Project: The Duke Obstetric Fistula Working Group

Project Title: Ethical Issues in Maternal Birth Trauma in the Developing World

Submitted by:

Jeffrey P. Wilkinson, MD Duke University School of Medicine, Division of Urogynecology (Principal Investigator)
Anne Drapkin Lyerly, MD Duke University School of Medicine Faculty, Obstetrics and Gynecology, Duke Center for the Study of Medical Ethics and Humanities; Women's Studies
Kathryn Whetten, Ph. D., Director Duke Center for Health Policy, Law and Management
Nikki Vangsnes, Associate Director, Center for the Study of Medical Ethics and Humanities

Abstract:

Prolonged, obstructed labor in resource poor areas of the world can lead to obstetric fistula. A fistula is a hole between the vagina and bladder and/or rectum which results in continuous leaking of urine or feces. This condition has been virtually eliminated in industrialized countries as a result of safe maternal health care and cesarean section. This is not the case in sub-Saharan Africa and parts of Asia. Women with fistulae in these regions are typically young, poor, uneducated and represent the most vulnerable members of society. They are often ostracized from their communities and suffer lives of abject misery. Many organizations have begun sending gynecologic and urologic surgeons to developing nations to help women with this condition. Despite best intentions, a number of serious ethical challenges arise in this setting. These include issues with surgery and post-operative follow-up, resource allocation, research and more wide reaching socio-cultural and religious implications. The Duke Obstetric Fistula Working Group is taking the lead in addressing the ethical dimensions of work in this arena. We are proposing an interdisciplinary approach to address these ethical challenges by bringing together faculty from the School of Medicine, Health Policy, Women's Studies and the Duke Center for the Study of Medical Ethics and Humanities. The focus of our initial work will be a consensus building conference of thought leaders in the field. The outcome of this conference will be a consensus statement and guidelines for managing the ethical challenges posed by obstetric fistula work in developing countries. These will be submitted for publication, presentation and be prospectively evaluated in a relevant setting in West Africa. This effort will serve as a model for the development of an ethical framework for Global Health projects at Duke and perfectly complements the interdisciplinary Duke Global Health Initiative.

Introduction:

Obstetric fistula is a devastating consequence of maternal birth trauma which affects women in developing countries throughout the world. The majority of cases occur in Sub-Saharan Africa. Obstetric fistula occurs when prolonged, obstructed labor results in pressure of the baby's head against the soft tissues of the maternal pelvis, including the bladder, vagina and rectum. This pressure causes tissue necrosis, and a hole forms between the bladder and the vagina (a vesicovaginal fistula) or between the rectum and the vagina (a rectovaginal fistula). The condition is more common in girls who have not finished puberty. They have small, undeveloped pelvic bones and are not able to deliver an otherwise normally grown baby. Risk factors for fistula formation include poverty, living in a rural area, young age, lack of education, and potentially other factors such as seclusion of women. Other co-factors, such as female genital cutting, are associated, yet not necessarily causal. Obstetric fistula is almost entirely preventable with timely intervention for obstructed labor by cesarean section. Access to cesarean section has all but eliminated obstetric fistula in developed countries.

Obstetric fistula has tragic consequences for both women and neonates. Coincident with the formation of an obstetric fistula is the nearly 100% chance of neonatal death during the birth process. After laboring for up to six days without assistance, if she survives, a woman is left with a dead baby and various other sequelae including disabling incontinence of urine and feces. A host of other medical conditions coexist with fistula including neurological disorders, orthopedic injury, infertility, dermatologic problems and depression. Perhaps most tragic, women with fistulae are stigmatized and become social outcasts. They have a constant offensive odor from the incontinence which limits their participation in all aspects of community life. There are no reliable sources of clean water and sanitary devices in areas where fistula is common. They are unable to participate in day-to-day activities including gainful employment, sexual relations and religious practices. The debilitating physical and social consequences of fistula often result in depression, shame and isolation.

A number of international organizations are addressing the issue of obstetric fistula including a recent major effort by the UN Population Fund (UNFPA Campaign to End Fistula)(3). There are also a host of independent groups, academic institutions and non-governmental organizations that are working on this problem. The issue of obstetric fistula has gained widespread attention recently from articles in the New York Times, The Wall Street Journal and features on the Oprah show. Despite the increased awareness and funding for obstetric fistula, there has been no systematic effort to address the numerous ethical challenges one encounters when working on this problem.

To date, the majority of efforts have focused on surgical repair of the backlog of patients (an estimated 2 million women worldwide) (1) who currently suffer from this condition. Groups of gynecologic and urologic surgeons from the United States, European nations, Australia and other countries have instituted their own programs by taking short surgical

mission trips (generally one to three weeks) to Africa and Asia to perform fistula surgery. These surgeries often provide little long term, sustainable change in the host country's ability to deal with the problem. Surgeons from western countries are typically not adequately trained to perform the complicated surgical repairs that one encounters in areas where obstetric fistula is common (2). This is due to the extensive scarring and abnormally large or complex anatomic defects that arise in the setting of prolonged obstructed labor (2). This complexity combined with often poor surgical facilities, equipment, lighting, etc can compromise the individual patient's chance for a successful operation and perhaps serve only as an interesting training experience for the western learner. While the anatomic defect between the bladder and vagina can almost always be repaired surgically, the patient is often left with residual incontinence because of the profound muscle and nerve damage that resulted from the initial insult. Western surgeons who perform fistula operations usually leave the country shortly after the surgery and are unavailable to tend to complications which arise at a later date. These complications can include worsening incontinence, sepsis, urinary tract obstruction and death. Precious resources of already impoverished hospitals are heavily directed toward fistula patients while other patients with equally serious illnesses languish in areas out of view of the visiting doctors.

