International Journal of Research Studies in Psychology
2023 Volume 9 Number 2, 1-13

Challenges experienced by healthcare workers during reprocessing of medical devices

Faral, Janet Macatangay ✉
Graduate School, Lyceum of the Philippines University – Batangas, Philippines

Received: 30 November 2023 **Revised**: 20 December 2023 **Accepted**: 31 December 2023
Available Online: 31 December 2023 **DOI**: 10.5861/ijrsp.2023.2009

ISSN: 2243-7681
Online ISSN: 2243-769X

OPEN ACCESS

Abstract

Surgical site infections (SSIs) are the most common healthcare-associated infections (HAIs) and can be prevented by reprocessing reusable medical devices. This study aimed to determine the challenges experienced by healthcare workers during the reprocessing of reusable medical devices in the hospital setting in the Philippines and to formulate a practice-based guideline based on the identified challenges. A qualitative phenomenological design was used with healthcare workers employed in a government hospital in Lipa City who had experience in reprocessing medical devices. In-depth interviews were conducted to gather data. The results showed that the respondents identified challenges in each stage of reprocessing, including Inadequate cleaning due to unavailable or limited cleaning supplies, hard-to-clean medical devices due to design features and retained debris, unregulated disinfectant due to scarcity of supplies and unsterile soaking solution, perforated packaging and insufficient packaging supplies, limited medical-surgical devices, malfunctioning of medical devices, occasional weak water flow, lack of training, exposure to infectious substances, failure to clean the medical device immediately and adequately, malfunctioning of autoclave machine, unsterile and unorganized storage room. The study concluded that the availability of resources, management, and awareness of the respondents regarding proper reprocessing of medical devices greatly affects their compliance with proper reprocessing, which in turn significantly impacts patient safety and infection control. Recommendations were provided for the management of proper reprocessing in case healthcare workers encountered these challenges.

Keywords: decontamination, healthcare-associated infections, reprocessing, reusable medical device, surgical site infection

Challenges experienced by healthcare workers during reprocessing of medical devices

1. Introduction

The World Health Organization estimates that infections related with healthcare impact hundreds of individuals worldwide. Millions of surgeries are done throughout the world every day, and one of the most prevalent diseases linked to healthcare is surgical site infection. The impacts are very extensive which includes morbidity, mortality, and increased hospitalization/ treatment costs. Due to poor hospital sanitation standards, more than 500,000 patients in the Philippines alone get surgical site infections (SSI) every year. These infections cause around 10% of deaths as cited by Talaver (2018).Nonetheless, surgical site infections are also included in the most preventable healthcare-associated infections which could be attained only if proper reprocessing of reusable medical device in the hospital will be performed.

Reusable medical devices" are instruments that medical workers can reprocess to diagnose and manage various clients or patients as defined by Food and Drug Administration (2023). These items include (1) devices used in medicine or surgery that introduced into the skin, mucus, or the human body (e.g., surgical devices, laryngoscopes, flexible endoscopes, dental devices); (2) apparatus machineries getting in touch with a patient that are used in diagnosing, examining, and treatment; (3) equipment for transporting bodily fluids, tissues, or materials prepared for use in humans (e.g., hemodialysis). When utilized on patients, these tools get dirty and infected with pathogens. Reusable medical devices go through "reprocessing or decontamination" to remove any chance of infection from a contaminated device. This is defined by the European Medical Device Regulation as "cleaning, sterilization, and other associated processes performed on a used equipment in order to permit its safe reuse. Additionally, the technical and functional safety of the used device is tested and restored." while FDA (2023) defines it as the procedures necessary to guarantee that a reusable medical device can be safely used for its intended purpose. Cleaning, examination, assemblage, testing for functionality (if necessary), disinfection (if necessary), packing and labeling, sterilization (if necessary), and storage are all steps in the process. These procedures are intended to clean up dirt and pollutants and disinfect or sterilize to render microorganisms inactive. To ensure the safety of patients, reusable medical equipment must be reprocessed properly. Some forms of reusable medical instruments may have residual debris, blood, tissue, or chemical disinfectants if they are not thoroughly cleansed after every patient usage which may lead to tissue irritation and other Health Care-Associated Infections (HAIs).

Improving reprocessing of reusable medical devices should be considered a main target for healthcare institutions; its success depends on several facility departments and healthcare staff in the Philippine context. Because all health workers play a critical role and share responsibilities in medical device reprocessing, compliance with the reprocessing standards is essential to avoid the transmission of communicable pathogens to patients with reusable medical devices. Healthcare procedures must categorize whether cleansing, disinfection, or sterilization is necessary based largely on each item's purpose, supplier's guidelines, and standards since sterilization is not always necessary for medical equipment. Multiple studies in various countries have identified challenges experienced by central sterile supply personnel in reprocessing of reusable medical devices which primarily includes adherence to reprocessing standards. The methods in reprocessing are complicated, requiring well-trained personnel with certain tools and infrastructure, and involve multiple subsequent steps that should be done correctly - starting with instrument or apparatus collection and receiving, processing, storage, and distribution across the institution by decontamination employees (WHO, 2022). Quality assurance system, such as validation, at each stage of the reprocessing is crucial to guarantee the device's safety, proper operation, and processes.

By determining the challenges experienced by healthcare workers during reprocessing of reusable medical devices, this study will be able to provide the points to improve in the current reprocessing procedure of the

institution. The study will also provide updates about current innovations developed across the globe on how to perform reprocessing systematically and aseptically. Hence, this study will not only benefit the central supplies department but also the infection prevention and control management of the whole institution in terms of reprocessing of reusable medical devices from a nursing viewpoint. With this study, the institution will be able to measure the effectiveness of its existing implementing guideline or procedure regarding reprocessing. Most of all, it will benefit the safety of the patients in terms of prevention of the spread of pathogens with the use of reusable medical devices. As a result of this study, the researcher will try to recommend a guideline regarding reprocessing of commonly used reusable medical devices, such as surgical instruments, which includes current trends or innovations on reprocessing procedures with respect to global standards.

