **Pathology waste:**

includes human or animal tissues such as placenta, uterus, organs, and body parts that are collected at autopsy or during surgery

- **Microbiological cultures,**

stocks and microbiological waste: items containing blood or other potentially infectious materials, as well as, discarded live and attenuated vaccines.

- **Sharps:**

used or unused sharps (e.g., hypodermic, intravenous or other needles; auto disposable syringes; syringes with attached needles; infusion sets; scalpels; pipettes; knives; blades; broken glass). etc.

B) Sorting of Infectious Waste:

Four (4) methods of waste segregation must be followed at the point of generation (i.e., by the end user):

- **Black bags:** Used to dispose of general hospital waste.

- **Yellow bags:** Used to dispose of infectious waste. Refer to categories of infectious waste

- **Red Bags** Use to transport body parts, organs, or fetuses for burial.

- **Sharp Containers Used** to dispose all used and unused sharps (e.g., Hypodermic, intravenous or other needles, auto-disable syringes, syringes with attached needles, scalpels, glass pipettes, knives, blades, broken glass).

C) Specifications of waste containers

a) **Sharps containers:**

- Must be rigid, puncture-proof, leak-proof and closable.

- Equipped with a hermetical seal with an opening aperture which allows insertion of sharp items (e.g., needles and lancets).

- Has a biohazard logo and labeled as "Sharp Items" which must be printed in both Arabic and English. etc.

b) Plastic bags

- Should be tear-resistant and leak proof
- Must not contain Polyvinyl Chloride (PVC).
- Thickness must not be less than 70 microns thick.
- All designated infectious waste containers should have a biohazard symbol or labeled with the word "Infectious" both in Arabic and English or be color-coded (i.e., yellow bags), rendering them identifiable by hospital staff.

D) Collection of infectious waste:

- Collect waste at least once per day and as needed.
- Wear personal protective equipment (PPE).
- Handle bags at the top so that the bags do not come in contact with your body.
- Do not use hands to compress (squeeze) waste in containers/bags.
- Tie all bags securely when $\frac{3}{4}$ full and remove to storage containers.
- Avoid overfilling carts with waste bags for transport to general storage room.
- Wash hands after handling waste. etc.
- Label the infectious waste bags or sharp containers with the following information:
 - A. Generating department
 - B. Date collected
 - C. Time etc.

E) Transportation of infectious waste:

- Internal & external systems used for the transportation of infectious waste must maintain integrity of packaging & protect handlers.
- Use leak-proof carts that are readily cleanable to transport infectious waste from the point of generation or storage to the point of disposal and treatment.
- Decontaminate carts used for transporting waste within the hospital daily using a hospital approved disinfectant solution
- Place yellow bags in a holding area for incineration
- ❖ **Transporting and storing regulated medical wastes within the health-care facility prior to terminal treatment is often necessary.**
- ❖ **Health-care facilities are instructed to dispose medical wastes regularly to avoid accumulation. Medical wastes requiring storage should be kept in labeled, leak-proof, puncture-resistant containers under conditions that minimize or prevent foul odors.**

The storage area should be well ventilated and be inaccessible to pests etc.

F) Storage of infectious waste:

There could be 2 types of storages in the hospital:

i. Temporary storage area:

- *Storage in the wards located in the dirty utility which are used to hold infectious waste temporarily to be collected and transported to the central storage area every after end of the shift or as needed.*

ii. Central storage area:

- *Used to hold infectious waste for not more than 24 hours to be eventually collected and transported off-site for treatment.*
- *The room must have a concrete floor and be well-sealed to protect it from water leakage, rain, spread of odor, from rodents, insects, birds and stray animals.*
- *Dispose infectious waste as soon as possible after generation.*
- *Minimize the storage time to reduce the risk of potential exposure and reduce odor.*
- *Limit access to storage areas and have a biohazard symbol labeled with the word "storage area" in both **Arabic and English**; and posted where it is **readily visible to anyone**.*

Other domains of Policies & procedures:

P/P for Infectious Waste Management should be :

- **Fully applicable**: all elements of the policy can be applied and comply with the hospital's scope of services
- **Based on scientific references** approved by MOH (**GCC, CDC, WHO & APIC**)
- **Signed** from authorized personnel (i.e., owner of the policy / hospital director or Medical director / concerned department)
- **Approved** by IC committee
- **Valid** (updated within 2 - 3 years and when indicated)

2

Sub-standard –02

All non-sharp generated medical waste disposed in black bags as general waste except that heavily soiled with liquid blood or other body fluid (dripping) except from isolation room all waste should be in yellow bag. (O,SI)

Observe:

In all patient care areas (ER, ICU, HDU etc.):

1. Availability of different sizes of color-coded waste bags.
2. If the number of waste receptacles are adequate according to amount of waste generated in specific unit.
3. If the number of sharp containers are adequate in number & appropriate sizes.
4. Waste receptacles. Sharp containers and color coded bags must meet the regulations of Ministry of Health.

❖ Waste bags & Waste containers :

- *Should be tear-resistant and leak proof*
- *Must not contain Polyvinyl Chloride (PVC).*
- *Thickness must not be less than 70 microns thick.*
- *All designated infectious waste containers should have a biohazard symbol or labeled with the word "Infectious" both in Arabic and English or be color-coded (i.e., yellow bags), rendering them identifiable by hospital staff.*

❖ Sharps containers :⁽¹⁾

- *Must be rigid, puncture-proof, leak-proof and closable.*
- *Equipped with a hermetical seal with an opening aperture which allows insertion of sharp items (e.g., needles and lancets).*
- *Have a biohazard logo and labeled as "Sharp Items" which must be printed in both Arabic and English. etc.*

Interview

Ask the staff about waste segregation.

Observation
(O)

Staff Interview
(SI)

3

Sub-standard –03

Except in GENERAL WARDS (supplies and consumables required for infectious waste segregation (waste containers, colored coded bags, and sharp containers) are of appropriate sizes, adequate in number at points of production, Sharp containers are wall mounted or Placed on a stand and available inside the patient zone. (O,SI)

Observe:

In all Critical care areas (ER, ICU, HDU etc.) & Isolation Rooms:

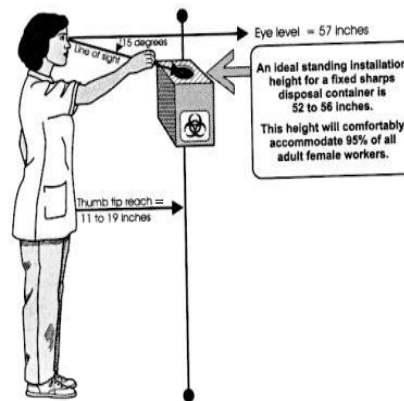
Location of the sharp containers should be wall mounted or placed on stand.

- ❖ Observe if height of sharp container is meeting the international standards. *(You may observe sharp containers placed directly on floor, mounted very high above the eye level & at locations inaccessible for the healthcare workers.)*
- ❖ *Healthcare workers should be able to view the entire opening of the sharps disposal container while comfortably standing within arm's reach.*
- ❖ *NIOSH provides an ergonomically ideal formula by establishing the eye-level height, maximum thumb tip reach of the worker population, and including a drop angle drop 15 degrees (see illustration below).*

Sharps disposal container height should be:

- *Standing workstation: 52 to 56 inches above the standing surface of the user*
- *Seated workstation: 38 to 42 inches above the floor on which the chair rests*

These height installation suggestions will “comfortably accommodate 95% of all adult female workers,” according to NIOSH.



Comment:

Sharp boxes should be puncture proof, leak-proof, and present no risk to staff or patients

Observation
(O)

4

Sub-standard –04

In GENERAL WARDS, all clinical procedures are performed using procedural trolley equipped with biohazard waste bag and sharp container. **(O, SI)**

Observation
(O)

Observe:

During visit of general wards (Medical wards, surgical wards, Maternity wards etc.):

- ❖ If they are using procedural trolley for performing all bed side clinical procedures like wound dressing, changing IV cannulas, etc.
- ❖ Observe the availability of sharp container and biohazard waste bag of appropriate size hanging with the procedural trolley.
- *Location of sharp container & waste bag should be at level that should not contaminate the clean / sterile supply.*
- *Position of waste bag and sharp container must be at different levels.*

Staff Interview
(SI)

Interview:

- ❖ Staff in general wards regarding their practice in terms of waste disposal.
- ❖ Ask If they are using procedural trolley equipped with sharp container and biohazard waste bag for discarding waste and sharps.

5

Sub-standard –05

Needles are not bent, broken, separated or recapped. (O,SI)

Observe:

During visit of all patient care areas general wards, Critical care units etc.

- ❖ Open lid of sharp containers at random and check if any broken, bent , recapped or separated needles are present.

Sharp containers are used:

- *To dispose all used and unused sharps (e.g., Hypodermic, intravenous or other needles, auto-disable syringes, syringes with attached needles, scalpels, glass pipettes, knives, blades, broken glass).*
- *Blades or needles should not be disassembled from the equipment.*
- *Recapping, bending needles etc. pose healthcare workers to significant risk of acquiring Needle stick Injuries from accidental exposure to sharps.*

Interview:

- ❖ The staff about safe handling of sharps.
- ❖ Ask her / him to simulate how to discard the used syringe after use.
- ❖ Ask if she find any sharp item on floor (***e.g. broken glass, guide wire etc.) how she will safely discard. *****
- ❖ The staff about the safe zone movement of handling sharps.

Comment (if any):

*****Pick up and discard broken glass or any sharp using a mechanical device such as forceps or a brush and dust pan.***

Broken glass should never be handled with gloved or non-gloved hands

Observation
(O)

Staff Interview
(SI)

6

Sub-standard -06

No infectious medical waste or sharps are observed outside specified containers. (O)

Observe:

During hospital visit of all patient care areas like general wards, Critical care units, dental, lab, etc.

- ❖ Observe if the healthcare workers are discarding the waste in specified containers or not.
- ❖ Randomly open the containers to observe if discarded waste is appropriate for that receptacle.

You may observe card boxes. Papers & plastic wrappers & sharp object discarded in infectious waste receptacle and N – 95 masks & blood soaked gauzes discarded in general waste. Sometimes you may observe a paper tissue & surgical mask discarded in sharp container.

- ❖ Observe if HCWs are compliant with waste segregation Protocols.):
- **Black: To dispose general waste**
- **Yellow: To dispose infectious waste, soaked items with blood or body fluid**
- **Red: To dispose body parts and organs**
- **Sharp Containers: To dispose all kinds of sharps (needles, broken/ glass, syringes with attached needles, blades; etc.)**

Observation
(O)

7

Sub-standard –07

Medical waste bags are collected after being securely closed when filled to 3/4 of its maximum capacity and labeled with the date and place of production.

(O,SI)

Observation
(O)

Observe:

- ❖ Medical waste bags in the temporary holding areas in & Infectious waste room which shouldn't be overfilled.
- ❖ If waste bags are well secured & tied with a **self-lock plastic tie** before placing them in a temporary holding area such as a dirty utility room.
- ❖ Observe the label of infectious waste bags with the following information:
 - a. **Generating department**
 - b. **Date collected**
 - c. **Time etc.**

Staff Interview
(SI)

Interview:

- ❖ Housekeeping / waste collection staff about the Procedure / mechanism of waste collection.
- ❖ Ask at which level / capacity/level are they going to remove waste bag from the specified receptacles/containers. *(Should be collected when filled to 3/4 of its maximum capacity.*
- ❖ Ask if they have tags / stickers for labeling the waste bags & what is the necessary information that needs to be recorded *(Date / Department /unit etc.)*
- ❖ Ask what they are using to tie the waste bags at the time of collection.

Comment:

Extreme care must be taken while handling waste bags.

- *Waste bags should be handled at the top so that the bags do not come in contact with body.*
- *Never use hands to compress (squeeze) waste in containers/bags. ⁽¹⁾*

∞

Sub-standard –08

Sharp boxes are collected after being securely closed when filled to 3/4 of its maximum capacity and labeled with the date and place of production. (O,SI)

Observation
(O)

Observe:

- ❖ Sharp containers in the temporary holding areas / Infectious waste room & assess the levels.
- ❖ If sharp containers are being replaced promptly when container is $\frac{3}{4}$ filled (and reaches the fill line)
- ❖ Observe the label on the sharp container with the following information:
 - a. **Generating department**
 - b. **Date collected**
 - c. **Time etc.**

Staff Interview
(SI)

Interview:

1. Nursing staff:

- ❖ **About** about their responsibility regarding sharp containers & at which level / capacity / level are they going to close the sharp container.
 - *(Nurses are responsible to close the sharp containers when $\frac{3}{4}$ full or reaches the fill line and to inform the medical waste staff to replace)*
- ❖ Ask if they have tags / stickers for labeling the sharp containers & what is the necessary information that needs to be recorded (*Date / Department /unit etc.*)

2. Waste Collection staff:

- ❖ Ask about the Procedure / mechanism of collection of sharp containers.
- ❖ Assess if they are aware about their responsibility to collect the sharp containers and to replace it immediately with a new one.

9

Sub-standard –09

Collection & transportation of medical waste are done by allocated workers wearing proper PPE at fixed times and on demand. (D,O,SI)

Document
(D)

Review:

- ❖ Schedule of waste collection within the units and verify the frequency of waste collection.
(Frequency of waste collection should be clearly specified in the schedule / log sheet that must be at fixed intervals. (Every 2 hours, once per shift etc.)
- ❖ Any evidence of collection protocols e.g. *contacts numbers to call the medical waste staff when needed (In case of increased demand etc.)*

Observation
(O)

Observe;

- ❖ In the temporary holding areas i.e. dirty utility rooms etc. if collection frequency is matching with what is specified in schedule. *(You may observe large number of waste bags and sharp containers not collected as per schedule)*
- ❖ The practice of waste collection staff waste regarding using appropriate PPEs. *(PPE must be changed frequently when moving from one station to another station. Staff must perform hand hygiene after removing PPE. This has been observed that waste collection staff use on set of PPE throughout the hospital and use elevators with same gloved hands contributing / posing to infection risk)*

Staff Interview
(SI)

Interview;

- ❖ Waste collection staff about frequency of waste collection from different units. (ER, ICU, etc.).
- ❖ Where they keep the waste/ for how long it stays.
- ❖ Ask about the appropriate PPE and frequency of changing PPE?
- ❖ Ask them at random to simulate PPE donning and doffing and assess their performance.
- ❖ Ask if they have received any infection control training?

Waste collection staff may use below mentioned PPE based on type of work (Collection, transportation, cleaning / disinfection of carts etc.):

- Clean Gloves / Heavy duty gloves
- Safety Shoes
- Mask & Eye protection
- Protective Gown/Apron etc.

10

Sub-standard –10

Infectious medical waste is transported in closed and impervious specified carts with biohazard sign. Carts are cleaned after each use or at least daily.

(O,SI)

Observation
(O)

Observe:

- ❖ Availability of carts used for transportation of Infectious medical waste and assess if meeting the specifications.
 - *Closed*
 - *Impervious*
 - *Leak proof & readily cleanable*
 - *Clearly visible Biohazard Signage*
- ❖ Observe if transportation carts are regularly cleaned and well maintained (**Free from dust / Blood stains etc.**)

Staff Interview
(SI)

Interview;

- ❖ Waste collection staff about frequency of cleaning the transportation carts.
- ❖ Where & how carts are being cleaned??
- ❖ Which disinfectant they are using?
 - *Transportation carts used for transporting waste within the hospital must be decontaminated after each use or daily using a hospital approved disinfectant solution.*
 - *Decontaminate disposal bins / containers or frames when visibly soiled. These items should be cleaned weekly or as needed with hospital-approved disinfectant*

Sub-standard –11

11

The medical waste store is consistent with the approved national specifications (adequate in space, away from traffic, secured, well ventilated with temperature <18 °C., provided with water source & adequate drainage, and its walls & floors are easily cleanable) (D,O,SI)

Document
(D)

Review:

- ❖ Log for temperature control (*Check for any fluctuations in the log sheet*)
- ❖ Cleaning schedule / checklist

Observation
(O)

Observe:

Medical Waste store is fulfilling the following specifications:

- ❖ Secured and locked (away from traffic)
- ❖ Biohazard signage posted
- ❖ Adequate space
- ❖ Clean and well maintained. Walls and floors are smooth and of easily cleanable material. No cracks, openings etc.
- ❖ Well ventilated with temperature monitor (**displaying temperature <18°C**)
- ❖ The room must have a smooth floor (easy cleanable) and door well-sealed to protect it from water leakage, rain, and spread of odor, rodents, insects, birds and stray animals.
- ❖ Equipped with hygiene washing sink with required supplies like soap paper tissues etc. sewage hole must be well sealed. etc.

Staff
Interview
(SI)

Interview;

- ❖ Responsible staff about engineering controls of waste room. *What would be the actions taken in case of fluctuations / failure etc.??*
- ❖ Frequency of cleaning and disinfection of the room & type of disinfectants used.

12

Sub-standard –12

Infectious medical waste is transported outside the hospital every 24 hours to be disposed through the nationally approved system for medical waste management. (D,O,SI)

Document
(D)

Review:

- ❖ Daily collection log sheet / or any document provided by company for transportation & waste disposal outside the hospital with date and time.
- ❖ ***Infectious medical waste is transported outside the hospital every 24 hours***

Observation
(O)

Observe:

- ❖ Check the label on medical waste bags & sharp containers to confirm if exceeded 24 Hours collection time or as per standard.
- ❖ Observe the number of available waste bags and assess if its matching with policy of daily collection. *(Huge number would reflect lack of compliance)*

Staff Interview
(SI)

Interview:

- ❖ Responsible staff regarding frequency of waste collection by the designated waste management company.
- ❖ Ask on which day & time company is collecting waste for purpose of verification.

13

Sub-standard –13

Allocated infectious waste workers are vaccinated against Hepatitis B virus and trained on hand hygiene, use of PPE and safe handling of waste. **(D,MR,SI)**

Document
(D)

Review:

- ❖ Evidence of training conducted for infectious waste workers. (*Check for frequency*)
- ❖ Review the content of training provided.

Training activities include but not limited to:

- **Hand hygiene**
- **PPEs use including N - 95 mask**
- **Safe handling & other waste management protocols during collection, transportation etc.**
- **Labeling / coding that designates an item as infectious waste**
- **Sharp injuries & post exposure protocols etc.**
- **Cleaning & disinfection procedures etc.**

Medical Record
(MR)

Review:

- ❖ Medical records of infectious waste workers & check if they have received vaccination against **Hepatitis B**. (*Review files in unit or copies in Employee health clinic etc.*)
- ❖ Verify if they have completed the required dosing schedule.

Staff Interview
(SI)

Interview:

- ❖ Infectious waste workers regarding vaccination against hepatitis B.
- ❖ Ask if they have received any prior training from infection control team.
- ❖ Ask them to simulate hand hygiene & PPE donning / doffing.
- ❖ **Ask them about post exposure protocols in case of exposed to sharps** by giving a scenario:

If you experienced a needle stick or sharps injury during the course of your work, what immediate steps should be followed?

- **First Aid:**
 - ❖ *Wash needle sticks and cuts with soap and water*
 - ❖ *Then apply isopropyl alcohol 70%*
 - ❖ *Bandage appropriately*
 - ❖ *Reporting the injury to immediate his supervisor*
 - ❖ *Fill & submit and complete a reporting form (OVR : Occurrence Variance report)*
 - ❖ *The report should include:*
 - **Staff Information**
 - **The date and time of the incident**
 - **The location where the incident occurred**
 - **Details of exposure type**

1

Sub-standard –18: 01**There is a written policy and procedures for the medical storage. (D)****Review the policy, which should be:**

- 15) Comprehensive: it covers all aspects of IPC requirements in medical stores, including (but not limited to):
- Basic criteria of medical stores (i.e., space adequacy, being secured with access restriction, good maintenance, proper organization, regular cleaning and being away from contamination, direct sunlight and air vents)
 - Ventilation requirements for medical stores (i.e., temperature: 22 °C - 24 °C / relative humidity: up to 70%).
 - Recommended standards for storage shelves and containers that are used inside medical stores: accepted materials / design / essential installation requirements (i.e., 40 cm from the ceiling, 20 cm from the floor, and 5 cm from the wall).
 - Essential practices required for safe storage of sterile and clean items inside medical stores (i.e., completely separated from personal items, foods and drinks / no expired items / no broken or soiled packs / no original shipping boxes)
- 16) Fully applicable: all elements of the policy can be applied and comply with the hospital's scope of services
- 17) Based on scientific references approved by MOH (GCC, CDC, WHO & APIC)
- 18) Signed from authorized personnel (i.e., owner of the policy / hospital director or medical director / concerned department)
- 19) Approved by IC committee*
- 20) Valid (updated within 2 - 3 years and when indicated)

Document
(D)**Comment (if any):**

- Approval by IC committee is required for the infection control manual as a whole before distribution and also for individual policy after major changes
- **Another point of view: Staff Interview (SI) is required as it is mandatory for relevant staff to be fully aware about components of policy and procedure (i.e., without proper awareness, written policies and procedures are worthless).**

2

Sub-standard –18: 02

Medical storage areas are of adequate capacity, regularly cleaned, secured and away from contamination, air vents and direct sunlight. (D – O)

Review the following documents:

Document
(D)

- 1) Housekeeping schedule & updated detailed checklist.
 - Who is responsible for housekeeping (authorized staff who should be well trained on hand hygiene, use of PPE, methods of cleaning/disinfection, and proper and safe mixing of chemicals)
 - What are procedures or methods of cleaning/disinfection activities, materials and supplies and used agents (e.g., wet cleaning, MOH approved disinfectant/detergent, non-linting wipes ...)
 - Essential documents for used housekeeping ingredients (i.e., detergent/disinfectant's MSDS, preparation, usage, contact time, precautions and required PPE).
 - List of environmental surfaces intended to be cleaned/disinfected.
 - How frequent housekeeping activities are indicated with application of practical updated detailed checklist

Observation
(O)

Observe the storage area(s) in medical departments, which should be:

- 1) Adequate in space
 - 2) Secured with restricted access for only authorized personnel
 - 3) Properly maintained and well organized
 - 4) Away from contamination, direct sunlight and air vents.
 - 5) Regularly cleaned according to definite housekeeping schedule and updated detailed housekeeping checklist
- Environment is clean (at all times) and free of contamination (no dirt or dust): you can wipe out some environmental surfaces / check if tools, agents & materials used for cleaning/disinfection activities are available and matching MOH standards

3

Sub-standard –18: 03

Medical storage areas have controlled ventilation with adjusted temperature and humidity (temperature ranges from 22 °C to 24 °C / relative humidity up to 70%). (D – O)

Document
(D)

Review the following documents:

- 1) Local records for regular monitoring (**daily**) of temperatures and relative humidity during the last month.
- 2) Local records for corrective interventions which are taken if readings are not matching the acceptable values.
- 3) Copies of maintenance records for regular monitoring (**every 3 months**)* of temperatures and relative humidity with corrective interventions if readings are not matching the acceptable values.
- 4) Copies of records from the executing company (or copies of maintenance records) for regular calibration (**yearly**) of fixed temperatures and relative humidity monitors.

Observation
(O)

Observe the storage area(s) in medical departments for the following:

- 1) Storage area(s) is (are) centrally air conditioned with adjusted temperature and relative humidity.
- 2) Each storage area is equipped with a fixed device for regular monitoring of temperature and relative humidity: Observed temperature: 22 - 24°C - Observed relative humidity: up to 70%.
- 3) Fixed temperatures and relative humidity monitors are valid and recorded values in local department logs are identical to the actual readings.

4	<p>Sub-standard –18: 04</p> <p>Storage shelves are at least, 40 cm from the ceiling, 20 cm from the floor, and 5 cm from the wall. (O)</p> <p>Sub-standard –18: 05</p>
5	<p>Storage shelves are made of easily cleanable material, e.g., fenestrated stainless steel, Aluminum or hard plastic. (O)</p>
Observation (O)	<p>Observe the storage area(s) in medical departments for the following:</p> <ol style="list-style-type: none"> 1) Storage shelves are made of easily cleanable material (e.g., fenestrated stainless steel, Aluminum or hard plastic). 2) Storage shelves are: <ul style="list-style-type: none"> - 40 cm from the ceiling - 20 cm from the floor - 5 cm from the wall 3) If containers are used inside medical stores, they are made of easily cleanable material (e.g., hard plastic). <p>Comment (if any): Storage shelves made of wood or stainless steel wires are not acceptable</p>

6	<p>Sub-standard –18: 06</p> <p>Sterile and clean items are completely separated from personal items, foods and drinks. No expired items, broken packs or packs with stains are present. (O – S)</p> <p>Sub-standard –18: 07</p>
7	<p>No Items are kept in the original shipping boxes, especially in the clinical areas. (O – S)</p>
Observation (O)	<p>Observe the storage area(s) in medical departments for the following:</p> <ol style="list-style-type: none"> 1) To ensure that only sterile and clean items are allowed in the medical stores 2) To exclude the presence of any personal items, foods and drinks. 3) To exclude the presence of any expired, broken or soiled items/packs. 4) To exclude the presence of any original shipping boxes (i.e., boxes made of thick cardboard for shipping) <p>Comment (if any):</p> <p>N.B. It is allowed to keep non-shipping boxes made of thin smooth glazed cardboard inside medical stores (e.g., small boxes of medical supplies: clean gloves, surgical masks, syringes ...etc..)</p>

Ask the responsible staff (nurse in charge or storage area responsible nurse) about:

Instead of direct questions, indirect ones or scenarios are advisable, Examples:

- 7) What are the recommended safe practices for keeping of personal items, foods and drinks inside medical stores?
- 8) How can you safely keep the original shipping boxes of supplies inside medical stores of the clinical areas?
- 9) What are the applied interventions to solve problems of keeping non-shipping boxes of supplies inside medical stores of your department?
- 10) Are you aware about FIFO policy?
- 11) How you manage expired items/packs?
- 12) How you manage broken items/packs?
- 13) How you manage any items/packs with stains?

- **Answer:**

- Only sterile and clean items are allowed inside medical stores (i.e., keeping personal items, foods and drinks inside medical stores is strictly prohibited)
- It is strictly prohibited to keep items inside their original shipping boxes, especially for medical stores of the clinical areas.
- Actually, it is allowed to keep non-shipping boxes made of thin smooth glazed cardboard inside medical stores (e.g., small boxes of medical supplies: clean gloves, surgical masks, syringes ...etc.)
- **FIFO (*First In First Out*)**: is an inventory management and evaluation method in which items produced or acquired first are sold, used or disposed of first (i.e., we are assuming that the first product purchased or the oldest inventory items is the first product used or disposed. Hence the first product in the door is the first product out of the door).
- Expired, broken or soiled items/packs are not allowed inside medical stores (i.e., it should be discarded)

1

Sub-standard –19: 01

There is a written policy and procedures for IC considerations during demolition, renovation, and construction projects. (D)

Documentation review of policy and procedure, which should be:

- ❖ Comprehensive and well descriptive: it entails (but not limited to):
 - Establishment of multidisciplinary team which is composed of Infection Control, General Services, Risk Management and Housekeeping personnel. The team is responsible for planning and implementing proactive preventive measures for the whole duration of the construction project and in establishing clear lines of communication among all concerned to ensure patient safety.
 - Authority (directed to all departments and construction team) of infection control department to be pre-informed before starting any construction & renovation activities or projects (i.e., maintenance personnel should obtain an Infection Control Construction Permit)
 - Infection Control Risk Assessment Matrix of Precautions for Construction & Renovation (ICRA): infection control precautions during construction & renovation and upon completion of project (i.e., type I, II, III, and IV), after identifying:
 - a) Type of Construction Project Activity (i.e., type A, B, C and D).
 - b) PATIENT RISK GROUP that will be affected during construction & renovation activities (i.e. LOW RISK, MEDIUM RISK, HIGH RISK and HIGHEST RISK)
 - Role of infection control personnel in providing education to workers and staff involved in the project to ensure through periodic follow up that preventive measures are outlined, implemented and maintained during all phases of any construction and renovation projects
 - Authority of infection control department to stop construction projects if breaches in preventive measures arise that may expose patients and HCWs to infections or environmental hazards
- ❖ Fully applicable: all elements of the policy can be applied and comply with the hospital's scope of services
- ❖ Based on scientific references approved by MOH (GCC, CDC, WHO & APIC)
- ❖ Signed from authorized personnel (i.e., owner of the policy / hospital director or medical director / concerned department)
- ❖ Approved by IC committee*
- ❖ Valid (updated within 2 - 3 years and when indicated)

Document
(D)

Comment (if any):

- Approval by IC committee is required for the infection control manual as a whole before distribution and also for individual policy after major changes

2

Sub-standard –19: 02

IPC team is involved prior to, during, and after any construction, demolition, and renovation project (Planning, ICRA, IC permit, continuous follow - up and authority to stop the project). (D - SI)

Document
(D)

Documentation review for evidence of:

- 1) Multidisciplinary team meetings that indicate involvement of infection control team in planning and executing any construction & renovation projects
- 2) Infection Control Construction Permit: infection control department's permission was taken before starting any construction & renovation activities
- 3) Infection Control Risk Assessment Matrix (ICRA): posted at the construction & renovation site with all precautions (proactive preventive measures) are outlined and very well explained to the construction staff (or at least the supervisor of each shift) to be strictly implemented and maintained during all phases of the project
- 4) Periodic follow up of IC Practices and other preventive measures during all phases of the construction & renovation project. This is depending on the PATIENT RISK GROUP (e.g., construction projects involving HIGH RISK patient care areas as surgical units require frequent visits as compared to construction activities in LOW RISK areas as general administrative area)
- 5) Authority of infection control department to stop the construction project if there is breaches in IC practices that may expose patients and HCWs to infections or environmental hazards

Comment (if any):

Ask about the Infection Control Construction Permit / Infection Control Risk Assessment Matrix (ICRA) / documents for regular follow up / documents for stopping the construction projects (if any) **of an ongoing demolition, renovation, or construction project or the last project(s) that has (have) been executed**

Staff Interview
(SI)

Staff interview should focused on:

- 1) **Infection control director:** he/she should be aware of his/her department's involvement in planning and executing any construction & renovation projects (e.g., prior to execution of construction & renovation activities that involve critical units, there should be some arrangements to shift patients to other areas, isolation of construction & renovation site, creation of dust barriers, isolation of HVAC system ... etc.) and their understanding of importance of ICRA, permission, follow up and stopping the construction project when required
- 2) **Stakeholders of construction & renovation projects** (e.g. site manager or project's supervisor of the ongoing shift): he/she must be familiar with involving IC department in every step of the project starting from planning to execution to completion. Also he/she should understand that all personnel involved in construction & renovation activities must be very well aware of IC precautions (proactive preventive measures), to strictly implement and maintain IC practices during all phases of such activities

3

IPC measures are followed during the construction, demolition, and renovation projects by using infection control risk assessment (ICRA). **(D,O,SI)**

Document
(D)

Review the following documents:

- 1) **Infection Control Risk Assessment Matrix (ICRA)**, which should:
 - Be formulated and posted at the construction & renovation site
 - Identify accurately type of construction project activity (i.e., type A, B, C and D) & patient risk group that will be affected during construction & renovation activities (i.e. LOW RISK, MEDIUM RISK, HIGH RISK and HIGHEST RISK)
 - Entail all required IC precautions (i.e., proactive preventive measures: type I, II, III, and IV), that must to be strictly implemented, maintained and periodically observed through follow up visits during different phases of the project
 - Be signed by all involved stakeholders

Observation
(O)

Observe the ongoing construction & renovation project to:

- 1) Check the presence of formulated ICRA, that is posted appropriately in visual catchment of personnel involved in construction & renovation activities
- 2) Watch if all IC practices and other preventive measures highlighted in ICRA are strictly implemented and continuously practiced or not.

Ask the staff about:

IC precautions and other general preventive measures required during construction & renovation and upon completion of project (i.e., type I, II, III, and IV), Examples:

- Isolation of areas
- Traffic control plan with signage placement
- Moving/placement of patient in other areas
- Sealing of window/door/air ducts/plumbing penetrations
- Creation of dust barriers
- Exhaustion of air in construction side directly outside
- Use of negative pressure/HEPA filters to contain dust or other dust suppression mechanisms
- Use of appropriate PPE by workers involved in construction activities
- Removal of debris at periods of low activity in containers that are tightly covered
- Reporting an unusual observation like discoloration of water, dust in units above, below, beside, behind or in front of the construction site
- Post construction preventive measures (It mainly depends on the area involved, (e.g., critical units: oncology ward, OR ...etc.): housekeeping activities (cleaning and disinfection that may include HVAC system according to construction type), flushing of water lines and/or environmental sampling.

Infection Control Risk Assessment
Matrix of Precautions for Construction & Renovation

Use the following table to identify the **Type of Construction Project Activity** (Type A-D)

TYPE A	<p>Inspection and Non-Invasive Activities Includes, but is not limited to:</p> <ul style="list-style-type: none"> • Removal of ceiling tiles for visual inspection limited to 1 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.
TYPE B	<p>Small scale, short duration activities which create minimal dust Includes, but is not limited to:</p> <ul style="list-style-type: none"> • Installation of telephone and computer cabling • Access to chase spaces • Cutting of walls or ceiling where dust migration can be controlled
TYPE C	<p>Work that generates a moderate to high level of dust or requires demolition or removal of any fixed building components or assemblies Includes, but is not limited to:</p> <ul style="list-style-type: none"> • Sanding of walls for painting or wall covering • Removal of floor coverings, 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 work shift
TYPE D	<p>Major demolition and construction projects Includes, but is not limited to:</p> <ul style="list-style-type: none"> • Activities which require consecutive work shifts • Requires heavy demolition or removal of a complete cabling system • New construction

Use the following table to identify the **Patient Risk Groups** that will be affected.

N.B.: If more than one risk group will be affected, select the higher risk group

LOW RISK	MEDIUM RISK	HIGH RISK	HIGHEST RISK
<ul style="list-style-type: none"> • Office areas • Non patient areas 	<ul style="list-style-type: none"> • Patient areas not listed in groups 3 and 4 • Materials management • Admission/Discharge • Public corridors through which patients, supplies and linens pass • Laboratories not specified in group 3 • Echocardiography • Nuclear Medicine • Physical Therapy • MRI • Respiratory Therapy • Cafeteria • Dietary services 	<ul style="list-style-type: none"> • CCU • Emergency Room • Radiology • Labor & Delivery • Clinical laboratories • Intensive Care Units • Long term units • Newborn Nursery • Dialysis • Endoscopy • Outpatient Surgery • Pediatrics • Pharmacy • Post Anesthesia Care Unit • Surgical Units 	<ul style="list-style-type: none"> • Any area caring for immunocompromised patients • Burn Unit • Cardiac Cath Lab • CSICU • CSSD • Pharmacy Admixture • Negative pressure isolation rooms • Oncology • Anesthesia and pump areas • Operating Rooms

Description of Required Infection Control Precautions by Class (I, II, III, and IV)

	During Construction Project	Upon Completion of Project
CLASS I	<ol style="list-style-type: none"> 1) Execute work by methods to minimize raising dust from construction operations. 2) Immediately replace a ceiling tile displaced for visual inspection. 3) Provide MSDS for paint and disinfectants prior to use. 	<ol style="list-style-type: none"> 1) Clean work area upon completion of task.
CLASS II	<ol style="list-style-type: none"> 1) Provide active means to prevent airborne dust dispersing into atmosphere. 2) Water mist work surfaces to control dust while cutting. 3) Seal unused doors with duct tape. 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. 7) Provide MSDS for paint and disinfectants prior to use. 	<ol style="list-style-type: none"> 1) Wipe work surfaces with disinfectant. 2) Contain construction waste before transport in tightly covered containers. 3) Wet mop and/or vacuum with HEPA filtered vacuum before leaving work area. 4) Remove isolation of HVAC system in areas where work is being performed.
CLASS III	<ol style="list-style-type: none"> 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 for vacuuming prior to exit) before construction begins. 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. 6) Provide MSDS for paint and disinfectants prior to use. 	<ol style="list-style-type: none"> 1) Do not remove barriers from work area until completed project is inspected by the Safety Department & Infection Control Department and thoroughly cleaned by the General Services Department. 2) Remove barrier materials carefully to minimize spreading of dirt and debris associated with construction. 3) Vacuum work area with HEPA filtered vacuums. 4) Wet mop area with disinfectant. 5) Remove isolation of HVAC system in areas where work is being performed.


