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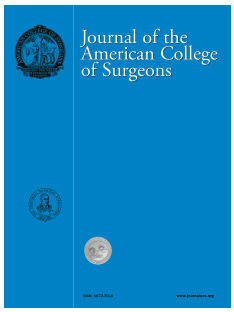

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Developing Process Maps as a Tool for a Surgical Infection Prevention Quality Improvement Initiative in Resource-Constrained Settings

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Running Head: Infection Prevention and Process Mapping

Abstract

Background: Surgical infections cause substantial morbidity and mortality in low-and middle-income countries (LMICs). To improve adherence to critical perioperative infection prevention standards, we developed Clean Cut, a checklist-based quality improvement program to improve compliance with best practices. We hypothesized that process mapping infection prevention activities can help clinicians identify strategies for improving surgical safety.

Study Design: We introduced Clean Cut at a tertiary hospital in Ethiopia. Infection prevention standards included skin antisepsis, ensuring a sterile field, instrument decontamination/sterilization, prophylactic antibiotic administration, routine swab/gauze counting, and use of a surgical safety checklist. Processes were mapped by a visiting surgical fellow and local operating theater staff to facilitate the development of contextually-relevant solutions; processes were re-assessed for improvements.

Results: Process mapping helped identify barriers to using alcohol-based hand solution due to skin irritation, inconsistent administration of prophylactic antibiotics due to variable delivery outside of the operating theater, inefficiencies in assuring sterility of surgical instruments through lack of confirmatory measures, and occurrences of retained surgical items through inappropriate guidelines, staffing, and training in proper routine gauze counting. Compliance with most processes improved significantly following organizational changes to align tasks with specific process goals.

Conclusion: Enumerating the steps involved in surgical infection prevention using a process mapping technique helped identify opportunities for improving adherence and plotting contextually relevant solutions, resulting in superior compliance with antiseptic standards.

Simplifying these process maps into an adaptable tool could be a powerful strategy for improving safe surgery delivery in LMICs.

Keywords: surgical safety; process mapping; quality improvement; guideline implementation; infection prevention; low- and middle-income countries (LMICs)

Abbreviations: low- and middle-income countries (LMICs), surgical safety checklist (SSC), Saving Lives Through Safe Surgery (SaLTS)

Introduction

Health systems able to provide safe surgical care are urgently needed in low-and middle-income countries (LMICs) in order to deliver the estimated 140 million additional operations required annually to meet health needs [1]–[3]. Addressing the global surgical disease burden is a public health imperative; mortality due to surgically treatable disease now outweighs that due to malaria, human immunodeficiency virus (HIV) and tuberculosis, combined[4]. As complications resulting from surgery are a huge added risk[3], ensuring surgical safety is crucial given both the need and projected increase of surgical volume in LMICs.

Surgical site infections (SSI) are the leading cause of post-operative morbidity and the most common source of all hospital acquired infections[5]. The burden of SSI disproportionately affects LMICs as estimated rates of SSI are at least twice that of high-resource countries[5]–[9]. Addressing and improving adherence to surgical standards represent modifiable factors that can prevent the development of SSI. Guidelines exist for reduction of SSI[10]–[14], but tools to aid in their implementation and compliance are notably lacking. Simple and effective methods for implementing best practices for infection prevention are needed for surgery, especially in resource-constrained settings.

The goal of this study was to evaluate and improve compliance with perioperative infection prevention standards embedded in the World Health Organization (WHO) Surgical Safety Checklist (SSC). We aimed to improve compliance by identifying barriers in the care process through institution-specific, visual process maps combined with quantifiably observable adherence data. Together with local stakeholders, we hypothesized that data feedback coupled with a process mapping exercise would allow local teams to generate contextually-relevant solutions. After local solution implementation, we continued to evaluate and monitor compliance

and outcomes in order to demonstrate improvement. Herein we describe the process mapping portion of our surgical infection prevention quality improvement program in Ethiopia and resulting changes.

Methods

Setting

We conducted a prospective, pre/post intervention study[15]–[17] observing adherence to critical perioperative infection prevention standards at Jimma University Specialized Hospital (JUSH), a 523 bed tertiary teaching hospital in Jimma, Ethiopia. JUSH is the primary referral hospital for 15 million people in southwestern Ethiopia. JUSH performs approximately 1,800 cesarean deliveries a year, along with 3,000 elective non-obstetric operations, another 3,000 emergency operations, and 300 minor procedures. At the time of the study, the hospital had 3 main, 1 pediatric, 1 ophthalmic and 2 separate obstetric operating theaters (OT). During this time, the Ethiopian Federal Ministry of Health launched a nationwide program Saving Lives Through Safe Surgery (SaLTS) to improve equitable access to safe and quality surgical and anesthetic care[18]–[20], including promoting use of the SSC. Thus, the timing was opportune for such work.

Strategy

Clean Cut was developed as a quality improvement program designed to facilitate data collection, process mapping, root cause analysis and identification of interventions to improve adherence with infection prevention standards embedded in the WHO SSC. The Clean Cut infection prevention standards targeted for improvement include: (i) hand & surgical site skin antisepsis; (ii) maintenance of the sterile field by ensuring integrity and sterility of gowns,

drapes, and gloves; (iii) appropriate instrument decontamination & sterilization; (iv) appropriate timing of prophylactic antibiotic administration; (v) routine surgical gauze/swab counting; and (vi) use of surgical safety checklist [Table 1]. Overall appropriate surgeon hand decontamination was defined as the application of alcohol-based solution to hands prior to gowning, regardless of prior scrubbing as soap and water was inconsistently available. Breaks in maintaining a sterile field were defined as holes and/or tears in the gowns/drapes or wet gowns/drape packages.

These standards were chosen based on the pilot results of the SSC demonstrating dramatic improvements in post-operative infectious complications [21]. We focused our Clean Cut program on evidenced-based infection prevention practices embedded in the checklist, including proper antibiotic prophylaxis, ensuring instrument sterility, and preventing retained surgical items through routine gauze/swab counts. As the Checklist is a communication tool with benefits not merely limited to post-operative outcomes, we also focused on the appropriate use of the checklist itself. Lastly, we emphasized common surgical practices inherent to asepsis and safety including appropriate skin decontamination and maintaining a sterile field, as these have been noted to be frequently overlooked in the most resource-limited settings but were seen as too fundamental to be included in the original checklist. Together, these six infection prevention standards became the focus of Clean Cut. While many potential opportunities exist, such as those outlined in the WHO Guidelines for Prevention of Surgical Site Infections[10], these six are common, feasible, and realistic areas to improve compliance, regardless of the operating room resources.

