



EBreast II

Aseptic safety in breast patient care Part 2



Introduction

- This presentation is the second of two presentations focusing on enabling safe breast cancer patients' pathway from the Surgical Site Infection (SSI) prevention and control points of view.
- This second part introduces standard precautions serving the minimum level for infection control and prevention for safe care of all patients, and current status of evidence-based recommendations for preventing and controlling surgical site infections (SSI).
- This presentation aims to build bridges between professionals and care environments for evidence-based infection prevention and control by revealing critical aseptic incidents and means to tackle them, crucial for all the professionals working in the breast surgery patients' pathway.
- In part two, The Aseptic Practices in Breast Surgery –model, applied from the Baseline Model for Intraoperative Aseptic Practices (1), is introduced for future use as a potential structure for planning, implementing and assessing clinical infection prevention and control measures in the breast surgery patients' pathway.



Learning outcomes

After this second presentations, the learner is able to demonstrate:

- 1) Critical implementation of evidence-based aseptic safety in breast surgery patient care.
- 2) Ability to develop patient and procedure specific infection prevention and control measures in breast surgery patient care.
- 3) Ability to facilitate the breast surgery patients, their next of kins, and healthcare personnel to prevent, follow-up, and report surgical site infection related outcomes.



The healthcare personnel and organizations have a shared responsibility for warranting and improving patient safety

To tackle HAIs, including SSIs, the EU Council (2) recommended among others to:

- ✓ Inform and empower patients involving them in the patient safety process.
- ✓ Set up, maintain, or improve comprehensive reporting and learning systems so that the extent and causes of adverse events can be captured in order to develop efficient solutions and interventions.
- ✓ Implement information and communication technology tools, such as electronic health records or e-prescriptions improving patient safety, and performing systematical screenings.
- ✓ Embed patient safety in the education and training of healthcare workers.



Some background to the current recommendations for preventing and controlling surgical site infections (SSI)

- In the US and Europe, from the 1960s to the 1990s the improvements in “infection control practices” focused on operating room ventilation, sterilization methods, “barriers” for isolating the sterile field, surgical technique, and availability of antimicrobial prophylaxis (3,4).
- In 1999, the emergence of antimicrobial resistant pathogens, the increased number of SSIs and surgical patients with changed characters, in addition to the advances in surgery (e.g. orthopaedic prosthesis implant surgery and transplantations), made it necessary to publish guidelines by the US Centres for Disease Control and Prevention (CDC) (4).
- The 1999 Guideline for Prevention of Surgical Site Infection updated and replaced previous guidelines and represented the consensus of the Hospital Infection Control Practices Advisory Committee (HICPAC) regarding strategies for the prevention of SSIs. **Whenever possible**, the recommendations were based on data from well-designed scientific studies.



The 1999 CDC Guideline recommended⁽⁴⁾

“Preoperative Issues”

Preoperative antiseptic showering of the patient.
Preoperative hair removal.
Patient skin preparation in the operating room.
Preoperative hand/forearm antisepsis.
Management of infected or colonized surgical personnel.
Antimicrobial prophylaxis.

“Intraoperative issues”

Routine cleaning of OR environmental surfaces.
OR Ventilation (min. 15 air changes of filtered air per hour, three (20%) of which must be fresh air...).
Microbiologic sampling.
Conventional sterilization of surgical instruments.
Use of surgical attire (scrub suits, caps/hoods, masks, gloves, gowns and shoe covers).
Asepsis and surgical technique.

“Postoperative Issues”

Incision care.
Discharge planning.



Some background ... *“To err is human”*

In 1999, The United States Institute of Medicine’s publication: *“To err is human”* opened the topic in the public with a general requisite: *“freedom for a patient from unnecessary harm or potential harm associated with health care”* from view point of learning from errors and education.

