

Study Title: Clinicians' cognitive process and desired computerised support needs when facing postoperative complications on the ward – a qualitative study

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Confidentiality Statement

This document contains confidential information that must not be disclosed to anyone other than the authorised individuals from the University of Oxford, the Investigator Team and members of the Medical Sciences Interdivisional Research Ethics Committee (MS IDREC), unless authorised to do so.

TABLE OF CONTENTS

1.	SYNOPSIS	3
2.	ABBREVIATIONS.....	3
3.	BACKGROUND AND RATIONALE	4
4.	OBJECTIVES AND OUTCOME MEASURES	5
5.	STUDY DESIGN	5
6.	PARTICIPANT IDENTIFICATION AND RECRUITMENT	6
6.1.	Study Participants.....	6
6.2.	Inclusion Criteria	6
6.3.	Exclusion Criteria	6
7.	STUDY PROCEDURES.....	6
7.1.	Procedure outline.....	6
7.2.	Recruitment.....	7
7.3.	Discontinuation/Withdrawal of Participants from Study	7
7.4.	Definition of End of Study	7
8.	STATISTICS AND ANALYSIS.....	8
8.1.	The Number of Participants	8
8.2.	Analysis of Outcome Measures	8
9.	DATA MANAGEMENT	8
9.1.	Access to Data	8
9.2.	Data Handling and Record Keeping	8
10.	ETHICAL AND REGULATORY CONSIDERATIONS	9
10.1.	Approvals.....	9
10.2.	Participant Confidentiality.....	9
10.3.	Expenses and Benefits.....	9
11.	PUBLICATION POLICY	9
12.	REFERENCES.....	10
13.	APPENDIX A: INTERVIEW PROTOCOL – JUNIOR CLINICIANS.....	11
14.	APPENDIX B: INTERVIEW PROTOCOL – SENIOR CLINICIANS.....	13
15.	APPENDIX C: AMENDMENT HISTORY	15

1. SYNOPSIS

Long Study Title	Clinicians' cognitive process and desired computerised support needs when facing postoperative complications on the ward – a qualitative study	
Nature of Study Participants	Surgical trainees and consultants at the Oxford University Hospitals NHS Foundation Trust and neighbouring trusts	
Intended number of participants	12 (6 juniors, 6 seniors)	
Planned Study Period	November 2020 to maximum October 2021	
	Objectives	Outcome Measures
Primary	To qualitatively describe the perceived cognitive challenges faced when attending a patient presenting with postoperative complications, highlighting the differences between junior and senior clinicians.	Domain experts' opinion and interview transcripts
Secondary	To produce a list of desired support modalities, and to identify discrepancies between needed support and commonly published CDSS in the literature.	Domain experts' opinion and interview transcripts

2. ABBREVIATIONS

ACTA	Applied cognitive task analysis
CDSS	Computer-aided decision support system
CT	Core Training
OUH	Oxford University Hospitals Foundation Trust
ST	Specialty Training
ML	Machine Learning

3. BACKGROUND AND RATIONALE

Clinical decision support systems (CDSS) offer opportunities to improve physicians' ability to acquire and analyse patient data. Beside the optimal display of routinely collected information, the progress of advanced computer analytics and machine learning has opened a new era of advanced information processing, with the potential to enhance physicians' understanding of a case and improve their decision-making. Automatic risk assessment, diagnosis suggestions and tailored treatment recommendations are examples amongst others. However, the exact support needs of surgeons facing postoperative complications on the wards have not been studied in detail so far and neither have been their expectations regarding possible CDSS outputs. This last point despite numerous authors highlighting synergetic human-computer interaction and a good integration in practitioners' workflow as essential characteristics of any future efficient CDSS (1)(2)(3)(4). The results of this study will provide important information to understand the differences in decision-making process between novice and experienced surgeons. In relation to other works being conducted to develop an algorithm supporting junior doctors' management of postoperative complications, the results will be used to inform the most appropriate CDSS outputs.