The program follows a typical plan-do-study-act (PDSA) cycle by which the locally-driven interventions were identified and implemented and process adherence continually re-assessed for improvements. To achieve these goals, Clean Cut used three sequential steps:

i) Team building through the introduction and local modification of the SSC with clinical stakeholders (administration, surgeons, anesthesia providers, operating theater nursing);

ii) Baseline assessments of 1) compliance with perioperative infection prevention standards coupled with a process mapping exercise, and 2) patient outcomes using trained data collectors

iii) Process improvement through a locally-led feedback cycle including stakeholder meetings to review compliance to infection prevention standards and patient outcomes, brainstorming of solutions, prioritization of interventions, and ongoing surveillance to assess improvements

Data Collection

Observed perioperative practices were recorded on a previously validated, standardized paper data form [22] by data collectors (three operating theater nurses and one nurse anesthetist) who were trained by a visiting surgical fellow (JAF). We included all patients undergoing surgical intervention in the main and obstetric OT regardless of age, gender, or diagnosis. Data collectors were assigned to the OT a minimum of five days a week, with a rotating schedule to ensure capture of emergency and nighttime operations. Patient outcomes were also followed for the duration of the study but are not discussed here. Qualitative information was recorded using field notes from informal interviews during the process mapping and intervention phase. Jottings

were taken by the visiting fellow and transcribed into brief descriptive notes within one day of initial capture. The field notes were generally from meetings and interactions at the facility which were instructive as to why and how particular interventions were successful or not. The field notes approach was chosen given its contextual relevance and accessibility in obtaining perspectives from front line workers of how processes failed, problems with compliance, and potential solutions; formal recorded interviews were not considered contextually appropriate given the culture and relationships that had developed.

Process Mapping

Process mapping is a technique adapted from business literature[23] to visually diagram activities, tasks, and decisions within a work flow in order to understand and subsequently improve the overall process[24]. For surgical processes, the process maps depict the particular steps, the responsible person, the location of activity, and the overall interaction within the surgical system. We created process maps for each of the six perioperative infection prevention standards in conjunction with local stakeholders. At our pilot site, process map generation included a visiting surgical fellow (JAF) leading a "walk around" with a hospital team leader utilizing direct work observation and short interviews with personnel directly responsible for a particular step. The maps were initially created with paper and sticky notes and subsequently transferred to Microsoft PowerPoint (Microsoft, 2013, Redmond, Washington, USA). The preliminary maps were then corrected through hospital team feedback until baseline process maps were generated (corresponding to the end of the baseline data collection period).

The JUSH-specific process maps were modified further after observing and performing "walk arounds" at four other Ethiopian tertiary referral hospitals by a visiting surgical fellow (JAF). Site-specific nuances were removed from the process maps, streamlining the tool to serve

as a modifiable template for ongoing programmatic work [Figures 1-6]. Questions generated from the development of initial process maps are included in eDocument 1.

Data Analysis, Feedback and Implementation

Quantitative adherence to the Clean Cut perioperative infection prevention standards was compiled over the baseline period (6 weeks). The degree of adherence and visual process map for each infection prevention standard were delivered to the local stakeholders through individual and focus group meetings. Pre-intervention process maps were analyzed using a combination of observation, root cause analysis and gap analysis[25] to identify barriers and areas of improvement. Barriers to compliance were identified systematically commencing from start position on each process map and following the map until completion of the activity. Barriers were categorized by type of limitation: resources, training, and personnel management. Local stakeholders and team members participated in a group brainstorming activity to generate solutions to identified barriers in compliance through discussion of both the quantitative findings as well as observations during process mapping. Proposed process improvements were rank-ordered by the group as relatively easier to accomplish versus those which would require more time and resources.

Direct consent from patients was not required as the intervention is a quality improvement strategy that does not introduce new clinical methods or involve any direct risk to patients. The study was approved by the institutional review boards at Stanford University and the College of Health Sciences at Jimma University. A chi-squared test was used to compare pre and post-intervention adherence to all infection prevention standards with $p<0.05$ considered significant. Microsoft Excel (Microsoft, 2013, Redmond, Washington, USA) was used for all statistical analysis.

Results

From August 2016 to March 2017 we directly observed 137 operations during the baseline assessment period (89.7% from the main OT) and 302 operations post-intervention (72.8% from the main OT). Low rates of compliance in all six infection prevention standards were observed during the baseline assessment period [Table 2]. Specific quantitative data, barriers to compliance identified through process mapping, and contextually-relevant solutions follow, organized by Clean Cut infection prevention standards [Table 3]. Rank ordering of the proposed interventions into an overall strategy can be found in Table 4.

Standard 1: Hand & Surgical Site Decontamination

Process mapping revealed issues with resources and policies. Resource limitations included unreliable running water, plain soap as the only option for hand scrub, and unavailability of alcohol-based hand gel which resulted in inconsistent hand decontamination. Proposed reasons for the inconsistency included the caustic nature of the available alcohol solution and the lack of hospital-specific policies and standards. After careful review of the available literature[26]–[28], the group consensus decision was to recommend the use of alcohol-based solution, allowing it to dry completely on the skin, regardless of whether or not plain soap and water was used to scrub. The recommendations were disseminated in a group session to the surgeons, obstetricians, and trainees. Afterwards, significant improvements to the defined hand decontamination standard were observed (24.1% vs 67.6%, $p<0.0001$).

Standard 2: Integrity & Sterility of Gowns, Drapes and Gloves

During the baseline assessment, there was low overall compliance with visual confirmation of a sterile indicator inside the gown and drape pack (7.3%). Of the thirteen

identified violations in sterile gowning and draping, only one resulted in a replacement of the gown or drapes. New, sterile surgical gloves were always used. Local stakeholders concluded that while potentially not directly impacting SSI risk, the lack of adequate gowns and drapes relative to surgical volume and the lack of a machine dryer decreased the ability to offer elective surgical cases, especially during the rainy season. Incorporating machine washers and dryers into a new facility under construction was a large focus. Post interventions, significant improvements were observed in the use of sterile indicators in the sterilized linens (3.7% vs 87.1%, $p<0.0001$) and a decreased number of holes or tears in gowns and drapes (2.9% vs 1.2%, $p=0.017872$). There was a slight increase in the number of observed wet gown and drapes, all in the obstetric OT (Main OT 3.3% vs 0.9%, $p=0.112426$; Obstetric OT 7.1% vs 18.5%, $p=0.293627$). Post-intervention, only one of 24 identified violations in the sterile field (wet gown/drapes n=17, holes in gown n=6, holes in drape n=1) resulted in replacing the gown or drape.

Standard 3: Instrument Decontamination & Sterilization

Initially there was low overall compliance with visual confirmation of a sterile indicator inside the instrument tray (Main OT 70.7%, Obstetric OT 14.3%). During baseline, 3 instrument trays had water condensation, 2 of which occurred in the obstetric OT. Four trays failed sterility compliance by quantitative measurements; none were exchanged for a new set. Process mapping revealed barriers in available resources, existing training, and personnel management.

The team identified the inclusion of a sterile indicator in all instrument trays as an early improvement focus. A locally modified internal indicator was developed from a piece of class I chemical sterile tape placed on a small piece of cardboard (the gold standard class V indicators [29] were unavailable). To improve accountability, the person responsible for instrument set packing initialed and dated the modified internal indicator. Addressing wet instruments required

more complex local solutions involving both education and rerouting hospital processes. The majority of wet instruments occurred in the obstetric OT, which used a separate table top autoclave which was found to be non-functional. Solutions included improved communication with biomedical engineering (BME) to repair autoclaves when malfunctioning, rerouting all instrument sterilization to the main central sterilization room (CSR) and updated training on the need for the scrub nurse to evaluate for water condensation and, if present, to procure a new instrument set. Additional local solutions included development of a logbook to accurately record responsible person, number of items, and cycle run time for the autoclaves. Procurement of a small amount of class V chemical sterile indicators helped confirm acceptable autoclave function, as some autoclaves' physical indicators such as the temperature gauge did not function.

