ASRM PAGES

Reproductive and infertility care in times of public health crises: an Ethics Committee opinion

Ethics Committee of the American Society for Reproductive Medicine and American Society for Reproductive Medicine

Public health crises often require a framework shift in which patient autonomy is balanced with the need to safeguard the health of the community. During such crises, physicians should ensure that reproductive care is not unfairly curtailed. Furthermore, the safe inclusion of both individuals wishing to reproduce and pregnant individuals should be a priority such that relevant data can be generated to aid patients in making decisions regarding their fertility. (Fertil Steril® 2022; ■ : ■ - ■ . ©2022 by American Society for Reproductive Medicine.)



DIALOG: You can discuss this article with its authors and other readers at https://www.fertstertdialog.com/posts/34741

KEY POINTS

- Public health crises may require a framework shift in the approach to medical care which balances patient autonomy with the need to safeguard the health of the community. This shift may impact the provison of fertility care, and create tension between individual and societal needs.
- Inequities in distribution of reproductive and fertility care may be heightened during these times.
- Mitigation strategies to reduce these tensions include constant reassessment of public health conditions to determine when
 fertility care may be safely reinstated, recognition when the allocation of scarce resources is unjust, and advocacy for atrisk populations when conditions improve.
- When reinstatement of fertility care is permissible, employers have a responsibility to provide a safe workplace with adequate protections in place to safeguard healthcare providers and patients.
- The safe inclusion in research of women who are pregnant or attempting to conceive should be a priority in the face of emerging public health challenges with the goal of providing data to this patient population for informed decision making in the face of health care crises.

ublic health crises often require a reassessment of clinical priorities and resource allocation across all fields of medicine in the interest of maximize the health of the population. This sometimes conflicts with patient autonomy and may create tension between individual and societal needs. Although the coronavirus disease 2019 (COVID-19) pandemic has presented significant challenges for the field of reproductive medicine, many of the ethical considerations are not unique to the novel coronavirus. Previously, the Zika virus, H1N1 influenza

pandemic, and human immunodeficiency virus epidemic posed challenges for clinicians practicing reproductive and fertility care. Given the increasingly connected global world in which we live, future global public health threats are likely. This article describes an ethical decision-making framework that is necessary to provide reproductive and fertility care responsibly in times of public health crises. This article reviews the responsibilities and conflicts that providers may face while rationing scarce resources counseling patients in the setting of rapidly evolving information regarding emerging threats to fertility or pregnancy.

The traditional principles of biomedical ethics-autonomy, beneficence, nonmaleficence, and justice-were developed at the clinical and individual levels, and these guide clinician-patient relationships (1). Autonomy is often recognized as the most important of these principles in Western medicine because clinicians highly value an individual's right to self-determination, particularly in the context of reproductive rights. However, in the setting of pandemics and other public health crises, the balance of a clinician's duty of care must shift from focus on individual patients to a strategy that balances individual patient care with safeguarding the health of the population (2). This public

Received February 9, 2022; accepted February 9, 2022.
Reprint requests: American Society for Reproductive Medicine, 1209 Montgomery Highway, Birmingham, Alabama 35216-2809 (E-mail: asrm@asrm.org).

Fertility and Sterility® Vol. ■, No. ■, ■ 2022 0015-0282/\$36.00
Copyright ©2022 American Society for Reproductive Medicine, Published by Elsevier Inc. https://doi.org/10.1016/j.fertnstert.2022.02.011

VOL. ■ NO. ■ / ■ 2022

health ethics approach is critical for promoting the safety of a community and succeeds by focusing on maximizing justice and benefits in the society while still considering personal autonomy. This approach can, at times, be at odds with the traditional bioethical principles, which conventionally govern a clinician's decision-making process, and this can create tension for all health care workers, including those in reproductive medicine. The mitigation strategies to reduce these tensions include the constant reassessment of public health conditions to determine when and how to reinstate fertility care safely, recognizing when the allocation of scarce resources is unjust, and advocating for access to care for at-risk populations when fertility care can be safely provided.

