BMJ Open

PakSurg 1: determining the epidemiology and risk factors of surgical site infections in Pakistan—a multicentre, prospective cohort study

PakSurg Collaborative

To cite: PakSurg Collaborative. PakSurg 1: determining the epidemiology and risk factors of surgical site infections in Pakistan—a multicentre, prospective cohort study. *BMJ Open* 2023;**13**:e070831. doi:10.1136/bmjopen-2022-070831

► Prepublication history and additional supplemental material for this paper are available online. To view these files, please visit the journal online (http://dx.doi.org/10.1136/bmjopen-2022-070831).

Received 07 January 2023
Accepted 28 April 2023

Correspondence to
PakSurg Collaborative; ather.enam@aku.edu and Syed Ather Enam; ather.enam@aku.edu

ABSTRACT

Introduction Surgical site infections (SSIs) are among the the most common postoperative complications, despite being highly preventable. Multiple studies have explored the incidence and risk factors of SSIs globally. However, nationally representative data capable of informing evidence-based guidelines remain limited in Pakistan. Hence, the aim of this study is to identify the incidence and risk factors of developing SSIs following surgery and to explore existing SSI prevention practices in Pakistan.

Methods and analysis This study is a multicentre, prospective cohort study across various sites in Pakistan. All consecutive adult patients undergoing inpatient elective surgery in a 1 month patient recruitment window from one or more of the nine eligible subspecialties will be included in the study. Patients with preoperative infections, emergency surgeries or intraoperative mortality are to be excluded. The following surgical subspecialties are included: breast surgery, cardiac surgery, colorectal surgery, cranial surgery, general surgery, obstetrics and gynaecology, orthopaedics surgery, spine surgery and vascular surgery. Each mini-team of up to three collaborators can select one of the nine subspecialties and a 1 month patient recruitment window from 20 September 2022 to 31 March 2023. Multiple mini-teams from the same sites can recruit patients across the same subspecialty in distinct patient recruitment windows. Additionally, multiple mini-teams from the same sites can recruit patients across different subspecialties in the same or distinct patient recruitment windows. The primary outcome is 30 day SSIs. Secondary outcomes include 30 day antibiotic-resistant SSIs, organ-space infections, other healthcare associated infections, reinterventions and all-cause mortality.

Ethics and dissemination Approval was received by the Aga Khan University (AKU) Ethics Review Committee (ERC) and the National Bioethics Committee (NBC) Pakistan. The results from this study will be disseminated by the steering committee in journal publications, conference presentations and on other academic platforms. Evidence-based guidelines that result from these data will be disseminated to all surgical care providers in Pakistan through national networks.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ Being a multicentre observational study in a resource-limited setting, a major limitation would be the possibility of losing patients to follow-up before assessment of 30 days postoperative outcomes.
⇒ Given the differences in postoperative clinical care pathways and disparities in resources across different hospitals, there will be expected variations in methods of postoperative outpatient surgical site infection (SSI) surveillance. This ground reality has the potential to introduce methodological bias in our study.
⇒ Finally, as hospitals and patients across the country use different laboratory services for testing, the non-standardisation of microbiological analysis is another limitation.
⇒ However, the multicentric and national nature of this study ensures high generalisability of results to centres across the country.
⇒ The extensive breadth of variables collected in a prospective fashion, including patient-level, surgeon-level and hospital-level factors, will ensure a holistic analysis of risk factors for SSI and will reduce the chances of unmeasured confounding.

INTRODUCTION

Surgical site infections (SSIs) are one of the most common postoperative complications.[1] Apart from contributing to significant morbidity, SSIs also add to the financial expenditures incurred by patients undergoing surgery.[2–4] This is especially a huge burden for patients in Pakistan, most of whom are not covered with health insurances.[5] Multiple studies have explored the epidemiology and risk factors for the development of SSIs globally.[3 6–9] However, previous studies in Pakistan were mostly limited to retrospective, single-centre experiences.[4 10–13] Prospective, standardised and nationally comparable data on the incidence, risk factors and adverse events associated with SSIs are lacking in Pakistan.

These gaps in knowledge hinder effective resource allocation to alleviate the burden

of SSIs, particularly in resource-constrained settings like Pakistan. The WHO has published several recommendations regarding SSI prevention.[7 14] While these recommendations are very elaborate, they are mostly based on data generated from high-income countries. The validity of these recommendations has not been explored within the Pakistani setting.

SSIs are of significant epidemiological value and are preventable. However, there is a lack of high-quality national data to inform evidence-based strategies for SSI prevention. Such data can help prioritise resource utilisation and identify modifiable and non-modifiable patient-level, surgical practice-level and hospital-level risk factors for SSI development. Antimicrobial resistance is also concerning in patients with SSIs, and microbiological data on causative organisms is essential to refine preventative strategies.[7]

PakSurg 1 has been designed as a prospective, multicentre study aimed to identify and close existing gaps in SSI-based research across various surgical specialties in Pakistan by generating comprehensive data from most Pakistani provinces and cities. With this, we plan to develop a uniform protocol to reduce the incidence of preventable SSIs in Pakistan.

