The migration of gynecologic procedures to office-based settings provides numerous advantages for patients and providers alike, including reduced patient expenses, improved scheduling convenience, favorable provider reimbursement, and enhanced continuity of care and patient satisfaction. With rising health care costs—a major concern in health care—procedures will continue to shift to practice environments that optimize care, quality, value, and efficiency. It is imperative that gynecologic offices ensure that performance and quality variations are minimized across different sites of care; physicians should strive to provide care to patients that optimizes safety and is at least equivalent to that delivered at traditional sites. The gynecologic community should nonetheless heed the Institute of Medicine’s recommendations and embrace continuous quality improvement. By exercising leadership, office-based gynecologists can forge a culture of competency, teamwork, communication, and performance measurement.
small-diameter hysteroscopic tissue morcellator. The migration of gynecologic procedures to office-based settings confers numerous advantages for patients and providers alike, including reduced patient expenses, improved scheduling convenience, favorable provider reimbursement, and enhanced continuity of care and patient satisfaction. With rising health care costs, a major concern in health care, procedures will continue to shift to practice environments that optimize care, quality, value, and efficiency.

On the other hand, the shift toward office-based procedures recently has raised important issues related to patient safety, outcomes, and quality of care. In 2000, the Institute of Medicine (IOM) in its report, To Err is Human: Building a Safer Health System, launched a patient-safety movement that pertained to hospitalized patients. But 12 years later, there are no reliable data on patient morbidity and mortality related to ambulatory care, although 52% of paid medical malpractice claims in 2009 were for events in the outpatient setting, and two-thirds of these claims involved major injury or death. A recent review of research on ambulatory safety between 2000 and 2010 found that major gaps persist in the understanding of ambulatory safety and virtually no credible studies have shown how to improve it.

Gynecologic offices are not subject to the same regulatory and accreditation standards as hospitals or ASCs. In the interest of patient safety and quality, hospitals have designated personnel for areas such as risk management, quality assurance, credentialing, education, data reporting, information technology, and case management. Office-based practices may not have these delineations and would thus lack the operational structure that affords the same accountability to patients. There may even be variation among gynecologic offices in staff training in quality initiatives, cardiopulmonary resuscitation, sterilization techniques, and postprocedure care. Consequently, the differences in external and internal regulatory scope may lead to inconsistencies in quality among offices, ASCs, and hospitals. It is imperative that gynecologic offices ensure that performance and quality variations are minimized across different sites of care; physicians should strive to provide care to patients that optimizes safety and is at least equivalent to that delivered at traditional sites.

Are Office-based Obstetrics and Gynecology Procedures Safe and Effective?

The Evidence

There are numerous studies to corroborate the safety and efficacy of office-based gynecologic procedures. A summary of findings from key studies can be seen in Table 1. One study by Hiddlebaugh and colleagues assessed hysteroscopies that were performed in office and hospital sites. Although office hysteroscopies were less likely to result in failure (7.2% failure at offices vs 3.1% at hospitals), there were no major complications in either group. Furthermore, a cost analysis revealed that hysteroscopy charges in the hospital setting were $1799, whereas they were only $62 when performed in an office setting.

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Continuous Quality Improvement in Office Obstetric and Gynecologic Procedures

A wide array of evidence suggests that medicine and surgery have enormous scope to continuously improve value. The IOM has called for a health system that is safe, effective, patient-centered, timely, efficient, and equitable. Obstetrician-gynecologists should strive for continuous improvement in the safety of office procedures.

