Cover Page for ClinicalTrials.gov

Official Study Title:
Evaluation of a Cultural Dexterity Training Program for Surgeons: The PACTS Trial

NCT Number:
NCT03576495

Document:
Study Protocol

Document Date:
September 18, 2020

PARTNERS HUMAN RESEARCH COMMITTEE
PROTOCOL SUMMARY

Answer all questions accurately and completely in order to provide the PHRC with the relevant information to assess the risk-benefit ratio for the study. Do not leave sections blank.

PRINCIPAL/OVERALL INVESTIGATOR
Adil H. Haider, MD, MPH

PROTOCOL TITLE
The Provider Awareness and Cultural Dexterity Toolkit for Surgeons (PACTS) Trial

FUNDING

1R01MD011685-01A1

VERSION DATE

September 18, 2020

SPECIFIC AIMS

Concisely state the objectives of the study and the hypothesis being tested.

Racial disparities in surgical care have been well-documented. In response to the IOM's 2003 recommendations on taking a multi-pronged approach to alleviating disparities that includes cultural competency training, we have proposed cultural dexterity, rather than cultural competency, as a modality for imparting such training to surgical residents. The purpose of this protocol is to test the impact of this new curriculum, called Provider Awareness Cultural Dexterity Toolkit for Surgeons (PACTS), on surgical residents' cross-cultural knowledge, attitudes, and skills surrounding the care of diverse patients, as well as patient-reported and clinical outcomes for patients treated by surgical residents undergoing this training.

1. Aim 1: Evaluate the impact of PACTS on surgical residents' knowledge and attitudes about caring for culturally diverse patients using a pre- and post-assessment.
   Hypothesis 1: Residents receiving PACTS will show greater improvement in knowledge and attitudes compared to those who did not.

2. Aim 2: Determine the impact of PACTS on surgical residents' cross-cultural skills as demonstrated in a simulated clinical setting, using an Objective Structured Clinical Examination (OSCE) and by self-report. Each OSCE station will assess one of the four core topics covered by the PACTS training.

Hypothesis 2: Residents receiving PACTS will demonstrate greater improvements in cross-cultural skills.

3. Aim 3: Assess effectiveness of PACTS on improving clinical outcomes and patient-reported outcomes. We will survey patients cared for by residents enrolled in the study on: (1) satisfaction with pain management, (2) physician communication, (3) trust and (4) comprehension of informed consent. In addition, we will use data from the National Surgical Quality Improvement Program (NSQIP) to measure surgical complications, length of stay, 30-day mortality, morbidity, and readmissions for all patients.
   Hypothesis 3: Patients cared for by residents who have completed PACTS will exhibit better clinical and patient-reported outcomes.

BACKGROUND AND SIGNIFICANCE

Provide a brief paragraph summarizing prior experience important for understanding the proposed study and procedures.

Minority patients experience worse overall health outcomes, and these disparities are especially apparent in the costly, high-risk specialty of surgical care. To address this, the National Institute on Minority Health and Health Disparities (NIMHD) collaborated with the American College of Surgeons (ACS) to establish research priorities for surgical disparities. One of the top priorities was to evaluate the effect of improvement in culturally dexterous care on surgical outcomes for patients from disparity populations. Adverse outcomes for minority patients, including patients with limited English proficiency, have been demonstrated because of poor patient-provider communication. We propose that such deficiencies in communication contribute to treatment errors, inadequate pain management, less patient-centered care, decreased adherence to treatment plans, and worse overall clinical outcomes. Additionally, studies have illustrated the preponderance of pro-White implicit biases, which are unconscious, automated preferences that individuals may not even be aware of, among surgeons.

Formal training in cultural competency is generally integrated in the undergraduate medical education curricula, but this training rarely continues into specialty-specific post-graduate training. Few surgical programs have attempted to incorporate cross-cultural communication skills into their educational paradigms, and the approaches to doing so have been inconsistent. Our examination revealed that these programs' success was limited by a lack of specificity to the surgical context, as well as diminished applicability of the concepts to real-life practice. Therefore, we adapted a novel approach to cross-cultural communication for surgical trainees, known as cultural dexterity. Cultural dexterity refers to a set of skills and cognitive practices used to maximize communication across multiple dimensions of

cultural diversity, and deviates from the concept of cultural competency in that it does not demand that learners associate certain practices and behaviors with individuals based on generalizations. Our cultural dexterity curriculum, known as PACTS (Provider Awareness Cultural Dexterity Toolkit for Surgeons) focuses on developing cognitive skills to adapt to individual patients' needs to ensure personal, patient-centered surgical care. Experts in education and cross-cultural communication were convened, along with patient advocates and representatives, to inform the conceptual development of our curriculum. The curriculum is comprised of four educational modules on establishing trust in the physician-patient relationship, communicating effectively with patients with limited English proficiency, discussing informed consent, and issues surrounding pain management. Each module consists of an independent learning activity, an interactive role-play, and a post-lesson assessment. Cumulative evaluation of learners' knowledge, attitudes, and skills will take place after all four modules have been completed. Assessment tools are outcome measures are described in further detail below.

