YALE JOURNAL OF BIOLOGY AND MEDICINE 86 (2013), pp.89-98.

FOCUS: NURSING

Blending Genetics and Sociocultural Historical Inquiry: Ethics, Culture, and Human Subjects Protection in International Cross Cultural Research

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In this paper, we examine the implementation and difficulties when conducting genetics research in a rural, traditional West African culture within the frame of the United States' grounded research ethics. Research challenges are highlighted by Western researchers following U.S. Institutional Review Board (IRB†) guidelines and practices in a non-Western country. IRB concepts are culture bound in Western ideals that may not have synchronicity and compatibility with non-Western cultures. Differences in sociocultural norms, traditions, language, and geography were influencing factors that can affect application of IRB principles. Suggestions for change are offered, which will potentially aid researchers considering application of IRB requirements when conducting research in non-Westernized, non-industrialized countries.

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†Abbreviations: IRB, Institutional Review Board; REC, research ethics consultation; AAP, American Academy of Pediatrics.

Keywords: genetic, Dogon, Institutional Review Boards, ethics, Mali

Author contributions: DAS obtained funding from Dean Kate Potempa at the University of Michigan as well as conducted the literature review, collected data, and assisted with writing. JYT conceptualized, designed, obtained funding, conducted the study, and assisted with writing. DC assisted with the literature review and writing. JYT and ADT collected data, conducted synthesis, and assisted with writing.

UNITED STATES INSTITUTIONAL REVIEW BOARD WITHIN THE DOGON COMMUNITY

The ethical challenges and implications faced when performing research in a non-Western nation can be unexpected and complex. Prior to the 20th century, researchers conducted scientific experiments using individual conscience and professional codes of conduct to guide ethical practice. After adverse events and maltreatment of participants in research studies (i.e., Tuskegee Study, the Nazi experiments, the Milgram study, etc.), the Belmont Report, which includes principles of respect for persons, justice, and beneficence, was created, just as the Nuremberg Code and Declaration of Helsinki were, to protect research participants [1]. In addition, accompanying these protections were federal regulations mandating the formation of Institutional Review Boards (IRB) in the United States.

This paper is a report of a genetics hypertension research project conducted in the Dogon region of Mali (2007). We provide information on how U.S. IRB standards were applied within the context of a non-Westernized developing nation [2,3]. We describe the ethical and practical aspects of the project along with the challenges of communicating, interacting, and collecting data within Dogon cultural norms while simultaneously assuring compliance with U.S. university IRB requirements. Sociocultural constraints pertaining to the central aspects of family, health, and illness data collection were especially problematic. At various points in data collection, non-Western cultural norms conflicted with Western attitudes and beliefs. An overview of challenges and struggles confronted while performing research in Mali follows, with suggestions to refine current U.S. IRB requirements for research conducted in a developing country.

INSTITUTIONAL REVIEW BOARDS (IRBs)

Although the intent of IRBs is to protect research participants from harm, the current IRB process for health research is geared toward a U.S. health care infrastructure, system, and culture. Principles of autonomy, respect for persons, beneficence, non-maleficence, and justice were foundations created to determine the ethical nature of research studies. These principles are conceptualized by IRBs within a structure that promotes values of individual autonomy and choice; where modern science is a cultural foundation; where men and women are assumed to have equal rights of participation choice; where full disclosure of risks and benefits are in a technically written script; and where a signature is the hallmark of consent. These principles evolve from concern regarding previous research studies that were subsequently determined to have violated ethical standards. The Belmont Report, produced in 1974, was created with the purpose of identifying basic ethical principles and guidelines to tackle and resolve ethical problems that could arise during the pursuit of research [1]. IRBs have been instituted as useful tools to provide guidance and support to researchers, but these ethical principles were developed from U.S. legal and moral values. Areas of research exist that are not adequately addressed by IRBs, such as the implications of obtaining informed consent in non-Westernized cultures or the handling of genetic data within developing nations. We report our experience of the conflicts we experienced within these conditions.

