COVID, Reproductive Health, and Public Policy:

Lessons Learned after Two Years of the Ongoing Pandemic

ASRM Center for Policy and Leadership ASRM COVID-19 Task Force

"Pandemics are a real possibility in the here and now; there is nothing future about them (1)" - Rand Corporation — 2012

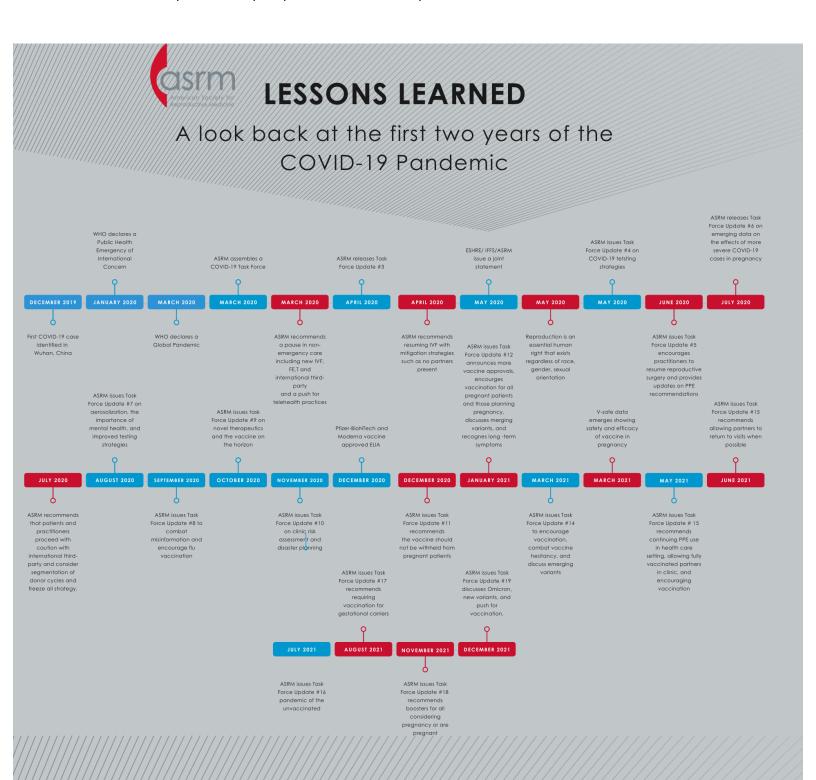
Background

The possibility of a global pandemic disrupting our way of life seemed remote in late 2019 when reports of an outbreak of the novel coronavirus, SARS CoV-2, began to emerge from China. Previous isolated clusters of viruses including Severe Acute Respiratory Syndrome (SARS), Middle East Respiratory Syndrome (MERS), and Ebola exhibited limited spread before ebbing out of the public consciousness.

What started as another seemingly isolated viral outbreak in China has impacted nearly all individuals in the world in one way or another. A unique set of considerations were present for those interested in conceiving during the viral outbreak. Individuals contemplating pregnancy faced uncertainty surrounding reproductive decision making and the provision of care. Concerns emerged regarding the potential effect of the virus on the chance of conception and the risk of adverse outcomes for individuals undergoing treatment to enhance the chance of pregnancy, those contemplating pregnancy, and throughout pregnancy, lactation, and the post-partum period. The absence of data regarding the effect of the virus on reproductive health coupled with the exclusion of pregnant patients from vaccine trials accentuated the hurdles faced by those considering pregnancy. In anticipation, the American Society for Reproductive Medicine (ASRM) rapidly assembled a COVID-19 Task Force early in the course of the pandemic. The purpose was to guide its members and those it serves on all aspects of reproduction and the provision of care in the face of emerging, and sometimes conflicting, data.

With uncertainty ahead, the Task Force recommended a pause on fertility treatment. The principal reasons for this recommendation were to help blunt the exponential spread of disease, redirect a declining cache of critical medical supplies, and mitigate risks to patients and staff while identifying effective protective measures. The experience highlights the importance of reproductive considerations not only during crises but also during times of stability.

Unfortunately, the COVID-19 pandemic is neither the first nor last of challenges that the world may face (2). To streamline future responses, it is essential to realize that reproduction is a human right that should be prioritized. Reproductive health should be considered early and often in the trajectory of emerging threats to public health. The recommendations detailed below from the experience of the ASRM COVID-19 Task Force over the past 2 years can be used as a template to prepare for future public health threats.



Assemble Your Team

In mid-March 2020, when reliable evidence that the novel coronavirus was becoming a true global pandemic, ASRM leadership mobilized a national COVID-19 Task Force. At the same time, ASRM reaffirmed the importance of reproduction, and disseminated the scientific facts related to the virus, vaccination, and reproduction.

