

**AN EDUCATION AND BEHAVIORAL, SINGLE-CENTER,
OBSERVATIONAL COHORT STUDY EVALUATING THE
EFFECT OF EMOTION REGULATION AND BURNOUT ON
MEDICAL TRAINEES' LEARNING AND DOCUMENTATION OF
SERIOUS ILLNESS COMMUNICATION**

Regulatory Sponsor: *Garrett T. Wasp
Internal Medicine, Section of Hematology-Oncology
1 Medical Center Dr, Lebanon, NH 03765
603-650-6715*

Funding Sponsor: *Norris Cotton Cancer Center
1 Medical Center Dr, Lebanon, NH 03765
603-650-5000*

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List of Abbreviations

ERSQ – Emotion Regulation skills questionnaire. Definition on page 2

MBI – Maslach Burnout inventory. Definition on Page 2

PI – principal investigator

SICG© - Serious illness conversation guide. Defined on page 3.

Study Summary

Title	<i>An Education and behavioral, single-center, Observational Cohort study evaluating the effect of emotion regulation and burnout on medical trainees' Learning and Documentation of serious illness communication</i>
Short Title	<i>Emotion Regulation and Burnout Impact on Communication Documentation</i>
Protocol Number	<i>The standard protocol number used to identify this study.</i>
Phase	<i>n/a</i>
Methodology	<i>Observation cohort Study</i>
Study Duration	<i>Two Years</i>
Study Center(s)	<i>Single-center: Dartmouth-Hitchcock Medical Center</i>
Objectives	<i>Aim 1. Evaluate the efficacy of our multimodal communication skills training on trainee documentation, confidence and observed communication skills over 12 months.</i> <i>Aim 2. Test the relationship between emotion regulation, and burnout on trainee skill enactment over 12 months.</i>
Number of Subjects	<i>42</i>
Diagnosis and Main Inclusion Criteria	<i>Internal Medicine Residents and Hematology-Oncology who undergo palliative care elective AND Serious Illness Communication training</i>
Study Product, Dose, Route, Regimen	<i>n/a</i>
Duration of administration	<i>n/a</i>
Reference therapy	<i>No gold standard for communication skills training</i>
Statistical Methodology	<i>one-side proportion test with exact test for primary outcome. Secondary outcomes use different statistical tests: 1) a linear mixed model with random subject effect to test whether three different scores in simulated encounters are different; 2) summary statistics, 3) t-tests</i>

1 Introduction

This document is a protocol for a human research study. This study is to be conducted according to US and international standards of Good Clinical Practice (FDA Title 21 part 312 and International Conference on Harmonization guidelines), applicable government regulations and Institutional research policies and procedures.

1.1 Background

Effective communication around serious illness is an essential clinical competency for all physicians. Physicians, however, often fail to disclose prognostic information and to adequately solicit patient values.^{1,2,3} Cited barriers to effective communication include insufficient physician training in communication and difficulty in dealing with patient emotion.^{4,5}

While formal communication skills training programs improve learners' behaviors in proximate, controlled settings (e.g., simulation), the evidence that this training has long-term impacts on learners' behavior and associated patient outcomes is limited and mostly demonstrates null effects.^{6,7} Human behavior can be resistant to change, and psychologic theory suggests twelve domains for why physician behavior does not change.⁸ One of these twelve domains is emotion regulation. Emotion regulation, defined as the ability to respond to ongoing demands of experience with a sufficiently flexible range of emotions, is necessary for effective prognostic disclosure, given both patient and provider have emotional reactions to such information. Burnout, a process involving emotional exhaustion, depersonalization, and low personal accomplishment, adversely impacts emotion regulation. No studies have addressed the potential role of emotion regulation and burnout as physician factors affecting the acquisition of physician communication skills.

The purpose of this study is to twofold. First, evaluate the efficacy of a communication skill training we integrated into graduate medical education by longitudinally tracking participants' documentation behavior. Second, perform exploratory analyses of physicians' emotion regulation skills and burnout as potential mechanisms for communication skill acquisition.

1.2 Study Assessment Tools

Confidence Survey – Using a 5 point Likert scale (i.e. 1=strongly disagree, 2=disagree, 3=neutral, 4=agree 5=strongly agree) participants were asked to rate their confidence in various communication skills domains pre- and post-intervention via online survey.