Improving the autoclave function proved to be a challenging long-term issue. The lack of distilled/deionized water caused considerable corrosion and mineral buildup on the autoclave, leading to frequent malfunction. Following discussions with the local surgical team, hospital administration procured a water distillation machine. After interventions, significant improvements were observed with visual confirmation of a sterile indicator inside the instrument tray (65.0% vs 98.0%, $p<0.0001$). However, the use of wet instruments also increased significantly (2.2% vs 9.9%, $p=0.004$) with all violations occurring in the obstetric OT. Despite the intervention, no instrument trays were exchanged if sterility was unconfirmed.

Standard 4: Prophylactic Antibiotic Administration

Process mapping identified issues in antibiotic selection and proper timing of administration. Ceftriaxone was the antibiotic of choice for the main OT, regardless of intervention, and was administered by the designated ward surgical intern in the hallway outside of the main OT. Ampicillin was the antibiotic of choice for cesarean sections in the obstetric OT,

administered by the designated intern in the labor ward prior to the surgical procedure. Local stakeholders recognized the inefficiency of antibiotic administration outside of the operating theater, frequently well outside the recommended timing for prophylaxis. For the main OT, responsibility for antibiotic administration was changed to either the anesthetist or surgical resident with timing to occur in the OT prior to anesthesia induction. In the obstetric OT, the timing of antibiotic administration was less problematic as patients received it once the room was clean and ready for the operation.

Within obstetrics, historical hospital data demonstrated an 11.4% SSI rate after cesarean section[30]; our early findings noted a 14% SSI rate along with high rates of endometritis [16]. Furthermore, hospital data demonstrated high antimicrobial resistance to ampicillin[31]. Hospital-specific data in combination with international guidelines and literature review [32]–[34] informed a change in hospital policy to ceftriaxone before cesarean section. Post-intervention, there was a significant improvement in the timing of antibiotic administration (administration of antibiotics inside the OT: 12.4% vs 23.8%, p=0.003038).

Standard 5: Surgical Gauze/Swab Counting

Surgical gauze counting was noted to be inconsistent; in fact, two cases of retained gauze were noted to have occurred in the obstetric OT after cesarean section, though not directly captured in our observational assessment sample. A root cause analysis of the retained gauze found staffing issues and lack of appropriate training. Hospital-led solutions included mandating an additional staff member for all cesarean sections assigned to neonatal resuscitation allowing the circulating nurse to complete a surgical gauze/swab count with the scrub nurse. Although inconsistently utilized, a designated bucket for collecting used gauze was introduced to ensure correct counts. To help ensure accountability and improve future training, a document outlining

the nurses' roles and responsibilities was developed for the hospital. Post-intervention, significant improvements were observed in counting surgical gauze/swabs before incision (51.1% vs 90.1%, p<0.0001) and after closure (45.3% vs 83.1%, p<0.0001); combined pre and post counting improved from 38.7% to 82.8%, p<0.0001.

Standard 6: Use of Surgical Safety Checklist

The WHO Surgical Safety Checklist was introduced to surgical staff over a two-day period in September 2015 by a member of the research team (TGW). During the baseline period, surgical staff utilized a paper photocopy of the original WHO Surgical Safety Checklist, which was difficult to read and lacked appropriate modification to the hospital setting. Observations noted a focus on performing a team "time out" (pause before skin incision), with less emphasis on performing the "sign-in" (pause point prior to anesthesia induction) and "sign-out" (pause point prior to the patient leaving the OT after the operation). The paper checklist was filled out and placed into the patient's chart by the circulating nurse, but inconsistently read aloud. A modified hospital checklist was developed including further details on how instrument sterility is confirmed (no wet instruments, internal sterile indicator changed), the actual timing of antibiotic prophylaxis administration, spaces for surgical item count reconciliation, and facility-specific operating room flow changes. A subsequent refresher course for surgical staff was held after the baseline assessment to emphasize the importance of verbal communication and provide group practice. A significant improvement was observed in announcing the planned operation (63.5% vs 79.5%, p=000377).

Discussion

Ensuring surgical safety in resource-constrained settings requires aligning available resources with pertinent training through an effective management infrastructure. At a tertiary hospital in Ethiopia, we combined hospital-specific visual process maps with objective observable adherence data in order to identify barriers in compliance to infection prevention standards. This process allowed local stakeholders to generate contextually-relevant solutions and subsequent prioritization of interventions. Through implementation of these interventions and ongoing surveillance to compliance, all six infection prevention standards improved markedly.

Many guidelines detail evidenced-based practices that should be followed in order to reduce the risk of infections after surgery[10]–[14]. The WHO published a synthesis of available evidence for preventing SSI with twenty-six core recommendations[10]. Likewise, the Centers for Disease Control and Prevention (CDC) published a similar guideline including 14 categories resulting in 39 recommendations for reducing SSI risk[11]. While thorough in methodology, these guidelines lack implementation strategies to translate evidence-based infection prevention practices into human behavior change. Additionally, many of the proposed guidelines focus on data driven research that ignore some of the simpler elements of decontamination and sterilization. Others may be beyond the capacity of many low-resource settings, such as maintaining normothermia[10]. Notably some guidelines, like high fraction of inspired oxygen and tight glucose control, could be dangerous to patients given existing OT infrastructure and practices. In resource-constrained settings, we believe that process maps in the context of a larger overall quality improvement initiative can be a sound and effective method for implementing best practices for surgical infection prevention.

We developed our infection prevention program around the WHO Surgical Safety Checklist, an internationally accepted surgical safety standard proven to decrease surgical infections when correctly implemented[21]. The checklist consists of nineteen perioperative communication steps, of which three are crucial to sterile surgery: appropriate antibiotic prophylaxis, ensuring sterile instrument usage, and decreasing retained surgical items through standardized gauze and instrument counts. Each step is a simple binary confirmation; however, it underscores a complex process required to deliver the end result. The checklist is often difficult to implement, particularly in low-resource settings where these complex processes may be lacking[20], [35], [36]. We utilized visual process mapping to identify gaps in existing processes in order to improve the delivery of aseptic surgery and compliance with and use of the SSC. In coupling this work with directly observable practice habits, we were able to generate a robust tool for local stakeholders to understand current practices, identify barriers in processes, and develop contextually-relevant solutions to improve compliance with these best practices. Demonstrating success at one hospital is important; however, institution-specific process maps are not readily accessible for adaptation to other surgical sites. We therefore used the process maps as a guide for walk-arounds at four tertiary level hospitals in Ethiopia, which allowed us to modify and streamline the maps into a more generic, widely applicable tool for identifying issues in the existing hospital system for infection prevention.

Process mapping is a promising tool for improving compliance with best practices and understanding the various components that affect care during any patient encounter [24]. It has been used in conjunction with lean organizational theory, particularly with respect to production and assembly in mechanized industry[37]. Successful interventions using this technique have been described in diverse but highly complex health encounters such as emergency room visits

[38] and cancer treatment [39]. In an interventional study in Colombia, process mapping and compliance improvement resulted in a marked reduction in infections following cesarean section [40]. Ultimately, success of such an intervention relies on strong management practices, a structured framework for improvement, and clear targets and objectives [41], [42].

Limitations

While the process maps were generated specific to a tertiary hospital in the southwest of Ethiopia and thus may be of limited generalizability, we attempted to improve its generalizability by refining them at four other tertiary referral centers in the country. Despite the Ethiopia focus, the maps highlight basic needs and requirements for offering sterile and safe surgery, wherever it is performed. Therefore, we believe these maps can serve as a useful quality improvement tool in many LMICs with similar breakdowns in infection prevention processes.

