PakSurg 1: Determining the epidemiology and risk factors of surgical site infections in Pakistan - A multicenter, prospective cohort study

PakSurg Collaborative

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Table of Contents

STUDY SUMMARY

Title: PakSurg 1: Determining the epidemiology and risk factors of surgical site infections in Pakistan - A multicenter, prospective cohort study

Background: Surgical site infections (SSIs) are among the commonest 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.

Aim: To identify incidence and risk factors of developing SSIs following surgery and to explore existing SSI prevention practices in Pakistan.

Design: Multicenter, prospective cohort study across various sites in Pakistan.

Eligibility: All consecutive adult patients undergoing inpatient elective surgery in a one-month patient recruitment window from one or more of the nine eligible subspecialties. Patients with preoperative infections, emergency surgeries, or intraoperative mortality are to be excluded.

Subspecialties: The following surgical subspecialties are included: Breast surgery, cardiac surgery, colorectal surgery, cranial surgery, general surgery, obstetrics & gynecology, orthopedics surgery, spine surgery, and vascular surgery. Among subspecialties, only procedures listed in the Appendix – Included Procedures are eligible for inclusion.

Mini-teams: Each mini-team of up to three collaborators can select one of the nine subspecialties and a one-month patient recruitment window from 1st September 2022 to 31st March 2023. Multiple mini-teams from same sites can recruit patients across the same subspecialty in distinct patient recruitment windows. Additionally, multiple mini-teams from same sites can recruit patients across different subspecialties in same or distinct patient recruitment windows.

Outcomes: 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.

Dissemination: The results from this study will be disseminated by steering committee in the form of research publication(s), conference presentation(s), and other formats. All collaborators will be PubMed-citable authors according to the corporate authorship model on resulting publication(s).

SURGERY INTEREST GROUP

The Surgery Interest Group (SIG) at the Aga Khan University 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, organizing 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 not only caters to the surgically inclined students at the Aga Khan University but also to those beyond it as well 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 organization, 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 Surgery Interest Group at the Aga Khan University to promote national coordination in surgical research. Supported by the Department of Surgery and Center for Global Surgical Care at the Aga Khan University, this collaborative network aims to initiate multicenter research studies across Pakistan to enhance surgical research output which will lead to an improvement in surgical outcomes in Pakistan.

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-center experiences.[4,10-13] Prospective, standardized, 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 World Health Organization has published several recommendations with regards to SSI prevention.[8,14,15] While these recommendations are very elaborate, they are mostly based on data generated from high-income countries. Validity of these recommendations has not been explored greatly within the Pakistani setting.

SSIs are of significant epidemiological value and are largely preventable. However, there is a lack of high-quality national data to inform evidence-based strategies for SSI prevention. Such data can help prioritize resource utilization and identify modifiable and non-modifiable patient, surgical practice, 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.[8,15]

PakSurg 1 has been designed as a prospective, multi-center 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

- 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, multicenter, observational study on a national level with recruitment of centers throughout Pakistan to have a diverse yet holistic view of SSIs across the country.

From each center, one or more subspecialties from the shortlisted ones (Appendix – Included Procedures) can be selected for data collection. However, while recommended, it is not mandatory for centers 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 center. 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 center, 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.
- Same 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 September 1st, 2022, to March 31st, 2023 (with the last patient followed up till April 30th, 2023; Figure 1). This recruitment period will include patients undergoing specific surgeries for the included subspecialties as highlighted in Appendix – Included Procedures. Each registered 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.