In anticipation of this protocol, we have pilot-tested the curriculum at three affiliated institutions with general surgery residents at varying levels of training. Focus group data was collected to garner feedback on the effectiveness and feasibility of the curriculum. **The purpose of the current protocol is to implement the curriculum across eight institutions and measure resident-level competency outcomes, as well as patient-reported and clinical outcomes, following this training.**

RESEARCH DESIGN AND METHODS

Briefly describe study design and anticipated enrollment, i.e., number of subjects to be enrolled by researchers study-wide and by Partners researchers. Provide a brief summary of the eligibility criteria (for example, age range, gender, medical condition). Include any local site restrictions, for example, "Enrollment at Partners will be limited to adults although the sponsor's protocol is open to both children and adults."

We will conduct a cross-over, cluster-randomized trial at 8 academic medical centers (AMCs) to capture the effect of PACTS on: 1) resident knowledge and attitudes regarding cross-cultural health care [Specific Aim (SA)1], 2) interpersonal and communication skills in simulated patient-clinician encounters [SA2], and 3) patient-reported satisfaction with resident physicians involved in their care, and clinical outcomes [SA3]. Sites will be assigned to an early intervention/retention assessment group or a control group with delayed intervention for examination of the effectiveness of the intervention as well as learner retention. After cluster-randomization, we will assess the residents' knowledge, attitudes, and skills prior to and after the PACTS curriculum at half the sites (Early Intervention/Retention Group). We plan to conduct follow-up testing after one year to evaluate learner retention.

At the other sites (Delayed Intervention Group), we will conduct baseline testing prior to the standard residency curriculum, and administer the PACTS curriculum the following year. This study design will enable us to examine both between- and within-group differences based on curriculum exposure in intervention year 1 as well as within-group differences for the Delayed Intervention Group at the end of year 2. Further, we will also be able to test post-exposure effect retention in the Early Intervention Group at the end of year 2.

We are partnering with eight general surgery residency programs and their affiliated hospitals to conduct the PACTS Trial. Programs have been matched to achieve balanced cohorts in terms of program size and diversity of patient population. Based on case mix, we anticipate approximately 40% of the patient population in this study will be of minority descent. The eight programs that will be participating in this study are: 1) Johns Hopkins University, 2) Brigham and Women's Hospital, 3) Brown University, 4) Eastern Virginia Medical School, 5) Massachusetts General Hospital, 6) Beth Israel Deaconess Medical Center, 7) Howard University, and 8) Washington University in St. Louis.

Briefly describe study procedures. Include any local site restrictions, for example, "Subjects enrolled at Partners will not participate in the pharmacokinetic portion of the study." Describe study endpoints.

Surgery Focus Group

In anticipation of the implementation of the cross-over, cluster-randomized trial at the 8 academic medical centers, we hope to gather feedback from surgical residents, medical students, and surgical faculty in training programs outside of these sites to assist in the development of the cultural dexterity curriculum. We believe that surgical conferences would be the best opportunity to gain insight regarding the current curriculum content as well as curriculum implementation. Contributions from surgical residents, medical students, and surgical faculty will be important to supplement the previous input from surgical faculty and program directors.

We plan to recruit participants from the surgical specialty excluding those from our 8 academic medical centers. We will disseminate one of four modules of the curriculum in advance for review. Participants will then be scheduled for a 1 hour-long focus group based on their availability, with a total of four focus groups. Focus groups will be facilitated by two study staff in a semi-structured focus group model. We believe this input will be integral in ensuring that our cultural dexterity curriculum can eventually be implemented in all surgical training programs across the country.

Patients Focus Group

Patient advisors will be recruited through Brigham and Women's Hospital Center for Patients and Families as well as other Centers for Patients from participating sites. This will consist of 1 hour-long focus groups to collect feedback from former and existing patients to ensure that the curriculum is appropriate in addressing the needs of culturally diverse patient groups. Additionally, we will be collecting feedback regarding the patient survey that will be used by patients treated by residents who have undergone the cultural dexterity training to evaluate their satisfaction and clinical quality. The survey will be used to evaluate patient satisfaction with pain management, communication, trust-building, and comprehension of the informed consent.