INTRODUCTION TO THE RESEARCH STUDY

In the spring of 2007, a University of Michigan pediatric nurse practitioner and genetics researcher initiated plans to replicate a three-generation study examining familial genetic hypertension and addressing specific genetic mutations among the Dogon people living in the Bandiagarra region of Mali, Africa [2,3]. The researcher collaborated with a University of Michigan sociocultural historian and family nurse practitioner who studies gender, geography, culture, class, and racial constructions affecting health. While the genetics researcher planned and directed the quantitative and genetic research process

related to the study, the nurse historian conducted the qualitative historical-cultural component. The Sangha villages within the Bandiagarra region of Mali offered important support for the research validity and were a practical choice for the research. Other University of Michigan researchers in anthropology had experience working in the region and were instrumental in arranging essential Malian governmental approvals, travel, lodging, identifying local translators, and building relations with Dogon leaders (needed for consent and assent for the present study). The population in this region was very stable and without much migration; therefore, adequate family groups would be available for multiple generation genetic research, a necessary component for the genetic research design. West Africa, as one of the centers of the slave Diaspora from which many present-day African heritage individuals in the Americas descended, could also support comparative genetic-based analysis with prior genetics work on African heritage women with hypertension in the greater Detroit area. Social structure, climate, nutrition, activity, living conditions, and health had not been studied among the Dogon tribe from a nursing perspective, which was yet another advantage to the research study. While genetic research is significantly valuable in understanding human health, the translation and application of these results among and between cultures required a social and historical context. Therefore, merging two research perspectives, quantitative/genetics and sociocultural history, allowed for greater scientific insights, richness of perspective, and knowledge development.

PROJECT PREPARATION

Project preparation, data collection, and analysis tasks were divided up according to an individual's skill set, educational training, and research interests. Historical and social qualitative research, including research of Dogon and Malian history, culture, geography, climate, social structures, preparation for language differences, and practical travel arrangements not provided by the University, comprised one set of tasks handled by the first author, historian Dr. Sampson. The other project components included establishing a working relationship with another University of Michigan researcher in Mali, determining specific genetic methods and analyses needed to address research questions, data collection plans, purchase and collection of research supplies, multiple IRB applications and approval for qualitative, anthropological, and genetics research, oversight of data collection procedures, and analysis of the data, provided by genetics researcher Dr. J. Taylor.

BACKGROUND OF THE DOGON AND THE BANDIAGARA ESCARPMENT REGION

The Bandiagara Escarpment is located in the eastern region of the country close to the southern edge of the Sahara Desert, west of Timbuktu and bordering the Niger River. The Dogon tribe has resided in this remote Bandiagara Escarpment region of Mali, West Africa since the 1400s, and while different Dogon village groups and families intermarry, no intermingling from groups outside of the Dogon is allowed [4]. The Sangha village region of the Escarpment, within which the majority of Dogons live, has no electricity with the exception of generators at a few hotels and clinics [4]. The agrarian and herding lifestyle depends on weather conditions, fluctuating between torrential rains in summer months to arid dryness in winter. Food varies little from staples of mutton, chicken, peas, rice, couscous, millet, dry fish, bread, onion soup, garlic, and spaghetti [4]. Social structure is patriarchal and hierarchical within villages, with formal power and decision-making controlled by the village chief. Women are responsible for the majority of food production and preparation. Although recent improvements in Malian infrastructure has brought a paved road to the Escarpment area, travel is still a challenge, particularly during rainy summer months when flash floods wash out paved roads and bridges. Due to the lack of migration over time, the

Dogon people possess a relatively stable and rich heritage that aids genetic research endeavors. Serendipitously, the Dogon religion, a blend of Islam and animism, includes the tribe's use of a symbol remarkably similar to that of the DNA double helix as a symbol of life [5].

Several challenges became apparent as the research plan, university project paperwork, and Malian government requirements developed. Language was the first apparent barrier. The Dogon language includes several local dialects, and only educated Dogon men speak the official Malian languages of Bambara and French. English is rarely spoken by anyone native to the region or even in surrounding urban areas of Mali. While one researcher could speak, read, and write in French, an English-speaking local Dogon translator, a resident in the Dogon region, was needed to bridge cultural and language gaps. An anthropology researcher from the University of Michigan who had worked in the Dogon area for more than 20 years was in the area during the time of the genetic study and was essential for identifying, negotiating, and assisting this group with hiring a translator.

