The Surgical Education Culture Optimization through targeted interventions based on National comparative Data (SECOND) Trial

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In conjunction with the ACGME, ACS, ABS, and APDS

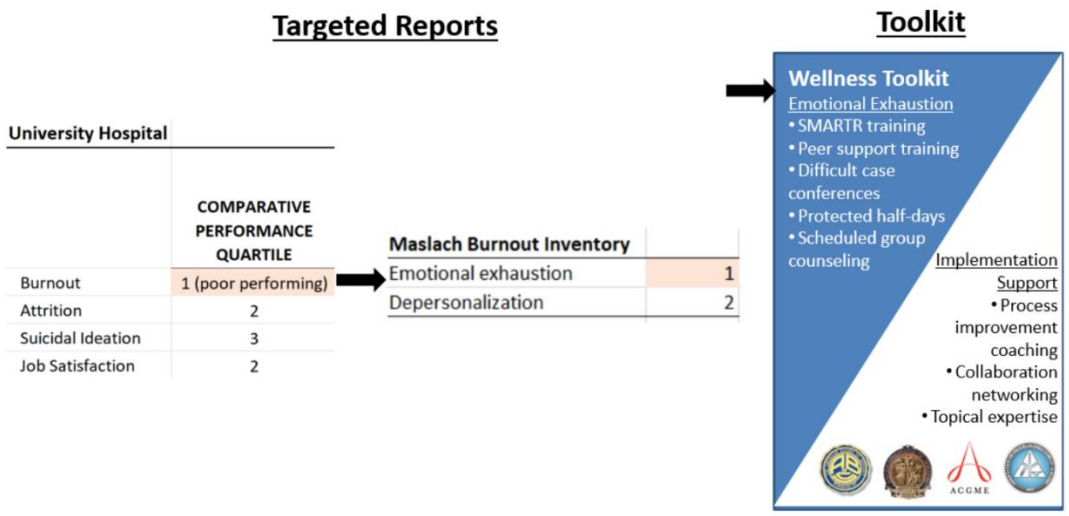
Overview

Well-being continues to be a pressing issue in surgical training. In the Flexibility in duty-hour Requirements for Surgical Trainees (FIRST) Trial, we found that 39% of U.S. general surgery residents experienced weekly burnout symptoms and that numerous aspects of the learning environment, not just duty hours, drive poor well-being. Currently, programs have no data about their performance on these issues compared to others in the country. More importantly, programs lack readily available strategies to make improvements. The SECOND Trial will begin with a national mixed-methods analysis to examine a variety of programs with respect to the learning environment and resident wellness. Lessons learned from these programs will be incorporated into a multidimensional Wellness Toolkit. The SECOND Trial will be a prospective, pragmatic cluster-randomized trial in which programs will be given a confidential report of data on their residents' well-being, compared to other programs in the country, then randomized to Control vs. Intervention. Intervention arm programs will receive reports with additional granular details as well as access to the Wellness Toolkit with implementation support to determine how best to improve their learning environment and residents' well-being.

Aim 1. To perform a national mixed-methods evaluation of program culture and resident wellness in surgery

Using an innovative, advanced mixed-methods approach, we will study the learning environment and resident well-being at surgical residency programs around the country. We will identify programs of interest using (1) a survey of program directors that seeks to inventory wellness initiatives/resources, (2) the ABSITE survey which measures various environmental exposures and resident outcomes, and (3) snowball sampling (i.e., asking others to name programs with robust wellness programs). By visiting these programs or conducting phone interviews, we will learn from their experiences, leadership, policies, interventions, and culture. Coupled with existing best practice guidelines from national societies, evidence from the literature, and guidance from experts, we will develop the Wellness Toolkit, a set of ready-to-use interventions from which programs can choose individual strategies to implement.

Aim 2. To conduct a prospective, pragmatic cluster-randomized trial (The SECOND Trial) attempting to improve residency program culture and resident wellness.



All 320 ACGME-accredited general surgery residency programs in the U.S. will be eligible for enrollment in this prospective, pragmatic cluster-randomized trial. Each participating program will receive a report of their resident well-being, as measured by the ABSITE survey (i.e., burnout, thoughts of attrition, suicidal thoughts). Programs will then be randomized to Control vs. a multifaceted Intervention, consisting of (1) a Learning Environment Report that includes additional wellness themes and data that are under development, (2) access to the Wellness Toolkit built in Aim 1, from which they may select interventions, ideally based upon opportunities identified through their Learning Environment Reports, and (3) implementation support to facilitate adaption of their selected interventions to their local environments (e.g., collaboration calls to discuss with peers, coaching calls to discuss with topical experts).

