Minimizing OR Cancellations, Maximizing OR Utilization: A Pilot Study

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I. Statement of Purpose

The purpose of this pilot study is to prospectively identify operating room time delays, and assess the contributing impact of non-technical skills, team performance, and environmental factors in the operating room. This analysis will be used to identify root causes leading to delays and define areas for improvement.

II. Background and Rationale

Time delays in the operating room play a role in increasing wait time length, number of cancelled cases, health care expenditure and resources. Furthermore, they inconvenience patients and families, and delay care. Minimally invasive surgery (laparoscopy) affords same-day discharge, faster recovery, and decreased morbidity. However, performing laparoscopy requires special equipment and multiple steps during set-up that can lead to time delays if not performed efficiently. Multiple factors have been identified to contribute to inefficient care delivery including (1): communication error, equipment failure, lack of teamwork among nursing, surgical or anesthesia teams, and duplication of tasks.

The Institute of Medicine (IOM) report "To err is human," released in 2000, set off numerous studies to identify errors in healthcare and to develop strategies to avoid adverse outcome (2). The most commonly used types of interventions in surgery to date have been preoperative "surgical safety checklist" for aviation-style briefing (3-5). Other interventions have focused on training isolated components of non-technical skills, such as communication (6, 7).

The systems approach to human error is based on the assumption that human error is inevitable and looks for failures in the system rather than in the individual. This novel approach has led to the current concept of Crew Resource Management training as a strategy to enhance non-technical skills in order to avoid, trap and mitigate error and ultimately increase safety (8-10). This concept can be extended to the area of interest of time delays. Unanticipated events such as human resource absenteeism, equipment failure or malfunction, and unscheduled emergency add-on cases as examples, inevitably will arise

to cause time delays. These delays can occur in the OR directly, or in other areas of the hospital which can in turn affect the flow in the OR. Efficient use of the OR requires expert technical skills of the surgical team, but more importantly teamwork within the peri-operative team and administration that are prepared to accommodate an array of potential unforeseen circumstances that can lead to time delays. Understanding what are the most common types of delays, the frequency and trends in which they occur, and the root causes for the delays can help prevent delay by being prepared, that is, anticipating delay possibilities and having a plan in place to minimize delay. Although factors outside of the OR can influence the intra-operative period, this study focuses specifically on determining which factors within the OR can be targeted to improve efficiency.

An innovative technology, the OR Black Box, has been developed for the OR to mimic the blackbox in airline industry. It has the ability to record the surgical field, the anesthetic equipment, and the level of noise in the OR. This technology also has the ability to time stamp all activities that take place in the OR. Using this technology, we will be able to record all of the important check points that take place in the course of a complex laparoscopic procedure (i.e. total laparoscopic hysterectomy). This will in turn highlight several potential areas for examining efficiency that can be generalized to other surgical specialities. This analysis will be used to identify root cause(s) leading to OR delays and define areas for improvement. The causes of delays can be reported to the team members through formative performance-based feedback (11).

Summary

OR delays are a result of a chain of events spanning multiple phases of operative patient care. Currently, there are no reported methods available to objectively observe and evaluate causes for OR efficiency including non-technical skills factors. Delays are tracked by the nursing staff which is a subjective process fraught with inconsistency and associated biases. Objective measures of intra-operative OR delays, identification of their root causes, and creation of an intervention to improve OR efficiency has the potential for the development of a standardized framework to minimize OR efficiency, which could be generalized to any surgical discipline to improve OR efficiency.

III. Research Objectives

1) To prospectively identify patterns or chain of events leading to prolonged case duration in total laparoscopic hysterectomy procedure in a gynecologic surgical population.
2) To assess how non-technical skills and team performance of surgeon, nursing and anesthesiology teams correlate with case duration and subsequent cancellations.

IV. Hypothesis & Novelty

We hypothesize that non-technical skills and teamwork in the OR are correlated with operating room efficiency. Furthermore, we hypothesize that time delays can be tracked to a chain of events that is influenced by non-technical skills as well as environmental factors in addition to technical skills. Together, this knowledge can be used to identify areas for organizational, technological, and team or individual improvement, and to design a standardized framework to improve individual and team performance and ultimately increase OR efficiency that can be applied to any surgical department. The novelty of this approach is the prospective assessment of non-technical, team performance, and environmental factors in the OR as well as delays, inefficiencies, and patient outcome in order to identify areas for improvement and characterize a chain of events.