While discrete, observable adherence measures were used to provide quantitative data to the visual process maps, such data are not indicative of a functioning system. For example, assessment of location for prophylactic antibiotic administration is not equivalent to determining if the drug was given within the recommended 1 hour before skin incision[13]. However, they provide an operational and measurable assessment of proper antibiotic timing as the gold standard is administration just before induction of anesthesia.

As with any intervention focused on human behavior change, ongoing engagement and participation by local stakeholders are essential for sustained improvement. At our pilot site, a move to a newly-built hospital coinciding with social unrest and management turnover resulted in an inability to offer elective surgical services and a collapse in adherence to these standards.

Existing management infrastructure and commitment to quality improvement are necessary to deliver on the goals of the Clean Cut program.

Additionally, while improvement in adherence to infection prevention standards was demonstrated, the lack of clinical outcome data can limit the direct interpretation and impact. We are compiling outcomes data at several other hospital sites to provide a stronger evidenced-based argument for this surgical quality improvement initiative. Likewise, the long-term sustainability impact has yet to be assessed.

Conclusions

Process mapping the steps involved in surgical infection prevention helped identify strategies for improving adherence to international standards. Coupling the detailed, visual process maps with operational, measurable, and observable data helped local teams plan for and prioritize contextually-relevant solutions. Implementing these site-specific interventions resulted in higher compliance with antiseptic standards. Streamlining and simplifying these process maps into an adaptable tool could be a powerful means for improving safe surgery delivery in LMICs.

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Table 1. Observable Measurements to Clean Cut Infection Prevention Standards

Infection prevention standard	**Quantitative measure**
Hand and surgical site decontamination	
Surgeon hands	Enters the operating theater with wet hands, in sterile fashion; if alcohol solution used on hands prior to gowning; materials available for hand washing
Surgical site	Material used for patient skin preparation
Integrity and sterility of gowns, drapes, and gloves	
Gown/drape	Visual assessment of holes, tears, or violations of sterile field
Glove	Use of new sterile gloves
Instrument decontamination and sterilization	Visual confirmation of color change from sterile indicator inside all instrument trays and gown/drape packs used in surgery; confirmation of no wet instruments or gown/drape packs (“wet packs”) used in surgery
Prophylactic antibiotic administration	Confirmation of time and location of antibiotic administration; type of antibiotic(s); if the patient is on scheduled antibiotics
Surgical gauze/swab counting	Visual confirmation of gauze counts (pre- and postoperative); number of gauze per count
Use of the surgical safety checklist	Announcement of operation before skin incision; introduction of all team members; announcement of estimated blood loss

Table 2. Adherence to Infection Prevention Standards at Jimma University Specialized Hospital

Infection prevention standard, specific measurement	**All OT**			
	Baseline, % (n=137)	**Post-intervention, % (n=302)**	**% change**	**p Value**
Hand and surgical site decontamination				
Appropriate surgeon hand decontamination	24.1	67.6	+180.4	<0.0001
Integrity and sterility of gowns, drapes, and gloves				
Sterile indicator inside gown/drape pack	7.3	87.1	+1,093.1	<0.0001
Wet gowns/drapes usage	3.7	5.6	+54.2	0.378431
Instrument decontamination and sterilization				
Sterile indicator inside instrument tray	65.0	98.0	+50.9	<0.0001
Wet instruments after sterilization	2.2	9.9	+353.6	0.004354
Prophylactic antibiotic administration				
Unknown time of administration	69.3	63.9	-7.8	0.266613
Administered in OT	12.4	23.8	+92.1	0.003038
Surgical gauze/swab counting				
Before incision	51.1	90.1	+76.3	<0.0001
After closure	45.3	83.1	+83.7	<0.0001
Use of the surgical safety checklist				
Operation announcement before incision	63.5	79.5	+25.1	0.000377
Introduction of all team members	21.9	30.1	+37.6	0.073599
Estimated blood loss announcement	90.5	92.7	+2.4	0.429516

OT, operating theater.

Table 3. Barriers and Corresponding Contextually-Relevant Improvements at Jimma University Specialized Hospital

Infection prevention standard	**Barrier identified**	**Process improvement**
Hand and surgical site decontamination		
Resource	Only plain soap available for hand washing; no running water in maternity OT; unreliable supply of povidone	
Training	No training established for proper hand or surgical site preparation; ineffective use of alcohol-based preparation	Group based education program on proper use of alcohol-based preparation
Personnel management	No hospital protocol for proper hand preparation	Education and development of hospital standard for hand preparation
Integrity and sterility of gowns, drapes, and gloves		
Resource	Inadequate supply given to surgical volume; inconsistent power supply for hospital machines (new hospital)	Procurement of additional gowns/drapes relative to surgical volume; laundry moved to new hospital (machine wash/dry)
Training	Use of wet gowns/drapes or those with holes/tears	Group education on sterile gown use
Instrument decontamination and sterilization		
Resource	Unavailable proper chemical sterile indicators; non-functional autoclave in maternity; no distilled water; lack of appropriate enzymatic detergent; lack of running water in obstetrics; insufficient number of obstetric trays	Hospital purchase of appropriate autoclave with attached water distiller; local solution: indicator tape with responsible person inside tray/pack
Training	Frequent nursing turnover with inadequate onboarding; improper brushing and decontamination methods; use of corrosive bleach	Standardization of decontamination and packing
Personal management	No protocols for appropriate autoclave use; no protocols for confirmation of autoclave function; no protocol for	Assignment of roles and responsibilities for CSR; rerouting maternity sterilization to main CSR;

	addressing “wet packs”; inadequate communication between CSR and administration; poor overall communication with BME; different protocols based on OT location	posting of proper communication for BME
Prophylactic antibiotic administration		
Training	Ineffective antibiotic prophylaxis selection for cesarean section	Broadening of antibiotic prophylaxis for cesarean sections
Personnel management	>90% of antibiotics administered outside main OT; no designated personnel for antibiotic administration	Rerouting of antibiotic delivery to inside main OT
Surgical gauze/swab counting		
Training	Unclear roles and responsibilities for OT nurses; lack of hospital protocol for standardized counts	Development of hospital protocol for OT nurse responsibility
Personnel management	Inappropriate nurse staffing for cesarean section; retained gauze in maternity OT after cesarean section	Addition of midwife/nurse for neonate resuscitation in maternity OT
Use of the SSC		
Resource	No local adaptation of WHO SSC	Creation of hospital-specific SSC
Training	Inconsistent usage between various surgical specialties	Checklist refresher course to improve effective use

BME, biomedical engineering; CSR, central sterilization room; OT, operating theater; SSC, surgical safety checklist.

Table 4. Organized Jimma University Specialized Hospital Game Plan

Organization, initiative	**Proposed quality improvement focus**
Easy win	Indicator tape with responsible person inside tray/pack; modification of surgical safety checklist to local environment; group education session on skin decontamination and maintenance of sterile field
Medium win	Development of hospital protocol: skin decontamination; instrument decontamination, packing, and sterilization; checklist refresher course to improve effective use; improving antibiotic prophylaxis timing and selection: rerouting of antibiotic delivery to inside main OT; broadening of antibiotic prophylaxis for cesarean sections
Long-term win	Confirmation of sterilization: procurement of chemical and biologic indicators; hospital purchase of appropriate autoclave with attached water distiller; procurement of additional gowns/drapes relative to surgical volume; laundry moved to new hospital (machine wash/dry)
Additional initiative	Addition of midwife/nurse for neonate resuscitation in maternity OT; development of hospital protocol for OT nurse responsibility

OT, operating theater.

