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IRB PROPOSAL
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Effectiveness of additional simulation training program on residents' performance during codes

A. Study Purpose and Rationale

In the recent years, simulation training has been increasingly popular in medical education.
The goal of simulation-based learning is to help trainees acquire and refine the technical and cognitive skills necessary to perform clinical procedures. Medical education at all levels increasingly relies on simulation technology to provide a tool to increase learner knowledge, provide controlled, safe, and forgiving practice opportunities , and shape the acquisition of physician's clinical skills. [1]

The use of simulation technology has great potential to shape medical education, certification, licensure, and quality of care. Simulation has demonstrated its effectiveness to achieve, measure, and maintain trainee skill in the performance of variety of clinical procedures including laparoscopic surgery, endoscopy, emergency airway management, trauma resuscitation, bronchoscopy, and carotid angiography. [3]

During residency training, young physicians take care of very sick patients and repeatedly deal with life threatening emergencies where quick decision making and solid medical knowledge are key to patient survival and good outcome. Codes in particular provide for this kind of emergent situation when quick and accurate decisions have to be made.

However, it has been suggested that internal medicine residents are expected to recognize and manage life-threatening events for which they may be poorly prepared and insufficiently practiced. [2] Specifically, data on in-hospital cardiac arrests from the University of Chicago demonstrated that the quality of resuscitation efforts varied and often did not meet published guidelines, even when performed by well-trained hospital personnel. [1]

At CUMC, most codes are run by the short call second year CCU resident if the code occurs before 5 pm or by the long call CCU resident if the code occurs after 5 pm. The cardiology on call resident or cardiology overnight resident usually arrives to the code as well and is able to relieve the CCU resident if the CCU resident has to return to the unit. In practice, most of the time, the CCU resident remains the code leader for the duration of the code.

Currently, all residents receive ACLS training before starting their intern year. Additionally, CUMC residents receive a brief review course outlining ACLS algorithms prior to starting their CCU rotation.

Studies have shown that simulations in general are highly effective at promoting skill acquisition among medical learners. [4] In a study by Waye at el a curriculum featuring deliberate practice using simulator training dramatically increased the skills of residents in ACLS scenarios. [1] In one RTC, 38% improvement was demonstrated in ACLS skills after an 8 hour simulation-based educational intervention. [5]

The purpose of this study is to determine whether additional simulation training will improve the way residents run real codes occurring at CUMC.

In addition to the usual training outlined above, the study group will receive additional intensive simulation training followed by a debriefing session. The purpose of the simulation and debriefing will be to emphasize and review effective medical management during the code as well as effective team leadership skills.

B. Study Design and Statistical Analysis

The study will be designed as a randomized observer blinded parallel arm study. Second year resident pods starting their CCU rotation will be randomly assigned to a regular or simulation/intensive training group. To account for confounding, such as time of the year that residents are taking the CCU rotation, randomization will be done in 2s. Specifically, pods doing their CCU rotation in block 1 and 2 will be randomly assigned to experimental or control group. Similar randomization will be done with pods doing CCU rotation in blocks 3 and 4, 5 and 6 and so on. Randomization will be performed using Excel spreadsheet.
All second year residents will be enrolled in the study thus allowing for 22 subjects in each group. With the power of 80% and P =0.05, minimum effect to achieve statistical significance can be calculated using the following formula:

$$N \text{ (in each group)} = 1 + 16 (\text{st.dev/effect})^2$$

SD can be estimated to be (50-10)/4 = 10
Calculated effect = 8.7

One group of residents will receive intensive training using a medical simulator. Using computer software, a mannequin will display multiple physiologic and pharmacologic responses observed during code situations. Residents will be trained in 6 scenarios commonly encountered during codes – asystole, ventricular fibrillation, supraventricular tachycardia, ventricular tachycardia, symptomatic bradycardia and pulseless electrical activity. Teaching simulation sessions will be standardized and involve multidisciplinary teams including nurses and anesthesiologists.

The second group of residents will act as controls and will only receive a ACLS “refresher” course prior to start of their CCU rotation.

During the course of their CCU rotation, residents will likely have an opportunity to participate in at least one code as a code leader. There will be an independent expert observer such as a cardiology or CCU attending present during each code (the observer will carry a code pager and respond to codes). The observer will be blinded to weather the resident running the code received any additional training or not. The observer will grade residents’ performance based on the questionnaire outlined below.

Outcome measures:
Residents’ performance will be graded on a scale of 1 to 5 according to the questionnaire outlined below (Questions 1-10). Questions 11 and 12 are overall assessment of performance and will be graded as “yes” or “no”. The scores for questions 1-10 will be added to produce a final score of 10-50. The scores of all residents in each group (experimental and control) will be averaged. The two averages will be compared using unpaired t-test to analyze for presence of statistically significant difference in the results.

