The process of developing a comprehensive maternal-fetal surgery center



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Introduction

Definition of a maternal-fetal surgery center

T here are over 50 maternal-fetal surgery centers across the United States which provide varying levels of prenatal diagnostic services as well as medical and surgical therapies that either treat (eg, laser ablation for twintwin transfusion syndrome [TTTS]) or optimize (eg, prenatal spina bifida repair) the fetal condition. Several

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institutions provide comprehensive care including prenatal diagnosis and fetal therapies, while others provide prenatal diagnosis without fetal intervention services.¹ Organizations such as the International Fetal Medicine and Surgical Society and North American Fetal Therapy Network (NAFTNet) have published on the scope of fetal therapy and proposed necessary components of centers offering fetal treatments in the modern era.²

In a recent consensus statement, NAFTNet further stratified maternalfetal care centers by proposing different levels of care (I, II, and III) based on the complexity of the maternal, fetal, and neonatal diagnosis and need for care.³ Within this stratification system, all centers meet ACOG-SMFM level III (subspeciality care) or IV (regional perinatal center) obstetric care center standards; both of which have obstetricians, maternal-fetal medicine (MFM) subspecialists, obstetric anesthesiologists, adult subspecialists, and intensive care units onsite able to manage complex and critically ill patients throughout the antepartum, antepartum and postpartum period.⁴ A level I center offers less invasive fetal interventions (eg, needle procedures, fetal shunt placement) and maternal care resources should meet ACOG-SMFM level III obstetric care standards. A level II center offers more complex fetal interventions that could result in very preterm birth as well as increased maternal risks, including adult and neonatal intensive care unit admission (eg, laser surgery for TTTS, uncomplicated ex utero intrapartum treatment [EXIT] procedures). Maternal care resources should meet ACOG-SMFM level III or IV obstetric care center standards. A level III center offers the full spectrum of minimally invasive and open fetal interventions and can support all procedure-related maternal (ACOG-SMFM level III or IV obstetric care center standards) and neonatal risks (eg, fetoscopic spina bifida repair, fetoscopic tracheal occlusion [FETO], complex EXIT procedures).^{2,3}

While well-established maternal-fetal surgery centers have published literature about their programs, limited information is available on the conceptualization and inception of nascent maternal-fetal surgery centers. As a group of centers with varying years of experience and geographic locations, we present a staged approach to building a comprehensive (level III) maternal-fetal surgery center and the lessons learned. We will provide an overview of the components of a maternal-fetal surgery center and then describe a phased approach to developing a maternal-fetal surgery center.

Historical perspective

In many institutions, the MFM division performs both the routine anatomy ultrasounds and diagnosis of complex fetal anomalies. In early stages of program development, referrals to pediatric subspecialists for fetal conditions are often coordinated by the MFM providers on a case-by-case basis. As the program expands and as diagnosed anomalies are more complex, there is a natural effort to provide a more concerted multidisciplinary approach to consultations through partnerships between MFM/Genetics, Radiology, Neonatology, Pediatric Cardiology, Pediatric Surgery, Complex Family Planning, Medical Ethics, and many other pediatric subspecialities.

Scope and complexity of fetal interventions

We propose a tier system in which fetal intervention services can be implemented in a staged manner. Tier 1a-c are noninvasive medical as well as needle and trocar-based procedures with minimal maternal risks. Tier 2 procedures require additional surgical equipment such as operative fetoscopy and incur slightly more maternal risk and discomfort with use of a trocar-cannula apparatus. Tier 3 includes complex fetoscopic procedures requiring a larger subspeciality multidisciplinary team along with open maternal-fetal surgical procedures. This classification system is not without limitations as certain procedures with minimal maternal risk may carry significant fetal risk and require complex planning for successful execution. For instance, fetal sclerotherapy for a microcystic congenital pulmonary airway malformation is a needle procedure with minimal maternal risk but may carry as much or more fetal risk (eg, fetal demise) as more invasive procedures.⁵ Tier 1 procedures can be performed by fetal interventionalists skilled in needle-based procedures. During the initial years of establishing a maternalfetal surgery center, patients with Tier 2 or 3 conditions considering in utero treatment would require referral to a higher-level maternal-fetal surgery center (including out-of-state).

The time needed to achieve programmatic growth toward becoming a Level III³ maternal-fetal surgery center allowing for expansion to Tier 2 and 3 (Table 1) fetal interventions may be on the order of several years. Expansion of services to Tier 2 and 3 interventions requires the recruitment of fetal surgeons who are capable of providing in utero treatment of complex conditions such as TTTS, amniotic band sequence, vasa previa, open spina bifida, and congenital diaphragmatic hernia (CDH). Alternatively, collaboration with another experienced center to provide additional services while training MFM and/or pediatric surgeons to eventually perform more complex procedures can be considered. This process to educate, mentor, and develop a robust team capable of such procedures is both financially and time intensive.

Regardless of the route chosen, the series of decisions and years of planning for this breadth of programmatic change and development are challenging but may offer guidance to other institutions seeking to expand their scope of fetal interventions.

