



CHILDREN'S & WOMEN'S HEALTH CENTRE OF BRITISH COLUMBIA

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PART 2 SUBJECT INFORMATION AND CONSENT FORM

Title of Study: eVENT: An expert system for detecting ventilatory events during anesthesia

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INTRODUCTION

You are invited to participate in this study because you are an anesthesiologist. We would like your expert opinion in developing a definition for three adverse events during anesthesia.

YOUR PARTICIPATION IS VOLUNTARY

Your participation is entirely voluntary, so it is up to you to decide whether or not to take part in this study. Before you decide, it is important for you to understand what the research involves. This consent form will tell you about the study, why the research is being done, what will happen to you during the study and the possible benefits, risks and discomforts.

If you wish to participate, you will be asked to sign this form. If you do decide to take part in this study, you are still free to withdraw at any time and without giving any reasons for your decision.

If you do not wish to participate, you do not have to provide any reason for your decision not to participate nor will you lose the benefit of any medical care to which you are entitled or are presently receiving.

Please take time to read the following information carefully before you decide.

WHO IS CONDUCTING THE STUDY?

The study is being conducted by Dr. Mark Ansermino (Principal Investigator) and Dr's Guy Dumont, Nicola Shaw, and Peter Choi from the Departments of Anesthesia and Computer and Electrical Engineering at the University of British Columbia, and Pediatrics at the University of Alberta. This study has received funding from the Canadian Institutes of Health Research to develop a prototype of the final product.

BACKGROUND

Every year, hundreds of thousands of dollars are spent on injuries associated with anesthesia. Of these events, 72% are considered avoidable with increased clinician vigilance. Improving the performance of skilled medical professionals is unlikely to be achieved by asking them to work better or faster. Instead, it will require some form of assistance. However, advances in patient monitoring have actually increased the chances of human error by adding greater complexity to the anesthesiologist's workload. One of the main causes of this is that while a monitoring system is able to detect abnormalities, it does not necessarily transfer this information to the clinician in a meaningful manner.

Expert systems are well established for the prevention of human error in the aviation and atomic energy industries. Contrastingly, decision support systems in healthcare are limited by the complexity of the environment and lack of validation in the clinical setting. An expert system in healthcare has potential for improving the current decision support system, aiding the clinician, and decreasing adverse outcomes of anesthesia.

Critical ventilatory events are an example of the type of events that an expert system could aid the clinician in identifying and treating. However, currently there are no clear definitions of critical ventilatory events in the literature and anesthesiologists make judgment calls to assess the events.

WHAT IS THE PURPOSE OF THE STUDY?

The purpose of this study is to generate specific rules for identifying three dangerous ventilatory critical events:

- a. Disconnection or significant leak in the anesthesia circuit based on spirometry and inhaled exhaled gas concentration differences.

- b. Reduced lung compliance or increased resistance (i.e. bronchospasm and stiff lung).

c. Anesthetic overdose from inhaled anesthetics based on inhaled and exhaled concentrations and the systemic effects produced by the inhaled anesthetics such as a decrease in blood pressure.

WHO CAN PARTICIPATE IN THE STUDY?

Chosen anesthesiologists will be invited by the investigators on the basis of years of experience and subspecialty. Anesthesiologists must also have internet access.

WHO SHOULD NOT PARTICIPATE IN THE STUDY?

Anesthesiologists whose characteristics have already been represented in the sample will not be asked to participate. Those who do not have internet access will also be unable to participate.

WHAT DOES THE STUDY INVOLVE?

This study involves 10 anesthesiologists with a diverse range of experience. Data will be collected via internet in the form of a questionnaire.

You will receive an email with an ID number and a link to an online questionnaire. The questionnaire will ask you to rate your agreement with definitions of 3 critical ventilatory events during anesthesia. The questionnaire will take approximately 15 minutes to complete. We ask that you submit your answers within 7 days of receiving it.

You will then receive a summary of the results once all participants have submitted their questionnaire and the statistics have been calculated (approximately 1 month). You will be asked to retake the questionnaire after reviewing the results.

