





## Practising ISBAR approach in preoperative handover by using desktop VR: Content adaption, Usability Testing and A Randomized Controlled Trial

Protocol

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## Practising ISBAR approach in preoperative handover by using desktop VR: Content adaption, Usability testing and A Randomized Controlled Trial

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## **1.0 INTRODUCTION**

### 1.1 Background

The exchange of relevant clinical information from one provider to another is crucial for the surgical pathway (Nagpal et al., 2012). Structured and precise communication is essential for good cooperation between health care providers to avoid necessary information get lost (Haig et al., 2006; Leonard et al., 2004). Missing information and incorrect data transfer can lead to adverse patient outcomes (Nagpal et al., 2012). Poor communication among health care providers has been identified as the third leading root cause of sentinel incidents (The Joint Commission, 2016). Although there is limited high-quality research investigating whether handover techniques have an impact on patient-related outcomes in nursing care (Bukoh & Siah, 2020; Rosenthal et al., 2018), structured handovers are effective in reducing the number of mistakes in information transfer (Bukoh & Siah, 2020; Müller et al., 2018).

Different types of structured communication tools have been developed for handover (Bukoh & Siah, 2020; Mardis et al., 2016). The Information-Situation-Background-Assessment-Recommendation (ISBAR) instrument provides a method for consistent, structured communication between healthcare providers (Müller et al., 2018). ISBAR was introduced by airline crew programs for effective team communication and was later adopted by the hospital in 2002 at Kaiser Permanente of California as part of fostering a culture of patient safety (Haig et al., 2006). The ISBAR approach constitutes a generic, transferable non-technical skill (McCabe & Timmins, 2013), also needed in inter-and interprofessional collaboration with patients who undergo surgery (Kitney et al., 2018; Kitney et al., 2016; Nilsson et al., 2020). The goal of ISBAR is to achieve increased patient safety by providing necessary and accurate information. Through a structured communication, the participants can share the same mental models when caring for patients (Shahid & Thomas, 2018). ISBAR can improve communication (Jeong & Kim, 2020; Raurell-Torredà et al., 2021) and reduce communication errors (Randmaa et al., 2014). ISBAR is used as a communication tool in Norway today (Helsedirektoratet, 2020) and is an integrated part of the curricula in nursing education.

Earlier studies investigating the effect of structure communication through the ISBAR approach have mainly investigated satisfaction among the users (Müller et al., 2018). Few studies have investigated the effectiveness of teaching methods (Jeong & Kim, 2020). A systematic search done for this project identified one RCT study (Raurell-Torredà et al., 2021), one single-blinded randomized control pretest-posttest study (Jeong & Kim, 2020), and one randomized posttest with a comparison group (Lanz & Wood, 2018). Thus more studies are needed.

Communication tools like ISBAR can also be learned using digital technology as emphasized in the Norwegian Government Digitalization Strategy for the university and college sector 2017-2021 (The Norwegian Ministry of Education and Research, 2017): "through digitalization, new opportunities will be created for new and changed learning and teaching processes" (p. 5). One example is desktop virtual reality (VR) which is a three-dimensional computer environment where the users can interact with an environment displayed on a computer monitor with a mouse, keyboard, and a screen on a computer/laptop/tablet (Shorey & Ng, 2020).

Desktop VR is typically built around user interaction, such as typing commands and interacting with others in the group-practicing. The advantage of desktop VR is the potential for letting users practice without supervision while receiving audio and visual instruction and instant feedback from the VR itself in a safe environment (Shorey & Ng, 2020). The development of active learning forms through desktop VR aligns with research studies recommending interactive teaching strategies curricula (Horntvedt et al., 2018). COVID-19 and resulting campus lockdowns have created challenges for nursing students' learning opportunities (Morin, 2020; Ulenaers et al., 2021). Increased numbers of nursing students being educated in nursing programs also show the need for effective and practical group-based learning in nursing education programs.

Previous, a version of the ISBAR web application has been developed by members of the research group for this project (<u>www.virsam.no</u>). In this project a Preoperative ISBAR desktop VR will be built based on this existing version. The pedagogical approach is based on the student-centered theory of *Constructive alignment* (Biggs, 2001). *Constructive* refers to the theory that the students construct meaning through relevant learning activities and *alignment* refers to the teaching and learning situation. Alignment is achieved when the designed learning activity is devised to fit the learning outcome and the assessment (Biggs & Tang, 2007). The Preoperative ISBAR desktop VR is thus developed to address the need for effective student-centered learning.

