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REVIEW

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The value and limitations of using predetermined criteria in decision making for maternal-fetal interventions

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Abstract

Maternal-fetal interventions—such as prenatal fetal myelomeningocele (MMC) repair—are at the forefront of clinical innovation within maternal-fetal medicine, pediatric surgery, and neonatology. Many centers determine eligibility for innovative procedures using pre-determined inclusion and exclusion criteria based on seminal studies, for example, the "Management of Myelomeningocele Study" for prenatal MMC repair. What if a person's clinical presentation does not conform to predetermined criteria for maternal-fetal intervention? Does changing criteria on a case-by-case basis (i.e., ad hoc) constitute an innovation in practice and flexible personalized care or transgression of commonly held standards with potential negative consequences? We outline principle-based, bioethically justified answers to these questions using fetal MMC repair as an example. We pay special attention to the historical origins of inclusion and exclusion criteria, risks and benefits to the pregnant person and the fetus, and team dynamics. We include recommendations for maternal-fetal centers facing these questions.

Key points

What's already known about this topic?

- Though trial-based data form the basis of recommendations for maternal-fetal interventions, other information and clinicians' views, both of which may be subject to multiple biases, are commonly incorporated.

What does this review add?

- Ethical justification for including other information and clinicians' views when predetermined eligibility criteria exist for maternal-fetal interventions.
- Recommendations for how maternal-fetal care centers should include processes for ad-hoc exceptions and regular review of predetermined criteria for maternal-fetal interventions to uphold the bioethical principles of maternal autonomy and nonmaleficence.

The interdisciplinary team of providers who comprise a maternal-fetal surgery program receive referrals for the following pregnant patients and are tasked with considering whether to offer in-utero myelomeningocele (MMC) repair or postnatal repair:

Case 1: A 19-year-old G1P0000 presents at 22 weeks gestational age (GA) with ultrasonographic findings consistent with a L3-S1 MMC for counseling. The patient's medical history is notable for a body mass index (BMI) of 42 kg/m^2.

Case 2: A 35- year-old G3P0111 (1 preterm birth, 1 abortion or miscarriage, 1 live birth) presents at 19 weeks GA with ultrasonographic findings consistent with a T10-S1 MMC for counseling. The patient has a prior history of spontaneous preterm birth (PTB) at 28 weeks GA.

1 | INTRODUCTION

Maternal-fetal interventions—such as prenatal MMC repair—are at the forefront of clinical innovation within maternal-fetal medicine (MFM), pediatric surgery, and neonatology. Following the antenatal diagnosis of fetal MMC, pregnant people considering intervention will present for evaluation at maternal-fetal care centers to determine whether they are eligible for prenatal MMC repair.[1] Many centers determine eligibility for prenatal MMC repair using the inclusion criteria contained within the seminal "Management Of Myelomeningocele Study (MOMS)", a randomized controlled trial of prenatal versus postnatal MMC repair.[2] In both of the cases presented, the hypothetical pregnant people had medical conditions considered exclusionary in the MOMS trial (case 1 secondary to body mass index (BMI) >35 kg/m^2 and case 2 secondary to prior history of preterm birth). If exclusion criteria from the MOMS trial are extrapolated to clinical practice, the pregnant people and their fetuses in these hypothetical examples would not be offered prenatal repair.

The value of inclusion and exclusion criteria—particularly the framework used to determine the criteria and the supposed harm of practicing outside the criteria—is a crucial consideration. There may be multiple, sometimes competing, medical factors which multidisciplinary team members (e.g., pediatric surgery, neonatology, maternal-fetal medicine) must consider. In addition to comorbid medical conditions, the pregnant person's social lifeworld[3] may challenge pre-defined criteria for intervention. In addition to comorbid medical conditions, the pregnant women may have their own reasons for challenging pre-defined criteria. For example, an individual may self-advocate to undergo a maternal-fetal intervention outside the standard indicates due to factors like prior adverse pregnancy outcomes or sociostructural difficulties. When a clinical team determines that a pregnant person's overall presentation does not conform to pre-determined criteria for maternal-fetal intervention, but reasons to consider the procedure exist, does changing criteria on a case-by-case basis constitute an innovation in practice and flexible personalized care or transgression of commonly held standards with potential negative consequences?

