

Recruitment Best Practices Guide

A Guide to Optimizing Recruitment and Data Collection in Multi-Site Studies

Produced for

The HMO Research Network

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1.0 INTRODUCTION

This guide is intended to assist researchers with the design and implementation of multi-site studies involving participants from the HMO Research Network (HMORN). Based on discussions with multiple representatives from the HMORN member sites, the Coordinated Clinical Studies Network (CCSN) has identified various strategies to optimize recruitment and data collection in a multi-site environment, using various modalities, including mail, telephone and web. Where possible, the strategies presented in this guide are based on past experiences of HMORN members, survey research literature, or both.

About this guide...

The *Overview of Recruitment Approaches* gives a general description of various recruitment methods, including mail, telephone, in-person, web, community outreach, and mixed mode approaches. Strategies for optimizing each approach are provided. The introduction to this section includes a list of considerations when conducting multi-site research. Additional details and considerations for multi-site recruitment within the HMORN are included in the discussion of each mode listed above. A comprehensive table comparing common approaches to data collection concludes this section.

Procedures for Enhancing Response Rates and Retention begins with a discussion of participant incentives, including special considerations for incentive use within the HMORN. Considerations by mode and sub-population are also provided. Other strategies for enhancing initial participation are listed by mode, and this section concludes with a list of innovations and procedures to enhance retention in longitudinal studies.

Considerations for Special Populations describes challenges to take into account when recruiting from certain groups. At this time, we have included information about depressed populations, the elderly, minorities, children, and clinicians. Additional groups will be added over time. For each group, we have provided a list of potential barriers to recruitment, as well as recommendations and possible solutions.

Success Stories is a catalogue of information about various HMORN studies that were notably successful in recruiting and retaining participants, often in adverse or challenging situations. Whenever possible, we have included relevant study publications and contact information for study staff.

The *Appendix* provides detailed reference information, “must reads,” and examples of actual study materials used by various sites within the HMORN.

To contribute comments or ideas for this guide, e-mail boudreau.d@ghc.org

Why should such a guide exist?

As researchers from centers based in healthcare delivery systems, we have unique opportunities, privileges and obligations where our enrolled populations are concerned. Opportunities are presented by the size and diversity of our populations, facilitating study of numerous conditions and intervention strategies, all designed to improve health. We are privileged to have the ability to research this population, and our members are often pleased to know that their health “insurer” is also finding ways to deliver better care.

But with these opportunities, there are also heightened precautions and considerations. These populations, and especially certain subgroups, get “hit up” for new research projects quite often. Missteps in the research process can create ill feelings not only about the research project, but the health plan itself. Thus, we’re obliged to conduct research that is attuned to the unique relationship we have with the population.

Additionally, since the HMORN has done so much multi-site research, we’ve learned some tips and approaches along the way that will make our projects more efficient and effective. We hope that by capturing these “lessons learned,” we will help each other, avoid reinventing the wheel, and utilize strategies that have been successful in previous studies. We are particularly interested in connecting our HMO research community to strategies that are cost-effective and replicable, yet also adaptable to different sites or populations. Finally, we also want to share innovations and build on our collective knowledge base. To contribute comments or ideas for this guide, e-mail boudreau.d@ghc.org

An important note about IRB approval

Users of this guide should keep in mind that a fundamental step in the multi-site research process is obtaining institutional review board (IRB) approval. While the experiential strategies and success stories presented here were approved by respective sites’ IRBs, it may not always be the case that the same proposed recruitment or data collection strategy that was approved two years ago would be approved today. Research is a dynamic process, and nuances of different studies, or different IRBs mean that the research approval process is likely to continue evolving. To aid HMORN researchers with efficiencies in obtaining research review and approval, users of this guide are also urged to consider information about navigating IRB and other research review at various HMORN sites.

2.0 OVERVIEW OF RECRUITMENT APPROACHES

Introduction

This section offers a general orientation to various recruitment modalities, which may be used alone or in combination. With all of these approaches, collaborators in multi-site projects should carefully walk through all recruitment procedures to ensure that they can be implemented consistently across sites.

General considerations for multi-site studies

- Do recruitment materials and procedures need to be identical at all sites?
 - In some cases, consistency may be balanced against other study needs, such as accrual, in which case different sites might use different, locally-proven strategies to meet recruitment goals.
 - An upfront conversation about whether to allow variation in the recruitment protocol will help the study team anticipate local needs.
 - Ensure all site needs are addressed. Make sure every site has an opportunity to contribute to development and review of materials – having each site’s local nuances and preferred word choices is very important, even if this may mean minor variations in materials across sites.
 - Identify resources and procedures that differ from site to site. Can all sites recruit for the study in the same way? Do all sites access relevant data from EMRs? Do all sites have member newsletters? Do physicians need to be contacted before recruiting patients on their panel? Do some sites have required procedures or language for invite letters or consent scripts? Which sites have a Survey Department for data collection? Which sites face special restrictions on research due to state laws?
 - Sites may have different requirements for who signs any invite letters.
 - Sites vary in how they describe research studies and research participants – e.g., patient, individual, study subject, etc.
- Should recruitment and data collection activities be centralized? The local capabilities of participating sites (e.g., does the site have a Survey Research Unit?) will factor into this discussion. See the Table of Potential Advantages and Disadvantages of Centralized Mail Recruitment in the appendix for an overview of the tradeoffs involved.

2.1 RECRUITMENT BY MAIL

Introduction

Mail-based recruitment is used in many studies, even those that go on to collect data through other means. It can be a strategy for informing or contacting people about a study and can also include a data collection element. Mail recruitment can be an effective strategy when cost is an issue and when there is adequate time for follow up mailings and telephone contacts to maximize response rate.

Examples of situations that are well suited for mail recruitment include:

- Implementing a simple, short survey to be completed and returned.
- Inviting individuals to visit a web site for an Internet-based study.
- Informing people they have been selected to participate in a telephone interview and will soon receive a phone call.
- Screening large numbers of people for response to an invitation for which eligibility may be low (asking parents about firearm ownership and storage, or inviting people to participate in a 2 hour discussion about an abstract health issue, for example).

Components of an effective mail-based recruitment approach

- A compelling invitation letter.
- A cash incentive of appropriate amount considering the length of the questionnaire and the burden of responding. The amount could be as little as \$1 or \$2, or you might consider a \$10 or \$20 if the survey is long or the topic of low salience to those who are invited to respond. However, check individual sites for caveats or guidelines in regard to using cash incentives.
- If materials are to be mailed back, include a postage-paid / business reply envelope.
- Clear step-by-step directions about what the recipient is asked to do (return a questionnaire, visit a web site, etc.)

Planning mailing logistics

Conducting mailed recruitment in a multi-site study requires coordination around issues like data transfers, timing, and quality assurance.

- For mail recruitment, consider a post-card reminder or other second mailing to people who have not responded to the initial invitation.
- For telephone follow up, budget enough time to allow the letter to arrive before phone calling begins – often 1 week. Send a test letter to a study staff member so that you have an idea when letters arrive in consumer/ customer/ patient mailboxes.
- Do not assume the respondent has read the letter thoroughly if following up by phone.
- There are pros and cons of centralizing mail-based recruitment. Since its inception in 1999, the CRN has undertaken several mailed surveys typically involving at least five data collections sites. Summary the Table of Potential Advantages and Disadvantages of Centralized Mail Recruitment, in the appendix, was prepared to harness the collective learnings from those who have been involved in these multi-site efforts. This table includes experiences gleaned from a 10-site survey of nearly 50,000 enrollees.

About invitation letters...

Overwhelmingly, sending an invitation letter to a prospective respondent is the first step in most studies in the HMORN, due to its well-defined population base. Letters are a non-intrusive means of introducing a potential participant to a research study. Many IRBs require, or at least strongly recommend, that invitation letters be sent in advance of further contact with a potential participant, making sure to allow adequate time for recipients to actively decline to participate.

Sending an initial invitation letter has a number of advantages:

- The ability to target a population.
- The opportunity to apprise study participants of study details and alert them to additional future contacts.
- The non-intrusive nature of the contact.

Numerous studies have been conducted on the impact of invitation letters. In general, methodologists conclude that advance letters are both cost-effective and increase response rates (Hembroff, et.al., 2005) Especially in studies that indicate a purpose of benefiting a valued group (e.g., the immunization of children), letters increased cooperation and decreased refusals in comparison to less explicit or no letters (Camburn et.al.,1996).

Essential components of an invitation letter

- Personalization
- Purpose of the study, including why it is useful
- Sponsor of the study
- Collaborators
- Description of participation, including duration
- Description of incentives (if any)
- Voluntary and confidential nature of the research
- Indication of how the individual's data will be used
- Notification that decision about participation won't impact health care or benefits
- Contact information for a study team member and IRB administrator (could be in a footer)
- Description of opt-out procedures
- A thank you, sometimes including a token of appreciation/incentive
- Signature of the local principal investigator
- For more ideas Dillman, 2002, in the references section.

Sample invitation letters

Sample invitation letters used in HMORN studies are included in the appendix.

Strategies for optimizing invitation letters

A major challenge in using advance letters (examples in the appendix) is in the careful consideration of the amount and the way that information is presented about the study. Respondents may get enough information to intentionally avoid eligibility for a full interview or recruitment by answering questions inaccurately. Alternatively, if the information presented is not compelling enough, they may refuse to consider participation.