Usability is an essential component of good practice in developing a product (Rubin & Chisnell, 2008). The International Organization for Standardization has defined usability as "the extent to which a product can be used by specified users to achieve specified goals with effectiveness, efficiency and satisfaction in a specified context of use" (Bevan et al., 2016). Systems should be intuitive and easy to use for the end-users, and perceived usability is an essential determinant for successful implementation (Rubin & Chisnell, 2008). Thus, investigating the usability is a central part of developing The Preoperative ISBAR desktop VR.

## 1.2 Aims of the project

This project is part of the larger research project "Learning activities for undergraduate nursing students who are learning pre- and postoperative nursing". In the larger research project, a scoping review has been conducted to systematically map and summarize learning activities for undergraduate nursing students who are learning pre- and postoperative nursing prior to clinical placement (Andreasen, Slettebø & Opsal, 2021, in review). This work, together with the project described in this protocol, will constitute a PhD project.

The overall aim of the project described in this protocol concerns the development and testing of the effect of a desktop VR application to practice ISBAR communication along a

preoperative patient pathway. This will be investigated in two studies with the following aims:

- 1. To describe the development of a desktop VR application to practice preoperative ISBAR communication and evaluate the usability. The specific research question is: What are the number, type and severity of usability issues evaluated by second-year nursing students in terms of effectiveness, efficiency and satisfaction?
- 2. To investigate the effect of a desktop VR application to practice preoperative ISBAR communication compared to traditional teaching methods. The specific research question is: *Does practicing preoperative ISBAR approach in a web application provide a non-inferior learning outcome compared to a traditional group practicing for second-year nursing students?*

## **2.0 METHODS**

To answer the research questions, two different studies will be conducted, a qualitative study (aim 1) and a randomized controlled trial (aim 2)

## 2.1 Qualitative study (aim 1 - usability)

#### 2.1.1 Study design

This study has a qualitative study design with two interlinked activities.

Activity 1 includes developing the Preoperative ISBAR on desktop VR based on the already existing ISBAR Web Application (prehospital version from <u>www.virsam.no</u>). This will be done iteratively along with the usability tests, and in continuous dialog within the research group and between the research group and the programmer.

A report from Immersive Healthcare Collaboration (2020) has highlighted three aspects which is lacking in the development of immersive healthcare training. These aspects have been considered in when designing this project. Firstly, design and development have been driven by learning needs. Secondly, implementation will go together with rigorous evaluation, and lastly, collaboration have been fostered to ensure efficient and effective use of immersive technology.

In activity 2, end-users will test the usability of Preoperative ISBAR on desktop VR. The methodological method used will be think-aloud, questionnaire, and student interviews. These methods will be suitable for collecting data on the students' practical use of Preoperative ISBAR desktop VR and providing insight into usability issues.

The study design ensures that the end-users are actively involved in the development stage before the solution is used in the randomized controlled trial to test the learning outcome of the Preoperative ISBAR desktop VR with a larger sample of participants (aim 2).

#### 2.1.2 Participants and recruitment

Activity 1: The main participants will be the research group and the programmer. In addition, an expert panel will be used in the content revision process of the ISBAR web application. Three nursing teachers, two doctors, and one nurse will be asked to join an expert group and give their opinions about the web application and proposed changes. They will be recruited through the network of the research group members, ensuring that those recruited do not have any impartiality issues with the members of the research group.

**Activity 2:** The aim is to include second-year nursing students. The recruitment of students will be done at the Department of Health and Nursing Science at the University of Agder, Norway. The participants will be nursing students in their second study year. A purposeful sample of ten participants is considered adequate for robust usability testing (Virzi, 1992). Still, as the training is organized in groups of three, nine will be the number of participants. Recruitment will be purposive sampling to ensure variation in age, gender, and anticipated digital competence. A variety of students can enhance the generalizability of results (Rubin & Chisnell, 2008).

#### 2.1.3 Data collection

In activity 1, the data collected will consist of notes from the meetings in the research group and with the programmer, and the meetings in the expert panel. The focus of the data collection will be on the arguments used for suggesting and deciding on the chosen solutions.