RATIONING HEALTH DURING TIMES OF PUBLIC HEALTH CRISES

The tension between public health ethics and individual patient needs can be dramatic when rationing is required. Emerging viral pandemics, such as the COVID-19 pandemic, place extraordinary and sustained demands on public health and health systems and on the providers of essential community services, requiring the rationing of limited resources. This was seen almost immediately at the onset of the COVID-19 pandemic, with the near-immediate recognition that there were not enough high-filtration N-95 masks for US health care workers, prompting contingency guidance on how to reuse masks designed for a single use (3). This also quickly became the case for other forms of personal protective equipment (PPE), terminal cleaning supplies, and ventilators. In the setting of this extreme scarcity, medical services had to be curbed in all fields, including fertility and reproductive medicine.

Efforts to do this ethically focus on 4 fundamental values: maximizing benefits in situations of scarce resources, treating people equally, promoting and rewarding instrumental value, and giving priority to the most affected (4). In practice, this required temporarily halting some procedures and services to direct PPE toward frontline workers directly interacting with patients with COVID-19. Given that fertility care requires multiple in-person interactions involving multidisciplinary teams of health care professionals and staff, the American Society for Reproductive Medicine COVID-19 Task Force issued a recommendation at the beginning of the pandemic to suspend most fertility treatments, pointing, in part, toward the need to safeguard limited health resources (5). Although the decision to temporarily cease to offer critical reproductive services is difficult, the ramifications of not doing so in the setting of an emerging pandemic can be catastrophic. Mathematic modeling at the outset of the pandemic helped determine that in the setting of a multiplicative viral epidemic, the balance between individual and community rights may change such that acting against individual interests benefits the society as a whole (6). An examination of individual and systemic risks showed that "panic" at the individual level, in the form of strict self-isolation and other measures to curb the spread of the disease, is required to stave off societal collapse in situations in which the risk posed to any 1 individual is small, but the risks are common to all. Practically, this required taking steps such as closing fertility

centers to conserve PPE and decrease the spread of the disease. By temporarily forgoing offering treatment to curb the spread of the disease and decrease the use of resources for all but the most critical medical services, health care workers can ultimately help the society return to functioning at normalcy more quickly.

However, this shift from clinical ethics to public health ethics is difficult for providers and patients. At the core of this conflict is the sense that many patients and providers feel that reproductive medicine is at risk of being overlooked. The practitioners of reproductive medicine serve a unique population that has struggled for recognition within the medical community and society at large. Although infertility affects approximately 12% of reproductive-aged individuals in the United States, infertility was only recently acknowledged as a disease state, and comprehensive insurance coverage for fertility services is often lacking (7, 8). Furthermore, infertility is a progressive disease that requires timesensitive care for the highest chance of successful therapy. In particular, the cessation of elective surgeries was particularly problematic to many patients and clinicians who provide reproductive care. Although the use of the term "elective" in the framework of public health ethics refers to surgery that is not urgent or emergent and surgery that can be delayed for a period of time without undue risk to the patient, this term has historically been problematic in the context of reproductive medicine (5). In debates on abortion, the label "elective" is typically not used as a medical term to indicate the urgency of a procedure but rather as a moral term about the permissibility of a procedure. Similarly, in conversations about infertility treatments, particularly regarding insurance coverage for infertility treatments, the language elective is often used morally, not medically, to convey that such treatments are of low in priority.

STRATEGIES FOR MITIGATING THE EFFECTS OF RATIONING ON REPRODUCTIVE MEDICINE

Recognizing these specific needs of the reproductive medicine population is a critical step for mitigating the fallout effects of the rationing of services to this unique population. Reproduction is an essential human right that exists regardless of race, sex, or sexual orientation. Public health responses should strive to minimize health inequalities, resume fertility services when safe and feasible to do so, and protect assisted reproductive technology services against future disruption. The mitigation strategies include frequent reassessment of circumstances to determine when, for instance, viral transmission rates or equipment stockpiles may allow for the consideration of increasing the provision of infertility services.

At the basic level, within practices, plans for reoffering services must take into account local governmental guidance and ensure that adequate PPE and additional safeguards are available for employees so as not to cause the undue risk of increased transmission. Although pandemics require materials such as PPE, future crises, such as environmental catastrophes, may require other types of protections. Health care organizations are major employers, and responding to public health emergencies includes securing the safety of the health

care workforce. Therefore, it is also ethically acceptable for clinics to mandate vaccination against the disease for their employees. Reproductive health practitioners have an obligation to ensure that they are making decisions to maximize their ability to care for those who need help, which requires protecting their employees and teams, and to minimize exposure to risk for the patients they care for.