The study aims to determine the challenges experienced by healthcare workers during the reprocessing of reusable medical devices in terms of compliance, safety, infection control, and management and formulate a practice-based guideline based on the identified challenges.

2. Methods

Research Design **-** This qualitative research utilized a phenomenological design which determined the challenges experienced by healthcare workers during reprocessing of reusable medical devices. Deakin University (2021), described a descriptive-phenomenological study as a type of qualitative research study design that discusses how people experience a certain situation or occurrence and reflects their lived experiences.

Participants of the Study **-** The participants of the study were healthcare workers employed in a selected government hospital in Lipa City. The researcher used a purposive sampling method which selects individuals based non-random criteria. These 13 healthcare workers (e.g., doctors, nurses, midwife, & nursing attendants) was determined through data saturation. The participants were all working in a government hospital in Lipa City, and Hasan had experience in reprocessing reusable medical devices such as those assigned in the Operating Room, Delivery Room, Emergency Room, Ward, OPD-OB, and/ or OPD-Surgery. The reusable medical devices used by the respondents are limited to surgical instruments used for major and minor operation, as well as laryngoscope for intubation. Those instruments utilized by the respondents were being decontaminated through either High-Level Disinfection or Steam Sterilization.

Data Gathering Instrument **-** The researcher used an in-depth interview with the involved participants as the data-gathering instrument. The open-ended questions focused on the challenges experienced by the healthcare workers during reprocessing of reusable medical devices while the closed-ended questions were more on the participants' demographic profile which includes age, gender, academic background (health/non-health related course), years of experience, area of assignment (Operating Room, Delivery Room, Emergency Room, Ward, OPD-OB, and/ or OPD-Surgery) and work group (Doctor, Nurse, Midwife, Nurse Attendant, etc.). Listed below served as the survey interview's guide questions; (1) What is your perception with regards to reprocessing of reusable medical devices? (2) What challenges have you experienced in each stage of reprocessing, and how do you deal with it? 2.a) Cleaning, 2.b) Inspection, 2.c) High-Level Disinfection (HLD)- (this step is not required if performing sterilization), 2.d) Packaging- (this step is not required if performing HLD), 2.e) Sterilization- (this step is not required if performing HLD), 2.f) Transport to storage, 2.g) Storage, 2.h) Transport after use; (3) How do you deal with the scarcity or unavailability of reusable medical device especially in an emergency scenario? (4) If there would be an instance when you must take the risk of issuing/ using incompletely decontaminated or reprocessed reusable medical device just to perform an emergency procedure, what additional measures will you make to reduce the risk for the patient? (5) How do you validate the safety of your reusable medical device?

The study's research tool was used to (1) gather data from the respondents and read any readily accessible contexts, (2) draw crucial information from those declarations, (3) develop interpretations, (4) arrange these interpretations into concepts, (5) connect these concepts into groups of logical and organized framework, (6)

develop essential justification of event, and lastly (7) to get additional details from the respondents and confirm actual responses related to their experiences.

Data Gathering Procedure - To collect the necessary data for this study, the researcher applied for approval from the Lyceum of the Philippines University-Batangas Campus and the selected government hospital in Lipa city. A letter and copy of the proposed study were sent to their respective Ethics Review Board for ethical consideration of the study. Following approval, the researcher prepared an informed consent form for the participants which was given before the study commences. A structured face-to-face interview was used to gather data to elicit the individual's challenges experienced, opinions, and feelings regarding the reprocessing of reusable medical devices. The researcher formulated guide questions based on the information gained from the related literature as the research instrument and then presented them to their adviser for sentiments, suggestions, and approval. Following approval of the study tool, the researcher gave the tool to participants with experience in reprocessing reusable medical devices. The researcher chose the month of July 2023 as the timeframe from which data from the respondents of the study will be gathered. The interview with each of the respondents would last for about one hour at a time. This includes the introduction, the purpose and explanation of the study, and the supposed interview together with a written document containing the purpose of the interview and a written consent paper to be signed by the respondent, stating their full knowledge and consent over the course of the interview. The interview was done during the respondent's free time based on the respondent's preferred schedule. The complete data collection process took about two (2) weeks. An audio recording device was used to accurately gather the statements from the research respondents, and its use is also for the intention of more reliable and valid documentation for the purposes of the study.

Ethical Considerations - Ethical issues were prioritized to guarantee that the study would be done in an ethical way. The study was examined by the Research Ethics Committee of the Lyceum of the Philippines University (LPU) – Batangas before the conduct of the study. This study adhered to the protocol set by the LPU-Batangas. After their approval, the researcher began to conduct the study, starting by obtaining the participant's full consent, which gave them a full explanation of all essential information about the study while ensuring their privacy and confidentiality.

Data Analysis - All the answers that were obtained in the structured research instrument was sorted, analyzed, and transcribed. Colaizzi's phenomenological approach to data analysis was utilized by the researcher to record the respondents' actual experiences, wherein the significant data was extracted and applied to create logical interpretations. These meanings were sorted and organized to a theme that was integrated together in a well- defined description that forms the framework structure of the phenomenon. For final validation of the result, the respondents were presented with the result of the analysis and let them determine if it is an exact match of their actual experiences.

3. Results and discussion

The researcher, using Colaizzi's methodology, analyzed the transcripts of interviews from the 13 respondents. The applications of the Environmental theory and Novice to Expert theory were explored leading to the formulation of themes with associated meanings derived from the findings of this study. The narrative statements of the 13 respondents were reviewed and clustered based on their affinity. Analysis was done in the form of major themes supported by sub-themes which were symbolically presented along with the supporting literatures that closely resembles the results as a part of the entire concept theory in general.

