Opinion Paper

Moti Gulersen*, Burton Rochelson, Eran Bornstein, Laurence B. McCullough and Frank A. Chervenak

Ethical challenges in management of critically ill pregnant patients with coronavirus disease 2019 (COVID-19)

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Abstract: Despite the overwhelming number of coronavirus disease 2019 (COVID-19) cases worldwide, data regarding the optimal clinical guidance in pregnant patients is not uniform or well established. As a result, clinical decisions to optimize maternal and fetal benefit, particularly in patients with critical COVID-19 in the early preterm period, continue to be a challenge for obstetricians. There is often uncertainty in clinical judgment about fetal monitoring, timing of delivery, and mode of delivery because of the challenge in balancing maternal and fetal interests in reducing morbidity and mortality. The obstetrician and critical care team should empower pregnant patients or their surrogate decision maker to make informed decisions in response to the team's clinical evaluation. A clinically grounded ethical framework, based on the concepts of the moral management of medical uncertainty, beneficence-based obligations, and preventive ethics, should guide the decision-making process.

Keywords: beneficence; critical COVID-19; ethics; fetal monitoring; maternal mortality; preterm period; SARS-CoV-2.

***Corresponding author: Moti Gulersen**, MD, MSc, Department of Obstetrics and Gynecology, Division of Maternal-Fetal Medicine, North Shore University Hospital, 300 Community Drive, Manhasset, NY 11030, USA, E-mail: mgulersen1@northwell.edu. https://orcid.org/0000-0002-1966-9578
Burton Rochelson, Department of Obstetrics and Gynecology, Division of Maternal-Fetal Medicine, North Shore University Hospital – Zucker School of Medicine at Hofstra/Northwell, Manhasset, NY, USA
Eran Bornstein, Laurence B. McCullough and Frank A. Chervenak, Department of Obstetrics and Gynecology, Lenox Hill Hospital – Zucker School of Medicine at Hofstra/Northwell, New York, NY, USA. https://orcid.org/0000-0002-2603-8272 (E. Bornstein)

Introduction

It has been over a year since the World Health Organization declared the outbreak of the novel coronavirus (severe acute respiratory distress syndrome coronavirus 2 [SARS-CoV-2]) a global pandemic [1]. Millions of confirmed infections and deaths from complications related to coronavirus disease 2019 (COVID-19) have been reported worldwide [2].

Despite the overwhelming number of cases, data regarding the optimal clinical guidance in pregnant patients is not uniform or well established. Although the majority of symptomatic patients recover, data from the Centers for Disease Control and Prevention have indicated that pregnant patients with COVID-19 are at increased risk for intensive care unit admission, invasive ventilation, extracorporeal membrane oxygenation, and death [3]. Furthermore, the majority of pregnant patients with COVID-19 who progress to critical illness and require delivery will undergo a cesarean birth, a procedure that is independently associated with maternal morbidity and mortality [4–6]. The postpartum course in infected patients is indeterminate and variable, and may depend on the severity of presenting symptoms and the timing and route of delivery [7].

Fetal monitoring may play an important role in assessing the well-being of the fetal patient and clinical decision-making about the timing of delivery, particularly in the periviable or early preterm period [8]. The obstetrician and critical care team should empower pregnant patients or their surrogate decision maker (when the patient lacks decision-making capacity) to make informed decisions about the use of fetal monitoring and the timing of delivery, in response to the team's clinical evaluation. This paper provides a clinically grounded ethical framework to guide this decision-making process.

Clinical considerations

A critically ill pregnant patient poses several challenges for the managing obstetrician and multidisciplinary team, as

any pathologic process that affects the pregnant patient has the potential to affect the fetal patient [9]. Determining the use of fetal monitoring and timing of delivery in the periviable period (i.e. 23 0/7 to 25 6/7 weeks) and decision-making on these issues become further complicated by conditions with an unpredictable disease course, such as in critical COVID-19 [4, 10–12].