Determining eligibility for a particular procedure or therapy is especially challenging for maternal-fetal interventions. First, there are important independent risks to consider for the pregnant person and the fetus.[4] With open fetal MMC repair, pregnant people experience a high frequency of spontaneous uterine rupture in subsequent pregnancies (9.6%), which can lead to life-threatening hemorrhage and hysterectomy, as well as markedly increased perinatal risk.[5–7] Further, the pregnant individual will require cesarean delivery for the index pregnancy and every subsequent pregnancy, potentially increasing the likelihood of issues like placenta accreta spectrum disorder, hemorrhage, and hysterectomy.[8] Though fetal MMC repair is performed to benefit the offspring, it also confers risk to the offspring primarily through the complication of preterm birth. Significant prematurity (birth at less than 30 weeks gestational age) was reported in 13% of prenatal MOMS trial participants, compared to 0% in the postnatal group participants.[1] Any medical condition which raises the likelihood of preterm birth increases the potential risk of perinatal morbidity and mortality. Decision making must balance preservation of maternal autonomy with beneficence and non-maleficence, both for the pregnant person and the fetus.[9–13] This balance requires disclosure to the pregnant person of the uncertainty inherent in any intervention.

Second, factors external to an individual patient's situation may impact how eligibility for a procedure is determined. Maternal-fetal intervention is a team sport, requiring group collaboration, shared understanding, and predefined processes for addressing conflict.[14] Within a complex maternal-fetal clinical team, opinions about offering a particular procedure may differ based on specialty, seniority, and individuals' biases (e.g., misogyny, racism, ableism).[15,16] While working in teams typically confirms benefits to clinicians, when opinions differ, teamwork can create conflict. Unresolved conflicts may threaten the quality of care and ultimately patient health outcomes.[17] Also, individual centers do not operate in a vacuum; clinicians commonly look to other maternal-fetal intervention centers or registry data to assess what criteria others use when considering deviations from "standard" inclusion criteria for a given procedure.[18] Ongoing biomedical research and innovative procedures, such as the development of fetoscopic approaches to prenatal MMC repair,[19] can change the scope of criteria used to offer intervention. Finally, the slow alterations in practice patterns over time, based both on center comfort with the surgical technique and peer-reviewed experiences of other centers, change who is offered a given intervention. All of these factors can call into question the logic underlying inclusion criteria.[18]

Given the complexity of decision-making related to determination of eligibility for maternal-fetal interventions, we explore the benefits and limitations of setting criteria before a given consultation (i.e., predetermined criteria) as well as those related to ad hoc changes to predetermined inclusion criteria. We first describe the

origins of predetermined criteria, discuss using predetermined criteria to assess risks and benefits for the pregnant person and fetus, and consider the impacts of predetermined criteria on team dynamics and care delivery. Utilizing this ethical analysis, we provide recommendations for maternal-fetal centers to address the challenges related to having predetermined criteria for novel procedures.

2 | THE ORIGINS OF PREDETERMINED CRITERIA

The use of inclusion and exclusion criteria harkens to the rise of evidence-based medicine, particularly the introduction of randomized controlled trials in the 1940s[20] Criteria for participation in a clinical trial are created for a variety of reasons: (1) To identify a defined population that would potentially benefit from a given intervention; (2) To ensure that participants can participate in all trial activities, such as repeated blood draws, study visits, and longitudinal follow up; (3) To minimize risks and, in some cases, maximize benefits of an intervention to trial participants given the presumed morbidity and/or mortality of the condition under investigation[21]; and (4) To minimize untoward side effects related to conditions beyond the studied condition/intervention. Clinical trial participation criteria are critical for the ability of the study to achieve both internal and external validity.

