# Multi-Grantee Technical Assistance Meeting—Patient Recruitment: Challenges, Trends, and Best Practices

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# Chapter 1. Background

Recruiting patients for research studies is an essential component for many Agency for Healthcare Research and Quality (AHRQ) research grants. Carefully planned design and implementation of sound recruitment and enrollment strategies, as well as follow-through, contribute to the efficiency and success of studies, from initiation to study completion.

Recruiting patients can be challenging and often lead to delays in meeting project milestones. The AHRQ National Resource Center for Health IT (NRC) has received a number of technical assistance requests regarding patient recruitment challenges. Samples of these requests have included the following:

- How to recruit a specific population (e.g., pediatrics, hypertension) in an urban setting
- How to effectively use online recruiting methods (e.g., Google™ ads, Craig's List, and so on)
- How to create recruitment materials that generate a high response rate from potential participants
- How to maximize recruitment efforts with a limited budget
- How to retain participants in research studies

To assist grantees with these challenges, the NRC conducted a multi-grantee Webinar in April 2010 to provide an opportunity for grantees to learn about possible strategies and approaches to common patient recruitment challenges. To address patient recruitment topics relevant to the invited grantees, presenters were asked to respond to several specific questions related to recruitment methods, identification of participants, and barriers or roadblocks. Specifically, the questions addressed during the Webinar included the following:

| Recruitment Methods |
| --- |
| *Question #1:* What barriers may be encountered when recruiting patients and how can they be overcome? Variables may include:<br>• Community settings versus institutional settings<br>• Targeting a specific patient-population (diabetes patients, etc.) versus wide-ranging patient recruitment<br>• Focus groups versus individual patient recruitment<br>• Closed system (physician office, hospital) versus broad-based recruitment efforts. |
| *Question #2:* What strategies are most effective when using traditional recruitment methods?<br>• Recruiting via physician practices<br>• Recruiting large numbers of patients for studies<br>• Recruiting patients directly and developing patient-centered messages<br><br>*Question #3:* What nontraditional recruitment methods are effective for patient recruitment? (e.g., Web-based recruiting or Google™ ads) |
| **Identifying Participants** |
| *Question # 1:* How do researchers determine which data sources will yield the best patients for research? |
| *Question # 2:* How is the optimal sample size determined? What if researchers are unable to recruit the number of patients targeted? |
| **Challenges and Roadblocks** |
| *Question # 1:* What top three challenges are commonly experienced by researchers, and what are suggested strategies to overcome these challenges? |
| *Question # 2:* What strategies can be used to overcome these challenges and roadblocks? |

Presenters for the Webinar included the following subject matter experts:

- Margaret Rukstalis, M.D., Geisinger Health System Center, University of Pennsylvania School of Medicine
- Jonathan Wald, M.D., M.P.H., Partners HealthCare System
- Alfred Bove, M.D., Ph.D., Temple University
- Silke von Esenwein, Ph.D., Emory University

# Chapter 2. Meeting Summary

This section provides an overview of each of the presenter's materials and concludes with a recap of questions asked during the presentations.

## *Margaret Rukstalis, M.D.*

In her presentation, Dr. Rukstalis provided guidance to grantees on four main topics:

- Recruitment overview
- Traditional recruitment strategies and considerations
- Nontraditional recruitment strategies and considerations
- Top three recruitment challenges

*Recruitment overview.* Recruitment for "translational research" (translating the findings in basic research quickly and efficiently into clinical practice and, thus, meaningful health outcomes) includes recruiting for basic research, preclinical research, and clinical trials. Researchers often work synergistically with the clinical enterprise, asking clinicians to donate their time to help recruit their patients as participants. The time and effort required for effective patient recruiting may be a barrier for some clinicians involved in day-to-day patient care. Clinicians should be encouraged to be an active part of the research team and should be appropriately supported by their practice. The team should stay closely involved with the clinicians and keep them informed. For example, if recruitment letters are sent to patients, their clinicians should be notified that they may be contacted and asked questions by their patients who are being recruited as part of the research study.

*Traditional recruitment strategies and considerations.* Budget and Institutional Review Board (IRB) approval often dictates both recruiting content and venue. That is, following approval of the recruitment strategy and protocols, an IRB may specify content and venue; e.g., where posters may be displayed, where flyers may be distributed, and which radio announcements need IRB approval. Researchers must be sensitive to multiple stakeholders and take them into account when designing the research methodology. For example, the IRB may require written permission from superintendents of area school districts to send flyers home to recruit 4- to 8-year-olds for an obesity prevention study. In addition, when developing recruitment materials, researchers must be sensitive to health literacy concerns and need to ensure they are written so their target audience can understand what is required of them.