As a field, it is critical to recognize that public health requirements for the temporary cessation of infertility treatment creates several important inequalities in reproductive care and to try to address these when fertility services are restored. In contrast to fertile heterosexual couples, the impact of limiting reproductive services is more heavily borne by groups that require fertility care to procreate, including individuals who are unpartnered or in same-sex relationships. Furthermore, guidelines used to prioritize surgical cases emphasize morbidity and do not emphasize procedures that impact wellbeing, especially for women (9). The time-sensitive nature of fertility treatment makes assisted reproduction particularly vulnerable to delays in care, particularly for those at advanced reproductive ages, those with diminished ovarian reserve, and those undergoing gonadotoxic treatments.

Given that preexisting health disparities may widen during a crisis, health care providers should ensure that the strategies implemented to ration resources during such times do not further burden already vulnerable populations to the extent possible.

Distributive justice encompasses the concept that the burden and benefit of treatment should be distributed equally among all groups in the society and that medical decisions are fair. With respect to fairness, an ethical policy does not require that all persons be treated in an identical fashion but does require that differences in treatment be based on appropriate differences among individuals (10). Therefore, prioritizing the reduction of barriers to access to avoid exacerbating health disparities is reasonable. In practice, this could take the form of increased telemedicine visits to reach individuals in underserved areas and continued advocacy to expand insurance coverage for fertility services.

Finally, when public health conditions improve to allow the provision of fertility services, clinicians must consider when it is prudent to escalate care for patients, given the increased morbidity with significant delays in treatment. Recent studies have shown that even in women with decreased ovarian reserve, delays in starting treatment up to 6 months do not impact the overall treatment success (11). However, the effect of delays beyond that point is unknown. Furthermore, even in the absence of an effect on clinical outcomes, there is significant emotional impact associated with delays in care, and individual perceptions of treatment postponement are important. Many hospitals use the Centers for Medicare and Medicaid Services elective surgical tier system for the consideration of surgical cases that have a potential for future morbidity if untreated (tier 2a), even in times of limited resources (12). Women with advanced maternal age requiring oocyte retrieval or male patients with older female partners requiring reproductive urologic procedures may qualify for being considered for this tier and the escalation and prioritization of care.

CHALLENGES OF EVOLVING HEALTH THREATS WITH UNKNOWN CONSEQUENCES FOR REPRODUCTION

Another significant challenge that the providers of reproductive medicine face while grappling with novel public health crises is how to deal with threats that have unknown effects on reproductive function. Reproductive endocrinologists have an obligation to provide preconception counseling to ensure that patients have an opportunity to optimize their health before pregnancy (13). It is challenging for clinicians to counsel patients in the setting of new biothreats that pose unknown risks that are poorly understood (14, 15). In the absence of data, pregnant women and their clinicians often focuses on fears about the unknown risks of intervention during pregnancy (e.g., receiving a vaccine) rather than on a more balanced approach that also considers the risks of failing to intervene (16).

Importantly, despite the significant unease that clinicians may feel regarding the unknown reproductive risks of a new pathogen, respect for reproductive autonomy requires that the ethical bar be set quite high for physicians to decline to provide reproductive care. Given that reproductive autonomy is highly valued, the risks of a potential threat must be severe, well-understood, and unable to be mitigated (17).

Importantly, however, clinicians are entitled to feel that it is out of their scope of comfort to assist with reproductive treatment in the setting of public health threats that could have effects on future offspring. Although individuals have the right to make decisions about reproduction without interference from others, including public health governing bodies, they do not necessarily have the right to provide assistance with executing these. Given that the reproductive risks in the early stages of emerging pandemics and other public health crises are unclear, it is ethically acceptable for a clinician or clinics to decline assisted reproductive technology services because of concerns regarding the impact of the disease on pregnancy. For example, firsttrimester risks in patients with COVID-19 are not yet well understood (18). Should a clinician have a concern regarding assisting with the creation of pregnancies that could be at risk because of a pandemic, that individual is not obligated to provide assistance, similar to other cases in which the autonomy of the clinician conflicts with the wishes of the patient (19).