Several studies have investigated physicians' information display needs in order to design software appropriately in other settings, such as general wards (5)(6), the operating room and post-anesthesia care unit (7), and the neonatal ICU (8). However, these studies focused on univariates and did not investigate the complex information needs linked to task specific cognitive processes. In surgery, attempts have been made to better understand the decision-making process of surgeons, mostly in the domain of surgical education (9)(10) or for specific procedures (11)(12). To the best of our knowledge, no such efforts have been carried out regarding postoperative complications. The applied cognitive task analysis (ACTA) methodology was developed by Militello et al. in 1998 and is described by its authors as "a set of streamlined cognitive task analysis tools that have been developed specifically for use by professionals who have not been trained in cognitive psychology, but who do develop applications that can benefit from the use of cognitive task analysis" (13). It aims at understanding the cognitive elements underlying decision-making and goals generation in a specific situation. To this end, it uses a four steps approach, namely the creation of a task diagram, knowledge audits, simulation interviews, creation of a cognitive demands table. Interviews with subject matter experts are the primary mean of data collection. For practical reasons related to medical professionals' time constraints, steps 3 and 4 will be combined in one single interview.

Despite the results being specific to postoperative complications, the methodological approach used could be applied to other medical specialties or clinical problems in the future. This work will also be, to the best of our knowledge, the first attempt to systematically investigate clinicians' cognitive support needs in the perspective of developing a ML-based CDSS.

4. OBJECTIVES AND OUTCOME MEASURES

Objectives	Outcome Measures	Timepoint(s) of evaluation of this outcome measure
Primary outcome To qualitatively describe the perceived cognitive challenges faced when attending a patient presenting with postoperative complications, highlighting the differences between junior and senior clinicians.	Domain experts (senior and junior)' opinion and interview transcripts	NA
Secondary outcome To produce a list of desired support modalities, and to identify discrepancies between needed support and commonly published CDSS in the literature.	Domain experts (senior and junior)' opinion and interview transcripts	NA

5. STUDY DESIGN

This study is a series of single time point interviews using qualitative research methodology.

Semi-structured interviews will be carried out based on the ACTA methodology (13). Interviews will be carried out in parallel for the two study groups and without pre-defined order.

The University of Oxford Clinical Trials and Research Governance study classification group considered the proposed study as service development, hence dispensing it from ethic committee review.

The semi-structured interview protocols can be found in Appendix A and B.

6. PARTICIPANT IDENTIFICATION AND RECRUITMENT

6.1. Study Participants

6 core surgical trainees (CT1-2) or specialty surgical trainees (ST3-4) (hereafter the junior clinicians).

6 specialty trainees (ST6-8), fellows or consultant in surgery or intensive medicine (hereafter the senior clinicians). For surgeons, participation will be limited to general surgery and its subspecialties.

The investigator aims to recruit participants in at least 3 different locations, mainly from the Oxford University Hospitals NHS Foundation Trust.

Additional participants will be recruited if data saturation has not occurred in each group after 6 participants.

6.2. Inclusion Criteria

- Participants are employees of an NHS Trust
- Participants are either CT1-2/ST3-4 surgical trainees or ST6-8/consultants in general surgery/a general surgery subspecialty or ST6-8/consultants in perioperative medicine/intensive medicine.

6.3. Exclusion Criteria

None

7. STUDY PROCEDURES

7.1. Procedure outline

A semi-structured interview protocol has been developed for each of the study group. They are based on the ACTA methodology (13) and were piloted with one consultant surgeon, one junior surgeon and one qualitative research specialist.

Interviews will be carried out virtually or in-person. They should last between 30 and 45 minutes and the conversations will be recorded. The same brief introduction about the study will be read to all participants.

The interviews with the senior clinicians will be primarily aimed at understanding the cognitive challenges faced, the type of CDSS support needed and the nature of the gap between junior and senior clinicians.

The interviews with the junior clinicians will be primarily aimed at investigating the cognitive challenges faced and the type of CDSS support needed.

7.2. Recruitment

Trainees will be contacted through their Training Program Director and direct contacts.

Consultants will be contacted through personal recommendations and snowballing as well as directly approached at events.

Individual consent will be obtained at the beginning of each interview.

7.3. Discontinuation/Withdrawal of Participants from Study

Every participant has the right to withdraw consent at any time. If consent is withdrawn between the beginning of the interview and ten working days after the end of the interview, all collected data will be deleted. If consent is withdrawn later on, personal data will be deleted but the content of the interview will remain part of the analysis.

In addition, the Investigator may discontinue a participant from the study at any time if the Investigator considers it necessary for any reason including:

- Significant non-compliance with the study requirements
- Obvious lack of consideration in their answers

Discontinuation will lead to exclusion of all data from the analysis.

Withdrawn or discontinued participants will be replaced if their withdrawal compromised the saturation of data.

The reason for withdrawal will be recorded in the Study Record.

