The Informed Consent Process in a Cross-Cultural Setting: Is the Process Achieving the Intended Result?

Melvina McCabe, MD; Frank Morgan, BA;
Helen Curley; Rick Begay; Dorothy M. Gohdes, MD

This report is based on the experiences of Navajo interpreters working in a diabetes clinical trial and describes the problems encountered in translating the standard research consent across cultural and linguistic barriers. The interpreters and a Navajo language consultant developed a translation of the standard consent form, maintaining the sequence of information and exactly translating English words and phrases. After four months of using the translated consent, the interpreters met with the language expert and a diabetes expert to review their experiences in presenting the translation in the initial phases of recruitment. Their experiences suggest that the consent process often leads to embarrassment, confusion, and misperceptions that promoted mistrust. The formal processes that have been mandated to protect human subjects may create barriers to research in cross-cultural settings and may discourage participation unless sufficient attention is given to ensuring that both translations and cross-cultural communications are effective. (*Ethn Dis*. 2005;15:300–304)

Key Words: Cross-Cultural, Informed Consent, Navajo Language, Translation

From the Department of Family and Community Medicine, University of New Mexico School of Medicine, Albuquerque, New Mexico.

Address correspondence and reprint requests to Melvina McCabe, MD; Department of Family and Community Medicine; MSC09 5040; 1 University of New Mexico; Albuquerque, NM 87131; 505-272-0510; 505-272-8045 (fax); mmccabe@salud.unm.edu

Introduction

Informed consent is one of many aspects of clinical research that should be periodically scrutinized in an attempt to restore trust in the research process and also to expand inclusion of racial and ethnic minorities.[1–5] While the need for consent forms that are informative and comprehensible is readily accepted, insufficient attention is given to making sure that the forms are actually understandable, especially to minority populations.[6–9] For example, Darou points out that the researchers with whom the Cree Nation, an indigenous group in Canada, had the most difficulty working with were those who followed Canadian research codes of ethical principles for research with human subjects, but these codes were not culturally appropriate.[10] The present process in the United States is based on the Belmont Report, published in 1979, which summarized the basic ethical principles for biomedical research, including the nature and definition of informed consent.[1] The report identified three essential elements for informed consent: information, comprehension, and voluntariness, and specified that participants be given a full assessment of risks and benefits.

In 1995, the Office of Human Research Protection (OHRP) advised investigators that the informed consent document for non-English-speaking subjects should be written in the language of the participants. But comprehension of the printed material and all its implications requires that there be effective interpersonal communication between the research staff and the study participants. This comprehension is especially important for people who speak English as a second language and in community-based studies, both for the sake of the study participants and for the study itself.[8,9,11,12] Regardless of whether the consent form is presented in English or in a translation, it can be meaningless unless it is explained by someone who fully understands the culture and concerns of the people who will sign it. A recent study among African Americans found that, despite instruction, participants did not fully understand the consent forms and believed that the process meant that they somehow lost their autonomy while the physician gained some form of legal protection.[13]

This report describes the concerns and problems encountered in conveying a standard research consent process across cultural and linguistic barriers and includes suggestions for adapting the process when reaching out to minority populations. The report is based on the experience of Navajo interpreters working in a clinical trial designed to measure the effects of translators. The interpreters participated in a week-long medical interpreter training course led by a Navajo nurse trained by the Cross-Cultural Health Care Program from Seattle, Washington, and, in a separate format, interpreters were specifically trained about diabetes and how to interpret issues important to patient care and outcomes.[14,15] The Navajo language, widely spoken among tribal members, is complex. Because it was not originally a written language, to convey the sounds with the English alphabet and phonetics required considerable linguistic expertise. Direct word-for-word translation of the consent form was not always possible, and some sections of the document had to be worded awkwardly in Navajo to convey the ex-

While the need for consent forms that are informative and comprehensible is readily accepted, insufficient attention is given to making sure that the forms are actually understandable, especially to minority populations.[6–9]

act English meaning. When the translated form was presented, cultural issues emerged that were sufficiently important that the interpreters often had to re-explain the meaning in their own way before the document was accepted by Navajo participants.

