

CUSTOMER SERVICE

The Key to Successful Recruitment and Retention in Clinical Research Programs

Despite scientific community motivation and federal incentives¹, recruitment and retention of research participants, particularly infants and young children, continues to be a basic dilemma for investigators. The process of enrolling and retaining subjects is complicated by:

- dwindling recruitment budgets,
- increasing costs of retention with a mobile society,
- continuing skepticism about research, particularly from minority/vulnerable populations, and
- difficulty in establishing and maintaining positive relationships with feeder clinics and primary care providers (PCPs).

Workgroups and conferences continue analyzing and proposing techniques for recruitment and retention success. Nonetheless, reaching established goals remains elusive.

This article offers a case study perspective about a successful clinical research recruitment and retention effort for a cohort of approximately 300 pediatric subjects at the University of Wisconsin—Madison (UWM), giving particular emphasis to “customer service” aspects of this research effort.

The Childhood Origins of ASThma (COAST) study is an NIH-funded prospective, longitudinal, epidemiological birth cohort investigating the origins of childhood asthma, located at UWM and approved by the Health Sciences Institutional Review Board of UWM Medical School. To address the primary research hypothesis adequately, COAST needed to recruit a sample size of at least 180 newborns within a one- to two-year time frame, and retain the children until they reached at least their sixth birthday. Remarkably, COAST successfully enrolled 312 high-risk children (one or both parents had to have diagnosed allergies or asthma) prior to their birth, from which 287 were retained as the original COAST cohort after meeting birth criteria (at least 36 weeks gestation, no congenital defects) and cord blood collection requirements.

The foundation for both recruitment and retention strategies for COAST was, and is, the application of the same “customer service” principles that have allowed businesses to be successful in building and maintaining clientele. Customer service is defined “as increasing client satisfaction through continuous concern for client preferences, staff accountability to clients, and respect for the rights of clients.”² The COAST staff maintained that the “customer (participant) always comes first” and responded to the understanding that

“today’s society expects and demands immediate service, results and access to information.”³

Recruitment Overview

COAST, based at the UWM Medical School, was challenged by the fact that the university hospital does not have an obstetrical department. Partnerships with affiliated and non-affiliated hospitals and their physicians, clinics, and nurses were critical to achieving recruitment of subjects and recovery of necessary data and samples. During the course of recruitment, the COAST subjects and their families were cared for by 98 obstetrical practitioners, certified nurse midwives, and family practitioners.

The COAST staff answered study information inquiries from 526 families. Subsequently, 160 families decided not to participate, and an additional 54 did not participate because they contacted the study after recruitment was closed. Reasons for nonparticipation are shown in Figure 1; length of study and fre-

quency of visits, blood draws, and nasal mucus samplings were significant considerations [n=53 (23%)].

Retention Overview

COAST was originally funded as a four-year grant to recruit and follow subjects for the first three years of life. In 2002 COAST II was funded as a Program Project Grant to follow the same subjects from age three through seven years. Of the 287 subjects who met original inclusion criteria, 278 completed the first three years of the study (96%); 267 agreed to participate in COAST II (93%); and 262 (91%) remained in the study at age six.

During the six years of the research, the subjects and their families have lived in six different countries and more than 20 different states. Not only have these families been retained in the study, they have been active participants by completing

- 99% of the 2,565 scheduled study visits in the first three years,

- 93% of the nasal washes during an illness (this data verified by complete medical record reviews), and
- 93% of the 1,670 blood draws scheduled for the first three years.

The COAST subjects have subsequently agreed to participate in ancillary studies relating to obesity and asthma⁴ and environmental and immunologic exposure (T-regulatory cell number and function) studies⁵.