Emotion Regulation Skills Questionnaire (ERSQ) – This validated instrument consists of 27 items, and includes subscales related to nine competencies of coping with negative emotion (awareness, sensations, clarity, understanding, acceptance, tolerance, readiness to confront, compassionate self-support and modification) which can be summed to a total score (TOTAL).⁹ The ERSQ assesses each skill by means of three items introduced by the phrase “In the last week...” and answered on a 5-point Likert-scale. Higher scores indicate stronger emotion regulation skills.¹⁰ We will administer the ERSQ via online survey.

Maslach Burnout Inventory™ (MBI) –This validated, psychological inventory consists of 22 items related to occupational burnout, and includes subscales related to Emotional exhaustion (EE; 9 items), Depersonalization (DP; 5-items), and Personal Accomplishment (PA; 8 items). The MBI assesses each item on a 7-point Likert-scale. Higher scores indicated greater burnout. . We will use the MBI / Human Services Survey for Medical Personnel administered via online survey.¹¹

Semi-structured interview – At 6 months, participants (e.g. trained faculty, residents, and fellows) are asked a series of preselected questions in a one-on-one interview about their experience with the training, using the SICG with patients, benefits and difficulties of the training in the clinical setting.

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Serious Illness Conversation Guide (SICG®) – improve the timing, frequency, quality, and tolerability (for both patient and clinician) of patient-centered values and goals conversations for patients living with serious illness.¹² The SICG® was co-produced by clinicians, patients, and families and is a checklist of best-practice communication steps for use in patients with serious illness.

Skills acquisition checklist - used by independent observer during simulated patient encounters to evaluate trainees. One point is assigned for each item used by the trainee. The checklist contains three scores: conversation guide specific items (16 points), global communication skills (9 points), and a combined score (25 points). This checklist was developed internally and based on the experience training residents in the Serious Illness Conversation Guide (SICG).

Template Use –The analytics team at our institution is able to link the smartform to the physician who made alterations, the content of those alterations, patient and date of change.

1.3 Study Systems-based Interventions

Audit and profile feedback –*Injunctive norms messaging with social comparisons* is used to change attitudes by communicating approval or disapproval of behavior.^{13–19} This acknowledges that people make decisions based on social cues, self-image, local values and identities. We also leverage pre-commitment contracts.²⁰ Trainees will receive their personal template use frequency compared to top performers via email. Non-top and top performers will receive different messages, customized through pre-testing with non-study residents and fellows. For example: “Talking to patients about their values is important but can take some pre-visit planning. Choose a patient you will see in the next two weeks to use the SICG” (non top-performers) or “Good job! Talking to patients about their values is important. The way we continue to improve is by having more conversations. Choose a patient you will see in the next two weeks to use the SICG.” (top-performers).

Priming – Priming physicians to reflect on whether their patients have serious illness is associated with more goals-of-care discussions.²¹ Using the chart review, we will generate a list unique to each trainee enriched for outpatients with a high likelihood of having serious illness. After completing the first training session, each trainee will review their list and be asked four “yes or no” questions: 1) “Does this patient have serious illness?”; 2) “Would you be surprised if this patient died in the next 12 months?”; 3) “Would this patient benefit from a serious illness guide conversation?”; 4) “If you saw this patient again, would you use the serious illness conversation guide with him/ her?”

Template – We designed a template to standardize SICG documentation and embedded it in the medical record. This template exists in two forms: a “dotphrase” (user enters text in a note to display template) and as a central smartform where patient responses can be recorded.

1.4 Prior Work

Starting in 2017, we designed and implemented annual communication skills training. We trained 16 internal medicine residents (hereafter referred to as residents), 6 hematology-oncology fellows (hereafter referred to as fellows), and used a train-the-trainer model to train faculty attendings to serve as trainers in the clinical setting with trainees: 5 hospitalists, 4 primary care and 4 oncologists. We designed and embedded a template into the electronic medical record to standardize the documentation of the SICG. We developed a structured chart review protocol to identify outpatients with a high-likelihood of serious illness and evaluate trainee documentation habits

2 Study Objectives

Aim 1. Evaluate the efficacy of our multimodal communication skills training on trainee documentation, confidence and observed communication skills over 12 months.

