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Recruitment Strategies at the Iowa Site for Parent/Infant Pairs in a Longitudinal Dental Caries Study

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Abstract

Background/Aims—Recruitment of parent/infant pairs can be more difficult and challenging than recruitment of adult subjects alone, as the parent has to consider themselves along with the infant to be study participants. In order to determine which recruitment methods most effectively resulted in accrual of subjects, recruitment efforts at the University of Iowa were evaluated, one of three clinical sites involved in a longitudinal prospective study of dental caries.

Methods—Enrollment goals were 300 parent/infant pairs within a year. Recruitment strategies included 1) a direct mailing to potential subjects who were University of Iowa Hospitals and Clinics patients and potentially met inclusion criteria; 2) face-to-face recruitment visits at medical offices; 3) provision of recruitment materials to staff at off-campus agencies and medical offices serving low-income individuals; 4) a campus-wide mass e-mail; 5) recruitment materials to daycare centers and neighborhood centers; and 6) recruitment at a children's museum.

Results—From these recruitment efforts, 515 potential participants expressed interest and were screened for this study and 348 (68%) were enrolled during an 11-month time period. The face-to-face strategy had the highest recruitment rate of 25%, followed by direct individual mailings at 9% and follow-up telephone calls at 7%. For the face-to-face strategy, the contact at the children's museum was most successful compared to the other office settings. The lowest rate of recruitment of 0.09% was attained with the mass e-mail. However, in terms of actual numbers recruited, the mass e-mail remained an important modality, since it yielded 21 recruits and was much less time-intensive.

Conclusion—An intensive, multi-pronged recruitment strategy proved successful in meeting enrollment goals and resulted in finishing the enrollment prior to the projected study deadline. Effective recruitment approaches are imperative for a study's success and each recruitment strategy needs to be budgeted and planned for in a study. Investigators may need to adapt their approach to attain the needed number of subjects. Planning needs to include the numbers needed

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to be approached to attain your recruitment goal, how you will recruit, who will be responsible, and the costs and time commitment for various strategies.

Keywords

Study recruitment; practice-based research network; family physicians; dental caries

Participant recruitment, the “process of screening and enrolling a predetermined number of subjects within a planned time,” is essential for successful research.¹ It can be difficult and sometimes is the most arduous part of the research process.^{2, 3} Recruitment of parent/infant pairs can be especially challenging, as the parent has to consider themselves along with the infant⁴ and, for research, infants are considered a vulnerable population.⁵ While the purpose of the larger parent prospective study is to develop and validate a dental caries risk tool to be used in primary care medical settings to identify young children at risk of dental caries, the purpose of this paper is to report on which recruitment strategies were most effective in accrual of parent/infant pairs at one clinical site, the University of Iowa.

Recruiting subjects in family physician offices or agencies that serve populations of interest for the research adds another level of recruitment complexity. For successful recruitment, the family physician and office staff need to be willing to have their patients involved in research and help facilitate recruitment.⁶ When recruitment is planned through offices or agencies, aspects that impact participation can include project topics, recruitment processes, office time demands, institutional requirements, resource limitations, scheduling of meetings, staffing, space, and time.⁷

Walson⁸ identified six steps in the recruitment process for clinical trials: 1) identify eligible patient population(s); 2) adequately explain the study to potential subjects; 3) recruit a representative sample; 4) obtain informed consent; 5) maintain ethical standards; and 6) retain subjects until completion of the study. Elaborating on the identified recruitment steps, additional steps are necessary to prepare for various settings: 1) identifying family physicians/agency administrators willing to participate; 2) educating the physicians/administrators and their staff about the study; 3) obtaining physicians'/administrators' written approval; 4) determining approaches for recruitment at each office/agency; 5) obtaining Institutional Review Board approval; and 6) arranging for staffing and materials and/or compensating the collaborating entities for their part in the recruitment.