If one of the residents in the study will not have an opportunity to be a code leader, a mock code will be initiated so the resident can be evaluated and graded on his/her performance. A mock code will be initiated and organized by the chief residents using SimMan. The code will be called overhead and paged to the appropriate team members as in a real code situation. Medicine residents as well as other members of

the interdisciplinary team (nurses, anesthesiology, etc) will not be aware that the code is a simulation exercise until they arrive at the bedside. When the team leader arrives, he/she will be expected to manage a pre-programmed scenario. All members of the interdisciplinary team will be expected to participate in the "mock" code as if it were a real code.

Only the first code lead by each resident will be graded and included in the study.
Power will be set at 80%; P value = 0.05

C. Study Procedure

All residents receive ACLS training before starting their intern year. Additionally, all residents receive a brief review course outlining ACLS algorithms.
In addition to the above training, the study group will receive additional intensive simulation training, followed by a debriefing session. The purpose of the simulation and debriefing will be to emphasize and review effective medical management during the code as well as effective ways of team leadership.
The training session will likely take about a day. The duration of the entire study will span over a 1 year period with different groups of residents participating at different times.

D. Study Drugs

Epinephrine, Vasopressin, Atropine, Adenosine, Amiodarone, Diltiazem, beta blockers, fluids, electrolyte replacement therapies will be administered to all patients in accordance with the most recent ACLS guidelines based on patient's clinical presentation and status.

E. Medical device

AED/defibrillator will be used during codes on all patients who warrant intervention.

F. Study questionnaires

Independent observer will observe all codes run by the residents and answer the following questions ranking resident's performance:

1. Resident used closed loop communication
2. Resident delegated tasks appropriately/assigned team member roles
3. Resident had appropriate view of the patient's bed/was standing back from the bed
4. Resident did not get directly involved in the procedures
5. Resident cleared the room of extra personal
6. Resident made sure that effective compressions and respirations were given
7. Resident gave appropriate drugs and doses
8. Resident used appropriate cycles of drug administration/rhythm check/shock-CPR
9. Resident started fluids/pressors when appropriate
10. Resident obtained relevant/necessary patient information in a timely manner
11. Overall, the resident managed the patient appropriately, according to guidelines.
12. Overall, the resident was an effective team leader during the code.

Questions 1-10 will be rated on a scale of 1 to 5. With 5 being all the time during the code; 4 being most of the time; 3 sometimes; 2 minority of the time; 1 none of the time
Question 11 and 12 are supplemental yes or no questions that will be coded as 1 for yes and 0 for no.

G. Study subjects

Second year medicine residents

H. Recruitment of subjects

All internal medicine second year residents will be recruited for the study as part of their residency training.

I. Confidentiality of study data

Results of individual resident's performance will be kept confidential.

J. Potential conflict of interest

None

K. Location of the study

Study will be conducted at New York-Presbyterian Hospital.

L. Potential risks

Since all residents are expected to have sufficient knowledge and skill to run the codes by the beginning of their second year without receiving any additional simulation training, there will be no risk to the patients.

M. Potential benefits

The potential benefits of this study are better prepared residents for their role as a code team leader by improving both their leadership skills and medical knowledge. It may be hypothesized that by being a better team leader, codes will run more smoothly and will have better patient outcomes. Additionally, every resident should be confident and comfortable in running a code and have sufficient medical knowledge to be able to appropriately manage the patients.

N. Alternative therapies

Not Applicable

O. Compensation to subjects

There will be no compensation to subjects since participation in the training program is part of their educational experience and will take place during regular work hours, without violating 80 hour/week or other ACGME regulations

P. Costs to subjects

The training will be conducted at no cost to subjects

Q. Minors as research subjects

Not Applicable

R. **Radiation or radioactive substances**

Not Applicable

References:

1 Abella BS, Alvarado JP, Myklebust H, et al. Quality of cardiopulmonary resuscitation during in-hospital cardiac arrest. JAMA 2005. 1999; 181: 861-6

2. Wayne DB, Siddall VJ, Butter J, et al. A longitudinal study of internal medicine residents' retention of advanced cardiac life support (ACLS) skills. Acad Med 2006; 81 (suppl):S9-12

3. Wayne DB, Didwania A, Feinglass J, et al. Simulation-Based education imporves quality of care during cardiac arrest team responses at an academic teaching hospital. Chest 2008; 133:56-61

4. Wayne DB, Butter J, Siddal VJ et al. Mastry learning of advanced cariac life support skill by internal medicine residents using simulation technology and deliberate practice. J Gen Intern Med 2006; 21:251-256

5. Wayne BD, Butter J , Siddall VJ et al. Simulation-based training of internal medicine residents in advanced cardiac life support protocols: a randomized trial. Teach Learn Med. 2005; 17:210-6