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The Challenge of Cross-Cultural Clinical Trials Research: Case Report from the Tibetan Autonomous Region, People's Republic of China

Efforts to conduct Western clinical research in non-Western medical settings with little or no familiarity with such methodologies are on the rise, but documented accounts of the ways that biomedical science requires negotiation and translation across cultures are not plentiful. This article adds to this literature through analysis of an NICHD-funded collaborative

MEDICAL ANTHROPOLOGY QUARTERLY, Vol. 19, Issue 3, pp. 267–289, ISSN 0745-5194, electronic ISSN 1548-1387. © 2005 by the American Anthropological Association. All rights reserved. Please direct all requests for permission to photocopy or reproduce article content through the University of California Press's Rights and Permissions website, www.ucpress.edu/journals/rights.htm.

research effort in women's health carried out in the Tibetan Autonomous Region of the People's Republic of China. The research involved a feasibility study for an eventual clinical trial comparing Tibetan medicine with misoprostol for preventing postpartum hemorrhage in delivering women. It explores strategies of negotiation and translation in and around notions of the scientific method, informed consent procedures, randomization, blinding, placebo, and concepts of medical standardization. [clinical trials research, Tibet, informed consent, transnational science]

Although medical research has been undertaken in cross-cultural settings for centuries, in some cases preceding the colonial era and in other cases proliferating under colonialism (Anderson 2003; Brown 1978; Prakash 1999; Vaughan 1991), medical research continues to expand into the global arena today in new and exciting ways. Medical scientists have long collaborated on specific high-technology research programs (Rabinow 1999; Traweek 1992), but medical researchers are increasingly forming collaborative programs with novice researchers from nations with no history of Western scientific or (what we will henceforth call) biomedical research. In particular, the last decade has witnessed a growth in efforts to conduct biomedical clinical trials in research settings outside of the industrialized world. In such cases, researchers are faced with the need to develop even the most basic infrastructures for collaboration, including the development of institutional review boards (IRBs), informed consent (IC) procedures, data collection and management systems, and research protocols that are feasible in local settings.

Such collaborative efforts pose unique challenges. Some of these challenges stem from differentials in research infrastructure (including technological resources and funding) and some stem from different national laws regarding research. Perhaps the most significant of these challenges are those stemming from the cross-cultural context of the research itself. Different cultures have different approaches to such things as the meaning of research, the ethics of protecting human participants, or the meaning of consent, as well as what constitutes a legitimate research methodology or comprises a suitable cohort and how to read the empirical basis for evidentiary claims. When brought together, these different cultural views create the need for negotiation and flexibility for collaboration to work.

Here, we outline some of the challenges of cross-cultural clinical trials research that have emerged in the course of an ongoing National Institutes of Health (NIH)-National Institute of Child Health and Human Development (NICHD), Global Network for Mother's and Children's Health Research funded collaborative project in the Tibetan Autonomous Region (TAR) of the People's Republic of China (PRC). First, we describe the project's history and current activities and give a brief overview of the methodologies we have employed and the medications we are using to conduct this clinical study. Next, we offer specific examples of what we mean by the challenges of cross-cultural clinical research—issues that raise ethical, epistemological, and practical questions. Here, we discuss the different meanings of research, development of IC procedures, standardization

of medicines, and meeting both national and international standards for research protocols.

The theme of "translation" runs through our work and is an organizing principle throughout this essay. By translation, we do not simply point to linguistic issues that arise in cross-cultural research environments, although we briefly discuss this as well. Indeed, it is virtually impossible, we argue, to disaggregate linguistic difference from the larger cultural systems and, in this case, medical and scientific vocabularies, in which our work is embedded. In pursuing the points of translation and negotiation in this article, we do not suggest that there is a complete lack of integration between the systems, nor that the two medical or cultural systems should be thought of as discrete, essential, or internally uniform. We are more interested in the points of disjuncture and misunderstanding, and the lessons that might be learned from the negotiations that followed. Additionally, we do not take Western biomedical research as uniform or extra-cultural itself. Rather, we understand that the very idea of a clinical trial, along with all of its methodological accoutrements (from blinding and randomization to IRBs) is itself culturally unique and contingent on certain cultural and social priorities and possibilities. However, we do not explore the contingent or cultural basis of clinical trials protocols here. Nor is it our purpose to report the findings of our clinical study, since that research is ongoing. Rather, this article is a report on the ways in which cross-cultural challenges have arisen because of the attempt to insert a Western research methodology into the clinical setting in Tibet. We thus also discuss how such challenges have been met and addressed to date in this particular context.

Beyond the possibility of gleaning insights about what does or does not succeed in such collaborations, we also see this analysis as part of a growing literature on postcolonial science studies and, in particular, on how the practices of science are negotiated in places far from the centers of funding and intellectual domination in biomedicine. Postcolonial science studies take into account the historical, cultural, and social contingencies of new medical scientific endeavors, while paying close attention to concerns about social, political, and epistemological inequalities that surface in contexts such as the one we describe, as well as shifts in the terms by which medicine and science are practiced as they unfold in local contexts.[1]

A History of the Collaborative Project

Beginning in 2000, a team of clinicians and researchers[2] from the University of Utah and the University of California, San Francisco, began collaborating with clinicians and public health professionals in Lhasa, the capital of the Tibetan Autonomous Region. The TAR is the westernmost and one of the least developed regions of the PRC. Its population is 2.8 million, spread out over roughly 1.2 million km, and consists mostly of Tibetan nomads and farmers along with an urban population of approximately 450,000 Tibetan and immigrant Chinese. Health infrastructure is sorely lacking in most of the nonurban areas of the region, despite heroic efforts by the state to develop health services over the last 40 years. Rural health services include county-level hospitals fed by rural health clinics. These two levels of rural health service are staffed by health care workers who have varied levels of medical training, from as little as three months to as much as

six years. Most rural Tibetans live considerable distances (from several hours' to several days' travel) from village clinics. Urban hospitals in the capital of Lhasa are numerous, though unevenly equipped, offering either biomedical or traditional Tibetan medical services. Two urban hospitals are devoted to maternal and child health. Most Tibetans are guaranteed minimal health coverage by the government, although urban Tibetans who do not work within official work units are required to pay for their own health care.

The government of the TAR has its own health bureau, although it bases its policies and programs on directives that are produced in Beijing in collaboration with health experts in the TAR. The emphasis of the central government is on increasing the quantity and improving the quality of care in the urban setting and using the urban facilities to establish best practices, which can, in some cases, be transferred to rural facilities. The emphasis is on expanding biomedical resources, even though there is a historical and continuing effort to sustain indigenous medical institutions (Janes 1995). In addition to subsidizing all of the biomedical hospital and clinic facilities in urban Tibet, the government also supports several urban hospitals and several large pharmaceutical factories for traditional Tibetan medicine.