Theme 1: Perception with regards to Reprocessing of Reusable Medical Devices - This theme discusses the respondent's perspective with regards to reprocessing of reusable medical devices based on their acquired knowledge, what they learn from their experience, its importance, and how it affects the patient, the healthcare workers, as well as the institution.

Sub-Theme 1: Impact in patient's safety and infection control - Majority of the respondents' perception

with regards to reprocessing reusable medical devices werestating the importance of awareness and compliance to proper reprocessing procedure, its effect to patient safety as well as the infection control. As stated by respondent 7, 28-year-old female doctor assigned in Emergency Room/ ward with 3 years of experience, “It should be standard and must adhere to the sanitary guidelines that will ensure sterile and adequately autoclaved materials for every usage. It must prevent any transmissible infection to its users. Also, awareness and compliance to the proper reprocessing of reusable medical device strengthens the infection control and hygiene.”.Respondent12,47-year-old female midwife assigned in Emergency Room/ Ward Delivery Room with 22 years of experience said that “Proper decontamination of reusable medical device is crucial to patient in order to prevent infection and especially for the procedure to become successful.” The statements of the respondents can be correlated to the Environmental theory coined by Nightingale which she highlighted the importance of cleanliness as an environmental aspect to improve a patient's condition. This supports the importance of proper decontamination as part of reprocessing reusable medical devices to prevent transmission of illness or pathogens to patients. In addition, Forrester, et al (2018) stated in their study that when surgical instruments are ineffectively reprocessed, it may harbor pathogens. Likewise, Rutala, et al. (2019), quoted that the possibility of contamination involved in using health care equipment can be reduced when these cleaning, disinfection, and sterilization procedures are utilized properly. In contrast, for these procedures to be successful, medical workers must be aware of the decontamination guidelines and devotedly abide with it.

Sub-Theme 2: Supports in hospital and patient expenditure - In this theme, the focus is about how the use of reusable medical devices as well as its proper reprocessing affects the hospital and patient expenditure. As stated by respondent 2, 36-year-old female nurse assigned in Operating Room/ Ward/ Emergency Room with 14 years of experience, stating that “Reprocessing medical device is more convenient especially for the patient’s expenditure but poses risk to infection control due to repeated use.” While, Respondent 8, a 31-year-old female doctor assigned in Emergency Room/ ward with 5 years of experience said, “It is widely used in the setting of a government or public hospital as it is very cost effective. Minimizing the cost for every person admitted in the hospital. Awareness and compliance to proper reprocessing or decontamination of reusable medical device reduces the risk for possible transmission of infection to other patients as well as making sure that the device is fully functional and will prevent delays on the delivery of timely medical management.”. This implies the correlation to the article released by Omnia Health (2019), which reveals that due to the complexity and expense of medical devices, institutions prefer quick turnaround times from central decontamination division over buying lots of equities. Therefore, the goal of central decontamination division is to extend each instrument's life by adequate disinfection and reprocessing.

Theme 2: Challenges experienced in each stage of reprocessing and its’ management

This theme describes the challenges experienced by respondents to each stage of reprocessing and how they deal with those challenges. According to the article written by Henry Schein Medical, (n.d.), attaining acceptable criteria at every step of the life cycle (reprocessing) is necessary for effective decontamination. Inadequate decontamination will come from failing to address problems at any of these steps.

Sub-Theme 1: Inadequate cleaning of medical device due to the unavailable or limited cleaning supplies - This sub-theme is one of the most crucial stages of reprocessing because most of the concern regarding the effectiveness of reprocessing starts with cleaning. As Evangelista et al, (2019) emphasized in their study that if biological debris is left behind after cleaning, it could serve as a solid barrier to protect trapped pathogens from the sterilizing chemical. Additionally, it can contribute to the formation of a conditioning film, which promotes microbial adhesion by absorbing molecules from bodily fluid precipitation, such as proteins, lipids, and polysaccharides, to the surgical instrument's surface. Because blood may act as a source of sustenance for germs, its presence during surgery may encourage bacterial proliferation.

Most of the respondents’ perceived challenge in cleaning stage is the unavailability or scarcity of cleaning supplies which includes medical grade liquid soap or detergent and suitable brush. As Respondent 1, 35-year-old

female nurse assigned in Delivery Room/ Ward/ Operating Room with 13 years of experience, stated that “In cleaning, due to scarcity of supplies, sometimes we just settle on just brush and water since cleaning agents are not available.” Respondent 2, a 36-year-old female nurse assigned to the Operating Room/ Ward/ Emergency Room with 14 years of experience, also said, “In my facility, limited resources, such as availability of cleaning supplies, is a main problem”. In addition, according to Respondent 6,a 33-year-old female doctor assigned in Emergency Room/ ward with 7 years of experience, stated that “Unavailability of water and cleaning supply (e.g., detergent) in cleaning laryngoscope is a perceived concern. “These statements can be associated with the study conducted by Huynh, et al (2019), wherein the researchers mentioned that there are various limitations in medical settings, some of which are unavoidable, such as the wide range of equipment kits and the quantity of supplies available. Furthermore, Cuncannon et al., 2021, stated that it is challenging to perform sufficient sterile processing because of the lack of supplies and equipment necessary for the activity, such as warm water, instrument brushes, detergent or soap, sterilization indicators, and personal protection equipment.