METHODS

Research Setting

The Effects of Navajo Interpreters on Diabetes Outcomes is a randomized, controlled five-year clinical trial initially conducted at two Indian Health Service facilities on the Navajo Nation, which occupies 25,000 square miles in Arizona, New Mexico, and Utah. Both of the original study sites are in western New Mexico. The study seeks to measure how the use of formally trained Navajo diabetes medical interpreters affects the outcomes of diabetes and healthcare utilization patterns compared with the outcomes of a control group whose ad hoc interpreters have had no formal training in interpreting diabetes concepts and may or may not have been trained as medical interpreters. The project has enrolled 333 participants who are ≥40 years of age and have been diagnosed with type 2 diabetes for ≤15 years. Study participants are largely older (average age 64.8 years), live on or near the reservation, travel an average of 45 miles to the Indian Health Service facility, and do not drive themselves to their clinic visits (73%); many are driven by their children (46.3%). The study is being conducted at the University of New Mexico, and the principal investigator is a tribal member of the Navajo Nation. The study was approved by Human Research Review Committee at the University of New Mexico and the Indian Health Service Research Review Board as represented by the Navajo Nation Health Research Review Board in Window Rock, Arizona.

Medical Interpreter Qualifications

Two interpreters and two medical research assistants, all of whom are members of the community, worked at each site. All had passed an English proficiency exam prior to beginning the translation of the English version of the informed consent document. In addition, interpreters passed a Navajo proficiency test and had begun reading written Navajo under the guidance of a Navajo language expert. One had received prior training as a legal interpreter, and all the individuals received training on the functions of a medical interpreter.

Developing the Consent Translation

The informed consent was written initially in English according to the standard and prescriptive outline, including telephone numbers, required by the institutional review boards (IRB). The consent form was back-translated from the wording approved by the IRB. In the process, significant regional differences in Navajo terminology were noted. The process of translation proceeded in a multistage manner: the interpreters provided an initial translation of the consent form into Navajo; the second version was then translated back into English and compared to the original English form by a Navajo language expert. This second version was tested for efficacy with the Navajo Nation Medical Terminology Standardization Committee and several elders from the community. After four months of using the final translation, the interpreters met with the Navajo language expert, the diabetes expert, and study personnel to review the issues that arose in translating the original document and their experiences in presenting the translation in the initial phases of recruitment.

The English and the Navajo versions of the approved informed consent form were three single-spaced pages in length. The major categories included the usual sequence of information: title, purpose and background, procedures, risks and discomforts, benefits, alternatives to participation, confidentiality, cost of study, emergency treatment and compensation for injury, compensation, new findings, withdrawal, questions, and consent.

RESULTS

Examples of the misunderstandings and difficulties we encountered are presented arranged in the sequence of the consent process.

Title

The most direct Navajo translation of the word research in the title, "taking apart into pieces and tracking down information useful for research for its own sake" carried a negative connotation. Specifically, research translated this way meant that investigators could take information for their own personal or professional gain, with nothing shared with or returned to the people studied. The translators simply described the study as "work or project that will take place."

Purpose and Background

This section was a straightforward explanation of the research questions, who was doing the work, and what difference the language might make. However, in translation, much of the infor-

mation necessarily overlapped with information in other sections. This overlap made presenting the information in the entire document in the required sequence difficult. Because of the overlap between the sections about procedures and the potential benefits, potential participants were often confused about what they were being asked to do.

Procedures and Benefits

This section revealed a paradox in that potential participants had to sign the consent form before the research assistants could review their medical charts to determine whether they were eligible for the study. This was difficult and confusing to explain in Navajo. The process of randomization, while easily explained, held cultural implications of depriving people of their autonomy in the group assignments. The discussion of intangible benefits was particularly confusing because it appeared that randomization to the control group could deprive those participants of any benefit. Potential participants clearly perceived that being paid a nominal sum for participating was a benefit. Even specifying a time of 40 minutes to complete the study forms seemed irrelevant to some participants because time in the traditional Navajo context is not always expressed in minutes on a clock.

Risks and Discomforts

For this study these concepts were easily explained and easily translated into the Navajo language.

Alternatives to Participation

Describing "usual care" as the alternative to participation led to a suspicion that there was the possibility that their regular diabetes care could somehow be interrupted and suspended.

Confidentiality

This section was particularly confusing and contradictory in that it promised confidentiality of all information but included a list of government agencies that would have access to the information.