In activity 2, The data collection will be conducted accordingly to (1) the think-aloud method, (2) the questionnaire, and (3) a focus group interview, as described in detail below.

#### Think-aloud method

Think-aloud is a research method in which participants speak aloud any words in their mind as they complete a task and provide a valuable source of data about participant thinking (Charters, 2003). Each training participant will be placed in a separate room with a researcher collecting the data during a predefined task. First, the researcher will ask background questions about age, gender, comfort with technology and knowledge about ISBAR (Appendix 1). Secondly, the participants will be encouraged to think aloud, i.e., to verbalize their thoughts and respond to the tasks constantly. If the students are unsure how to proceed, they will be encouraged to do what they will find most intuitive before being assisted by the researcher. Data will be collected by three researchers observing the students as they use the desktop VR. Filed notes will be made based on a predefined observation template covering navigation errors, ease of use, apparent misunderstandings, or technical difficulties (Appendix 1). Each think-aloud session will be video recorded. After task completion, each student will take part in a questionnaire.

#### Questionnaire

The System Usability Scale (SUS) questionnaire (Bangor et al., 2009) will evaluate user satisfaction and comprises 11 open-ended questions (Appendix 2). The average scores will be categorized based on ratings.

#### Focus group interview

After the think-aloud session and questionnaire, the participants from the same group will gather in a room and participate in a focus group interview. An interview guide explicitly designed for this study will be followed (Appendix 3), systematically developed based on the research question and usability theory (Castillo-Montoya, 2016; Rubin & Chrisnell, 2008). The interview will also address specific usability issues that will be observed when the participants did the predefined task. The same guide will be followed for all participants. The interview sessions will be audio recorded.

#### 2.1.4 Analysis

Descriptive statistics measured from the think-aloud session and data from the SUS questionnaire will be categorized in IBM SPSS Statistics for Windows, version 27 (IBM Corp). Qualitative data from the focus group interviews will be transcribed verbatim and NVivo for Windows (QSR International Pty Ltd, version 18, 2021) will be used for managing the transcript data. Qualitative data will be analyzed using deductive content analysis (Elo & Kyngäs, 2008). Collected data will be coded according to the predefined categories. Predefined categories are usability issues in terms of effectiveness (task completion, navigation errors, ease of use, apparent misunderstandings, technical difficulties), efficiency (fatigue), and satisfaction (Bevan et al., 2016). Each issue will be graded on a scale from 1 to 4 (I = irritant, 2 = moderate, 3 = severe, and 4 = unusable) (Rubin & Chisnell, 2008). The grading will be done by two of the authors (EMA, KH) and independently and subsequently discussed until consensus will be reached on each issue of divergence.

#### 2.2 Randomised controlled trial (aim 2 - effect)

#### 2.2.1 Study design

The study design will be a non-inferior, parallel-group randomized controlled trial (RCT). As web applications may have some disadvantages compared to real-life skill practice, the study will be conducted as a non-inferior study (Piaggio et al., 2012). The *Reporting of Noninferiority and Equivalence Randomized Trials. Extension of the CONSORT 2010 statement* (Piaggio et al., 2012) have been used to guide the design phase and will be used

throughout the reporting process. The study will be registered in www.clinicaltrials.gov before data collection for the RCT is started.

#### 2.2.2 Participants and recruitment

The inclusion criteria will be second-year nursing students at one of the two campus sites of the Faculty of Health and Nursing Sciences, University of Agder.

The students will be informed both oral and written a week before and at the start of the session. The students who attend the session will be eligible and those who consent will be included in the study.

#### 2.2.3 Randomization and allocation

The participants will take part in a teaching program integrated into their curriculum. As a part of this study, they will be randomized into groups of three who then are randomized to take part in two different types of practicing the ISBAR approach. The group size of three is based on earlier studies reporting no difference in performance between groups of three, four, or five (Rezmer et al., 2011).

The participants will be organized in groups of three with a predefined group number that will be given to them before they start practicing.

Randomization will consider the practical organization of the teaching, which includes batches of students which must be allocated at separate times. For randomization, separate lists will be prepared for each batch using the Microsoft Excel RAND function. The lists will be printed on identifying stickers with identification (ID) numbers and codes for the type of practice in which the students were to participate. The allocation will be done by asking each student entering the classroom to sequentially seat themselves at the desk with the lowest available ID number. They will not be informed about what the allocation codes on their stickers mean.