The TAR also has its own medical schools for both biomedicine and traditional Tibetan medicine. Although basic principles of biomedical science have been taught at the university level, very little clinical research has been done in the country. Descriptive statistical data collection on the outcomes of various Tibetan treatments have been carried out under the auspices of Tibet's premier Tibetan medical institution (the Menstikhang) and the Tibetan Medical College (including research on treatment for hypoxia, liver disorders, and digestive disorders, for example). Similarly, statistical data collection on incidence and prevalence of various diseases has been undertaken by the TAR Health Bureau. Clinical research using the techniques of control, blinding, randomization, and statistical analysis have been minimal to nonexistent.

Both Tibetan medicine and biomedicine can be described as "allopathic" systems of healing. However, Tibetan medicine is predicated on fundamentally different theories of disease than that of biomedicine. The definition of health within Tibet's *gso ba rig pa*, or "science of healing" is based on maintaining a balance of the three *nye pa,* often translated as "humors": "wind," "bile," and "phlegm" and the five cosmo–physical elements of earth, fire, water, air, and space/ether. Tibetan medical practice, as well as more theoretical discussions about the causes, conditions, and treatments of illness, rely on pulse diagnosis and include prescriptions for medicinal compounds, sometimes with as many as 60 ingredients, as well as other healing modalities (moxibustion, golden needle acupuncture, massage, spiritual–medical ritual, and so on (Clark 1995).

Given these conditions, the goals of collaboration in the research described herein were, and remain, twofold: (1) to conduct a three-phase project (including a feasibility study and a randomized clinical trial [RCT]) to determine how well the Tibetan medicine called *zhi byed bcu gcig* (hereafter ZB11) works in comparison with a biomedicine called misoprostol for prevention of postpartum hemorrhage (PPH); and (2) to help Tibetans develop a self-sustaining infrastructure within their own medical institutions for conducting research at a level that would be

acceptable to the international scientific community (including the PRC). Phases I, II, and III of the research are described in detail below, noting that Phase III will only be pursued if ZB11 is shown to have the effect of reducing the incidence of PPH.

Research Rationale and Methodology

As per NICHD guidelines, as well as for the interests of the Tibetan research team members, we needed to focus this clinical study around an issue that was directly impacting maternal mortality and morbidity in the TAR. Approximately 80–95 percent of Tibetan women deliver outside of hospitals, often at home or in an animal shed adjoining the house. There is rarely a trained attendant at these out-of-hospital births. Most delivery-related deaths are reportedly caused by hemorrhage, obstructed labor, preeclampsia, postpartum sepsis, or some combination of these. In 2002, the TAR Health Bureau reported that the maternal mortality rates were as high as 400–500/100,000 in the rural areas. Thus, Tibetan colleagues wanted to develop a research project that would not only provide useful information about the effectiveness of Tibetan medicine, but could be of benefit to a large number of women in Tibet's rural areas who were dying from PPH. Validating the efficacy, or inefficacy, of ZB11 would help health officials to decide whether to authorize it as an officially recognized treatment option. If ZB11 were proven effective within the context of a clinical trial, then it would further validate the use of this Tibetan medicine in both rural and urban settings. If misoprostol was more effective at controlling postpartum blood loss, *under these clinical research conditions*, then our Tibetan colleagues could try to ensure its widespread distribution for home births as a prophylactic for PPH (ICM/FIGO Statement 2004). Finally, being able to show that this Tibetan medicine was effective would help the Tibetan collaborators establish more credibility within the PRC, not just as researchers but also as producers of effective medicine. Given the distance these researchers are from the centers of scientific activity within the PRC, this was important to them.

To ensure that the research benefited the health of Tibetan mothers and children, to maximize the transfer of research knowledge, and to ensure that we would have at least a minimal cohort of patients, we first developed collaborative ties with the TAR Health Bureau (our sponsoring agency in the Chinese government). Following their advice, we established research contacts at three hospitals in Lhasa: the Mentsikhang (traditional Tibetan medical hospital), the Maternal and Child Health Hospital (a biomedical institution), and the Lhasa Municipal Hospital (a biomedical institution). Because our research involved use of a traditional Tibetan medicine, we also recruited research scholars from the Tibetan Medical College. To ensure participation of these collaborative institutions, we formed a research committee (hereafter RC) with representatives from each institution; the RC meets at least twice a month to discuss issues of research design and protocol, infrastructure development, data collection and management, and research training with the U.S. researchers.

The Tibetan members of the RC are either obstetrics- and gynecology-trained physicians who are the directors of their institution's women's health departments, or professors of Tibetan medicine from the Tibetan Medical College in Lhasa.

Our physician team members were previously trained in either biomedicine or Tibetan medicine, and a few members had received training in both medical systems. In addition to this committee's regular meetings, we conducted numerous training seminars, one each on evidence-based obstetric practice, two on IRBs and rights of human participants, and one on research techniques for all clinical and research staff at the three hospitals and from the health bureau. In addition, we have conducted several hands-on workshops in preparation for data collection and management in clinical settings. These courses were designed primarily to transfer biomedical knowledge (theory, concept, method) to the Tibetan research committee members and other relevant providers, rather than transferring knowledge about traditional Tibetan medicine to the U.S. researchers.[3]

The U.S.-based research team members (an obstetrician, a nurse-midwife, a nurse-practitioner, and two medical anthropologists) in consultation with the RC and with the NICHD staff consultants, decided on a three-phase research protocol, described below. From the perspective of the Western researchers and clinicians, it was important to develop a feasibility protocol that would enhance our ability to do an eventual trial consistent with clinical trial research methodology considered acceptable in an international scientific community. This goal meant introducing and, to the extent possible, using randomization, blinding, controls, and large enough patient cohorts to do statistical analysis on the data.

Additionally, each phase required IRB approval from all U.S. and TAR institutions involved. However, there was no IRB in place at the time our collaborative project began. The U.S. investigators were instrumental in helping establish the first IRB in Tibet in December 2002. This committee is based at the Mentsikhang and is comprised of both Tibetan medicine–trained and biomedically trained providers, as well as members of the lay Tibetan community in Lhasa, the Women's Federation,[4] and the Tibet Drug Administration. Since the initial IRB and research ethics training, the U.S. researchers have led two refresher courses on these topics. IRBs in both Tibet and the United States have approved protocols for both the Phase I and Feasibility Study and the Phase II (for effect size). IRB protocols for Phase III (RCT) will be initiated in 2005, if Phase III is pursued.