TEMPORAL RHYTHMS, CLIMATE, AND CULTURE

Sangha villages and the surrounding Bandiagarra region experienced more than the usual rain during August 2007. Travel was difficult due to washed-out bridges and paved highway. A lengthy detour through the bush and over dirt paths was required due to heavy rains and flooding. The timing of this arrival made the availability of research participants complicated. Temporal rhythm of village life and work in this agricultural society is dictated by the growing season. This study, focusing on matrilineal genetics and hypertension, took place during planting and harvest season, a particularly busy time for all women in villages. Many potential female research participants were up at dawn and working in the fields until just before dark, making it difficult to interact with them without asking them to take time off from their critical and time sensitive food production. Therefore, one practical dilemma arose in that research participants were only available for data collection during daylight hours, interfering with time needed for food production and gathering. Market Day became yet another obstacle. This event occurred every 5 days, and all tribal women would travel to socialize, buy, and sell goods, making it difficult to ensure consistent data collection. Having sensitivity to the essential nature of women's work and cultural norms meant that data collection would need to be performed in a way that assured minimal disruption to daily life. The translator recommended specimen collection in the early morning and late afternoon, so women would be able to participate with minimal disruption to work life while honoring cultural efforts. The translator was a local college-educated Dogon male who worked for Western organizations, spoke English, and could bridge these cultural divides.

INFORMED CONSENT, INDIVIDUAL AUTONOMY VS. GROUP CONSENT AND GENDER

Cultural notions of individuality, personal choice, and autonomy, on which U.S. scientific research-informed consent principles are based, were difficult to translate conceptually in Mali. IRBs usually require each individual research participant to sign an informed consent form that often contains pages of technical language. Because of harm to research participants in past medical research, IRBs are particularly sensitive to details of genetic or medical research projects particularly in vulnerable populations such as children, the elderly, women, and people considered economically deprived by Western standards. University and institutional IRBs inherently have a conflict of interest within the informed consent process due to the potential for institutional liability for untoward research outcomes. Therefore, IRBs may be influenced by these concerns without having a sound knowledge of cultural intricacies in non-Western cultures [6].

In developing countries, including among the Dogon tribe, the process of informed consent could not be an individual choice. The village chief or his designated community elder, as opposed to the individual, first determines all individual decisions in a village. Even men in a village have limited autonomy and must assure the chief's consent to activities. Further, when the chief gives consent to any activity, individuals rarely refuse. To impose Western notions of personal individual rights in this cultural context would be, perhaps, paternalistic. Adding to this conundrum, reading and writing illiteracy is the norm among women and many men; thereby, using complex written consent documents and signatures had little real meaning for informed consent [6]. Lastly, the challenge of assuring full informed consent was exacerbated by the fact that tribe members had little or no Western scientific knowledge, experience with Western medicine, or contextual paradigm within which to understand the research purposes or risks and benefits to them as defined by the IRB requirements [6]. Therefore, it was impractical to expect consent strategies used in the U.S. to apply in such a dissimilar setting.

Social structures within the Dogon tribe were rigid, hierarchical, and gender bound. Each village had a chief who was appointed by the village men as the leader. All village members were expected to honor the chief's decisions. Before the researchers were able to enter the village, the chief had to provide consent, and village men were the gateway to village entry. The translator, who also functioned as a practical and cultural guide, understood the research and had some knowledge of IRB requirements. He was able to provide an explanation of the research purpose and terms of informed consent that fit the Dogon context, but due to cultural and customary traditions, reading the informed consent to each participant and asking for a signature would insult the village chief and end the research study. Therefore, the researchers and translator sought verbal consent from the chief for all participants in the village and asked the chief to allow individuals to opt out of their own choosing.

This was perhaps the most reasonable, respectful, and participant protective effort given the culture and social norms. Although the basics and intent of oral informed consent IRB standards were instituted, the experience of interacting with an unindustrialized, non-Westernized society commanded by a village chief required adaptation of consent methods within vulnerable populations.

While the Dogon have a strict male dominated and rigid gender bounded society, women were permitted to keep cash earned from work for their own personal activities. All study participants were paid the equivalent of one dollar (U.S.) to participate in the study. The majority of the Dogon women were enthusiastic about participating in the research study and were able to keep payment for their service.