As resources are redirected towards wellness, we will ensure that the intervention does not have the unintended consequence of detracting from residents' educational experience by monitoring ABSITE scores, ABS Qualifying and Certifying Examination pass rates, residents' perceptions of their education as assessed on the ABSITE survey, ACGME case logs, and potentially frequent technical assessments in the subset of programs who already use the SIMPL or

ZwischMe apps. To ensure that patient care is not compromised by the intervention, we will also monitor patient outcomes in the subset of programs who participate in ACS NSQIP.

Aim 3. To refine the Wellness Toolkit by identifying the most successful context-specific interventions and expand access to both arms.
Based upon the annual Program Director Survey and regular contact with enrolled programs, we will closely track which interventions have been selected by each program. We will assess the impact of each intervention's local implementation based upon the ABSITE survey data. By synthesizing quantitative and qualitative data across all intervention arm programs, we will identify the most impactful for each context. We will then incorporate these data into the final Wellness Toolkit. Access to the Toolkit will be then expanded to both study arms.

Frequently Asked Questions
How will the SECOND Trial examine whether program-specific data and/or the Toolkit work?
At the conclusion of the trial, metrics of the learning environment and resident well-being (e.g., burnout) will be compared between the intervention and control groups to assess the intervention's effectiveness. Both baseline and follow-up data will be obtained from the ABSITE survey, which is administered to all residents in ACGME-approved general surgery programs and typically has a high response rate. We will also conduct an annual Program Director survey to assess what interventions programs in both arms have implemented.

Why randomize? Isn't it unethical to withhold resources from the control group?
Both trial arms will have access to data about their residents' well-being (i.e.., burnout, thoughts of attrition, and suicidal thoughts), but only intervention arm programs will have access to the Learning Environment Report, Wellness Toolkit, and the implementation support. Because there is currently very little data about the effectiveness of any wellness interventions and many are expensive and/or time/effort-intensive, the SECOND Trial Bioethics Panel concluded that the SECOND Trial has good equipoise.

Randomization also will allow us to address the secular trend of increasing emphasis on wellness, as programs who are independently embarking on wellness initiatives should be evenly divided between intervention and control arms. We will closely track the wellness changes implemented at all programs in both study arms annually with the Program Director Survey. At the conclusion of the trial, the Wellness Toolkit will be refined and access expanded to all enrolled programs.

Who is conducting the SECOND Trial?
Like the FIRST Trial, the SECOND Trial is a joint effort among the Accreditation Council for Graduate Medical Education, the American College of Surgeons, the Association of Program Directors in Surgery, and the American Board of Surgery. As in the FIRST Trial, the ACGME will not have access to the data; this is clearly stated in our contract with each program and with the ACGME. The Surgical Outcomes and Quality Improvement Center (SOQIC) at the Northwestern University Feinberg School of Medicine will serve as the data center for the trial.

How will the confidentiality of individual residents be protected?
We recognize that these are sensitive topics. All individual resident identifiers are removed from survey data prior to transfer to the data center; identification of individual residents is not possible. Program reports will provide data in quartiles (i.e., for burnout, your program ranks in the best quartile of programs in the country). We will not provide programs with the responses of individual residents or even the proportion of their residents that reported any particular metric, thus precluding attempts to identify the residents who might have reported any particular issue. During Program Tours, all interviews and focus groups will be conducted confidentially.

How will the confidentiality of programs be protected?
ABSITE survey data are sent to the data center, and programs are immediately de-identified. Data remain de-identified throughout all analyses. Program reports will be generated using securely-maintained program-level linkages.

Much like other clinical quality improvement programs, we will mandate that programs cannot disseminate or publicize/advertise the data in their reports outside of their institutions. We encourage sharing within each institution (i.e., with residents and faculty), but this decision will be left to the discretion of each program director, chair, and DIO.

When will the SECOND Trial start and end?
Recruitment for the trial will occur in summer 2019, with randomization occurring in fall 2019. All programs will receive data in fall 2019. Wellness Toolkit access will occur in late 2019/early 2020. Resident wellness surveys will be conducted in January 2019, 2020, 2021, and 2022. All programs will be given access to the Wellness Toolkit at the end of the study.