Costs also affect the approach and ability to recruit patients. An effective strategy includes leveraging the institution's public relations (PR) office to help with recruitment. The PR office typically understands costs, resources, and local communities, and understands what resonates in the targeted community. The office can promote the study using word of mouth and by talking to

radio stations on public interest topics. The PR office may also assist with writing and disseminating press releases on the study.

The least expensive strategies are often the most successful—podcasts on the institution's Web site, posters in the hospital, or recruitment notes sent home in children's backpacks (with approval). Low or no-cost recruiting in a community setting may include communications via announcements in church bulletins, brochure inserts in church and school mailings, posters and brochures in clinics, hospital tabletop cards, continuing medical education talks, and health fair booths. In rural settings, advertising is often not cost effective; however, public service radio announcements, community round table discussions, and press releases are very effective and are low-cost recruiting tools.

*Nontraditional recruitment strategies and considerations.* Newer, nontraditional recruitment methods involve information technology, including the use of electronic health records (EHRs) to create disease registries. Researchers can search registries using inclusion or exclusion criteria, letters can be sent to patients (low cost and high yield), and alerts can be sent through an EHR system to notify clinicians of specific patients with matching criteria for the research project.

The Web may also be a low-cost/high-yield recruitment tool, e.g., publishing ads on employee intranet sites, public Web sites, or National Institutes of Health Web sites, and using podcasts. Researchers can use patient portals (secure access to patients' EHRs from the Web) to contact eligible participants via secure email.

*Top three recruitment challenges.* The top three challenges for recruiting are: (1) working within a budget, (2) determining the target audience, and (3) underestimating how long the process will take.

Researchers should consider using outside help from a professional recruiter or from call centers. While it may seem expensive, these resources may be very cost effective in the long run. Researchers should maximize low-cost recruitment, be sensitive to health literacy issues in advertisements and letters, tailor media advertisements to the audience, and carefully track responses for each recruitment effort.

## *Jonathan Wald, M.D., M.P.H.*

Dr. Wald served as a co-principal investigator on a randomized controlled trial at Partners HealthCare System called Prepare for Care. In his presentation, Dr. Wald provided:

- Prepare for Care overview
- Prepare for Care - recruitment approaches and challenges
- General recruitment considerations
- Recruitment considerations during the study

*Prepare for Care overview.* The study proposed that patients and clinicians who use eJournals and the physician's electronic medical record (EMR) to share health information and communicate would have improved clinical outcomes, more complete EMR documentation, increased patient knowledge (e.g., of medications), and improved patient and physician satisfaction with care. A study invitation was sent to every patient who signed up for the Partners Healthcare System patient portal—Patient Gateway (PG). The patient completed the online consent and became eligible to fill out a pre-visit eJournal. The providers would be notified about the eJournal and would use the entries to inform and document the patient history for the visit.

The goal of the study was to recruit 5,400 consented patients and at least 2,000 per arm of the research study. All patients were required to be PG users, which was a challenge. The major recruitment effort was to get patients to sign up for PG. When the Prepare for Care study was initially funded, only 1,000 patients had signed up, which meant additional recruitment of nearly 400 patients per week was needed. It was clear that the researchers both had to push harder and might have to extend the timeline for achieving their recruitment goals—a common challenge at the beginning of many research projects. Rolling out the patient portal in 12 primary care practices also required additional time, given the need for training and practice readiness to take on an additional IT project.

*Prepare for Care—recruitment approaches and challenges.* Marketing and outreach to patients was practice-dependent, i.e., dependent on how a practice offered PG to its patients. Marketing efforts varied at each practice. The research team was not resourced to be responsible for the ongoing rollout and use of PG itself, which was separate from the study. Posters, postcards, and dialogue with physicians and staff were used effectively to roll out Patient Gateway. After patients were signed up for PG, they were invited to the study.

Once patients signed up for PG, they received a notice alerting them about the study. The notice was brief but was designed to provide enough detail to educate those considering enrollment in the study. A link in the notice accessed a separate window that opened to the research home page. Patients could learn more about the study on this page and could also complete the consent form. The IRB approved the online consent form because it was located inside a secure portal. A specific workflow was set up inside the portal for patients to follow if they joined the study.

Once the consent form was completed, individuals were given the link for the study survey. If the individual chose to consent but did not take the study survey, he or she was not offered the eJournal. As an incentive, participants could also specify a charity of their choice, and the research team would make a small donation via the charity's Web site as an alternative to a direct incentive, for their participation in the study.

