Kelly Schoenbeck Internal Medicine CRC IRB Proposal 5 June 2013

Training at the Bedside: RCT of residents as clinical leaders on a general medicine service

A. Study Purpose and Rationale

Bedside rounding has been a part of medical training dating back to Osler, and it enables attendings to model values of professionalism and teamwork as well as patient interviewing and physical examination skills, all of which medical trainees hope to learn and implement in their development as physicians. However, bedside rounds and teaching has declined from 85% in teaching hospitals during the early twentieth century to approximately 16-20% by the late 1970s, ⁱ with current estimates placing bedside presentations to be less than 25% of rounds.ⁱⁱ Literature has identified several limitations sited by physicians that prevent them from performing bedside rounds, including time constraints and concern over patient discomfort;" however, studies have shown that patients generally prefer bedside rounds, ^{iv,v,vi} and the time spent at the bedside compared to conference room rounding is equivalent.^{vii} Other identified barriers include a lack of confidence in how to lead bedside rounds and in demonstrating physical exam skills.^{viii} Incidentally, there has also been a noted decline in physical examination demonstration and subsequent skill development in medical trainees, causing physical examination skills of residents to largely remain stagnant at the level of a senior medical student. This has led to a decreased familiarity with signs and use of physical exam skills, resulting in increased reliance on lab and imaging data for diagnoses.^{ix} Such instances only lead to perpetuate the cycle of decline in physical exam skills for future medical trainees,^x with likely further avoidance of bedside teaching.

Literature has supported that residency programs with successful bedside teaching have clear guidelines for how bedside rounds should be performed.^{xi} Such guidelines have included having the attending lead the bedside rounds ideally after having performed training on clinical skills and teaching^{xii-xiii} to having the resident lead the team with the attending present to provide support as needed.^{xiv} Physical examination skills have also been able to be improved as evident by a physical exam teaching program at Brigham and Women's Hospital, which demonstrated an improvement in residents' physical examination skills and increased confidence for teaching the physical exam after they went through four 90-minute teaching sessions.^{xv} Such leadership and skill training for housestaff has been shown to be beneficial, and could be considered particularly pertinent in light of new ACGME guidelines that are meant to evaluate residents through milestones of demonstrating key-competencies of professionalism, communication skills, practice-based learning and improvement, and systems evaluation.^{xvi}

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Currently at NYP-CUMC, there is no standard or formal training for bedside teaching to the residents, and the attendings receive a brief orientation. As a consequence, housestaff experience wide variability in the frequency and in how bedside rounds are conducted and in development of their physical examination skills. The role of the resident may also vary, with them leading the team on rounds in some instances whereas others may be limited in their role as clinician leaders. The purpose of this study is to evaluate if implementing bedside round and physical exam training to residents improves the satisfaction of bedside rounds amongst medical trainees.

Hypothesis: Intern and medical student satisfaction with bedside rounds will increase after implementing a resident-targeted training intervention focused on bedside teaching and physical examination skills

B. Study Design and Statistical Analysis

This is a randomized controlled trial involving the Internal Medicine housestaff and medical students at New York Presbyterian, Columbia University Medical Center who rotate through the General Medicine 1 service. General Medicine 1 was selected as the targeted teaching service because is it typically has few to no private patients, meaning that almost all patients are being cared for by the resident team. Prior to starting their rotation on the General Medicine 1 teaching service, the internal medicine residents and medical students are randomly assigned to one of two teams, either team A/C or B/D. Each team is composed of two residents, two interns, and two medical students, and is supervised by two attendings. The attendings are usually paired so that one is more clinically focused while the other is more research based, and they are randomly assigned as well. The study participants are randomized by their predetermined medical student and residency schedule. There will be no cross-over of subjects as each medical student and resident only completes the General Medicine 1 rotation one time per year over a 4 week period.

