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Incidence of Wet and Compromised Sterile Surgical Packs in Association with Competence of Operating Room Staff in a Tertiary Care Teaching Hospital: A Cross-Sectional Study

Hassan Latif
hassanlatif898@gmail.com
Imran Idrees Institute of Rehabilitation Sciences Sialkot

***Muhammad Wajid Munir (Corresponding Author)**
wajidmunir97@gmail.com
Head of Department, Operation Theater Technology, Imran Idrees Institute of Rehabilitation Sciences Sialkot
ORCID iD: https://orcid.org/0009-0003-6126-1941

Fatima Jaweria
fatimajaweria25@gmail.com
Ibadat International University Islamabad

Tariq Saeed
tariqsaeed6675@gmail.com
Lecturer, Operation Theater Technology, Imran Idrees Institute of Rehabilitation Sciences Sialkot

Ammanuel Masih
ammanuelmasih033@gmail.com
Surgical Technologist, Farooq Hospital, Thokar Niaz Baig, Lahore

Memona Akbar
memonaakbar907@gmail.com
Imran Idrees Institute of Rehabilitation Sciences Sialkot

Author Details

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Corresponding E-mail & Author*:

Muhammad Wajid Munir
Head of Department, Operation Theater Technology, Imran Idrees Institute of Rehabilitation Sciences Sialkot
wajidmunir97@gmail.com

Abstract

Background Wet and compromised sterile packs are patient safety issues in surgical practice because any remaining moisture and packaging flaws provide avenues of microbial contamination of sterilized instruments. Although there is increasing evidence on this matter at international levels only, no Pakistani operating room data were available, especially on the incidence of packs and employee knowledge, attitudes, and practices (KAP). Wrapping made of linen, which continues to be popular in resource constrained environments, has been linked with increased moisture retention and loss of sterility. **Objective:** This research will establish the rate and nature of wet and compromised sterile packs reaching the operating room, and the knowledge, attitudes and practices of the operating room staff in identifying and dealing with them. **Methods:** Over the course of four weeks, data will be gathered for this cross-sectional study in a teaching tertiary care hospital. Two sets of data collection tools will be used simultaneously: a validated KAP questionnaire to be distributed to the staff of the operating room and central sterile supply department, and a pack observation checklist as a structured pack to record the condition of all sterile packages entering the operating room. Sterile packs utilized during the study period will be all included. The group of 20-60 staff members will be used as a convenience sample. The SPSS will be used to analyze data and will involve the use of descriptive statistics, frequency, percentage, and chi-square tests to determine relationships between staff demographics and KAP scores. **Expected Results:** According to similar regional and international literature, wet and compromised packs should occur at different rates in different types of packs and different materials used in its packaging. KAP scores in the operating room personnel are expected to vary based on years of experience, title, and training on sterile processing in the past. The knowledge-practice gap revealed will be understood within the framework of the available educational and systemic aspects at the institutional level. This study will generate the first documented evidence on wet and compromised sterile pack incidence and staff KAP from a Pakistani operating room setting. The results will be used to guide specific training interventions, institutional policy change, and will also serve as a basis to enhance the sterile processing practice in resource-constrained healthcare settings.

INTRODUCTION

1.1 Background

Surgical site infections (SSIs) are among the most common and preventable healthcare-associated infections worldwide. They contribute to prolonged hospital stays, increased patient morbidity, and substantial financial burden on healthcare systems (Calderwood et al., 2023). A critical yet frequently underappreciated factor in SSI risk is the physical integrity of sterilized surgical instrument packs at the point of use. After the sterilization cycle, the only protection of sterility of the instruments will be the barrier of the packaging material until the pack is opened in the operating room (OR) (Buckner, 2024).

Any package that is sterile, but has some moisture seen on the inner or outer surface after the completion of the sterilizing and cooling cycles is considered a wet sterile pack. (Basu, 2016). This moisture results in a capillary path that runs through the

packaging material. In this way, the microorganisms in the environment can travel into the sterile contents. This is referred to as "strike-through" contamination (Dreikausen et al., 2023). Bacterial culture positive rates as high as 50% have been reported for wet packs, which indicate that a wet pack is a true sterility failure and not simply a minor operational inconvenience (Chen et al., 2024).

The term compromised sterile pack is a more general term. Any sterile package that does not comply with the physical and/or processing integrity necessary for maintaining the sterility of the package contents. This includes wet packs, packs with tears, broken seals, failed chemical indicators, expired packs for sterilization dating or very visible soiling (Buckner, 2024; Dreikausen et al., 2023).

Internationally, documented incidence rates vary widely. Basu (2016) reported approximately 1% in an Indian tertiary cancer centre, attributing this primarily to reusable linen wrapping and poor steam quality. Chen et al. (2024) identified a 3.12% wet pack rate among 4,099 packs inspected in a Chinese medical centre. A survey of 125 hospitals found wet pack events in 78% of facilities, with Chinese institutional rates ranging from 1.67% to 19.7% (Chen et al., 2024). The consequences extend beyond sterility concerns. Compromised packs cause operating room scheduling delays, increased CSSD workload, material waste, and most importantly, an elevated patient risk of SSI (Basu, 2016; Busada, 2024).

Staff competence is a directly modifiable determinant of how reliably these risks are identified and managed at the point of use. Last human barrier between instruments and the sterile field is the scrub practitioner receiving the pack at the operating table. Lack of knowledge about what is considered compromised and attitudes that would tolerate time pressure instead of safety permit sterility failures to go undetected into surgery (Moore, 2008). Previous knowledge, attitude, and practice (KAP) studies in low and middle income country (LMIC) settings have reported on lack of knowledge, attitudes, and practices among perioperative staff. Habtewold et al. (2024) found adequate sterile technique knowledge in only 58.1% of operating room nurses surveyed across seven hospitals in Addis Ababa, Ethiopia.

1.2 Problem Statement

In a tertiary care teaching hospital in Pakistan, the incidence and type of wet and compromised sterile surgical packs arriving at the operating room are unknown. The knowledge, attitudes, and practices of OR and CSSD staff regarding their identification and management have not been assessed. This is a combined knowledge gap which is a patient safety risk that cannot be quantified and limits the institution's ability to implement targeted, evidence-based quality improvements.

1.3 Objectives of the Study

The study was conducted with the following objectives:

1. To determine the incidence and type of wet and compromised sterile surgical packs received in the operating room of a tertiary care teaching hospital.
2. To assess the knowledge, attitudes, and practices of OR and CSSD staff regarding the identification and management of wet and compromised sterile packs.

1.4 Research Questions

1. What is the incidence of wet and compromised sterile packs among all packs received in the OR during the study period?
2. What types of compromise are most frequently observed, and does incidence vary by packaging material or pack type?
3. What are the KAP levels of OR and CSSD staff regarding sterile pack management?
4. Is there a statistically significant association between staff demographics and KAP scores?

1.5 Significance of the Study

This study is the one to show what really happens in a Pakistani operating room when

it comes to sterile packs that are not completely sterile and what the staff knows about this. The study looks at the incidence of compromised packs and the staffs knowledge and practices in this area, which is really important, for clinical practice. The KAP data collected in this research will also provide a scientific basis for education/training programs to develop curricula to help fill identified knowledge deficits rather than ones based on assumptions. At the policy level, results from this study may influence decision-making processes such as what types of materials should be used for packaging; whether or how much additional education/training needs to be provided to hospital employees working with sterilized packs; what criteria need to be met for packs to be rejected; and what mechanisms are needed for documenting incidents related to compromised packs.

1.6 Operational Definitions

1.6.1 Wet Sterile Pack

Any sterilized package in which residual moisture is detectable on any inner or outer surface following the completion of the sterilization and post-sterilization cooling cycles (Basu, 2016).

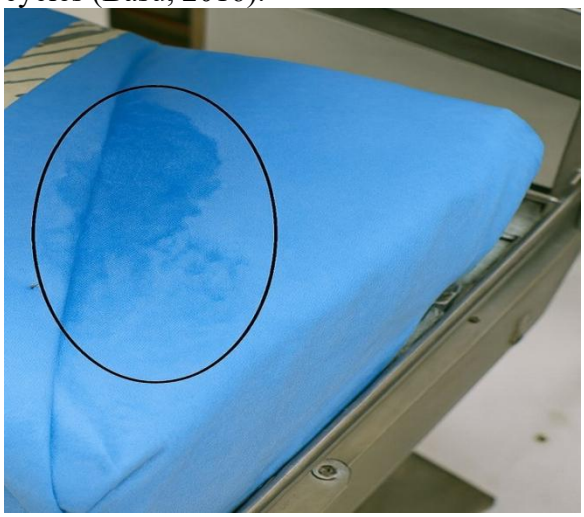

Figure 1.1: Wet sterile pack showing visible moisture staining on the non-woven SMS outer wrap (circled). Pack must be rejected, documented, and returned to CSSD for reprocessing

1.6.2 Compromised Sterile Pack

Any sterilized package failing to satisfy physical and process integrity requirements needed to ensure continued sterility of its contents. This includes: (a) wet packs as defined above; (b) packs with torn, punctured, or structurally damaged outer wrapping; (c) packs with broken or incomplete heat seals; (d) packs with failed, absent, or incorrect chemical sterilization indicators; (e) packs with expired sterilization dating; and (f) packs with gross visible soiling, blood, or pest damage (Buckner, 2024; Dreikausen et al., 2023).

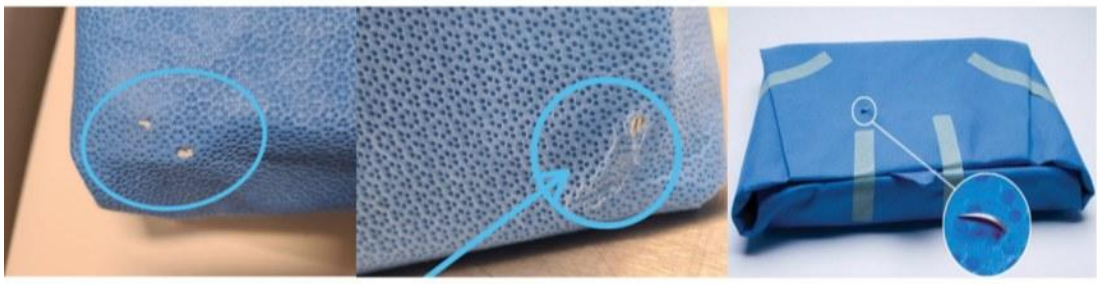

Figure 1.5: Three examples of punctured and torn SMS non-woven wrap. Left and centre: close-up views showing small puncture holes (circled in blue). Right: intact-appearing pack with a close-up inset revealing a needle tip protruding through the

wrap — a common cause of hidden packaging breach.