OBJECTIVES

Primary

1. Determine the incidence of SSI in Pakistan across different surgical subspecialties.

Secondary

1. Assess the existing preoperative, intraoperative and postoperative practices for prevention of SSI.
2. Determine incidence of antibiotic-resistant SSI across different surgical subspecialties.
3. Assess the risk factors for the development of SSIs across various surgical subspecialties.

METHODS

PakSurg 1 will be conducted as a prospective, multicentre, observational study on a national level with recruitment of centres throughout Pakistan to have a diverse yet holistic view of SSIs across the country.

From each centre, one or more subspecialties from the shortlisted ones (online supplemental appendix 1—Included Procedures) can be selected for data collection. However, while recommended, it is not mandatory for centres to collect data across all subspecialties. Nonetheless, the process of data collection will be monitored and distributed by the steering committee in a way that all selected subspecialties are represented to give a national estimate of the incidence of SSIs.

Mini-teams

For the process of data collection within different subspecialties, mini-teams of up to three collaborators can register from each centre. Each mini-team per subspecialty will collect data on all consecutive patients presenting in a 1 month patient recruitment period.

- Multiple mini-teams can recruit patients across different subspecialties at the same centre, irrespective of whether they recruit patients in the same or distinct 1 month patient recruitment periods.
- Multiple mini-teams can recruit patients in the same subspecialty during distinct 1 month patient recruitment periods.
- Collaborators can be part of multiple mini-teams collecting data across different subspecialties.
  - Collecting data across multiple specialties will make collaborators eligible for potentially more authorship opportunities (see the 'Authorship' section).

Each subspecialty must be supervised by at least one consultant who can facilitate study setup, local approvals, patient recruitment, data collection and submission.

Study duration

The patient recruitment window for PakSurg 1 will proceed from 20 September 2022 to 31 March 2023 (with the last patient followed up till 30 April 2023; figure 1). This recruitment period will include patients undergoing specific surgeries for the included subspecialties as highlighted in online supplemental appendix 1—Included Procedures. Each mini-team will recruit all consecutive patients within their scope of practice for a particular subspecialty during their selected 1 month period. All patients will be evaluated till 30 days postoperatively for outcome assessment.

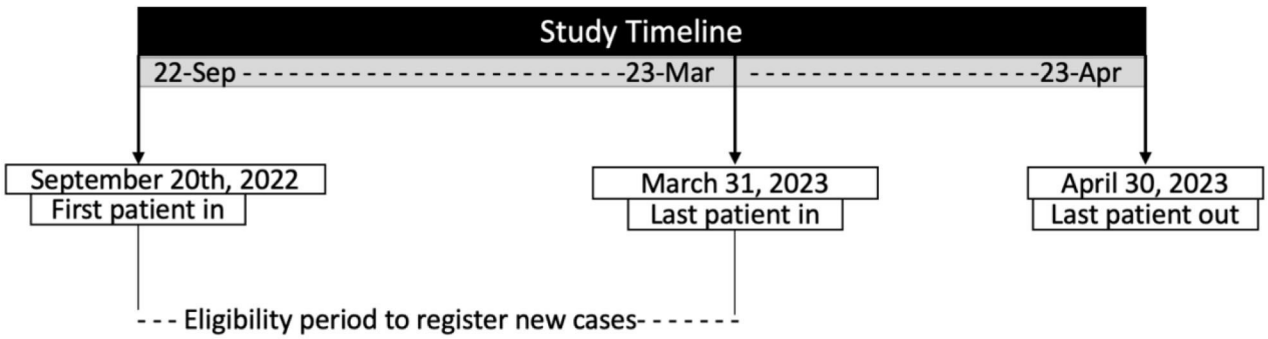

Figure 1 Study timeline for PakSurg 1

Centre inclusion criteria

- Hospitals that perform elective surgeries.

Eligibility criteria for patients

Inclusion criteria

- Adult patients (age ≥18 years).
- All consecutive patients who are due to undergo elective surgery.
- The following surgical subspecialties will be included: breast surgery, cardiac surgery, colorectal surgery, cranial surgery, general surgery, obstetrics and gynaecology, orthopaedics surgery, spine surgery and vascular surgery (online supplemental appendix 1—Included Procedures).
- Only patients undergoing surgeries listed in the online supplemental appendix 1—Included Procedures are to be included.
- Patients who consent to join the study.

Exclusion criteria

- Patients with preoperative infections.
- Emergency surgeries.
- Patients with intraoperative mortality.

Outcomes

Primary

- SSI within 30 days of index surgery.

Secondary

- Antibiotic-resistant SSI within 30 days of index surgery.
- Perioperative antibiotic administration.
- Other healthcare associated infections within 30 days of index surgery.
- Unexpected reintervention within 30 days of index surgery.
- All-cause mortality within 30 days of index surgery.

