SUMMARY STATEMENT

PROGRAM CONTACT: **(Privileged Communication)** ***Release Date:*** **04/23/2010**

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Application Number: **1 R01 HS018979-01**

Principal Investigator

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Applicant Organization: VANDERBILT UNIVERSITY

Review Group: **HTDS**
Health Care Technology and Decision Science
Health Care Technology and Decision Sciences

Meeting Date: **02/23/2010** ***RFA/PA:*** **PA09-070**
Council: **MAY 2010** ***PCC:*** **CQUIPS**
Requested Start: **07/01/2010**

Project Title: **Comparative Effectiveness of Two Handover Training Interventions**

SRG Action: **Priority Score: 256 Percentile: 33.9**
Human Subjects: **44-Human subjects involved - SRG concerns**
Animal Subjects: **10-No live vertebrate animals involved for competing appl.**
Gender: **1A-Both genders, scientifically acceptable**
Minority: **1A-Minorities and non-minorities, scientifically acceptable**
Clinical Research - not NIH-defined Phase III Trial

Project Year	Direct Costs Requested	Estimated Total Cost
1	322,409	502,148
2	320,272	498,820
3	320,422	499,053
4	320,474	499,134
TOTAL	1,283,577	1,999,156

ADMINISTRATIVE BUDGET NOTE: The budget shown is the requested budget and has not been adjusted to reflect any recommendations made by reviewers. If an award is planned, the costs will be calculated by Agency grants management staff based on the recommendations outlined below in the COMMITTEE BUDGET RECOMMENDATIONS section.

PROTECTION OF HUMAN SUBJECTS UNACCEPTABLE

RESUME/SUMMARY OF DISCUSSION: This R01 research grant from Dr. Matthew Weinger, from Vanderbilt University Medical Center (VUMC) in Nashville, TN, proposes to conduct a randomized comparative effectiveness trial of two training interventions that would improve patient handovers, and thus, reduce the risk of transition-related care lapses. The reviewers noted that this application is very significant because of its potential to minimize those errors through improved quality of patient care. They cited the appropriateness of VUMC's strong multidisciplinary team and environment for conducting this research. Also, the reviewers agreed this project's use of web-based tools and simulations is innovative, as is electronic handoffs. However, several weaknesses were also cited regarding the proposed approach: a lack of a well articulated difference in benefits between the medium- and high-intensity interventions; a lack of measurement of acuity of patient's condition and of safety issues during handoff; the lack of objective data collection methods for some measures; the lack of statistical power which may hinder determining which arm is most effective; and a conceptual model on which to build the training model is not discussed. The reviewers noted concerns with the protection of human subjects citing that the study design does not describe methods for assuring intern confidentiality. Overall, the reviewers recommended this application for further consideration with a "good" to "very good" level of enthusiasm.

DESCRIPTION (provided by applicant): The care of hospitalized patients is marked by numerous transitions in care, including handovers of patient care responsibility at changes of shift. If executed poorly, such handovers can lead to lapses in care, yet few clinician trainees learn the potential risk of these transitions or the strategies to improve patient care during handovers. We propose a comparative effectiveness trial of two training interventions to improve change of shift handovers and thus reduce the risk of transition-related care lapses. An experienced multidisciplinary team will conduct a randomized controlled trial using a blinded prospective cohort design with repeated measures. Two consecutive years' cohorts of medicine and pediatrics interns will be randomized to receive a mid-intensity intervention (webinar plus 1-hour simulation-based training), a high-intensity intervention (webinar plus 2-hour simulation-based training and monthly handover performance feedback), or a control group (routine didactics on handovers). The mid-intensity training intervention will follow the method used by Arora et al. The high-intensity training and feedback intervention will be modeled after a prior AHRQ-funded handover project conducted by our team. In Specific Aim 1, we will compare the effects of simulation-based handover training on the quality of interns' change of shift handovers to test the hypothesis that intervention group interns will perform more effective handovers than those in the control group. The primary measure will be trained observers' ratings of actual inpatient change of shift handovers using validated measures of handover effectiveness. In SA2, we will compare the effect of the handover training interventions on the occurrence and severity of handover-related non-routine events (HNRE) to test the hypothesis that, among observed handovers, patients of intervention group interns will experience fewer and/or less severe HNRE than will patients of control group interns. HNRE, to be collected by structured interviews of handover providers and recipients, are defined as any event possibly related to the handover that deviates from optimal care for that particular patient given their specific clinical circumstances at the time of the handover. In SA3, we will assess the effect of the handover training interventions on patient rescue events. We hypothesize that for all handovers (whether or not observed), patients of intervention group interns will experience fewer rescue events than will patients of control group interns. In this study, the rescue events (defined as an intervention to mitigate a potentially life-threatening event) will be the occurrence of Rapid Response Team calls and unexpected transfers to the intensive care unit. Multivariate logistic models will be used to compare the three groups' handover effectiveness, HNRE incidence/severity, and rescue events over time, adjusting for important covariates including clinical discipline (medicine or pediatrics), training status of handover giver and receiver, time of year, and the acuity of patients on the day of the handover. These results will inform improvements in clinician-clinician communication, care transitions, and work schedules.