TRANSLATION AND FACILITATING THE RESEARCH PROCESS

Perhaps the most critical aspect of this research was having a translator/guide who not only understood the culture of the Dogon people, but who could also translate Western concepts in ways that made sense to natives while also keeping researchers aware of cultural traditions. Much of the study's success was in part due to the translator being born and raised within one of the Dogon villages, being a member of an elite Dogon family, a local leader in public health initiatives, and respected due to his college education. He worked for the United Nations in Africa, was fluent in French, English, Italian, and all Dogon dialects, and had extensive interaction with Western culture. He also understood the rules for courteous interaction in Dogon culture so that direct research questions were asked and answered in a way that was considered culturally appropriate. The translator was able to negotiate by obtaining information from participants in ways that were accurate contextually across cultures, a task the researchers could not have accomplished alone. He knew and was undoubtedly related in some way to all village leaders, had

their respect, and knew of all family lineages and linkages within and between villages that were critical components to the genetic and family lineage portion of the study. Also, as a male, he had power to enter into negotiations with other village chiefs, something a woman would not have been able to do regardless of education or knowledge regarding Western culture. However, typically, Dogon women are not allowed to discuss their female bodily functions such as menstruation in front of men as this was taboo in a culture that relegated menstruating women to a separate "menstruating hut." Nonetheless, due to the translator's position as president of the regional public health committee and work with local physicians and midwives, he was able to phrase questions within gendered boundaries of bodily modesty while eliciting necessary responses to research questions.

DATA COLLECTION, MEDICAL TECHNOLOGY, AND KNOWLEDGE

Data gathering included standard medical assessments of a participant's cardiovascular and overall health status using technological equipment, such as blood pressure cuffs, weight scales, measuring tape, and saliva collection tube for DNA sampling. The majority of medical equipment used to assess health status was not part of any form of standard care that would be received by members of the Dogon community. Therefore, researchers thought it fitting to provide knowledge related to illnesses that were identified and to suggest community resources to treat illness. In addition, an appropriate custom among the Dogon required the offering of technologies and clinical expertise to non-participants such as the chief regarding the medical condition(s) of his tribe members. Often this meant being called upon to consult regarding non-cardiovascular illnesses, to validate the appropriateness of medications prescribed at the local clinic, or to provide medications from the supply brought by researchers to treat cases of extreme hypertension. There were some participants who had extremely elevated blood pressure readings that in the United States would have required immediate hospitalization due to risk of stroke and heart attack. In the Escarpment, though, all researchers could do was offer a limited supply of medications, monitor blood pressure, and collaborate with the translator/guide for follow-up care.

All discussions and advice concerning medical conditions were provided in simple language that considered practical concerns of illiteracy, lack of financial resources, medicines and treatments, lengthy travel distances to the hospital, and limitations of food variety inherent within this population. Advice was given to limit dietary salt and to seek medical follow-up at the local clinic. The translator was helpful with identifying those who needed follow-up care and was able to refer participants to appropriate public health resources. The most important ethical concern researchers experienced was the provision of appropriate health care within cultural norms and contexts with the least amount of harm.

ETHICS, GENETIC RESEARCH, AND CHILDREN

Specific areas of science and medicine such as genetics are gaining much ground among IRBs and ethicists. For instance, the use of anonymized samples have not technically been considered human subject research. The Declaration of Helsinki, which considers only research on identifiable human materials as human subjects research, does not cover ethical questions that arise given the storage and handling of genetic tissue after de-identification [7,8]. This area of research has been a growing concern for geneticists, particularly the handling of pediatric genetic information and the processes of informed consent and child assent. Debates exist for the reason that children are considered a vulnerable population due to their lack of capacity to consent for their own participation. In a study by Ries, LeGrandeur, and Caulfield (2010), cohort studies were analyzed for how key ethical, legal, and social issues were handled [9]. The need to seek assent/consent as the child

matures across the early lifespan has been considered by some as ideal practice among the pediatric population [9]. Other studies similarly suggest providing children with an opportunity to sustain or refuse a parental decision made on the child's behalf, in accordance with respect for the maturity of the child and personal interests in crafting autonomous choices [9].