The Task Force included a broad representation of key stakeholders. These included individuals with diverse expertise in all aspects of reproduction and the provision of fertility care, including reproductive endocrinology and infertility specialists, urologists, embryologists, reproductive surgeons, mental health experts, legal experts, ethicists, and both basic and clinical research scientists. Subject matter experts in infectious disease and epidemiology, as well as patient representatives were invited to join in these efforts. The composition of the Task Force reinforced the importance of including voices from a wide range of perspectives in face of the broad spectrum of challenges and uncertainties that emerged as the pandemic unfolded.

Quick and effective action, timely updates, and a focus on both science and patient care were considered paramount. Team members were apolitical in approach and generous in time investments as required, to remain responsive to the ever-changing landscape resulting from the novel coronavirus, SARS CoV-2. Over the course of the past two years, the Task Force met regularly, usually monthly plus whenever else was needed, and published revised recommendations on a regular and frequent basis. These updates were written by members with expertise on the topic and then ultimately approved by the Task Force in its entirety. They were made freely available on the ASRM website. When faced with conflicting viewpoints, the Task Force actively sought a wide variety of perspectives and carefully and thoroughly considered these as recommendations were developed. Dissent arose due to disagreement in prioritization coupled with scientific uncertainty. Consensus was ultimately reached through robust discussion with key stakeholders and consideration of all positions.

From its inception, the Task Force recognized the importance of collaborating with other societies such as The European Society for Human Reproduction and Embryology (ESHRE), the International Federation of Fertility Societies (IFFS), the Society for Maternal Fetal Medicine (SMFM), the American College of Obstetricians and Gynecologists (ACOG), the National Institutes of Health (NIH), the Centers for Disease Control (CDC) and the Federal Drug Administration (FDA).

It is highly probable that this pandemic will continue in various iterations, and that it will not be our last. The above description of the creation and work of a task force can serve as a model for other societies to aid in their development of a plan of action to ensure quick and efficient team representation in the face of a serious health pandemic. In light of the experience with the COVID-19 pandemic, it has become evident that medical societies are best served when their leadership is proactive in maintaining a pool of experts and stakeholders to function as a "first response" team that can be rapidly reconstituted as needed to combat future threats.

Science and Data Should Be Priorities

Central to the mission of the ASRM COVID-19 Task Force was recognition that scientific knowledge should be the primary driver of its work and recommendations. This data driven focus guided both current practice recommendations and suggestions for new or additional studies to direct future patient care and public health considerations. A bewildering onslaught of confusing non-scientific statements arose that presented unsubstantiated opinions broadly expressed on social media and elsewhere. This noise regarding the effects of COVID-19 on fertility was addressed by the Task Force with a prompt, direct, data-based, and consistent overview of the scientific information available at that time. Task Force guidance was independent of political or social agendas. Most important, a broad recognition of the ever-evolving nature of scientific information led to ongoing efforts to release frequent updates that reflected the current level of knowledge.

The unique role of a specialty medical society is to integrate emerging data to guide clinical care with expertise present in its members and bolstered by representative experts. A medical specialty society also has the resources that can provide critical data to guide care. Initially, knowledge gaps will exist. The ASRM, through its Task Force, identified where new information was needed, and guided the types of research studies required to direct future recommendations. Similarly, we recognize the importance of the Task Force to identify the knowledge gaps to better direct future clinical care. Transparency regarding what is known and unknown has been paramount, thereby building trust between the Task Force, ASRM's members, those it serves, and society at large.

Advocacy

Reproduction is a fundamental human right (2). This right merits protection at all times, and is particularly fragile during periods in human history when external factors risk to infringe upon it.

In the setting of pandemics and other public health crises, there may be a need to temporarily shift the balance of care away from individual patient care needs and towards care that safeguards the community at-large. Such a shift may impact the provision of infertility care and create tension between individual and societal needs (3). However, this acute necessity does not obviate the need to consider the time-sensitive nature of fertility care and work towards its resumption as expeditiously as possible once conditions permit.

In determining which procedures are urgent, it must be emphasized that fertility care is not elective. Delay in care often has dire consequences, particularly for patients with diminished ovarian reserve or those facing gonadotoxic therapy who require fertility preservation within a narrow time horizon. Access to evaluation and testing should similarly be considered time-sensitive, as the results help inform the level of urgency of fertility care.

In balancing societal with individual patient needs, access to care and utilization of resources must be considered early in the course of a crisis and revisited frequently. The ASRM COVID-19 Task Force fulfilled this role and continues to ensure that appropriate guidance is regularly shared with the physicians, clinics, patients, researchers, and government agencies (4).