Operational definitions

SSI (superficial incisional, deep incisional or organ space): PakSurg 1 will use the 2023 Centre for Disease Control definitions of SSIs.[15] The definitions are abridged as follows:

1. Superficial incisional SSI (must meet the following criteria):
   - Date of event occurs within 30 days following the National Healthcare Safety Network (NHSN operative procedure (where day 1=the procedure date).
   - Involves only skin and subcutaneous tissue of the incision.
   - Patient has at least one of the following:
     - Purulent drainage from the superficial incision.
     - Organism(s) identified from an aseptically obtained specimen from the superficial incision or subcutaneous tissue by a culture or non-culture-based microbiological testing method which is performed for purposes of clinical diagnosis or treatment (eg, not Active Surveillance Culture/Testing [ASC/AST]).
     - A superficial incision that is deliberately opened by a surgeon, physician* or physician designee and culture or non-culture-based testing of the superficial incision or subcutaneous tissue is not performed and patient has at least one of the following signs or symptoms: localised pain or tenderness; localised swelling; erythema or heat.
     - Diagnosis of superficial incisional SSI by a physician* or physician designee.
2. Deep incisional SSI (must meet the following criteria):
   - Date of event occurs within 30 days** following the NHSN operative procedure (where day 1=the procedure date) according to the list in Table 2 from the Centre of Disease Control's National Healthcare Safety Network January 2023 protocol on SSI events.[15]
   - Involves deep soft tissues of the incision (eg, fascial and muscle layers).
   - Patient has at least one of the following:
     - Purulent drainage from the deep incision.
     - A deep incision that is deliberately opened or aspirated by a surgeon, physician* or physician designee or spontaneously dehisces.
       - Organism(s) identified from the deep soft tissues of the incision by a culture or non-culture-based microbiological testing method which is performed for purposes of clinical diagnosis or treatment (eg, not ASC/AST) or culture or non-culture-based microbiological testing method is not performed. A culture or non-culture-based test from the deep soft tissues of the incision that has a negative finding does not meet this criterion.
       - Patient has at least one of the following signs or symptoms: fever (>38°C); localised pain or tenderness.
     - An abscess or other evidence of infection involving the deep incision detected on gross anatomical examination, histopathological examination or imaging test.
3. Organ/Space SSI (must meet the following criteria):
   - Date of event occurs within 30 days** following the NHSN operative procedure (where day 1=the procedure date) according to the list in Table 2 from the Centre of Disease Control's National Healthcare Safety Network January 2023 protocol on SSI events[15] and involves any part of the body deeper than the fascial/muscle layers that is opened or manipulated during the operative procedure.
   - Patient has at least one of the following:
     - A purulent drainage from a drain placed into the organ/space (eg, closed suction drainage system, open drain, T-tube drain CT-guided drainage).
     - Organism(s) identified from fluid or tissue in the organ/space by a culture or non-culture-based microbiological testing method which is

performed for purposes of clinical diagnosis or treatment (eg, not ASC/AST).
- An abscess or other evidence of infection involving the organ/space detected on gross anatomical examination or histopathological examination or imaging test evidence definitive or equivocal for infection; meets at least one criterion for a specific organ/space infection site listed in Table 3 from the Centre of Disease Control's National Healthcare Safety Network January 2023 protocol on SSI Events.[15]

*The term physician for the purpose of application of the NHSN SSI criteria may be interpreted to mean a surgeon, infectious disease physician, emergency physician, other physician on the case or physician's designee (nurse practitioner or physician's assistant).

**One important differentiation between the SSI criteria used in our study and that reported by the CDC is that we use a 30 day cut-off for postoperative SSI identification for all operations. This is because the 90 day surveillance required to identify SSIs after some operations is extremely unfeasible in many hospitals in Pakistan, as most of these centres do not have structured surveillance systems or electronic medical records.

1. Emergency procedures: unplanned, non-elective procedures, including reoperations following previous procedures.
2. Postoperative mortality rate: mortality till the 30th day of index surgery.
3. 30 day unexpected reintervention: operative, endoscopic or radiological reintervention after skin closure till the 30th day postoperatively. Relook surgeries planned at the time of original operation are not to be included in 'unexpected' reinterventions.
4. Other healthcare-associated infection: an infection that was not present or not incubating at the time of admission but occurs while the patient is receiving care in a hospital or other healthcare facility. These can also be referred to as nosocomial infections. Infections other than SSI are to be included in this category. Healthcare-associated infection was defined as infection first occurring a minimum of 48 hours after admission or within 30 days of discharge.[16]
5. Inpatient: refers to the hospital admission for the index surgery.
6. Antimicrobial resistance: resistance in the species presumed to be pathological to the antimicrobial used for prophylaxis.

Sample size estimation

According to existing literature, incidence rate of SSIs in Pakistan ranges from 9.3% to 33.6% across multiple subspecialties.[4 10–13] Assuming an unlimited population size, we estimated a sample size of 1845 patients to estimate incidence rate of SSIs with a 95% CI, 5% precision and 20% inflation rate for loss-to-follow-up using the Sample Size Calculator by the WHO.