CLASS IV	<ol style="list-style-type: none"> 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. 5) Construct anteroom and require all personnel to pass through this room 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 Safety Department and Infection Control Department and thoroughly cleaned by the General Services Department. 8) Provide MSDS for paint and disinfectants prior to use. 	<ol style="list-style-type: none"> 1) Remove barrier material carefully to minimize spreading of dirt and debris associated with construction. 2) Contain construction waste before transport in tightly covered containers. 3) Cover transport receptacles or carts. Tape covering unless solid lid. 4) Vacuum work area with HEPA filtered vacuums. 5) Wet mop area with disinfectant. 6) Remove isolation of HVAC system in areas where work is being performed.
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The Infection Control team member and General services team member will match the

- **Patient Risk Group (Low, Medium, High, Highest)** with the planned ...
- **Construction Project Type (A, B, C, D)** to find the ...
- **Class of Precautions (I, II, III or IV)** or level of infection control activities required as per the IC Matrix-Class of Precautions: Construction Project by Patient Risk given below

Patient Risk Group	TYPE A	TYPE B	TYPE C	TYPE D
LOW Risk Group	I	II	II	III/IV
MEDIUM Risk Group	I	II	III	IV
HIGH Risk Group	I	II	III/IV	IV
HIGHEST Risk Group	II	III/IV	III/IV	IV

Note: Infection Control approval will be required when the Construction Activity and Risk Level indicate that **Class III** or **Class IV** control procedures are necessary.

 Ministry of Health Infection Prevention and Control Compliance Monitoring Tools: Construction and Renovation Form: (page 1 of 2)			
Hospital Name:		Project Title:	
Location of Construction:		Project Start Date:	
Project Coordinator:	ID#:	Estimated Duration:	
Contractor Performing Work:		Permit Expiration Date:	
Supervisor:	ID#:	Tel Ext.:	Mobile #:
CONSTRUCTION ACTIVITY	Click on type of Activity (see Guide 1)	INFECTION CONTROL RISK GROUP	Click on Risk Group (see Guide 2)
TYPE A: Inspection, non-invasive activity		GROUP 1: Low Risk	
TYPE B: Small scale, short duration, Moderate to high levels		GROUP 2: Medium Risk	
TYPE C: Activity generates moderate to high levels of Dust, requires greater 1 work shift for completion		GROUP 3: Medium/High Risk	
TYPE D: Major duration and construction activities Requiring consecutive work shifts		GROUP 4: Highest Risk	
IDENTIFY and CIRCLE CLASSES OF REQUIRED PREVENTIVE MEASURES			
INFECTION CONTROL RISK GROUP	CONSTRUCTION ACTIVITY		
	TYPE "A"	TYPE "B"	TYPE "C"
Group 1	I	I	II
Group 2	I	I	III
Group 3	II	III	III/IV
Group 4	III	II/IV	III/IV
CLASSES OF PREVENTIVE MEASURES (click on measures applied):			
Class I	<input type="checkbox"/> Execute work by methods to minimize raising dust from construction operations. <input type="checkbox"/> Immediately replace any ceiling tile displaced for visual inspection.	<input type="checkbox"/> Minor Demolition for Remodeling <input type="checkbox"/> Other _____	
Class II	<input type="checkbox"/> Provides active means to prevent air-borne dust from dispersing into atmosphere. <input type="checkbox"/> Water mist work surfaces to control dust while cutting. <input type="checkbox"/> Seal unused doors with duct tape. <input type="checkbox"/> Block off and seal air vents. <input type="checkbox"/> Wipe surfaces with disinfectant. <input type="checkbox"/> Contain construction waste before transport in tightly covered containers.	<input type="checkbox"/> Wet mop and/or vacuum with HEPA filtered vacuum before leaving work area. <input type="checkbox"/> Place dust mat at entrance and exit of work area. <input type="checkbox"/> Remove or isolate HVAC system in areas where work is being performed. <input type="checkbox"/> Other _____	



Ministry of Health
Infection Prevention and Control Compliance Monitoring Tools:
Construction and Renovation Form: (page 2 of 2)

CLASSES OF PREVENTIVE MEASURES (click on measures applied):

<p>Class III</p> <p>DATE: _____</p> <p>INITIAL: _____</p>	<ul style="list-style-type: none"> <input type="checkbox"/> Obtain infection control permit before construction begins <input type="checkbox"/> Isolate HVAC system in area where work is being done to prevent contamination of the duct system. <input type="checkbox"/> Complete all critical barriers or implement control cube method before construction begins. <input type="checkbox"/> Maintain negative air pressure within work site utilizing HEPA equipped air filtration units. <input type="checkbox"/> Do not remove barriers from work area until complete project is thoroughly cleaned by housekeeping. 	<ul style="list-style-type: none"> <input type="checkbox"/> Contain construction waste before transport in tightly covered containers. <input type="checkbox"/> Vacuum work with HEPA filtered vacuums. <input type="checkbox"/> Wet mop with disinfectant. <input type="checkbox"/> Remove barrier materials carefully to minimize spreading of dirt and debris associated with construction. <input type="checkbox"/> Contain construction waste before transporting. <input type="checkbox"/> Cover transport receptacles or carts. Tape covering. <input type="checkbox"/> Remove or isolate HVAC system in areas where work is being performed <input type="checkbox"/> Other _____
<p>Class IV</p> <p>DATE: _____</p> <p>INITIAL: _____</p>	<ul style="list-style-type: none"> <input type="checkbox"/> Obtain infection control permit before construction begins. <input type="checkbox"/> Isolate HVAC system in area where work is being done to prevent contamination of duct system. <input type="checkbox"/> Complete all critical barriers or implement control cube method before construction begins. <input type="checkbox"/> Maintain negative air pressure within work site utilizing HEPA equipped air filtration units. <input type="checkbox"/> Seal holes, pipes, conduits, and punctures appropriately. <input type="checkbox"/> Construct anteroom and require all personnel to pass through this room 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. 	<ul style="list-style-type: none"> <input type="checkbox"/> All personnel entering work site are required to wear shoe covers. <input type="checkbox"/> Do not remove barriers from work area until completed project is thoroughly cleaned by the Environmental Service Department. <input type="checkbox"/> Vacuum work area with HEPA filtered vacuums. <input type="checkbox"/> Wet mop with disinfectant. <input type="checkbox"/> Remove barrier materials carefully to minimize spreading of dirt and debris associated with construction. <input type="checkbox"/> Contain construction waste before transport in tightly covered containers. <input type="checkbox"/> Cover transport receptacles or carts. Tape covering. <input type="checkbox"/> Remove or isolate HVAC system in areas where is being done. <input type="checkbox"/> Other _____
Project Description:		Estimated Duration:
Inspections : <input type="checkbox"/> Daily <input type="checkbox"/> Weekly <input type="checkbox"/> Every other day <input type="checkbox"/> Twice per week <input type="checkbox"/> Other _____		
Permit Requested By: Date:		Permit Authorized By: Date:

1

Sub-standard –20: 01

Medical equipment are cleaned / disinfected properly as per hospital's policies and manufacturer recommendations (regularity, recommended products, methods ... etc..) (D, O, SI)

Review the following documents:**1 - Policies & procedures for cleaning & disinfection of medical equipment, which should be:**

- ❖ **Comprehensive:** it covers all aspects of cleaning & disinfection of medical equipment which should include (but not limited to):
 - Classification items based on associated risk (**Critical, Semi critical, and Non-critical items**)
 - Definitions of cleaning & disinfection
 - Frequency of cleaning & disinfection
 - Detailed procedure / methods of cleaning activities,
 - Disinfection is done locally (i.e., inside the department) or centrally (i.e., sent to CSSD)
 - Types of used disinfectants with dilutions & contact times based on manufacturer's instructions.
 - Roles & responsibilities of staff in the process of cleaning & disinfection ...etc..
- ❖ **Fully applicable:** all elements of the policy can be applied and comply with the hospital's scope of services (***Applies to all inpatient units including areas where all invasive and noninvasive procedures are carried out***).
- ❖ **Based on scientific references** approved by MOH (GCC, CDC, WHO & APIC)
- ❖ **Signed** from authorized personnel (i.e., owner of the policy / hospital director or medical director / concerned department)
- ❖ **Approved** by IC committee*
- ❖ **Valid** (updated within 2 - 3 years and when indicated)

2: Cleaning & disinfection activity logs / checklists:

- 1) Check the activity logs which should be detailed including all items/equipment intended to be cleaned according to relevant area/unit e.g. bedside monitors, ventilators, ECG machines etc..

3: Orientation attendance and competency assessment for each machines:

- 1) The unit should have the abovementioned document to indicate that staff have received orientation regarding cleaning & disinfection of particular machine to become competent (e.g., orientation about cleaning & disinfection of dialysis machines: suitable disinfectants, frequency of use, dilutions & contact times ... etc.)

- Policy for cleaning & disinfection of medical equipment can be a separate policy or as a part of major policy like patient care equipment.
 - According to Spaulding Classification system, medical devices are divided into categories based on the risk of infection related to their use.
- 1) Critical Items:**
 - This category includes objects and items entering the vascular system and sterile tissue.
 - **Examples of critical items are surgical and dental instruments, cardiac and blood catheters, implants and needles ...etc..**
 - These items present a high risk of infections and require sterilization after each patient use in CSSD.
 - 2) Semi-critical Items:**
 - This category includes objects and items that come in contact with intact mucous membranes and non-intact skin but do not penetrate body tissues or the vascular system.
 - **Examples of semi-critical items are non-invasive medical equipment, gastrointestinal endoscopes, invasive ultrasound probes, respiratory therapy or anesthesia equipment: laryngoscope blades ...etc..**
 - These items require high level disinfection after each patient use in CSSD or clinical area responsible for high level disinfection e.g. endoscopy unit
 - 3) Non-critical Items:**
 - This category includes items and objects that come in contact with intact skin only.
 - **Examples of non-critical items are stethoscopes, bedpans, blood pressure cuffs, tourniquet cuffs, and crutches. that touch intact skin**
 - These items could potentially contribute to secondary transmission of microorganisms to healthcare workers' hands; therefore, they require low level disinfection with hospital-approved disinfectant at the point of use.

Observation
(O)

Observe the process in all patient care areas (ER, ICUs, HDs, OR ... etc..)

- 1) Wipe surfaces of various medical equipment (e.g., bed side machines, monitors, ventilators ... etc..) to exclude the presence of dust, dirt or stains.
- 2) Check the availability of supplies e.g., agents & materials used for cleaning/disinfection activities: approved chemicals and disinfectants, wipes, spray bottles and/or buckets ... etc..
- 3) Check that available agents & materials used for cleaning/disinfection are matching MOH specifications
- 1) Observe any ongoing cleaning & disinfection activity and notice responsible person (should be a nurse), procedure of cleaning process, type(s) of used disinfectant(s), dilutions & contact times ... etc..

Staff Interview
(SI)

Ask the nurse (nurse in charge or nurse responsible for each unit) about:

- 1) Cleaning schedule for various medical equipment
- 2) Nurses role & responsibility in cleaning & disinfection activities (i.e., housekeeping staff are involved in cleaning & disinfection of medical equipment, which are supposed to be cleaned by nurses like bed side monitors, bedside rails, bed mattress etc.)
- 3) Methods of cleaning – agents & materials to be used (Ask staff to demonstrate cleaning by giving her specific task e.g., bedside monitor
- 4) Cleaning logs & checklists for cleaning & disinfection of medical equipment: should be practical, detailed, duly signed and fully applicable (i.e., check for appropriateness, because sometimes items are checked in spite of being not available in the relevant unit/room).
- 5) Cleaning & disinfection activities after patients with infectious transmissible diseases – handling of body fluids spills.

Further Reading / References:

- ❖ <https://www.cdc.gov/infectioncontrol/guidelines/disinfection/index.html>
- ❖ <http://ictraining.net/index.php/component/k2/gcc-manual>

1

Sub-standard –21: 01

Infection control team is involved in the evaluation and purchase of antiseptics and disinfectant supplies. (D – S)

Review the following documents (just review samples):

- 21) **Requests** from hospital leaders (e.g., hospital director, medical director, head of medical stores, head nurse, head of housekeeping staff ... etc..) which are directed to IC team for assessment and approval of antiseptics, disinfectants and other supplies used in different levels of disinfection. These documents confirm that IC team is involved in the purchasing process
- 22) **Requests** from hospital leaders (e.g., hospital director, medical director, head of medical stores, head of CSSD ... etc..) which are directed to IC team for assessment and approval of equipment and supplies used in sterilization (e.g. washer-disinfectors, ultrasonic cleaners, sterilizers and other CSSD equipment with relevant supplies). These documents confirm that IC team is involved in the purchasing process
- 23) **Approval forms:** special forms which are signed by IC practitioners to indicate that equipment, antiseptics, disinfectants and other supplies used for disinfection and/or sterilization pass through definite assessment and approval process before purchasing
- 24) **Purchasing orders** for antiseptics, disinfectants and other supplies used in different levels of disinfection to check if IC team is involved in the process or not
- 25) **Purchasing orders** for equipment and supplies used in sterilization (e.g. washer-disinfectors, ultrasonic cleaners, sterilizers and other CSSD equipment with relevant supplies) to check if IC team is involved in the process or not

Document
(D)

Comment (if any):

We suggest modification to add purchase of equipment and supplies used in sterilization:

“Infection control team is involved in the evaluation and purchase of equipment, antiseptics, disinfectants and other supplies used for disinfection and/or sterilization”

Ask:

- 1) **Head of the IC department:** about definite assessment and approval process before purchasing new equipment, antiseptics, disinfectants and other supplies used for disinfection and/or sterilization
- 2) **Head of the medical stores:** about the process of purchasing new equipment, antiseptics, disinfectants and other supplies used for disinfection and/or sterilization
- 3) **Other responsible staff:** (e.g., head nurse, head of CSSD, head of housekeeping staff ...etc..) about the process of requesting new equipment, antiseptics, disinfectants and other supplies used for disinfection and/or sterilization

Staff Interview
(SI)

2

Sub-standard –21: 02

Antiseptics, disinfectants and detergent/disinfectants are used in accordance with current scientific guidelines and recommended practices. (D – O – S)

Document
(D)

Review the following documents in IC department:

- 1) List of antiseptics, disinfectants and detergent/disinfectants' with related documents which are essential for safe and effective use (Material Safety Data Sheet (**MSDS**) – preparation or dilution – usage and contact time – precautions and required PPE) verify if compatible with current scientific guidelines and recommended practices.
- 2) Examples of antiseptic, disinfectant or detergent/disinfectant's approval by recognized professional organizations such as **Food and Drug Administration (FDA)** – **Environmental Protection Agency (EPA)**

Observation
(O)

Observe different department's especially clinical areas to ensure that:

- 1) The available antiseptics, disinfectants and detergent/disinfectants in different clinical areas are consistent with reviewed list.
- 2) The use of antiseptic, disinfectant and detergent/disinfectant in different clinical areas is according to instructions listed in Material Safety Data Sheet (**MSDS**) regarding preparation, dilution, usage, contact time and precautions with required PPE

Staff Interview
(SI)

Staff Interview:

- 3) Interview IPC practitioners to confirm that they are familiar with the guidelines for different antiseptics, disinfectants and detergent/disinfectants' use and aware about their **MSDS** instructions.
- 4) Interview staff involved in the use of antiseptics, disinfectants and detergent/disinfectants (e.g., housekeeping staff in different clinical areas, endoscopy unit, laundry, kitchen ... etc..) to check if they are familiar with their guidelines for use and aware about **MSDS** instructions.

1

Sub-standard –22: 01

According to current scientific guidelines and MOH regulations, no reuse for single use items. (D, O, SI)

Review the following documents:**1 - Policies & procedures for Single Use Device (SUD).**

- ❖ Policy should clearly define and state single use device:
 - Single Use Device: a medical device that is intended for single use only, on an individual patient for a single procedure, and then should be discarded. It should not be reprocessed or reused again even on the same patient.
 - These device are packaged and marked as “single use” or have the international sign for single use items:
- ❖ Policy should include (but not limited to):
 - Classification items based on associated risk
(Critical, Semi critical, and Non-critical items)
 - A device labelled as ‘Single Use Device – SUD’ **MUST NOT** be reused.
 - SUD should only be used on an individual patient during a single procedure and then discarded.
 - Single-use device should not be reprocessed or used again, even on the same patient.
 - Disposable single-use devices that have been opened and not used; should not be reprocessed (i.e., re-sterilized).
 - SUDs must be discarded by the end user at the point of use as per hospital protocols.
- ❖ **Fully applicable:** the policy can be applied and comply with the hospital’s scope of services.
- ❖ **Policy is based on scientific references** approved by MOH
Check MEMO from GDIPC - MOH regarding regulations for SUD stating (no reuse of Single Use Device - SUD).
- ❖ Signed from authorized personnel and approved by IC committee*
- ❖ **Valid** (updated within 2 - 3 years and when indicated)



Document
(D)

2 - Review OVR (Occurrence Variance Reports) to check if single use items were sent to CSSD for reprocessing.**Comments:**

- Policy for single use items can be a separate policy or as a part of major policy like reprocessing of instruments.

Note:

- The re-use of Single Use Device has legal implications. Anyone who reprocesses or re-uses device intended for use on one occasion by the manufacturer, bears full responsibility for its safety and effectiveness.

Observation
(O)

Observe the use of single use devices by the staff in different patient care areas to notice any breach in practice, Examples:

- 1) You may find used gowns hanging at the backside of doors in units (Lab, dental unit etc.)
- 2) You may also find single use tourniquets used for multiple patients in phlebotomy room.
- 3) Reuse of face shields is also a common practice.

Staff Interview
(SI)

Staff interview to ensure effective implementation of single use policy:

- 1) Randomly ask clinical staff about the protocols of handling Single Use Devices.

Comments:

Instead of direct questions, indirect ones or scenarios are advisable:

- How will you disinfect this single use item to be reused safely???
- Can you demonstrate the procedure(s) that should be applied on this device before re-use???

Examples: airway circuits, suction catheters, Intravenous sets, needles & syringes, PPE (gowns, face shields) ... etc.,

- The answer should be we never reuse single use device, because it can be used only once

RATIONALE:

- Using disposable items improves patient safety by eliminating the risk of patient-to-patient contamination because the item is discarded and not used on another patient. (CDC)
- The institutional facilities should not reprocess used SUDs for reuse because it is not safe.
- Reprocessing a SUD may affect the function of the device and/or material from which the device is made.
- Single-use devices may not be designed for thorough decontamination and re-sterilization processes after the first use.
- Unforeseen problems such as inadequate decontamination, material alteration, mechanical failure, and residual chemical agents can render the reprocessed item unsafe. In addition, validation of the SUD's functionality after reprocessing cannot be guaranteed.

1

Sub-standard – 23:01

There are a written policies and procedures for surveillance of health care associated in fections, using updated CDC-NHSN definitions. (e.g., VAP/VAE, CLABSI, CAUTI, SSI and MDROs according to the hospital's scope of services). (D)

Document
(D)

- ❖ *Surveillance is an essential component of an effective infection prevention and control (IPC) program. Surveillance is a systematic method of ongoing collecting, consolidating, and analyzing data concerning the distribution and determinates of a given disease or event, followed by the dissemination of that information to those who can improve the outcome.*
- ❖ *Surveillance is a critically important component of any MDRO control program, allowing detection of newly emerging pathogens, monitoring epidemiologic trends, and measuring the effectiveness of interventions. Multiple MDRO surveillance strategies have been employed, ranging from surveillance of clinical microbiology laboratory results obtained as part of routine clinical care, to use of active surveillance cultures (ASC) to detect asymptomatic colonization.*

Health Care Associated Infections (HAIs) are defined as a localized or systemic condition resulting from an adverse reaction to the presence of an infectious agent(s) or its toxin(s).

- *There must be no evidence that the infection was present or incubating at the time of admission to the care setting. ·*
- *Clinical evidence may be derived from direct observation of the infection site or review of information in the patient chart or other clinical records. ·*
- *An infection is considered HAI if the date of event of the NHSN site-specific infection criterion occurs on or after the 3rd calendar day of admission to an inpatient location where day of admission is calendar day 1*

Surveillance can be used for the following purposes:

- *To measure the incidence of healthcare associated infections (HAI) and organisms*
- *To establish an endemic rates of HAI*
- *To detect, investigate and control hospital clusters or outbreaks of HAI*
- *To monitor, evaluate, and implement the necessary preventive measures*
- *To work on reducing HAI using standard bundles*
- *To monitor antimicrobial susceptibilities etc.*

- *Policies & procedures for HAI surveillance could be a separate policy for each type of device associated HAIs or it could be a combined policy for all 03 device associated HAIs (CLABSI, CAUTI, & VAE/ VAP)*
- *Preferably a separate policy for procedure associated HAI (SSI)*
- *Preferably a Separate policy for Surveillance of MDROs.*

Review the policies & procedures for HAI Surveillance which should be:

1) **Comprehensive:** It covers all aspects of HAI Surveillance which define the types of surveillance to be carried out with regard to healthcare-associated infections. Policy should include but not limited to:

❖ **Written standardized definitions /Criteria:** for identification of each type of HAIs (device associated HAIs (*VAE/VAP, CLABSI, CAUTI*), procedure associated HAIs (*SSIs*) & *MDROs*).

❖ **Related Criteria of HAI Definition should be mentioned:** ²

- 1) *Infection Window Period for HAI*
- 2) *Date of HAI event*
- 3) *Present on admission (POA)*
- 4) *Repeat Infection Timeframe (RIT)*
- 5) *Secondary BSI Attribution Period*
- 6) *Device removal and reinsertion*
- 7) *Transfer Rule*
- 8) *Multiple Transfer*

➤ **Infection Window Period for HAI:**

It is the 7-days during which all site-specific infection criteria must be met. o It includes the day the first positive diagnostic test that is an element of the site-specific infection criterion, was obtained, the 3 calendar days before and the 3 calendar days after.

➤ **Date of HAI event:**

It is the date the first element used to meet an NHSN site-specific infection criterion occurs for the first time within the seven-day infection window period

➤ **Present on admission (POA):**

An infection is considered POA if the date of event of the NHSN site-specific infection criterion occur o Two calendar days before day of admission o First day of admission (day 1) o Day after admission (day 2)

➤ **Repeat Infection Timeframe (RIT):**

It is a 14-day timeframe during which no new infections of the same type are reported.

➤ **Secondary BSI Attribution Period:**

It is the period in which a positive blood culture must be collected to be considered as a secondary bloodstream infection to a primary site infection o This period includes the Infection Window Period combined with RIT

1: For device associated HAI surveillance:

- ❖ Policies and procedures should define the detailed methodology of how the numerator & denominator data will be collected.

Numerator: (*Number of events of VAP / VAE, CAUTI, CLABSI etc.*)

Denominator: (*Patient days, device days etc..*)

- ❖ How data will be analyzed, interpreted & presented. (VAP rate, CLABSI rate, Device utilization ratios etc..). Usually displayed as graphs / trends in comparison with CDC /NHSN benchmark*.
- ❖ How data will be disseminated to all stakeholders. (Feedback to all units about HAI trends) for further action. (email or written document etc.)

NOTE: Hospitals reporting through HESN system should clearly describe all steps related to HESN system (Data entry & creating encounters, frequency of bundle review, encounter UDFs to be filled in case of device and non-device associated events etc..).

2: For Procedure associated HAI surveillance:

- ❖ Policies and procedures for SSI Surveillance should define methodology of SSI surveillance using CDC definitions.
 - **Superficial incisional SSI**
 - **Deep incisional SSI**
 - **organ /space SSIs**
- ❖ Policy should describe the steps of data collection for specific surgical procedure (**Patient information, procedure information, wound class, ASA score etc..**).
- ❖ Criteria for selection of surgical procedures.
- ❖ Post discharge surveillance protocols and frequency of follow up (**30/90 days**)
- ❖ How data will be analyzed, interpreted & presented. (VAP rate, CLABSI rate, Device utilization ratios etc..). Usually displayed as graphs / trends in comparison with CDC /NHSN benchmark*.
- ❖ How data will be disseminated to all stakeholders. (Feedback to all units about HAI trends) for further action. (email or written document etc.)

NOTE: (Hospitals reporting through HESN should describe all steps for SSI surveillance based on HESN - SSI flowchart including encounters, SSI bundle review, encounters for SSI event & post discharge follow up methodology)

2: MDROs Surveillance:

MDROs are defined as microorganisms, predominantly bacteria, that are resistant to one or more classes of antimicrobial agents. Although the names of certain MDROs describe resistance to only one agent (e.g_MRSA, VRE), these pathogens are frequently resistant to most available antimicrobial agents.

- ❖ **MDRO surveillance policy** must clearly state the methodology of MDRO surveillance. ⁽²⁾
- ❖ MDRO policy should have clear & specific definitions of **Gram positive MDROs** (include **MRSA and VRE etc.**) & **Gram negative MDROs. (CephR-Klebsiella Carbapenem resistant Enterobacteriaceae) (CRE): MDR Acinetobacter, MDR Klebsiella or Pseudomonas, ESBLs etc.**

Methicillin-resistant Staphylococcus aureus (MRSA):

Includes S. aureus cultured from any specimen that tests oxacillin-resistant, ceftazidime-resistant, or methicillin-resistant by standard susceptibility testing methods

Vancomycin-resistant Enterococci (VRE):

Enterococcus faecalis, Enterococcus faecium, or Enterococcus species unspecified that is resistant to Vancomycin, by standard susceptibility testing methods

Cephalosporin-resistant Klebsiella:

Klebsiella oxytoca or Klebsiella pneumoniae testing non-susceptible (i.e., resistant or intermediate) to ceftazidime, cefotaxime, ceftriaxone, or cefepime

Carbapenem-resistant Enterobacteriaceae (CRE):

Any Escherichia coli, Klebsiella oxytoca, Klebsiella pneumoniae, or Enterobacter spp. testing resistant to imipenem, meropenem, doripenem, or ertapenem by standard susceptibility testing methods OR by production of a carbapenemase demonstrated using a recognized test (e.g., PCR or modified-Hodge test)

MDR-Acinetobacter:

Any Acinetobacter spp. testing non-susceptible (i.e., resistant or intermediate) to at least one agent in at least 3 antimicrobial classes of the following 6 antimicrobial class

MDR Pseudomonas or MDR Klebsiella:

Non-susceptible (resistant or intermediate) to at least one agent in at least 3 out of 5 antimicrobial classes

MDRO Isolate:

Any specimen, obtained for clinical decision making, testing positive for an MDRO (excludes tests related to active surveillance testing)

Duplicate MDRO Isolate:

If monitoring all specimens, any MDRO isolate from the same patient and location after an initial isolation of the specific MDRO during a calendar month, regardless of specimen source, except unique blood source.

Unique Blood Source: For this organism and location, an MDRO isolate from blood in a patient with no prior positive blood culture for the same MDRO and location in ≤ 2 weeks, even across calendar months and different facility admissions & There should be 14 days with no positive blood culture result from the laboratory for the patient, MDRO, and location before another Blood LabID Event is considered with the date of specimen collection is considered Day 1

b) Methodology of MDRO Surveillance:

- Policy should describe which **MDROs are being monitored for purpose of surveillance.**
- (Facilities may choose to monitor one or more of the following MDROs: **MRSA, VRE, Ceph R- Klebsiella, CRE, and/or multidrug-resistant Acinetobacter spp.**
- Specify Type of locations for MDRO surveillance: **Facility wide or Selected locations within the facility (1 or more)**

- Data collection protocols for MDRO surveillance (*patient information, MDRO types, Specimen sites (Blood, rectal, stool, urine, axilla etc., MDRO presentation (colonization Vs. Clinical infection etc. & source: Hospital acquired Vs. Community acquired)*)
(*Standardized forms to be used for data collection (GCC/CDC)*)
- *MDROs surveillance policy should specify that MDROs will be monitored for all Specimen types or for Blood Specimens Only. (e.g. MRSA Bacteremia)*

Other domains of Policies & procedures:

P/P for Hand Hygiene should be:

- **Fully applicable:** all elements of the policy can be applied and comply with the hospital's scope of services
- **Based on scientific references** approved by MOH (*GCC, CDC*)
- **Signed** from authorized personnel (i.e., owner of the policy / hospital director or Medical Director / concerned department)
- **Approved** by IC committee
- **Valid** (updated within 2 - 3 years and when indicated).

NOTE:

- ❖ *Small hospitals who do not have capacity to provide intensive care service to the patient or the patient will not stay more than 1 day & patients will be referred to the nearby tertiary care hospital must have clear policy and procedures for HAI Surveillance matching with scope of service.*
- ❖ *Policies and procedures for HAI surveillance must be tailored according to hospital situation and scope of service.*

2

Sub-standard – 23:02

There are a written policies and procedures for surveillance of dialysis event, using CDC-NHSN definitions which are approved by MOH.. *(Applicable to MOH Hospitals which have outpatients hemodialysis centers, if only inpatients this surveillance module not applicable).*(D)

Review the policies & procedures for dialysis event Surveillance that should be:

Comprehensive: It covers all aspects of dialysis event Surveillance, which define the setting, targeted populations, and case definitions using CDC-NHSN case definitions, data collections methods, data analysis and reporting instructions.

Setting:

Surveillance occurs in outpatient's hemodialysis centers, if inpatients or peritoneal dialysis patient's presents exclude from the DE surveillance.

Populations:

Hemodialysis outpatients which include:

- transient patients.
- peritoneal dialysis patients or transplant patients undergoing temporary hemodialysis.
- outpatients with acute kidney injury.

Data collections:

- ❖ Policies and procedures should define the detailed methodology of how the numerator & denominator data will be collected.

Numerator: *(Number of dialysis events)*

Denominator: *(patients months)*

Hemodialysis outpatients with each vascular access type for the first 2 working days each month are used on the denominators for dialysis event surveillance.

- If the patients have multiple vascular access, only the vascular access with highest risk of infections is reported.

Event definitions:

Three types of dialysis events are reported: IV antimicrobial start, positive blood culture and pus, redness, or increased swelling at the vascular access site.

- 21 day rule : 21 or more days must exist between two dialysis events of the same type for the second occurrence to be reported as a separate dialysis event.

Data analysis and reporting instructions:

- ❖ How data will be analyzed, interpreted & presented. (DE rate) in comparison with CDC /NHSN benchmark*.
- ❖ How data will be disseminated to all stakeholders.

NOTE: *Hospitals reporting through HESN system should clearly describe all steps related to HESN system (Data entry & creating encounters, frequency of bundle review, encounter*

UDFs to be filled in case of dialysis events).

Other domains of Policies & procedures:

P/P for DE should be:

- **Fully applicable**: all elements of the policy can be applied and comply with the hospital's scope of services
- **Based on scientific references** approved by MOH (***GCC, CDC***)
- **Signed** from authorized personnel (i.e., owner of the policy / hospital director or Medical Director / concerned department)
- **Approved** by IC committee
- **Valid** (updated within 2 - 3 years and when indicated).

3

Sub-standard – 23:03

Adequate number of computers and a reliable internet service is available for electronic surveillance to be carried out continuously without any interruption. (*Applicable to MOH Hospitals registered in HESN for Surveillance only.*) (O)

Observe:

- ❖ The number of computers provided for the IC department and match with the number of Infection control preventionists working in the unit.
- ❖ Ideally each ICP has a separate computer with internet connection. But if separate computer not provided for each ICP, would be considered fully compliant if it's not interfering with continuity of work.

Observation
(D)

Interview:

- ❖ The staff about the access and reliability of internet service and backup plan to ensure the continuity of work if there is no availability of internet service.
- ❖ Randomly ask staff to access HESN Website & dashboards to assess the quality of provided internet service.
- ❖ Ask staff about IT support & troubleshooting time.

Staff Interview
(SI)

4

Sub-standard – 23:04

IC practitioners are well trained regarding electronic IC-HESN surveillance system and familiar with latest CDC-NHSN definitions.
(Applicable to MOH Hospitals registered in HESN for Surveillance only.) (D,SI)

Document
(D)

Review the following:

- 1) CDC – NHSN definitions & surveillance protocols according to HESN.
- 2) Surveillance data collection sheets, CDC / HESN manual paper forms.
- 3) Monthly surveillance report with charts from HESN system.
- 4) Additional documents could be screenshots of reports from HESN system for different domains to assess their competency of working with HESN.

Comments:

Note: This substandard is applicable only for hospitals HAI surveillance data using HESN system.

Staff Interview
(SI)

Interview IPC team;

- ❖ To confirm in-depth understanding of identification of HAI events based on CDC Criteria.
- ❖ Ask for methodology of client registration in HESN system and creating different type of encounters e.g. *(Encounter for Central line insertions, Encounter for CLABSI event, Encounter for end of surveillance etc..)* and how to fill the electronic forms.
(ICPs should register all patients admitted in critical care units as clients)
- ❖ Interview IPC team to assess knowledge on how data is collected, entered, analyzed using HESN system.
- ❖ Ask how to make corrections in HESN system *(HESN data quality dashboards display errors with client ID, Form ID and type of error like duplicate dates, no bundle review, missing hospital admission or unit admission dates etc..).*

Comments:

(All auditors must receive brief orientation regarding HESN Surveillance system from regional surveillance coordinators before going for audit)

Sub-standard – 23:05**Surveillance of health Care associated Infections (HAIs)**

is carried out in all critical care units (active, prospective, targeted and patient based surveillance). *(Applicable to MOH Hospitals registered in HESN for Surveillance only.) (D,SI)*

Review the surveillance methodology for each type (Device, non-device & procedure associated HAI) and surveillance data collection sheets to make sure its implemented in all critical care units (ICU, CCU, NICU, PICU, Burn Units etc.. based on availability of critical care units in each hospital.

Assess the surveillance protocols which should be:

1: Active Vs Passive:**a: Active surveillance:**

- ❖ Infection Preventionists (ICPs) vigorously look for HAIs by applying the CDC criteria during a patient's stay.
- ❖ Information accumulated by using a variety of data sources within and beyond the nursing ward such as laboratory, admission/discharge/transfer, radiology/imaging, as well as patient charts, nurses /physicians notes, temperature charts, etc..

b: Passive surveillance:

- ❖ Persons who do not have a primary surveillance role, such as ward nurses or respiratory therapists, identify and report HAI

2: Patient Based Vs Laboratory Based:**Patient-based:**

- ❖ Count HAI, assess risk factors, and monitor patient care procedures and practices for adherence to infection control principles.
- ❖ Requires ward rounds and discussion with caregivers.