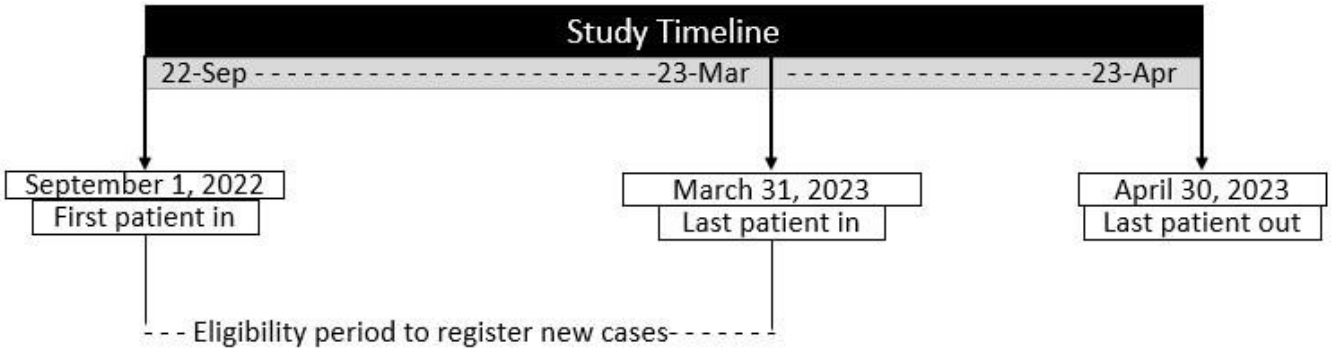

Figure 1. Study timeline for PakSurg 1.

Center Inclusion Criteria

- Hospitals performing elective surgeries.

Eligibility Criteria for Patients

Inclusion Criteria

- Adult patients (age ≥18 years).
- All consecutive patients undergoing elective surgery.
- The following surgical subspecialties will be included: Breast surgery, cardiac surgery, colorectal surgery, cranial surgery, general surgery, obstetrics & gynecology, orthopedics surgery, spine surgery, and vascular surgery (Appendix – Included Procedures).
- Only patients undergoing surgeries listed in the Appendix – 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 (superficial or deep) within 30 days of index surgery.

Secondary

- Organ-space infection within 30 days of index surgery.
- 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

Surgical site infection (superficial or deep): PakSurg 1 will use the 2008 Center for Disease Control definitions of SSI.[16] According to these, the patient should have **at least** one of the following to meet the criteria for SSI: ○ Purulent drainage from the superficial or deep (fascia or muscle) incision but not from within the organ/space component of the surgical site(s). ○ Deliberate opening or spontaneous dehiscence of incision along with at least one of: localized swelling; pain or tenderness; heat; redness; fever (≥100.4°F). ○ Abscess within the wound (detected clinically or radiologically).
Organ space infection: Intra-abdominal or pelvic infections detected clinically or symptomatically, radiologically, or intraoperatively.
Emergency procedures: Unplanned, non-elective procedures, including reoperations following previous procedures.
Postoperative mortality rate (POMR): Mortality till the 30th day of index surgery.
30-day unexpected reintervention: Operative, endoscopic, or radiological reintervention after skin closure till the 30th day postoperatively. Re-look surgeries planned at the time of original operation are not to be included in "unexpected" reinterventions.
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.
Inpatient: Refers to the hospital admission for the index surgery.
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 surgical site infections with a 95% confidence interval, 5% precision, and 20% inflation rate for loss-to-follow-up using the Sample Size Calculator by the World Health Organization.

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 & Subspecialty Surveys

Upon registration, each mini-team will complete the hospital and subspecialty surveys (Appendix – Hospital Questionnaire & Appendix – Subspecialty Questionnaire). These would explore hospital details and subspecialty patient and surgeon volumes.

Patient Questionnaire

Each mini-team will collect patient-level data using Appendix – 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, anesthesia, surgical wound class, and antimicrobial prophylaxis), postoperative details (intensive care unit stay, surgical site infections, reinterventions, other hospital-acquired infections, and mortality).

Follow-up & Outcome Assessment

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

1. Follow-up during the inpatient hospital stay

   Designated hospital staff should actively monitor each patient for signs of infection. This can be accomplished by:

   i) Liaising with ward staff and reviewing medical and nursing records regularly to identify signs and symptoms related to SSIs.

   ii) Reviewing microbiology reports for any positive surgical site cultures and checking with the ward why cultures were taken and if there were any signs of infection.

2. Detecting SSIs during hospital readmissions

   Collaborators should devise systems to identify patients included in the study that are subsequently readmitted to their hospital. The following measures should be taken to identify such patients:

i) Wards most likely to receive readmitted patients: Patient with SSI may not be readmitted that they were discharged from. Collaborators should identify wards that could accept such readmissions and contact them regularly to enquire about suspected SSI patients.
ii) Patient surveillance systems: Establish systems to alert collaborators if a patient included in this study is readmitted.
iii) Medical notes: Flagging medical records to prompt reporting of SSI-related readmissions to collaborators.
iv) Bed managers: Bed managers should be made aware of the surveillance and requested to inform collaborators about patients included in the study if they are readmitted.
v) Hospital records: Reviewing medical and nursing records regularly to identify signs and symptoms related to SSIs.
vi) Microbiology: Reports for any positive surgical site cultures and checking with the ward why cultures were taken and if there were any signs of infection.