Consecutive patients identification

Collaborators are primarily expected to review theatre logbooks/operating lists from all potential operating theatres daily to identify all eligible patients. Additionally, they can also review handover sheets or ward lists. All consecutive patients presenting in selected 1 month periods are to be recruited.

Data collection

Hospital and subspecialty surveys

On registration, each mini-team will complete the hospital and subspecialty surveys (online supplemental appendix 2—Hospital Questionnaire and online supplemental appendix 3—Subspecialty Questionnaire). These would explore hospital details and subspecialty patient and surgeon volumes.

Patient questionnaire

Each mini-team will collect patient-level data using online supplemental appendix 4—Patient Questionnaire. This tool comprises of baseline variables (demographics, comorbidities and American Society of Anesthesiologists (ASA) physical status), intraoperative details (surgical priority, indication, SSI prevention practices, theatre volume, operative approach, operative duration, anaesthesia, surgical wound class and antimicrobial prophylaxis), postoperative details (intensive care unit stay, SSIs, reinterventions, other hospital-acquired infections and mortality).

Mini-teams will identify eligible patients and begin patient-level data collection preoperatively. Data collection will continue prospectively throughout a patient's hospital course. Special care will be taken to record intraoperative variables (such as skin preparation details and headcount) in real time via coordination with the operation theatre staff, as these are not routinely recorded and would be difficult to record retroactively later during a patient's hospital course.

Collaborators from each mini-team should monitor patients to identify SSIs up till 30 days in accordance with the SSI surveillance protocol by Public Health England (PHE).[17] These may include the following:

Follow-up and outcome assessment

1. Follow-up during the inpatient hospital stay: designated hospital staff should actively monitor each patient for signs of infection. This can be achieved by direct observation or by daily file/record review, as follows:
   1. Liaising with ward staff and reviewing medical and nursing records regularly to identify signs and symptoms related to SSIs.
   2. Reviewing microbiology reports for any positive surgical site cultures, and checking with the hospital ward to identify why cultures were taken and if there were any signs of infection.
2. Detecting hospital readmissions: collaborators should devise systems to identify patients included in the study that are subsequently readmitted to their hospital. The

following measures could be taken to identify such patients:

1. Coordinating with hospital admission services to flag identifying information (name, medical record number) for patients included in the study, so that they may be identified if readmitted within 30 days.
2. Monitor patient electronic health records (if available) to check if patient is readmitted.
3. Direct inquiry of the patient during telephonic follow-up (detailed below).

3. Post-discharge outpatient clinic follow-up:
   1. Identifying information (name, medical record number) for included patients should be flagged to notify collaborators of outpatient or emergency department visits.
4. Post-discharge telephonic follow-up:
   1. Patients included in this study should be contacted by collaborators telephonically on the third, 15th and 30th day of surgery.
   2. Telephonic interviews should be in accordance with the attached online supplemental appendix 5—Telephonic Follow-Up (English) and online supplemental appendix 6—Telephonic Follow-Up (Urdu), which is based on the SSI surveillance protocol by the PHE.[17]

Given the differences in clinical care pathways and hospital resources across different centres, follow-up assessments should be structured around the pre-existing patient follow-up pathways for each hospital. All collaborators will describe methods used for obtaining follow-up data at their respective centres.

Data submission

Data collected by the collaborators will be submitted via a secure network based on the Redcap system (http://project-redcap.org/), which will be provided by Aga Khan University (AKU), Karachi. Redcap is being employed globally to gather research-related data in a secure way.[18] We will configure our questionnaire on Redcap with several quality checks to ensure data are entered correctly and avoid potential errors.

Designated collaborators at each participating site will be provided access to the Redcap project server by the steering committee. This will allow them to submit the data they have collected. Collaborators will create a record for each patient on Redcap, and each record will be automatically assigned a Redcap ID. Collaborators should maintain an encrypted Microsoft Excel sheet to link Redcap IDs to specific patient identification numbers for their own use (please see the template provided on website).

Redcap accounts will be set up using the data access groups feature. This would ensure that collaborators have access to the data submitted by their own mini-team and not to the data submitted by other mini-teams. Only members from the Writing and Analysis Team and Operations Team of the steering committee will have access to all data.

Data transmission will be anonymous, and no patient identifiers will be submitted via Redcap. Furthermore, no hospital identifiers will be published; only aggregated results will be disseminated.

