Lessons Learned From a Pilot Study on the Health Status of Children From Itinerant Populations

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ABSTRACT

The pilot study is used to guide development of a research design or to test an already developed plan; however, results of pilot work often are not reported. Pilot work can yield many valuable lessons and provide investigative training to the principal investigator and as well as evidence to funding agencies that the research is feasible and worthwhile. The pilot study described here is preliminary work on health disparities in two itinerant populations: carnival and migrant farmworker children. This pilot study had three aims: (a) identify the most productive methods to recruit subjects from these two "invisible" populations; (b) test feasibility of the research protocol; and (c) collect preliminary data on the children's health status for future research proposals. J Pediatr Health Care. (2006) *20*, 253-260.

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A pilot study is a critical step in the research process that yields information on both process and potential outcomes that is applied to the conduct of a larger study. Pilot studies are used to test the feasibility and logistics of a research protocol with a small sample or to field test a questionnaire or research instrument with a specific population (Teijlingen & Hundley, 2001). Pilot studies also help refine methodology and give the researcher experience with subject recruitment techniques, measurement methods, data collection, and analysis (Burns & Grove, 2001). However, published pilot studies rarely include a report of the practical problems encountered by researchers that resulted in improved research design and protocols (Teijlingen, Rennie, Hundley, & Graham, 2001). Reports on these "lessons learned" could be invaluable to other researchers as they design similar studies.

BACKGROUND OF THE PILOT STUDY

The pilot study reported here concerns the health status of children from two groups of itinerant families: migrant farmworkers and carnival workers. Quality pediatric health care necessitates developing knowledge about marginalized populations and making them visible (Meleis & Im, 1998). *Healthy People 2010,* launched by the United States Department of Health and Human Services (USDHHS), targets objectives for improving health promotion and disease prevention and eliminating disparities among vulnerable populations (USDHHS, 2000). One objective is to close the gap in access to care and health status indicators. Leading indicators of success toward meeting that goal for children include immunization rates, oral health, and weight and body

fat within normal limits (US-DHHS). More recently, health-related quality of life (HRQOL) has appeared as an outcome of interest (Varni, Burwinkle, Seid, & Skarr, 2003; Varni, Seid, & Kurtin, 2001; Varni, Seid, & Rode, 1999). Well-being often has been equated with quality of life (QOL) and is an attempt to describe how well or poorly one's life "works" at a given point in time (Meeberg, 1993; Muldoon, Barger, Flory, & Manuck, 1998; Newacheck, Hughes, Hung, Wong, & Stoddard, 2000; Wallander, Schmitt, & Koot, 2001). QOL is a holistic concept that includes daily functioning, perceived well-being, and mental and physical health (Muldoon et al).

Approximately 4.7 million children younger than 18 years have at least one unmet need for health care annually, and this number increases three to five times if they are near-poor, poor, or uninsured (Newacheck et al., 2000). Nationally it is estimated that there are 3 to 5 million seasonal and migrant farmworkers; 51% are parents, 66% of whom travel with their children, resulting in an estimated 500,000 children migrating with their parents every year (National Center for Farmworker Health Inc., 2004; United States Department of Labor, 2005). A survey of migrant farmworker children revealed that 73% were uninsured, 53% had an unmet need for health care in the past year, 34% had never had a well-child examination, and 79% had never had an evaluation by a dentist (Weathers, Minkovitz, O'Campo, & Dierner-West, 2003).

Annually, nearly every county and every state in the United States holds a fair, which requires contracts with outdoor amusement companies. Because carnival workers are itinerant and relatively invisible, they engage little attention or concern from either the public or health care providers. The number of children who travel with their families on the carnival circuit is unknown. Similar to children of migrant farmworkers, children of carnival workers may lack a primary "medical home" and may lack consistent delivery of preventive health care. No studies have reported on their health status or health care needs.

This pilot study had three aims: (a) identify the most productive methods to recruit subjects from these two "invisible" populations; (b) test the feasibility of the research protocol; and (c) collect preliminary data on the children's health status for future research proposals.