Pediatricians and family physicians generally see infants and toddlers much more often in their first years of life than dentists do. The American Academy of Pediatrics and Bright Futures recommend by consensus that infants see a primary care provider 10 times for well-child checks and vaccinations by age two compared with a single oral health visit about 12 months of age.⁹ Thus, physicians can be important players in the interdisciplinary teams needed to prevent this disease of childhood caries. One approach to new models of oral health care is expanded partnerships with the medical community, which has great potential for reducing the large disparities in children's dental caries experience.^{10, 11}

To illustrate the variety of recruitment strategies that were involved to attain recruitment goals, the processes will be described and examined. This work could help others attempting to recruit parent/child pairs for other longitudinal studies.

Methods

The principal investigator and Data and Clinical Coordinating Center at the University of Michigan (Ann Arbor, MI) provide overall administration for the study. The universities conducting participant recruitment for this project were Duke University (Durham, NC), Indiana University (Indianapolis, IN), and the University of Iowa (Iowa City, IA). Each clinical site was selected because of its unique connection with a medical primary care practice-based research network which facilitated and enhanced potential participant recruitment. Institutional Review Board approval was obtained at all four universities.

In this study, infants received a dental screening examination and parents completed a questionnaire at recruitment when the infant was 12 months of age, with follow-up exams and questionnaires planned for ages 30 and 48 months. Recruitment was expected to be completed in a year. Power calculations for recruitment and retention projections for the multisite cohort study showed that 1,326 pairs of parents and infants 12 months of age (± 3 months) needed to be recruited across sites. The University of Iowa was to recruit 300 subjects from the projected 429 parent/infant pairs that would be approached. A monetary incentive was to be provided after each of three dental visits and eight intermediate follow-up telephone calls.¹⁵ Sites allowing in-person research assistant recruitment were provided a \$250 gratuity.

Recruitment strategies

Various approaches and sites for recruitment with target audiences were discussed during Iowa team meetings. Research team members met with various office/agency staff caring for infants, discussed the study's purpose, and explored various options for recruitment that would result in minimal disruption. The Iowa Research Network is a practice-based research network, and both Iowa Research Network and non-Iowa Research Network sites were approached. If the site was amenable, educational sessions were held to apprise all staff of the project and obtain input regarding recruitment. Letters of support were obtained and attached to the Institutional Review Board application for approval. Seven strategies were used over the course of recruitment: 1) recruitment mailings sent to University of Iowa Hospitals and Clinics (UIHC) patients; 2) face-to-face recruitment visits at the UIHC family medicine and pediatric clinics (two separate locations) and the local children's museum; 3) face-to-face recruitment visits at a Federally Qualified Health Center located 28 miles from Iowa City; 4) provision of recruitment materials to the administrators in the Johnson and Muscatine County Supplemental Nutrition Program for Women, Infants, and Children programs and the I-SMILE program held at the Women, Infants, and Children program in Johnson County, county Neighborhood Centers, daycare centers, apartment complexes, the UIHC Otolaryngology Clinic, St. Luke's Dental Health Center and the Hawkeye Area Community Action Program, Inc., which oversees Women, Infants, and Children dental and other programs in Linn County (adjacent to Johnson County, Iowa, where the University of

Iowa is located); 5) provision of recruitment materials to three UIHC outlying family medicine clinics, a pediatrics clinic, and five UIHC QuickCare Clinics; 6) a campus-wide mass e-mail; and 7) newspaper advertisement.

Using the UIHC database of potential subjects, a cover letter, study flier, and postage-paid return postcard were mailed to the potential participants. A postcard was included in the mailing for the potential participant to indicate interest and to be contacted to arrange a study visit. There was no further contact with individuals who did not return a postcard. Information collected on the postcard included the date, parent's full name, child's full name, home telephone number, cell telephone number, address, e-mail, and convenient time to contact them.

For the face-to-face visits at the pediatrics and family medicine clinics, a part-time research assistant reviewed the clinic schedule list for potential participants in order to try to meet the parent, provide a brief introduction to the study, and give them a flier and postage-paid return postcard. If they were interested, they could fill out the postcard and return it right then or later in the mail. For the Federally Qualified Health Center site, a part-time research assistant was stationed in the waiting room during peak parent/infant visit times.