An important role for the ASRM is advocacy. Advocacy can be broadly divided into several categories:

Advocacy for access to care. ASRM advocates for broad-based and global fertility coverage for all individuals and couples interested in family building. In times of crisis, the most vulnerable members of society are at risk of losing income sources and insurance coverage for fertility care. Special attention should be paid to the fragility of communities and groups for whom discrimination can limit access. Efforts to ensure access to care should be heightened during times of scarcity.

Advocacy for research funding. The critical nature of basic science and clinical research has been underscored during the current pandemic. Knowledge gained in the areas of placental biology, implantation, and virology has helped inform an understanding of the effects of COVID-19 infection on fertility, implantation, and early pregnancy.

Advocacy for inclusion in research. Unprecedented financial and academic resources were utilized in rapidly developing and distributing safe and effective vaccines against COVID-19 infection. However, the Common Rule which oversees human subjects research intentionally excludes pregnant patients and those contemplating pregnancy from most types of vaccine research (5). In the future, the safe inclusion of these groups in well-designed studies would help protect them by research and not disadvantage them by the misdirected desire to protect them from research (6).

Funding: Present and Future

Among the many lessons learned during the COVD-19 crisis is that there is simply no replacement for science-led, data driven, coordinated action. In the US the main public health agencies, the Centers for Disease Control and Prevention (CDC), the National Institutes of Health (NIH), and the Food and Drug Administration (FDA) all play key roles in this effort. The current pandemic has highlighted awareness of the important work of these institutions, and the fact that the funding required to support this critical work must begin well before the next as yet unforeseen pandemic arrives.

Government funding for basic and applied research must be robust and steady. Too often research studies do not reflect the diversity of the human population. Research of new drugs and vaccines has historically excluded women in general, and those who are pregnant in particular. It is inevitable that women will be exposed to new pathogens, including during pregnancy. It is vital that researchers seek to understand and study how new diseases and new drugs effect all susceptible subgroups of the population, every step of the way. Moreover, the impact of these treatments on the reproductive system must be considered and examined. Safe inclusion of reproductive aged and pregnant women in vaccine and drug development trials during a pandemic is critical for obtaining the knowledge needed to be able to provide preventative and therapeutic options. During a pandemic, society cannot afford to deny such inclusions. Understanding a vaccine or drug's impact on the reproductive system of both sexes cannot simply be an afterthought, it must be at the forefront of research efforts.

Be The Voice

The impact of ASRM's COVID-19 Task Force recommendations was amplified using different media including the society's website, news interviews, Op Eds, podcasts, webinars, and social platforms. Specialty societies should not be afraid to speak up on behalf of their members and those they serve. Societies should collaborate with one another when their members have complementary interests and needs. A unified voice among societies can be powerful, but individual societies should not hesitate to convey their own messaging in the face of differing opinions among societies serving unique patient groups.

The frequent release of Task Force recommendations and updates early in the pandemic reflected the rapidly emerging nature of the crisis. Updates were time stamped with expiration dates to reflect the current state of data and guidance and to alert members to the timing of new updates. Updates were affirmed when guidance remained relevant and new updates were created as data evolved.

The Society expanded its website to contain an easily accessible hub for COVID-19 information that included all task force recommendations, podcasts, webinars, and links to relevant literature. The society utilized a single point person to collaborate with trusted media sources, and society members were identified who were able to rapidly respond to media requests. Task Force members were encouraged to amplify ASRM's voice through social media. All messaging was transparent, data driven, and politically neutral.

Be Nimble

During any rapidly evolving novel situation what is known and unknown shifts over time. As a result, recommendations change as data are gathered. Setting an expectation early in the course of a pandemic that guidelines will change as knowledge is gained will build trust as expert advice evolves over time. As the virus mutates, strategies must be monitored, reassessed, and modified in an ongoing cycle. Such evolution in guidance has the potential to be frustrating, particularly to individuals who are unaware of the scientific premise behind the modifications. Valuable lessons can be learned that ultimately contribute to wider acceptance of rapidly evolving strategies and a decrease in hesitancy in the face of new vaccines and therapies. The organized group must be nimble, be humble, be transparent, be receptive to feedback, and be willing to continuously adapt recommendations as the data evolve.

Conclusion

Effective pandemic management requires a joint effort on the part of physicians, scientists, government agencies, subject area experts, and funders. Advance preparation in anticipation of a global health crisis should include appointment of a standing group of experts in their respective fields so that a response is both informed and immediate when a pandemic emerges. This approach will help ensure that the ultimate objective - preserving the safety and well-being patients and health care workers - is fulfilled.

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