<table>
<thead>
<tr>
<th>Study</th>
<th>Description</th>
<th>Conclusion</th>
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<tr>
<td>Hidlebaugh D (1996)</td>
<td>Compared outcomes and costs of hysteroscopy with dilation curettage at office and hospital settings; 473 office cases and 95 hospital cases were retrospectively analyzed</td>
<td>The completion failure rate for office and hospital hysteroscopies were 7.2% and 3.1%, respectively. No major complications were observed in either group, but minor complication rates for office hysteroscopy were 1.9% and for hospital hysteroscopy 4.2%. The mean charges, excluding professional fees (which were the same in both groups), for the hospital were $1799 vs $62 for office hysteroscopy. Office hysteroscopy had greater diagnostic accuracy.</td>
</tr>
<tr>
<td>van Kerkvoorde TC et al    (2012)</td>
<td>Retrospective cohort study evaluated 1028 office hysteroscopies that used a vaginoscopic approach; procedures were performed in a university-affiliated Canadian teaching hospital</td>
<td>Only one major complication was observed. Approximately 8% of procedures failed. On balance, there is an extremely low risk of long-term complications from office hysteroscopy with a vaginoscopic approach.</td>
</tr>
<tr>
<td>Mercier RJ, Zerden ML (2012)</td>
<td>Meta-analysis consisting of 23 randomized, controlled trials assessed intrauterine local anesthesia for pain control in office gynecological procedures</td>
<td>There is good evidence to support the use of intrauterine anesthesia in endometrial biopsy and curettage. There is moderate evidence to support such anesthesia in hysteroscopy. No evidence suggests that intrauterine anesthesia is effective in pain control during hysterosalpingography. There was insufficient evidence on whether intrauterine anesthesia is effective in first-trimester abortion, saline-infusion ultrasonogram, tubal sterilization, or intrauterine device insertion.</td>
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Intrauterine anesthesia improved pain control during endometrial biopsy and curettage. Even though the researchers reported two good-quality studies that showed intrauterine anesthesia to be ineffective in hysteroscopies, they also noted that there were three studies (one was a good caliber study whereas the other two were poor to fair in quality) that corroborated the use of such anesthesia. As a result, the authors consider intrauterine anesthesia to be reasonable and clinically appropriate for outpatient endometrial biopsy, curettage, and hysteroscopy. It should be noted that three well-performed studies in the review demonstrated intrauterine anesthesia to be ineffective at controlling pain during hysterosalpingography; there was not a single good-quality study to substantiate its effectiveness. Data also appeared to demonstrate insufficient evidence to justify the use of intrauterine anesthesia for the following procedures: first-trimester abortion, saline-infusion ultrasonogram, tubal sterilization, and intrauterine device insertion.
The American Congress of Obstetricians and Gynecologists (ACOG) has exercised leadership in promoting safety in office-based practice with its Presidential Task Force, which published its recommendations in 2010. Clinicians could reduce performance variation in office procedures by focusing on leadership, competency and assessment, teamwork and communication, measurement, anesthesia safety, quality, and “low-tech” solutions such as checklists and simulation learning (see Table 2).

**Leadership**

Leadership is critical to instilling a culture of patient safety and ensuring accountability in the establishment and achievement of quality improvement goals. Large hospital and health systems are able to outsource responsibilities to different risk management and quality-control departments. In solo and smaller group practices, the responsibility for care improvement will inevitably be assigned to the solo doctor or one of the practice’s physician partners. In larger group practices, responsibilities can be delegated to a separate position such as a medical director or another official within the organization. The practice’s quality improvement person(s) have multiple responsibilities including: (1) creating an ethos of safety, cooperation between clinicians and staff, and coordination; (2) ensuring the proper certification of clinicians and staff; (3) complying with best practices for patient safety; (4) monitoring of medical errors; (5) promoting learning through simulations and team exercises; and (6) fostering a non-threatening, learning environment that is conducive to identifying and eliminating medical errors.

**Competency and Assessment**

In order for obstetric and gynecologic procedures to be safe in office settings, practitioners need to minimize performance variation between hospital and office sites. As a result, the same expectations and standards that hospitals and ASCs must comply with should be extended to office practice. ACOG’s Presidential Task Force agrees and recommends a litmus test for procedures that are initially performed exclusively in inpatient settings. Such interventions could be performed at an office once the provider has shown competency in delivering the same procedure in an accredited operating room setting.

**Teamwork and Communication**

Office practices must recognize the importance of working in teams in order to promote safety and improve patient outcomes. Outpatient physician groups employ nurse practitioners, physician assistants, nurses, medical assistants, and office staff. Therefore, they need to be involved in quality-improvement activities. The multidisciplinary team’s clinician and staff members should engage in consensus building when establishing or evaluating safety principles and protocols. Hospitals have grand rounds, mortality and morbidity sessions, and other quality-improvement forums. Office medical groups should emulate these institutional practices. Although offices may not be as large as hospital settings, smaller-scale quality improvement forums in offices help forge a culture of patient safety and allow different parties to work together in communicating and achieving quality aims.

**Measurement**

Lapses in quality cannot be rectified unless they can be first identified and quantified. Therefore, it is critical for office practices to embrace a culture of measurement. A variety of measurement systems could be employed such as written logs, databases, and registries. The proliferation of electronic medical records among physicians and other providers could facilitate the development of enhanced information storage and gathering.

