

A Program for Promoting Clinical Scholarship in General Surgery

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OBJECTIVE: The Accreditation Council for Graduate Medical Education mandates resident physician training in the principles and applications of research. To provide a robust early foundation for effective engagement in scholarship, we designed a novel clinical scholarship program (CSP) for PGY1 general surgery residents.

SETTING, DESIGN AND OUTCOMES: In a general surgery residency training program, we assessed resident academic productivity (i.e., presentations, publications, and sustained engagement in clinical research) and self-efficacy to conduct clinical research, as well as the overall satisfaction of both residents and faculty mentors. The clinical research appraisal inventory was administered both before and after completion of the CSP rotation.

RESULTS: Totally, 44 categorical general surgery trainees and 23 faculty research mentors participated in the CSP from 2011 to 2016; 26 residents (59%) presented at regional or national meetings. Of the 35 residents who were 24 or more months beyond their PGY1 training period, 16 (46%) have published their CSP project, 5 (14%) report continued commitment towards publication, and 22 (63%) have ≥ 1 clinical research publications beyond their CSP participation during residency, excluding publications arising from subsequent formal research fellowships. Clinical research appraisal inventory responses indicate significant improvement ($p < 0.005$) in clinical research self-efficacy.

CONCLUSIONS: A structured CSP increases the confidence of trainees to perform clinical research and leads to significant contributions directed at addressing clinically meaningful problems in surgery. Faculty-guided resident

research at a very early stage of clinical training supplements other mentorship experiences and encourages the development of surgeons who will engage in life-long clinical problem solving. (J Surg Ed ■■■■-■■■■. © 2018 Association of Program Directors in Surgery. Published by Elsevier Inc. All rights reserved.)

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COMPETENCIES: Medical Knowledge, Practice-Based Learning and Improvement, Professionalism

INTRODUCTION

Critical challenges exist in all facets of the care of the surgical patient, both within and outside of the operating room. Our ability to effectively address these challenges will depend upon the development of future leaders who will embrace these challenges and engage in their solution as an intrinsic component of their role as skilled and compassionate clinicians. The capacity to assess and analyze the current state of clinical care as reported in the medical literature, the identification of associated clinical gaps in care, and the ability to effectively close these gaps through the formation of collaborative teams is the primary motivation for developing skills to engage in scholarship of all kinds. The Accreditation Council for Graduate Medical Education (ACGME) has established common program requirements that outline standards for training residents and fellows across all specialties in a variety of core competencies.¹ Educational program requirements mandate that residency curricula incorporate scholarly activities that “advance residents’ knowledge of the basic principles of research, including how research is conducted, evaluated, explained to patients, and applied to patient care.”¹

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Additionally, it is recommended that programs “allocate adequate educational resources to facilitate resident involvement in scholarly activities” and require that faculty “establish and maintain an environment of inquiry and scholarship with an active research component.”¹ Although requirements for resident scholarly activity are available for certain disciplines, guidance has not been provided regarding how best to achieve this goal.² Furthermore, the stringent mandates related to clinical time commitments during residency training makes it difficult to designate a dedicated research block, apart from more formal extended research fellowships.

A standard approach does not currently exist for providing surgical residents with a foundational framework to engage in scholarly activity. Each training program may choose to develop its own system for ensuring exposure and participation of residents. Thus, substantial variability exists in resident research curriculum.³ To date, there exists a paucity of reports, which describe strategies to meaningfully incorporate a curriculum to promote scholarship during the course of a residency in general surgery. Most program descriptions have been derived from community-based surgical residencies, as a consequence of the need to address citations by the residency review committee.⁴⁻⁸ Barriers to resident participation in scholarly activity include uncertainty in understanding the clinical relevance of scholarship, challenges establishing a mentor-mentee relationship, and difficulty in developing an approach to engage with and complete a scholarly project.⁹

To meet the pertinent ACGME requirements and, more importantly, foster an inquisitive environment that embraces early and sustained scholarship, we designed a program to promote the engagement of PGY1 general surgery residents in clinical research to address existing gaps in the care of the surgical patient. We report herein the curricular design of this initiative, termed the *Clinical Scholarship Program (CSP)*, and present our initial experience with respect to resident academic productivity, satisfaction, and self-assessed clinical research efficacy.