Residents

The curriculum incorporates contemporary learning practices such as the "flipped classroom" model, team-based learning, and independent study that have been studied in undergraduate medical education but have not yet been examined in the graduate medical education setting. It consists of a 30-minute e-learning module that is accessed via secure login on personal computers, smart phones, or tablets. The module is built in the Werkz platform and hosted on participating institutions' servers. Following completion of e-learning modules, learners will attend interactive sessions in which residents will apply concepts from the e-learning to role-play scenarios constructed in a team-based learning format. Residents will be given detailed, scripted prompts for the role-play sessions, for which they will be divided into small groups. Structured feedback will be solicited from peers and facilitators. The group will reconvene for discussion and reflection at the end of the session. During the delivery of the curriculum, residents will also be provided opportunities for spaced-learning in the form of multiple choice questions based on the curriculum emailed through the REDCap system.

To evaluate the impact of PACTS on surgical residents' knowledge and attitudes about caring for diverse patients, we will use a pre- and post-test in the form of validated instruments that assess knowledge, attitudes, and self-reported skills on a Likert-type scale. This pre- and post-test will be piloted among a group of surgical residents (N=40) to assess the survey length and clarity of questions. Residents will be recruited using a convenience sampling method from those who participated in the surgery focus groups at ASC 2019. Exclusion criteria from this pilot will be residents at one of the trial AMCs.

Resident skills will also be objectively assessed through an Objective Structured Clinical Examination (OSCE) that will be created by the study

staff and administered immediately before the intervention and within 1-6 months after the intervention has been completed. The OSCE uses 5-point Likert scale questions to evaluate resident performance across multiple domains. A Standardized Patient evaluator and a third-party trained impartial observer will evaluate the residents on these domains, and the resulting numerical scores will be averaged. It will serve both a summative and educational purpose in this context. Due to the COVID-19 pandemic, in order to adhere to social distancing protocols, the OSCE may also be delivered virtually using a secured web-based video-conference software.

We have also developed a novel survey instrument to assess resident knowledge, attitudes, and self-reported skills. This instrument is adapted from pre-existing, validated instruments such as the Cultural Competence Health Practitioner Assessment (CCHPA), developed by the National Center for Cultural Competence, and modified to be relevant to surgical training and practice. Residents will be required to take a knowledge survey before and after receiving the PACTS curriculum or standard training. Attitudes regarding the importance of facing cross-cultural health care situations will be assessed across multiple domains using a novel survey instrument that is based on a survey that was used in a similar curriculum aimed at medical students, as well as the Values and Belief Systems domain.

Patients

To evaluate patients' satisfaction and clinical quality related to PACTS training, we will employ research assistants to administer surveys to patients treated by residents to determine satisfaction with pain management, communication, trust-building, and comprehension of the informed consent discussion two months before and after the intervention is implemented. Patient satisfaction will be assessed using elements of the validated Pain Treatment Satisfaction Scale (PTSS). Patients will complete this survey privately after a brief explanation and informed consent from the research assistant. Patients will be asked to provide their self-reported race/ethnicity. Finally, clinical surgical outcomes obtained from the NSQIP database and/or electronic health record will be assessed for each patient participant before and after the PACTS curriculum is implemented to measure individual outcomes such as length of stay, postoperative complications, unplanned reoperations, and 30-day morbidity/mortality. The survey will be translated into 5 additional languages (Spanish, Portuguese, Haitian Creole, Simplified Chinese, and Traditional Chinese) in order to ensure a representative patient sample from diverse groups of patients. This survey will be piloted (N=10) from Partners sites using a convenience sampling method to assess the length of time required for survey completion and clarity of questions.

Resident Curriculum Impact Focus Groups

Due to the COVID-19 pandemic and increased focus on structural racism and equity in medicine, we believe that residents undergoing our curriculum may have had experiences that could provide further insight into providing equitable care. We believe that surgical residents who are receiving the curriculum would offer the best opportunity to gain insight regarding how the current curriculum content has impacted the care they provide their patients.

Focus group participants will be recruited from current PACTS participants. Two focus groups will be conducted at each PACTS site, with 8-10 participants in each focus group. Focus groups will be facilitated by study staff in a semi-structured focus group model.

PACTS Program/ Curriculum Evaluation

In order to assess the components of the curriculum by the residents who have participated in the curriculum we plan to provide the residents an evaluation form via REDCap. The program evaluation will provide feedback based on a 5-point Likert scale questions to rate components of the curriculum. The residents will also have open-ended questions to provide any additional comments or suggestions on the curriculum.

For studies involving treatment or diagnosis, provide information about standard of care at Partners (e.g., BWH, MGH) and indicate how the study procedures differ from standard care. Provide information on available alternative treatments, procedures, or methods of diagnosis.

Currently, there is no standard for cultural dexterity training among surgical residents. The ACGME identifies core competencies, two of which address cross-cultural communication and patient-centered care, but these do not correspond to standardized educational curricula across residency programs.

