QUARC

Proposal to Academic Medical Center re: Usability Study

MEDarchon is conducting the first ever FDA/NIST level usability study to derive and validate a patient handoff tool via (R21) Exploratory and Developmental Grant to Improve Health Quality through Health Information Technology (PA-14-001). MEDarchon has a three-phase study protocol and grant application for that it intends to submit to the Agency for Healthcare Research and Quality in January 2015. MEDarchon would like qualified, interested Academic Medical Centers (AMCs) to join its Academic Consortium.

It is very well known that well executed patient handoff can have significant impact on improving patient outcomes (preventing medical errors, decreasing length of stay, improving quality metrics, etc.). Unfortunately, we know that patient handoff is not done well today: the individual giving handoff provides incomplete or inaccurate data, the individual receiving the handoff forgets information told to them and the important aspects of handoff is missing. Clinical studies have found that incorporating an electronic handoff format into oral handoff dramatically improves patient condition.

Almost all of the commercially available handoff tools have incredibly poor usability and do not get used. These tools do not respect workflow and fail to incorporate all of the detail and customization that providers need. Additionally, they do not enable cross-role (e.g. physician to nurse) collaboration or facilitate the different types of handoff that occur (medical, surgical, inpatient-to-outpatient).

MEDarchon is conducting, to our knowledge, the first ever FDA/NIST level usability study to derive and validate a patient handoff tool. It is specifically seeking to prove endpoints around handoff efficiency, efficacy to clinicians and efficacy to patients.

AMC Involvement

MEDarchon is seeking a diverse group of healthcare thought leaders to help us understand their workflow and preferences by engaging in simulations and exercises during the first two phase of the study. We also are looking to leverage our existing EMR integrations and analytic capabilities to automate the process of handoff.

Phase three of the study will validate the impact of the tool on patient related outcomes.. There is institution compensation for participating in the studies via the (R21) Exploratory and Developmental Grant to Improve Health Quality through Health Information Technology (PA-14-001).

As part of this project, the AMC will provide the following:

- AMC will be a listed co-sponsor on the grant application
- AMC's Chief Medical Information Officer and Patient Safety Officer (or equivalents) will act as listed study investigators
- Protocol review and budgetary input
- Facility and Administration Fees (F&A) capped at 15%
- Provision of personnel to execute key aspects of the study (e.g. clinician participants for the usability study (phase I and II), and study personnel for informed consent, participant follow-up during phase III)
- System-adoption of the QUARC Communication Platform
- Execution of a Business Associate Agreement with MEDarchon and subsequent provision of relevant outcomes for consented patients (medical errors, length of stay, cost of care, readmissions) – note: AMC retains all data ownership rights.
- Input and review of data analysis
- Participation in publishing and presenting the results of the study

In return, MEDarchon will provide the following to AMC:

- Reimbursement for budgeted study expenses through the R21 Grant
- Free use of the derivative work (QUARC Handoff)
- Royalty payments from revenue generated by the derivative work
- Significant discount on all other QUARC modules

Timeline of Events

In order to participate in the Academic Consortium, the following deadlines must be met:

January 9th	Electronic notice of Intent to Investigate Execution of Mutual NDA Distribution of Study Protocol Informational Meetings Scheduled As Needed
January 19th	Execution of Letter of Intent
February 6th	Final R21 Grant Submitted to AHRQ
February 6th	Contract Execution
February 9th	Phase I Begins
April 13th	Phase II Begins
Upon Grant Notification	Phase III Institutional IRB Approval Sought
Upon Grant Funding	Phase III Study Begins