1.6.3 Knowledge, Attitudes, and Practices (KAP)

Knowledge refers to accurate understanding of sterilization principles, sterility maintenance, and identification and management of compromised packs. Attitude refers to the degree to which staff support evidence-based practices in identifying, removing, and reporting compromised packs. Practice refers to self-reported behaviours in routine pack inspection, handling, rejection decision-making, and incident reporting (Moore, 2008).

1.6.4 Incidence of Compromised Packs

The proportion of all sterile packs received in the OR during the study period that were classified as wet or compromised upon systematic inspection, expressed as a percentage.

1.6.5 Central Sterile Supply Department (CSSD)

CSSD is defined as the designated hospital unit responsible for decontamination, assembly, packaging, sterilization, storage, and distribution of sterile goods to the operating room and other clinical areas.

LITERATURE REVIEW

2.1 Introduction

This chapter provides a comprehensive review of the published literature related to the two main objectives of the present study: how often surgical packs get wet or damaged and what the people who work in the operating room know and do about keeping these packs sterile and preventing infections. We looked at studies from countries, including China, India and some places in Africa and the Middle East. We used databases like PubMed and Google Scholar to find the information we needed. We searched for things like " pack" and "surgical site infections" to find the right studies. We mostly looked at articles that were published between 2008 and 2025.

2.2 Surgical Site Infections and the Sterile Processing Chain

Surgical site infections (SSI) is defined as any infection at or near the surgical incision that occurs in the 30 days following a procedure or 90 days following a procedure if a prosthetic implant is used (Calderwood et al., 2022). They are the most common health-care-associated infection (HAI) in low and middle-income country (LMIC) settings, with an estimated incidence of 11.8% in surgical patients, and as high as 19% or more in some high-risk surgical procedures, such as orthopedic implant procedures and abdominal surgery (World Health Organization, 2018). In high income countries, the SSI rate is much lower at 1-3%, mainly because of the systematic use of evidence-based SSI prevention bundles, effective surveillance, and secure sterile supply chains. The difference in these rates shows that SSIs are not a normal result of surgery, but rather one that can be avoided or prevented, and that the frequency of SSIs is dependent on the quality of the perioperative systems that are in place. Calderwood et al. (2022) updated the Society for Healthcare Epidemiology of America (SHEA) and the Infectious Diseases Society of America (IDSA) evidence-based guidelines on SSI prevention. In the 2022 update, peri-operative staff education (including sterile technique, handling of sterile instruments, and risk factors for SSI) is included as an essential, evidence-based recommendation that is applicable in all acute-care hospitals, regardless of resource levels.

The importance of the classification is that it elevates the status of staff education to the level of evidence and urgency as surgical hand preparation and preoperative antimicrobial prophylaxis

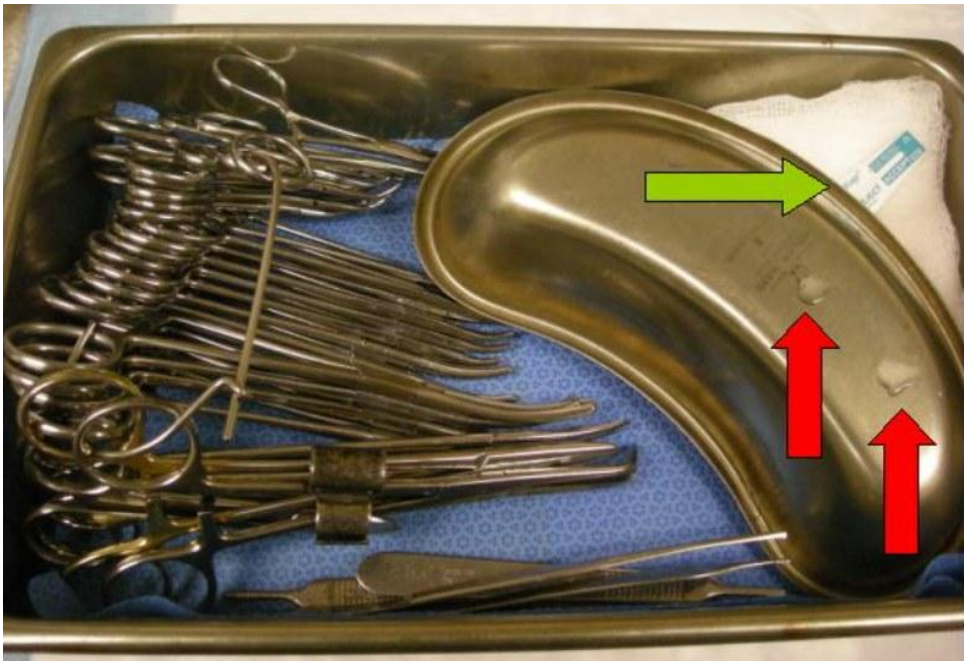

Figure 1.8: Instrument tray after sterilization. Green arrow indicates residual moisture on the emesis basin surface; red arrows show pooled water/condensation at the base of the tray. This tray constitutes a wet pack and is not safe for surgical use.

2.3 Wet and Compromised Sterile Packs: Incidence and Aetiology

2.3.1 Reported Incidence Rates

Different studies have found rates of wet packs. Chen et al. (2024) examined 4,099 packs from a Chinese CSSD, found that 3.12% of packs were wet. Another study (Chen et al., 2024) found that 1.67% to 19.7% of packs were wet in different hospitals. A survey of 125 hospitals found that 78% of them had problems with packs. Another study in India found that 1% of packs were wet. There is not information about this problem, in Pakistan. (Munir et al., 2025)

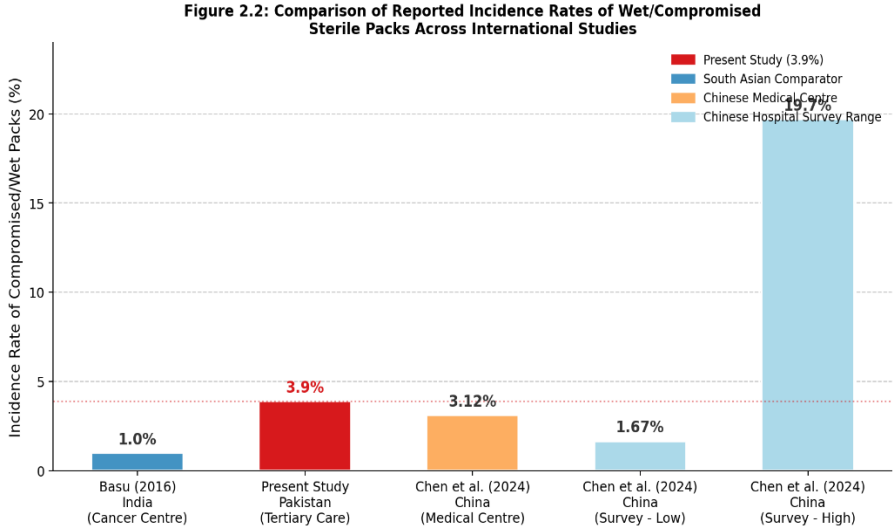

Figure 2.2: Comparison of Reported Incidence Rates of Wet/Compromised Sterile Packs Across International Studies

2.3.2 Contributing Factors: Equipment and Steam Quality

Moore (2008) found that the steam supply is a problem. It causes 60 percent of the incidents where the packs are wet. The equipment in the sterilizer fails about 30 percent of the time.. The way the packs are wrapped or loaded is bad about 10 percent of the time. Moore said this in 2008. Basu explained in 2016 how the steam gets all condensed and turns into water. This makes the packs all wet. Chen and his team found out in 2024

that when it is rainy outside the packs are more likely to be wet. This is because the steam pipes that are buried underground do not work well when it is humid.
If the drain valves are not working right or if the vacuum pumps are broken or if the door gaskets are not tight it can all cause problems. These problems can make it so the steam does not get out of the sterilizer. That makes the packs all wet (Basu, 2016).

2.3.3 Contributing Factors: Packaging Material and Process

(Basu, 2016) found that the kind of material used to package the instruments is very important. In some hospitals in Pakistan they still use the woven linen because it is cheaper.. This material holds onto the moisture and that makes the packs all wet. The rules say that the linen packs should not be too heavy or too dense or they will get all wet. Chen and his team found out in 2024 that the non-woven fabric packaging is more likely to get wet than the cotton packaging.. They said this is just because you can see the moisture more on the non-woven fabric.

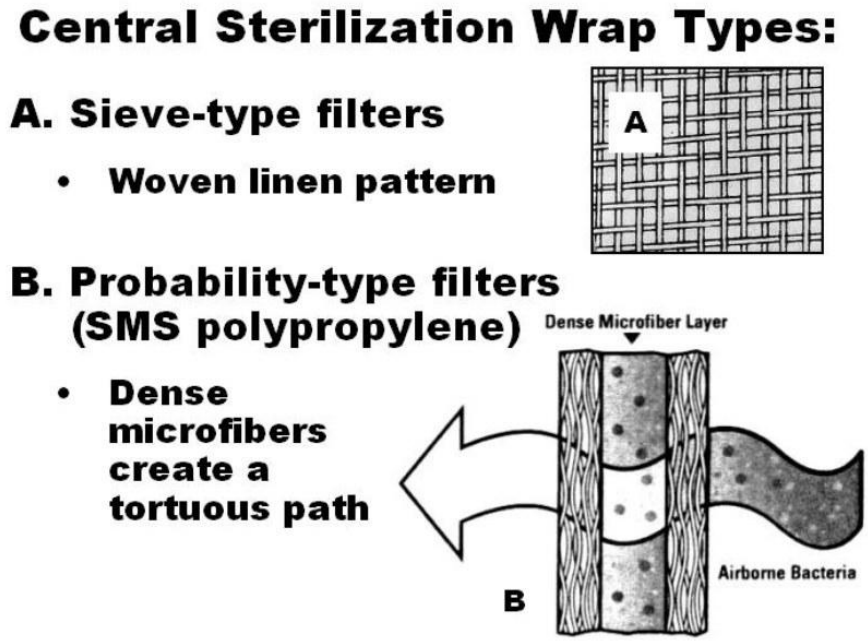

Figure 2.1: Two mechanisms of sterile barrier filtration. Type A (sieve-type): woven linen provides a grid pattern that filters by size — vulnerable to fibre fatigue and pinhole formation. Type B (probability-type): SMS polypropylene non-woven creates a tortuous path for airborne bacteria through dense microfibre layers — more resistant to strike-through than linen.

