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Models of Excellence in Research

Recruitment of Women Research Participants: The Women's Health Registry at the University of Michigan

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ABSTRACT

Objective: **The goal was to develop the Women's Health Registry, a research participant database that prospectively collects detailed information on potential research subjects to assist in linking them with open research protocols and to assess investigator use and satisfaction with this Registry.**

Methods: **The Women's Health Registry was launched in 1999. Women aged ≥18 years were recruited to enroll in a database of women with interest in research participation and to complete a health questionnaire. Women's health researchers with IRB-approved projects were encouraged to apply for access to the Registry participants. In 2003, the first 15 investigators to use the Women's Health Registry were asked to participate in a standardized open-ended interview to assess investigator satisfaction with this recruitment tool.**

Results: **The Women's Health Registry is currently populated with 2436 women: 36.8% aged 18–34, 39.9% aged 35–54, 16.8% aged 55–69, and 6.4% aged ≥70 years. Of these women, 84% are Caucasian and 8.5% are African American. Structured interviews with 13 of the 15 investigators contacted revealed that 36.4% of the total subject enrollment recruited by these investigators was recruited from the Women's Health Registry. In addition, Registry participants were more likely to enroll in their research protocols than women contacted through other methods. Most of the investigators' expectations from the Women's Health Registry were met, except for access to menopausal women.**

Conclusions: **The Women's Health Registry was successfully developed, and the goal of linking women with appropriate protocols was met with significant investigator satisfaction.**

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INTRODUCTION

Recruitment of women into clinical research trials remains one of the greatest challenges to conducting research that is compliant with requirements for analyses of gender differences in federally funded research.[1,2] Failure to recruit members of specific populations to trials that require adequate representation reduces the external validity or generalizability of the study results. Investigators interested in women's health research face the common process barriers of publicity, initial contact, and screening, all of which prove costly and complicate subject recruitment.[3–5] In fact, recruitment is one of the most significant challenges to completing a research study on time and on budget. In most trials, recruitment takes longer, is more expensive, and produces fewer subjects than planned.[6]

Knowledge about successful recruitment and retention techniques for women and ethnic minorities in clinical trials is limited by experience and a dearth of reports on recruitment experiences.[7] Most interventions are designed to address the low accrual rates attributable to patient factors, such as lack of patient-friendly information about trial participation, and organizational barriers and obstacles. Increasingly, attention is being paid to the barriers to participation that physicians and healthcare systems create as well.[7,8] It is likely that successful recruitment strategies will feature versatile, dynamic, and multidisciplinary approaches that ultimately link women with investigators by overcoming these common barriers.

The Women's Health Registry is a conceptual model and practical tool for increasing recruitment of women into clinical trials and health services research protocols at the University of Michigan. Recognizing the notable difficulties of recruiting subjects locally, the Women's Health Registry was launched by the University of Michigan Health System (UMHS) National Center of Excellence in Women's Health in 1999. The Registry was planned to provide value to women and the research community by eliminating the basic barriers that complicate the recruitment process. Designed to identify, prescreen, collect information on, and contact women interested in research participation, it has connected over 900 women with UMHS investigators conducting gender-based research.

This report describes the development and implementation of the Women's Health Registry, a research participant database that prospectively collects information on potential research subjects to assist in linking them with research protocols, as well as outcomes related to recruiting women into the database and investigator experiences with using the Women's Health Registry.

MATERIALS AND METHODS

The Michigan model

Institutional Review Board (IRB) approval was obtained to develop the University of Michigan Women's Health Registry in response to the investigator-identified challenges of subject recruitment. The Women's Health Registry was initiated in 1997 by a collaborative team at the UMHS. The objectives of the Women's Health Registry were and are to (1) identify women (aged $\geq$18) who are interested in being contacted for participation in trials and clinical research with women's health foci and collect basic demographic and health histories for each woman, (2) collect signed statements of prospective informed consent to be contacted by UM researchers, and (3) facilitate comfortable, convenient initial contact between the investigator and the interested participant. As part of a multitiered, multidisciplinary strategy to increase research activities in women's health at the University of Michigan, the Women's Health Registry project created and maintains a pool of potential research subjects with expressed interest in participating in clinical trials and research who have given prospective informed consent to be contacted by researchers.