Figure Legends

Figure 1. Hand and surgical site skin antisepsis process map. The map is to be read from the top left starting with the light blue oval proceeding to the bottom right with the red box. Diamond shapes represent a decision, a rectangle represents a process, and a rectangle with 2 vertical bars represents a predefined process, i.e. a process with multiple steps. The red text "Study Measurement" indicates the recorded decisions by data collectors. The question "What is the primary reason" is a qualitative question to assess barriers. The blue rectangle including "Process?" is assessing what is the institution-specific process. Italicized text underneath a symbol indicates the person performing the process. A symbol shaded in green denotes a step requiring electrical power. Top half of map corresponds to surgeon hand decontamination with the bottom half corresponding to patient surgical site decontamination. OT, operating theater. (Reprinted from Lifebox Foundation, with permission.)

Figure 2. Integrity and sterility gowns and drapes process map. The map is to be read from the top left starting with the light blue oval proceeding to the bottom right with the red box. Diamond shapes represent a decision, a rectangle represents a process, and a rectangle with 2 vertical bars represents a predefined process, i.e. a process with multiple steps. The red text "Study Measurement" indicates the recorded decisions by data collectors. The question "What is the primary reason" is a qualitative question to assess barriers. The blue rectangle including "Process?" is assessing what is the institution-specific process. Italicized text underneath a symbol indicates the person performing the process. A symbol shaded in green denotes a step requiring electrical power. OT, operating theater. (Reprinted from Lifebox Foundation, with permission.)

Figure 3. Instrument decontamination and sterilization process map. The map is to be read from the top left starting with the light blue oval proceeding to the bottom right with the red box. Diamond shapes represent a decision, a rectangle represents a process, and a rectangle with 2 vertical bars represents a predefined process, i.e. a process with multiple steps. The red text "Study Measurement" indicates the recorded decisions by data collectors. The question "What is the primary reason" is a qualitative question to assess barriers. The blue rectangle including "Process?" is assessing what is the institution-specific process. Italicized text underneath a symbol indicates the person performing the process. A symbol shaded in green denotes a step requiring electrical power. OT, operating theater. (Reprinted from Lifebox Foundation, with permission.)

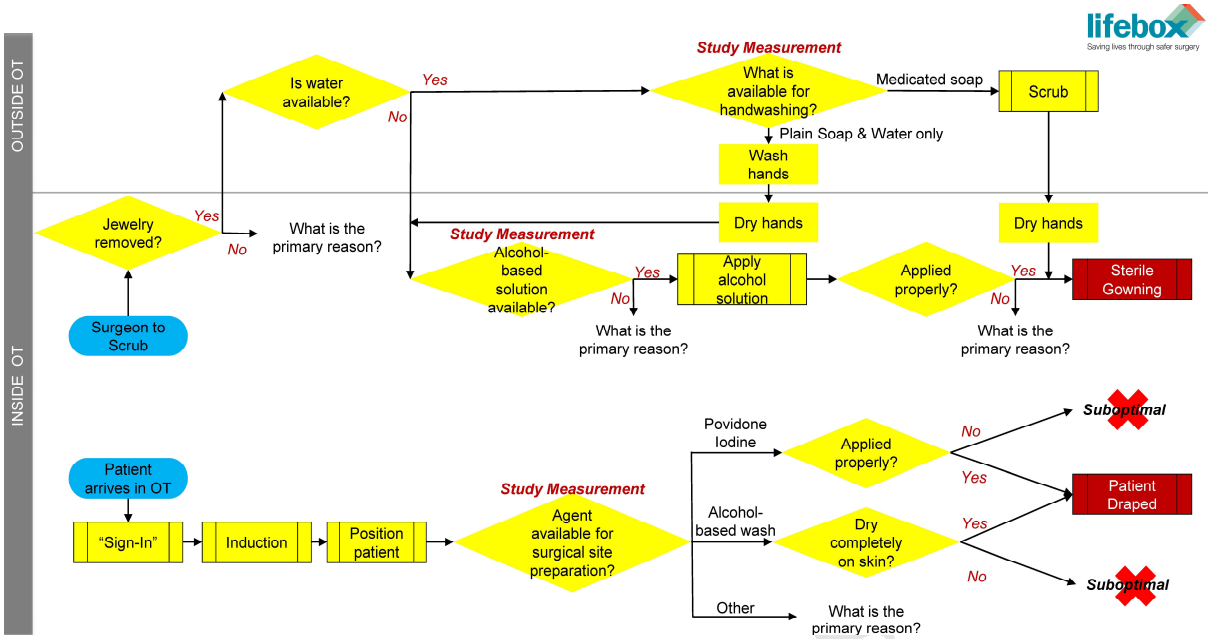
Figure 4. Prophylactic antibiotic administration process map. The map is to be read from the top left starting with the light blue oval proceeding to the bottom right with the red box. Diamond shapes represent a decision, a rectangle represents a process, and a rectangle with 2 vertical bars represents a predefined process, i.e. a process with multiple steps. The red text "Study Measurement" indicates the recorded decisions by data collectors. The question "What is the primary reason" is a qualitative question to assess barriers. The blue rectangle including "Process?" is assessing what is the institution-specific process. Italicized text underneath a symbol indicates the person performing the process. A symbol shaded in green denotes a step requiring electrical power. Abx, antibiotics; OT, operating theater. (Reprinted from Lifebox Foundation, with permission.)