METHODS

CSP Objectives and Design

The CSP, implemented in July 2011, is a structured faculty-guided clinical research experience for all first-year categorical general surgery residents. The overall aim of the program is to provide a robust early foundation for effective engagement in scholarship, to foster a curious and inquisitive environment, and ultimately to promote the development of future leaders who will engage in solving current deficiencies that exist in the care the surgical patient. The program’s learning objectives are focused on meeting these aims (Table 1).

TABLE 1. Clinical Scholarship Program (CSP) Learning Objectives

- Understand the importance of scholarly activity
- Increase knowledge of study design and clinical research methodology
- Increase awareness of institutional and national clinical databases
- Learn how to apply basic statistical methods to analyze research data
- Increase awareness of the ethical issues in conducting clinical research
- Learn the requirements for the protection of human research participants
- Learn the institutional review board (IRB) processes, procedures, and policies
- Disseminate research findings to the broader scientific community

The CSP was designed with a focus on involvement of key department leaders, individualized pairing of resident participants with faculty research mentors, delivery of key didactic content, and application of knowledge through completion of a defined project (Table 2). Logistically, all incoming categorical surgical residents are paired with a faculty research mentor early in the academic year. Department faculty are solicited to submit to the CSP Director clinical research project descriptions that are reviewed for scope and resources necessary to complete the project. Potential faculty mentors are full-time surgical faculty with academic appointments at Harvard Medical School who are actively engaged in conducting clinical research, have demonstrated scholarly productivity, and are able to dedicate the effort necessary to facilitate a productive mentorship experience. Residents are required to meet with at least three potential faculty members and submit a rank-ordered list of project and mentor preferences. Pairings are made at the discretion of the CSP leadership team. This program focuses solely on clinical research, as a meaningful experience in translational science during the course of active clinical responsibilities is not considered feasible at the internship level.

Once resident-mentor pairings have been assigned, trainees further develop the proposed research project. In some instances, based on prior clinical research experience and graduate training, residents may submit their own project proposal with appropriate guidance from their mentor and final approval by the CSP Director. Residents meet with their mentors at least monthly to discuss the specifics of their project and design an action plan. In addition to the time devoted throughout the academic year, a 4-week period without clinical duties is allotted during the PGY1 year to provide a focused period of time to pursue the clinical research project and to allow engagement in CSP-related didactics. Data request, training for data and safety monitoring for human subjects research, and institutional

TABLE 2. Clinical Scholarship Program (CSP) Curricular Design**Leadership**

- Department Chair
- Residency Program Director
- Vice Chair for Clinical Research (CSP Director: Experienced clinical researcher responsible for coordination of program including didactics, oversight of projects, resident and faculty mentorship, and assessment of program impact)

Participants

- All first-year categorical surgery residents
- Faculty research mentors

Didactics

- Lecture series on five core research competencies: (1) study design, (2) biostatistics, (3) communicating research findings, (4) ethics and regulatory issues, and (5) grant writing
- Active participation in the department's weekly clinical research meeting
- Attend laboratory meetings with faculty research mentor

Research Project

- Implement a clinical research project
- Direct faculty research mentorship at least monthly while clinically active and throughout the dedicated 1-month research rotation
- Prepare an abstract for regional and/or national presentation as well as submit a manuscript for peer-reviewed publication

review board (IRB) submissions are expected to have been completed before the initiation of this period. Trainees are required to present their clinical research plans at the department's weekly clinical research meeting where faculty, residents, and research fellows critique the project, help identify possible challenges and pitfalls, and offer suggestions for improvements. During the 1-month clinical research block, residents participate in self-directed curricula through weekly research meetings, targeted readings, and the Harvard Catalyst webinar series (www.catalyst.harvard.edu) on 5 core clinical research topics: (1) study design, (2) biostatistics, (3) communicating research findings, (4) ethics and regulatory issues, and (5) grant writing. At the end of the block, residents are required to present their completed project or a summary of its status, where interval progress is assessed, suggestions for further analysis is provided, and plans for dissemination of the research findings are addressed. The immediate goal of the CSP project is to prepare and submit an abstract for conference presentation and an article for peer-reviewed publication.

