Final Progress Report

1. Title Page

Title of Project: Patient Centered Virtual Multimedia Interactive Informed Consent (VIC)

Principal Investigator: Fuad Abujarad, PhD.

Team Members: Sandra Alfano PharmD, Peter Peduzzi PhD, Geoffrey Chupp MD

Organization: Yale University, School of Medicine, Department of Emergency Medicine

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Federal Project Officer: CDR Derrick Wyatt, derrick.wyatt@ahrq.hhs.gov

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2. Structured Abstract

Purpose:

In this study, we developed and evaluated an *m*Health tool called Patient Centered Virtual Multimedia Interactive Informed Consent (VIC) that enables the informed consent process to be performed on a handheld device (e.g. iPad®), which utilizes virtual coaching and interactive multimedia libraries that are designed to enhance patient comprehension and quality of care.

Scope:

To develop, test, and refine the *m*Health tool VIC to enhance patient comprehension while improving the efficiency of obtaining patient consent. Further, we aim to evaluate the feasibility of VIC compared to a standard consent in a real-world clinical research study.

Methods:

We conducted a mixed methods study to develop and evaluate VIC. To develop the informed consent (IC) tool, we used the User-Centered Design (UCD) approach including: requirement gathering and analysis, conceptual design, focus groups, design and development of mockup screen and prototype, usability evaluation of the prototype, and usability evaluation. To evaluate the feasibility of VIC, we tested VIC in an ongoing study at the Yale Center for Asthma and Airway Disease. The VIC evaluation study was a clinical trial conducted with 50 eligible patients randomized to receive either standard paper consent (PC) or consent via VIC on an iPad.

Results:

We created an innovative *m*Health tool that runs on an iPad to deliver the IC process to patients. Information and messages are displayed on the iPad screen and spoken through headphones for patient privacy. The patient can view demos and presentations, listen to comments and explanations, get customized information, ask questions and get answers, and rewind and replay as needed.

Key Words: informed consent, *m*Health, virtual coaching

3. Purpose

The informed consent process protects patients and ensures ethical conduct of research. For patients to fully understand the content of the informed consent process, it should clearly explain the purpose, process, risks, benefits and alternatives to medical procedures or clinical research as well as a patient's rights and responsibilities. Adoption of methods that allow clinicians and researchers to use virtual coaching to complete the informed consent process using tablet computers (e.g. iPads) with a comprehensive multimedia library (e.g. video clips, animations, presentations, etc.) to explains the risks, benefits, and alternatives of the clinical care will enhance patient comprehension. The goal of this project is to increase the efficiency and implementation of patient centered outcomes research (PCOR) by engaging key stakeholders. Engaging stakeholders through the development and evaluation of a new mobile health (*m*Health) informed consent tool will help disseminate PCOR findings in informed consent research. We enhanced the traditional informed consent process by developing the Patient Centered Virtual Multimedia Interactive Informed Consent tool (VIC). VIC was developed as a patient-centered, web-based application that runs on mobile devices. VIC was tested in an existing clinical research study to demonstrate that it can facilitate the study of complex interventions in real-world clinical settings. The goals of this project are: 1) To develop, test and refine the Patient Centered Virtual Multimedia Interactive Informed Consent (VIC) to enhance patient comprehension while improving the efficiency of obtaining patient consent; and 2) To evaluate the feasibility of VIC compared to a standard PI/coordinator-delivered consent in a real-world clinical research study.

4. Scope

Background: Informed consent (IC) for medical treatment is the process by which providers educate patients on a recommendation or treatment plan.[1,2] However, studies have revealed that many patients do not fully comprehend the information in the IC form.[3-5] The deficiencies in provider-patient communication in explaining the IC process, in addition to health literacy issues, place the patient at greater risk.[6] In 2007, the Joint Commission reported that "among patients who sign an IC form, 44% do not understand the nature of the procedure to be performed, and 60 to 70% do not read or understand the information contained in the form".[6] In order for patients to absorb the content of an IC, the form should diligently explain the purpose, process, risks, benefits and alternatives to medical procedures or clinical research.[1,2] To minimize cost and risks, many providers opt for electronic IC, but these rarely go beyond the paper-based IC process.[1,5,7-10] Most importantly, the standard consent (***paper and electronic***) process does not ***always guarantee*** patient comprehension or ***improve*** the quality of care.[3-5,11-13] The real challenge is that many patients lack the means to truly comprehend existing IC forms.[14] As a result, many patients are consenting without understanding the content of the consent form.

