Primary Care Procedures in Women's Health

An International Guide for the Primary Care Setting

Cathryn B. Heath Sandra M. Sulik *Editors*

Second Edition



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In memory of my mom, who provided constant faithful support and encouragement; and to my family, Jeff, Maryann, Julie, Read, Tammy, Abbie, Joe, Lydia, and Lisa, who have always believed in me. Special thanks to Ferne for her photo help, to my nurses and my many patients who graciously allowed picture taking during their procedures. My thanks to Cathy for her friendship, support, and energy throughout this process. Thanks to all our contributing authors for sharing their expertise and wisdom.

SMS

Special thanks to my wonderful husband John and my dear friend Sandy. To my family, friends, new and old colleagues, staff, and patients: How lucky I am to be surrounded by such wonderful people! To Brendan, Austin, and Claire who have provided strength, encouragement, wisdom, and patience. Thank you to all who contributed their time writing and rewriting chapters and to our colleagues at Springer Nature for assisting us with this journey. CBH

Preface

Despite the common perception that medicine is becoming specialty driven, there are many reasons for primary care providers to offer women's health procedures in an office setting. Women feel more comfortable having procedures done by clinicians whom they already know and trust. Continuity of care is still valued by patients, who trust their primary care providers to work with them as collaborators in the decision-making process. Women have found that their options for care have become limited, not by their own decision but by the lack of training of their provider. In rural areas, the barriers of time, expense, and travel often prevent many women from obtaining necessary care; yet many of the procedures that these women are requesting are relatively easy to learn. Women who then refer friends and family by word of mouth share positive experiences.

This book is designed to assist not only the clinician performing the procedures covered, but also the office staff with setting up the equipment tray prior to performing the procedure and with preparing office documents and coding information needed to complete the procedure. Most procedures covered can be done with a minimum investment in equipment and require minimal training. Some of the procedures either require or are best performed after a training course; however, even in these cases, this book will serve as a solid aid and review to the practitioner in performing the procedures within the office setting. The book can be used as a quick reference guide to re-familiarize the practitioner with the steps to a given procedure.

The book begins with basic chapters that are applicable to all procedures. Each chapter thereafter outlines one women's health procedure and contains an overview of background information, indications, contraindications, complications, equipment needed, procedure steps, an office note, patient instructions, and a patient handout. Typical case studies and case study outcomes serve as illustrations of typical women found in practices who have needed each procedure. The "tricks and helpful hints" section draws on the years of experience of providers who have performed each procedure many times and have overcome common difficulties often encountered by newcomers to the procedure. A setup picture of equipment is included to assist office staff in gathering the appropriate materials prior to starting

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the procedure. Algorithms assisting the provider with the steps to take at decision points of each procedure are also included to serve as a quick guide. References and additional resources are provided for further education, learning, and equipment needs. Key words and questions for learners are available to spark a discussion related to a specific procedure while teaching the procedure. Illustrations, images, and photos further enrich the chapters.

We have elected to start our procedure book with the most common of procedures found in women's health – these include pelvic examinations and Pap smear collection – and its content extends to some of the more complicated office procedures, such as manual vacuum abortions and loop electrical excision procedure (LEEP). There are sections on basic women's health, contraceptive, diagnostic, and therapeutic procedures. A primary care physician (family physicians and a pediatrician) experienced with performing the procedure has written the chapter content. Also included are specific chapters on coding and billing, authored by a physician who oversees a large student health center. A separate chapter is included on the medico-legal aspects of performing women's health procedures in an office setting. This chapter outlines the necessary legal and regulatory considerations to address before adding many of these procedures to an office practice. We have also included a chapter on population health in this edition.

Many procedures have become a "lost art." For example, as fewer patients choose diaphragms as a method of contraception, fewer clinicians are trained in fitting and inserting them. A number of these common women's health procedures are not routinely taught in residency or training programs, and, hence, many practitioners do not offer them in their offices. Some are trained during residency but have not performed the procedure for some time and need a review prior to performing the procedure. This book will serve as a quick refresher for those procedures for which the clinician may have had previous training but may not have performed for a while.