The way the instruments are packaged is also very important. Chen and his team found out in 2024 that some things can make the packs more likely to be wet. These things include weather, the kind of instruments that are being packaged the kind of material used for packaging not following the rules for packaging putting the packs on the bottom shelf and not letting them cool for long enough. The STERIS Knowledge Centre said in 2021 that you should not open the sterilizer door soon because that can make it harder for the packs to dry. Meng and his team found out in 2025 that if you make the packs cool for least 30 minutes after they are sterilized it can reduce the number of wet packs by 63 percent (Basu, 2016).

2.4 Packaging Defects and Quality Improvement

Many studies have shown that the defects in the packaging can be reduced a lot if we use the methods. Chen et al. (2022) examined 5,000 packages of instruments in 2022 and found out that the people who packaged them made a lot of mistakes. The mistakes happened often when the people who packaged the instruments did not have a lot of experience or education.

2.7 Research Gap and Study Hypothesis

Even though there is a lot of research about the problems with the sterilization of instruments there is no research about this problem in Pakistan. This is a gap, in our knowledge and it can affect the safety of the patients. We need to do research to find out what the problems are and how we can solve them. Based on the reviewed evidence, the following hypothesis is proposed:

H1: Wet and compromised sterile packs are present at a measurable incidence among packs received in the operating room of the study institution, and KAP scores of OR and CSSD staff regarding sterile pack management are suboptimal, with significant variation associated with professional category, educational level, and prior sterile processing training.

The null hypothesis states that there is no significant incidence of wet or compromised packs beyond random variation, and no significant association between staff characteristics and KAP scores.

MATERIALS AND METHODS

3.1 Research Design

The study was a cross sectional observational survey study. A cross-sectional design is proper when the study purpose is to estimate the incidence proportion of a condition at one time, and to describe the KAP of a defined population (Kelley et al., 2003). A structured Pack Observation Checklist was used simultaneously with a self-administered validated KAP questionnaire completed by eligible OR and CSSD staff members. These tools were used together to quantify pack integrity failures as well as the competence of staff, meeting the study objectives directly during a single data collection.

3.2 Study Setting and Duration

This study was carried out in the OR complex and CSSD of a tertiary care teaching hospital in Sialkot, Pakistan. The setting was chosen because it had a high and wide surgical volume, which covered general surgery, orthopedics, obstetrics and gynecology, urology and ENT. A functional CSSD has an existing instrument reprocessing workflow, and a relatively large perioperative staff. An active data collection period of four weeks took place. Study period was three months, starting from the time of approval of the synopsis.

3.3 Study Population and Sample

3.3.1 Pack Observation

. Total enumeration sampling was used to obtain all sterile packs sent to the operating room by CSSD in four weeks of data collection. There was no pack that did not get checked unless opened in exceptional circumstances in advance of the systematic inspection. These were reported separately. Total enumeration was used to maximise representativeness of the incidence estimate and avoid sampling bias.

3.3.2 KAP Survey

Convenience sampling was used to invite all OR and CSSD staff in attendance during data collection to participate. The anticipated number of participants was 20-60 people. The use of convenience sampling was justified as the intent was not to obtain a representative estimate of the population, but to provide a descriptive KAP profile, and because the perioperative population at the study institution was relatively homogeneous with respect to the variables of interest.

3.4 Selection Criteria

3.4.1 Inclusion Criteria

All sterile packs used in the OR during the study period, regardless of type of pack, material and method of sterilisation.

OR staff: All scrub nurses, circulating nurses, OR technicians and surgical technologists on active-duty in the OR during the period of data collection.

CSSD staff: All CSSD technicians and supervisors working at the study institution during the time of data collection.

3.4.2 Exclusion Criteria

Commercial single use devices that are processed by the institutional CSSD were included in the pack observation, whereas those that are commercially pre-sterilized are processed in the institutional CSSD but are not part of the scope of the quality indicators under investigation. Those who refused to give written informed consent were not included in the KAP survey.

3.5 Data Collection Instruments

3.5.1 Pack Observation Checklist

A structured Pack Observation Checklist has been created using criteria set forth in AORN Perioperative Standards and Recommended Practices and ANSI/AAMI ST79 (AAMI, 2017; AORN, 2023). All packs entering the OR were checked against the following parameters: date and time received; pack type (instrument tray, linen pack, peel pouch, rigid container); type of packaging material (woven linen, SMS non-woven, paper-plastic peel pouch, rigid container); sterilization method; sterility indicator status (pass or fail, or absent); integrity of the outer wrap; moisture status; and sterility indicator expiry date status. Those packs that did not meet one or more of these criteria were considered compromised. This checklist was tested during the first two days of data collection with 30 packs before the main data collection period. Inter-rater reliability (Cohen kappa coefficient) was calculated between the main investigator and a second trained observer. Landis and Koch (1977) have established a criterion for acceptable agreement of ≥ 0.80 for a kappa value. (Landis & Koch, 1977).

3.5.2 KAP Questionnaire

The KAP questionnaire was self-administered and framed after reviewing the validated questionnaires in the literature which were adapted to the local hospital situation in Pakistan. The first part include Information on socio-demographic and professional profile was gathered, encompassing nine items: age, gender, designation, highest qualification, years of experience in OR or CSSD, formal sterile processing training history, department, shift pattern and prior infection prevention and control training. In Section B, a total of 10 items on multiple-choice and true/false type questions were used to assess the knowledge, with a maximum score of 10. Section C measured attitudes using seven questions on a five-point Likert-type scale from 1 (Strongly Disagree) to 5 (Strongly Agree), two of which were negatively worded and were reversed in scoring prior to totaling up (maximum score: 35). Section D evaluated practices using six questions related to how often packs were inspected,indicator was checked, what was done, whether an incident was reported or not

3.6 Scoring and Interpretation

The adequacy of knowledge was interpreted as adequate knowledge = score $\geq 7/10$, insufficient knowledge = score $<7/10$. Positive attitude (after reverse scoring the items formulated with a negative frame) was coded as $\geq 25/35$, negative / neutral attitude as $<25/35$. Practice scores were classified according to the number of "safe" responses. Safe practice was described as the selection of 'Always' for all pack inspection items and the wet pack response scenario items (indicator checking).

3.7 Data Analysis

All data were entered and analysed using IBM SPSS Statistics version 26.0. The following statistical procedures were applied based on the nature and level of measurement of each variable.

Descriptive statistics — including frequencies, percentages, means, and standard deviations — were computed for all demographic variables, pack observation findings, and KAP scores. Pack incidence was calculated as the proportion of compromised packs among all packs inspected, reported overall and stratified by type of compromise, packaging material, and pack category. KAP scoring was applied as described in Section 3.6 to classify participants into adequate or inadequate knowledge, positive or

borderline attitude, and safe or unsafe practice categories.

For inferential analysis, Fisher's Exact Test was used to examine associations between categorical variables — specifically department, training status, and binary KAP categories — where any expected cell frequency fell below 5.0. The chi-square test of independence was applied to 2×2 contingency tables where all expected cell frequencies were ≥5.0, including the association between department and safe wet pack response (D3, collapsed to safe vs unsafe) and the association between department and composite safe practice. The Mann-Whitney U test was used to compare knowledge score distributions between CSSD and OR staff, given the ordinal level of measurement of the knowledge subscale. An independent samples t-test was used to compare continuous attitude score distributions between departments. Spearman's rank-order correlation coefficient was computed to examine the relationship between years of experience in OR or CSSD and knowledge score. The statistical significance threshold was set at $p < .05$ for all tests. A summary of all analytical procedures is presented in Table 3.1.

Table 3.1: Summary of Statistical Analysis Procedures

Procedure	Variables	Purpose
Descriptive statistics (frequency, %, mean, SD)	All demographic, pack observation, and KAP variables	Characterise the sample and describe distributions
Pack incidence calculation	Compromised packs by type, packaging material, and pack category	Calculate overall and stratified incidence proportions
KAP scoring and classification	Knowledge (/10), Attitude (/35), and composite safe practice criterion	Classify participants as adequate/inadequate (knowledge), positive/borderline (attitude), and safe/unsafe (composite practice)
Fisher's Exact Test	Department × knowledge adequacy; Department × attitude category; Training × knowledge adequacy; Department × incident reporting (D4)	Test associations where expected cell frequency < 5.0
Chi-square test of independence	Department × wet pack response D3 (safe vs unsafe); Department × composite safe practice	Test associations in 2×2 tables where all expected cells ≥ 5.0
Mann-Whitney U test	CSSD vs OR — knowledge scores (continuous)	Compare knowledge score distributions between departments; used because knowledge subscale is ordinal

Procedure	Variables	Purpose
Independent samples t-test	CSSD vs OR — attitude scores (continuous)	Compare mean attitude scores between departments; used because attitude scores approximate interval level
Spearman's rank-order correlation (ρ)	Years of experience in OR/CSSD vs knowledge score	Examine the relationship between experience and knowledge; Spearman selected for ordinal variables

Note. Fisher's Exact Test was selected over chi-square where minimum expected cell frequency < 5.0. Chi-square was used for D3 (min expected = 5.6) and composite practice (min expected = 6.0) where the condition was met. Significance level: $p < .05$ for all tests. df = degrees of freedom reported for chi-square and t-test.

3.8 Ethical Considerations

Participants were informed they could withdraw at any time without professional consequence. All data were collected anonymously. No identifying information was recorded on either instrument. Data were stored securely and accessed only by the principal investigator and supervisor. Pack observation was conducted as a non-interventional prospective audit. No patient data were collected and no clinical workflows were modified.

3.9 Validity and Reliability

Content validity of both instruments was supported by their derivation from established international standards (AAMI ST79 and AORN Guidelines) and by expert review by specialists in perioperative nursing and infection prevention. Face validity of the KAP questionnaire was confirmed through cognitive interviews with five OR staff members prior to deployment. Inter-rater reliability of the Pack Observation Checklist was assessed by kappa coefficient during the pilot phase. Internal consistency of the attitude subscale was assessed using Cronbach's alpha, with a threshold of ≥0.70 considered acceptable for research instruments in health professional studies (Taber, 2018).

