Stefanie Reiff IRB Proposal 5/5/14

## **Study Purpose and Rationale**

All residents must become competent in advanced cardiac life support (ACLS) in order to become board certified or graduate. ACLS courses largely focus on the technical skills, drug regimens, and overall algorithms involved with cardiopulmonary resuscitation (CPR).<sup>1</sup> While guidelines exist for termination of CPR, it is ultimately the decision of the physician and medical team, leading to drastic differences in reports of reasonable length of time for resuscitative efforts (8-81 minutes) and reasons for termination.<sup>2-4</sup> On average only about 15% of patients who undergo cardiac arrest ultimately survive to discharge.<sup>5-11</sup> The uncertainty of termination decisions and the high mortality rate of patients create a potentially confusing and emotionally overwhelming educational atmosphere for residents. While many studies examine the impact of end of life issues on patients and their families, fewer studies focus their attention on the emotions of the providers, especially those in training such as the residents. When surveyed residents report feeling underprepared for end of life care as well as needing more emotional support than an attending physician would require. <sup>12-14</sup> Up to 73% of residents report routine CPR as being stressful and 46-77% found it difficult to have discussions regarding CPR with their patients and the patients' families.

A deficiency in CPR and code education could contribute to a lack of knowledge and potential increased stress levels amongst trainees participating in codes. About 50% of medical residents within the United States report that they feel inadequately trained to lead a cardiac arrest team. Soar et al. 2011 identified inexperienced leaders, task overload, and an inability to effectively organize a code as major barriers to performing adequate CPR. Numerous studies convey that clear leadership, team management and resource allocation are the keys to success in a code (which is defined as return of spontaneous circulation). Such skills are generally acquired through repeated training and exposure to CPR.

An important aspect of both emotional management and educational processing is the debriefing session post-CPR. Debriefing can include formal or informal sessions during which any aspect of the code is discussed amongst code participants. Studies demonstrate greater emotional concern and detachment in medical students who do not participate in a debriefing session after resuscitation is performed, while teams that consistently participate in debriefing sessions report improved success of codes over time. However, only 5.9-12% of those polled report participating in post-cardiac arrest debriefing sessions.

In light of the known benefits of debriefing after CPR, the current research aims to address the lack of debriefing by providing a teaching session to upper level residents with the aims to increase the amount of debriefing carried out as well as increase the educational value and emotional well-being of residents after codes. This will be assessed by providing a survey to the first year residents asking them about their emotional attitudes and educational experience after each code experience.

# **Study Design**

The proposed study will involve internal medicine residents currently undergoing training at Columbia University. The study will take place over the course of one academic year and involve residents rotating in the medical intensive care unit as well as the cardiac intensive care unit. Residents will be randomized to the experimental arm ("debriefing group") or the control arm ("standard training"). Randomization will occur based on the schedules of the first year residents with the first month being a standard training month, the second month being a debriefing group month, the third month being a standard month, and alternate as such until the study has terminated. In alternating months we hope to help control for differences or variations in residents' experience that they might gain from becoming more advanced in their training as the year progresses.

Residents randomized to the debriefing group will undergo the proposed intervention. This means that at the beginning of the month the senior residents (includes all who are not within their first year of training) will undergo a brief educational session led by the study leader that highlights the importance of debriefing after codes, provides suggestions for how a debriefing sessions might run, and involves role play to practice debriefing skills. This session should take about 30-60 minutes total. During the session the study leader will ensure that all senior residents demonstrate competent skills to lead a debriefing session. They will then be instructed to lead debriefing sessions after all codes that occur during the following month with their first year residents as the recipients of this session. The study leader will then check into the ICUs on a weekly basis with surveys (attached) about emotional impact and educational value of codes that will be provided to the first year residents. They will then fill these out with regards to the codes that occurred during that week's time course and return them to the study leader.

Residents who are assigned to standard training will not undergo a debriefing training session and will receive no instruction as to whether they should or should not lead debriefing sessions. In this way the study hopes to capture the current standard training that occurs in the ICUs prior to any intervention. The study leader will provide surveys on a weekly basis to the first year residents as in the debriefing group to assess emotional impact and educational value of the codes experienced.