Below is a list of considerations and strategies for enhancing the appearance and usability of invitation letters:

- Keep it short and informative. Consider using a study information sheet or flyer instead of putting all information in the text of the letter.
- Develop a "hook" that makes your recipient want to learn more about the study. Consider incorporating a question, e.g., "Over 10 million people will try to quit smoking this year. Would you like to be one of these people?"
- Consider following the **3-30-3** rule: people make snap decisions when they observe something--so the theory goes that they will look at a letter (or web page) for 3 seconds before deciding whether it is worth reviewing further. If you use your three seconds well, readers will move on to the next level of decision-making, and grant you 30 more seconds. In that time they will decide whether or not your message deserves more calculated consideration. If they were persuaded, they'll take 3 minutes to ruminate about whether to take part.
- ? Graphical logos, clever study names or acronyms can make a project more memorable. See table below for examples of creative study names used by HMORN member sites.

| Actual Study Name | Memorable and Meaningful Study Name for Participants |
|--|--|
| Multi-site Assessment of Colon Polyp Risk Factors | The REACH Study: REsearch And Colon Health |
| Understanding Patient, Provider and Organizational Factors Affecting Adherence to Tobacco Cessation Guidelines | HMOs Investigating Tobacco (HIT Study) |
| Making Effective Nutritional Choices for Cancer Prevention | MENU |
| Actions to Control Cardiovascular Risk in Diabetes | ACCORD |

- Bullets can help break up long paragraphs, and are especially useful when describing eligibility criteria in printed study materials.
- Keep it easy to read. Write invitation letters targeted at a 6th to 8th grade reading level. See appendix for a readability information sheet. Use a grammar-checking tool like that in Microsoft® Word that can provide a Flesch-Kincaid grade level and other readability statistics.
- Use easy to read fonts such as Arial and Times Roman. Make sure the font is large enough, particularly if targeting an older population. Use white space; crowding content onto a single page can be overwhelming to participants.

Special considerations for invitation letters within the HMORN

- Certain sites require providers be notified before contacting patients for participation in research.
- Sites vary in how they describe research studies and research participants – e.g., patient, individual, study subject, etc.
- Sites may have different requirements on who signs invite letter.
- The existing relationship between a health care provider (or HMO) and its patients may increase the likelihood the letter will be opened and read. If sending materials to participants, use the HMO's envelopes and stationery. As demonstrated by focus group data from one HMORN site, recipients may be more likely to open letters that arrive in the HMO's envelope.

2.3 TELEPHONE RECRUITMENT

Introduction

Telephone calls to recruit prospective participants are typically more successful but also more expensive than a mail recruitment strategy. Often, an introductory letter precedes a phone contact. In general, it is most appropriate to contact individuals at home first, rather than at work. An example script is included in the appendix.

Essential components of a telephone recruitment script

- The caller's name and the organization represented (e.g., "Hello, this is Wilma, from/calling for Kaiser Permanente...")
- Confirmation that you are speaking with the designated respondent
- Description of the research study or program, including the sponsor and topic
- Assurance that participation is voluntary and respondent can withdraw at any time
- Assurance that the information will be kept confidential and (if appropriate) will not be recorded in their medical record
- Assurance that the decision of whether to participate will not affect their relationship with their health care provider in any way
- Obligation of time or expected activity
- If recruitment is combined with oral consent, description of risks and benefits
- If recruiting participant is to visit a study site, directions, or confirmation of address to which to mail additional directions and information

What are the pros and cons?

| <u>Advantages</u> | <u>Challenges</u> |
|---|--|
| <ul style="list-style-type: none">• The opportunity to develop immediate rapport with a respondent (Couper and Groves, 2002).• An engaging and engaged telephone recruiter/interviewer can help yield high cooperation rates.*• Participant questions can be answered immediately.• If the project includes collecting data (e.g., eligibility or baseline questions), that step can sometimes proceed immediately in the context of the recruitment call, minimizing loss to follow-up. | <ul style="list-style-type: none">• Voicemail, answering machines, and caller ID are potential impediments.• If an interviewer states that they're calling on behalf of a health plan, the respondent may assume that the call pertains to a bill or medical issue.• The artful use of answering machine messages and careful scripting can mitigate many of these barriers. Leaving messages on answering machines can improve response rates in studies where there is salience of topic and sponsor to the respondent, and this is quite often the case of studies conducted in the health care setting (Link, et.al., 2000). See the sample protocol for leaving phone messages in the appendix. |

*An Interviewer Training Guide is under development and will be available in September 2006.

Special considerations for telephone recruitment within the HMORN

In the HMO setting, we are fortunate to have access to automated membership data that can often be the source for obtaining the telephone numbers for potential respondents. Some HMOs have multiple telephone numbers for members, which can be useful if it is necessary to trace a respondent. However, some HMOs may have policies about the release of telephone numbers other than a “primary” phone number in the membership record.

It is important to bear in mind that researchers within an HMO are serving a dual role, both as representatives of the research project *and* as representatives of the health plan. In every interaction with study participants, consider how study procedures and protocols reflect upon the institution.

Remember that the HMORN covers 5 time zones, which significantly impacts the coordination of recruitment phone calls. Some HMORN sites have survey programs. They have the capacity to conduct interviews for multiple sites across varying time zones.

2.4 IN-PERSON / IN CLINIC RECRUITMENT

About in-person recruitment

There are many occasions in which an in-person intercept is a suitable recruitment strategy. This is particularly true if a project has a clinical or laboratory component. Often, a clinic visit with a study team member may be coordinated with a scheduled health care visit.

A variation in this recruitment approach would be to enlist the provider to recruit participants. This could be done by having the provider hand out a flyer or recruitment packet, or to “write a prescription” for a patient to take part in a suitable research study.

What are the pros and cons?

| Advantages | Challenges |
|---|--|
| <ul style="list-style-type: none">• The ability to rapidly establish rapport with study participants and immediately defuse concerns or questions about research or their data.• Multiple types of data can be collected during a single intercept, creating efficiencies.• If respondents were asked to complete a survey prior to a clinic visit, the study team member can review the questionnaire data on the spot and clarify any problems such as missing or inaccurate information.• If clinicians are involved in recruitment, such as a patient’s primary care physician, this lends enormous credibility to the research and can enhance cooperation. | <ul style="list-style-type: none">• The potentially higher cost of sending staff to clinics to intercept only one or a few patients at a time.• It may be somewhat more challenging to standardize in-person recruitment given staffing variations across HMOs, and the extent to which all HMOs have a stand-alone research clinic.• Training personnel on the recruitment protocol could also be time consuming and costly if trainers or trainees have to travel to a particular location to learn how to execute the study protocol. |

Special considerations when conducting clinic-based research studies within the HMORN

- Each of our research centers has a different relationship with its affiliated health care system. Clinicians in the health care system may conduct research regularly with the research center, with other researchers, or not at all.
- Some sites have research clinics, thus increasing the capacity for clinical research encounters.
- Identify a clinic-based Principal Investigator or Local Champion as early as possible. The Local Champion may be the clinic's Medical Director or an individual with a strong interest in the research topic. Meet with the Principal Investigator or Local Champion to discuss the research question(s) and study objectives and insure early buy-in.
- Identify other nursing, administration, and administrative personnel who would be key to the conduct of the study. Meet with these individuals to discuss the research question(s) and study objectives. Insure that all clinic personnel are on board throughout the study design.
- Identify current clinic roles, policies, procedures, and processes. Evaluate the roles, policies, procedures, and processes that would be impacted by the study. Using a participatory approach, elicit input from the clinic staff on solutions to potential conflicts with clinic processes and subsequent disruptions of flow.
- Conduct a tour of the physical facility to determine space limitations. Plan how to utilize existing space to meet the requirements of the study. Be cognizant of HIPAA considerations if actively performing informed consent and enrolling study participants in the clinic.
- Conduct a brief training of all clinic personnel to enable understanding of the study and its objectives. Transfer a positive attitude about research and the specific study to the clinic staff. Clarify clinic roles and responsibilities during the research study versus research staff roles and responsibilities during the research study.
- Pilot the process and elicit input from the clinic staff. Revise processes as necessary.
- Monitor the conduct of the study periodically for adherence to study protocol.
- Provide periodic feedback to the clinic staff during study period and after results are available.
- Provide reminder calls for all appointments and key study points (mailing a diary back, etc); an appointment reminder call should include the: day, date and time of the appt; where it is; who is expected; what to bring; long it is expected to take; a number to call if there are questions or a need to reschedule.
- Encourage questions and phone calls; one study number plus toll-free; pager for after hours questions/issues (very few people use it but it's a great reassurance).
- Minimize the number and length of visits; are there procedures that can be eliminated? What can be done pre-appointment, like reading the consent form, completing a medical history and medication sheet at home and bringing it into visit?

Special considerations when conducting clinic-based research studies within the HMORN continued..

- Arrange for clinic visits that are in as highly an accessible location as possible, with easy parking.
- Post the key study documents (consent; driving and parking instructions, visit instruction sheet) on a web site for easy access in addition to mailing out the items.
- Staff needs to be well prepared and well versed in the study procedures and have ready answers to as many anticipated questions as possible. If the staff is not confident or knowledgeable, the person is not going to be comfortable with enrolling in the study. Encourage all questions beyond the scope of the recruiter to an “expert” or “I will ask X, our study nurse” or “ I will ask Dr. X, our investigator and get back to you”.