FRAMEWORK, DESIGN AND METHOD

This study was guided by the Determinants of Health Model postulated by Evans and Stoddart (1990). The model distinguishes among disease, health, function, and well-being as it embraces the World Health Organization's (WHO) classic definition of health as a state of complete physical, mental, and social well-being and not merely the absence of disease or injury (WHO, 1948). This study incorporated five of the nine model constructs: social environment, physical environment, health and function, health care, and well-being, which are interrelated and codependent.

A cross-sectional design was used to test the following hypotheses: (a) children of migrant farmworkers will have better health status indicators compared with the children of carnival workers, suggesting greater access to health care; and (b) children of migrant farmworkers and carnival workers will have poorer health status indicators than national or community samples of children. Health status indicators used as outcomes in this study included: (a) children's adherence to the American Academy of Pediatrics (AAP) schedule of immunizations and well-child examinations (AAP, 2004, 2005); (b) dental health status per age-appropriate guidelines established by the American Dental Association (2004); (c) growth parameters and body mass index (BMI)-for-age percentiles per Centers for Disease Control and Prevention growth chart standards (2004); and (d) perceived QOL based on parent/proxy and/or child self-report, depending on the age of the child.

AIM # 1: LESSONS LEARNED ON RECRUITMENT OF SUBJECTS FROM "INVISIBLE POPULATIONS"

Preparations for Recruitment

It is necessary to obtain Internal Review Board (IRB) approval to conduct pilot studies, but one should not expect the process to be any less rigorous than for a larger study. The Ohio State University (OSU) Behavioral Sciences IRB for the Protection of Human Subjects approved this pilot study. The investigators determined that a sample of 10 children from each group would be sufficient to test the feasibility of the recruitment and research protocol and to obtain preliminary data.

Inclusion criteria within these two groups of children were: (a) ages birth to 12 years; (b) parent or legal guardian to sign consent and to complete questionnaires in either English or Spanish; (c) child present and assent given if older than 9 years, although cooperation and approval was asked of all verbal participants; and (d) immunization/well-child examination record available. There were no exclusion criteria.

In retrospect, the recruitment of participants represented the greatest portion of time in workload of the pilot study, while this experience made the path to subject recruitment much easier for the larger (dissertation) study (Aitken, Gallagher, & Madronio, 2003). Practicalities and logistics of sampling were tested as the investiga-

tor learned about the prospective subjects and the communities in which they reside, while above all ensuring the merit of the investigative study in terms of cost-effectiveness and potential data obtained (Sutton, Erlen, Glad, & Siminoff, 2003). Self-imposed limitations set by the principal investigator (PI) confined subject recruitment to areas within a reasonable driving distance and farms and carnival sites that would be operational during the summer months, the time available for the pilot study. While random selection of farms and carnivals would be ideal, there was no sampling frame from which to choose. The three major tasks for the PI were: (a) discovering where the workers would be in the future; (b) the name of the company or farm for which they worked; and (c) the "gatekeeper" or person who could approve access. The coveted approval letter then had to be submitted to IRB for its approval before subject recruitment could begin. Thus, the PI could not simply show up at a farm or carnival without all of this preliminary work.

Locating the Families

Community newspaper articles and state festival calendars proved to be an excellent starting point to obtain information about future carnivals, fairs, and festivals that employ carnival workers. The snowball technique and chain referral sampling were then used as one gatekeeper (migrant farmworker community liaison or amusement company owner) would then name another key person within their specific group (Penrod, Preston, Cain, & Starks, 2003; Streeton, Cooke, & Campbell, 2005). Networks emerged as names of key contact people were provided. Establishing trust and credibility through communication, dialogue, and respect was essential (Sutton et al., 2003). The researcher also volunteered in a free migrant health clinic to demonstrate her integrity and sincerity among those who are advocates for the migrant farmworkers. For this pilot study, the migrant families were secured for participation after one phone call to a large vegetable farm owner who was featured in a local newspaper.