V. Methods

Experimental Design

1. Prospective observational study
2. Randomized trial (Sub-study/branch of pilot study: Measuring the impact of standardized efficiency framework to optimize OR utilization)

General Design

Study Subjects

A minimum of sixty elective total laparoscopic hysterectomy procedures performed in one operating room of an academic tertiary care center during a twelve-month period will be included in this study. Procedures will only be excluded if data collection is in any part

incomplete or patient or OR staff consent was declined or withdrawn. Studying total laparoscopic hysterectomy was selected as a marker to analyze OR efficiency as this is a commonly performed procedure that requires moderate degree of complexity in equipment set-up and can be generalized to other laparoscopic procedures. Health professionals that will be participating in the study are OR nursing staff, technical (scrub) assistants, anesthesia staff, and surgeons. The nursing team involved in each procedure typically consists of one scrub technical assistant or nurse and one circulating nurse. The anesthesia team is typically represented by either a staff anesthesiologist or an anesthesia resident (who is always supervised by a staff anesthesiologist). The surgical team is comprised of the staff surgeon, and two other surgeons, typically a fellow and a surgical resident. The staff surgeon will be present during all cases and perform the majority of procedures however, some full procedures, or particular steps of procedures, will be performed by a clinical fellow or a surgical resident under staff surgeon's direct supervision, which is standard practice in teaching hospitals. Medical students will occasionally also be part of the surgical OR team as part of their surgical rotation during clinical clerkships.

Recruitment and consent of patients

All patients that are scheduled for elective surgery will be eligible for participation in the study. Minors and patients with mental disability or impairment are not eligible for the study. Pregnant women will also not be enrolled. All eligible patients will be informed about the study by the treating surgeon during their appointment in the clinics. Each patient will then receive written information (see Patient Consent form) to read at home in order to provide adequate time for consideration. All patients that have been scheduled for surgery routinely return for a second presentation for a consult with Anesthesiology, this is typically two to three weeks prior to the surgery. Upon this pre-admission appointment, the Research Coordinator, who is not involved in patient treatment, will provide additional information regarding the details of the study to the patients and will obtain informed consent. Patients that are scheduled for elective total laparoscopic hysterectomy surgery will be enrolled in the study, provided that informed consent has been obtained. It is furthermore important to note that participation in the study will not result in any deviation

of the standard treatment of patients in our unit. This includes all visits prior to the procedure, the surgery and hospital stay, and postoperative care.

Recruitment of nursing staff

Prior to the start of the study, approval will be obtained from the clinical manager of perioperative services (OR leader). Nursing staff will be identified through the roster and addressed by the Clinical Leader Managers of Perioperative Services, via their St. Michael's Hospital email addresses. All nursing staff scheduled to work with this unit will be invited by the clinical manager via email to attend an informative presentation given by one of the researchers (see Appendix 1). After the presentation, the Research Coordinator will then obtain written informed consent. All staff members who did not have the opportunity to attend the presentation will be informed of the study by the Research Coordinator. Nursing students are occasionally scheduled in the unit's OR, mostly to observe the procedure for training purposes (i.e., not active participants). Nursing students who are scheduled to attend one of the unit's OR lists will be informed of the study by the Nurse Educator and informed consent will be obtained by the Research Coordinator. If any member of the staff declines consent or withdraws consent at any point during the study, procedures involving that staff member will not be recorded from that point on. A reminder e-mail will be sent to staff who are scheduled in the OR but who did not provide informed consent or were unable to attend the Grand Rounds presentation (see "E-mail consent reminder"). This e-mail will remind them of the study and provide another opportunity to sign the consent form if they wish to participate.

