Consensus Statement: Response to Consensus Guidelines for Facilities Performing Outpatient Procedures

American Association of Pro-life Obstetricians & Gynecologists

In receipt of a recent article entitled "Consensus Guidelines for Facilities Performing Outpatient Procedures, Evidence Over Ideology" authored by Barbara Levy MD, Debra Ness MS, and Steven Weinberger, MD, we wish to respond to its reception as high-quality medical evidence and its position that abortions should be provided without restrictions that apply to similar facilities performing similar procedures.

First, it is important to understand what level of evidence the article is and what level it portrays itself as, since these differ. Evidence-based medicine has been defined as "the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients."[1,2] Levy *et al* is an attempt to "develop evidence informed consensus guidelines to promote health care quality, safety, and accessibility,"[3] which will likely affect abortion access legislation. The authors admit that "very little research exists regarding outpatient facility factors."[4] Indeed, only *one peer-reviewed reference is cited*. Undaunted, the authors sought "verbal input from a diverse set of experts about relevant evidence to consider."[5] We must assume that the "relevant evidence" was the single systematic review cited. In evidence-based medicine, "verbal input" from experts is called expert opinion, and is usually considered the lowest level of evidence acceptable in practice, comparable in many guidelines to single rare case reports.[6]

The experts did not opine that there were" patient safety or quality-of-care problems related to the examined facility factors in offices or clinics that provide primary care and gynecology procedures" and that there is "insufficient research to find that particular

[1] Sacket et al., Evidence based medicine: what it is and what it isn't; BMJ Vol. 312, 13 Jan. 1996, pp. 71-72.

[2] Levy et al., Consensus Guidelines for Facilities Performing Outpatient Procedures, Evidence Over Ideology, Obstetrics & Gynecology, Vol 133, No. 2, pp. 255-260.

[3] Ibid p. 255.

[4] Ibid p. 257.

[5] Ibid.

[6] Burns PB, Rohrich RJ, Chung KC. The Levels of Evidence and their role in Evidence-Based Medicine. Plast Reconstr Surg. 2011 Jul; 128(1): 305–310.

facility factors have either a positive or negative effect on patient safety or experience (very little research has been conducted in these areas, and the findings from that limited research are not definitive)."[7]

We take no issue with provision of opinion, but the authors' claim that this article constitutes a higher level of evidence is dishonest. The authors call their work a "thorough review and analysis"[8] that will "provide an evidence-informed basis for evaluating legislation and regulations that use patient safety as a justification for restrictive and ideologically driven policies."[9] Astonishingly, this claim is made despite the earlier statement that there is insufficient research in this area to find that facility factors have either a positive or negative effect on patient safety, and despite the fact that the conclusion is based on one peer-reviewed article and expert opinion.

Second, it is important to respond to the validity of the expert opinion offered, which is problematic in several ways. The authors' objective is "to address only facility factors (those relating to physical environment or office and clinic operations)…not [to] delve into matters of clinical practice or scope of practice.… [or] to define which procedures may appropriately be performed in offices and clinics"[10] or to "articulate guidelines... for the provision of sedation and anesthesia."[11] This avoidance of clinical scope of practice, type of procedure performed and level of anesthesia is remarkable, considering the fact that these factors are the very factors that bear on the safety of outpatient procedures.

The authors conclude that "requiring facilities that perform office-based procedures, including abortion, to meet standards beyond those currently in effect for all general medical offices and clinics is unjustified...."[12] One reason they list is that "[o]ffering procedures in office and clinic settings has the potential to significantly improve patient care, access, affordability, and experience."[13] AAPLOG agrees that is certainly true with many types of medical procedures. It is also undeniably true that performing other procedures in an office or outpatient setting may ***increase*** the risk of the procedure to the patient. It all depends on the procedure.The authors' conclusions ignores the fact that abortion facilities are performing levels of procedures which are generally performed in an ambulatory surgery facility, but most abortion clinics do not meet ambulatory surgery facility requirements for level of procedure and level of anesthesia administered.

The safety considerations for patients involve both level of anesthesia and type of procedure undertaken. Skin biopsies and cervical biopsies involve very little risk. First trimester abortions, on the other hand, involve about a 1-2% risk of major com-

7 Ibid pp. 258-9.
8 Ibid p. 260.
9 Ibid.
10 Ibid p. 256.
11 Ibid p. 256-7.
12 Ibid p. 260.
13 Ibid p. 256.

plications,[14,15] including some for which laparoscopy is frequently indicated to rule out damage to nearby bowel, bladder and major blood vessels. Laparoscopy requires general anesthesia in an operating room. Most abortion clinics do not have this capability, as most abortion clinics do not comply with standard ambulatory surgery facility requirements.