CSP Effect Assessment

To assess the effect of the CSP on trainees and faculty, the academic productivity of participants who completed the program over a 5-year period (2011-2012 to 2015-2016 residency cohorts) was studied. The number of CSP-related

presentations was evaluated for all residents. The number of publications resulting directly from the CSP project was examined for the first 4 cohorts only (2011-2012 to 2014-2015) since we considered 24 months to be a reasonable time for residents to have published their CSP project findings. Also, as a proxy measure of continued clinical research engagement, we assessed the publication of additional clinical research (beyond the CSP project) during residency. The clinical research publication productivity during residency for the CSP cohort was compared to the 36 general surgery residents who began training in the 4 years preceding CSP implementation. For the CSP cohort, we also examined whether the resident pursued formal clinical research fellowship training, and the publication of additional clinical research during fellowship. Satisfaction with the program was determined by formal survey of all residents and faculty 1 year after completion of the CSP experience. Initial surveys were limited in nature with residents and faculty asked to respond to the following questions, respectively: (1) "When reflecting on all aspects of the CSP, including project, mentorship, development as a clinical researcher, opportunities for disseminating project findings, available resources, time provided for project scope, how satisfied were you with the CSP experience?" (2) "When reflecting on your most recent experience with the CSP, how would you rate your overall satisfaction with the program?" (1 = not at all satisfied to 7 = extremely satisfied). Beginning with the 2014 to 2015 cohort of residents, we implemented a standardized self-assessment to examine perceived change in self-efficacy or confidence to perform different components of clinical research. Upon entering the surgical residency program, CSP participants completed a modified version of the clinical research appraisal inventory (CRAI)¹⁰ and repeated this self-assessment approximately one year following the CSP rotation. The original CRAI comprised 92 items across 10 domains or content areas pertaining to clinical research, such as designing a study, protecting research subjects, and collaborating with others. Although a shorter, 12-item version of the instrument has been developed,¹¹ we selected 30 items from the original CRAI that best reflected CSP goals and objectives, representing 9 of the 10 original domains.¹⁰ An additional item was included in a revised instrument to determine the degree of confidence in completing the necessary documentation for clinical research IRB approval. Each item has a response scale ranging from 0 (no confidence) to 10 (total confidence). The preversions and postversions are identical and are completed online using Qualtrics software (Qualtrics, Provo, UT).

Continuous data are presented as mean \pm standard deviation and categorical data are reported as percent (%). For CRAI domains, Cronbach α coefficients were calculated to assess for internal consistency and scale reliability. Associated mean \pm standard deviation scores and p values for repeated measures ANOVA for those respondents who

completed both the pre-CSP and post-CSP self-assessments were calculated using SPSS (New York, NY). Statistical significance was defined at a p value threshold of less than 0.05. On November 14, 2016, the IRB at Beth Israel Deaconess Medical Center determined that the program review, as described herein, did not constitute human subjects research.

RESULTS

Over the 5-year period from 2011-2012 to 2015-2016, 44 categorical general surgery residents and 23 faculty research mentors (4 instructors, 10 assistant professors, 5 associate professors, and 4 professors) participated in the CSP. Of these 44 residents, 26 (59%) presented their CSP project at a regional or national meeting, totaling 36 presentations (16 regional and 20 national), as some projects yielded multiple presentations. Of the 35 residents in the 4 cohorts through the 2014 to 2015 academic year, 24 or more months beyond their PGY1 training period, 16 (46%) published their CSP project and 5 (14%) others report continued commitment towards this end. Most articles ($n = 10$, 63%) were published in surgical specialty journals, such as the *Journal of Vascular Surgery* or *Annals of Surgical Oncology* and the mean impact factor of those journals accepting CSP sponsored publications was 3.46 (range: 1.73-5.70). Mean time from CSP rotation to publication was 25.9 months. Twenty-three (66%) residents have one or more clinical research publications beyond their CSP participation during residency, excluding publications arising from subsequent formal research fellowships, a proxy measure of continued engagement in clinical research. This cohort of 23 residents published 69 clinical research papers (mean = 3.0; range: 1-12). Nearly two-thirds ($n = 22$, 63%) of the 35 residents who were eligible at time of this analysis have pursued formal clinical research fellowship training and have published an additional 161 total articles during fellowship (mean = 7.3; range: 0-28).

Compared to residents in the 4 years pre-CSP implementation (2007-2008 to 2010-2011, $n = 36$), residents in the first 4 CSP cohorts (2011-2012 to 2014-2015, $n = 35$) had a higher likelihood of publishing one or more clinical research articles (44% vs 77%, $\chi^2 = 7.9$, $p = 0.005$) and published 30% more such articles during residency (pre-CSP: 56 articles, range: 0-13, mean = 1.56 vs CSP: 73 articles, range: 0-12, mean = 2.09).

