Journal of Immigrant Health, Vol. 6, No. 1, January 2004 (© 2004)

Ethical Issues in Conducting Migrant Farmworker Studies

Sharon P. Cooper,[1,7] Elizabeth Heitman,[2] Erin E. Fox,[3] Beth Quill,[3] Paula Knudson,[4] Sheila H. Zahm,[5] Nancy MacNaughton,[3] and Roberta Ryder[6]

Migrant farmworkers should be considered a vulnerable population because they work in a hazardous industry, are often members of an ethnic minority, have known difficulty in accessing health care, and are often of lower socioeconomic status. For these reasons, too, it is extremely important to conduct health-related research with this often-underserved group. However, because migrant farmworkers are vulnerable, investigators must be especially vigilant in protecting them from the potential harms of research and in ensuring that the special ethical issues that arise in research with this population are identified and addressed for every project. In response to the National Cancer Institute's concerns about the feasibility of conducting epidemiologic studies among migrant farmworkers, researchers undertook four feasibility studies near the Texas-Mexico border. Each study raised different, complex ethical questions that challenged the investigators, but whose resolution turned out to be crucial to the success of the studies.

KEY WORDS: farmwork; migrant; ethics; Texas; Hispanics; informed consent; vulnerable population.

INTRODUCTION

Agriculture has always been one of the most hazardous industries in the United States and in Texas in particular (1, 2). Nonetheless, little is known about the magnitude of injuries and illnesses that affect migrant farmworker populations, which consist of both adults and children. Despite the importance of migrant farmworkers to the agricultural economy and food production in this country, their work is not assured, their wages are low, and their work conditions are conducive to injury and hazardous exposures (3).

Members of the farmworker population in the United States are increasingly foreign-born and undocumented. Their median annual income is less than $7500, and on average they have completed only 6 years of education (4). While both documented and undocumented immigrants lack health insurance and delay seeking health care (5), the undocumented will have the more severe situation (6), and avoid seeking medical care because of fear of immigration penalties (7). Most farmworkers are Hispanics who have limited proficiency in English, and many are functionally illiterate in Spanish as well. The Office for Protection from Research Risks, National Institutes of Health, has considered a vulnerable population to be a group of "individuals whose ability to give informed consent to participate in research is, in some way, compromised" (8). This usually refers to children, fetuses, the mentally handicapped, prisoners, those with limited language proficiency, and the economically or educationally disadvantaged. The economic, educational, and language proficiency designations, and the sometimes inclusion of children in studies, make farmworkers and their families a vulnerable population for research.

[1]Texas A&M School of Rural Public Health, Bryan, Texas.
[2]Vanderbilt University Medical Center, Nashville, Tennesee.
[3]The University of Texas Health Science Center at Houston, School of Public Health, Houston, Texas.
[4]Committee for the Protection of Human Subjects, The University of Texas Health Science Center at Houston, Houston, Texas.
[5]National Cancer Institute, Bethesda, Maryland.
[6]National Center for Farmworker Health, Buda, Texas.
[7]Correspondence should be directed to Sharon Cooper, PhD, Texas A&M School of Rural Public Health, 3000 Briarcrest, Suite 300, Bryan, Texas 77802; e-mail: spcooper@srph.tamushsc.edu.

1096-4045/04/0100-0029/0 © 2004 Plenum Publishing Corporation

Texas is the permanent residence of many migrant farmworkers in the United States. Approximately half of the estimated 360,000 migrant and seasonal farmworkers and their household members in Texas live along the Texas–Mexico border (9). Many live in Starr County, listed by the 2000 Census as the poorest county in the United States, where the population is 97% Hispanic (primarily Mexican American) (10, 11). In response to the National Cancer Institute's (NCI's) concerns about the feasibility of conducting epidemiologic cancer studies among migrant farmworkers, investigators at The University of Texas School of Public Health conducted a series of four NCI-funded feasibility studies in Starr and nearby Hidalgo Counties to examine issues such as accessibility, participation, and follow-up. However, in addition to scientific issues, these studies raised many ethical questions related to research with this population. Some were expected, but many were unanticipated. Recognizing and addressing these issues proved to be essential to the success of all four projects.

Ethical Principles in Research With Human Subjects

Formal ethical standards for medical research date from only the end of World War II, and ethical norms for epidemiologic research are even more recent (12). The first international statement of ethical requirements for biomedical research, the Nuremberg Code, focused on defining the ethical treatment of research participants (13). In response to the medical war crimes of Nazi research, the first principle of the Nuremberg Code proclaimed that the "voluntary consent of the human subject is absolutely essential" for ethical research; the Code subsequently outlined other provisions that researchers now take for granted, such as the investigator's duty to prevent "physical and mental suffering and injury" among study participants (13). Later, written statements on the ethical treatment of human participants in research, such as the 1964 Declaration of Helsinki (14), the 1978 Belmont Report (15), and the International Ethical Guidelines for Biomedical Research Involving Human Subjects (16) expanded the ideas brought forth by the Nuremberg Code.