Types of errors

- Diagnostic:** Error of delay in diagnosis.
Failure to employ indicated tests.
Use of outmoded tests or therapy.
- Treatment:** Error in the performance of an operation/procedure/test.
Error in administering the treatment.
Error in the dose or method of using drug.
Avoidable delay in treatment or in responding to an abnormal test.
Inadequate monitoring or follow-up treatment.
- Other:** Failure of communication.
Equipment failure.
Other system failure. (5)



WHO's Standard Precautions (6)

- In 2007, World Health Organization (WHO) published Standard Precautions (6) “to reduce the risk of transmission of blood-borne and other pathogens from both recognized and unrecognized sources”.
- SPs defined the basic level of IPC precautions to be used as a minimum, in the care of all patients.
- Hand hygiene defined a major component of SP in addition to the use of personal protective equipment (PPE) guided by risk assessment and the extent of expected contact with blood and body fluids, or pathogens.
- Respiratory hygiene/cough etiquette included in the SPs during the acute respiratory syndrome (SARS) outbreak.
- Some precautions include indicators and technique, but not all.



WHO's Standard Precautions introduced in the Check list and in more detailed manner ⁽⁶⁾

Health policy:

Promote a safety climate.

Develop policies which facilitate the implementation of infection control measures.



WHO's Hand Hygiene Precautions (6)

Hand hygiene check list:

Perform hand hygiene by means of hand rubbing or hand washing.

Perform hand washing with soap and water if hands are visibly soiled, or exposure to spore-forming organisms is proven or strongly suspected, or after using the restroom.

Otherwise, if resources permit, perform hand rubbing with an alcohol-based preparation.

Ensure availability of hand-washing facilities with clean running water.

Ensure availability of hand hygiene products (clean water, soap, single use clean towels, alcohol-based hand rub).

Alcohol-based hand rubs should ideally be available at the point of care.



Hand hygiene indications:

Before and after any direct patient contact and between patients, whether or not gloves are worn.

Immediately after gloves are removed.

Before handling an invasive device.

After touching blood, body fluids, secretions, excretions, non-intact skin, and contaminated items, even if gloves are worn.

During patient care, when moving from a contaminated to a clean body site of the patient.

After contact with inanimate objects in the immediate vicinity of the patient.

Hand hygiene technique:

Hand washing (40–60 sec): wet hands and apply soap; rub all surfaces; rinse hands and dry thoroughly with a single use towel; use towel to turn off the faucet (= water tap).

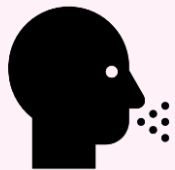
Hand rubbing (20–30 sec): apply enough product to cover all areas of the hands; rub hands until dry.



WHO's Respiratory Precautions (6)

Respiratory hygiene and cough etiquette:

Educate health workers, patients and visitors.
Cover mouth and nose when coughing or sneezing.
Perform hand hygiene after contact with respiratory secretions.
Perform spatial separation of persons with acute febrile respiratory symptoms.



Respiratory hygiene indications:




Persons with respiratory symptoms should apply source control measures:
Cover their nose and mouth when coughing/sneezing with tissue or mask, dispose of used tissues and masks, and perform hand hygiene after contact with respiratory secretions.

Respiratory hygiene technique:

Health-care facilities should:
Place acute febrile respiratory symptomatic patients at least 1 metre away from others in common waiting areas, if possible.
Post visual alerts at the entrance to health-care facilities instructing persons with respiratory symptoms to practise respiratory hygiene/cough etiquette.
Consider making hand hygiene resources, tissues and masks available in common areas and areas used for the evaluation of patients with respiratory illnesses.



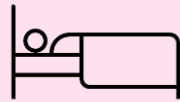



WHO's PPE Precautions (6)

| Personal protective equipment (PPE): | Indications and/or technique: |
|--|--|
| <p>Asses the risk of exposure to body substances or contaminated surfaces before any health-care activity.</p> <p>Make this a routine!</p> <p>Select PPE based on the assessment of risk: clean non-sterile gloves, clean non-sterile fluid-resistant gown, mask, and eye protection or a face shield.</p> | <p>Gloves:</p> <p>Wear when touching blood, body fluids, secretions, excretions, mucous membranes, nonintact skin.</p> <p>Change between tasks and procedures on the same patient after contact with potentially infectious material.</p> <p>Remove after use, before touching non-contaminated items and surfaces, and before going to another patient.</p> <p>Perform hand hygiene immediately after removal.</p>  |
|  | <p>Facial protection:</p> <p>Wear a surgical or procedure mask and eye protection (eye visor, goggles) OR a face shield to protect mucous membranes of the eyes, nose, and mouth during activities that are likely to generate splashes or sprays of blood, body fluids, secretions, and excretions.</p> |
|  | <p>Gown:</p> <p>Wear to protect skin and prevent soiling of clothing during activities that are likely to generate splashes or sprays of blood, body fluids, secretions, or excretions.</p> <p>Remove soiled gown as soon as possible and perform hand hygiene.</p> |