Most CSP residents ($n = 36$, 82%) reported a moderately high level of overall satisfaction (5.3 ± 1.7 ; range: 2-7). Of the 23 faculty members that served as a mentor for one or more of the 44 residents who completed the program, 34 unique satisfaction responses were provided, similarly yielding a moderately high level of overall satisfaction (5.3 ± 1.8 ; range: 1-7). Fourteen (78%) residents completed both the pre-CSP and post-CSP CRAI assessment. Cronbach's α was

TABLE 3. Cronbach alpha, Mean (Standard Deviation), and Repeated Measures Analysis of Variance (ANOVA) for Each Clinical Research Appraisal Inventory (CRAI) Domain and Total, Before (Pre) and 1 Year After (Post) Clinical Scholarship Program (CSP) Participation

Domain (Number of Items)	Cronbach α	Mean (Standard Deviation)	Repeated Measures ANOVA (p Value)
Conceptualizing a study (3)			
Pre	0.89	18.5 (6.1)	
Post	0.95	21.8 (6.8)	0.03
Designing a study (5)			
Pre	0.92	25.0 (10.9)	
Post	0.96	31.4 (10.7)	0.04
Collaborating with others (3)			
Pre	0.86	17.7 (6.7)	
Post	0.91	20.9 (6.5)	0.08
Funding a study (3)			
Pre	0.91	10.5 (8.4)	
Post	0.89	13.4 (6.7)	0.04
Planning and managing a study (3)			
Pre	0.84	16.0 (5.6)	
Post	0.84	19.6 (4.4)	0.01
Responsible research conduct (4)			
Pre	0.84	25.4 (9.3)	
Post	0.79	30.6 (6.3)	0.02
Collecting/recording/analyzing data (3)			
Pre	0.92	12.1 (7.9)	
Post	0.90	17.4 (6.0)	0.01
Reporting a study (5)			
Pre	0.91	25.9 (10.3)	
Post	0.93	35.4 (10.0)	0.01
Presenting a study (2)			
Pre	0.88	8.9 (3.9)	
Post	0.93	14.0 (4.3)	0.01
Total (31)			
Pre	0.97	160.0 (61.9)	
Post	0.98	204.6 (53.4)	0.01

Note: Each domain contains multiple items, each of which has a response scale ranging from 0 (no confidence) to 10 (total confidence).

high for all domains and for the total scale, demonstrating a high level of internal consistency (Table 3). Significant improvement in self-efficacy was observed across 8 of 9 domains and for total score ($p < 0.005$).

DISCUSSION

The development of thoughtful, clinically skilled surgeons remains at the forefront of all residency training. Nonetheless, it is the capacity to creatively apply established knowledge to address unresolved shortcomings in clinical management that is central to advancing the care of the patient. Engagement in scholarly activity not only supports the acquisition of the acknowledged ACGME core competencies, but also aids in the growth of effective problem

finders and problem solvers who can disseminate their ideas to others and engage in debate¹. Given the importance of scholarly activity, a framework for promoting sustainable clinical scholarship is critical to career development for both residents and faculty. The design and implementation of the *CSP* at our institution encourages at the earliest stage of residency training the development of surgeons who will have the confidence and skills to address unmet needs through a critical assessment of the state-of-the-art, the formulation of a problem, and the execution of strategy for its solution. As learning is a life-long process so too is scholarship. With more than half of participating residents achieving a presentation or publication and a third demonstrating ongoing engagement in unrelated clinical research, this initiative has increased early academic productivity and, perhaps most importantly, self-perception of efficacy in the conduct of clinical research.

The literature describing resident research curricula in general surgery residency programs is limited.⁴⁻⁸ In efforts to address a citation by the residency review committee due to lack of scholarly activity within their community residency program, Chung et al.⁵ proposed teaching conferences as a source of projects with the assignment of a “principal resident investigator” to lead completion of clinical research projects. Sabir et al.⁶ described the positive impact of a mandatory requirement to complete a set number of research projects during the course of residency, noting that scholarship had a perceived benefit to improving the career in 75% of resident participants. Implementation of mandatory scholarly activity at a university-based general surgery program increased the number of scientific presentations 3-fold.⁴ The curriculum involved voluntary faculty mentors, an electronic research project repository developed by faculty, a Director of Research, Research Coordinator and statistical support, along with an annual resident research day.⁴ Our findings mirror those reported by these investigators, suggesting that a formal research component to the residency program is likely to increase academic productivity during residency training.