Medical research is often conducted in the clinical setting, whereas epidemiologic research is often conducted in the community setting and is therefore also subject to community norms and political influences. Although the ethical principles remain intact, the context of the research may require special consideration. As the field of epidemiology and the scope of its research grew in the 1980s and 1990s, ethical guidelines were also published by professional epidemiologic organizations directed to epidemiologists (17–19). These guidelines share a common ethical underpinning, based on fundamental ethical principles laid out in the Belmont Report: respect for persons—often presented today as the principle of autonomy, beneficence and its counterpart nonmaleficence, and justice (15). *Autonomy* refers to the ability of an individual or a community to be self-governing and to make decisions about participation in research based on full disclosure (through the process of informed consent). In research, respect for persons requires investigators to treat individuals as autonomous agents, informing them fully of the nature, purpose, and potential benefits and risks of a research project for which they are recruited. Investigators must ensure that potential participants fully understand these elements of a study and honor their voluntary, informed decision whether or not to take part. As a corollary, the Belmont Report also calls for researchers to protect individuals and groups with diminished autonomy, such as children, the comatose, or prisoners (15), now often referred to as members of vulnerable populations as noted earlier.

The Belmont Report's presentation of *beneficence* combines the historical medical commitment to provide benefit with the physician's ethical duty of *nonmaleficence* (avoiding harm). In research, according to the Belmont Report, beneficence incorporates two general rules: to do no harm to research participants and to maximize the benefits of research while reducing its risks (15). Elsewhere in the literature on ethics in epidemiology (19–21) beneficence is typically characterized as requiring the balancing of the risks and benefits of research, but simply having a positive benefit-to-risk ratio is a less demanding requirement than minimizing the risk of potential harms and maximizing the potential benefits.

Justice refers to the ethical requirement to distribute the benefits and burdens of research fairly among participating individuals and populations and in society at large. However, as the Belmont Report points out, determining equity is not an easy process, at least in part because it depends on a clear definition of these benefits and burdens (15). Researchers and institutional review boards (IRBs) must consider who will benefit from research and the cost to others of that benefit before beginning a study. Because migrant farmworkers and their families are a vulnerable population, researchers must take extra care to

consider and address the unique dimensions of respect for persons, beneficence/nonmaleficence, and justice that may arise when conducting a study among them. These considerations need to be made at the onset of a study and throughout its process.

Conducting studies with migrant farmworkers is a cross-cultural experience for many epidemiologists and their staff members, depending upon the researchers' own cultural backgrounds. Fieldwork often exposes investigators to farmworkers' significantly different values, which are typically based in farmworkers' common experiences and understanding of events, as well as their language, nationality, religion, and socioeconomic status. Moreover, although the authors of the Belmont Report and many researchers once presumed that its ethical principles were universal, the growth of international biomedical research and related ethical reflection have called into question the universality of their application to human studies (22–24). The cultural values that underlie the Belmont Report and subsequent U.S. governmental and institutional efforts to promote ethical research are now recognized to conflict with the values of many traditional, non-Anglo cultures, especially in unindustrialized societies. Thus it is essential for researchers to identify potential points of cultural misunderstanding between themselves and the participant-farmworkers, to consider how such differences may affect the study, and to make plans to prevent or resolve these issues to the greatest extent possible. Experience with four projects in Starr County or nearby Hidalgo County along the Texas–Mexico border highlights some of the complications that may arise as investigators attempt to honor their professional commitments to ethical research. A summary of these studies is provided below.

Four Feasibility Studies Involving Migrant Farmworkers

1. *Study A*: In the first study, the objective was to follow a cohort of approximately 200 migrant farmworkers, self-identified in diabetes/gallbladder studies conducted 10 years earlier, with no interim contact for the majority of this group. The investigators located 91% of this cohort and administered a questionnaire about migration patterns, crops, and employment. Among those who were successfully traced and still living ($n = 163$), 100% were interviewed (25).
2. *Study B*: In the second feasibility study, three focus groups were conducted among migrant farmworker mothers and their sons and daughters aged 8–14 years who attended a middle school in Starr County. In this study, focus groups were used to consider possible approaches for soliciting information about the activities and pesticide exposures of migrant and seasonal farmworker children (26).
3. *Study C*: The third feasibility study assessed biologic measures of exposure to pesticides and several volatile compounds in maternal urine, umbilical cord blood, and placental tissue among a total of nine migrant and seasonal farmworkers and their newborns in Hidalgo County. This study highlighted the difficulties in measuring biologic indices of farmworkers' exposure to pesticides with short biologic half-lives and the contributions of questionnaire data to exposure assessment. Many of the contaminants were measurable, but not interpretable in terms of health effects, raising ethical issues about the sharing of study results with participants (27).
4. *Study D*: The final feasibility study was a pretest among older farmworkers of a questionnaire to assess a lifetime work history. This questionnaire utilized a creative approach involving affixing icon stickers to a calendar to solicit work history tasks and anchor life events in time. This questionnaire took from 1 to 3 h to complete, depending on the farmworker's age and work history, and was administered in the homes of the farmworkers during the summer months in south Texas (28).