This project is driven by the Agency for Healthcare Research and Quality (AHRQ) mission to improve the quality of life and the safety, efficiency and effectiveness of healthcare. In 2009, AHRQ developed the *IC and Authorization Toolkit for Minimal Risk Research* to facilitate the process of obtaining IC.[22,23] The AHRQ emphasized that potential research subjects may not be comfortable with signing written materials and, therefore, researchers should supplement the IC process with additional multimedia materials to enhance comprehension so that patients are comfortable with the material.

Context:

Studies have shown that the lack of sufficient comprehension of information included in the IC

document negatively impacts patient safety and quality of care.[14,24-33] Patients want to be involved in making decisions about their own care.[34-42] Therefore, multiple PCOR studies have called for providing more efficient and effective Patient-Centered informed consent processes.[18-21] Also, patient decision aid tools have become more common.[43-52] These tools provide a myriad of benefits, which include informing patients about options, clarifying patient values, supporting the patients' preference construction process, and enabling patients to more actively engage in shared decisionmaking with their health care providers.[15,16,32-40,44,53-55]

Research has shown that the addition of audio and visual elements to informed consent increases subject interest and retention.[12] However, the robust capabilities of emerging multimedia technology, such as documents with variable reading levels and adaptive learning styles, have not yet been fully utilized or rigorously tested in the IC process.

VIC offers a *m*Health IC tool that allows providers to conduct brief and virtual interviews with patients using tablets (e.g. iPads) with a comprehensive multimedia library (e.g. video clips, animations, presentations, etc.) to explain the risks, benefits, and alternatives of the clinical procedure. VIC enhances patient comprehension, reduces risks, improves efficiency, and minimizes the burden on the health care providers and researchers.

Setting:

This project was conducted at the Department of Emergency Medicine at Yale School of Medicine. Founded in 1810, the Yale School of Medicine is a world-renowned center for biomedical research, education and advanced health care. The extensive academic, social, and physical resources available to scientific investigators at Yale University facilitate the proliferation of creative scientific inquiry. Moreover, such resources enabled the successful implementation of this complex, interdisciplinary research study. The Department of Emergency Medicine at Yale School of Medicine includes 41 faculty members with 36 clinicians who have responsibility for 82,000 adult patient visits a year at Yale-New Haven Hospital and 27,000 visits annually at our satellite ED, the Yale-New Haven Shoreline Medical Center in Guilford, CT. The department's focus increasingly involves elements of public health and prevention, including screening for hypertension, diabetes and HIV, and treatment and referral for alcohol use, drug addiction, domestic violence, mood disorders and other mental health issues.

To evaluate the feasibility of VIC, we tested VIC in an ongoing study at the Yale Center for Asthma and Airways Disease (YCAAD). Subjects were recruited from the Yale Winchester Asthma Clinic. Yale-New Haven Hospital is the largest referral center in the state and YCAAD is the only dedicated adult asthma center in the region. This active, rapidly growing center receives over 3000 visits a year and is the hub of the asthma clinical/translational research program at Yale. For the last 10 years, Dr. Geoffrey Chupp has built a center and infrastructure to phenotype and study human asthma in a longitudinal, high throughput fashion. This protocol has enrolled over 500 subjects (now expanded to include subjects > 12 years of age) over the last 10 years. Two years ago, the protocol was expanded to include a 2-hour study visit that includes an extensive coordinator-administered asthma questionnaire, lung function testing, hypertonic saline sputum induction and blood drawing for genomic level analyses of RNA isolated from the blood and sputum. We now enroll new asthma subjects at a rate of approximately 50 per year and evaluate existing subjects at follow up visits. We are using this unique infrastructure to develop a

biorepository of genomic, proteomic, phenotypic, and physiologic data from the blood and airway to pursue basic pathogenesis research in humans. This infrastructure is central to the studies outlined in this proposal.

