



Pre-conception Counseling and Challenges Clinicians Face in Uncertain Times

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Introduction

Coronavirus Disease 2019 (COVID-19) has and continues to challenge the ideal healthcare model that focuses on maintaining quality care that meets patient's needs while preserving a clinical environment that keeps both healthcare personnel and patients' safe. In response, each clinical specialty had to outline the prioritization of patients' medical treatment based on multiple factors including: evaluation of their current resources, clinical workflow, and patient susceptibility to disease and local hospital or state regulations. It is safe to say that balancing these factors was not easy and furthermore, difficult to standardize within each specialty.

Research continues to evaluate how COVID-19 impacted different patient types, including pregnant patients and their newborns. While there have been multiple studies, there have been many limitations in producing conclusive evidence of vertical transmission, increased risk of premature birth or maternal complications secondary to COVID-19 [1]. However, the most recent meta-analysis of pregnancy and COVID-19 reported no evidence of increased maternal morbidity relative to non-pregnant populations [1].

Given that we do not have adequate evidence to understand the virus's effect on pregnancy and conception, guidelines for management of pregnant patients with suspected or confirmed COVID-19 were mainly created in reference to past guidelines for infectious disease outbreaks e.g. influenza pandemic [2]. Identifying disease status in pregnant patients has been challenging given that many COVID-19 patients were in fact, asymptomatic [3]. Therefore, universal screening of all pregnant patients was recommended in order to guide safety measures for newborns, mothers, and the hospital personnel [3].

As the medical world took on the challenge of reducing hospital visits and sharing limited resources, multiple professional societies continued to provide updated recommendations for their respective specialties e.g. American Society for Reproductive Medicine (ASRM). American College of Obstetricians and Gynecologists (ACOG) produced an outpatient algorithm to aid providers in evaluating pregnant patients at risk or with suspected COVID-19 [4]. In the fertility community, there was conflict between the universal definition of "medically urgent" and individual practices' prioritization criteria in the context of their local hospital regulations and patient needs.

Our primary aim is to produce recommendations specifically for fertility specialists and primary care providers in the realm of pre-conception counseling. Our second objective is to use these recommendations to prepare our clinical teams for future medical or non-medical emergency situations.

Infectious Disease and Pregnancy

There continues to be a lack of knowledge on how these large infectious disease outbreaks affect conception and early pregnancy, making it difficult to navigate recommendations during pre-conception counseling. Pregnant patients have historically been defined as "high risk" or "vulnerable" to infectious diseases such as H1N1, Zika, SARS-CoV-1, and MERS. For example, SARS-CoV-1 and MERS resulted in higher Case Fatality Rates (CFRs) amongst pregnant women relative to non-pregnant women. SARS-CoV-1 also resulted in reported cases of fetal growth restriction and miscarriages - serving a negative clinical impact on these patients [5]. Precautions at the time of SARS-CoV-1 were largely based on preventative guidelines, since data on pregnancy and SARS-CoV-1 was limited [6]. Therefore, most of the precautions that have been taken for past infectious disease outbreaks and the current COVID-19 are prophylactic guidelines rather than evidence-based recommendations.

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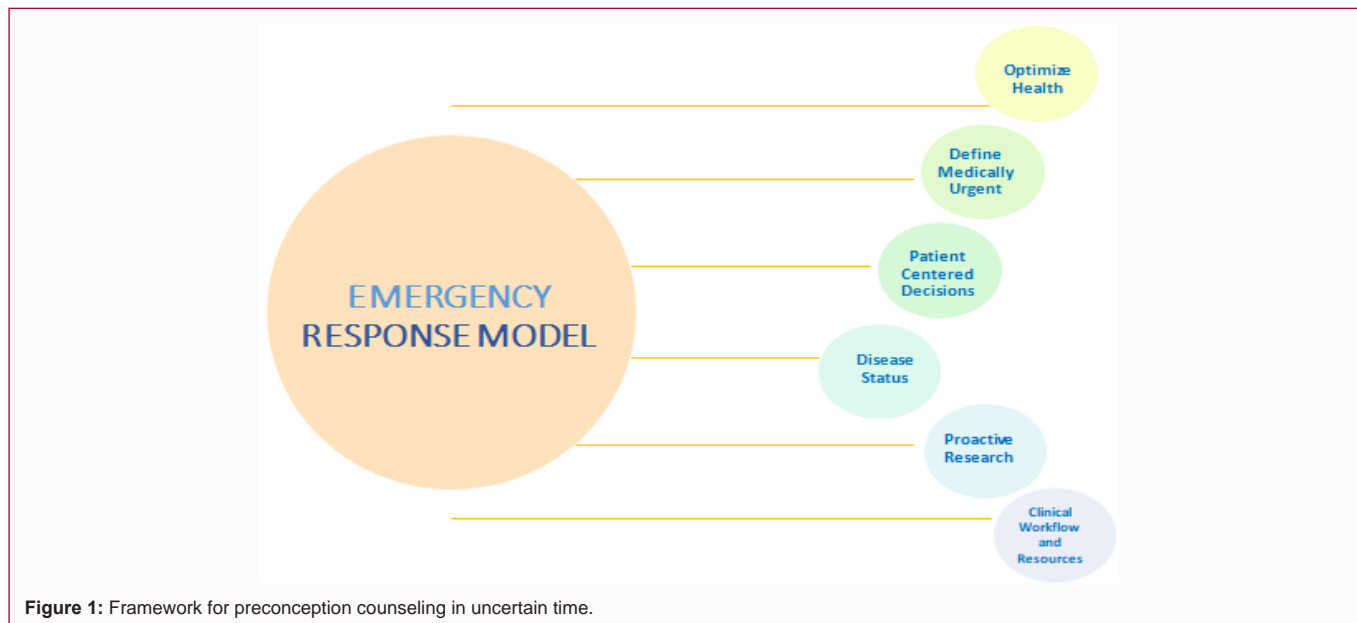