2.5 WEB-BASED APPROACHES

Introduction

The web or Internet can be an effective recruitment approach for some populations. This technology has only recently been applied to research settings, primarily for enrollment or on-line interventions, so the impact and efficacy of this mode is still evolving. There are a number of permutations of the use of new technologies for recruitment:

- Use email to invite individuals to participate in a study
- Post a recruitment ad on a web site
- Outreach through Internet chat rooms or “blogs” to inform people about a study
- Use interactive voice recognition software to allow potential participants to call in and enter eligibility data, report outcomes, etc.

The reach of the web is broad, and posting information on the web is often a low-cost endeavor, but control over digital information is more difficult than print-based information. So-called ‘best practices’ for the use of technology in recruitment have not yet been established; so at this juncture, use of these modalities warrants careful consideration. Take into account the following challenges when designing web-based recruitment strategies:

- Email is typically considered a non-secure means of transferring information.
- Acquiring email addresses for populations in our health plans is generally not possible for recruitment purposes (although once participants enroll in studies, email can be an efficient way to remind them to complete study tasks). It is possible to acquire large samples of email addresses to conduct general population research, but these lists are somewhat biased, since members self-select to be a part of a list sample.
- Given the novel nature of these approaches, IRBs are still becoming acquainted with the risks and benefits they entail.
- Computer literacy is highly variable, and disparities in Internet access are not uncommon in some populations.
- Keep web-based recruitment interfaces easy to read. Use a large enough font and don’t crowd too much content onto a page. If it’s necessary to use long screens, include arrows, “top” links and other navigational icons liberally.

Experience within the HMORN

Recent HMORN studies including MENU and the Center for Health Communications Research projects, “Project Quit” and “Guide to Decide,” will be helpful for illuminating the challenges of this approach. Each of these projects has entailed collaboration with an experienced web design and development team to develop the web-based interventions. Recruitment was accomplished via introductory letters (and newsletters and ads for Project Quit) that encouraged potential participants to visit the web for eligibility questions, baseline questionnaire administration, and the intervention.

For multi-site studies, the Internet may be a great way to centralize data collection or administration of an intervention (such as a behavioral intervention). But the time and cost of designing and testing warrant careful consideration and consultation with the intrepid HMORN researchers who have already ventured down this path.

2.6 MEDIA AND COMMUNITY OUTREACH

Introduction

There are a number of outreach strategies that can be used alone or in combination with other recruitment modalities. These strategies may be particularly useful for studies with a community component (i.e., not limited to health plan members). It is most cost-effective to use a media outlet that is likely to reach the desired demographic for the study. Thus, studies of adolescents might utilize weekly “alternative” newspapers that are common in most big cities. Studies targeting older adults might consider posting flyers in libraries or local senior centers. General population recruitment can be boosted by using signs on mass transit. When trying to target a certain health condition, placing notifications in medical centers may be appropriate.

A partial list of advertising outlets

- Daily newspapers
- Weekly newspapers / magazines
- Local alternative press
- Radio
- Television
- Bus/transit ads
- Flyers in clinics, libraries and other public spaces
- Notices on web sites, such as the health plan’s or research center’s public web page

Essential components of an advertisement

- A hook that makes people want to learn more about the study and appeals to the population being sought
- One or two key eligibility criteria
- Incentive, if applicable
- A person to contact if interested along with contact information

Media and Community Outreach

What are the pros and cons?

| Advantages | Challenges |
|--|---|
| <ul style="list-style-type: none">• Outreach strategies can give wide exposure about a study, and thus can be a very cost-effective means to recruit participants.• If recruiting a sensitive population, such as persons with HIV or victims of domestic partner violence, for example, this anonymous strategy enables prospective participants to self-identify, rather than being identified through mass mailings, or obtaining IRB approval to review highly confidential data. | <ul style="list-style-type: none">• Some advertisements can be expensive.• One-time or limited exposure ads means that there may be an initial “spike” in enrollment, but accrual over a longer duration may dissipate.• The concise nature of advertising may limit a project’s ability to include extensive detail about the data collection or eligibility criteria.• The resulting sample may be subject to criticism for self-selection bias and a lack of accurate representation. |

2.7 MIXED MODES OF RECRUITMENT

Multiple modes are often employed to recruit participants. A recent multi-site study targeting people for a smoking cessation study utilized letters, 2nd mailings consisting of greeting card-sized invitations, referrals from friends and family members, stories in health plan news magazines, and web site advertisements (see appendix). Budgetary constraints, reach of various recruitment modes, relative importance of standardizing approaches across multiple sites, and minimization of selection bias are important considerations when planning recruitment.

Although one may consider multiple and mixed modes for recruiting subjects, it is recommended that careful consideration be given to more than one mode of survey research for information/data collection, especially for evaluative (not fact or experience-based) research. One HMO mailed a survey to patients, calling those who did not respond to the mail survey to answer the questions by telephone. While the demographic characteristics of the respondents were consistent across modes, responses to survey items were significantly different with no apparent theoretical reason to explain why. Mixing modes for collecting data, then, could impact the quality of your data and confound your analysis.

Additional strategies for optimizing recruitment in multi-site studies are provided in the *Procedures for Enhancing Response Rates and Retention* section. Lessons learned from previous studies and real-world examples of how other sites/projects have overcome barriers to recruitment are provided in the *Success Stories* section. Also see Spilker and Cramer, 1992.

2.8 COMPARISON OF COMMON APPROACHES TO DATA COLLECTION

Every approach to data collection and recruitment has assorted tradeoffs. Cost, level of effort, topic of the research, and respondent characteristics all play into the determination of the best strategy(ies) to reach a population. The table below enumerates and compares strategies.

| | MAIL SURVEYS | TELEPHONE INTERVIEWS | IN-PERSON INTERVIEWS |
|--------------------------------|--|--|---|
| Cost | Can be less expensive, but multiple mailings and incentives can rapidly increase the costs. | Moderately expensive, quite efficient, most successful with only modest incentive. | Most expensive because it often requires phone contact to set interview time, requires travel for participant or interviewer, & often coupled w/ significant incentive. |
| Effort | Response rates are better if respondents are motivated about the topic, there are multiple mailings – a reminder & 2 nd surveys to non-responders, the survey is short and simple, and pre-incentive is included w/the initial mailing. | Callbacks typically required, but high response rates are often achieved in healthcare setting. Most effective for populations who are at home a lot (additional effort often needed for young adults). | Callbacks often needed to schedule interview. Participants are sometimes reluctant to allow an interviewer into their home or to travel a distance to an interview location. Missed interviews often add expense. |
| Time | Need to allow minimum of 8-10 weeks for multiple mailings. | Can resolve majority of cases in 4-6 week window. Over half should be resolved within one week of being released for calling (after invitation letter sent). Use of CATI software eliminates data entry after interview is complete. | Significant time needed to complete interviews with a large sample of participants. |
| Literacy | Must be written to the literacy and understanding of your study population. | Allows interviewer to provide clarification if participant does not understand the question or requirements. | Visual aids are possible: pictures, show-cards with responses printed on them for respondents to hold. Interviewer can hear AND see if respondent does not seem to understand and offer clarification |
| Anonymity | Most anonymous, but integrity of responses to sensitive questions is debatable since they are recording answers in writing. | Quite anonymous, integrity of sensitive questions is debatable and dependent on topic and context of question in survey. | Least amount of anonymity, but the interviewer can assess both verbal and non-verbal responses to topics. |
| Complexity of questions | Respondents can access records to provide accurate fact-based answers, but questionnaire must be short and without complex skip patterns or contingency questions | Less convenient to access records. Little ability to provide visual aids. Using CATI, easy to ask complex questionnaires with many contingency questions. | During in-home visits, respondents can access records to provide accurate fact-based answers. If using CAPI, complex questionnaires and skip patterns can be handled easily. Consider implications of using a computer (power source, intimidation, etc.) |
| Length of interview | Shorter for highest response rates; longer must be accompanied by incentive, preferably sent with the questionnaire, not promised. | Recommended under 30 minutes. Over 20 often requires high topic salience and/or incentive. | Interview can be longer than telephone or self-administered survey, and this is often necessary if interviewing those who are currently ill. |

3.0 PROCEDURES FOR ENHANCING RESPONSE RATES AND RETENTION

3.1 PARTICIPANT INCENTIVES

Introduction

Incentives are frequently used strategies for enhancing initial response rates to data collection, and are also used to maintain participant involvement over time (i.e., retention for a longitudinal study). Incentives are intended to serve as a thank you or an attention-grabber to encourage people to take the time to read the advance materials and/or survey.

Incentives can be given upfront (known as a pre-incentive), or furnished to the participant upon completion of data collection (promised incentive). Most literature has demonstrated that pre-incentives are more effective than promised incentives (Singer, 2002). Blending both kinds of incentives can also be efficacious, for example including a token pre-incentive with an invitation letter, with the promise of a larger amount or gift at the conclusion of intermediate or final data points.

Kinds of incentives

- Cash, checks, gift cards, or other in-kind incentives (of these, cash is most effective).
- In clinical research studies or trials, the intervention or possible treatment can often serve as incentive.
- Sharing information about the study results is often important to preserving the relationship with the consumer.
- Free medical treatment or services (aside from the study intervention) is often perceived as incentive, for example nicotine patches or acupuncture.