The ethical principles and associated research issues encountered in the planning and conduct of these studies and the actions taken by the research team are displayed in Table I.

Special Ethical Problems in Working With Migrant Farmworkers

Autonomy and Informed Consent

Clearly the most difficult ethical principle to apply in research with migrant farmworkers is respect for persons and their autonomy. The most important safeguard for research participants' autonomy is the process of informed consent. However, U.S. researchers and migrant farmworkers often have

Table I. Examples of Ethical Principles Encountered and Actions Taken in Research With Migrant Farmworkers

Ethical principle	Research issue	Example	Research action
1. Autonomy/ informed consent	Cultural perspectives	Extremely high participation rates in Study A	Used caution in what was asked; used bilingual/ bicultural community interviewers; formed community advisory board with input on subsequent studies
2. Autonomy	Selection of study population	Examining health effects of work conditions (Studies A, B, C, and D)	Recruited and conducted study away from worksite
3. Autonomy	Compensation	Compensation vs. coercion (Studies A, B, C, and D)	Provided fair compensation for time and effort, but not excessive to minimize coercion
4. Informed consent/communication with participants	Appropriate language, cultural sensitivity, trust	Preference for Spanish/mixed language; nonliteracy in Spanish and English (Studies A, B, C, and D)	Bilingual community members helped in questionnaire development; translated informed consent/all instruments into Spanish; used bilingual interviewers, conducted face-to-face interviews
5. Standards of confidentiality and professional discretion	Confidentiality of participant responses	Use of community interviewers in close-knit community (Studies A, B, C, and D)	Trained interviewers and had them sign confidentiality agreement as condition of employment
6. Informed consent	Use of signed informed consent	Use of signed informed consent in nonliterate populations, possibly undocumented legal status (Studies A, C, and D)	Trained interviewers to use good communication that emphasized process of consent; provided copy and phone numbers for questions; avoided collection of social security numbers, documentation status
7. Children's assent	Inclusion of children in research when not directly beneficial	Inclusion of children in focus groups to report activities and job tasks that may involve exposure to pesticides (Study B)	Obtained verbal consent from mothers for child's participation in focus group; obtained oral assent from children when not in presence of mothers; were sensitive to allowing nonparticipation in focus groups
8. Beneficence/nonmaleficence	Sharing of individual study results of contaminant levels in biological samples	Study team nor health providers could interpret levels of contaminants in biological samples (Study C)	IRB did not allow investigators to share individual results with participants or health care providers (unless very high levels requiring clinical intervention)
9. Beneficence/nonmaleficence	Administration of long questionnaire	Administered interview in nonairconditioned home environment in hot summer months (Study D)	Reduced administration time, scheduled interviews during cooler time of day

vastly different interpretations of the meaning of individuality, the possibility of individuals' self-determination, and participants' roles and responsibilities in their community that may make it dangerous to rely only on standard informed consent procedures to protect potential research participants from coercion. To minimize the effect of differences in culturally based concepts on participants' decision making, it is important for the researcher to identify the relevant culturally based expectations of

the group under study and to address them as part of the consent process, clarifying everyone's perceptions and understanding of the project.

Cultural values and assumptions lie at the very heart of informed consent. The U.S. health care system and contemporary medical ethics consider the individual patient or research participant to be the focus of attention. However, in many agrarian societies individuality is not as important a value as family and community responsibility (29,30). Legal requirements for individual informed consent may create a dilemma for researchers working with populations that include persons who do not consider themselves to be "self-determining," especially in relation to health and illness (23). The concept of patient autonomy that is common in the United States is largely foreign among migrant farmworkers, where illness is seen to affect families, not just individual family members. In traditional Mexican and Mexican American society, the family or community leader may take on the sick person's responsibilities, including medical decision making, as a means of supporting the patient through illness. Family and community leaders may also expect to play a role in their members' decisions to participate in medical research (29).

Research ethicists and investigators have long recognized that members of vulnerable populations may unwillingly agree to participate in studies because of their assumptions about investigators' position and authority over them (31), which are based in part on culturally influenced perceptions of class, education, and occupation, and cultural interpretations of age, gender, and dress (30, 32, 33). The perceived role and authority of the researcher is a complex issue in migrant worker communities. People from traditional societies are often unfamiliar with the multiple professions in the U.S. health care system, and may presume that anyone in health care is a doctor or nurse. Where access to health care is extremely limited, a solicitation to participate in a study may be misunderstood as a valuable opportunity to receive medical care. Alternatively, if potential participants interpret a researcher's role in light of the community's experience with more familiar investigative authorities, such the school nurse, the government social service worker, or the immigration officer, they may acquiesce out of fear, mistrusting the investigator's real purposes.