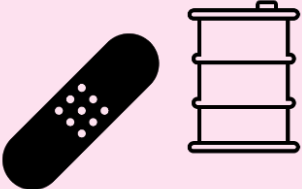
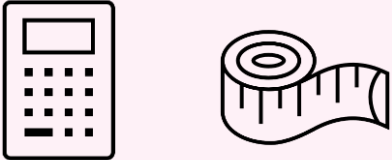


Additional Precautions (6)

| Precaution | Indications and/or technique: |
|---|---|
| <p>Prevention of needle stick and injuries from other sharp instruments:</p>  | <p>Use care when:</p> <p>Handling needles, scalpels, and other sharp instruments or devices. Cleaning used instruments.</p> <p>Disposing of used needles and other sharp instruments.</p> |
| <p>Environmental cleaning:</p>  | <p>Use adequate procedures for the routine cleaning and disinfection of environmental and other frequently touched surfaces.</p> |
| <p>Linens:</p>   | <p>Handle, transport, and process used linen in a manner which:</p> <p>Prevents skin and mucous membrane exposures and contamination of clothing.</p> <p>Avoids transfer of pathogens to other patients and or the environment.</p> |



Additional Precautions (6)

| Precaution | Indications and/or technique: |
|---|--|
| <p data-bbox="326 482 601 522">Waste disposal:</p>  <p>The icons show a black bandage with white dots and a white trash bin with a lid.</p> | <p data-bbox="1253 502 2125 629">Ensure safe waste management. Treat waste contaminated with blood, body fluids, secretions and excretions as clinical waste, in accordance with local regulations.</p> <p data-bbox="1253 658 2040 753">Human tissues and laboratory waste that is directly associated with specimen processing should also be treated as clinical waste.</p> <p data-bbox="1253 782 1765 818">Discard single use items properly.</p> |
| <p data-bbox="326 986 746 1026">Patient care equipment:</p>  <p>The icons show a calculator and a roll of white tape.</p> | <p data-bbox="1276 1006 2147 1162">Handle equipment soiled with blood, body fluids, secretions, and excretions in a manner that prevents skin and mucous membrane exposures, contamination of clothing, and transfer of pathogens to other patients or the environment.</p> <p data-bbox="1276 1190 2058 1258">Clean, disinfect, and reprocess reusable equipment appropriately before use with another patient.</p> |



Some Notes Concerning the WHO Standard Precautions

Nota Bene!

- Promotion of an institutional safety climate (not the error definition) was considered important in risk reduction in these SPs.
- Not all recommendations were included in the checklist.
- No evidence appraisal is included in this SP publication.
- WHO encourages for local and cultural review before implementation of the Standard Precautions.



WHO's Surgical Patient Safety Check List For Safer Surgery ⁽⁷⁾

- In 2009, WHO revised the Surgical Patient Safety Check List For Safer Surgery.
- No evidence appraisal have included in this checklist either.
- WHO: “This checklist is not intended to be comprehensive. Additions and modifications to fit local practice are encouraged.”



Before induction of anaesthesia (7)

(with at least nurse and anaesthetist)

- The patient has confirmed his/her identity, site, procedure, and consent.
- The operation site is marked.
- The anaesthesia machine and medication check is completed.
- The pulse oximeter is on the patient and functioning.
- Patient's allergy is known.
- Difficult airway or aspiration risk is known and equipment/assistance is available.
- Risk of over 500ml blood loss (7ml/kg in children) is known and two IV/central access and fluids are planned.

=> No aseptic practice related criteria!