RESULTS

4.1 Overview

This chapter is about what we found out in our study. It is divided into two parts. The first part is about what we saw when we looked at the packs. We saw how many packs were wet or not sterile and what kind of problems they had. The second part is about the knowledge and practice of the the people. We asked them questions. We then looked at all the answers to see if there were any connections, between what department people work in if they have had training how long they have been working and what they know and do. We looked at 385 packs over four weeks. 30 People filled out our questionnaire. They were people who work in the operating room and CSSD which is the place where they clean and sterilize instruments.

4.2 Pack Observation Findings

4.2.1 Overall Incidence of Compromised Sterile Packs

During the study period 15 of 385 (3.9%) of the packs were judged as wet or compromised packs using the criteria on the Pack Observation Checklist. The remaining 370 packs (96.1%) passed all the physical and process integrity tests and were considered satisfactory. Table 4.1 summarises the overall pack observation findings.

Table 4.1: Overall Incidence of Compromised Sterile Packs (N = 385)

Pack Status	N	%
Satisfactory packs	370	96.1
Compromised / Wet packs	15	3.9
Total packs inspected	**385**	**100.0**

4.2.2 Distribution by Type of Compromise

8 packs (53.3%) contained residual moisture. Torn or punctured outer wrapping was the second most common type of pack (5 packs, 33.3%). The smallest number of failures or expiration of chemical indicators, 2 packs (13.4 %), were observed. Table 4.2 presents the distribution by compromise type.

Figure 4.1: Distribution of Compromised Packs by Type of Compromise (n = 15)

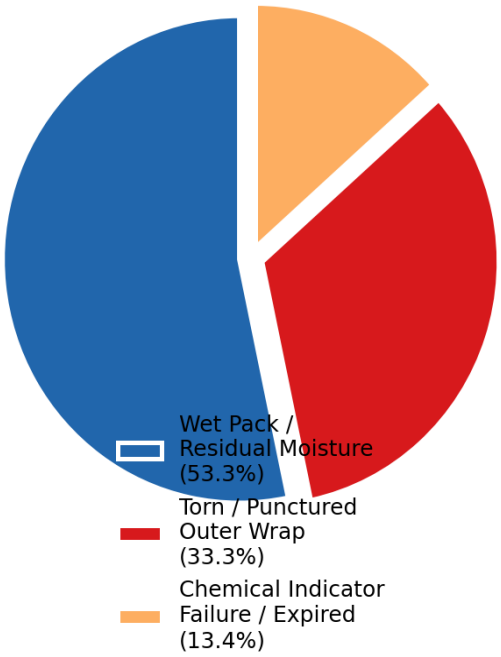

Figure 4.1: Distribution of Compromised Packs by Type of Compromise (n = 15)

Table 4.2: Distribution of Compromised Packs by Type of Compromise (n = 15)

Type of Compromise	N	% of Compromised
Wet pack / Residual moisture	8	53.3
Torn / Punctured outer wrap	5	33.3
Chemical indicator failure / Expired	2	13.4
Total	**15**	**100.0**

4.2.3 Distribution by Packaging Material

The most common type of compromised packs (73.3%) was reusable woven linen/muslin wrapping. SMS non-woven wrap accounted for 3 packs (20.0%) and

paper-plastic peel pouch for 1 pack (6.7%). Table 4.3 presents these findings.

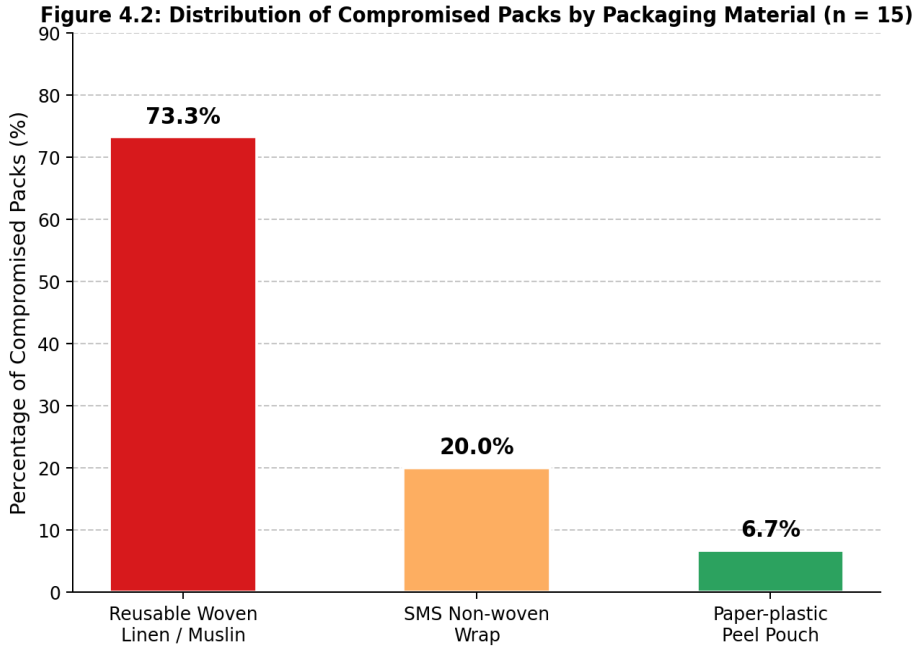

Figure 4.2: Distribution of Compromised Packs by Packaging Material (n = 15)

Table 4.3: Distribution of Compromised Packs by Packaging Material (n = 15)

Packaging Material	N	% of Compromised
Reusable woven linen / Muslin	11	73.3
SMS non-woven wrap	3	20.0
Paper-plastic peel pouch	1	6.7
Total	**15**	**100.0**

4.2.4 Distribution by Pack Category

The highest number of failures was in instrument trays (8 packs 53.3%), followed by the basin sets (5 packs 33.3%) and single instrument pouches (2 packs 13.4%). Table 4.4 presents these findings.

Table 4.4: Distribution of Compromised Packs by Pack Category (n = 15)

Pack Category	N	% of Compromised
Instrument trays (heavy sets)	8	53.3
Basin sets / Dressing packs	5	33.3
Single instrument pouches	2	13.4
Total	**15**	**100.0**

4.3 KAP Survey Findings

4.3.1 Demographic and Professional Profile of Participants

A total of 30 OR and CSSD staff participated in the KAP survey, representing a 100%

response rate among those approached. Of these, 18 (60.0%) were from the OR and 12 (40.0%) from the CSSD. The sample comprised 16 females (53.3%) and 14 males (46.7%). In terms of qualification, 17 participants (56.7%) had a Diploma and 13 (43.3%) a BSc degree. The largest experience group had 4–6 years (n = 10, 33.3%), followed by 1–3 years (n = 9, 30.0%), 7–10 years (n = 7, 23.3%), and more than 10 years (n = 4, 13.4%). Formal sterile processing training was received by all 12 CSSD staff (100%) and 4 of 18 OR staff (22.2%) for a total training rate of 53.3% for all staff compared to all 12 CSSD staff. The complete demographic profile is presented in Table 4.5.

Figure 4.8: Participant Experience and Training Profile

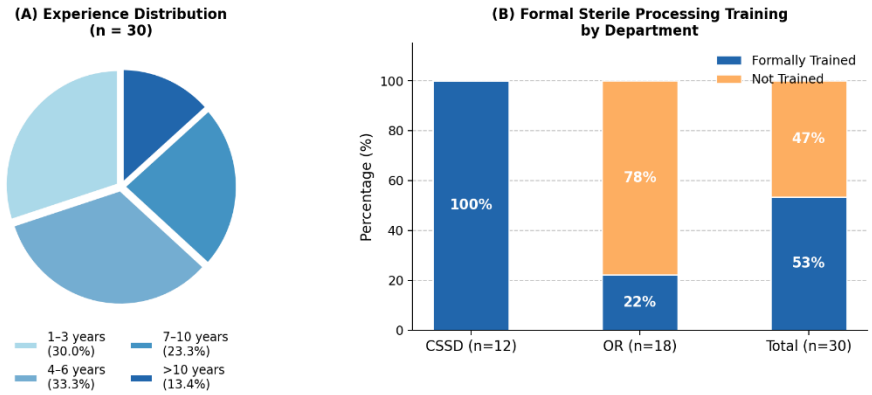

Figure 4.8: Participant Experience and Training Profile

Table 4.5: Demographic and Professional Profile of Study Participants (n = 30)

Variable	Category	N	%
Department	Operation Theatre (OR)	18	60.0
	CSSD	12	40.0
Gender	Female	16	53.3
	Male	14	46.7
Qualification	Diploma	17	56.7
	BSc	13	43.3
Years of Experience	1–3 years	9	30.0
	4–6 years	10	33.3
	7–10 years	7	23.3
	> 10 years	4	13.4
Formal Sterile Processing Training	Yes	16	53.3
	No	14	46.7
Total		**30**	**100.0**

4.3.2 Knowledge Assessment

The knowledge subscale consisted of 10 questions that were designed to measure knowledge of sterilization principles, sterility maintenance and identification of a compromised pack. The data for this study informed a cut-off of ≥7 out of 10 for adequate knowledge, as similar benchmarks have been applied in health profession KAP studies (Habtewold et al., 2024). The overall mean knowledge score was 6.8 (SD ±1.4). The findings showed 56.7% and 43.3% of the participants had adequate and inadequate knowledge respectively. The mean scores were calculated directly based on the frequency data: CSSD staff: mean = 7.8; OR staff: mean = 6.1. Among CSSD staff, 10 out of 12 (83.3%) achieved adequate scores; among OR staff, only 7 out of 18 (38.9%) did so. The knowledge findings are provided in table 4.6 below.