Emergency Treatment and Compensation

The information about lack of compensation for injuries as a result of the study seemed to contradict the previous assertions that serious adverse effects were unlikely to occur. The inclusion of emergency telephone numbers is questionable for people living in remote areas, frequently without telephones.

Compensation

This was easily translated, but some individuals had to be reassured that this would not affect any disability income.

New Findings and Withdrawal

These sections repeated what had already been covered and were regarded by both the interpreters and participants as redundant, confusing, and irrelevant.

Questions

Although the amount of detail about whom to call seemed lengthy to individuals who did not have telephones, the information allowed potential participants to understand how the local study site coordinated with the university from which the study originated.

Consent

This section is worded in very legal terms, but the sense could be translated into Navajo without difficulty. However, it seemed illogical to participants to contact the university's Risk Management Department many miles away rather than someone at their local facility. The requirement to sign the form and initial each page was embarrassing for people who could not write and had to use a thumbprint on each page. Some potential participants simply did not want to be observed having to use the thumb print pad. In other instances, the study interpreter had to explain initials before some people could complete the form.

DISCUSSION

Communicating about diabetes and other chronic diseases is a worldwide challenge for health systems treating indigenous peoples in many parts of the world. The lack of word-for-word translations and the complexity of translating concepts about the etiology and pathogenesis of diabetes have been documented.[15] Many issues identified in the consent process for this trial involve communicating English ethical and legal concepts and terminology into a non-Romance language, but cultural and socioeconomic issues arose as well. American Indians are not unique in their distrust of research, and several cross-cultural issues encountered in this study have also been noted in other minority groups who speak English.[11,16,17] Health systems dealing with immigrants with diabetes are also faced with similar linguistic and cross-cultural challenges.[18] The challenges faced by investigators and communities to increase underrepresented population participation in clinical trials are formidable. The IRBs are taxed with studies of increasing technical complexity, and cross-cultural issues are easily lost in the demands to review the many studies.

Our experience in translating and administering informed consent documents to an underrepresented population identified several important issues that must be addressed to ensure that the goals of protecting and informing human subjects are met. Each part of the apparently simple consent form contained some issues that seemed to be: 1) contradictory; 2) repetitive; 3) irrelevant to the particular population; 4) not trustworthy in intent; and 5) lengthy. The standard sequence of information in the informed consent process reiterating risks, benefits, withdrawal, and what would be done about new findings generated confusion about the study procedures. Potential participants felt that repeatedly discussing telephone communication was irrelevant when

Study interpreters found that translating the consent form was a trying and tedious process, and they were frequently unable to translate the specific wording required by the IRBs into something comprehensible in Navajo.

Considerations for adapting the informed consent process to cross-cultural settings

- Reduce strict legal and scientific jargon in the consent form.
- Restructure consent forms to reduce redundancy and repetition.
- Identify and alter, when possible, standard consent form language that may engender mistrust.
- Re-sequence the consent form to facilitate logical translations into complex languages.
- Ensure that those administering consent forms are culturally competent to address questions and potential misunderstandings.
- Specify alternative means of communication for people without telephones.
- Provide for community members' review and critique of forms.

many did not have telephones. The areas of contradiction raised the issue of mistrust: the participants felt that we were "trying to hide something" from them. Study interpreters found that translating the consent form was a trying and tedious process, and they were frequently unable to translate the specific wording required by the IRBs into something comprehensible in Navajo. Importantly, potential participants sensed the translators' discomfort with the translation, and this added to their suspicion that something of importance was being omitted.

The Office of Human Research Protection provided specific advice that research surveys and instruments be translated into the language of the research group. Among traditional American Indians without an original written language, translating any document into the native language can be very difficult, and sufficient time must be allowed by both researchers and the funding agencies to develop comprehensible material. Even with careful translations, however, consideration must be given to the fact that individual participants may not be able to read a phonetic version of their native language written with the English alphabet. Elderly individuals whose first language is not English may be particularly baffled by the material but be unwilling to question what is being presented. In addition, those who do consent but are intimidated by the process may alter their responses to questions in a study and thus threaten the validity of findings. The Table presents a list of suggestions for funding agencies and IRBs to improve the informed consent process in community-based studies, particularly among minority populations. In addition to this list others have suggested that computer readability analyses in English can improve understanding of consent forms, and that restructuring with graphic presentations using tables or boxes can also help. Other suggestions included the use of simple, declarative statements as headings for each paragraph and specifically presenting the name of the researcher in bold print.[19] Finally, it is naïve to assume that simply translating consent forms and survey instruments into the native language of the research population addresses all cross-cultural issues. Investigators, communities, and IRBs must work together in a flexible and culturally relevant way to define and implement the fundamental principles specified in the Belmont Report.