Data validation

Independent data validators will be recruited for data validation. These validators may be identified by the local teams, provided they were not part of any team involved in primary data collection. Validation will be performed in two phases:

1. Case completeness: case completeness will be assessed in 50% of hospitals randomly selected from participating hospitals. Independent data validators will confirm the number of eligible cases in specified periods at the participating sites. The steering committee will cross-check this with the number of patients submitted to assess the site-specific capture rate. These case ascertainment rates will be compared between provinces, public and private hospitals, and secondary and tertiary case healthcare services. Case ascertainment rate correlations (number of patients identified by validator vs number of records entered by the collaborators) will be assessed. A case ascertainment >80% will be deemed acceptable at the level of individual hospitals. Hospitals not meeting this criterion will be excluded from analysis.
2. Data accuracy: assessment of data accuracy will be performed for 25% cases randomly selected from total cases enrolled by each hospital. An independent data validator will be provided Redcap IDs of selected patients. Each validator will be responsible for obtaining patient identifiers corresponding to Redcap IDs from local data collection teams and extracting the following variables from patient records.
   1. Patient variables: age and gender
   2. Operation variables: indication and operative approach
   3. Outcome variables: 30-day mortality and unexpected reintervention

Data extracted by validators will be compared with that extracted by local data collectors for degree of agreement. This will be assessed using Cohen's Kappa coefficient for categorical variables and Pearson correlation for age. Data accuracy will be assessed for hospitals nationwide and individual provinces. Data accuracy ≥95% will be deemed acceptable at hospital-level, and hospitals not meeting this criterion will be excluded from analysis.

Statistical analysis

All analyses will be conducted using the IBM Statistical Package for Social Sciences (SPSS) version 26. Continuous variables will be converted to categorical variables and presented as frequencies (percentages). Differences among clinicodemographic groups will be assessed via χ^2 test. Fisher's exact test will be used when conditions for χ^2 tests are not met. Missing data will be included in

flowcharts and summary tables, allowing denominators to remain consistent in calculations.

We plan to use the National Nosocomial Infections Surveillance (NNIS) risk index, which is based on wound classification, duration of procedure and ASA score, as a composite measure of a patient's risk for development of SSI.[19] However, given that some previous studies have questioned the appropriateness of the NNIS as a composite measure in certain surgical subspecialties,[20 21] we will also conduct a sensitivity analysis using wound classification, duration of procedure, and ASA score as single, independent variables.

We will employ multivariable cox regression models to assess the influence of clinicodemographic variables on various outcomes for each surgical subspecialty. Predefined clinically plausible variables which occurred prior to the outcome events will be inputted into these models to adjust the main explanatory variables. Relative risk along with their 95% CIs will be presented. All statistical analyses will be two-sided, and p value<0.05 will be considered the threshold for statistical significance.

For assessing the incidence of antibiotic-resistant SSI, we will not be standardising laboratory assessment, techniques or definitions used, since it is impractical over many centres. Thus, this will be an exploratory analysis only, with full appreciation of the limitations in this measure.

Finally, additional sensitivity analysis will be performed to ascertain the robustness and credibility of our results. This will be performed using the following approaches:[22]

- *Outliers*: outliers will be reported, and regression analysis will be performed with and without outliers.
- *Missing data*: missing data will be reported, and regression analysis will be performed excluding and including (using simple imputation) cases with missing data.
- *Subgroup analysis*: regression analysis will be in subgroups created according to province, level of medical services (secondary *vs* tertiary medical centre), teaching status, hospital volume and mode of 30 day outcome assessment (outpatient assessment or telephonic follow-up).

ETHICS AND DISSEMINATION

Local approvals

PakSurg 1 will preserve the standard clinical care at the collaborating centres. No data will be presented with individual patient, surgeon or hospital identifiers. Collaborating centres might have differing regulations to gain permission for joining this study. Therefore, it is primarily the responsibility of local collaborators to gain approval as per their institutional policy, and this can be done via one of the following:

- Audit committee/department (as audit or service evaluation).
- Research departments/Institutional Review Boards/Ethics Review Committees (as observational research study or service evaluation).
- Few collaborating centres may not have these departments. In such cases, local investigators must receive written permission from the next best available source. These can include hospital chief, chair of department of surgery, a supervising consultant, or an attending physician (see template letter).

Please note: collaborators will be asked to confirm local approval prior to data submission. Once this is confirmed, collaborators will be provided access to the Redcap project server by the steering committee. The study steering committee will also apply for ethical clearance from the National Bioethics Committee to make the ethical approval process easier for the collaborating sites.

Whatever pathway for local approval is followed, it should be highlighted that PakSurg 1 is an investigator-led, observational, non-commercial study with no changes to existing local patient management pathways. This is an extremely low-risk study as we only aim to collect routinely available anonymized data.

The study will be carried out in accordance with national and international guidelines, as well as the basic principles of the protection of the rights and dignity of Human Beings as set out in the Helsinki Declaration (2013), and according to locally applicable legislation.

Informed consent

Participation in the research is strictly voluntary for patients. All patients who agreed to participate will be given details about the study. The scope and goals of the study would be described, as well as the contribution of the participant to the study. The participant will be assured confidentiality would be maintained and could withdraw from the study at any time. Prior to participation, informed written consent will be obtained.

Please note

- Informed written consent should be taken by local collaborators at an appropriate time while the patient is admitted.
- Sample consent forms have been attached with this protocol and are available in English and Urdu as online supplemental appendix 7—Consent Form (English) and online supplemental appendix 8—Consent Form (Urdu).