Core components of a maternal-fetal surgery center

The care of pregnant patients with complex fetal conditions is a unique intersection of medicine, surgery, and ethics.⁶⁻⁹ The challenges of providing fetal therapy include both diagnostic (eg, advanced fetal imaging and genetics) and treatment (eg, efficacy, surgical technique, fetal/maternal safety, timing/ route of delivery) considerations involving multiple obstetric and pediatric disciplines. The cornerstones of a maternal-fetal surgery center include hospital financial and administrative support, institutional culture and mission in alignment with the pursuit of fetal interventions, advanced imaging capabilities, surgical equipment, clinical services, patient-client services, and research (Table 2). Essential clinical services needed include obstetrics, adult and pediatric specialties, anesthesiology, imaging experts, dedicated nursing teams, and perinatal or pediatric palliative care. Due to the complexity of clinical care plans, nurse coordinators have a critical role in the communication between the patient and subspeciality providers. Clinical ethicists have an integral role in the decision-making process when considering fetal intervention in controversial cases which considers patient autonomy, the risks of invasive procedures, and lack of sufficient data regarding long-term outcomes. Patient services, such as social workers, psychologists, case managers, and certified interpreters are necessary to provide equitable care to all patients, irrespective of socioeconomic status, identity within a marginalized race, ethnicity, or gender class, language spoken, geographical distance, and insurance coverage status. Having financial coordinators obtaining insurance authorization (public and private networks) for specialized fetal procedures is critical to being able to evaluate patients in a timely manner (ie, within 24-48 hours of receiving the referral). Financial

level of complexity	Condition and treatment
Tier-1a-Medical	Fetal arrythmias • Transplacental antiarrhythmic Rh(D) alloimmunization prevention • Rh immune globulin Fetal/neonatal alloimmune thrombocytopenia • Intravenous immunoglobulin, corticosteroids
Tier 1b—Needle-based	Symptomatic polyhydramnios Amnioreduction latrogenic PPROM Amniopatch Fetal anemia Fetal blood sampling/intrauterine transfusions Congenital hypothyroidism Intraamniotic levothyroxine Microcystic congenital lung lesion Sclerotherapy Multifetal reduction Intraamniotic/intra-fetal feticidal injection
Tier 1c—Trocar-based	Lower urinary tract obstruction Vesico-amniotic shunt placement Cystic congenital lung lesion and pleural effusion Thoraco-amniotic shunt placement
Tier 2	 Monochorionic multiple gestations (TTTS, sFGR) Laser photocoagulation of communicating vessels Selective fetal reduction in monochorionic multiple gestations Radiofrequency ablation Cord occlusion—laser, bipolar forceps Twin reversed arterial perfusion sequence Radiofrequency ablation Sacrococcygeal teratoma Radiofrequency ablation or laser ablation of feeding vessel Chorioangioma Laser ablation of feeding vessel Vasa previa Laser ablation of fetal vessels
Tier 3	Amniotic band sequence • Fetoscopic lysis of bands Spina bifida • Fetoscopic or open repair Congenital lung lesion • Open fetal resection Sacrococcygeal teratoma • Open fetal resection Congenital diaphragmatic hernia • Fetoscopic endoluminal tracheal occlusion (FETO) Congenital high airway obstruction • Fetoscopic laser ablation, EXIT procedure Neck masses • Fetal endoscopic tracheal intubation, EXIT procedure Fetal cardiac interventions • Valvuloplasty, stenting, etc.

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coordinators also facilitate equitable access to services by assessing financial need and advocating on the patient's behalf. These aspects are complemented by research capability and support to collect and analyze patient data, conduct clinical trials, follow long-term outcomes, and achieve surgical innovation. Establishing a framework for research support is critical to the upstart of a maternal-fetal surgery center as purchasing certain equipment (eg, fetoscopy, shunts) which are categorized as Food and Drug Administration (FDA) Humanitarian Use Devices requires Institutional Review Board (IRB) approval. Also, upfront investing in data and information management to perform data entry with real-time data validation, data audits, and data query management is essential to conducting studies and quality assurance.

Ensuring that each of these components of a maternal-fetal surgery center are available and developed adequately requires a phased approach. We describe below Phases 1 through 3: (1) creation of the business and strategic plan; (2) recruitment of a fetal surgeon (s); and (3) implementation of fetal surgeries.

Phase 1—Business and strategic plan

Regional market analysis. The creation of a sustainable maternal-fetal surgery center requires clinical vision and strategic business foresight. Understanding the regional patient catchment area is critical to estimate case rates and referral patterns amongst existing neighboring fetal programs. The regional market analysis should include both the local (in-state) and regional (out-of-state) annual number of births and estimates of fetal conditions that would benefit from fetal surgery. For instance, in a state with 40,000 annual births, an estimated 4 to 12 TTTS cases per year would be anticipated based on a prevalence of 1 to 3 per 10,000 births.¹⁰ Laser surgery for TTTS is often used as the

TABLE 2 Core components of a maternal-fetal surgery center		
Component	Function	
Administration		
Leadership a. Physician b. Nursing	Infrastructure designed to have balanced representation of physician and nursing interests	
Program director/manager	Responsible for all administrative and clinical oversight, including strategic priorities and growth	
Financial specialist	Responsible for budget, revenue, and financial management	
Quality and improvement committee	Involves members across multiple systems and disciplines to execute improvement efforts	
Clinical services		
Fetal surgeons	Maternal-fetal medicine and/or pediatric surgeon with additional training in fetal interventions	
Prenatal imaging physicians and technologists a. Ultrasound b. MRI c. Echocardiogram	Accurate diagnosis of fetal condition. Provide ultrasound guidance during <i>in utero</i> procedures	
Obstetrical care services a. Maternal-fetal medicine b. Obstetrics & gynecology c. Family planning	Complete spectrum of high-risk obstetrical care including pregnancy termination services	
Adult medicine a. Subspecialists b. Critical care	Provide inpatient and outpatient comprehensive care for pregnant patients with mild to complex comorbidities	
Genetics	Provide screening and diagnostic genetic testing. Counseling regarding implications of genetic disorders	
Pediatric specialists a. Pediatric surgery and surgical specialties b. Medical subspecialties	Provide inpatient and outpatient comprehensive care for neonates with mild to complex critical conditions	
Nursing—obstetrics and pediatrics	Nurses experienced and trained in perinatal and neonatal care	
Obstetrical anesthesia	Management of pregnant patient during fetal procedures	
Pediatric anesthesia	Management of the fetus/neonate during surgical procedures	
Perioperative staff	Maintenance of instrumentation Performance of fetal surgeries Support for pre- and postoperative phases of care	
Neonatology a. NICU b. ECMO	Prenatal consultations Complex delivery planning in advance of birth Neonatal resuscitation Comprehensive postnatal medical and surgical care based on NICU level (II-IV)	
Palliative care	Provide medical and social support when the child has a severe condition and guarded prognosis	
Laboratory services	Process specimens including chorionic villus sampling, amniocentesis, and fetal blood sampling	
Blood bank	Preparation of blood products for intrauterine transfusion Provide maternal and neonatal blood product support	
Patient services		
Mental health and wellness a. Psychiatrists b. Psychologist	Providers who specialize in reproductive psychiatry and perinatal mental health issues	
Social services a. Social worker b. Ethicist c. Spiritual support d. Language interpreters	Optimize delivery of equitable care to patients by minimizing barriers social and language barriers.	