After the introduction, the participants will be informed about where to go for their training according to the allocation codes on their stickers by the person in charge of the session. The instructors for the self-practice part will not influence the allocation and will ensure that they get students with the correct allocation.

#### 2.2.4 Interventions

The teaching session will include 20 minutes of introduction, 45 minutes of self-practice, and approximately 20 minutes of individual testing. The introduction session and the test will be the same for all participants.

For the participants allocated in the intervention group, each participant will be placed in a separate room to practice Preoperative ISBAR through desktop VR on their own pc/mac.

The participants allocated to traditional group practice will receive a printed sheet with the same patient case and ISBAR instructions as the intervention groups They will be informed to practice in a group of three. The traditional training will consist of giving oral handover to each other with the ISBAR structure and chose which content is relevant from the printed sheet when giving handover.

The minimum help from the instructors in both groups will be given to reflect a self-training situation.

#### 2.2.5 Data collection

For both the control and intervention groups, the data collection will be done digitally on their own pc/mac in Microsoft Forms before and right after the interventions.

#### 2.2.6 Outcome measures

The primary learning outcome is to keep the order of the ISBAR structure, include relevant content within a time frame of five minutes or shorter. The outcome measures are the content and structure of ISBAR and time spent solving the task. A digital test will be used to measure the main outcome. The candidate receives a written patient case in one Word document and a blank Word document. The candidate must retrieve the ISBAR information from the case and structure it in the correct ISBAR order in the blank Word document. The ISBAR letters are not visible, and the candidate must remember ISBAR. A time limit of five minutes will be prespecified as the maximum time for the participant to score correctly.

Additional outcomes will be the participants' experience, self-perceived learning outcome, and level of engagement with the desktop VR training (System Usability Scale (SUS) questionnaire (Bangor et al., 2009).

In addition data on background (age, gender, and knowledge about ISBAR) will be collected to describe the sample.

#### 2.2.7 Statistics

For the sample size calculation, a non-inferior limit of 13% points is chosen based on other studies on clinical observation (Berg & Steinsbekk, 2021; Curran et al., 2015; Mpotos et al., 2014), expecting that 20% will have everything correct due to structure and content (Berg & Steinsbekk, 2021). With a power (1-B) of 80% and a significance level (alpha) of 0.05, 118 participants are needed in each group (Sealed Envelope Ltd., 2012), and a total of 250 students will be recruited.

The analysis will be conducted using a two-sample test of proportions for continuous variables and an independent samples t-test for categorical data. The absolute difference will be presented. The usual arguments that intention to treat (ITT) is the best approach in superior studies do not apply to non-inferior studies. The recommendation is to use per-protocol analysis and ITT as a sensitivity analysis. All analyses will be performed using IBM Statistical Package for the Social Sciences (SPSS) version 25.0 (IBM Corp). The data will be stored securely on a password-protected computer without connecting the data and personally identifiable information. The data will be available after project completion.

## 2.3 Ethical considerations

The seven ethical requirements will be considered and discussed during all stages of the research project (Emanuel et al., 2000): 1) value of the project, 2) scientific validity, 3) fair subject selection, 4) favorable risk-benefit ratios, 5) independent review, 6) informed consent, and 7) respect for enrolled subjects. For both studies participants will receive oral and written information about the study's purpose, confidentiality, and anonymity (see student participant information letters). Informed consent will be obtained from all individual participants included in the study. Participants will particularly be informed about their right to withdraw without sanctions. Further, participation or withdrawal from the research project will not affect the students' overall assessment.

We will report the project to the Norwegian Centre for Research Data and the Faculty Ethics Committee at the University of Agder (FEK). The study does not fall under the Health Research Act and is considered non-contributory to the Regional Committee for Medical Research Ethics (REK).

The project design ensure that the end-users are actively involved in the development stage by identifying usability-issues. To compensate for the students' participation in the usability study, a gift card at 100 NOK from the university cafeteria will be given to each participant.