Describe how risks to subjects are minimized, for example, by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk or by using procedures already being performed on the subject for diagnostic or treatment purposes.

To minimize risk, such as the risk of residency program directors learning of individual residents' scores or of residents learning of patients' individual evaluations of their communication skills, all participants will be assigned a unique, de-identified study ID number. Only the study ID will be used on surveys and outcomes assessments.

Describe explicitly the methods for ensuring the safety of subjects. Provide objective criteria for removing a subject from the study, for example, objective criteria for worsening disease/lack of

improvement and/or unacceptable adverse events. The inclusion of objective drop criteria is especially important in studies designed with placebo control groups.

The focus groups will be recorded through digital voice recorders or conducted via secured virtual web-based video conference software. After the focus groups, the recordings will be stored securely within the Center for Surgery and Public Health and transcribed by study staff members. All patient and resident data will be de-identified.

All patient information will be completely de-identified and the research assistant administering the survey will not be permitted to share information about patients' participation in the trial with the resident subjects providing their care, to protect patients against potential differential treatment based on their participation or lack thereof in the study.

Similarly, information about resident participation will not be shared with the residency program directors, and residents' performances on assessment measures will be removed of any potential identifying information such that these performance evaluations will not be factored into the residents' overall performance in their residency training program. Furthermore, though the curriculum will be delivered as part of all general surgery residents' didactic training, the research team will explain that participation in the study is entirely voluntary and declining to participate will have no bearing on residents' status within their program. To protect against risk of program directors learning of individual residents' scores or residents learning of patients' individual responses, all participants will be assigned a unique study ID. Only the study ID will be used on surveys and outcomes measures.

FORESEEABLE RISKS AND DISCOMFORTS

Provide a brief description of any foreseeable risks and discomforts to subjects. Include those related to drugs/devices/procedures being studied and/or administered/performed solely for research purposes. In addition, include psychosocial risks, and risks related to privacy and confidentiality. When applicable, describe risks to a developing fetus or nursing infant.

The study poses low risk to residents and patients. Participants in the focus groups may feel nervous sharing their opinions. We will ensure that all participants know that they do not need to share anything in the focus groups that they are uncomfortable with. For surgical residents, they may experience nervousness or concern knowing that their clinical interactions are being monitored and assessed; however, we will assure them that their individual performance will remain unknown to anyone at their site and therefore will not impact their performance in residency. For patients, they may experience minor psychological distress while participating in the study

in the setting of acute illness. However, the research assistants will be instructed to screen patients for physical and mental fitness prior to beginning the survey. Research assistants will also stop the survey if the patient demonstrates or verbalizes any distress. Patients may also be concerned about their negative responses impacting their care. To address this, we will try to focus on patients who are approaching discharge and assure all patients that their individual responses will not be shared with their care team.

EXPECTED BENEFITS

Describe both the expected benefits to individual subjects participating in the research and the importance of the knowledge that may reasonably be expected to result from the study. Provide a brief, realistic summary of potential benefits to subjects, for example, "It is hoped that the treatment will result in a partial reduction in tumor size in at least 25% of the enrolled subjects." Indicate how the results of the study will benefit future patients with the disease/condition being studied and/or society, e.g., through increased knowledge of human physiology or behavior, improved safety, or technological advances.

The research will benefit residents by giving them tools to better navigate patient care. It could also benefit patients by better equipping their physicians to investigate health beliefs, work with medical interpreters, and facilitate informed patient-centered care. The research will also benefit future surgical residents who will undergo this type of training, as well as future patients who will be cared for by these residents. The anticipated benefits outweigh the low potential risks of this study.

EQUITABLE SELECTION OF SUBJECTS

The risks and benefits of the research must be fairly distributed among the populations that stand to benefit from it. No group of persons, for example, men, women, pregnant women, children, and minorities, should be categorically excluded from the research without a good scientific or ethical reason to do so. Please provide the basis for concluding that the study population is representative of the population that stands to potentially benefit from this research.

Four populations of human subjects will be involved in this study: 1) surgical residents (clinical post-graduate years 1-5) from the 8 academic medical centers, 2) patients treated by those residents, 3) surgical residents outside of the 8 academic medical centers who will participate in focus groups and survey pilot, and 4) previous or current nonsurgical patients prior to the implementation of the PACTS curriculum who will participate in the patient focus group and patient survey pilots.