(continued)

TABLE 2

Component	Function
Patient care support a. Patient access representative b. Nursing care coordinators	Referral intake and scheduling of consultations Coordination of multidisciplinary care (eg, imaging, consultations) for the pregnant patient and neonate
Billing and insurance	Financial coordinators who handle all prior insurance authorizations, billing, and financial suppor for the patient
Program support	
Outreach and referral development	Maintaining and establishing new local and regional referring networks
Marketing and communications	Foster awareness and create resources including print and web. Brand marketing and media relations
Research	
Research staff a. Project manager b. Data specialists c. Institutional Review Board	Provide support to perform clinical studies including protocol development, patient enrollment, and obtaining long-term outcomes

benchmark for maternal-fetal surgery centers as it is the most common operative fetoscopic procedure performed and creates a framework for additional fetoscopic procedures such as spina bifida repair (1.9-4.2 per 10,000 live births),^{11–16} and FETO for CDH $(1.6-2.3 \text{ per } 10,000 \text{ live births})^{17}$ and vasa previa laser ablation.

Changing current referral patterns for a new service line requires time and the initial market analysis should take into account that some referring providers may wait until the newly established center can demonstrate consistent outcomes. For example, one of the represented centers experienced lower number of TTTS referrals during the first year than the initial estimates partly because of continued out-of-state referrals by one large MFM practice but has since begun to refer patients after establishing initial outcomes. New centers are encouraged to be transparent with both referring providers and patients regarding caseload and surgical outcomes. Offering a second opinion at another experienced center respects patient autonomy and ultimately builds trust. In addition, new centers can highlight services that may not be offered by other institutions such as financial

assistance through Social Work or comprehensive reproductive options with Family Planning.

Financial analysis and pro forma creation. The creation of a pro forma aides in forecasting if the creation of a maternal-fetal surgery program is financially profitable for a particular institution using certain projections and assumptions. It should factor in clinic hours/space, physician productivity, and volume (surgical and nonsurgical patients). Initial stakeholders should include members of the hospital executive leadership team as well as Departments of Pediatrics, Obstetrics & Gynecology, and Surgery as the pro forma analyzes prior gross clinical revenue, net revenue, and direct costs (including staffing). Clinical volume projections can be created for the initial five fiscal years of the program using a subset of the highest revenue cases from the regional market analysis. Many maternal-fetal surgery centers will be augmenting existing fetal programs which have an established referral base for anomalies such as congenital cardiac anomalies and abdominal wall defects. The estimated direct margin should therefore account for direct revenue of

the fetal surgery service line (ie, TTTS, FETO, etc.) as well as income tied to the downstream revenue associated with additional referrals of previously cared for conditions (eg, imaging studies, consultant care, NICU/PICU admissions, extracorporeal membrane oxygenation (ECMO) utilization, and pediatric surgical volume). For example, in a study analyzing California in-hospital deliveries, the mean cost for all newborns delivered less than 28 and 32 weeks was \$317,982 and \$223,941, respectively.¹⁸ Of note, certain conditions such as TTTS generate revenue for the perioperative services for the surgery center but typically not downstream NICU as the majority of patients will resume prenatal care with referring providers and deliver elsewhere. In contrast, FETO for CDH generates additional downstream (eg, NICU, ECMO, etc.) as many of these patients will delivery at the maternal-fetal surgery center to receive specialized postnatal care.

Capital investments should include equipment to perform the operative fetoscopy (Table 3). Depending on existing operating room equipment, the budget for this initial startup may be in the \$500,000 to \$900,000 range. Additional operating expenses include

TABLE 3 Capital investment and salaries/wages considerations for a maternal-fetal surgery program			
Equipment			
Operative fetoscopy Video integration • Trocars • High-resolution camera system • Diagnostic and operative endoscopes • Camera heads and light cables • Instruments (eg, graspers, scissors) • Monitors			
Laser Ultrasound machine Diode laser machine Laser fibers Laser filter Safety glasses Laser fiber stripper and scribe Ultrasound machine Abdominal and vaginal probes Probe disinfection technology Sterile probe covers and gel			
Umbilical cord occlusionFetoscopic spina bifida repair• Bipolar forceps• Operative fetoscopy setup• Radiofrequency ablation• Laparoscopic instruments• Generator and grounding pads• Carbon dioxide insufflator• Needle electrodes• Dura substitute materials			
Fluid management system and suction Fetal shunts (Harrison fetal stent set) irrigator			
FETO for CDH Miscellaneous • Operative fetoscopy setup • Needles, syringes, cerclage supplies, etc. • Tracheal occlusion balloon device • Uterine stapler for EXIT procedures			
Salaries and wages			
Clinical Administrative • Fetal surgeons • Program director • Fetal surgery nurse • Schedulers • Medical assistant • Insurance authorization personnel			
Social services Research • Social work • Research manager • Case managers • Data analyst			
<i>CDH</i> , congenital diaphragmatic hernia; <i>EXII</i> , ex utero intrapartum treatment; <i>FETO</i> , fetoscopic tracheal occlusion. <i>Chon. Developing a comprehensive maternal-fetal surgery center. Am J Obstet Gynecol MFM 2024.</i>			

salaries & wages, employee benefits, marketing and outreach expenses, consultation fees, minor equipment for startup, surgical, and other direct costs, along with depreciation and amortization (Table 3). The cost center not exclusively residing under one division (MFM or pediatric surgery) is strategically important to allow for a more collaborative approach and comprehensive view of the pregnant patient and fetus.