3. Post-discharge outpatient clinic follow-up
   i) Patient surveillance systems should be established to alert collaborators if a patient included in this study visits for an outpatient follow-up.
   ii) Medical records of included patients should be flagged to prompt reporting of SSI-related outpatient clinics visits to collaborators.
   iii) Hospital records: Reviewing medical and nursing records regularly to identify signs and symptoms related to SSIs.
   iv) Microbiology: Reports for any positive surgical site cultures and checking with the ward why cultures were taken and if there were any signs of infection.

4. Post-discharge telephonic follow-up
   i) Patients included in this study should be contacted by collaborators telephonically at 3rd, 15th, and 30th day of surgery.
   ii) Telephonic interviews should be in accordance with the attached Appendix – Telephonic Follow-Up, which is based on the SSI surveillance protocol by the Public Health England (PHE).[17]

Please note that follow-up assessments for this study should be structured around already existing patient follow-up pathways in the collaborating centers. All collaborators will self-report methods used for obtaining follow-up data at their respective centers.

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 the Aga Khan University, 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 is 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 setup 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 & 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 referred by the local teams, provided that 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:

    a. Patient variables: Age and gender
    b. Operation variables: Indication and operative approach
    c. Outcome variables: 30-day mortality and unexpected reintervention

    Data extracted by validators will be compared to 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 as well as 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 (Chi-squared) 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 stratify cases by already known patient-level risk factors using the National Nosocomial Infections Surveillance (NNIS) risk index which is based on wound classification, duration of procedure, and American Society of Anesthesiologists (ASA) score.[19]

We will employ multivariable cox regression models to assess the influence of clinicodemographic variables on various outcomes for each surgical subspecialty. Pre-defined 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% confidence intervals will be presented. All statistical analyses will be two-sided, and p-value <0.05 will be considered threshold for statistical significance.

One of our secondary aims is to access the incidence of antibiotic-resistant SSI. For this, we will not be standardizing laboratory assessment, techniques or definitions used, since it is impractical over so many centers. Thus, this will be an exploratory analysis only with full appreciation of the limitations in this measure.

Lastly, sensitivity analysis will be performed to ascertain the robustness and credibility of our results. This will be performed using the following approaches:[20]

- *Taking into account 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 center), teaching status, and hospital volume.

Ethical Considerations

Local Approvals

PakSurg 1 will preserve the standard clinical care at the collaborating centers. No data will be presented with individual patient, surgeon, or hospital identifiers. Collaborating centers 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 (IRBs)/ ethics review committees (ERCs) (as observational research study or service evaluation).
- Few collaborating centers may not have these departments. In such cases, local investigators must receive a 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 (64th Assembly Fortaleza, Brazil, in October 2013), and according to locally applicable legislation.

Informed Consent

Participation in the research is strictly voluntary for patients. All patients who agree 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 would be assured that confidentiality would be maintained, and that they 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.

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 & 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 centers.

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 the Aga Khan University, Karachi.

Data Disposition

In accordance with the data retention policy of the Aga Khan University, all data will be kept electronically and in an external hard drive for a period of 7 years following completion of the study. After this period, the steering committee will permanently delete all data related to this study.

Appendices

- Appendix – Included Procedures
- Appendix – Hospital Survey
- Appendix – Subspecialty Questionnaire
- Appendix – Patient Questionnaire
- Appendix – Telephonic Follow-Up (English)
- Appendix – Telephonic Follow-Up (Urdu)
- Appendix – Consent Form (English)
- Appendix – Consent Form (Urdu)

Collaborators

Steering Committee

1. Planning and conceptualizing the study.
2. Site recruitment.
3. Coordinating with collaborators.
4. Managing finances and logistics.
5. Data management and analysis.
6. Writing and submitting manuscript(s) for publication.

Institutional Lead Collaborator

1. Coordinating teams in their centers by ensuring that no overlapping teams are collecting data from the same patients within the same time period.
2. Obtaining the necessary ethical approvals in their centers.
3. Inviting their colleagues to participate in the study and formulating additional data collection teams in their center.
4. Providing information about their center 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 centers.
3. Inviting their colleagues to participate in the study and formulating additional data collection teams in their center.
4. Providing information about their center'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 centers 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 on 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

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