The carnival sample was more elusive. A network of potential amusement companies that were licensed in the state were identified via the PI's great resourcefulness and patience with Internet exploration, state fair schedules, and newspapers. Carnival companies initially were concerned that information on the children's health status would be used against them or the parents and detailed verbal explanation of the research study, followed by copies of the written proposal and the researcher's curriculum vitae, were presented for review. Support from the fairground's first-aid station staff of registered nurses who often render care to the carnival workers encouraged the PI to be persistent. The PI was indefatigable in telephone and letter solicitation for support and access, and after approximately six phone calls to various companies, a smaller carnival owner agreed to participate. Dealings with the carnival companies proved to be laborious, but once credibility was established with one outdoor amusement company, the road to entry into the next became easier. A larger carnival company was obtained after an interview with the operations manager of the state fairgrounds, where fortuitously, a personal meeting with the carnival owner was arranged. For her own organizational purposes, the PI utilized concept mapping to record the conduits to recruitment that lead to the samples for this pilot study. This information later served as a pathway to recruitment for the larger study as many previous contacts were revisited.

One week before the data collection date, recruitment advertising posters in English, and also in Spanish for the vegetable farm, were posted in break rooms or other areas where workers congregate. Flyers and recruitment letters also were mailed to the distant carnival owners for distribution to the families before the arrival of the researcher. Once on the site, potential participants were solicited from their response to the flyers, from participants telling their fellow employees, or through contacts made by the researcher while walking the fair grounds distributing flyers. This investigator's experience was consistent with the findings of a previous review of literature on population-based recruitment. Specifically, the communication variable via telephone and interpersonal strategies had the greatest potential to increase recruitment when compared with mailings (McDonald, 1999).

Sample Results

The final samples of these two itinerant populations were secured from two traveling carnivals, one a smaller family-run business and the second a much larger traveling company, and a large vegetable farm. What remained to be seen was if the pilot samples would be reasonably representative of the target population to provide evidence that the samples for the larger study would be representative. A larger sample should be a broad cross-section of the target population that would yield the heterogeneity and characteristics evenly distributed among the sample and the population (Semaan, Lauby, & Liebman, 2002).

Although only 10 subjects per group was the goal, a total of 17 children of carnival families were recruited from two carnival companies on three locations, and the one vegetable farm yielded 24 children of migrant workers. Enrollment was not stopped at 10 subjects because the investigator was reluctant to turn

TABLE 1. Pilot Sample Demographics

	Total (%)	Carnival children (%)	Migrant children (%)
Sample size	n = 41	n = 17 (42)	n = 24 (58)
Ethnicity			
Hispanic/Latino	21 (51)		21 (87)
Non-Hispanic/ Latino	16 (39)	13 (76)	3 (13)
Missing	4 (10)	4 (24)	
Race			
White	26 (64)	15 (88)	11 (46)
Native American	3 (7)	2 (12)	1 (4)
Missing	12 (29)		12 (50)
Sex			
Male	21 (51)	9 (53)	12 (50)
Female	20 (49)	8 (47)	12 (50)
Age			
Mean	5 years	4 years 2 months	5 years 11 months
Range	0.5 months-12 years	0.5-12 years 1month	4 months-12 years

away families who were interested in participation. The total pilot sample of 41 subjects' self-identified ethnicity and race are shown in Table 1. The investigator realized that there are no national demographic data on carnival and migrant children with which to evaluate the samples' representativeness. In addition, the investigator learned the importance of being prepared with sufficient time, cash, and toy incentives in case of a very large participant turnout.

AIM # 2: LESSONS LEARNED ON FEASIBILITY OF THE PROTOCOL

Procedure

Parents were escorted to a private area where they signed the informed consent and HIPPA form. The investigator's experience as a public health nurse was useful in being flexible about where data were collected. Data collection sites varied from inside a first-aid station, under a colorful canopy, inside a mobile recreational vehicle, and in a worker coffee room. All scenarios demonstrated no difficulty in securing data. Participant privacy and comfort were able to be maintained throughout the study. All forms used in the research project were available in both English and Spanish to facilitate better understanding of the research project, because many of the potential participants were Latino and native Spanish speakers. Parents then answered demographic questions that covered a range of child development and parenting questions that are routinely asked of parents to facilitate anticipatory guidance during a typical well-child examination. Secondly, the parents completed the QOL study utilizing the PedsQL 4.0, a parent-proxy QOL for children ages birth to 18 years developed by Dr. James W. Varni (Varni et al., 1999).