Second and third trimester abortions involve even greater risk to the mother, as illustrated by the CDC review of abortion mortality,[16] in which the risk of death from abortion increases by 38% for each additional week of gestation. Especially risky are abortions done by dilation and extraction (D&E), in which the fetus is dismembered in utero prior to removal of the pieces of the fetal body. Both the instruments involved with the D&E as well as the fetal bones crushed during the dismemberment process involve significant risk to the mother from uterine perforation, which would require exploratory surgery in an operating room under general anesthesia. Most abortion clinics do not have this capability, as most abortion clinics do not comply with standard ambulatory surgery facility requirements.

Additionally, all abortions can be complicated by major bleeding, and the ability to manage hemorrhage is one of the requirements for ambulatory surgery facilities. But most abortion clinics do not meet ambulatory surgery facility requirements.

AAPLOG acknowledges that it may be difficult for the authors to quantify the risks of abortion, since accurate statistics on morbidity and maternal mortality from abortion are lacking in the United States. According to the Centers for Disease Control (CDC) Abortion Surveillance website, "states and areas voluntarily report data to CDC for inclusion in its annual Abortion Surveillance Report…. There is no national requirement for data submission or reporting." In its last report in 2018[17] on 2015 data, the states of California, Maryland and New Hampshire did not report their abortion numbers, when California is the most populous state. Abortion-related maternal deaths are tracked through the Pregnancy Mortality Surveillance System, vital statistics and newspaper articles and not through any central reporting. There is no central registry for reporting maternal complications from abortion.

Regardless of the availability of data, it is telling that the authors obscure the difference in risk between simple procedures such as a vulvar punch biopsy or directed cervical

[14] Niinimaki M, Pouta A, Bloigu A, Gissler M, Hemminki E, Suhonen S, Heikinheimo O. Immediate Complications After Medical Compared With Surgical Termination of Pregnancy Obstet. Gynecol 2009 114 (4) 795-804.

[15] JOINT STUDY OF THE ROYAL COLLEGE OF GENERAL PRACTITIONERS AND THE ROYAL COLLEGE OF OBSTETRICIANS AND GYNAECOLOGISTS Induced abortion operations and their early sequelae J RCOP April 1985.

[16] Bartlett L, Berg C, Shulman H, Zane S, Green C, Whitehead S, Atrash H. Risk Factors for Legal Induced Abortion-Related Mortality in the United States (Obstet Gynecol 2004; 103:729–37.

[17] Abortion Surveillance — United States, 2015. MMWR Surveill Summ 2018;67(No. SS-13).

biopsy at colposcopy, and invasive procedures such as first-trimester, second-trimester and third-trimester abortion, despite clear differences in levels of anesthesia needed, and clear differences in the risks of major complications including hemorrhage, perforation of the uterus, and risk to major pelvic organs. This obscuring of risks reveals that the major audience for this paper is the courtroom, not clinicians, and renders meaningless the conclusions of this paper. Without a serious long-term study of risk experience with ***specific*** procedures in various outpatient settings, no meaningful conclusions can possibly be reached. By failing to address safety issues inherent to individual procedures, the authors have invalidated their own claim that their research is of any use whatever in evaluating legislation that seeks to improve the health and safety of citizens.

Another issue related to abortion provision and restriction is appropriate follow-up after a medical or surgical procedure, which is a basic patient right. Any patient who has allowed a health care provider to perform any medical procedure on her body has a right to be seen and cared for by that same provider should complications arise. However, abortionists frequently do not care for the complications they create, but rather have office staff direct women with complications to go to the emergency room for care. Any physician who performs abortions, especially in the second or third trimester, should be required to have hospital admitting privileges or, at least, a transfer agreement with a designated gynecologist to provide such care based on the serious nature of these procedures and the gravity of the possible complications. Second- and third-trimester abortions are sufficiently complex that the American Board of Obstetrics and Gynecology (ABOG), with the support of the American College of Obstetricians and Gynecologists (ACOG), has proposed a new post-graduate fellowship in Complex Family Planning with a major focus on increasing the number of gynecologists who perform second and third-trimester abortions. If those procedures are sufficiently complex to require a two-year fellowship, surely patients who have undergone such procedures deserve to be evaluated and cared for by the very abortionist who performed that procedure and benefit from his or her advanced knowledge and not be simply abandoned to fine the nearest emergency room and left to the care of a generalist who likely has little or no experience in abortion care at these advanced stages.

In addition, the authors stated that, "requiring abortion providers have hospital admitting privileges may result in decreased service availability for women seeking abortion."[18] This statement is political, not medical, and designed to trigger "undue burden" considerations by the courts. But is any effect on abortion services the fault of appropriate restrictions? We opine that any decrease in abortion availability is the fault of abortionists who do not wish to be bothered with the obligations of hospital privileges and not on the legislators who pass laws to protect the safety of women undergoing abortion.

In short, women deserve medical services at an appropriate level, and physicians and lawmakers deserve honest papers that do not overstate their level of evidence.

[18] Ibid p. 257.