Title:

Surgical site infection following abdominal operations: a prospective, multicenter cohort study across Nigeria

National Study Steering Committee

Name	Institution
Prof Adewale Adisa **wadisc@gmail.com**;	Obafemi Awolowo University Teaching Hospital, Ile-Ife
Dr Hyginus Ekwunife **hyginusekwunife@yahoo.com**;	Nnamdi Azikiwe University Teaching Hospital, Nnewi
Prof Adesoji Ademuyiwa **adesojiademuyiwa@yahoo.co.uk**;	Lagos University Teaching Hospital, Lagos
Prof Abdur Rahman Lukman **bolarjide@yahoo.com**;	University of Ilorin Teaching Hospital, Ilorin
Prof Lofty-John Anyanwu **loftyjohnc@yahoo.com**;	Aminu Kano Teaching Hospital, Kano

National Study Advisory Committee

Name	Institution
Prof Olusola Jeje	Lagos University Teaching Hospital, Lagos
Prof Stanley Anyanwu	Nnamdi Azikiwe University Teaching Hospital, Nnewi
Prof Alexander Nwofor	Nnamdi Azikiwe University Teaching Hospital, Nnewi
Prof Oluwole Atoyebi	Lagos University Teaching Hospital, Lagos
Prof Mohammed Aminu	Aminu Kano Teaching Hospital, Kano
Prof Venyir Ramyil	Jos University Teaching Hospital, Jos

Correspondence to:

Professor Adewale Adisa

Department of Surgery,

Obafemi Awolowo University Teaching Hospitals Complex

Ile-Ife 220005

Email: wadisc@gmail.com, ao.adisa@oauife.edu.ng;

Study Summary

Title: Surgical site infections following abdominal surgeries: a prospective, multicentre cohort study across Nigeria

Aim: To determine the national incidence of surgical site infections (SSI) following abdominal surgeries in adults and children operated in secondary and tertiary hospitals across Nigeria

Design: Prospective, multicentre observational study of all consecutive adults and children undergoing abdominal operations in all participating public and private secondary and tertiary hospitals across Nigeria

Participants: Children and adults undergoing surgery with abdominal incision of 3cm or more in children and 5cm or more in adults. All categories of wounds, including clean, clean-contaminated, contaminated or dirty wounds will be included. Participants undergoing emergency or elective, and open or laparoscopic surgeries are eligible.

Outcomes*:* The primary outcome is surgical site infection (SSI) 30 days post operation, defined according to Centre for Disease Control criteria.

Sample size**:** All consecutive cases that fulfil the inclusion criteria in all participating hospitals over a 3month period will be included

Introduction

Surgical site infection (SSI) is now the most common nosocomial infection and constitute a global burden occurring in different countries across all human development indices [1]. When SSI occurs, it is associated with increased morbidity, healthcare cost and mortality [2]. This is why several interventions to reduce SSI are recommended particularly in low resource settings. It has been estimated that when appropriate evidence-based strategies are employed, up to half of SSIs may be preventable [3]. In low-, and middle-income countries (LMICs) such as Nigeria, studies have shown that a disproportionately greater burden of SSI and higher rates of antibiotic resistance may be present [4]. Conversely, interventions to reduce SSIs are usually developed in high-income settings limiting their adoption in LMICs. Recent efforts spearheaded by the GlobalSurg Collaborative has initiated testing of some of these interventions in LMICs raising awareness among surgeons to improved surveillance for SSIs as well as adoption of preventive measures [5.6].

There are several reports on the incidence of SSI in Nigeria [7-10]. Majority of these studies are retrospective, single center studies that involved a small number of patients. The demerits of such retrospective studies where SSI was not actively surveyed equally limited the result of a meta-analysis carried out on those studies [7]. With these limitations, findings from those previous studies cannot be generalised for national planning. This study is therefore proposed as a prospective, multi-center observational study across Nigeria to observe the incidence of SSI following abdominal operations.

Justification

This study will provide a baseline incidence of surgical site infection following abdominal surgeries across Nigeria in a prospective multicenter study that would avoid the inherent defects of previous studies thereby providing data that is generalizable and useful for planning nationwide interventions through the health supervisory and policy making frameworks.

The rate of use of microbiology for diagnosis of SSI following abdominal surgeries has not been reported on a national scale. This study will collect information on the use of microbiology laboratory services in the diagnosis and treatment of SSI and provide information on the bacteriology of such infections across the country.