In addition to establishing an IRB in Tibet, Phase I of the research has consisted of the following components: (1) establishing frequencies of delivery and rates of delivery complications, including hemorrhage and volume of blood loss, at the three hospitals; (2) developing culturally appropriate IC procedures and an IC document to be used in Phase II; (3) undertaking laboratory tests for toxicity and standardization of ZB11, as well as qualitative research on the history, production, and use of this medicine in its Tibetan context; and (4) developing training courses in the rights of human participants, ethics of research, and IC procedures; research methodology, techniques of data collection, entry and management; and the use of a blood-collection drape.[5] Phase I was completed in approximately 16 months, including 4 months of clinical data collection and analysis of postpartum blood loss.

Phase II of the study will compare measured blood loss between women receiving ZB11 prophylaxis and women receiving a placebo[6] in order to (1) estimate the beneficial effect of ZB11 on PPH reduction, if any; and (2) to introduce randomization procedures. Phase II will take approximately 12 months to complete.

If ZB11 is shown to be effective versus a placebo (or no prophylaxis, which is the current standard of care), then Phase III of the study will be a randomized comparison of ZB11 versus misoprostol to reduce blood loss in the third stage of labor, if Phase III is warranted. All three phases will be performed in all three of the aforementioned hospitals.

Choice of Medications

Zhi byed bcu gcig (ZB11) is a medication that has been used for centuries in traditional Tibetan medicine for the prevention and treatment of excessive postpartum vaginal bleeding and uterine atony. According to Tibetan medical theory and practice, this medicine helps balance the "downward expelling wind" humor (*thur sel rlung*), which, in turn, promotes a quick and less painful delivery. In Tibetan medical texts that describe ZB11's ingredients, as well as its indications and contraindications, the medicine is said to promote uterine contractions and help expel the placenta; it is also indicated for certain kinds of uterine tumors. Tibetan medical sources corroborate contemporary Tibetan physicians' perceptions of ZB11 as a "uterotonic":

> De'u dmar writes in his *Bsdu pod bdud rtsi'i gter sgron* that "in addition to the ingredients of ZB 6, adding hippophae, flesh of snake, salammoniacum, and crab secretion becomes a medicine called ZB11. This medicine is particularly beneficial for treating clots in wombs and postpartum infection. At the same time, this medicine makes the baby easily born and placenta comes out easily. No option is better than ZB11 found by Jomo Menmo. [*de'u dmar pa*, 1627]

Another text, *Sman sbyor nus pa phyogs bsdus phan bde'i legs bshad*, records: "ZB11 helps women to reduce the antenatal pains, break up clots, and particularly it is beneficial for delivering postnatal fragments, including placenta, in the uterus of the gravida [*srin glang 'dril ro*, in Tibetan]."

As indicated above, the 11 ingredients in ZB11 include plant, animal, and mineral products, as is typical for most Tibetan medical compounds (Dawa 1999; Dhonden 1986; Dorje 1995; Kletter and Kreitchbaum 2001; Meyer 1995). One of the most important ingredients is Podophyllum hexandrum Royale, known in Tibetan as *'ol mo se*. According to several Tibetan medical texts, this plant improves assimilation and circulation of blood, accelerates circulation of *rlung*, the "wind" humor, corrects menstrual irregularity, is used for treating gynecological diseases, including those of uterus, and is used to clear out placenta and ease childbirth (Dawa 1999; Kletter and Kreichbaum 2001).

Among lay Tibetans, ZB11 is known colloquially as *skye su rilbu* or "birth helping pill," *skye zug rilbu* or "birth pain pill," and *mgyogs ril* or "fast delivery pill"; names vary depending on region, dialect, and lay exposure to Tibetan medicine in general. ZB11 is still used among both rural and urban Tibetans, although it is more common for Tibetan women between the ages of 45 and 65 years to have had personal experience taking this medication. It is common for a Tibetan physician to give a woman several ZB11 pills with specific instructions on when and how to take them during labor and delivery, especially if the woman will not be attended by a medical provider during the birth itself. ZB11 also is one of the few Tibetan

medications used regularly in the Mentsikhang, where it is considered a delivery aid for women in advanced labor.

Today, government-owned and private Tibetan medicine factories, as well as individual private practice Tibetan physicians, produce ZB11 throughout the TAR and other culturally Tibetan regions of the PRC. Although producers monitor the contents and concentrations of ingredients, ZB11 is not required to be produced under Chinese Good Manufacturing Practices guidelines at this time. Like many Tibetan medicines used in clinical settings throughout the TAR, it is not currently a "registered drug," even though it is available for clinical use. Not being registered with the government means that it cannot be sold on national markets (or exported for sale as a medication to international markets).

Misoprostol is a prostaglandin E_1 analog that is used for a variety of obstetrical indications. It has been used effectively for cervical ripening, induction of labor, and prevention and treatment of PPH due to uterine atony. Misoprostol is affordable, easily stored at room temperature, and has a shelf life of at least 2 years. Although the recent WHO multicenter collaborative trial suggests that misoprostol was somewhat less effective than intramuscularly administered oxytocin, it was still effective for reducing PPH as compared to placebo and is (in contrast to intramuscularly administered oxytocin) a viable alternative for the prevention of PPH for deliveries occurring out of hospitals.[7] Because the overwhelming majority of deliveries in the TAR occur at home or at rural health clinics and because oxytocin requires refrigeration, the choice of misoprostol for this study allows the results to be directly applicable to TAR circumstances.

Indeed, misoprostol and ZB11 share a number of similarities: (1) they are both administered orally; (2) they are described by physicians in both Tibetan and biomedical contexts as having similar indications, risks, and benefits, in addition to being used as a uterotonic; and (3) they are both considered affordable medications. The latter is an important consideration in the Tibetan socioeconomic context. Misoprostol and oxytocin are the two most commonly used uterotonics employed in the biomedical sphere in the TAR; they are used to treat PPH at all three of the Lhasa hospitals with which our project is affiliated. ZB11, however, is only given at the Mentsikhang at this time, in addition to being used in rural settings.

The Challenges of "Translation" in Cross-Cultural Research

Although the idea of doing clinical research on Tibetan medicine in Tibetan hospitals is attractive for a variety of reasons (including the fact that many of the research participants are familiar with using the medicine being tested), doing such research presents a variety of challenges in protocol design, data collection, and interpretation of results. One might call these collectively "challenges of translation." Again, by translation, we mean two things: the first is linguistic translation between the three languages used in this study: Tibetan, Mandarin Chinese (Putong Hua or "common" dialect), and English. The second is the whole range of translation issues that arise from larger contextual factors such as the fact that the work straddles two different systems of knowledge and practice, two different conceptions of the body and bases for health, and two different ways of establishing "truth" from empirical evidence.[8] Some of the challenges presented here were rendered visible in the context of work at all three hospitals, whereas others were

primarily evident only at the Mentsikhang where the normative treatment models were organized around an integrated Tibetan medicine and biomedical model.

