The M-Safety Lab: Enhancing Patient Safety through Cognition & Communication- Project 2, Phase II

VA Ann Arbor Healthcare System- IRB 2018-1131
University of Michigan- HUM 00145793

NCT03757884

Included: University of Michigan Consent Form
Dated: 6/18/2019

UNIVERSITY OF MICHIGAN
CONSENT TO BE PART OF A RESEARCH STUDY

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title: M-Safety Project 2: Improving Medical-Decisions Through Cognition, Technology and Communication- Phase II

Company or agency sponsoring the study: This project was supported by a grant from the Agency for Healthcare Research and Quality.

Principal Investigator: Vineet Chopra MD, MSc- Department of Internal Medicine, University of Michigan

1.Key Study Information
You may be eligible to take part in a research study. This form contains information that will help you decide whether to join the study. All information in this form is important. Take time to carefully review this information. After you finish, you should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others such as your friends, family, or other doctors about your possible participation in this study. If you decide to take part in the study, you will be asked to sign this form. Before you do, be sure you understand what the study is about.

2. PURPOSE OF THIS STUDY

2. Study purpose:
In this project, we will introduce and evaluate an intervention designed to improve diagnostic decision making. The intervention will attempt to increase clinician mindfulness and reduce environmental distractions to improve diagnostic and therapeutic decision making.

3. WHO MAY PARTICIPATE IN THE STUDY

Taking part in this study is completely **voluntary**. You do not have to participate if you don't want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

3.1 Who can take part in this study?
Hospital medicine physicians will take part in this study.

3.2 How many people are expected to take part in this study?
Up to 100 hospitalists will participate in this study.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

This study has two phases: Phase 1 Pre-test & Phase 2. Post-test You may participate in the Phase 1 Pre-test and/or Phase 2 Post-test depending on your work schedule.

During the Phase 1 Pre-test, study staff will collect some baseline information from hospitalists on service. If you agree to participate, you will be asked to wear a Spire stone monitor during your work shift. The Spire monitor is about 1 X 2 inches and clips on at the waist (i.e., belt, pant-waistband). The Spire monitor measures breathing patterns to determine when you are focused, tense, calm and involved in physical activity. We will also ask you to carry a study iPod with you during your work shift, for example in a coat pocket. The Spire will link to the study iPod using a blue-tooth connection to download your breathing data. We will also ask you your age, gender, height and weight. Spire uses this information to calculate your breathing patterns. Study staff will meet with you before and after specified work shifts to provide you with the Spire and study iPod and collect these devices before you leave for the day.

We will also ask you to complete a short survey at the end of each work shift about mindfulness and workflow. The survey will take you a few minutes to complete.

In addition to the Spire data, we will also collect some information from the hospital electronic medical record about the patient care provided each day you participate in the study. This data will only be collected on patients you care for on the days that you are asked to wear a Spire monitor. We will also review your page alerts. This will be done by collecting the frequency of page alerts and texted information from the page data.

For the Phase 2 Post-test of this study, you will be asked to wear the Spire monitor as described in Phase 1. Study staff will also collect information from the electronic medical record about the patient care provided on that day.

In addition, you will be offered the following tools and equipment that may help reduce environmental distractions and promote mindfulness. You do not have to use these tools, but they will be available to you and may help you focus your thoughts.

- Dedicated work spaces that are designed to promote focus. You will have the option of using one of these spaces during your work shift.
- Noise cancelling headphones to drown out room noise.
- If space allows, a table screen set around the computer to provide a private space and relieve visual distractions.
- A diagnostic checklist to assist with diagnosis and help ensure nothing is missed.

During Phase 2, you will be asked to complete the following.

- A brief mindful breathing exercise using the Spire iPod application. This exercise will take approximately 2 minutes before the start of your shift.
- A short survey at the end of each work shift about what Phase 2 tools you used during that work shift. The survey will take you a few minutes to complete.

4.2 How much of my time will be needed to take part in this study?

You will be asked to participate is the study during selected work shifts over the next year. Participation will require 10-15 minutes of time before your work shift and approximately 5 minutes after your work shift. Study staff will notify you before any selected work shifts to set up a time and place to meet

before the start of your shift. Depending on the schedule, you may participate up to 20 days in the study

4.3 When will my participation in the study be over?
Your participation will be over after your last work shift during the study period. The study will continue for up to 1 year.

4.4 What will happen with my information used in this study?
All data collected from you will be identified using a unique study ID number. Your name and any other identifying information will not be directly linked to any study data. Study staff will use a web-based dashboard to access the SPIRE data. However, this data will not contain any personal identifiers. All other electronic study data will be stored on a secure University of Michigan server. All paper forms will be stored in a locked filing cabinet.

