ASCOb's Community Research Forum: Addressing Challenges of Community-Based Research from the Grass Roots

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OVERVIEW

ASCOb’s Community Research Forum is a solution-oriented venue for community research sites to overcome barriers to conducting clinical trials. The key objectives of the Forum are to (1) convene community-based researchers to identify challenges to conducting research that ASCO can address, (2) develop solution-oriented projects to address these challenges to facilitate clinical trial participation in community research settings, and (3) shape ASCO programs and policies to support members engaged in community research. The Community Research Forum holds an annual in-person meeting that convenes physician investigators, research administrators, research nurses, and clinical research associates from community-based research programs and practices. To meet identified needs, the Community Research Forum has developed the ASCO Clinical Trial Workload Assessment Tool and the ASCO Research Program Quality Assessment Tool. Both of these tools will be available to the public in 2014. The Forum is currently exploring the concept and potential metrics of a research certification program to formally assess community-based research programs, and to identify gaps and areas to improve the program in order to meet quality standards. The Community Research Forum’s website aims to serve as a go-to resource for community-based physician investigators and research staff. The Community Research Forum will continue to provide a forum for community-based researchers to network, share challenges, and develop initiatives that provide solutions and facilitate the conduct of clinical trials.

THE IMPORTANCE OF COMMUNITY-BASED RESEARCH

The participation of community-based practices in oncology is a critical factor in the advancement of treatment options and achieving the goal of conquering cancer. The inclusion of community-based research sites contributes significantly to the reliability and validity of findings from clinical trials by helping to increase the diversity and representativeness of participants. Clinical trials also provide beneficial opportunities for community-based sites and their patients, including access to new treatment options.

There are several initiatives that provide a mechanism and an important opportunity for community-based investigators, research staff, and patients to participate in trials that might not otherwise be available in a local venue. These include federally funded initiatives (e.g., National Cancer Institute at the National Institutes of Health [NCI] Community Oncology Research Program [NCORP], NCI Community Cancer Centers Program [NCCCP], Community Clinical Oncology Programs [CCOPs], Cooperative Groups) as well as privately funded ones (e.g., U.S. Oncology Network, Sarah Cannon Research Institute).

Unfortunately, there are a host of challenges that community-based physician investigators and their research staff encounter when it comes to participating in and implementing clinical trials.

This manuscript describes how ASCO’s Community Research Forum has begun to identify and address some of the common challenges and barriers faced by community-based physician investigators and research staff in their participation in research and implementation of clinical trials.

ASCO’S COMMUNITY RESEARCH FORUM

The American Society of Clinical Oncology (ASCO) recognizes the value and contributions of community-based research. ASCO’s Community Research Forum was conceived from ASCO Board of Directors’ Clinical Trials Strategic Plan of 2010, which in part defined ASCO’s role in supporting clinical investigators and increasing their participation in cancer clinical trials. In response, ASCO’s Cancer Research Committee convened an advisory council in December of 2010 to implement the Community Research Forum as a solution-oriented venue for community research sites to overcome barriers to conducting clinical trials.

The three key objectives of the Forum are to (1) convene community-based researchers to identify challenges to conducting research that ASCO can address, (2) develop
solution-oriented projects to address these challenges and facilitate clinical trial participation in community research settings, and (3) shape ASCO programs and policies to support members engaged in community research.

The Community Research Forum’s activities and products are intended for physician investigators as well as research staff (i.e., research administrators, research nurses, and clinical research associates) from any type of community-based research site and/or program that is not academic-based and is currently conducting clinical trials.

COMMUNITY RESEARCH FORUM ANNUAL MEETING
In 2012, the Community Research Forum began holding an annual in-person meeting that convenes up to 100 participants from community-based practices, including physician investigators, research administrators, research nurses, and clinical research associates. The meeting provides a forum for participants to discuss barriers and propose solutions to common challenges in conducting research, provide input on ASCO programs and policy issues that affect clinical research, and network and collaborate with investigators and research staff from a range of community-based research sites.

Presentations and discussions have included addressing clinical trial–associated workload, strategies to assess and ensure the quality of research programs, and late-breaking news and recent changes in oncology research. Participants also have the opportunity to engage in discussions about new initiatives and policies that ASCO could pursue to support community-based research programs. The 2014 meeting will take place at ASCO headquarters in Alexandria, Virginia. Refer to the Forum’s website for more information (asco.org/communityresearchforum).

ASSESSING THE NEEDS OF COMMUNITY-BASED RESEARCHERS
The Forum Council actively seeks feedback from physician investigators and research staff to identify and select initiatives. In addition to the Community Research Forum Annual Meeting, online surveys are periodically conducted to obtain input from research professionals who represent a variety of types of community-based research programs.