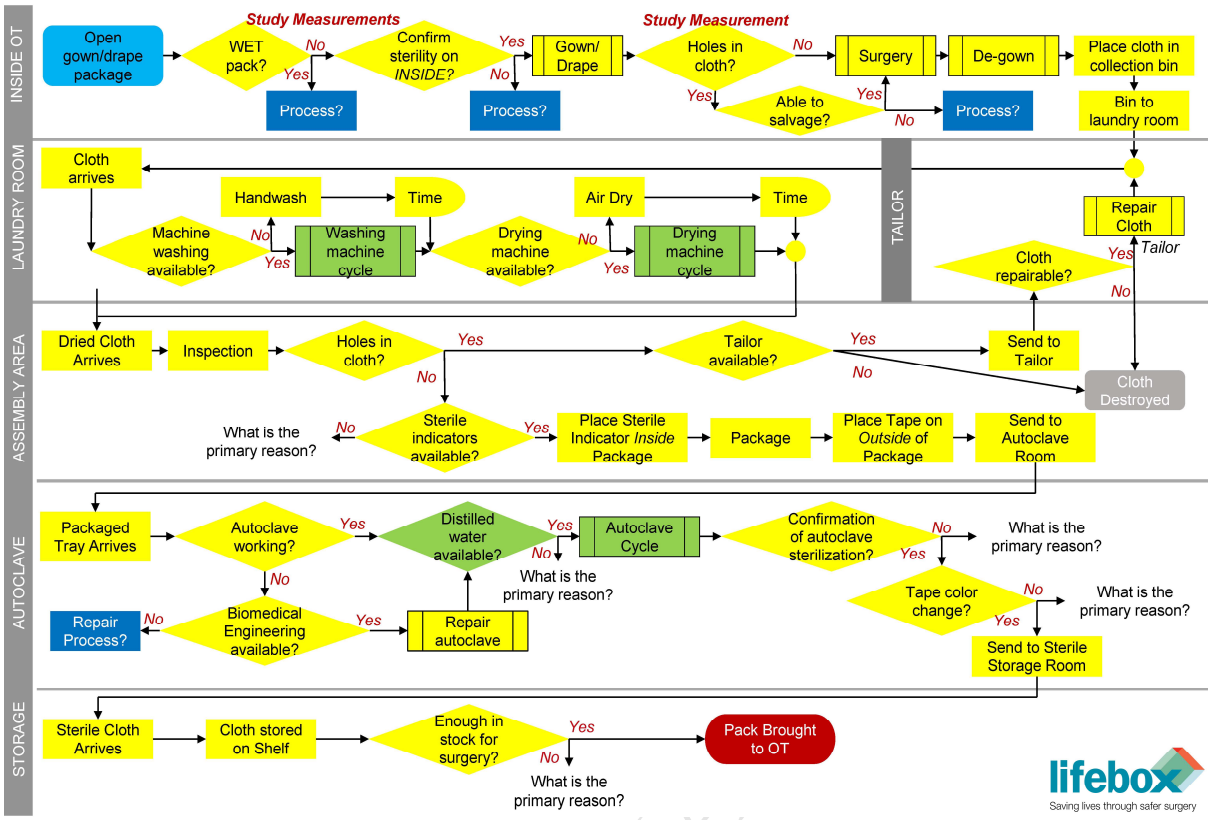
Figure 5. Surgical gauze/swab process map. The map is to be read from the top left starting with the light blue oval proceeding to the bottom right with the red box. Diamond shapes represent a decision, a rectangle represents a process, and a rectangle with 2 vertical bars represents a predefined process, i.e. a process with multiple steps. The red text “Study Measurement” indicates the recorded decisions by data collectors. The question “What is the primary reason” is a qualitative question to assess barriers. The blue rectangle including “Process?” is assessing what is the institution-specific process. Italicized text underneath a symbol indicates the person performing the process. A symbol shaded in green denotes a step requiring electrical power. OT, operating theater. (Reprinted from Lifebox Foundation, with permission.)

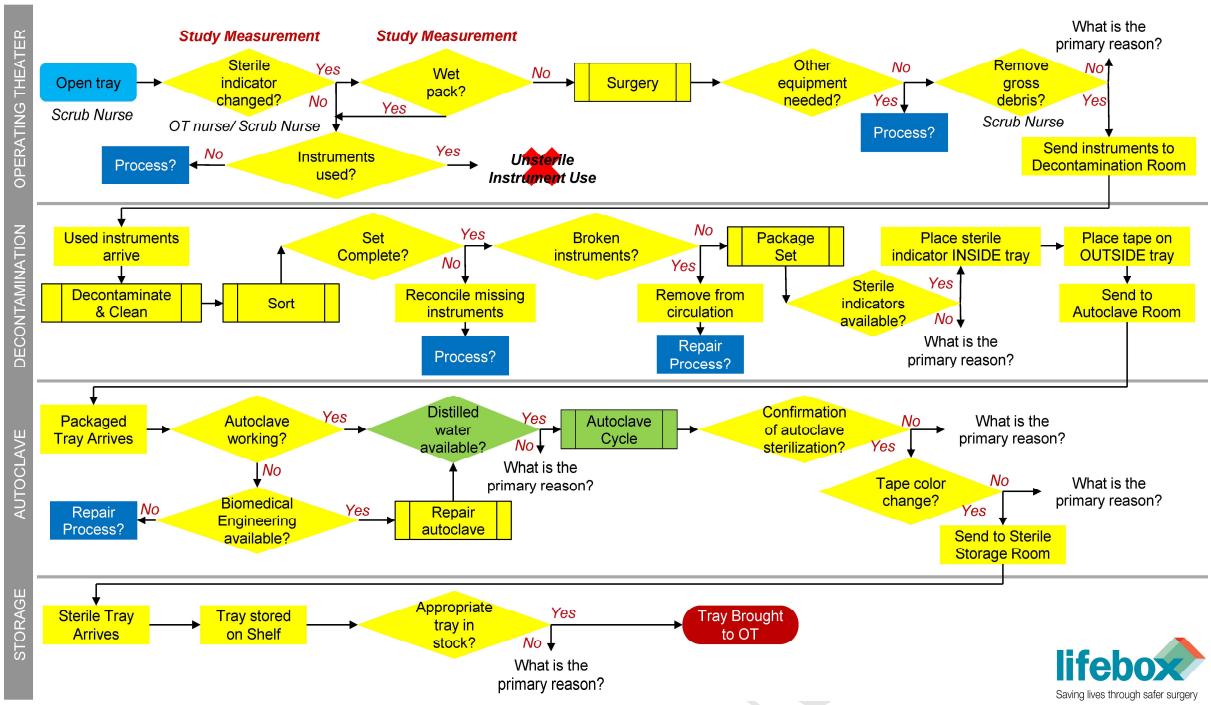
Figure 6. Surgical safety checklist process map. The map is to be read from the top left starting with the light blue oval proceeding to the bottom right with the red box. Diamond shapes represent a decision, a rectangle represents a process, and a rectangle with 2 vertical bars represents a predefined process, i.e. a process with multiple steps. The red text “Study Measurement” indicates the recorded decisions by data collectors. The question “What is the primary reason” is a qualitative question to assess barriers. The blue rectangle including “Process?” is assessing what is the institution-specific process. Italicized text underneath a symbol indicates the person performing the process. A symbol shaded in green denotes a step requiring electrical power. Abx, antibiotics; OT, operating theater. (Reprinted from Lifebox Foundation, with permission.)