Patient confidentiality

All data transmission will be conducted using a secure network based on Redcap. Data access groups will be created for each mini-team; these will limit the access of collaborators to the data they have submitted. Only members from the Writing and Analysis Team and Operations Team of the steering committee will have access to the whole dataset.

Local collaborators will create a record for each patient on Redcap, and each record will be automatically assigned a Redcap ID. Local collaborators will be expected to maintain an encrypted Microsoft Excel sheet to link Redcap IDs to specific patient identification numbers for their own use (see template provided). However, no

patient identifiers, such as names, telephone numbers, or medical record numbers, will be submitted on Redcap.

Please note: it will be the responsibility of local collaborators to safeguard confidentiality of their data locally at their respective centres.

The steering committee will protect all data electronically using encryptions. Data will also be kept in a separate encrypted external hard drive as backup which will be kept securely at AKU, Karachi.

Data disposition

In accordance with AKU's data retention policy, all data will be kept electronically and in an external hard drive for 7 years after the study. After this period, the steering committee will permanently delete all data related to this study.

Patient and public involvement

Patients or the public will not be involved in the design, conduct, reporting, or dissemination plans of our research.

Surgery interest group

The Surgery Interest Group (SIG) at the AKU is a student-led body working under the mentorship of Dr Sadaf Khan and Dr Syed Ather Enam. SIG aims to increase opportunities within the field of surgery for medical students by promoting surgical research, organising conferences, conducting workshops, hosting panel discussions, facilitating outreach to surgical alumni, and collaborating with various surgical organizations.

To achieve these objectives, SIG consists of five divisions: Education and Skills Development, Events and Outreach, Research, Media and Marketing and Ambassadors. SIG caters to the surgically inclined students at AKU and to those beyond it through its country-wide Ambassadors Program and International Networks. These networks include but are not limited to the American College of Surgeons, Association of Women Surgeons and International Association of Student Surgical Societies.

As an organisation, SIG is constantly looking for dedicated mentors and enthusiastic students to be a part of this journey.

PakSurg: National Research Collaborative

PakSurg is the first national trainee-led surgical research collaborative in Pakistan. It was established by the SIG at AKU to promote national coordination in surgical research. Supported by the Department of Surgery and Centre for Global Surgical Care at AKU, this collaborative network aims to initiate multicentre research studies across Pakistan to enhance surgical research output which will lead to an improvement in surgical outcomes in Pakistan.

Collaborators PakSurg Collaborative: Steering Committee: Committee Leads: Usama Waqar: Steering Committee Lead (Medical College, Aga Khan University Hospital, Karachi, Pakistan, 74800), Maheen Mansoor (Medical College, Aga Khan University Hospital, Karachi, Pakistan, 74800); Writing & Analysis Team: Asma Altaf Hussain Merchant: Team lead (Medical College, Aga Khan University Hospital, Karachi, Pakistan, 74800), Ronika Devi Ukrani: Team lead (Medical College, Aga Khan University Hospital, Karachi, Pakistan, 74800), Asad Saulat Fatimi (Medical College, Aga Khan University Hospital, Karachi, Pakistan, 74800), Manzar Abbas (Medical College, Aga Khan University Hospital, Karachi, Pakistan, 74800), Muskaan Abdul Qadir (Medical College, Aga Khan University Hospital, Karachi, Pakistan, 74800), Russell Seth Martins (Department of Surgery, JFK University Medical Center, Hackensack Meridian School of Medicine, Edison, New Jersey, USA); Operations Team: Sehar Salim Virani: Team lead (Medical College, Aga Khan University Hospital, Karachi, Pakistan, 74800), Faiqa Binte Aamir: Team lead (Medical College, Aga Khan University Hospital, Karachi, Pakistan, 74800), Hamna Ganny (Medical College, Aga Khan University Hospital, Karachi, Pakistan, 74800), Javeria Tariq (Medical College, Aga Khan University Hospital, Karachi, Pakistan, 74800), Mabrooka Kazi (Medical College, Aga Khan University Hospital, Karachi, Pakistan, 74800), Muhammad Uzair (Medical College, Aga Khan University Hospital, Karachi, Pakistan, 74800), Muhammad Umar Mahar (Medical College, Aga Khan University Hospital, Karachi, Pakistan, 74800); Outreach Team: Izza Tahir: Team lead (Medical College, Aga Khan University Hospital, Karachi, Pakistan, 74800), Shaheer Ahmed: Team lead (Medical College, Islamabad Medical and Dental College, Islamabad, Pakistan), Daniyal Ali Khan (Medical College, Aga Khan University Hospital, Karachi, Pakistan, 74800), Hareem Rauf (Medical College, Aga Khan University Hospital, Karachi, Pakistan, 74800), Mahnoor Javaid (Medical College, Aga Khan University Hospital, Karachi, Pakistan, 74800), Momina Faisal (Medical College, Aga Khan University Hospital, Karachi, Pakistan, 74800), Sarim Raheel (Medical College, Aga Khan University Hospital, Karachi, Pakistan, 74800); Dissemination Team: Hajra Arshad: Team lead (Medical College, Aga Khan University Hospital, Karachi, Pakistan, 74800), Muhammad Abbas Raza (Medical College, Aga Khan University Hospital, Karachi, Pakistan, 74800), Muhammad Jawad Amin Malik (Medical College, Aga Khan University Hospital, Karachi, Pakistan, 74800), Muhammad Ozair Awan (Medical College, Aga Khan University Hospital, Karachi, Pakistan, 74800); Faculty Advisors: Amna Urooba (Department of Surgery, Aga Khan University Hospital, Karachi, Pakistan, 74800), Mashal Murad Shah (Department of Surgery, Aga Khan University Hospital, Karachi, Pakistan, 74800), Hina Inam (Department of Surgery, Aga Khan University Hospital, Karachi, Pakistan, 74800), Abida Sattar (Department of Surgery, Aga Khan University Hospital, Karachi, Pakistan, 74800), Aliya Begum Aziz (Department of Surgery, Aga Khan University Hospital, Karachi, Pakistan, 74800), Erum Baig (Department of Surgery, Aga Khan University Hospital, Karachi, Pakistan, 74800), Muhammad Shahzad Shamim (Department of Surgery, Aga Khan University Hospital, Karachi, Pakistan, 74800), Nadeem Siddiqui (Department of Surgery, Aga Khan University Hospital, Karachi, Pakistan, 74800), Amna Rehana Siddiqui (Department of Surgery, Aga Khan University Hospital, Karachi, Pakistan, 74800), Sadaf Khan (Department of Surgery, Aga Khan University Hospital, Karachi, Pakistan, 74800), Shahryar Noordin (Department of Surgery, Aga Khan University Hospital, Karachi, Pakistan, 74800), Tabish Chawla (Department of Surgery, Aga Khan University Hospital, Karachi, Pakistan, 74800), Syed Ather Enam: Principal investigator (Department of Surgery, Aga Khan University Hospital, Karachi, Pakistan, 74800).