Hypotheses: Template use for both trainee subgroups will increase from zero after training for $\geq 50\%$ of trainees (H_{a1a}). Trainee and faculty confidence will increase after training for $\geq 50\%$ of participants (H_{a1b}). Observed communication skills scores at the second and third simulated patient encounter will improve over the first encounter. (H_{a1c}).

Rationale: Augmenting standard training with priming, structured documentation templates, documentation audit and feedback, and embedded faculty coaches, we hope to increase the effect of communication skills training on clinical behavior change.

Outcomes: Participant template use at 12 months (Primary). Trainee, post-intervention self-rated confidence and performance in simulated patient encounters (Secondary).

Aim 2. Test the relationship between emotion regulation and burnout on trainee skill enactment over 12 months.

Hypothesis: Trainees in the top half of template users will have higher a TOTAL emotion-regulation score than trainees in the bottom half (H_{a2a}). Trainees in the top half of template users will have lower Emotional Exhaustion scores than trainees in the bottom half (H_{a2b}).

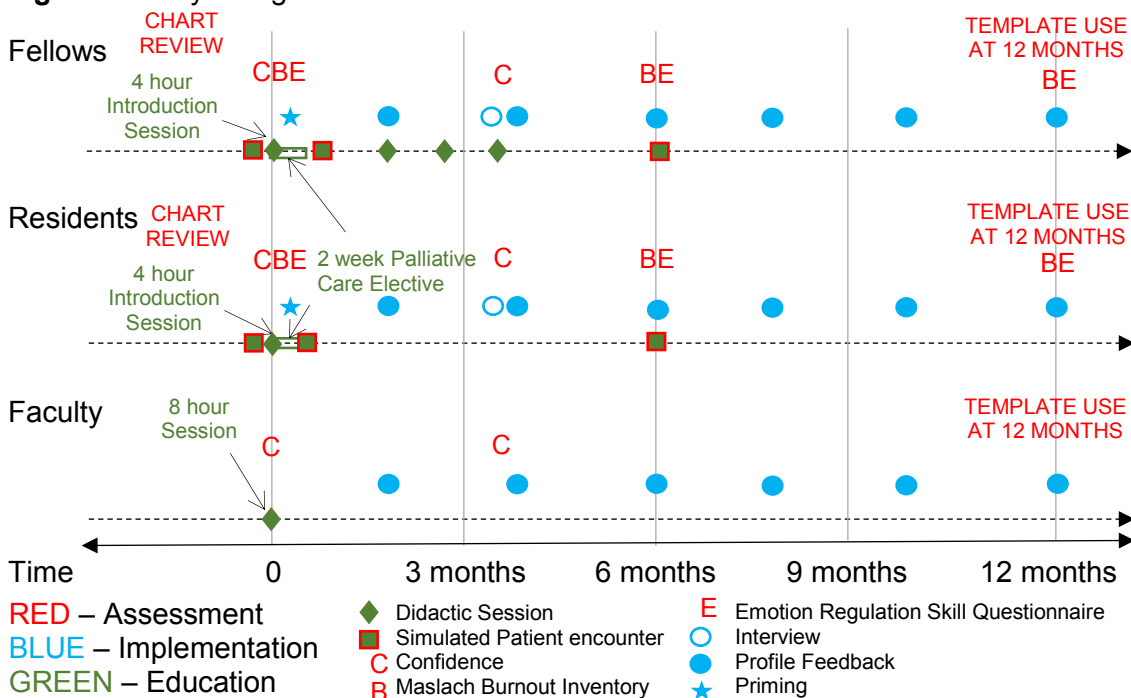
Rationale: Given their high emotional content, a physician's ability to regulate their own emotions and emotional exhaustion may impact their capacity to engage in serious illness conversations.²³ In a healthcare setting, the ESRQ was used to assess non-physician participants' competence to cope with specific and general aspects of negative emotions.¹⁰ We know of no studies examining its role in physicians and specifically medical trainees.

Outcomes: For ERSQ and MBI achieve complete data collection in $\geq 80\%$ of willing participants (primary).

3 Study Design

3.1 General Design

This is a single-institution cohort study with two tiers. Tier 1 is an education study where participants can complete electronic surveys on their pre and post intervention confidence, perform two simulated patient encounters and have their documentation of electronic template monitored longitudinally over 12 months. Participants are free to opt out of any activity related to education assessment or system-based interventions to promote the use of learned skills (e.g. priming or profile feedback). Signed informed consent will Not be required for this tier. Tier 2 is a behavioral study where participants, in addition to all of Tier 1 activities, also complete psychological inventories at three time points to measure emotion regulation and burnout, and participate in a semi-structured interview. We will require signed informed consent to participate in Tier 2.

