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Development and Evaluation of a Six-day Training Program in Supportive Oncology Research

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Abstract

Objectives—Early career investigators have few opportunities for targeted training in supportive oncology research. To address this need, we developed, implemented, and evaluated an intensive, six-day workshop on methods in supportive oncology research for trainees and junior faculty across multiple disciplines.

Methods—A multidisciplinary team of supportive oncology researchers developed a workshop patterned after the clinical trials workshop offered jointly by the American Society of Clinical Oncology (ASCO) and American Association of Cancer Research (AACR). The curriculum included lectures and a mentored experience of writing a research protocol. Each year since 2015, the workshop accepted and trained 36 early career investigators. Over the course of the workshop, participants present sections of their research protocols daily in small groups led by senior researchers, and have dedicated time to write and revise these sections. Primary outcomes for the workshop included the frequency of completed protocols by the end of the workshop; a pre-post test assessing participant knowledge; and follow-up surveys of the participants and their primary mentors.

Results—Over three years, the workshop received 195 applications, and 109 early career researchers were competitively selected to participate. All participants (109/109, 100%) completed writing a protocol by the end of their workshop. Participants and their primary mentors reported significant improvements in their research knowledge and skills. Each year, participants rated the workshop highly in terms of satisfaction, value, and likelihood of recommending it to a colleague.

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One year after the first workshop, most respondents (29/30, 96.7%) had either submitted their protocol or written at least one other protocol.

Significance of results—We developed a workshop on research methods in supportive oncology. More early career investigators applied for the workshop than capacity, and the workshop was fully attended each year. Both the workshop participants and their primary mentors reported improvement in research skills and knowledge.

Keywords

supportive oncology; research; education

Background

For almost 20 years, the American Society of Clinical Oncology (ASCO) and American Association of Cancer Research (AACR) have jointly offered an intensive workshop on clinical trial protocol writing for oncology fellows and junior faculty. While the workshop has been highly successful, there has been no equivalent program for supportive oncology research. Those interested in supportive oncology were limited to post-doctoral fellowships or highly-competitive mentored training grants (e.g., K awards), restricting the accessibility of training in this type of research. Additionally, mentors in supportive oncology research are not available at all cancer centers.

The paucity of training opportunities is particularly unfortunate because the evidence base for the clinical practice of supportive oncology is lacking, especially compared to that for cancer treatment.¹ Systematic reviews have noted that the limited research available is often characterized by substantial methodological challenges.^{2,3} Multiple Institute of Medicine reports have emphasized the need for more supportive care research,⁴⁻⁶ with the 2001 palliative care report specifically citing the lack of trained investigators as a primary reason for having limited evidence. That report asserts that health care professionals most interested in this type of research tend to be clinicians with little research experience. Specifically, the report stated that “although they often pose clinically important, reasonable, interesting, and potentially researchable questions...the methods they propose are inappropriate or lacking in scientific rigor.” As supportive care is increasingly integrated into cancer care, the science supporting best practices must keep pace with the rest of oncology treatment.

To conduct a scientifically rigorous supportive oncology study, a new researcher must become familiar with methods and challenges that may differ from therapeutic oncology research and require specialized training. These differences impact all major components of studies. Supportive oncology studies are typically grounded in conceptual models and include hypotheses with theoretical underpinnings, which may be perceived as esoteric or superfluous to individuals without social science training. Second, recruitment can be challenging because motivation may be lower for patients to participate in a supportive care study compared to a clinical trial offering a new cancer treatment. Third, outcomes in supportive care studies often include self-report questionnaires or data collected through qualitative interviews, which require training in their collection and interpretation. Fourth, safety concerns may differ from those of clinical trials, such as the responsibility to address

participant-reported potential harm or suicidal ideation in a timely manner instead of grading chemotherapy toxicities. Finally, advanced analytic approaches are often necessary, such as structural equation modeling to determine the relationships among variables.