Development of governance and management structure. The expansion of an existing maternal-fetal center (ie, at an institution providing at minimum high-risk obstetrical care and multidisciplinary prenatal diagnosis services) to include full-service fetal surgery services adds complexity across several domains. Numerous institutional leaders share responsibility for aligning operational practices, philosophies, market strategies, and approaches to quality management. Thus, an interdisciplinary governance structure should be developed to reduce bias toward individual departments or divisions. Understanding each institution will have their own unique organizational characteristics, we propose a governance structure composed of four mixed discipline committees: Operations, Finance, Strategy, and Executive. The Executive Committee oversees the former three governance bodies each of which have defined roles to support elements of early programmatic design and launch as well as early management of the integrated fetal care program (Table 4). Depending on physician disposition and team-building experience, creating a paradigm shift within the maternalfetal center by introducing a fetal surgery service line can pose challenges. Therefore, getting buy-in early on with a unified vision from existing team members is critical to the long-term success of a maternal-fetal surgery center.

Provider relations. Marketing and outreach are an essential component to starting a new program or service line within the hospital or region.¹⁹ A highfunctioning referral network translates to high-quality results and positive patient experiences.²⁰ The business and strategic plans should focus on the specific regional market analysis and patient needs.¹⁹ Even if the fetal surgery service line is added to a center with an established regional referral network, messaging to MFM providers in the region about the development of the level III center even prior to having the fetal surgeons in place can be beneficial to increasing eventual referral volume. Once the fetal surgeons are employed, concerted efforts can be placed on strengthening relationships with referring providers within the state and outside geographic regions by directly communicating and sharing patient diagnostic, treatment, and management plans.^{20,21} Relationships with referring providers can further be strengthened with regular educational sessions on the screening, diagnosis, and treatment options for relevant fetal conditions.

Phase 2—Surgeon recruitment

A maternal-fetal surgery center may be led by an individual (pediatric surgeon or MFM) or group of surgeons depending on the location of the surgeries (adult, pediatric, L&D), which departments provide the financial support, and institutional preferences and culture. Whether or not the fetal surgeon is formally fellowship-trained is another important consideration. Fetal surgery

TABLE 4

Proposed model of a governance structure for a comprehensive maternal-fetal surgery center.

	Fetal committees			
	Executive	Operations	Finance	Strategy
Proposed membership	 Chairs: Dept. of Surgery, Dept. Obstetrics & Gynecology, Dept. of Pediatrics Division Heads: Pediatric Surgery, MFM, Neonatology Executive team: Vice President of the children's hospital, Surgeon-in-Chief of the children's hospital Nursing: CNO of the children's hospital 	 Medical Directors: Fetal Program, L&D, OR services, Anesthesiology, Pediatric Cardiology, Fetal Imaging, Neonatology Managers: L&D, OR, Fetal Program, NICU, diagnostic imaging, pharmacy, anesthesia support services, respiratory therapy Front-line staff representatives: MFM, genetic counseling, social work, patient experience, ultrasound Nursing representatives: fetal, cardiac, NICU 	 Directors: Finance, Strategy & Outreach, ambulatory nursing, inpatient nursing Medical Directors: fetal care, fetal surgery Fetal Program Manager 	 Director: Outreach & Strategy Vice Chair for obstetrics outreach Managers: fetal program, marketing, provider relations Medical directors: Fetal Program
Objectives	 Makes critical decisions regarding program direction and oversees the other committees Annual operating and capital budgets Oversight of the execution of new fetal procedures Locations where the fetal program will provide services Capital prioritization and procurement Marketing, outreach, fundraising, and philanthropic oversight 	 Establish medical and nursing structure and staffing of all disciplines to provide operational oversight of activities Establish and oversee taskforces required in the implementation and management of operational initiatives Identify and prioritize clinical guidelines and protocols for patient care; establish measurable goals and track progress toward key metrics Establish appropriate educational curriculum to support new procedures Ensure a focus on measuring and improving quality and patient safety Partner with Finance and Strategy & External Affairs Committees to manage business operations, programmatic proposals, strategic initiatives and priorities Establish core research components for the fetal program 	 Monitor and support procurement of new capital spaces and products Implementation of new billing related to expanded services Ensure focus on measuring and improving the financial health of Fetal services Identify/prioritize financial activities for timely action planning and resolution Measure performance against pro forma Evaluate programmatic/position requests and make recommendations to Executive Oversight Monitor, review, and make recommendations regarding financial proposals 	 Focuses on the external consumer experience with the fetal program Develop and guide process for strategic plan development, implementation, and tracking Create a virtual clearinghouse where issues and initiatives can be elevated and evaluated as it relates to acquisitions, new sites, partnerships, network development, expansions Monitor market changes and proactively identify opportunities, challenges, and strategies to mitigate impact to the program Serve as the competitor and business intelligence

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FIGURE

The six pillars of a comprehensive maternal-fetal surgery center. Shared goals include exploring minimally invasive surgical approaches, caring for underserved populations, participating in national and international conferences, and conducting research.



fellowships vary in duration (1-2 years), procedural experience, and research requirements.²² With only a handful of fetal surgery fellowships in the country,²² many practicing fetal surgeons are not formally fellowship-trained. Instead, some have completed a 1-year observership or were trained informally by more experienced faculty within their same center.²²

The workload to upstart a new center can be daunting, particularly when undertaken by an individual fetal surgeon. Physician "burnout" can be mitigated by allowing the fetal surgeon to have significant protected administrative effort to be able to create the foundational elements (eg, protocols, staff training, clinical outreach, etc.). In addition, referrals for fetal surgery consultations often come in an unpredictable manner, and providing flexibility for the surgeon to see patients is paramount. As clinical volume grows, recruitment of additional fetal surgeons should be considered. Hiring fetal surgeons from two different disciplines such as MFM and pediatric surgery would balance sharing of the workload and allow each surgeon to still have impactful clinical roles within their respective division.