These issues were exemplified in our first feasibility study (Study A), a follow-up of approximately 200 migrant farmworkers who were self-identified in diabetes/gallbladder studies conducted 10 years prior (34, 35). Community-based interviewers with extensive research experience recruited 100% of those traced and living, all of whom agreed to be interviewed with a short questionnaire (25). Because of the astonishingly high response rate, the study team was extremely concerned about why the participants had agreed to take part (i.e., autonomy). To protect respondents from any perceived obligation to reveal personal information as well as to protect the study from participants' potentially misleading responses, investigators had to be clear about their role as researchers and cautious about what they asked in the interviews (Table I, 1). The study team attempted to be especially respectful of the participants' willingness to talk to them.

Much of the epidemiologic research that involves migrant farmworkers relates to the health effects of their work conditions. Regardless of whether a research project is carried out in conjunction with an employer, workers' autonomy may be compromised if they feel any pressure either to participate or not to participate as a result of their employer's real or perceived opinion of the research. For this reason, recruitment at a farm or any other place connected to the farmworker's employment is ethically complicated. Voluntary consent may not be obtainable under these conditions. In our series of studies, recruitment that was conducted away from the worksite, in farmworkers' own homes or a nearby clinic, enhanced participation and minimized threats to the autonomy of potential participants (Table I, 2).

Compensation for participants' time and incentives to enroll in studies may also compromise autonomous choice among migrant farmworker populations. Participants should be compensated for the time and effort they contribute to research projects, but because of their comparatively low incomes what may seem like a small payment to a researcher may actually be a strong financial motivation to participate in a study. Researchers must be aware that even small incentives that may be acceptable in other circumstances can pose an undue influence in a vulnerable population that has few opportunities to make money or obtain goods or medical services (15). We provided discount store gift cards ranging from $10.00 to $20.00 across the studies depending on the time involved in participation (Table I, 3).

Informed Consent and Communication. Both during recruitment and over the course of a project, differences between participants' and researchers' understanding of the study and expectations of their respective roles can lead to serious miscommunication,

which can lead, in turn, to poor outcomes, loss to follow-up, and the failure of the interaction generally. The most difficult challenge to communication occurs when the participant and the researcher do not speak a common language, which is often the case when researchers work with Spanish-speaking migrant farmworkers. The legal and ethical standard in health care and health-related research is that anything important enough to communicate about with an English-speaking participant should be discussed with a participant who does not speak English in a language in which he or she communicates comfortably (36). Bilingual researchers and trained medical interpreters are essential to the quality of all aspects of communication between investigators and study participants (37), but particularly with respect to informed consent. Both Health and Human Services regulations (37) and FDA regulations (38) require researchers to provide all relevant information to research participants in a language that they understand, and to document the process of disclosure and discussion in a translated consent document.

In our work with migrant farmworkers in Starr County, Texas, all questionnaires, consent forms, and any other material given to participants were prepared in both Spanish and English (Table I, 4), and participants were allowed to choose the version they preferred, or a combination of both, which was often the choice. These projects illustrated the particular importance of involving a bilingual community member in questionnaire development or translation. We found that even among people whom researchers identify as a single population, different groups may use different words to convey the same idea. Translated documents that are worded appropriately for one group may inadvertently be incomprehensible, misleading, or even insulting when used with another community, potentially upsetting the participants and skewing the study's results.

Additionally, structured informed consent processes that focus on factual information about a study may provide little safeguard against coercion for individuals from cultures that do not easily say *no*. Members of traditionally collective cultures, such as rural Mexican and Mexican American societies, often consider an outright refusal to be extremely rude; they may communicate "no" indirectly in ways that still sound like "yes" to outsiders with different expectations (29, 30, 32). Researchers working in such communities must pay close attention to hesitant or evasive responses to recruitment in order to avoid enrolling individuals against their will or indirectly encouraging them to give inaccurate responses that seems to fit the investigators' expressed interests. Trained interpreters can be particularly valuable in recognizing and addressing these subtle cultural and linguistic factors that can otherwise handicap the best planned project (36). On the basis of their cultural background and their many years of research experience, interviewers and study staff advised investigators that the population's reluctance to say "no" may be reflected in our unprecedented response rates. In our subsequent studies, we have been quite sensitive to repeated missing of scheduled interviews, which we now consider to be a passive refusal to participate. Typically, researchers push for "refusal conversions" and repeated contact for "missed appointments," but perhaps this approach may become coercive with this population.

Communication is more than spoken words; it also involves body language and behavior, which are also influenced by culture. Misunderstandings and even conflict between participants and researchers may result over different interpretations of specific body language and behaviors that are often subtle and unconscious. Eye contact, expression, bodily position, gestures, personal space, and touching may all reflect different things in different cultures (30, pp. 161–188; 32, pp. 11–33). In addition, directness, voice volume, clarity, and accent may all impact communication (30, pp. 149–154). Even a concerned researcher may give study participants a very different message if unaware of how his or her efforts to communicate may be interpreted through other cultural lenses. Again, bilingual and bicultural researchers together with trained medical interpreters can significantly improve the quality of interaction with non-English speaking participants, helping them to become true participants in the study. The researchers must understand the populations and subpopulations they are studying, build trust in the community, and be aware of the implications of verbal and nonverbal cues.