Recruitment of anesthesia staff

Anesthesia staff (including residents and fellows) who are scheduled in the unit's OR will be informed of the study by staff anesthetists via their St. Michael's email addresses (see Appendix 1). All anesthesia staff will be invited to join an informative presentation about the study that will be held by one of the researchers at departmental Grand Rounds. After the presentation, the Research Coordinator will obtain written informed consent from all anesthesiology staff who wish to participate. If consent is declined or withdrawn by an anesthesia staff member, resident, or fellow, procedures will not be recorded when the

respective person is scheduled for the unit's OR list. Anesthesia staff, residents, and fellows will be informed that a decision not to participate in the study will not affect their rotation or professional standing at St. Michael's Hospital in any way. A reminder e-mail will also be sent to anesthesiology staff who are scheduled in the OR, but who did not provide informed consent or were unable to attend the Grand Rounds presentation

Recruitment of surgical staff

The project investigator as well as the participating staff surgeons in the Department of Gynecologic Surgery at St. Michael's Hospital will be study subjects in all observed procedures, and therefore will also sign the written informed consent. All gynecology surgical staff (including fellows and trainees) will be initially contacted about the study via e-mail and will be invited to attend an informative presentation at the next Grand Rounds session (see Appendix 1). Surgical residents will be contacted via e-mail by the Program Director's office. Occasionally, medical students participate in the unit's OR for clinical clerkships. The rotation plan of surgical clerkship students is known to the undergraduate medical education coordinator for Fitzgerald academy, St. Michael's Hospital, medical students scheduled for the unit's OR lists will be contacted through the medical student speaker as a student representative. Informed consent will be obtained from all surgical staff who wish to participate in the study. This will be obtained by the Research Coordinator at the end of the Grand Rounds presentation. Prior to the day of scheduled surgery, a reminder email will be sent to all staff who have not yet provided informed consent or who were unable to attend the Grand Rounds presentation.

Declined or withdrawn consent

The informed consent of all participants (patients, healthcare staff, residents and students) has the highest priority for the researchers. If any team member in the OR has not given consent or has previously withdrawn consent, the procedure will not be recorded. If a staff member agrees, he or she may be scheduled for a different OR. To ensure that all members of the operating team have given consent, the Research Coordinator will monitor the OR lists and staff schedules one day prior to the list to ensure valid informed consent is available of all team members scheduled for that day. For that purpose, the Research

Coordinator will keep a master log that contains all names and roles of participants that have given informed consent (Appendix 7). If an OR team member has not given valid consent or has withdrawn consent, the Research Coordinator will ensure that on that particular day no recording is made. Consent of staff members will be valid for 12 months. This is explained in the staff consent form. Every study participant can withdraw consent at any point in time during the study. If a participating staff member withdraws consent, no procedures will be recorded from that point on, if the respective staff member is present. A patient participating in the study can also withdraw consent at any point before her procedure. Both staff members and patients can withdraw consent for procedures that have already been recorded, if they do so within 48 hours of the procedure. In order to maintain the scientific integrity of the study and avoid bias, the recordings may not be withdrawn beyond the 48-hour timeframe, nor may the other data collected up to the point of withdrawal. Data from procedures that have already been video-audio recorded *and evaluated* while valid consent existed cannot be withdrawn. This is a requirement to maintain the scientific integrity of the study and this will be clarified in the consent forms.

The researchers acknowledge that the OR staff may feel pressured by the recording and the assessment of their performance. Nursing staff will only be evaluated with regards to non-technical and team skills. It is important to acknowledge, that individual performance of staff members will not be evaluated. Instead, the respective roles in the OR (primary surgeon, secondary surgeons, circulating nurse, scrub nurse) are evaluated, thus no names or subject numbers will be linked to the analysis of OR delays. Each procedure will only be linked to a patient code, to ensure procedure, team performance, and outcome can be correlated to this case. Healthcare staff will not appear on any data collection forms. Consent forms and the staff consent master log are the only documents containing healthcare staff names and will be kept secure in a locked office at all times that can only be accessed by the researchers. Consent forms of healthcare staff cannot be linked to a particular case.

To avoid any feeling of coercion or pressure to participate, the Research Coordinator who is not involved in surgical procedures can be contacted by the participants in order to withdraw informed consent. Contact details will be provided on the final version of the consent form. The Research Coordinator will keep the name of the person who has

withdrawn consent anonymous and delete their name from the master log to ensure no further procedures will be recorded when this staff member is in the OR. As an additional safety barrier, a sign will be affixed on all doors of the unit's OR to inform any person entering the OR that recording may be in progress (Appendix 9).

