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Development and implementation of an intraoperative documentation protocol for enhancing patient safety in the operating room: A mixed methods protocol study

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Abstract:

BACKGROUND: Documentation is an important part of the patient care process; however, there is no regular program for documenting intraoperative care in Iran. This study was conducted to design an intraoperative documentation for enhancing patient safety in the operating room (OR).

MATERIALS AND METHODS: This exploratory, mixed-methods, qualitative-quantitative study (in 2021) consists of four phases. The first phase involves a conventional content analysis of healthcare providers in the OR to identify the needs, strategies, and content of a pertinent documentation. In this phase, purposeful sampling will be used to collect data through semi-structured interviews. In the second phase, a literature review will be carried out to extract the documentation procedures in the intraoperative period in many other countries. In the third phase, a panel of experts is recruited and the classic Delphi (RAND) technique is run to validate the initial draft of the designed program and, the protocol is then finalized. In the last phase, the designed protocol will be implemented through a quasi-experimental study in one group (before and after intervention), and the effectiveness of the intervention will be evaluated.

DISCUSSION: To design a protocol for intraoperative documentation, healthcare providers' experiences during surgery in the Iranian healthcare setting, where the lack of documentation might forensically harm both the healthcare providers and the patients, will be explored. This information alongside some universal standards developed in other countries should help improve patients' safety in ORs.

Keywords:

Documentation, intraoperative, operating room, patient care, patient safety, protocol

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Background

Intraoperative care is a practice that requires effective cooperation between different healthcare providers with the assistance of various tools.[1] Documentation is one of the integral tools used to ensure the continuity of care and comparability of patient outcomes in the intraoperative period.[2,3] Intraoperative documentation has several advantages, such as facilitating access to all patient information, finding out the steps that have not yet been performed for the patient to complete the care plan, and providing an informational base for the management of hospital expenditures and staffing procedures.[1,4,5] Intraoperative documentation establishes a communication system among healthcare providers.[6]

Documents and documentations are also important in disclosing events that might lead to serious injury to the patients. The results of a study by Maraki *et al*. (2019) showed that the

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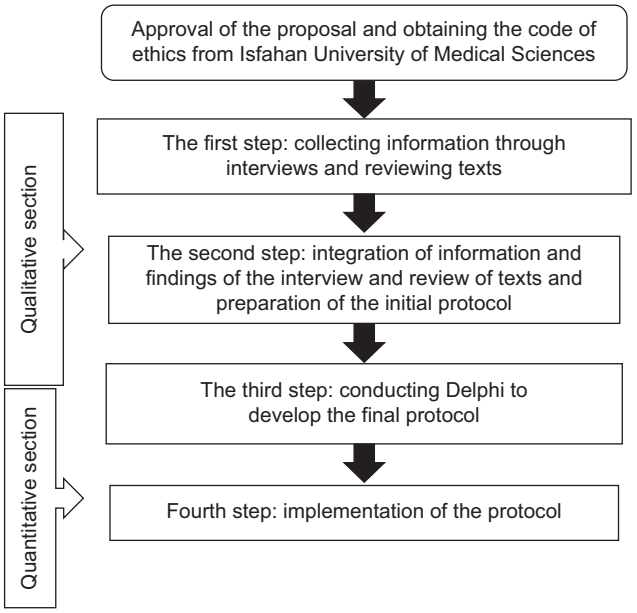

Figure 1: Diagram of study steps

operating room (OR) staff's use of a new documentation system effectively decreased their apathy towards reporting errors over two months.[7] According to the Australian sentinel events list, in 2017, 16% of all sentinel events in the OR were related to verbal and written communications. Nonetheless, hospital policies and procedure guidelines included only 43% of these sentinel events.[6]

Several ways have been recommended to help improve intraoperative documentation. First, the operational standards of procedures should be studied; however, implementing standards without using proper checklists is not a secure practice.[7-10] The Association of intraoperative Registered Nurses (AORN) has recommended using the Intraoperative Nursing Data Set (PNDS).[11] According to the PNDS, when, for example, the skin is prepped for surgery, the following documentation information is required: type of skin prep, type of solution, site on the body, and name of the person who has done the prepping.[11,12] The completed checklists must contain signs of alteration, improper use of medical abbreviations, and other types of deficiency that occur based on personal biases during documentation which make these forms illegal.[13-15] Since intraoperative documentation is a poorly performed practice in Iran, the innovation of our study will be the preparation of a protocol for recording information during surgery. This exploratory mixed-methods study is designed and will be performed to establish a protocol for intraoperative documentation for enhancing patient safety in the OR.

Materials and Methods

Study design and setting

This exploratory, mixed-methods, qualitative-quantitative study (in 2021) consists of four phases.

