INTERIM UPDATE

The American College of Obstetricians and Gynecologists
WOMEN'S HEALTH CARE PHYSICIANS

ACOG COMMITTEE OPINION

Number 792

(Replaces Committee Opinion Number 629, April 2015)

Committee on Patient Safety and Quality Improvement

INTERIM UPDATE: This Committee Opinion has been updated to reflect content oversight by the Committee on Patient Safety and Quality Improvement.

Clinical Guidelines and Standardization of Practice to Improve Outcomes

ABSTRACT: Protocols and checklists have been shown to reduce patient harm through improved standardization and communication. Implementation of protocols and guidelines often is delayed because of lack of health care provider awareness or difficult clinical algorithms in medical institutions. However, the use of checklists and protocols clearly has been demonstrated to improve outcomes and their use is strongly encouraged. Checklists and protocols should be incorporated into systems as a way to help practitioners provide the best evidence-based care to their patients.

Recommendations

The American College of Obstetricians and Gynecologists (the College) makes the following recommendations regarding clinical guidelines and standardization of practice to improve outcomes:

- Protocols and checklists should be recognized as guides to the management of a clinical situation or process of care that will apply to most patients. For any patient whose care cannot be managed by standardized protocols because of clinically valid reasons, the physician should document in the medical record why the protocol or checklist is not being followed.
- Obstetrician–gynecologists should be engaged in the process of developing guidelines and presenting data to help foster stakeholder buy-in and create consensus, thus improving adherence to guidelines and protocols.

Background

Protocols and checklists have been shown to reduce patient harm through improved standardization and communication (1–7). In the absence of evidenced-based medicine for a given clinical decision, development of these protocols sometimes may be challenging (8). However, the use of checklists and protocols has been clearly demonstrated to improve outcomes and their use is strongly encouraged (1). Refinement and sophistication of checklists have shown decreased morbidity and mortality (9). Factors other than patient safety and quality, such as cost containment and utilization, should not be the prime consideration for using these tools.

The College develops a variety of documents that can help in the standardization of the delivery of patient care. These include, among others, Practice Bulletins, Committee Opinions, and Patient Safety Checklists. It is important to note that there are barriers to putting the recommendations into practice. One such barrier is the physicians' lack of awareness of all guidelines and the difficulty in applying the guidelines to practice. For 78% of medical practice guidelines, more than 10% of physicians are not aware of their existence (10). Therefore, Fellows should be familiar with the College's practice recommendations and evidence-based guideline publications to make full use of them. The aforementioned College documents are regularly updated to ensure current relevance. Every practitioner should review new and existing College guidelines.

Standardization of practice is an important goal because of the wide variation that exists in many areas of practice within obstetrics and gynecology. There are two types of variation recognized in the field of process improvement: 1) necessary clinical variation is that which is dictated by, among others, differences such as a patient's age, ethnicity, weight, medical history, and desired outcomes of therapy and 2) unexplained clinical

variation is that which is not accounted for by any of these things. Variation in processes of care is problematic because it may lead to increased rates of error. Performing critical tasks the same way every time can reduce the kind of errors that all human beings are subject to, especially when fatigue is a factor and in stressful environments such as the labor and delivery suite or operating room. Elimination of variation in processes has been a cornerstone of improved performance and reliability over the past several decades in commercial aviation, military flight operations, and the nuclear energy industry. In health care, a similar level of success has been achieved in the field of anesthesia, where adverse events have been significantly reduced over the past 25 years through standardization of patient monitoring, dispensing of inhaled gases, and medication administration. In obstetrics, standardization of antenatal testing for group B streptococci, combined with standardized antibiotic prophylaxis, has resulted in a marked reduction in the incidence of neonatal group B streptococcal infection. Similarly, standardization of any process of care through the use of protocols and checklists can be expected to achieve a similar reduction in harmful events.