TARGETED/PLANNED ENROLLMENT: Resident subjects (n=400)			
Ethnic Category	**Females**	**Males**	**Total**
Hispanic or Latino	9	19	28
Not Hispanic or Latino	123	249	372

Ethnic Category: Total of All Subjects	*132*	*268*	*400*
Racial Categories			
American Indian/Alaska Native	1	3	4
Asian, Native Hawaiian, or Other Pacific Islander	25	51	76
Black or African American	8	16	20
Other	16	32	48
White	73	147	220
Racial Categories: Total of All Subjects	*123*	*249*	*372*

TARGETED/PLANNED ENROLLMENT: Patient subjects (n=2400)			
Ethnic Category	**Females**	**Males**	**Total**
Hispanic or Latino	300	300	600
Not Hispanic or Latino	900	900	1800
Ethnic Category: Total of All Subjects	*1200*	*1200*	*2400*
Racial Categories			
American Indian/Alaska Native	24	24	48
Asian, Native Hawaiian or Other Pacific Islander	120	120	240
Black or African American	300	300	600
White	456	456	912
Racial Categories: Total of All Subjects	*900*	*900*	*1800*

Surgical residents: All residents at each study site will receive the educational intervention. Enrollment and consent will be discussed by the research assistant, and program directors will not have access to resident enrollment information. We anticipate enrolling 400 surgical residents at the beginning of the study. We expect that the population will have the following racial composition based on average racial composition of surgical residency programs as reported by the Accreditation Council of Graduate Medical Education (ACGME): 55% White, 6% Black, 7% Hispanic, 19% Asian/Pacific Islander, <1% Native American, and 12% other.1 They will range in age from 25 to 36. Based on the ACGME reports, approximately 33% of these residents will be female, and resident subjects will not be excluded from the study based on their gender.

Patients: We will recruit 3,105 patients overall, and approximately 345 patients per site. To be included in the study, patient subjects must be admitted to a surgical service under the care of a resident enrolled in the study, able to recognize a photo of the resident as a main care provider, fluent in English, Spanish, Portuguese, Haitian Creole, Simplified Chinese, or Traditional Chinese, and older than 18 years of age. We will oversample

minority patients to achieve at least 40% Black and Hispanic patients. We will identify patients using the patient list from each resident enrolled in the study during the 2-month pre- and post- data collection windows. We are targeting underrepresented minority patients because they are at most risk for poor communication with providers and such interactions have greater potential for improvements.

White patients will not be excluded from the study; the emphasis is on racially discordant physician/patient dyads, and white patients will be included for the assessment of non-white resident subjects. As we expect that the gender demographics of the patient subject group will somewhat reflect the gender demographics of the general population, we anticipate 50% of the patient subjects to be female. There will be no exclusion of subjects based on gender or ethnicity.

Residents and patients will be recruited from 8 sites: Brigham and Women's Hospital, Beth Israel Deaconess Medical Center, Massachusetts General Hospital, Brown University, Howard University, Johns Hopkins University, Eastern Virginia Medical School, and Washington University in St. Louis. Each of these sites is in or near a major metropolitan area, with racially and ethnically diverse patient populations. Research assistants at each site will have access to each resident subject's panel of inpatients, which will also allow the research assistant to identify the patients' racial information and proximity to discharge from the hospital. For the Residents Curriculum Impact Focus Groups, the residents will be recruited from the residents already consented and enrolled in the trial. The PACTS Program/ Curriculum Evaluation will be provided to all residents who have undergone the curriculum.

Focus group participants outside of the 8 AMCs

Participants will be recruited for focus group and survey recruitment outside of the 8 AMCs participating in the trial. Individuals will be recruited from a random sample of academic medical centers without any emphasis or exclusion criteria on any specific gender, race, or ethnicity. As such, this should allow for a fairly representative sample. The goal will be to recruit 40 total participants for the focus groups at each academic conference.

Participants will also be asked to pilot the resident survey using a convenience sampling method based on focus group participation.

Previous or current patients prior to the implementation of the PACTS curriculum

These patient advisors for the focus groups will be recruited from a random sample through Brigham and Women's Hospital Center for Patients and Families and other Centers for Patients without any emphasis or exclusion criteria on any specific gender, race, or ethnicity. As such, this should allow for a fairly representative sample. The goal is to recruit 10 participants per focus group.

When people who do not speak English are excluded from participation in the research, provide the scientific rationale for doing so. Individuals who do not speak English should not be denied participation in research simply because it is inconvenient to translate the consent form in different languages and to have an interpreter present.

To be included in the study, patient subjects must be fluent in English or Spanish, and older than 18 years of age. We will oversample minority patients to achieve at least 40% Black and Hispanic patients. The language requirement is needed to ensure that the instruments and survey tools are accurately conveyed.

For guidance, refer to the following Partners policy:
Obtaining and Documenting Informed Consent of Subjects who do not Speak English
https://partnershealthcare-public.sharepoint.com/ClinicalResearch/Non-English_Speaking_Subjects.1.10.pdf

RECRUITMENT PROCEDURES

Explain in detail the specific methodology that will be used to recruit subjects. Specifically address how, when, where and by whom subjects will be identified and approached about participation. Include any specific recruitment methods used to enhance recruitment of women and minorities.