Data collection

All eligible procedures will be continuously video- and audio- recorded. A panoramic view of the entire OR will be obtained using multiple surveillance cameras. The inside view of the laparoscopic camera will be recorded, as it is already standard practice. Video and audio recordings will start once the patient has entered the operating room and the user has started capture. Recordings will end when the patient exits the room and the user ends capture. The video and audio recordings will be automatically encrypted at the point of capture and stored behind a secure firewall within St. Michael's hospital. The encrypted videos will be transferred by secure socket connection to a St. Michael's Hospital research center - the International Centre for Surgical Safety (ICSS) – which is also protected by a secure firewall, where the videos will remain in a 'badge-access-only' office, on a multiple-password-protected computer. Next, a single study staff member with access to this computer will decrypt the videos and "blur" any frames in which the patient's face and/or sensitive body parts (i.e. genital area, breasts) are visible in order to preserve the patient's anonymity and dignity. The study staff member will then re-encrypt the files which will remain encrypted in the same protected environment until a certified clinical data analyst (i.e. a non-study-staff employee of ICSS who is rigorously trained to review operative videos) decrypts the videos and analyzes the videos for variables of interest as described in detail below.

Patient demographics as well as diagnoses and risk factors will be collected on an electronic patient data sheet (Appendix 2). The information on the patient data sheet is important for the study to stratify the data for patient risk factors and to identify organizational factors such as delays and environmental influences such as time of day. Video- and audio- recordings as well as all other recordings of data will capture time but not date. The time of day is important, since some factors such as vigilance can be affected

by circadian rhythms of individuals. Additionally, we will record if any cases were cancelled following the hysterectomy that was captured. All data records, documentation or information containing patient data will be de-identified with study numbers to ensure that persons outside of the study will not be able to identify the participating patients. The code will be kept on a password protected hard drive that will only be accessible by the Research Coordinator. The researchers will however be given access to the data sheets as required to enter additional information such as follow-up data.

The recorded, analyzed, de-identified video files will be retained until completion of the recording review period (30 days). After 30 days the video and audio files will be deleted. A small sample of "segments of interest" (i.e. short video segments deemed to be highly educational) may be kept beyond 30 days, however these will not contain any identifying information for either the patient or staff members. Any retained "segments of interest" will undergo further de-identification processes in which *all* faces are blurred and *all* voices are pitched, thus preserving the anonymity of all members of the operating room team throughout these segments. The research data will be stored and the code linking the case data to a patient name will be deleted at 30 days. After that, the data will be permanently anonymized.

Hawthorne effect

The Hawthorne effect describes a phenomenon of an unintentional change in behavior in response to the presence of an observer. The Hawthorne effect can affect any study that involves observation of the study subjects and can therefore not be completely eliminated (12). It is known that the Hawthorne effect typically fades with time, as the subjects are getting used to the observation, especially if the presence of an observer is not directly visible. Two factors may reduce the Hawthorne effect in our study: 1) long duration of the study over 12 months, which is likely to lead to an acclimatization of the subjects once the novelty of the cameras wears off. 2) Video recordings will be made with small surveillance cameras that are mounted on the wall. The unobtrusive nature of the observation is likely going to accelerate the habituation, further reducing the Hawthorne effect.

Disclosure of errors and adverse events

Technical errors in our study are defined as the smallest measurable unit reflecting a non-deliberate action or deviation from a plan. These alone may not have the potential to lead to adverse outcome. Such errors may be the dropping the needle whilst suturing or the incorrect orientation of the needle driver, or communication that does not follow a closed loop reconfirmation. “Events” represent the next level of error analysis and these have the potential to influence outcome, if not rectified. Examples would be a serosal injury of small bowel, which would require suture repair. An event in communication representing miscommunication for example would be poor instructions leading to the opening of the wrong sterile instrument causing additional cost. In the case of patient events needing medical rectification these will naturally as per standard practice be described in the OR notes and documented. This is the standard operating procedure for these types of events. In cases with more severe consequences the intraoperative complication will be discussed with the patient as per standard of care.