Table 4.6: Knowledge Scores by Department

Knowledge Category	CSSD (n=12)	OR (n=18)	Total (n=30)
Adequate knowledge (score ≥ 7)	10 (83.3%)	7 (38.9%)	17 (56.7%)
Inadequate knowledge (score < 7)	2 (16.7%)	11 (61.1%)	13 (43.3%)
Mean score	**7.8**	**6.1**	**6.8 (±1.4)**

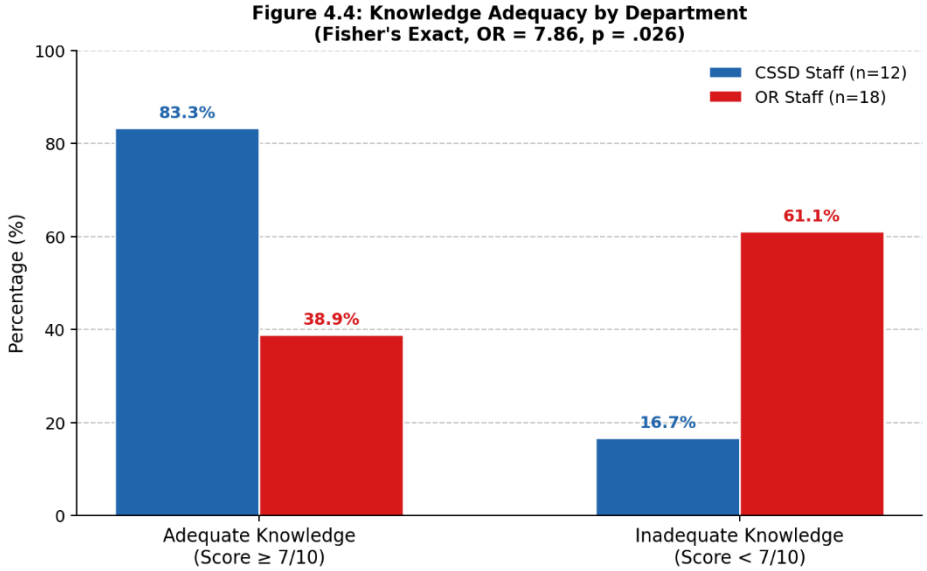

Figure 4.4: Knowledge Adequacy by Department (Fisher's Exact, OR = 7.86, p = .026)

4.3.3 Attitude Assessment

The attitude subscale consisted of 7 items on a Likert scale (1–5) with a maximum score of 35. A score ≥25 was considered to represent a positive attitude towards evidence-based sterile pack management. The mean attitude score was 27.6 (SD ±2.9) overall. Eighty six point seven percent (26 participants) had positive attitudes and 13.3 percent (4 participants) scored below threshold. For the departmental data, means were calculated directly from frequency data: The mean for CSSD staff was 29.2, and the mean for OR staff was 26.5. 14 of 18 (77.8%) OR staff had positive attitudes while all 12 (100%) CSSD staff had positive attitudes. The results of the attitudinal questions are summarized in Table 4.7.

Table 4.7: Attitude Scores by Department

Attitude Category	CSSD (n=12)	OR (n=18)	Total (n=30)
Positive attitude (score ≥ 25)	12 (100.0%)	14 (77.8%)	26 (86.7%)
Borderline / Negative attitude (< 25)	0 (0.0%)	4 (22.2%)	4 (13.3%)
Mean score	**29.2**	**26.5**	**27.6 (±2.9)**

4.3.4 Practice Assessment

A safe practice criterion was a priori defined as choosing 'Always' for both D1 (wrap inspection) and D2 (indicator checking), D3 (wet pack response) (Remove immediately and report), and D5 (peer intervention) (Inform immediately and request removal). The formal documentation (D4) was treated separately because it is an administrative document and was not used in the composite. This composite criterion was then inferentially tested in Section 4.3.5. The highest rate of safe practice was for indicator checking (D2 83.3% always safe). The inspection rate for wrap inspection was safe at 76.7% (D1). Peer intervention (D5) had 66.7% safe response. The most clinically relevant response was wet pack response (D3) with just 53.3% selecting the fully safe answer, removing and reporting. 9 (30.0%) participants removed the pack without reporting, and 5 (16.7%) — all OR staff — reported drying the pack on the outside and using it. Formal documentation (D4) was the lowest scoring domain with only 6 participants (20.0%) always recording incidents and 10 (33.3%) rarely or not at all recording incidents. All practice findings are reported in table 4.8.

Figure 4.6: Self-Reported Response to Receiving a Wet Sterile Pack (D3)

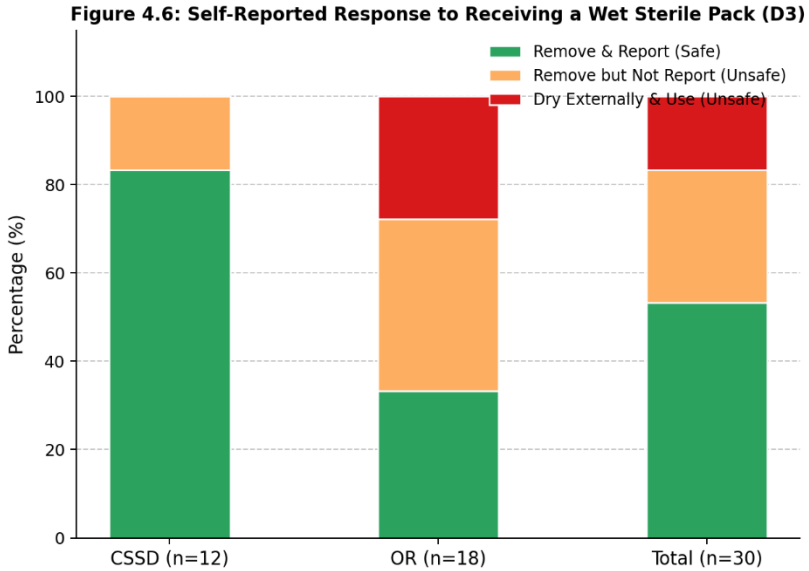

Figure 4.6: Self-Reported Response to Receiving a Wet Sterile Pack (D3)

Table 4.8: Self-Reported Practice Findings by Department (n = 30)

Practice Item / Response	CSSD n=12	OR n=18	Total n=30	%
D1. Inspect outer wrap integrity before use				
Always (Safe)	11	12	23	76.7

Practice Item / Response	CSSD n=12	OR n=18	Total n=30	%
Inconsistently (Unsafe)	1	6	7	23.3
D2. Check chemical indicator before opening				
Always (Safe)	12	13	25	83.3
Inconsistently (Unsafe)	0	5	5	16.7
D3. Action on receiving a wet sterile pack				
Remove immediately & report (Safe)	10	6	16	53.3
Remove but do not report (Unsafe)	2	7	9	30.0
Dry externally and use (Unsafe)	0	5	5	16.7
D4. Formally document compromised pack incidents				
Always (Safe)	4	2	6	20.0
Inconsistently (Unsafe)	6	8	14	46.7
Rarely / Never (Unsafe)	2	8	10	33.3
D5. Intervene if colleague uses compromised pack				
Inform immediately & request removal (Safe)	11	9	20	66.7
Mention concern but defer (Unsafe)	1	9	10	33.3

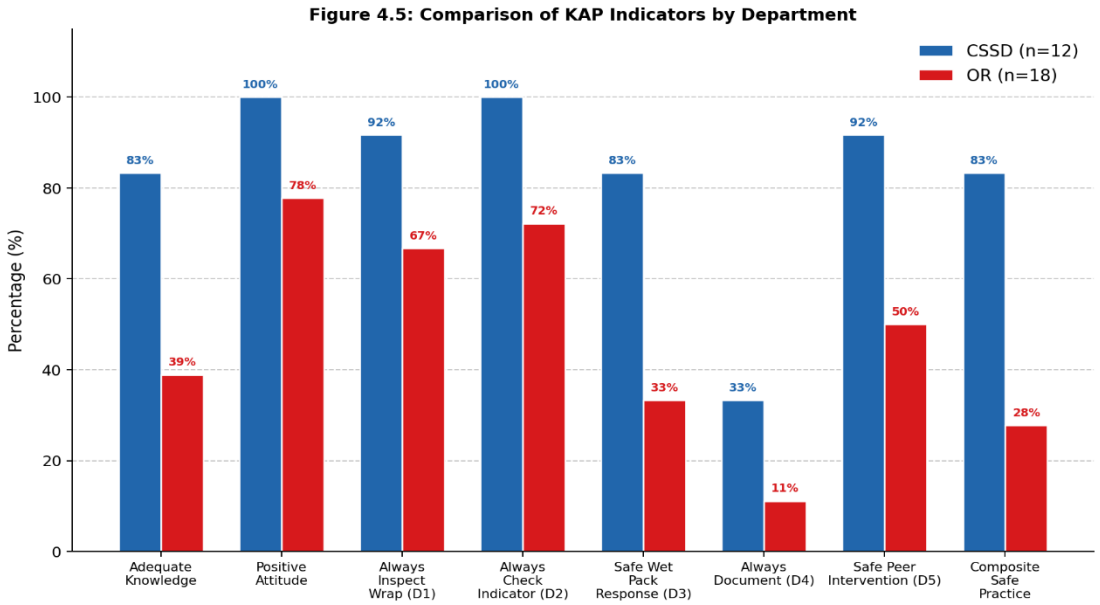

Figure 4.5: Comparison of KAP Indicators by Department

4.3.5 Inferential Statistical Analysis

The associations between departmental affiliation, training status and years of experience with KAP outcomes were examined using inferential statistics. Fisher's Exact Test was used in cases where expected cell frequencies were less than five. For 2×2 contingency tables with all expected cell frequencies ≥ 5.0 the chi-square test of independence was applied. Due to the ordinal nature of the scoring on the knowledge subscale, the Mann-Whitney U test was used to compare continuous knowledge score distributions across departments. A t-test was used to compare attitude scores (continuous) across departments independent of one another. Spearman's rank order correlation was used to determine the relationship between years of experience and knowledge score. Throughout, the level of significance was $p < .05$. The results of all tests are summarized in Table 4.9.

Table 4.9: Summary of Inferential Statistical Test Results

Association Tested	Test	Statistic	Df	p-value
Department × Knowledge adequacy	Fisher's Exact	OR = 7.86	—	.026 *
Department × Positive attitude	Fisher's Exact	OR = ∞	—	.130 (ns)
Department × Wet pack response D3 (safe vs unsafe)	Chi-square	χ^2 = 7.23, OR = 10.0	1	.007 **
Department × Incident reporting D4 (always vs not always)	Fisher's Exact	OR = 4.00	—	.184 (ns)
Department × Composite safe practice (D1+D2+D3+D5)	Chi-square	χ^2 = 8.89, OR = 13.0	1	.003 **

Association Tested	Test	Statistic	Df	p-value
Training status × Knowledge adequacy	Fisher's Exact	OR = 25.67	—	< .001 ***
CSSD vs OR — Knowledge scores (continuous)	Mann-Whitney U	U = 183.0	—	.002 **
CSSD vs OR — Attitude scores (continuous)	Independent t-test	t = 2.84	28	.008 **
Years of experience × Knowledge score	Spearman ρ	ρ = 0.439	—	.015 *

*Note. * $p < .05$ ** $p < .01$ *** $p < .001$ ns = not significant. OR = odds ratio. Fisher's Exact used where minimum expected cell frequency < 5.0. Chi-square used for D3 and Composite Practice where all expected cells ≥ 5.0 (minimum = 5.6 and 6.0 respectively). Composite safe practice = safe on D1 + D2 + D3 + D5.*

There was a significant association found between Department and knowledge adequacy (Fisher's Exact, OR = 7.86, p = .026). The likelihood of attaining adequate knowledge scores was 7.86 times greater for CSSD staff compared with OR staff. The distributions of continuous knowledge scores were compared to each other using Mann-Whitney U tests and these tests also supported the finding that scores were significantly higher among the CSSD staff than OR staff (U = 183.0, p = .002).