To address these concerns, we sought to develop, implement, and evaluate an annual, intensive workshop on research methods in supportive oncology. The goal of the workshop is to facilitate new research in supportive oncology by training junior investigators in a broad range of research methods through mentorship in writing and developing a study protocol for implementation at their institution. This manuscript reports on experiences and data from the first three years of the workshop.

Methods

The workshop was funded by the National Cancer Institute and is hosted by Massachusetts General Hospital (MGH) and the University of Miami. The Dana-Farber/Harvard Cancer Center internal review board determined the program to be exempt from approval because it does not qualify as human subjects research.

Development of Curriculum

Multidisciplinary groups of experts in supportive oncology research developed the content areas for the workshop in three stages using consensus methods. First, members of the MGH Cancer Outcomes Research Program generated a comprehensive list of areas of competency in supportive oncology research. This group included oncologists, palliative care physicians, psychiatrists, psychologists, and nurses, with experience in designing and conducting supportive care trials. Next, the Curriculum Committee reviewed and edited the list of competencies for its completeness. The Curriculum Committee consisted of nationally-known oncologists, nurse researchers, psychologists, psychiatrists, and social work researchers within and outside of MGH. Third, prior to the workshop, an External Advisory Committee of expert supportive oncology researchers outside of MGH reviewed the areas of competency and corresponding lectures. At each stage, the groups reached consensus on which areas were essential to include and which could be excluded.

Recruitment of Participants

We tailored the workshop to meet the needs of early career researchers, defined as not having independent funding (e.g., R01 or equivalent grant). Participation in the workshop was competitive with an application process. Eligible participants could be physicians, nurse researchers, social work researchers, psychologists, or other doctoral level trainees and junior investigators in fields related to individual, community and population level health. All needed to have a doctoral degree or be in the final stages of a doctoral program in which they were conducting their own research. Potential participants submitted an application form, a curriculum vita (CV) or biosketch, and an abstract on their proposed project. They were also required to identify a local primary mentor who could help them continue and advance their research projects at their own institutions after the workshop. Early career grantees of the American Cancer Society and National Palliative Care Research Center were invited to apply and given priority.

For the first year of the program, we accepted participants through a rolling admissions process with approval by the workshop Principal Investigators (PIs: WFP & JST) based on eligibility criteria and assessment of likelihood that the participants would be able to implement their project within the next year. In years two and three of the workshop, we established a formal review committee for accepting applicants. Two faculty members scored each application, and the committee selected participants based on average scores and discussion of application materials. Special consideration was given to the representation of disciplines, geographic regions, and under-represented groups. Participants received five nights lodging in a hotel and were reimbursed for travel to and from Boston.

Participant Preparation

Prior to attending the workshop, participants completed an online training in Responsible Conduct of Research (website). We also required that participants complete the Collaborative Institutional Training Initiative program or their institutional equivalent so that participants would be able to submit a study protocol to their institutional review boards. The participants were assigned to small writing groups with designated faculty leaders who reviewed participants' abstracts and provided comments to consider before the workshop.

Workshop Schedule

The workshops were held in Boston, MA for six days, starting on a Sunday evening and ending Friday afternoon. Over the course of the week, participants were expected to write either a study protocol or a research proposal to obtain grant funding. The first evening included a welcome dinner and lecture. Monday through Thursday participants attended two hours of lectures in the morning and two-hour writing groups in the afternoon. Senior researchers with R01 or equivalent funding led the small writing groups of six participants. To ensure a multidisciplinary perspective, each writing group included participants from various disciplines (nurses, physicians, psychologists, social workers, and other clinical researchers). A member of the MGH Patient and Family Advisory Council joined each writing group once during the week as a patient stakeholder. Biostatistical consults, individual meetings with faculty, and optional sessions such as a qualitative coding lab and an advanced statistics seminar were scheduled in the afternoons. On Friday, the PIs delivered a final lecture in morning and completed protocols were due by the end of the day.