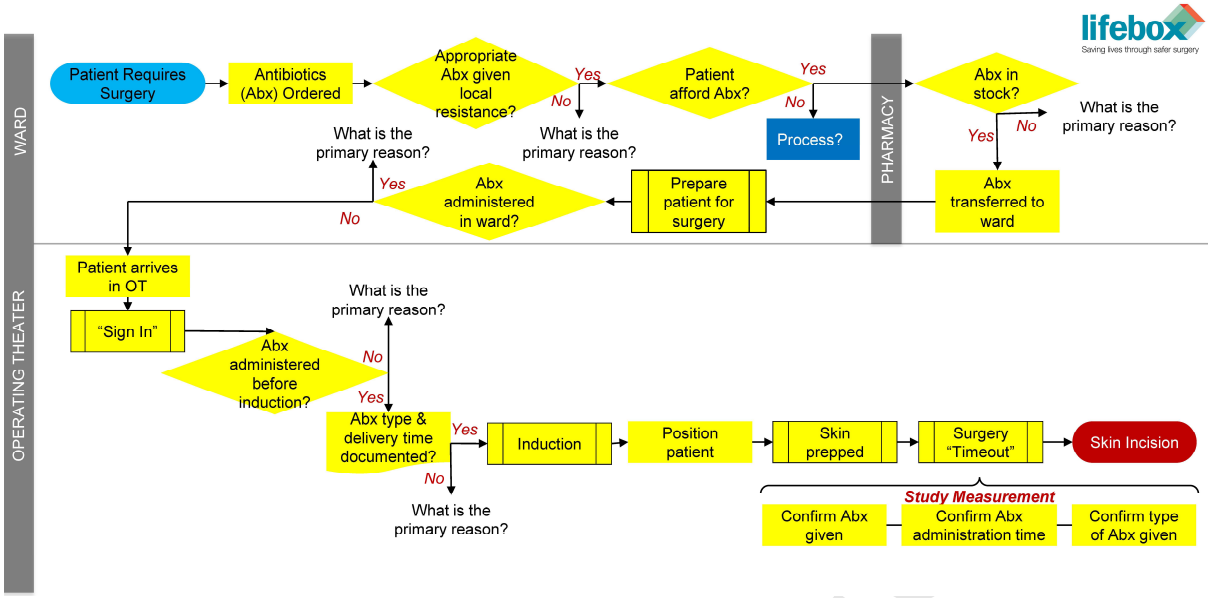
Precis

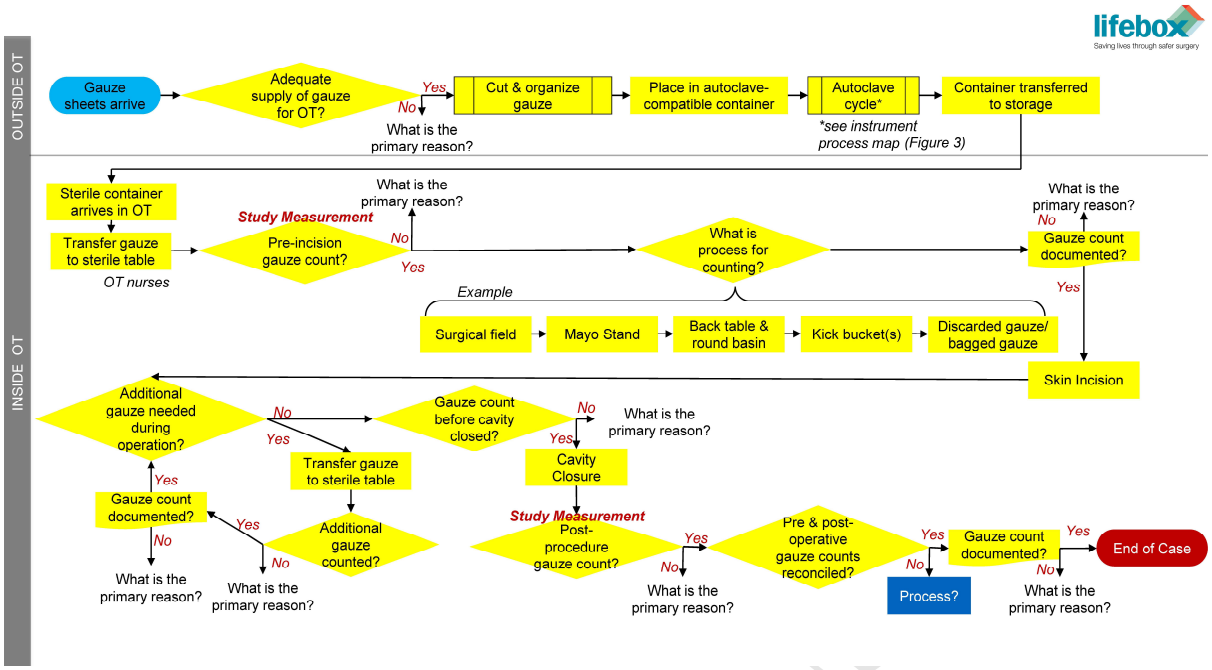
Surgical infections undermine surgical safety in resource-constrained environments. Identifying barriers and systematically improving adherence with surgical infection prevention standards can be accomplished through coupling observable practice data with visual process maps.

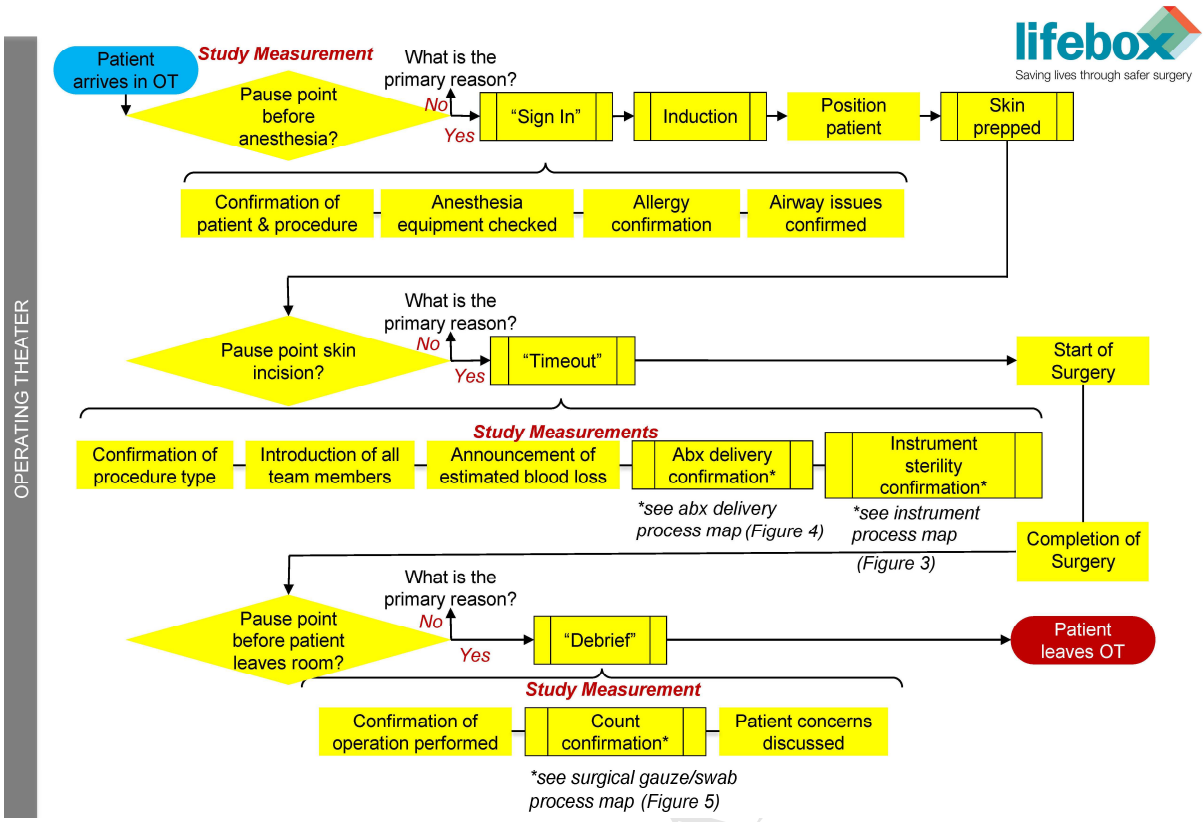












eDocument 1. Questions to Generate Process Maps for Clean Cut Infection Prevention Standards