To minimize the effects of professional intimidation and real or perceived asymmetrical knowledge between the research team and the potential participant, the Registry uses a multitiered, subject support approach. Several stages and safeguards are in place, designed to protect enrollees from unwanted or inappropriate contact by investigators and assist them once they begin consideration of enrollment into a trial. The rights of individual enrollees in all stages of the process are made clear to them, and a support line is available for discussion of any questions or concerns. At any stage in the process, the enrolled woman can call the Registry staff members or e-mail the team directly with questions about

a protocol under consideration, changes in her health status that would require a change to her Registry profile (she may also do this online with her personal ID and password), her participation in a trial, or any other issue.

One aspect of the Women's Health Registry standard operating procedures was essential to the IRB approval of the project: the decision to maintain a database that would be completely separate from the UMHS medical record and patient databases. This separation guarantees that enrollment in the Women's Health Registry is never documented in paper or electronic medical records of those enrollees who are also patients at the UMHS. In addition to guaranteeing no electronic linkage between the medical record or patient database and the Registry database, the Women's Health Registry does not ask for patient status of enrollees, names or affiliations of care providers or insurers, or any commonly used unique identifiers, such as patient identification number or social security number.

The standard operating procedures for the Women's Health Registry also strictly prohibit investigators from accessing patient medical records for any women whose contact information they receive from the Registry unless the subject specifically gives consent for this to the recruiting investigator. The purpose of going to such lengths is to ensure that the personal health information that is used for research purposes involving the Women's Health Registry is limited to that information supplied voluntarily by the enrollee in her self-reported completion of the health history questionnaire.

Participant access

The core of the Registry is an electronic Microsoft Access database with an Oracle-based web interface that stores demographic information and a comprehensive personal health history for each participant on a secure server. Initially, an interested woman returns a paper survey with signed informed consent to participate or visits the website (*www.womensregistry.org*) to complete the online application and consent form that is transferred with encryption to a secure server housed at the University of Michigan. Registry information and application forms are available throughout the University and the Health System, its affiliated clinics, and community locations and are distributed at health fairs and community events. Large-scale recruitment efforts using print and radio advertising have been undertaken twice and with mixed results. These efforts are detailed in other publications.[9,10] For a relatively healthy woman with few chronic conditions, completion of the application form takes approximately 12–16 minutes and slightly less time for the online version, which has automatic skip patterns that keep nonapplicable questions from being displayed. Online applications are processed and immediately eligible for selection; paper surveys are processed by Registry staff (with IRB-approved database access) on the day they are received. For confidentiality and security purposes, paper surveys are destroyed once data entry is completed.

Each enrollee receives a letter confirming her registration, welcoming her to the Registry, and containing a refrigerator magnet with instructions detailing how she may update her entry in the event that contact information or personal health history changes. Potential participants and registered enrollees are also provided with a toll-free number connecting them directly with Registry staff in the event that they need personal assistance or wish to be removed from the Registry database. To maintain accuracy in participant records, enrollees receive a quarterly newsletter containing project updates, research findings, a reminder of the importance of regularly updating their Registry profile, and contact information for the facilitation of any necessary changes to their records. The newsletter also serves as a reminder/confirmation of enrollment for participants who recently have not met inclusion criteria for a trial or survey. Representations of subgroups of women by age, ethnicity, and education are tracked.

Investigator access

University of Michigan investigators may apply for access to participants in the Women's Health Registry database by submitting a completed Application for Use of the Women's Registry form to Registry staff. Completed applications include contact information for the applicant, a detailed description of the proposed research (including project abstract, type and length of study, peer review feedback, source of funding, IRB approval number, number of subjects needed), and a completed checklist of inclusion/exclusion criteria. Priority is given to Reg-

istry applications that illustrate the following qualities:

- Clinical research or investigations conducted solely on women or research that only enrolls women subjects
- Clinical research or investigations that assess the biological/physiological differences between women and men; a minimum of one primary research hypothesis will explore and evaluate the gender differences between women and men
- Clinical research or investigations that study health conditions that disproportionately affect women over men

Another available service of the Women's Health Registry is feasibility queries. Investigators preparing women's health research proposals may submit their inclusion and exclusion criteria to obtain information on the number of subjects in the Registry that could serve as potential subjects for the proposed research. In these cases, the Women's Health Registry provides a letter describing the Registry and documenting the results of the feasibility inquiry, which can be included in grant applications. This allows investigators to demonstrate adequate recruitment power for proposed trials.