5. INFORMATION ABOUT STUDY RISKS AND BENEFITS

5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?
There may be a risk of loss to confidentiality or privacy. See Section 9 of this document for more information on how the study team will protect your confidentiality and privacy.

As with any research study, there may be additional risks that are unknown or unexpected.

5.2 If I take part in this study, can I also participate in other studies?
You may take part in other studies while involved with this study. Please inform research staff of your involvement.

5.3 How could I benefit if I take part in this study? How could others benefit?
You may or may not receive any personal benefits from being in this study. It is possible that participation in Phase 2 may result in less distraction and increased focus. Others may also benefit from the knowledge gained from this study. Results from this study may direct physician patient care to decrease diagnostic error and improve patient safety.

5.4 Will the researchers tell me if they learn of new information that could change my willingness to stay in this study?
Yes, the researchers will tell you if they learn of important new information that may change your willingness to stay in this study. If new information is provided to you after you have joined the study, it is possible that you may be asked to sign a new consent form that includes the new information.

5.4 Additional Risks.
Vineet Chopra, MD, Chief of Hospital Medicine is the principal investigator for this study. However, he will not be involved with participant activities and will not know who chooses to participate and who does not. Your participation or non- participation in this study will not reflect on your position at the hospital or any evaluations. Any questions, concerns, or comments about the study can be directed to Ashwin Gupta, MD, hospitalist and study co-investigator. His contact information is at the end of this form.

6. ALTERNATIVES TO PARTICIPATING IN THE STUDY

6. If I decide not to take part in this study, what other options do I have?
Your participation is completely voluntary. You may choose not to participate.

7. ENDING THE STUDY

7 If I want to stop participating in the study, what should I do?
You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you. You will not lose any benefits to which you may otherwise be entitled. If you choose to tell the researchers why you are leaving the study, your reasons for leaving may be kept as part of the study record. If you decide to leave the study before it is finished, please tell one of the persons listed in Section 10 "Contact Information".

8. FINANCIAL INFORMATION

8.1 Will I be paid or given anything for taking part in this study?
You will receive a $10 gift card for each work shift you participate in the study.

8.2 Who could profit or financially benefit from the study results?
There will be no financial gains from this study.

9. CONFIDENTIALITY OF SUBJECT RECORDS

The information below describes how the confidentiality of your research records will be protected in this study.

9.1 How will the researchers protect my information?
All data from this study will be coded with a unique study ID. Data will not contain any direct information that can idenfiy you. Your research information will be stored in a locked cabinet and/or a UM secure server. The study will not collect any data that is not described in this form.

Other information regarding my data.
The University, Food and Drug Administration (FDA) and/or other government officials, auditors, and/or the IRB may need the information to make sure that the study is done in a safe and proper manner.

The results of this study could be published in an article but would not include any information that would let others know who you are.

10. CONTACT INFORMATION

10 Who can I contact about this study?
Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study activities
- Leave the study before it is finished
- Express a concern about the study

Co- Investigator: Ashwin Gupta MD

Mailing Address: 1500 E. Medical Dr., Ann Arbor, MI 48109
Telephone: 734-615-4807, Email: ashwing@med.umich.edu

Study Coordinator: Suzanne Winter MS
Mailing Address: 2800 Plymouth Rd., BLDG 16- 407, Ann Arbor, MI 48109
Telephone: 734-615-3754, Email: wsuzanne@med.umich.edu

You may also express a question or concern about a study by contacting the Institutional Review Board listed below:

University of Michigan Medical School Institutional Review Board (IRBMED)
2800 Plymouth Road
Building 520, Room 3214
Ann Arbor, MI 48109-2800
Telephone: 734-763-4768 (For International Studies, include the appropriate calling codes.)
Fax: 734-763-1234
e-mail: irbmed@umich.edu

If you are concerned about a possible violation of your privacy or concerned about a study you may contact the University of Michigan Health System Compliance Help Line at 1-866-990-0111.
When you call or write about a concern, please provide as much information as possible, including the name of the researcher, the IRBMED number (at the top of this form), and details about the problem. This will help University officials to look into your concern. When reporting a concern, you do not have to give your name unless you want to.

11. RECORD OF INFORMATION PROVIDED

11. What documents will be given to me?
You will receive a signed informed consent form.

12. SIGNATURES

Consent to Participate in the Research Study
I understand the information printed on this form. I have discussed this study, its risks and potential benefits, and my other choices with _____. My questions so far have been answered. I understand that if I have more questions or concerns about the study or my participation as a research subject, I may contact one of the people listed in Section 10 (above). I understand that I will receive a copy of this form at the time I sign it and later upon request. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

Print Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy):

Principal Investigator or Designee
I have provided this participant and/or his/her legally authorized representative(s) with information about this study that I believe to be accurate and complete. The participant and/or his/her legally authorized representative(s) indicated that he or she understands the nature of the study, including risks and benefits of participating.