Before skin incision (7)

(with nurse, anaesthetist and surgeon)

- All team members have introduced themselves by name and role.
- The patient's name, procedure, and where the incision will be made are confirmed.
- **The antibiotic prophylaxis is given within the last 60 minutes if applicable.**
- Anticipated Critical Events

To Surgeon:

What are the critical or non-routine steps?
How long will the case take?
What is the anticipated blood loss?

To Anaesthetist:

Are there any patient-specific concerns?

To Nursing Team:

Has sterility (including indicator results) been confirmed?
Potential equipment issues or any concerns are solved.
The essential imaging displayed if applicable.



Before patient leaves operating room (7)

(with nurse, anaesthetist and surgeon)

Nurse verbally confirms:

The name of the procedure.

Completion of instrument, sponge and needle counts.

Specimen labelling (read specimen labels aloud, including patient name).

Whether there are any equipment problems to be addressed.

Surgeon, Anaesthetist and Nurse:

What are the key concerns for recovery and management of this patient?



Some improvement for the evidence-base of the current recommendations ...

- In 2017, Berríos-Torres et al. (8) published updated evidence-based guideline aiming to expand the CDC 1999 guidelines (4) and facilitate surgical quality improvement programs improving patient safety.
- The “guideline focused on select areas for the prevention of SSI deemed important to undergo evidence assessment for the advancement of the field” (8). In spite of this, the level and amount of actual evidence supporting the guideline is very limited.
- The 2017 CDC guideline (8) does not cover the entire perioperative process of the surgical patient, and they do not have the support of comprehensive and high quality research (9).
- They introduce the recommendations by partly implementing the perioperative phases of surgery, but do not implement more detailed conceptual model for clinical practice.



CDC 2017 recommendations with IA and IB category evidence (8)

| | |
|-------------------------------|---|
| Glycemic Control | “Implement perioperative glycemic control and use blood glucose target levels less than 200 mg/dL in patients with and without diabetes.” (Category IA evidence) |
| Normothermia | “Maintain perioperative normothermia.” (Category IA evidence) |
| Oxygenation | “For patients with normal pulmonary function undergoing general anesthesia with endotracheal intubation, administer increased FIO ₂ during surgery and after extubation in the immediate postoperative period. To optimize tissue oxygen delivery, maintain perioperative normothermia and adequate volume replacement. (Category IA evidence) |
| Antiseptic Prophylaxis | “Advise patients to shower or bathe (full body) with soap (antimicrobial or nonantimicrobial) or an antiseptic agent on at least the night before the operative day.” (Category IB evidence) “Perform intraoperative skin preparation with an alcohol-based antiseptic agent unless contraindicated. (Category IA evidence) |



Categories implemented in the appraisal of the CDC 1999 and 2017 recommendations

The CDC Recommendations, updated by Berríos-Torres et al. (8) categorized using the following standard system that reflects the level of supporting evidence or regulations:

- Category IA: A strong recommendation supported by high to moderate quality evidence suggesting net clinical benefits or harms.
- Category IB: A strong recommendation supported by low-quality evidence suggesting net clinical benefits or harms or an accepted practice (for example aseptic technique) supported by low to very low-quality evidence.
- Category IC: A strong recommendation required by state or federal regulation.
- Category II: A weak recommendation supported by any quality evidence suggesting a trade-off between clinical benefits and harms.
- No recommendation/unresolved issue: An issue for which there is low to very low-quality evidence with uncertain trade-offs between the benefits and harms or no published evidence on outcomes deemed critical to weighing the risks and benefits of a given intervention.



Some outcomes after implementing the applied WHO Surgical Safety Checklist

Haynes et al. (10) reported improvement in the surgical care outcomes after the use of the Surgical Safety Checklist in several countries globally. The mortality rate was 1.5% before the checklist was introduced and 0.8% afterward ($P = 0.003$). Inpatient complications decreased from 11.0% to 7.0% after introduction of the checklist ($P < 0.001$). The overall SSI rates and unplanned reoperations also declined significantly ($P < 0.001$ and $P = 0.047$, respectively).