When measuring quality, practices should assess processes and outcomes. Processes are how different inputs (eg, clinicians, staff, equipment, operating rooms) are used in clinical practice. Outcomes are the results of those processes. Office practices should measure compliance with those safety processes that are relevant to each procedure that is performed. Possible processes that could be measured include “equipment malfunction, compliance with checklists, adequacy of anesthesia and post-operative analgesia, and maintenance of sterile technique.” Patient-oriented outcomes that should be constantly evaluated should be patient satisfaction and any intraoperative and postoperative complications that are specific
to the procedure that is performed. Patient satisfaction surveys could provide invaluable insights into how practices should improve.

Data that are accumulated from different measurement systems should be constantly reviewed by the leadership and appropriate office personnel. After reviewing the data, different stakeholder groups should establish improvement goals by consensus. A plan of action in order to achieve such targets should also be devised.\textsuperscript{13}

**Anesthesia and Sedation Safety**

Because a wide variety of procedures can be performed in the office (Table 3), anesthesia and sedation safety is another aspect that must be considered. Proper patient selection is key to achieving optimal patient outcomes. Appropriate anesthetics and sedatives should be selected depending on the nature of the procedure and the type of patient, and should reflect the patient's preference when different options are available. ACOG explicitly mentions certain patient populations that may not be appropriate for the office-based setting. Such groups include (but are not limited to) those with a personal or family history of adverse events during anesthesia and sedative administration, low pain threshold and/or previous failure to respond to anesthesia and sedation, respiratory disease, history of substance abuse, morbid obesity and/or severe airway risk, and abnormal blood sugars.

ACOG does not deem one particular type of anesthetic or sedative as "safe" for office settings. The organization believes "the level of anesthesia" or sedation achieved is most important when making determinations of patient safety. Office practices require certain personnel and equipment depending on the level of anesthesia or sedation administered. For office-based delivery of anesthesia, ACOG has endorsed the guidelines of the American Society of Anesthesiologists (ASA).\textsuperscript{14,15}

Offices that perform Level I anesthesia (mild sedation/anxiolysis) must have staff who are trained in Basic Life Support and are capable of immediately performing duties during emergencies. Level I practices should also have equipment and personnel capabilities that can readily respond to anaphylactic episodes and provide cardiorespiratory support. Appropriate staff and equipment must be on site until patients are discharged.

Level II offices that deliver moderate sedation/anesthesia should have at least two office personnel on site; one of them must be a licensed health care professional with Advanced Cardiac Life Support training. There must also be a physician in the office when patients are present. Similar to those offices deemed Level I, Level II offices need to have the necessary equipment and personnel for addressing anaphylactic and cardiorespiratory crises. Oxygen and suction should also be present in Level II offices.

### Low-Cost, Low-Tech Strategies

Low-cost, low-tech strategies could also be promoted in order to reduce performance variation in office-based obstetric and gynecologic procedures. Such strategies include the use of checklists and simulation learning. Checklists lessen reliance on human memory, ensuring that certain critical practices are consistently implemented. Checklists are prominent in aviation, nuclear power, and other high-risk industries. Medical literature recently confirmed that they are proven to be effective in slashing medical errors and complications in inpatient settings.\textsuperscript{16} Consequently, checklists should be adapted to

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**TABLE 3**

Sample CPT Codes for Commonly Performed Gynecologic Procedures in the Office-based Setting

<table>
<thead>
<tr>
<th>Procedure</th>
<th>CPT Code</th>
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<tbody>
<tr>
<td>Anesthesia for vaginal procedures (including biopsy of labia, vagina, cervix or endometrium); hysteroscopy and/or hysterosalpingography</td>
<td>00952</td>
</tr>
<tr>
<td>Anesthesia for intraperitoneal procedures in lower abdomen including laparoscopy; tubal ligation/transaction</td>
<td>00851</td>
</tr>
<tr>
<td>Hysteroscopy, diagnostic</td>
<td>58555</td>
</tr>
<tr>
<td>Hysteroscopy, surgical; with sampling (biopsy) of endometrium and/or polypectomy, with or without dilation and curettage</td>
<td>58558</td>
</tr>
<tr>
<td>Hysteroscopy, surgical; with endometrial ablation (eg, endometrial resection, electrosurgical ablation, thermoablation)</td>
<td>58563</td>
</tr>
<tr>
<td>Endometrial ablation, thermal, without hysteroscopic guidance</td>
<td>58353</td>
</tr>
<tr>
<td>Insertion of IUD</td>
<td>58300</td>
</tr>
<tr>
<td>Colposcopy of the cervix including upper/adjacent vagina; with loop electrode conization of the cervix</td>
<td>57461</td>
</tr>
<tr>
<td>Permanent implantable contraceptive intratubal occlusion device(s) and delivery system</td>
<td>A4264</td>
</tr>
</tbody>
</table>

office practice. A recent study from the Institute for Safety in Office-based Surgery presented at the ASA meeting in October 2012 demonstrated improved documentation of quality safety indicators and decreased complications in an office-based plastic surgical setting. The abstract discussion highlighted the importance of customizing the safety checklist and implementing it in a variety of office settings.17