In the Starr County feasibility studies, interviews were conducted by members of the community who had been selected and specially trained for that role (Studies A, B, and D). Thus many of the potential problems of language, nonverbal communication, and cultural sensitivity were prevented by the interviewers' ability to establish a relationship built on a common background and trust (*confianza*). However, because the community is close-knit and the participants' confidentiality had to be assured, it was important to train the interviewers in the ethical standards of confidentiality and professional discretion that are

essential to participants' trust in all health professionals. All interviewers were also required to sign a confidentiality agreement as a condition of employment (Table I, 5).

Health researchers often rely on documents, both written educational information and informed consent documents, to convey essential information about the project or the condition that it addresses. Federal regulations typically require researchers to disclose essential information about a study in the consent document, and mandate that participants with limited English proficiency receive written informational material in their primary language. The limited effectiveness of such educational literature with a semiliterate or illiterate population is widely recognized (39, 40). What is less well recognized is that in these populations the written consent document itself may communicate negative messages about the study and the researcher.

Many nonliterate people respond to legal-looking paper with anxiety and interpret a signature as an extremely serious and binding commitment. More importantly, individuals from nonliterate societies may interpret a request to sign a consent form as an indication that something dangerous may happen, that they agree to waive certain rights, or promise to fulfill some serious obligation—despite the researcher's explanation of the study's requirements—simply because they must give formal written permission (41). Many rightly recognize that the consent form is largely for the researcher's legal protection, and they may be hesitant to trust the investigator who will not simply take their word that they will participate. Many prospective subjects with limited literacy would rather refuse to take part in research than sign a paper that they do not understand, out of fear of some unspecified commitment they may inadvertently make in the process. They may still be doubtful about their role in the study even if someone reads them the actual text of the consent form (42).

Nonetheless, consent documents are required to document the researchers' compliance with informed consent regulations (42), and it is hard to conceive of a means to document the informed consent process without asking for the subject's signature on a legal-looking form. Researchers working with semiliterate and unschooled farmworkers, especially those with limited proficiency in English, must emphasize good communication in the consent *process* rather than focusing on the consent *form*, and be careful to explain that the signed form merely documents what the investigator and participant discussed. To assuage participants' anxiety by documenting the legitimacy of the research and our interest in their individual protection investigators in each of our feasibility studies gave each participant a copy of the consent form along with telephone numbers of the Principal Investigator and IRB committee office, as required by the IRB, to call in the event that they had questions or problems later on. Further, in all of our studies, we never asked for social security numbers or documentation status, despite the common use of these legal identifiers to provide compensation for participating in research (Table I, 6).

In some epidemiologic research, it may also be necessary to obtain informed consent from the study population's community before beginning a research project. Although community leaders should never be authorized to consent for any other individual, the permission or support of the target population's recognized leader(s) to undertake the research and begin recruitment is often beneficial (42–44). Any study that is likely to single out a specific population or group that will be identifiable to others should allow the group as a whole to be stakeholders in the research, both as a matter of respect and to ensure the legitimacy of the researchers' interpretation of the group's experience. Moreover, if the community is included in planning during various stages of the study, the project will likely benefit from higher visibility and better participation, and the resulting sense of community "ownership" will enhance the community's satisfaction with the research process and its results.

After the NCI feasibility studies were completed, researchers sought community participation and support for future projects by forming a study advisory board. The advisory board was selected to provide a wide scope of input from community leaders, advocates, health providers, school administrators, former farmworkers, and academic researchers. This is a small, well-established community that is suspicious of outsiders and the sincerity of their requests. Multiple interactions and demonstrated follow-up with initial study results and prolonged contact was needed to establish credibility and trust. The investigators have consulted with these community leaders on subsequent research to obtain their input into perceived health problems, to solicit their help and advice in conducting focus groups, and to facilitate obtaining of community participation. Despite substantial mistrust at the outset, our effort to work with the community has resulted in identifiable community support: for example, a principal of a participating school

who served on the initial advisory board agreed to continue to facilitate our research, providing space for community meetings and welcoming us to his school for the next 5 years for ongoing research projects.

Another ethical issue in consent that became evident in working with migrant farmworkers in Starr County was the importance of research with farmworkers' children and the need for and varying ability of children, to give their voluntary assent to participate in such research (Study B). Because little is known about the effects of pesticide exposure among children, the second feasibility study assessed a range of job tasks and activities that may involve pesticide exposure to children and young adolescents attending elementary and middle school, using three focus groups in La Grulla, Texas (one each with farmworker mothers, their sons, and their daughters aged 8–14) (26). Since 1998 the NIH has required all NIH-funded human research to include children unless there are scientific or ethical reasons not to include them in a specific project (45). Whether it is ethical for children to participate in research not directly beneficial to them has been debated in the literature (46) and more recently in court (47). Federal regulations governing research involving minors (48) stipulate that research that presents no more than minimal risk to the child, irrespective of the presence of direct benefit to the child, is acceptable with the assent of the child and the permission of one parent. Investigators believed that this feasibility study was ethically acceptable because the participating children would be subjected to virtually no risk and the unique and potentially important information gained from the focus groups would help in designing subsequent research to investigate health effects of pesticide exposure in children.