Thus, one approach is to harness the strengths of having both perinatal and pediatric surgery expertise to develop a center with a collaborative codirectorship model. To accomplish this, recruitment of at least two fetal surgeons, one trained in MFM and the other in pediatric surgery is needed. The benefit of this model is each surgeon contributes their own unique subspecialty experiences and skills to procedures and can thoroughly cocounsel patients from both an obstetric health and a pediatric lens.

The perinatal focus helps to better characterize maternal risks, including risks to future pregnancies while maximizing pregnant patient autonomy, activity, and delivery options. In parallel, the pediatric surgery focus allows for more comprehensive counseling about the anticipated postnatal medical and surgical needs of the future neonate. Combining these areas of expertise ensures that patients will be counseled beyond the immediate risk/benefit of a procedure and with consideration of long-term pediatric quality-of-life issues and long-term obstetric morbidity.

To achieve program success, both codirectors should operate together and share a collaborative vision. Recruitment of two surgeons with similar levels of experience, who express a common vision for the center, but with different clinical training backgrounds may aide in collaboration while promoting diversity (Figure). For successful development, program early-stage career fetal surgeons would benefit from tele-surgery mentorship to maximize chances of procedure success while minimizing risk for complications. Additionally, enlisting the support of experienced faculty from both MFM and Pediatric Surgery to provide program oversight is critical.

Phase 3—Surgical implementation and performance

Phase 3 includes surgical implementation and quality assurance on surgical performance. The first step is purchasing and testing the instruments required to perform the procedures. Although some equipment can be specific to individual surgeons, there should be a concerted effort to create an inventory of instruments that is compatible with a single video integration unit to minimize costs. Upon arrival of the equipment, the next steps involve internal training and workflow development (from initial referral to delivery and postpartum care); including educational presentations, hands-on teaching sessions, and operating room simulations to train staff members on the new surgical procedures and equipment use and contingency planning in case of a complication such as fetal distress necessitating delivery. As some of the represented centers have learned, mishandling of the equipment can lead to costly repairs or replacements. Operating room workflows should also be created for surgical equipment maintenance and inventory.

Unlike other surgical specialties, fetal surgery lacks uniform surgical quality metrics. Given the complexity and rarity of fetal procedures, all maternal-fetal surgery centers are encouraged to have a systematic approach to track quality measures. Precepting and proctoring are key components to surgical education and improving patient care.²³ The objective of a quality improvement program is to provide feedback during or after the completion every fetal surgery case. There are numerous acceptable approaches to quality assurance. We suggest a model in which in-person proctoring as well as intraoperative teleconsultation options are available given the nature and timing of certain urgent interventions (TTTS), and potentially the lack of local experts in the region. Some of the authors modeled their quality improvement program after the principles of the American College of Surgeons National Surgical Quality Improvement Program (NSQIP), the first nationally validated, outcomebased, risk-adjusted, peer-controlled program to improve delivery of surgical quality care.²⁴ Adhering to NSQIP, quarterly peer-controlled and outcomebased case reviews are held for surgical cases^{25,26} with pediatric surgeons, MFM, and with mentors of the fellowship-trained fetal surgeons who act as expert consultants. The goal of such quality improvement measures is to promote transparency and accountability for each maternal-fetal surgery center.

Multidisciplinary collaboration

A multidisciplinary approach to fetal surgery is critical. There are a range of environments within which a maternalfetal surgery center might be developed including a children's hospital with or without a special delivery unit (SDU), an adult hospital that includes obstetric care and a NICU, or a hospital complex that includes both a full-service adult hospital as well as a children's hospital. For the latter, the adult and children's hospital may be part of a single health system or owned separately. There are a range of challenges for these different hospital and practice environments. For example, for a freestanding children's hospital, there would be a need to incorporate MFM specialists and potentially the need to create an obstetric imaging suite. Even with these, without access to a labor and delivery unit, there may be challenges in caring for the pregnant patient, particularly with complications or comorbidities. Some freestanding children's hospitals have therefore created an SDU within the pediatric hospital. An SDU within a pediatric hospital has its own set of challenges, including how to manage or transfer a critically ill peripartum patient to the adult hospital for ICU or other specialized care.²⁷ Since an SDU in a freestanding children's hospital will not have direct access to the complete breadth of adult services (including ICU), such centers would not meet the obstetrical criteria to be a NAFTNet level I to III maternal-fetal center.^{3,27} However, many pregnant patients can still undergo the fetal procedure and safely delivery at the SDU when carefully triaged in collaboration with MFM specialists. Thus, even with an SDU, ongoing partnership between children's and adult hospitals remains vital.

