Improving Providers' Decision-Making and Reducing Information Overload Using Information Visualization in EHRs

NCT number NCT05937646
Document Date 06/24/2023

University of North Carolina at Chapel Hill
Consent to Participate in a Research Study
Adult Participants

Consent Form Version Date: 6/24/2023
IRB Study # 20-3384
Title of Study: Improving Providers' Decision-Making and Reducing Information Overload Using Information Visualization in EHRs
Principal Investigator: Khairat, Saif
Principal Investigator Department: School of Nursing
Principal Investigator Phone number: (919) 843-5413
Principal Investigator Email Address: saif@unc.edu
Funding Source and/or Sponsor: NIH National Library of Medicine [Federal]

CONCISE SUMMARY

The purpose of this study is to evaluate the effect of information visualization on providers' decision-making; performance; efficiency; fatigue; workload; and satisfaction.

During the session, you will review two patient cases in a training environment of the institutional EHR and two cases in AWARE. After you complete the patient record review, the RA will ask you a series of decision-based Q&A activities requiring verbal responses or task completion in the EHR or AWARE. You may use the EHR or AWARE to complete the Q&A activity. Cases will be in random order to avoid selection or order bias. After usability testing, you will be asked to fill out the NASA-TLX survey and the System Usability Scale (SUS).

The study session will last for one hour.

This study contains no more than minimal risk.

A description of this clinical trial will be available on www.clinicaltrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

What are some general things you should know about research studies?
You are being asked to take part in a research study. To join the study is voluntary.

You may choose not to participate, or you may withdraw your consent to be in the study, for any reason, without penalty.

Research studies are designed to obtain new knowledge. This new information may help people in the future. You may not receive any direct benefit from being in the research study. There

also may be risks to being in research studies.
Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study.

You will be given a copy of this consent form. You should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

What is the purpose of this study?

The purpose of this research study is to improve the decision-making process through better information representation.

You are being asked to be in the study because you were identified as a medical ICU clinician.

Are there any reasons you should not be in this study?
You should not be in this study if you do not practice in the MICU as a physician, (attending, fellow, resident) nurse practitioner, or physician assistant.

How many people will take part in this study?
Approximately 120 people at multiple institutions will take part in this study.

How long will your part in this study last?
One session of one-hour duration.

What will happen if you take part in the study?
We will randomize consented participants into two groups: the control (EHR) group and the intervention (AWARE) group. During the RCT crossover, providers in each group will review the same patient records and will perform the same tasks, and complete the same survey instruments. Providers in the control groups will review two patient cases in their institution EHR (Epic or Cerner) first and then, two new cases in AWARE, and providers in the intervention group will review two patient cases in AWARE and then two new cases in the EHR.

For the cases in the EHR, participants will navigate through the EHR as per their usual routine in the ICU, with no added training sessions before the study. For the cases in AWARE, participants will receive a short training presentation by the study team, explaining the functionality and design of AWARE. Also, a day before each session, the RA will send an email to the provider with a short demonstration video of AWARE to become familiar with the tool.

The study will be conducted in simulation or Biobehavioral labs at each site. The PI, or research assistant, will explain the study procedure and obtain consent; participants will be asked to use Tobii Pro Fusion during the session, participants will not need to wear anything, the eye-tracker will be mounted to the monitor. During the session, participants will review 2 patient cases in their institutional EHR and two in AWARE. After the participant completes the patient record review, the RA will ask the participant a series of decision-based Q&A activities requiring verbal responses or task completion in the EHR or AWARE. The provider may use the EHR or AWARE to complete the Q&A activity. Cases will be in random order for each participant to

avoid selection or order bias. After usability testing, we will ask the participant to fill out the NASA-TLX survey and the System Usability Scale (SUS). The NASA-TLX measures the perceived workload of using the EHR, and the SUS measures that level of satisfaction as a result of using the EHR.

The session will be recorded.

What are the possible benefits from being in this study?

Research is designed to benefit society by gaining new knowledge. There is little chance you will benefit from being in this research study.

What are the possible risks or discomforts involved from being in this study?