The common first step is to determine the most accurate gestational age and likely viability of the fetus, as subsequent management strategies and interventions are often geared to optimize both maternal and fetal well-being in the setting of viability. Critical COVID-19 is predominantly associated with respiratory failure and multiorgan system dysfunction, which may also have profound implications for the fetal patient [4, 10]. Furthermore, disease progression may be associated with either rapid or protracted deterioration, or improvement [4, 10–12]. Clinical trials of therapeutic options have mostly included nonpregnant subjects, leaving obstetrical providers with limited guidance in determining optimal management strategies in the pregnant patient [13].

While maternal infection with SARS-CoV-2 itself is not an indication for delivery, delivery is a commonly explored, and often heavily debated, particularly in the early viable preterm period [12, 14]. The Society for Maternal-Fetal Medicine has suggested individualizing timing of delivery for critically ill patients with decisions based on maternal status, concurrent pulmonary disease, ability to wean off the ventilator and ventilator mechanics if intubated, and gestational age at time of delivery [14]. Shared decision-making with the patient or healthcare proxy is encouraged [14].

Maternal considerations, in the absence of proven definitive treatment, have centered on the hypothesis of whether an improvement in maternal lung mechanics is achieved with early delivery. Given that functional residual capacity and inspiratory and expiratory reserve volume can decrease in the third trimester due to uterine compression and elevation of the diaphragm, the risk of severe hypoxemia may be increased in critically ill pregnant patients [15]. However, it is unclear whether delivery and uterine decompression will improve respiratory status [11, 12, 14]. Data describing early delivery in patients with acute respiratory distress syndrome as a possible benefit are limited to small case series [16, 17].

Fetal considerations have focused on the impact of prolonged maternal hypoxemia, which may be significant, given the protracted clinical course of COVID-19, balanced against the risks associated with delivery at a given gestational age. The fetal risks associated with prematurity are well known and decrease with increasing gestational age at delivery [18]. Fetal assessment with electronic fetal monitoring and ultrasonography may be useful for evaluating fetal well-being. The primary, but not sole, value of fetal evaluation is to document an indication for delivery in order to optimize neonatal outcome. Therefore, fetal monitoring is most often considered only when delivery for fetal indication is an option. It is also unclear whether evidence of fetal distress from maternal hypoxemia may resolve with aggressive maternal care, or with spontaneous improvement in disease course, further complicating clinical decision-making. Comparisons with other critical care maternal conditions are imprecise and may contribute little, or faulty, guidance to forming reliable clinical judgment. For example, in treatable, but severe, metabolic abnormalities such as diabetic ketoacidosis (DKA), there may be very significant and concerning changes in the fetal heart rate [19–21]. However, with aggressive treatment of maternal DKA, the fetal heart rate tracing predictably improves in most cases, as the maternal metabolic disorder is corrected [20, 21]. There is far less certainty of improvement in the treatment course of critically ill pregnant patients with COVID-19.

Cesarean birth is the more common mode of delivery in this scenario and has its own implications, as maternal morbidity and mortality is increased in cesarean births and may alter the recovery in critically ill patients [5, 6]. Furthermore, worsening clinical status after delivery has been reported, which may have been a result of the COVID-19 disease trajectory or an exacerbation caused by physiologic immune changes in the immediate postpartum period [22–24]. There is some theoretical consideration that cytokine storm may, at times, be accelerated in the postpartum period [25].

Ethical considerations

There is often uncertainty in clinical judgment about the timing and mode of delivery because of the challenge in balancing maternal and fetal interests in reducing morbidity and mortality. Empowering pregnant patients or their surrogate decision makers begins with an explanation of this uncertainty and why it cannot be eliminated.

A step-wise approach to the moral management of medical uncertainty

Morreim has described the clinical ethical challenge that arises when uncertainty in clinical judgment cannot be eliminated: the moral management of medical uncertainty [26]. This means that there are clinical circumstances in which additional information does not reduce uncertainty or may even increase uncertainty. Professional ethics in

obstetrics provides the clinically applicable conceptual tools for morally managing the medical uncertainties of the timing of delivery for critically ill pregnant patients with COVID-19 [27].