Translation of Participation Forms

All forms were translated into Spanish by a native speaker from Central America. The local high school foreign language teacher was asked to perform this duty and was compensated for her efforts. The researcher is aware that in best practice any form translated into another language needs to be back-translated in the original language and compared (Behling & Law, 2000). Because of budgetary constraints the forms were not back-translated by a second native Spanish speaker until additional funding was secured. In fact, no changes were necessary, and these forms will be used in the dissertation study.

All but one of the migrant worker parents and five out of six of their children used the available Spanish translated forms. It is noteworthy that in a few instances some migrant farmworker parents were reading the Spanish questions to other parents, while they privately selected their answers. The PI suspected that literacy in their native Spanish might be the source of the difficulty, although this suspicion was not validated. None of the carnival worker parents used the Spanish versions. The potential problem of reading literacy must be acknowledged in both populations. The demographic questionnaire had a Flesch-Kincaid grade level of 3.9 and the PedsQL 4.0 has been written at reported age-appropriate reading levels (Varni et al., 1999). The demographic questionnaire was refined after reviews by the Dissertation Committee, and some questions were rewritten to be more concise. The questionnaire size and format also was redesigned to be more user-friendly.

Collection of Data

The investigator reviewed immunization and well-child records for adherence to the recommended schedules established by the recommendations for Preventive Pediatric Health Care (RE 9535) developed by the Committee

on Practice and Ambulatory Medicine of the AAP (AAP, 2004). Each required immunization was dated and checked as "met" or "not met," and a percentage of required immunizations versus age recommendation and the number of missing immunizations for age was used in analysis.

After parents completed their forms, children were asked for the researcher's permission to measure them and to look at their teeth. Children older than 9 years were formally asked if they would like to participate and were asked for their verbal assent (Allmark, 2003). The investigator weighed and measured the children on calibrated sensitive scale, a measure mat for recumbent length or a stadiometer. Lastly, the investigator conducted an oral dental screening of caries, fillings, number of teeth, and oral hygiene. These dental measurements served as an indicator of the amount of services a child does or does not receive. At the conclusion of the dental screening, the children received a new toothbrush compliments of the OSU College of Dentistry.

The PedsQL 4.0 begins its child self-report version at age 5 years, and those capable of reading either Spanish or English were asked to complete the age-appropriate version of the QOL instrument. Only one child younger than age 7 years was able to participate, but this was not surprising to the PI; few 5- and 6-year-olds can read that well, even with the use of a picture response scale. Adhering to instrument administration directions, parents were not permitted to assist their children in completion of the QOL survey (Varni et al., 1999). The researcher had eight children aged 5 to 12 years who declined to complete the PedsQL 4.0 in the migrant group and one out of four children who declined in the carnival group. The migrant worker children might have needed assistance in completing the form; however, the researcher was limited in her ability to speak Spanish, and the waiting crowd was large. The researcher realized the need for assistance in handling large groups of participants that often are seen when gathering data on the migrant farms. To correct for this missed data, in the full dissertation study the researcher employed assistants who were able to communicate in Spanish, especially during research work done with the migrant children.

After data collection, parents were given a written report on the child's height, weight, and recommendations for follow-up care for well-child examinations, immunizations, or dental care. The entire process took approximately 15 minutes. Obtaining the health status of these vulnerable children involved the assistance of their parents, and a $10 cash incentive was awarded to the parent respondent. The researcher needed to carry a large number of $10 bills on her person because participation numbers were unknown, and extra cash was stored in her nearby car. Many parents were reluctant to accept the monies given but then said it would be put into the child's college fund. Others parents were seen soon afterward with a lunch treat from a fast-food restaurant. Then again, other parents saw this as a fast way to earn $10.