Study data is abstract and at this point not linked to outcome. Only factors, which actually influence the treatment or need rectification will be discussed with the patient. This is already the standard procedure and will not be changed during the study. Incidental findings during the surgery will naturally be discussed with the patient since this is standard medical care.

Sample size

This study represents a pilot study to establish knowledge about time delay rates, surgical technical and non-technical skill components as well as to determine failures in technology (equipment failure). These numbers are currently unknown and we therefore hope to obtain an adequate knowledge base for future research in this field. What is known is that operating room cancellations and delays occur. These represent aberrations from the ideal task execution, which occur non-deliberately. They do not necessarily cause measureable effects in outcome. It is more likely, that an accumulation of events (that results from an issue that requires corrective measure) can influence a number of outcome parameters such as OR time, cost, and even patient outcome. But the delay rate itself may be influenced by other parameters such as patient factors (weight, gender, comorbidities, etc.).

Setting

The study will be conducted at St. Michael's Hospital – a University of Toronto affiliated, tertiary-care teaching hospital.

Evaluation of collected data

1) Time delays

Data for the time period that the patient enters and exits the OR will be captured with the OR Black Box technology. Recordings will begin once the patient enters the operating room and will be stopped once she leaves. Blurring of her face and sensitive body parts will be performed by a study team member prior to data analysis. The objective time stamps and occurrence of events to be collected are outlined in Appendix 3.

2) Non-Technical Skills

Video- and audio-recordings of all procedures will be evaluated by the OR Black Box data analysts with formal training in CRM-evaluation using SPLINTS(13), NOTSS (14), and/or the ANTS rating scales (Appendix 4, 5, 6). The SPLINTS and the NOTSS rating scales were derived from frameworks for the observation of team behaviors and have been modified for use in surgical teams (13-15). The ANTS framework has been developed to assess the non-technical skills of the anesthesia team. These rating scales have previously been shown to have construct validity and good inter-rater reliability. Recordings of any patients that encounter complications directly related to the index procedure will be reviewed and screened again using the SPLINTS, ANTS and the NOTSS rating scales (Appendix 4, 5, 6). Twenty percent of recorded procedures will be randomly selected for evaluation by a second observer using these tools. The second observer for the blinded evaluation of the audiovisual recordings will be a surgeon with experience in the use of behavioural rating scales. The intra-class correlation coefficient (ICC) will be determined for the results of both observers. An ICC equal or greater than 0.75 will be considered acceptable.

Primary Outcome Measure

The primary objective of this study is to measure the incidence and categorization of intra-operative time delays. Secondary outcome measures will be the incidence of events leading to time delays when evaluating in retrospection, the interaction of non-technical skills and their impact on events leading to time delays, correlation of time delay to its root cause, the amount of time taken to complete a procedure, the number of canceled cases, and OR utilization (ratio of number of canceled/completed cases).

Statistical Analysis

This observational study represents a pilot study. Therefore, an *a priori* analysis of statistical power and sample size cannot be performed (see also chapter *sample size*). Descriptive statistical analysis of defined events and outcomes will be performed. Correlation statistic will be performed to evaluate the team's conscious awareness of incidents and adverse events. Logistic regression analysis will be performed to identify influencing non-technical and team performance factors. A biostatistician will be involved in the statistical analysis of the results.

VI. Ethics

Ethics approval for this study will be obtained from the Research and Ethics Boards from the participating hospital and the University of Toronto.

VII. Relevance

OR delays due to inefficiency can result from a chain of intraoperative events including technical factors (ie. equipment failure or case complexity) and from non-technical human factors (ie. communication errors or lack of coordinated teamwork within and between OR teams). Objective measures of intraoperative OR delays and identification of their causes can lead to the development of a standardized framework that could be generalized to any surgical discipline to improve OR efficiency. Anticipated outcomes include: reduced cancellation of cases, increased OR utilization, reduced time delays, increased number of completed cases, improved patient flow within peri-operative department, and

improvement in non-technical skills of surgeons, anesthetists, nursing, and administrative team when facing challenges in time delays.

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