The Challenge of Linguistic Translations

Given that our research is being carried out in Tibet, we have had to develop a working infrastructure for translating across three languages: Tibetan, English, and Chinese (Putong Hua). While most of the patients with whom we work speak only Tibetan, most of the medical researchers and providers are literate and fluent in both Tibetan and Chinese. Because Chinese is the official language of the country, and of the government, it has become important to provide Chinese versions of our work to all of our government health bureau affiliates. Moreover, because biomedicine had first made its way into Tibet by way of the Chinese language, it has been useful to do much of our training work in Chinese rather than in Tibetan. The language used among providers and preferred by providers for discussing biomedicine is Chinese. The Chinese dialect already has a well-established vocabulary for biomedical concepts. However, working in Tibetan remains a priority for our team, not only because we will eventually be working with participants who only speak Tibetan, but because many of the concepts we work with in Tibetan medicine are only found in Tibetan language.

Moreover, because our foreign research team is largely English speaking, with only a few members of the team fluent in Tibetan or Chinese, it has become imperative to hire staff for the project who are fluent and literate in all three languages. Finding Tibetans with this level of proficiency in multiple languages was difficult, and finding individuals who had an interest in leaving their existing occupations (generally with the government) to work for our project has been extremely challenging. We have worked around this obstacle in part by hiring staff to work part time for our project until full-time staff persons could be identified. Even with such qualified persons, however, we could not have anticipated the amount of time and infrastructure that would be required to ensure that our training and research materials were fully translated into three languages. And even with this infrastructure in place, we continue to encounter problems of poor translation, giving wrong information or, at times, critical misunderstandings of key concepts. Our timeline expectations for getting started and producing results have been greatly modified by the time needed for translations in the linguistic sense.

The Meaning of "Research"

It became clear early in this project that for many members of the research team, particularly those from Tibetan medical institutions, the meaning of "research" was somewhat different from that held by the U.S. participants as well as from the understanding of their exclusively biomedically trained colleagues in Lhasa. Although we all share the notion that medical research involves investigation based on empirical data collection and observable results, with the intention of improving both clinical techniques and outcomes, there remain many areas of difference.

Tibetan explanations for mechanisms of effectiveness of medicines generally involve concurrent social or religious input, or both. Tibetan medicine maintains

that all material substances are made up of the five elements and that no substance on earth is devoid of medicinal value; this conceptual framework is also derived from Tibetan Buddhist religious ideology in which the root cause of suffering is ignorance (*ma rig pa*), and in which the three poisons of Buddhist thought—desire, anger, and delusion—are directly connected to imbalances of the three humors. In the Tibetan medical view, each cosmo–physical element can be recognized by its qualities: viscosity, taste, heaviness, color, and so on. Thus, plants, minerals, and animal substances contain varying strengths of the five elements. A plant root that is thought to contain fire, for example, is considered to have qualities of "heating" or "warming," especially if it grows, for example, only on the sunny side of mountains, or only in the summer months, when it is warm.

For the last 30 years of formal government support for traditional medical systems research in the PRC, Tibetan medical research involved pharmaceutical efforts based on the theoretical principles of the five cosmo–physical elements in Tibetan medicine. Research in Tibetan medicine has historically focused on finding new ingredients with equivalent potencies or stronger potencies for use in compounding medicines for treating known conditions, often tied to specific humoral and elemental imbalances. It was not uncommon for medical researchers to rely heavily on the astrological calendars, produced within the Mentsikhang's research division or by other institutions, in order to calculate the potencies of various plant, animal, or mineral ingredients. The length of the seasons, the amount of rainfall, the alignment of the planets, and the like are all taken into account in creating these calendars and, therefore, in deciphering elemental composition of ingredients.

In keeping with the centuries-old practice of testing on one's own patients in a simple case-based observation, Tibetan medical practitioners still relied on a version of this method in their research in the late 20th century. Most Tibetan medical practitioners historically compounded their own medicines and used them on their patients, observing the benefits and effects of their own patient cohorts in what biomedical researchers would today call a "case series without controls." In Tibetan medical institutions today, similar observations are being made and published with no standardized research protocols, small numbers of patients, usually no control groups, and little cross-communication among practitioners about methods of research or developing viable bases for comparative analysis. Questions of reproducibility and proof vis-à-vis standard research methodologies are often not actively debated.

Contemporary biomedical research on new medicines consists of a combination of laboratory research and clinical research focused on safety and efficacy. Generally, biomedical research is driven by the desire to improve medical outcomes for specific diseases, making the clinical testing of medicines a priority and a necessity. For this, contemporary biomedical research holds as the most valuable warrant of evidence the RCT. Having large enough sample sizes to demonstrate a statistically significant result (statistical "power"), randomizing participants to control for bias use of placebos, and masking patients and doctors to whether patients receive the intervention medication or the placebo are all methods biomedically trained scientists use to obtain reliable information on medical efficacy. Such results are taken to be reliable because they can be subjected to further scrutiny

by peer review processes prior to publication and consideration of the theoretical reproducibility and generalizability of the methods and results.[9]

We soon learned that many Tibetan-trained medical colleagues were unfamiliar with concepts of biomedical research and that many Tibetan colleagues who had been trained in biomedicine were also unfamiliar with the basics of research methods. Beyond this, very few lay Tibetans had ever heard of research or had any exposure to the concept of research. We had to "translate" the Western concept of research into training programs that would enable the Tibetan research counterparts to participate in the design and execution of the project, but we had to introduce the concept of "research" as a whole to many of our research participants. We undertook a lengthy process of establishing an IC procedure that would be comprehensible to our research participants followed (see below). Before this, however, the foreign team of biomedical experts conducted a series of training programs, which included lectures, readings, role plays, and other training activities, and examinations for the Tibetan research team participants and staff at the three hospitals.

Differences in exposure to and familiarity with research methodologies also led us to see other significant incompatibilities in translating ideas of research. Because in the traditional Tibetan context, research is currently focused on the effort to develop more potent medicines for known conditions and for disorders that are recognized as new, we have had to negotiate some concepts that are new to the Tibetan plateau (such as HIV) and some that are simply disorders that have been reclassified according to a biomedical nomenclature (for example, diabetes and hepatitis). In some cases, biomedically named diseases do not translate to a single, named Tibetan disease but rather to a variety of different humoral imbalances that affect the strength of the liver, other organs, digestion, and so on. The complexities of naming disorders across the two different medical systems continue to be contested topics among scholars at the Mentsikhang and the Tibetan Medical College. Although no systematic program has been developed for the process, most clinicians follow a practical system in which the diagnosing physician who names the disorder (with either a Tibetan or biomedical name) ultimately decides how best to classify each patient and, in so doing, designates a course of treatment that either follows a largely Tibetan or biomedical treatment program (Adams and Li Forthcoming).