Study participants and sampling

This study will be conducted in two major governmental hospitals with 40 ORs in Isfahan. The word "intraoperative" mainly signifies the intraoperative period in this study, since it comprises a period with the most unacceptable documentation practices in Iran. We follow the program development and evaluation model of Talbot and Verrinder in this research.[16]

Data collection tool and technique

The design of the program [Figure 1] and its implementation will take place as follows:

Phase I: Qualitative research (evaluating the needs and protocol strategies).

We will conduct qualitative research with the aim of exploring the needs, experiences, and strategies regarding a documentation protocol using deep interviews. This phase of the study is set in two major teaching hospitals in Isfahan. All the interviews will be conducted in a calm and private environment based on the participant's preferences. After analyzing the data by conventional content analysis, the protocol needs and strategies will be extracted.

The participants in the qualitative phase of this study are made up of intraoperative healthcare providers (surgical technologists, OR nurses, surgeons, and anesthesiologists). These participants will be selected by purposive sampling with maximum variation in terms of work experience, education, experience working in the OR, and history of exposure to errors, and based on the inclusion and exclusion criteria, any eligible candidates will be interviewed. The interviews will continue until no new information can be obtained and data saturation is reached.[17]

Inclusion and exclusion criteria

In the qualitative phase of the research, all the healthcare providers with at least six months of consecutive work experience in the OR will be selected.

Qualitative data collection and analysis

In the qualitative phase, data will be collected through deep interviews and field notes. To observe the ethical principles of research, the aim of the study will be explained to all the participants and informed written consent will be obtained from them for recording their voices. The time and length of the interviews and the setting will be determined based on each participant's preference. Data will be analyzed using conventional content analysis. First, the meaning units will be determined; then, the meaning units will be coded, and the codes will be condensed; finally, the codes will be categorized into sub-categories and main categories.[18]

To ensure the trustworthiness of the data, four criteria will be observed, including credibility, dependability, confirmability, and transferability.[19]

Phase II: A literature review will be conducted to retrieve any documenting care procedures performed during the intraoperative period in other countries. To find relevant information, a search will be carried out in both Iranian and international databases, including Pubmed, Scopus, Web of Science, CINAHL, ProQuest, Magiran, SID, Noormags, and ISC. The papers published between 2000 and 2021 in Persian and English will be included. Studies focusing on subjects other than documentation in ORs and studies without full-text access are excluded.

To start the review process, first, suitable keywords are identified using Mesh, SNOMED, Embase, and other relevant sources. A specific search strategy for these databases will then be made and followed by the researchers through guidance from three experienced medical librarians. After removing the duplicates, the title and abstract of the retrieved articles will be reviewed by two researchers according to the inclusion criteria. In the case of disagreement between the two assessors, the articles will be reviewed by the third researcher.

Publications by intraoperative associations such as AORN and the Association of Surgical Technologists (AST) and other relevant associations about intraoperative documentation will also be searched. The preference is for publications in countries that are more dominant in intraoperative care and publish research papers in English, such as the United States, Canada, Australia, the United Kingdom, and Scandinavian countries. As Turkey is a country that is most similar to Iran in terms of the number of research publications and some cultural characteristics, this country will also be one of the options for the publications' origin. The results of this review will demonstrate the gap between the present and the desired situation and also help provide a protocol that is closer to the standards.

Phase III: Design and validation of the protocol.

In phase three, the priorities of the protocol will be developed based on the results of the first and second phases of the study. First, the objectives and the operational program for achieving each objective will be developed. Then, using the Delphi (RAND) method, the validity of the protocol will be evaluated.

Holding a panel of experts

In this stage, the classic Delphi method will be used to evaluate the final version of the protocol's initial draft and determine the protocol priorities and experts' consensus. The members of the panel will consist of OR head nurses/supervisors/key personnel, faculty members of OR departments, and medical faculty members. The protocol is expected to be finalized after four rounds. In the first round, an electronic version of the protocol (or hard copies just in case) together with open-ended questions will be sent to the panel members' email addresses. These questions intend to get the written comments of the experts about the components and details of the protocol. Likert items will be used for the responses, such as essential, relevant, non-essential, and irrelevant. In the second round, after collecting the experts' written feedback, the content analysis method will be developed and the experts' opinion will be applied. Then, in the third round, the modified version along with an assessment checklist will be sent to the members via email. After the collection of their opinions, the final modified version will be given to the experts as the fourth round.

Phase IV: Implementation of the protocol as an intervention (quantitative research).

In this phase, quantitative research will be conducted with one group in two stages before and after intervention carried out in the field.

Study sample

The study is set in two major teaching hospitals in Isfahan, including Al-Zahra Hospital and Ayatollah Kashani Hospital. The target population consists of OR personnel with bachelor's and associate degrees in surgical technology or OR nursing who work both in scrub and circulate roles. The samples will be selected randomly and the before-after design will be adopted. Considering a confidence interval of 95%, test power of 90%, and least mean differences of 0.8S between the groups, the number of samples in each group will be 32. The total sample size is 70.