1. **<u>Hand & Surgical Site Decontamination</u>**
    a. Surgeon Hand Prep
        i. Is there a hospital protocol for hand scrubbing? If so, what is it? If not, why?
        ii. Is jewelry removed prior to scrubbing the hands?
        iii. Is water available for scrubbing?
            1. If yes…
                a. What is available for scrubbing (ie plain soap and water, medicated soap, etc)
                b. How long do people scrub for?
                c. Do people use the sterile towels correctly to dry the hands (ie using sterile technique)
                d. Is there training on hand scrubbing for medical students/trainees?
                e. After drying the hands, is alcohol solution used to decontaminate?
                    i. If yes…
                        1. How is it applied to the hands?
                        2. Is it allowed to dry completely?
                    ii. If no…
                        1. Why not?
            2. If no…
                a. Is there an alcohol-based solution available?
                    i. If yes…
                        1. How is it applied to the hands?
                        2. Is it allowed to dry completely?
                    ii. If no…
                        1. Why not?
    b. Surgical Site
        i. Is the surgical site shaved before skin prep? If so, why? And with what? (ie there is a difference between using a razor blade [*not recommended, increases SSI risk*] versus using a hair clipper [okay for use, though not usually available in low-resource settings]
        ii. What agent is available for skin decontamination?
            1. Is there enough available supply to always have available?
            2. Is the skin agent allowed to dry completely on the skin prior to incision? If no, why?
2. **<u>Integrity and sterility of gowns, drapes, and gloves</u>** *(assuming facility is using reusable gowns/drapes)*

a. When the "sterilized" (ie washed and put through the autoclave) gown drape pack is opened in the OT, is there a sterile indicator *inside* the gown/drape pack to indicate sterilization?
    i. If no, why not?
    ii. If yes, is it confirmed that the color changes (ie that the package was indeed sterilized?
        1. If it did not change, what action is taken by the staff?
b. Are there occurrences of wet gown/drapes ("wet packs")?
    i. If yes, how frequent do they occur? What action is taken by the staff when there is a "wet pack"?
c. Are there occurrences of holes/tears in the gowns or drapes?
    i. If yes, how frequently? What action is taken by the staff when there is a hole/tear?
d. Where are the gowns/drapes placed after use in the operating theater?
e. Is there machine washing available?
    i. If yes, how often is it non-functional?
    ii. If no, is there adequate staffing, space, and resources available for hand washing?
f. Is there machine drying available?
    i. If yes, how often is it non-functional?
    ii. If no, does air drying impact the turnover or availability to provide adequate gowns/drapes for surgery?
g. Are the gowns/drapes inspected for holes/tears prior to packaging for sterilization?
h. If holes are found in the gowns/drapes, is there a way to repair them?
    i. If no, what happens to the gowns/drapes?
i. For rest of process, there is overlap with the autoclave section for the instrument process map, please refer there

3. <u>Instrument Decontamination & Sterilization</u>

a. What is the current method to assess for instrument sterilization?
b. Is there a sterile indicator on the inside of the instrument tray?
    i. If yes, is there a confirmation process for color change? If so, who is involved and what is the process?
    ii. If no, why?
c. How frequently are instruments wet or have proteinaceous material on them after opening in the operating theater?
    i. If they are wet instruments or condensation on the inside of the tray ("wet pack"), what is the process that occurs by staff after identification? Are they still used for the operation?
d. In the operating theater, is gross proteinaceous material rinsed from the instruments with water or saline? If no, why?
e. What is the current process for cleaning/decontaminating the instruments? Who developed these processes? What is the training methods for new staff?

   i. If bleach is used, how long is it soaked for? How frequently is this greater than 10 minutes?
   ii. What type of detergent is used? Are the instruments brushed? Please have staff model the process through which they clean the instrument [SPECT CAN HELP WITH ALL OF THIS PART]
   iii. Are the instruments rinsed with deionized water after detergent/brushing? If no, why?
   iv. How are the instruments dried?
   v. How are the instruments organized and packed into sets/trays?
   vi. Are the instruments inspected to assess for unusability/repair?
   vii. Is there a repair process for surgical instruments? If so, what is it?
f. Are sterile indicators placed inside the tray prior to sending to autoclave? If no, why?
g. Is sterile indicator placed on the outside of the tray prior to sending to autoclave? If no, why?
h. Who operates the autoclave on a daily basis? Is there a training process they go through?
i. How frequently is the autoclave non-functional?
j. What is the process to repair the autoclave when it is non-functional? (ie is the biomedical engineering available, how responsive are they, how well trained are they, etc)
k. Is distilled water available?
   i. If yes, what volume is available? How much is required to run the autoclave? Is there enough as well for washing the instruments? How frequently is it not available?
   ii. If no, why?
l. Is there a process to confirm autoclave function? ie is there use of biological or chemical sterile indicators to confirm the autoclave actually reaches the correct time, temperature and pressure to sterilize? Are there functioning temperature gauges on the machine? Is there a system for recording/logging the autoclave cycle runs? If so, what is it?
m. How frequently does the sterile indicator tape on the outside of the package not change color? If it doesn't change color, what is the process to address it?
n. Is there a sterile instrument storage area? If yes, how are they transferred there?
o. Is there appropriate amount of instruments for your surgical volume?

4. <u>Prophylactic Antibiotic Administration</u>

a. Who orders the antibiotics prior to surgery? How are the antibiotics selected for the operation?
b. Is there a hospital policy for the recommended antibiotics to administer before certain types of surgery?
c. Are documented antibiotic resistance patterns at the hospital available?
   i. If yes, is the prescribed antibiotics appropriate given the resistance patterns? If not, why?

d. What happens if the patient cannot afford the antibiotic?
e. Is there enough antibiotic in stock for surgery?
f. Where is the antibiotic administered for surgery? If it is not in the operating theater, why? Who administers the antibiotic for surgery?
g. What is the goal time for delivery of antibiotic before skin incision? Is this measured at your facility? If not, why?
h. How frequently is the operation cancelled after the patient has already received the antibiotic?
i. Is there a confirmation process to ensure that the antibiotic was administered? If so, what is it?

5. <u>Surgical Gauze/Swab Counting</u>

a. Describe your current process for counting gauze
b. Is there an adequate supply of gauze for the operating volume?
c. Who counts the gauze before skin incision? What is the process that they use to count the gauze? Is there documentation of the number of gauze used before skin incision? If not, why?
d. If more gauze are required than the number stared with, how are they added? Is this documented?
e. When the gauze are used, where are they placed? ie is there a separate bucket to collect the gauze to allow for easier counting later on? If not, why?
f. Are the gauze counted before fascia is closed? If there is an incorrect number compared to the start of the case, what is the process that occurs?
g. Is there a final gauze count when skin is closed? If there is an incorrect number compared to the start of the case, what is the process that occurs?
h. How frequently has there been a retained surgical gauze or item? If there is, what is the process that occurs to make sure it does not happen in your facility?

6. <u>Use of Surgical Safety Checklist</u>

a. Is it currently being used in your facility?
    i. If yes, has it been modified to your facility?
b. Is there a pause point before anesthesia is administered?
    i. If yes, who communicates at this time? What is actually communicated? (ie patient,
c. Is there a pause point before skin incision?
    i. If yes, who communicates at this time? What is actually communicated during your time out? (ie abx confirmation, patient, surgery, estimated blood loss, sterility of instruments etc)
d. Is there a pause point before the patient leaves the room?
    i. If yes, who communicates at this time? What is actually communicated during the debriefing? (ie. gauze count confirmation, operation performed, etc)