Laboratory-based:

Detection is based solely on the findings of laboratory studies of clinical specimens.

3: Targeted Vs. Comprehensive:

Targeted / Priority-directed:

1: Focus is on specific events, processes, organisms, and/or patient populations.

2: Targeted Units (Critical Care Units only) (ICU, CCU, NICU, PICU, Burn Units etc..)

3: Targeted devices associated HAIs (Ventilator, Central Line, Urinary catheter associated)

4: Targeted Non device associated events (Pneumonia, BSIs, UTIs etc.)

5: Targeted procedures for SSI (High risk – high volume) Select Procedures which are done more frequently and associated with increased infection risk.

Comprehensive

- ❖ Continuous monitoring of all patients for all events and/or processes
- ❖ Highly personnel resource intensive if done manually

4: Prospective Vs Retrospective:

Prospective surveillance:

- ❖ Monitor patients during their hospitalization: Prospective surveillance of events (CLABSI, CAUTI, VAP, SSI etc.. and their corresponding denominator data (Patient days, Device days, number of selected surgical procedures etc.) by a trained Infection Preventionist (IP).
- ❖ For SSIs, also monitor during the post-discharge period. (30 / 90 Days depending on surveillance period and the type of surgery accordingly) ** (Refer to attached reference)
- ❖ Process of Post discharge surveillance follow up for SSI:
 1. Post discharge follow up form to be available in Surgical OPDs & Wards, ER etc. for patients coming for follow up after surgery.
 2. Follow up via Phone call etc..

Retrospective surveillance:

1: Identify infections via chart reviews after patient discharge or death. Also required during outbreaks.

Interview IPC team:

- ❖ To confirm in-depth understanding of surveillance methodology to be carried out with regard to HAIs based on above mentioned description.
- ❖ Ask staff at random what is meant by active, patient based, prospective & targeted surveillance.
- ❖ Ask indirect questions to confirm like how frequently ICPs are collecting surveillance data? How frequently are they going for rounds in ICU, NICU, PICU etc..

Sub-standard – 23:06

SSI surveillance is applied according to GDIPC guidelines (i.e. selecting only 1 - 3 types of high risk procedures or most common surgeries for at least 6 months).

(Applicable to MOH Hospitals registered in HESN for Surveillance only.) (D,SI)

Review the following:

- ❖ SSI Surveillance policies & Procedures including post discharge surveillance protocols
- ❖ SSI Surveillance data collection sheet
- ❖ Charts & graphs to assess SSI Surveillance statistics for targeted high risk, high volume surgical procedures.
- ❖ SSI surveillance report for past 6 months to confirm if the same surgeries were followed.
- ❖ Review the document for total number of surgical procedures done in last few months to confirm if it's a high volume procedure. **(Selected Surgical Procedures) (HESN + Non HESN hospitals)**
- ❖ Review the list of surgeries with number performed in last year to assess the logical selection for SSI Surveillance. **(High risk & high volume)** etc.

Document
(D)

Interview IPC team to confirm the following:

- ❖ Type & number of surgical procedures followed with duration of each.
- ❖ Ask about most common surgeries done in the hospital to match their selection.
- ❖ In-depth understanding of SSI Surveillance protocols.

Interview the staff in Surgical wards, Obs /Gynae unit etc.:

- ❖ To countercheck for implementation of *SSI process Surveillance. (SSI Bundle etc.)*
- ❖ Interview nursing staff in ER & Surgical OPDs to check for implementation of post discharge surveillance follow up & reporting to ICPS.

Staff Interview
(SI)

Sub-standard – 23:07

Surveillance data [targeted patients, numerators, denominators and device utilization ratio and patient under surveillance (PUS) compared with the number of beds in a critical care unit] are validated by IC practitioners at least once monthly. *(Applicable to MOH Hospitals registered in HESN for Surveillance only.)* (D,SI)

- ❖ *Validation is the process to ensure that the data collected is accurate. Data collected by ICPs should match the actual number of patient admissions, patient days, device days & total number of correctly identified events using the CDC – NHSN – HESN data collection forms.*
- ❖ *ICPs should ensure monthly validation of data by comparing with census of critical care units & bed management department (if needed)*

Review:

- ❖ Surveillance collection data sheets containing data of [targeted patients](#) in critical care units (ICU, NICU, PICU & Burn Units etc.. Total admissions in critical care units and total patient days in a month.
- *Patient days is the number of days admitted patients are utilizing the services of hospital.*
- *For e.g. if 5 patients stayed in adult ICU for 6 days it will be counted as 30 patient days.*
- ❖ Review Numerator_data collection sheets for Identification of VAP, CLABSI, CAUTI & SSI events). Review the line lists and lab results to check accuracy of numerator data.

(Numerator is the upper portion of a fraction used to calculate a rate or ratio. In surveillance, it is usually the number of cases of a disease or event being studied, number of CLABSI, number of VAPs etc..)

- ❖ Review **Denominator** data: Patient days, Device days like *Ventilator days, Central line days, Urinary Catheter days & Total number of selected surgical* procedures as denominator for SSI rates.

(Denominator is the lower portion of a fraction used to calculate a rate or ratio. Denominator data may be collected by someone other than the ICP as long as that person is trained)

$$\text{CLABSI Rate} = \frac{\text{Number of CLABSI (Numerator)}}{\text{Central Line days (Denominator)}} \times 1000$$

$$\text{SSI Rate} = \frac{\text{Number of SSI (Numerator)}}{\text{Total number of specific operative procedures (Denominator)}} \times 100$$

- ❖ **Device Utilization Ratio** data validation from staff of critical care units. Device utilization ratio is calculated by dividing the device days by patient days.

$$\text{Device Utilization Ratio (DUR)} = \frac{\text{Device Days (Numerator)}}{\text{Patient Days (Denominator)}}$$

- ❖ **Patient Under Surveillance** in a day should be compared with the number of beds in a critical care unit. It should not exceed the number of beds. (+5% is acceptable in case of improvised beds are there)

MDRO-Infection Surveillance:

MDRO infection incidence rate is calculated by dividing the number of infections of a certain MDRO type by the number of patient days and multiplying the results by 1000.

Example:

$$\text{MRSA Rate:} = \frac{\text{Number of infections with MRSA (Numerator)}}{\text{Patient Days (Denominator)}} \times 1000$$

The total "patient days" represents the sum of the number of days during which services were provided to all inpatients during the given time period.

- ❖ For hospitals reporting HAI Surveillance data through HESN electronic system, additional validation of manual data with HESN data is to be reviewed. Ask for last validation report sent to regional directorate)

(All auditors must receive brief orientation regarding HAI Surveillance Validation Process from regional surveillance coordinators before going for audit) Manual Vs HESN data

Interview

Infection Control Practitioners about process of data validation:

- ❖ Ask how the data regarding targeted patients in critical care units is validated. For HESN surveillance system, each patient admitted in critical care unit has to be entered in HESN system.
- ❖ Ask about process of validation of numerator data. Correct identification of **VAP, CLABSI, CAUTI & SSI events (Numerators) by apply CDC-NHSN case definitions.**
- ❖ Ask how denominator data is validated. Wrongly collected denominator data would affect the HAI Rates and device utilization Ratios.
- ❖ Ask about the validation process for HESN Surveillance. ICP should respond about importance of data validation for accurate implementation of surveillance system.

∞

Sub-standard – 23:08

Surveillance data are regularly collected & reported to IC regional directorate and GD IPC-MOH through IC-HESN electronic surveillance system. *(Applicable to MOH Hospitals registered in HESN for Surveillance only.) (D,SI)*

This substandard is applicable only for HESN based hospitals for surveillance data reporting.

Review the following:

- 1) Manual data collection forms for both numerator & denominator data.
- 2) Ask about record of total patient admissions in each critical care units.

Document
(D)

Staff Interview
(SI)

Interview IPC team to verify the following:

- 1) Number of critical care unit's admissions and confirm whether entered in HESN system as CLIENTS.
- 2) Randomly ask ICP to access the HESN dashboards and get count of **Patients under Surveillance** for that particular audit visit date and compare with manual data.
- 3) Ask indirect question as: *If the patient is not on any device in the ICU, will you register this patient in HESN????*
Answer should be yes because ICPs have to register all patients admitted in critical care units with or without devices) as clients in HESN.

Sub-standard – 23:09

Results of surveillance are regularly analyzed, interpreted and communicated to staff and concerned departments. (D,SI)

Review the following:

- 1) Review the monthly / Quarterly Surveillance statistics.
- 2) Review trended data over time for the rate of HAI over the months and compared to the **benchmark***** and check whether trend is increasing or decreasing. (*Projected trends of VAP, CLABSI, CAUTI, SSI and MDROs*)
- 3) Check for last HAI report shared with concerned units (ICU, Surgical unit & high rank administration etc..) (*Copy of manual or sent email*)
- 4) Check the reports in concerned areas i.e. **ICU, Burn Unit, NICU, etc..**

- ❖ *****Benchmarking is the process of “comparing oneself to others performing similar activities, so as to continuously improve.**
- ❖ ***National Healthcare Safety Network (NHSN) in US acute care hospitals is the oldest and most widely used of benchmarking.***
- ❖ ***A written report should be developed to provide a mechanism to interpret and disseminate surveillance data to stimulate performance improvement activities. Tables, graphs, and charts are effective tools for organizing, summarizing, and visually displaying data and should be used as applicable.***
- ❖ ***Title should be clear and specific for each category of HAIs (e.g., surgical site infections in patients undergoing coronary artery bypass graft in hospital A form January through December 2019)***

Document
(D)

Interview the following:

- 1) Head and staff nurses if surveillance data was being communicated to them. Ask them to show trends posted on bulletin boards.
- 2) Ask medical staff in critical care units at random as example for VAP rate of their unit in any Quarter 2019 etc..
- 3) Ask Surgeons and OR staff for SSI trends for last quarter etc..
- 4) Ask ICPs about the mechanism of data communication / reporting to concerned units (electronic, manual etc.) and frequency of reporting.

High infection rates should be notified immediately to the relevant unit without waiting for discussions in IC Committee meeting or quarter to over in order to take necessary actions to decrease the infection rates immediately.

Staff Interview
(SI)

10

Sub-standard – 23:10

Results of surveillance are regularly reviewed by the IC committee, and an action plan is developed based on evidence based intervention and followed up accordingly (at least once quarterly). (D, SI)

Document
(D)

Review the following:

- ❖ IC committee meeting minutes for the past months to confirm discussion of HAI surveillance trends.
- ❖ Results of HAI trends to be disseminated monthly as well.
- ❖ Review the action plan for corrective actions based on the results of surveillance. All interventions should be evidence based. **(If applicable)**
- ❖ Review updated status of action plan after needed interventions and follow up. **(If applicable)**

Staff Interview
(SI)

Interview IPC team & members of IC committee to confirm the following:

- ❖ Ask about the mode of discussion and review of HAI surveillance statistics.
- ❖ Ask about recent interventions done for significantly high rates. Ask to give example for past 1 year and mention what interventions were done & how the follow up was done.

Example 1: Increased CAUTI rate in Quarter II – 2019

Causes of high CAUTI rate:

- ❖ *Poor aseptic technique upon insertion,*
- ❖ *Lack of implementation of Urinary Catheter Bundle*
- ❖ *Prolonged use of catheter without indication*
- ❖ *Collection bag not kept below the level of the bladder at all times*
- ❖ *Lack of sterile technique & continuously closed drainage system etc.*

Interventions:

- ❖ *Strict implementation of Urinary Catheter Bundle,*
- ❖ *Daily review of necessity & prompt removal.,*
- ❖ *Strict adherence to aseptic technique upon insertion.*
- ❖ *Appropriate hand hygiene practice.*
- ❖ *Maximal Barrier Precautions (Gloves, Drape, Sponges)*
- ❖ *Sterile or antiseptic solution for cleaning the urethral meatus*
- ❖ *Single-use packet of sterile lubricant jelly for insertion etc..*

Example 2: Increased SSI rate in Quarter I & II – 2019

If SSI rate is on higher side for the last few quarters, IC team members should develop a corrective action plan to find out the causes of increased SSI rate over past few months.

Causes could be: decreased compliance to SSI bundle, non-availability of prophylactic antibiotic, use of razors instead of hair clippers etc., poor aseptic technique during the procedure etc.

Interventions would include increased adherence to SSI bundle elements, strict implementation of aseptic technique in OR, continuous education & training activities etc..

11

Sub-standard – 23:11

Results of surveillance are used to reduce HAIs through well designed quality improvement projects. (D, SI)

Review the following:

- ❖ Review performance Improvement project related to Surveillance based on results of HAI statistics.
- ❖ Check if the department has selected these specific indicators after reviewing results of surveillance and consideration of their attributable morbidity, cost, preventability and transmission risks. They reflect the current priority areas according to infection control program and policy development.

Example: If surveillance trends show the projected rate for specific HAI e.g. Increased CLABSI rate in NICU. IC department should design a CLABSI improvement project for NICU.

A Performance Improvement Project (PIP) is a quality tool with concentrated effort on a particular problem in one or more areas of the facility. It involves gathering information systematically to clarify issues or problems, and intervening for improvements.

The Steps Defined by FOCUS PDCA. The FOCUS PDCA acronym describes the basic components of the improvement process.

F - FIND A PROCESS / OPPORTUNITY FOR IMPROVEMENT

O - ORGANIZE A TEAM

C - CLARIFY THE CURRENT UNDERSTANDING OF THE PROCESS

U - UNDERSTAND VARIATION IN THE PROCESS

S - SELECT A STRATEGY FOR IMPROVEMENT

P - PLAN

D - DO

C - CHECK


A - ACT

Interview IPC team to confirm the following:

- ❖ Ask IPC team how they have selected a specific project to assess knowledge that hospital uses risk, rate, and trend information to design or modify processes to reduce healthcare-associated infections to the lowest possible level.
- ❖ Interview head and charge nurses, medical staff in critical care units regarding any ongoing Performance Improvement Project (PIP).
- ❖ Interview head of the department and charge nurses, medical staff in critical care units, IPC team to confirm that the hospital makes the necessary improvements for the identified epidemiologically important infections, processes, and devices

Document
(D)

Staff Interview
(SI)



that are associated with risk of healthcare-associated infections specific to the selected Performance Improvement Project (PIP).

For example, if there is ongoing SSI improvement project, we can interview relevant staff involved in the project during visit like surgical ward, OR staff, etc.

What specific interventions have been communicated to you as part of SSI performance improvement project? *(To verify if they are oriented about the project or not.)*

REFERENCES / WEB BASED RESOURCES:

1. **National Healthcare Safety Network (NHSN) Patient Safety Component Manual to be accessed at URL https://www.cdc.gov/nhsn/pdfs/pscmanual/pscmanual_current.pdf**
2. Health Care Associated Infections Surveillance Manual **GCC (Gulf Corporation Council) 2018 (3rd Edition)**
3. Healthcare-associated Infections <https://www.cdc.gov/hai/index.html>
4. **Multidrug-Resistant Organism & Clostridium difficile Infection (MDRO/CDI) Module; National Healthcare Safety Network (NHSN) Patient Safety Component Manual - 2019 Chapter 12**
5. <https://www.cdc.gov/infectioncontrol/guidelines/MDRO/index.html>
HESN – HAI Surveillance Manual (GDIPC) <https://hesn.moh.gov.sa/webportal/infection-control>

1

Sub-standard – 24:01

There are written policies and procedures concerning patient's care bundles for prevention of CLABSI, CAUTI, VAP/VAE, SSI and MDROs. **(D)**

- *Patients' care bundles are the series of evidence based practices / interventions related to devices or process of care that, when implemented together, will achieve significantly better outcomes than when implemented individually.*
- *Bundle is an implementation tool aiming to improve the care process and patient outcomes in a structured manner. It comprises a small, straightforward set of evidence-based practices (generally 3 to 5) that have been proven to improve patient outcomes when performed collectively and reliably.*

Review:

Policies & Procedures for prevention of **CLABSI, CAUTI, VAP, SSI & MDROs** incorporating **care bundles** which should be with clear **Title** & **comprehensive** as follows:

❖ **Title :**

- **Prevention of Central Line Associated Blood Stream Infections / Central Line Care Bundles**
- **Prevention of Ventilator Associated Pneumonia - VAE / Ventilator Care Bundles**
- **Prevention of Catheter Associated Urinary tract Infection / Urinary Catheter Care Bundles**
- **Prevention of Surgical Site Infections / Surgical Care Bundles**
- **Prevention of Multidrug resistant Organisms (MDROs) / MDROs Prevention Bundle**

❖ **Purpose: (Clearly stated purpose of each)**

E.g. Strict adherence to infection control measures during insertion & maintenance phase of CVCs in order to prevent device - related blood stream infection.

❖ **Procedure:**

- Policies should clearly describe procedures with rationale of each bundle element.
- P/P should clearly describe applicability of all care bundles according to location (critical care unit (ICU, NICU, PICU), surgical wards, Medical Wards etc.
- The policies and procedures should define how data on care bundles will be collected, analyzed, interpreted, and disseminated with necessary correction actions when needed. **(Find details under specific substandard etc.)**

- P/P should define **Roles and responsibilities** of concerned unit in implementation of health care bundles.
 - Daily review is the responsibility of assigned staff of critical care units for all devices.
 - Role of Infection control Practitioners is to ensure implementation of all elements of care bundles in daily rounds.
 - SSI bundle implementation is the **shared responsibility** of surgical / maternity wards team, OR team & infection control Team to follow for implementation. etc.
 - For **MOH** hospitals reporting via **HESN, policies should be tailored accordingly.**

Other domains of Policies & procedures:

P/P for Care Bundles should be :

- ❖ **Fully applicable:** all elements of the policy can be applied and comply with the hospital's scope of services
- ❖ **Based on scientific references** (IHI and GCC & CDC Surveillance guidelines).
- ❖ **Signed** from authorized personnel (i.e., owner of the policy / hospital director or Medical director / concerned department)
- ❖ **Approved** by IC committee
- ❖ **Valid** (updated within 2 - 3 years and when indicated).

Comment (if any):

*Approval by IC committee is required for the infection control manual as a whole before distribution and also for individual policy after major changes.

Sub-standard – 24:02

There are written policies and procedures concerning patient's care bundles for prevention of DE(catheter, fistula and graft care bundle) (D)

- *Patients' care bundles are the series of evidence based practices / interventions related to devices or process of care that, when implemented together, will achieve significantly better outcomes than when implemented individually.*
- *Bundle is an implementation tool aiming to improve the care process and patient outcomes in a structured manner. It comprises a small, straightforward set of evidence-based practices (generally 3 to 5) that have been proven to improve patient outcomes when performed collectively and reliably.*

Review:

Policies & Procedures for prevention of DE incorporating **care bundles** which should be with clear **Title** & **comprehensive** as follows:

❖ **Title :**

- **Prevention of DIALYSIS EVENTS (hemodialysis bundle) / catheter, fistula and graft Care Bundles.**

❖ **Purpose: (Clearly stated purpose of it)**

E.g. Strict adherence to infection control measures during connection and disconnections phase of the catheter and during cannulation and decannulations of fistula and graft in order to prevent dialysis event.

❖ **Procedure:**

- Policies should clearly describe procedures with rationale of each bundle element.
- P/P should clearly describe applicability of all care bundles according to location (hemodialysis center)
- The policies and procedures should define how data on care bundles will be collected, analyzed, interpreted, disseminated with necessary correction actions when needed.
- P/P should define **Roles and responsibilities** of concerned unit in implementation of health care bundles.
 - Daily review is the responsibility of assigned staff of hemodialysis center or unit.
 - Role of Infection control Practitioners is to ensure implementation of all elements of care bundles in daily rounds.
 - For MOH hospitals reporting via HESN, policies should be tailored accordingly.

Other domains of Policies & procedures:

P/P for Care Bundles should be :

- ❖ **Fully applicable:** all elements of the policy can be applied and comply with the hospital's scope of services
- ❖ **Based on scientific references** (IHI and GCC & CDC Surveillance guidelines).
- ❖ **Signed** from authorized personnel (i.e., owner of the policy / hospital director or Medical director / concerned department)
- ❖ **Approved** by IC committee
- ❖ **Valid** (updated within 2 - 3 years and when indicated).

Comment (if any):

*Approval by IC committee is required for the infection control manual as a whole before distribution and also for individual policy after major changes.

Sub-standard – 24:03

Hospital adopts and implements patient's care bundles for prevention of VAP/VAE according to GDIPC guidelines and data are collected, analyzed, evaluated regularly and corrective interventions are considered (or taken) accordingly. **(D,O,SI)**

VAP arises when there is bacterial invasion of the pulmonary parenchyma in a patient receiving mechanical ventilation.

- Inoculation of the formerly sterile lower respiratory tract typically arises from
- Aspiration of secretions
- Colonization of the aerodigestive tract
- Use of contaminated equipment or medications

Risk factors for VAP include:

- Prolonged intubation,
- Enteral feeding,
- Aspiration,
- Paralytic agents,
- underlying illness,
- Extremes of age
- **Complications of mechanical ventilation include:**
 - VAP Sepsis
 - Acute Respiratory Distress Syndrome (ARDS)
 - Pulmonary embolism
 - Barotrauma
 - Pulmonary edema

Review: (in Infection Control Department)

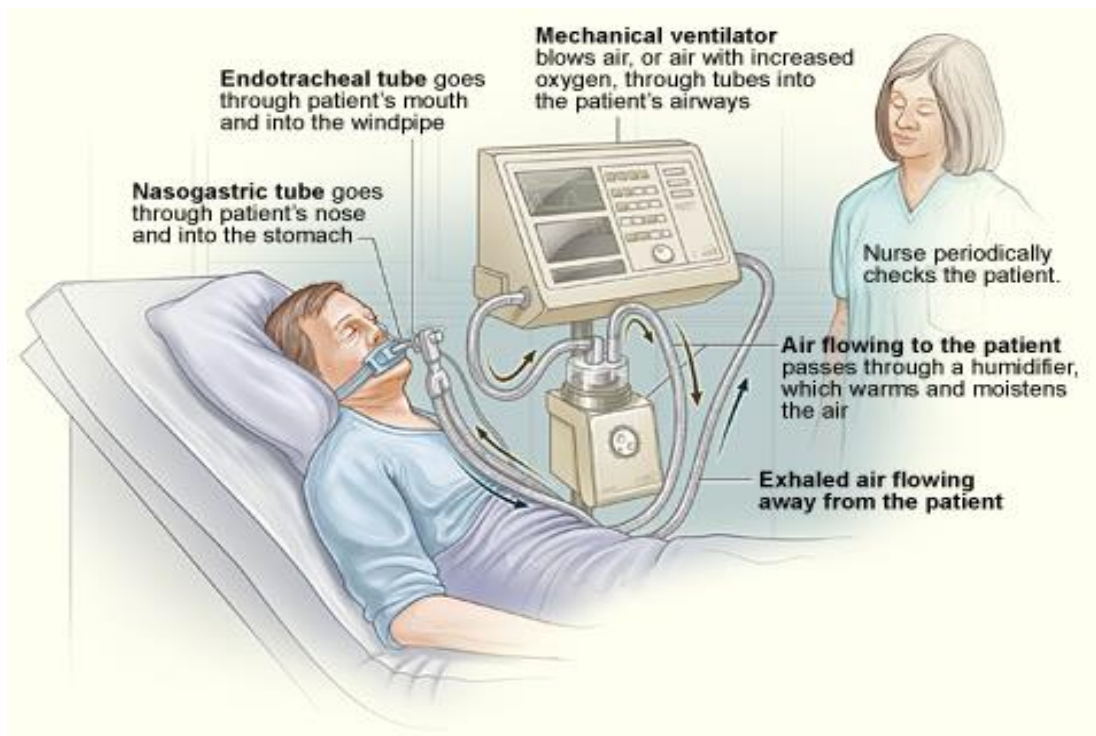
- ❖ Bundle forms for the prevention of Ventilator Associated Pneumonia (VAP).
- ❖ Bundle forms should be standardized adopted from **Institute of Healthcare Improvement (IHI) & GDIPC**
- ❖ **Ventilator Bundle Compliance Rates (Trend Analysis over months)**
- ❖ **Document for corrective actions**

Elements of Ventilator Bundle:

- 1) ***Elevate the head of the bed to 30-45degrees***
- 2) ***Provide a daily sedation vacation and assess the readiness to extubate***
- 3) ***Provide peptic ulcer disease prophylaxis***
- 4) ***Provide deep vein thrombosis prophylaxis (unless contraindicated***
- 5) ***Provide oral care using chlorhexidine***

1: Elevate the head of the bed to 30-45 degrees:

- a. ***Reduces potential for aspiration***
- b. ***Potential to improve ventilation***



2: Provide a daily sedation vacation and assess the readiness to extubate:

- *Has been demonstrated to reduce overall patient sedation*
- *Promotes early weaning*

3: Provide peptic ulcer disease prophylaxis:

- *Patients with respiratory failure have an increased risk of “stress ulcers” and associated GI bleeding.*
- *Acid-suppressive therapy (H2 blockers, sucralfate, PPI) decrease the risk of GI bleeding*

4: Provide deep vein thrombosis prophylaxis (unless contraindicated):

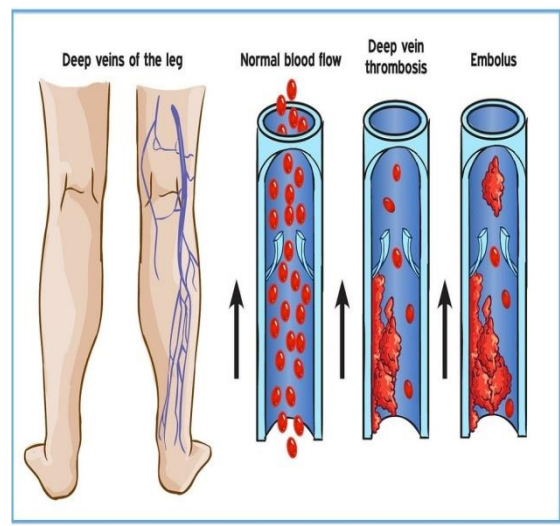
- *Patients with respiratory failure have an increased risk of deep vein thrombosis*
- *Treatment with anticoagulants (e.g., heparin) has been shown to reduce this risk and the potential for pulmonary emboli*

5: Daily oral care.

The US FDA recommends 0.12% oral chlorhexidine for use as mouth rinse.

- *Dental plaque develops in patients that are mechanically ventilated because of the lack of mechanical chewing and the absence of saliva, which minimizes the development of biofilm on the teeth.*
- *Dental plaque can be a significant reservoir for potential respiratory pathogens that cause ventilator-associated pneumonia (VAP).*

Chlorhexidine Gluconate 0.12% Oral Rinse



❖ **Data Collection:**

- ❖ Ventilator bundle review need to be documented **daily** by the assigned nurse in the critical care units while patient is on ventilator including patients with tracheostomy.
- ❖ Manual or Electronic forms adopted from **(IHI – GDIPC)** need to be utilized.
- ❖ **ICPS** would collect data once or twice per week as per hospital’s **bundle data collection Plan.**

Surveillance plan date: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>		Facility ID: <input type="text"/> <input type="text"/> <input type="text"/>		Follow up location:					
M M Y Y		S # #		<input type="checkbox"/> ICU:..... <input type="checkbox"/> SCA:..... <input type="checkbox"/> Others inpatients:.....					
	Patient ID	VNT insertion location	1- Elevate bed head	2- Sedation interruption	3- Peptic ulcer	4- DVT	5- Oral care	Overall (5 items)	Comments
1			<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	
2			<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	
3			<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	
4			<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	

Note: If a bundle element is contraindicated for a particular patient and this is documented appropriately, the bundle is considered compliant with regard to that element. (e.g. no bed elevation for patients with cervical injury etc.)

- **Sampling strategy:** Compliance can be measured by selecting all patients in the unit(s) on a randomly selected day each week. Sample should include all vented patients.

EXAMPLE:

Ventilator Bundle Data Collection Plan by ICPs: (Ref : IHI)

- On a given day, select all the patients and assess them for compliance with the Bundle. If even one element is missing, the case is not in compliance with the bundle. **ALL or NONE Principle**
- For example if there are 7 ventilated patients, and 6 patients have all five bundle elements completed then there is **86 percent** (6 divided by 7) compliance with the Ventilator Bundle. If all 7 patients had all five elements completed, compliance would be **100 percent**. If all 7 patients were missing even a single bundle item, compliance would be **0 percent**.
- Conduct the sample once or twice day per week. The sample should include all patients on mechanical ventilation in the ICU. Only patients with all five elements of the Ventilator Bundle in place are recorded as being in compliance with the Ventilator Bundle. This is a weekly prevalence measure. Rotate the days of the week and the shifts. On the day of the sample, all patients on mechanical ventilation and their respective medical records are examined for evidence of bundle compliance.

Data Analysis: (*Ventilator Bundle Compliance*):

- **Numerator:**

Total number of vented patients in the sample with all 5 components of the IHI ventilator bundle documented.

- **Denominator:**

Total number of patients reviewed who were on mechanical ventilation

FORMULA :

$$\text{Ventilator Bundle Compliance} = \frac{\text{Number of patients on mechanical ventilation who have received all five elements of the Ventilator Bundle}}{\text{Total number of patients on mechanical ventilation reviewed for bundle compliance}} \times 100$$

(Calculate Bundle compliance for individual element would guide towards targeted corrective interventions in case of low compliance.

Data Evaluation:

- ❖ Evaluation of bundle compliance rates must be done at intervals as per hospital plan.
- ❖ For instance evaluate the bundle compliance monthly / quarterly and assess over time if decreasing which should prompt immediate corrective interventions.
- ❖ Review the Ventilator Bundle Compliance for past quarters (**Trended Analysis**)
- ❖ Evaluate goals set in annual plan for bundle compliance for specific device. (**% increase / decrease**)
 - **Goal: Reduction of VAP by 50% in one year in a certain ICU unit**
 - **Goal: 95% of all patients on mechanical ventilation in the intensive care unit(s) receive all five elements of the ventilator bundle.**

Corrective Interventions:

- ❖ Results of low Ventilator bundle compliance to be linked with corrective interventions & improvement projects.

Review: (*In Critical Care Units*):

- ❖ Patients files (*Manual / electronic*) to ensure implementation of VAP bundle. (Real contraindication should be clearly documented e.g. No Head elevation in case cervical injury and contraindication of DVT prophylaxis in certain conditions.
- ❖ Ensure daily review is done for patient since day 1 of patient on Ventilator.

Observation
(O)

Observe:

1. Implementation of the care bundle for prevention of VAP in Critical Care Areas.
2. Randomly check patients for head elevation.

Interview:

Staff in Critical Care areas:

- ❖ To confirm in-depth understanding and implementation of care bundle for prevention of VAP.
- ❖ Ask staff at random about elements of ventilator Bundle and give her/him task to simulate oral care.
- ❖ Countercheck by asking availability of **oral chlorhexidine in the unit.**

Infection Preventionists:

- ❖ Interview the ICPs to confirm in-depth understanding of methodology of data collection, analysis and evaluation.
- ❖ Ask about corrective interventions for low bundle compliance.

5

Sub-standard – 24:05

Hospital adopts and implements patient's care bundle for prevention of CAUTI according to GDIPC guidelines and data are collected, analyzed, evaluated regularly and corrective interventions are considered (or taken) accordingly. **(D, O, SI)**

- ❖ *Catheter Associated Urinary Tract Infection (CAUTI) is the most common site of HAI in acute care hospitals (>30% of all HAIs reported). The attributable mortality for CAUTI is approximately 2.3% & leading cause of secondary BSI with ~10% mortality.*
- ❖ *In developing countries: crude mortality of CAUTI is 17% with attributable mortality 7%*
- ❖ *Prolongs ICU stay by an average 5-6 days & excess cost of \$3,000 per patient*
- ❖ *One-third of antimicrobial use inappropriately aimed at treatment of asymptomatic bacteriuria ⁽¹⁾*
- ❖ *Indwelling Catheter is a drainage tube that is inserted into the urinary bladder through the urethra, is left in place, and is connected to a closed collection system (Foley's catheter). It does not include straight in and out catheters, suprapubic or nephrostomy catheters*
- ❖ *CAUTI can be prevented by strict implementation of evidence based best practices in the form of care bundles, training & education , surveillance and feedback.*

Review: (in Infection Control Department)

- ❖ *Bundle forms for the prevention of catheter-associated urinary tract infections (CAUTI).*
- ❖ *Bundle forms should be standardized adopted from **Institute of Healthcare Improvement (IHI) & GDIPC***
- ❖ ***Urinary Catheter Bundle Compliance Rates (Trended Analysis over months)***
- ❖ ***Document for corrective actions & Improvement projects (If any)***

Elements / Components of Urinary Catheter Bundle:

- 1) ***Avoid unnecessary urinary catheters***
- 2) ***Insert using aseptic technique***
- 3) ***Maintain catheters based on recommended guidelines (daily care)***
- 4) ***Review catheter necessity daily and remove promptly***

1) *Avoid unnecessary urinary catheters:*

- a) Catheters Are **uncomfortable** for patients
- b) Decrease mobility, which may impair recovery and contribute to other complications (e.g., **pressure ulcers, deep vein thrombosis.**
- c) Studies have shown that **21% of catheters not indicated at insertion**

41-58% in place found to be unnecessary

❖ **Appropriate catheter indications:** ⁽⁵⁾

- *Perioperative use for selected surgical procedures;*
- *Urine output monitoring in critically ill patients;*
- *Management of acute urinary retention and urinary obstruction;*

Document
(D)

- Assistance in healing of open sacral or perineal wounds in incontinent patients;
- Patient requires prolonged immobilization (e.g., potentially unstable thoracic or lumbar spine, multiple traumatic injuries such as pelvic fractures)
- As an exception, at patient request to improve comfort (SHEA-IDSA) or for comfort during end-of-life care (CDC)

❖ **Inappropriate catheter indications:**

- As a substitute for nursing care of the patient with incontinence
- As a means of obtaining urine for culture or other diagnostic tests when the patient can voluntarily void
- For prolonged postoperative duration without appropriate indications

2- Insert catheter using aseptic technique:

- Hand hygiene immediately before and after insertion
- Aseptic technique of catheter insertion by using Gloves, a drape, and sponges
- Sterile or antiseptic solution for cleaning the urethral meatus; and
- Single-use packet of sterile lubricant jelly for insertion.
- Using as small a catheter as possible that is consistent with proper drainage, to minimize urethral trauma.



Foley Catheter Insertion Trays

3: Appropriate catheter maintenance:

- Maintain a sterile, continuously closed drainage system.
- Keep catheter properly secured to prevent movement and urethral traction.
- Keep collection bag below the level of the bladder at all times.
- Maintain unobstructed urine flow.
- Empty collection bag regularly, using a separate collecting container for each patient, and avoid allowing the draining spigot to touch the collecting container.
- Maintain meatal care with routine hygiene (bathing).
- Use aseptic technique when the collection system must be replaced (*in case of obstruction or infection*)



(Avoid allowing the draining spigot to touch the collecting

4: Daily review of catheter necessity:

- a) Daily review of catheter necessity should be conducted for all patients with urinary catheters **(using the same criteria for appropriate insertion mentioned above)**
- b) Prompt removal of devices would significantly decrease associated risk of acquiring infection.