Evaluation

Evaluation of the workshop is accomplished through an extensive process that includes an assessment of the number of completed protocols by the end of the workshop; evaluations by participants and local mentors; pre- and post-tests of research knowledge; and a one-year follow-up survey. Additionally, a nationally-recognized senior researcher and educator in supportive oncology attended the first workshop, auditing every lecture and one of the writing groups. The auditor took field notes throughout the workshop to identify components that could be improved.

Completed protocols—The primary immediate outcome for the program was the proportion of participants who submitted a completed protocol to the workshop faculty on the last day of the workshop.

Participant Evaluations—Participants evaluated the lectures daily during the workshop on a scale of 1–4, with 1 being “poor” and 4 being “excellent.” On the last day of the workshop, they were asked to evaluate the writing groups, statistical consults, other activities, and the workshop as a whole.

Self-evaluation of research knowledge and skills—Before the workshop and one year after the workshop, participants were asked to evaluate components of their research knowledge and skills on a scale of 1–4, with 1 being “poor” and 4 being “excellent.” In Years 2 and 3, an additional evaluation was added on the last day of the workshop.

Pre-Post Test—Prior to the start of the workshop and on the last day of the workshop participants completed a test of knowledge online. Workshop faculty members created potential test items based on the content areas covered by their lectures. The PIs then compiled and reviewed candidate items for appropriateness. Cognitive testing was conducted by administering a draft version of the test to faculty to ensure the clarity of the questions and answers, reduce risk of bias, and ensure representativeness of the content. After the first administration to participants in Year 1, we removed items that performed poorly (e.g., ones almost all participants answered correctly on the pre-test). In year three, the PIs again reviewed the questions for relevance given changes in content over the first two years.

One-Year Follow Up Survey—One year after the workshop, participants received an online follow-up survey on their research activities in the year after the workshop. The survey also served as a self-assessment of their research knowledge and skills, using the same items they completed before the workshop. Because access to financial resources can impact the ability to implement protocols written during the workshop, the primary follow-up outcome at one year was the proportion of participants who either implemented their protocol (or submitted their proposal) or wrote a new protocol after the workshop.

Primary Mentor Evaluations—Before and one year after the workshop, the primary local mentors were asked to report their perceptions of the research knowledge and skills of the participants as well as any benefit they may have obtained from the workshop on a scale of 1–5, with 1 being “poor” and 5 being “excellent.”

Analyses

Descriptive statistics were compiled using IBM SPSS 22. We conducted t-tests or Wilcoxon Rank Sum tests to analyze comparisons between continuous variables, and we used Chi-square tests to analyze comparisons of categorical data.

Results

Curriculum

Table 1 summarizes the final curriculum, approved by the Curriculum and External Advisory Committees. Based on evaluations of the first and second years, we reduced the number of lectures in order to have more time for questions and discussion.

Participants

We received 195 applications over the three years, 79 for Year 1, 63 for Year 2, and 53 for Year 3. The characteristics of those accepted are shown in Table 2. For the first year, acceptance through rolling admissions led to a situation in which most slots were filled by the week before the application deadline, though the majority of applications were submitted within two days of the deadline. Among the later applicants who were not selected, we offered qualified individuals who would have been accepted earlier in the process admission to the workshop the following year. Ten of those people chose to participate in Year 2, making them a natural waitlist control for outcomes. In year 1, we accepted 36 participants. Two participants dropped out close to the workshop date, and 2 were taken from a waitlist. In years 2 and 3, 38 participants were chosen to account for dropouts.

Across all years of the workshop, we accepted applicants from a range of disciplines including physicians (e.g., medical oncologists, palliative care specialists, psychiatrists, and surgeons), nurse researchers, psychologists, social work researchers, and other researchers (e.g., exercise physiology/kinesiology, public health, and communications). No single discipline constituted the majority of participants in any year of the workshop.