Needs Assessment Surveys
In 2011, an online survey was conducted to assess the needs of community-based researchers and to identify the inaugural solution-oriented projects of the Forum. Respondents included physician investigators from a wide range of research programs, including NCI CCOP, NCCCP, Sarah Cannon Research Institute, and U.S. Oncology. ASCO Clinical Trial Participation Award recipients also participated. Of the projects identified by the respondents that were not already addressed by the ASCO Board of Directors, the Community Research Forum Council selected the Workload Assessment Tool and the Research Program Quality Assessment Tool for further development. These projects are described later in this manuscript.

In response to a continued desire to support high-quality research at community-based research sites, a needs assessment was conducted in 2013 to determine interest in specific types of products that the Forum could develop to facilitate conducting quality research in community settings. A broad perspective was obtained by including community-based researchers, industry sponsors, cooperative groups, and contract research organizations in telephone interviews and focus groups to discuss and generate project ideas. An online needs assessment survey was ultimately conducted with community-based physician investigators and research staff. The five most frequently selected initiatives identified by the 123 survey respondents were (1) a research certification program (53.9%), (2) an online repository of resources (53.0%), (3) a quality self-assessment tool for research programs (52.2%), (4) online training opportunities (47.0%), and (5) an ASCO framework/statement that clearly defines quality criteria (44.3%). Findings from the survey were used by the Community Research Forum Council to identify new initiatives for the Forum to pursue beginning in 2014.

COMMUNITY RESEARCH FORUM INITIATIVES
The Forum Council convenes Working Groups to work on specific projects throughout each year to tackle the chal-
Challenges faced by community-based physician investigators and their research staff. Working Groups include the Workload Assessment Working Group, Research Quality Assessment Working Group, Research Certification Concept Working Group, and Resources for Researchers Working Group. The activities of these Working Groups are described below.

ASCO Clinical Trial Workload Assessment Tool
For a variety of reasons, in particular differences in complexity among trials, managers and administrators often struggle with the proper staffing of research personnel. Furthermore, data regarding the optimal number of patients that can be safely handled by research staff are lacking. Respondents to the 2011 Needs Assessment Survey ranked a tool to assist in determining clinical trial associated workload very highly.

The Workload Assessment Working Group performed an environmental scan and literature search to assess whether there was a tool already available to meet this need. The searches identified several groups that had begun the process of developing workload measurement tools using complex scoring formulas that often encompass measurements of time associated with individual trial-related tasks and/or detailed ranking options. However, no sufficiently validated measurement tools were found. There was also no established or recommended maximum metric for staff workload (i.e., the ratio of research participants to staff).

After reviewing the literature and available tools, the Working Group concluded that characteristics of the most useful workload measurement tool would include simplicity, reproducibility, and long-term usability. It was evident that a workload measurement tool would not be used if it is too complex and requires too many layers of measurement, and therefore too much time and effort. Furthermore, a tool needed to be able to withstand changes in the design of clinical trials and have the flexibility to adapt to new requirements in the long term.

The Wichita Protocol Acuity Tool, which was used by a single oncology-focused research program for over 10 years,1 was selected as the model on which the ASCO tool would be based. The Forum adapted this Wichita tool to create the ASCO Clinical Trial Workload Assessment Tool, which is designed to have widespread applicability among community-based research sites. The prototype of this online tool was developed in 2013.

An important step in the development of the Tool was to conduct an evaluation of its effectiveness and utility in diverse research settings. Community-based research programs were recruited to participate in a project to determine the utility of the tool and to collect data on clinical trial workload benchmarks for community-based research programs. The specific objectives of the project were (1) to determine the feasibility of using a common clinical trial workload assessment tool among multiple community-based oncology research programs, including its ease of adoption and use, and how well it fits within the workload of its intended users; (2) to gather information regarding average acuity levels per research nurse and clinical research associate full-time equivalent for various types of industry- and NCI-funded clinical trials based on patient status within a trial (i.e., receiving active treatment versus on follow-up); (3) to compare the number of patients per research nurse and clinical research associate with the complexity rating for various types of industry- and NCI-funded clinical trials; (4) to use the findings to further inform the development and applicability of the tool for adoption within the broader ASCO membership and the oncology research field; and (5) to assess how many research programs collect general data on patients screened for and excluded from clinical trials.

Community-based oncology programs that were accruing to industry- and/or NCI-funded cooperative group trials were eligible for the project. Sites were recruited through the ASCO Community Research Forum, NCI CCOPs, NCI Minority-Based CCOPs, NCCCPs, Oncology Nursing Society’s Clinical Trial Nurses’ Special Interest Group, Sarah Cannon Research Institute, and the U.S. Oncology Network. Site-specific information related to each research program’s structure, staffing, and portfolio of active trials was collected. Using a 4-point rating scale, participating sites assigned a score to each of their trials based on its complexity. Workload data were entered into the tool monthly for 6 consecutive months.

