KEY WORDS: OPERATING ROOM TRAY, SURGICAL TRAY OPENING, SURGICAL TRAY.

EVALUATION OF THE SURGICAL TRAY OPENING PROCEDURE IN OPERATING SUITES: SYSTEMATIC REVIEW AND RECOMMENDATIONS

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ABSTRACT:

Introduction: Optimizing the processes involved in managing operating suite activities is an essential element in obtaining gains in efficiency. The early opening of surgical trays could represent an innovative practice for reducing operating times and wait periods between surgeries as well as for increasing the number of daily surgeries. The purpose of this systematic review is to assess the risks and benefits of introducing this practice in the operating room.

The early opening of surgical trays is a practice that has generated interest among certain clinicians

Methodology: A systematic literature review was conducted in various indexed databases as well as in the grey literature in order to identify synthesis studies, clinical guidelines and randomized and non-randomized studies on the impact of opening surgical trays early. The following indicators were sought: time lapse between the patient's entrance and the beginning of surgery, the frequency of surgical tray contamination, and the rate of surgical wound infection.

Results: An original study and four practice guides were included after a quality assessment. No studies on efficiency gains associated with the early opening of surgical trays were found. The results of the experimental study suggest that the contamination rate for uncovered surgical trays is low for the first 30 minutes (4%) and increases over time with exposure to the ambient air. Most clinical guidelines recommend preparing the surgical instruments as close to the beginning of surgery as possible without specifying the minimum time interval to be respected as well as whether or not the patient is in the operating room.

Discussion: The analysis of all the available data does not make it possible to determine the optimal moment for opening the surgical trays. Given the uncertainty regarding the risks of infection, and the lack of data on the associated benefits, the decision to opt for a change in practice in the opening of surgical trays should be based on a range of factors. An assessment of the data therefore suggests caution and that a feasibility analysis, including a review of all processes and parameters for managing the risks associated with the early opening of surgical trays, be conducted before initiating any changes in the institutions where a change of practice is being sought.

INTRODUCTION

Optimizing the processes involved in managing operating suite activities is an essential element in obtaining efficiency gains. The early opening of surgical trays is a practice that has generated interest among certain clinicians. The expected potential gains from this practice include a reduction in operating times and wait periods between surgeries as well as a possible increase in the number of daily surgeries. The introduction of this practice also, however, raises certain fears, namely in regards to the possible increase in the risk of instrument contamination as well as the rate of surgical site infections.

Surgical site infections (SSIs) are a major source of morbidity and mortality for patients undergoing surgical procedures and they represent one of the more frequent causes of nosocomial infections.[1-3] This type of infection manifests in 2 to 5% of surgical cases where the viscera are not opened and in 20% of intra-abdominal surgeries.[2-4] The prevalence of SSIs tends, however, to be underestimated in studies since these infections can develop after the patient has left the hospital.[3] SSIs contribute to the extension of hospital stays by an average of seven to ten days and increase the risk of mortality by two to eleven times in comparison with patients who have undergone the same surgery without infection.[1,2,5] The risk of SSIs is subject to a large number of factors including those associated with the patient including obesity, malnutrition, smoking, and diabetes.[2] Various factors associated with surgical procedures have also been associated with SSIs. Insufficient scrubbing by the surgical team as well as inadequate antiseptic preparation of the skin surface at the surgical site seems to have an effect on the risk of SSIs.[6] The length of a surgical procedure also constitutes a significant risk factor that has been documented.[6] Surgical procedures lasting more than three or four hours have increased risk of SSI6 as well as inadvertent perioperative hypothermia.[25] Other factors such as the non-optimal use of antimicrobial prophylaxis, surgical materials left behind in a patient cavity, and sub-optimal surgical drainage can also increase the risk of SSI.[6]

The purpose of this systematic review is to review the available data regarding the risks and benefits associated with the

early opening of surgical trays in the operating room.

METHODOLOGY

Identification of studies

Scientific publications were reviewed using the indexed databases Medline (PubMed), Embase, the Centre for Reviews and Dissemination, the Cochrane Library, and the grey literature in order to identify synthesis studies, with or without meta-analysis, as well as practice guides. The publications were selected by combining keywords and indexed terms specifically associated with surgical trays and operating rooms (surgical tray, instrument tray, operating-room tray, operating rooms, surgical instruments, operating theater) with keywords and indexed terms pertaining to infection risks (cross infection/prevention and control, equipment contamination/prevention and control, surgical wound infection/prevention and control, surgical wound infection, equipment contamination, cross infection). The research strategies used for each of the indexed databases are available by consulting the UETMIS report.[7] The websites of ETMIS organizations and those of professional associations were consulted in order to search for relevant documents. The list of organizations and websites consulted is available in the appendices of the UETMIS report.[7] The eligibility criteria, the limits, as well as the a priori-defined indicators used to complete the document search are presented in Table 1. The bibliographies of consulted articles were examined to find other references of interest. Two evaluators (MB and SL) worked independently in identifying the studies. Disagreements were resolved by consensus with the help of a third evaluator (MR).