The use of predetermined criteria for participation in a trial and subsequent extrapolation to real-world practice provide the opportunity to evaluate the effectiveness, rather than merely the efficacy, of an intervention for the population that had been studied.[22] Work done by scholars in science and technology studies[23,24] shows that predetermined inclusion criteria often find their way into the clinical setting, structuring clinical decision-making about therapeutic options for patients. Clinicians "tinker with"[25]—that is, improvise, alter, or otherwise manipulate—predetermined inclusion criteria in the name of adaptability to unique clinical scenarios or structural limitations at a given clinical site.[23]

Tinkering with predetermined inclusion criteria occurs when the criteria derived from a foundational randomized trial begin to expand and the pool of eligibility for a given intervention is enlarged. Some critics argue that as inclusion criteria for an intervention begin to expand beyond those tested in an initial study, future randomized trials must be conducted. These trials are thought to be necessary to evaluate whether efficacy is still observed among individuals who did not initially meet the primary trial's inclusion criteria. However, as noted with recent arguments focused on the utility of randomized trials to evaluate fetoscopic approaches to fetal MMC repair,[26] the time, cost, and coordination required to conduct a trial, as well as the proposed utility of the information to be obtained, are key to inform whether future trials should occur. In most circumstances, the eligibility pool for an intervention expands without conducting follow-up trials; therefore, how data derived from non-randomized studies – limited due to multiple levels of biases that are traditionally minimized in a randomized controlled trial—become integrated into clinical counseling and recommendations must be evaluated from a bioethical perspective.

While we support the inclusion of new data or adaptation to unique scenarios while providing high-quality, evidence-based care, changing criteria on an ad hoc basis may be reasonable but also introduces important concerns. We turn to a bioethically informed discussion of how to consider risks and benefits of predetermined versus *ad-hoc* criteria for inclusion in maternal-fetal therapy for both the pregnant person and their fetus(es).

3 | USING PREDETERMINED CRITERIA TO ASSESS RISKS AND BENEFITS FOR THE PREGNANT PERSON AND FETUS

Considering the impact of maternal-fetal interventions on the pregnant person is pivotal, as any intervention is performed through the pregnant person for the benefit of the fetus.[12,13,27] The maternal and fetal risks of particular procedures (e.g., bleeding, preterm birth, subsequent adverse reproductive health outcomes[5,6,28]) must always be weighed against the potential future benefit of the offspring (e.g., improvement in motor function and neurocognitive outcomes for prenatal MMC repair[29–32]). From a principle-based bioethical perspective, nonmaleficence must be weighed against maternal autonomy. To create a calculus for assessing when the risks of a given procedure outweigh the proposed benefits (or vice versa), predetermined criteria based on clinical trials help centers offer procedures to reasonable surgical candidates based on established evidence.

In the example of open fetal MMC repair, many centers use strict inclusion and exclusion criteria derived from the MOMS trial protocol.[2] However, limiting predetermined criteria may not optimize decision making for all prenatal situations and for all pregnant people. Centering decision making from the pregnant individual's perspective (i.e., giving weight to maternal autonomy and shared decision making) it is important to identify the patient's priorities for care. Often, a pregnant person is seeking an intervention that will dramatically alter fetal viability (e.g., fetoscopic laser photocoagulation for treatment of twin-to-twin transfusion syndrome) or postnatal quality of life (e.g., prenatal MMC repair). For some pregnant people, these goals of fetal or childhood beneficence take priority over their own health, leading the pregnant person to assume procedural risks with no physical benefit (or even a decrement of health) to themself (i.e., the outcomes desired by the pregnant person apply to their fetus and occur after birth). Viewed from this perspective, many of the criteria created for clinical trials could be thought to limit maternal autonomy in lieu of fetal or childhood beneficence.