❖ **Data Collection:**

- ❖ Urinary catheter bundle review need to be documented **daily** by the assigned nurse in the critical care units / inpatient locations while patient is on urinary catheter.
- ❖ Manual or Electronic forms adopted from **(IHI – GDIPC)** need to be utilized.
- ❖ **ICPS** would collect data once or twice per week as per hospital’s **bundle data collection Plan**

Surveillance plan date: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <small>M M Y Y</small>	Facility ID: <input type="text"/> <input type="text"/> <input type="text"/> <small>S # #</small>	Follow up location: <input type="checkbox"/> ICU:----- <input type="checkbox"/> NICU:----- <input type="checkbox"/> SCA:----- <input type="checkbox"/> Others inpatients:-----						
	Patient ID	Catheter insertion location	1- Avoid unnecessary	2- Aseptic technique	3-Appropriate maintenance	4- Daily review	Overall (4 items)	Comments
1			<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	
2			<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	
3			<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	
4			<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	

Note: Data collection & sampling strategy would be exactly similar for all devices as described for ventilator bundle

Data Analysis: (Urinary catheter Bundle Compliance):

❖ **Numerator:**

Total number of patients with indwelling urinary catheter in the sample reviewed with all applicable components of the urinary catheter bundle documented

❖ **Denominator:**

Total number of patients reviewed with indwelling urinary catheter

FORMULA :

$$\text{Urinary Catheter Bundle Compliance} = \frac{\text{Number of patients on urinary catheter who have received all four elements of the UC Bundle}}{\text{Total number of patients with Urinary Catheter reviewed for bundle compliance}} \times 100$$

(Calculate Bundle compliance for individual element would guide towards targeted corrective interventions in case of low compliance.)

Data Evaluation:

- ❖ Evaluation of bundle compliance rates must be done at intervals as per hospital plan.
- ❖ For instance evaluate the bundle compliance monthly / quarterly and assess over time if decreasing which should prompt immediate corrective interventions.
- ❖ Review the Ventilator Bundle Compliance for past quarters **(Trended analysis)**

- ❖ Evaluate goals set in annual plan for bundle compliance for specific device. (**% increase / decrease**)
 - **Goal: reduction of UTI by 50% using UC bundle**
 - **Goal: 95% compliance of urinary catheter bundle components**

Corrective Interventions:

- ❖ Results of low UC bundle compliance to be linked with corrective interventions & improvement projects.

Review: (In Critical Care Units & other inpatient locations):

- ❖ Patients files (*Manual / electronic*) to ensure implementation of urinary catheter bundle.
- ❖ Ensure daily review is done for patient since day 1 of patient on Urinary Catheter.

Observation
(O)

Observe:

- 1) Implementation of the care bundle for prevention of **CAUTI** in Critical Care Areas.
- 2) Randomly check patients for position of urinary catheter. (**Collection bag to be below the level of bladder at all times & properly secured**)
- 3) Observe if staff are following aseptic technique and PPE during insertion & maintenance phase (**If possible to observe real situation**)

Staff Interview
(SI)

Interview:

Staff in Critical Care areas & inpatient locations :

- ❖ To confirm in-depth understanding and implementation of care bundle for prevention of urinary tract infections associated with devices.
- ❖ Ask staff at random about elements of UC Bundle and give her/him task to how they will empty the collection bag.

Answer:

Collection bag should be emptied regularly, using a separate collecting container for each patient, and avoid allowing the draining spigot to touch the collecting container.

Interview Infection Preventionists:

- ❖ Interview the ICPs regarding methodology of data collection, analysis and evaluation.
- ❖ Ask about corrective interventions for low bundle compliance.

Sub-standard –06

Hospital adopts and implements patient's care bundle for prevention of CLABSI according to GDIPC guidelines and data are collected, analyzed, evaluated regularly and corrective interventions are considered (or taken) accordingly. **(D,O,SI)**

An intravascular catheter that terminates at or close to the heart or in one of the great vessels which is used for infusion, withdrawal of blood, or hemodynamic monitoring

Review: (in Infection Control Department)

- ❖ Bundle forms for the prevention of Central Line Associated Blood Stream Infections (CLABSI).
- ❖ Bundle forms should be standardized adopted from *Institute of Healthcare Improvement (IHI) & GDIPC*
- ❖ *Central Line Bundle Compliance Rates (Trended Analysis over months)*
- ❖ *Document for corrective actions & Improvement projects (If any)*

Elements / Components of Central Line Bundle:

- 1) *Hand hygiene*
- 2) *Maximal barrier precautions*
- 3) *Chlorhexidine skin antisepsis*
- 4) *Optimal catheter site selection, with subclavian vein as the preferred site for non-tunneled catheters*
- 5) *Daily review of line necessity, with prompt removal of unnecessary lines*

1- Hand hygiene:

- *Wash hands if they are obviously soiled*
- *Wash hands or use an alcohol-based waterless hand cleaner between patients, after removing gloves.*
- *Use alcohol based waterless hand sanitizers:*
 - *Before and after palpating catheter insertion sites*
 - *Before and after inserting, replacing, accessing, repairing, or dressing and intravascular catheter*

2- Maximal barrier Precautions:**❖ For the Provider:**

- *Non-sterile cap and mask*
- *All hair should be under cap*
- *Mask should cover nose and mouth tightly*
- *Sterile gown and gloves*

**❖ For the Patient:**

- *Cover patient's head and body with a large*
- *sterile drape (use more than one if needed for*
- *patients with large body size)*



3: Chlorhexidine Skin Antisepsis:

a) Prepare skin with antiseptic Chlorhexidine:

- Adults: 2% chlorhexidine in alcohol
- Pediatric: 2% chlorhexidine in alcohol

Neonates:

- Neonates < 2 wk OR < 1500 gms:
2% aqueous chlorhexidine
- Neonates > 2 wk OR > 1500 gms:
2% chlorhexidine in alcohol

b) Apply chlorhexidine solution using a back and forth friction scrub for at least 30 seconds. Do not wipe or blot.

c) Allow antiseptic solution time to dry completely before puncturing the site (~ 2 minutes).

4: Optimal Site Selection:

- Femoral site: greatest risk of infection, especially in overweight patients
- Subclavian site: lower risk of CLABSI than the internal jugular vein
 - i. Preferred when infection is only consideration
 - ii. Higher risk of mechanical complications (Pneumothorax, subclavian artery puncture, hemothorax, subclavian vein stenosis etc)
- Physicians must weigh risk-benefit of site selection for individual patient

❖ **Adults:** Subclavian site

❖ **Pediatric:** Femoral site

❖ **Neonates:** Umbilical or PICC site

5: Daily review of line necessity:

Goal: Reduce central line days

- 1) Include daily review of line necessity in multidisciplinary rounds
- 2) Remove promptly when no longer needed
- 3) Many times, central lines remain in place simply because they provide reliable access and because personnel have not considered removing them.

➤ Data Collection:

- Central Line bundle review need to be documented **daily** by the assigned nurse in the critical care units while patient is on central line.
- Manual or Electronic forms adopted from (IHI – GDIPC) need to be utilized.

- ICPS would collect data once or twice per week as per

Surveillance plan date: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> M M Y Y		Facility ID: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> S # #		Follow up location: <input type="checkbox"/> ICU:----- <input type="checkbox"/> NICU:----- <input type="checkbox"/> SCA:----- <input type="checkbox"/> Others inpatients:-----				
Patient ID	CL insertion location	1- Hand hygiene	2- Max barrier	3- Chlorhex antiseptis	4- Optimal site	5- Daily review	Overall (5 items)	Comments
1		<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	
2		<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	
3		<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	

hospital's **bundle data collection Plan**

Note: Data collection & sampling strategy would be exactly similar for all devices as described for ventilator bundle

- ❖ *If a bundle element is contraindicated for a particular patient and this is documented appropriately, the bundle is considered compliant with regard to that element.*
- ❖ *Sampling strategy: On the randomly selected day, all patients with central lines should be examined for evidence of the bundle compliance. Rotate the days of the week and shifts within a day.*

Data Analysis: (Central Line Bundle Compliance):

❖ **Numerator:**

Total number of patients with central lines who have all 5 components of the IHI central line bundle documented.

❖ **Denominator:**

Total number of patients reviewed with central lines

FORMULA :

Number of patients with central line who have received all elements of the central line Bundle

$$\text{Central Line Bundle Compliance} = \frac{\text{Number of patients with central line who have received all elements of the central line Bundle}}{\text{Total number of patients with central line reviewed for bundle compliance}} \times 100$$

(Calculating Bundle compliance for individual element would guide towards targeted corrective interventions in case of low compliance.

➤ **Data Evaluation:**

- ❖ Evaluation of bundle compliance rates must be done at intervals as per hospital plan.
- ❖ For instance evaluate the bundle compliance monthly / quarterly and assess over time if decreasing which should prompt immediate corrective interventions.
- ❖ Review the Central Line Bundle Compliance for past quarters (*Trended analysis*)

- ❖ Evaluate goals set in annual plan for bundle compliance for specific device. (*% increase / decrease*)

Goal: Reduction of BSI by 50% in one year using the central line bundle

Goal: 95% of all patients with central lines in the included intensive care units received all five elements of the central line bundle.

➤ **Corrective Interventions:**

- ❖ Results of low UC bundle compliance to be linked with corrective interventions & improvement projects.

Review: (In Critical Care Units):

- ❖ Patients files (*Manual / electronic*) to ensure implementation of central line bundle.
- ❖ Ensure daily review is done for patient since day 1 of patient on central line.

B) Central Line Maintenance Bundle:

- 1) Hand hygiene before catheter access/manipulation**
- 2) Daily review/assessment of catheter necessity with prompt removal of unnecessary lines**
- 3) Proper dressing choice:**
 - Use transparent semipermeable dressing
 - Use gauze only if the site is bleeding or oozing
- 4) Proper frequency of dressing change:**
 - Replace transparent dressing every 7 days
 - Replace gauze dressing every 48 hours
 - Replace immediately any dressing that is soiled, dampened, or loosened
- 5) Proper replacement of administrative sets:**

Surveillance plan date: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>		Facility ID: <input type="text"/> <input type="text"/> <input type="text"/>		Follow up location:				
M M Y Y		S # #		<input type="checkbox"/> ICU:----- <input type="checkbox"/> NICU:----- <input type="checkbox"/> SCA:----- <input type="checkbox"/> Others inpatients:-----				
Patient MRN	1- Hand hygiene	2- Daily review	3- Dressing choice	4- Dressing change	5- Replace admin Sets	6- Aseptic technique	7-Central line kit	Comments
1	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	
2	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	
3	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	
4	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	

- In patients not receiving blood, blood products or fat emulsions, replace administration sets no more frequently than at 96-hour intervals, but at least every 7 days **(2,7)**
- If used for blood/blood products or fat emulsions replace administration sets within 24 hours of initiating the infusion etc

6) Aseptic technique:

- For accessing and changing needleless connector, catheter hubs and injection ports using chlorhexidine 2% (30-second scrub and 30-second air-dry)

7) Use a prepackaged dressing-change kit

Observation
(O)

Observe:

1. Implementation of the care bundle for prevention of **CLABSI** in Critical Care Areas.
2. Randomly check patients to observe for aseptic technique practices. *(Notice any discoloration, oozing or any other signs of infection at the CL insertion site.)*
3. Observe if staff are following aseptic technique and PPE during insertion & maintenance phase *(If possible to observe real situation)*

Staff Interview
(SI)

Interview:

Staff in Critical Care areas:

- ❖ To confirm in-depth understanding and implementation of care bundle for prevention of central line associated blood stream infections. (**CLABSI**)

Interview Infection Preventionists:

- ❖ Interview the ICPs regarding methodology of data collection, analysis and evaluation of central line bundle.
- ❖ Ask about corrective interventions for low bundle compliance.

Sub-standard – 24:07

Hospital adopts and implements patient's care bundle for prevention of DE (catheter, fistula and graft bundle) according to GDIPC guidelines and data are regularly collected, analyzed, evaluated and corrective interventions are considered (or taken) accordingly. **(D, O, SI)**



Review: (in Infection Control Department)

- ❖ Catheter, fistula and graft Bundle forms for the prevention of dialysis events.
- ❖ Bundle forms should be standardized adopted from *Institute of Healthcare Improvement (IHI) & GDIPC*
- ❖ *Dialysis events Bundle Compliance Rates (Trended Analysis over months)*
- ❖ *Document for corrective actions & Improvement projects (If any)*

Elements / Components of Catheter, fistula and graft Bundle:

For the catheter:



1. *Hemodialysis catheter connections*
2. *Hemodialysis catheter disconnections*
3. *Hemodialysis catheter exit site care*
4. *Dialysis station routine disinfections*
5. *Hemodialysis injectable medications preparations*
6. *Hemodialysis injectable medications administrations.*

 Hemodialysis Bundle Form for Catheter 	
<p>CDC Hemodialysis Bundle Components for Catheter:</p> <p>1-Hemodialysis Catheter Connection</p> <ul style="list-style-type: none"> o Perform hand hygiene o Don proper PPE (mask with face shield or mask with goggles, plus gown & gloves) o Provide mask for the patient o Soak dialysis catheter with Betadine 3-5 minutes o Scrub catheter hub with antiseptic and allow to dry o Connect catheter to blood lines aseptically o Attach new caps aseptically / weekly (Saturday or Sunday) <p>2-Hemodialysis Catheter Disconnection</p> <ul style="list-style-type: none"> o Perform hand hygiene o Don proper PPE (mask with face shield or mask with goggles, plus gown & gloves) o Provide mask for the patient o Soak dialysis catheter with Betadine 3-5 minutes o Disconnect catheter from blood lines aseptically o Discard tubing in a leak-proof container o Scrub catheter hub with antiseptic and allow to dry <p>3-Hemodialysis Catheter Exit Site Care</p> <ul style="list-style-type: none"> o Perform hand hygiene o Apply skin antiseptic o Allow skin antiseptic to dry o Apply dressing aseptically 	<p>4-Dialysis Station Routine Disinfection</p> <ul style="list-style-type: none"> o Don Proper PPE (as per indication but at least use gloves) o Ensure that the patient has left the dialysis station before cleaning o Discard all single-use supplies, Clean and disinfect reusable equipment o Nursing: Clean and disinfect dialysis station (dialysis machine and bedside table) o Keep used or potentially contaminated items away from the disinfected surfaces o Housekeeping: Clean and disinfect dialysis chair or bed (rails, armrests & mattresses) <p>5-Hemodialysis injectable medication preparation</p> <ul style="list-style-type: none"> o Perform hand hygiene o Prepare medications in clean designated areas o Inspect all vials o Prepare medications using aseptic techniques o Use new needle and new syringe to enter all vials o Discard all single dose vial(s) o Discard or properly store all multi dose vial(s) <p>6- Hemodialysis injectable medication administration</p> <ul style="list-style-type: none"> o Perform hand hygiene (before and after) o Use proper PPE (gloves) o Properly transport medication to patient station o Disinfect injection port with appropriate antiseptic o Administer medications using aseptic techniques o Discard syringe at point of use

For the fistula and graft:

1. *Arteriovenous fistula and graft cannulations*

2. *Arteriovenous fistula and graft decannulations*
3. *Dialysis stations routine disinfections*
4. *Hemodialysis injectable medications preparations*
5. *Hemodialysis injectable medications administrations.*

	Hemodialysis Bundle Form for Fistula/Graft	
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<p>CDC Hemodialysis Bundle Components for Fistula/Graft:</p> <p>1-Arteriovenous Fistula / Graft Cannulation</p> <ul style="list-style-type: none"> • Perform hand hygiene • Don proper PPE (mask with face shield or mask with goggles, plus gown & gloves) • Clean site with 2% CHG wipes or Soap and water • Apply skin antiseptic (Chlorhexidine 2% or 10 % Povidone Iodine) & allow it to dry • Do not contact site (after antiseptis) • Insert needles & Connect to blood lines aseptically <p>2- Arteriovenous Fistula/Graft Decannulation</p> <ul style="list-style-type: none"> • Perform hand hygiene • Don proper PPE (mask with face shield or mask with goggles, plus gown & gloves) • Disconnect from blood lines aseptically • Discard tubing in a leak-proof container • Wear clean gloves (patient and/or staff) to compress site • Remove needles aseptically • Apply clean gauze/bandage to site <p>3- Dialysis Station Routine Disinfection</p> <ul style="list-style-type: none"> • Don Proper PPE (as per indication but at least use gloves) • Ensure that the patient has left the dialysis station before cleaning • Discard all single-use supplies, Clean and disinfect reusable equipment • Nursing: Clean and disinfect dialysis station (dialysis machine and bedside table) • Keep used or potentially contaminated items away from the disinfected surfaces • o Housekeeping: Clean and disinfect dialysis chair or bed (rails, armrests & mattresses) 	<p>4-Hemodialysis injectable medication preparation</p> <ul style="list-style-type: none"> • Perform hand hygiene • Prepare medications in clean designated areas • Inspect all vials • Prepare medications using aseptic techniques • Use new needle and new syringe to enter all vials • Discard all single dose vial(s) • Discard or properly store all multi dose vial(s) <p>5- Hemodialysis injectable medication administration</p> <ul style="list-style-type: none"> • Perform hand hygiene (before and after) • Use proper PPE (gloves) • Properly transport medication to patient station • Disinfect injection port with appropriate antiseptic • Administer medications using aseptic techniques • Discard syringe at point of use
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Sub-standard – 24:08

Hospital adopts and implements patient's care bundle for prevention of MDROs according to GDIPC guidelines and data are regularly collected, analyzed, evaluated and corrective interventions are considered (or taken) accordingly. (D,O, SI)

- ❖ *Multidrug Resistant Organisms (MDROs) develops resistance to one or more commonly used antibiotics. These includes MRSA: Methicillin-Resistant Staphylococcus aureus VRE: Vancomycin-resistant Enterococcus, MDR Pseudomonas aeruginosa, Klebsiella pneumoniae, and Acinetobacter baumannii , MDR-ESBLs etc*
- ❖ *Factors contributing to MDRO in healthcare setting:*
 - *Inappropriate and uncontrolled use of antimicrobial agents in healthcare setting*
 - *Inadequate adherence to infection control measures*
 - *Availability of vulnerable host (Sever underlying disease Compromised host defenses, Recent surgery, Indwelling medical devices, ICU patients etc)*
 - *Selective pressure exerted by exposure to antimicrobial in the community*
- ❖ *Up to 70% of HAIs are due to micro-organisms resistant to one or more antimicrobials*
- ❖ *Options for treating patients with HAIs caused by MDRO are often extremely limited*
- ❖ *Antimicrobial resistance is implicated in at least 2 million illnesses and 23,000 deaths in the US each year.*
- ❖ *MDROs transmission within the healthcare facilities could be either Indirect contact transmission (Transfer from contaminated environment / surfaces / reusable medical equipment or Direct contact transmission By healthcare worker's hands or By direct contact with the organism (in an open wound.*
- ❖ *Environment is the reservoir for infectious organisms . MDROs may survive (even thrive) on environmental surfaces for months if the surfaces are not cleaned or disinfected.*
 - *E. coli & Pseudomonas aeruginosa – up to 16 months*
 - *MRSA – up to 9 - 10 months*
 - *TB & C. diff – up to 5 months*
 - *VRE – up to 4 months*
- ❖ *Strict adherence to infection control measures including proper cleaning & disinfecting is essential to reduce transmissions / infections !!!*
- ❖ *To prevent and control the transmission of epidemiologically significant organisms such as Multidrug Resistant Organisms (MDROs), the hospital should have a policy for MDROs prevention & care bundle; the concerned hospital staff must be fully educated about the elements of adopted care bundle. The hospital should regularly collect and analyzed the data and assess bundle compliance rate for performance improvement.*

Review: (in Infection Control Department)

- Bundle forms for the prevention of Multidrug Resistant Organisms (**MDROs**)
- MDRO Bundle forms could be adopted from CDC (*prevention of Multidrug-resistant organisms (MDROs), as no ready to use MDRO bundle form is available yet*)
- **MDRO Bundle Compliance Rates (Trended Analysis over months)**
- **Document for corrective actions/ improvement projects (if any)**
- Review how hospital defines the data collection methods and sources (e.g., hospital information system, verbal and written communication, medical record review, direct observation).

Elements / Components of MDRO Bundle:

- 1) **Administrative Measures / Structure & system administrative support**
- 2) **Prevention MDRO transmission / Infection Control Measures**
- 3) **Judicious use of antimicrobials**
- 4) **MDRO surveillance**
- 5) **Education and Training of Healthcare Personnel**

1: Structure & system administrative support:

Human resources: trained infection control practitioners and adequate staffing level

- *Implement system changes to ensure prompt and effective communication e.g., computer alerts to identify patients previously known to be colonized/infected with MDROs*
- *Providing hand hygiene facilities and environmental cleaning*
- *Enforcing adherence to recommended infection control practices and compliance monitoring*
- *Feedback to health care workers*
- *Written plan for implementation*

2: Prevention of MDRO transmission / Infection Control Measures:

- *Improvement in Hand Hygiene: >90% compliance rate*
- *PPE: Wear gloves and gown when entering the room, removing before exiting*
- *Active Surveillance Cultures: to detect asymptomatic patients*
- *Use of isolation precautions: standard & contact for patients colonized or infected with MDRO*
- *Follow recommended **cleaning, disinfection and sterilization** for maintaining patient care areas and equipment*
- *Disinfect **reusable medical equipment** between patients*
- *Increased cleaning and disinfection of frequently- touched surfaces*
- *Monitor (i.e., supervise and inspect) cleaning performance to ensure consistent cleaning and disinfection of surfaces*

3: Judicious use of antimicrobials:

- *Limit antimicrobial prescription*
- *Use local antibiogram to effectively treat infections*
- *Treat infection, not contamination*
- *Treat infection, not colonization*
- *Stop treatment when infection is cured or unlikely*
- *Avoid excessive duration of treatment*

- Use narrow spectrum agent and put restriction on broad spectrum and potent antibiotics.

4: MDRO surveillance:

- A critical component of any MDRO control program
- Important patient safety component
- Allows detection of newly emerging resistance pattern
- Monitors epidemiologic trends in incidence of MDROs over time
- Measures the effectiveness of interventions

5: Education:

- Facility-wide, unit-targeted, and informal, educational interventions for prevention of MDRO transmission.
- Provide basic education on preventive measures to patients and visitors.

➤ **Data Collection:**

- MDRO bundle review need to be documented **daily** by the assigned nurse in the critical care units / other inpatient locations while patient is under isolation.
- Manual or Electronic forms need to be utilized.
- ICPS would collect data once or twice per week as per hospital's **bundle data collection Plan**

Sampling strategy: Compliance can be measured by selecting all patients in the unit(s) on a randomly selected day / days each week. Sample should include all patients with MDROs on the date of review.

Data Analysis: (MDROs Bundle Compliance):

- **Numerator:**
Total number of patients with MDROs in the sample with all components of the bundle documented.
- **Denominator:**
Total number of patients reviewed who were with MDROs

FORMULA :

$$\begin{array}{l}
 \text{Bundle} \\
 \text{MDRO} \\
 \text{Bundle Compliance} \\
 100
 \end{array}
 = \frac{\begin{array}{l} \text{Number of patients with MDROs who} \\ \text{have} \\ \text{received all elements of the MDRO} \end{array}}{\begin{array}{l} \text{Total number of patients with MDROs} \\ \text{on day of week of sample} \end{array}} \times$$

(Calculating Bundle compliance for individual element would guide towards targeted corrective interventions in case of low compliance.

Data Evaluation:

- ❖ Evaluation of bundle compliance rates must be done at regular intervals as per hospital plan.
- ❖ For instance evaluate the bundle compliance monthly / quarterly and assess over time: if decreasing it should prompt immediate corrective interventions.
- ❖ Review the MDROs Bundle Compliance for past quarters.
(Trend analysis)

Corrective Interventions:

- ❖ Results of low MDRO compliance to be linked with corrective interventions & improvement projects.

Observe:

- ❖ In critical care areas the implementation of care bundle for prevention of Multidrug Resistant Organisms (**MDROs**) consistent with recognized professional practices.
- ❖ Observe the appropriate implementation of isolation precautions for patients with **MDROs**. *(You may observe patients with MDROs without isolation signage etc. in open cubicles)*
- ❖ Observe if file of patient with MDROs is appropriately flagged.

Interview:

- ❖ Staff in Critical Care areas to assess understanding and compliance with the care bundle for prevention of Multi-drug Resistant Organisms (MDROs). (***Klebsiella: Carbapenem resistant Enterobacteriaceae (CRE): MDR Acinetobacter MDR Klebsiella, Pseudomonas & Gram positive MDROs include MRSA and VRE.***)
- ❖ Ask staff at random about the MDROs and elements of MDROs bundle.
- ❖ Interview IPC staff to confirm that data on the care bundle for prevention of Multi-drug Resistant Organisms (MDROs) are regularly collected, analyzed, and evaluated.

6

Sub-standard – 24:09

Patient's care bundles are followed daily by nursing staff of critical care units. IC practitioners check the compliance and validate the data (at least once weekly). (D, O, SI)

- ❖ *Compliance with the any bundle is defined as the percentage of intensive care patients on the elements of the Bundle are documented on daily goals sheets and/or elsewhere in the medical record.*
- ❖ *NOTE: This is an "ALL-OR-NONE" INDICATOR. If any of the elements are not documented, the patient is not counted in the numerator. If a bundle element is contraindicated for a particular patient and this is documented appropriately in the medical record, then the patient is considered compliant with regard to that measure. (Ref: IHI)*

Review:

- ❖ Review the patient files to check for daily review of bundles done for **targeted patients** in critical care units (ICU, NICU, & Burn Units, surgical units etc.)
- ❖ Daily review of patient care bundles is the responsibility of nursing staff of critical care units.
- ❖ Review the ICPs data collection sheets for bundles and ensure validation of data collected from Critical Care units.
- ❖ For hospitals reporting HAI Surveillance data through HESN electronic system, additional validation of manual bundle compliance with bundle compliance in HESN is to be reviewed.

(All auditors must receive brief orientation regarding HAI Surveillance Validation Process from regional surveillance coordinators before going for audit) Manual Vs HESN data

Observe:

- ❖ In critical care & other inpatient locations areas the implementation of **patient's care bundles for prevention of VAP, CAUTI, CLABSI, and MDROs & SSI (Surgical wards etc)**
- ❖ Randomly observe patients to match information available in patient's files and that provided by nursing staff of concerned unit.

Interview the nursing staff in critical care units & Infection Control Practitioners about process of data validation:

- ❖ Ask how the data regarding targeted patients in critical care units is documented and validated. Bundle review has to be started for each patient on devices, with MDROs and undergoing surgical procedure.
- ❖ Ask ICPs how frequently they are doing rounds to check for compliance with bundle elements.
- ❖ Randomly ask about elements of different bundles and how they will be implemented.
- ❖ Assess if the ICPs are familiarized with **all or none principle** for bundle compliance.

Document
(D)

Observation
(O)

Staff Interview
(SI)

Sub-standard – 24:10

Data of patient's care bundles are regularly reported to IC regional directorate and GDIPC-MOH through IC-HESN electronic system. **(D, SI)**

Review the following:

- ❖ Manual data collection forms for all prevention bundles.
- ❖ Access HESN dashboards to compare the manual bundle compliance with that displayed in HESN system.*

Comment (if any):

**This substandard is applicable only for hospitals reporting surveillance data through HESN electronic system. Auditors must coordinate with regional surveillance to get updated information about the number of hospitals reporting HAI Surveillance data via HESN electronic system.*

Interview IPC team to verify the following:

- ❖ Ask about number of times bundles data has to be entered in HESN system.
(Devices + Surgical Bundle **)
- ❖ Randomly ask ICP to access the HESN dashboards and show Bundle compliance for devices.
- ❖ Indirect confirmation from regional coordinator regarding scheduled hospital in terms of overall performance and completeness of data reporting via HESN.

Comment (if any): *MDRO bundle is not yet embedded in HESN system.*

REFERENCES / WEB BASED RESOURCES:

- 1) Guidelines for the Prevention of Intravascular Catheter-Related Infections, 2011
<https://www.cdc.gov/infectioncontrol/guidelines/bsi/index.html>
- 2) Health Care Associated Infections Surveillance Manual *GCC - 2018 (3rd Edition)*
- 3) HESN – HAI Surveillance Manual (GDIPC)
<https://hesn.moh.gov.sa/webportal/infection-control>
- 4) GCC - NHGA *HAI course content – 2019*
- 5) Guidelines for the Prevention of Intravascular Catheter-Related Infections, 2011
<https://www.cdc.gov/hai/pdfs/bsi-guidelines-2011.pdf>
- 6) <https://www.cdc.gov/infectioncontrol/guidelines/bsi/recommendations.html#rec18>
- 7) MDRO Prevention and Control
<https://www.cdc.gov/infectioncontrol/guidelines/mdro/prevention-control.html>.
- 8) https://www.cdc.gov/hai/prevent/prevention_tools.html Prevention Toolkits

**Note: All relevant standards should be reviewed in ICU, CCU if Haemodialysis is performed there

Sub-standard – 25:01

There is a written policy and procedures for infection control in Hemodialysis unit (D)

Review the policy, which should be:

- ❖ Comprehensive: it covers all aspects of infection control in HD unit.
- ❖ Fully applicable: all elements of the policy can be applied and comply with the hospital's or unit's scope of services, including (but not limited to):
 1. Infection control precautions in dialysis units.
 - Hand hygiene
 - Recommended PPE (gloves: clean/sterile - gowns: clean/sterile - face shield or goggles - surgical mask or N95 respirators)
 - Aseptic techniques (e.g., insertion and handling of CVC and other vascular accesses, preparation of parenteral medications, use of multi dose vials ... etc.)
 - Environmental cleaning and disinfection: internal cleaning and disinfection of dialysis machines in-between patients (as per manufacturer's recommendations) / cleaning and disinfection of Haemodialysis patients' environment after each treatment session / regular cleaning and disinfection of the water treatment system, distribution system and dialysis machines (as per manufacturers' recommendations)
 - Employee safety: staff immunization as per employee clinic policy, exposure and post exposure management
 - Waste management
 2. Handling dialysis patients with suspected MERS-CoV infection
 3. Prevention of Blood Borne Pathogens (BBP) transmission, serology protocols and immunization for dialysis patients
 4. Water treatment & required quality testing: microbiological testing, chemical testing and water quality daily parameters.
- ❖ Based on scientific references approved by MOH (MOH Guideline for Infection Prevention and Control in Haemodialysis Units - 2018, GCC, CDC, APIC & WHO)
- ❖ Signed from authorized personnel (i.e., owner of the policy / hospital or unit director or medical director / concerned department)
- ❖ Approved by IC committee*
- ❖ Valid (updated within 2 - 3 years and when indicated)

Comment (if any):

- Approval by IC committee is required for the infection control manual as a whole before distribution and also for individual policy after major changes

2 **Sub-standard – 25:02**
The minimum floor area of an individual Hemodialysis patient's station is 80 feet (7.43 m²) and the distance separating adjacent dialysis chairs/beds is not less than 1.2 m. **(O)**

Observation (O)
Observe the dialysis stations:
4) Sufficient space between dialysis stations to allow free movement of HD staff and accessibility for adequate cleaning (i.e. dialysis machines are not closed to each other's)
5) Required items are arranged in an orderly fashion, while unneeded items are eliminated
6) Excess lengths of tubes, hoses, and wires are removed from the floor

3 **Sub-standard – 25:03**
Special room is available for central venous line insertion, and it is equipped with appropriate hand washing facility and required PPE. **(O, SI)**

Observation (O)
Observe the room allocated for central venous line insertion:
1) Physically separated room from other areas in a way that ensures proper traffic control while insertion procedure is ongoing.
2) Available hand washing sink and ABHR container
3) Required PPE (sterile gloves - sterile gowns - face shield / goggles - surgical mask / N95 respirators)

Staff Interview (SI)
Ask HD staff about the actual place used for insertion of central venous catheter within the dialysis unit
1) If this service is provided within the dialysis unit, the answer should be "in a special room allocated for central venous catheter insertion only"
2) If this service is not provided within the dialysis unit, the answer should be "the patient is transferred to ICU or operating room, and this is included in the departmental policies (D)"

4

Sub-standard – 25:04

Within the Hemodialysis unit, there is an Airborne Infection Isolation Room – AIIR is available to provide care for patients with suspected MERS-CoV infection, otherwise there is an applied written protocol to transfer them another healthcare facility to get their dialysis sessions while applying airborne infection isolation precautions. (D - O - SI)

Document
(D)

Review the following documents:

- 1) Respiratory triage forms to evaluate or score all dialysis patients before getting their dialysis sessions.

If Airborne Infection Isolation Room – AIIR is available within the unit:

- 2) Bilingual color coded blue isolation signs used to indicate airborne infection isolation precautions when applied for patients with suspected MERS-CoV infection

If Airborne Infection Isolation Room – AIIR is not available within the unit:

- 3) Departmental policies should include written protocol for transferring dialysis patient with suspected MERS-CoV infection to another healthcare facility, which has an AIIR to get their dialysis sessions while applying airborne infection isolation precautions.
- 4) Evidence of applied protocol for transferring dialysis patient with suspected MERS-CoV infection to another healthcare facility to get their dialysis sessions (e.g., forms used for contact and transfer)

Observation
(O)

Observe the following areas:

- 1) Respiratory triage area that should be reached by dialysis patients before they get in contact with staff or other patients in the unit (also can be evaluated in standard 12)

If Airborne Infection Isolation Room – AIIR is available within the unit:

- 1) Observe Airborne Infection Isolation Room – AIIR, which should fulfill all MOH specifications for airborne isolation room (also can be evaluated in standard 21)
- 2) Observe any case inside the AIIR room, and what type of isolation precautions is applied there?

Ask the HD staff about:

- 1) Staff knowledge about Respiratory triage policy (also can be evaluated in standard 12)
- 2) Staff knowledge about the case definition of MERS- CoV (also can be evaluated in standard 12)
- 3) Ask the staff about the required interventions for dialysis patient with suspected MERS-CoV infection, who need dialysis based on the approved policy (also can be evaluated in standard 12)

Comments:

Instead of direct questions, indirect ones or scenarios are advisable, Examples:

“In emergency situations, where you can perform dialysis sessions for 3 dialysis patients with suspected MERS-CoV infections during the same shift?”