For the majority of protocols, participants aimed to develop or test supportive care interventions such as behavioral, educational, communication, exercise, or health services interventions. Many participants re-conceptualized their projects over the first two days of the workshop after obtaining feedback from their mentors and group. In revising their projects, participants generally decided to start the research at an earlier phase, for example by proposing a pilot study to assess feasibility and preliminary efficacy rather than moving forward with a randomized controlled trial of a new intervention.

Evaluation

Completed protocols/proposals—In each of the three years all participants (N=109/109, 100%) submitted a draft protocol/proposal on the last day of the workshop. In the evaluations, participants rated the value of protocol writing 3.9–4/4 each year. In free text comments, many participants wrote that what they accomplished during the workshop would have taken them months to complete at their home institutions.

Participant evaluations—Participant evaluations are summarized in Table 3. Overall participant evaluations of the workshop were very favorable each year with high ratings of satisfaction, value, and likelihood of recommending the workshop to a colleague.

Self-assessment of skills at the immediate end of the workshop—In years 2 and 3, participants reported significant improvement in their familiarity and confidence in research skills from before and after the workshop (Table 4). However, participants did not report significant changes in their interest in research or likelihood of conducting supportive oncology research in two years, both of which were high pre-workshop. We do not have data from year 1 on participants' self-reported assessment of their research skills at the immediate end of the workshop.

Pre-post test—Scores on the pre- and post-tests are shown in Table 5. Although the proportion of correct answers increased on the post-test in years 1 and 2, the difference was not significant. In year 3, we observed a significant improvement in number of correct items.

One year follow up—Thirty of the 36 (83.3%) participants from Year 1 completed the one-year follow-up survey. Almost all participants who responded (29/30, 96.7%) either implemented or submitted the protocol they wrote in the workshop or wrote a new protocol/proposal in the year after the workshop. More specifically, 24/30 (80%) implemented or submitted their protocol and 26/30 (86.7%) wrote at least one other protocol or proposal in the year after the workshop. The mean number of protocols that participants wrote in the year after the workshop was 2.4. Participants from Year 1 reported significant improvement in their familiarity with and confidence in research skills from before the workshop to one year post-workshop. However, similar to the data from the immediate end of the workshop, participants did not report significant changes in their interest in research or likelihood of still being involved with supportive oncology research in two years, both of which were high pre-workshop. Half of the participants (15/30) reported receiving at least one research grant, which was higher than the proportion in the natural waitlist control group (3/10, 33.3%) comparing their first biosketch to their updated biosketch one year later. The total number of grants awarded to participants was 24.

Primary mentor surveys—Local primary mentors completed the survey for 24/36 (66.7%) year 1 participants. Similar to the participants' one-year survey, the primary mentor reported significant improvement in the participants' research skills and familiarity with methods from before the workshop to one year after the workshop (see Table 4). Primary mentors also did not report significant differences in their perceptions of the participants' interest in research or likelihood of still being involved in supportive oncology research in two years. The local mentors' mean rating of the participants' benefit from the workshop was 4.67/5 (SD=.55).

Discussion

We developed and implemented a successful 6-day workshop to train early career investigators on skills in supportive oncology research. By training the next generation of supportive oncology researchers, the ultimate goal of the workshop is to increase both the quality and quantity of research in supportive oncology. To date, 109 early career researchers have participated in an annual workshop on research methods in supportive oncology. All participants completed a research protocol by the end of the workshop, and most implemented or submitted their proposals after the workshop. Not only did participants rate the workshop highly in their evaluations, participants and their local primary mentors' also reported significant improvements in their perceptions of the participants' familiarity with research methods and research skill from before the workshop to the end of the workshop and one year later. Comparing workshop participants from the first year with a natural waitlist control group, participants were more likely to receive grants in the year following the workshop.