Subjects will not be crossed over to other arms of the study.

The survey is attached. It will examine 3 overall scores: negative emotional state, positive emotional state, and educational value. Each score involves 4 questions graded on a scale of 1-5 with 1 indicating the resident does not agree with that statement or is not feeling that emotion and 5 being the resident strongly agrees with that statement or emotion. Each emotional score will have a minimum score of 4 and a maximum score of 20. It is hypothesized that those who undergo a debriefing session will have lower negative emotional scores, higher positive emotional scores, and higher ratings of educational value compared to the standard group.

## Statistical analysis

The survey data will be analyzed using an unpaired t-test on the three scores: negative emotional state, positive emotional state, and educational value. These scores will be analyzed based on whether a debriefing occurred or not regardless of study month, study month randomization, gender, ICU location, and code success. An alpha value of p less than or equal to 0.05 will be considered significant. Power analysis was calculated using a beta value of 0.80. The standard deviation in the population was assumed to be 4 with a predicted effect size of 3 leading to the total number of subjects enrolled for adequate powering of 30. We expect that 44 subjects will be enrolled in the study. **Study Procedure** 

The only procedure that will be done solely for research purpose will be the teaching session given to senior residents and the survey provided to the first year residents. There is no anticipated interruption or change of care that will occur with the patients who are being taken care of within the ICUs during the study time period.

## **Study Questionnaires**

Survey

Did you undergo a debriefing session after your most recent code?

Yes No

Was your most recent code successful in returning spontaneous circulation for greater than 24 hours?

Yes No

Please indicate your emotional reaction that you felt after the code on a scale of 1 to 5 with 1 being "I did not experience this emotion at all" to 5 being "I experienced this emotion very strongly"

i							
1	2	3	4	5			
Overwhelmed							
1	2	3	4	5			
Anxious							
1	2	3	4	5			
1	2	3	4	5			
1	2	3	4	5			
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	1	2	3	4	5
Calm					
	1	2	3	4	5
Amaze	ed				
	1	2	3	4	5

Please indicate how much you agree with the following statements with 1 being "Strongly disagree" and 5 being "Strongly agree"

I know the sequence of medications given during a code

1 2 3 4 5

I know important procedures that need to be performed during a code

1 2 3 4 5

I know good indications for terminating resuscitative efforts

1 2 3 4 5

I would feel comfortable being a code leader

1 2 3 4 5

## Gender

Male Female Other

I am currently working in the:

CCU MICU

# **Study Subjects**

Inclusion criteria for subjects will be all first year (includes categorical and preliminary positions) internal medicine residents who work in the MICU or CCU during the study period. Those excluded from the study will be first year residents who have already participated in a previous month. No vulnerable populations will be included.

# **Recruitment of Subjects**

During the first year of internal medicine residency both CCU and MICU are required rotations. The subjects will be identified based on their participation within the program. At the beginning of the month when the subjects initially begin to work in the ICUs they will be approached by the study leader and informed of the current study involving their attitudes towards CPR and codes. They will be informed that after each code they participate in they will be given a survey asking them about their emotional response as well as questions regarding their comfort with codes. They will be given the option to not participate in the study and all willing to participate will sign the consent form.

# **Confidentiality of Study Data**

All survey data will be anonymous with no identifiers collected. A database separate from the survey answers will be kept to ensure that each study participant only participates once. This database will include the names of all first year internal medicine residents and no other personal information. It will be a locked excel spreadsheet contained within an encrypted study computer.

## **Potential Conflict of Interest**

There are no conflicts of interest.

#### Location of the Study

The study will take place within the medical intensive care unit and the cardiac intensive care unit.

#### **Potential Risks**

There are no anticipated risks or harms for the study subjects.

#### **Potential Benefits**

There are no direct benefits to the participants of the study subjects.

## **Compensation to Subjects**

No compensation will be provided.

## **Costs to Subjects**

The subjects will not incur any costs during the study.

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