Eligible patients were required to be members of a participating practice: patients signed up for PG, signed a consent form, completed the survey, and had an eligible visit. Dr. Wald noted that quite a bit of drop-off in participation occurred during the study. Participating physicians were required to stay with the practice for the length of the study, in order for a patient's

participation to be valid. In addition, not all physicians received eJournal submissions from their patients, and so only a subset of the physicians could be used for some parts of the analysis.

There were 20,000 enrolled patients in PG who were invited to participate in the study; of these, 4,000 consented to participate (20-percent consent rate). Because the researchers did not have many other similar studies for comparison, it is unknown whether this is a typical response rate for online recruiting via a patient portal. Half of those who consented (2,000 patients), or 10 percent of PG enrollees, were invited to start an eJournal. Three-fourths of those invited to open an eJournal (1,500 patients), did so, and 7 percent overall (1360 patients), submitted the eJournal.

One recruitment barrier confronted when using this method—recruiting through a patient portal such as PG—is nonparticipation even after signing up. In this case, more than one-third of patients who signed up for the portal did not use it. Similarly, not all participating providers actually received an eJournal from their patients, resulting in a smaller number of providers who experienced the intervention.

*General recruitment considerations.* Dr. Wald noted several issues to consider during every phase of a research study. At pre-intervention, researchers need a detailed walk-through of the recruitment and consent process to estimate the ability to achieve study targets and anticipate drop-offs. Recruitment should begin as early as possible in the study, and extension of the trial should be considered to realize recruitment targets.

*Recruitment considerations during the study.* Care must be taken to keep practice staff and patients engaged. If recruitment is done in a practice setting, it is best to get *all* physicians involved in the study; otherwise, the staff may need to use different workflows for participating and nonparticipating physicians and patients. It is recommended to engage the entire clinic at one time.

It is important for researchers to know whether they are dealing with technology-oriented patients or not. Small incentives may help retain study participants. Carefully consider the intensity of exposure of patients and providers to the study intervention (dose-response). Finally, it is often very useful to engage a statistician in the study

## *Alfred Bove, M.D., Ph.D.*

Dr. Bove reviewed his research project, which uses an Internet communication tool in a large cardiology study. In the study, patients log on to a secure study site, enter their health information, and direct questions to their providers. In return, practitioners provide feedback through the same secure site. Dr. Bove's current AHRQ grant uses this tool to manage hypertension for patients in inner-city and underserved populations. In addition, a cellular telephone-enabled tool is used, which has been demonstrated to be more effective with this patient population.

Dr. Bove identified five challenges that should be considered in health IT studies:

- The digital divide
- Medical divide (health literacy)
- Medical status
- Communication and advertising
- Financial reward

*The digital divide.* Approximately half of the people in underserved communities have computers in their homes. There are options to overcome this challenge. For example, computers located at community centers and libraries can also work well for studies because users can log off and not be tracked. Computers can be purchased for a church or community center, and an Internet service provider (ISP) engaged for the duration of the study. Patients can enter their data in a journal at home and then enter this data on a computer, when possible.

Dr. Bove's study is also now using cellular telephones, which use an interactive voice response system and the same user interface as the computer. Thirty to 40 percent of the study participants are using cellular telephones. The study database calls the patients and reminds them to send in their data. The tool also asks the patient for his or her blood pressure and/or blood sugar.

*Medical divide (health literacy).* Dr. Bove noted the need for health education, especially for patients with heart failure, hypertension, type II diabetes, and hyperlipidemia. Patient recruiting is often done through radio stations, local newspapers, and clinics at institutions. The recruiting includes educating patients about the importance of the need to monitor their health and the need for them to provide data regularly. Patients also receive information about the study's goals to help them understand its purpose and impact.

*Medical status.* A patient's health status can also present recruiting challenges. It is easier to recruit patients when they have an obvious health problem such as heart failure. Recruiting for diseases such as hypertension is often more difficult because patients may be asymptomatic and do not always understand that this type of illness needs to be monitored.

*Communication and advertising.* Recruiting for disease-specific studies may involve the use of local newspapers, radio ads, health center and clinic bulletin boards, and health fairs. Brochures about the study can be used to explain the study and the importance of care. For studies where provider engagement is important, the research team can meet with the staff and providers to educate them about the value of the study. The research staff may conduct a chart review to determine eligibility, but the patient's personal provider should recommend participation directly to the patient.