Protocols and checklists should be recognized as a guide to the management of a clinical situation or process of care that will apply to most patients. Randomized controlled trials alone are not necessary to provide evidence that one particular method of approaching a clinical situation is preferable to others before adopting a protocol or algorithm in a clinical setting. In fact, input based on multiple team members in an effort to achieve optimal results, using standardization, will often yield improved results. Further, unless one approach to care has been demonstrated to be superior to others through clinical trials, it may not be necessary to demonstrate the superiority of one specific approach over others that are likely to be equivalent. According to one study, "the adoption by the clinical care team of one appropriate specific management plan will, by virtue of standardization alone, yield results superior to those achieved by random application of several individually equivalent approaches. This is particularly true at the facility level" (11).

For any patient whose care cannot be managed by standardized protocols because of clinically valid reasons, the physician should document in the medical record why the protocol or checklist is not being followed. A practitioner should always be able to explain and document clearly the rationale for deviation from any recommended practice. As stated in the College's publication Quality and Safety in Women's Health Care, "once the protocol has been finalized, staff should be reminded that they may deviate from the protocol as long as the record reflects awareness of the protocol and documents the rationale and reasoning for not following it" (12).

It is imperative that obstetrician–gynecologists take the lead in designing and collaboratively implementing standardized protocols and checklists for their practices in the hospital and the office setting. If physicians are not actively engaged in defining the process, it may be imposed on them from external sources, such as governmental organizations and health insurance companies. If externally crafted, the process and requirements may or may not be evidence-based or appropriate. This illustrates why it is even more important that obstetric and gynecologic practitioners—the leaders in women's health—create and follow their own protocols instead of following orders from outside parties on how to practice medicine or being driven by payor incentives (13). For example, the College, in collaboration with other specialty societies, has strongly cautioned against legislative intrusion into clinical decision making (14). The motivation and intent for any protocol or checklist should be to ensure high quality, safe and, when possible, evidence-based practice. Although not driven by economics, standardization often will result in significant economic savings. When standardized care is used, quality increases, variation decreases, and cost decreases (8, 15–18).

The process to develop protocols must be collaborative, inclusive, and multidisciplinary, and should include hospital administration working with and supporting physicians, nurses, patient advocates, and other staff members. When checklists or protocols are developed at a national level, it is often advisable to adapt them to individual practice settings. Local practice conditions should be taken into account when these tools are introduced in any institution. It is important that physicians are informed whenever checklists or protocols are to be initiated. Encouraging input from physicians in the review and distribution of checklists and protocols will help foster buy-in from physicians for their use. Procedures should be in place for notifying and training all practitioners whenever the use of these tools is to be implemented.

Finally, there is some support for the concept that improved patient safety has a positive effect on liability. A study investigating California patient safety and medical liability data from 2001 to 2005 analyzed the relationship between changes in the frequency of potential adverse safety events and malpractice claims during that period. The study showed a highly significant correlation between the frequency of adverse events and malpractice claims. However, the study did recognize that a number of factors influence malpractice claims, including patient–provider communication and the liability climate. Therefore, it is hard to clearly demonstrate that guideline implementation is solely responsible for the relationship between improvement in safety outcomes and a decrease in liability. Nonetheless, the association is very important and improvement in patient safety increases the quality of care provided (19).

Conclusions

Obstetrician–gynecologists are committed to continuously improving safety in the care of their patients. Adverse outcomes often occur because of system deficiencies or inadequate safety measures that fail to prevent error from causing harm. Standardization is a process to be used to overcome system deficiencies, which with data analysis will decrease or prevent errors or reduce the likelihood of their recurrence. Standardization of practice to improve quality outcomes is an important tool in achieving the inspired shared vision of patients and their health care providers. The responsibility clearly focuses on innovative, empowered, and committed physician leadership. Obstetrician–gynecologists should be familiar with and able to implement the practice recommendations and evidence-based guidelines published by the College. Checklists and protocols should be incorporated into systems as a way to help practitioners provide the best evidence-based care to their patients. Continuous quality improvement depends on a disciplined and well-defined data-driven process that constantly is monitored and improved. The process ideally is led by obstetrician–gynecologists in collaboration with nurses (and other health care professionals) and patients to achieve the highest level of quality and safety in women's health care.

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