Sub-Theme 2: Hard-to-clean medical device due to its design feature and retained debris such as blood stain or secretions - This sub-theme is one of the commonly encountered challenges not only by the healthcare worker in developing countries but even by the healthcare worker in developed countries. As stated by respondent 4, a 48-year-old female midwife assigned in Delivery Room/Ward/ Emergency Room with 6 years of experience, “In inspection, most of the time, the instruments are not properly cleaned and there is a lot of blood residue remaining in the instrument and once it was autoclaved, the blood was trapped in the serration of the instrument. “Respondent 9, a 36-year-old male nursing attendant assigned in Operating Room/ Emergency Room with 4 years of experience, shared that “It is hard for us to remove the blood stain especially when it already dried up. And when the cleaned instrument was not well dried prior to packaging and sterilization, rust forms so we soak it again and remove it with brush.” Respondent 11, who is a 37-year-old female nurse assigned in the Delivery Room/ Emergency Room/Ward with 4 years of experience, mentioned that “We repeat the cleaning when we noticed that there is remaining dirt. It can not be used since we are holding a patient’s life. It might cause infection to the patient.” In summary, when the respondents noticed upon inspection that when the instrument still has presence of debris or blood stain, they repeat the cleaning process. Those statements can be correlated with the study conducted by FDA (2018) which declared that with the device design such as (1) elongated, narrow lumens, (2) the hinges, (3) sleeves around rods, blades, catalysts, inserters, etc., (4) surrounding instrument areas where biological waste can be trapped while in use, (5) O-rings, (6) stopcocks, and (7) equipment with these or additional design characteristics that cannot be detached for reprocessing makes the device prone to retain fragments and biological contaminants. Moreso, Cuncannon et al., 2021, cited in his study that biofilm generation and bioburden retention have both been linked to insufficient cleaning, especially in complex-design devices that are difficult to manually clean. In the end, contaminated tools cannot be sterilized successfully.

Sub-Theme 3: Occasional weak water flow or loss of water supply - This challenge may not be as frequent as other challenges experienced by the respondents but it has a huge impact on reprocessing since water is a primary element used, especially in cleaning. As respondent 5, 33-year-old female nurse assigned in Emergency Room/ OPD- Surgery/ Ward with 14 years of experience, declared that “In our case, we experienced problem in water supply. Occasionally, we do not have water supply. Sometimes, we have prepared a soaking solution. We soak the instrument first to prevent blood from drying on the instrument. We have an available tray for the used instrument.” On the other hand, respondent 12, a 47-year-old female midwife assigned in the Emergency Room/ Ward Delivery Room with 22 years of experience said that, “Sometimes we encounter weak water flow or loss of water supply in the hospital that is why after OR procedure, we cannot perform immediate cleaning of instruments resulting to drying of blood and other debris on the used instruments. The same scenario with the laryngoscope wherein secretions and blood stains dried up, making it difficult to clean. “These statements can be assimilated to the news presented by Crisostomo (2019), wherein several DOH hospitals in Metro Manila experienced a water crisis hampering their operation and putting patient’s health at risk. Duque stated that water is essential for maintaining sanitation as well as hygiene, both of which are necessary for hospitals to function.

Moreover, water is vital for infection prevention and control procedures.

Sub-theme 4: Exposure to infectious substances - During reprocessing, the healthcare workers get exposed to infectious substances from the medical device, which puts them at risk of acquiring the disease, especially if they are not properly wearing complete personal protective equipment. Awareness of healthcare workers with regards to proper handling of medical devices, particularly sharp ones and those with visible contamination of body secretions, is vital. As respondent7, a 28-year-old female doctor assigned to the Emergency Room/ ward with 3 years of experience, said, "It (reprocessing of reusable medical device) should be standard and must adhere to the sanitary guidelines that will ensure sterile and adequately autoclaved materials for every usage. It must prevent any transmissible infection to its users. Also, being aware and compliance to the proper reprocessing of reusable medical device strengthens the infection control and hygiene". Moreover, the respondent 8,31-year-old female doctor assigned to the Emergency Room/ ward with 5 years of experience stated that "Healthcare workers and patients being exposed to fomite of infectious substance (is one of the noted risk or challenge during transport of medical instrument after use)." These statements can be associated with the study conducted by Ofstead et al. (2021), wherein he cited that when reusable medical devices and equipment are being decontaminated, employees who work in sterile processing face a serious risk of encountering tissue, blood, and patient fluids. When exposed to clean water and cleaning solution during simulated tasks, which are assumed to be heavily polluted during regular everyday activities, SPD staff were not sufficiently protected by the PPE currently suggested. Reprocessing staff should be given priority when it comes to high-quality, well-fitting PPE and training on donning and doffing to protect them against splash exposure in the setting of PPE shortages.

Sub-theme 5: Lack of training - Many studies with regards to reprocessing of medical devices declared lack of training as one of the hindrances to the attainment of adequate decontamination. This sub-theme was discussed by Respondent 13, a 33-year-old male nurse assigned in Emergency Room/ Ward/ Operating Room with 12 years of experience, stating that "what happens in our instrument during cleaning is merely brushing. Once it was brushed and get dried, we set it to autoclave. Back then, during the time of our strict OR nurse, we still manage to soak the instruments in a solution after cleaning. That is our practice before. After we brush the instrument, next step is we soak it in soaking solution with soap so that we can brush the parts of the instrument with remnants of blood. Nowadays, after we barely brush (clean)the instrument, when it dried, we immediately set it to autoclave because the OR procedure is continuous and we only have five CS sets. So, once you have done five CS procedure the whole day, what will you use for emergency at night? We immediately reprocess the instrument (so we can have available instrument to use again). That is why our instruments worn-out easily. "Respondent 8, a 31-year-old female doctor assigned in Emergency Room/ ward, also mentioned that "(one of the challenges identified during cleaning is healthcare workers are) not trained in the proper technique in cleaning the reusable medical devices...". This can be coincided to the article written by Nadeau (2022) wherein the author emphasized that CSSD personnel should understand the rationale of each step of the procedure for them to realize its importance in reprocessing. With education and training, they could perform reprocessing correctly and safely. Forrester, et al (2018) also stressed in their study that the most prevalent obstacles to efficient surgical tool reprocessing were ineffective education and training along with lack of adequate resources and insufficient guidelines. Moreover, it revealed that when it comes to washing healthcare equipment, insufficient training of the personnel is one of the identified concerns with regard to reprocessing. Thus, additional work needs to be done to ensure that those expected to reprocess medical devices receive quality education, training, and certification. Those are essential considerations to be included in the guideline. Lastly, in the study led by Sahiledengle (2019) in which they assessed the nurses' practice in reprocessing and other related aspects, they determined that in order to refine decontamination practice, training along with posting procedures focused on medical device decontamination per division must be provided.