What to consider when using incentives

The type and amount of incentive for any given study should be commensurate with the burden of participation. Researchers should avoid any incentive that could be considered coercive. A \$2 pre-incentive may be appropriate to induce response to a short paper survey or a brief telephone interview, but a study requiring a clinic visit might consider a \$20 cash or in-kind incentive (one HMO reported using gas cards) at the time of the visit or paid shortly thereafter. For longitudinal studies, consider using graduated incentives for follow-up data collection, rather than offering balloon incentive up front.

Incentives should also reflect consideration of the salience of the topic to the respondent. Someone who had a procedure (like a mammogram) or injury (perhaps lower back pain) recently may be much more interested in participating in a study or completing a survey about that subject than someone who is surveyed about general health and well-being or someone else who is frequently invited to participate in studies or complete surveys (like a diabetic or asthmatic in some HMO populations). Recruitment and/or surveys about one's recent diagnosis or a specific current condition may thus result in higher response rates because the topic is very relevant to a respondent. However, recruitments or surveys about general conditions, such as wellness studies; recruiting people to see if they develop certain conditions over time; or studies about behaviors such as smoking or drinking, or conditions such as depression, obesity, or domestic violence may require incentive to participate to achieve acceptable response rates.

What to consider when using incentives

continued

Sending a cash incentive with an advance letter, or with a survey, in the mail is a dependable strategy for increasing response rates to recruitments and surveys. However, there are a number of factors to consider when determining whether the use of pre-incentives is an efficient and cost-effective technique for each project undertaken. An incentive sent with an advance letter and/or questionnaire can produce an increase in response rates of 8% to 20%, but it also means higher up-front costs and a proportion of people who received the incentive but who never complete the survey. Savings are then realized because fewer people need to be contacted overall to reach the desired sample size and by a response rate that is higher than it would have been without the pre-incentive.

Special considerations for incentive use within the HMORN

First, different sites may have different policies or requirements about incentives. Policies may be issued by the site's IRB, or there may be administrative policies about disbursement of cash. If a multi-site study is unable to furnish the same type of incentive at all sites, differential response rates may result. The varied incentive, then, could not be ruled out as a possible driver of response bias.

Also, because we conduct research within a health care organization, we must be careful to preserve the relationship with the consumer, and we must be mindful of the culture we create when we offer incentives for participation in studies. At some sites, some conditions are frequently studied, and we need to avoid creating the impression that incentives are compensation for time by specifying that they are intended to serve as a thank you. Promised incentives are often less effective than pre-incentives at increasing response rates significantly, but they may be effective to preserve our relationship both as a research organization and as a healthcare organization with our consumers. In addition, since promised incentives are only issued after data collection is completed, they offer the cost savings of being sent only to those who have fulfilled the desired task.

For ultimate effect of incentives by mode

- Mail – Incentives should be sent with the survey when a consumer or household is first contacted to complete a mailed survey
- Telephone – Incentives should be mailed with the advance letter informing the consumer of the impending phone call
- In-person interviews and focus group participation – Some recommend that respondents be paid in cash before the interview or focus group begins. This often legitimizes the interview and may lend itself to more complete answers to questions resulting in higher data quality overall. However, because the consumer has an established relationship with the health care organization, the necessity of presenting cash at the time of the interview may be null.

Use of incentives for selected sub-populations

- Clinicians as respondents – If the burden of completing the survey or recruitment is significant, this group is most likely to see the incentive as a payment for time. Effectiveness of incentives also varies across area of practice. HMORN researchers have extensive experience surveying providers, and have published study-specific (Puleo et al, 2002) and review articles (Field et al, 2002) describing surveys with providers.
- Physician Notification If a study requires physician contact or consent to recruit among their patients, some organizations have had luck with offering informational lunches at the physician's clinics, reducing burden and increasing interest in the research.
- Controls – Incentives, especially pre-incentives, can be highly effective at improving participation among controls.
- Employees – Because of recent IRS requirements, some sites may experience challenges delivering incentives for participation to employees of the health care organization. It is imperative to work with your payroll administrators to determine what protocols should be established.

3.2 OTHER STRATEGIES FOR MAXIMIZING PARTICIPATION AND RETENTION

Get creative! The multi-site studies in the HMORN have employed myriad strategies to pique interest among potential participants and encourage participants to stay with the study through multi-year data collection efforts. The topical list below offers some approaches to enhancing participation.

Mailings

- Use a recruitment brochure instead of a study information sheet (see appendix)
- Use a newsletter style welcome letter (see appendix)
- If mailing a second study invitation or recruitment package to non-responders, consider using a dramatically different approach. For instance, after sending an invitation letter, try sending a brochure or post card for the second mailing. (see appendix)
- Use Dillman procedure and formatting for questionnaires
- For mailed surveys in which a participant mails back the completed questionnaire, consider using a stamped return envelope rather than a metered or business reply envelope. People may be less likely to want to waste a stamp

In-person/In-clinic studies (including focus groups)

- Give participants a wallet appointment card to help them remember scheduled visits
- Offer childcare
- Provide the participant with a map and clear driving directions. If possible, pay for parking or cab fare
- Consider sending interviewers to participant homes when working with elderly or disabled populations (or other populations for whom transportation is a challenge)
- Consider refreshments for diabetic or pediatric populations, especially if there is a blood draw involved
- Try to make appointments available at different times of the day

Telephone

- Use bilingual interviewers
- Consider offering phone interview as alternatives to mailed questionnaire or in-person visit
- Try to arrange for interviewer availability outside of normal business hours

Incentives

- Try gas cards
- A crisp, new \$1 or \$2 bill with an invitation letter is an effective and eye-catching way to enhance response. (see Incentives section 3.1)

Miscellaneous

- If possible, complete a pilot phase and make revisions to procedures and protocols as necessary
- Use a dedicated study contact number (including a toll-free option, if possible) and print it clearly and consistently on study materials. (NOTE: some sites require 800 numbers for opt-out)
- Prepare a list of anticipated questions and recommended responses; add to this list as new issues arise
- Go through the consent form with participants before (or as) they sign a consent form or give oral consent (see appendix). This gives an opportunity for the participant to voice misgivings and for the interviewer to allay any concerns about participation. This will also help ensure that participants fully understand what is being asked of them as the study moves forward. A slide show or video can help explain the consent process to potential participants. For some studies, consider mailing the consent form to participants ahead of time
- Ask willing participants to fill out a “study evaluation” upon completing the study. (As stated by one researcher in the HMORN whose team uses this tactic, “How can you find out what worked and what didn't if you don't ask the participants”?) (see appendix)
- Help people understand the value of research. Consider preparing information about the research center.(see appendix)
- Use a variety of data collection activities that extend beyond traditional mail or telephone surveys; i.e., internet; in-home interviews

Procedures to enhance retention

- Encourage questions and phone calls from study participants; use a dedicated study number, with a toll-free option and a pager for after-hours calls, if possible. Include this number on all materials given to the participant
- Reminder letters – Use language that reminds participants that their contribution is important and significant. Restate the purpose of the study and the expected benefits. When appropriate, report study stats (# enrolled, timeline, milestones)(see appendix)
- Reminder postcards (see appendix)
- Reminder calls one or two evenings before a scheduled in-person visit or focus group.
- Usual care or eligibility notification letters – Use an enthusiastic statement, such as, “We are excited that you are eligible to participate in the [] study.” (see appendix)
- No contact letters – Use when participants are difficult to reach (or unreachable by phone). Ask them to call an 800 number, and make sure this information stands out. Use language that reminds participants that their contribution is important and significant. Restate the purpose of the study and the expected benefits (see appendix)

Procedures to enhance retention
continued

- Newsletters – For intensive longitudinal studies, it's not uncommon to use periodic newsletters to stay in touch with participants. These can include enrollment stats, relevant research news, etc. (see appendix)
- Collect phone numbers for and ask permission to contact two people who will know how to reach the study participant.
- Send birthday or holiday cards to participants.
- Consider using graduated incentives for follow-up data collection, rather than offering a balloon incentive up front.
- Try to make appointments available at different times of the day.
- For projects where a subject's participation is vital over a period of time with 2 or more data points, consider a small incentive after each intermediate data point and a balloon incentive if all data points are completed.

4. CONSIDERATIONS FOR SPECIAL POPULATIONS

Some groups warrant unique considerations, either because of the condition under study, characteristics of the population, or the fact that the group itself is frequently targeted for research studies. This section describes some elements of recruitment or data collection that should be undertaken thoughtfully so as to preserve the best possible relationship between the participant and the research team / HMO. Many of these strategies may have wider applicability beyond the specified population.

4.1 *DEPRESSED POPULATIONS:*

Challenges and barriers to recruitment

- May require additional contact attempts to recruit and retain.
- Participants often become upset, distracted, or confused. They are also more likely to launch into lengthy narratives when responding to interview questions.
- Do not use the words “depression” or “antidepressant” in the advance letter (or other materials mailed in the recruitment package) because of the risk that someone else may open the letter.
- Increased risk of suicidality discovered during interview.