Printed Legal Name: _____

Title: _____

Signature: _____

Date of Signature (mm/dd/yy)

Department of Veterans Affairs Research Consent Form		VA AAHS Research IRB Approved 1/10/2019
Title of Study:	M-Safety Project 2: Improving Medical-Decisions Through Cognition, Technology and Communication- Phase II	
Principal Investigator:	Vineet Chopra, MD, MSC	**VAMC**: VA Ann Arbor Healthcare System
Version Date:	January 10, 2019	

PURPOSE OF RESEARCH STUDY: In this project, we will introduce and evaluate an intervention designed to improve diagnostic decision making. The intervention will attempt to increase clinician mindfulness and reduce environmental distractions to improve diagnostic and therapeutic decision making.

DESCRIPTION:
About 20 hospital medicine physicians will take part in this study at the VA Ann Arbor Hospital.

This study has two phases: Phase 1 Pre-test & Phase 2 Intervention with Post-test. You may participate in the Phase 1 Pre-test and/or Phase 2 Post-test depending on your work schedule.

During the Phase 1 Pre-test, study staff will collect some baseline information from hospitalists on service. If you agree to participate, you will be asked to wear a Spire stone monitor during your work shift. The Spire monitor is about 1 X 2 inches and clips on at the waist (i.e., belt, pant-waistband). The Spire monitor measures breathing patterns to determine when you are focused, tense, calm and involved in physical activity. We will also ask you to carry a study iPod with you during your work shift, for example in a coat pocket. The Spire will link to the study iPod using a blue-tooth connection to download your breathing data. We will also ask you your age, gender, height and weight. Spire uses this information to calculate your breathing patterns. Study staff will meet with you before and after specified work shifts to provide you with the Spire and study iPod and collect these devices before you leave for the day.

We will also ask you to complete a short survey at the end of each work shift about mindfulness and workflow. The survey will take you a few minutes to complete.

In addition to the Spire data, we will also collect some information from the hospital electronic medical record about the patient care provided each day you participate in the study. This data will only be collected on patients you care for on the days that you are asked to wear a Spire monitor. We will also review your page alerts. This will be done by collecting the frequency of page alerts and texted page information.

For the Phase 2 Intervention with Post-test of this study, you will be asked to wear the Spire monitor as described in Phase 1. Study staff will also collect information from the electronic medical record about the patient care provided on that day. Patient data collected will be differential diagnosis, tests and consultations ordered and hospital re-admissions. Although we will not be able to identify improvement in diagnostic and therapeutic decision measures, we are reviewing these data as proxy measures for future studies in diagnostic error. We will review the possible change in the number of tests/consultations ordered, diagnosis and Spire metrics.

RESEARCH SUBJECT IDENTIFICATION: (Required information)

			NA - Staff	
			| | |	/ /
Last Name	**First Name**	**Mid. Init.**	**Last-4 SSN**	**Todays Date (mm/dd/yy)**

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In addition, you will be offered the following tools and equipment that may help reduce environmental distractions and promote mindfulness. You do not have to use these tools, but they will be available to you and may help you focus your thoughts.

- Dedicated work spaces that are designed to promote focus. You will have the option of using one of these spaces during your work shift.
- Noise cancelling headphones to drown out room noise.
- If space allows, a table screen set around the computer to provide a private space and relieve visual distractions.
- A diagnostic checklist to assist with diagnosis and help ensure nothing is missed.

During Phase 2 Intervention with Post-test, you will be asked to complete the following.

- A brief mindful breathing exercise using the Spire iPod application. This exercise will take approximately 2 minutes before the start of your shift.
- A short survey at the end of each work shift about what Phase 2 Intervention with Post-test tools you used during that work shift. The survey will take you a few minutes to complete.

You will be asked to participate in the study during selected work shifts over the next several months. Participation will require 10-15 minutes of time before your work shift and approximately 5 minutes after your work shift. Study staff will notify you before any selected work shifts to set up a time and place to meet before the start of your shift. Depending on the schedule, you may participate up to 40 days in the study.

Your participation will be over after your last work shift during the study period.

We will invite some participants to participate in a focus group discussion. This will be scheduled at your convenience and will take about one hour. We will discuss your experience with the interventional tools. The discussions will take place in an office or conference room. The focus group session will be audio-recorded. You may request that the recorder is turned off at any time and you may choose not to answer any questions. The focus groups will seek to understand whether the intervention provided was beneficial and how the this may be improved.

All data collected from you will be identified using a unique study ID number. Your name and any other identifying information will not be directly linked to any study data. All other electronic study data will be stored on a secure VAAAHS Health Services Research and Development (HSR&D) computer network. All paper forms will be stored in a locked filing cabinet.