Figure 1: Framework for preconception counseling in uncertain time.

Furthermore, the unclear understanding of the immune system in pregnancy leaves a knowledge gap in how we can manipulate and fight these infections. Contrary to the common belief that a pregnant woman is “systemically immunosuppressed”, our current knowledge of hormone regulation and changes in innate and adaptive immunity throughout pregnancy define a rather “modulatory dysfunction of the immune system” in pregnancy [7].

Infertility-Uncertainty at Its Finest

Infertility is a medical disease that at baseline creates a constant feeling of uncertainty. Moreover, it is emotionally taxing, financially burdensome and physically exhausting. Many patients have been concerned about the effect of delaying their fertility treatment on chances of a successful pregnancy. Patient factors such as age, duration of infertility, and phase of treatment remain important in provider’s decisions to move forward with treatment during COVID-19. There is debate about the effect of delaying IVF treatment and its impact on pregnancy outcomes. Recently, a retrospective study reported that delaying IVF treatment up to six months in women with diminished ovarian reserve does not affect pregnancy outcomes; however this is not generalizable to all types of infertility patients [8]. Therefore, moving forward, we propose a comprehensive standardized framework that aids healthcare providers in developing a response that satisfies patient needs and maintains quality care in the time of uncertainty. The response itself cannot be standardized (Figure 1).

Optimize patient’s general health: Strengthen patient for future pregnancy

1. Mental health
2. Physical health e.g. working on diet, exercise, alcohol or drug use that may affect future pregnancy
3. Improve comorbidity management: e.g. diabetes, hypertension, anemia

Patient centered decision making

1. Understand patient goals and concerns
2. Educate patient on current knowledge about COVID-19 e.g. symptoms

3. Encourage shared decision making
4. Discuss financial burden
 - Restrictive insurance plan
 - Large investment in infertility treatment

Define criteria for “Medically Urgent”

1. Will the patient outcome change if treatment is delayed?
2. How much do patient goals and financial burden contribute to “urgency?”
3. Does provider definition of “medically urgent” comply with local safety regulations?
4. Integrate both hospital and regional mandates for safety regulations

Evaluate clinical workflow and available resources: Find a means to continue to see patients in a safe, convenient way

1. What clinical boundaries do we have through telemedicine?
2. What clinical benefits do we have through telemedicine?
3. Do we have enough resources for all of our patients?
4. Do we have resources for the near future? How can we prepare?
5. What extra lab precautions should we consider for oocytes, sperm, and embryos?

Proactive research: Better understand the impact of infectious disease outbreaks such as COVID-19 on conception and the first trimester of pregnancy

1. Aids in providing evidence-based guidelines and interventions
2. The ASPIRE (Attitude/Arrange Survey Piece Investigate Re-examine Reflect Relay Evaluate Examine Explore) Study is an excellent research model to reproduce at your own institution or contribute nationally to similar studies [9].

Disease status: Positive, negative, or at risk?

1. Factors to consider: Exposure to healthcare personnel, travel, group events, high risk comorbidities

2. If facility has enough testing, universally test your patients

End goal: Validate the preparedness model

1. Evidence based support for a standardized-personalized approach

Discussion

Providers must be cognizant that when a pandemic occurs, attention to local, regional and national healthcare center recommendations is of paramount importance. We must have a modus operandi that takes into consideration patient wants and needs. We must be attuned to the patient's perspective. If COVID-19 has done anything it is making us aware of alternative approaches to patient care such as telemedicine expansion; in addition, refocusing on delivery of care as the pregnant patient is given a home BP monitor and has her visits via telemedicine. The "hands on" aspect of medicine must always be preserved and the importance of communication between staff, providers and the healthcare system in general.

It is understood that viral entry appears to bind SARS-CoV-2 spikes which are glycoproteins to the host receptor. It appears that the host receptor Angiotensin-Converting Enzyme 2 (ACE 2) is involved in this process [10]. There is evidence that neonates of mothers effected by COVID-19 have IgM levels reflective of COVID-19 exposure and abnormal placental weights, thus implying an effect of transmission and maternal compartment affect [11,12]. With the above provisos the infrastructure is in place:

1. We are proposing a template of factors that each Infertility provider should consider in approaching unexpected circumstances such as COVID-19. It is our consideration of these factors that can be standardized and validated as an evidence-based approach to fertility counseling in an emergency.

Times are a changing' as the term goes, we provide a modus operandi for consideration in delivery of care to the infertility population.

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