The old standard of "see one, teach one, do one" gets more difficult as procedures become more complex and require more training before they can be performed. A number of excellent procedures courses are offered by the American Academy of Family Physicians, American College of Obstetrics and Gynecology, and the American Society of Colposcopy and Cervical Pathology. Suppliers of medical equipment also offer training courses. Often, a training package is offered as part of the purchase of more expensive pieces of equipment. Finding a local experienced physician to precept and mentor a less experienced clinician in the initial few procedures is another way to become skilled in performing most of these procedures after a training course has been taken. Proctoring or precepted experience is crucial, especially for complex procedures, not only to reduce medico-legal liability but also to ensure patient safety.

Having the patient schedule a separate appointment to have a procedure performed allows the patient time to read the information provided about the upcoming procedure, ask appropriate questions, and prepare herself for the actual procedure. This allows for the proper amount of time to be scheduled for the procedure to be done; for the inexperienced clinician, additional time should be scheduled.

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Scheduling new procedures at the end of an office session allows more time. As the practitioner's confidence grows, scheduling times can be adjusted. Scheduling an office session dedicated to just procedures can also be helpful.

A well-trained staff is the clinician's best asset. A lunchtime training session can be very helpful for teaching the staff proper sterilization of instruments, sterile and nonsterile equipment setup, and how best to assist with the procedure itself. Appropriate equipment setups can greatly ease the procedure. Proper Occupational Safety and Health Administration (OSHA) guidelines must also be followed. For most women's health procedures, it is wise to have an assistant in the room with the provider, to assist as well as to comfort and chaperone the patient. A written consent should be done prior to most procedures.

It is important to understand the appropriate billing of your services in order to be properly compensated for your work. Both CPT® codes developed by the American Medical Association and the ICD10 (International Classification of Diseases, 10th Revision, Center for Disease Control and Prevention) codes are provided as suggested codes for each procedure. There may be other more appropriate codes; therefore, each procedure should be coded based on the procedures done or services rendered. Some minor procedures, such as cervical polyp removal, do not have a specific CPT® code. In those circumstances, the CPT® manual recommends that the clinician code the appropriate-level office visit. As covered in our billing and coding chapter, certain insurance plans reimburse differently for some of the contraception devices, and insurance reimbursement varies across the county. It is important that the provider be aware of these differences as these procedures are offered to the patient in the office. Prior authorization is sometimes necessary as well. Some devices (levonorgestrel intrauterine system or etonorgestrel implantables) may need to be ordered through the patient's insurance company and delivered to the office before insertion.

It is our hope that this book will act as a manual for women's health procedures for all providers, including family physicians, gynecologists, general internists, residents, nurse practitioners, nurse midwives, and physician's assistants. There are presently no other texts specifically written for providers and staff of women's health services. It is our hope that this book will allow the clinician to become competent, efficient, and comfortable in performing each procedure in the office on a regular basis.

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Chapter 1 Introduction: The Case for Procedures in Primary Care



1

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Case Studies

Dr. Jerri Neilsen had a problem. She needed to do a procedure that she had never performed on anyone. There were no specialists available to do it. The nearest specialist was a continent away. What did she do? According to her first-hand account in *Ice Bound: A Doctor's Incredible Battle for Survival at the South Pole*, she received instructions by computer and by satellite telephone on how to do a Fine Needle Aspiration (FNA). She and her assistant, who was an emergency medical technician (EMT), practiced the aspiration technique on some fruit, and then they both did an FNA of a breast mass – on Dr. Jerri Neilsen [1].