Sub-theme 6: Malfunctioning of medical device - Issues in functionality of medical device is a common challenge experienced by the respondents during inspection stage of reprocessing particularly during the actual usage of the instrument. Respondent 2, a 36-year-old female nurse assigned in Operating Room/ Ward/

Emergency Room with 14 years of experience, declared that “Sometimes, the instruments are too old and fragile due to continuous usage and exposure to autoclave that’s why it easily gets broken, so we sort it out. “In addition, respondent 11, a 37-year-old female nurse assigned in Delivery Room/ Emergency Room/Ward with 4 years of experience, said that “Sometimes the needle holder is already swaying. Maybe, its tired on doing its function. Whenever we encounter that kind of incident, we remove the item and replace it so that it will not be used in the next procedure. We remove the impaired or unserviceable device and return it to their supplies office for condemn.” According to the article written by Nadeau (2022), aside from cleanliness, instruments should also be inspected for damage and malfunction to prevent it from causing harm to the patient. Furthermore, Zamzam et al. (2021) mentioned in their study that malfunctioning or unavailability of medical device greatly impacts the provision of healthcare services to the patient. The issues are typically brought on by a failure on the part of the accountable party to manage and maintain the state of the medical equipment. To improve availability, performance, and safety, it is crucial to analyze the state of medical device throughout maintenance and life cycle management.

Sub-theme 7: Unregulated disinfectant due to scarcity of supplies and unsterile soaking solution - In High-Level Disinfection (HLD) stage, the most significant challenge noted from the respondents are the scarcity of chemical disinfectants and presence of debris which includes blood, secretions, dirt, other contaminants. This can be supported by the statement of respondent 1, a 35-year-old female nurse assigned in Delivery Room/ Ward/ Operating Room with 13 years of experience, stating that “The disinfecting solution is not well regulated. Sometimes, the disinfecting solution already has blood debris. Still, due to insufficient supplies, we need to prolong the time of changing the soaking solution. The idea usually is weekly, or it depends on what is written in the chemical gallon because they have different concentrations. “Also, respondent 2, a 36-year-old female nurse assigned in Operating Room/ Ward/ Emergency Room with 14 years of experience said, “Due to insufficient supply of disinfectant (solution) sometimes we tend to add water in order to sustain the amount we need in everyday duty. Disinfection is not adequate.” In addition, respondent 4, a 48-year-old female midwife assigned to the Delivery Room/Ward/ Emergency Room with 6 years of experience, mentioned that “(In my experience) due to prolonged use of Cidex (Glutaraldehyde), the viscosity of the solution become jelly-like. And whenever it is raining, we often see some insects floating on the soaking tray. “These statements of the respondents can be correlated with the study conducted by Rutala et al. (2019), wherein the researchers asserted that to properly disinfect the medical device, the disinfecting agent, concentration, and duration of exposure are selected depending on other factors including the risks for infection brought on by using the equipment. While in the study conducted by Forrester et al. (2018), they specified that some of the obstacles to efficient surgical tool reprocessing includes (1) lack of adequate resources, (2) ineffective education and training, and (3) insufficient guidelines. Also, Cuncannon et al. (2021), mentioned that several writers addressed how it is challenging to perform sufficient sterile processing because of the lack of supplies and equipment necessary for the activity, such as warm water, instrument brushes, detergent or soap, sterilization indicators, and personal protection equipment.

Sub-theme 8: Perforated packaging and insufficient packaging supplies - The importance of the availability of supplies needed for proper packaging and its intactness is the notable challenge experienced by the respondents during packaging. As respondent 1, a 35-year-old female nurse assigned in Delivery Room/ Ward/ Operating Room with 13 years of experience, said “Still, limited supplies. We need to re-use the inner cover of the (sterile) gloves to use as packaging. We also use cloth, but sometimes there is no available supply (extra cover, particularly when it is raining and the cloth cover is still wet). Sometimes, we use three sheets; we fold them depending on the instrument's sharpness, like a mosquito. It gets perforated when exposed to an autoclave due to moisture. We do not have a tray; we packed it (the instrument) directly with the sheet.” Respondent 5, the 33-year-old female nurse assigned to Emergency Room/ OPD- Surgery/ Ward with 14 years of experience, also mentioned that “Sometimes, it (the packaging) easily gets perforated if you use paper. Sometimes, it gets perforated inside the autoclave machine due to moisture.” This statement of the respondents can still be supported by the study conducted by Forrester et al (2018) wherein the supply of resources is cited as

one of the obstacles to to efficient surgical tool reprocessing. Huynh, et al (2019) also mentioned that in medical settings, instrumentation delivery delays are a frequent source of disorganization wherein they identified that one of the causes of delays is due to the packaging that is non-woven or packed in highly heavy containers (which increases the danger of residual dampness or piercing upon autoclave departure, thus necessitating reprocessing). Moreover, Chobin (2019), revealed that one of the factors which affects the sterility of the item is the materials used for packaging.