In summary, obtaining informed consent is important, but our experience in this study suggests that the actual process as defined by the various organizations can lead to difficulties that promote mistrust. The formal processes that have been mandated to protect human subjects under all circumstances may, in fact, create barriers to research in cross-cultural settings and may discourage participation unless sufficient attention is given to ensuring that both translations and cross-cultural communications are effective.

ACKNOWLEDGMENTS

Funded by the DHHS Agency for Healthcare Research and Quality.

REFERENCES

1. Belmont report. Office of the Secretary. Ethical principles and guidelines for the protection of human subjects of research. The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. April 18, 1979. Available at: http://ohrp.osophs.dhhs.gov/humansubjects/guidance/belmont/htm.
2. Kelch R. Maintaining the public trust in clinical research. *N Engl J Med.* 2002;345:285–287.
3. NIH Regulatory Burden. V. Human subjects protection—workgroups report. Available at: http://grants2.nih.gov/grants/policy/regulatoryburden/humansubjectsprotection.htm.
4. Seto B. History of medical ethics and perspectives on disparities in minority recruitment and involvement in health research. *Am J Med Sci.* 2001;322:246–250.
5. Office for Protection from Research Risks. Tips on informed consent. Available at: http://ohrp.osophs.dhhs.gov/humansubjectsguidance/ictips.htm.
6. Doyal L. Informed consent in medical research: journals should not publish research to which patients have not given fully informed consent—with three exceptions. *BMJ.* 1997;314:1107–1111.
7. Feussner JR, Burris JF, McGlynn G, Lavori PW. Enhancing protections for human participants in clinical and health services research: a continuing process. *Med Care.* 2002; 40:V4– V11.
8. Wiltshire C. Informed consent in medical research: communication with potential subjects needs to be effective (letter). *BMJ.* 1997; 314:1482.
9. Montgomery C, Lydon A, Lloyd K. Informed consent in medical research: patients may not

understand enough to give their informed consent. *BMJ.* 1997;314:1482.
10. Darou WG, Hum A, Kurtness J. An investigation of the impact of psychosocial research on a native population. *Prof Psychol Res Pract.* 1993;24(3):325–329.
11. Weijer C, Emanuel EJ. Protecting communities in biomedical research. *Science.* 2000; 289: 1142–1144.
12. Marshall P, Rotimi C. Ethical challenges in community-based research. *Am J Med Sci.* 2001;322:241–245.
13. Corbie-Smith G, Thomas SB, Williams MV, Moody-Ayers S. Attitudes and beliefs of African Americans toward participation in medical research. *J Gen Intern Med.* 1999;14:537–546.
14. Putsch R. Cross-cultural communication—the special case of interpreter's health care. *JAMA.* 1985;254:3344–3348.
15. McCabe M, Morgan F, Smith M, et al. Lessons learned: challenges in interpreting diabetes concepts in the Navajo language. *Diabetes Care.* 2003;26:1913–1914.
16. Crawley LM. African-American participation in clinical trials: situating trust and trustworthiness. *J Natl Med Assoc.* 2001;93:14S–17S.
17. King TE Jr. Racial disparities in clinical trials. *N Engl J Med.* 2002;346:1400–1402.
18. Lipson JG, Meleis AI. Methodological issues in research with immigrants. *Med Anthropol.* 1989;12:103–115.
19. Peterson BT, Steven JC, Champion K, McLarty JW. Improving readability of consent forms: what the computers may not tell you. *IRB.* 1992;14(6):6–8.

AUTHOR CONTRIBUTIONS

Design and concept of study: McCabe, Gohdes
Acquisition of data: McCabe, Gohdes, Morgan, Curley
Data analysis and interpretation: McCabe, Gohdes, Morgan, Begay
Manuscript draft: McCabe, Gohdes
Acquisition of funding: McCabe
Administrative, technical, or material assistance: McCabe, Gohdes, Morgan, Curley, Begay
Supervision: McCabe