Moreover, biomedical theory assumes a fundamental relationship between a specific drug (in this case, misoprostol), prevention of a condition (PPH), and a patient population (pregnant Tibetan women), whereas Tibetan medicine is theoretically predicated on the potential for differences in treatment regimes and outcomes when faced with the same set of parameters, based on a patient's humoral balance, karmic inheritance, and other physiological, cultural, and even spiritual factors. This sort of difference occurs at the level of epistemology, of basic assumptions about how we know, or establish, truth about medical efficacy. Similarly, even though both medical traditions may begin with a shared assumption about the condition that is the object of study (in our case, PPH), theories about how to appropriately prevent or redress the condition derive from different theoretical models about how the body works and what causes its dysfunction in the first place. These differences point to the need for negotiation over research protocol—again, negotiations that ultimately reveal differences in basic epistemology. For

our study, it became clear early on that one of our objectives was to develop a more robust infrastructure for research that met biomedical standards. Biomedical theory was fundamental in structuring this cross-cultural clinical research in that the methodologies, disease nosology, and etiology, even which drugs were chosen for trial, emerged from biomedical knowledge about a biomedically named condition, in this case, PPH.

Although efforts to educate the research team in order to cultivate a shared sense of a biomedical meaning of research methods have been obvious, many questions about different meanings of research or different assumptions about how best to establish truth in research have operated largely at a subsurface level. These only emerged in rare moments when it has occurred to some of our research team that our chosen methods conflict with a Tibetan approach to these empirical situations. We explore more of these moments of rupture and negotiation below.

Informed Consent Procedures

One of the most challenging aspects of our effort has been the development of culturally appropriate IC procedures for use in the Tibetan context, specifically for Phase II of our research project. Although the PRC has national policies regarding the protection of research participants and institutional review board policies to ensure that IC procedures are uniformly followed throughout the country, no such infrastructure existed in the TAR when the project began in 2000. During the first two years, an IRB was established in Tibet that satisfied both Chinese government policy and the NIH's requirements, including the signing of a Federal Wide Assurance (FWA) from Tibet. The latter was intended to ensure that Chinese IRB policy met U.S. standards—a legal mandate that required a great amount of communication between health officials in Beijing and Washington, DC. After 2 years of effort, our team secured a FWA and established an IRB at the Mentsikhang that, with support of the TAR and Lhasa Municipal Health Bureaus, serves as the review board for research at all three Lhasa hospitals.

Simultaneous with this effort, data were collected through ethnographic, semi-structured interviews with providers and patients about Tibetans' level of knowledge and understanding of research, notions of risk, benefit, and consent. This qualitative research has informed the development and pilot testing of various iterations of an IC document. A summary of the research on which culturally appropriate IC procedures were based is in preparation (Miller et al. 2004). These data have also been used to develop further training programs for providers about research methodology, the ethical requirements of voluntary IC, and other research-related issues involving human participants.

Several cross-cultural challenges emerged in the effort develop an appropriate consent document that were related to problems of translation—both in terms of the language differences between English, Tibetan, and Chinese and in terms of the larger cultural and contextual implications of these choices of words and phrasing.

Disclosing Risk

One of the first issues raised by IC was that of disclosing notions of "risk." From our initial ethnographic interviews, we learned that lay Tibetans are loath to openly discuss potential hazards that may arise, whether or not they are related to

participating in research. These fears surrounding descriptions of risk are related to Tibetan concepts of well-being and, in particular, to their belief that if the patient envisions herself or himself as possibly suffering or being harmed or experiencing any type of misfortune, then her or his emotions will agitate the wind humor. Because the wind humor is, in the Tibetan medical view, responsible for all movement in the body (from breathing to muscular movement), agitated winds are believed to produce effects that are felt throughout the whole body (digestion, the flow of blood, functioning of organs, and so on). Thus, many Tibetans believe that if they talk about possible negative outcomes of, for example, childbirth, it generates forces that will bring a negative outcome into reality.

As researchers, we were faced with the question of how to be honest in disclosing possible risks of both childbirth and of participation in our project, including enumerating the causes of obstetric mortality related to hemorrhage, without creating disturbances of the wind humor or other, related problems in potential participants. Such disturbances might discourage women from participating in our research, but more significantly they might feel that hearing about complications caused the medical complications, even if they chose not to participate.[10] This issue presented us with a scenario that was nearly the opposite of what we would do if we were conducting the research in the United States, where patients would be presented with the maximum information possible about the risks, and describing high rates of mortality from hemorrhage would be seen as useful information for justifying the research.

Here the question of how and how much to discuss risk displaced the ethical certainty that undergirded our own IC priorities. Ultimately, we chose to present the critical information, eliminating much of the discussion of risk factors involved in delivery in general, rates of hemorrhage, and descriptions of hemorrhage itself. Instead, we included general statements about the fact that all women bleed during a normal delivery and stated that if any of our participants appeared to be bleeding excessively, they would be given the normal course of treatment at that hospital to ensure their safety.

Randomization

Another concept that presented challenges to the research team was that of "randomization." There was no direct translation for this concept in Tibetan, and most patients were not familiar with the concept of an equal chance of two options. The U.S. IRB recommended that we introduce the idea of randomization by describing it as being "like flipping a coin." The relevant conceptual facts conveyed in this image are that chance determines the outcome of the coin toss and the outcome would determine the group to which one would be assigned (ZB11 or placebo). However, the concept of flipping a coin is also culturally embedded and has no real cultural referent in the Tibetan world. For many Tibetans, the concept of "chance" is understood differently than it is understood in the West; it is linked with the Buddhist notion of *las,* the karmic laws of cause and effect, in which past actions—even in previous lives—bear on one's present circumstances and impact that which in the West we might attribute to fate or chance.

Efforts were made to devise ways of to explain randomization that would resonate with traditional Tibetan cultural patterns. A number of ethnographers[11] of Tibetan communities have documented a general Tibetan notion that shares the

sense of randomization: *gyan gyab* [*rgyan rgyab*], a system for drawing lots, often involving the use of dice, as a means of distributing scarce resources equitably to a group of families in a community. Gyan gyab is more complex than flipping a coin. It involves several procedures that, in combination, ensure a randomization of the chances of being allocated a portion of a given resource.[12] Thus, the concept of gyan gyab was useful in describing randomization in our IC document because it helped us describe a process by which people were divided into study groups in a random but equitable way. However, unlike gyan gyab, a notion of transparency as well as the concept of equality and chance were modified. The second version of our pilot IC document was worded: "This process is similar to the Tibetan system of drawing lots, or gyan gyab. But, unlike gyan gyab, you will not know which group you are in. Only the doctors will know." In this instance, the issue of translation was not one of merely picking the right Tibetan or Chinese word to substitute for the English randomization, but rather involved complex understanding of the language and culture, to choose comprehensible language and concepts.