The goal of the moral management of medical uncertainty is to responsibly reduce variation in clinical judgment and practice to a minimum, which may be accomplished by adopting a disciplined process of clinical judgment and medical decision-making. This process begins with an ethical analysis: achieving clarity regarding clinically relevant ethical concepts. The next steps are to identify general clinical rules and using these concepts to formulate clinical judgments. The output of these two steps is deliberative clinical judgment (Table 1) about fetal monitoring and the timing of cesarean delivery. Deliberative clinical judgment becomes the antidote to unmanaged uncertainty that only increases the preventable risk of uncontrolled variation in clinical judgment, recommendations based on it, and decision-making with pregnant patients [27].

Table 1: Key ethical concepts.

Ethical principle of beneficence in obstetrics	An ethical principle that creates the *prima facie* ethical obligation of the obstetrician to provide clinical management that in deliberative clinical judgment is predicted to result in net clinical benefit for the pregnant and fetal patient (when the fetus is a patient) and to the future neonatal patient and therefore protect and promote their health-related interests.
Medically reasonable clinical management	A form of clinical management that in deliberative clinical judgment is both technically feasible and supported in beneficence-based clinical judgment.
Deliberative clinical judgment	Clinical judgment that is evidence-based (an appeal to the best available, critically appraised evidence), rigorous (especially in the effort to identify and reduce the influence of bias), transparent (the physician can explain the judgment to other clinicians, especially team members and the patient), and accountable (to meet an essential component of patient safety and quality).
Ethical principle of respect for patient autonomy in obstetrics	An ethical principle that creates the *prima facie* ethical obligation to empower the pregnant patient to make informed and voluntary decisions about the management of her pregnancy by providing her with information about the medical reasonable alternatives for its clinical management.

McCullough LB, Coverdale JH, Chervenak FA. Professional Ethics in Obstetrics and Gynecology. New York and Cambridge: Cambridge University Press, 2020. Used with permission.

Clarity about the ethical concept of the fetus as a patient

The ethical concept of the fetus as a patient plays an essential role in to the moral management of medical uncertainty about the timing and mode of delivery, because this concept requires balancing of maternal and fetal interests in reducing mortality and morbidity. This concept comprises beneficence-based and autonomy-based ethical obligations to the pregnant patient and beneficence-based ethical obligations to the fetal and neonatal patient (Table 1). Beneficence-based ethical obligations to pregnant patients are *prima facie* limited, because they are ethically obligated to take only reasonable clinical risks to themselves for fetal and neonatal benefit [27].

The logic of beneficence-based ethical obligations to pregnant and fetal patients

The timing and mode of delivery in this patient population may create tension between beneficence-based ethical obligations to the pregnant patient and beneficence-based ethical obligations to the fetal patient, which becomes more pronounced as critical illness greatly accentuates the risk of maternal mortality. The intrinsic logic of beneficence is central to understanding this tension. Beneficence-based clinical judgment has a clear logic: as a rule, an increasing risk of mortality is more important to prevent than an increasing risk of morbidity and disability. This has two crucial implications: First, the reasonableness of maternal risk for fetal and neonatal benefit decreases as the risk of maternal mortality increases. This risk may be reduced by early delivery, which would increase the risks of morbidity and disability for the neonatal patient. Second, the burden of proof is on the merits of delaying delivery as maternal risk of mortality increases. Meeting this burden of proof, is not straightforward because of the multidimensional uncertainty described above.

There is a beneficence-based ethical obligation to pregnant and fetal patients to prevent clinical harm, especially serious, far-reaching, and irreversible harm. Serious harm occurs when one or more organ systems are injured or

cease to function and can be far-reaching when it goes beyond the biological to adversely impact many aspects of the patient's life. Irreversible means that the harm is permanent. Death obviously counts as serious, far-reaching, and irreversible. Injury to organs without the capacity to recover, even with intervention, also counts as serious, far-reaching, and irreversible, especially brain injury [27].