Oral consent was obtained by phone from the mothers at the time the children were invited to participate and was confirmed at the time of the focus group. Oral assent was obtained separately from the children, while not in the presence of their mothers (Table I, 7). The children caught on quickly to the focus group process and were more comfortable with the language and research setting than their mothers. They seemed enthusiastic to be part of the process, and no child overtly refused participation. When a mother gives consent for a child, it is often difficult for a child to refuse to participate. However, a number of children were observers and did not actively participate once they were in the groups, and the leaders were sensitive to allowing nonparticipation within the group. The results of our focus groups confirmed the importance of including children directly in migrant farmworker research, as they reported some new and different information from their mothers (26).

Beneficence/Nonmaleficence

Beneficence and nonmaleficence are a concern more often in clinical trials than in nonexperimental epidemiologic studies. The maxim "do no harm," which is often interpreted in terms of physical harm, has long been the province of physicians. Nonetheless, psychological, social, legal, and economic harm are real possibilities in nonexperimental studies (15). In working with vulnerable populations, such as migrant farmworkers, the researcher must be extra vigilant in ensuring that his or her results and conclusions do not stigmatize or further marginalize the group, and neither create nor enhance any negative stereotypes (43). There is no basic right for researchers either to collect or to report epidemiologic data, especially if it will cause an individual research participant or group harm to do so.

The third feasibility study (Study C) conducted in Starr County provided an unexpected example of the consideration of beneficence/nonmaleficence by the IRB. Investigators recruited nine pregnant farmworker women to obtain biologic measures of pesticide exposure on the basis of maternal urine, umbilical cord blood, and placenta samples (27). Contrary to the study team's expectations, The University of Texas Health Science Center's IRB would not allow researchers to share individual test results with the participants or with their treating health care providers (Table I, 8). This proscription for sharing individual results was therefore known by the study investigators from the very beginning of the study and implemented in the informed consent. The rationale for this prohibition was that neither the study team nor any other health professional could adequately interpret the results with respect to the health effects for the woman or her fetus; thus the potential for *psychological* harm caused by reporting the results to the participant would not be mitigated by any direct benefit, such as early diagnosis and treatment (49). The IRB's only exception was for medical referral in the event of evidence of very high pesticide levels or acute pesticide poisoning. The results of the study, did, in fact, support the wisdom of this approach, since many of the contaminants were measurable, but not interpretable in terms of health effects. Group results were provided

to the clinic staff, and giving the group mean and/or range may also have helped to alleviate unnecessary worry (27, 50)

Even in well-prepared and reviewed studies, researchers may encounter unexpected and undue harms that can introduce ethical dilemmas about how to proceed. In the fourth and final feasibility study (Study D), a pretest of a questionnaire was conducted to assess a lifetime work history among older farmworkers. The interview portion took from 1 to 3 h to complete, depending on the farmworker's age and work history, and was carried out in the respondents' homes for their convenience (28). For the longest interviews, i.e., with farmworkers who may have had a 50-year work history, administering the questionnaire in the farmworkers' unairconditioned homes during the hot summer months in south Texas raised the issue of unexpected discomfort, both to the participants and to study staff (Table I, 9). Although the questionnaire did not seem excessively long in the investigators' air-conditioned offices or in other locations across the United States, where the climate was cooler or the farmworkers younger (and therefore responses shorter), it was perhaps excessively long in extreme hot weather conditions for farmworkers with a long lifetime work history. Rather than expose participants and study team members to this discomfort, the investigators tried to shorten the time it took to administer the questionnaire by streamlining response recording, and they made every attempt to schedule interviews during cooler times of the day. Although the study participants live in this environment irrespective of the research, their potential discomfort as well as that of the study staff should always be considered in study logistics and instrument development.

Justice

As a population, migrant farmworkers and their children are subject to a host of socioeconomic burdens, occupational exposures, and injustices that both negatively affect their health and warrant effective redress. Because of migrant farmworkers' status as a vulnerable population, justice is an important but complex factor to consider in designing studies related to their health. Justice requires that the burdens and benefits of research be distributed equitably on both the individual and the population levels. Migrant farmworkers and other vulnerable populations should not be selected to participate in studies simply because they are convenient or because the investigator has been involved in prior successful studies with that group. However, justice also demands that the significant health problems associated with migrant farmwork receive appropriate attention. Where farmworkers' health risks and the consequences of their occupational exposures are not well understood, research must be carried out for the benefit of the farmworker population (rationale for all the feasibility studies).

Justice also demands a careful weighing of benefits and burdens in the design and execution of studies involving farmworkers and their families. Most importantly, researchers must protect those who are vulnerable by ensuring that the study in question is relevant to the study population's needs (42). Farmworkers should be recruited into research only when the problem being studied affects them and the results of studies with less vulnerable populations cannot be applied to their situation. Individual farmworkers should not be excluded from general population studies solely on the basis that they are members of a vulnerable population (42, 50) if doing so would affect the representativeness of the results. Finally, research into the health concerns expressed by farmworkers themselves, when possible, can often serve the demands of justice by providing farmworkers with important new knowledge and a voice in defining what knowledge is important to them.