At the two Women, Infants, and Children clinics, personnel placed the study information in the financial assistance packets that were picked up by clients every three months. Starting in the fourth month of recruitment, a research assistant waited in the waiting room at the local clinic at peak parent/infant visit times to explain the study. In adjacent Linn county, at the St. Luke's Dental Health Center and Hawkeye Area Community Action Program, Inc., which oversees Women, Infants, and Children dental and other programs, the dental hygienists agreed to hand out recruitment fliers and postcards to eligible potential participants.

Recruitment materials were given to staff at the three outlying UIHC family medicine clinics and five UIHC QuickCare Clinics. The same flier was used for all recruitment. The administrators at the different sites chose the disbursement strategy for the recruitment materials.

The Iowa Department of Human Services licenses child care centers and maintains an online registry of licensed child care centers that includes the name and address of the provider, provider capacity, and age range for services. After reviewing the age categories for each daycare, centers in six counties near the University of Iowa providing care for infants less than 15 months of age were selected. An information letter and fliers with postage-paid return postcards attached were sent to the administrators of those daycares. In addition, fliers were taken to the managers of two large apartment complexes in the area and the two local Neighborhood Centers.

The Otolaryngology Clinic at the UIHC has a high number of infants having myringotomy tubes placed, thus providing a potential pool of study subjects. Fliers were given to potentially eligible participants as they checked in for their appointments.

University of Iowa Information Technology Services provides a mass e-mail service for study recruitment, defined as any single or group of identical e-mails that goes to more than 1,000 individuals. After Institutional Review Board approval of the specific script for the e-mail text, an online application form was completed to inform IT of the request and to identify the target audience of approximately 22,000 faculty, staff, and graduate students.

The local children's museum's hosted the study staff twice when the theme for the month was children's dental health. On the last Friday of the month, the entry fee is waived in the evening hours, resulting in large numbers of families in attendance. The Executive Director supported the idea of recruiting subjects and conducting dental examinations there. A table for recruitment was placed at the entrance to the museum and a private room was provided for the dental examinations to be conducted on site.

A paid advertisement was placed in three nearby small town newspapers. The advertisement ran for a week at a total cost of \$105.

A physician and some of the staff at one Iowa Research Network UIHC outlying family medicine office were fluent in Spanish and see a large number of Latino patients. The study materials were translated into Spanish by the Translation Department Manager of the University Translators Services at the University of Michigan. Staff at the clinic called potential subjects and invited patients, with emphasis on those fluent in Spanish, to come to the clinic to enroll in the study and complete the baseline dental examination.

The I-SMILE infant oral health program at the Johnson County Public Health Department provides oral screenings, fluoride varnish applications, oral hygiene instruction, dental nutrition counseling, and referral services. A direct mailing was sent to I-SMILE program participants who had signed a release to be contacted about research and who had infants in the eligible age range.

In the seventh month of recruitment, an Institutional Review Board modification was submitted to allow up to four follow-up telephone calls to be conducted after the UIHC direct mailing as another strategy to increase recruitment. Recruitment calls were made to 347 persons, stopping before calling everyone, as the recruitment goal had been met.

Data tracking and analysis

A database was created using Microsoft Access (Microsoft Corp., Redmond, WA) to track participant recruitment, contact information, and study appointments. As each postcard was received from a potential subject either through a face-to-face visit or the mail, a screening number was assigned. The screening number, approach date (either the date of the mailing or date met at a clinic), recruitment strategy, and location were entered into the database. In addition, the child's demographic information was entered, along with the parent's demographic and contact information. Once a potential subject/parent came in for the age 12 month baseline dental exam, informed consent was administered, the subject was considered enrolled, and they were assigned a unique study identification number.

The term "contact" is used when a potential subject received communication about the study, either through a flier, direct mailing, or face-to-face meeting. Screening for the study

included review of the inclusion/exclusion criteria to make sure infants were eligible for the study. Enrolled meant the subject/parent met the inclusion criteria and informed consent was obtained. The percentage yield was calculated as the number of individuals enrolled divided by the number contacted. Determination of the infant's eligibility based on age was built into the database. Once the birthdate was entered, a built in calendar displayed the date range allowed for the baseline visit, which was from three months before to three months after the first birthday.