For example, in Case 1, the MOMS trial excluded individuals whose BMI was greater than or equal to 35 kg/m^2. Many maternal-fetal intervention centers have expanded their criteria, allowing eligibility for prenatal MMC repair to individuals with a higher BMI without clear data about the risks to the pregnant person and fetus.[18] Many propose that numeric cutoffs (in this case for BMI) are less

important than the relative ability to perform the proposed intervention safely, such as appropriate visualization which may be hampered by body fat distribution, and additional perioperative risks posed by elevated BMI, such as poor wound healing, cellulitis, seroma formation, and venous thromboembolism.

In Case 2, prior PTB was an exclusion criterion for open fetal MMC repair in the MOMS trial because of the creation of hysterotomy and potential failure of the amniotic membranes to reseal (e.g., chorion-amnion separation). The latter may increase the risk of PTB, which may potentially increase the risks to the offspring. From the perspective of the trial architects, if there is a greater proportion of preterm births, multisystem complications resulting from a preterm delivery may drown out the potential benefits of a prenatal MMC repair.[33] Based on informal conversations between the authors and members of maternal-fetal intervention centers across the U.S., individual centers have adjusted this criterion, extending eligibility for prenatal MMC repair to include some individuals who have a history of PTB. The decision to offer prenatal MMC repair to people who have a history of PTB is couched in the assumption that the etiology for prior PTB might be distinct from the supposed pathophysiology that puts people at risk of PTB with a prenatal MMC repair. For example, an individual who undergoes an induction of labor at 34 weeks' gestation due to the development of preeclampsia with severe features has a different etiology for their preterm birth (i.e., medically indicated, based on ACOG recommendations[34]) than someone who has a history of a spontaneous vaginal delivery at 28 weeks in the setting of preterm labor. In the former example, a prenatal MMC repair may not increase the likelihood of preterm delivery due to hypertensive disorders of pregnancy. In the latter example, a prenatal MMC repair may increase the likelihood of a preterm delivery due to disruption of the fused chorion-amnion, which brings with it the increased chance of preterm prelabor rupture of the membranes or labor. Therefore, the maternal-fetal care team must determine whether it is ethically and medically appropriate to offer the intervention considering the potential harms of PTB, based on a person's history, given that the potential benefits of the intervention to the offspring may no longer exist (in which case there is no longer a rationale for performance of the procedure or any beneficence to apply).

The exceptional nature of both cases demonstrates an opportunity for maternal-fetal care teams to scrutinize predetermined criteria, particularly the rationale behind them and their associated risks and benefits and incorporate ad hoc changes to determine eligibility for prenatal MMC repair. However, ad hoc changes have the potential to create challenges. For example, they could knowingly or unknowingly lead to inconsistencies in implementation and thus inequitable practice. Biases (implicit or explicit) from members of the maternal-fetal care team could motivate specific ad hoc changes. Basing practice upon bias rather than evidence has the potential to increase both maternal and fetal risks and worsen inequity, thus challenging the principles of nonmaleficence and justice.[35]

4 | IMPACT OF PREDETERMINED CRITERIA ON MATERNAL-FETAL CARE TEAM DYNAMICS

Multidisciplinary collaboration is intrinsic to and crucial for successful high-quality maternal-fetal intervention programs. Such programs include (but are not limited to) MFM subspecialists, fetal surgeons (either from a pediatric surgery or MFM background), pediatric surgeons, neonatologists, neurosurgeons, radiologists, cardiologists, neurologists, geneticists, nurses (advanced practice, operating room, peripartum, neonatal), developmental pediatricians, developmental therapists, social workers, case managers, and spiritual care providers.[14,36–38] In this complicated milieu, attention to team dynamics is essential. Care plans or protocols provide one approach to ensure a shared mental model and cohesive strategy among many different providers.[38] In the cases presented, a multidisciplinary group is asked to modify established protocols by offering a procedure in a situation in which predetermined inclusion and exclusion criteria are not met. Modifying predetermined criteria (i.e., established protocols) risks disrupting a fragile and often complex team dynamic. Disruptions in team dynamics may lead to team member dissatisfaction, problems with team member retention, and impaired or suboptimal patient care.[39,40] Viewed in this light, consideration of team dynamics is an ethical imperative.