Figure 1 Study Design

Participant duration – each participant will be followed for 12 months beginning with their first communication training

3.2 Primary Study Endpoints

Resident, Fellow and Faculty template use at 12 months.

3.3 Secondary Study Endpoints

Resident, Fellow and Faculty post-intervention self-rated confidence and performance in simulated patient encounters.

4 Subject Selection and Withdrawal

4.1 Inclusion Criteria

All second-year internal medicine residents. All first-year hematology-oncology fellows.

4.2 Exclusion Criteria

Missed more than five days (out of 10 possible days) of the two week palliative care elective

4.3 Subject Recruitment and Screening

Designated study staff will make a brief presentation at a residency meeting (e.g. morning report) to advertise study, send emails and study members who do not have a role in evaluating residents or fellows will approach residents in person. Any resident who indicates they do not want to participate will not be approached again. Study staff who evaluate residents and fellows, specifically Drs. Vergo, Cullinan and Chamberlin, will not be involved in the recruitment or consenting process.

4.4 Early Withdrawal of Subjects

4.4.1 When and How to Withdraw Subjects

The scenarios we imagine when a study subject would withdraw is when he or she indicated to study staff that they no longer wanted to participate OR no longer. Verbal or electronic communication to the PI

4.4.2 Data Collection and Follow-up for Withdrawn Subjects

We would continue to follow to participants' documentation over the 12 months from his or her initial training. If no longer working at study institution would follow documentation until last day of employment.

5 Study Procedures

Please refer to Figure 1 – Study Design detailing study overview for the timing of interventions and assessments.

5.1 Before Communication Training Activities

Tier 1 (education-only subjects): Three to four weeks prior to the subject's two-week palliative care elective they will be sent an email to complete an online confidence survey. They will receive email reminders to complete the survey until survey is completed.

Tier 2 (education + behavioral subjects): Subjects will have reviewed and signed consent documentation. In addition to the above online confidence survey, they will also receive email to complete electronic ERSQ and MBI.

5.2 Two week palliative care elective

Tier 1 – Integrated into the two-week elective with the palliative care department, subjects undergo a 1) four-hour training focused on the SICG®; 2) two simulated patient encounters with trained actors and feedback provided after training, 3) participant sent electronic notification to take post intervention survey of confidence

Tier 2 – In addition to above, these subjects will also complete a Priming intervention. They will receive a list of patients whom 1) the study subjected documented at least one note on in the past and 2) have a high likelihood of serious illness as determined by a chart review process. This list will be shared securely through Dartmouth secure file electronically, and participants will be asked three questions for each patient: 1) "Does this patient have serious illness?"; 2) "Would you be surprised if this patient died in the next 12 months?"; 3) "Would this patient benefit from a serious illness guide conversation?"; 4) "If you saw this patient again, would you use the serious illness conversation guide with him/ her?" Subjects will be asked to review no more than 30 patients. Subjects will be asked to return the completed email via Dartmouth secure file share.

5.3 Electronic communication every two months following completion of elective

Tier 1 – Every two months after completing the training, participants will receive email compare his or her own documentation of the taught template to top and average performers (comparison results given are anonymous). Non-top and top performers will receive different messages, customized through pre-testing with non-study residents and fellows. For example: "Talking to patients about their values is important but can take some pre-visit planning. Choose a patient you will see in the next two weeks to use the SICG" (non top-performers) or "Good job! Talking to

patients about their values is important. The way we continue to improve is by having more conversations. Choose a patient you will see in the next two weeks to use the SICG.” (top-performers). At four months, subjects will be asked electronically to complete their final confidence survey.

Tier 2 – For this part of the study, identical to Tier 1

5.4 Semi-structured interviews

Tier 2 only – Planned to occur about three months following training. Subjects are asked a series of questions designed to assess subject perception of serious illness communication, obstacles to implementing the training in practice, barriers to documentation and coaching sessions in real patient encounters with trained faculty. Interviews will be recorded, and expected duration is 20-40 minutes.