A strength of institutions with both a children's and adult hospital within the same health system on a single campus is having the L&D and NICU in close proximity. The advantage of this design is that it allows the pregnant patientfetal duo to undergo surgery, delivery, and receive subspecialty or ICU care if needed while remaining in close proximity to their infant(s) in the NICU. Physical proximity of L&D to the NICU also facilitates important conversations about how best to support the pregnancy as well as postpartum/neonatal needs. Many pregnant patients with fetal congenital anomalies show high rates of depression symptoms as well as high rates of poverty, unemployment, transportation barriers, and food insecurity.²⁸ These economic stressors may be amplified for fetal surgery patients coming from a wide geographic catchment area. Thus, additional requests from the neonatology division in advance of starting a maternal-fetal surgery program may include increased socioeconomic support for families and provision of transportation, lodging, and food for fetal surgery clinic visits and during their NICU stay.²⁹ Centers with separate locations for obstetrical, adult and pediatric services may face challenges when patients with complex conditions require service lines in physically separate locations. However, there remain important limitations even in centers with adult and pediatric hospital systems located on the same campus. Some maternal-fetal surgery centers may be located in states with restrictive abortion policies thereby impacting a patient's options for pregnancy care. Similarly, access to neonatal palliative care may vary by individual center or state.

The care of pregnant patients with complex fetal conditions, particularly those undergoing *in utero* intervention, requires clinical team members who understand the nuances of providing unbiased nondirected care options. Some conditions, despite having a technically successful fetal intervention, may require long-term postnatal care, such as vesicoamniotic shunt placement for fetal lower urinary tract obstruction which may decrease mortality from pulmonary hypoplasia, but survivors often still require long-term care, including dialysis and kidney transplant.³⁰⁻³ Other conditions (eg, hydrops fetalis) may not have an etiology determined until after delivery despite extensive prenatal evaluation.³⁴ This decision-making process is understandably stressful, and patients often face challenging decisions with regards to qualmortality.35 and ity-of-life The physicians counseling these pregnant patients should provide unbiased, objective information about pregnancy and neonatal care options aligned with the patient's stated values and information needs.^{8,36} Social workers, palliative care providers, and ethicists are often integral members of a holistic care team.

Within the institution, a subset of clinicians within each specialty are often identified as the preferred prenatal consultants and provided divisional support for dedicated clinical and administrative time. Prenatal consults for complex fetal conditions require lengthier appointments, as well as additional effort to coordinate pregnancy and postnatal care (eg, delivery planning, ECMO requirements, etc.). Regular (eg, weekly) multidisciplinary case conferences facilitate the creation and dissemination of clinical plans and coordination of care for the remainder of the pregnancy and after delivery.

One approach to fostering ongoing clinical collaboration amongst team members is through scientific research, which promotes innovation and facilitates sharing of insights and best practices by different field experts. Maternalfetal surgery centers are encouraged to publish their center-specific outcomes as well as participate in multi-institution national registries (eg, NAFTNet) designed to standardize clinical care and generate hypotheses for future studies. This transparency is beneficial by identifying areas of care that need improvement. Given fetal conditions eligible for *in utero* interventions are uncommon, multi-institutional studies allow for adequate sample size and promote patient accessibility for study enrollment. Consortiums such as NAFTNet promote cooperation between medical centers and lead to advancements in fetal diagnosis and therapy. Examples include laser surgery for TTTS,³⁷ FETO for CDH,³⁸ and serial amnioinfusions for renal causes of anhydramnios.³⁹

The integration of the research infrastructure into clinical workflow should occur preferably during the initial stages of the program onset to allow for prospective patient enrollment and maintenance of a data repository. The clinical research teams are responsible for establishing protocols, data collection, and data analysis on an ongoing basis. In particular, when performing prospective studies such as a feasibility trial for FETO, an investigational device exemption by the FDA is needed, which concurrently requires institutional IRB approval. Ideally, the research efforts are supported by members experienced in enrolling vulnerable obstetrical patients with financial support shared by stakeholder divisions (eg MFM, pediatric surgery). The core components of this research model are research manager to handle study protocols and IRB regulations, study coordinator for patient enrollment and follow-up, and data specialist for the creation and maintenance of electronic databases (eg, REDCap).

Challenges and lessons learned

Regardless of the institution, there were several overlapping important programmatic upstart lessons learned during the planning phases and the initial years of the program's course (Table 5). Prior to launching a maternal-fetal surgery center, it would be well-advised for hospital executives and programmatic leaders to visit existing maternal-fetal surgery centers across the country to develop a model of best practices. A critical assessment of the strengths and weaknesses of one's own existing healthcare "ecosystem" can be performed to better integrate the experiences of the recruited fetal surgeons. The goal is to create a program that harmonizes the expertise of the fetal surgeons with the existing infrastructure of the fetal program to create a distinctive center within the region. Every institution will encounter unique challenges when initially starting a maternal-fetal surgery center.

Integrating into existing institutional culture and practices. Center success is dependent on member engagement and willingness to adjust and adapt. However, barriers to team building and transition are common.⁴⁰ Although wellintentioned, the addition of fetal surgeons into an existing program can be disruptive because it may lead to changes in individual scope of practice, leadership roles, clinic flow, and overall team dynamics. When certain programmatic issues cannot be fully resolved by individual team members amicably, it is beneficial to have a set process utilizing an overnight leadership committee to provide support and guidance to resolve the conflict in a transparent and equitable fashion. In particular, a visionary leader with experience can propel a growing program past such friction points and promote stability by through a well-defined chain of conflict resolution and holding members accountable. Creation of a truly multi-disciplinary program requires the initiation from the executive leadership by removing silos of care. Unbiased executive coaching may assist new leaders in developing administrative skills and navigating these challenging scenarios.