If Airborne Infection Isolation Room – AIIR is available within the unit:

Answer: Only Airborne Infection Isolation Room – AIIR can be used

If Airborne Infection Isolation Room – AIIR is not available within the unit:

Answer: Patients should be transferred to another healthcare facility, which has an AIIR to get their dialysis sessions

Guide to score this sub-standard:

- If there is AIIR room within the unit for dialyzing patients with suspected MERS-CoV infections **or** evidence of an applied protocol for transferring them to another appropriate facility (Score 2 is given)
- If there is no AIIR room within the unit, but a single room with portable HEPA filter is used for dialyzing patients with suspected MERS-CoV infections while applying risk assessment (Score 1 is given)
- If none of the above are available (Score 0 is given)

5

Sub-standard – 25:05

Easy accessible hand washing sinks are available in adequate number (one for every 2-4 chairs/beds)(O)

Observation
(O)

Observe hand washing preparations in the HD unit:

- 1) At least one hand washing sink in each HD room or any physically separated area (i.e., to reach 1 to 1 ratio = one for every chair/bed in single room)
- 2) Minimum accepted ratio: one hand washing sink for every 4 chairs/beds in the units that are designed as open areas without physical barriers
- 3) Hand sinks are conveniently located (i.e., accessible or easy to be reached by the HD staff)
- 4) Hand washing sinks are equipped with hot & cold water / plain and antimicrobial soap / towels

6

Sub-standard – 25:06

Alcohol hand rub dispensers are available (one for every patient's chair/bed) (O)

Observation
(O)

Observe waterless hand hygiene preparations in the HD unit:

- 1) Minimum accepted ratio: one alcohol based hand rub dispenser for every chair/bed
- 2) Alcohol based hand rub dispensers are conveniently located (i.e., accessible or easy to be reached by the HD staff)

Sub-standard – 25:07

7

Appropriate PPE are available and used according to standard and/or transmission based precautions (gloves: clean/sterile - gowns: clean/sterile - face shield or goggles - mask or N95 respirators) (O - S)

Observation
(O)

- 1) Observe the availability of the PPE at all dialysis areas or rooms (PPE should be available in adequate amounts in each area)
- 2) Observe the specifications of available PPE (PPE should be of proper qualities and fulfill MOH approved specifications)
- 3) Observe staff members while using available PPE: they should use PPE in isolation room and other dialysis areas properly (i.e., as per transmission based precautions and/or infection control precautions required during haemodialysis sessions):
 - Gloves are needed whenever caring for a patient or touching the patient's equipment, as exposure to blood and potentially contaminated items are routinely anticipated
 - HD staff should wear fluid resistant gowns, face shields, eyewear, and masks to protect themselves and prevent soiling of clothing during:
 - a) Initiation and termination of dialysis session
 - b) Insertion of dialysis catheter
 - c) Manipulation of patient's access at any time
 - d) Cleaning of the dialysis station.

Staff Interview
(SI)

Ask HD staff members (2 - 3 HCW of different job categories):

- 1) How to properly wear PPE and what is the correct sequence?
- 2) How to safely remove PPE and what is the proper sequence?
- 3) About: their BICSL licenses / Fit test dates / knowledge about their fitted N95 sizes.

8	Sub-standard – 25:08 Central Venous Catheter (CVC) selection, insertion, maintenance, dressing change, connection and disconnection are done according to CDC guidelines (O - SI)
9	Sub-standard – 25:09 Patient and staff members wear masks for all Central Venous Catheter (CVC) access connections (O - SI)
Observation (O)	<ol style="list-style-type: none"> 1) Observe the availability of the supplies required for applying these precautions (e.g., PPE: gloves: clean/sterile – gowns: clean/sterile – mask – face shield or goggles / sterile supplies: sterile drapes – sterile dressings / antiseptics: chlorhexidine gluconate with alcohol (> 0.5%) – povidone-iodine) 2) Observe staff members while dealing with CVC (insertion, maintenance, dressing change, connection and disconnection), they should follow the accepted infection control practices as per CDC guidelines: <ul style="list-style-type: none"> - Hand hygiene - PPE: gloves: clean/sterile / gowns: clean/sterile / mask / face shield or goggles - Aseptic technique with use of appropriate antiseptic.

Comment (if any):

For successful observation, it is advisable to plan your visit to be during initiation or termination of dialysis sessions (i.e., at connection or termination time)

Staff Interview (SI)	<p>Ask HD staff members:</p> <ol style="list-style-type: none"> 1) How to properly select and insert Central Venous Catheter (CVC) and what are required precautions (i.e., place, HH, PPE, supplies, technique ...etc..) 2) How to safely maintain and perform dressing change for Central Venous Catheter (CVC) and what are required precautions (i.e., HH, PPE, supplies, technique ...etc..) 3) How to properly handle Central Venous Catheter (CVC) during connection and disconnection of patient to dialysis machine and what are required precautions (i.e., HH, PPE, supplies, technique ...etc..) 4) Ask HCWs who are involved in the handling Central Venous Catheter (CVC) about: <ul style="list-style-type: none"> - Date of last training or education received about proper infection control measures for (CVC) selection, insertion, maintenance, dressing change, connection and disconnection - Date of last assessment of knowledge and adherence to CDC guidelines as regard infection control measures for (CVC) selection, insertion, maintenance, dressing change, connection and disconnection <p>Regular training or education activities are required with periodic assessment of HCWs knowledge and their adherence to the guidelines</p>
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Comment (if any):

You can ask 2 -3 HCWs to demonstrate procedures that are applied

10

Sub-standard – 25:10

Mobile common medication carts or trays are strictly prohibited (O - SI)

Observation
(O)

1) Check if there is any mobile carts or common trays used within haemodialysis unit (i.e., the treatment areas) to prepare and/or distribute medications and supplies between patients

Mobile carts and common trays should not be used to prepare and/or distribute medications and supplies

Comment (if any):

For successful observation, it is advisable to plan your visit to be during initiation or termination of dialysis sessions (i.e., time for preparation and/or distribution of medications and supplies)

Staff Interview
(SI)

Ask HD staff members:

1) How are they preparing and/or distributing supplies or medications between patients

Comment (if any):

Instead of direct questions, indirect ones or scenarios are advisable

11

Sub-standard – 25:11

For preparation of medications, a central area (clean area) is specified for this purpose, and this area is physically separated from patients' treatment areas (contaminated areas). (O - SI)

Observation
(O)

4) Check the availability of the dedicated medication preparation area(s) which is (are) physically separated from patients' treatment areas.

5) Observe if any patient requires medication during dialysis session, and where and how the responsible nurse is preparing this treatment.

Medication preparation area is the place for preparing and preservation of the multi-dose medications, while single dose medications can be taken to patient's dialysis station for single use purposes and any remaining doses should be discarded immediately (i.e., single-dose vials can not be stored for future use even on the same patient)

Comment (if any):

For successful observation, it is advisable to plan your visit to be during initiation or termination of dialysis sessions (i.e., time for preparation and/or distribution of medications)

Staff Interview
(SI)

Ask HD staff members:

7) Where and how are they preparing medications (e.g. multi-dose vials and ointment for dressing change)?

Comment (if any):

Instead of direct questions, indirect ones or scenarios are advisable

12

Sub-standard – 25:12

Unused supplies or medications within the patient's station are not used on other patients and never returned to the common clean area. (O - SI)

Observation
(O)

1) Observe the attitude of the staff members towards unused supplies and single-use medications that are taken to patient's dialysis station

Supplies and single-use medications are brought to patient's station only when needed

After termination of dialysis session:

- **All remaining single-use items are discarded (are not used on other patients and never returned to a clean area), even unused ones with intact original wrap.**
- **All reusable items are sent for reprocessing, even unused ones with intact original wrap.**

Comment (if any):

For successful observation, it is advisable to plan your visit to be during initiation or termination of dialysis sessions (i.e., time for preparation and/or distribution of medications and supplies)

Staff Interview
(SI)

Ask HD staff members:

Instead of direct questions, indirect ones or scenarios are advisable.

Examples:

- 4) What to do with extra supplies or single-use medications that are taken to patient's dialysis station without being used during dialysis session (items are still unused with intact original wrap)?
- 5) How you safely handle or disinfect unused supplies and medications that are taken to patient's station which are not used during dialysis sessions before being used for other patients?
- 6) In emergency situations, what are the rules that should be considered before returning unused supplies or medications that are taken to patient's dialysis station to the central preparation area?

Answer:

Reuse of these items is prohibited; they should be discarded even if unused and their original wrappers are intact.

13

Sub-standard – 25:13

Patient care equipment such as blood pressure cuffs, stethoscopes, scissors and thermometers are allocated to a single patient during the whole session and are disposed (if single use) or cleaned and disinfected (if reusable) at the end of each patient's treatment session. (O - SI)

Observation
(O)

- 1) Observe the attitude of the staff members towards patient care equipment such as blood pressure cuffs, stethoscopes, scissors and thermometers:
 - These items are allocated to a single patient during the whole session (or not)?
 - Single use items are disposed at the end of each patient's dialysis session (or not)?
 - Reusable items are reprocessed (i.e., cleaned and disinfected) at the end of each patient's dialysis session (or not)?

Staff Interview
(SI)

Ask HD staff members:

Instead of direct questions, indirect ones or scenarios are advisable,

Examples:

- 1) How you safely handle or disinfect single-use patient care equipment such as disposable stethoscope after being used during dialysis session before being used for another patient?
- 2) In emergency situations, what are the precautions to be followed before using shared reusable items such as blood pressure cuffs and scissors for more than one patient during the same shift?

Answer:

- 1) Reuse of single-use patient care equipment is strictly prohibited (i.e., single-use items should be discarded)
- 2) Reusable patient care equipment are allocated to a single patient during the whole session (i.e., these items should not be shared between patients during the same shift. They can be reused only after being cleaned and disinfected after termination of the dialysis session).

14

Sub-standard – 25:14

Written rules are strictly followed for the process of internal cleaning and disinfection of dialysis machines in-between patients (as per manufacturer's recommendations). (D - O - SI)

15

Sub-standard – 25:15

Written rules are strictly followed for cleaning and disinfection of hemodialysis patients' environment after each treatment session with MOH approved disinfectants (checklist is used to cover all environmental surfaces at every dialysis station: surfaces of machines specially frequently touched surfaces: control panels and knobs, chairs/beds, over-bed table, BP cuff with its tubing, TV remote control, ... etc..). (D - O - SI)

Review the following documents:

- 1) Documents that demonstrate the process of internal cleaning and disinfection of dialysis machines (appropriate evidence of application whether hard copy or electronic record of the machine) and check whether the applied process is compatible with manufacturer's recommendation and the approved departmental policy.
 - The evidence should specify the method of disinfection (whether thermal or chemical), temperatures, used chemicals and required concentrations & times as per HD approved policy.
- 2) Documents that demonstrate the process of cleaning and disinfection of haemodialysis patients' environment after each treatment session (appropriate evidence of application: checklist for HD patients' environment for each station) and check whether the applied process is compatible with manufacturer's recommendation and the approved unit's policy.
 - The checklist should be practical and cover all environmental surfaces in the haemodialysis station. Also it should include responsible staff (whether nursing staff or housekeeping staff with names – if applicable – and signatures and signatures) / dates & times / chemicals and disinfectants used (types – concentrations – contact times)

Document
(D)

Observe the processes of internal cleaning & disinfection of dialysis machines and cleaning and disinfection of haemodialysis patients' environment:

Observation
(O)

- 1) Internal cleaning and disinfection of dialysis machines is performed as per manufacturer's recommendation and the approved departmental policy.
 - Method of disinfection (whether thermal or chemical)
 - Temperatures, used chemicals and required concentrations & times.
- 2) Cleaning and disinfection of haemodialysis patients' environment as per the unit's policy
 - Frequency: after each shift and at the end of the day
 - Responsible staff & used PPE: nursing staff & housekeeping staff / PPE: clean gloves, clean gowns, surgical masks and face shield or goggles
 - Supplies: check the availability of supplies e.g., approved chemicals and disinfectants, non-linting wipes, spray bottles and/or buckets, ...etc..
 - Procedure: The disinfection method should be:
 - a) With no patient present
 - b) With approved disinfectants and proper contact times (i.e., surfaces are visibly wet with disinfectant and allowed to air-dry)
 - c) From up downwards, and from less soiled to the more soiled
 - d) Comprehensive to cover all environmental surfaces: surfaces frequently touched by HCWs (e.g., control panel; top, front and sides of dialysis machine; touchscreens; countertops) & surfaces in contact with the patient (e.g., dialysis chair/bed, tray tables, BP cuff with its tubing, TV remote control, ... etc..)

Observation
(O)

- 3) Check the quality of housekeeping activities: observe the presence of dust, soil, stickers ...etc. that demonstrate defective cleaning and disinfection of patients' environment after termination of haemodialysis sessions

Comment (if any):

For successful observation, it is advisable to plan your visit to be during termination of dialysis sessions (i.e., time for cleaning and disinfection of patients' environment)

Ask Nursing staff members about:

1) The processes of internal cleaning & disinfection of dialysis machines:

- Method of disinfection (whether thermal or chemical)
- Temperatures, used chemicals and required concentrations & times.

Their knowledge should be compatible with unit's policy and the actual practices

Ask Nursing staff and housekeeping staff members about:

2) The processes of cleaning and disinfection of haemodialysis patients' environment:

- Frequency: after each shift and at the end of the day
- Responsibilities & used PPE: nursing staff responsibilities & housekeeping staff responsibilities / clean gloves, clean gowns, surgical masks and face shield or goggles
- Supplies: e.g., chemicals and disinfectants, non-linting wipes, spray bottles and/or buckets, ...etc..
- Procedure: with no patient present / with approved disinfectants and proper contact times / comprehensive to cover all environmental surfaces wheter frequently touched by HCWs or in contact with the patient

Their knowledge should be compatible with unit's policy and the actual practices

Comment (if any):

- Instead of direct questions, indirect ones or scenarios are advisable

16**Sub-standard – 25:16**

Water treatment system is regularly maintained with change of filters according to the manufacturer's instructions. (D)

Review the following documents:

- 1) Preventative Maintenance (PPM) schedule for water treatment system.
- 2) Copies of PPM records for regular maintenance for water treatment system (as frequent as recommended by the manufacturer):
 - Regular check-up with replacement of filters as per the manufacturer recommendations
 - Corrective interventions when indicated.
- 3) Copies of records from the executing company (or maintenance records) for regular calibration of monitors of water treatment system (yearly).

17

Sub-standard – 25:17

Cleaning and disinfection of the water treatment and distribution system is performed at least once weekly. Complete dialysis system is considered during the disinfection procedure (water treatment system, distribution system and dialysis machines). (D - SI)

Document
(D)

Review the following documents:

- 1) Documented evidence for the process of cleaning and disinfection of the water treatment components, distribution system and of dialysis machines (appropriate evidence of application: e.g., checklist) and check if the applied process is compatible with manufacturer's recommendation and the approved departmental policy or not.
- 2) The evidence should specify:
 - Frequency of disinfection
 - Method of disinfection (whether thermal or chemical) as per unit's policy
 - Temperatures, used chemicals and required concentrations & times as per approved unit's policy.

Ask Nursing staff members about:

- 1) The processes of internal cleaning & disinfection of dialysis machines:
 - Frequency of disinfection
 - Method of disinfection (whether thermal or chemical) as per unit's policy
 - Temperatures, used chemicals and required concentrations & times.

Their knowledge should be compatible with unit's policy and the actual practices

Staff Interview
(SI)

Ask staff responsible for water treatment and distribution system about:

- 1) The Protocol for cleaning & disinfection of water treatment and distribution system:
 - Frequency of disinfection
 - Method of disinfection (whether thermal or chemical)
 - Temperatures, used chemicals and required concentrations & times.

Their knowledge should be compatible with unit's policy and the actual practices

Comment (if any):

- Cleaning and disinfection of the water treatment and distribution system should be performed at least weekly or as per manufacturer recommendations
- All components of the dialysis system should be considered as one unit during the cleaning and disinfection process (i.e., water treatment system, distribution system and dialysis machines)

Sub-standard – 25:18

Chemical monitoring of treated water is performed semiannually or at least annually or after modifications to the system or occurrence of symptoms suggestive for chemical contamination of the water system (full chemical analysis in an accredited laboratory).

(D, SI)

Document
(D)

Review the following documents:

- 1) Documented evidence for chemical monitoring of treated water (appropriate evidence of application: e.g., chemical testing reports).
- 2) The evidence of chemical monitoring should be:
 - Chemical testing that is compatible with AAMI standards (i.e., detailed quantitative results of required chemicals: aluminum, chloramines, fluoride, copper, zinc, ... etc..)
 - Matched with the MOH-approved frequency: semiannually or at least annually / after modifications to the system / after occurrence of symptoms suggestive for chemical contamination of treated water

Staff Interview
(SI)

Ask haemodialysis nurse in charge or responsible nephrologist about:

- 1) Chemical monitoring of treated water:
 - Approved frequency for chemical testing
 - Approved standards for chemical monitoring
 - Symptoms suggestive for chemical contamination of treated water

Their knowledge should be compatible with MOH guidelines, unit's policy and the actual practices

Ask staff responsible for water treatment system about:

- 1) Chemical monitoring of treated water:
 - Approved frequency for chemical testing
 - Approved standards for chemical monitoring

Their knowledge should be compatible with MOH guidelines, unit's policy and the actual practices

Comment (if any):

- Instead of direct questions, indirect ones or scenarios are advisable

Maximum allowable levels of chemical contaminants as determined by AAMI and their effects if exceeded

Chemical	Contamination level	Effects
Aluminum	0.01 mg/L	Associated with anemia, bone disease, and neurological deterioration; can lead to a progressive syndrome of neurologic deterioration and encephalopathy known as dialysis dementia.
Chloramines (combined chlorines)	0.10 mg/L	Associated with hemolysis, hemolytic anemia, and methemoglobinemia.
Fluoride	0.2 mg/L	Associated with bone disease, pruritus, chest pain, nausea, vomiting, and cardiac arrest due to ventricular fibrillation.
Copper	0.1 mg/L	Associated with chills, nausea, vomiting, and headaches as well as anemia, liver damage, and fatal hemolysis.
Zinc	0.1 mg/L	Associated with nausea, vomiting, fever, and anemia.
Nitrate	2 mg/L	Associated with methemoglobinemia, cyanosis, hypotension, and nausea.
Sulfate	100 mg/L	Associated with nausea, vomiting, and metabolic acidosis.
Calcium Magnesium	2 mg/L (0.1 mEq/L) 4 mg/L (0.3 mEq/L)	Has resulted in a syndrome characterized by nausea, vomiting, muscular weakness, skin flushing, and hypertension or hypotension.
Sodium	70 mg/L (3.0 mEq/L)	Can lead to hypernatremia, increased thirst, and excess water intake.
Source: ANSI/AAMI/ISO . Water for Haemodialysis and related therapies 13959:2009. Association for the Advancement of Medical Instrumentation; Arlington, VA: 2009.		

Sub-standard – 25:19

On-site testing of Chlorine and Chloramines, water hardness, and PH is performed correctly at the beginning of the day and every 4 hours while patients are undergoing Hemodialysis (using commercially available test kits). (D, SI)

Review the following documents:

- 1) Documented evidence for on-site testing of Chlorine and Chloramines, water hardness, and PH:
 - Review the records of individual tests of the same day of the visit.
 - Review the dedicated form for routine regular daily recording (if applicable, check the form of the previous month).
 - Records should include the name(s) of the person(s) responsible for daily check.
 - Records and/or forms should be reviewed by personnel responsible for water treatment system and/or maintenance department (*+ public health personnel and nurse in charge or responsible nephrologist of the unit if results are out of limits*).
 - Review the approved policy for on-site testing of Chlorine and Chloramines, water hardness, and PH that should include approved sites to take water samples and required corrective interventions if results are out of limits.
 - Review the dedicated form for corrective interventions if results are out of limits. These forms should be reviewed by personnel responsible for water treatment system and/or maintenance department and public health personnel (in coordination with nurse in charge or responsible nephrologist) before resuming of dialysis.

Ask haemodialysis nurse in charge or responsible nephrologist about:

- 1) On-site testing of Chlorine and Chloramines, water hardness, and PH:
- Approved frequency of testing
 - Interpretation of results & corrective interventions when allowable levels are exceeded
 - Symptoms suggestive for chemical contamination when allowable levels are exceeded

Their knowledge should be compatible with MOH guidelines, unit’s policy and the actual practices

Ask staff responsible for water treatment system about:

- 1) The Protocol for on-site testing of Chlorine and Chloramines, water hardness, and PH:
- Approved frequency of testing
 - Approved sites for taking water samples
 - Approved methods for testing different parameters
 - Interpretation of results & corrective interventions when allowable levels is exceeded

Their knowledge should be compatible with MOH guidelines, unit’s policy and the actual practices

Comments:

- Approved sites for taking water samples

TDS or conductivity	Raw water
PH	Raw water
Chlorine and chloramine	After the first carbon filter
Water hardness	After the softener

20

Sub-standard – 25:20

Microbiological testing for water and dialysate is conducted at least monthly, and if standards are exceeded, testing is done weekly until meeting standards.

Maximum acceptable level is 100 CFU/ml / action level is 50 CFU/ml. Samples are taken before disinfection of the system from all required sites. (D, SI)

21

Sub-standard – 25:21

Endotoxin testing for water and dialysate is performed at least once per month, and if not up to the standards, testing is repeated weekly until the problem is resolved.

For processed water: maximum acceptable level is 0.25 EU/ml / action level is 0.125 EU/ml.

For dialysate: maximum acceptable level is 0.5 EU/ml / action level is 0.25 EU/ml. (D, SI)

Review the following documents:

1) Documented evidence for microbiological & endotoxin testing for water and dialysate:

- Review microbiological testing reports & dates of these reports
- Review endotoxin testing reports & dates of these reports
- Review the schedule for water and dialysate sampling including sequence of HD machines testing (i.e., rotation of samples so that each machine is tested at least once yearly)
 - Reports should demonstrate **Quantitative Results** (i.e., microbiological testing results in CFU/ml & endotoxin testing results in EU/ml)
 - Reports should be reviewed & signed by personnel responsible for water treatment system and/or maintenance department and public health personnel (in coordination with staff of Haemodialysis unit)
- Review the approved policy for microbiological & endotoxin testing including the required corrective interventions if results are out of limits.
- Review the dedicated form for corrective interventions if results are above the maximal acceptable levels. These forms should be reviewed & signed by personnel responsible for water treatment system and/or maintenance department and public health personnel (in coordination with staff of Haemodialysis unit) before resuming of dialysis.

Document
(D)

Comments:

- Testing requirements and interpretation of renal dialysis fluid and water used for the preparation of dialysis fluid

Hazard/hygiene indicator	Timing/frequency of testing	Result	Interpretation	Action
Bacterial Colony Counts (CFU)	Monthly (or more frequently if necessary)	0 - < 50 / ml	Satisfactory	No action; system under control
		≥ 50 - < 100/ ml	Borderline	Investigate cause and put corrective action in place
		≥ 100 / ml	Unsatisfactory	Take out of use until corrective action implemented
Endotoxin Levels (EU/ml)		0 - < 0.125 EU/ml	Satisfactory	No action; system under control
		≥ 0.125 - < 0.25 EU/ml	Borderline	Investigate cause and put corrective action in place
		≥ 0.25 EU/ml	Unsatisfactory	Take out of use until corrective action implemented

References UK renal association, 2009

Staff Interview (SI)

Ask haemodialysis nurse in charge or responsible nephrologist about:

1) Microbiological & endotoxin testing for water and dialysate:

- Approved frequency of testing
- Interpretation of results (e.g., satisfactory, borderline and unsatisfactory) & corrective interventions when levels are borderline or unsatisfactory
- Symptoms suggestive for bacterial and/or endotoxin contamination when allowable levels are exceeded

Ask staff responsible for taking samples for testing water and dialysate (public health personnel) about:

1) The Protocol for microbiological & endotoxin testing for water and dialysate:

- Approved frequency of testing
- Approved sites for taking water samples & sequence of HD machines testing
- Interpretation of results & corrective interventions when allowable levels is exceeded

Ask staff responsible for water treatment system about:

1) The Protocol for microbiological & endotoxin testing for water and dialysate:

- Approved frequency of testing
- Approved sites for taking water samples & sequence of HD machines testing
- Interpretation of results & corrective interventions when required

Their knowledge should be compatible with MOH guidelines, unit's policy and the actual practices

Comments:

Water samples for Microbiological testing should be obtained & processed correctly:

- Samples are taken before disinfection of the water system or dialysis machines
- Sites of sampling:
 - From Post RO membrane - first point of the water distribution loop (i.e., first outlet or first machine port) - last point of the water distribution loop (i.e., last outlet or last machine port)
 - If a problem with the water system is suspected, additional test sites may be included (e.g., before and after the RO membrane, after the storage tank, before and after deionization tanks, and other locations in the water distribution loop)
 - Test at least 2 machines / month & rotate so that each machine is tested at least once yearly (however more frequent or extensive testing be performed if a problem is suspected (e.g. cluster of patient infections).
 - Obtain sample from the dialysate port of the dialyzer or a sampling port
- Method for taking water and dialysate samples:
 - **Hand Hygiene**
 - Preparation of the port or the outlet:
 - a) Wipe the port with alcohol
 - b) Let it to dry completely
 - c) Run for at least one minute before collection
 - d) Use sterile containers
 - e) Sample site, date, and time should be written on the label of each sample
 - f) Process immediately or refrigerate to retard growth

22

Sub-standard – 25:22

The results of chemical and microbiological testing of water are available and reviewed by responsible nephrologist and infection control practitioners, and actions are taken accordingly. (D - SI)

Review the following documents:

- 1) Documented evidence of reviewing chemical, microbiological and endotoxin testing results by responsible nephrologist and infection control practitioners (e.g. signature):
 - Review last chemical testing reports for signature
 - Review last few microbiological testing reports for signature
 - Review last few endotoxin testing reports for signature
- 2) Documented evidence of corrective interventions as per the approved unit's policy if results are out of acceptable levels (e.g. dedicated form):
 - Review the dedicated form for corrective interventions if results are out of limits. These forms should be reviewed & signed by personnel responsible for water treatment system and/or maintenance department and public health personnel (in coordination with staff of Haemodialysis unit & infection control practitioners) before resuming of dialysis.
 - Review the approved policy for chemical, microbiological and endotoxin testing including responsibility of revision of the testing results and required corrective interventions if results are out of limits.

Document
(D)

Comments:

- Chemical, microbiological and endotoxin testing reports should be reviewed & signed by personnel responsible for water treatment system and/or maintenance department and public health personnel (in coordination with staff of Haemodialysis unit & infection control practitioners)

Ask haemodialysis nurse in charge or responsible nephrologist about:

- 1) Chemical, microbiological and endotoxin testing for water and dialysate:
 - Approved frequency of testing
 - Interpretation of results (e.g., satisfactory, borderline and unsatisfactory) & corrective interventions when levels are borderline or unsatisfactory
 - Symptoms suggestive for chemical, bacterial and/or endotoxin contamination when allowable levels are exceeded

Ask infection control practitioners (& responsible public health personnel if available) about:

- 1) Chemical, microbiological and endotoxin testing for water and dialysate:
 - Approved frequency of testing
 - Interpretation of results (e.g., satisfactory, borderline and unsatisfactory) & corrective interventions when levels are borderline or unsatisfactory
 - Symptoms suggestive for chemical, bacterial and/or endotoxin contamination when allowable levels are exceeded

Their knowledge should be compatible with MOH guidelines, approved unit's policy and the actual practices

Comment (if any):

- Instead of direct questions, indirect ones or scenarios are advisable

23	<p>Sub-standard – 25:23</p> <p>Patient is tested for HBV markers on admission with vaccination of susceptible one. Patient with negative results are periodically re-tested with prompt review of results.</p> <ul style="list-style-type: none"> ○ For unvaccinated patient and vaccine non responder: HBsAg monthly ○ For vaccine responder (anti-HBc –ve & anti-HBs +ve > 10 mIU/mL): anti-HBs annually (D - MR)
24	<p>Sub-standard – 25:24</p> <p>Patient is tested for HCV markers on admission (ALT and anti-HCV – ELISA) Patient with negative results are periodically re-tested with prompt review of results.</p> <ul style="list-style-type: none"> ○ For anti-HCV –ve patient: ALT monthly, and anti-HCV (ELISA) semi-annually ○ For anti-HCV –ve patient with unexplained elevated ALT: Repeated anti-HCV (ELISA) tests ○ For patient with persistent unexplained elevated ALT & repeated anti-HCV –ve tests (ELISA): HCV-RNA (PCR) testing (D - MR)
25	<p>Sub-standard – 25:25</p> <p>Previously HCV +ve patient who was treated with DAAs (Direct Antiviral Agents) and achieved SVR (Sustained Virologic Response) is tested for HCV-RNA (PCR) semi-annually to detect relapse. (D - MR)</p>
26	<p>Sub-standard – 25:26</p> <p>Only patients with risk factors for HIV infection (high-risk behaviors, e.g., injecting drug abuse, sexual activity or tattoos) are tested for HIV markers.</p> <ul style="list-style-type: none"> ○ Routine testing of dialysis patient for markers of HIV infection is not recommended (D - MR)
<p>Document (D)</p>	<p>Review the following documents:</p> <ol style="list-style-type: none"> 1) Documents for serological testing of dialysis patients on admission & periodically (when indicated) with vaccination of susceptible ones: <ul style="list-style-type: none"> - Review records for serological testing of dialysis patients for HBV, HCV and HIV (either hard copies or soft copies / either individual patient’s records or whole unit’s records) - Review special records for vaccination against HBV: <ol style="list-style-type: none"> a) Susceptible unvaccinated patients b) Susceptible patients on vaccination c) Vaccine responder d) Vaccine non responders - List of previously HCV +ve patients who was treated with DAAs (Direct Antiviral Agents) and achieved SVR (Sustained Virologic Response) (hard copy or soft copy) - List of patients with risk factors for HIV infection (high-risk behaviors, e.g., injecting drug abuse, sexual activity or tattoos) (hard copy or soft copy) - Seroconversion rates for HBV & HCV (a whole unit’s record)

Randomly review medical records of patients (from different groups):

- 1) Medical records of **HBV susceptible patients** (unvaccinated patients and vaccine non responders): to check routine monthly testing of HBsAg
- 2) Medical records of **HBV immune patients** (vaccine responders :anti-HBc –ve & anti-HBs +ve > 10 mIU/mL): to check routine testing of anti-HBs annually
- 3) Medical records of **HCV –ve patients** (anti-HCV –ve): to check routine testing of ALT & anti-HCV by ELISA (and HCV-RNA (PCR) when indicated)
- 4) Medical records of **previously HCV +ve patients who are treated and achieved SVR (Sustained Virologic Response)** (anti-HCV +ve): to check routine testing of HCV-RNA (PCR) every 6 months
- 5) Medical records of **patients with risk factors for HIV infection**: to check testing markers of HIV infection

Sub-standard – 25:27

HCWs are tested for HBV, HCV, and HIV upon hiring and vaccine is given for those who are susceptible to hepatitis B
(routine annual serologic testing of HD staff for HBV, HCV and HIV is not recommended) (D - MR)

Review the following documents:

- 1) Documents for baseline serological testing of dialysis staff upon hiring with vaccination of susceptible ones:
 - Review records of staff baseline screening data for HBV, HCV and HIV (either hard copies or soft copies / either individual HCW's record or whole unit's record)
- 2) Evidence of HBV vaccination upon hiring:
 - Review records for vaccination of staff against HBV:
 - a) HD target group & coverage rate
 - b) List of susceptible staff still on vaccination
 - c) List of vaccine responder
 - d) List of susceptible staff (vaccine non responders)

Randomly review 3 - 4 medical records of haemodialysis staff:

- 6) Check for evidence of baseline screening for HBV, HCV and HIV
- 7) Check for evidence of immunity status against HBV upon hiring:
 - Documented vaccination with serological evidence of immunity (i.e., vaccine responder)
 - Documented failed vaccination (i.e., vaccine non responder)
- 8) Check for evidence of administration of vaccine against HBV to HCWs who are susceptible and not previously vaccinated.

Comment (if any):

- Routine annual serological testing of HD haemodialysis staff for HBV, HCV and HIV is no longer recommended, as their risk is not greater than that of other healthcare personnel

28

Sub-standard – 25:28

HVB +ve patients are strictly segregated in a separate room(s), treated by dedicated staff during dialysis sessions using designated machines, equipment, instruments, supplies and medications which are used only for them.

Strict adherence to infection control precautions which is recommended for all dialysis patients efficiently prevents HCV and HIV transmission within the dialysis environment.

No need to isolate patients +ve for HCV and/or HIV (if –ve for HBV) from other patients. It is not required to receive dialysis sessions in separate areas/rooms or to use dedicated machines or supplies. (D - O - SI)

Document
(D)

Review the nursing staff roster to ensure that:

- 1) Number of nursing staff is compatible with number of haemodialysis patients and their distribution on unit's rooms (especially room(s) for HVB +ve patients)
- 2) A dedicated nursing staff is only assigned for HBV +ve haemodialysis patients and strictly not handling any HBV –ve patient outside HBV +ve room(s) during dialysis sessions.

Observation
(O)

Observe room(s) for HBV +ve patients to ensure that they are strictly segregated:

- 1) Physically separated room(s) with accessible hand washing facilities within the room(s).
- 2) Dedicated HD machines
- 3) Designated patients care equipment
- 4) Separate storage for medications, instruments, supplies and consumables (e.g. definite store(s) or cabinet(s) away from patients' zones)
- 5) Assigned nursing staff available within the room(s) during the current shift & whether it is matching the nursing staff roster or not.
- 6) Nursing staff properly use PPE according to infection control precautions which is recommended for all dialysis patients

Ask nursing staff about:

- 1) Current nursing staff roster of the unit.
- 2) Placement of HBV +ve HD patients.
- 3) Equipment used for HBV +ve HD patients
- 4) HD machine used for HBV +ve HD patients
- 5) Stores for medications, instruments, supplies and consumables used for HBV +ve HD patients

Their knowledge should be compatible with MOH guidelines, approved unit's policy and the actual practices

Comment (if any):

- Instead of direct questions, indirect ones or scenarios are advisable

Example: From where can you get any missed or forgotten equipment, medications, supplies or other consumables required for HBV +ve patients during their dialysis sessions?

Answer: Nothing should be missed (i.e., required equipment, medications, supplies and other consumables must be available within the area/room(s) that is(are) dedicated for HBV +ve patients during their dialysis sessions)

Sub-standard -01

There is a written IC policy and procedures for compound sterile preparation (CSP).**(D)**

- ❖ *A CSP is a sterile drug that was prepared by compounding or underwent other handling or manipulation prior to administration. Pharmacy is responsible for preparing & storing most sterile medications.*
- ❖ *Compounding is the process of combining drug ingredients to prepare medications that are not commercially available or to alter commercially available medications to meet specific patient needs such as dye-free or liquid formulations.*
(1)
- ❖ *Understanding the risks inherent in sterile compounding and incorporating established standards are essential for patient safety.*
- ❖ *Patient morbidity and mortality can result from contaminated pharmaceutical items. Sterile pharmaceutical products can become contaminated via two general methods:*
 - a. *Intrinsic contamination: occurs during the manufacturing process.*
 - b. *Extrinsic contamination: occurs subsequent to manufacturing (during the Admixture process or while the infusate is used.*
- ❖ *Infection control breaches that may lead to contamination includes: (CDC)*
 - *Failure to follow aseptic practices (Lack of proper hand hygiene) In*
 - *Lack of trained / qualified personnel performing sterile compounding*
 - *Sterile compounding occurring in absence of proper controls*
 - *Sterile compounding hood adjacent to open window*
 - *Compounding hood disinfected with alcohol of insufficient strength*
 - *Improper storage of sterile medication vials etc.*

Commonly prepared commonly sterile products are susceptible to microbial contamination.

Specific organism has the ability to proliferate in different fluids:

- *Klebsiella, Serratia, and Enterobacter species can multiply in 5% dextrose.*
- *Candida albicans can grow slowly whereas Staphylococcus, Proteus, Escherichia coli, and Pseudomonas aeruginosa die slowly in dextrose*
- *Pseudomonas aeruginosa Acinetobacter, and Serratia will grow in distilled water*
- *Pseudomonas aeruginosa, Enterobacter, and Serratia can grow in lactated Ringer's solutions. Microbial growth, with the exception of Candida species is possible in 0.9% sodium chloride.*

(Further reading : APIC Text Book Pharmacy services chapter 1100

Review:

Policies & Procedures for compound sterile preparation (CSP) which should be **comprehensive** incorporating all aspects of sterile compounding as follows:

Methods for Preventing Contamination of Compounded Sterile Preparations:

❖ Aseptic technique during CSPs: ⁽¹⁾

- Practice aseptic technique to prevent contamination of pharmaceuticals which are associated with epidemics.
- Remove any hand / wrist jewelry and perform hand scrubbing before each procedure.
- Scrub nails, hands, and forearms with antimicrobial soap before handling sterile products.
- Wear a gown closed at the collar with knit cuffs, a facemask, shoe covers, hair covers, and a cover for facial hair, when applicable, upon entering the preparation area.
- Wear sterile gloves before preparing intravenous (IV) admixtures.
- Gloves should be removed when exiting the preparation area.
- Gloved personnel should not touch any surface outside of the hood. Etc.