5.5 Simulated Patient encounter at six months

Tier 1 – Subject is contacted to arrange one-hour for simulated patient encounter, about 20-30 minutes for skill practice and the remainder for debrief. Subject has permission from program to have this hour to be away from their clinical duties.

Tier 2 – identical to Tier 1.

5.6 Six and 12 month ERSQ and MBI assessment

Tier 2 only – emails will be sent to participant to take ERSQ and MBI at month six and 12 following training

6 Statistical Plan

6.1 Sample Size Justification

Primary Hypothesis: Template use for both trainee subgroups will increase from zero after training for $\geq 50\%$ of trainee (H_{a1a})

Let null hypothesis H_{null1a} be $p < 50\%$ and alternative hypothesis be H_{a1a} be $p = p_1 \geq 50\%$, where p is proportion of trainees who have any documented template use. Sample size of 42 (12 fellows and 30 eligible residents who have completed the education intervention by the end of the grant award period [June 2020]) enables us to have Minimum Detectable Difference (MDD) 19.05%, i.e., the least p_1 is 69.05%, with 80% of power and 2.5% significance level using one-side proportion test with exact test.

6.2 Analysis Plan

Primary Hypothesis: H_{a1a}

We will calculate the proportion of trainees with template use and provide 95% confidence intervals with exact method, then we will test the hypothesis using a proportion test.

Secondary Hypotheses

H_{a1b} : Trainee and faculty confidence will increase after training for $\geq 50\%$ of participants.

We define increased confidence as trainee and faculty post-intervention confidence scores of 4 or 5 on a 5-point Likert scale. We will calculate proportion of subjects who have increased confidence and show 95% confidence intervals as well, then we will use a proportion test for the hypothesis.

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H_a1c: Observed communication skills scores at the second and third simulated patient encounter will improve over the first encounter.

The observed communication skills scores have three different scores (two sub-scores and one combined/total score). We will apply a linear mixed model with random subject effect to test whether each of three scores are different from encounter 1 to 2 and 3 separately. P-values will be adjusted for multiple tests by the Dunnett method.

H_a2a: Trainees in the top half of template users will have higher total emotion-regulation competences (TOTAL) than trainees in the bottom.

The ERSQ yields 10 different scales of emotion regulation: 9 specific competences and 1 TOTAL competency which is the average of the nine scales. We will provide summary statistics (mean and standard deviation) of TOTAL competency and use a two-sample t-test to test differences between the top half and low half groups of patients. P-value will be presented.

H_a2b: Trainees in the top half of template users will have lower Emotional Exhaustion (EE) scores than trainees in the bottom half.

We will provide summary statistics (mean and standard deviation) of EE scores and use a two-sample t-test to test differences between the top half and low half groups of patients. P-value will be presented

6.3 Subject Population(s) for Analysis

Primary outcome is all residents and fellows trained. Secondary outcomes evaluating emotion regulation skill and burnout are in all residents and fellows who consented to be part of Tier 2 – the behavioral study part.

7 Investigator reporting: notifying the Dartmouth IRB

7.1 Definitions

This section describes the requirements for safety reporting by investigators who are Dartmouth faculty, affiliated with a Dartmouth research site, or otherwise responsible for safety reporting to the Dartmouth IRB. The Dartmouth IRB requires reporting of those events related to study participation that are unforeseen and indicate that participants or others are at increased risk of harm. The Dartmouth IRB requires researchers to submit reports of *any incident, experience, or outcome that meets each of the following criteria:*

- **Unanticipated** in terms of nature, severity, or frequency given: (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and consent document; and (b) the characteristics of the subject population being studied; and
- **Possibly related** to participation in the research means there is a reasonable possibility that the incident, experience, or outcome may have been associated with research participation; and
- The problem suggests that the research places subjects or others at a **greater risk of harm** (including physical, psychological, emotional, economic, legal, or social harms) than was previously known or recognized.

7.2 Reporting Process

Unanticipated problems posing risks to subjects or others as noted above will be reported to the Dartmouth IRB using the form: “Unanticipated Problem Involving Risks to Subjects or Others (UPR).”

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Copies of each report and documentation of IRB notification and receipt will be kept in the Clinical Investigator's study file.