The likelihood that a particular decision disrupts team dynamics is naturally heightened when differences of opinion exist about the proper course of action. For such cases, the group needs to have clear plans in place for how the decision-making process should proceed and how to address conflicting views about whether to proceed with ad hoc alterations to criteria. One important component of this decision-making process should involve a review of relevant literature. In addition, for a rapidly evolving field like maternal-fetal interventions, consideration of practice patterns and outcomes—culled through interactions with other medical centers and through organizations such as the North American Fetal Therapy Network, the Fetal Medicine Foundation, Society for Maternal Fetal Medicine, the International Fetal Medicine and Surgery Society, and the Children's Hospital Neonatal Consortium—can be informative. We submit that teams should consider in advance how they would use such information. Would the group decline to offer a procedure that has not been reported or only performed at a single other program? Similarly, the group should know in advance how to handle split team decisions. Would the decision to proceed with a particular procedure only occur if everyone agrees to avoid leaving some feeling that their view(s) do not matter?

Despite potential risks to team dynamics, there are benefits to allowing for decisional flexibility. Without such capacity, programs risk stifling innovation and may lose opportunities to improve care, provide care to more people, and advance knowledge. The benefit of having predetermined criteria set forth is that team dynamics are cordoned into a particular set of discussions that emphasize maternal and fetal/neonatal beneficence and nonmaleficence. However, ad hoc changes, if considered in the context of a pre-planned approach with

opportunities for the incorporation of different team member perspectives and ethical principles to guide decision making, can allow for continued innovation and expansion of treatment benefits while limiting the potential of untoward harms either for patients or the medical teams that care for them.

5 | RECOMMENDATIONS

We posit that maternal-fetal intervention centers should:

1. Collaboratively establish predetermined clinical criteria for deciding the eligibility for procedures.
2. Create clearly defined processes for considering ad hoc exceptions. This could utilize a pre-defined multidisciplinary oversight committee or other similar kind of committee as some have recommended.[41,42]
3. Regularly review predetermined criteria, taking into consideration center-specific experiences, new literature, and input from other centers with particular attention to evidence of bias and/or inconsistencies.
4. Develop a structured approach to evaluating situations that commonly arise in maternal-fetal care so that similar concerns can be considered in a regimented fashion.
5. Support an open, egalitarian environment to enable members of the team to help define the circumstances under which particular maternal-fetal interventions would be offered—based on skills, expertise, and resources available—to allow for coordinated decision-making.
6. Ensure established processes to allow for assessing team disagreements about a given case prior to discussing the resulting recommendations with a patient.
7. Regularly review limitations of available evidence informing recommendations for care, based on a predefined frequency.
8. Provide full transparency to all patients regarding the maternal-fetal care team's recommendations for their care, based upon the existing predetermined criteria, the care team's process for ad hoc changes, and the patient's own desires to undergo maternal-fetal therapy, if present.[43]

Specifically, points #3, 6, 7, 8 can be tracked and measured on a regular basis (annually or more frequently) as a form of quality control for a maternal-fetal intervention center. We argue that this approach is a bioethically justified method for determining eligibility for maternal-fetal inventions as it supports nonmaleficence, beneficence and justice towards the pregnant person and the fetus. Furthermore, we submit this approach promotes innovative care (i.e., ad hoc changes in inclusion criteria, enacted and reviewed through a pre-defined center-derived methodology), which could improve patient outcomes, further generalizable knowledge, foster staff engagement, and enhance job satisfaction. We have illustrated, through historical exegesis of evidence-based medicine and a principle-based bioethical evaluation, that ad hoc changes to predetermined criteria can be performed in a bioethically justifiable manner to allow for innovation in care that centers decision-making of the pregnant person and focuses on maximizing outcomes for them and their fetus.

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CONFLICT OF INTEREST STATEMENT

The authors report no relevant disclosures.

DATA AVAILABILITY STATEMENT

Data sharing is not applicable to this article as no new data were created or analyzed in this study.

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