Allegranzi et al. (11) completed a pre-post-cohort study at five African hospitals. They implemented or strengthened multiple SSI prevention measures, combined with an adaptive approach aimed at the improvement of teamwork and the safety climate. In the 4322 operations the cumulative incidence of SSIs decreased after the intervention, from 8.0% (95% CI 6.8–9.5; $n = 129$) to 3.8% (3.0–4.8; $n = 70$; $p < 0.0001$). The likelihood of SSI during follow-up was significantly lower than before the intervention (OR 0.40, 95% CI 0.29–0.54; $p < 0.0001$). The likelihood of death was not significantly reduced (OR 0.72, CI 0.42–1.24; $p = 0.2360$). The compliance with SSI prevention measures was followed. (11)



Improvement in SSI rates after implementing

(11)

Technical SSI preventive measures

Patient preoperative bathing with plain or antiseptic soap.

Appropriate hair removal (avoidance of or using clippers).

Optimised patient skin preparation (alcohol-based and chlorhexidine-based skin disinfection product).

Optimised surgical hand preparation (alcohol-based hand rub product and appropriate technique).

Appropriate antibiotic prophylaxis according to local policy (given within 1-h preoperatively and discontinued postoperatively).

Improved operating theatre discipline.

Including limitation of the number of individuals and reduction of intraoperative movement.

Team-working and safety elements

Formation of local Surgical Unit-based Safety Programme perioperative team.

Engagement of surgical leads and senior executives.

Patient safety culture survey.

Patient safety video played by local surgical leaders.

Use of adaptive tools (Staff safety assessment and Learning from defects).

Morbidity and mortality meetings.

Participation in monthly webinars.

Conduct of local educational meetings.

Feedback of data on SSI surveillance.

Compliance with the SSI preventive measures (SSI rates).



Quality of recommendations selected as part of the Aseptic Practices in Breast Surgery -model

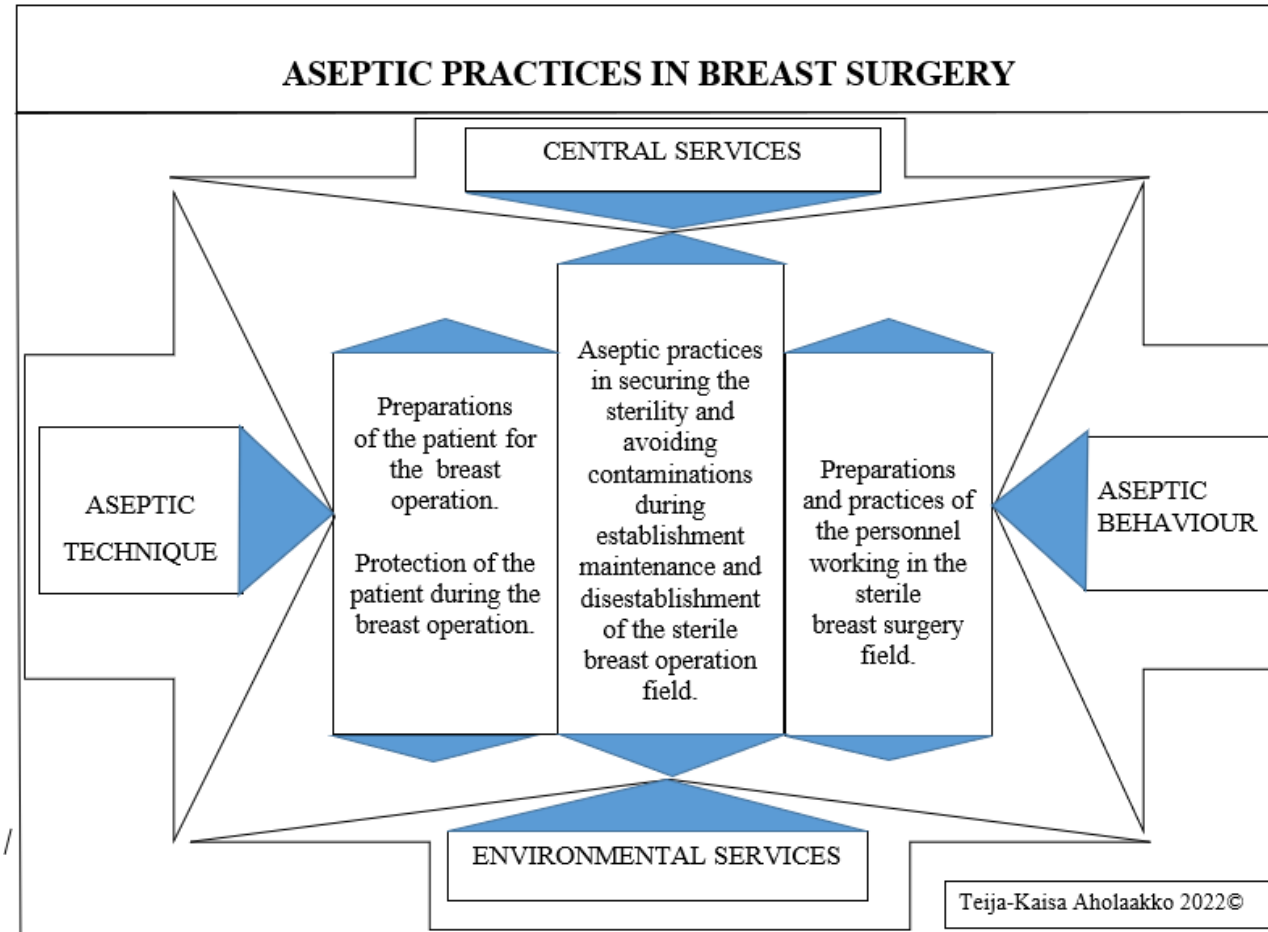
- Berríos-Torres et al. (8) did not re-evaluate all the recommendations in the year 1999 CDC Guideline for Prevention of Surgical Site Infection (4), but consider them to be accepted practice for the prevention of SSI.
- Lipsett (9), stated in her invited comments for the DCD 2017 updated recommendations (8) that the twelve Category 1A and Category 1B recommendations are based on moderate or high-quality evidence, and those practices should be used in practice.
- In this presentation, the WHO recommendations (7,6) with no appraisal of supporting evidence are included with intention to advance critical discussion related to the current status of the evidence in guiding the surgical infection prevention and control.