The randomization scheme for Phase II of the ZB11 study provides for consenting patients to be assigned consecutively numbered opaque envelopes containing a number. Each number corresponds to a packet that contains identical capsules containing either ZB11 or placebo pills. To make randomization more understandable to patients during the consent process, we used illustrations that showed a patient drawing an envelope and handing it to her provider rather than using gyan gyab. Use of a placebo masked both practitioners and patients to the treatment assignment. However, we encountered difficulties in trying to use the language of "masking" or "blinding" in explaining our procedures.

Blinding and Placebo

Like the concept of randomization, we could not find an easy translation for the concept of "blinding" in Tibetan. Blinding, in its normal usage in biomedical research settings, refers to the process whereby patient (and provider in the case of double-blinded studies, and researchers in the case of triple-blind studies) are not aware of which patient receives the study drug. The assumption being made by researchers using this design is that it will distribute the unknown/unmeasured biases and confounders equally between the treatment groups. If patients do not know whether or not they receive the study medicine, then there is an equal chance that patients in both groups will experience placebo effects similarly. In the case of providers and researchers, it prevents biases in interpreting or reading data (Harrington 1997). Blinding is a simple concept in biomedicine that is not difficult to explain to patients. However, attempts to translate the term into Tibetan often ended up with phrases like "keeping in the dark, obscuring the environment of the research, like darkness in the middle of the night." When translated, patients often responded with concerns such as one patient who said: "One should not blind or obscure the meanings or goals of the research from the patient" (Interview 7/19/03).

Efforts to devise better ways of translating the term and concepts of blinding were difficult because the purpose of blinding is to prevent the researcher, provider, or patient from knowledge of who is getting the intervention medication or the placebo. However, translating the idea of "keeping someone in the dark"

as a necessary step to achieving the benefits of research takes time and lengthy digressions back to the basics, and the ethics, of the Western scientific method. In some sense, it requires educating participants in the idea of a different kind of ethics altogether. For many Tibetans, the idea of keeping something secret was taken as ethically questionable, even when putatively for the greater good. When explained in terms of needing to prevent the possibility of researchers or doctors "treating patients differently," it made more sense to patients. Efforts to explain how the outcomes of the research would be more accurate if potential biases in treatment were reduced proved helpful.

At a minimum, we initially thought that explaining ideas about blinding would require lengthy descriptions of the concept of "placebo effect." However, this raised the possibility of other complications: Tibetans who know even a small amount about Tibetan medical theory know that what we call placebo is a necessary part of good medical treatment in the Tibetan system. In biomedicine, the placebo effect is often used to show that a given medicine does not really work (or works no better than a placebo—that is, it works no better than no medicine at all). But in Tibetan medicine, the manner in which a medicine is given to a patient is stressed in practical terms as well as in textual sources like the *rgyud bzhi* (the Four Tantras) as a significant part of the healing process. Tibetan doctors are taught about the importance of good bedside manner. They say that "Even if you give a weak medicine but with the right words the medicine will be more potent than if you give a strong medicine but with words that are harsh or frighten the patients" (Adams 2001b). Moreover, we learned that Tibetan medicine holds that all substances are potentially medicinal or will have some effect on the body. We thought this would make it virtually impossible to devise a true placebo.

Ultimately, the difference between the way Western medicine distinguishes mind from body and the way Tibetan medicine links them, and the Tibetan approach to the concept of "medicines" could have lead to potential misunderstanding between the two systems, begging the question of whose methods—in fact—whose understanding of physiology in connection with the doctor–patient relationship—should be prioritized. In our study, we did not explore the nuances of how this might change our research protocol, but followed the lead of the RC, which argued for use of a placebo.[13] In fact, the RC ultimately settled the problem by suggesting that although it is true that in Tibetan medicine it is believed that there is no substance that is not potentially medicinal, there would be a way to design a pill that had very little medicinal effect on delivering women (use of a flour/starch ingredient that had none of the ingredients used in ZB11). Moreover, they did not delve into the possibility that a placebo might produce a positive outcome in patients, but were concerned (following a biomedical assumption) that if patients knew they were in a placebo group, this might have a negative effect on their outcome.

When we initially attempted to use the term "placebo" in our IC document, we ran into other complications. Because the Tibetan language had no term for placebo until recently, and because the term used in Tibetan is a literal translation of the Chinese term for placebo it could be translated literally as: "mind-healing medicine." Use of this term in our back-translated English language versions of the IC forms, which had to be approved by our U.S. institutions, made the process more complicated, since that translation implies that we are suggesting that there is some active medicinal effect of the placebo (other than the placebo effect).

In the end, debates over the meaning and rationale behind placebo were not belabored by the RC, even while concerns about how to make sense of the concept of placebo in the interstitial zone between two cultural approaches to medicines continued. The research team felt that a suitable method was arrived at by using a "fake" ZB11 pill and ensuring that neither doctors nor patients knew who was to be given which medicine. In our final IC document, we added a phrase that alluded to the placebo effect: "A placebo is a substance that has no medical effect, but is made to look just like ZB11."

Indication of Consent

Another interesting issue that was raised by our attempts to develop an IC procedure that would be suitable to illiterate, rural Tibetan women was how to indicate their consent. Our first preference was to have them sign, but knowing that this would not be possible for many of the illiterate participants, we thought that perhaps using a thumbprint would be better than simply obtaining verbal consent. However, interviews uncovered the fact that many women felt that asking for a fingerprint was associated with bad memories many Tibetans had of the Cultural Revolution. Apparently, as elsewhere in China, Tibetans being accused of political crimes during the Cultural Revolution (a fate that could potentially befall anyone) were forced to admit their guilt by signing with a thumbprint. To solve this problem, we removed this as an option for indicating consent and asked for either signature (of patient or person administering the IC form) or verbal consent. Although concern about thumbprints was not uniform among patients, we decided it was best not to use this option, for fear of the impact it might have on potential participants. But the Tibet IRB required it in the end.

Translating Standardization

Our first efforts to discuss issues of standardization revealed that the concept meant something different to physicians and researchers working across cultural divides. Our biomedical partners used the term "standardization" to refer mainly to the problem of ensuring that each batch of Tibetan medicine used in the research had uniform quantity and quality of ingredients, and therefore could be assumed to produce uniform effects on the body. The Tibetan medicine partners, however, prioritized discussions about whose recipes (and which practitioners), which ingredients (from where, blessed by whom, how gathered), and whose production processes could ensure the best (strongest) potency of the medicine.