❖ Engineering Controls CSP: ⁽¹⁾

It is recommended that in preparing compound sterile procedures use a primary engineering control device (e.g., laminar air flow hood (LAFH) or biological safety cabinet (BSC) capable of maintaining International Organization for Standardization (ISO) class 5.

❖ Laminar air flow hood (LAFH) or biological safety cabinet (BSC): ⁽¹⁾

- Operate the LAFH continuously. Before processing sterile products, the hood should be running for a period of time long enough to purge room air from the work area (at least 30 minutes or as per the manufacturer's recommendations).
- Do not disrupt the air flow between the HEPA filter and any sterile objects to avoid contamination.
- Complete all work at least 6 inches from the edge in the interior of the LAFH.

a) Cleaning & disinfection of LAFH: ⁽¹⁾

- 1) Disinfect the work surfaces and all accessible interior surfaces of the hood with a hospital approved disinfectant before beginning work.
- 2) Clean the exterior surfaces of the hood daily with a hospital-approved disinfectant.
- 3) Inspect the containers of the ingredients used to prepare the sterile product for defects, product integrity, and the expiration date.
- 4) Do not use defective or expired products.
- 5) Disinfect the entire surface of all ampoules, vials and containers with 70% isopropyl alcohol before entry into the LAFH, and allow them to air dry.
- 6) Handle all ampoules, vials, needles and syringes in such a way as to maintain asepsis and avoid unnecessary turbulence within the LAFH.

b) Maintenance of LAFH: ⁽¹⁾

- 1) Ensure certification of the LAFH annually, or more frequently as needed, and maintain certification records.

c) Sterile Product Preparation Area: ⁽¹⁾

- 1) Separate the functional areas from other area.
- 2) Should have a controlled airflow under **positive pressure** that should not be disrupted by air ducts, vents or excess traffic that could produce air currents, introducing contaminants.
- 3) Should be free of particle-shedding materials such as cardboard boxes or powdered gloves. Such materials should not be stored in any area surrounding the hood.
- 4) Should not have carpets, drapes or other particulate-shedding materials in the preparation area.
- 5) Should have minimal personnel traffic confined to those persons directly engaged in IV admixture procedures or their supervision. etc.

❖ Authorized Personnel for CSPs:

- 1) Pharmacist and pharmacy technicians are the professionals responsible for the preparation and storage of compound sterile and non-sterile products.
- 2) Failure to follow sterile compounding standards and proper aseptic technique could lead to intrinsic and extrinsic contamination.

❖ Quality Control Monitoring: ⁽¹⁾

- 1) Use single-dose vials whenever possible for admixing parenteral preparations.
- 2) Monitor the temperature of refrigerators used in pharmacy to store medications continuously and set alarms to indicate excessively high or low temperatures.
- 3) Examine the final sterile product for any leaks, cracks, turbidity or particulate matter.
- 4) Label all mixed parental fluids appropriately. ⁽¹⁾

Other domains of Policies & procedures:

P/P for Compound Sterile Preparations should be :

1. **Fully applicable:** all elements of the policy can be applied and comply with the hospital's scope of services
2. **Based on scientific references** approved by MOH (**GCC, CDC, WHO & APIC**)
3. **Signed** from authorized personnel (i.e., owner of the policy / hospital director or Medical director / concerned department)
4. **Approved** by IC committee
5. **Valid** (updated within 2 - 3 years and when indicated).

2

Sub-standard - 02

Compound sterile preparation (CSP) is restricted to competent pharmaceutical staff (except during emergency situations), who are familiar with aseptic techniques and proper use of appropriate PPE. (O,SI)

Observation
(O)

Observe:

- ❖ Staff working in Compound sterile preparation (CSP) how the personnel are entering in the CSP i.e. presence of **biometric /coded entrance** for the personnel working in CSP.
- ❖ Staff compliance with appropriate PPE use. Notice if PPE is donned appropriately. Observe for any breach in practice (*e.g. staff moving in out with same set of PPE & frequently touching the surfaces with gloved hands etc.*)
- ❖ Observe if authorized personnel working in CSP are familiarized with rules of aseptic technique and adhering strictly to it.

(e.g. Hand hygiene , Use a sterile device (e.g., a needle) each time a vial is accessed and avoid touch contamination of sterile supplies , Disinfect the rubber stoppers of containers and the diaphragms of vials with 70% alcohol wipe prior to use. etc.)

Staff Interview
(SI)

Interview:

- ❖ Compounding personnel working in CSP about their privileges and authorization to work in CSP.
- ❖ Ask which staff will be assigned to work in CSP during *emergency /contingency situations* & if they are trained on compound sterile preparation (CSPs) including PPE use and rules of aseptic technique.
- ❖ Inquire CSP personnel regarding last comprehensive training on aseptic technique and PPE use.
- ❖ Ask randomly selected staff to demonstrate hand hygiene technique & PPE donning & doffing.

(NOT all authorised to work and enter in CSP apart from privilege or special condition)

3

Sub-standard -03

Compound sterile preparation (CSP) room/area is a functionally separate facility which is under positive pressure. **(D,O)**

Document
(D)

Review the following documents:

- ❖ Log sheet with records of positive pressure differentials (at least one month) of **+2.5 pascals**,
- ❖ Observe if there are any deranged values in the past and evidence / document for necessary action taken by CSP personnel to address the issue **(If any)**

Observation
(O)

Observe:

- ❖ The location of Compound sterile preparation (CSP) room/area if physically separated from other areas of pharmacy.
- ❖ Availability of pressure gauge / fixed monitor for continuous monitoring of positive pressure differentials.

(Monitor must have inbuilt audiovisual alarm system to alert staff in case of deranged pressure gradients.)

4

Sub-standard -04

The doors of the compound sterile preparation (CSP) room/area are equipped with an auto-closure mechanism. **(O)**

Observation
(O)

Observe:

- ❖ The doors of the compound sterile preparation (CSP) room are equipped with an auto-closure mechanism.
- ❖ Self-closing doors / doors with auto closure mechanism will ensure pressure control inside the CSP room.

5 **Sub-standard –05**
Mixing IV medications is performed in laminar air flow hood or safety cabinet, with air supplied through High-Efficiency Particulate Air (HEPA) filter.(D,O)

Document
(D)

Review

- ❖ Manufacturer’s manual of ***laminar air flow hood or safety cabinet*** that must be available in the unit. (***Laminar air flow hood or safety cabinet*** is designed to generate laminar air flow and supplied air is through **HEPA Filter** installed in the opening channel of hood / biosafety cabinet)
- ❖ Document stating last time when HEPA **Filter** was being changed. (PPM for the safety cabinet/hood, quality monitoring and checking of safety cabinet/hood)

Observation
(O)

Observe:

- ❖ Compounding personnel practices when they are working inside the CSP area.
- ❖ If all mixing of IV medication inside the laminar flow safety cabinet/hood or not.

Laminar Flow Cabinets create particle-free working environments by projecting air through a filtration system and exhausting it across a work surface in a laminar or uni-directional air stream. They provide an excellent clean air environment

Laminar airflow is defined as air moving at the same speed and in the same direction, with no or minimal cross-over of air streams (or “lamina”).

6

Sub-standard –06

Compound sterile preparation (CSP) room/area is cleaned and disinfected with an approved detergent/disinfectant and assigned staff are well trained on cleaning / disinfection process. **(D,O,SI)**

Document
(D)

Review

- ❖ Cleaning and disinfection schedule of the Compound sterile preparation (CSP) room/area

(Roles and responsibilities of CSP personnel & housekeeping during cleaning process must be specified. (Authorized and trained housekeeping must be dedicated for housekeeping surfaces ONLY i.e. Floors, walls, ceilings, HW sinks, emptying trash receptacles etc.)

- ❖ Check for MSDS of disinfectant used in CSP.

Observation
(O)

Observe:

- ❖ Type of Detergent/disinfectant are being used (**Check for active ingredients and expire dates**) & verify if approved by MOH.
- ❖ How the process of cleaning and disinfection is being carried out inside the CSP room. (**Technique i.e. from inside to outside, from top to down etc.**).
- ❖ If floor and other areas are kept clean and tidy. (*Randomly wipe any surface to confirm.*)
- ❖ Place where cleaning equipment and detergent / disinfectants are being kept.

Staff Interview
(SI)

Interview:

- ❖ Housekeeping about his responsibility in cleaning process and frequency of cleaning.
- ❖ Type of disinfectants / detergents they are using with dilutions & contact time etc.
- ❖ Ask if they have dedicated mops for CSP and how mop heads are processed after use.

7

Sub-standard –07

Working surface (under the laminar air flow hood) is regularly disinfected by an approved disinfectant using non-linting wipes. (O,SI)

Observation
(O)

Observe:

- ❖ How the compounding personnel are disinfecting the working surface (under the laminar air flow hood) (**Observe technique & type of disinfectant being used if possible to observe real situation**)
- ❖ Availability of disinfectant inside CSP to ensure the disinfectant process.
- ❖ If non linting wipes are available & used.

Comments:

A lint free cloth is a special type of cleaning cloth that does not give up any fluff / fibers when used and less likely to generate electrostatic charges.

Staff Interview
(SI)

Observe:

- ❖ Ask compounding personnel about frequency of cleaning of LAFH working surface.
- ❖ Ask her / him to explain technique, type of disinfectant being used & contact time etc.

(Preferably disinfection process to be documented in daily log sheets after each work process / work shift on LAFH in order to promote accountability and proof)

8

Sub-standard –08

Maintenance records for hoods and safety cabinets are available. **(D)**

Document
(D)

Review:

- ❖ Quality control records & Periodic Preventive Maintenance (PPM) records of hoods and safety cabinets
(Ensure certification of the LAFH annually, or more frequently as needed, and maintain certification records. ⁽¹⁾)
- ❖ Check for validity of LAFH certificate / PPM.
 - *Maintenance records should include functionality, HEPA filter change etc.)*
 - *All maintenance records must be kept in the CSP, documentation only with maintenance department isn't enough.*

Comment (if any):

PPM is Planned Preventive Maintenance / Periodic Preventative Maintenance.

9

Sub-standard –09

All supplies and containers used in CSPs preparations are sterile. **(O,SI)**

Observation
(O)

Observe:

- ❖ Availability of all supplies and containers in the CSP & confirm if they are sterile.
- ❖ Observe if supply is stored at appropriate storage areas. *(Sometimes huge amount of sterile supply is kept in the anteroom with increased risk of contamination)*

(Example of sterile supply : Sterile gloves , gowns, syringes, single use containers like ampules, single dose vials, IV bags, irrigation bottles etc. and multidose vials MDVs

Interview:

Staff Interview
(SI)

- ❖ Compounding personnel regarding type of supplies and containers are being used during compound sterile preparations.
- ❖ Ask how to ensure sterility of containers??
Pharmaceutical container is a device in which drug is enclosed & is in direct contact with drug.
(E.g. single dose containers, multidose containers .light resistant containers, aerosol containers etc.

Ensuring sterility of all supply during compounding is of utmost important in order to avoid contamination & subsequent infection risk to patients.

REFERENCES / WEB BASED RESOURCES:

20. *GCC Infection Prevention & Control Manual 3rd Edition 2018 – ICM -VIII- 03 PHARMACY : (Page 254 – 258)*
21. *APIC text of Infection Control & Epidemiology: Pharmacy Services*
[http:// text.apic.org/toc/infection-prevention-for-support-services-and-the-care-environment/pharmacy-services](http://text.apic.org/toc/infection-prevention-for-support-services-and-the-care-environment/pharmacy-services)
22. *Association for Professionals in Infection Control (APIC) and Epidemiology, Inc. (2014). Chapter 30: Aseptic technique. In APIC Text of infection control and epidemiology (4th ed.).*
23. *United States Pharmacopeial (USP)2004, Convention published the first national standards and enforceable standards for **compounded sterile preparations (CSP) to protect patients against preventable harm** (i.e., General Chapter 797-Pharmaceutical Compounding-Sterile Preparations).*

1

Sub-standard – 27:01

There are a written policies and procedures for infection control in OR including a clear policy to handle patients under Air-borne Infection Isolation Precautions inside OR (e.g., TB). (D)

Document
(D)

Review the policy, which should be:

- ❖ Comprehensive: it covers all aspects of infection control in OR including special protocols to handle patients with infectious transmissible diseases and patients under Air-borne Infection Isolation Precautions (e.g.,TB) inside OR .
- ❖ Fully applicable: all elements of the policy can be applied and comply with the hospital's scope of services
- ❖ Based on scientific references approved by MOH (GCC, CDC, WHO & APIC)
- ❖ Signed from authorized personnel (i.e., owner of the policy / hospital director or medical director / concerned department)
- ❖ Approved by IC committee*
- ❖ Valid (updated within 2 - 3 years and when indicated)

Comment (if any):

- Approval by IC committee is required for the infection control manual as a whole before distribution and also for individual policy after major changes

Sub-standard – 27:02

There is a clear demarcation between unrestricted, semi-restricted and restricted zones of OR with restrictions and special precautions for movement between these zones. (O - SI)

Observe the OR suite that should be divided into three clearly demarcated zones*:

Unrestricted area: area with limited public access that may include

- 5) Central control point: it may be established to monitor the entrance of patients, personnel, and materials from the unrestricted area into the semi-restricted area .
- 6) Locker rooms: lead into semi-restricted area
- 7) Pre-operative admission area .
- 8) Offices & waiting areas .
- 9) Post-anesthesia care units (PACUs).

Semi-restricted area: (Peripheral support areas of the surgical suite)

- 1) Corridors leading from the unrestricted area to the restricted area of the surgical suite .
- 2) Storage areas for clean and sterile supplies

Restricted area: A designated space with restricted access that can be reached only through a semi- restricted area (this is primarily intended to support high level of asepsis control not necessarily for security purposes):

- 1) Operating rooms
- 2) Scrub stations (large scrub sink close to or at entry of operating room).
- 3) Areas for preparation of sterile surgical instruments and supplies (opening of sterile surgical sets & sterile field preparation), which directly leads to operating rooms

Observe traffic control (movement of the patients, personnel, instruments and materials) between different zones of the OR suite: to ensure that restrictions and special precautions for movement between different zones are strictly applied

Unrestricted area:

- 1) Limited public access / Street clothes are permitted in this area / Patients are switched between units' beds and OR trolleys or beds in this area

Semi-restricted area:

- 2) Limited access to authorized personnel and patients accompanied by authorized personnel / Personnel in this area were wearing surgical attire and covering head and facial hair / No units' beds in this area (only OR trolleys or beds)

Restricted area:

- 3) Restricted access to authorized personnel and patients / Personnel in these areas are required to wear surgical attire and cover head and facial hair - masks are required where open sterile supplies or scrubbed persons may be located + appropriate use of sterile gowns and sterile gloves when indicated (operating room scrub clothing).

Staff Interview
(SI)

Ask the OR staff about:

restrictions, traffic control and special precautions to be applied in different zones of the OR suite (e.g., required PPE in different zones)

3

Sub-standard – 27:03

Floors, walls, ceiling are: formed of one piece without connections, cracks, or decorative parts, with minimal openings that are completely sealed, and withstand repeated cleaning and disinfection. (O)

Observation
(O)

Observe the internal finishing of the operating theater (floors, walls and ceilings), which should be :

- 7) Formed of one piece without connections (if formed of separate units or tiles, connections between units should be completely sealed)
- 8) No breaks, gaps, cracks or decorative parts are observed
- 9) Only necessary openings (i.e., O₂ supply ports, suction ports, electricity plugs ...) that are completely sealed to keep pressure differences
- 10) Made of suitable materials (easily cleanable / withstand repeated cleaning and disinfection).

4

Sub-standard – 27:04

A large deep scrubbing sink with hands free control is available at the entry of each operating theater. (O)

Observation
(O)

Observe the scrubbing sink(s) of the operating theater(s), which should be:

- 1) Large, deep and with hands free control
- 2) Close to or at the entry of each operating theater.
- 3) Dedicated only for hand hygiene & surgical scrubbing
- 4) Provided with dispenser of antiseptic hand soap for surgical hand hygiene (ideal to be single use dispenser not refillable) and disposable surgical scrubbing brushes/sponges

Comment (if any):

- One large scrubbing sink, which is shared between two adjacent operating theaters is an acceptable option.

5

Sub-standard – 27:05

Storage areas in the OR are organized and well maintained. (D - O)

Document
(D)

Review the following documents:

- 1) Housekeeping recodes: housekeeping schedule with clear procedures for cleaning/disinfection activities at least daily + practical detailed checklists
- 2) Local records for regular monitoring (daily) of temperatures and relative humidity

Observation
(O)

Observe the storage area(s) of the OR, which should be:

- 1) Of adequate capacity, well maintained, secured and away from contamination, air vents and direct sunlight.
- 2) Well organized and regularly cleaned according to definite housekeeping schedule / no personal items, foods or drinks / no items are kept in the original shipping boxes
- 3) Storage shelves are made of easily cleanable material (e.g., fenestrated stainless steel, Aluminum or hard plastic).
- 4) Storage shelves: 40 cm from the ceiling, 20 cm from the floor, and 5 cm from the wall.
- 5) Centrally air conditioned with adjusted temperature and relative humidity (temperature: 22 - 24°C / relative humidity: up to 70%) + fixed device for monitoring

6	<p>Sub-standard – 27:06 Only necessary items are kept in the restricted area of the OR. (O - SI)</p>
7	<p>Sub-standard – 27:07 Doors are kept closed and only necessary personnel are allowed in the theater (O - SI)</p>
<p style="writing-mode: vertical-rl; transform: rotate(180deg);">Observation (O)</p>	<p>Observe the restricted area of the OR (operating theater), which should fulfill the following:</p> <ol style="list-style-type: none"> 1) Unnecessary items are kept outside: Only items prepared to be used with just one patient, and extra supplies, as little as possible, may be also prepared to get ready for some emergency situations. 2) The use of storage cabinets in operating rooms should be minimized 3) Unnecessary personnel are excluded: Only anesthesia team + surgical team + unscrubbed assistant(s) + equipment technician(s) if needed (as little as possible) 4) Cleaning/maintenance activities should be avoided during the procedures 5) Doors are continuously kept closed during the procedures
<p style="writing-mode: vertical-rl; transform: rotate(180deg);">Staff Interview (SI)</p>	<p>Ask the OR staff about:</p> <ol style="list-style-type: none"> 1) Pre-operative preparation of operating room & how to apply concept of “Only necessary items are kept in the restricted area” 2) Protocols to exclude unnecessary personnel (e.g., unauthorized HCWs, trainees, visitors ...) / conducting cleaning/maintenance activities inside operating room

8

Sub-standard – 27:08

OR environment is maintained clean and there are clear procedures for cleaning and disinfection by allocated housekeeping staff after each surgical procedure and at least daily. (D - O - SI)

Document
(D)

Review the following documents:

- 1) OR should have housekeeping schedule with cleaning/ disinfection activities log that records:
 1. Responsible housekeeping staff (Only experienced staff are allowed. They should be well trained on hand hygiene, use of PPE, methods of cleaning, and proper and safe mixing of chemicals).
 2. Methods of cleaning and used agents, materials and supplies (wet cleaning, MOH approved disinfectant/detergent, non-linting wipes ...)
 3. Environmental surfaces intended to be cleaned & frequency.
 4. Clear procedures for cleaning/disinfection activities after each surgical procedure and at least daily with practical updated detailed checklist.
 5. Clear procedures for cleaning and disinfecting anesthesia machines by anesthesia technicians after each case and toward the end of working hours with practical detailed checklist.

Observation
(O)

Observe OR to ensure that:

OR environment is clean (at all times) and free of contamination (no dirt or dust): you can wipe out the main operative light lamp, operative table, or other environmental surfaces / check if tools, agents & materials used for cleaning/disinfection activities are available and matching MOH standards.

Staff Interview
(SI)

Ask the OR nurse (nurse in charge or nurse responsible for theater) and allocated housekeeping staff about:

OR housekeeping schedule / nurse role & responsibility in cleaning/disinfection activities / methods of cleaning / tools, agents & materials to be used / terminal cleaning checklists / cleaning/disinfection activities after patients with infectious transmissible diseases / handling body fluids spills.

9	Sub-standard – 27:09 Ventilation system operates all the time and never shuts down even in long holidays / air is introduced from the ceiling and exhausted near the floor. (D - O - SI)
10	Sub-standard – 27:10 All re-circulated or fresh air is filtered through High-Efficiency Particulate Air (HEPA) filters that are maintained and replaced as per the manufacturer recommendations. (D)
11	Sub-standard – 27:11 Operating Room is maintained at positive pressure (at least +2.5 Pascal) with respect to adjacent corridors. (D - O)
12	Sub-standard – 27:12 Operating room ventilation is maintained at a minimum of 15 or 20 air changes per hour (ACH) with 20% fresh air. (D - O)
13	Sub-standard – 27:13 Operating Room temperature ranges from 21 to 24 °C and relative humidity from 20% to 60%. (D - O)

Document (D)	<p>Review the following documents:</p> <ol style="list-style-type: none"> 1) Copies of the original charts or project scheme for ventilation system: air supply from central AC through with at least 20 % fresh air / all re-circulated and fresh air is filtered through High-Efficiency Particulate Air (HEPA) filters / air is introduced from the ceiling (or high air vents in the wall) and exhausted near the floor. 2) Local records for regular monitoring (daily) of: positive pressure differences + temperatures and relative humidity ± air changes per hour (ACH) with corrective interventions if readings are not matching the acceptable values 3) Copies of maintenance records for regular monitoring (every 3 months) of: positive pressure differences + temperatures and relative humidity + air changes per hour (ACH) with corrective interventions if readings are not matching the acceptable values. 4) Copies of records from the executing company (or maintenance records) for regular check-up and replacement High-Efficiency Particulate Air (HEPA) filters as per the manufacturer recommendations. 5) Copies of records from the executing company (or maintenance records) for regular calibration (annually) of OR monitors.
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Observation (O)	<p>Observe OR theater to ensure that:</p> <ol style="list-style-type: none"> 1) Air is introduced from the ceiling (or high air vents in the wall) and exhausted near the floor 2) OR monitors are valid and recorded values in local OR logs are identical to the actual readings
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Ask the OR staff (nurse in charge or nurse responsible for theater) about:

- Handling ventilation system of the OR during long holidays.
- Local controls for the OR ventilation system (e.g., presence of a local On/Off switch / adjustment of the ventilation parameters on personnel's request)

Ask the maintenance staff responsible for the OR ventilation system about:

- Handling ventilation system of the OR during long holidays.
- Central adjustment of temperatures and relative humidity
- Local controls for the OR ventilation system (e.g., presence of a local On/Off switch / adjustment of the ventilation parameters on personnel's request)

Sub-standard – 27:14

Patients with infectious transmissible diseases, are scheduled towards the end of the operating list. (D - SI)

Review the following documents:

- 1) OR policy: to review handling patients with transmissible diseases (patient +ve for one of blood borne pathogens / patients under air-borne transmission-based precaution / patients under contact and/or droplet transmission-based precaution) / scheduling cases with infected wounds (e.g., dirty wounds).
- 2) Operating lists: to review the last event for dealing with patients with transmissible diseases or cases with infected wounds.

Ask the OR staff (nurse in charge or nurse responsible for theater) about:

- 1) Proper handling of patients with transmissible diseases (patient +ve for one of blood borne pathogens / patients under air-borne transmission-based precaution / patients under contact and/or droplet transmission-based precaution)
- 2) Appropriate management of cases with infected wounds (e.g., dirty wounds)
- 3) Cleaning/disinfection activities after patients with infectious transmissible diseases or cases with infected wounds

1

Sub-standard – 28:01**There is a written policy and procedures for IC in the laboratory. (D)****Review the policy, which should be:**

- 1) Comprehensive: it covers all aspects of infection control in the laboratory, including (but not limited to):
 - Laboratory biosafety
 - Laboratory aerosol generating procedures / Biological Safety Cabinets (BSC) & other containment devices
 - Infection control practices: Hand hygiene / PPE / Transporting and handling of biohazardous materials / Infectious waste management (specially high risk laboratory waste as cultures plates) / Environmental cleaning & disinfection / Dealing with different types of spills ...etc.
 - Reporting, follow up and management of occupational exposures: sharp injuries, blood or body fluid exposures and chemical exposures
 - Biosafety in mycobacteriology laboratory that manipulates suspected or confirmed cultures of *Mycobacterium tuberculosis* (*if applicable*)
- 2) Fully applicable: all elements of the policy can be applied and comply with the hospital's and/or laboratory's scope of services.
- 3) Based on scientific references approved by MOH (GCC, CDC & WHO)
- 4) Signed from authorized personnel (i.e., owner of the policy / medical director or hospital director / concerned department)
- 5) Approved by IC committee*
- 6) Valid (updated within 2-3 years and when required).

Document
(D)**Comment (if any):**

- Approval by IC committee is required for the infection control manual as a whole before distribution and also for individual policy after major changes

2

Sub-standard – 28:02**Access is restricted with a sign incorporating the universal biohazard symbol posted at the entrance. (O)**Observation
(O)**Observe the laboratory entrance:**

- 1) There is a sign that indicates “restricted area – for authorized personnel only”.
- 2) There is an universal bio-hazard sign posted at the entrance.

3

Sub-standard – 28:03

Eating, drinking, handling contact lenses, and storing food are not permitted. (O – SI)

Observation
(O)

Observe different laboratory area(s) and supplies' refrigerator(s):

- 5) To exclude the presence of any foods or drinks.

Staff Interview
(SI)

Ask the laboratory staff:

- 1) Where can they take their break
- 2) Where can they handle contact lenses and lipsticks

4

Sub-standard – 28:04

All manipulations of infectious materials that may generate aerosols are properly contained or conducted in a biological safety cabinet (BSC - class II-B). (O – SI)

Observation
(O)

Observe the laboratory area(s):

- 1) If biological safety cabinet (BSC) is available, determine its class: it should be class II-B (*exhaust air from BSC discharged to outside through HEPA filters*)
- 2) If biological safety cabinet (BSC) is not available or not used, aerosol generating procedures are properly contained.

Comment (if any):

Aerosol generating procedures include blowing out pipettes, shaking or vortexing tubes, stirring, opening snap top tubes, breakage of culture containers, flaming loops or slides, pulling needles out of septa, filling a syringe, pouring liquids, centrifugation steps such as filling centrifuge tubes, removing plugs or caps from tubes after centrifugation, removing supernatant, breakage of tubes during centrifugation, and centrifugation itself

Biosafety Cabinet:

Biosafety cabinet is primary containment device designed to draw air inward by mechanical means in order to contain infectious splashes or aerosols generated during certain laboratory procedures. There are three types of biosafety cabinets, class I, II and class III. Most laboratories use class I and class II cabinets.

Class 1: Ventilated negative pressure cabinet, which is usually operated with an open front and inward airflow at a minimum velocity of 75 linear feet/minute (75 lfpm) to protect personnel (not product protection).

Class 2: Ventilated negative pressure cabinet, which is designed with inward airflow at a velocity to protect personnel (75 – 100 linear feet/minute (75 - 100 lfpm)); HEPA-filtered downward vertical laminar airflow for product protection and HEPA-filtered exhaust air for environmental protection. These are further subdivided into two types (A and B) based on construction, airflow velocities and patterns, and exhaust systems.

Class 2, Type A: Type A cabinets are suitable for microbiological research in the absence of volatile or toxic chemicals and radio-nucleotides, since air is recirculated within the cabinets. The HEPA filtered air is conducted into the room.

Class 2, Type B: Type B cabinets are hard-ducted to the building exhaust system and contain negative pressure plenum. Type B permit work to be done with toxic chemicals or radio-nucleotides. The HEPA filtered air is conducted outside the room.

Class 3 or Glove box: Class 3 are totally enclosed, ventilated cabinet of gas-tight construction and offers the highest degree of personnel and environmental protection from infectious aerosols, as well as protection of research materials from microbiological contaminants. Operations are conducted through attached rubber gloves. Both supply and exhaust air are HEPA filter.

Notes:

- HEPA filters (High efficiency particle air filter). It removes the bacteria, viruses, fungi and spores by 99.97% efficiency.
- Biosafety cabinets should be tested and certified at the time of installation within the laboratory, at any time the BSC is moved, and at least annually

Staff Interview
(SI)

Ask the laboratory staff:

- 1) What are the aerosol generating procedures inside the laboratory
- 2) How can they handle aerosol generating procedures in presence or absence of biological safety cabinet (BSC) (proper containment)
- 3) What are the safety measures that are required during operation of biological safety cabinet (BSC)

5

Sub-standard – 28:05

Biological Safety Cabinets (BSC - class II-B) dedicated for aerosols generating procedures are well maintained, tested and certified at least annually. (D)

Document
(D)

Review the following documents for the biological safety cabinet (BSC):

- 1) Copy of maintenance records: PPM and Quality control records for the last 2 years
- 2) Valid annual certificate from authorized company

6

Sub-standard – 28:06

Whenever possible, plastic tubes are used instead of glass ones to avoid sharp injuries. (O – SI)

Observation
(O)

Observe the laboratory area(s):

- 1) To exclude the presence of any glass tubes.

Staff Interview
(SI)

Ask the laboratory staff:

- 1) Is there a need to use glass tubes during some procedures inside the laboratory?
- 2) What are the indications for using glass tubes inside the laboratory (if any)?

7

Sub-standard – 28:07

Each work area contains a dedicated well equipped sink for washing hands together with easily accessible eyewash facility to be used in emergency in case of exposure to blood and body fluids. (D – O – SI)

Document
(D)

Request documents for periodic maintenance and regular testing of eyewash station.

Observation
(O)

-Observe the laboratory area(s) for the presence of easily accessible dedicated sink for handwashing at each working area which well equipped with paper-towel and soap dispensers.

-Observe the laboratory area(s) for easily accessible eyewash station for emergency in case of accidental exposure to blood and body fluids.

Staff Interview
(SI)

Ask the laboratory staff:

-What are the first aid measures in case of exposure to blood or body fluid splashes inside the laboratory (if any)?

8

Sub-standard – 28:08

Specimen collection and receiving area are equipped with hand washing facilities, waterless hand hygiene facilities (optional) and proper PPEs. (O)

Observation
(O)

Observe the specimen collection area and receiving area for:

- 1) The availability of easily accessible hand washing facilities and supplies (sinks with hot & cold water / plain soap / towels) and other waterless hand hygiene facilities (alcohol - based hand rub dispensers).
- 2) The availability of PPEs (as regard their quantities and qualities)

9

Sub-standard – 28:09

Mycobacteriology Laboratory that manipulates cultures suspected or confirmed to contain Mycobacterium tuberculosis complex is at least Biosafety Level III Laboratory (BSL-3 laboratory). (D – O – SI)

Document
(D)

Request the following documents:

- ❖ Special policy with definite procedures for manipulating suspected or confirmed cultures of Mycobacterium tuberculosis in the mycobacteriology laboratory
- ❖ Copies of the original charts or project scheme for ventilation system inside mycobacteriology laboratory: one-pass (non-recirculating) separated ventilation system / directional airflow pattern is from clean to least clean area / exhaust air is filtered through High-Efficiency Particulate Air (HEPA) filters.
- ❖ Local laboratory records for regular monitoring (**daily recording by laboratory staff**)* of negative pressure differences \pm air changes per hour **ACH** (optional) with corrective interventions if readings are not matching the acceptable values
- ❖ Copies of maintenance records for regular monitoring (**recording by maintenance team every 3 months**)* of negative pressure differences + air changes per hour (mandatory **6 – 12 ACH**) with corrective interventions if values are out of acceptable range
- ❖ Preventative Maintenance (PPM) schedule for Biological Safety Cabinet - BSC with copies from PPM records for regular maintenance in the last 2 years (regular check-up with replacement of filters as per the manufacturer recommendations - corrective interventions when indicated).
- ❖ Valid annual certificate for BSC - class II-B from authorized company

Observation
(O)

Observe the suite specified for growth and manipulation of TB cultures:

- 1) Separate suite specifically designed for mycobacterial culture (i.e., isolated from other parts of building with a controlled entrance through an anteroom)
- 2) The availability of biological safety cabinet and its class (Biological Safety Cabinet Class II, or III with exhaust air discharged to outside through HEPA filters).
- 3) Ventilation monitoring device in culture area (to record negative pressure differences \pm air exchanges per hour **ACH**): it is valid and recorded values in local laboratory logs are identical to the actual readings

Ask the laboratory staff:

- 1) What is meant by Biosafety Level III?
- 2) What is meant by BICSL & N95 fit testing?
- 3) Show me your card of BICSL license (it should be a valid license)
- 4) How do you safely operate Biological Safety Cabinet – BSC or other containment devices?
- 5) How do you correctly manipulate cultures suspected or confirmed to contain Mycobacterium tuberculosis complex?
- 6) How can you report a lab? Technician who had exposed who had exposed to a case of open pulmonary TB?

Comment (if any):

- Instead of direct questions, indirect ones or scenarios are advisable.

Sub-standard – 28:10

Microbiological cultures should be autoclaved within the laboratory in an autoclave that is placed in appropriate location and fulfils quality control parameters (except cultures for organisms not mentioned in the approved list of highly infectious microorganisms, that could be double packed and send to the contractor for final disposal as infectious medical waste. (D – O – SI)

Review the following documents:

- 1) Log book for the autoclave that must have the loads number and date.
- 2) Quality performance tests for the autoclave operation (results of physical indicators (bowie dick), chemical indicators and biological indicators).
- 3) Infection control list of highly infectious microorganisms that their cultures must be autoclaved in the laboratory department before being disposed as infectious medical waste. (the list mentioned below)

Observe the following:

- 3) Presence of working autoclave in a dedicated well ventilated place that is physically separated from other areas in the department.
- 4) Presence of the autoclavable bags that are used to sterilize the culture plates to avoid adherence of the load in the autoclave chamber.
- 5) Availability of physical indicator (bowie dick), chemical indicator strips and biological indicator.

Review the staff knowledge about :

- 7) Cultures that must be destroyed before being disposed in yellow biohazard bags.
- 8) Awareness about the list of that cultures and samples.
- 9) The method of disposal of the cultures that not included in the list

Comment (if any):

- Instead of direct questions, indirect ones or scenarios are advisable.