Surgery Focus Group Recruitment

Participants will be recruited using a convenience sampling method. Trial investigators will reach out to residency program directors at organizations not participating in the trial to ask that an information sheet be shared with medical students, surgical residents, or surgical faculty. Individuals will be able to register to participate in a focus group online and will be provided with provided additional information about the focus group and scheduling information at that time. In addition, twitter may be used to recruit participants at a specific conference or event by using the conference hashtag to reach a broad audience of attendees and providing the online registration information.

Resident Survey Pilot Recruitment

Participants of the resident focus group will be asked to pilot the resident pre- post-test. In addition, research fellows at the Center for Surgery and Public Health who are not part of participating residency programs may also be asked to pilot the survey.

Patient Focus Group Recruitment

Participants will be patient advisors who were selected by their providers to participate on their respective Patient Family Advisory Council. These patient advisors are current or previous patients who have demonstrated an interest in trial. The patient advisors will be recruited through Brigham and Women's Hospital Center for Patients and Families and other Centers for Patients at participating sites.

Patient Survey Pilot Recruitment

Patient advocates from the patient focus group will be asked to pilot the patient survey. Additional patients may be recruited from a convenience sampling from the Patient Family Advisory Council. These patient advisors are current or previous patients who have demonstrated an interest in trial. The patient advisors will be recruited through Brigham and Women's Hospital Center for Patients and Families and other Centers for Patients at participating Partners sites.

Resident Recruitment

All general surgery residents will receive the educational curriculum; each site's Program Director (PD) has agreed to schedule PACTS training during compulsory didactic sessions, when residents are free from clinical duties. However, participation in study assessments (OSCEs and knowledge-testing) is voluntary and will not impact residents' performance in their program. Final analyses will include enrolled residents regardless of their attendance in live modules, reflecting an "intention-to-treat" analysis approach. This will more accurately demonstrate the "real world" benefit of PACTS, as not all residents may be able or willing to attend all live sessions. Based on the size of the residency programs, which ranges between 46 and 72 residents, and the away rotation schedules, we expect to enroll 200 residents per arm for analysis (an average of 50 residents per site).

Patient Recruitment

At the onset of clinical rotations, the Program Manager will contact surgical residency Program Coordinators to attain general surgery resident rotation schedules. The Program Manager will identify the dates and times of resident study participants' rotations. On these dates and times, Research Assistants working under the supervision of the Program Manager will verify that the resident is on rotation and use the EHR at the surgical service site to

randomly select at least two eligible patients from the EHR. First, the RA will approach the patients' nurse and ask whether the nurse might have a concern regarding the selected patients' cognitive status. If the nurse has no concerns, the nurse will be asked to introduce study staff to the patient. Staff will provide an information sheet, describe the study, and ask them to identify a resident participating in the PACTS trial who they recall interacting with. The RA will explain the study and provide the patient with a copy of the Patient Information Sheet and survey, which will be administered via tablet or laptop computer to access the survey in the Partners-hosted REDCap database. Completion of the English or Spanish language survey will indicate consent to participate in the study and the patient will be enrolled.

If the nurse has a concern, the nurse will be asked to introduce the RA will approach the patient, and the RA will assess interest in the study, and administer a validated cognitive impairment screening tool (e.g. the Brief Confusion Assessment Method or the 4AT). If the patient is not interested in participating in the study or has a positive screen for cognitive impairment, the RA will not enroll the patient. If the patient does not screen positive, they will then be showed the picture of the resident for confirmation as above.

Please see the Patient Recruitment Flowchart in the attachments for an overview.

Patient inclusion criteria are: (1) admitted to surgical service under care of a participating resident; (2) able to recognize resident as a main care provider from a photo; (3) fluent in English, Spanish, Portuguese, Haitian Creole, Simplified Chinese, or Traditional Chinese. Patient exclusion criteria are: (1) admitted to Intensive Care; (2) mentally impaired and/or not oriented to person/time/ place.

In total, we will enroll 3105 patients across all sites (Table 7). If the patient is ineligible or unwilling to participate, another patient will be randomly selected from the e-mail list of patients. Patient sampling will be such that 40% of included patients will be racial or ethnic minorities. The overall proportion of racial/ethnic minority patients at each institution ranges from 24%-47% (excluding Howard University which has 90%), suggesting sufficient diversity across sites. Patient populations in surgical service will likely be even more diverse, as this includes both emergency surgery and trauma patients.

Provide details of remuneration, when applicable. Even when subjects may derive medical benefit from participation, it is often the case that extra hospital visits, meals at the hospital, parking fees or other inconveniences will result in additional out-of-pocket expenses related to

study participation. Investigators may wish to consider providing reimbursement for such expenses when funding is available

Not applicable.