Creation of specialty teams. Similar to other highly specialized collaborative service lines (eg, transplant surgery), the performance of fetal surgeries requires a core team that is both readily available and consistent with executing complex workflows. Institutional infrastructure may present unique challenges in creating a dedicated fetal surgery care team. For instance, some institutions have relationships with multiple labor unions (eg nurses and sonographers in different

TABLE 5

Programmatic themes for an early maternal-fetal surgery center to consider and the lessons learned from our own experiences

Themes	Lessons learned
Planning for complexity	 Understanding the unique institutional structures already in place Recognize specific institutional strengths and limitations Identify who the drivers are and who will be impacted by programmatic planning Learn from those connected to the work what limitations they perceive Map out the entire patient process from referral through neonatal hospital discharge Identify physical workspaces that will be impacted both directly, and indirectly
Decision-making capacity	 Clear governance structure to guide the overall program Ensure top tier is limited to a small group who have institutional authority, but also enough distance from the programmatic operations to remain "neutral" in decision-making Establish tiers within the structure to allocate local authority to front-line staff and local managers, and facilitate structured escalation when needed Ensure governing authority crosses all direct impacted departments
Team building	 Ensure impacted teams are included in the programmatic planning stages Be transparent about planning and vision, and include input from frontline teams Include local leaders from impacted departments to participate in identifying limitations and opportunities Facilitate frontline team relationship building early and often Help departments learn the strengths of other department members, so that expertise can be maximized Acknowledge and give space for the emotional processing of the programmatic launch, new interventions, and ethical questions that inevitably arise when programs of this nature are introduced to new team members Success of the programmatic launch will often be predicated on <i>perceived</i> impact by stakeholder departments on early decision-making
Communication across multiple teams	 Program leaders should speak on behalf of the leadership team, not individual perspectives Recognize that the complexity of these programs comes primarily from the need for complex, coordinated care from teams not practiced in working together Relationship building, shared purpose, and optimized communication are the keys to ongoing programmatic resilience Create redundant, structured team communication across departments and disciplines Identify specific structures to discuss individual patient care plans, surgical cases, and ad hoc patient discussions Maximize digital and automatized communication methods to ensure successful communication

unions). Creation of something as niche as a maternal-fetal surgery center requires careful consideration of existing collective bargaining agreements. Fetal surgery consultations and operations may occur outside of normal working weekday hours in an urgent fashion, requiring the establishment of an "on-call" team. The creation of additional support teams requires navigating topics of work-hour restrictions, compensation, and equitable opportunities for individuals to join the subspeciality team. Similarly, some institutions utilize sonographers that perform obstetrics, adult, and pediatric imaging under the direction of the Department of Radiology. Therefore, staffing with dedicated

obstetric-specific or fetal surgery-specific sonographers may not be feasible. Instead, efforts would need to be focused on educating a broader roster of sonographers on fetal surgery-specific imaging through the development of specific protocols. Institutions must consider these challenges, especially during the early phases when revenue may not support dedicated support personnel. In small to moderate-sized centers, "cross-training" will both be a bridge for growth as well as a backstop during departures and transitions.

Location of fetal surgeries. Another logistical issue to address is the location where fetal surgeries will be performed.

Options may include main adult or pediatric surgery ORs, standard L&D ORs, or a dedicated perinatal OR within L&D. Several factors should be considered when deciding the location including physical space, case scheduling logistics, proximity to L&D and NICU, surgeon preference, anesthesia support, and OR staffing needs. The pros and cons of each location specific to the institution should be considered (Table 6). For instance, having anesthesiologists trained in obstetrics as well as pediatrics is not only paramount to safely performing fetal surgeries, but also allows versatility in where the surgeries can occur (adult, L&D, or pediatric ORs). In some

TABLE 6 Critical factors to consider for location of performing fetal surgeries (adult OR, pediatric OR, L&D)		
	Considerations	
Physical space	 Adequate space to accommodate surgeons, staff, equipment, observers Capable of laparoscopy and video integration Ability to create dimly lit environment for laser surgeries Adequate storage space for equipment and supplies Established workflow for stocking and maintain supplies Proximity to labor and delivery and NICU How to manage obstetrical emergencies (cesarean delivery, hemorrhage, etc.) Recovery space (private room vs open area) 	
Scheduling	 Ability to schedule urgent cases Scheduling system integration with other OR locations in the hospital 	
Electronic medical records	 Cross-compatibility of the pregnant patient medical records between locations and institutions Creation of fetal charts to record lab and test results and plans of care that can seamlessly be transitioned to the neonatal chart after delivery 	
Anesthesia	 Comfortable with regional and general anesthesia for pregnant patients Capable of dosing fetal medications. Participate in neonatal resuscitation in complex cases (EXIT procedures) 	
Nursing	 Experienced obstetrical and pediatric nurses comfortable caring for high-risk pregnant patients Willingness to learn and adapt to new workflows for fetal surgery patients 	
Surgical techs	 Skilled with minimally invasive (fetoscopy/laparoscopy) surgeries Capable of OB procedures (cesarean deliveries, cerclage placement) 	
EXIT, ex-utero intrapartum treatment; N Chon. Developing a comprehensive	IICU, neonatal intensive care unit. maternal-fetal surgery center. Am J Obstet Gynecol MFM 2024.	

circumstances, certain procedures may be performed in one location (eg, L&D for intrauterine transfusions) while more complex procedures may be performed in larger spaces (eg, main adult OR for fetoscopic spina bifida repair).

With the introduction of new procedures including laser surgery for TTTS, there needs to be considerable planning and re-organization of existing workflows to accommodate surgery scheduling, new instruments, sterile processing, video equipment, storage needs, and staff training. The education can be disseminated in the form of presentations, Q&A sessions, and hands-on simulations. Surgical techs and nursing will require training to become competent in the use of laparoscopic instruments, video equipment, fluid management systems, etc. Prior to the performance of the first laser surgery, the surgeons, sonographers, anesthesiologists, surgical technicians, and nurses are encouraged to perform full-scale simulations, preferably using a TTTS-specific simulator. Use of high-fidelity models (self-made or commercially manufactured) that accurately depict the steps of the surgery (eg, anatomic details, port insertion, equipment handling, etc.) is an invaluable tool in training staff and achieving competence. Additional simulations involving conversion of the procedure to delivery of the neonates should be employed to familiarize the NICU team with the OR setup and define procedures for emergently mobilizing the NICU team for such highacuity and short-notice births. The entire process from equipment purchasing to staff readiness for laser surgery may take 6 to 12 months. Flexibility in timelines to match the actual training and critical appraisal of simulations is important in determining the preparation of the team.