Prior to starting the rotation, B/D pair of residents will undergo bedside round training by watching videos of physical examination skills and instructions for how to standardize interactions during bedside rounds. The B/D residents will watch a video performed by CUMC residents and attendings that exemplify how all members of the medical team should interact at the bedside, with the residents leading the bedside rounds. The residents who watch the training video will also receive a checklist for key steps in order to perform successful bedside presentations that they can take with them on rounds to help standardize the approach. The rounding checklist is an adaptation of 6 keys steps to a patient encounter from "The Art of Bedside Rounds" from Gonzalo, JD et al^{xvii} and "Twelve tips to improve bedside teaching" from Subha Ramani.^{xviii} The residents will also watch videos from the Standford 25 online series^{xix} on how to perform common but distinct physical exam findings, such as demonstration of a fluid wave on abdominal exam, JVP, or pulsus paradoxus.

Bedside Rounding Checklist

	Determine if notions is conversions for hadride reunds (berriere, ANAC, mental illuses, language)				
	Determine if patient is appropriate for bedside rounds (barriers: AMS, mental illness, language)				
	Receive patient's permission for bedside presentation prior to rounds				
	Introduction of team members and roles				
	Explain purpose of bedside rounds to patient				
(for educational purposes & for patient to clarify any aspects of the history)					
	Ensure patient modesty throughout encounter				
	HPI is presented concisely at bedside (goal: <5 minutes. HPI should include pertinent aspects of social history, family history, medications, and allergies). Co-resident is in charge of time-tracking.				
	Resident hears case, and tapers patient & medical trainee interactions to focus on expanding on teaching points from history or physical exam				
	Resident asks attending for expert contributions				
	(options: physical exam demonstration, EBM, or asking neglected history question)				
	Presenter briefly summarizes the HPI, potential diagnosis, and plan for the patient				
	(Example: "Mr. Smith, you came in with cough & fever, we think you have a pneumonia, and our				
	plan is to treat you with antibiotics")				
	Ask patient what questions they might have. If there are more than 1-2, tell the patient that the				
	team resident will be back later to discuss things further.				

For time management, bedside rounds will only be performed on new patients. The A/C group will perform rounds how they are currently performed. The attendings will lead rounds in a conference room away from the bedside and will visit new patient admissions as a team afterward, with the attending leading the interaction.

On the last day of the General Medicine 1 service, medical students and interns will complete a survey to address the perception and educational value of rounds to evaluate if there is a difference in satisfaction between the group where the resident underwent training compared to the control group. The survey is a 4-point Likert scale (ranging from "strongly agree" to "strongly disagree") about their beliefs and values of rounding and their experience.

The primary outcome will be intern and medical student satisfaction with attending rounds on the General Medicine 1 ward service. In order to achieve 80% power with an alpha-error rate 0.05, a sample size of 48 patients per study group was calculated using the Chi-square test, assuming a placebo response of 30% and a treatment response rate of 60% (effect size 30%).

C. Study Procedure

Patient rounds are a standard part of clinical care as the patients admitted under the medical service are presented by the residents and medical students to the attendings every day. New patient admissions tend to be longer and more detailed in presentation style

compared to follow-up cases, which typically update things that have changed from the prior day. New patients are seen by the team together upon being admitted. However, the case may be performed in a conference room away from patients with the team evaluating the patient together afterward, or with the case presented at the bedside in the presence of the patient and the entire medical team. Bedside rounds may take 15-20 minutes in the patient's room. The patient should not experience pain, discomfort, or inconvenience. Standard clinical care would not be compromised. Each subject participant would participate for 4 weeks of their General Medicine 1 rotation. The study would have to last for at least 12 months to achieve 48 responses per study arm.