Possible solutions and recommendations

- Plan to make more contact attempts than usual. Try to reach participants at all times of day, including evenings and weekends. The worst time to call is typically early morning. Whenever possible try to get alternative phone numbers, especially a work phone.
- For participants that are extremely hard to reach by phone, consider sending a “no contact” letter reminding them about the study and encouraging them to call back. If participants call a study message line, ask that they indicate the best phone numbers and times to reach them in their message. (Note: This tactic works best for one-time contacts or for contacts that occur later in the study. If recruiting participants into a treatment program or other intervention involving multiple contacts and follow-up data collection, consider that people who are extremely hard to reach at baseline will likely be extremely hard to reach for treatment and follow-up, as well.)
- Plan for telephone and in-person interviews to take longer than usual, and train interviewing staff to be especially sensitive in their interactions with depressed participants. Provide interviewers with tools and resources (ie – Recommended Responses) to help them tactfully keep the interview moving when participants become upset, distracted, or long-winded.
- Use (or develop) specific guidelines for assessment of suicide risk.
- Develop specific action plan for suicidal subjects that is aligned with IRB requirements.

4.2 ELDERLY POPULATIONS

Challenges and barriers to recruitment

- More likely to have mental and/or physical challenges, any of which may suggest the need to consider a proxy or surrogate respondent:
 - ? Poor eyesight ? Difficulty hearing ? Otherwise seriously ill ? And/or cognitive difficulties
- May be in an institutional setting such as a skilled nursing facility where there is no private phone line.
- May cite distrust of research and/or government sponsor or answering date-of-birth questions.

Possible solutions and recommendations

- Print materials (advance letter, survey) in at least a 12 point font. Some serif (Times New Roman is frequently recommended for print material for the elderly) typefaces are more legible. Other popular sans serif (such as Arial or Verdana) typefaces are less legible. See <http://www.otol.umd.edu/uupractice/elderly/>
- Train interviewers to speak in lower vocal ranges and clearly enunciate to help those hard of hearing.
- To measure cognitive capacity, consider a brief cognitive screener such as using the memory items from the Mini Mental Status Exam (MMSE)
- If inclusion of those who are too cognitively impaired or otherwise unable to complete the interview on their own behalf is desired, consider identification of a proxy or surrogate respondent:
 - Proxy designation - Consider allowing the respondent who fails a brief cognitive screener or otherwise says that s/he cannot complete the interview to identify a proxy or surrogate (the technical term in Washington State) to complete the interview.
 - Proxy interview - Determine which items or sections in the interview can be appropriately completed (fact-based items) vs. those that cannot (feeling- or personal-experience based items). (see appendix)
- Consider “show cards” that can be sent in the advance letter for complex questions or response scales on a phone survey or recruitment. Color-code the set so the interviewer can refer to the color of the card as well as the header to aid the respondent in identification.
- Determine whether a person in a skilled nursing facility on a permanent basis may be ineligible for the study.
- If respondent feels s/he is “too old,” indicate that it is important to collect information from people of all ages.
- Daytime calls are often preferable to evening calls when an elderly person may be more suspicious of a stranger calling.
- Be ready to offer to do the interview in segments over successive times to avert refusals based on a long interview.

4.3 MINORITY POPULATIONS

Challenges and barriers to recruitment

- May cite distrust of research and the medical establishment and a fear of large institutional settings
- In general, minorities lag behind the general population with regards to Internet access, potentially biasing those studies involving the use of the Internet
- May not immediately disclose barriers such as transportation, parking, meals, children or elders requiring care while they are visiting the clinic
- Recruitment and instructional materials may contain inappropriate language or be at an inappropriate literacy level
- Staff may not be culturally diverse and may lack cultural sensitivity
- May be particularly concerned about interference with primary care or with continuity of care

Possible solutions and recommendations

- Staff should interact in a manner that is appropriate to the participants. It may be useful to recruit minority investigators and staff.
- For health information, focus groups have found that African Americans prefer visual formats to written formats and personalized form letters containing generic information.
- Staff should be trained to pick up on clues that a participant may have logistical barriers. For example, the inconvenience of study visits can be overcome by adjusting the study schedule to meet the participants' needs, e.g., scheduling visits for weekends, holidays, or vacations. The location of the clinic should be convenient to participants, and the hours of operation should be flexible.
- Make available the use of a special service available to elderly individuals through the public transportation system or use of taxi vouchers.
- Payments and other incentives should not be of such magnitude as to appear coercive.
- Consulting with minority community leaders can help determine whether incentives are appropriate, materials are appropriate in terms of language, literacy levels and avoidance of jargon, and can help emphasize the personal and ethnic group benefits from participation.
- Use a creative approach to recruitment including telephone calls, letters to solicit referrals, seminars in hospitals or clinics, notices on bulletin boards or journals or in community newspapers, talks at neighborhood forums.

4.4 PEDIATRIC POPULATIONS

Challenges and barriers to recruitment

Pediatric populations can be among the most difficult population to recruit due to parent's time constraints, stress level, and a heightened level of concern about their child's safety. However, parents may also have a stronger sense of wanting to help their child and other children. The ease of recruiting this population might depend on whether the study is seeking a healthy population of children or studying children with a particular disease or condition.

Possible solutions and recommendations

Consider what will make the child and parents feel the most comfortable, relaxed and appreciated. If members of the study team are parents ask them how they would feel about the protocol, the clinic visit site, and ask them how they would feel if their child were in the study. From other HMORN pediatric studies, we've derived the following list of ways to enhance the pediatric visit.

- Accommodate appointment times to the age of the population: day-time for pre-school children, after school or early evening for school-age and adolescents; know the local school holidays and book a full day of appointment on these days if possible.
- Child-friendly age-appropriate environment (posters in the walls; age-appropriate magazines and books; canyons and paper; post the kids drawings)
- Snacks and drinks, especially for elementary school-age children and after school appointments
- Distractions in waiting room and especially during a procedure like a blood draw or vaccination; video running continuously in a protective Plexiglas shell; interactive posters like "Can you find the?" or "How many cats can you count?"
- Minimize wait times for appointments and during visits between next step/procedure
- Really friendly, upbeat staff who greet and interact w/ the child as well as the parents; staff should introduce themselves to child by name and use the child's name
- Treat children's questions very seriously and respectfully
- Give kids lots of clear, concise, just-in-time instructions; lots of encouragement, behavior reinforcement ("I know that was hard to do, you were great!" "Wow, you were brave!" and thanks (verbal and other), closure with more thanks and verbal and written next steps

4.5 NONNATIVE ENGLISH SPEAKERS

- If materials will be created for multiple languages, have them translated and back-translated.

4.6 CLINICIANS & PROFESSIONALS

- If the interview is more than 15-20 minutes, you will probably have to make two calls. One to schedule an appointment, and one to conduct the interview.
- Trying to contact the physician is usually difficult. Ask the receptionist or nurse for very specific help, with questions such as, "When should I call back?" "Will you please ask the doctor to return my call?" "What time of the day does the doctor usually return or take calls?"
- Expect to call all hours of the day, sometimes very early in the morning. Anticipate a lot of phone tag with providers and other professionals. Your most valued contact may be the secretary or clinic receptionist.
- Consider an incentive that benefits a clinic or other type of office, for example, a gift basket for the employee lounge, or a plant for the waiting room. Even sending a coffee card with a comment like, "we would like to buy you a cup of coffee while you fill out the questionnaire," will develop rapport.
- Interoffice mail or email can be a useful approach to contacting clinic providers. However, some degree of tailoring may be necessary. Some providers or administrators may prefer receiving a survey via email rather than a hard copy.

5. SUCCESS STORIES

Highlighted area of success: Recruitment for in-person interview over short time period

Study name: Long-Term Cost and Outcomes of Breast Cancer Screening (COBRAS)

Topic: Quality of life (utility) ratings for mammography screening, breast cancer diagnosis, and breast cancer treatment

Secret to success: Gave women option of phone interview if they could not come into clinic. Adequately staffed interviewers to complete interviews in only a few months.

Population: Women 50+ years enrolled in GHC mammography screening program

Type of study: Cross-sectional in-person interview

Duration of follow-up: N/A

Mode of recruitment: Letter and phone

Mode of data collection: In-person and phone interview

Incentives: \$15 gift card to Barnes and Noble

Response rate: 34% over 3-month period

Retention rate: N/A

Site(s): GHC

Other notable highlights or features: Brought 120 women into clinic for 1-hour interviews over course of 3-months. Conducted pilot study of 20 women to work out process.

Principal Investigator: Paul Fishman

Contact person: Christine Mahoney: mahoney.c@ghc.org

Publications from this study: N/A at this time

Highlighted area of success: Recruitment and retention

Study name: Hernia Study

Topic: Inguinal Hernia Management: Watchful Waiting versus Tension Free Repair

Secret to success: Diligence in contacting patients every three months per protocol; efforts to continue contact and data collection with patients who moved from the area or were deployed; diligence in encouraging patients to make protocol visits

Population: Male patients 18 years of age and older

Type of study: Prospective, randomized controlled research study

Duration of follow-up: Two to five year follow-up (minimum two year follow-up)

Mode of recruitment: Referrals from PCPs (recruitment method varied by site; other sites relied on various media advertisements)

Mode of data collection: Self-administered surveys; three month semi-structured telephone interviews; provider and coordinator-completed CRFs

Incentives: \$100 check at the conclusion of the study; telephone cards mailed to patients at New Year's; telephone card/car wash coupon presented to participant at annual protocol visits

Response rate: Not applicable

Retention rate: 11 patients terminated; 8 deaths, 3 lost-to-follow up (1 due to change in medical condition)

Sites(s): Multi-site study, Lovelace one of five participating sites

Other notable highlights or features: At the end of enrollment period, instituted a quarterly participant newsletter to keep participants connected with the study. Each newsletter had a lead article focused on the study. The remainder of the newsletter was focused on a theme; each site coordinator contributed an article based on the local study area.