These and many other issues result in numerous ethical challenges in the care of patients with obstetric fistula and the formation of programs designed to prevent fistula:

- Who is qualified to perform obstetric fistula surgery?
- What infrastructure and hospital resources are necessary to safely perform surgical fistula repair?
- How can informed consent for surgery be assured in areas where education, culture and language limit communication between physician and patient?
- What financial and social resources must the patient have before undergoing more advanced fistula surgery including urinary diversion?
- How can hospitals with minimal resources protect the rights of patients and communities in the face of mounting pressure to deal with the fistula problem with outside assistance?
- What is the role of research in the care of women with obstetric fistula?
- What percent of resources should be directed towards prevention efforts instead of reparative efforts?
- What cultural and religious practices that are thought to be risk factors are amenable to change and what are the ethical ramifications of trying to change these?

Proposal:

To answer these questions, the Duke Obstetric Fistula Working Group was formed. It includes Drs. Wilkinson, Lyerly and Whetten, Nikki Vangsnes and six medical students (Rashmi Kudesia, Kara King, Nora Dennis, Ashley Wysong, Sarah Pradka, and Lisa Kaiser). We are seeking Commonfund support to jumpstart the efforts of the working group with an international consensus building conference on this topic to be held at Duke in the fall 2006. Thought leaders in the area of ethics and obstetric fistula, from

both international and national sites, will convene to develop a consensus statement which addresses these issues in depth. A series of guidelines will be created which clarify the ethical standard that must be met by an obstetric fistula program in the developing world. This consensus statement and the guidelines will be submitted for publication in the most relevant journals including: Obstetrics and Gynecology, The American Journal of Obstetrics and Gynecology or the International Urogynecology Journal.

There is ample reason to believe that the efforts of the Duke Obstetric Fistula Working Group will result in a sustained interdisciplinary effort that will continue to benefit Duke far in to the future. With Dr. Wilkinson, Duke is an integral part of a recently formed multi-university collaboration which includes Johns Hopkins, University of Pennsylvania, Columbia and Mt. Sinai (NY). Working with the International Organization for Women and Development (4) this group has been approved by the Nigerien government to develop a comprehensive program for obstetric fistula care in Niamey, the capitol city of Niger. Niger is one of the poorest countries on earth and suffers a disproportionate burden in terms of maternal morbidity and mortality. A fistula treatment center is expected to open in 2007 in Niamey under the direction of the multi-university collaboration. The guidelines developed by the Duke Obstetric Fistula Working group will be integrated in to the center and prospectively validated for their usefulness in this setting. The presence of this center, the international focus on fistula by groups such as UNFPA and the commitment of Duke University to the Global Health Initiative will ensure the sustainability of this effort beyond the consensus conference.

It is anticipated that the ethical guidelines established as a result of the consensus building by the Duke Obstetric Fistula Working Group will also serve as a model for similar endeavors under the Duke Global Health initiative. Every future effort made by the Duke Global Health Initiative in the developing world will encounter challenges such as resource scarcity, patient's rights, the role of women in society, sexuality and other issues. We expect the product of our efforts to be the standard by which other efforts are judged from an ethical standpoint.

To this end, the team is composed of key people with different areas of expertise and accomplishments. Dr. Wilkinson began international health care work as a medical student at Johns Hopkins and has since traveled to India, the West Indies, Cuba, the Middle East and West Africa with women's health care projects. As a Duke faculty member, he remains active in projects in the Middle East and West Africa. His primary research and clinical interest is in obstetric fistula. He has seen first hand the devastating effects of this tragedy on the lives of women in developing nations. Dr. Lyerly is a nationally recognized expert in ethics and women's health and serves as the vice chair for the American College of Obstetrics and Gynecology's Committee on Ethics. She is a member of the Duke Ethics Committee and holds many other regional and national positions in ethics and policy. Dr. Whetten is the director of the Center for Health Policy, Law and Management at Duke. Her exceptional leadership in public policy at Duke as well as her experience in cross-cultural training, maternal child health and health care disparities will be invaluable to this process. Nikki Vangsnes is the Associate Director of

the Duke Center for the Study of Medical Ethics and Humanities (CSMEH). She is responsible for strategic planning, research and development for the center. She is uniquely positioned and experienced to assist in bridging the gaps between schools and departments in the university when ethics is the focus.

References:

1. The UN Population Fund Global Campaign to End Fistula. Obstetric Fistula Needs Assessment Report: Findings from Nine African Countries 2003

2. L. Lewis Wall . Steven D. Arrowsmith .Anyetei T. Lassey . Kwabena Danso Humanitarian ventures or 'fistula tourism?': the ethical perils of pelvic surgery in the developing world. Int Urogynecol J Jan 2006

3. www.endfistula.org (UNFPA Global Campaign to End Fistula)
4. www.nigerfistula.org (International Organization for Women and Development)

PERSONNEL:

TBD, Administrative Assistant, 50% effort for 6 months: $12,000. We are requesting funds to support 50% salary and fringe benefits for an Administrative Assistant for six months duration. The assistant will be responsible for all administrative functions of the workgroup, including scheduling space and equipment rentals, assisting with flights and hotel accommodations, ordering food, production of any materials related to this workgroup, and other assistance normally required for a project of