For guidance, refer to the following Partners policies:

Recruitment of Research Subjects
https://partnershealthcare-public.sharepoint.com/ClinicalResearch/Recruitment_Of_Research_Subjects.pdf

Guidelines for Advertisements for Recruiting Subjects
https://partnershealthcare-public.sharepoint.com/ClinicalResearch/Guidelines_For_Advertisements.1.11.pdf

Remuneration for Research Subjects
https://partnershealthcare-public.sharepoint.com/ClinicalResearch/Remuneration_for_Research_Subjects.pdf

CONSENT PROCEDURES

Explain in detail how, when, where, and by whom consent is obtained, and the timing of consent (i.e., how long subjects will be given to consider participation). For most studies involving more than minimal risk and all studies involving investigational drugs/devices, a licensed physician investigator must obtain informed consent. When subjects are to be enrolled from among the investigators' own patients, describe how the potential for coercion will be avoided.

Focus Groups

Participants will be provided a fact sheet that contains information regarding the focus group that they will be participating in. Consent will be indicated either through completion of an online registration form or through participation in the focus group.

Survey Pilots

Participants will be provided with a fact sheet that contains information regarding the survey pilot. Consent will be indicated through voluntary completion of the survey.

Residents

Each program director will initiate recruitment for their site and provide email contacts, but a research assistant will enroll and consent residents. Following the didactic curriculum and prior to the first testing sessions, residents will review an informational sheet that they may keep for reference. Completing the resident surveys will indicate consent to participate in the study. Prospective subjects will be reminded that their decision to enroll in the study will remain confidential, as will their performance evaluations if they choose to participate. De-identified informed

consent documents will be maintained by the research assistant in a locked folder on-site or on a protected and secure database.

Patients

Patients who meet our inclusion criteria will be explained the study aims, protocol, and risks and benefits of participation by a research assistant. They will have a chance to review the consent form and receive a copy if they so choose. Information/Consent forms have been developed in all languages in which the survey is available (Spanish, Portuguese, Haitian Creole, Simplified Chinese, and Traditional Chinese) by certified translators. If needed, Research Assistants will utilize translators to communicate with patients speaking languages other than English. Completing the patient surveys will indicate consent to participate in the study. De-identified informed consent documents will be maintained by the research assistant in a locked folder on-site or on a protected and secure database.

NOTE: When subjects are unable to give consent due to age (minors) or impaired decision-making capacity, complete the forms for Research Involving Children as Subjects of Research and/or Research Involving Individuals with Impaired Decision-making Capacity, available on the New Submissions page on the PHRC website:
https://partnershealthcare.sharepoint.com/sites/phrmApply/aieipa/irb

For guidance, refer to the following Partners policy:
Informed Consent of Research Subjects:
https://partnershealthcare-public.sharepoint.com/ClinicalResearch/Informed_Consent_of_Research_Subjects.pdf

DATA AND SAFETY MONITORING

Describe the plan for monitoring the data to ensure the safety of subjects. The plan should include a brief description of (1) the safety and/or efficacy data that will be reviewed; (2) the planned frequency of review; and (3) who will be responsible for this review and for determining whether the research should be altered or stopped. Include a brief description of any stopping rules for the study, when appropriate. Depending upon the risk, size and complexity of the study, the investigator, an expert group, an independent Data and Safety Monitoring Board (DSMB) or others might be assigned primary responsibility for this monitoring activity.

NOTE: Regardless of data and safety monitoring plans by the sponsor or others, the principal investigator is ultimately responsible for protecting the rights, safety, and welfare of subjects under his/her care.

All patient and resident data will be de-identified for storage. Data will be stored on a password-protected server. Only the PI and the researchers

will have access to the server. The PI will be responsible for reviewing the data and for the confidentiality of the data.

Describe the plan to be followed by the Principal Investigator/study staff for review of adverse events experienced by subjects under his/her care, and when applicable, for review of sponsor safety reports and DSMB reports. Describe the plan for reporting adverse events to the sponsor and the Partners' IRB and, when applicable, for submitting sponsor safety reports and DSMB reports to the Partners' IRBs. When the investigator is also the sponsor of the IND/IDE, include the plan for reporting of adverse events to the FDA and, when applicable, to investigators at other sites.

NOTE: In addition to the adverse event reporting requirements of the sponsor, the principal investigator must follow the Partners Human Research Committee guidelines for Adverse Event Reporting

Research assistants will be advised to notify the patient's attending physician if the patient divulges suicidal or homicidal ideation during the survey. Otherwise, there are no anticipated opportunities for discovery of incidental findings. If any subject feels uncomfortable and wishes not to participate, they will be able to speak with the PI at any time and/or withdraw from the study with no consequences for their participation in their residency program nor their ability to receive care at our participation institutions.