The Baseline Model for Intraoperative Aseptic Practices (1) was modified to improve the transparency of the evidence-based recommendations and lack of them. The CDC 1999 (4) and 2017 recommendations (8), The WHO Standard Precautions (7) and the WHO Surgical Safety Checklist (8) recommendations included in the infection prevention and control practices in the breast surgery patient's pathway.



The Aseptic Practices in Breast Surgery – a model for SSI-prevention and control, education and research



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Preparations and protection of the patient

Preparations of the patient for the breast operation:

Performing preoperative antiseptic showering of the patient. (4,8)

Performing preoperative hair removal. (4,8)

Performing patient skin preparation in the operating room. (4,8)



Protection of the patient during the breast operation:

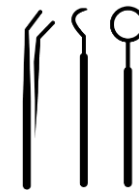
Performing antimicrobial prophylaxis. (4,8)

... within the last 60 minutes if applicable (7).

Implementing glycemic control. (8)

Maintaining normothermia of the patient. (8)

Implementing oxygenation of the patient. (8)



“Preparations and practices of the personnel working in the sterile breast surgery field”

Performing preoperative hand/forearm antiseptis. (4,8)



Using surgical attire (scrub suits, caps/hoods, masks, gloves, gowns and earlier **shoe covers**). (4,8)



Using personal protective equipment (6)



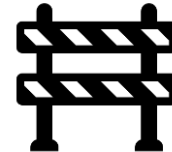
ASEPTIC TECHNIQUE

Performing asepsis and surgical technique. (4,8)



Preventing needle stick and injuries from other sharp instruments. (6)

Confirming the sterility (including the indicator results). (7)



ASEPTIC BEHAVIOUR

Managing infected or colonized surgical personnel. (4,8)

Performing hand hygiene. (6)

Performing respiratory hygiene and cough etiquette. (6)

Using personal protective equipment (PPE). (6)

Preventing needle stick and injuries from other sharp instruments. (6)

Handling patient care equipment. (6)



ENVIRONMENTAL SERVICES

Performing environmental cleaning in OR. (6)



Performing routine cleaning of OR surfaces. (4,8)

Securing OR ventilation. (4,8)

Performing microbiologic sampling. (4,8)



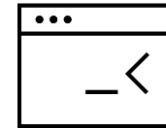
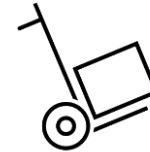
Handling linens with care. (6)

Securing waste disposal. (6)

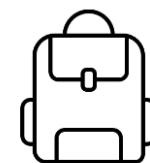


CENTRAL SERVICES

Performing conventional sterilization of surgical instruments. (4,8)



More evidence is required to enabling safe surgery?