Several different medical factories in Lhasa produced ZB11, including the Tibetan Medical College factory, the Mentsikhang factory, and a privately owned factory called Shongbala Chu. We visited each of these factories and conducted interviews with the producers during Phase I. As it turned out, each institution used the same general recipes for the medicine, although amounts of specific ingredients varied depending on the source text. However, each institution had different ideas and levels of knowledge about the sources of particular ingredients, as well as the pharmacological interaction between ingredients, from a Tibetan pharmacological perspective. During discussions with the RC about who would produce the ZB11 to be used in our study, debates over which institution produced the

best, most efficacious medicine emerged. The RC was particularly concerned over the ingredients because Tibetan medicine stipulates strict rules about collection and production etiquette—rules that often differ from the PRC policies on drug standardization and preparation in hygienic conditions. Debates over which institution would then be able to register its recipes with the government to guarantee patent ownership of the final tested medicine also ensued. In the end, we decided to forge a relationship with the Mentsikhang factory, as the Mentsikhang is one of our principal institutional partners.

National Research Standards

Another debate that emerged over the course of preparation for a clinical trial in Lhasa was the degree to which our research ought to attempt to follow the standard protocols developed in China for testing, regulating, and marketing medicines, both traditional and biomedical. The standards developed by the U.S. Federal Drug Administration regulations to guarantee safety and scientific efficacy are similar to, but not exactly the same as, those found in the PRC. In particular, although both nations require a three-step process, including laboratory testing for toxicity, animal testing, and finally clinical trials with human participants, the protocols are not exactly the same. The question of whose method should be followed has emerged as a critical issue for the Tibetan partners. For them to reap the rewards of such research within their own country, they continue to be interested in following the Chinese protocols as closely as possible. However, given that the funding institution was the U.S. government, it was important to design a project that met with U.S. regulatory demands and procedures constituted in the agency's framework as "good science." A recurring question for our team: how can the research aid and enable Tibetans to gain scientific recognition within the Chinese context, as a step toward international recognition and legitimacy, while balancing the differences between nations in standard protocol for such research?

Diagnostic Models

Throughout the early stages of this research, questions arose about the ways in which we defined the clinical endpoint. Although PPH is described in both medical systems as excessive loss of blood during the final stage of labor, the fact that the two medical systems understand the possible etiologies of this condition differently has led to some debates over how and when to administer treatments. During initial interviews with Tibetan physicians, and in ongoing discussions with the RC, we learned that ZB11 is typically given earlier in delivery than either misoprostol or oxytocin are given. Second, we learned that ZB11 might be given in combination with other Tibetan medicines for patients who present different etiologies. For example, if Tibetan medicine sees hemorrhage as related to weakened downward expelling wind, thur sel rlung, it may be considered as resulting from several possible causes connected to function of the liver, the kidneys, the wind, or bile energies. Other medicines might be given to women early in the delivery process to treat these imbalances long before the use of ZB11.[14] Because Tibetan medicine maintains that in order for medicines directly affecting the liver to work, a patient must first have sufficient digestive ability to break down and absorb this medicine.

Thus, some patients will be given treatments for their digestive function prior to being given treatments for the liver.

These empirical realities have presented us with several challenges. The first has been to determine the timing of ZB11 treatment so that it will produce the maximum effect in preventing PPH while still using it in a way that will make its use comparable to that of misoprostol. Early in the research process, Tibetan colleagues informed us that ZB11 took longer to be digested and longer to show physical effects than misoprostol. Therefore, we realized that during Phase II, providers would have to administer the ZB11 earlier in the labor process than would be the case for misoprostol. For prophylaxis of PPH, misoprostol is given at the time of delivery of the baby or immediately after the birth. The Tibetan physicians determined that the optimum time to administer ZB11 for PPH prophylaxis would be when a woman's cervix was fully dilated.

The other challenge was to develop a method that could accommodate a complete course of Tibetan treatments in order to determine whether its benefits were enhanced by complementary Tibetan medicines. We designed data collection methods that would enable us to record all medicines given during the course of labor and delivery at all the hospitals. Thus, this problem was solved in part by the fact that we were conducting research at three different facilities, though only one hospital has the capacity to offer a full course of Tibetan medical treatments. Because some hospitals would only be giving ZB11 or misoprostol, and other necessary biomedical drugs, it would provide us with the ability to compare the outcomes between different treatment modalities as Phase II and III (if pursued) are undertaken.

Interpreting Empirical Evidence

Although we are not yet at this stage with our current research project in Tibet, issues of translation across cultures also pertain to the ways in which data will be analyzed and empirical results interpreted. Previous research by members of our RC and other scholars of Tibetan medicine serve as useful examples of how different cultural and medical traditions might interpret empirical evidence differently, leading to different conclusions about outcomes and efficacy. These cases point to some of the translation issues, which will emerge in our current research project.

In one case, Adams and Ranzini[15] attempted to design a clinical study of treatment for growths in the uterus or ovaries (*skran*) and for treatment of what Tibetan medicine calls "bile-related-womb-disorder." Although Tibetan and biomedical clinical participants were able to agree on accurate translations of the names for the different sorts of growths that occur in the reproductive tract, it became clear that use of ultrasound to determine the efficacy of Tibetan medical treatments for such growths was contested. Whereas signs of growths in the uterus or ovaries were read by the biomedical participants as evidence of persistence of the disease, the Tibetan physicians were, in some cases, unconvinced that this evidence was proof that the underlying disorder persisted. The humoral imbalance that led to the eventual development of growths had been corrected, according to all the other diagnostic signs used by Tibetan physicians (pulse, urine, tongue analysis), even if

residual evidence of disorder's effects lingered and were visible in the ultrasound. The ultrasound, they reasoned, was not the final arbiter of empirical validity.

In a second case, Fei Fei Li[16] carried out research on Tibetan treatments for symptoms associated with *Helicobactor pylori* (Hp) infection, an infection found in roughly 80 percent of rural Tibetans. Using an isotopic breath test to diagnose Hp and Tibetan diagnostic techniques (including patient reporting of symptoms), after a year-long study of rural patients infected with Hp, Li found that the Tibetan treatments were able to completely eradicate gastric symptoms associated with Hp. Moreover, their symptoms were still gone a year after the end of treatments. However, the biomedical measures showed that Tibetan treatments did not eliminate the Hp itself. The question that should have arisen from this research is does the person who is symptom free, even while infected with Hp, still have the disease? Or, does the eradication of symptoms prevent sequelae of Hp infection (peptic ulcer and gastric cancer)? However, Tibetan doctors read the results of the research as an indication that Tibetan medicine did not work, that it was ineffective. Ironically, Li noted, these doctors did not even know of the bacteria Hp until she arrived and conducted the study, but having carried out the study in this way, she realized, the Tibetan doctors now took only this biomedical measure as the most important indication of cure.

