

Increased Quality and Access to Fetal Therapy for Reduced Infant Mortality by Tara Sander Lee, Ph.D. and Colleen Malloy, M.D.

Birth defects are the leading cause of infant mortality and morbidity, affecting approximately one in every 33 live births (about 3%) in the United States each year and accounting for 20% of all infant deaths.^{1,2}

Fetal therapy, which treats the fetus in the womb, is an exciting advancement in maternal-fetal medicine with the goal to repair structural defects before birth and possibly even cure disease in the prenatal period. Such revolutionary advancements in fetal surgery have proven successful for reducing infant mortality in treatment of several conditions including sacrococcygeal teratoma (SCT), congenital diaphragmatic hernia (CDH), congenital cystic adenomatoid malformations (CCAM), severe kidney obstruction and oligohydramnios, spina bifida, twin to twin transfusion syndrome (TTTS), and many others.³

Significant infant improvements have been observed in myelomeningocele, the most severe form of spina bifida, The Management of Myelomeningocele Study (MOMS) found that fetal surgery on fetuses with spina bifida before 26 weeks' gestation was associated with a decreased risk of death or shunting before postnatal age 12 months, as well as improved mental and motor function (including independent walking) at 30 months of age.⁴ Researchers in the follow-up MOMS2 trial have shown those benefits continue into childhood, up to 10 years after birth.⁵

In another example, minimally invasive surgery for treating twin to twin transfusion syndrome (TTTS) between 16-26 weeks' gestation has saved the lives of both twins at all stages of disease. High volume fetal therapy centers, such as the Children's Hospital of Philadelphia (CHOP) Center for Fetal Diagnosis and Treatment, [report a higher than 90% survival rate](#) of at least one twin and a higher than 80% survival rate of both twins after laser ablation. The Cincinnati Children's Fetal Center [reports similar data of higher than 80%](#) overall survival of at least one or both twins.

However, not all women who face a prenatal diagnosis of a severe birth defect have access to fetal therapy and several improvements can be made to increase the quality of prenatal surgical care in the United States. Recommendations for improvement are outlined below:

- 1.** Accurate Fetal Diagnosis and Prenatal Monitoring
 - a. Position advanced maternal-fetal diagnostic clinics in rural and urban areas to eliminate access barriers.

¹ Centers for Disease Control and Prevention, Data and Statistics on Birth Defects. Available at: <https://www.cdc.gov/ncbddd/birthdefects/data.html> [Accessed June 10, 2020].

² Egbe AC. Birth defects in the newborn population: race and ethnicity. *Pediatr Neonatol.* 2015;56(3):183-188.

³ C. Malloy, M. C. Wubbenhorst, T. Sander Lee, The Perinatal Revolution. *Issues in Law and Medicine* **34** (1), 15-41 (2019).

⁴ Adzick, N.S., et al., A randomized trial of prenatal versus postnatal repair of myelomeningocele. *N Engl J Med,* 2011. 364(11): p. 993-1004

⁵ Houtrow AJ, Thom EA, Fletcher JM, et al. Prenatal Repair of Myelomeningocele and School-age Functional *Pediatrics*

- b. Make specialized fetal health monitoring units (mobile or wireless) available to moms that can diagnose and monitor mother and fetus at all stages of pregnancy.
 - c. Implement maternal-fetal telemedicine programs to eliminate access barriers.
- 2. Maternal-Fetal Therapy Awareness**
- a. More information, resources, advertising, and public awareness regarding birth defects, fetal therapy, and perinatal hospice options need to be readily available to physicians and patients at all stages of pregnancy.
 - b. Time plays a critical role in fetal therapy, especially for women suffering with diseases that can rapidly progress like TTTS. It has been reported that rapid progression, along with delays between diagnosis and treatment, contribute to a subset of women becoming ineligible for fetal surgery and resulted in fetal demise.⁶ There are also reports where physicians did not inform or refer pregnant women to fetal therapy care clinics who were eligible and desired care.
 - c. The [North American Fetal Therapy Network](#) (NAFTnet), [The Fetal Health Foundation](#), and [International Society for Prenatal Diagnosis](#) (ISPD) are examples of current resources, but greater access to this information is needed.
- 3. Financial Assistance and Childcare Support**
- a. The pre- and post-operative costs and support requirements associated with fetal surgery may prohibit women from receiving desired care. Bedrest and 24/7 support may be required by the fetal therapy center prior to receiving surgery.
 - b. Establish emergency grants for financial assistance.
 - c. Establish temporary housing (e.g., Ronald MacDonald House, churches, etc.) for families that have to travel out of state to receive care
 - d. Offer childcare support during and following surgery
- 4. Mandatory Reporting of Outcomes**
- a. There are no formal procedures currently in place for reporting fetal surgery outcomes.⁷ Such knowledge about the quality of each fetal therapy program is necessary for women making informed decisions.
 - b. Fetal therapy centers should transparently monitor and provide mandatory report outcomes of their procedures.
- 5. Accredited Fellowship Training Program**
- a. There exists no formal accredited fellowship program for physicians in fetal intervention.⁸ Further training is mostly done on an apprenticeship basis.
 - b. Accredited training is needed, especially when fetal surgery procedures involve treating rare conditions with inherently low volume.
- 6. Research and Clinical Trials**
- a. Research is needed to determine medical necessity and identify maternal-fetal risks associated with fetal therapy procedures.