Beneficence-based judgment should be a function of the best available evidence, to maximize the predictive value of a prognosis of serious, far-reaching, and irreversible harm. When high quality evidence is unavailable resulting in uncertainty, physicians should not rely solely on their individual clinical judgment but consider deliberative clinical judgment from a team of colleagues involving critical care medicine, obstetrics, and neonatology. Critical care medicine colleagues have the relevant knowledge and experience base for prognostic judgments about harm to the pregnant patient, while obstetricians have the relevant experience to assess fetal harm, and neonatologists to assess neonatal harm.

There are several beneficence-based guidelines. Decreasing ability to adequately oxygenate the pregnant patient puts the fetal patient at risk of organ injury. The later the gestational age after viability (23–24 weeks of gestation), the less anticipated is fetal and neonatal harm from early delivery. Planned cesarean delivery is usually safer than emergency cesarean delivery.

Cesarean delivery in a critically ill pregnant patient has an increased risk of mortality and morbidity compared to cesarean delivery in a healthy pregnant patient. Beneficence requires that these risks be minimized. Thus, cesarean delivery should not be considered medically reasonable until it becomes ethically or medically obligatory for either maternal or fetal indications.

When beneficence-based ethical obligations to the pregnant and fetal patient are congruent [27, 28]

When maternal oxygen levels drop to the point that is predictive of maternal death or irreversible organ damage, and cesarean delivery is reliably expected to reverse this condition, cesarean delivery becomes ethically obligatory. Failure to perform cesarean delivery when this deliberative clinical judgment is justified increases risk of harm, including serious, far-reaching, and irreversible harm, to the fetal and neonatal patient. There is a beneficence-based ethical obligation to prevent this outcome.

The pregnant patient is ethically obligated to take only reasonable risk to herself for fetal and neonatal benefit. When the risk of harm to the fetal and neonatal patient increases, there is no benefit to be gained for the fetal and neonatal patient from delay of cesarean delivery. The risks of cesarean delivery for the pregnant patient are therefore reasonable.

This ethical reasoning shows that the beneficence-based ethical obligations to the pregnant, fetal, and neonatal patient are congruent in this example. It follows that cesarean delivery should be recommended.

When beneficence-based ethical obligations are not congruent [27, 28]

At times, the beneficence-based ethical obligations to the pregnant patient and the fetal and neonatal patient are not congruent. When fetal distress occurs secondary to refractory maternal hypoxia that would warrant consideration of cesarean delivery absent this complication, cesarean delivery becomes a medically reasonable option. As fetal distress worsens, there may be a beneficence-based ethical obligation to the fetal and neonatal patient to perform a cesarean delivery. Fetal distress can occur in the absence of maternal hypoxia. Cesarean delivery becomes medically reasonable (Table 1) when fetal distress is predictive of fetal and neonatal morbidity and mortality and becomes ethically obligatory when consensus judgment is that immediate cesarean delivery is required to prevent serious, far-reaching, and irreversible harm.

This is only one part of the two-part beneficence-based ethical reasoning required by the ethical concept of the fetus as a patient: beneficence-based ethical obligations to the pregnant patient must also be considered. In a critically ill pregnant patient, the risks of mortality and morbidity to the pregnant patient from cesarean delivery may increase. This puts the burden of proof on justifying cesarean delivery for fetal and neonatal benefit. This burden is not met when fetal distress is concerning but is not in deliberative clinical judgment considered to pose the risk of mortality or serious, far-reaching, and irreversible clinical harm. This is especially the case when fetal distress is intermittent. When fetal distress becomes persistent and worsens, that is the time to consider whether the burden of proof is met or if there is a strong trend toward it being met. When consensus deliberative clinical judgment is that cesarean delivery might increase the effectiveness of mechanical ventilation, the ability to meet the burden of proof strengthens. This line of reasoning is further strengthened if the pregnant is clinically stable.