In fact, it is not surprising that, in some cases, traditional Tibetan doctors and biomedical doctors interpret empirical results differently, or that, in the opposite pattern, when they agree on a method of interpreting results, it is one that prioritizes the biomedical view. The biomedical model is increasingly taken as the definition of "science" and a rigorous empirical method, even though this probably has more to do with the cultural accoutrements that come with biomedical science in this locale (including political legitimacy and support, huge financial support in comparison with Tibetan medicine, and international visibility) than with the belief that its methods are intrinsically better than other possible approaches. Even so, it sometimes becomes necessary to negotiate between the two systems and to recognize that Tibetan indicators, their ways of interpreting empirical facts, and even their willingness to adopt biomedical approaches must be taken into account.

Conclusions

In attempting to build an infrastructure for undertaking randomized clinical trial research in Tibet, we have gained respect for the concept and practices of translation, not simply linguistic translation, but also negotiating understandings of the body, of health and the causes of disease, of the nature and priorities of research, and even of how to establish empirical truth, that are not always shared across cultures. The burden of accountability within, or between, two cultural and medical systems poses challenges to researchers and participants from both cultures. One aspect of efforts to overcome these challenges is a new kind of integration between the medical practices.

Although a detailed discussion of what such integration might entail is beyond the scope of this article, work is under way in a variety of cultural and clinical contexts to do just this. Just as efforts to explain a biomedical model of research take hold, so do these new understandings set in motion new ways of conceptualizing Tibetan approaches to research that can, in turn, produce new ways of approaching

clinical practice and medical theory. The same is true for researchers arriving with a fixed idea of how best to do biomedical clinical research and who, early on, learned the need for flexibility and adaptability for work in Tibet. Although this research project was admittedly lopsided in its ability to nurture a two-way flow of priorities for accommodating the two medical models, placing much more emphasis on teaching Tibetan medical practitioners how to adjust their practices so that they approximated or could be fit into a biomedical model, we note that such an effort may be the first step in working toward a more bidirectional integration of medical research models. In the end, the hope is that this exchange of ideas and practices provokes hybrid forms of research that gain international legitimacy yet still sustain accountability to the local groups and alternative forms of medical theory and practice involved.

The implications of translating between cultures in order to define terms, protocols, and standards for clinical biomedical research are interesting from both intellectual and ethical standpoints. In an era when the demands for globalized research strategies are increasing, as a result of both the proliferation of increasingly complicated models for epidemiological research and the increase in interest in not simply providing medical aid but also medical research tools to postcolonial nations, the need for analysis of the ways such translation across global spaces and across cultural divides also increases. Debates about how to set up IC procedures point to the ways in which different cultures think about ethical issues and how the terms of ethical standards have to be negotiated between nations and cultures, not simply imposed on one by the other. Moreover, efforts to ensure that research designs do not entirely efface indigenous medical concepts are also important. At a minimum, research teams should be prepared for bidirectional negotiations, sometimes modifying the typical patterns of treatment so that both approaches can be fully represented. It is important to remember that these translation negotiations are not simply about scientific ways of knowing, but about how what gets defined as legitimately scientific in these settings is about power in a discursive sense: what gets defined as legitimate can be key to financial rewards, political power, the health of populations, and in some ways, the very survival of cultures.

NOTES

Acknowledgments. This research was funded in part by the NICHD, Global Network for Women's and Children's Health, #HD 40613, in conjunction with The Bill and Melinda Gates Foundation. The authors also acknowledge with great appreciation the University of Utah, University of California San Francisco, Lhasa Health Bureau, Lhasa Municipal Health Bureau, Mentsikhang, Lhasa Municipal Hospital, and the Maternal and Child Health Hospital. We also thank the anonymous reviewers and the editors of MAQ.

1. This was articulated well by Warwick Anderson, Postcolonial Technoscience Workshop, UCSF/UCB, 2003.

2. See authors of the essay. The Tibetan research team included authors as well as Thubten, Ngawang Drolma, Dromdul, Nyima Lhamo.

3. This process included training in simple statistical analysis, use of controls, hypothesis, deduction, cohort size, and data collection and management, as well as a lengthy course on the institutions of IC and IRBs. The TAR Health Bureau inaugurated an IRB for the purposes of this project.

4. The Women's Federation consists of officially appointed government councils located throughout rural and urban Tibet that are responsible for political education of women, particularly regarding women's reproduction and reproductive health, in relation to state policies on these matters.

5. Global Network Site Eight is the source of research on use of the drape, see A. Patel, "A New Approach for Collecting and Estimating Postpartum Blood Loss in Rural India," Proceedings from the XVII FIGO World Congress of Gynecology and Obstetrics, Santiago, Chile, November 2–7, 2003.

6. The placebo was suggested by the Tibetan research team. It was to be made of a starch-like paste made of flour, with no ingredients contained in the actual medicine.

7. See Gulmezoglu et al. 2001.

8. The data here are drawn from the NICHD research and in small part from previous work conducted by Vincanne Adams in the Women's Division of Mentsikhang (on women's disorders called "bile-related-womb disorder) (Adams 2001a) and by Fei Fei Li in the Digestive Division of Mentsikhang (on treatments for peptic conditions related to *Helicobacter pylori* infection) (Adams and Li Forthcoming).

9. For more details on what clinical trials look like in their idealized form, see the journal *Controlled Clinical Trials*, published by Elsevier.

10. It should also be noted, however, that many Tibetan women interviewed also recognized PPH as being a problem in their communities or in themselves and viewed participation in research as potentially beneficial to other Tibetan women in the long term.

11. This includes Toni Huber (personal communication), Ken Bauer (2004), Robert Ekvall (1968), and others.

12. For example, if a nomad hunter returns with a supply of meat, he calls all household heads in his nomad group to a meeting. He divides up the meat in equal portions (or as close to equal as possible) and then assigns a number to each portion. He distributes these numbers to each member on small pieces of paper. Then he leaves the group, leaving his numbered paper in his place. Then, another person from the group who has not seen and has no knowledge of the portions attached to each number is asked to redistribute the numbers to all members of the group, including the provider. Then, when the provider returns, there is a new allocation based on the redistribution. In this way, each member ends up with his portion by "chance" or without knowledge of the actual amount of meat allocated to each member and, because the hunter is hopeful of an equal share as well but does not get to distribute it himself, he is sure to try as best he can to divide up the shares equally (Toni Huber, personal communication, 9/03).

13. This would be compromised somewhat by the fact that the patients might know whether or not they were getting the medicine or not in Phase II, and in Phase III which medicine they were getting because of the fact that the two medicines were delivered in different ways. The Tibetan medicine had to be crushed and drunk as a tea.

14. This was only true at the Tibetan medical hospital.

15. V. Adams and A. Ranzini carried out this research together in 1998. Publication of some of the findings can be found in Adams (2001b).

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