7.2 Other Reportable events:

For behavioral trials, the following events are also reportable to the Dartmouth IRB:

- Breach of confidentiality
- Change to the protocol taken without prior IRB review to eliminate apparent immediate hazard to a research participant.
- Complaint of a participant when the complaint indicates unexpected risks or the complaint cannot be resolved by the research team.
- Protocol deviation (meaning an accidental or unintentional deviation from the IRB approved protocol) that in the opinion of the investigator placed one or more participants at increased risk, or affects the rights or welfare of subjects.

8 Data Handling and Record Keeping

8.1 Confidentiality

Information about study subjects will be kept confidential. Presentations of any results of the data that results from this study will be de-identified. Results that could be linked to an individual will be aggregated or omitted in publication or presentations.

In the event that a subject revokes authorization to collect or use their data, the investigator, by regulation, retains the ability to use all information collected prior to the revocation of subject authorization.

8.2 Source Documents

Source data is all information, original records of surveys, observations, interviews, or other activities in a study necessary for the reconstruction and evaluation of the study. Source data are contained in source documents. Examples of these original documents, and data records include: electronic survey results, psychologic inventory results (e.g. ERSQ and MBI), simulated patient encounter assessments, recorded semi-structured interviews, patient lists with subjects responses to priming questions, and documentation of template in the electronic medical record.

8.3 Records Retention

We plan to retain record of study subject for one year following the study completion of the last study participant enrolled (an additional 12 months after the subject's initial 12 month assessment following training completion). This will allow for additional data analysis as the investigators plan to publish the results of the study.

9 Study Monitoring

This study will be monitored according to the monitoring plan outlined IRB research plan, entitled Study Progress Monitoring. The investigator will allocate adequate time for such monitoring activities.

10 Ethical Considerations

This study is to be conducted according to US and international standards of Good Clinical Practice (FDA Title 21 part 312 and International Conference on Harmonization guidelines), applicable government regulations and Institutional research policies and procedures.

This protocol and any amendments will be submitted to a properly constituted independent Ethics Committee (EC) or Institutional Review Board (IRB), in agreement with local legal prescriptions, for formal approval of the study conduct. The decision of the EC/IRB concerning the conduct of the study will be made in writing to the investigator and a copy of this decision will be provided to the sponsor before commencement of this study. The investigator should provide a list of EC/IRB members and their affiliate to the sponsor.

For this study, participants in Tier 2 (behavioral research) will be provided a consent form describing this study and providing sufficient information for subjects to make an informed decision about their participation in this study. See Attachment for a copy of the Subject Informed Consent Form. This consent form will be submitted with the protocol for review and approval by the EC/IRB for the study. The formal consent of a subject, using the EC/IRB-approved consent form, must be obtained before that subject undergoes any study procedure. The consent form must be signed by the subject or legally acceptable surrogate, and the investigator-designated research professional obtaining the consent.

11 Study Finances

11.1 Funding Source

Funding from the Dartmouth-Hitchcock Medical Center Department of Internal Medicine section of Hematology-Oncology. A grant application to the American Society of Clinical Oncology for this projected was submitted and its status is pending.

11.2 Conflict of Interest

Any investigator who has a conflict of interest with this study (patent ownership, royalties, or financial gain greater than the minimum allowable by their institution, etc.) must have the conflict reviewed by a properly constituted Conflict of Interest Committee with a Committee-sanctioned conflict management plan that has been reviewed and approved by the study sponsor prior to participation in this study. All Dartmouth-Hitchcock investigators will follow the Dartmouth-Hitchcock conflict of interest policy.

11.3 Subject Stipends or Payments

For residents and fellows who enroll into the human subjects arm of the study (Tier 2), we plan to offer \$20 in the form of gift card at four separate time points. Each study time point is associated with the completion of study activities that do not provide the participants direct benefit and intended to compensate them for their time spent doing the activity. The first compensation is around study start and is the completion of the psychological inventories (ERSQ and MBI). The second compensation is around 3-4 months and provided for completing the second confidence survey and semi-structured interview. The third compensation is at 6 months for completion of psychological inventories (ERSQ and MBI) and last simulated patient encounter. The last compensation is at 12 months for completing the final psychological inventories (ERSQ and MBI). We plan at our first internal assessment time point (November 2019) to assess our recruitment

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and participant time to complete study activities, and may decide at that time to modify compensation. In the event of any changes to compensation regimen, we will notify this IRB.

12 Publication Plan

Study investigators do not need permission from study sponsor prior to publishing results of the study to a third party.

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