*Financial reward.* In the urban environment where Dr. Bove conducts his study, patients frequently need to travel on public transportation, hire babysitters, or use their cellular telephones to participate in the study. Financial awards are offered for some studies but typically

require IRB approval. These awards should be offered to cover usual expenses. Incentives should be carefully structured so they are not coercive or considered an enticement or payment for risk.

Dr. Bove noted that researchers should ensure that the IRB has a very clear understanding of their study, so that recruitment hurdles are minimal.

## *Silke von Esenwein, Ph.D.*

Dr. von Esenwein is involved with an AHRQ study that includes a randomized trial of patient health record (PHR) use versus usual care for patients with one or more chronic conditions. The study is being performed among an underserved population. In his presentation, Dr. von Esenwein provided guidance about:

- Recruitment strategies and considerations
- Retention strategies

*Recruitment strategies and considerations.* Dr. von Esenwein identified several different recruitment strategies to consider when beginning the research project. One recruitment strategy is finding participants from previously completed research studies because they are often willing to participate. Another approach is the use of focus groups to get to know the target audience. The recruitment and study materials are reviewed by the focus group and then revised based on feedback from the group. Other effective recruitment methods include clinician referrals, flyers, and word of mouth. Flyers are not generally productive, but word of mouth can be very effective.

Understanding the study audience is critical. Materials should be written using language on a fourth- or fifth-grade reading level and legal jargon should be avoided in recruitment materials. Using the term "project" instead of "study" is often more effective, because the term "study" may be perceived as negative.

It is important to state a benefit for the participants in recruitment efforts. Often, simply knowing that they, as participants, can help others by participating in the study is important enough, even if they do not receive a direct benefit by being in the control group. It is also very important to find good recruiters who can relate to patients and who patients can trust. Researchers should be cautious of hiring recent college graduates as recruiters because they are often less experienced in communicating with some target populations. Dr. von Esenwein has had good success using unemployed social workers as recruiters because of their natural communication and interpersonal skills.

*Retention strategies.* Initially, the retention rate in Dr. von Esenwein's study was only 60 percent; however, use of some specific strategies increased the retention rate to 80 percent. Financial incentives were increased for those who continued their participation in the study. Contact information was routinely updated so that researchers did not lose track of participants. For example, birthday cards were sent to study participants, using envelopes with an address

correction request. Careful thought should be given to determining barriers to continued participation in the study. Dr. von Esenwein realized that some participants could not and/or did not want to use a computer. To overcome this barrier, the research team offered a computer training course to these participants.

It is important to increase clinician engagement for recruitment. Effective approaches for engagement include hosting "lunch and learn" sessions, providing clinicians with low-cost promotional materials (e.g., pens, or notepads), and providing feedback to clinicians on their referrals and on the study.

# Chapter 3. Questions and Answers

A question was received from a grantee regarding recruitment issues encountered in a current AHRQ project. In this project, the research team is building: (1) a health IT system to provide parents of pediatric cancer survivors with information about their child's future health and (2) a storage system for health care planning and health maintenance via a personal health record. To pilot this system, the research team plans to recruit a random sample of parents of childhood cancer survivors throughout a State. Subjects are the parents of children who are more than 2 years post cancer treatment, were identified through State cancer registry, and who come from all socioeconomic levels.

The recruitment strategy includes contacting parents by mail. A recruitment letter will be sent from their treating institution asking them to participate in this project. The recruitment mailing will also include an introduction to the project, an invitation to participate, and a consent form informing parents that they will be asked to complete a baseline and follow-up surveys.

*Question. What is the best strategy for first contact of parents to maximize recruitment? We want them to agree to participate in this project by going to the Web site, registering, and completing a questionnaire either online or on paper. If we do not receive a response from the first contact, what is the best method of follow-up—use of email, social media, or text messages?*

It was suggested that a letter be sent directly from the potential participant's provider and not from the physician in the oncology group where the patient received treatment. It may be effective to include an envelope or email address for the potential participant to contact the study team to volunteer for the study. If there is no response, a call center member can reach out to make a personal connection, explain the study, and invite the participant to join the study. The goal is to make the process as effortless as possible for the participants.

It was noted that, in general, it is very important that potential participants, whether they are patients or parents, understand who is reaching out to them and why. They need an easy way to validate that the recruitment is for a legitimate purpose and that it is designed to help them. There is much concern among the public about how their health information is being stored, shared, and used. It was recommended that the grantee leverage coworkers to review recruitment materials to ensure the correct tone is used and that the message is clear for the target population prior to sending anything out.