The goal of the majority of published reports has been to increase academic productivity and critical appraisal skills³. We believe that sustained scholarship through the development of research skills promotes clinical curiosity, drives intrinsic motivation, which further catalyzes the acquisition of higher order research skills, broad debate and dialog, and the resulting insight required for posing more sophisticated questions. Curricular design that aligns with the mission of the departmental leadership, focuses attention on mentorship, delivers tailored didactic curriculum, and allots dedicated time to apply learned knowledge are central in developing a successful and sustainable program. A structured program that exposes residents early in training to epidemiologists, behavioral health professionals, biostatisticians, and clinical trials specialists, as well as access to software, server space, and open access databases by no

means precludes future pursuits in translational research. Indeed, we believe that this experience lowers the barrier for future research engagement of all types as residents recognize the effect of these endeavors. Lastly, although most curricula focus on developing the trainee, *CSP* was also designed to provide an opportunity for junior faculty to increase their own experience in mentorship. An Annual Award was established to recognize Excellence in Clinical Research Mentorship, which has further encouraged faculty to participate in this program. Notably, the research mentor augments the support already provided by the primary mentor assigned by the residency program director at the onset of training.

While more than half of the residents disseminated their findings by peer-reviewed presentation or publication, it is important to acknowledge that several did not. Barriers to project completion and dissemination included an overly expansive project scope, insufficient mentorship, limited clinical research infrastructure, delays in meeting regulatory requirements, and the inability to cope with clinical responsibilities and duties. We have implemented several strategies to address these barriers and to increase the likelihood of project completion and dissemination. Each *CSP* project is assessed not only for scope, but also for alignment with existing research conducted by the faculty member, available resources, such as grant support, research fellows, and clinical research staff, scientific rigor, and potential impact of the study. A more robust mentorship program for junior faculty was also implemented with the pairing of faculty with limited research experience with more established faculty. In addition, the department implemented a new clinical research infrastructure program to provide faculty and residents with the resources and guidance necessary to engage in clinical research (www.bidmcFIRST.com), including access to clinical research staff, regulatory assistance, biostatistics consultation, survey development, data management, and project mentorship. Funds are also provided to support project implementation and dissemination. We now only permit residents to engage in this experience if they are in good standing with all academic and administrative expectations. Faculty and residents are uniformly required to submit formal evaluations of respective performance to the residency program director and a written summary of the project outcome to the *CSP* director.

As each residency program has its own focus and constraints, there are several challenges in implementation that should be addressed. Firstly, the *CSP* requires a robust infrastructure to provide the necessary support for residents, including local expertise in clinical research, regulatory guidance, and biostatistics support, as well as faculty mentors that recognize the importance of promoting scholarly activity. A positive outcome for this program is dependent upon appropriate resident-faculty pairing, which depends upon the availability of mentors and nurturing of

junior faculty whose research programs are nascent. Secondly, support from the residency program director is imperative, given the 1-month allotted to nonclinical time that necessitates flexible service coverage. More importantly, an optimized clinical curriculum is required so as not to compromise surgical training during the internship year as well as to maintain compliance with American Board of Surgery training requirements. Thirdly, objectively and meaningfully measuring compliance with the CSP is an important challenge. The ACGME has adopted an outcomes based approach, which requires reporting the number of publications, abstracts, presentations, posters, and chapters, as well as participation in research projects and teaching conducted by residents.¹² Although documenting the magnitude of scholarly activity is beneficial, this alone does not assess the quality of the scholarship or the impact of this activity on the development of the trainee.¹³ We recommend the development of instruments that assess the maturation of clinicians whose ability to identify and address clinical problems both within and outside the operating room is increasingly sophisticated. Finally, costs associated with program implementation and maintenance must be carefully considered. These include curricular development expenses, time and effort costs (e.g., research program director, faculty mentors, and biostatistician), dissemination expenses (e.g., registration, travel, and lodging for residents to present their projects at meetings), and other incidental costs not otherwise covered by faculty mentors (statistical software packages, access to regional or national databases, payment of study participants, etc.).

CONCLUSIONS

The CSP represents a curriculum directed at fostering resident engagement in clinical research. In addition to fulfilling the ACGME scholarly activity requirement and the promotion of academic productivity among trainees, the program significantly increases the confidence of participants to conceptualize, design, plan, conduct, and present clinical research. Through imparting this skillset early in training, residents are able to participate in scholarly activity more confidently as they seek to address clinically meaningful problems and, thereby, recognize the importance of life-long scholarship.

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