1. Parents facing decisions for fetal surgery have many areas of concern, not the least of which is their future financial burden. How are the financial repercussions of their decision presented to the parents? Are the parents provided with estimates of costs of treatment and costs for care if they decline treatment? If so, what are those estimated costs? Are these procedures considered “experimental” and not eligible for coverage by third-party payers?

Response from Dr. Nancy Chescheir:

As with all medical care, there are financial consequences following the diagnosis of a fetus with a birth defect that requires any sort of treatment. This is true whether frequent ultrasound examinations, MRI studies, and karyotype analysis are recommended to fully diagnose the fetal condition, postnatal surgical or medical care is recommended, or fetal interventions are possible. Full disclosure of anticipated financial impact is important but unlikely in any circumstance to be completely possible. For instance, the lifetime financial costs for the care of a child with spina bifida requiring a neonatal shunt and leg braces, physical therapy, urinary catheterization, and wheel chairs that need to be fitted multiple times as the child grows are of course not possible to predict fully, despite efforts in the past to do so. If maternal-fetal surgery for spina bifida in fact does decrease the need for neonatal shunting (an unknown at present) how much of the “lifetime” costs for the child should be subtracted from the above estimate?
Because of these sorts of difficulties, in my experience the detailed financial discussions relate to the actual procedure-related costs. Maternal-fetal surgery teams include financial counselors who work with patients to discuss the details of the immediate financial implications. Often times, whether a patient undergoes a fetal intervention at a fetal center or declines the intervention, she will return to her home hospital for the continuation of her care and delivery of the child. The maternal-fetal surgical team financial counselors cannot, of course, provide site-specific counseling about costs at other centers.

The “experimental” question is an important one. Insurance companies vary in their interpretations of this. Patients and financial counselors need to work with insurers closely in order to determine the exact level of support by the payor, if any. If a procedure is being studied formally under a protocol, the funding agency (such as the NICHD) usually pays for the investigational portion of the protocol.

Out-of-pocket expenses must be made clear to the patients, independent of the “experimental” or “established” nature of the procedure and independent of their insurance status. Some of the centers have funding available to assist families through charitable donations; however, this is neither universally available nor unlimited in scope. As with other types of medical care in this country, the access to these services can be limited by financial ability to pay—a failure of our health care system to fully meet the Institute of Medicine’s Aims for Quality of Care in terms of equity. This is, however, not unique to fetal interventions.
2. We live in a time of limited resources for health care. Acknowledging the difficulties of estimating health-care costs, has there been any cost-utility analysis of these procedures? What is the estimated cost per quality-adjusted life year [QALY] for fetal surgery for congenital diaphragmatic hernia, open neural tube defect, and twin-twin transfusion syndrome?

Response from Dr. Nancy Chescheir:

In the Textbook of Perinatal Medicine edited by Kurjak, Kurjak, and Chervenak (CRC Press, 2006), there is a discussion of cost-utility analysis in the chapter by Z. Stembera. A cost-utility analysis, as described there, requires “the calculation of the change of costs divided by the change in outcome adjusted for the quality-adjusted life saved, or quality-adjusted life-years saved” (page 281). In addition, the outcomes include the satisfaction gained from the consumption of a service.

This type of analysis would be important to do but I am unaware of any such analysis in the area of fetal treatment. Some of the unique variables to consider in the realm of fetal interventions that may differ from other types of health care include the potential impact on the future pregnancies of the maternal patient. Should these be considered in such an analysis? Additionally, most obstetricians are aware that the overwhelming majority of women will make any sacrifices for the potential benefit of their unborn child, even at the risk of significant contemporaneous or future harm to the mother. How then would one value the “satisfaction gained from the consumption of” maternal fetal surgery in this setting?
3. What resources beyond those typically found in a university-based regional perinatal referral center are required to provide this type of specialized clinical service? Are those requirements the same for all three procedures?

Response from Dr. Nancy Chescheir:

For a hospital to offer a maternal-fetal therapy program there must be a substantial commitment of physical resources as well as a team of individuals with fetal diagnosis and maternal-fetal treatment as their primary purpose. Access to the physical resources, such as fetoscopes, lasers, ultrasounds and MRIs are fundamentally based on financial allocation decisions and cannot be underestimated. The major differentiator between the typical academic medical center and one with a comprehensive maternal-fetal surgery teams is in the intellectual capital. Teams include perinatologists, pediatric surgeons of various subspecialties (such as neurosurgery, general surgery, and cardiac surgery in some cases), subspecialty pediatricians (neonatologists, cardiologists, neurologists, geneticists), anesthesiologists, and radiologists. Specialty nurses who assist with the procedures and patient care are critical. Each of the physician leaders of the maternal-fetal surgery centers that I know feels that their service coordinators are critical to the successful operations of the center. Genetic counselors play a key role. There must as well be technical expertise in terms of maintaining and operating laser equipment, ultrasound equipment, and operating equipment.