The Stanford 25 is a web based curriculum developed by a team led by Dr. Abraham Verghese for the Internal Medicine residents at Stanford University, with a mission of helping residents perform, demonstrate, and ultimately teach bedside physical examination skills. The curriculum was created as a means to develop and enhance physical examination skills amongst the housestaff. There are 25 topics and examination skills, ranging from the thyroid examination to assessing cerebellar injury, and there is an explanation and video accompaniment for each topic. Of note, the curriculum is ideally meant to be practiced and demonstrated and not only a web education.

D. Study Drugs

Not applicable

E. Medical Device

Not applicable

F. Study Questionnaire

	Rounding Survey							
1.	I prefer bedside rounds compared to conference room or hallway rounds							
	Strongly agree	Agree	Disagree	Strongly disagree				
2.	. Bedside rounds are better for patient care compared to conference room or hallway round							
	Strongly agree	Agree	Disagree	Strongly disagree				
3.	Bedside rounds are more efficient compared to conference room or hallway rounds							

- Strongly agree Agree Disagree Strongly disagree
- 4. Bedside rounds are more educational compared to conference room or hallway rounds

 Strongly agree
 Agree
 Disagree
 Strongly disagree
- 5. I feel more engaged in rounds during conference room or hallway rounds compared to bedside rounding

	Strongly agree	Agree	Disagree	Strongly disagree		
		-	-			
6.	. I learned new physical examination skills this rotation					
	Strongly agree	Agree	Disagree	Strongly disagree		
7.	I was given specific feedback on my clinical skills this rotation					
	Strongly agree	Agree	Disagree	Strongly disagree		

G. Study Subjects

Study subjects will include internal medicine residents at NYP-CUMC who are PGY1 and medical students during the academic years 2013 through 2014. There will be approximately 100 participants with approximately 1/2 of the participants from each of the postgraduate years. PGY2 and PGY3 are excluded from the survey as they could introduce bias as some would undergo the training sessions. No personalized health information will be recorded for any of the resident physicians.

H. Recruitment of Subjects

Study subjects will be recruited as they participate in the General Medicine 1 ward service. They will have the right to refuse participation in the study without penalization.

I. Confidentiality of Study Data

All information collected as part of the study will be kept confidential. The responses from the survey will be assigned a unique study identification number and will be de-identified from all personal information. Research files will be kept on a secure password protected server. Everything will be done to keep your data secure, however, complete confidentiality cannot be promised. The following individuals and/or agencies will have access to research files: Study Investigators, Authorities from Columbia University and New York Presbyterian Hospital, including the Institutional Review Board ('IRB') and/or the Office of Human Research Protections ('OHRP'). Although full efforts will be made to maintain your privacy, unanticipated problems may occur.

J. Potential Conflict of Interest

The developer of this protocol is affiliated with the CUMC residency program, but does not stand to directly benefit from this study. There is no conflict of interest to disclose.

K. Location of the Study

The study will be performed at NYP-CUMC, Milstein Hospital, in the general medicine wards.

L. Potential Risks

There are no anticipated risks to participants that go beyond what is encountered in daily life because all data will be de-identified and kept on a secure server. Subjects will not be evaluated or penalized in anyway based on the results of this study. Subjects will not be individually identified in any internal report, external presentation or publication of this research.

M. Potential Benefits

There may or may not be direct benefits to participants as a result of this study. The information gathered will be used to design curriculum aimed at improving the quality of bedside teaching during medical rounds. This may benefit the residency program and patients of NYP-CUMC.

N. Alternative Therapies

The alternative for each resident is to not participate in the research study. The residents and medical students could be changed from General Medicine 1 to General Medicine 2; if no subjects consent during a particular month, the study will be temporarily held during that 4 week period.

O. Compensation to Subjects

There is no direct compensation provided for participating in the study.

P. Costs to Subjects

There is no cost to subjects.

Q. Minors as Research Subjects

All of the participants in this research study will be adults. No minors will be included as research subjects.

R. Radiation or Radioactive Substances

Not applicable.

References:

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xix The Stanford 25. <u>http://stanfordmedicine25.stanford.edu/</u>