AGENTS TO BE DESTROYED ONSITE BEFORE DISPOSAL		
NO	Pathogen type	Select agents
1	Viruses	Crimean-Congo hemorrhagic fever virus; Ebola viruses; Cercopithecine herpesvirus 1 (herpes B virus); Lassa fever virus; Marburg virus; monkeypox virus; South American hemorrhagic fever viruses (Junin, Machupo, Sabia, Flexal, Guanarito); tick-borne encephalitis complex (flavi) viruses (Central European tick-borne encephalitis, Far Eastern tick-borne encephalitis [Russian spring and summer encephalitis, Kyasnaur Forest disease, Omsk hemorrhagic fever]); variola major virus (smallpox virus); and variola minor virus (alastrim) Exclusions: Vaccine strain of Junin virus (Candid. \#)
2	Bacteria	Rickettsia prowazekii, R. rickettsii, Yersinia pestis, TB, Brucella
3	Fungi	Coccidioides posadasii
4	Toxins	Abrin; conotoxins; diacetoxyscirpenol; ricin; saxitoxin; Shiga-like ribosome inactivating proteins; tetrodotoxin Exclusions: The following toxins (in purified form or in combinations of pure and impure forms) if the aggregate amount under the control of a principal investigator does not, at any time, exceed the amount specified: 100 mg of abrin; 100 mg of conotoxins; 1,000 mg of diacetoxyscirpenol; 100 mg of ricin; 100 mg of saxitoxin; 100 mg of Shiga-like ribosome inactivating proteins; or 100 mg of tetrodotoxin
5	Genetic elements, recombinant nucleic acids, and recombinant organisms	<ul style="list-style-type: none"> • Select agent viral nucleic acids (synthetic or naturally-derived, contiguous or fragmented, in host chromosomes or in expression vectors) that can encode infectious and/or replication competent forms of any of the select agent viruses; • Nucleic acids (synthetic or naturally-derived) that encode for the functional form(s) of any of the toxins listed in this table if the nucleic acids: <ol style="list-style-type: none"> a. are in a vector or host chromosome; b. can be expressed <i>in vivo</i> or <i>in vitro</i>; or c. are in a vector or host chromosome and can be expressed <i>in vivo</i> or <i>in vitro</i>; • Viruses, bacteria, fungi, and toxins listed in this table that have been genetically modified.

11

Sub-standard – 28:11

Working surfaces and equipment are regularly cleaned and disinfected. (D – O – SI)

Document
(D)

Review the following documents:

- 1) Housekeeping schedules for the laboratory environmental surfaces and equipment & checklists.
 - Who is responsible for housekeeping (authorized and trained staff)
 - What are procedures or methods of cleaning/disinfection activities and list of environmental surfaces intended to be cleaned
 - Which housekeeping ingredients and equipment are used (detergent/disinfectant MSDS, preparation, usage, contact time, precautions and required PPE).
 - How frequent housekeeping activities are indicated with practical detailed checklist

Observation
(O)

Observe the laboratory environment for the following:

- 1) To exclude the presence of any dust or dirt.
- 2) To exclude the presence of any blood or body fluid spills.
- 3) The availability of housekeeping ingredients, supplies and equipment (as regard their quantities and qualities)
- 4) The availability of biological and chemical spill kits.

Staff Interview
(SI)

Ask the laboratory staff (lab. technicians) and allocated housekeeping staff about:

Laboratory housekeeping schedule / lab. technicians role & responsibility in cleaning/disinfection activities (e.g., recommended procedure for cleaning and disinfection of certain equipment) / methods of cleaning / tools, agents & materials to be used / handling blood or body fluids spills / handling spills of chemicals.

12

Sub-standard – 28:12

Laboratory personnel perform hand hygiene and wear appropriate PPE when indicated. **(O – SI)**

Observation
(O)

Observe (2 - 3) of the laboratory staff or laboratory housekeeping personnel:

- 1) To evaluate how they are properly performing hand hygiene (Indications for HH "5 moments" / Technique / Duration)
- 2) To evaluate how they are correctly using PPE according to the standard and transmission-based precautions (Indications for use / Technique of donning & doffing / Safety measures during use)

Staff Interview
(SI)

Ask (2 - 3) of the laboratory staff or laboratory housekeeping personnel:

- 1) When HH is required (Indications for HH "5 moments")?
- 2) To do hand hygiene in front of you to evaluate how they are properly performing hand hygiene (Technique / Duration)
- 3) How to select appropriate PPE / When to wear / When to remove (Indications for use / Safety measures during use)?
- 4) To use some PPE in front of you to evaluate how they are correctly using PPE (Technique of donning & doffing / Safety measures during use)

1

Sub-standard – 29:01**There are written IC policies and procedures for the dental setting. (D)****Review the policy, which should be:**

- ❖ Comprehensive and well descriptive: it covers all aspects of infection control practices in dental unit including (but not limited to):
 - Hand hygiene
 - Recommended PPE (gloves: nitrile or butyl rubber or sterile [sterile when performing surgical procedures], mask/respirator, goggles/face shield and gowns [sterile gowns-when performing surgical procedures])
 - Aseptic technique for parenteral medication (use of multi dose vials)
 - Cleaning and disinfection of equipment: classification as per Spaulding criteria to be sent to CSSD for reprocessing (None of the critical and semi critical equipment reprocessing to be carried out in dental clinic), transportation of items to CSSD, MSDS of chemicals that being used in cleaning and disinfection, storage rules for sterile and clean dental supplies
 - Dental prostheses and prosthodontic cleaning and disinfection, handling of extracted teeth, handling of biopsy specimen
 - Dental unit waterline disinfection technique and water quality testing
 - Precautions in dental radiology unit
 - Employee safety: staff immunization as per employee clinic policy, exposure and post exposure management
 - Environmental cleaning and disinfection: including clinical contact surfaces and housekeeping surfaces with use of surface barriers
 - Single used devices and waste management
- ❖ Fully applicable: all elements of the policy can be applied and comply with the hospital's scope of services
- ❖ Based on scientific references approved by MOH (Manual of Infection Prevention and Control in Dental Setting, Second Edition - 2018, GCC, CDC, WHO & APIC)
- ❖ Signed from authorized personnel (i.e., owner of the policy / hospital director or medical director / concerned department)
- ❖ Approved by IC committee*
- ❖ Valid (updated within 2 - 3 years and when indicated)

Document
(D)**Comment (if any):**

- Approval by IC committee is required for the infection control manual as a whole before distribution and also for individual policy after major changes

2	<p>Sub-standard – 29:02</p> <p>No reprocessing of instruments is carried inside the dental clinic (all the contaminated items are sent to the central sterilization department). (O,SI)</p>
3	<p>Sub-standard – 29:03</p> <p>All reusable dental instruments (critical and semicritical dental items) are sent to CSSD after each patient. (O,SI)</p>
4	<p>Sub-standard – 29:04</p> <p>Contaminated dental instruments including dental handpieces are transferred to the central sterilization department in a closed, sealed, and puncture resistant containers. (O,SI)</p>
5	<p>Sub-standard – 29:05</p> <p>If transportation to CSSD is not expected within two hours, instruments inside transferring containers are sprayed with transportation gel/spray before sending them. (O,SI)</p>
<p style="writing-mode: vertical-rl; transform: rotate(180deg);">Observation (O)</p>	<p>Observe reprocessing of the critical items and the semi critical items, which should be :</p> <ol style="list-style-type: none"> 11) The critical and semi critical items must not be reprocessed in dental unit (must be sent to CSSD for reprocessing) 12) Preparation of dirty equipment before being sent to CSSD: <ul style="list-style-type: none"> - Collection of used equipment in closed, sealed, and puncture resistant containers - Spraying of Pre Klenz spray or any other surfactant-based gel with corrosion inhibitors [if transportation is not expected within two hours according to the hospital policy, e.g., items are collected and sent once daily] 13) If there is a separate room for temporary storage of used equipment before sending to CSSD: <ul style="list-style-type: none"> - It must be an area with limited access, and closed when not in use - The door must be labelled with BIOHAZAD sign - No equipment should be left exposed or outside the transportation container (see container specification above)

Ask the dental staff about:

- 1) Spaulding classification of items and which items are needed to be sent for reprocessing in CSSD
- 2) Preparation of dirty equipment and sending them to CSSD (i.e. collection in closed, sealed, and puncture resistant containers / spraying of Pre Klenz spray or any other surfactant-based gel with corrosion inhibitors if transportation is not expected within two hours / when and how used equipment are transported to CSSD).

Comment (if any):

Instead of direct questions, indirect ones or scenarios are advisable

6**Sub-standard – 29:06**

Single-use devices (e.g., disposable examination set, anesthesia carpule/cartridge, etc.. ...) are discarded immediately after each patient. (O, SI)

Observation
(O)

Observe all the single used items, which should be :

- 1) Single-use device is used only once (used on one patient, discarded appropriately after being used)

General guidance:

- Single-use devices in dentistry (e.g., needles, prophylaxis cups and brushes, and plastic orthodontic brackets.) are not heat-tolerant and cannot be reliably cleaned.
- Certain items (e.g., prophylaxis angles, saliva ejectors, high-volume evacuator tips, and air/water syringe tips) are commonly available in a disposable form and should be disposed of appropriately after each use.
- Handle disposable items aseptically. If an item is stored in a bulk container or package, use an aseptic technique when retrieving it (e.g., use sterile cotton pliers to retrieve an item for use).
- Dispense disposable items in small amounts (i.e., unit dose) sufficient for care of one patient before treatment begins and discard whatever is not used.
- Any single-use device or item (e.g., cotton rolls, gauze, and irrigating syringes) used during oral surgical procedures should be sterile at the time of use.

Comment (if any):

REFERENCE: Manual of Infection Prevention and Control in Dental Setting, Second Edition, 2018

Staff Interview
(SI)

Ask the dental staff about:

- 1) Universal label for SUDs 'single use only' on packed items
- 2) Can single-use device be reused?

Comment (if any):

Instead of direct questions, indirect ones or scenarios are advisable, Examples:

“In emergency situations, how these items are disinfected properly before being used for other patients?” / “what are the situations that justify the reuse of SUDs and precautions that should be strictly followed?”

- The answer should be reuse of SUDs is prohibited

7

Sub-standard – 29:07

If needles with self-sheathing mechanism and recapping devices are not available, dental care personnel use one-handed recapping (scoop technique) for recapping needles (O,SI)

Observation
(O)

- 5) Observe for the presence of needles with self-sheathing mechanism or other safety design
- 6) Observe for the presence of recapping devices
- 7) If such items are not available, observe the staff for the use of one-handed recapping /scoop technique to recap needles.

Staff Interview
(SI)

Ask the dental staff about:

- 1) The proper use of needles with self-sheathing mechanism or other safety design
- 2) The proper use of recapping devices
- 3) If such items are not available, ask the staff to demonstrate or explain what is one-handed recapping /scoop technique.

8

Sub-standard – 29:08

Clinical contact surfaces (contaminated and frequently touched surfaces in the patient-care area): light handles, bracket trays, switches on dental units, computer equipment are either barrier protected or cleaned and disinfected after each patient. (D, O, SI)

Document
(D)

Review housekeeping recodes:

- 3) Housekeeping schedule with clear procedures for cleaning/disinfection activities
- 4) Dental staff & housekeeping staff responsibilities: Who is responsible to clean and disinfect which part/item (e.g., highly touch clinical surfaces, computers, dental chairs, light handles, tray, dental chair sinks, floor, wall etc.)

Observation
(O)

- 1) Observe the clinical and other highly touched contact surfaces (light handles, bracket trays, switches on dental units, computer equipment, telephone, drawer handles, etc.), whether they are protected by surface barriers or not.
- 2) If surface barriers are used: observe for the availability of surface barrier rolls / observe how frequently surface barriers are changed (they should be changed after every patient)
- 3) If surface barriers are not available:
 - Observe the disinfectants that are being used
 - Observe how surface disinfectants are being used (e.g., back and forth procedure for cleaning and disinfection isn't advisable)
 - Observe whether contact time is correct or not
 - Observe where disinfectants are being stored (e.g., away from clinical surfaces and supplies, preferably in separate cabinet or stock room).

Ask the dental staff:

- 1) How the clinical and other highly touched contact surfaces (light handles, bracket trays, switches on dental units, computer equipment, telephone, drawer handles, ... etc.), are being protected by surface barriers
- 2) How frequently surface barriers are being changed (they should be changed after every patient)
- 3) If surface barriers are not available:
 - What are the disinfectants that are being used
 - How surface disinfectants are being used (e.g., back and forth procedure for cleaning and disinfection isn't advisable)
 - What is the proper contact time that should be followed
 - How disinfectants are being stored (e.g., away from clinical surfaces and supplies, preferably in separate cabinet or stock room).

Comment (if any):

- Instead of direct questions, indirect ones or scenarios are advisable
- You can ask kitchen staff to demonstrate procedures that they are applying

Sub-standard – 29:09

Housekeeping surfaces (e.g., floors, walls, and sinks) cleaned with water and detergent or disinfectant/detergent on a routine basis or when they are visibly dusty or soiled. (D, O, SI)

Review housekeeping recodes:

- 1) Housekeeping schedule with clear procedures for cleaning/disinfection activities
- 2) Dental staff & housekeeping staff responsibilities: Who is responsible to clean and disinfect which part/item (e.g., highly touch clinical surfaces, computers, dental chairs, light handles, tray, dental chair sinks, floor, wall ... etc..)

- 6) Observe the housekeeping surfaces, whether they are clean or not (by using wet tissue or gauze to wipe different housekeeping surfaces especially difficult to reach surfaces, e.g. corners, top surfaces and underneath equipment).
- 7) Observe the housekeeping supplies that are being used (detergents, disinfectants and other supplies e.g. lint free wipes ... etc..)
- 8) Observe how housekeeping staff are preparing the disinfectant(s), if applicable (i.e. dilution procedure: water to disinfectant(s) ratio)
- 9) Observe how disinfecting solution(s) are being used (e.g., back and forth procedure for cleaning and disinfection isn't advisable) / whether contact time(s) is(are) correct or not
- 10) Observe where housekeeping staff are keeping their supplies (observe the janitor's room, if available).

Ask the housekeeping staff:

- 1) How frequent housekeeping surfaces are cleaned & disinfected guided by cleaning schedule (if available)
- 2) What are the housekeeping supplies that are being used (e.g., detergent, disinfectants and other supplies e.g. lint free wipes ... etc..)
- 3) How to prepare housekeeping disinfectant(s), if applicable (i.e. dilution procedure: water to disinfectant(s) ratio)
- 4) What is(are) the correct contact time(s) that should be followed
- 5) How disinfecting solution(s) are being used (e.g., back and forth procedure for cleaning and disinfection isn't advisable)
- 6) How housekeeping supplies are being stored (e.g., ask to see the janitor's room, if available)

10	<p>Sub-standard – 29:10</p> <p>Appropriate dental unit waterlines treatment products and devices are used to ensure that water quality meets regulatory standards for drinking water during routine dental treatment. Disinfection of dental unit waterlines is performed as per manufacturer's recommendations. (D,SI)</p>
11	<p>Sub-standard – 29:11</p> <p>A pooled water sample taken from all dental unit waterlines (e.g., air water syringe, handpiece, ultrasonic scaler) is tested at least semiannually (the maximum acceptable level is 500 CFU/ml of heterotrophic water bacteria).(D,SI)</p>
Document (D)	<p>Review the following documents:</p> <ol style="list-style-type: none"> 1) Check and review if manufacture's instruction copy & documentation evidence of daily waterline treatment are available and dental staff is following the manufacturer's recommendations for treating dental unit waterlines 2) Documentation evidence of: <ul style="list-style-type: none"> - Flushing lines for several minutes each morning - Flushing handpieces with air/water for 20 to 30 seconds between patients (CDC, OSAP, ADA). 3) Check and review the QUANTITATIVE results of microbiological sampling of water being used in dental clinics. QUALITATIVE results (i.e., Positive and negative results) that are observed in some facilities are not acceptable. <p>Reference & further reading: Manual of Infection Prevention and Control in Dental Setting, Second Edition, 2018</p>
Staff Interview (SI)	<p>Ask the dental staff:</p> <ol style="list-style-type: none"> 1) What is the applied protocol for dental waterline treatment / what are the supplies that are being used, if applicable / how & how frequent the above mentioned procedure(s) is(are) performed (All answers must match manufacture's recommendation) 2) To demonstrate verbally the process of dental unit flushing: <ul style="list-style-type: none"> - Flushing lines for several minutes each morning - Flushing handpieces with air/water for 20 to 30 seconds between patients (All answers must match approved recommendation, i.e., CDC, OSAP, ADA). 3) Who is(are) responsible for taking water samples / what is(are) the applied technique(s) of collecting water samples / which containers are being used for taking samples / what are the different sites to be included in the water sampling process (must be all sites, i.e. turbine handpieces, ultrasonic scalers, three-way air/water syringes ...etc..) <p>Reference & further reading: Manual of Infection Prevention and Control in Dental Setting, Second Edition, 2018</p>

12

Sub-standard – 29:12

During surgical procedures, only sterile solutions are used as a coolant / irrigant using an appropriate delivery device. (O,SI)

Observation
(O)

- 1) Observe supplies of sterile solutions that are used in dental surgical procedures and check for opened sterile solution bottle(s) that is (are) not discarded after being used for one patient (e.g. sterile saline, sterile water).

Comment (if any):

For irrigation, curved Needles are used, observe the availability of such devices

Staff Interview
(SI)

Ask the dental staff:

- 1) What is (are) the type(s) of sterile solution(s) being used for different dental surgical procedures / How sterile solution(s) is (are) being used for different dental surgical procedures (i.e., either for single patient, or for multiple patients)

Comment (if any):

Instead of direct questions, indirect ones or scenarios are advisable, Examples:

“How they are preserving opened sterile bottles for the next patient?” / “For how long, sterile solution(s) can be used after opening safely?”

- The answer should be we never preserve any opened sterile solution, because it can be used for one patient only

Sub-standard – 29:13

Dental care personnel apply standard precautions while performing dental x-rays. (O,SI)

Surfaces that should be protected prior to radiographic procedures:

- 1) Tubehead/yoke
- 2) X-ray cone
- 3) Control panel
- 4) Exposure button
- 5) Headrest
- 6) Headrest adjustment control
- 7) Chair adjustment control
- 8) Work area or countertop

Infection Control Practices BEFORE film exposure:

- 1) **Before the patient is seated:** The DHCW should unit dose the following items: preprocedural mouthrinse; paper towels; surface disinfectant; surface barriers; gloves; radiographic film(s); sterile or disposable film holders; paper cups or plastic bags; over- gloves; lead apron with thyroid collar; and cotton rolls. The patient should rinse with a preprocedural mouthrinse to reduce the number of oral microorganisms and minimize the potential for cross-contamination via direct contact .
- 2) **After the patient is seated:** Adjust the headrest and chair position. Place the lead apron with thyroid collar. Have the patient remove any items that may interfere with film exposure (eye- glasses, dentures, and so forth). After completing these procedures, the DHCW should wash his or her hands thoroughly and don gloves. If using reusable film-holding devices, they should be removed from the sterilized package and assembled. All of these steps should be performed in the patient's presence.

Infection Control Practices DURING film exposure:

- 1) The DHCW should touch as few surfaces as possible; those surfaces should be barrier- protected.
- 2) Dry each film with a paper towel after taking it from the patient's mouth to remove excess saliva.
- 3) Place the film in a disposable container such as a paper cup or plastic bag before transporting it to the processing area.
- 4) Do not touch the disposable container while wearing contaminated gloves .
- 5) During exposures, film-holding devices should be transferred to a covered work sur- face protected by a surface barrier
- 6) If the DHCW must leave the work area during film exposure, gloves must be removed and hands washed. Before resuming with film exposures, the hands should be washed again and new gloves donned.

Infection Control Practices AFTER film exposure:

- 1) After use, reusable film-holding devices should be placed in an area designated for contaminated instruments.
- 2) All disposable contaminated items (for example, cotton rolls, bitewing tabs, paper towels, and surface barriers) should be discarded in accordance with local and state environmental regulations; gloves should be worn when handling them.
- 3) The DHCW should unwrap all covered surfaces carefully while ensuring that the underlying surface remains untouched with the contaminated gloves.
- 4) The gloves should be removed and hands washed once all contaminated items are re- moved and disposed. At that point, the lead apron may be removed and the patient dismissed from the x-ray exposure area .
- 5) Any uncovered areas that were contaminated during the procedure should be cleaned and disinfected using an EPA-registered, hospital-grade, tuberculocidal disinfectant. Because these disinfectants can be skin irritants, DHCWs should wear utility gloves when using them. Remember that chemical germicides may affect the control panel’s electrical connections, so avoid applying them too liberally.

Infection Control Practices FOR film exposure:

- 1) Exposed films should be transported to the processing area in a disposable container such as a paper cup or plastic bag. The container should never be touched with contaminated, gloved hands .
- 2) Prior to taking the films to the processing area, the gloves should be removed, the hands washed, the area cleaned up, and the patient dismissed .
- 3) The following items should be unit dosed in the processing area prior to starting the pro- cessing procedure: gloves; paper towels; paper cups; and film mount or paper envelope .
- 4) The gloves, paper towels, and paper cups are necessary for film handling prior to processing .
- 5) A paper envelope or film mount is used to hold and store the film(s) after processing and should be labelled with the patient’s name and date.

Procedures for Handling films WITH film barrier:

- Place a paper towel on the work surface.
- Next to the paper towel, place the disposable container containing the films. Don gloves.
- Remove one contaminated film from the container.
- Open the film barrier, carefully avoiding contact with the film packet.
- Allow the film packet to drop onto the paper towel.
- Dispose of the film barrier.
- After all film barriers have been opened, dispose of the container.
- Remove gloves and wash hands.
- Secure the door and turn out the darkroom lights (if applicable).
- Unwrap and process the films, handling them by the film edges only .

Label a film mount or paper envelope with the patient’s name and date, using it to hold the processed films

Procedures for Handling films WITHOUT film barrier:

- Place a paper towel on the work surface .
- Place the disposable container containing the films next to the paper towel .
- Secure the door and turn out the darkroom lights (if applicable) .
- Don gloves .
- Remove one contaminated film from the container .
- Open the film packet tab, slide out the lead foil backing and black paper, and discard the film packet wrapping .
- Rotate the lead foil away from the black paper and discard as per local/state regulations .
- Open the black paper wrapping without touching the film and allow the film to drop onto the paper towel.
- Discard the black paper wrapping .
- Discard the container after all film packets have been opened .
- Remove gloves and wash hands .
- Process films, handling them by their film edges .
- Label a film mount or paper envelope with the patient's name and date and use it to hold the processed films .
- Any area touched by contaminated, gloved hands should be cleaned and disinfected

Procedures For Handling Films WITHOUT Film Barrier In An Automated film processor having a day light loader:

- Place a paper towel on the surface inside the daylight loader compartment.
- Place a paper cup and powder-free gloves in the daylight loader compartment.
- Place the container with contaminated films next to the paper cup.
- Close the daylight loader lid and place hands through the sleeves.
- Don gloves.
- Remove one contaminated film from the container .
- Open the film packet (as advised before)
- Allow the film to drop onto the paper towel or processor film feed slot.
- Dispose of the film packet contents in the empty paper cup.
- After all film packets have been opened, remove gloves and place them in the paper cup. Feed all unwrapped films into the processor, handling them only by their edges. Remove hands from daylight loader.
- Wash hands.
- Lift the lid of the daylight loader to remove all contents. Label a film mount or paper envelope with the patient's name and date, using it to hold the processed films.

Infection Control Practices during EXTRA ORAL Radiographic Procedures:

- Prior to taking an extraoral radiograph, the DHCW should wash his or her hands .
- The patient should rinse with a preprocedural mouthwash before the procedure. If barriers are used, they should be placed before positioning the patient. After the procedure, ask the patient to remove the barrier on the bite guide (or the disposable bite guide) and place it in the regular waste bin .
- If this procedure is performed by the DHCW, he or she should don gloves before removing the contaminated item. The gloves should be discarded and hands washed prior to handling the film cassette .
- For hygienic purposes, the patient chin rest, head-positioning guides, and handgrips can be barrier-protected or cleaned after film exposure. Since patient secretions normally do not contaminate extraoral cassettes, cassettes can be handled with ungloved hands .
- No other infection control steps are necessary for processing.

Reference & further reading: Manual of Infection Prevention and Control in Dental Setting, Second Edition, 2018

14	<p>Sub-standard – 29:14</p> <p>Dental lab personnel adhere to standard precautions while performing dental lab procedures. (O,SI)</p>
15	<p>Sub-standard – 29:15</p> <p>Before handling dental prostheses and prosthodontics materials in the dental lab (e.g., impressions, bite registrations, and occlusal rims), they are cleaned and disinfected according to manufacturer’s instructions. (O,SI)</p>
<p style="writing-mode: vertical-rl; transform: rotate(180deg);">Observation (O)</p>	<p>If dental prostheses, impressions and other prosthodontic materials are cleaned & disinfected manually:</p> <p>Observe the applied technique(s) of cleaning & disinfection:</p> <ul style="list-style-type: none"> - Check how these materials are collected and cleaned? (e.g., safe handling of soiled items and appropriate PPE being used to prevent exposure / rinsing under running water to remove visibly saliva and blood / gently scrubbing with a hair head brush [i.e., artists brush] and a liquid detergent / rinsing under running water after cleaning) - Check what is (are) disinfectant(s) being used / what is (are) the used method(s) (i.e., spraying, short term submersion or immersion methods / what is (are) the contact time(s) used for disinfectant(s) (e.g., immersion time) / what are PPE being used to prevent aerosol exposure (e.g., gloves and mask)
	<p>In case of automated cleaning of dental prostheses, impressions and other prosthodontic materials:</p> <p>Observe the applied technique(s) of cleaning & disinfection:</p> <p>Check what is (are) disinfectant(s) being used / how frequent is (are) disinfectant(s) being changed (or mechanical reprocessor automatically activates alarm when it should be changed) / if routine regular PPM of automated reprocessor(s) is available / availability of MSDS of used chemicals.</p>

Ask the dental staff:**If dental prostheses, impressions and other prosthodontic materials are cleaned & disinfected manually:**

- 1) Ask the dental staff to demonstrate applied technique(s) of cleaning & disinfection:
 - How these materials are collected and cleaned? (e.g., safe handling of soiled items and appropriate PPE being used to prevent exposure / rinsing under running water to remove visibly saliva and blood / gently scrubbing with a hair head brush [i.e., artists brush] and a liquid detergent / rinsing under running water after cleaning)
 - What is (are) disinfectant(s) being used / what is (are) the used method(s) (i.e., spraying, short term submersion or immersion methods / what is (are) the contact time(s) used for disinfectant(s) (e.g., immersion time) / what are PPE being used to prevent aerosol exposure (e.g., gloves and mask)

In case of automated cleaning of dental prostheses, impressions and other prosthodontic materials:

- 1) Ask the dental staff about demonstrate the applied technique(s) of cleaning & disinfection:
 - How they install the dental impressions/prosthesis in automated reprocessor and what cycle(s) is (are) being selected
 - What is (are) disinfectant(s) being used / how disinfectant(s) is (are) being stored?
 - How frequent is (are) disinfectant(s) being changed (or mechanical reprocessor automatically activates alarm when it should be changed)
 - Is routine PPM of automated reprocessor(s) is regular performed?
 - Availability of MSDS of used chemicals.

Comment (if any):

Instead of direct questions, indirect ones or scenarios are advisable

1

Sub-standard – 30:01

There is a written policies and procedures addressing dietary services and kitchen staff hygiene. (D)


Review the policy, which should be:

- ❖ **Comprehensive and well descriptive: it covers all aspects of infection control practices in dietary unit including (but not limited to):**
 - **Infection control practices:** i.e. frequent hand hygiene (hand hygiene: moments, techniques and times of hand hygiene) and personal hygiene practices, recommended PPE (gloves, hair covers, masks) to be used, maintaining clean attire during food preparation and handling
 - **Pre-Employment Screening & Periodic Evaluation:** are required for food handler and other supporting staff in dietary unit, which include (and not limited to) clinical examination, investigations [chest x-rays blood, and stool analysis] and vaccination with periodic evaluation i.e. biannually and after returning from long vocations
 - **Work restriction policy:** which includes that diseases or conditions in which the staff refrain from coming to work and present to employee's clinic, no staff is allowed to join back until he/she has lab evidence of free of disease (specially diarrheal disease)
 - **Components of dietary unit:** receiving, storage, preparation, display, transporting and serving, equipment (separate for different foodstuffs, e.g., vegetables and meat)

Design and construction considerations: sequential handling of the product from the receiving dock, into the storage area, to the preparation area, process area, packaging area, and serving area, location of hand hygiene facilities, slopping of floor for proper draining ... etc..

- **Temperature Requirements:**
 - A temperature range for dry storage from 10 °C to 21 °C
 - **Low-temperature storage maintenance:** Fruit and vegetables (except those in dry storage): from 4 °C to 7 °C / Dairy products, eggs, meats, poultry, fish, and shellfish: from 0 °C to 4 °C / Frozen foods: from -18 °C to -23 °C
 - High-risk food must be heated to at least 74 °C (all parts of the food item), and once the food has been heated to this temperature it should not be allowed to drop under 60 °C until it is served. Food may be rapidly reheated up to a temperature of 74 °C etc..
 - Leftover cooked foods should be chilled to 5°C or less within 2 to 4 hours of preparation
 - Backup system for any shortfall or malfunctioning and steps to be taken in such conditions

Document
(D)

- 
- Isolation precautions: precautions to be followed for serving foods to patients under isolation (Contact, Droplet or Airborne Isolation), BICSL & Fit Testing (if applicable)
 - Water quality testing (microbiologically & chemically)
 - Waste management (collection schedule and storage of waste in an area, which is physically separated from other working areas),
 - Environmental cleaning and pest control
 - ❖ Fully applicable: all elements can be applied and comply with the hospital's scope of services
 - ❖ Based on scientific references approved by MOH (GCC, CDC, WHO & APIC)
 - ❖ Signed from authorized personnel and approved by IC committee*
 - ❖ Valid (updated within 2 - 3 years and when indicated)

Comment (if any):

Approval by IC committee is required for the infection control manual as a whole before distribution and also for individual policy after major change

2

Sub-standard – 30:02

Kitchen staff practice hand hygiene properly and use suitable PPE while handling food.
(O - SI)

Observe the kitchen staff for:

- 1) Hand washing/hand rubbing
 - a) TIME (20-30 sec ABHR, 40-60 Sec HW)
 - b) TECHNIQUE (completely and thoroughly)
 - c) Moments of hand hygiene for dietary staff:
 - Before starting work
 - After using the toilet
 - After touching their ears, nose, mouth, or hair
 - After handling raw food
 - Before moving from a raw food preparation area to cooked food preparation area
 - After handling food or food waste
 - Before and after any cleaning procedures
 - Before & after eating, drinking, or smoking
 - After handling soiled articles or trash and
 - After removing PPE, e.g., gloves
- 2) Appropriate use of PPE:
 - a) Disposable protective gloves should be worn when serving food and/or handling cooked and uncooked food
 - b) Proper protective clothing should be worn when required, which include clean uniforms, aprons, hair nets, gloves, masks and closed shoes (open sandals and bare feet are prohibited in the food handling areas).

Observation
(O)

Ask the kitchen staff about:

- 1) Hand Hygiene (hand washing/hand rubbing): times / techniques / moments of hand hygiene
- 2) Protective clothing & PPE: types / indications / technique & sequence of donning and doffing

Randomly ask 3 to 5 of the kitchen staff:

- 3) To demonstrate techniques of hand washing/hand rubbing
- 4) To demonstrate donning and doffing of PPE

Staff Interview
(SI)

Comment (if any):

Instead of direct questions, indirect ones or scenarios are advisable

3**Sub-standard – 30:03****Kitchen staff with respiratory infections, gastroenteritis, diarrhea or hand infection's or wounds are restricted from handling food. (D - MR - SI)****Document
(D)****Review the following documents:**

- 3) Check for work restriction policy and related procedures for the dietary staff and kitchen personnel that outline the above-mentioned infections or conditions: respiratory infections, gastroenteritis, diarrhea, hand infections or wounds ...etc..
- 4) Consent form with signature of dietary staff and kitchen personnel (preferably Multilingual: Arabic, English, language of kitchen personnel for better understanding of work restrictions & symptoms that require prompt reporting and follow up

**Medical record
(MR)****Review the following documents:**

- 14) Review documents that demonstrate application of the work restriction policy:
 - Medical sickness reports, which were fulfilled during the last 3 - 6 months for kitchen personnel who were suffering from any of the above-mentioned infections or conditions
 - Evaluation of their infections or conditions in employee's clinic, ER or medical department
 - Investigation & treatment reports
 - Check how the supervisor allows kitchen personnel to join back after recovery (for some infections in which the organism is isolated e.g. C. difficile in stool, the patient must be free of it before joining back his/her duty in the kitchen)

Comment:

- Review files of kitchen personnel who were restricted from work in the last 3 - 6 months to see whether protocols were properly applied or not (the evidence should specify restriction condition, interventions, management and duration of restriction)

**Staff Interview
(SI)****Ask the kitchen staff:**

- 11) Work restriction policy and related infections or conditions (i.e., symptoms or conditions require restriction from handling food: respiratory infections, gastroenteritis, diarrhea or hand infections or wounds)
- 12) How they will inform kitchen's supervisor and follow approved protocols for work restriction
i.e. presenting to employee clinic or emergency department
- 13) How they will be allowed to join back their duties in the kitchen after recovery
i.e., some conditions require specific investigations to ensure that personnel is free of infections before joining back his/her duty

Comment (if any):

- Instead of direct questions, indirect ones or scenarios are advisable

4

Sub-standard – 30:04

Stool tests and cultures are performed routinely upon hiring, every 6 months and after returning from long vacation. Results are reviewed by the employee’s health clinic and the IC team. **(MR - SI)**

Medical record
(MR)

Review the following documents:

- 1) Review medical records that demonstrate proper application of this sub-standard:
 - Check for the presence of upon hiring results of stool tests and cultures, and updated results every 6 month and after returning from long vocations
 - The above-mentioned results are reviewed by **(SIGNED)** employee’s health clinic doctor and IC practitioner for the evidence of viewing the medical records and **promoting accountability**.

Comment:

- Review the file(s) of employee(s) who came from long vocation(s) lastly to see whether protocols were properly applied or not
- Pick/memorize names of 3 - 5 personnel during the visit and ask for their medical records

Staff Interview
(SI)

Ask 3 – 5 of the kitchen staff about:

- 1) Frequency of stool tests and cultures for them
- 2) The last investigations that have been offered to them

Comment (if any):

- Instead of direct questions, indirect ones or scenarios are advisable

5

Sub-standard – 30:05

All of the kitchen staff receive vaccines against hepatitis-A, typhoid and meningococcal meningitis. **(MR)**

Medical record
(MR)

Review the following documents:

- 1) Review medical records that demonstrate proper application of this sub-standard: check for the presence of updated certificates of vaccinations:
 - Hepatitis-A vaccination: every year
 - Typhoid vaccination: every 5 years
 - Meningitis vaccination: every 5 years

Comment:

- Pick/memorize names of 3 - 5 personnel during the visit and ask for their medical records

6

Sub-standard – 30:06

Kitchen is designed as physically separated areas with specified equipment & supplies (e.g., Mixers, juicers, boards, plates, knives ... etc.) for different types of food. Boards, plates and knives used to cut meat, poultry, fish or vegetables are identifiably separated (color- coded) and immediately washed after use.