There are no costs to the investigator for using the Women's Health Registry for subject recruitment or for feasibility queries. Standard operating procedures are in place and must be followed for all applications for access to Registry participants and processes, including feasibility queries, participant identification and enrollment lists for clinical trials, and health survey questionnaires. The Registry Advisory Committee is responsible for judging the appropriateness of applications and determining the number of subjects that will be released. Registry Advisory Committee members review applications for completeness, significance, and relevance to women's health and scientific merit. Applications without prior peer review are sent to two independent reviewers.

Creating the connection

The Registry has a dedicated data analyst who has exclusive, IRB-approved access to the participants' records. The analyst generates a list of subjects who meet the stated inclusion/exclusion criteria expressed in the investigator's approved application for use of the Registry database. Letters are sent to each participant identified as a match. The letter contains a brief description of the study for which the enrollee has met criteria and provides instructions on how the recipient may opt out of being contacted by an investigator by calling the Registry coordinator and stating her preference not to be contacted by the respective study's investigator. If contact with the Registry coordinator is not made within 2 weeks of receipt of the letter, the study investigator or recruitment coordinator will receive the contact information (not entire profile) and may contact the enrollee. Recent Health Insurance Portability and Accountability Act (HIPPA) regulations did not require procedural changes in this opt out mechanism.

Investigators are provided only a limited number of participants to contact at a time (50–100 women maximum, depending on the study design). Once a name is given to an investigator, that woman is removed from the pool of available participants. The investigators are required to provide monthly information regarding whether contact was made and whether the woman enrolled in the study for each potential participant the Registry provided. Those women who have been contacted and have not enrolled or who have completed a study are then replaced into the pool of available research subjects.

Cost and funding

There are many costs associated with starting and maintaining a Women's Health Registry, including personnel, information technology, web hosting, postage and printing, and marketing. The startup and initial year are the most cost-intensive phase, as database programmers, an enrollment coordinator, and faculty members in advisory and active capacities are all necessary. The key personnel needed to operate an established Registry are a coordinator and a database programmer. With annual salaries of $40,000–50,000 and $80,000–100,000 respectively, we estimate the personnel expenses for a full-time coordinator and part-time programmer (0.20 appointment) to be about $55,000–70,000 per year.

Marketing expenses are estimated at approximately $25,000 per year, but targeted campaigns to recruit minority or underrepresented groups have exceeded $50,000 per year.[9,11] Institutions lacking robust information technology infrastructures should expect high costs for starting a

registry. Fortunately, costs of housing the database itself, data redundancy, and technological capital were covered by the University of Michigan's basic technological services, and no additional expenses were incurred for these services.

The University of Michigan Center of Excellence in Women's Health was fortunate to receive four sources of support for the Registry to date. The first was a $35,000 startup grant to develop the Registry concept. This was a gift from Parke-Davis pharmaceuticals (now Pfizer) in 1997. The second source was Contract 282-97-0071, funded by the Office on Women's Health, Public Health Service, U.S. Department of Health and Human Services. The third source was RFQ 03T030042 from the Office on Women's Health to evaluate the Women's Health Registry in relation to minority women's participation in clinical research.[11] Finally, a private donor gave $10,000 in support of the outreach efforts to attract underrepresented communities to the Registry in 2002.

The approach taken by the University of Michigan was to attempt to reduce overall costs by using existing personnel, computers, software, and marketing resources. This was successful in the short term, but in the longer term, it is not a sustainable option. Institutional funds (hard budget) from the department of obstetrics and gynecology support the Registry coordinator, along with unrestricted development funds (soft budget) from the hospital (used for postage, printing, web hosting costs and so on) at varying rates each year. In addition, as part of an overall commitment to women's health initiatives at the University of Michigan, multidisciplinary collaborators in nonhospital departments, such as biostatistics, have supported the Registry through graduate research assistants who work as database analysts at no cost to the Registry budget. A similar arrangement is in place with the information technology division. Without such in-kind support, maintaining and improving the database would prove difficult to achieve without an extensive and sustainable budget.