MONITORING AND QUALITY ASSURANCE

Describe the plan to be followed by the principal investigator/study staff to monitor and assure the validity and integrity of the data and adherence to the IRB-approved protocol. Specify who will be responsible for monitoring, and the planned frequency of monitoring. For example, specify who will review the accuracy and completeness of case report form entries, source documents, and informed consent.

NOTE: Regardless of monitoring plans by the sponsor or others, the principal investigator is ultimately responsible for ensuring that the study is conducted at his/her investigative site in accordance with the IRB-approved protocol, and applicable regulations and requirements of the IRB.

The focus groups will be facilitated by two study staff. The digital recorders used to record the focus groups will be securely stored in the Center for Surgery and Public Health, and transcriptions will be stored in a secure, password-protected database. The virtual focus group data will be recorded and saved digitally on a Mass General Brigham encrypted computer and stored in a secure, password-protected database.

Data collection and monitoring will be coordinated across the 8 AMCs through a multimedia approach. Video teleconferencing will be utilized and a

website will be created to ensure smooth coordination and scheduling of the PACTS curriculum across the sites. Each site investigator will be responsible for managing research assistants and data collection at their institution. Survey data (such as patient surveys, resident pre- and post-tests, and OSCCE scoring) will be collected via a Partners-hosted REDCap survey. Data will be stored in a secure location at each AMC and will be accessed by the research assistant, who will be trained to enter the de-identified data into the secure, password-protected database. The Project Director will have access to the unique IDs assigned to the subjects, but the individual site co-investigators will not. There are no anticipated limitations to confidentiality.

For guidance, refer to the following Partners policies:

Data and Safety Monitoring Plans and Quality Assurance
https://partnershealthcare-public.sharepoint.com/ClinicalResearch/DSMP_in_Human_Subjects_Research.pdf

Reporting Unanticipated Problems (including Adverse Events)
https://partnershealthcare-public.sharepoint.com/ClinicalResearch/Reporting_Unanticipated_Problems_including_Adverse_Events.pdf

PRIVACY AND CONFIDENTIALITY

Describe methods used to protect the privacy of subjects and maintain confidentiality of data collected. This typically includes such practices as substituting codes for names and/or medical record numbers; removing face sheets or other identifiers from completed surveys/questionnaires; proper disposal of printed computer data; limited access to study data; use of password-protected computer databases; training for research staff on the importance of confidentiality of data, and storing research records in a secure location.

NOTE: Additional measures, such as obtaining a Certificate of Confidentiality, should be considered and are strongly encouraged when the research involves the collection of sensitive data, such as sexual, criminal or illegal behaviors.

The focus groups will be recorded through digital voice recorders or virtual via secured web-based video conference software. After the focus groups, the recorders will be stored securely within the Center for Surgery and Public Health for transcription. All patient and resident data will be de-identified for storage. Data will be stored on a password-protected server. Only the PI and the researchers will have access to the server. The PI will be responsible for reviewing the data and for the confidentiality of the data.

Resident subjects' performance on surveys and simulated clinical encounters will be kept confidential through de-identification of the data. All residents in the program will receive the training and will be required to

participate in the interactive learning sessions as a quality improvement initiative; residents' divulging of information during these sessions will be kept private in the confines of the didactic sessions that are restricted to surgical trainees.

Patients will be surveyed face-to-face in private hospital rooms, and patient participants will have the opportunity to include a legally authorized representative in the interview if desired. No minors will be included in the study.

SENDING SPECIMENS/DATA TO RESEARCH COLLABORATORS OUTSIDE PARTNERS

Specimens or data collected by Partners investigators will be sent to research collaborators outside Partners, indicate to whom specimens/data will be sent, what information will be sent, and whether the specimens/data will contain identifiers that could be used by the outside collaborators to link the specimens/data to individual subjects.

Not applicable.

Specifically address whether specimens/data will be stored at collaborating sites outside Partners for future use not described in the protocol. Include whether subjects can withdraw their specimens/data, and how they would do so. When appropriate, submit documentation of IRB approval from the recipient institution.

Not applicable.

RECEIVING SPECIMENS/DATA FROM RESEARCH COLLABORATORS OUTSIDE PARTNERS

When specimens or data collected by research collaborators outside Partners will be sent to Partners investigators, indicate from where the specimens/data will be obtained and whether the specimens/data will contain identifiers that could be used by Partners investigators to link the specimens/data to individual subjects. When appropriate, submit documentation of IRB approval and a copy of the IRB-approved consent form from the institution where the specimens/data were collected.

For the purposes of research dissemination, de-identified and aggregate data will be shared from external AMCs with Partners sites. These data will be shared on password-protected, secure servers at BWH.