Counter to this position is the Committee on Bioethics of the American Academy of Pediatrics (AAP), which recommends against genetic testing of children for conditions that begin in adulthood [10]. They argue that genetic testing should be protected until adulthood or late adolescence, when the individual has developed an ability to make mature decisions. The Clinical Genetics Society in the United Kingdom also conveys analogous views suggesting that unless the child requests such tests (acting as an autonomous adult), predictive testing should not be undertaken for an adult onset disorder [11]. While a case can be made that the benefits of genetic testing for adult onset diseases may not apply to the child for many years, this lies in opposition to the former mentioned literature. The American Society of Human Genetics' position in cases where there exists uncertainty related to the benefit of genetic testing and the child is deemed to have the capacity to choose genetic testing is that this could be considered ethically permissible [12].

Inconsistencies in the literature on genetic testing in children are controversial and lead to many questions regarding matters of ethics in this population. Addressing issues based on respect for the well-being of the participant at the time of research should be a primary motivation, as with the protection of participants and methods of least harm [13]. This particularly holds true when working with vulnerable populations and groups that are not well integrated into a health care system due to ethnic, cultural, economic, geographic, or health characteristics as isolation provides concern for increased risks [14]. Yet, within these tenets of ethical research, research that is permissible, authentic, realistic, and probable must be recognized in non-Western, non-industrialized, and Westernized countries. Within this study, the research, acknowledgement, and blood pressure measurements on Dogon children helped families seek medical care when indicated (i.e., medication administration, regular checkups in a local village) and address concerns that otherwise may not have been identified.

GENETIC RESEARCH WITHIN THE DOGON TRIBE

While the genetics of hypertension has not been studied in the Dogon community before, the immunity status of Dogon children within the realm of genetics and helper T cells has been examined. As malaria continues to be a growing concern in West Africa, the Dogon tribe has been observed for the potential of lowered susceptibility. Within *Plasmodium falciparum* malaria infection, Dogon children possess an inhibited toll-like receptor response with altered antigen-presenting cells when compared to the Fulani children (a nearby tribe in Mali) [15]. The Fulani children have been found to mount a stronger inflammatory antibody response as well against this parasite from an early age, when compared to the Dogon children [16]. Additionally, a TLR2 polymorphism has been implicated within the Dogon population as with alleles (HLA-A*30:01 and HLA-A*33:01), giving rise to the potential of susceptibility factors in cerebral malaria within the MHC genes [17,18]. A major epidemic of cutaneous Leishmaniasis (diffuse hypopigmented skin lesions mimicking borderline-tuberculoid leprosy) present within Dogon country also has been noted in the literature [19,20]. Addressing many of these medical concerns from a genetic/genomic framework could offer significant insights into immunity, increased susceptibilities, vaccines, and pharmacotherapy efficacy. Understanding clinical manifestations and symptoms in this population could provide guidance to family members on how soon the child should seek medical attention. Because of the isolated nature of the Dogon tribe, language bar-

rier(s), male-dominated society, and inclusion of women and children in the study, these participants were considered a vulnerable population and, therefore, additional steps were required to ensure the ethical nature of research and care.

ETHICAL RESEARCH IN AFRICA

Klintzman (2008) suggests that U.S. IRB beliefs regarding the effectiveness of an informed consent process poses potential problems as these beliefs may not be ethically sound across cultures and may undermine effective efforts to obtain informed consent [21]. In a South African study addressing various treatment protocols for HIV, he proposes the usefulness of involving localized IRBs to support details concerning participant comprehension. He recommends asking questions that might be answered more knowledgably locally, compared to attempting to answer non-Westernized culture's potential research questions and concerns from a U.S. perspective [21].

In a rural Northern Ghana study by Onvomaha Tindana, Kass, and Akweongo (2006), researchers found a similar community structure to that of the Dogon tribe [22]. Due to a lack of individual autonomy and a non-literate population, written consent documents were problematic, impractical, and unrealistic. In this case, some of the U.S. IRB requirements were perhaps not addressing feasibility issues or the implementation of ethical best practice. IRBs are at risk for imposing variable and inappropriate or unnecessary standards to research, which could impede the conduct of evidence-based research [23]. In this case study, researchers reported that a knowledge gap existed between IRB committee members in the United States and what was plausible in Dogon country.