The safe inclusion in research of individuals who are pregnant or attempting to conceive should be a priority to inform decision making in the face of health care crises. Along those lines, robust long-term follow-up and data standardization are critical. Although the exclusion of pregnant women from initial COVID-19 vaccine trials was meant to prevent harm, this decision pushed the risk out of the carefully controlled environment of a clinical trial and into the real world. The practice of excluding pregnant women from clinical research has forced patients and providers to weigh the critical concerns with scant hard data about safety or effectiveness. A key tenet of autonomy is that it requires self-determination that is free from both controlling interferences by others and limitations preventing meaningful

VOL. ■ NO. ■ / ■ 2022

choices (including inadequate understanding). Therefore, the provision of information and data regarding the risks, benefits, safety, and efficacy of any particular therapy or vaccine in the pregnant population is critical to protecting an individual's reproductive autonomy. Although the intention is often to protect women from harm, by excluding pregnant women from the clinical trials of vaccines or treatments, women are denied the ability to exercise reproductive autonomy by not being provided with important information for making decisions. In the case of COVID-19, the difficulty with vaccine implementation in pregnant persons is attributable to delays in the development and conduct of studies of COVID-19 in this special population.

CONCLUSION

Public health challenges continue to task the field of reproductive medicine and will continue to do so for as long as we live in a global and interconnected world. It is critical in the setting of pandemic crises that clinicians balance actions that protect the good of the society as a whole with those that emphasize individual needs (e.g., delaying fertility care for a couple in which the woman has advanced maternal age). Furthermore, this potential curbing of reproductive services disproportionately targets already at-risk groups, including those in same-sex relationships, single parents, and those of advanced reproductive age. Consistently reevaluating the public health situation and advocating for access for patients when situations improve is critical for the mitigation of these inequities. Although public health threats require clinicians to provide incomplete information to patients in the setting of new diseases, care should be taken to avoid curbing the reproductive autonomy of patients. At the same time, a clinician who feels concerned about providing reproductive services in the face of the unknown effects of a pathogen is within their right to withhold treatment, so long as it is done in a just and fair manner and without a bias or discrimination. Finally, future research in times of public health crises must emphasize the safe inclusion of individuals who are pregnant or contemplating pregnancy. Failure to do so results in a dearth of scientific data for pregnant persons and those attempting to conceive, which extends to not just the lack of an understanding of the disease in this special population but also the lack of information about the safety and efficacy of potential treatments, vaccines, and other pandemic management strategies.

Acknowledgments: This report was developed under the direction of the ethics committee of the American Society for Reproductive Medicine as a service to its members and other practicing clinicians. Although this document reflects the appropriate management of a problem encountered in the practice of reproductive medicine, it is not intended to be the only approved standard of practice or dictate an exclusive course of treatment. Other plans of management may be appropriate, taking into account the needs of individual patients, available resources, and institutional or clinical practice limitations. The ethics committee and the board of directors of the American Society for

Reproductive Medicine have approved this report. This document was reviewed by American Society for Reproductive Medicine members, and their input was considered in the preparation of the final document. The following members of the American Society for Reproductive Medicine Ethics Committee participated in the development of this document: Sigal Klipstein, M.D., Kativa Shah Arora, M.D., M.B.E.; Ricardo Azziz, M.D., M.P.H., M.B.A.; Deborah Anderson-Bialis; Tolulope Bakare, M.D., M.P.H.; Katherine Cameron, M.D.; Susan Crockin, J.D.; Ruth Farrell, M.D.; Catherine Hammack-Aviran, M.A., J.D.; Elizabeth Ginsburg, M.D.; Mandy Katz-Jaffe, Ph.D.; Jennifer Kawwass, M.D.; Edward Martinez, M.H.A., M.S.; Joshua Morris, M.D.; Catherine Racowsky, Ph.D.; Robert Rebar, M.D.; Eli Reshef, M.D.; Mary Samplaski, M.D.; David Shalowitz, M.D.; Chevis N. Shannon, DrP.H., M.P.H., M.B.A.; Hugh Taylor, M.D.; Sean Tipton, M.A.; Lynn Westphal, M.D.; Julianne Zweifel, Ph.D. All the committee members disclosed commercial and financial relationships with the manufacturers or distributors of goods or services used to treat patients. The members of the committee who were found to have conflicts of interest based on the relationships disclosed did not participate in the discussion or development of this document.