Only research team members will have access to collected data. Thus, the potential for breach of confidentiality by individuals other than research team members is minimal.

What if we learn about new findings or information during the study?

You will be given any new information gained during the course of the study that might affect your willingness to continue your participation.

How will information about you be protected?

Participants will not be identified in any report or publication about this study. We may use de-identified data and/or specimens from this study in future research without additional consent.

Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, UNC-Chapel Hill will take steps allowable by law to protect the privacy of personal information. In some cases, your information in this research study could be reviewed by representatives of the University, research sponsors, or government agencies for purposes such as quality control or safety.

All data recorded and captured will be securely stored in a HIPAA-compliant, secure server with authorized access to the study researchers.

What is a Certificate of Confidentiality?

This research is covered by a Certificate of Confidentiality. With this Certificate, the researchers may not disclose or use information, documents or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings in the United States, for example, if there is a court subpoena, unless you have consented for this use.

The Certificate cannot be used to refuse a request for information from personnel of a federal or state agency that is sponsoring the study for auditing or evaluation purposes or for information

that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law, such as mandatory reporting requirements for child abuse or neglect, disabled adult abuse or neglect, communicable diseases, injuries caused by suspected criminal violence, cancer diagnosis or benign brain or central nervous system tumors or other mandatory reporting requirement under applicable law. The Certificate of Confidentiality will not be used if disclosure is for other scientific research, as allowed by federal regulations protecting research subjects or for any purpose you have consented to in this informed consent document.

You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

What will happen if you are injured by this research?

All research involves a chance that something bad might happen to you. If you are hurt, become sick, or develop a reaction from something that was done as part of this study, the researcher will help you get medical care, but the University of North Carolina at Chapel Hill has not set aside funds to pay you for any such injuries, illnesses or reactions, or for the related medical care. Any costs for medical expenses will be billed to you or your insurance company. You may be responsible for any co-payments and your insurance may not cover the costs of study-related injuries.

If you think you have been injured from taking part in this study, call the Principal Investigator at the phone number provided on this consent form. They will let you know what you should do.

By signing this form, you do not give up your right to seek payment or other rights if you are harmed as a result of being in this study.

What if you want to stop before your part in the study is complete?

You can withdraw from this study at any time, without penalty. The investigators also have the right to stop your participation at any time. This could be because you have had an unexpected reaction, failed to follow instructions, or stopped the entire study.

If you withdraw or are withdrawn from this study all data collected up until the point of withdrawal will be retained, however, no additional information will be collected unless you provide additional written permission for further data collection at the time of your withdrawal.

Will you receive anything for being in this study?

You will be receiving $100 for taking part in this study. Any payment provided for participation in this study may be subject to applicable tax withholding obligations

Will it cost you anything to be in this study?
It will not cost you anything to be in this study.

What if you are a UNC employee?

Taking part in this research is not a part of your University duties, and refusing will not affect your job. You will not be offered or receive any special job-related consideration if you take part in this research.

Who is sponsoring this study?
This research is funded by the National Institutes of Health. This means that the research team is being paid by the sponsor for doing the study. The researchers do not, however, have a direct financial interest in the sponsor or in the final results of the study.

What if you have questions about this study?
You have the right to ask and have answered, any questions you may have about this research. If you have questions about the study (including payments), complaints, or concerns, or if a research-related injury occurs, you should contact the researchers listed on the first page of this form.

What if you have questions about your rights as a research participant?
All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject, or if you would like to obtain information or offer input, you may contact the Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu.

Participant's Agreement:

I have read the information provided above. I have asked all the questions I have at this time. I voluntarily agree to participate in this research study.

_____
Signature of Research Participant

_____
Date

_____
Printed Name of Research Participant

_____
Signature of Research Team Member Obtaining Consent

_____
Date

_____
Printed Name of Research Team Member Obtaining Consent

_____
Signature of Witness if applicable; e.g. literacy issues, visually impaired, physically unable to sign, witness/interpreter for non-English speaking participants using the short form)

_____
Date

_____
Printed Name of Witness