Fetal surgery impact on other programmatic areas. Creation of a maternal-fetal surgery center increases both outpatient and inpatient volume in several clinical arenas. A team-based approach to planning for an increase in clinic visits (prenatal, pediatric specialists, genetics, social work, etc.) imaging (ultrasound, echocardiogram, MRI), and NICU admissions is prudent. This plan to accommodate increased patient volume should account for both physical space needs and ability for clinicians to see a higher number of patients.

For example, an active maternal-fetal surgery program is expected to further increase the NICU census. Physical bed space, unit capacity, and staffing ability will need to match the expected increase in volume. Institutions already operating at NICU capacity would need to find creative approaches to accommodating the additional admissions such as increasing the NICU physical capacity by remodeling or repurposing adjacent spaces (eg, converting well-baby nursery spaces to NICU beds) and increasing staffing to care for the additional patients, transferring patients to the pediatric ward, and/or transporting patients to other NICUs in the region. Furthermore, the increase in patient volume and acuity can place additional burden on ECMO resources (pediatric perfusionists and ECMO circuits). The clinical volume for both L&D and NICU may increase enough to justify building additional facilities on campus. Capacity must be a central consideration for growing programs.

Setting expectations of outcomes. Despite meticulous planning, many maternal-fetal surgery centers will not meet the anticipated volume/revenue in the first year due to fewer than projected surgeries due to various causes such as delays in procurement of equipment, staff readiness, slower than expected changes in referral patterns, etc. To better capture financial growth, the calculations should include surgeries as well as related clinical volume including outpatient visits, imaging (including fetal echocardiograms), and NICU census days.

However, mere volume and individual expertise do not assure good outcomes at a maternal-fetal surgery center. Fetal surgery patients, by virtue of having a condition warranting an invasive in utero procedure, have baseline risks of preterm premature rupture of membranes, miscarriage, preterm delivery, and fetal or neonatal demise. Thus, a fetal surgery can be completed successfully from a technical standpoint, but still have a poor outcome due to postoperative complications or as a result of a high-risk disease process. This concept is important to emphasize to clinical staff in preparation for starting fetal surgeries. For example, despite laser surgery definitively treating TTTS, preterm delivery (mean gestational age of delivery is approximately 32 weeks)41,42 and death (survival of atleast-one twin and dual survivorship ranges from 82% to 97% and 45% to 89%, respectively) $^{41-44}$ still occur even in the absence of attributable operative complications.^{45–51} The aforementioned range of possible outcomes and complications should be disseminated to MFMs, NICU, Radiology, operating room personnel, and nursing staff through numerous educational symposia throughout the year preceding actual implementation of the surgeries. Relevant to a developing program is the difficulty of delineating which surgical complications were preventable with an improvement in systems or technical

approach versus those that were inevitable despite best efforts.

The focus of any maternal-fetal surgery center should be patient-centered care. For this reason, maternal-fetal surgery centers in the early stages of development should disclose that their institution is a relatively young program with a limited number of surgeries performed thus far and discuss the option of a second opinion at another center. In select cases, due to the anticipated level of technical difficulty, the surgeons may help the patient seek out evaluation at a more experienced center. Using this approach, patients have expressed gratitude for the transparency and felt empowered to make a well-informed decision under stressful circumstances.

Future directions for program growth

After a center achieves consistent results from laser surgery for TTTS, steps can be taken to introduce additional procedures such as fetoscopic spina bifida repair. Additional spina bifida surgery readiness steps commonly include training the pediatric neurosurgeons on the laparoscopic skills required to perform fetoscopic repair using training models along with external site visits to observe cases. The time commitment from the fetal surgeons and pediatric neurosurgeons is considerable for this additional training (approximately 12 months). Given fetoscopic spina bifida repair is a new procedure unfamiliar to most pediatric neurosurgeons, there is administrative effort required to obtain hospital credentials including contracts with outside consultant experts in proctoring the initial cases.

In addition to becoming a level III³ maternal-fetal surgery center offering the full spectrum of fetal intervention, the institution should strive to make meaningful contributions to research and innovation in order to continue to advance the field of fetal therapy (Figure). For example, fetal intubation,⁵² fetoscopic laser photocoagulation for vasa previa,⁵³ and balloon dilation/stent placement for congenital high airway obstruction,⁵⁴ are some examples of more recent innovative techniques reported in the literature

that programs can explore as they mature. As a center begins to join national multi-institutional studies, there is a recognized need for growing the research team to include additional research coordinators and data analysts to maintain study enrollment and prospective data entry. As the maternalfetal surgery center matures, continuing to cultivate a culture of effective teamwork that focuses on delivering exceptional care to patients is vitally important. Lastly, once a center has achieved a consistent high volume of cases and robust research infrastructure, consideration should be given to establishing a fellowship program to train the future generation of fetal surgeons.

Conclusion

The establishment and growth of a comprehensive maternal-fetal surgery center represents an immense journey through progressive phases of development. The strategic planning phases from business and recruitment to surgical implementation and collaboration underscore the meticulous planning and forethought that is needed to build and sustain a successful maternal-fetal surgery center. Challenges and lessons learned in the integration process emphasize the need for adaptability and a shared vision among all stakeholders, including navigating existing institutional cultures, setting performance expectations, and optimizing physical spaces. Looking to the future, early maternal-fetal surgery centers should envision long-term goals for ongoing expansion by adding new fetal interventions, leveraging research and innovation. and nurturing professional multidisciplinary relationships.

CRediT authorship contribution statement

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