Sub-theme 9: Limited medical-surgical devices **-** Scarcity or unavailability of reusable medical device specially during an emergency scenario is one of the most difficult challenges experienced by the respondents because the success of the operation greatly depends on the availability of the medical device needed for the procedure. As stated by respondent 1, a 35-year-old female nurse assigned in Delivery Room/ Ward/ Operating Room with 13 years of experience, “Being in government hospital, we learned to be resourceful in all aspect. Especially, sometimes, the patient is fully, for delivery. We don not have any available materials to use. Because, here (at the hospital), not all items are available. Or sometimes, from ER, the instrument was used in minor operation, you do not have anything to use. You need to be resourceful because it is only one set. Like the cord clamp, we ask to purchase. But if there is no available cord clamp, sometimes we use tie (sterile knot tie). Sometimes, if there is profuse bleeding, we will pack it first with, “those days”, napkin. Then you must stay alert and focus in every situation. Likewise, respondent 5, a 33-year-old female nurse assigned in Emergency Room/ OPD- Surgery/ Ward with 14 years of experience, stated that “We just settle on what is available (in the instrument set), we just reuse what is on the (mayo) table. We clean the instrument and wash it with the solution. Sometimes, after we clean it with soap, we soak it shortly in the Cidex (Glutaraldehyde) then we rinse it with PNSS. These statements can be attributed with the study of Zamzam et al. (2021) in which they declared that the efficacy of healthcare services is significantly influenced by medical device. Malfunctioning or unavailability of medical device greatly impacts the provision of healthcare services to the patient. The issues are typically brought on by a failure on the part of the accountable party to manage and maintain the state of the medical equipment. To improve availability, performance, and safety, it is crucial to analyze the state of medical device throughout maintenance and life cycle management. Cuncannon et al. (2021), also stated that deficits in the availability, quality, and continuing maintenance of resources, notably priceless surgical tools, and equipment, limit the ability of developing country’s health institutions to perform surgery.

Sub-theme 10: Failure to clean the medical device immediately and adequately **-** One of the identified challenges in the transport after use stage is the delay in pre-cleaning of the instruments. As respondent 5, 33-year-old female nurse assigned in Emergency Room/ OPD- Surgery/ Ward with 14 years of experience, stated that “In our case, water. Sometimes, we do not have water supply. Sometimes, we have prepared soaking solution. We soak the instrument first to avoid blood from getting dried on the instrument. We have available tray for the used instrument.” While respondent 10, 34-year-old male nurse assigned in Emergency Room/ ward with 9 years of experience, stated that “Sometimes, the instrument was being left. Sometimes, it was not immediately cleaned by NA (nursing attendant). It is just there at the sink. Because of that (blood dried on the instrument), we clean it again and soak it in the Cidex. There is like a flat tray there for the used instruments. The used instrument is just placed there. Because, sometimes, the doctor is so busy, he forgets to instruct to clean the instrument.” These concerns can be associated to the study of Evangelista, et al, (2019), wherein they mentioned that aside from the advice to begin cleaning the surgical instrument as soon as possible, its prompt transport is crucial, in within 2 hours, to begin reprocessing in the central sterile supply facility for adequate cleansing and subsequently the patient's safety.

Sub-theme 11: Malfunctioning of autoclave machine **-** In the sterilization stage of reprocessing, the challenge perceived by the respondents is the availability of spare autoclave machine once their autoclave machine malfunctioned. Respondent 2, 36-year-old female nurse assigned in Operating Room/ Ward/ Emergency Room with 14 years of experience stated, “Every time our autoclave machine malfunctions, we still have to conduct the sterilization of our instruments and other packs in nearby district hospitals.” Similarly, respondent 9, 36-year-old male nursing attendant assigned in Operating Room/ Emergency Room with 4 years of experience,

stated that “When our autoclave machine malfunctioned, our nurse coordinate to other district hospital so that we can autoclave our pack and instruments in their autoclave machine.” This challenge experienced by the respondents, still coincides with the study by Forrester, et al (2018) wherein the supply of resources is cited as one of the obstacles to efficient surgical tool reprocessing. According to Huynh, et al. (2019), instruments supply delays are a common cause of disarray in medical settings. Instrument sets are likely to experience shortage due to equipment malfunction (autoclave or washer) or environmental concerns.

Sub-theme 12: Unsterile/ Disorganized storage room - The highlight in the storage phase of reprocessing is the cleanliness, safety, and sterility of the storage area. However, the respondents encountered challenges in this stage when the cleanliness, safety, and sterility of the storage area were not maintained. The respondent, 37-year-old female nurse assigned in Delivery Room/ Ward/ Emergency Room with 16 years of experience, mentioned that “We are encountering ceiling leak, sometimes when it is raining heavy, we transfer our supplies to other areas. “Respondent 9, a 36-year-old male nursing attendant assigned in the Operating Room/ Emergency Room with 4 years of experience, also said, “Sometimes, we cannot avoid the ceiling leak when there is heavy rain; we just transfer the instruments to the part where there is no leakage. “These statements can be associated with the article of Chobin (2019), wherein she stated that materials used for packaging, storage procedures and conditions, handling procedures, and distribution techniques all have an impact on maintaining sterility. All sterile items must be maintained and kept in such a way as to ensure that sterility is maintained until a product is utilized, regardless of whether they were sterilized in the facility or obtained from an outside manufacturer. Storage and handling circumstances have an impact on package physical damage as well as package exposure to moisture or soil. In other words, whether a package's contents stay sterile depends on how it is handled and stored.

Theme 3: Coping Strategies and Risk-Management

Sub-theme 1: Improvise/ Provide alternative medical device - In this study, most of the respondents improvise or provide alternative item in lieu of the unavailable medical device. As stated by respondent 1, a 35-year-old female nurse assigned in the Delivery Room/ Ward/ Operating Room with 13 years of experience, “Being in a government hospital, we learned to be resourceful in all aspects. Especially sometimes the patient is full for delivery. We do not have any available materials to use. Because, here (at the hospital), not all items are available. Sometimes, in the ER, the instrument was used in the minor operation, and you do not have anything to use. You need to be resourceful because it is only one set. Like the cord clamp, we ask to purchase. But if there is no available cord clamp, sometimes we use tie (sterile knot tie). Sometimes, if there is profuse bleeding, we will pack it first with “those days” napkin. Then you must stay alert and focus in every situation. Respondent 6, 33-year-old female doctor assigned in Emergency Room/ ward with 7 years of experience, also said that “Being resourceful by looking for alternatives in lacking devices or personally procuring some affordable devices (e.g., penlight for laryngoscope when its bulb is busted).” These statements of the respondents can be associated with Patricia Benner’s theory of “From Novice to Expert.” As per Dr. Benner, through a solid academic foundation and wide range of experiences, nurses acquire expertise and skills in patient care over time as cited by Current Nursing (2020). In this scenario, the respondents have identified ways or alternatives to managing the scarcity of medical devices through the vast amount of experience.