ACOG suggests the same; checklists should be designed and maintained by the medical director and be specific to the procedure or class of procedures that are performed. Each class of procedures should be performed in accordance with preoperative, intraoperative, and postoperative checklists. Preoperative checklists are created to ensure appropriate patient selection for the office procedure. This system of screening should be used to consistently identify patients belonging to populations that ACOG considers to be ineligible for office procedures. Intraoperative checklists should be used to ensure that critical steps are not missed during the procedure. Intraoperative checklists must contain “documentation of the time-out, intraoperative medications, and alertness every 5 minutes if sedation is used.”18 Finally, postoperative checklists should “include documentation of vital signs, level of consciousness, pain control, and a discharge instruction sheet.”18

Simulation learning is another strategy to assist office-based clinicians and staff in minimizing performance variation.18 In addition to checklists, defense and other high-risk industries use simulations to train individuals for emergency situations. Similarly, office practices should use drills to prepare personnel for the most common medical and surgical emergencies such as anaphylaxis, airway compromise, and hemorrhage.19 ACOG recommends performing simulations every quarter. In order for simulations to effectively prepare the office team, offices must clearly delineate roles for the different members of the team. There should also be postsimulation feedback sessions in which team members are evaluated on how well they fulfilled their duties and communicated with one another. Feedback sessions could play video recordings of the simulation event in order for participants to see how they functioned. Participants should also make their own assessment of how they and other members performed.

**Safety Certification**

In order to disseminate best practices among gynecologic offices, ACOG has created a voluntary, two-step safety certification program known as the Safety Certification in Outpatient Practice Excellence (SCOPE). Office practices that exhibit features of continuous quality improvement as seen in Table 2 could qualify for SCOPE certification.

Applications are available for interested offices. Parties must provide documentation regarding medication, equipment, and procedural safety practices as well as evidence of performance measurement and quality improvement efforts.

Upon completion and approval of the application, offices receive a visit from a SCOPE site evaluator. Office inspections typically entail visual inspections, a review of patient charts, and interviews and demonstrations from office personnel.20 Offices that sufficiently meet SCOPE requirements will be awarded a 3-year certification. If a practice completes two consecutive 3-year certification cycles, the next certification would last for 5 years.21

**Graduate Medical Education Reforms**

In addition to practicing continuous quality improvement in office settings, gynecologists should call for reforms of graduate medical education. As medical technology advances to enable more procedures to be performed in outpatient settings, workforce training and education requirements will have to adjust. Graduate medical programs should incorporate office-based care into residency and fellowship curriculums. Large, integrated medical groups like Kaiser Permanente report deficiencies in office-based practice among clinicians who recently graduated from residency. In one survey of clinical department chiefs (this included obstetrics-gynecology chiefs), half of respondents reported at least one deficit in physicians’ ability to deliver office-based care.22 Furthermore, the most frequently reported shortcoming was in the category of technical and procedure skills.

Obstetrics-gynecology residencies should reform the training of apprentice doctors by requiring extensive clinical opportuni-

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**Obstetrics-gynecology residencies should reform the training of apprentice doctors by requiring extensive clinical opportunities in office procedures. This will aid in creating a workforce that is well-suited for the delivery of safe outpatient interventions in this burgeoning environment.**
There is no evidence to substantiate office-based gynecologic procedures being inherently unsafe. On the contrary, gynecologists can perform procedures in the office setting in a safe, effective, efficient, patient-centered fashion. The gynecologic community should nonetheless heed the IOM’s recommendations and embrace continuous quality improvement. By exercising leadership, office-based gynecologists can forge a culture of competency, teamwork, communication, and performance measurement. Adherence to anesthesia/sedation safety protocols and adoption of simulations and checklists can ensure that safety and quality targets are achieved. Offices that excel at these functions could seek SCOPE accreditation in order to certify that structure and process measures of quality are met. Finally, reforms of the obstetrics-gynecology graduate medical curriculum should be considered in order to produce a physician workforce that can reliably perform safe, effective outpatient procedures.

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12. Kunkel S, Rosenqvist U, Westerling R. The structure of quality systems is important to the process and outcome, an empirical study of 386 hospital departments in Sweden. BMC Health Serv Res. 2007;7:104.