⁶ Fischbein R, Nicholas L, Aultman J, Baughman K, Falletta L. Twin-twin transfusion syndrome screening and diagnosis in the United States: A triangulation design of patient experiences. *PLoS One*. 2018;13(7):e0200087.

⁷ Editorial, Fetal medicine: past, present, and future. *The Lancet* 393:717, 2019. Available at [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(19\)30404-0/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(19)30404-0/fulltext)

⁸ Ibid

- b. Challenges include expanding patient selection criteria and accessibility in clinical trials, so that women and fetuses are not denied or excluded from receiving advanced treatments and potentially life-saving care.
- c. Increase targeted funding from private and public government entities (i.e., the National Institutes of Health) for research initiatives and clinical trials that appropriately advance the field of fetal repair in an efficient manner is needed.
- d. Insurance companies are more likely to provide coverage of procedures that have proven medical necessity.

Telehealth and the Contribution to Infant Welfare

Colleen Malloy, MD

Given the great strides in technology and wearable technology, telehealth offers an exciting method to promote healthier pregnancies and healthier babies. For many women, finding the time and resources to attend appointments with an obstetrician or midwife office can be fraught with challenges. Often women deal with conflicts related to child care, work obligations, financial limitations, and home life issues. Telehealth offers a great way to augment prenatal care. Telehealth lifestyle interventions are being used in pregnancy for management of complications such as gestational diabetes¹ and for monitoring of blood pressure.² Telehealth has also been used in low-income and middle-income countries, particularly in rural communities where access to antenatal care is challenging.³ For example, the GLOW study was a randomized trial of a weight management intervention delivered by telephone with an aim of reducing gestational weight gain (GWG) in women with overweight or obesity (BMI 25.0–40.0 kg/m²).⁴ Eligible pregnant women received two face-to-face consultations and 11 telephone sessions using behavioral strategies to improve weight, diet, and physical activity. Women in the intervention group had less gestational weight gain and improved lifestyle and metabolic parameters than did those in the usual care group. 96 (48%) of 199 women in the lifestyle intervention telehealth group and 134 (69%) of 195 women in the usual care group exceeded standards for rate of GWG per week (relative risk 0.70, 95% CI 0.59–0.83). Compared to usual care, women in the telemedicine group also had

¹ Xie W, Dai P, Qin Y, Wu M, Yang B, and Yu X: Effectiveness of telemedicine for pregnant women with gestational diabetes mellitus: an updated meta-analysis of 32 randomized controlled trials with trial sequential analysis. *BMC Pregnancy Childbirth* 2020; 20: pp. 198.

² Kalafat E, Benlioglu C, Thilaganathan B, and Khalil A: Home blood pressure monitoring in the antenatal and postpartum period: a systematic review meta-analysis. *Pregnancy Hypertens* 2020; 19: pp. 44-51

³ Modi D, Dholakia N, Gopalan R, et al: mHealth intervention “ImTeCHO” to improve delivery of maternal, neonatal, and child care services-A cluster-randomized trial in tribal areas of Gujarat, India. *PLoS Med* 2019; 16.

⁴ Reynolds, R. Telehealth in pregnancy. *The Lancet. Diabetes & endocrinology*, June 2020, Vol.8(6), pp.459-461, 2020.

reduced calorie intake, reduced proportion of calories from saturated fat, and less sedentary behavior. Metabolic markers including insulin, homoeostatic model assessment of insulin resistance, and leptin were also lower in the intervention group than in the usual care group.

Other uses for telemedicine exist for caring for neonates after birth. Providers can assist with the breast feeding, safe sleeping, and feeding practices through the phone or internet. Such support systems are welcomed by families and save them the time and effort required to go into the clinic. Today's families are much better educated regarding technology. With the ease of a Facetime call, a provider can check in and assist if needed, providing resources, education, and follow-up.