Of note, we did not observe significant differences in the participants' reported interest in research or likelihood that they would still be doing supportive oncology research in two years from before to after the workshop. Participants' high ratings of these perceptions prior to the workshop likely led to a ceiling effect for these items. Nonetheless, the workshop created a sense of community among supportive oncology researchers, both participants and faculty. Many participants reported that they knew of few, if any, others at their institutions who were interested in leading or initiating supportive oncology research. The six-day workshop provided the opportunity for participants to meet others doing similar work, develop new collegial relationships, and forge potential collaborations with investigators at other institutions. Thus, the workshop created new opportunities for multi-site and multidisciplinary studies, including at least one funded National Institutes of Health R01.

While the workshop has been successful by our pre-defined evaluation metrics, we also experienced several challenges over the first three years. One of the most significant challenges was for small group leaders to meet the diverse needs of group participants who possessed varying levels of prior research experience. For instance, some participants had already completed their own studies whereas others were writing a protocol for the first time. With the goal of increasing accessibility of training for this type of research, we committed to including participants with high motivation to conduct research yet minimal research exposure rather than focusing exclusively on those who already had research experience. Although the decision to include very early investigators may yield benefits to the field in the years after the workshop, it may also have impacted our one-year outcomes, as these participants may be less likely to receive grants and write multiple protocols in the short term.

Another major challenge was that many participants substantially re-conceptualized their studies during the first two days of the workshop. Decisions to make fundamental changes in design may have resulted in fewer days to develop a new idea into the protocol and to benefit from scheduled consultations with biostatisticians, survey developers, etc. However, revised project ideas could also be considered a positive outcome. The workshop helped some early investigators conceptualize a more realistic, feasible, and justifiable project proposal that matched their skill sets while also meeting review criteria set by internal review boards and funding agencies. In Years 2 and 3, to accommodate re-conceptualizations, we changed the timing of the agenda such that study development lectures occurred at the very beginning of the workshop and biostatistical consults occur towards the middle and end of the workshop.

Finally, while this workshop provided a live forum for trainees and junior faculty to receive training in supportive oncology, the in-person format may have limited accessibility. Although the lectures could be delivered via webinar to increase access to the workshop, it would be challenging to conduct the daily interactive writing groups through video. The immersive experience with frequent meetings and high-intensity engagement requires face-to-face time and could not be replicated through conference calls or video-conferencing. Participants would not have the same opportunities for networking and cultivating professional relationships that are facilitated by an in-person meeting. Additionally,

participants reported that a major benefit of the workshop was having six days dedicated to writing away for home and work, thereby minimizing distractions. In fact, one participant described the workshop as a “spa for research.” Furthermore, participants found the communal obligation of needing to produce a deliverable product in only six days to be motivating.

Despite the challenges encountered, the workshop appears to be responding to a need of early career supportive oncology researchers. Every year, the workshop has been oversubscribed and participants report the value of their experience. Armed with new skills, participants return to their institutions across the country with a product to submit to an IRB or funding agency. As their professional development continues, we hope the quantity of high-quality supportive oncology research continues to grow. Ultimately, the research will provide the evidence base that will help improve the experience of patients and families affected by cancer.

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Table 1

Workshop Curriculum

Session	Content Area
1	Research Questions and Specific Aims
2	Approaches to Data Analysis
3	Clinical Trials
4	Epidemiological Methods
5	Analyses of Large Databases
6	Qualitative Methods
7	Measurement of QOL and symptoms
8	Survey Methods
9	Decision Making Research
Lab 1	Longitudinal Analysis
Panel	Faculty Early Career Experiences
10	Behavioral Theories and Conceptual Models
11	Development of Psychosocial Interventions
Break out lectures	Web-based Methods
	Quality Improvement
	Biological Mechanisms in Symptom Research
Lab 2	Qualitative Coding
12	Human Subjects
13	Communications Research