Selection and evaluation of publication eligibility

The studies were selected independently by two evaluators (MB and SL) based on the criteria for inclusion and the limits specified in Table 1. In the event of a disagreement, a third evaluator (MR) was consulted in order to reach a consensus.

Evaluation of the methodological quality of the publications and data extraction

The methodological quality of the publications and the data extraction were reviewed independently by two evaluators (MB and SL). The methodological quality evaluation of the systematic reviews as well as the practice guides were completed using the R-AMSTAR[8] and AGREE II[9] grids respectively. The original studies were evaluated based on the analysis grids adapted from the methodology guide used by the UETMIS at the CHU de Québec.[10] The opinion of a third evaluator (MR) was requested, when there was a disagreement on the quality assessment, in order to reach a consensus. Studies in which the methodological quality was deemed insufficient were excluded. The list of excluded publications and reasons for exclusion is available in the appendices of the UETMIS report.[7]

RESULTS

The research strategy made it possible to identify an observational study[11] and four practice guides[12-15] focusing on the

Table 1. Eligibility Criteria and Limits

CRITERIA FOR INCLUSION	
Population	Patients hospitalized for surgery
Action	Opening of the surgical tray before the patient enters the operating room
Comparator	Standard practice (tray opened as close to time of surgery as possible)
Results	**Effectiveness:** • Primary indicator: time lapse between patient's arrival and beginning of surgery **Safety:** • Primary indicator: surgical wound infection rate • Secondary indicator: frequency of surgical tray contamination

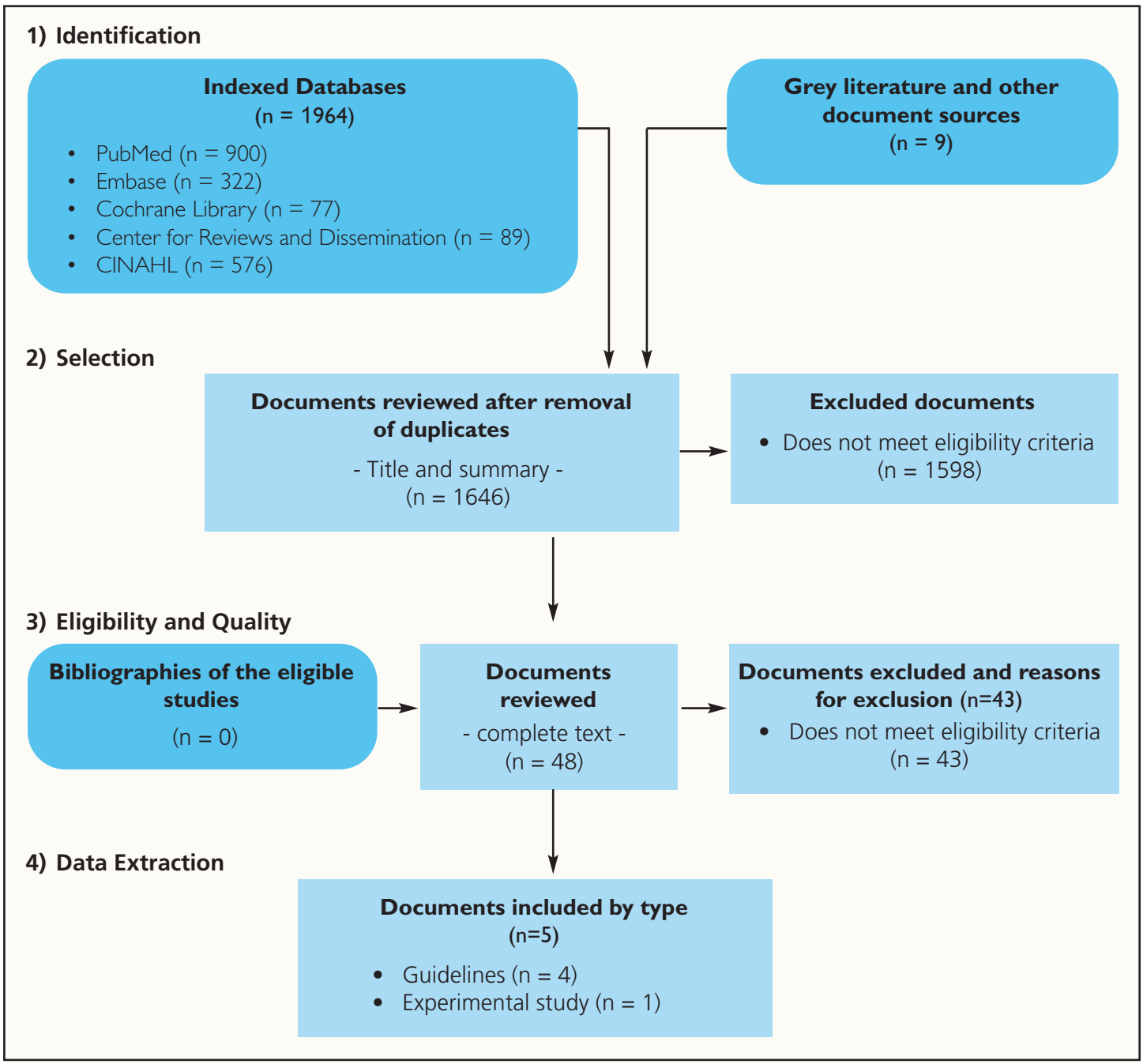
LIMITS	CRITERIA FOR EXCLUSION
• Languages: English and French • Period: beginning of databases to August 18, 2015	• Conference summaries