One of the authors and editors of this book (CBH) was taking care of one of her patients in New Jersey, a state with more specialist physicians per capita than any state in the United States. A woman requested an intrauterine device (IUD) placement, a procedure that the author had not done in several years. She told the patient that she had not done this procedure in quite some time and offered to send her to another physician. The patient's response was that she preferred her own primary care physician do the procedure, and the patient suggested that the author "just read the book and then go ahead." The procedure was successful and was the first of many IUD placements within this physician's practice in New Jersey.

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A patient came in to see one of the other authors and editors of this book (SMS) with symptoms of pressure in her vagina which worsened upon standing. With many health problems, the patient was considered at high risk for major morbidity and mortality from surgery. She came to the author's office for a pessary fitting, as there were few physicians in town who fit pessaries. SMS successfully treated the woman's symptoms with a pessary, which avoided major surgery and relieved her urinary incontinence. The grateful woman used the pessary successfully for many years.

Location of Practice

These cases exemplify the necessity for women's health procedures being done by primary care physicians such as family physicians, internists, pediatricians, and obstetricians/gynecologists and by primary care practitioners such as midwives, advanced nurse practitioners, and physician's assistants. Although obviously an extreme case, Dr. Neilsen's case typified a situation in which a woman has difficulty finding a physician to do a basic procedure, a concern common with many women who reside in rural areas. Currently, a significant healthcare disparity exists for women who reside in rural areas. Over 20% of the population of the United States resides in rural areas with rates as low as 26.5 primary care providers/100,000 patients in Mississippi and the rates in Georgia and Texas being only slightly higher (31/100,000 and 33.61/100,000, respectively) [2]. Primary care providers in this study included physicians, physician assistants, and advanced practice nurses.

The scope of practice of rural physicians has by necessity been broad, although the rate of surgical procedures reported by rural physicians in Canada was similar to those who practice in a more urban setting [3]. In a study of Canadian physicians, younger male physicians were more likely than middle-aged to older physicians to do procedures, except for women's health procedures, which were more likely to be done by women physicians [4]. In a survey of Wisconsin family physicians, Eliason and colleagues noted that 40% of family physicians reported doing skin surgery, flexible sigmoidoscopy, breast cyst aspiration, joint arthrocentesis, and Norplant® (Population Council, New York, NY, and Washington, DC) insertion. Female physicians performed more women's health procedures than other procedures in any setting [4].

In many instances, access to a specialist for routine procedures is difficult, and, thus, many generalist providers are doing procedures that in more suburban and urban regions are considered reserved for specialists. In a study of colonoscopy in rural communities, family physicians performed colonoscopies on patients with symptoms as well as on patients for screening. Family physicians successfully reached the cecum in 96% of the cases, with an average time of 15.9 min, finding neoplastic polyps in 22% of the patients and cancer in 2.5% of the patients [5].

Continuity of Care: "The Medical Home"

Patients prefer seeing the same provider and consider seeing the same provider every time they have a health problem as very important [6]. Patients prefer, in many cases, to have procedures done by a practitioner whom they know and trust. For instance, in a study conducted at an inner city clinic, 70% of patients thought it appropriate for their family physicians to do medical abortions. Forty-seven percent thought it appropriate for their family physicians to do first-trimester surgical abortions. Of the women who would personally consider an abortion, 73% preferred to have it done by their family physician, 22% preferred to go to a freestanding abortion clinic, and 5% had no preference [7]. In a survey done by the Kaiser Family Foundation, 54% of obstetricians/gynecologists stated that they would be very or somewhat likely to prescribe mifepristone for medication abortions. Fifty percent of family physicians, nurse practitioners, and physician's assistants reported interest in prescribing mifepristone. At the time of the survey, only 5% of family physicians currently performed surgical abortions [8].

In 2017, the rate of clinical procedures performed by family physicians at their practice revealed that 31% performed endometrial sampling, 74% performed skin procedures including biopsy and cryotherapy, and 12% performed colposcopy, among a variety of other procedures [9].