# **3.0 PROJECT PLAN, PROJECT MANAGEMENT AND DISSEMINATION**

Project timeline		2021			2022			2023					
		Q 1	Q 2	Q 3	Q 4	Q 1	Q 2	Q 3	Q 4	Q 1	Q 2	Q 3	Q 4
Ethical approval													
Usability study	Planning												
	Data collection												
	Analysis												
	Writing												
RCT study	Planning												
	Data collection												
	Analysis												
	Writing												

#### Table 1. Project timeframe.

Note: Q = quartal year

Table 1 shows the timeframe of the project. The project is a part of Eva Mari Andreasen's doctorate and are connected to the Faculty of Health and Sport Sciences and the research group HEIFA, University of Agder (UiA), and the Faculty of Medicine and Health Sciences, Norwegian University of Science and Technology (NTNU), Norway. The Faculty of Health and Nursing Sciences, University of Agder (UiA), funds the doctorate. The Faculty of Medicine and Health Sciences, the Norwegian University of Science and Technology (NTNU), pays for the web application.

The main supervisor in this project is Professor Kristin Haraldstad, and the co-supervisor is Professor Rune Høigaard. Co-authors are Professor Aslak Steinsbekk and Associate Professor Helen Berg.

The results will be shared in an open-access scientific journal, for example, BMJ Open with the titles *Practicing ISBAR approach in preoperative handover by using desktop VR: Content adaption and Usability Testing* and *The effect of self-practicing preoperative handover ISBAR by using desktop VR versus traditional teaching: a randomized controlled trial.* 

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## Appendix I. Observasjonsskjema – brukbarhetstest

Observatør:	Dato:	Tid: (fra) (i	til)
Produskt som testes:	Testleder:		
Testperson:	Alder:	Kjønn:	
Teknologisk kjennskap (1-4 hvor fire er bes	st):		

Har deltaker deltatt på obligatorisk undervisning i 1. og 2. studieår om ISBAR (kryss av)?

\_\_\_\_ja \_\_\_\_nei

Tid	Type problem	Årsak	Antall	Alvorlighetsgrad (1-4)*	Forslag til løsning
	Navigasjon				
	Utfordringer med å bruke				
	Misforståelser				
	Tekniske problemer				
	Annet?				

\*Merk: (1 = distraherende, 2 = moderat, 3 = alvorlig, and 4 = ubrukelig) (Rubin & Chisnell, 2008).

## Appendix II. Spørreskjema Velg ett svaralternativ for hvert utsagn:

Utsagn	Helt ue	nig 1	2	3	3	4	Helt enig 5
Jeg tror jeg ønsker å bruke dette systemet ofte	0		0	C	)	0	0
Jeg fant systemet unødig komplisert	0		0	C	)	0	0
Jeg synes systemet var enkelt å bruke	0		0	C	$\mathbf{D}$	0	0
Jeg tror jeg vil trenge støtte fra en teknisk person for å kunne bruke systemet	0		0	C	)	0	0
Jeg fant de ulike funksjonene i dette systemet godt integrert (hang godt sammen)	0		0	C	)	0	0
Jeg synes det var for mye inkonsistens (uoverensstemmelser) i dette systemet	0		0	(	С	0	0
Jeg forestiller meg at de fleste vil lære seg å bruke dette systemet svært raskt	0		0	C	)	0	0
Jeg fant systemet tungvint å bruke	0		0	C	C	0	0
Jeg følte meg veldig trygg ved bruk av systemet	0		0	C	)	0	0
Jeg trengte å lære mange ting før jeg kunne komme i gang med dette systemet	0		0	(	)	0	0
Totalt sett vil jeg vurdere brukervennligheten av dette produktet som	Verst tenkelig	Fryktelig	Lite	Ok	God	Utmerket	Best tenkelig

## Appendix III. Intervju guide

- 1. Hva likte du best ved å bruke Preoperativ ISBAR desktop VR?
- 2. Hva likte du minst ved å bruke Preoperativ ISBAR desktop VR?
- 3. Kan du foreslå noen endringer for å forbedre produktet knyttet til:
- 4. Navigering?
- 5. Utfordringer med å bruke?
- 6. Misforståelser?
- 7. Tekniske problemer?
- 8. Var det noe som gjorde deg utmattet under læringsaktiviteten? Hva var grunnen til utmattelsen?
- 9. Dersom du anbefaler denne måten å lære på til andre, hva er grunnen til det?
- 10. Har du andre kommentarer?

## Appendix IV. Spørreskjema RCT

Microsoft Forms Microsoft Forms