Potential subjects approached with various recruitment strategies were not mutually exclusive. For example, some subjects who received a mailing as a patient of a clinic were also approached in the waiting room of that clinic. Because the subject's recruitment strategy was not mutually exclusive, there was potential overlap of recruitment strategies, and the chi-square test was not valid for comparison of recruitment methods. However, only the strategy by which the person was successfully recruited was recorded in the database, and all other strategies were not tracked in the database.

The main recruitment strategies for which we have information for comparison of recruitment percentages are the UIHC and Women, Infants, and Children direct mailings; the mass e-mail to University of Iowa faculty, staff, and students; face-to-face contact at the Federally Qualified Health Center, Women, Infants, and Children, and UIHC Family Medicine and Pediatrics offices; and fliers provided to daycare and neighborhood centers or at family physician offices.

Results

From this intensive recruitment effort during 11 months, 515 potential participants expressed interest and were screened for this study, and 348 (68%) enrolled (See Table 1). During this period, 1,354 recruitment letters were mailed to individual UIHC patients and 70 letters were sent to Johnson County Women, Infants, and Children participants. In an attempt to reach parents using daycare centers, the administrators of 52 daycare centers caring for children aged 15 months or less were mailed 1,164 fliers and postage-paid return postcards. After calling two local Neighborhood Centers, the administrators were each sent 50 fliers to display on an information table. Twenty-six other agencies/offices were provided an in-service education program about the study and materials for recruitment. The 550 fliers left at the apartment buildings, trailer courts, food banks, otolaryngology clinic, Federally Qualified Health Center receptionist desk, and children's museum generated no inquiries for the study.

Recruitment started in early November 2012 and, after three months, 89 potential participants had expressed interest in the study. Seventy-eight of those 89 potential participants eventually were enrolled in the study (See Figure 1). Forty-one of these enrolled in the study within the first three months and the remaining 37 enrolled in the study by August 2013, due to having to wait to meet the minimum age criterion. Iowa's recruitment goal of 300 was met nine months into recruitment (See Figure 1). Other sites were behind in meeting their respective recruitment goals, so this site gained Institutional Review Board approval to recruit additional participants.

A summary of the main initial recruitment methods used and numbers of participants contacted, screened, and enrolled shows that the face-to-face recruitment method had the highest percentage yield at 22% (See Table 1). Four part-time research assistants individually approached approximately 500 persons in clinic waiting rooms and 258 of those completed a recruitment postcard, with 247 eligible for the study. Each face-to-face method was slightly different. At the Federally Qualified Health Center, the research assistant placed a stand-alone 11" × 17" poster on a table in the waiting room and waited for parents and children to come and sit in the waiting room. If a child appearing to be the appropriate age or younger was present, the adult was approached and told about the study. In contrast, at the UIHC Family Medicine clinic, the office visit schedule was reviewed each morning. The research assistant approached potential participants without disrupting the office flow. The schedule included the child's name, age, and time of appointment. A few minutes prior to the appointment time, the research assistant went to the waiting room to approach the appropriate person. If a person was late for their appointment, the research assistant waited until they arrived. At the Hawkeye Area Community Action Program site, two dental hygienist employees provided fliers to their clients having dental exams and encouraged participation, but were not involved in the consent process (See Table 1). Their relatively high percentage yield (32%) reflected their enthusiasm for the study.

Direct mailings resulted in the second highest percentage yield, with a 9.1% rate on the 1,424 direct mailings (See Table 1). Adding a recruitment call to non-responders after the UIHC mailings gave a 7.2% return for the call. The mass e-mail was distributed on campus to approximately 22,000 persons one time, with a percentage yield of 0.09% (See Table 1).

Thirteen recruited subjects were not able to be accounted for by the listed study recruitment methods. For example, a study subject told a friend about the study and the friend called to determine eligibility and enroll. Another example was that one subject took fliers to hand out at her child's birthday party.