Many patients expect their generalist providers to perform common procedures, especially those done in an outpatient setting. Most patients appreciate continuity and find that receiving care (including procedures) from one provider improved the physician–patient relationship [10].

Procedure Training

A number of procedures have become a lost art, making it difficult for patients to access providers who feel comfortable performing these procedures. Physicians in the past have relied on learning procedures in medical school or residency; yet newer, more advanced procedures can only be offered in a postgraduate setting for most practicing physicians.

In medical school, family medicine clerkships provide some basis for learning common women's health procedures, such as obtaining a Pap smear. In a procedure knowledge survey, Pap smear was the only women's health procedure that students felt competent of being able to perform independently [11]. In Canada, 91% of physicians reported learning procedures in medical school or in a family medicine residency, whereas only 12.6% learned procedures in clinical practice settings, followed by 6.4% who reported learning procedures in formal skills training. Those in rural practice learned a relatively greater proportion of procedural skills through formal skills training [12].

While the general guidelines for women's health procedure skills within a family medicine residency [13] have mandatory procedures (endometrial biopsy, Pap smears, wet mount, and KOH prep), some less common procedures are no longer considered mandatory but are "recommended" (breast cyst aspiration, diaphragm fitting, IUD insertion and removal). Bartholin cyst or abscess treatment and colposcopy are considered "elective." There are some significant barriers to teaching and performing office-based procedures, which need to be overcome by residency practices, including assuring adequate volume to be able to teach the procedure, that the appropriate faculty are available, and that there is enough given time in the schedule to be able to perform the procedure [14].

The American Board of Internal Medicine requires as part of its core competency that all internal medicine residents perform Pap smears and endocervical cultures safely and competently [15].

Lack of experience may subvert the physician's confidence about incorporating procedures into his/her office setting. Sempowski and colleagues did a cross-sectional survey of Canadian family physicians' provision of minor office procedures and found that of the 108 family physicians and general practitioners in Kingston, Ontario, only 35.4% reported performing endometrial biopsies. The most common reason for not performing a specific procedure was the "lack of up-to-date skills" [16].

Insurance Coverage

The good news is that many insurance plans across the United States are covering contraceptive procedures more commonly than ever before. Due to the Patient Protection and Affordable Care Act, the United States now mandates that insurances cover the cost of preventive care and contraceptives. However, there are still many women who do not currently have healthcare coverage.

Conclusion

Whatever the rationale, women's health procedures are in demand, especially in a primary care setting, and are rewarding for both physician and patient alike. No matter where the location of the practice or what type of patient or provider may be involved, generalist providers can offer these procedures as part of their daily practice. All of these procedures are easy to learn, most require minimal equipment, and they offer services that improve women's health and the range of options for the care that all patients wish to receive from their provider.

Ouestions

- What are the advantages and disadvantages to primary care providers learning procedures?
- Which procedures are the easiest and hardest to implement within an office setting?
- What are some of the potential barriers to providing outpatient women's health procedures?

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Chapter 2 Coding, Billing, and Reimbursement for Procedures



Cathryn B. Heath

Introduction

Coding, billing, and reimbursement are an integral part of the procedures performed in today's modern medical office. Gone are the days when one could learn a procedure and then just expect payment for services rendered. Performing the actual procedure is only part of the process. At times, billing and coding can be even more complicated and time-consuming than actually performing the procedure itself. Appropriate billing with concomitant reimbursement is very satisfying and can gradually change the emphasis and tenor of a clinician's practice. It is crucial that, prior to instituting a new office procedure, the clinician and the billing staff review the proper billing and coding to ensure that payment will occur.

Procedure Coding

As seen in the various procedure chapters in this book, included within each chapter are appropriate codes that must be compatible with the procedures discussed and shown. If a clinician is seeing a patient for diagnoses other than just the procedure, each diagnosis and procedure needs to be coded separately. For instance, if a patient is being seen for a gynecologic exam and requests that her intrauterine device (IUD) be removed, the clinician would code the appropriate health maintenance code for the exam, use a -25 modifier, and then code for the IUD removal [1]. If the patient

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prefers to return another day for the IUD removal, one would only code for the actual procedure on the IUD removal visit.