time lapse for opening the surgical trays and meeting the eligibility criteria for the present evaluation (Figure 1). No study focusing on the impact of the early opening of the surgical trays on the SSI rate, or the time lapse between the patient's entrance and the beginning of surgery, was found.

Observational Study

The purpose of this study was to determine the time lapse between the opening of a sterile tray in an operating room and the occurrence of a first contamination of the surgical instruments as well as the rate of tray contamination based on exposure time. Three experimental groups, each completed using 15 trays, were conducted in order to reproduce various conditions in an unused operating room. The results revealed that the percentage of contaminated trays among those that were not covered increased with time of exposure to the ambient air (Table 2). Of the number of uncovered trays, eight trays out of 27 (29.6%) were contaminated after four hours of exposure to the ambient air (Table 2). The percentage of contaminated trays based on the other exposure times was 4% after 30 minutes, 15% after an hour and 22% after two hours. No bacterial contamination was observed in the experimental group without circulation of personnel where the surgical trays

Image 1. Document Selection Diagram



were covered after being opened. The authors concluded that the trays should not be opened until they are needed for the procedure. The potential for generalizing these results is rather limited considering the size of the sample and the experimental conditions that were not very representative of reality.

Clinical Guidelines

The main recommendations stemming from the selected guides associated with the maintaining of sterile fields and the opening of surgical trays are presented in Table 3. There is a consensus from the majority of the clinical guidelines to the effect that the instruments should be prepared as close as possible to the beginning of surgery. The minimum time interval to be respected between the opening of the surgical trays and the beginning of surgery is, however, not specified by any of these organizations. A review of these guides does not make it possible to state if the concept of opening surgical trays as close as possible to the time of surgery is intrinsically associated with the patient's presence in the room. This recommendation in particular, along with others, is based on the results of studies hampered by limitations in terms of methodology.[15-21] For example, the literature research methods as well as the methods used to prepare the recommendations are rarely mentioned by the authors.

DISCUSSION

The optimization of surgical processes is a key element in the ongoing improvement of services offered in operating rooms. The purpose of this current systematic review is to review the available data regarding the early opening of surgical trays before the patient's arrival in the operating room in terms of the risks and benefits that such a change in practice might entail.

The optimal moment for preparing surgical instruments before a surgery

The available data does not make it possible to determine the optimal moment for opening the surgical trays. In fact the recommendations included in the practice guides are unclear regarding the maximum time a sterile field can remain open to the ambient air without being used.[12-15] The data clearly states that surgical instruments should be prepared as close as possible to the time of surgery, without an acceptable time lapse being indicated. Without reducing the importance and relevance of the opinions of the experts who contributed in the development of these guides, most of them, with the exception of AORN,[12] did not mention their methodology for summarizing the literature or the method used to prepare their recommendations. The AORN recommendations regarding the opening of surgical trays are based on the results

Table 2. Rate and average time lapse for the bacterial contamination of the surgical trays observed after four hours of continuous exposure to the ambient air based on experimental conditions