Principal Investigator: William Syme

Contact person: Ann Von Worley: ann@LCFresearch.org

Publications from this study: N/A at this time

Highlighted area of success: Recruitment for intervention study of at-risk drinking population

Study name: Cutting Back®

Topic: Clinic-based Screening and Brief Intervention (SBI) for at-risk drinking

Secret to success: Senior management buy-in; clinic buy-in; comprehensive clinic training prior to the start of the study; close monitoring of study sites with a feedback loop to providers and clinic staff

Population: Patients 18 years of age and over presenting to participating primary care clinics for an office visit

Type of study: Interventional

Duration of follow-up: Follow-up limited to two telephone surveys at 2 months and 1 year; no clinic-based follow-up unless in alcohol dependent category

Mode of recruitment: Clinic-based study; surveys distributed to all patients 18 years of age and older presenting to participating primary care clinics during a 19 month period; short informed consent document on reverse side of screening survey

Mode of data collection: 2 patient self-administered surveys, patient telephone surveys, provider surveys, and utilization data

Incentives: Clinic incentive; later in the study, patient incentive

Response rate: Unknown, clinics were to distribute surveys at check-in; no mechanism for determining number of patients who refused

Retention rate: Unknown, survey group conducting telephone survey notified us if unable to contact a patient by phone; Lovelace site researched current phone number and forwarded that if available, however Lovelace site was not informed of number of patients that were ultimately not able to be contacted by phone.

Site(s): Multi-site study; Lovelace one of five participating sites; 3 clinics involved at local Lovelace site

Other notable highlights or features: Enthusiasm of Lovelace Medical Directors in the intervention clinics led to translation of this research into everyday practice

Principal Investigator: Maggie Gunter

Contact person: Ann Von Worley: ann@LCFresearch.org

Publications from this study:

Barbor TF, Higgins-Biddle J, Dauser D, Higgins P, Bureson J. Alcohol screening and brief intervention in primary care settings: Implementation models and predictors. *J Stud Alcohol* 2005; 66(3):361-369.

Zarkin GA, Bray, JW, Babor TF, Higgins-Biddle JC. Alcohol drinking patterns and health care utilization in a managed care organization. *Health Serv Res* 2004; 39:553-70.

Zarkin, GA, Bray JE, Davis K, Babor TF, Higgins-Biddle JC. The costs of screening and brief intervention for risky alcohol use. *J Stud Alcohol* 2003; 64:849-857.

Barbor TF, Higgins-Biddle JC, Higgins PS, Gassman RA, Gould BE. Training medical providers to conduct alcohol screening and brief interventions. *Substance Abuse*. 2004. 25(1):17-26.

Highlighted area of success: Recruitment to the program and data collection

Study name: Operation Zero Evaluation (OZ)

Topic: Testing two models of an adolescent and pre-adolescent group medical appointment for weight management.

Secret to success: N/A

Population: Pediatrics ages 11-17 with BMI-for-age percentile =95th and =85th with risk factors, such as family history and/or concern for weight, who were referred by their clinician to attend the OZ program.

Type of study: Longitudinal

Duration of follow-up: baseline, 8-week (end of OZ program) and 1-year post.

Mode of recruitment: Clinician referral. Member is given a brochure that explains the program and encourages them to enroll. Different models exist for how members enroll – they can register with the receptionist (health care team model) or through the Call Center (health education model). At KPMAS, members called the Program Coordinator directly – this proved advantageous, because the Program Coordinator was very effective at screening for motivation and eligibility. As a result, KPMAS has experienced better retention rates than KPGA (~80% versus 42%), because KPMAS enrollees were more motivated to attend an ongoing 8-week program.

Mode of data collection: Collection of clinical measurements (weight, height, %body fat, waist size) plus a survey. Clinical measurements are collected at every OZ session and After-OZ session. Surveys are given at session #1 and #8 (baseline and 8-week post) and the 4th After-OZ session (1-year post). If participants don't attend the 8th session or the 4th After-OZ program, then the survey is mailed to their homes. If 3-weeks pass and the survey is not returned, then attempts are made to complete the survey over the telephone.

Incentives: \$25 given for completing the final survey.

Response rate: For KPGA: 34% response rate for the 8-week post survey data collection. 1-year post survey data collection is in progress and approaches 40%.

Retention rate: 37% attended 6 or more OZ sessions at KPGA. Data for KPMAS is preliminary, but far surpasses KPGA due mainly to improvements in processes. On top of screening for motivation before enrolling members into the program, KPMAS' program coordinator also makes weekly reminder calls to participants between OZ sessions.

Site(s): KPG and KPMAS

Other notable highlights or features: KPGA actually did not implement quarterly After-OZ sessions, therefore, the 1-year post data collection has been difficult. KPMAS is implementing quarterly After-OZ sessions and hopefully will ascertain a better 1-year post response rate. The first OZ session was always difficult because 30-minutes was utilized for completing the survey and IRB forms. The program had to schedule for this and participants asked to arrive early. Nonetheless, most participants arrived late, which made starting the 1st session on time very difficult. Members who did arrive on time were dissatisfied. Instead of asking the OZ facilitator to manage data collection, it proved essential to have a member of the Research Team attend session 1 and be responsible for it.

Principal Investigator: Luke Beno

Contact person: Josephine Hinchman: Josephine.Hinchman@kp.org

Publications from this study: N/A at this time

Highlighted area of success: 95% retention of African American males over 7-year follow-up

Study name: SELECT

Topic: Effect of selenium and vitamin E on prostate cancer prevention

Secret to success: Frequent communication and addressing patients' concerns.

Population: Caucasian (55%), Asian (1%), African American (45%)

Type of study: Phase III double-blinded randomized placebo controlled

Duration of follow-up: 7 years

Mode of recruitment: 1) Mass mailing of invitation letters. 2) Evening group meetings (education/ information/ question and answer session) for potential subjects and spouses/ family members once a month. Refreshments were served. 3) Study presentation to entire facility medical staff for patient referral 4) Neon colored flyers posted in patients waiting areas and pharmacy.

Mode of data collection: Phone and face-to-face clinic visits

Incentives: Birthday cards; \$5.00 Target Gift Card adherence Program

Response rate: Not applicable

Retention rate: 95%

Site(s): KPG

Other notable highlights or features: Flexibility of patient scheduling (i.e. early morning or late afternoon visits) to accommodate patients' work schedule.

Principal Investigator: Joshua Barzilay

Contact person: Carol Mayers

Publications from this study: N/A at this time

Highlighted area of success: 95% retention of study subjects at 5-years

Study name: SHEP

Topic: Hypertension management

Secret to success: N/A

Population: Persons over 65 with isolated systolic hypertension

Type of study: randomized clinical trial

Duration of follow-up: five years

Mode of recruitment: Health plan and community; primarily mass mailings

Mode of data collection: Questionnaire and physical assessment

Incentives: None.

Response rate: Percent screened for eligibility varied widely depending on target groups; about a third of health plan members recruited were screened; because of very rigid enrollment criteria, only about 1.5% of those screened were randomized.

Retention rate: (estimated at 5 years) 95%

Site(s): KPNW and 15 other clinical sites

Other notable highlights or features:

Principal Investigator: Tom Vogt: Tom.M.Vogt@kp.org

Contact person: Tom Vogt

Publications from this study:

SHEP Cooperative Research Group. Prevention of stroke by antihypertensive drug treatment in older persons with isolated systolic hypertension: Final results of the Systolic Hypertension in the Elderly Program (SHEP). JAMA 1991;265:3255-64.

Hulley SB, Furberg CD, Gurland B, et al. Systolic Hypertension in the Elderly Program (SHEP): Antihypertensive efficacy of chlorthalidone. Am J Cardiol 1985;56:913-20.

Study name: SHEP

Publications continued

Petrovitch H, Vogt TM, Berge KG on behalf of the SHEP Cooperative Research Group. Isolated systolic hypertension: Lowering the risk of stroke in older patients. *Geriatrics* 1992;47:30-38.

Black HR, Curb JD, Pressel S, Probstfield JL, Stamler J, eds. Systolic Hypertension in the Elderly Program (SHEP): Baseline characteristics of the randomized sample. *Hypertension* 1991;17(suppl II):1-171.

Highlighted area of success: Recruitment and retention of pregnant moms and their babies

Study name: Project Viva

Topic: To examine the roles of prenatal and perinatal factors in outcomes of pregnancy and childhood (and beyond).

Examples of what is being investigated:

- effects of diet on child development and obesity
- how diet and the environment influence the development of asthma in children
- how a woman's pregnancy is affected by lifetime experiences of racism or violence

Secret to success:

- In-person recruitment by research assistants
- During the recruitment time period, 2+ years, recruitment sites and research office were part of a modified staff model HMO
- Well trained research assistants
- Numerous contacts each year – participants change of contact info is learned earlier
- If needed, in-person visits are conducted at the participant's home

Population:

Women and their children.

- Enrolled participants sought obstetrical care at one of the Harvard Vanguard Medical Associates sites in the greater Boston, MA area.
- No restrictions by age, race/ethnicity

Eligibility exclusions:

- \geq 22 weeks gestation at initial visit
- plans to move away
- not able to respond in English
- multiple gestation (twins, triplets)

Type of study: epidemiologic "pre-birth" cohort study (n=2128)

Duration of follow-up: currently funded to follow-up until children are age 5, seeking funds to follow-up until children are age 9.