Fisher's Exact p-values did not show significance when using binary categories (p = .130). But, the independent samples t-test for the continuous attitude scores between the two departments, CSSD and OR, was statistically significant, t = 2.84, df = 28, p = .008, with significantly higher scores on the average for the CSSD staff (mean = 29.2) than for the OR staff (mean = 26.5).

The difference between these findings is due to the increased statistical power of continuous score analysis compared to binary classification, especially with small cell sizes. For transparency both are reported. There was a statistically significant relationship between department and safe wet pack response on item D3 ($\chi^2 = 7.23$, df = 1, p = .007, OR = 10.0). Responses for D3 were collapsed and made into a valid 2×2 contingency table (all cell frequencies greater than or equal to 5.0 with a minimum of 5.6).

The percentage of staff choosing the safe response (CSSD staff) was 10 times that of OR staff. There was no association between department and formal incident documentation with item D4 (Fisher's Exact, OR = 4.0, p = .184), suggesting that underreporting of compromised pack incidents is not an OR-specific issue, but a systemic issue affecting both departments.

The relationship between department and composite safe practice criterion (safe on D1, D2, D3 and D5) was extremely significant ($\chi^2 = 8.89$, df = 1, p = .003, OR = 13.0). The CSSD staff had 13 times the odds of meeting the composite safe practice standard compared to the OR staff. This composite test shows that the departmental differences are not only found in individual tests, but also in the overall difference in safe practice performance, which is statistically significant and stable. Formal sterile processing training was the most statistically significant association with the knowledge level, Fisher's Exact (OR = 25.67, p < .001). In this sample, trained staff had approximately

26 times the odds of obtaining adequate knowledge scores as did untrained staff, strongly suggesting that training was the main modifiable factor of knowledge competence. Spearman's rank order correlation showed a significant positive correlation between years of experience and knowledge score ($\rho = 0.439$, $p = .015$). Knowledge scores tended to increase with the number of years in OR or CSSD service. The moderate effect size, however, indicates that experience is not enough to attain appropriate knowledge without the formal training.

Table 4.10: Summary of KAP Findings by Department

KAP Indicator	CSSD (n=12) n (%)	OR (n=18) n (%)
Adequate knowledge (≥7/10)	10 (83.3%)	7 (38.9%)
Positive attitude (≥25/35)	12 (100.0%)	14 (77.8%)
Always inspect wrap — D1	11 (91.7%)	12 (66.7%)
Always check indicator — D2	12 (100.0%)	13 (72.2%)
Remove & report wet pack — D3 (Safe)	10 (83.3%)	6 (33.3%)
Always document incidents — D4	4 (33.3%)	2 (11.1%)
Immediately intervene with peer — D5	11 (91.7%)	9 (50.0%)
Meet composite safe practice criterion	10 (83.3%)	5 (27.8%)
Formal sterile processing training received	12 (100.0%)	4 (22.2%)

DISCUSSION

5.1 Overview

This chapter interprets and puts into context the findings reported in Chapter 4, based on literature search conducted in Chapter 2. The two main study aims are discussed, namely incidence and typology of wet and compromised sterile surgical packs and the knowledge, attitudes, practices and determinants of OR and CSSD staff. The strengths and limitations of the study are described in the last section, along with implications of the findings for clinical practice and institutional policy.

5.2 Incidence of Wet and Compromised Sterile Packs

In this study, 385 packs were inspected and the overall incidence of wet and/or contaminated sterile packs was 3.9%. This figure is within the middle range of internationally reported rates, placing the study institution in the middle position. The rates reported around the world are approximately 1% (Basu 2016, the only published South Asian comparator), 3.12% (Chen et al. 2024, across 4,099 packs at a Chinese medical centre) and range between 1.67% and 19.7% (institutional surveys in China). This rate falls in the lower part of the range of 2.5% to 5.0% and is most comparable with the 3.9% from the study by Chen et al., (2024), which was conducted in a similar tertiary hospital setting with a similar prospective observation methodology. It is interesting to note that the rate of the present institution is almost four times higher than

that of Indian institution (Basu, 2016) as both the institutions are public tertiary hospitals and have similar context. One possible explanation is methodological: Basu's number was calculated from incident reports and was thus a lower bound on true incidence, as packs passing through the OR without being inspected might have gone undetected. This detection bias may contribute to the higher rate reported in the present study because the total enumeration design (inspection of each pack arriving in the OR) is more sensitive and less susceptive to this type of detection bias. The largest proportion of compromised packs (53.3% of all packs compromised) were wet packs with residual moisture, which is consistent with the literature from other countries. In both studies, moisture was determined as the main sterility failure mechanism, and in Basu's (2016) study at his institution, wet packs were the most common CSSD quality failure. The second most frequent finding, outer wrapping that is torn or punctured (33.3%), is also a handling and transport-related issue, not related to failures during the sterilization process. This distribution indicates both wet pack prevention and physical pack protection are two intervention targets that are somewhat independent and both are important. The evidence reviewed in Chapter 2 is directly confirmed from the local perspective because the number of reusable woven linen packs is strongly correlated with the number of compromised packs, at 73.3% of all compromised packs were wrapped in linen (which is not the only material used for pack wrap). Basu (2016) proposed that moisture retention is due to hygroscopic nature of cotton fibre, which is why ANSI/AAMI ST79 sets weight and density limits for linen packs. The findings of the present study further substantiate these concerns as the use of linen wrapping as the major packaging method in Pakistan is still prevalent due to cost considerations. Higher occurrence of wet packs was also found for instrument trays and heavy sets (OR = 53.3%), consistent with Chen et al. (2024) who found that heavy instrument loads had a higher thermal mass and metal condensation surface area than other instrument pack types, which resulted in a higher occurrence of wet packs.

5.3 Staff Knowledge of Sterile Pack Management

The overall mean knowledge score (6.8/10, SD ±1.4) means that there is an overall gap in the knowledge of the study institution's perioperative workforce with only 56.7% of workers having adequate knowledge. This is very similar to the 58.1% reported by Habtewold et al. (2024) out of 423 OR nurses in seven hospitals in Ethiopia, where conditions were generally comparable to those in the current study hospital. Given that the knowledge levels are very similar in two geographically different LMICs, it is difficult to argue that a KAR of less than 60% represents an institution-specific anomaly and more likely a systemic issue in the perioperative context.

The knowledge gap was highly significant and stark between the department and the other groups. The knowledge rate was adequate, with 83.3% of staff at CSSD compared to 38.9% of staff at OR (Fisher's Exact, OR = 7.86, $p = .026$) and Mann-Whitney U analysis of continuous scores confirmed the difference ($U = 183.0$, $p = .002$). This trend can be directly attributed to the training differential as all 12 CSSD staff had received formal sterile processing training, whereas only 4 of 18 OR staff (22.2%) had received formal sterile processing training. The highest association was between training and knowledge adequacy (Fisher's Exact, OR = 25.67, $p < .001$), where staff who were trained were almost 26 times more likely to have adequate knowledge than staff who were not trained. This result corroborates the findings of Habtewold et al. (2024), who determined training exposure as an independent factor of adequate knowledge (AOR = 1.99) and in the same way, the finding of Chen et al. (2022), which determined educational background as one of the significant factors affecting packaging quality in CSSD operations. There was moderate positive correlation between years of experience and knowledge score, Spearman $\rho = .439$, $p = .015$, suggesting that experiential learning is important for the development of knowledge over time, but that this does not compensate for the lack of formal training. Even those who had been working in the OR for many years, but had not received formal sterile processing training, showed

gaps in their knowledge on formal testing.

5.4 Staff Attitudes Toward Sterile Pack Safety

The overall attitude profile of the study sample was mainly positive as 86.7% of the participants scored ≥25 points out of 35 points. At a first glance, this is a positive discovery, and indicates that the attitudes of most staff (in both departments) are generally supportive of evidence-based sterile pack management. The positive attitudes of all CSSD staff (100%) as compared to 77.8% of OR staff was similar with the training and knowledge difference between the two departments, thus supporting the relationship between knowledge, attitude and practice alignment. Two caveats, however, must be attached to this positive finding of attitude.

The first is that the attitude scores were obtained by using self-reported responses on a Likert scale, and as such are subject to social-desirability bias; that is, the responses may have been based on the socially desirable response, rather than on the actual attitude of the participants. Second, and more importantly, the practice data show that there are inconsistencies between stated attitudes and actual actions. The attitudes of the participants were mostly positive, but only 53.3% selected the fully safe response in the wet pack scenario (D3), while only 20.0% always formally documented compromised pack incidents (D4). This attitude-behaviour disconnect – having positive attitudes but not performing consistently safe behaviours – is also known in similar contexts.

Attitude measurement and practice measurement should be treated independently, as Almedaini et al. (2021) concluded that the attitudes of the CSSD staff in Saudi MOH hospitals were positive toward the use of evidence-based sterile processing but there was still inconsistent practice. Average scores on the continuous attitude score comparison between OR and CSSD staff were statistically different ($t = 2.84$, $df = 28$, $p = .008$) with the CSSD staff's scores being higher.

The category comparison to the binary attitude was not significant (Fisher's Exact, $p = .130$), however, due to small cell frequencies, a binary cut-off may not have the discriminatory power. The continuous result is more informative, and reflects a genuine attitudinal difference between the departments beyond the binary threshold. The attitude findings suggest that there is a general positive attitude toward safe practice, but attitudinal alignment is not necessarily enough for safe practice without adequate systems and knowledge.