Aim and Objectives

Aim

To determine the incidence of surgical site infections following abdominal operations in adults and children across Nigeria

Primary objective

To determine the incidence of postoperative surgical site infections in patients undergoing abdominal operations across Nigeria in a prospective, multicenter study

Secondary objectives

1. To determine the CDC classifications of SSI in specific procedures across Nigerian hospitals
2. To determine the influence of SSI on postoperative length of stay
3. To determine the association (if any), of SSI with postoperative mortality
4. To determine the profile of bacteria culture from wound swabs from abdominal SSIs across Nigeria

Eligibility Criteria

Inclusion Criteria

1. Patient able and willing to provide written informed consent (signature or a fingerprint) or assent from parent or guardian.
2. All children and adult patients undergoing emergency or elective abdominal operations
3. Benign, malignant and trauma cases can all be included.
4. Abdominal incision with an anticipated clean-contaminated, contaminated or dirty surgical wound.
5. Anticipated abdominal incision of 3cm in children or 5cm or more in adults
6. Both open surgery and laparoscopic surgery can be included.

7. All hospitals, secondary, tertiary, public and privately funded, that performs abdominal surgeries will be eligible.

Exclusion Criteria

1. Abdominal operations with clean surgical wound, such as simple hernia repair
2. Patients undergoing caesarean section will be excluded.
3. Patients who are unable to complete follow-up at post-operative day 30
4. Patient already enrolled in another trial assessing surgical site infection.

Primary Outcome

Surgical site infection will be assessed up to 30 days after the abdominal operation. SSI will be defined according to the Centre for Disease Control (CDC) criteria (11). The following CDC definition will be used to identify deep incisional or superficial incisional SSIs:

- The infection must occur within 30-days of the index operation
- The infection must involve the skin, subcutaneous, muscular or fascial layers of the incision
- The patient must have at least one of the following:
    - Purulent drainage from the wound
    - Organisms are detected from a wound swab
    - Wound opened spontaneously or by a clinician AND, at the surgical wound, the patient has at least one of: pain or tenderness; localised swelling; redness; heat; systemic fever (>38°C).
    - Diagnosis of SSI by a clinician or on imaging

Secondary outcomes

- Profile of organisms detected from wound swab
- Patient-reported time taken to return to normal activities
- Patient-reported time taken to return to work.
- Mortality at day 30 after operation and its relationship to SSIs

Ethical considerations

Ethical approval for the study will be sought from the National Health Research Ethics Committee to cover the multiple centers that will participate in this study. Individual hospital leads will be responsible for obtaining the institutional ethical approval from the local hospital ethical committee. Approval will cover the access to patients records as well as the day 30 follow-up to which all the participating patients will be required to give a written consent for adults or assent from parents or guardians for the children. Patient information sheets (PIS, Appendix I) will be made available to patients and this would be explained in the local language to those who cannot read English on their own. Those consenting will be required to either append signature or a thumb print. For children, assent for the study will be obtained from the parents or legal guardian. All patients will be consented for their abdominal operations as per local hospital protocol.

Procedure

The site principal investigator and members of the local surgical team will identify patients who fulfill the inclusion criteria. This will be either from the clinic for elective cases or emergency room for trauma and other emergency cases. A subject information sheet will be provided for the patient in English or the native language best understood by them. The patients that have given consent for the proposed operations will then be required to provide written consent for inclusion in this study. Operations, intraoperative and postoperative care will be carried out according to the local protocol as no intervention is required for this study, On the day of operation, details of the procedure will be recorded. Surveillance for SSI during wound inspection and dressing will be required and occurrence of SSI documented. When purulent discharge is encountered, wound swab for local microbiological diagnosis will be encouraged. The profile of organisms as well as the sensitivity and resistance to them will be documented. Documentations of occurrence of SSI, other morbidities and mortalities will be done at discharge and at a day 30 follow up visit. An in-person inspection of the wound on day 30 will be preferred. Where this is not possible, a telephone follow-up may be accepted.

Data handling

Patient's deidentified data will be recorded in the case report form (Appendix II) from the preoperative, intraoperative and postoperative periods terminating in the 30-day follow-up

events. The data will be uploaded to a dedicated RedCap page by the site principal investigator who will stand as guarantor for the privacy and integrity of the data.

All submitted data will be reviewed centrally by the trial steering committee and the national data management team in the NIHR Nigeria Hub in the College of Medicine, University of Lagos handling the RedCap for this study. Every attempt will be made to collect 30-day follow-up data on all study participants as this will influence the primary outcome of this observation. The team will contact the local site principal investigator for any inaccurate or missing data for corrections and completion. All completed records will be included in the final analysis while validated records that remains incomplete will be included in patients records but excluded from outcome analysis.

Statistical consideration

No individual, patient, or surgeon specific analyses will be performed. Operative procedures will be classified according to wound types for sub-analyses Hierarchical logistic regression multivariate analysis to determine the influence of patient characteristics, disease type, operative procedure and wound class on SSI rates will be performed.

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