Mode of recruitment: Project Viva research assistants recruited the participants just after their first clinical prenatal appointment. Clinician informed potential participant about the study and research assistants were available in the OB/GYN department to speak with the woman after her appointment.

Study name: Project Viva
continued...

Mode of data collection:

- Electronic & paper medical records
- Paper birth logs
- Electronic claims
- Study visits conducted by research assistants
 - in-person visits at 1st prenatal appt., 26-28 wks gestation, birth, 6 months old, and 3 years old
 - mailed visits at 1, 2, 4, and 5 years old
 - interviews, self-administered questionnaires, examination measurements, biosamples

Incentives: Toys R Us gift cards, raffles for cash prizes, magazines, Onesies, picture magnets, baby books, cash – up to \$80 for the age 3 in-person visit

Response rate: Recruited 64% of eligible women

Retention rate: In pregnancy, >90%

After birth,

- mailed visits: ~90% for the 75% of participants who enrolled their children
- in-person visits: projected >80% for ongoing age 3 visit

Site(s): Harvard Pilgrim Health Care/Harvard Medical School

Other notable highlights or features: birth cohort study where recruited pregnant women and followed mom and kid for 3 years.

Principal Investigator: Matt Gillman: matthew_gillman@hms.harvard.edu

Contact person: Jane Craycroft: jane_craycroft@harvardpilgrim.org

Publications from this study: <http://www.dacp.org/viva/index.html>

Highlighted area of success: Response rate

Study name: Disclosure Survey

Topic: Disclosure of Medical Errors

Secret to success: Possibly high interest topic; use of repeated mailings & incentives as per Dillman

Population: Random sample of health plan members

Type of study: Mailed questionnaire

Duration of follow-up: NA

Mode of recruitment: Mail

Mode of data collection: Mail questionnaire

Incentives: \$5 cash

Response rate: 66% on 8-page questionnaire

Retention rate: NA

Site(s): Meyers

Other notable highlights or features: N/A

Principal Investigator: Kathy Mazor: Kathy.Mazor@meyersprimary.org

Contact person: Kathy Mazor

Publications from this study:

Mazor KM, Simon SR, Yood RA, Martinson BC, Gunter MK, Reed GW, Gurwitz JH. Health plan members' views about disclosure of medical errors. *Annals of Internal Medicine*, 2004;140:409-418.

Mazor KM, Simon SR, Yood RA, Martinson BC, Gunter MK, Reed GW, Gurwitz JH. Health plan members' views on forgiving medical errors. *American Journal of Managed Care*. 2005;11:151-155.

Highlighted area of success: 98% Retention in RCT

Study name: SPINE

Topic: Efficacy of Acupuncture for Chronic Low Back Pain

Secret to success: Large population of back pain sufferers; well-seasoned team; topic of interest to team; PI treats team with respect

Population: 18-70 years old, chronic low back pain

Type of study: RCT

Duration of follow-up: 1 year

Mode of recruitment: Mass mailing of recruitment brochure; advertisement in NW Health; flyer postings in the clinics. Responders to brochure, advertisements or flyers receive a telephone call from study team

Mode of data collection: Follow-up telephone interviews by masked interviewers; clinical data collected by study acupuncturists

Incentives: Free acupuncture (for those in acupuncture groups); small cash incentive for completing follow-up interviews

Response rate: Cannot calculate since it is unknown what percentage of brochure recipients have the condition we are studying (low back pain)

Retention rate: 98%

Site(s): 1) GHC, 2) Kaiser Permanente Northern California, 3) UW

Other notable highlights or features:

Principal Investigator: Dan Cherkin

Contact person: Janet Erro: erro.j@ghc.org

Publications from this study: N/A at this time

Highlighted area of success: Successful recruitment in sensitive topic area - intimate partner violence, risky sexual practices, alcohol and illicit drug use

Study name: Long-term effects of intimate partner violence on women's health and use of health services

Topic: Intimate partner violence

Secret to success: Our interview team (CHS Survey Program) did a remarkable job initiating contact and completing interviews with participants, through their persistence with repeated telephone contacts and their skill in carrying out difficult interviews. The advance letter mailed to participants described the study as relating to women's health issues, rather than "intimate partner violence." This procedure was approved by our IRB to preserve the safety of women, some of whom may have been living with an abusive partner.

Population: 3,249 women ages 18-64

Type of study: Cross-sectional survey

Duration of follow-up: N/A

Mode of recruitment: Advance mail letter followed by telephone call

Mode of data collection: Telephone interview

Incentives: Gift card

Response rate: 57.5%

Retention rate: N/A

Site(s): GHC

Other notable highlights or features: N/A

Principal Investigator: Amy Bonomi

Contact person: Barbara Monsey: monsey.b@ghc.org

Publications from this study: N/A at this time

Highlighted area of success: Successfully recruited and conducted a study in 16/19 eligible medical groups to help us do reliability and internal validity testing of a new survey designed with National Committee for Quality Assurance to serve as a means of documenting the presence and function of practice systems to implement the Chronic Care Model. A version of this survey will be used in P4P demonstrations nationally.

Study name: Testing the Practice Systems Assessment Survey (PSAS) for Evaluating the Chronic Care Model in Practice

Topic: Internal validation study of the Practice Systems Assessment Survey[®] a survey designed to document practice systems in individual and small practices to improve chronic disease. The test was designed to learn which personnel would be the most reliable and valid responders. The instrument assesses the presence and function of systems related to elements of the Chronic Care Model. The survey was followed by an on-site audit that required demonstration and documentation of systems indicated as present on the survey.

Secret to success: We obtained contact information from the Institute for Clinical Systems Improvement (ICSI) for 19 of their 38 medical group members who provide primary care to adults. The PI personally contacted each medical group physician leader to discuss the study, invite them to participate, and introduce the Data Collection Center (DCC) director who would be coordinating the on-site visit. The PI signed each recruitment and confirmation letter with an original inked signature, and also inked in a first name on letters where he knew the physician. We developed an information brochure and fact sheet that was enclosed with the recruitment letter. At the end of the study, a confidential summary of the survey and site visit findings in comparison to the blinded results from other medical groups was sent to the medical director and QI coordinator, along with recommendations for care improvement.

Population: Medical groups and clinic sites

Type of study: Survey instrument validation, test-retest

Duration of follow-up: NA

Mode of recruitment: Introduction letter followed by personal phone call followed by confirmation letter

Mode of data collection: Survey, telephone interview and on-site audit

Incentives: We gave a \$15.00 gift card to survey participants and a \$200.00 reimbursement check to medical groups who participated in the audit.

Response rate: Only three medical groups declined participation (each on the grounds of having too much activity or turmoil at the time) and two groups agreed too late to be included. Three medical groups participated in pre-testing the survey and audit, leaving 11 groups with complete information.

Retention rate: NA

Site(s): HealthPartners Research Foundation. The study was conducted in Minnesota in collaboration with the Institute for Clinical Systems Improvement (ICSI), a quality improvement collaborative that includes most of the medical groups and hospitals in the area among its members.

Other notable highlights or features: Collaboration of National Committee on Quality Assurance, HealthPartners Research Foundation and the Institute for Clinical Systems Improvement

Principal Investigator: Leif I. Solberg

Contact person: Merry Jo Thoele: Merry.J.Thoele@HealthPartners.Com

Publications from this study: N/A at this time.

Highlighted area of success: Bilingual interviewers

Study name: Telephone Advice to Problem Drinkers: Feasibility Study

Topic: Alcohol use and injury prevention

Secret to success: We used native Spanish speakers to develop questionnaires and field test them.

Population: individuals 18+ with injury seen in urgent care approx 30% Spanish-only or Spanish-preferred speakers

Type of study: Cross-sectional design

Duration of follow-up: Single interview

Mode of recruitment: In person at clinic or on telephone

Mode of data collection: Point of View Boxes (electronic direct data entry devices), paper questionnaire, or over the phone data collection

Incentives: N/A

Response rate: 67%

Retention rate: N/A

Site(s): KPCO

Other notable highlights or features: We recruited Spanish-speaking Research Interviewers, thus interviews were conducted in Spanish with a native Spanish speaker.

Principal Investigator: Allan Graham

Contact person: Elizabeth Nugent: Elizabeth.w.nugent@kp.org

Publications from this study: N/A

Highlighted area of success: Web based survey

Study name: CMI TheME

Topic: Non-responders survey

Secret to success: N/A

Population: Participants enrolled in 'Balance' a web-based weight management program who failed to complete 12 month FU questionnaires on the internet.

Type of study: Non-respondent telephone survey to determine whether significant biases existed as a result of the relatively low response rate to the web-based 6-month survey

Duration of follow-up: N/A

Mode of recruitment: Telephone

Mode of data collection: Telephone

Incentives: None

Response rate: 41%

Retention rate: N/A

Site(s): KPG and KPNW

Other notable highlights or features: N/A

Principal Investigator: Kendra Rothert

Contact person: Josephine Hinchman: Josephine.Hinchman@kp.org

Reference to any publications from this study: N/A at this time

Highlighted area of success: 91% response rate from MDs

Study name: DETECT

Topic: Adherence and attitudes to breast and cervical cancer screening guidelines

Secret to success: Four stage data collection approach: careful attention to survey design and layout, extensive piloting, choice of token incentive, use of "local champions," and denominator management.