At the conclusion of the data gathering, children were invited to select a toy from the well-stocked toy table. Age-appropriate toys were gathered into an attractive table display or toy box arrangement. A large national toy company was asked if they would provide a discount for the purchase of toys for this research project, and they graciously offered a 10% discount. Nonviolent, child-safe toys were purchased, and favorite toys selected were baby dolls, Disney Princess Barbie dolls, matchbox cars, Lego-type building blocks, developmental baby stacking toys, and board games. Because it was unknown how many children of various ages may appear to participate, numerous quantities of toys were purchased so choices would be available. Research participants view incentives differently, and some may be more positive and effective in encouraging participation in the study (Rice & Broome, 2004). The toys were a strong incentive for children and parents to participate. The investigator noted that while dolls often are White or African American, few are made for Latino children. The toy store chain was most gracious and accepted return of toys that were not selected at the conclusion of the study. Participants' opinions and advice regarding the study procedures were verbally solicited and noted by the investigator. Attrition was not a factor because all data from each subject were secured at one time.

Inclusion Criteria

Availability of immunization records originally was part of the inclusion criteria. However, pilot study work soon showed that valuable information on the other health status indicators would be lost by elimination of parents who have had difficulty accessing care and have incomplete or lost records. By maintaining the necessity of presenting the immunization record for evaluation, parents also might have been reluctant to participate, fearing reprisal for their child lacking recommended medical care. Stamped self-addressed envelopes were given to parents who did not present with the required record, and two out of three families returned the requested information. In consideration of these findings, the dissertation study revised the inclusion criteria from presenting an immunization record, to requesting the immunization record if available.

TABLE 2. Data summary of Pilot Study Findings

	Carnival children	Migrant children	Comparison and significance $\alpha = .05$
Health records available	82% (n = 17)	87% (n = 24)	
Immunizations	n = 14	n = 21	
Received age-appropriate immunizations as per recommended schedule set by AAP	90% (SD = 8.17; range 82%-100%)	78% (SD = 23.57; range 19%-100%)	*t* test 2.034; $P = 0.052$; carnival children greater than migrant children
Dental health 20 teeth or more	n = 12	n = 21	
Mean caries treated	0.92 (SD = 1.73; range 0-5)	2.95 (SD = 3.25; range 0-10)	*t* test –2.348; $P = 0.03$; carnival children less than migrant children
Mean caries treated			
Mean dft	2.25 dft (SD = 1.82; range 0-5)	3.38 dft (SD = 3.63; range 0-11)	*t* test –1.192; $P = .24$
Mean caries present	1.25 (SD = 1.77; range 0-4)	0.29 (SD = 0.56; range 0-2)	*t* test 1.841; $P = .09$
Children caries free: n (%)	3 (25)	9 (43)	Chi square = 1.052; cv = 3.84
Regular dental care provider: n (%)	9 (75)	19 (86)	Chi-square = 1.422; cv = 3.84
Saw a dentist in the last year: n (%)	7 (58)	17 (80)	Chi-square = 1.970; cv = 3.84
BMI-for-age 2 years and older	n = 12	n = 20	
BMI >95th percentile for age/sex: n (%)	4 (42)	6 (33)	Chi-square = 0.039; cv = 3.84
BMI >85 and <95 percentile for age/sex: n (%)	3 (17)	3 (19)	Chi-square = 0.492; cv = 3.84
PedsQL 4.0 ages 2 years and older			Cronbach's α 0.86 total score parent-proxy and 0.82 for total score child report
Parent-proxy	n = 11	n = 19	
Parent-proxy total mean score	66.77 (SD = 21.38; range 44.74-100)	77.52 (SD = 11.01; range 56.52-94.05)	*t* test –1.552; $P = .144$
Psychological subscale (one of six subscales)	59.30 (SD = 25.07; range 8.46-100)	76.15 (SD = 13.62; range 55.00-94.23)	*t* test –2.355; $P = .026$ Carnival less than migrant psychological subscale parent-proxy
Child self-report	n = 4	n = 6	
Child self-report total mean score	72.82 (SD = 10.12; range 58.70-82.61)	78.93 (SD = 16.81; range 46.74-94.69)	*t* test –.645; $P = .537$

BMI, Body mass index; cv, critical value; dft, decayed filled teeth.