CONCLUSIONS

The investigators identified a number of ethical issues that arose from a series of feasibility studies, some of which have been well described in the ethics literature and were fairly intuitive, but some quite unexpected. Issues of language, differing cultural values, appropriate compensation, and the ethical principles that guide epidemiologic and other types of research—beneficence, nonmaleficence, autonomy, and justice—are complex, but to be expected in research with migrant farmworkers. The investigators also learned about less obvious or well-described issues through the conduct of these feasibility studies: The conduct of scientific studies is not an automatic right in academia; the inclusion of children in research is important; the scope of human subject considerations in research is a large part of the planning and conduct of studies; and although initially counterintuitive, there are times when it is not appropriate to share results of research with individual study participants.

The need for intensive manual labor performed by migrant farmworkers and their children is expected to increase in the United States (51), suggesting that the health risks to migrant farmworker families will continue and likely proliferate. The need for more research is clear, but the vulnerability of these populations requires the obligatory consideration of complex ethical concerns.

ACKNOWLEDGMENTS

The authors thank all of the study participants and staff in each of the described studies and the contract grant sponsor, the National Cancer Institute.

REFERENCES

1. National Institute for Occupational Safety and Health: Worker Health Chartbook, 2000. NIOSH Pub no 2002–117, May 2002
2. May-Lambert S, Richardson S, Herrmann K: Fatal work injuries involving farmworkers, 1991–1995. J Agri Saf Health 1998; 1:47–55
3. National Center for Farmworker Health: Facts About Farmworkers www.222.ncfh.org/aboutfws, 2001
4. U.S. Department of Labor: National Agricultural Workers Survey. U.S. Department of Labor; 2000
5. Palinkas LA, Arciniega JI: Immigration reform and the health of Latino immigrants in California. J Immigrant Health 1999; 1:19–30
6. Hubbell FA, Waitzman H, Mishra SI, Dombrink J, Chavez LR: Access to medical care for documented and undocumented Latinos in a southern California county. West J Med 1999; 154: 414–417
7. Loue S, Faust M, Bunce A: The effect of immigration and welfare reform legislation on immigrant's access to health care, Cuyahoga and Lorain counties. J Immigrant Health 2000; 2:23–30
8. Human Subjects Research Program, U.S. Department of Energy: Creating an Ethical Framework for Studies that Involve the Worker Community. U.S Government Printing Office; 2000: Chapter 1, p. 7–8
9. Larson AC: Migrant and Seasonal Farmworker Enumeration Profile Study Texas, September 2000 http://bphc.hrsa.gov./migrant/Enumeration/final-tx.pdf
10. The University of Texas System Texas–Mexico Border Health Coordination Office, Texas-Mexico Border Counties, 1995. Demographics and Health Statistics, 1998
11. 2000 U.S. Census poverty by county www.census.gov/hhes/poerty/2000 census/poppvstatoo.htm
12. Coughlin SS, Beauchamp TL: Historical foundation: In: Coughlin SS, Beauchamp TL, eds. Ethics and Epidemiology. New York: Oxford University Press; 1996:5–23
13. Trials of War Criminals before the Nuremberg Military tribunals under Control Council Law No 10, Vol 2. Washington, DC: U.S. Government Printing Office; 1949:181–182
14. World Medical Association: Declaration of Helsinki. Recommendations Guiding Medical Doctors in Biomedical Research Involving Human Subjects. Helsinki, Finland: WMA; 1964
15. The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research: The Belmont Report: Ethical principles and guidelines for the protection of human subjects of research, 1979. http://ohsr.od.nih.gov/mpa/belmont.php3
16. Council for International Organizations of Medical Sciences: Internatonal Ethical Guidelines for Biomedical Research Involving Human Subjects. Geneva: WHO; 2002
17. American College of Epidemiology: American College of Epidemiology Ethics Guidelines. Raleigh, NC: ACE; 2000 http://acepidemiology.org/policystmts/EthicsGuide.htm
18. Council for International Organizations of Medical Sciences. International guidelines for ethical review of epidemiological studies. Law Med Health Care 1991; 19:247–258
19. Beauchamp TL, Cook RR, Fayerweather WE, Raabe GK, Thar WE, Cowles SR, Spivey GH: Ethical guidelines for epidemiologists. J Clin Epidemiol 1991: 44 (Suppl 1):151S–169S
20. Beauchamp TL: Moral foundations: In: Coughlin SS Beauchamp TL, eds. Ethics and Epidemiology. New York: Oxford University Press; 1996:24–52
21. Last JM: Obligations and responsibilities of epidemiologists to research subjects. J Clin Epidemiol 1991; 44(Suppl 1):95S–101S
22. Barry M: Ethical considerations of human investigation in developing countries: The AIDS dilemma. N Engl J Med 1988; 319:1083–1086
23. Levine RJ: Informed consent: Some challenges to the universal validity of the western model. Law Med Health Care 1992; 19:207–213
24. Brennan TA: Proposed revisions to the Declaration of Helsinki—Will they weaken the ethical principles underlying human research? N Eng J Med 1999; 341:527–531
25. Cooper S, Burau K, Hanis C, Henry J, MacNaughton N, Robison T, Smith MA, Sweeney A, Vernon SW, Zahm S: Tracing migrant farmworkers in Starr County, Texas. Am J Ind Med 2001; 40:586–591
26. Cooper SP, Darragh AR, Vernon SW, Stallones L, MacNaughton N, Robison T, Hanis C, Zahm SH: Ascertainment of pesticide exposures of migrant and seasonal farmworker children: Findings from focus groups. Am J Ind Med 2001; 40:531–537
27. Cooper SP, Burau K, Sweeney A, Robison T, Smith MA, Symanski E, Colt JS, Laseter J, Zahm SH: Prenatal exposure to pesticides: A feasibility study among migrant and seasonal farmworkers. Am J Ind Med 2001; 40:578–585
28. Zahm SH, Colt JS, Engel LS, Keifer MC, Alvarado AJ, Butterfield P, Caldera S, Cooper SP, Garcia D, Hendrikson E, Heyer N, Hunt LM, Krauska M, MacNaughton N, McDonnell, Mills PK, Mull D, Nordstrom DL, Outterson B, Slesinger DP, Stallones L, Stephens C, Sweeney A, Sweitzer K, Vernon SW, Burau K, Smith M, Hanis C, Blair A: Development of a life events/icon calendar questionnaire to ascertain occupational histories and other characteristics of migrant farmworkers. Am J Ind Med 2001; 40:490–501
29. Geissler EM: Cultural Assessment, 2nd edn. St. Louis, MO: Mosby; 1998
30. Rogers EM, Steinfatt TM: Intercultural Communication. Prospect Heights, IL: Waveland; 1999
31. Khan KS: Epidemiology and ethics: The people's perspective. Law Med Health Care 1991; 19(3/4):202–206
32. Dresser N: Multicultural Manners: New Rules of Etiquette for a Changing Society. New York: Wiley; 1996
33. Saville-Troike M: The Ethnography of Communication: An Introduction, 2nd edn. Oxford: Butterworth; 1994
34. Hanis CL, Ferrell RE, Barton SA, Aguilar L, Garza-Ibarra A, Tulloch BR, Garcia CA, Schull WJ: Diabetes among Mexican Americans in Starr County, Texas. Am J Epidemiol 1983; 118:659–672
35. Hanis CL, Hewett-Emmett D, Kubrusly LF, Maklad MN, Douglas TC, Mueller WH, Barton SA, Yoshimaru H, Kubrusly DB, Gonzalez R, Schull WJ: An ultrasound survey of gallbladder disease among Mexican Americans in Starr