Population: Physicians from 3- sites

Type of study: Observational

Duration of follow-up: Seven weeks

Mode of recruitment: Mailed recruitment letter which included the champion's signature and also signed by the Director of NCI; totally anonymous because of use of a separate mail back post-card; second full mailing after two weeks; phone, email or personal follow-up to non-responders by local "champion"; last, telephone follow-up by a survey form with detailed protocol for call-back. The champion was a recognized clinical leader in each case (eg the PI from the site)

Mode of data collection: Survey (self-administered with some telephone administration in Phase 4).

Incentives: \$3 Starbucks coffee gift card

Response rate: 91%

Retention rate: N/A

Site(s): GHC, KPCO, KPNC

Other notable highlights or features: N/A

Principal Investigator: Meyers and UMASS - Jane Zapka; NCI-Steve Taplin

Contact person: Jane Zapka

Publications from this study: <http://ehp.sagepub.com/cgi/reprint/25/2/169>

Puleo, E., Zapka, J., White, M.J., Mouchawar, J., Somkin, C., Taplin, S. Caffeine, Cajoling and Other Strategies to Maximize Clinician Survey Response Rates. *Eval Health Prof* 25(2):169-184, 2002

Mouchawar, J., Goins, K.V., Somkin, C., Puleo, E., Alford, S.H., Geiger, A., Taplin, S., Gilbert, J., Weinmann, S., Zapka, J.G. Guidelines for Breast and Ovarian Cancer Genetic Counseling Referral: Adoption and Implementation in HMOs. *Genet Med* 5(6):444-450, 2003.

Zapka, J.G., Puleo, E., Taplin, S.H., . Breast and Cervical Cancer Screening Guidelines: HMO Clinicians' Views on Guidelines, Implementation and Plan Efforts, *J Natl Cancer Inst Monogr* in press, 2005.

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Couper, M.P. and Groves, R.M. 2002. "Introductory Interactions in Telephone Surveys and Nonresponse." In D.W. Maynard, H. Houtkoop-Steenstra, N.C. Schaeffer, and J. van der Zouwen (eds.), 2002. *Standardization and Tacit Knowledge; Interaction and Practice in the Survey Interview*. New York: Wiley, pp. 161-177.

Dillman, Don A. 2000. *Mail and Internet Surveys: The Tailored Design Method 2nd edition*. John Wiley & Sons, Inc.

Hembroff, L.A., Rusz, D., Rafferty, A., McGee, H., & Ehrlich, N. 2005. "The Cost Effectiveness of Alternative Advance Mailings in A Telephone Survey." *Public Opinion Quarterly* 69:232-245. http://poq.oxfordjournals.org/cgi/content/abstract/69/2/232?maxtoshow=&HITS=10&hits=10&RESULTFORMAT=1&andorexacttitle=and&andorexacttitleabs=and&fulltext=advance+letter&andorexactfulltext=phrase&searchid=1120777763527_2086&stored_search=&FIRSTINDEX=0&sortspec=relevance&tdate=7/31/2005&eaf

Koepsell, TD, McGuire, V, Longstreth, WT, Nelson, LM, van Belle, G. Randomized Trial of Leaving Messages on Telephone Answering Machines for Control Recruitment in an Epidemiologic Study. *Am J of Epidemiol.*1996;144: 704-706.

Link, M.W., and Malizio, A. Telephone answering messages as a tool for reducing survey nonresponse. Paper presented at: Annual Conference of the American Association for Public Opinion Research; May 18, 2000;Portland, Oregon

Spilker, B. and Cramer, J.A. 1992. *Patient Recruitment in Clinical Trials*. New York: Raven Press.

MUST READS

In phone surveys:

Singer, Eleanor, John Van Hoewyk, and Mary P. Maher. 2000. "Experiments with Incentives in Telephone Surveys." *Public Opinion Quarterly* 64:171-188.

In mailed surveys:

Edwards, Phil, Ian Roberts, Mike Clarke, Carolyn DiGuseppi, Sarah Pratap, Reinhard Wentz, and Irene Kwan. 2002. "Increasing response rates to postal questionnaires: systematic review." *BMJ* 2002; 324:1183

Must Reads - continued

Among physicians:

Delnevo, Cristine D., Diane J. Abatemarco, Michael B. Steinberg. 2004. "Physician Response Rates to a Mail Survey by Specialty and Timing of Incentive." *American Journal of Preventive Medicine* 2004;26(3).

Puleo E, Zapka J, White MJ, Mouchawar J, Somkin C, Taplin S. Caffeine, cajoling, and other strategies to maximize clinician survey response rates. *Eval. Health Prof.* 2002 Jun;25(2):169-84.

Field TS, Cadoret CA, Brown ML, Ford M, Greene SM, Hill D, Hornbrook MC, Meenan RT, White MJ, Zapka JM. Surveying physicians: do components of the "Total Design Approach" to optimizing survey response rates apply to physicians? *Med Care.* 2002 Jul; 40 (7): 596-605. Review.

Among controls:

Coogan, Patricia F. and Lynn Rosenberg. 2004. "Impact of a Financial Incentive on Case and Control Participation in a Telephone Interview." *American Journal of Epidemiology, Aug 2004; 160: 295 - 298.*

INCENTIVE MUST READS

Incentives overview:

Pre better than promised incentives:

Singer, E . (2002). The use of incentives to reduce nonresponse in household surveys. In R.M. Groves, D. A. Dillman, J. L. Eltinge, & R. J. A. Little (Eds.), *Survey nonresponse* (pp.163-177). Chchester: Wiley.

Comparison of cash versus in-kind incentives across modes:

Erica Ryu, Mick P. Couper, and Robert W. Marans. 2005. "Survey Incentives: Cash Vs. In-Kind; Face-To-Face Vs. Mail; Response Rate Vs. Nonresponse Error." *International Journal of Public Opinion Research, Aug 2005.*

In phone surveys:

Singer, Eleanor, John Van Hoewyk, and Mary P. Maher. 2000. "Experiments with Incentives in Telephone Surveys." *Public Opinion Quarterly* 64:171-188.

In mailed surveys:

Edwards, Phil, Ian Roberts, Mike Clarke, Carolyn DiGuseppi, Sarah Pratap, Reinhard Wentz, and Irene Kwan. 2002. "Increasing response rates to postal questionnaires: systematic review." *BMJ* 2002; 324:1183

Among physicians:

Delnevo, Cristine D., Diane J. Abatemarco, Michael B. Steinberg. 2004. "Physician Response Rates to a Mail Survey by Specialty and Timing of Incentive." *American Journal of Preventive Medicine* 2004;26(3).

Among controls:

Coogan, Patricia F. and Lynn Rosenberg. 2004. "Impact of a Financial Incentive on Case and Control Participation in a Telephone Interview." *American Journal of Epidemiology, Aug 2004; 160: 295 - 298.*

7. APPENDIX

Invitation Letters

CMI TheME, Balance Sub Study, KPGA study of a web-based weight management program

COBRAS, GHC study of quality of life ratings for mammography screening, breast cancer diagnosis, and breast cancer treatment

DETECT, MPCl study of physicians' adherence and attitudes to breast and cervical cancer screening guidelines

Disclosure Survey, MPCl study of disclosure of medical errors (3 pages)

Intimate Partner Violence (IPV), GHC study on long-term effects of intimate partner violence on women's health and use of health services

Project Quit, GHC web-based study of online support for smoking cessation

SELECT, KPGA study of the effect of selenium and vitamin E on prostate cancer prevention

Study Information Sheets

DETECT, MPCl study of physicians' adherence and attitudes to breast and cervical cancer screening guidelines

Practice Systems Assessment Survey (PSAS) for evaluating the Chronic Care Model in Practice, HPRF internal validation study of the PSAS, a survey designed to document practice systems in individual and small practices to improve chronic disease

Study Brochures

Equol Breast and Bone Density Study (EBB), GHC study to identify differences in hormone levels & hormone-related factors (such as bone density and breast density), between individuals with and without the bacteria that process daidzein to equol

Herbal Alternatives for Menopause Symptoms (HALT), GHC study examining how well some commonly used herbal products control hot flashes and night sweats

Practice Systems Assessment Survey (PSAS) for evaluating the Chronic Care Model in Practice, HPRF internal validation study of the PSAS, a survey designed to document practice systems in individual & small practices to improve chronic disease

Study Fliers

CMI TheME, Breathe Sub Study, KPGA study of a web-based smoking cessation program

Scripts

Project Viva, HPHC study examining the roles of prenatal and perinatal factors in outcomes of pregnancy and childhood (and beyond)

Project Quit, GHC web-based study of online support for smoking cessation

Reminder Letters and Postcards

DETECT, MPCl study of physicians' adherence and attitudes to breast and cervical cancer screening guidelines

Operation Zero Evaluation (OZ), KPGA study testing two models of an adolescent and pre-adolescent group medical appointment for weight management

No Contact Letters

STRIDE, GHC study of systematic treatment for chronic depression

Newsletters

Equol Breast and Bone Density Study (EBB), GHC study to identify differences in hormone levels and hormone-related factors (such as bone density and breast density), between individuals with and without the bacteria that process daidzein to equol

Hernia Study, LCF study of inguinal hernia management

Protocols

Sample Answering Machine / Voice Mail Protocol

Sample Protocol for Procuring Cash for Incentives

Miscellaneous Resources

What is the Center for Health Studies, GHC general information card describing the research center

Table of Potential Advantages and Disadvantages of Centralized Mail Recruitment

Readability Information