PUBLIC HEALTH RELEVANCE: Communication failures during patient handovers can produce care lapses that lead to errors and adverse outcomes, yet few clinician trainees learn the potential risks of these transitions or strategies to improve patient care during handovers. This randomized study will compare the effectiveness of two types of handover training interventions aimed at medical and pediatric interns: a mid-intensity intervention (a webinar and a single 1-hr simulation-based training session that focuses on inpatient handover best- practices) versus a high-intensity intervention (the same webinar and a 2-hr simulation- based training session that also addresses best practices while focusing on interpersonal skills development, together with ongoing personalized performance feedback). We hypothesize that interns receiving the high-intensity intervention will practice higher-quality handovers and that their patients will have fewer care lapses, compared to interns receiving the mid-intensity intervention or no intervention at all (control group).

CRITIQUE NOTE: The sections that follow are the essentially unedited, verbatim comments of the individual committee members assigned to review this application. The attached commentaries may not necessarily reflect the position of the reviewers at the close of group discussion, nor the final majority opinion of the group. The above RESUME/SUMMARY OF DISCUSSION represents the evaluation of the application by the entire committee.

CRITIQUE 1:

Significance:
Strengths: The application addresses an important issue: handoffs (transitions in care) as performed by inexperienced healthcare providers(interns) The investigators plan to investigate the link between handovers in care and non-routine events, rapid response teams and unexpected ICU transfers. The mandated reduction in resident work hours has increased the number of handovers. The proposed further reduction in work hours will further increase the number of handoffs.

Weaknesses: The current application is limited to one institution and one discipline (physicians) so it is not clear that the results will be generalizable.

Approach:
Strengths: The investigators propose a three armed trial examining no training vs. medium and high intensity simulation training as an intervention to improve the quality of handoffs. The investigators propose to link the intensity of training and quality of handoffs to unexpected patient events. The linkage to clinical outcomes is key in this project.

Weaknesses:
The investigators acknowledge the safety issues with handoffs generally and in their own institution in spite of their usual practices. Given the acknowledged importance of handovers, it seems that the control group (and more importantly their patients) is distinctively disadvantaged. The investigators believe that the additional training will result in safer care for the patients. It seems that the important question is whether simulation training (intense or not) incrementally improves patient handoffs compared to “conventional education”. Given that simulation is resource intensive, it is important to determine the added value that simulation brings to patient care. If the control group were, at a minimum, exposed to the webinar it might answer an important question as to the incremental effect of moderate and intense simulation training compared to a conventional educational experience. Alternatively, a randomized trial with wait list controls and cross over (eg.: Wayne and McGaghie: Teaching and Learning in Medicine**,** *17*(3), 210–216) would be a method to ensure both groups received training and help to isolate the effect of the training.

There are a number of confounders that don’t seem to be addressed including the number of patients covered per intern and the acuity of the patients covered by the various interns. Not explicitly stated that the pediatric and medical interns are randomized equally between the three groups. The proposed

definition of HNRE.-seems to include trivial or issues not controllable by improved training, (eg. workload, and technology failures, as well as items that could be considered not clinically significant). The participants in the mid-intensity group are described as receiving feedback following their “practice handover” is this a debriefing in the usual sense?

It would seem important that institutional adverse event data be used to develop handover scenarios-does this occur?

The application describes handovers to occurring at bedside in the simulations and requiring 10 minutes/ pt handover. This doesn’t seem to be realistic in actual clinical practice.