County, Texas: Frequencies and risk factors. Ethn Dis 1993; 3:32–43
36. Garcia C: The Role of Medical Interpreters. ATA Chronicle 2000
37. 45 CFR 46.116 Protection of Human Subjects, 2001
38. 21 CFR 50.20 Protection of Human Subjects, 1998
39. Doak CC, Doak LG, Root JH: Teaching Patients With Low Literacy Skills. Philadelphia: Lippencott; 1985
40. Weiss BD, Coyne C: Communicating with patients who cannot read. NEJM 1997; 337: 272–274
41. Soler M, Peters C: Who Should Know What? Confidentiality and Information Sharing in Service Integration. Des Moines, IA: National Center for Service Integration; 1993
42. Gostin L: Ethical principles for the conduct of human subject research: Population-based research and ethics. Law Med Health Care 1991; 19(3/4): 191–201
43. Dickens BM: Issues in preparing ethical guidelines for epidemiologic studies. Law Med Health Care 1991; 19(3/4):175–183
44. Weijer C, Emmanuel EJ: Protecting communities in biomedical research. Science 2000; 298: 1142–1144
45. NIH Policy and Guidelines on the Inclusion of Children as Participants in Research Involving Human Subjects, 1998. http://grants.nih.gov/grants/guide/notice-files/not98-024.html
46. Leikin S: Ethical issues in epidemiologic research with children: In: Coughlin SS, Beauchamp TL, eds. Ethics and Epidemiology. New York: Oxford University Press; 1996:24–52
47. Ross LF: In defense of the Hopkins Lead Abatement Studies. J Law Med Ethics 2002; 30(1):50–57
48. 45 CFR 46 Part D Protection of Human Subjects, Additional Protection for Children Involved as Subjects in Research, 1994
49. Higginson J, Chu F: Ethical considerations and responsibilities in communicating health risk information. J Clin Epidemiol 1991; 44(Suppl 1): 51S–56S
50. Schulte PA, Singall M: Ethical issues in the interaction with subjects and disclosure of results: In: Coughlin SS, Beauchamp TL, eds. Ethics and Epidemiology. New York: Oxford University Press; 1996:178–196
51. General Accounting Office: Child Labor in Agriculture: Characteristics and Legality of Work. GAO/HEHS–98-112R; 1998