Contributors UW, MM, AS, AU, AB, EB, HI, MMS, MSS, NS, ARS, SK, SN, TC and SAE were involved in the conceptualisation of the project. SSV, FBA, HG, JT, MK, MU, MUM, IT, SA, DAK, HR, MJ, MF, SR, HA, MAR, MJAM and MOA were involved in the logistical planning of this study and will be involved in its execution in the future. AAH Merchant, RDU, ASF, MA, MAQ and RSM were involved in the writing of the initial draft of the manuscript. All authors provided their critical review on the initial draft of the manuscript. The final version of this manuscript was approved by all the authors. Steering Committee: writing and analysis team: conceptualisation, protocol writing, securing ethical approvals, data analysis and manuscript writing. Operations Team: managing Redcap, developing the training module, facilitating data sharing, finalisation of agreements. Outreach Team: corresponding with lead collaborators, troubleshooting data collection, recruiting centres and facilitating them. Dissemination Team: marketing of the project and dissemination of results via social media. Institutional Lead Collaborator: 1. Coordinating teams in their centres by ensuring that no overlapping teams are collecting data from the same patients within the same period. 2. Obtaining the necessary ethical approvals in their centres. 3. Inviting their colleagues to participate in the study and formulating additional data collection teams in their centre. 4. Providing information about their centre surgical capacity and facilities. 5. Same responsibilities as collaborators. Please note: medical students, trainees, hospital administration and faculty are eligible to become institutional lead collaborators. Institutional Supervising Consultant: 1. Leading and supervising institutional mini team(s). 2. Obtaining the necessary ethical approvals in their centres. 3. Inviting their colleagues to participate in the study and formulating additional data collection teams in their centre. 4. Providing information about their centre's surgical capacity and facilities. Please note: only faculty members/consultants/registrars are eligible to become institutional supervising consultants. If an institution registers for multiple subspecialties, there should be 1 supervising consultant per subspecialty registered. Institutional Collaborator: 1. Applying for ethical approval in their centres

if the ethical approval has not been already obtained by another colleague. 2. Devising appropriate methods/pathways to identify and include all eligible cases. 3. Devising appropriate methods/pathways to collect the required patient data accurately. 4. Collecting data. 5. Submitting data through the Redcap system. Please note: medical students, trainees, hospital administration and faculty are eligible to become institutional collaborators. Institutional Data Validator: refer to the validation protocol. Please note: medical students, trainees, hospital administration and faculty are eligible to become institutional data validators. Authorship: all collaborators contributing data as per the requirements specified in this protocol would be eligible for authorship in the primary manuscript that will aim to identify incidence rates of surgical site infections in Pakistan across various subspecialties. Additionally, we might publish subspecialty-specific manuscripts based on risk factors for development of surgical site infections. Collaborators contributing data to a specific subspecialty would be eligible for authorship on any publications specific to that subspecialty as well as the primary manuscript. For authorships, we will use the corporate authorship model for the primary manuscript whereby one main group name (PakSurg Collaborative) will be employed to author subsequent publications. Names and affiliations of individual collaborators along with their roles will be published with the manuscript as a separate appendix. This corporate model has been employed successfully in prior collaborative studies. For example, COVIDSurg Collaborative. Mortality and pulmonary complications in patients undergoing surgery with perioperative SARS-CoV-2 infection: an international cohort study. The Lancet. 2020 May 29. https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)31182-X/fulltext.