Sub-theme 2: Borrow device from other area - Since the performance or implementation of the procedure highly depends on the availability of the medical instruments, borrowing devices from other areas is the initial action done by the respondents in the management of scarcity or unavailability of medical instruments. Respondent 10, a 34-year-old male nurse assigned in the Emergency Room/ ward with 9 years of experience, declared that “Usually, we borrow instruments or medical device to other area or hospital when we really have nothing to use (we request to other hospital) if we can use their autoclave machine or if we can borrow instruments. “Respondent 12, a 47-year-old female midwife assigned to the Emergency Room/ Ward Delivery Room with 22 years of experience, also stated that “(when we have limited medical instruments) we need to clean the instrument first and sterilize it prior to next utilization. If it is urgently required to clean the wound of

the next patient, we borrow instruments from OR to perform the procedure."

Sub-theme 3: Immediate disinfection/ sterilization - This sub-theme highlights the risk management and contingency plan of the respondents in case they need to use an incompletely decontaminated or reprocessed reusable medical device in an emergency scenario. Immediate disinfection using Alcohol, Betadine, or Glutaraldehyde (Cidex) as a mode of decontamination is the one that stands out among all the answers of the respondents regarding most practiced risk-management techniques, particularly during emergencies. As respondent 3, 37-year-old female nurse assigned in Delivery Room/ Ward/ Emergency Room with 16 years of experience, stated that "If this scenario came, we will make sure to at least soak materials or supplies to cidex or disinfectant to reduce risk for infection." In addition, respondent 6, a 33-year-old female doctor assigned in the Emergency Room/ ward with 7 years of experience, said that "At least disinfect the laryngoscope with alcohol and monitor patients for possible occurrence of sepsis for early initiation of antibiotics." Respondent 13, the 33-year-old male nurse assigned in Emergency Room/ Ward/ Operating Room with 12 years of experience, even said that "For example, if you really have no choice. It happens when it is a loaner instrument, more on ortho cases. For example, we only have one bone curette. Let's pretend that it was autoclaved and used, then it suddenly falls. The only choice is to soak it in the Cidex immediately for you to be able to use it again. So, there is really a risk for infection. But at least we soaked it in the Cidex." The respondent's answers can be correlated with the study of Rutala et al. (2019), wherein they cited that alcohols, glutaraldehyde, and chlorine as some of the commonly used chemical disinfectants for medical devices. The disinfecting agent, concentration, and duration of exposure are selected depending on other factors including the risks for infection brought on by using the equipment. Furthermore, Omnia Health (2019) revealed in their article that inadequate decontamination of instruments might result in HAI's or even patient harm. Thus, challenges from workers are to do it quick, correct, and ensure the safety of the patients and the personnel. Additional concern is loaner instrument which needs immediate reprocessing/ decontamination.

Sub-theme 4: Perform Post Exposure Prophylaxis - Aside from ensuring proper reprocessing of complex designed reusable medical device such as endoscopes, provision of post exposure prophylaxis as an advance means of reducing risk for the patient is one of the exclusive roles of the medical practitioners. As respondent 6, a 33-year-old female doctor assigned in Emergency Room/ ward with 7 years of experience, stated "At least disinfect the laryngoscope with alcohol (after thorough cleaning) and monitor patients for possible occurrence of sepsis for early initiation of antibiotics. (when exposed in an emergency scenario wherein there is only one laryngoscope and should be used immediately after the next patient)." Respondent 8, 31-year-old female doctor assigned in Emergency Room/ ward with 5 years of experience, also mentioned that "(we) perform post exposure prophylaxis to possible contaminants and clearly observe the patient. (We) make sure that the reusable medical device (e.glaryngoscope) is completely decontaminated next time somebody will use it". The respondent's answers can be correlated with the article Evolved Sterile Processing (ESP) (2021), wherein it is declared that proper reprocessing of instruments is as essential as adherence to the aseptic technique in the operating room when it comes to patient safety. Thus, the provision of additional antibiotics to patients at the award was given to fight infection when failures occur. Concern on sterile processing department's involvement in patient safety was evident in both quantitative and qualitative data, particularly about procedures like the use of immediate-use steam sterilization. It must concentrate on investigating every aspect of surgery, including crucial role played by sterile processing departments in the prevention of adverse patient events and surgical patient safety (Brooks et al., 2019).

Sub-theme 5: Validation of Reprocessed Reusable Medical Device - This sub-theme describes the means of validation used by respondents to consider the reprocessed reusable medical device as safe to use, hence, reducing risk to the patient. The identified means of validation commonly used by the respondents are through autoclave chemical indicator tape, exposure time to and cleanliness of disinfectant solution, intact packaging, and physical inspection (cleanliness, intactness & functionality of device). The respondent relied mostly on autoclave chemical indicator tape as a means of validation. As Respondent 2, a 36-year-old female nurse assigned to the Operating Room/ Ward/ Emergency Room with 14 years of experience, said, "We checked the

autoclave tape if it turned to color black." Moreover, respondent 9, a 36-year-old male nursing attendant assigned to the Operating Room/ Emergency Room with 4 years of experience, "I can say that the instrument is safe to use when it is clean and sterilized in autoclave machine. When you see that autoclave tape turned black or if it (instrument) was soaked for at least 1 hour." This can be associated with the study conducted by Ling et al (2018), wherein validation of the reprocessed equipment (device's cleanliness, sterility, and functionality is done) is cited as one of the best practices to ensure patient safety. In addition, it stated that professional groups are striving to establish guidelines that all organizations can follow. For reprocessing of medical devices, (1) mandatory implementation of close inspections and quality assurance, as well as (2) verifications during the reprocessing, are some of the notable considerations to be included in the guideline.