HNRE contributing factor assessment is completed after the event and as presented would seem to be subject to recall bias. Would recommend applying the same assessment (re: occurrence of non-routine events) and unexpected escalations in care for interns covering their own patients. Is it realistic for two nurse observers to remain blinded when observing the same interns over two years? The observations of the actual transitions by an individual could conceivably affect the quality of the simulations. While there may be desensitivation over time the observers will be interacting with the interns during the handovers to identify patients, etc. . The investigators acknowledge but do not provide possible solutions to the issue of which elements of the intervention is most important, the training or the feedback.

Innovation:
Strengths: The use of simulation to train for handovers is innovative and the linkage of the simulation training to clinical outcomes is both necessary and innovative but rarely occurs.

Weaknesses: In addition to the use of a structured handoff evaluation, video and/or a qualitative analysis would potentially provide significant insight into the most critical aspects of the handoff.

Investigators:
Strengths: Strong multidisciplinary team including recognized experts in simulation and patient safety. Also includes specialists in organizational psychology and biostatistics.

Environment:
Strengths: The institution is recognized for its commitment to patient safety and innovative approaches to quality and transparency.

Weaknesses: A relatively small number of residents are available for this project and in order to meet the power calculations, essentially 100% resident participation is necessary.

Degree of Responsiveness:
Strengths: The application is responsive to and fits within the patient safety portfolio especially with respect to the focus on handoffs.

Protection of Human Subjects from Research Risks: Unacceptable. Though the interns need to participate in mandatory training, it is not clear that they have the ability to opt out of the research aspects of the project-including interviews, It appears that the application assumes 100% participation of residents which may not occur. Is the HNRE data protected from discovery by supervisors eg: residency directors.

There is also a concern that if the investigators truly believe that it is safer to provide some handoff training, that all groups should eventually receive the training. Will the DSM monitor for significant numbers of significant NRE and or escalations in the untrained groups?

Privacy and Security Protections for Patients: Acceptable.

Inclusion of Women and Minority Subjects: Strengths: The interns are the research participants. Women and minorities are not specifically included or excluded.

Inclusion of AHRQ Priority Populations: No specific priority populations are included.

Budget and Period of Support: Acceptable.

Summary of Strengths and Weakness:
Strengths: The linkage of the handover training to clinical outcome is a significant strength.

Weaknesses: The design is weakened by the lack of any type of training for the “control group”. There are multiple confounders that will impact the investigators’ ability to identify the factors that result in improved handoff behaviors (intensity of training, giver vs receiver, monthly feedback) and encourage adoption. The study relies on 100% participation of residents which may not occur.

CRITIQUE 2:

Significance:
Strengths: This is an important area of performance improvement for hospitals. This project could have significant impact on quality of hospital care and overall efficiency if handovers could be greatly improved.

Approach:
Strengths: A quasi-experimental design is proposed where standard training (low intensity version) on handovers for interns is compared to mid-intensity version with webinar and 1 hour of simulation training and a higher-intensity version with the webinar a two hours of training.

Investigators recognize that there will be a Hawthorne effect and that cross-contamination among groups will occur since the low-intensity group will learn from the mid and high intensity groups through daily contact. The have included identification of this phenomenon in their analysis plan.

The investigators will build upon two existing programs they have developed for the training. It is unclear how much additional development must be completed for this project.

The impact of training on rescue events appears to be the most objective aspect of this project and a strength of the approach.

Weaknesses:
It would certainly seem that the nurse observers would learn over time which groups the interns belonged to. This can impact the data collection through possible bias.

It’s not clear that all of the measures would be entirely objective. For example, hand-over related events will be obtained through interview. It would seem a more objective data collection approach is warranted.

Additional data on the HNRE will obtained from the intern who gave the handover through an e-mail survey that can be completed at his or her leisure. It would seem that would need to be done right away to avoid memory bias as time progresses.

Innovation:
Strengths: A web-based and simulation approach is proposed for the training. It will be interesting to find out what impact this approach has over standard training.

Investigators:
A well-qualified multidisciplinary team is proposed. Several of the investigators are leaders in this field.

Environment: This is an exceptional environment for this type of research.

Degree of Responsiveness:
This application is responsive in several ways. It uses a comparative effectiveness approach to determine which training mechanism for interns produces the best patient outcomes. It is also responsive in that it can lead to organizational changes that will improve efficiency and quality of care.