RISKS: Although the likelihood of this occurring is rare, there is a possibility of loss of confidentiality. If another employee, including the University of Michigan, VAAAHS or hospital leadership, was able to determine which patient data, survey responses or focus group responses were linked to you, then there could be unanticipated social or employment consequences. We have several layers of security protection in place to protect data. We will protect your confidentiality by restricting access to your data to only specific authorized study personnel. In addition, the patient data, audio recording and survey data will not contain your name, but will be given a unique study identifier, which will be linked to your name in a separate, restricted electronic file.

Your name or other identifying information will be kept in a separate limited-access file. You will not be identified in any reports from this study. In addition, all data will be handled per existing VHA policies.

Vineet Chopra, MD, University of Michigan Chief of Hospital Medicine is the principal investigator for this study and Sanjay Saint MD, VAAAHS Chief of Medicine is a co-investigator. However, they will not be involved with participant activities, will not know who chooses to participate and who does not, and will not have access to the file linking your identify to the study data. Your participation or non- participation in this study will not reflect on your position at the hospital or any evaluations. Any questions, concerns, or comments about the study can be directed to Ashwin Gupta MD, hospitalist and study co-investigator. His contact information is at the end of this form.

BENEFITS: You may or may not receive any personal benefits from being in this study. It is possible that participation in Phase 2 Intervention with Post-test may result in less distraction and increased focus. Others may also benefit from the knowledge gained from this study. Results from this study may direct physician patient care to decrease diagnostic error and improve patient safety.

ALTERNATE COURSES OF ACTION: Participation in this study is voluntary. You may choose not to participate or drop out of the study at any time without penalty. You may also choose to participate or decline intermittently throughout the study period. If you do agree to participate, you may skip any survey or focus group question you would prefer to not answer.

STATEMENT OF RESEARCH RESULTS: All research data collected as part of this study will be stored according to the privacy and security guidelines established by the Veterans Health Administration. The investigators will store participant names separately from study data. Survey data along with audio files and transcripts will be kept confidential and access will be limited to authorized research staff. The surveys and audio transcripts will include no identifying information about participants. As soon as your transcript has been verified or within 1 year of the focus group discussions, your audio recording will be destroyed. Printed copies of all research data, including signed informed consent forms, will be kept in a locked file cabinet, behind a locked door at the VAAAHS-HSR&D center. All electronic files will be stored on a restricted access secure VA computer network. Researchers at VAAAHS will analyze the data collected from this study.

If the results of this study are reported in medical journals or at meetings, you will not be identified by name, or by any other means. No information by which you can be identified will be released or published unless required by law.

SPECIAL CIRCUMSTANCES: There will be no costs to you for participation in this research study.

COMPENSATION: You will not receive any monetary payment for your participation in this study.

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RESEARCH SUBJECT'S RIGHTS:

_____ has explained this research study and answered all questions. The risks or discomforts and possible benefits of the study have been described. Other choices of available treatment have been explained. Some veterans are required to pay co-payments for medical care and services provided by VA. These co-payment requirements will continue to apply for VA care and services that are not part of this study.

Participation in this study is entirely voluntary. You may refuse to participate. Refusal to participate will involve no penalty or loss of rights to which individuals are entitled. Participants may withdraw from this study at any time without penalty or loss of VA or other benefits. VA will provide treatment for research related injury in accordance with applicable federal regulations. The VA will provide necessary medical treatment should you be injured by participation in this study. You will be treated for the injury at no cost to you, but no provisions have been made for additional compensation. No reimbursement, compensation or free medical care is offered by US Department of Health and Human Services. You have not waived any legal rights or released the hospital or its agents from liability for negligence by signing this form.

In case there are medical problems, an injury, or if you have questions, concerns or complaints about the research study, you can contact member(s) of the research study team: Co-Investigator Ashwin Gupta MD at telephone 734-615-4807 or email: ashwing@med.umich.edu and Project Manager Suzanne Winter MS at telephone 734-615-3754 or email: wsuzanne@med.umich.edu. The sponsor of this research study is US Department of Health and Human Services.

You may contact the VA Human Studies coordinator at 734-845-3440 to ask questions about your rights as a research subject and to verify this study is reviewed and approved by the VA. You may also call when research study staff are not available or to discuss your questions or concerns with someone other than study staff. You may learn more about research at the VA Ann Arbor Healthcare System at www.annarbor.research.va.gov

I have been informed about my rights as a research subject, and I voluntarily consent to participate in this study. I will receive a signed copy of this consent form.

x_____	x_____	x_____
Signature of Subject	(Print Name)	**Todays Date (mm/dd/yy)**
x_____	x_____	x_____
Signature of person obtaining consent (Study personnel must be approved by VA IRB)	(Print Name)	**Todays Date (mm/dd/yy)**

IF MORE THAN ONE PAGE IS USED, EACH PAGE (VAF 10-1086) MUST BE CONSECUTIVELY NUMBERED.