AIM # 3: COLLECTIONS OF PRELIMINARY DATA ON THE CHILDREN'S HEALTH STATUS FOR FUTURE RESEARCH PROPOSALS

All data collected were entered into a Standard Package for Social Sciences (SPSS) program file. BMI was calculated utilizing the free SAS program available from the Centers for Disease Control and Prevention Web site (2004). The response format of research forms were modified after the pilot study to make data entry more efficient and less error prone. The investigator also determined that it would be good to have her oral assessments validated. The PI arranged for a newly launched mobile dental clinic staffed by the OSU College of Dentistry to offer free dental cleaning and repair of carnival children's teeth. The investigator assessed the children's teeth, and then dental care providers recorded their assessment of children's teeth a second time on the same pilot study data form. Interrater agreement was 100%.

Discussion

Comprehensive information on the health status of migrant children is potentially inaccurate or misrepresented, and the status of itinerant carnival children is unknown. However, other factors need to be considered beyond numbers of adherence percentages and mean scores. Included in the carnival children level of immunization adherence data were two babies both younger than 2 months who had both received their first dose of hepatitis B immunization, but whose parents have no method or knowledge of how to secure well-child care or immunizations that are due at 2 months of age. A third child of 5 months of age was in a similar situation. In statistical analysis, these children

BOX. Lesson learned from the pilot study

Identify most productive methods to recruit subjects	Limited published literature turns investigator to alternate sources for information • Internet • Newspaper articles • Professional and fraternal trade organizations • Religious orders who provide services to these populations • Health care providers who serve these populations • Governmental agencies Start early 3 months prior to data collection • Telephone and personal contact yielded more results than information mailed • Be persistent with follow-up on contacts • Patience with people responding to requests • Ask for names of other potential helpful contacts • Record all contacts made with date, names, and telephone numbers • Record developing network • Send copies of research abstract, investigator's vitae with cover letter
Test feasibility of the research protocol	Stay organized • Test burden appropriate for parent and child • Incentives successful and well received • Pre-order appropriate denominations of incentive money from bank before data collection • Modified format of demographic questionnaire and made more user-friendly • Parents and children willing and interested in participation • Instruments and measurement yield desired information • Instruments easy to use • Traffic flow of data collection routine established Intervention fidelity established • Maintain procedure manual
Collect preliminary data	Actual data collection • Increase yield numbers by incorporating an assistant who will read QOL instrument to children if needed • Forms utilized by investigator modified for greater efficiency in data collection with less error • Need to established greater inter-rater reliability in dental screening Analysis of data • Centers for Disease Control and Prevention program to compute BMI-for-age needs to be learned • Developed code book • Learned how to better utilize SPSS program • Need to evaluate if BMI calculator is easier to use Attestation of pilot study • Present at national and regional conferences • Learned how to present study on a poster • Learned proceedings of poster sessions Record findings • Experience process of writing article • Experience peer review • Experience working with publisher

BMI, Body mass index; QOL, quality of life.

scored as being 100% level of adherence in following the recommended schedule of acquiring immunizations. However, if data collection was done 1 month later, these children would have had lower adherence scores. This parody of compliance tells of a more significant and realistic picture of access to health care.

CONCLUSIONS

A summary of the data collected from this pilot study are in Table 2. The differences between groups were used as preliminary data from which to calculate a power analysis for sample size for the dissertation study that is necessary to detect an existing difference (Rudy & Kerr, 1991). Based on the *t* test score means on the PedsQL 4.0 parent proxy and child-report total scores with an $\alpha = .05$ and a power of .80, calculations resulted in an effect size of .44, which is between a small effect of 0.20 and a medium effect of 0.50 (Cohen, 1988). The scores on the PedsQL 4.0 were one confirmation of the hypothesis that migrant children

had higher health status compared with carnival children. The pilot study on health disparities among carnival and migrant worker children was successful, and this novice researcher learned many valuable lessons. The initial barrier was a limited literature on the health status of the children of migrant farmworkers, and no literature the children of carnival workers. Lessons learned from this pilot study are summarized in the Box. These families face environmental issues, mobile lifestyles, restricted health care access, limited housing conditions; discontinuous school attendance, and safety hazards. Research is needed to further identify health disparities in itinerant and invisible populations of children, as piloted here in the families of carnival and migrant workers, and to prioritize target interventions. In addition, publication of pilot studies and the scholarly lessons attained would benefit others and assist PIs in the design and conduction of research in their areas of interest.

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