4. Conclusions and recommendations

The respondents' identified challenges in reprocessing of reusable medical devices in hospital setting includes (1) inadequate cleaning of medical device due to the unavailable or limited cleaning supplies, (2) hard-to-clean medical device due to its design feature and retained debris such as blood stain or secretions, (3) unregulated disinfectant due to scarcity of supplies and unsterile soaking solution, (4) perforated packaging and insufficient packaging supplies, (5) limited medical-surgical devices, (6) malfunctioning of medical device, (7) occasional weak water flow, (8) lack of training, (9) exposure to infectious substances, (10) failure to clean the medical device immediately and adequately, (11) malfunctioning of autoclave machine, and (12) unsterile storage room. The availability of resources, management, and awareness of the respondents regarding proper reprocessing of reusable medical devices greatly affects their compliance, which in turn poses a significant impact on patient safety and infection control.

The hospital management should ensure the availability of adequate resources for reprocessing medical devices, including cleaning supplies, disinfectants, packaging supplies, and medical-surgical devices. The hospital should also provide regular training to healthcare workers on proper reprocessing procedures and infection control measures. Healthcare workers should be aware of the challenges that may arise during reprocessing and be prepared to take appropriate measures to address them. Healthcare workers should also be vigilant in monitoring the quality of reprocessed medical devices and reporting any concerns to their supervisor immediately. Utilization of the proposed Practice-Based Guidelines in Reprocessing Reusable Medical Devices using Sterilization thru developed PIS-PQRS and IPHIMP-PD guidelines

5. References

Brooks, J. V., Williams, J. A., & Gorbenko, K. (2019). The work of sterile processing departments: An exploratory study using qualitative interviews and a quantitative process database. American journal of infection control, 47(7), 816-821.

Chobin, N. (2018). Maintaining Proper Sterile Storage Conditions. Retrieved from https://www.infectioncontroltoday.com/view/maintaining-proper-sterile-storage-conditions

Crisostomo, S. (2019). Hospitals also hit by water shortage. Retrieved from https://www.philstar.com/headlines/2019/03/14/1901349/hospitals-also-hit-water-shortage/amp/

Cuncannon, A., Dosani, A., & Fast, O. (2021). Sterile processing in low-and middle-income countries: an integrative review. Journal of Infection Prevention, 22(1), 28-38.

Deakin University. (2021). Qualitative Study Design. Retrieved from https://deakin.libguides.com/qualitative-study-designs/phenomenology

Evangelista, S. D. S., Santos, S. G. D., & Oliveira, A. C. D. (2021). Impact of the contamination time by Escherichia coli on biofilm formation in surgical instruments. Revista Brasileira de Enfermagem, 74.

Food and Drug Administration. (2023). Reprocessing of Reusable Medical Devices. Retrieved from www.fda.gov/medical-devices/products-and-medical-procedures/reprocessing-reusable-medical-devices

Forrester, J. A., Powell, B. L., Forrester, J. D., Fast, C., & Weiser, T. G. (2018). Surgical instrument reprocessing in resource-constrained countries: a scoping review of existing methods, policies, and barriers. Surgical

infections, 19(6), 593-602.

Huynh, E., Klouche, S., Martinet, C., Le Mercier, F., Bauer, T., & Lecoeur, A. (2019). Can the number of surgery delays and postponements due to unavailable instrumentation be reduced? Evaluating the benefits of enhanced collaboration between the sterilization and orthopedic surgery units. Orthopaedics & Traumatology: Surgery & Research, 105(3), 563-568.

Ling, M. L., Ching, P., Widitaputra, A., Stewart, A., Sirijindadirat, N., & Thu, L. T. A. (2018). APSIC guidelines for disinfection and sterilization of instruments in health care facilities. Antimicrobial Resistance & Infection Control, 7(1), 1-11.

Nadeau, K. (2022). Controlling the complexities of decontamination and cleaning. Retrieved from https://www.hpnonline.com/sterile-processing/article/21264313/controlling-the-complexities-of-decontamination-and-cleaning

Ofstead, C. L., Hopkins, K. M., Smart, A. G., & Brewer, M. K. (2022). Droplet dispersal in decontamination areas of instrument reprocessing suites. American Journal of Infection Control, 50(2), 126-132.

Rutala, W. A., & Weber, D. J. (2019). Guideline for disinfection and sterilization in healthcare facilities, 2008. Update: May 2019.

Sahiledengle, B. (2019). Decontamination of patient equipment: nurses' self-reported decontamination practice in hospitals of southeast Ethiopia. BMC research notes, 12(1), 1-7.

Talaver, N. (2018). Emerging medical tourism in the Philippines raises a question on medical device reprocessing in the country. Retrieved from https://www.linkedin.com/pulse/emerging-medical-tourism-philippines-raises-question-device-talaver

World Health Organization (WHO). (2022). Decontamination and reprocessing of medical devices for health-care facilities, Aide-memoire. www.who.int/publications/i/item/WHO-UHL-IHS-IPC-2022.4.

Zamzam, A. H., Abdul Wahab, A. K., Azizan, M. M., Satapathy, S. C., Lai, K. W., & Hasikin, K. (2021). A systematic review of medical equipment reliability assessment in improving the quality of healthcare services. Frontiers in Public Health, 9, 753951.