Respect for patient autonomy becomes determinative when consensus judgment does not clearly support the conclusion that the burden of proof has been met. Shared

decision-making (offering but not recommending medically reasonable clinical management) should guide the decision-making process [27, 29]. The patient or the patient's surrogate is in the best position to decide if the risks to her from cesarean delivery for fetal and neonatal benefit are reasonable and worth taking. The informed consent process should be deployed to empower the pregnant patient or her surrogate with information about the consensus judgment of the team that the burden of proof has not been met and about the clinical reality that fetal distress can suddenly worsen, a clinical event that cesarean delivery can ameliorate. The patient or surrogate should be assured that the team will support whatever decision is made.

The role of preventive ethics

Two of us (FAC, LBM) have advocated for a preventive ethics approach as the optimal way to manage ethical challenges in obstetric practice [27, 30]. To a feasible extent, pregnant patients and their obstetricians should discuss intrapartum management in advance, so that the patient can become informed about obstetric clinical judgment (i.e. need for cesarean delivery) and assess this information on the basis of their values and beliefs.

From a preventive ethics perspective, the time to initiate decision-making about timing of delivery should be as soon as the diagnosis of severe or critical COVID-19 has been made. Pregnant patients should be informed that in some cases ethical obligations to them and the fetal patient may be congruent, in which case recommendations will be made. They should also be informed that in some cases ethical obligations to them and to the fetal patient may become incongruent. In this clinical circumstance the team will not be able to decide the level of risk the patient should be willing to take for herself for fetal and neonatal benefit. The pregnant patient will need to make this decision, in a process known as shared decision making, and draw on their values, beliefs, and social support, including their partner, family members, and religious or spiritual advisors if preferred. The patient should be supported during this process and communicate their judgements to their surrogate decision maker.

Advance directives are an important preventive ethics tool [27]. They have been in use for more than four decades and can be used by patients, in advance of lost capacity to participate in the informed consent process to communicate their decisions, to appoint someone who will act as their surrogate decision maker, and communicate decisions to this individual. The team should consult hospital policy for the form that an advance directive should take. The pertinent form is known as a Durable Power of Attorney for Health Care or Medical Power of Attorney. The patient should be informed that, by completing this advance directive, the patient can control who will make decisions for them and the information about their values, beliefs, and preferences that the surrogate decision maker will use. In the absence of a written Medical Power of Attorney the patient should be informed that applicable law will determine who will serve as their surrogate decision maker. For a married patient this will be their spouse. For an unmarried patient, this will typically be one of her parents. The patient may have other preferences, which should be documented in her advance directive.

Providing information about their values, beliefs, and preferences will enable the surrogate decision maker to fulfill the ethically and legally preferred standard of substituted judgment [27]: a decision made reliably on the basis of the patient's values, beliefs, and preferences. When this standard cannot be reliably fulfilled, the best interests standard [27] applies: a comprehensive, beneficence-based judgment about the timing of delivery. To enable the surrogate to fulfill this standard the obstetrician should explain the applicable deliberative clinical judgment options.

Conclusions

The professionally responsible management of medical uncertainty about fetal monitoring and mode of delivery for critically ill pregnant patients with COVID-19 is accomplished by deploying the concept of the moral management of medical uncertainty in clinical judgment and decision-making with the patient or the patient's surrogate.

The first component of this moral management is a team approach aimed at forming deliberative clinical judgment about the medically reasonable alternatives in the context of evolving medical science about this patient population. A team approach will responsibly manage idiosyncratic bias. The second component is identification of the beneficence-based ethical obligations to the pregnant and fetal patient, as required by the ethical concept of the fetus as a patient. When these beneficence-based ethical obligations are congruent, directive counseling for maternal and fetal benefit should be deployed in the form of recommendations about fetal monitoring and mode of delivery. When these ethical obligations are not congruent, shared decision-making should be deployed to empower the pregnant patient or her surrogate to make decisions based on her informed, considered values and beliefs, as required by the ethical concept of respect for patient autonomy.

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