Evaluation

In 2003, a separate IRB approval was obtained to collect information from the investigators who had used the Women's Health Registry for recruitment into research projects. A standardized open-ended interview was conducted with each investigator to determine expectations of the Registry and overall usefulness of the Registry. The approach used an interview guide that provides carefully and fully worded questions that are asked of every participant in the same way and in the same order, using standard probes. Each interview followed the script exactly, and none exceeded 60 minutes. Each interview was audiorecorded, with participant permission, and transcribed verbatim. The interview transcripts were compiled, and content analysis was used to organize the information and flag relevant themes.[12] The content was organized in chunks in Microsoft Word, and a summative evaluation was performed to assess the Registry as a recruitment tool and to gain better understanding of its value to this targeted group of users.

In addition, document reviews of the original investigator applications to the Registry (preinterview) and study enrollment progress reports (postinterview) were done as a means of checking accuracy of the interview responses and providing supporting documentation of the Registry's contribution to each individual project's subject screening and enrollment success. Each of these documents was available for the entire potential sample pool of eligible investigators, including the two nonresponders.

RESULTS

The Registry pool of potential research participants numbered 2436 women in July 2006. Demographic information for the women is listed in Table 1. African American, Asian, and Native American women are underrepresented compared with the regional population. The Registry population historically has mirrored population demographics for those who participate in medical research protocols at the University of Michigan but is not representative in terms of ethnicity, education, or health insurance status of the overall population of the region, state, or United States. As a group, these women are highly educated, have primarily private or HMO health insurance, and are mostly in good to excellent health.

In 2003, a total of 15 investigators had used the Women's Health Registry for recruitment into 31 clinical and health services research projects. Of this faculty, 9 were Medical School faculty, 3 were School of Nursing faculty, 2 were School of Public Health faculty, and 1 was a graduate student

Table 1. Characteristics of Registry Participants in 2006

Total enrolled	*Total 2436*	*% of Total*
Age, years		
18–34	897	36.8
35–54	973	39.9
55–69	410	16.8
70+	156	6.4
Race/ethnicity		
Hispanic/Latina	85	3.5
Non-Hispanic/Latina	2351	96.5
White/Caucasian	2053	84.3
Black/African American	208	8.5
Asian/Asian American	73	3.0
American Indian/Alaska Native	30	1.2
Native Hawaiian/Pacific Islander	5	0.2
Other	67	2.8
Education		
Postgraduate training	736	30.2
Bachelor's degree	733	30.1
Some college	713	29.3
High school diploma	146	6.0
Some high school	16	0.7
Less than high school	4	0.2
Other	87	3.6
No response	1	0.1
Health insurance[a]		
Private Insurance/HMO	2097	86.1
Medicaid	77	3.2
Medicare	235	9.6
Do not have insurance	87	3.6
Don't know/No response	0	0
Self-reported health status		
Excellent	465	19.1
Very good	1022	41.9
Good	699	28.7
Fair	203	8.3
Poor	37	1.5
No response	10	0.4

[a]Participants can record more than one response for health insurance; therefore, the total number of responses is more than the total number of participants.

in the psychology department, College of Literature, Science, and the Arts. Medical School investigators represented the departments of dermatology, geriatrics, family medicine (2), obstetrics and gynecology (2), internal medicine (2, rheumatology and cardiology). These 15 principal investigators were contacted to be interviewed, and 13 agreed to participate (88.7% response rate). The goal of the interviews was to assess the diversity of disciplines and projects that might benefit from the availability of a Registry of potential research volunteers.

These investigators enrolled 914 women who completed protocols for their projects. Women from the Women's Health Registry represented 36.4% (333 of 914) of the total enrollment. Each of the investigators interviewed reported the Registry to be a useful tool and expressed intentions to use the Registry for future projects. During the time period under evaluation, the Women's Health Registry had a total enrollment of 1155 women eligible for participation in studies (August 2003 database count).

The interviews revealed that for the most part, the Registry met the most frequently expressed expectations of the investigators. These expectations included that they would find subjects who met criteria and would receive contact information for potential participants and that participants would be eager and willing to participate and to complete studies. The expectation expressed most frequently, but not met by the Registry, was that it would provide greater access to the hard-to-reach population of menopausal women (both taking and not taking hormonal supplements) than other methods of recruitment. Although women in the 45–64-year age group accounted for 31% of the total Registry enrollment at that time, both investigators and personal health information in the database confirmed that the extent to which women had or were currently using hormonal supplements to control symptoms of menopause was very high, leading to incompatibility for participation in several of the studies undertaken by our sample of investigators.