5.6 Training as the Primary Modifiable Determinant

The results of this study have led to a single over-arching finding: the most critical modifiable factor for adequate knowledge and safe practices and for departmental performance in sterile pack management at the institution studied is the training received by the formal sterile processing staff. This conclusion is supported by multiple and consistent lines of evidence.

5.7 Strengths of the Study

This study offers a number of methodological and contextual advantages. First, this is the first study from Pakistan that systematically and prospectively recorded the incidence of wet and compromised sterile surgical packs from pack-by-pack observations, which resulted in original baseline data not previously available in this setting. Second, the pack observation sampling method used (total enumeration – all 385 packs observed during the study period rather than a selected sample) maximised the sensitivity and representativeness of the incidence estimate. Third, both instruments, the Pack Observation Checklist and KAP questionnaire, were specifically developed and validated by experts, enabling the two objectives of the study to be met in one efficient data collection process. Fourth, as the questionnaire was bilingual (English and Urdu), the design improved the accessibility and decreased the language-related measurement error for those who speak Urdu as their working language. Fifth, the inferential statistical analysis was thorough, using several relevant and suitable tests for all combinations of variables and arriving with actionable evidence for the specific

factors influencing KAP outcomes.

5.8 Limitations of the Study

There are some limitations to be noted. First, the cross-sectional design only measures KAP at a specific time, and doesn't allow for causal claims. The correlation between training and knowledge is strong and consistent similar to previous studies, but it is not possible to deduce the causality from this cross-sectional data. Second, the KAP survey was self-reported, thus there was the possibility of social desirability bias and recall error, especially for practice items. Participants could have mentioned ideal behaviours rather than real life behaviours. Third, the KAP survey was convenience sampled, so the generalisability of KAP results to other institutions is constrained. The sample size of 30 participants is sufficient to describe the data and for moderate size inferential analyses, but is small for more detailed analyses of subgroups. Fourth, the departmental means for knowledge and attitude scores were based on the frequency distribution of scores, rather than the raw scores from individual items, leading to some imprecision in the continuous variable analyses. Future studies should take and store individual item scores to allow more exact calculations. Fifth, the study was performed in a single tertiary care teaching hospital and the results might not be generalizable to smaller district hospitals, rural hospitals, and other hospitals.

5.9 Implications for Practice and Policy

The results of this study have implications in three main areas. At the hospital level the fact that 3.9 percent of the packs were compromised means that about one in every 26 packs that arrived in the operating room was not safe to use. This is a problem for patient safety especially in busy hospitals where a lot of surgeries are performed. To fix this hospitals should have a policy for checking and reporting packs that are not safe to use. If a pack's wet it should not be used and hospital staff should be trained to follow this rule.

At the hospital level the study shows that it is very important to have a training program for hospital staff on how to handle and process equipment. This training should include information on how contamination can happen how to check if a pack's safe to use and what to do if a pack is compromised. All hospital staff, not the people who work in the sterilization department should have to complete this training and show that they understand it. The hospital should also make it easier for staff to report if a pack is compromised because now it is too hard and many staff members do not report these incidents.

At the level of hospital policy this study gives us information to help us make decisions about what kind of packaging to use for sterile equipment. We should consider using non-woven packaging instead of the old reusable linen packaging, especially for equipment that is used in high-risk surgeries. Even though this new packaging may cost more we have to think about the cost of having to reprocess compromised packs and the cost of treating patients who get infections because of equipment. We also need to make sure that our sterilization equipment is working properly and that we are following the procedures, for sterilizing equipment to prevent packs from getting wet.

SUMMARY, CONCLUSIONS, AND RECOMMENDATIONS

6.1 Summary of the Study

6.1.1 Summary of Pack Observation Findings

We looked at 385 packs during the study. We found that 15 of these packs were wet or damaged. This means that 3.9 percent of the packs were not good. This number is similar to what other people have found in countries. For example Chen and his team found that 3.12 percent of the packs were bad in a hospital in China. This is similar to what we found.. It is higher than what Basu found in a hospital, in India. He found that 1 percent of the sterile packs were bad. Our study is the one to look at this problem in

a Pakistani operating room. The sterile packs we are talking about are the ones used in operating rooms.

There were 15 packs that had problems. The common issue with these packs was that they still had moisture in them. This happened with 8 of the packs which's more than half. The next common problem was that the outside wrapping was torn or had holes in it. This happened with 5 packs. Then there were 2 packs that had problems with the chemical indicators, which are used to check if the packs are still good.

Reusable woven linen wrapping was used on 11 of the 15 packs that had problems. This shows that this type of wrapping is more likely to cause problems than types like SMS non-woven and peel pouch materials. Most of the packs that had problems were instrument trays and heavy sets. There were 8 packs like this which's also more than half. This makes sense because these packs have a lot of metal and are heavy which can cause condensation to form when they are cooling down after being sterilized. Reusable woven linen wrapping and instrument trays and heavy sets were the issues, with the compromised packs.

6.1.2 Summary of KAP Findings

Thirty OR and CSSD staff took part in the survey. The group included 18 OR staff, which was sixty percent of the total and 12 CSSD staff, which made up forty percent. Most of the CSSD staff had training in sterile processing, which was one hundred percent.Only 4, out of 18 OR staff had that same training. Overall fifty-three percent of the staff had sterile processing training.

The average score for knowledge was 6.8 out of 10. This score can vary by 1.4 points. To have knowledge a person needs a score of 7 or higher. Seventeen people got a score of 7 or higher which's 56.7 percent of the people who took the test. There was a difference in the scores between two groups of staff. The CSSD staff did well. 83.3 Percent of them got a good score.. Only 38.9 percent of the OR staff got a good score. This difference is significant. When we looked at all the scores we found that the CSSD staff generally knew more, than the OR staff.

The average attitude score was 27.6 out of 35. This score had a deviation of 2.9. Most people had an attitude with 86.7 percent of participants showing this. All of the CSSD staff had an attitude, which is 100 percent of them. On the hand 77.8 percent of the OR staff had a positive attitude. However when we looked at the scores we found that the CSSD staff had a higher attitude score than the OR staff and this was statistically significant.

6.2 Conclusions

6.2.1 Conclusion on Pack Incidence

This study confirms that wet and compromised sterile surgical packs are present at a clinically significant and measurable incidence of 3.9% in the operating room of the study institution. Approximately 1 in every 26 sterile packs received in the OR during the study period failed to meet the physical and process integrity criteria necessary to ensure continued sterility of its contents. The finding that residual moisture accounted for the majority of compromise events, and that reusable woven linen wrapping was associated with 73.3% of all compromised packs, confirms the specific vulnerability created by the continued use of cotton-based packaging materials in a Pakistani public sector hospital setting.

6.2.2 Conclusion on Staff Knowledge

The study shows that the people who work in the Operating Room and the Central Sterile Supply Department do not know enough about managing packs. 56.7 Percent of the people in the study knew what they were doing. The people who work in the Operating Room are the ones who do not know enough. 38.9 Percent of them knew what they were doing. But the people who work in the Central Sterile Supply Department did 83.3 percent of them knew what they were doing.

The reason the Operating Room staff do not know enough is that they did not get the training. The study found that getting the training is the most important thing for

knowing what to do. It is more important, than how long you have been working or what your job title is. The people who got the training were much more likely to know what to do.The Operating Room staff and the Central Sterile Supply Department staff need to know about pack management to do their jobs properly.

6.2.3 Conclusion on Staff Attitudes

The staff at the hospital really like the idea of using evidence to manage packs. In fact 86.7% of the people we talked to had an attitude about it. This is a thing because it means they are motivated to make changes. However just because they have an attitude does not mean they are doing things safely. We found that even though a lot of people had an attitude they were not always following safe practices. This means that having an attitude is not enough. The staff also need to know what they are doing and have rules to follow.

6.2.4 Conclusion on Staff Practices

The study found out that one big problem is that some people use packs that're wet after they have been dried on the outside. This is what 27.8% of the operating room staff said they do. This is very bad for safety because it makes the whole system of keeping things sterile uselessAnother big problem is that people do not write down what happens when a pack is compromised. 80.0% Of the people in the study said they do not always make a record of these events. This means the hospital does not have the information it needs to see what is going wrong to investigate or to fix the problem of packs not being intact.

The study also found out that people who work in the operating room are 13 times less likely to follow all the safety rules than people who work in the sterilization department. This shows that the problem is not just with one or two things it is, with the system of keeping packs sterile. It is a problem that we need to fix.

6.3 Recommendations

6.3.1 Recommendations for Clinical Practice

The people who work in the operating room need to follow some rules based on what we found out from this study. First we need to make a plan for what to do when a sterile pack gets wet. This plan should say that if a pack is wet it cannot be used, no matter what. It does not matter how recently it was sterilized or how busy the operating room is. Second everyone who works in the operating room needs to learn how to check packs to make sure they are okay to use. This training should teach people how to find problems with the packs like if they're wet or if something has gotten inside them. Third we need to add checking the packs to the list of things we do before surgery to make sure everything is safe. This means we need to check the packs before we start the operation to make sure they are not damaged or wet.

6.3.2 Recommendations for Institutional Policy

At the level here are some policy actions that are recommended. First the study institution should adopt a system to report pack integrity incidents. This system should be easy to use and take no than two minutes to complete at the point of rejection. It should collect information such as pack type, packaging material, type of problem sterilizer batch number and time of discovery. It should also generate reports for CSSD management and OR leadership. The fact that 80.0% of incidents were not documented in this study means that the real number of incidents is likely higher than 3.9%. This lack of data makes it hard to investigate the root cause of incidents. Second the institution should review its policy for buying packaging materials. Since 73.3% of compromised packs in this study were wrapped in linen and many studies show that linen increases the risk of wet packs it might be a good idea to switch to SMS non-woven wrapping for high-risk packs. Third, a regular programme for autoclave maintenance and steam quality monitoring should be set up. Since steam supply problems cause 60% of wet pack incidents. This will complement training-based interventions.

6.3.3 Recommendations for Training and Education

The problem with training that this study found. Where 22.2% of the people who work in the operating room have had formal training on how to handle sterile equipment compared to 100% of the people who work in the sterilization department. Needs to be fixed right away.Here are some ideas for training and education.First the hospital should make sure all operating room staff get training on how to handle sterile equipment not just the people who work in the sterilization department.Second the training should include practice with equipment that has been deliberately compromised. The staff can learn how to deal with problems. Third the training on how to handle equipment should be part of the regular college courses for operating room technicians. Fourth all operating room and sterilization staff should get refresher training every year with updated information on any changes in how Things're done, new equipment or new packaging materials.