Approximately a month later, you will receive a summary of the questionnaire and be asked to retake the questionnaire again. This process will continue until a conclusive definition of the three ventilatory events is achieved (approximately 3 months).

WHAT ARE MY RESPONSIBILITIES?

It is your responsibility to fill out the questionnaire and submit it within 7 days of receiving it.

WHAT ARE THE POSSIBLE HARMS AND SIDE EFFECTS OF PARTICIPATING?

There are no anticipated harms or side effects from participating in this study.

WHAT ARE THE BENEFITS FROM PARTICIPATING?

There is no direct benefit from participating in this study. The final outcome of this study (a clear set of rules in identifying 3 critical ventilatory events) will be a benefit to all anesthesiologists.

WHAT IF NEW INFORMATION BECOMES AVAILABLE THAT WILL AFFECT MY DECISION TO PARTICIPATE?

You will be notified immediately if new information becomes available.

WHAT HAPPENS IF I DECIDE TO WITHDRAW MY CONSENT TO PARTICIPATE?

Your participation in this research is entirely voluntary. You may withdraw from this study at any time. If you decide to enter the study and to withdraw at any time in the future, there will be no penalty or loss of benefits to which you are otherwise entitled, and your future medical care will not be affected.

The study investigators may decide to discontinue the study at any time, or withdraw you from the study at any time, if they feel that it is in your best interests.

If you choose to enter the study and then decide to withdraw at a later time, all data collected about you during your enrolment in the study will be retained for analysis. By law, this data cannot be destroyed.

WHAT HAPPENS IF SOMETHING GOES WRONG?

Signing this consent form in no way limits your legal rights against the sponsor, investigators, or anyone else.

CAN I BE ASKED TO LEAVE THE STUDY?

If you are not complying with the requirements of the study or for any other reason, the study investigator may withdraw you from the study.

AFTER THE STUDY IS FINISHED

Results of this study will likely be published in a relevant journal. Long terms goals of this study include a tool that will aid anesthesiologists in assessing adverse events.

WHAT WILL THE STUDY COST ME?

Participating in the study will not cost you anything and no reimbursement of arising expenses will be given. Additionally, no honoraria will be provided for participating.

WILL TAKING PART IN THIS STUDY BE KEPT CONFIDENTIAL?

Your confidentiality will be respected. No information that discloses your identity will be released or published without your specific consent to the disclosure. However, research records identifying you may be inspected in the presence of the Investigator or his or her designate by representatives of Canadian Institutes of Health Research, Health Canada, and the UBC Research Ethics Board for the purpose of monitoring the research. However, no records which identify you by name or initials will be allowed to leave the Investigators' offices.

Your responses will be kept confidential. You will be assigned a random subject number and analysis will be done without any identifiers. Electronic documents will be stored in a password protected computer in the locked research office along with any hard copies of your responses. You will not be identified by name in any reports of the completed study.

WHO DO I CONTACT IF I HAVE QUESTIONS ABOUT THE STUDY DURING MY PARTICIPATION?

If you have any questions or desire further information about this study before or during participation, you can contact Erica Amari at 604-875-2000 ext. 6920.

WHO DO I CONTACT IF I HAVE ANY QUESTIONS OR CONCERNS ABOUT MY RIGHTS AS A SUBJECT DURING THE STUDY?

If you have any concerns about your rights as a research subject and/or your experiences while participating in this study, contact the Research Subject Information Line in the University of British Columbia Office of Research Services at 604-822-8598.

SUBJECT CONSENT TO PARTICIPATE

I have read and understood the subject information and consent form. I have had sufficient time to consider the information provided and to ask for advice if necessary. I have had the opportunity to ask questions and have had satisfactory responses to my questions. I understand that all of the information collected will be kept confidential and that the result will only be used for scientific objectives. I understand that my participation in this study is voluntary and that I am completely free to refuse to participate or to withdraw from this study at any time without changing in any way the quality of care that I receive. I understand that I am not waiving any of my legal rights as a result of signing this consent form. I understand that there is no guarantee that this study will provide any benefits to me.

I have read this form and I freely consent to participate in this study. I have been told that I will receive a dated and signed copy of this form.

I Consent

I Decline