Discussion

Multiple strategies were used for alerting people about this study, with a total of six different main approaches used: direct mail, face-to-face, mass e-mail, fliers in offices or other public areas, newspaper advertisements, and post-mailing recruitment call. Most methods were labor-intensive.

Cooperation of the participating agencies/office staff was important to the success of our recruitment. It was effective and efficient at some sites to have dental staff facilitating the recruitment. In another study where primary care offices were the first line for recruitment, researchers noted that having their office in close proximity to the study was important.¹² Our dental study was limited to areas close to where the research team's dentists were located because of the dental examination required as part of the study. Another factor Margitic and colleagues noted that seemed to facilitate recruitment was knowing the office staff had participated in previous studies and had an interest in their respective study.¹²

In Margitic and colleagues' study, the patient mailing effort recruited 43% yield of subjects and the office-based questionnaire recruited a 33% yield, whereas the physician recruitment was the least successful at 1%.¹² Our study findings were different from theirs, as we did not have physicians recruit potential subjects and both studies realized an additional telephone call to recruit subjects is to labor intensive.

The face-to-face recruitment method was successful in terms of actual numbers of subjects enrolled in the study, but it also was the most time-consuming. At the site out of town, the research assistant spent 82 hours during a 4-month time-period, not including the 45 minute travel time each way to the clinic.

The mass e-mail recruitment was successful in terms of balance between the time invested and the actual number of subjects recruited for the study. It was used one time, but for other studies a mass e-mail could be used a number of times over a longer recruitment period. This strategy required the least amount of time and probably accrued the most subjects per unit of time involved. Twenty-one subjects were successfully recruited from this effort. In that regard, the return was excellent and boosted enrollment significantly, but the recruitment percentage yield for this method was low at 0.09%, as most of the e-mail recipients were ineligible to participate. It was not possible to target the e-mail to individuals who might have an eligible child, so we do not know the percentage of those with eligible infants who responded to the e-mail. It took less than a week to recruit the 21 subjects and schedule them for a dental examination in comparison to many dozens of hours of contact face-to-face over a four month period to recruit 14 subjects at the Federally Qualified Health Center. Researchers note that, for successful recruiting of children, partnering with health care professionals in pediatric settings can be more effective than mass advertisements, mailings, or posters.^{5, 13, 14} The Inventory of Best Recruitment Practices suggests fostering relationships with families and enhancing the environment for recruitment.¹⁴

We met with practitioners prior to the study; however, because they were not research team members, they could not actively recruit, but only refer potential subjects to material about the study. Another study used similar methods to engage subjects as this study.⁶ The clinical trial recruiting postmenopausal women initially used family physician recruiters to provide information and referrals in office settings.⁶ Finding limited success with family physicians recruiting subjects, other methods were added, including community presentations, newsletters, direct mailings, posters, and newspaper advertisements. The majority of enrolled women, 141 of 197, were recruited from 25 paid newspaper advertisements in the Toronto area at a cost of \$113/subject.⁶ With no budget allotted for paid newspaper advertisements for this study, the one week advertisement in three small town newspapers was all that was done, and it was unsuccessful. However, the content areas of the studies and ages of subjects make comparison of recruitment endeavors difficult across studies.

In the eighth month, the telephone recruitment calls were conducted to boost Iowa's enrollment. In the eleventh month, when Iowa had reached its initial enrollment target, calls were made to enhance total enrollment and compensate for the other two sites (Duke University and Indiana University) being behind in meeting their recruitment accrual goals. The recruitment call yield was slightly lower than for the actual mailing.