Guidelines and reports suggest the use of community approval and verbal consent when cultural values and practices emphasize oral, as opposed to written, agreements and where community leaders such as chiefs play a major role in decision making [22]. In Kenya, researchers found community engagement to provide the most opportunity for researchers to address opinions, issues, questions, and concerns related to the study. The community's understanding and trust of the researchers was also paramount to the project execution. Researchers were addressing informed consent issues in a genetic cohort study of severe childhood diseases and suggested the role of field workers is critical to the development of supporting informed consent and to discussions on concepts of inheritance [24]. There exists a pervasive need for flexibility and sensitivity based on the realities of non-Western culture, geography, and society, especially related to understanding equity, justice, and beneficence of research.

In Mwanza, Tanzania, researchers developed a locally appropriate pictorial flipchart to convey key messages about the trial to participants [25]. Researchers also created pre-recorded audiotapes to facilitate understanding of the research and used a continuous informed consent agenda, resulting in high levels of understanding and participant retention. It is essential to be creative and innovative within non-Westernized cultures with unique traditions while attempting to best address U.S. IRB ethic requirements. U.S. IRBs and ethic communities need to acknowledge differences and limitations that exist when working in non-Westernized, non-industrialzed community.

SUGGESTIONS FOR U.S. IRBs

Abbott and Grady (2011) conducted a systematic review of U.S. IRBs to determine what was known about the function of IRBs and to identify gaps [26]. They found IRBs differ significantly both in their application and interpretation of federal regulations over the time it took the group to review a study and in the process of decision making [26]. Due to these inconsistencies and the varied concerns that arise when partaking in a non-Westernized study, thought should be given to changes, adoptions, and dismissals of IRB protocols or Westernized frameworks when conducting a study in a non-Westernized country. Researchers should operate out of

respect to the culture under study and to incorporate social norms and traditions into an ethical framework to guide IRB approval. Furthermore, as many studies occur in non-Western, non-industrialized nations, continued emphasis should be placed on understanding the knowledge gaps within U.S. IRBs and the practical and ethical guidelines for research within developing countries. Sensitivity to non-Western cultures is an imperative for avoiding imposing Western values in paternalistic ways that, ultimately, negate the true purpose of IRBs — to protect others and do no harm.

CONCLUSION

The blending of scientific and humanities perspectives added a unique influence to this study. This complex research project was accomplished in a short amount of time, while struggling with conceptual transcultural translation of practical and ethical research practices, combined with the realities of performing clinical research in a remote non-Western environment. The distinct academic perspectives and variety of research skills were complimentary and added to enhancing the quality, rigor, and translation of this study.

Suggestions for future studies performed in non-Western or non-industrialized nations include using local means, such as a local translator to accomplish meeting IRB guidelines. Attempting to obtain a scientist to serve on a local IRB who has experience working in non-Western or non-industrialized countries could provide useful guidance and understanding related to cultural differences. Another option might be to ask the expertise of a research ethicist either from the country of interest or from the United States who was affiliated with non-Westernized or non-industrialized policies and initiatives, such as the World Health Organization or Unesco.

Yet, with as much time as the researchers spent in preparation of the trip, reading about the history, culture, climate, and living conditions of the Dogon, some of the issues encountered could not have been apparent to the research team until the actual arrival at the study site and interaction with the Dogon tribe developed. In this particular case study, it may have helped researchers to have collaborated with the Pan-African Bioethics Initiative, the Council for International Organizations of Medical Sciences, or a local research ethics consultation (REC) committee to best expand the understanding, relevancy, and mission of the IRB when dealing with the Dogon tribe [27]. The involvement of local entities such as a REC committee could be beneficial to the IRB approval process in educating IRB committee members and by increasing the protection of vulnerable populations [28,29]. While much was learned from this study, the researchers encourage future studies to continue examining differences in U.S. IRB requirements and ethical implications in a non-Western, non-industrialized nation. By conducting further research in developing countries, U.S. ethicists will be able to garner greater understanding and knowledge of best practice for the protection of vulnerable populations.

Acknowledgments: Funding for this research was provided in part by the Office of the Dean, University of Michigan School of Nursing and Office of the Vice Provost, University of Michigan and National Institutes of Health Grants 5-P30-AG015281-07 and 1 KL2 RR024987-01 to Jacquelyn Taylor.

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