Protection of Human Subjects from Research Risks: Unacceptable: Should address protection of interns (will their data be protected from assessment by supervisors).

Privacy and Security Protections for Patients:
The description does not address access of reviewers or raters of HRNE or rescue events at access to patient record for their review.

Inclusion of Women and Minority Subjects: Acceptable.

Inclusion of AHRQ Priority Populations: Acceptable.

Budget and Period of Support:
This is pretty high budget, but a lot of work is proposed over the time period. The justification would be strengthened if roles were a bit clearer. The project is heavy on staff that would develop the training materials.

The timeline is long but this is necessary to implement the training and study impact over time.

Summary of Strengths and Weakness:
This application describes an important project that could have a significant impact on patient outcomes. The project could be strengthened through the addition of more objective measures of impact such as the rescue event measure proposed.

CRITIQUE 3:

Significance:

Strengths: The investigators make an excellent argument for why studying change-of-shift handovers is an important problem. Communication problems are at the heart of many medical errors, and these are clearly more likely to happen during change-of-shift.
Approach:
Strengths: The entire project is well thought out and designed in a straightforward and thorough manner. Their mixed modeling approach to the analysis is to be commended.

Weaknesses: There is concern that the blinded nurses may be able to figure out which group the interns were randomized to. A lot hangs on the assumption that all interns will participate; however, if any consent is ultimately required (see human subjects concerns), then any non-participation could have an effect on the statistical power.

Innovation:
Strengths: The 3-arm design using simulations is very innovative.

Investigators:

Strengths: The multidisciplinary team (clinicians, educators, human factors engineers, quality improvement experts, psychologists, statisticians, and health services researchers) is especially well qualified to study the complex problem of change-of-shift handovers. They have preliminary studies demonstrating their ability to conduct this kind of study.

Environment:
Strengths: Vanderbilt is an excellent place to conduct this research project, and there is clear institutional support.

Degree of Responsiveness:
Strengths: This application directly deals with quality of care and is certainly responsive to the AHRQ Research Portfolio.

Protection of Human Subjects from Research Risks: Acceptable. The risks are minimal, and the investigators adequate address the management of those risks. However, the investigators should consider whether it is appropriate to 'force' interns to participate in the interviews.

Privacy and Security Protections for Patients: Strengths: Patients are not being studied in this project – the clinician interns are.

Inclusion of Women and Minority Subjects: Acceptable. Women and minority subjects will be included to the extent that they are represented in the pool of participating interns.

Inclusion of AHRQ Priority Populations: Acceptable. This project is relevant to any inpatient population, including all eight priority populations.

Budget and Period of Support:
Strengths: The budget appears to be adequate, as is the 4 year time period.

Summary of Strengths and Weakness:
Strengths: The investigative team is strong, as is the study design and analysis plan.

THE FOLLOWING RESUME SECTIONS WERE PREPARED BY THE SCIENTIFIC REVIEW OFFICER TO SUMMARIZE THE OUTCOME OF DISCUSSIONS OF THE REVIEW COMMITTEE ON THE FOLLOWING ISSUES:

PROTECTION OF HUMAN SUBJECTS (Resume): UNACCEPTABLE
The reviewers had the concern that the interns need to participate in mandatory training and it is not clear that they have the ability to opt out of the research aspects of the project interviews. It is not clear either if the data will be protected from discovery by supervisors.

INCLUSION OF WOMEN PLAN (Resume): ACCEPTABLE

INCLUSION OF MINORITIES PLAN (Resume): ACCEPTABLE

INCLUSION OF AHRQ PRIORITY POPULATIONS (Resume): ACCEPTABLE

COMMITTEE BUDGET RECOMMENDATIONS: The budget was recommended as requested.

MEETING ROSTER

Health Care Technology and Decision Science
Health Services Research Initial Review Group
AGENCY FOR HEALTHCARE RESEARCH AND QUALITY
Health Care Technology and Decision Sciences
HTDS 1
February 23, 2010 - February 24, 2010

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* Temporary Member. For grant applications, temporary members may participate in the entire meeting or may review only selected applications as needed.

Consultants are required to absent themselves from the room during the review of any application if their presence would constitute or appear to constitute a conflict of interest.