Inclusion and exclusion criteria

The inclusion criteria are willingness to participate in this phase of the study, any disclosed mental or emotional disturbances, and work experience in the OR in both scrub and circulate roles for at least six months. The exclusion criteria for this part of the study are unwillingness to participate in the intervention sessions, and not completing the questionnaire fully.

Data collection method

The intervention in this step consists of implementing the newly designed documentation protocol continuously for at least two months in both hospitals. Variables that will be evaluated before and after the intervention and one month after intervention are related to patient safety and include demographic characteristics (work experience in the OR, overall work experience, and work site based on the surgery field), conditions governing the workplace (extra work hours, sufficient number

of personnel, etc.), attitude toward the workplace OR, attitude toward the workplace hospital, characteristics of the manager or supervisor, communication with peers, number and frequency of reported errors in the OR, and patient safety grade. For assessing these variables, version 2 of the Survey on Patient Safety (SOPS) will be used in both groups before and after the intervention. This survey is a self-reported tool with 12 main items and 3 to 18 sub-items for each variable. Most items are scored on a Likert scale from 1 to 5 with the options being *never, seldom, sometimes, often*, and *always*, or *completely disagree, disagree, neither agree nor disagree, agree*, and *completely agree*. Scoring is based on the percentage of positive responses. All the options except *neither agree nor disagree* will be added separately for each sub-item, then divided by the sum of the responses to that sub-item, and then divided by 100. The mean percentages for all the sub-items are thus obtained as total percentages for each main item. This way, the *neither agree nor disagree* options will be extracted and reported separately. The validity and reliability of this tool have been confirmed by the Agency for Healthcare Research and Quality (AHRQ).[20]

Data analysis

Data will be analyzed in IBM SPSS Statistics for Windows, Version 19.0. Armonk, NY: IBM Corp using descriptive and inferential statistics. First, the normality of the data distribution will be evaluated by the Kolmogorov–Smirnov test. Then, the independent *t*-test will be used for comparing the quantitative variables, non-parametric statistical tests including Mann–Whitney's U-test and the Kruskal–Wallis test will be used for the qualitative variables, and the Chi-square test for the nominal qualitative variables. A repeated-measures multivariate analysis of variance (ANOVA) will finally be used to compare the mean score of patient safety from the perspective of the OR personnel on three occasions, including before, after, and one month after the intervention.

Ethical consideration

Before data collection, ethical approval was obtained. The Ethics Committee of Isfahan University of Medical Sciences in Isfahan, Iran, approved this research with the number IR.MUI.NUREMA.REC.1400.080. Participation was voluntary and participants could withdraw consent at any time.

Discussion

Poor documentation or non-documentation of the activities during surgery may impede patient safety and the establishment of a secure legal authority for healthcare providers in the OR. Meanwhile, using a simple WHO surgery safety checklist can decrease the death rate in the OR from 1.5% to 0.8%.[21] Therefore, the development of a written protocol for intraoperative documentation can modify or solve these problems.[22] A comprehensive and well-applicable protocol for intraoperative documentation is not valid without understanding the needs and experiences of healthcare providers concerning intraoperative events and the essential items that have to be documented in the intraoperative period.[23] By analyzing these needs and experiences, appropriate items that directly or indirectly affect patient safety during surgery will be identified in this research, and a protocol will then be designed based on the Iranian context. Literature has also shown that protocols developed based on the assessment and identification of needs and experiences are more successful.[16] International standards of care and documentation protocols will also be scrutinized and they will be adjusted to the present findings. Attempts for implementing interventions to change the practices, attitude, and knowledge of OR personnel can help increase patient safety in the intraoperative period and support legal aspects,[24] but evidence on this subject is insufficient.

The discussed protocol will be designed based on the needs and experiences of healthcare providers in the OR and it will be adjusted to the Iranian context. This protocol will also provide firm information about intraoperative documentation strategies. It also seems to be appropriate for countries with similar social and cultural backgrounds as Iran, such as some neighboring countries and West Asian countries, although many of the developed strategies may apply to other countries as well. This research thus seeks to develop strategies that apply to not only countries near Iran, but others as well. The designed protocol might have enough capacity for maintaining and improving both patients' and healthcare providers' safety in the OR.

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Ethics approval and consent to participate

We declare that to observe the ethical principles of research, the aim of the study will be explained to all the participants and informed written consent will be obtained from them for participation.

The Ethics Committee of Isfahan University of Medical Sciences in Isfahan, Iran, approved this research with the number IR.MUI.NUREMA.REC.1400.080.

Abbreviations

AORN: Association of intraoperative Registered Nurses
AST: Association of Surgical Technologists
PNDS: Intraoperative Nursing Data Set
AHRQ: Agency for Healthcare Research and Quality.

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Conflicts of interest

There are no conflicts of interest.

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