Funding This study was supported by monetary funding from the Student and Trainee Initiated Research Programme (MBBS Class of '88 Awards, Aga Khan University, Karachi, Pakistan).

Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting or dissemination plans of this research.

Patient consent for publication Not required.

Provenance and peer review Not commissioned; externally peer reviewed.

REFERENCES

1 Allegranzi B, Bagheri Nejad S, Combescure C, *et al*. Burden of endemic health-care-associated infection in developing countries: systematic review and meta-analysis. *Lancet* 2011;377:228–41.
2 Tanner J, Khan D, Aplin C, *et al*. Post-Discharge surveillance to identify colorectal surgical site infection rates and related costs. *J Hosp Infect* 2009;72:243–50.
3 Bhangu A, Ademuyiwa AO, Aguilera ML. Surgical site infection after gastrointestinal surgery in high-income, middle-income, and low-income countries: a prospective, international, multicentre cohort study. *Lancet Infect Dis* 2018;18:516–25.
4 Sattar F, Sattar Z, Zaman M, *et al*. Frequency of post-operative surgical site infections in a tertiary care hospital in abbottabad, Pakistan. *Cureus* 2019;11:e4243.
5 Gutierrez H, Shewade A, Dai M, *et al*. Health care coverage decision making in low- and middle-income countries: experiences from 25 coverage schemes. *Popul Health Manag* 2015;18:265–71.
6 Aiken AM, Karuri DM, Wanyoro AK, *et al*. Interventional studies for preventing surgical site infections in sub-Saharan Africa-a systematic review. *Int J Surg* 2012;10:242–9.
7 Allegranzi B, Zayed B, Bischoff P, *et al*. New who recommendations on intraoperative and postoperative measures for surgical site infection prevention: an evidence-based global perspective. *Lancet Infect Dis* 2016;16:e288–303.
8 Bagheri Nejad S, Allegranzi B, Syed SB, *et al*. Health-care-associated infection in Africa: a systematic review. *Bull World Health Organ* 2011;89:757–65.
9 Rosenthal VD, Richtmann R, Singh S, *et al*. Surgical site infections, International nosocomial infection control Consortium (INICC) report, data summary of 30 countries, 2005–2010. *Infect Control Hosp Epidemiol* 2013;34:597–604.
10 Ahmed D, Cheema FH, Ahmed YI, *et al*. Incidence and predictors of infection in patients undergoing primary isolated coronary artery bypass grafting: a report from a tertiary care hospital in a developing country. *J Cardiovasc Surg (Torino)* 2011;52:99–104.
11 Khan M, Khalil JRooh-ul-Muqim*et al*. Rate and risk factors for surgical site infection at a tertiary care facility in peshawar, Pakistan. *J Ayub Med Coll Abbottabad* 2011;23:15–8.
12 Sharif AM, Jabeen DF, Ali LA, *et al*. n.d. Surgical site infection in elective surgery.
13 Tariq A, Ali H, Zafar F, *et al*. Assesment of predictor variables and clinical consequences associated with surgical site infection in tertiary care setting, Karachi, Pakistan. *Pak J Pharm Sci* 2018;31:269–75.
14 World Health Organization. Global guidelines for the prevention of surgical site infection, second edition. *World Health Organization* 2016:27–37.
15 CDC. Chapter 9: surgical site infection (SSI) event-January 2023. 2023.
16 Haque M, Sartelli M, McKimm J, *et al*. Health care-associated infections-an overview. *Infect Drug Resist* 2018;11:2321–33.
17 WHO. n.d. Protocol for the surveillance of surgical site infection.
18 Harris PA, Taylor R, Thielke R, *et al*. Research electronic data capture (redcap) -- a metadata-driven methodology and workflow process for providing translational research informatics support. *J Biomed Inform* 2009;42:377–81.
19 World Health Organisation. n.d. Protocol for surgical site infection surveillance with a focus on settings with limited resources. *World Health Organisation*;2018:1–39.
20 Gaynes R, Epidemiology H. Surgical-Site infections (SSI) and the NNIS basic SSI risk index, part II: room for improvement. *Infect Control Hosp Epidemiol* 2001;22:266–7.
21 Friedman ND, Bull AL, Russo PL, *et al*. Performance of the National nosocomial infections surveillance risk index in predicting surgical site infection in Australia. *Infect Control Hosp Epidemiol* 2007;28:55–9.
22 Thabane L, Mbuagbaw L, Zhang S, *et al*. A tutorial on sensitivity analyses in clinical trials: the what, why, when and how. *BMC Med Res Methodol* 2013;13:92.