(O,SI)

Observe the kitchen to ensure that:

- 1) All specific areas are (**physically**) separated from each other:
 - Store of grocery
 - Storage for meat (i.e., freezers)
 - Storage for vegetables and fruits (i.e., refrigerators)
 - Washing area for vegetables and fruits (with or without) vegetable and salad cutting area.
 - Meat cutting area: it should be separated from other cutting areas (Vege and salad etc..) with specified equipment & supplies e.g. cutting boards and knives should be color coded and separate for poultry, meat and fish. Sawing machines can be same but proper cleaning is required before processing different type of meat.
 - Food cooking/preparation areas, process area & packaging area (all these activities can be grouped together without physical separation).
- 2) There are specified equipment & supplies (e.g., Mixers, juicers, , boards, plates, knives ... etc..) for different types of food.
- 3) There is orderly sequential handling of the product from the receiving area to the storage area, the preparation area, processing area, packaging area, and serving area.
- 4) Boards, plates and knives used to cut meat, poultry, fish or vegetables are identifiably separated (color- coded) and immediately washed after use.
- 5) There is a signboard for color-codes of boards, plates and knives that displays colors to be used for different purposes (e.g., cutting meat, poultry, fish or vegetables)
- 6) There is no signs of over usage of cutting boards (e.g., cutting boards are not cracked or having deep cuts)

Observation
(O)

Comments:

- Cutting boards with cracks or deep cuts cannot be cleaned and disinfected properly.
- Wooden cutting boards aren't acceptable

Staff Interview
(SI)

Ask the kitchen supervisor and/or kitchen personnel:

- 1) About which boards, plates and knives are used to cut meat, poultry, fish or vegetables and if they are clearly identified by different colors
- 2) What is the schedule of washing boards and knives
- 3) How are boards, plates and knives being washed

Answer: immediately after use in working area or dumped to be washed later on in dishwasher (i.e., it is not acceptable to leave them for a day or to the end of shift i.e. morning, afternoon or evening)

Comment (if any):

- Instead of direct questions, indirect ones or scenarios are advisable

7

Sub-standard – 30:07

Adequate numbers of hand washing facilities and/or hand rub antiseptic devices are available. (O)

Observation
(O)

Observe the kitchen to ensure that:

- 1) There are adequate hand washing facilities equipped with all required supplies and/or Alcohol Based Hand Rub (ABHR) dispensers
- 2) Definition of adequate hand hygiene facilities:
 - Adequate refers to presence of hand hygiene facility within the working area (i.e., personnel does not need to leave his working area to reach a hand hygiene facility of another area)
 - Adequate also refers to presence of **DEDICATED** hand washing facility with proper supplies apart from sinks used for any other working purposes (i.e., sinks used for washing vegetables and fruits are not acceptable)

Comments:

- Hand washing facility should be easily accessible (i.e., easy to reach within the working area or very close to it)
- Hand hygiene facilities are inadequate, if a kitchen personnel who is working in vegetable cutting area or meat cutting area, has to go to food processing area or another area to practice HH).

8

Sub-standard – 30:08

Temperature requirements and protection from contamination are considered during receiving, storage, preparation, display and transportation of food. Freezers & fridges temperatures are continuously monitored and documented on log sheets and relevant actions are taken. (D,O,SI)

Document
(D)

Review the following documents:

- 1) Temperature logs and records of the last month that should be maintained at all given areas (temperature checks are done at least twice a day)

Temperature Requirements:

- A temperature range for dry storage from 10 °C to 21 °C

Low-temperature storage maintenance:

- Fruit and vegetables (except those in dry storage): from 4 °C to 7 °C
 - Dairy products, eggs, meats, poultry, fish, and shellfish: from 0 °C to 4 °C
 - Frozen foods: from -18 °C to -23 °C
 - High-risk food must be heated to at least 74 °C (all parts of the food item), and once the food has been heated to this temperature it should not be allowed to drop under 60 °C until it is served. Food may be rapidly reheated up to a temperature of 74 °C etc..
 - Leftover perishable cooked foods should be chilled to 5°C or less within 2 to 4 hours of preparation
- 2) Planned Preventive Maintenance (PPM) and Quality check for freezers, refrigerators, transport trolleys (if applicable) and temperature display monitors
 - 3) Interventions records for atypical temperatures and failure situations

Observation
(O)

Observation:

- 1) Check temperature display monitors or thermometers at all given areas
- 2) See how the temperature requirements is being monitored during food cooking and reheating (i.e., observe the availability of food thermometer to make sure cooked food reaches a temperature hot enough to kill germs)
- 3) See how the food is being packed and saved during serving to overcome contamination by external factors. (i.e., observe the availability of close containers and/or surface barriers)
- 4) See valid PPM stickers on refrigerators, freezers and transport trolleys (if applicable)

Ask the kitchen supervisor and/or kitchen personnel:

- 1) What are optimal temperatures requirements during receiving, storage, preparation, display and transportation of food?
- 2) Who is (are) responsible for recording temperatures at different areas?
- 3) In malfunctioning or failure situations, what is the approved protocol and steps to be taken in such case:
 - What are the components of backup system (if applicable)
 - Who will be contacted
 - Who will be responsible for taking actions (i.e. calling for maintenance, discarding of food if necessary, ... etc..) & follow up

9

Sub-standard – 30:09

Water used for cooking is supplied by commercially approved companies or hospital water that is tested at least monthly to ensure that its quality meets regulatory standards for potable water (D - SI)

Document
(D)

Review the following documents:

- 1) Water testing results of the last 6 months (microbiological and chemical testing of water that should meet the regulatory standards of potable water).
- 2) Records for maintenance & interventions (as per hospital policy) if the water testing results don't match the acceptable standards for potable water.
- 3) Contract with commercially approved company for supplying water, if the kitchen is using ready-made water for cooking (i.e., no need for testing water microbiologically & chemically BUT the supply chain of the water must be checked)

Staff Interview
(SI)

Ask the kitchen supervisor and/or kitchen personnel:

- 1) Who will be responsible for collecting water samples?
- 2) How water samples are collected? / What are the sites used for collection? / What are containers' types used to send water samples?
- 3) If the kitchen is using ready-made water for cooking, you should ask about the supply chain and stock of such water

10

Sub-standard – 30:10

Food containers are properly labelled with expiry dates noted. Expiry dates of food stuffs are checked before use. (O - SI)

Observation
(O)

Observation of the store:

- 1) Check that all food containers are properly labelled while maintaining expiry dates.
- 2) See that all supplies of same kind are stocked together (for example stock of salt, tea, jam etc., that have the same lot numbers and expiry dates).
- 3) Check that expiry dates of all products are clearly noted with labelling of near to expiry foods in different color (i.e., stock of near to expiry food are clearly labelled)
- 4) Observe dispatch rules or shelve rules: “First Expiry First Out - FEFO”

Comment (if any):

- Storage logs/inventory (either electronic or manual system) can be checked to demonstrate expiry dates of all products with recognition of near to expiry foods

Staff Interview
(SI)

Ask the kitchen supervisor and/or kitchen personnel about:

- 1) Rules of storing new stock, organizing shelves and dispatching that are being followed
- 2) Labelling food containers while maintaining expiry dates.
- 3) Labelling of near to expiry food in different color
- 4) Checking expiry dates depending on hospital policy (i.e., at fixed intervals: weekly, or every 2 weeks / when the new stock arrives)

Comment (if any):

- Instead of direct questions, indirect ones or scenarios are advisable

11

Sub-standard – 30:11

Fruits and vegetables are washed and disinfected thoroughly. (O - SI)

Observation
(O)

Observation of the vegetables and fruits washing (cleaning and disinfection) area:

- 1) It is preferably to be a separate area (it is optional to be associated with vegetable and salad cutting area)
- 2) It is preferably to be equipped with two dedicated deep stainless steel sinks (one for washing and the second for disinfection)
- 3) See what is type of disinfectant being used and ensure that an appropriate concentration(s) and proper contact time(s) [immersion time(s)] is being followed
- 4) Check the presence of measuring device(s) or determined cup(s) for dilution of liquid disinfectant(s), MSDS for chemical disinfectant
- 5) Ask for MSDS for relevant chemicals & disinfectants

Comment (if any):

- One deep container is also acceptable in absence of double sinks (i.e., used for vegetables and fruits immersion for disinfection)

Staff Interview
(SI)

Ask the kitchen supervisor and/or kitchen personnel about:

- 1) Process of washing vegetables and fruits (cleaning and disinfection):
How to clean vegetables and fruits / how to immerse vegetables and fruits in diluted disinfectant(s) / how to get proper dilution(s) from disinfectant(s) / for how much time(s) the vegetables and fruits are immersed (i.e., contact time(s)) / how to rinse after disinfection has been achieved.

Comment (if any):

- Instead of direct questions, indirect ones or scenarios are advisable
- You can ask kitchen staff to demonstrate procedures that they are applying

12

Sub-standard – 30:12

Food containers and cooking utensils are washed immediately after being emptied. (O - SI)

Observation
(O)

Observation:

- 1) See when and how food containers and cooking utensils are washed after use
 - food containers and cooking utensils should be washed immediately after use in same working area or dumped to be washed later on in dishwasher (i.e., it is not acceptable to leave them for a day or to the end of shift i.e. morning, afternoon or evening)

Staff Interview
(SI)

Ask the kitchen supervisor and/or kitchen personnel:

- 1) What is the schedule of washing food containers and cooking utensils
- 2) How are food containers and cooking utensils being washed
Answer: immediately after use in working area or dumped to be washed later on in dishwasher (i.e., it is not acceptable to leave them for a day or to the end of shift.

Comment (if any):

- Instead of direct questions, indirect ones or scenarios are advisable
- You can ask kitchen staff to demonstrate procedures that they are applying

13

Sub-standard – 30:13

There is an Insect and rodent control plan that is strictly implemented. (D - O - SI)

Document
(D)

Review the following documents:

- 1) Insect and rodent control plan and the applied schedule (e.g., spraying chemicals and pesticides is done as per hospital's policy: a frequent routine task + when a threshold is reached)
- 1) Check the contract with a commercially approved company (i.e., these services are outsourced in most of hospitals)
- 2) See which chemicals and pesticides are used (check safety of the chemicals and pesticides used in kitchen / Ask for MSDS for these chemicals and pesticides)
- 3) Written protocol for spraying chemicals and pesticides with precautions to be taken before, during and after it
- 4) Checklists for routine inspection and monitoring of incoming deliveries and stores for infestation
- 5) Checklists for routine inspection of kitchen for roaches / rodents or their traces

Comment (if any):

- Public health department is responsible for applying insect and rodent control plan

Observation
(O)

Observe areas of the kitchen to ensure that insect and rodent control plan is properly applied:

- 2) Approved and safe chemicals and pesticides are available for use as per hospital's policy
- 3) Devices for insect and rodent control are available, e.g., sticky fly traps, ultrasonic pest repeller ...etc..
- 4) All windows that open to the outside have screens that are kept in good repair
- 5) All areas are kept clean, sanitized and in good repair
- 6) All openings and defects with risk of infestations are sealed (e.g., cracks, tears in windows' screens ... etc..)
- 7) Incoming deliveries are routinely inspected for infestation (i.e., the visit time may coincide with receiving shipping boxes and containers of food products)

Ask the kitchen supervisor and/or kitchen personnel about:

- 1) Insect and rodent control plan
 - 2) Protocol for spraying chemicals and pesticides (i.e., who, what, how, when, where and how much)
 - 3) Precautions to be taken before, during and after spraying chemicals and pesticides
 - 4) Routine inspection of incoming deliveries for infestation
 - 5) Regular monitoring of dry products in storage area
 - 6) Routinely checking of kitchen for roaches / rodents or their traces
- Their knowledge should be compatible with hospital's policy and the actual practices

Comment (if any):

- Instead of direct questions, indirect ones or scenarios are advisable
- You can ask kitchen staff to demonstrate some procedures that they are applying

14

Sub-standard – 30:14

The kitchen environment is clean (i.e., frequently cleaned, dry and dust free). (D - O - SI)

Document
(D)

Review documents that demonstrate housekeeping activities of the kitchen environment (appropriate evidence of application):

- 1) Kitchen housekeeping schedule with clear roles & responsibility of housekeeping and kitchen staff
- 2) Kitchen housekeeping checklists and check whether the applied processes are compatible with the approved policy or not
 - The checklists should be practical and cover all environmental surfaces in different areas.
 - Also it should include responsible staff (whether kitchen staff or housekeeping staff with names – if applicable – and signatures) / dates & times / cleaning ingredients and disinfectants to be used (types – concentrations – contact times)
- 3) Ask for MSDS for used chemicals and disinfectants

Observation
(O)

Observation:

- 1) Observe ongoing housekeeping activities and evaluate whether the applied processes are compatible with the approved policy or not:
 - Responsible staff (kitchen staff & housekeeping staff) & used PPE
 - Applied housekeeping schedule
 - Applied procedure
 - Consumed supplies: cleaning ingredients & disinfectants, mops, wipes, spray bottles, buckets ...etc..
- 2) Visit janitors room to check the availability & specifications of housekeeping supplies: e.g., cleaning ingredients, chemicals and disinfectants, mops, wipes, spray bottles, buckets ...etc..
- 3) Check the quality of housekeeping activities: observe the presence of dust, dirt, soil ...etc.. that demonstrate defective housekeeping:
 - Spaces under the cooking ranges, corners and hidden areas
 - Sinks and areas under them
 - Storage areas and shelves
 - Fridges & refrigerators

Ask kitchen staff & housekeeping staff about:**3) The process of cleaning and disinfection of kitchen's environment:**

- Roles, responsibilities and recommended PPE (what are areas to be cleaned by kitchen staff, and areas to be cleaned by housekeeping staff? / what are PPE to be used during cleaning & disinfection activities?)
- Applied housekeeping schedule
- Applied procedure (how cleaning & disinfection are being performed: preparation of cleaning ingredients and disinfectants / from up downwards – from clean to dirty / frequent change of wipes and/or mops – better to use different wipes and/or mops for different areas, e.g., food receiving area, storage area and food preparation area)
- Available supplies: e.g., cleaning ingredients, chemicals and disinfectants, mops, wipes, spray bottles, buckets ...etc..

4) Their knowledge should be compatible with hospital's policy and the actual practices

Comment (if any): – Instead of direct questions, indirect ones or scenarios are advisable

- You can ask kitchen staff to demonstrate procedures that they are applying

1

Sub-standard – 31:01

There is a written policies and procedures for linen management, (e.g., collection, transportation, sorting, washing, storing and dispensing). (D)

Review the policy, which should be:Document
(D)

- ❖ Comprehensive: it covers all aspects of infection control regarding linen management, including (but not limited to):
 - Collection & transportation
 - Sorting
 - Washing: different washing cycles in terms of temperatures, times and used chemicals.
 - Storage & dispensing
- ❖ Fully applicable: all elements of the policy can be applied and comply with the hospital's scope of services
- ❖ Based on scientific references approved by MOH (GCC, CDC, WHO & APIC)
- ❖ Signed from authorized personnel (i.e., owner of the policy / hospital director or medical director / concerned department)
- ❖ Approved by IC committee*
- ❖ Valid (updated within 2 - 3 years and when indicated)

Comments:

- Approval by IC committee is required for the infection control manual as a whole before distribution and also for individual policy after major changes

Definitions:

- **Cleaning:** A process that uses a cleaning agent and physical action, such as scrubbing or wiping, to remove visible soil, organic matter, and bioburden from a surface or object. This renders the surface of object safe to handle. The cleaning agent may be a wet or dry chemical. The specifics of a cleaning process are affected by factors associated with the item to be cleaned, e.g., chemical compatibility, wetness tolerance, surface topography and complexity ... etc..
- **Decontamination:** The use of physical or chemical means to remove, inactivate, or destroy blood borne pathogens on a surface or disinfecting the item to the point where it is no longer capable of transmitting infectious particles and the surface or item is rendered safe for handling, use, or disposal.
- **Receiving area:** An area where soiled textiles are sorted, usually by textile category and sometimes by degree of soiling or color. Warning signs about the presence of contaminated textiles and the need to follow Universal Precautions must be posted in this area
- **Washing (Processing) area:** An area where soiled textiles are washed and in which such equipment as washers, extractors, washer-extractors, continuous-batch washers and/or continuous processing systems is located.
- **Extraction area:** An area where excess water is removed from textiles after laundering, but before conditioning or drying.
- **Condition/Drying area:** An area where, after extraction, textiles are either conditioned (partly dried) or fully dried in a dryer or tumbler.
- **Folding area:** An area where textiles are folded.
- **Storage & Staging area:** An area for temporary storing and preparing textiles for delivery and having them wrapped and ready for transport to patient treatment units.

2

Sub-standard – 31:02

Work flow is unidirectional from a soiled area to clean area with complete physical separation between them. (O - SI)

Observation
(O)

Observe different zones of the laundry and the flow of work:

- 3) Work flow should be unidirectional from soiled areas to clean areas (Receiving & Sorting > Washing & Extraction > Condition/Drying & Folding > Storage & Dispensing)
- 4) Soiled areas should be physically separated from clean areas (complete physical separation is required, i.e., using double doors washing machines or installing walls or partitions)

Comments:

- Functional separation/barrier: An activity or structure that separates one movement, action, or space from another.

Examples: structures such as walls or partitions, carts, and ventilation parameters such as airflow directions and pressure difference.

Scoring Tips:

- **Score will be 1 out of 2:** if the work flow is unidirectional from soiled areas to clean areas without complete physical separation between them
- **Score will be 2 out of 2:** if the work flow is unidirectional from soiled areas to clean areas with complete physical separation between them by using double doors washing machines or installing walls or other physical barriers

3

Sub-standard – 31:03

Hand hygiene facilities and supplies are available & easily accessible, especially in the dirty area. (O)

Observation
(O)

Observe hand hygiene facilities in different zones of the laundry :

- 1) There are adequate hand washing facilities equipped with all required supplies and/or Alcohol Based Hand Rub (ABHR) dispensers in all working areas and in personnel support areas.
- 2) Definition of adequate hand hygiene facilities:
 - Adequate refers to the availability of hand hygiene facility within or around the working area (i.e., personnel does not need to leave his working area to reach a hand hygiene facility of another area or zone)
 - Adequate also refers to presence of **DEDICATED** hand washing facility with proper supplies apart from sinks used for any other working purposes (i.e., sink used for laundry soaking is not acceptable)

Comments:

- At least **ONE** dedicated hand washing sink is required in dirty or soiled area
- For practicing hand hygiene in clean areas, it is preferable to use Alcohol Based Hand Rub (ABHR) dispensers (at least **ONE**)

4

Sub-standard – 31:04

Dirty linen are separated from clean linen during collection & transport and linen carts used for clean and dirty linen are clearly identified. (O)

Observation
(O)

Observe the handling of clean and dirty linen and carts used for their collection & transport:

- 8) Dirty linen should be separated from clean linen during collection & transport (i.e., the laundry staff maintain functional separation of soiled from clean textiles in carts and/or vehicles at all times during the collection and transportation)
- 9) Carts used for collection & transport of dirty linen are clearly identified from those used of clean linen

Comments:

- The term “**clearly identified carts**” means the availability of carts with different design or shape **or** carts of the same design and shape but with different color codes or easily identified by evident signs

5

Sub-standard – 31:05

Soiled healthcare textiles are assumed to be contaminated, and personnel who handle soiled textiles follow Standard Precautions at all times (i.e., handled as little as possible, while using appropriate PPE and leak-proof laundry bags or containers for collection. (O - SI)

Observe handling soiled textiles in both patient-care areas and laundry areas:

- 14) Personnel who handle soiled healthcare textiles apply Standard Precautions at all times:
- Soiled textiles are handled as little as possible in both patient-care areas and laundry areas (i.e., only as necessary to complete the defined task, and in such a way as to minimize microbial contamination of the environment and the personnel handling the textiles).
 - Soiled textiles are not sorted or rinsed in patient-care areas.
 - Appropriate PPE are used properly during handling soiled textiles in both patient-care areas and laundry areas
- 15) Check the availability of all required PPE in patient-care areas and the laundry areas.
- 16) Check the quality of the laundry bags or containers:
- The laundry bags or containers are leak-proof, not torn when loaded to capacity and can be closed securely to prevent textiles from falling out (i.e., laundry bags or containers functionally contain wet or soiled textiles and prevent contamination of the environment during collection, transportation and temporary storage prior to processing).
 - Laundry bags or containers do not need to be color-coded or labeled, as hospital's laundry only receive soiled healthcare textiles, and all personnel should follow Standard Precautions when handling these textiles.

Observation
(O)

Ask personnel in both patient-care areas and laundry areas about handling healthcare textiles:

- 1) What are the required precautions that should be followed during handling healthcare textiles (textiles from common patient-care areas / soiled textiles / contaminated laundry / linen from patients under isolation precautions ...etc..)
- 2) What is the color-code of the laundry bags or containers used for collection and transport textiles from isolation rooms?

Answer: Personnel should follow Standard Precautions when handling healthcare textiles at all times.

Laundry bags used for isolation rooms do not need to be color-coded or labeled

- 3) How can healthcare textiles be classified?
- 4) What are the approved specifications of the laundry bags or containers?
- 5) What are the appropriate PPE that should be used during handling soiled textiles in patient-care areas and laundry areas

Comments:

- **Standard Precautions:** The term incorporates Universal Precautions and Body Substance Precautions and includes a group of infection prevention practices that apply to **ALL** patients regardless of suspected or confirmed infection status in any setting where healthcare is delivered.
- **Universal Precautions:** An approach to infection prevention that considers all textile products being sent to the laundry as being contaminated. Special note: Under these circumstances, it is not necessary to identify the bags in which the textiles are transported in any special manner, because they will all be handled/laundered the same way.
- **Contaminated:** The presence of blood or Other Potentially Infectious Material (OPIM) on an item or surface.
- **Contaminated laundry:** According to the Occupational Safety and Health Administration (OSHA), laundry that has been soiled with blood or Other Potentially Infectious Material (OPIM), or may contain sharps.
- **Soiled textile:** a textile product that has been used or worn and soiled by perspiration, body oils, or one of the many other items to which it may have been exposed.

6	<p>Sub-standard – 31:05</p> <p>During high temperature washing cycle, water temperature is at a minimum of 71°C for 25 minutes (heat disinfection), and this is recorded. (D - O - SI)</p>
7	<p>Sub-standard – 31:07</p> <p>During low temperature washing cycle (22°C - 50°C), sodium hypochlorite is added as a disinfectant during bleach wash cycle (chemical disinfection: residual bleach is 50 - 150 ppm: 50 - 150/1000000), this is monitored and controlled. (D - O - SI)</p>
Document (D)	<p>Review the following documents:</p> <p>7) <u>Documents that demonstrate proper application of these two sub-standards:</u></p> <ul style="list-style-type: none"> - Records of high temperature washing cycles including monitoring and control of washing cycles (i.e., recording processed loads / selected washing cycles / temperatures and times) - Records of low temperature washing cycles including monitoring and control of used chemicals (i.e., chemical types / preparations method / effective concentrations and contact times) - Planned Preventive Maintenance (PPM) for washing machines with Quality check for different parameters of washing cycles - Interventions records for abnormal temperatures and failure situations
Observation (O)	<p>Observe ongoing washing cycles:</p> <p>8) <u>For high temperature washing cycles:</u> check the content of processed load / selected washing cycle / chosen temperature and time)</p> <p>9) <u>For low temperature washing cycles:</u> check the type of chemical disinfectant used (i.e., sodium hypochlorite or activated oxygen-based chemicals) / preparations or dilution method / calculated concentrations and contact times</p> <p>10) Check the availability of chemical disinfectant(s) for low temperature washing cycles (i.e., sodium hypochlorite or activated oxygen-based chemicals) / MSDS for chemical disinfectant(s) and the presence of measuring device(s) for dilution or preparation of liquid disinfectant(s)</p> <p>11) See valid PPM stickers on washing machines (if applicable)</p>
Staff Interview (SI)	<p>Ask laundry supervisor and/or responsible personnel:</p> <p>6) How can you classify different healthcare textiles to choose appropriate washing cycle?</p> <p>7) <u>For textiles that withstand high temperature washing cycles:</u> How can you adjust the washing cycle parameters (i.e., cycle phases, required temperature and time)?</p> <p>8) <u>For textiles that cannot withstand high temperature washing cycles:</u> How can you adjust the washing cycle parameters (i.e., cycle phases, chemical disinfectant, preparation or dilution method, required concentration and contact time)?</p> <p>9) What are the different phases and expected parameters of selected washing cycles?</p>

Comment (if any):

- If sodium hypochlorite is not appropriate for the fabrics or not recommended by manufacturer's, Chlorine alternatives (e.g., activated oxygen-based detergents) may be used to ensure adequate disinfection of laundry during low temperature washing cycle

8	Sub-standard – 31:08 The processed textiles meet the needs and expectations of the user. Routine inspection is conducted after washing and linen with blood or/and body fluid stains is washed again. (O - SI)
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Observation (O)	Observe: <ol style="list-style-type: none">1) The end product: the washed textiles are properly processed without any stains or damage.2) Ongoing inspection process of washed textiles during the visit time.3) Availability of appropriate table with light source for routine inspection of processed textiles4) The presence of textiles with blood or/and body fluid stains or damaged textiles that are segregated after processing to be re-washed, repaired or disposed.
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Staff Interview (SI)	Ask laundry supervisor and/or responsible personnel: <ol style="list-style-type: none">10) How do you ensure that the processed textiles meet the approved requirements and expectations of the user?11) How do you manage processed textiles that fail to meet the approved requirements and expectations of the user (i.e., textiles with blood or/and body fluid stains or damaged textiles)?
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Comment (if any):

- Instead of direct questions, indirect ones or scenarios are advisable.
Example: What are you going to do if the surgical ward returns 4 bed sheets after being delivered this morning because of blood and body fluid stains?

1

Sub-standard – 32:01

There are written policies and procedures or infection control precautions inside the morgue, that address safe handling of dead bodies, including postmortem handling of patients under isolation precautions and bodies with open wounds. (D)

Review the policy, which should be:

- ❖ Comprehensive: it covers all aspects of infection control in the morgue including (but not limited to):
 - Safe removal of all external invasive lines and devices used during hospital interventions (if an autopsy is not anticipated) with packing all wounds and natural openings with absorbent material and bandaged to contain any potential secretion of body fluids
 - Protocol to transport the deceased to the facility morgue.
 - Postmortem safe handling of dead bodies (i.e., cleansing, bathing and preparing the deceased for burial), specially patients with infectious transmissible diseases or under isolation precautions and bodies with open wounds.
 - Specific protocols to preserve evidence if an autopsy is required or requested.
 - Protocol to transport of the body from morgue to a funeral home.
 - Occupational risks and work practices that delineate which tasks or conditions of employment require the use of personal protective equipment and engineering devices to minimize exposure.
 - Record keeping with protocol for reporting accidental exposures .
 - Management of waste and environmental cleaning procedures
- ❖ Fully applicable: all elements of the policy can be applied and comply with national and local regulations and the facility's scope of services
- ❖ Based on scientific references approved by MOH (GCC, CDC, WHO & APIC)
- ❖ Signed from authorized personnel (i.e., owner of the policy / hospital director or medical director / concerned department)
- ❖ Approved by IC committee*
- ❖ Valid (updated within 2 - 3 years and when indicated)

Document
(D)

Comment (if any):

- Approval by IC committee is required for the infection control manual as a whole before distribution and also for individual policy after major changes.

2

Sub-standard – 32:02

Hand hygiene facilities and supplies are available & easily accessible. (O)

Observation
(O)

Observe the morgue to ensure that:

- 3) There are adequate hand washing facilities equipped with all required supplies and/or Alcohol Based Hand Rub (ABHR) dispensers
- 4) Definition of adequate hand hygiene facilities:
 - Adequate refers to presence of hand hygiene facility within the working area (i.e., personnel does not need to leave his working area to reach a hand hygiene station of another area)
 - Adequate also refers to presence of **DEDICATED** hand washing facility with proper supplies apart from sinks used for any other working purposes

Comments:

- Hand washing facility should be easily accessible (i.e., easy to reach within the working area or very close to it)

3

Sub-standard – 32:03

The mortuary is generally clean, well ventilated, and well organized. There is a regular schedule of housekeeping activities (cleaning and disinfection) for all environmental surfaces including the inside of refrigerating and deep freezing equipment. (D - O - SI)

Document
(D)

Review documents that demonstrate ventilation and housekeeping activities of the morgue environment (appropriate evidence of application):

- 4) Morgue housekeeping schedule with clear roles & responsibility of housekeeping and morgue staff
- 5) Morgue housekeeping checklists and check whether the applied processes are compatible with the approved policy or not
 - The checklists should be practical and cover all environmental surfaces in different areas.
 - Also it should include responsible staff (whether morgue staff or housekeeping staff with names – if applicable – and signatures) / dates & times / cleaning ingredients and disinfectants to be used (types – concentrations – contact times)
- 6) Ask for MSDS for used chemicals and disinfectants

If autopsy room is available:

- 1) Copies of the original charts or project scheme for ventilation system of autopsy room: should be at negative pressure with respect to adjacent areas, and air exhausted directly outside with minimum 12 air changes per hour
- 2) Local records for regular ventilation monitoring of autopsy room: negative pressure differences with respect to adjacent areas + temperatures and relative humidity ± air changes per hour (ACH - minimum 12 air changes per hour is recommended) with corrective interventions if readings are not matching the acceptable values

Observation:

- 4) Observe ongoing housekeeping activities and evaluate whether the applied processes are compatible with the approved policy or not:
 - Responsible staff (morgue staff & housekeeping staff) & used PPE
 - Applied housekeeping schedule
 - Applied procedure
 - Consumed supplies: cleaning ingredients & disinfectants, mops, wipes, spray bottles, buckets ...etc..
- 5) Visit janitors room to check the availability & specifications of housekeeping supplies: e.g., cleaning ingredients, chemicals and disinfectants, mops, wipes, spray bottles, buckets ...etc..
- 6) Check the quality of housekeeping activities: observe the presence of dust, dirt, soil ...etc.. that demonstrate defective housekeeping:
 - Spaces under bathing board or autopsy table, corners and hidden areas
 - Sinks and areas under them
 - The inside of morgue refrigerator and deep freezing equipment
 - Storage areas
- 7) Observe working and storage areas which should be of adequate capacity, well maintained, well organized and regularly cleaned according to the approved housekeeping schedule / no personal items/ no foods or drinks / no Items are kept in the original shipping boxes

If autopsy room is available:

- 1) Observe autopsy room's monitor (if available) to ensure that it is valid and recorded values in local logs are identical to the actual readings

Ask morgue staff & housekeeping staff about:

- 5) The process of cleaning and disinfection of morgue environment:
 - Roles, responsibilities and recommended PPE (what are areas to be cleaned by morgue staff, and areas to be cleaned by housekeeping staff? / what are PPE to be used during cleaning & disinfection activities?)
 - Applied housekeeping schedule
 - Applied procedure (how cleaning & disinfection are being performed: preparation of cleaning ingredients and disinfectants / from up downwards – from clean to dirty / frequent change of wipes and/or mops – better to use different wipes and/or mops for different areas
 - Available supplies: e.g., cleaning ingredients, chemicals and disinfectants, mops, wipes, spray bottles, buckets ...etc..
- 6) Their knowledge should be compatible with hospital's policy and the actual practices

Comments:

- Instead of direct questions, indirect ones or scenarios are advisable
- You can ask morgue staff to demonstrate procedures that they are applying

4

Sub-standard – 32:04

Transport cadaver bags that fulfill MOH approved specifications are available in different sizes to be used for dead bodies especially deceased patients with infectious transmissible diseases or under isolation precautions and dead bodies with open wounds or oozing body fluids. (O)

Observation
(O)

Observe transport body bags and body tags & their specifications:

- 5) Heavy duty cadaver plastic pouch (made of tear-resistant, fluid-resistant and impervious material, e.g., waterproof Vinyl)
- 6) Bags are of different suitable sizes
- 7) Bag can be securely sealed for hygiene using a full length longitudinal zipper for closure
- 8) Bag has a convenient access for examination and enclosure through a full length longitudinal zipper.
- 9) Bag has a suitable pouch to hold the body tag

Staff Interview
(SI)

Ask the morgue staff:

- 17) Significance of using cadaver bags that fulfill MOH approved specifications for transport of dead bodies especially deceased patients with infectious transmissible diseases or under isolation precautions and dead bodies with open wounds or oozing body fluids.
- 18) To demonstrate procedures that they are applying to prepare the body for transport from morgue to a funeral home.

Comment:

- Instead of direct questions, indirect ones or scenarios are advisable

5

Sub-standard – 32:05

Only experienced personnel (specialists and/or technicians) are dealing with cadavers (i.e., the morgue staff are well trained on hand hygiene, safe use of PPE, and proper handling of dead bodies). (O - SI)

7

Sub-standard – 32:07

Mortuary staff are fully aware about handling deceased patients due to infectious diseases or died while under isolation precautions according to the relevant approved hospital policy. (O - SI)

Observation
(O)

Observe the morgue staff for:

- 3) Hand washing/hand rubbing
 - d) TIME (20-30 sec ABHR, 40-60 Sec HW)
 - e) TECHNIQUE (completely and thoroughly)
 - f) Moments of hand hygiene for the morgue staff: before starting work / after handling dead bodies / after handling soiled items or equipment and waste / after any cleaning procedures / after removing PPE, e.g., gloves / before & after eating, drinking, or smoking / after using the toilet / before leaving the work place
- 4) Appropriate use of PPE:
 - c) Recommended PPE (double layers of disposable gloves, protective eyewear or face shield, respiratory protection, fluid-resistant gowns or waterproof aprons, closed shoes or protective shoe covers and caps) should be worn when performing or assisting in postmortem procedures.
 - d) Use of metal mesh gloves or gloves made with "cut resistant fabric" underneath the outer gloves is suggested for prosectors to prevent injury from scalpels and other sharp objects other than needles (e.g., bone shards and fragmented projectiles).
 - e) Approved respiratory protection is required for prosectors when performing an autopsy on a known or suspected case of TB (high-risk procedure)

Ask the morgue staff about:

- 1) Hand Hygiene (hand washing/hand rubbing): times / techniques / moments of hand hygiene
 - Techniques.
 - Times.
 - Moments of hand hygiene
- 2) Protective clothing & PPE:
 - Types.
 - Indications.
 - Technique, sequence of donning and doffing and proper use while handling deceased patients due to different type of infectious diseases.
 - BICSL license & N95 fit testing.
- 3) If they received periodic training about standard precautions and handling of died while under isolation precautions.
- 4) If they are aware about hospital policy that covers dealing with deceased patients due to infectious diseases.
- 5) If they are properly trained about dealing with blood and body fluids spills.

Randomly ask 1 to 3 of the morgue staff:

- 1) To demonstrate techniques of hand washing/hand rubbing
- 2) To demonstrate donning and doffing of PPE
- 3) To demonstrate applied procedures for preparing dead bodies before transport from the morgue.
- 4) To demonstrate the technique of handling blood and body fluids spills.

Comment (if any):

Instead of direct questions, indirect ones or scenarios are advisable

6**Sub-standard – 32:06**

Transportation card that denotes the types of isolation precautions is attached to the dead body of patient under any type of isolation. (D - SI)

Review the following documents:

- 1) Log book used for recording of deceased while under isolation precautions and protective measures taken.
- 2) Morgue's transportation cards that should be attached to the dead bodies of patients under isolation precautions.

Ask the morgue staff:

- 1) If the nurse in charge communicate with the morgue staff to inform them about infectious status of the deceased and appropriate precautions required.
- 2) If they received periodic training about handling dead bodies of patient under isolation precautions.
- 3) If they are familiar with isolation precautions transportation cards used within the hospital.
- 4) If information regarding infectious status of the deceased is written on identification tag attached to the body bag.

Comment:

- Instead of direct questions, indirect ones or scenarios are advisable