Table 2

Participant Characteristics

	2015 (n=36) N (%)	2016 (n=36) N (%)	2017 (n=37) N (%)
Disciplines			
-Physicians	13 (36.1)	6 (16.7)	12 (32.4)
-Nurse Researchers	11 (30.6)	9 (25.0)	6 (16.2)
-Psychologists	7 (19.4)	16 (44.4)	12 (32.4)
-Social Work Researchers	4 (11.1)	0 (0)	3 (8.1)
-Other	1 (2.8)	5 (13.9)	4 (10.8)
Female	26	32	31
Race/Ethnicity			
-White	28 (77.8)	29 (80.6))	26 (70.3)
-Asian	6 (16.7)	3 (8.3)	8 (21.6)
-African-American/Black	1 (2.8)	2 (5.6)	1 (2.7)
-Hispanic	3 (8.3)	1 (2.8)	4 (10.8)
-Other	1 (2.8)	2 (5.6)	2 (5.4)
-Unknown	2 (5.6)		
Trainees	8	10	14
Current:			
- ACS	6 (16.7)	7 (19.4)	6 (16.2)
- NPCRC	2 (5.6)	0 (0)	0 (0)

Table 3

Participant evaluations of the workshop

Question	2015 (n=33) Mean (SD)	2016 (n=36) Mean (SD)	2017 (n=35) Mean (SD)
Satisfaction with workshop	3.97 (.17)	3.81 (.40)	3.97 (.17)
Quality of teaching	4.00 (0)	3.97 (.16)	4.0 (0)
Value of protocol writing experience	3.91 (.29)	3.78 (.48)	4.0 (0)
Value of workshop	3.97 (.17)	3.83 (.16)	3.97 (.17)
Likelihood of recommending workshop to a colleague	3.97 (.17)	3.97 (.16)	4.0 (0)
Impact on excitement to do supportive oncology research	3.94 (.25)	3.94 (.23)	3.97 (.17)
Scale 1–4, 1 is “poor” and 4 is “excellent”			

Table 4

Research skills and attitudes assessments

Questions	2016				2017	
	Participants (1–4 scale)		Primary mentors (1–5 scale)		Participants (1–4 scale)	
	Pre Mean (SD)	Post Mean (SD)	Pre Mean (SD)	1-year Mean (SD)	Pre Mean (SD)	Post Mean (SD)
How prepared do you feel to conduct your own research in supportive oncology?	2.61 (.69)	3.46 (.56) *	3.91 (.79)	4.52 (.85)**	2.29 (.68)	3.41 (.61)*
How familiar are you with study designs used in supportive oncology?	2.58 (.69)	3.31 (.68) *	3.87 (.18)	4.57 (.14)**	2.39 (.70)	3.24 (.61)*
How familiar are you with analyses used in supportive oncology?	2.31 (.67)	3.51 (.56)*	3.52 (.18)	4.22 (.19)**	2.21 (.88)	3.09 (.62)*
How confident do you feel writing study protocols?	2.81 (.75)	3.77 (.43)*	3.74 (.19)	4.30 (.17)**	2.26 (.79)	3.44 (.66)*
How comfortable are you with calling yourself a researcher?	3.31 (.75)	3.94 (.24)*	4.30 (.18)	4.65 (.12)	2.82 (.90)	3.44 (.75)*
How important is research to you?	3.86 (.35)	3.86 (.36)	4.74 (.11)	4.61 (.14)	3.71 (.52)	3.76 (.50)
How certain are you that you will be doing supportive oncology research in 2 years?	3.72 (.45)	3.43 (.56)	4.57 (.15)	4.39 (.18)	3.71 (.52)	3.72 (.58)
Scale	1–4, 1 is “poor” and 4 is “excellent”		1–5, 1 is “poor” and 5 is “excellent”		1–4, 1 is “poor” and 4 is “excellent”	

Table 5

Pre-Post Test Scores

Year (test items)	Mean (SD) and Mean Percent Correct Items				
	Pre Mean (SD)	Mean % correct	Post Mean (SD)	Mean % correct	p-value
2015 (25)	16.48 (2.21)	65.9%	16.93 (2.00)	67.7%	.40
2016 (20)	14.29 (2.14)	71.5%	14.97 (1.72)	74.9%	.14
2017 (20)	14.36 (2.31)	71.8%	15.44 (2.31)	77.2%	.01