Experimental Condition	Contaminated n (%)	Average time lapse for contamination in hours [CI at 95%]
Group 1 uncovered, without traffic (n = 13)	4 (30.7)	2.50 [1.80 to 3.20]
Group 2 uncovered, with traffic (n = 14)	4 (28.5)	2.37 [1.90 to 2.90]
Group 3 covered, without traffic (n = 15)	0 (0)	N/A

CI at 95%: confidence interval at 95%; N/A: not applicable

from seven original studies.[15-21] The majority of these studies focused on the risk of contamination associated with the environment, personnel traffic, or the wearing of surgical masks. However, the lack of a direct link with the contamination of the surgical trays in these studies raises questions regarding the strength of the evidence to support a recommendation on the optimal moment for preparing the surgical instruments for surgery. There is, moreover, little scientific literature specific to this subject with the document search having turned up only one experimental study.[11] The results from this study suggest that sterile instruments left in the ambient air present a low risk of contamination within the first 30 minutes of exposure in an unoccupied operating room.[11]These results are, however, based on a small number of replicates completed within a usage context that is different from that of an operating room. The nature of this study does not, furthermore, make it possible to evaluate the link between the contamination of surgical trays and the possible risk of wound infections.

Table 3. Summary of the recommendations associated with the preparation of sterile instruments for surgery stemming from clinical guidelines

Organization, year [ref]	Recommendations
AORN, 2015[12]	**A sterile field should be prepared for all patients undergoing surgery or any other type of invasive procedure.** • The field should be prepared where it is to be used and should not be moved (level 5). • The field should be prepared as close as possible to the time of use (level 1). **Sterile fields should be constantly monitored.** • A sterile field should not be left unmonitored until the operation is completed (level 5). • During periods of intense activity or unanticipated delays, the already-prepared sterile fields that have not been used can be covered with a sterile drape (level 2).
ORNAC, 2015[13]	• Allow the least amount of time to pass between the opening of the supplies and the beginning of the procedure. • Once a patient enters an operating room in which the sterile instruments have been prepared, these instruments must not be used in the event the surgery is cancelled. • Sterile instruments should not be left unmonitored after being opened. They should be constantly monitored for possible contamination. • Personnel deemed sterile should remain within the sterile zone and should not move around or leave the operating room. • Scrubbed personnel should remain near the sterile field and face it. Movements should be limited to between sterile zones only.
AST, 2011[14]	• Sterile surgical trays should be opened as close to the beginning of the surgery as possible. • Operating room equipment and supplies should be grouped and positioned before the opening of the sterile instruments. • Members of the surgical team should follow aseptic techniques when the sterile instruments and trays are open. • Traffic within and outside the operating room should be documented and controlled when the surgical team starts opening the sterile instruments.
CDC, 1999[15]	• The sterile equipment and solutions should be assembled immediately before being used (category 11*).

AORN: The Association of periOperative Registered Nurses; ORNAC: Operating Room Nurses Association of Canada; AST: Association of Surgical Technologists; CDC: Centers for Disease Control and Prevention

**Recommendation based on moderate-level data from clinical or epidemiological studies or a theoretic rationale.*

The ideal moment for the patient's arrival in the operating room

The patient's presence, before or after the beginning of surgical tray preparation, is not among the elements recommended by the organizations that developed the practice guides. It is possible that this element is intrinsically linked to the condition of opening the trays as close as possible to the time of surgery. The lack of clarification in this matter can, however, lead to different interpretations out in the field. A non-exhaustive survey, using a self-administered questionnaire regarding the process for opening of surgical trays, was completed in 12 Canadian hospital centres and revealed that the preparation of surgical instruments begins before the patient's arrival in the operating room with the exception of the health institutions surveyed in Quebec.[7] Survey data indicates, in fact, that the surgical instrument preparation procedure, in Quebec facilities, begins after the patient's arrival in the operating room.[7]

The current practice used in various Canadian and international hospitals seems to be more focused on opening surgical trays minutes prior to the patient's arrival in the operating room.[7] There are several questions regarding the opening of the surgical trays and the patient's arrival in the operating room. Would, for example, the patient's presence in the operating room, when the trays are opened, promote a reduction in personnel movement as the beginning of surgery approaches? Would introducing a practice for the early opening of trays before the patient's arrival make it possible to reduce the moving of sterile instruments or prevent leaving the patient unattended?[13] The information gathered as part of this evaluation project does not make it possible to answer these questions and explain the differences there might be in the organizational methods that are associated with the opening of surgical trays. It also cannot be ignored that the application of the operating room practice standards identified could be influenced by several factors such as the institution's organizational framework, the physical layout of the rooms, the availability of the instruments needed for the surgery, or the availability of nursing personnel.