DIALOG: You can discuss this article with its authors and other readers at https://www.fertstertdialog.com/posts/34741

REFERENCES

- Beauchamp T, Childress J. Principles of biomedical ethics: marking its fortieth anniversary. Am J Bioeth 2019;19:9–12.
- Berlinger N, Wynia M, Powell T, Hester M, Milliken A, Fabi R, et al. Ethical framework for health care institutions & guidelines for institutional ethics services responding to the coronavirus pandemic. Available at: https:// www.thehastingscenter.org/ethicalframeworkcovid19/. Accessed February 18, 2022.
- Centers for Disease Control. Strategies for optimizing the supply of N95 respirators. Available at: https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirators-strategy/index.html. Accessed February 18, 2022.
- Persad G, Wertheimer A, Emanuel EJ. Principles for allocation of scarce medical interventions. Lancet 2009;373:423–31.
- Centers for Medicaid & Medicare Services. Non-emergent, elective medical services, and treatment recommendations. Available at: https://www.cms. gov/files/document/cms-non-emergent-elective-medical-recommendations.pdf. Accessed February 18, 2022.
- Taleb NN, Norman J. Ethics of precaution individual and systemic risk. Available at: https://www.sri-online.org/UserFiles/1st%20Alert%20(2020)/Ethics_of_ Precaution_Individual_and_Syst1.pdf. Accessed February 9, 2022.
- Adashi EY. Infertility: a disease by any other name. JAMA Health Forum 2018;7. Available at: https://jamanetwork.com/channels/health-forum/ fullarticle/2760054. Accessed February 18, 2022.
- Zegers-Hochschild F, Adamson GD, Dyer S, Racowsky C, de Mouzon J, Sokol R, et al. The international glossary on infertility and fertility care. Hum Reprod 2017;32:1786–801.
- Gross MS, Harrington BJ, Sufrin CB, Faden RR. Rethinking "elective" procedures for women's reproduction during Covid-19. Hastings Cent Rep 2020; 50:40–3.
- 10. Institute of Medicine (US) Committee on Guidance for Establishing Standards of Care for Use in Disaster Situations; Altevogt BM, Stroud C, Hanson SL, Hanfling D, Gostin LO, editors. Guidance for establishing crisis standards of care for use in disaster situations: a letter report.

ARTICLE IN PRESS

Fertility and Sterility®

- Washington (DC): National Academies Press (US); 2009. Available at: https://www.ncbi.nlm.nih.gov/books/NBK219958/. Accessed February 18, 2022.
- Romanski PA, Bortoletto P, Rosenwaks Z, Schattman GL. Delay in IVF treatment up to 180 days does not affect pregnancy outcomes in women with diminished ovarian reserve. Hum Reprod 2020;35:1630–6.
- Centers for Medicare and Medicaid Services. Adult elective surgery and procedure recommendations. Available at: https://www.cms.gov/files/document/covid-elective-surgery-recommendations.pdf. Accessed February 18, 2022.
- American Society for Reproductive Medicine, American College of Obstetricians and Gynecologists' Committee on Gynecologic Practice. Prepregnancy counseling: committee opinion no. 762. Fertil Steril 2019;111:32–42.
- 14. Alford CE, Chen GL, Armstrong AY. 2009 H1N1 influenza prevention and treatment: counseling infertility patients. Fertil Steril 2010;94:1178–80.

- Dubaut JP, Agudelo Higuita NI, Quaas AM. Impact of Zika virus for infertility specialists: current literature, guidelines, and resources. J Assist Reprod Genet 2017;34:1237–50.
- American College of Obstetricians and Gynecologists. Committee opinion: no. 563: ethical issues in pandemic influenza planning concerning pregnant women. Obstet Gynecol 2013;121:1138–43.
- Rasmussen SA, Lyerly AD, Jamieson DJ. Delaying pregnancy during a public health crisis—examining public health recommendations for Covid-19 and beyond. N Engl J Med 2020;383:2097–9.
- Galang RR, Chang K, Strid P, Snead MC, Woodworth KR, House LD, et al. Severe coronavirus infections in pregnancy: a systematic review. Obstet Gynecol 2020;136:262–72.
- Ethics Committee of American Society for Reproductive Medicine. Childrearing ability and the provision of fertility services: a committee opinion. Fertil Steril 2013:100:50–3.

VOL. ■ NO. ■ / ■ 2022