Principles of Aseptic Practices with low level evidence (1)

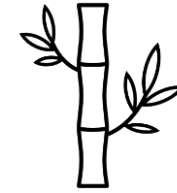
Intraoperative aseptic practices are recommended to be performed by

1. using clean disposable, disinfected and/or sterile items in a relevant manner
2. preparing the sterile/disinfected field as near to the time of performance as possible
3. preparing the sterile field inside the clean air zone in the operating theatre
4. covering all the skin and hair when working in the sterile field
5. avoiding unnecessary movements in the sterile field, respecting air-current models
6. avoiding unnecessary conversation during the operation
7. avoiding traffic in and out of OT
8. avoiding unnecessary handling of sterile items, drapes and sponges
9. using the hands-free technique with sharp items
10. implementing clean and dirty techniques



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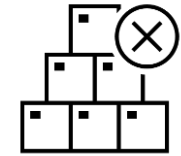




For your future cooperation developing more evidence for aseptic practices implement in the...



WHO 2021: Global Patient Safety Action Plan 2021–2030 (12)



Vision: A world in which no one is harmed in health care and every patient receives safe and respectful care, every time, everywhere.

Goal: Achieve the maximum possible reduction in avoidable harm due to unsafe health care globally.

Mission: Drive forward policies, strategies and actions based on science, patient experience, system design and partnerships to eliminate all sources of avoidable risk and harm to patients and health workers.



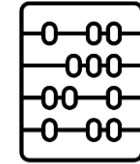
An updated definition for *Patient Safety*:



“A framework of organized activities that creates cultures, processes, procedures, behaviours, technologies and environments in health care that consistently and sustainably lower risks, reduce the occurrence of avoidable harm, make errors less likely and reduce the impact of harm when it does occur.”



Guiding principles (12)

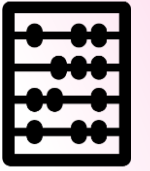


The Seven guiding principles establish underpinning values to shape the development and implementation of the action plan:

- 1) Engage patients and families as partners in safe care.
- 2) Achieve results through collaborative working.
- 3) Analyse and share data to generate learning.
- 4) Translate evidence into actionable and measurable improvement.
- 5) Base policies and action on the nature of the care setting.
- 6) Use both scientific expertise and patient experience to improve safety.
- 7) Instil a safety culture in the design and delivery of health care.



The seven strategic objectives (SOs) of the WHO Global Patient Safety Action Plan 2021–2030 (12)



SO1: Make zero avoidable harm to patients a state of mind and a rule of engagement in the planning and delivery of health care everywhere.

SO2: Build high-reliability health systems and health organizations that protect patients daily from harm.

SO3: **Assure the safety of every clinical process.**

SO4: Engage and empower patients and families to help and support the journey to safer health care.

SO5: Inspire, educate, skill and protect every health worker to contribute to the design and delivery of safe care systems.

SO6: Ensure a constant flow of information and knowledge to drive mitigation of risk, a reduction in levels of avoidable harm and improvements in the safety of care.

SO7: Develop and sustain multisectoral and multinational synergy, partnership and solidarity to improve patient safety and quality of care.



Implement localism in patient safety (12)



“All patient safety interventions will need to be carefully designed and tailored to meet countries’ and communities’ priorities, as well as their specific implementation needs”

“Global action can help, but the strength of the plan will lie in the passion and commitment for patient safety shown at the national, subnational and local levels.”

“Today, developing safe services for patients does not only involve the skills of planning, design and strategic investment, it also involves advocacy, awareness raising, political commitment, persuasion and localism.”



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*Thank you all for this opportunity to share my interests with
all the eBreast 11 partners!*



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