

Nancy F. Berglas, DrPH ■ Bonnie Scott Jones, JD ■ Sarah C. M. Roberts, DrPH

Background

State laws targeting abortion facilities for regulation are promoted as safeguarding women’s health. However, they are not supported by evidence of a patient safety problem or evidence showing that additional regulations would improve abortion patient safety.

As other procedures have transitioned from hospitals to outpatient settings, providers in varied medical specialties have faced questions of how best to ensure safety, and have witnessed a proliferation of facility standards.

This study examined how standards have been developed for procedures commonly performed in outpatient settings. It sought to identify lessons learned from the development of standards in less politicized areas of medicine.

Methods

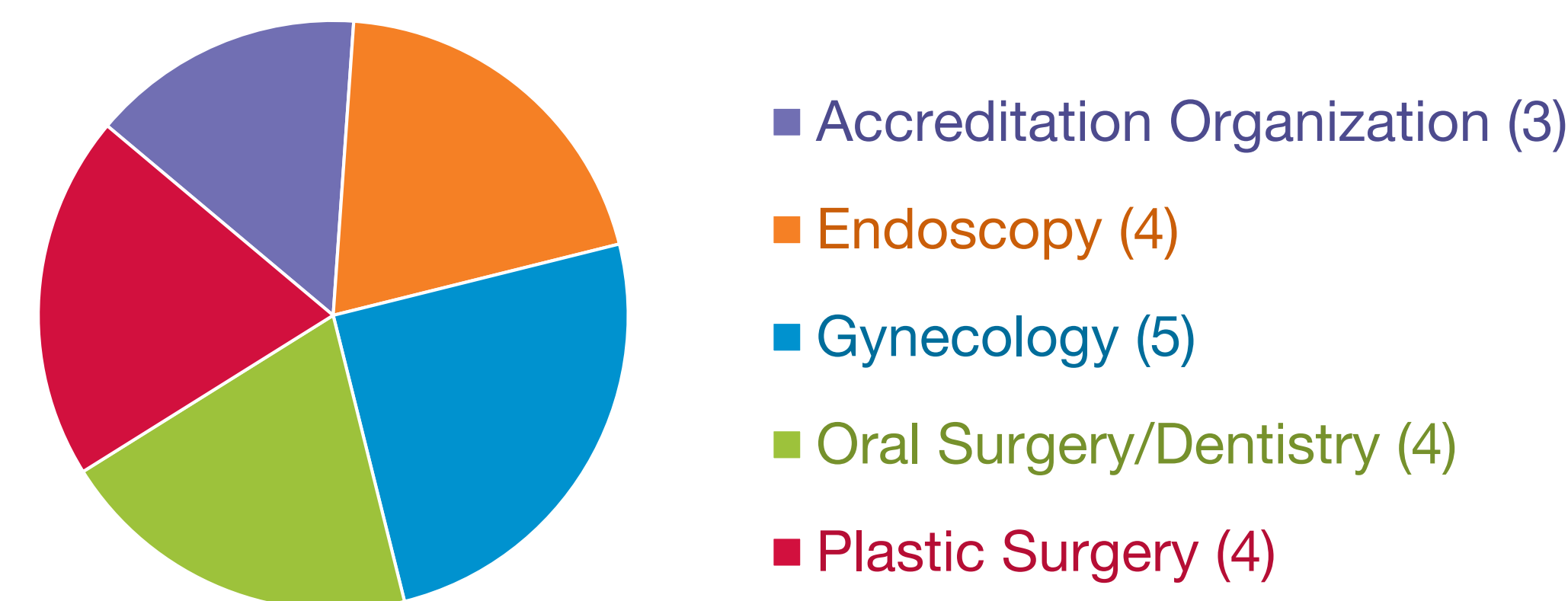
In-depth interviews (N=20) were conducted with experts involved in facility standards development across medical specialties about:

- Motivations for standards development
- Processes used to establish standards
- Types of evidence reviewed
- Decision-making in the absence of evidence

Data were analyzed using an iterative coding process and identification of thematic patterns.

Scope of Facility Standards (as defined by study)	
Domain	Example Facility Requirements
Physical plant requirements	Procedure and recovery rooms, instrument sterilization rooms, hall and/or door widths, emergency power, temperature/ventilation, NFPA compliance
Staffing requirements	Board certification, specific residency training, levels of nursing staff
Emergency response arrangements	Admitting privileges, transfer agreements with hospital or physicians, transfer plans
Other facility procedures	Infection control, disaster preparation, quality assurance

Respondent sample (N=20)



Results

■ Facility standards have been developed and implemented across medical specialties that provide procedures in outpatient settings. The push to develop standards is due in part to questions of how to ensure quality care when procedures transition out of hospitals.

■ Across specialties, the primary motivation voiced in favor of facility standards is protection of patient safety. While complications are rare for outpatient procedures, standards are often put into place to prevent and respond to uncommon events. A secondary motivation is addressing public concerns about the safety of procedures in outpatient settings. Standards are often initiated in response to adverse events that become public.

“It came about in the interest of patient care, promoting patient care, developing standards to try to ensure the highest level of care for the patient.” (plastic surgery)

“It’s not so much doing the procedure, which is pretty straightforward. It’s more what to do if things go wrong.” (gynecology)

■ Facility standards are typically developed by accreditation organizations or professional associations that bring together multidisciplinary experts to participate in a consensus process. Standards committees may seek input from other experts, review research evidence, incorporate public comment, and rely on their professional expertise.

■ These committees aim to ensure that facility standards reflect current practice, respond to the needs of practicing clinicians, and are not more burdensome than the procedure requires.

“That’s generally how we try to approach things: Be reasonable, keep a focus on the patient’s safety, and... study the data as much as we can.” (accreditation org.)

“There should be common sense in terms of the onerousness of the standards and the actual procedure being performed.” (endoscopy)

■ In concept, there is strong support for evidence-based facility standards. It is uncommon for committees to systematically review external research, which may reflect a lack of relevant studies on the impact of facility factors on patient outcomes. Some accreditation organizations review internal quality assurance data, including mandatory reports of adverse events and random case reviews.

“The trends in our journals, our meetings, and our presentations has very much shifted — and very consciously shifted — to much more methodical research design. Expert opinion is always important, but I think we’re recognizing the importance of objective parameters.” (plastic surgery)

■ New and different types of research are needed if facility standards for procedures in outpatient settings are to be more fully evidenced-based.

“Most evidence is not being collected to answer the questions that we want to deal with in consensus guidelines.” (endoscopy)

■ In the absence of research evidence, committees setting facility standards rely on their own clinical expertise and sense of best practices to establish appropriate and feasible facility standards.

“Where there is science, then we try to use the evidence available to use to justify the change. If there isn’t evidence, then it’s by consensus, based off people’s own clinical expertise.” (oral surgery/dentistry)

Conclusions

The processes used to develop facility standards across other medical specialties contrast with approaches that have been used for abortion in that: 1) professionals who provide the procedures play a central role in developing standards and 2) in the absence of clear research evidence, the expertise and needs of clinicians play a central role.

Given the larger trend of professional associations’ developing reasonable facility standards for procedures in outpatient settings, professionals who provide abortion care may want to consider defining reasonable facility standards as well.