Recruitment Strategies

Identify and Educate the Recruitment Team

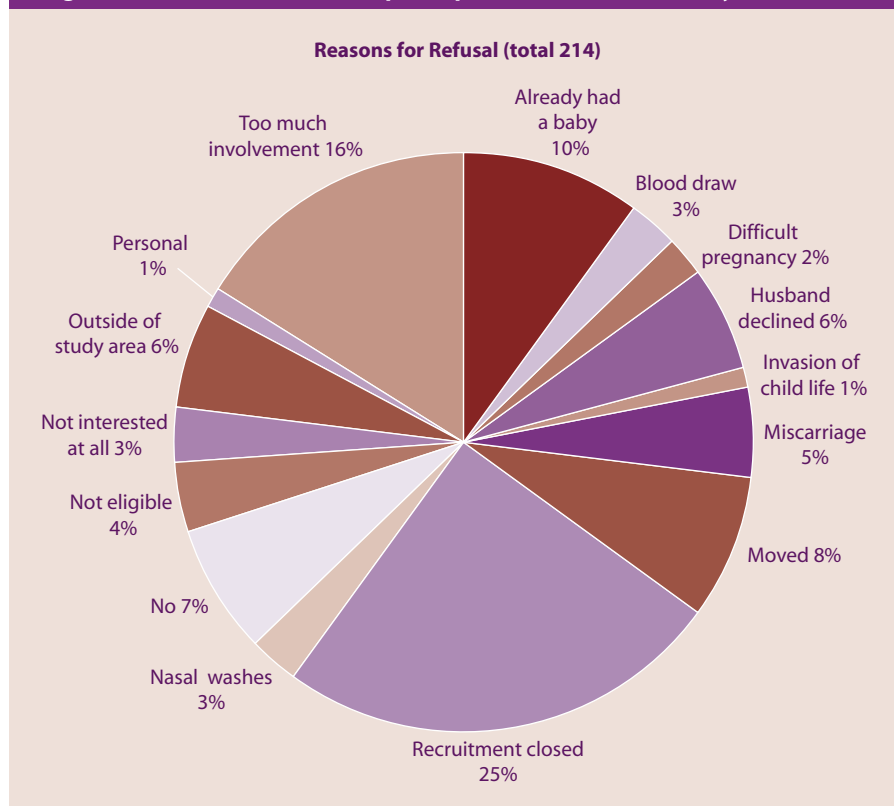
The COAST staff (originally 1.5 RN, 1.0 lab, and .4 student help) identified that the first focus of recruitment was to expand the team of recruiters, that is, the obstetrical and family practitioner physicians and clinic staff that, in the process of seeing their patients, would be able to present the COAST study. Although these were not the subjects of the study, the same principles of customer service were applied throughout this stage of the recruitment process.

A key to the success of this team development was establishing personal relationships with potential referring physicians. The principal investigator and nurse coordinator traveled to all potential referral sites to

- present the research objectives,
- discuss the role of the children and families in the study, and
- personally request that the physician or nurse inform families about the COAST study and hand out brochures.

These professional educational presentations occurred at the convenience of the “inviting” professionals, were kept brief, and, because they were frequently during a meal or break time, were often accompanied by a snack. Being brief and organized were methods for demonstrating respect and the “simplicity” of their involvement in COAST project. Educating the referring physicians as to their involvement in the study, specifically the

Figure 1. Reasons Given for Nonparticipation in the COAST Study



time commitment, was a key element for successful recruitment.

Recruitment of Subjects: Generating Interest in the Study

There are obvious considerations relative to recruitment of children of pregnant women: The unborn child as subject is consented by an unusually busy woman experiencing life changes. Targeting this audience required unique marketing skills. Having trusted health care professionals approach potential subjects about the study during regularly scheduled visits was a significant draw to the study for nearly half (48%) of COAST participants. Subsequently, meeting families at follow-up OB appointments to discuss the study was a clear demonstration of respect for the family's time. Newspaper, flyers, and media discussions were motivators for 35% of consenting families.

Once families contacted the COAST staff, finding a "selling point" for the study that was relevant for each patient was also important. Given that the cohort was high-risk and that family members by inclusion had allergies and/or asthma, obtaining knowledge was and continues to be a significant motivator for family participation. The fact that they could be contributing information to positively affect disease outcomes was also strong incentive for participation.

Retention

Retention of Recruiters

With recruiting teams in place, COAST was challenged to maintain these teams during the time it would take to recruit more than 300 families into the study. To this end, COAST developed an advisory board, comprised of key OB and primary care providers, and met with them quarterly to discuss the progress of the research and to ascertain and/or assure smooth interface with their clinics and staff.

COAST found that an important incentive motivating the professional staff to continue to support the COAST

project was feedback relative to both individual subject participation (for example, results of nasal wash cultures) and overall study results (for example, publications). In addition, as we completed milestones along the path of recruitment (that is, 100 babies were born, 150 babies were born, recruitment completed, first baby turned one year old, all babies were born), we acknowledged the efforts of the professionals by celebrating these milestones with cards and cakes delivered to the clinics and hospitals.

Retention of Families

COAST recognizes that the study children and their families are busy people with priorities other than COAST. Therefore, the COAST staff is constantly developing mechanisms in order to meet family needs by providing

- flexibility to meet their schedules,
- reminders that coincide with important activities in their lives,
- nonfinancial incentives that provide value to them, and
- indications that the staff respect them and their gift of time to COAST.

The following paragraphs elaborate on these steps, which were critical to translating consent into successful retention.

Visits during the first three years of the study were planned to coincide with well-child visits; to minimize parental time, the principal investigator and staff decided to modify the protocol and conduct these visits at the office of the PCP (113 MDs initially). Thus the COAST staff traveled, and the subject/family did not need to make an extra trip.

The first three years also included obtaining a sample of nasal mucus at the time of all significant respiratory infections (n=1,556). These visits were often conducted in conjunction with a sick visit to the PCP or as home visits. The visits to the PCP's office yielded a secondary benefit of maintaining communication with the primary providers, and thus the MDs/RNs would remind fami-

lies (at other visits) to contact COAST concerning a child's respiratory illness.