6.3.4 Recommendations for Future Research

The results of this study show that there are ways to do more research in Pakistan and other South Asian countries.First we should do a study in other hospitals in Pakistan to see if the results we found are true for all hospitals or just this one. We need to know if the problems we found are everywhere or just in this hospital. This will help us understand what is going on in all hospitals in Pakistan and find ways to make things better. Second we need to do a study that follows patients over time to see if there is a link between packs and infections after surgery in Pakistan. Our current study shows that there might be a link. We do not know for sure. If we follow patients and see what happens when packs get wet we can understand what really happens when packs are not used correctly. Third we should do a study to see what happens when we train hospital staff on how to clean and prepare equipment for surgery. Our study has given us a starting point. Now we can see how things change after staff get training. Fourth We found that many staff members do not report problems and we want to know why. Understanding why staff do not report problems will help us make things better and reduce the number of problems with packs. We can use the results of this study to make changes and improve care. Pakistan and other Asian countries will benefit from this research and we can make things better, for patients.

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APPENDICES

STERILE PACK OBSERVATION CHECKLIST

Observer: _____ Form No: _____

N	Pack Type	Material	Condition	Action Taken	Decision By
1	○ Instrument ○ Basin set ○ Dressing	○ Linen ○ Non-woven ○ Other: ____	○ Intact & dry ○ Compromised	○ Used directly ○ Rejected/replaced ○ Returned to CSSD	○ Scrub nurse ○ Surgeon ○ OT Tech
2	○ Instrument ○ Basin set ○ Dressing	○ Linen ○ Non-woven ○ Other: ____	○ Intact & dry ○ Compromised	○ Used directly ○ Rejected/replaced ○ Returned to CSSD	○ Scrub nurse ○ Surgeon ○ OT Tech
3	○ Instrument ○ Basin set ○ Dressing	○ Linen ○ Non-woven ○ Other: ____	○ Intact & dry ○ Compromised	○ Used directly ○ Rejected/replaced ○ Returned to CSSD	○ Scrub nurse ○ Surgeon ○ OT Tech

4	○ Instrument ○ Basin set ○ Dressing	○ Linen ○ Non-woven ○ Other: ____	○ Intact & dry ○ Compromised	○ Used directly ○ Rejected/replaced ○ Returned to CSSD	○ Scrub nurse ○ Surgeon ○ OT Tech
5	○ Instrument ○ Basin set ○ Dressing	○ Linen ○ Non-woven ○ Other: ____	○ Intact & dry ○ Compromised	○ Used directly ○ Rejected/replaced ○ Returned to CSSD	○ Scrub nurse ○ Surgeon ○ OT Tech
6	○ Instrument ○ Basin set ○ Dressing	○ Linen ○ Non-woven ○ Other: ____	○ Intact & dry ○ Compromised	○ Used directly ○ Rejected/replaced ○ Returned to CSSD	○ Scrub nurse ○ Surgeon ○ OT Tech
7	○ Instrument ○ Basin set ○ Dressing	○ Linen ○ Non-woven ○ Other: ____	○ Intact & dry ○ Compromised	○ Used directly ○ Rejected/replaced ○ Returned to CSSD	○ Scrub nurse ○ Surgeon ○ OT Tech
8	○ Instrument ○ Basin set ○ Dressing	○ Linen ○ Non-woven ○ Other: ____	○ Intact & dry ○ Compromised	○ Used directly ○ Rejected/replaced ○ Returned to CSSD	○ Scrub nurse ○ Surgeon ○ OT Tech
9	○ Instr	○ Linen	○ Intact & dry	○ Used directly	○ Scrub nurse

	○ Instrument ○ Basin set ○ Dressing	○ Non-woven ○ Other: ____	○ Compromised	○ Rejected/replaced ○ Returned to CSSD	○ Surgeon ○ OT Tech
10	○ Instrument ○ Basin set ○ Dressing	○ Linen ○ Non-woven ○ Other: ____	○ Intact & dry ○ Compromised	○ Used directly ○ Rejected/replaced ○ Returned to CSSD	○ Scrub nurse ○ Surgeon ○ OT Tech
11	○ Instrument ○ Basin set ○ Dressing	○ Linen ○ Non-woven ○ Other: ____	○ Intact & dry ○ Compromised	○ Used directly ○ Rejected/replaced ○ Returned to CSSD	○ Scrub nurse ○ Surgeon ○ OT Tech
12	○ Instrument ○ Basin set ○ Dressing	○ Linen ○ Non-woven ○ Other: ____	○ Intact & dry ○ Compromised	○ Used directly ○ Rejected/replaced ○ Returned to CSSD	○ Scrub nurse ○ Surgeon ○ OT Tech

KAP Questionnaire

STERILE PACK INTEGRITY & STAFF COMPETENCE DATA COLLECTION FORM

(Based on AAMI ST79, AORN Guidelines, and Validated KAP Instruments)

Reference: Adapted from Almedaini et al. (2021), Habtewold et al. (2024), AORN (2024), AAMI ST79:2017

SECTION A: DEMOGRAPHIC & PROFESSIONAL PROFILE

A1. Age (yrs):	A2. Gender: ☐M ☐F ☐Other	A3. Designation:	☐Scrub Nurse ☐Circulating Nurse ☐OR Tech ☐CSSD Staff ☐Other: ____	A4. Qualification:	☐Diploma ☐BSc ☐MSc ☐Other: ____
A5. Years in OR/CSSD:	☐<1yr ☐1-3yrs ☐4-6yrs ☐7-10yrs ☐>10yrs	A6. Formal sterile processing training?	☐Yes ☐No If Yes, last: ☐<1yr ☐1-3yrs ☐>3yrs	A7. Department:	☐General Surg ☐Ortho ☐Obs/Gyn ☐Urology ☐ENT ☐CSSD
A8. Shift:	☐Morning ☐Evening ☐Night ☐Rotating	A9. Prior IPC training?	☐Yes ☐No	A10. Date:	_____

SECTION B: KNOWLEDGE ASSESSMENT (10 items, 1 mark each — Total: /10)

B1. A wet sterile pack on arrival in the OR should be:

a) Dried with sterile towel & used b) Considered contaminated & returned to CSSD

c) Used if surgery cannot be delayed d) Stored for later use

B2. 'Strike-through contamination' refers to:

a) Physical tearing of outer wrap b) Passage of microorganisms through damp packaging c) Cross-contamination between trays d) Failure of heat seal on peel pouch

B3. MOST susceptible packaging material to wet pack events:

a) SMS non-woven wrap b) Rigid container c) Reusable woven linen/muslin d) Paper-plastic peel pouch

B4. True or False: Wet pack is safe if instruments appear visually dry.

☐ True ☐ False

B5. MOST common cause of wet packs in hospital CSSD:

a) Paper-plastic pouches for heavy sets b) Overloading sterilizer — inadequate steam penetration c) Failure to label with batch numbers d) Using wrong sterilization method

B6. A peel pouch should be REJECTED if:

a) Instrument visible through transparent side b) Heat seal broken or paper portion wet/torn

c) Indicator strip fully changed color d) Sterilized using H_2O_2 plasma

B7. Primarily responsible for inspecting sterile pack before use:

a) CSSD technician who packaged it b) Scrub nurse/tech opening the pack

c) Surgeon performing procedure d) Infection control officer

B8. True or False: Residual moisture creates pathway for microbial contamination.

☐ True ☐ False

B9. Optimal sterile storage conditions include:

a) High humidity to prevent drying b) 18–23°C, humidity 35–70%, closed shelving away from floors

c) Refrigeration at 4°C d) multi-purpose room with cleaning supplies

B10. True or False: Metal surfaces don't absorb condensate — higher wet pack risk.

☐ True ☐ False

SECTION C: ATTITUDES (7 items, 1–5 Likert scale — Total: /35) SD=1, D=2, N=3, A=4, SA=5 (*Reverse-score items before summing: 5↔1, 4↔2)

Statement	SD (1)	D (2)	N (3)	A (4)	SA (5)	Score
C1. Inspecting every sterile pack before use is a fundamental professional responsibility.	☐	☐	☐	☐	☐	___
C2. Removing a wet pack — even if it causes surgical delay — is always the correct action.	☐	☐	☐	☐	☐	___
C3*. Time pressure in the OR sometimes justifies using a slightly damp pack. [REVERSE SCORE]	☐	☐	☐	☐	☐	___
C4. I am confident in my ability to identify all types of compromised sterile packs.	☐	☐	☐	☐	☐	___
C5. My sterile pack practice directly affects the patient's risk of surgical site infection.	☐	☐	☐	☐	☐	___
C6*. Reporting a compromised pack may result in punitive action against me. [REVERSE SCORE]	☐	☐	☐	☐	☐	___
C7. Regular in-service training on sterile pack management would improve patient safety.	☐	☐	☐	☐	☐	___

SECTION D: PRACTICES (6 items — scored for safe practice frequency)

D1. How often do you inspect sterile pack outer wrap for integrity before use?

☐Always ☐Most of time ☐Sometimes ☐Rarely/Never

D2. How often do you check chemical indicator tape before opening sterile packs?

☐Always ☐Most of time ☐Sometimes ☐Rarely/Never

D3. If you receive a wet sterile pack just before surgery, you:

a) Remove immediately, inform surgeon, request replacement b) Remove but don't report

c) Dry outside & use if no replacement d) Use without action

D4. How often do you formally document/report wet/compromised pack incidents?

☐Always ☐Most of time ☐Sometimes ☐Rarely/Never

D5. If a colleague is about to use a pack you believe is compromised, you:

a) Immediately inform colleague & request removal b) Mention concern but defer c) Do not intervene

D6. In past 12 months, how many times have you personally rejected a compromised sterile pack?

☐None ☐1-2 times ☐3-5 times ☐>5 times

SCORING & INTERPRETATION (For Researcher Use Only)

B Score: ___/10 | C Score: ___/35 (after reverse-scoring C3 & C6) | D Score: Safe practice = 'Always/Remove immediately' responses

Interpretation: B ≥7/10 = Adequate Knowledge | C ≥25/35 = Positive Attitude | D: 'Always/Remove immediately' = Safe Practice

— Form ID: KAP-SPI-001 | Version 1.0 | Validated by: 3 perioperative specialists + 1 IPC specialist | Pilot: n=5 OR staff —