These teams are not casual groupings of individuals who occasionally meet to discuss a patient. There must be an active give-and-take amongst the team members to adequately provide a clear recommendation to each patient about their own aspect of the care to be provided prenatally and/or postnatally to the fetal patient. There must be a forum to discuss the patients and to review complications and outcomes.

Each center should have a mechanism in place to address ethical concerns raised either by the patients and their families or members of the health care team. These patients raise significant ethical issues and by having a formal mechanism in place to surface and explore
these issues, patients and teams benefit by being assured of their capacity for making ethically sound decisions.

Although said somewhat tongue-in-cheek, from an institutional perspective, one of the major hurdles must be the quality of flexibility. These patients typically are scheduled for care on very short notice. Mobilization of teams, access to operating rooms and imaging equipment have to be able to be accomplished on short order and the institution must be prepared to make that happen.

Although most centers are in major metropolitan areas, many patients will be traveling long distances and potentially staying for a prolonged period of time near the maternal-fetal surgery center. Arrangements with local hotels or short-stay residential hotels should be available.

4. The review notes mixed outcomes including fetal death, survival and intact survival. Do you feel there is sufficient experience with all three procedures to estimate accurately risks of maternal and fetal complications? How do these risk estimates influence patient selection?

Response from Dr. Nancy Chescheir:

Maternal-fetal interventions are like other surgical procedures in that there is an array of possible outcomes as described in Dr. Shackelford’s question. Importantly, in this instance there are also maternal risks and risks in future pregnancies that have to be considered. As I’ve described in my paper, the field of maternal-fetal surgery is quite dynamic as is the field of postnatal pediatric surgery and medical care. All of these considerations must be discussed with the patient to the best of the ability of the team members to do so. Each center should compile its own statistics. As noted as well, the U.S. and Canadian centers are increasingly collaborative and through groups like NAFTnet, the International Fetal Medicine and Surgical Society, and EuroFETUS, results are shared so patients should be told about the generally accepted risks and benefits. This is similar to standards which apply to other types of surgery.
I personally do not believe that we fully know the impact on future reproductive and health outcomes for the mother. Case series have been done which help to generate hypotheses and raise or soothe concerns. However, the MOMS trial is designed to report on the 3-year health outcomes of the mothers, randomly assigned to either prenatal or postnatal repair.

Risk estimates of course help some families to decline fetal intervention and deselect themselves or to opt-in. People weigh risks and benefits along a lengthy continuum. Certainly, there are some women who choose outright to terminate a pregnancy affected by a serious fetal defect and never consider fetal or postnatal treatment. I’ve worked with women who would undergo fetal intervention if the treatment could cure the problem but not if it would only lessen the consequences as well as women who would do anything if it would make even a minor improvement in outcome. It is clearly critical that patients receive non-biased, non-directive counseling about a fetal defect in order that they may make the best possible decisions for themselves within their own ethical framework.

Due to the need to balance maternal and fetal health risks, significant maternal illnesses that place her at increased surgical risks deselect some patients. The presence of an unaffected co-twin currently deselects patients due to the risks to the unaffected co-twin of premature birth with no potential benefit to that twin. Fetal patients with significant other defects currently are not candidates for maternal-fetal therapy as the co-morbidities may be the primary determinant of their long-term outcome and would not be improved by the fetal intervention.

5. What are the current technical challenges standing in the way of clinical breakthroughs for fetal surgery?

Response from Dr. Nancy Chescheir:

The biggest technical challenge is the prevention of premature rupture of the membranes—the Achilles heel of fetal interventions. Once this hurdle is crossed, the risk of prematurity following fetal intervention will decline. Hopefully, progress in this arena will
translate as well to the much-more-common occurrence of PROM in pregnancy and we’ll see breakthroughs there as well.

Other technical challenges relate to instrumentation. Smaller, safer, more flexible instrumentation with terrific optics and literally laser-sharp focus will improve our ability to operate on fetal patients. Drug delivery systems for the advent of genetic therapy, stem cell therapies, and more routine pharmacotherapies will be important in the next decade.

If it is ultimately shown that fetal interventions help a wide array of fetal disorders, then improved screening for fetal defects with rapid referral to appropriate centers will need to exist. This will likely require improved telemedicine services.