These scheduled study visits in conjunction with well-child exams were beneficial to all concerned. Although it meant that the COAST staff traveled, there was no study room set-up or clean-up time. The COAST staff were seen as being very considerate of the family's time by complying with their schedule. Because they were actually in the room during the exam, the COAST staff often provided child care so that mom could uninterruptedly discuss health care with the PCP. Also, by being in the room with the family, the COAST staff could learn more about the child's physical exam and could ensure proper communication between the clinic and the COAST study records. Further, because the COAST family would get reimbursed for their "study visit," families were motivated to comply with their well-child exam schedule, and the clinic providers appreciated this.

Home visits to collect nasal samples were a surprisingly valuable retention tool for the COAST study. On annual satisfaction surveys parents cited specific reasons for valuing the home visits, including increased knowledge about their child's specific viral illness, symptom relief in their child from the nasal washing procedure, and, most of all, added peace of mind in knowing that a health care professional was evaluating their ill child.

Once the children started to reach their third birthday, the decreasing frequency of the study visits (annual) and the type of procedures being conducted (skin prick testing and pulmonary function testing) required that the "study visits" be conducted at the university hospital and clinics General Clinical Research Center (GCRC). Arrangements for visits were made by phone contact with families. When families did not come for an appointment, the COAST staff telephoned them with a non-offensive message, such as: "We had on our calendar that we were going to do your child's annual COAST visit today. We must have gotten it wrong on our calendar, or maybe a problem came up

that prevented you from coming in. We hope that everything is okay with you. Please give us a call and we will be happy to reschedule.”

Unlike a clinic appointment where the responsibility to make and keep an appointment is for the benefit of the patient, a research study visit is for the benefit of the research project. Therefore, it is the study staff’s job to make it as easy as possible for the participant to attend appointments; when appointments are not kept, study staff must seek a way to make it even more convenient for the participant to attend the visit in the future. COAST staff often tells the research families that it is *our* job to keep up with the schedule of the study, and it is *their* job to raise their child.

When conducting visits at the hospital’s GCRC, COAST staff take several steps to ensure that the visits (usually a minimum of two hours) are as time efficient as possible. The first important step of the process is to meet the family in the lobby and walk them to the study room. Although this may involve some wait time, the side benefit of the trip upstairs with the family is that the conversation in the hallway must obviously be about casual things of interest to the child such as school, playthings, playtime, pets, teachers, elevators, siblings, or friends. Thus, a relationship based on comfortable topics is established upon arrival at the study room, and the visit can commence immediately.

The visit is conducted with two staff in order to have questionnaires being completed with the parent and procedures being completed with the child participant. Student staff is utilized to entertain nonparticipant siblings to release the parent from the distraction of caring for them, thereby facilitating timely completion of the paperwork and provide for a visit that is as nonchaotic and enjoyable as possible.

Finally, the COAST staff again walk the family back to the hospital entrance. This “saying good-bye” is perceived as a kind assist (by helping carry items, getting parking ticket stamped for free, giving the children a hug, and finding the

front door), but it also serves the purpose of summarizing the visit, reviewing the schedule for a return visit, and reviewing the need for calling concerning any respiratory illness of the child. Most importantly, this trip maintains a relationship with the family

Education has become a cornerstone of the project, especially after satisfaction surveys identified obtaining knowledge about allergies and asthma as a primary motivator for continuation in the study. COAST provides a newsletter to participant families, a Web site with updates of recent publications and new staff members, semiannual reunions that include entertainment for children (such as a gymnastics party or a day at the park) while parents can talk with the staff and the principal investigator, and informal teaching at study visits or by phone. Parents know that they can call and ask staff questions and obtain information, often in preparation for a conversation with their PCP, in order to assure that they remember to discuss issues relevant to their child’s health.

Conclusions

Dr. Leonard Berry, distinguished marketing professor and researcher of healthcare delivery systems, has stated that the “‘soul’ of healthcare service is better customer service” and goes on to say that “keeping promises meets [participant] expectations, but pleasant surprises exceeds them.”⁶ The objective of this article was to present a case study of a successful clinical research recruitment and retention effort. The COAST study implemented a recruitment and retention process based on education of all participants and “service” to participants by COAST staff.

The initial consent for participation can be translated into “I will do this”; successful ongoing consent is translated into “There is value in doing this.” COAST subjects have continued to participate in this study for more than six years because they believe that their participation is important. Given the changing nature of wheezing and asthma, the ideal continuation of the COAST proto-

col would follow this cohort through adolescence and young adulthood. COAST has had excellent (91%) retention through the first six years; by applying principles of “better than expected service,” COAST has a goal of 82% retention through age 17.

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