The goal was to obtain 25 to 30 participating research programs for this project. There was an overwhelming response and a total of 52 research programs completed data collection. The interest in this project, and in the workload tool, confirmed the need to address workload issues within community-based research programs.

Findings from the project will be available and the tool will be made available to the public in 2014.

ASCO Research Program Quality Assessment Tool
As part of its continuing efforts to best serve its members, ASCO published a special article in the Journal of Clinical Oncology in 2008: American Society of Clinical Oncology Statement on Minimum Standards and Exemplary Attributes of Clinical Trial Sites.2 This statement reflects ASCO’s commitment to support oncologists and other professionals engaged in clinical research. A series of papers published in the Journal of Oncology Practice elaborated on the attributes of exemplary research that were identified in the 2008 seminal paper.

ASCO’s identification of quality assurance as an exemplary attribute of a clinical research site highlights the important role of an internal quality assessment process. As noted in the ASCO statement on minimum standards and exemplary attributes, implementation of internal quality assurance programs promotes adherence to Good Clinical Practice guidelines and contributes to the ability of a clinical trial site to consistently produce high-quality data.2,3 A research site that establishes and routinely conducts an internal process for assessing the quality of their operations is more likely to be proactive in identifying and addressing quality problems before they arise. Routine implementation of an internal quality as-
assessments will also help demonstrate to trial sponsors, auditors, monitors, and regulators that the site devotes time and resources to protecting the validity of their research findings.

Unfortunately, many community-based programs do not have the resources to support an active internal quality assurance program and end up relying exclusively on external audits. Although valuable, these external audits are retrospective and do not always translate into modifications or prevent further deviations.

The Community Research Forum’s Research Program Quality Assessment Working Group developed a tool that is an extension of the elements of the papers published by ASCO on minimal standards and exemplary attributes of research sites. The ASCO Research Program Quality Assessment Tool is designed to help community-based research sites exceed the minimum standards of conducting clinical research and provides an overview of ASCO’s recommendations for the important components of an internal quality assessment program. A checklist tool is also provided to help sites conduct an assessment of whether their program includes these important components.

In 2013, the tool was reviewed by community-based physician investigators and research staff. Reviewers completed an online survey to provide content feedback and to confirm the utility of the tool for community-based research programs. There was overwhelming support of the tool, and respondents confirmed that the tool presented realistic expectations (e.g., in terms of time, staff, and resources required to implement it), and that it would be valuable for conducting a quality assessment of their research program.

The tool will be made available online in 2014 (visit asco.org/communityresearchforum).

Research Certification Concept Working Group
The Research Certification Concept Working Group was convened in 2014 to explore the concept and potential metrics for a research certification program for community-based programs. The NCI Clinical Trials Working Group and an Institute of Medicine Report previously recommended the development of a research site certification program. Furthermore, feedback received from community-based researchers through the Forum indicated a need and support for a research certification program.

The intent of the Working Group is to explore whether a certification program could be developed by ASCO that would identify high-quality research programs. It is thought that a research certification program might help to demonstrate the integrity and value of certified research programs by providing a formal assessment, based on objective quality criteria. It could also provide constructive feedback that would identify gaps in the program and areas for improvement to meet quality standards. Ultimately, a research certification may attract patients interested in research and trial sponsors interested in sites dedicated to quality research.

The research certification concept and metrics will be explored by the Working Group in 2014. The findings will be presented at the Community Research Forum Annual Meeting in the fall of 2014.

Resources for Researchers Working Group
The Resources for Researchers Working Group was created in 2014 to conduct an environmental scan of existing resources and tools for community-based physician investigators and research staff. The main objective is to compile lists of resources to be referenced on the Forum’s website to provide a go-to resource for community-based researchers. The Working Group will also perform a gap analysis to identify the types of resources that are not available, but are needed, for ASCO and the Forum to consider for future initiatives.

A comprehensive list of resources will be available on the Community Research Forum website (visit asco.org/communityresearchforum).

CONCLUSION
The ASCO Community Research Forum provides a means for ASCO to fulfill its mission of supporting members at community-based practices. The Forum aims to provide community-based physician investigators and research staff with a venue to discuss their challenges around conducting clinical trials and develop solution-oriented initiatives. Tools and resources continue to be developed and made available as ASCO-sponsored products to the membership at large. For more information, visit the Community Research Forum website at www.asco.org/communityresearchforum.

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Disclosures of Potential Conflicts of Interest

Relationships are considered self-held and compensated unless otherwise noted. Relationships marked “L” indicate leadership positions. Relationships marked “I” are those held by an immediate family member; those marked “B” are held by the author and an immediate family member. Relationships marked “U” are uncompensated.