Participants: Over the course of this project, we recruited 50 subjects who are 21 years old or older from the Yale Center for Asthma and Airway Diseases (YCAAD) population. There are no gender or racial restrictions to this study, and all sites for recruitment are racially diverse.

Incidence: N/A

Prevalence: N/A

5. Methods

Study Design: We developed the VIC system to support a patient-centered IC to enhance patient comprehension. The development of this tool relied on state-of-the-art software standards to design, develop, refine and test VIC, followed by assessments to evaluate the effectiveness. User Centered Design (UCD) techniques and user experience (UX) evaluations were used to produce usable and acceptable software that will deliver a more satisfying user experience. We conducted a mixed methodological study including both qualitative and quantitative research methods. IC materials were presented to patients using a multimedia library (e.g. graphics, video clips, animations, presentations, etc.) with the option to drill-down for additional information. Automated quizzes were used to assess patient comprehension.

Data Sources/Collection: The VIC evaluation study was a randomized trial that tested VIC in an ongoing clinical research study. Fifty eligible asthma patients were randomized to receive either standard paper consent or consent via VIC. The surveys were graded and analyzed.

Interventions: The main goal of VIC was to enhance patient comprehension of the IC document and enhance the IC process using virtual coaching and *m*Health. We adapted UCD to ensure that VIC has a user-friendly, self-driven, and step-by-step interface that seamlessly engages the patients in the IC process. VIC satisfied the highest standard for usability and acceptability to ensure effectiveness, efficiency and patient satisfaction. Our Web-based mobile VIC App with virtual coaching, text-to-speech audio translation, and iPad interface offers some compelling ways to surmount existing implementation barriers. Our App architecture intentionally and readily addresses literacy issues and patients' needs in the informed consent process. This has important implications for facilitating more meaningful and broader implementation of an IC tool, enhancing patient comprehension, and reducing staff burden in engaging patients in an interactive IC process. Our user-focused development approach resulted in a product that is usable, acceptable, and efficient. Overall, the VIC *m*Health tool had high usability as rated by the representative asthma patients.

Measures:
We conducted several usability evaluation studies during the software development phase of the VIC tool. Data collection instruments for usability are heuristic tools that analyze the implementation and integration process. Usability data analysis included percentage of successfully completed tasks, number and types of errors, time to successfully perform a

particular task, user satisfaction ratings, and verbal and written feedback from the sessions. Quantitative data was analyzed as numerical indicators and summarized using common descriptive statistics appropriate for discrete and continuous data. Non-numerical indicators were analyzed using qualitative methods. Key results were used to 1) Modify the VIC system to make it more usable and acceptable in terms of system's design, and 2) Normalize VIC by reducing process and structural problems. We conducted data analysis by using Camtasia 2®, a package that allowed simultaneous video recording, user screen capture, note-taking, and participant survey. Key usability measures included both qualitative and quantitative outcome measures. These included effectiveness (i.e., how well a system does what it is supposed to do), efficiency (i.e., the way a system supports users), and satisfaction (i.e., subjective responses from users about the system).

We evaluated the effectiveness of VIC compared to standard consent in a real-world clinical research study. The study assessments and measurements to be compared to the current and standard consent process are:

1) Participants' perceived understanding of the YCAAD GenEx 2.0 Study.
2) Total time required for the consent process for each participant as a measure of staff burden.
3) Percentage of screened patients enrolled in the YCAAD GenEx 2.0 Study.
4) Withdrawal of consent.
5) Cost of each method of consent.

Limitations: Limitations to the study include participant size, unforeseen technology issues, and length of time to recruit patients. It took longer than expected to recruit patients, in part due to patients cancelling their appointments. There was no feasible way to measure the total time required for the consent process for each participant as a measure of staff burden. Therefore, we replaced it with the participant's perceived length of time to complete the consent process.

6. Results

Principal Findings:

The overarching finding is that we were able to develop, test, and implement a **mobile informed consent tool**, which integrated a patient-centered informed consent process into clinical research. Initial observations from study coordinators show that VIC did reduce the time spent for initial instruction, explanation of the protocol, and answering of questions. There were also clear indicators of patient satisfaction. We are currently analyzing the VIC clinical trial data to find out if the use of VIC is feasible in enhancing patient comprehension while improving the efficiency of obtaining patient consent.