7.4. Definition of End of Study

The study will be ended:

- When data saturation has been reached, but
- No later than the 31.10.21

8. STATISTICS AND ANALYSIS

8.1. The Number of Participants

6 interviews in each group are planned in a first step. Additional interviews will be carried out if saturation of ideas has not been reached after the first stage, as it is commonly done in qualitative research.

8.2. Analysis of Outcome Measures

The interview will be analysed using a combination of the ACTA recommended analysis (13) and thematic analysis (14). The analysis will be performed with the NVivo software. The main objectives of the qualitative data analysis will be: to describe the perceived cognitive challenges faced when attending patients presenting with postoperative complications, to describe strategies used by experienced clinicians to address these situations, to produce a list of desired support modalities, to highlight the differences between junior and senior clinicians and to identify discrepancies between needed support and commonly published CDSS in the literature.

9. DATA MANAGEMENT

9.1. Access to Data

Direct access will be granted to authorised representatives from the University of Oxford and any host institution for monitoring and/or audit of the study to ensure compliance with regulations. The principal investigator's supervisors will also have access to the data on request.

9.2. Data Handling and Record Keeping

Interviews' recording will be transcribed fully or in part. The recording will be made using the Microsoft Teams software or a recording software on smartphone. The original recording will be kept until the content of the interviews have been transcribed but no longer than one month. The study data will be analysed using the NVivo software. Recording will be held on an encrypted drive until transcribed and anonymised. Study documents will be held on a password protected computer. Backups will be performed on the University of Oxford's backups service and the main investigator's private external hard drive (offline).

10. ETHICAL AND REGULATORY CONSIDERATIONS

10.1. Approvals

The University of Oxford Clinical Trials and Research Governance study classification group considered the proposed study as service development, hence dispensing it from ethic committee review.

The Investigator will communicate with and obtain approval from the relevant Oxford University Hospitals NHS Foundation Trust management.

10.2. Participant Confidentiality

The interviews will be recorded. The transcripts will be anonymised. Transcripts will be linked to the participants personal information through a unique identifier number. The unique identifier number list will be store on an encrypted drive. All documents and recording will be stored securely and only accessible to study staff and authorised personnel. The study will comply with the Data Protection Act, which requires data to be anonymised as soon as it is practical to do so.

10.3. Expenses and Benefits

Participants will not receive any financial compensation. Non-financial incentive such as participation certificates might be provided.

11. PUBLICATION POLICY

The investigators plan on publishing the results in a peer-reviewed journal, either as a stand-alone publication or as part of a broader project.

This study is part of the DPhil thesis of the principal investigator.

Authorship will be determined in accordance with the ICMJE guidelines and other contributors will be acknowledged.

The results will also be directly shared with participants who expressed their interest at the time of data collection.

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13. APPENDIX A: INTERVIEW PROTOCOL – JUNIOR CLINICIANS

Confirm consent

Introduction

Thank you very much for accepting to participate in this interview. The primary goal of the study is to understand clinicians', and more specifically junior clinicians', cognitive process and cognitive support needs when facing postoperative complications. The interview is based on the applied cognitive task analysis method from Laura Militello. It will start with a few short questions about yourself, followed by six main questions designed to reflect on the key components of experience. You will finally have the opportunity to add any further comment you would like to. The interview should last between 30 and 40 minutes. The study is part of a wider effort to develop a computer-aided decision support system for the management of postoperative complications.

Personal information

What is your current placement and what are your responsibilities in hospital? How many years have you been training in surgery?

In which hospital do you mainly work? How many surgical beds are there approximately? Is there a consultant surgeon onsite at all time? Is there an ICU?

ACTA questions

The first scenario used in this interview is intentionally very unspecific and I am well aware that the information given is insufficient to develop a realistic clinical management plan. The reason for this lack of details is to avoid constraining your thinking and to gather information applicable to a wider range of situations. Imagine it is 1am on a Wednesday morning. You are the on call surgical trainee for the night. You have just been called by a nurse to attend a patient whom the ward staff has become worried about and have arrived at the patients' bedside.

Could you please, in four to five steps, describe your decision-making process When attending this patient? Could you please identify the cognitively challenging aspects of this process? By cognitively challenging I mean tasks requiring judgements, assessments or problem-solving thinking. How could a computer or intelligent algorithm support you along this decision-making process? (Do you currently use one? What is missing? What could be improved?)

Let's now reflect at your experience with postoperative complications more generally.