Investigator interviews also revealed that the Registry increases the hit rate (number of people who enroll as a percentage of the total number of people contacted) for study coordinators. Three investigators compared their usual telephone hit rate, described as percentage of callers who qualify and enroll in response to fliers and newspaper ads, to the Registry hit rate during the evaluation survey. They each explained the need to contact two to six times as many contacts to yield the number of hits they experienced using the Registry. All reported that participants were "eager and willing," and per investigator reports, 95% of Registry women who met criteria were willing to enroll. Increased hit rates result in overall time savings, which translates into higher completion rates and greater likelihood of on-time and on-budget project completion. When speaking of higher hit rates, investigators credited the prescreening process (use of inclusion and exclusion criteria in the database search) and the fact that the pool of potential participants pre-

sented to the coordinators usually is knowledgeable about research practices and eager to participate.

Another aspect of investigator appreciation of the availability of the Women's Health Registry is in feasibility queries. Especially when a track record is lacking, feasibility query results offer investigators an opportunity to prove to potential project sponsors that a willing population of potential subjects who meet study criteria is available in the local geographic region.

At the time of this publication, the Women's Health Registry had assisted 45 women's health investigators recruit for 69 different projects.

DISCUSSION

The Women's Health Registry is successfully populated with women from the community and surrounding areas and is providing a valued service to a diverse group of women's health researchers at the University of Michigan.

When the Women's Health Registry began enrollment of women in late 1999, the UMHS was the only institution in the United States operating a research registry that was women-specific and open to all ages of adults, healthy or not.[9] The Women's Health Registry is also unique in that it collects detailed health history information on each enrollee and provides a search-and-match function that releases to researchers only the names and contact information for those women who likely will meet study criteria.

Based on the experiences of the Registry, on information in the literature on motivators and barriers to participation in research, and on feedback from investigator interviews, it is clear that recruitment is a local process.[13] Successful recruitment depends on many intersecting factors, most of which are locally determined. Transportation availability, population demographics, rapport with and trust within communities of potential subjects, and general or specific interest in medical research or science within the community are factors that are unique to a local environment and can be strong determinants of recruitment success or failure.[7,8] Thus, it is difficult to know the extent to which other institutions can expect to have similar experiences if they implement a tool similar to the Registry.

The Women's Health Registry was introduced to a community of women who were familiar with the sponsoring institution. The Registry was preceded by a 5-year history of extensive community outreach to women in the state of Michigan by the University of Michigan Women's Health Program (WHP) and its Women's Health Resource Center. During those years, the programs of the WHP and services of the Women's Health Resource Center, all of which were offered free of charge, reached over 70,000 women, primarily in the regional community but extending across the state. This history and cultivation of trust were probably instrumental in the success of the Women's Health Registry and the significantly positive response that it received. It is likely that the success of others who replicate the model will depend on the extent to which the sponsoring institution has invested in its communities of interest and built a sustainable relationship with its women clients and the general population of women.

Longer-term plans for the Registry, in addition to expanded enrollment, include greater outreach to the investigator community, expanded line of recruitment-related services, and enhanced community outreach and participant recognition activities. The immediate focus, however, will be on the continued and prioritized commitment to enrollment of potential research participants, especially those representing communities of minority, less educated, and older women (to address investigators' request for menopausal women). We also have recently begun working to incorporate the Women's Health Registry into a new and larger university effort to create a human subject database that will increase enrollment for all clinical research projects and that will secure long-term funding support for the Women's Health Registry.

The experiences of the University of Michigan Women's Health Registry have highlighted the success of this model implemented on a local level and in a defined population. Early indications demonstrate that this model would work equally well with a regional or national population, as long as the person-to-person interface remained a local pursuit. The possibility of developing a central repository for health profile information exists and has been explored. The challenge lies in the use of the information, the rules of access, and the maintenance of the relationship between participants and the database or model. The Women's Health Registry works well not because it is technologically sophisticated but because the participants are invested in

research as a means of improving women's health overall and have developed trust in the Registry team and in the University of Michigan. This personal touch and investment in the human side of the model were and remain the cornerstone of the Women's Health Registry's success.

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