Using the UCD approach, we were able to design, develop, and evaluate a highly interactive *m*Health App to deliver the IC process. The UCD approach facilitated our collaboration with multiple stakeholders and helped us plan and execute many tasks, including requirement gathering and analysis, conceptual design, focus groups, design and development of mockup screen and prototype, usability evaluation of the prototype, development of the VIC system, rapid prototyping, and usability evaluation of VIC App.

Outcomes: We are currently analyzing the VIC clinical trial data to measure the main outcomes and determine if the use of VIC is feasible in enhancing patient comprehension while improving the efficiency of obtaining patient consent. During the VIC feasibility study, patients answered surveys based on the information they received either from VIC or paper consent depending on the randomization process. The data is being analyzed to test if the patients who used VIC performed the same or better compared to patients who were given paper consent. VIC scores that were ≥ 10 percentage points over PC were considered better. VIC scores that were ≤ 10 percentage points over PC were considered worse. Scores that were within 5 percentage points between VIC and PC were considered the same. The questions that VIC patients answered at a higher % correct were:

- Q6: "While you are in this research study, what will happen to your personal health information?" VIC patients answered 96% correct while paper consent patients answered 77 % correct.
- Q8: "How can you withdraw from this study?" VIC patients answered 96% correct while paper consent patients answered 81% correct.
- Q9: "Who can you call if you have questions about your rights as a participant in this study?" VIC patients answered 75% correct while paper consent patients answered 62% correct.

The question that VIC patients answered at a higher % incorrect was Q1: "Why did we ask you to participate in this study?" VIC patients answered 71% correct while paper consent patients answered 81% correct.

Discussion: Data analysis will show if patients who received their informed consent through the VIC tool understood the material the same or better than patients who received traditional paper consent. When asked questions to test their understanding, patients who used VIC selected "I understood this very well" the majority of the time, whereas patients who took paper consent selected this answer less often. Patients who used VIC were more satisfied with being able to complete the IC process on their own compared to patients who took PC.

Successful research increasingly requires multi-disciplinary and inter-disciplinary teams. Our team has unique and complementary backgrounds encompassing: HIT, human computer interaction, *m*Health, UCD, UX evaluation, system design and architecture, human subjects protection, and clinical and translational research. This study presents how our team is a success story of interdisciplinary collaboration among several entities.

Possible future directions include assessing the VIC tool capabilities for different chronic diseases. Potential modifications include improving the reusable infrastructure of the VIC App by using a larger and more diverse sample size to create a more patient-centered *m*Health tool. In the longer term, we are also interested in assessing whether VIC predicts more positive health outcomes for patients.

Conclusions:

The use of *m*Health can be successful in delivering health communications, specifically in developing a usable, acceptable, and efficient tool to deliver the IC process. Care must be taken to address the challenges that come with designing a new IC tool. One such challenge is ensuring

that the new IC tool improves patient comprehension. This study focused on testing the feasibility of developing and evaluating such a tool.

Using the UCD approach, we were able to design, develop, and evaluate a highly interactive *m*Health App to deliver the IC process. This approach facilitated our collaboration with multiple stakeholders and helped us plan and execute various tasks, such as requirement gathering and analysis, conducting focus groups, design and development of mockup screen and prototype, development of the VIC system, rapid prototyping, and usability evaluation of the VIC App.

Our Web-based mobile VIC App with virtual coaching and text-to-speech audio translation and iPad interface offers some compelling ways to surmount existing implementation barriers. Our App architecture intentionally and readily addresses literacy issues and patients' needs in the informed consent process. This has important implications for facilitating more meaningful and broader implementation of an IC tool, enhancing patient comprehension, and reducing provider burden engaging patients in an interactive IC process. Our user-focused development approach resulted in a product that is usable, acceptable, and efficient. Overall, the VIC *m*Health tool had high usability as rated by the representative asthma patients.