In a Cochrane review of strategies to identify methods to improve recruitment for randomized controlled trials with interventions, investigators found for 45 trials that telephone reminders to non-responders, use of opt-out procedures rather than opt-in, inclusion of financial incentives, and open designs where the participant knew the treatment they would be receiving were successful.¹⁵ Our study was similar to the studies in this Cochrane review in that it was longitudinal, included an examination known by the participant, and provided financial incentives. In another systematic review comparing direct contact (letters or telephone calls) to medical referral, it was found that adding monetary incentives increased recruitment between 4% and 23%.¹⁶

A limitation in recruitment efforts was that none of the research staff were fluent in Spanish. The Center had study materials, informed consent documents and baseline questionnaires translated. The staff at the Iowa Research Network site whose medical director and staff were fluent in Spanish became certified in human subjects procedures, called potential subjects and arranged scheduling for enrollment and dental exams at their office on a specified day. This effort involved three of the office staff, four research assistants, a family physician, and the dentist to enroll and examine eight subjects in a morning session involving approximately 36 person hours. It was efficient in that the session was successful with enrollment of 8 subjects.

A unique recruitment endeavor was the arrangement at the local children's museum housed in a large, local mall. At that site, recruitment, consent, and the first dental visit were conducted at the same time. It was an intense effort to have most of the research team participate in the 3-hour evening session with some team members recruiting, others consenting, and the rest conducting the dental examinations, recording the examinations, and making sure questionnaires were completed.

Strategies that augment recruitment and have minimal cost are important for all studies. Our efforts suggest that face-to-face recruitment could be the most effective strategy; however, it was much more time- and resource-intensive compared to the other methods. While the mass emailing strategy produced the lowest yield, it remains a useful modality, as it yielded a moderate number of subjects, while requiring modest time commitment and resources. The effect of resending the mass e-mail is unknown if similar recruitment results would have occurred.

A multi-pronged recruitment strategy proved successful in meeting enrollment goals and resulted in finishing the enrollment prior to the study's projected deadline. Planning for recruitment and including a multi-pronged strategy is, thus, an essential component of a good proposal.¹⁷ Effective recruitment strategies and resources are imperative for a study's success, along with careful tracking of enrolled participants. Investigators must budget appropriately for recruitment. Study recruitment is a major component that, if not done effectively and efficiently, can delay the entire study. These results seem to confirm that personal contact is important for recruitment. As noted in this study, the face-to-face recruitment strategy was successful and the follow-up telephone calls boosted enrollment.

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Figure 1.
Two-Week Cumulative Enrollment Goals for Iowa Site — Targeted vs. Actual.

Table 1

Numbers of Subjects Contacted, Screened, and Enrolled by Method and Site.

Recruitment Method & Site	Contacted	Screened	Enrolled	Effective Yield (Percentage)
Individual Mailings				
Johnson County Women, Infants, and Children Individual Mailings ***	70	0	0	0
UIHC Individual Mailings	1,354	159	131	10
Total Individual Mailings	1,424	159	131	9.19
Fliers				
Daycare Fliers	52 sites ** 1,164 fliers	5	5	0.4
Neighborhood Centers Fliers	100	2	0	0
Women, Infants, and Children Fliers at 2 sites	1,100	13	5	0.5
UIHC Fliers	1,020	14	12	1
Total Fliers	3,384	34	22	0.07
Face-to-Face				
Children's Museum	25	15	15	60
Federally Qualified Health Center	66	24	14	21
Johnson County Women, Infants, and Children	~200	103	50	~25
Hawkeye Area Community Action Program Face-to Face with Dental Hygienists at 1 Site	123	87	39	32
Neighborhood Center Mother Support Group Meeting	12	3	3	25
Dental Health Center	71	11	5	7
UIHC Family Medicine Office	~55	6	4	~7
UIHC Pediatrics Office	~75	9	6	~8
Total Face-to-Face	627	258	136	21.69
Mass Email				
Mass e-mail	~22,000	24	21	~0.09
Recruitment Call				
Recruitment Call after UIHC Mailings	347	40	25	7.20
Total All Recruitment Methods	27,782	515	335*	1.20

* The total enrolled was 348; column total enrolled 335, with the remaining 13 recruited by other methods.

** These numbers are the numerator of daycare administrators who received fliers to hand to parents and total number of fliers delivered to the sites, but it is not known if they were given to the parents.

*** The direct mailing and face-to-face recruitment overlapped for some individuals.