1. Can you remember a situation where the solution to a problem just "popped up" at you, where you noticed things going on that other didn't? How could a computer or intelligent algorithm support you along this decision-making process? (Do you currently use one? What is missing? What could be improved?)

2. Can you think of a time when you realised you were going in the wrong direction, that you needed to change the way you were performing in order to get the job done? How could a computer or intelligent algorithm support you along this decision-making process? (Do you currently use one? What is missing? What could be improved?)
3. Can you give me an example of what is important about the big picture when attending postoperative complications? What are the major elements you have to be aware and keep track of? How could a computer or intelligent algorithm support you along this decision-making process? (Do you currently use one? What is missing? What could be improved?)
4. When attending patients with suspected postoperative complications, are there ways of “working smart” or accomplishing more with less? Can you think of an example? How could a computer or intelligent algorithm support you along this decision-making process? (Do you currently use one? What is missing? What could be improved?)
5. Can you describe an instance when you very quickly spotted a deviation from the norm or knew something in your patient was really amiss? How could a computer or intelligent algorithm support you along this decision-making process? (Do you currently use one? What is missing? What could be improved?)

Further comments

Are there any other particular challenges linked to the management of postoperative complications which you would like to address? How could a computer or intelligent algorithm support you along this decision-making process? (Do you currently use one? What is missing? What could be improved?)

14. APPENDIX B: INTERVIEW PROTOCOL – SENIOR CLINICIANS

Confirm consent

Introduction

Thank you very much for accepting to participate in this interview. The primary goal of the study is to understand clinicians', and more specifically junior clinicians', cognitive process and cognitive support needs when facing postoperative complications. In order to understand the needs of novices it is also important to gain insights in how experts think, and this is why senior clinicians have also been invited to participate. The interview is based on the applied cognitive task analysis method from Laura Militello. It will start with a few short questions about yourself, followed by six main questions designed to reflect on the key components of experience. You will finally have the opportunity to add any further comment you would like to. The interview should last between 30 and 40 minutes. The study is part of a wider effort to develop a computer-aided decision support system for the management of postoperative complications.

Personal information

What are your current position and responsibilities in hospital? How many years have you been working as a surgeon/an intensivist?

In which hospital do you mainly work? How many surgical beds are there approximately? (Is there an ICU?)

ACTA questions

The first scenario used in this interview is intentionally very unspecific and I am well aware that the information given is insufficient to develop a realistic clinical management plan. The reason for this lack of details is to avoid constraining your thinking and to gather information applicable to a wider range of situations. Imagine it is 1am on a Wednesday morning. You are the consultant on call for the night. You have been called by one of your residents, who is worried about a postoperative patient on the ward, and you have just arrived at the patients' bedside.

Could you please, in four to five steps, describe your decision-making process When attending this patient? Could you please identify the cognitively challenging aspects of this process? By cognitively challenging I mean tasks requiring judgements, assessments or problem-solving thinking. How do you think novices would act differently or what other challenges do you think they might encounter?

Let's now reflect at your experience with postoperative complications more generally.

1. Can you remember a situation where the solution to a problem just "popped up" at you, where you noticed things going on that other didn't? What do you think novices would do differently in such situation?
2. Can you think of a time when you realised you were going in the wrong direction, that you needed to change the way you were performing in order to get the job done? What do you think novices would do differently in such situation?

3. Can you give me an example of what is important about the big picture when attending postoperative complications? What are the major elements you have to be aware and keep track of? What do you think novices would do differently in such situation?
4. When attending patients with suspected postoperative complications, are there ways of “working smart” or accomplishing more with less? Can you think of an example? What do you think novices would do differently in such situation?
5. Can you describe an instance when you very quickly spotted a deviation from the norm or knew something in your patient was really amiss? What do you think novices would do differently in such situation?

Further comments

Are there any other particular challenges linked to the management of postoperative complications which you would like to address? What do you think novices would do differently in such situation?

15. APPENDIX C: AMENDMENT HISTORY

Amendment No.	Protocol Version No.	Date issued	Author(s) of changes	Details of Changes made
1	V2	Feb 4 th 2021	Baptiste Vasey	End date of the study extended to October 31 st 2021.
2	V2	Feb 4 th 2021	Baptiste Vasey	Number of initial target interviews reduced from 20 to 12 (6 in each group).
3	V3	May 4 th 2021	Baptiste Vasey	Double review of interview transcripts changed to single review.