We are currently analyzing the data collected from the VIC study to determine if patients who receive their IC through an engaging IC tool were able to retain more information about their protected health information and the clinical trial procedure, and also if they demonstrated a more positive experience compared to patients who receive the traditional paper consent.

Significance: This study addresses an area of high significance, which is ensuring patient comprehension through an effective informed consent process. To ensure patient comprehension, the IC process must successfully convey information to the patient in a way that they fully understand. This can be accomplished by using *m*Health tools with virtual coaching, images, animations, and video clips demonstrating the procedures. The use of multimedia is more engaging to the patient and thus result in greater patient satisfaction.

Implications:

We expect that IC tools with a reusable infrastructure for integrating the IC process into research studies and the clinical workflow will enhance patient comprehension while improving efficiency. We are working on an open and timely dissemination of our research outcomes and sharing research resources. Dr. Abujarad is working with Yale Center for Clinical Investigation to disseminate results as widely as possible while safeguarding the privacy of research participants and protecting confidential and proprietary data. As a CTSA, Yale will share the study results with other CTSA institutions and academic or healthcare institutions that would find them useful. In addition, the research team will inform the larger scale real world health IT implementation of the results of this research study through publication in peer-reviewed journals and presentations at national meetings to share and demonstrate the findings and the lessons learned from this project. This way, we will inform future research in *m*Health regarding the dissemination and implementation of PCOR evidence into clinical practice. With additional funding, our future plan is to disseminate the findings and further enhance VIC to accommodate its use as a tool in the clinical and research setting at YNHH and make it a standard of care and rollout at least within the YNHH system. We hope to achieve this by interfacing VIC to YNHH's

electronic medical record (EPIC) and the MyChart feature, which gives patients portal access to view their medical records.

7. List of Publications and Products

Peer-Reviewed Poster presentation:

2018: "Usability of Informed Consent *m*Health Tool", Yale Innovation Summit, New Haven, CT. 2018

2018: "Usability of Informed Consent *m*Health Tool", mHealth and Social Media Conference, Storrs CT. 2018

2017: "Improving the Informed Consent Dialogue in the Healthcare Space: Development and Usability of the VIC *m*Health Tool", Academy Health's Annual Research Meeting, New Orleans, LA. 2017

2017: "Usability of Informed Consent *m*Health Tool" 1st Annual UMass *m*Health and Social Media Conference, Worcester, MA. 2017

2016: "*m*Health Approach to the Informed Consent", Yale Technology Summit, New Haven, CT. 2016.

2016: "*m*Health Approach to the Informed Consent Data, Yale Day of Data, New Haven, CT. Oct 2016.

Talks and invited speaker/Presentation:

2018: *m*Health Approach for Patient-Centered Informed Consent Process, CHealthWorld, Boston, MA. Sep 2018

2017: Building an Informed Consent Tool Starting with the Patient: The Patient- Centered Virtual Multimedia Interactive Informed Consent (VIC), American Medical Informatics Association (AMIA) 2017 Annual Symposium, Full Paper Presentation, Washington, D.C. 2017

2017: *m*Health Tool for Patient-Centered Informed Consent Communication, International Conference on Communication in Healthcare & Health Literacy Annual Research Conference (AACH), Oral Abstract Presentation, Baltimore, Maryland. 2017

2016: Invited speaker at Cancer Outcomes, Public Policy and Effectiveness Research Center (COPPER) , "*m*Health approach to the Informed Consent", New Haven CT. Oct 2016

2016: Invited speaker at *m*Yale, *m*Health Research Group (include: School of Medicine, School of Public Health, School of Nursing), New Haven CT. Oct 2016

2016: Invited speaker at Informatics Fellow Seminar at the VA , Sep 20th at the VA Connecticut Health Care System ""*m*Health Approach to the Informed Consent" West Haven, CT. 2016

Published Papers

1. **Abujarad**, F, Alfano, S, Bright, T J. Kannoth, S, Grant, N, Gueble, M, Peduzzi, Chupp, G, Building an Informed Consent Tool Starting with the Patient: The Patient- Centered Virtual Multimedia Interactive Informed Consent (VIC), American Medical Informatics Association (**AMIA**) 2017 Annual Symposium, Washington, D.C.

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