The elements to be considered before looking at a change in practice

The decision to switch practices in the opening of surgical trays must be based on a range of factors, including personnel traffic in the operating room, how often the doors are opened, and how the room is organized to accommodate the equipment. The evidence currently available does not make it possible to determine the impact, of a change in the practice of opening surgical trays, on the SSI rate, the time lapse between the patient's arrival and the beginning of surgery, or the organization of work in the operating suite. An improvement in the patient experience and in the organization of the nurses' work could be potential benefits that might stem from such a change in practice. The early opening of the surgical trays could, in fact, allow the available external nurse to go get the patient, assist the anesthesiologist, and complete a count of the instruments needed for the operation. The data currently available does not, however, make it possible to verify the validity of these hypotheses. The efficiency gains and SSI rates in the operating suite are not, furthermore, influenced solely by the practice for opening surgical trays.

Within this context, before making such a change, it would seem prudent to complete a thorough evaluation of all parameters that might impact the integrity of the surgical drapes. Included among the factors to be considered are personnel movements and, indirectly, the opening of operating room doors. The recommendations covering the integrity of sterile surgical instruments indicate that personnel movements must be minimized and monitored once a tray has been opened.[12,13] Opening the surgical trays before the patient arrives in the operating room could increase the risk of instrument contamination if personnel traffic around the tray and the opening of doors are not minimized. In fact, according to the Centers for Disease Control and Prevention (CDC), the

The early opening of the surgical trays could, for example, require faster preparation in the room to minimize traffic.

frequent opening of doors as well as personnel movements contribute to the positive pressure changes observed in operating rooms.[15,19] The variations in positive pressure do suggest that personnel movements might contribute to an increase in the contamination risk of surgical trays left opened.[19] Although limited in scope, the experimental data available on this subject, taken from a study conducted in an environment where traffic was controlled, suggests that there might be a secure window of time since the risk of contamination within the first 30 minutes following the opening of the surgical trays is less than 4%.[11] The recommendations from the various organizations suggest that the option of opening the surgical trays before the patient arrives in the room would only be supported if traffic inside the operating room was controlled,[14] if the instruments were kept under constant surveillance after being opened[12,13,22] and if the instrument table was positioned in the place where it was to be used.[12,14]

Although there is no standardized model for the placement of equipment in an operating room, the layout of the rooms should, ideally, be designed to minimize unnecessary interactions between personnel, equipment, and the patient, while making it easy for personnel to move around.[23,24] Apart from room functionality, there are also various quality criteria that must be met in an operating suite, namely in terms of air quality and the quality of the work environment surfaces.[23,24] In terms of work organization it is generally accepted that the period of time just before the patient's arrival in the operating room is currently used for preparation and cleaning. The introduction of a new practice for opening trays must, therefore, take these factors into consideration in order to minimize the impact on work organization. The early opening of the surgical trays could, for example, require faster preparation in the room to minimize traffic.

A change in practice, whether in favour of the early opening of surgical trays or not, would invariably involve a modification of the organizational processes relating to the preparation of operating rooms which could certainly have an impact on the organization of the work teams, the human resources required, and the work schedules. High-volume surgeries that require fewer surgical instruments are probably the ones where the existing processes might more easily lend themselves to this optimization exercise in terms of changing the practice for opening trays. According to the experts consulted, however, surgeries that require the installation of a prosthesis (e.g. total hip prosthesis) or the placement of a graft should be excluded due to the increased protection measures needed to minimize the risk of surgical site infection for these types of surgeries. In the event where a health facility is looking to make a change in practice it would also be important, after conducting an analysis of the benefits and inconveniences, to consider indicator measurements to evaluate the efficiency gains and SSI rates associated with the surgeries for which a change of practice would be implemented.

CONCLUSION

Given the uncertainty of the infection risks and the lack of data regarding the benefits associated with the early opening of surgical trays, the decision to opt for a change of practice should be based on an analysis of all the factors unique to an operating suite in order to ensure the integrity of surgical drapes and patient safety at all times. A feasibility analysis, including a review of all processes and parameters for managing the risks associated with the early opening of surgical trays, is recommended before looking into such a change of practice. Several elements should also be considered, within the perspective that a change of practice might be possible, including the need to determine the level of monitoring associated with the surgical site infections for surgeries targeted by the change of practice.

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