Many procedures have global codes. Thus, if a procedure such as a Bartholin's gland excision requires a second visit for a recheck, the recheck is considered part of the original global procedure code and would not be billed as a second office visit. Similarly, if there are sutures being removed for a procedure done in the office, the suture removal should be covered in the global fee. There are some exceptions to the rule: for example, one can bill separately for a visit to review and discuss treatment options of colposcopy pathology.

Coding compatibility with the procedure is essential to ensure payment. Medicare's website (http://www.cms.gov) is an excellent place to start [2]. Healthcare Common Procedure Coding System ("HCPCS") has two levels. Level I coding is used to code for the procedure itself, associated with the appropriate ICD-10 code. There are stipulations for which ICD-10 (International Classification of Diseases, 10th Revision, Centers for Disease Control and Prevention) codes will be covered by private payers and CMS for a specific procedure. Level II HCPCS allows for coding for products and supplies.

It is imperative to have someone in your financial office who is prepared to review rejected claims, particularly for procedures, and who can pursue the reasons for rejection. As billing improves, rejected claims decrease in number. Coding also can be improved and facilitated by using specific coding software, websites, or standardized forms, some of which may even be accessed by either an electronic medical record or a handheld electronic device. There are many coding and billing software packages available in the market that will help promote effective coding.

Documentation of Procedures

All procedures need appropriate notes written by the clinician. Size and location of excised lesions should be documented, as reimbursement is determined by size, location, number of lesions removed, and the pathology of the lesion (benign versus malignant). Billing should be submitted based not only on the size of the lesion but also on the size of the margins. For instance, if a 1 cm lesion is removed using a margin of 0.2 cm on each side, the size would be considered 1.4 cm [3]. Follow-up should be clearly stated in order to document whether a subsequent visit should be considered part of the procedure.

Coding and billing for skin procedures is further complicated by the specific pathologic diagnosis of the lesion itself. For instance, coding for removal of a benign versus malignant lesion may be difficult until the biopsy results have returned to the office, which may be anywhere from 10 to 14 days after the date the actual procedure is performed. However, removal of a malignancy is generally reimbursed at an average of two to three times the amount of the removal of a benign lesion. Thus, in some instances in which the CPT® (AMA, Chicago, IL) code may be dra-

matically changed by the pathology results, it may be advisable to hold billing the particular procedure until the pathology report returns and is reviewed.

One can also attempt to bill for an unsuccessful procedure, though the likelihood of being reimbursed is much less [4]. Coding needs to be specific; for instance, if a procedure fails due to anatomic reasons, a -52 code is used as a failed procedure. If the procedure fails due to concern over a patient's well-being, as she has had severe pain or vasovagal symptom, it is considered a discontinued procedure and is coded as a -53. The payer will need to know the extent of what was done; attaching a copy of the office note to the claim will usually suffice. Some insurances do pay for an attempted procedure, while others do not.

Insurance Company Coverage

Medical procedures are highly scrutinized by insurance companies due to the expense of the procedure itself. Some insurance require prior authorization for procedures, which may include submitting prior office notes, labs, or radiology reports to substantiate the need for the actual procedure [5]. This varies nationally by region and by the policy negotiated by the patient's employer. The Patient Protection and Affordable Care Act, signed into law in 2010, currently requires that contraceptives be covered by insurance companies, including long-acting reversible contraceptives (LARCs). Medicaid coverage of LARCs is variable. It is best to check with the insurance company prior to performing the procedure.

The list of billable procedures may not be standardized, even by commercial insurance vendors. It is vital to obtain the region's billable procedure list from each one of the insurance companies that are accepted by an office. If a given procedure is not present on the billable list, the clinician may need to negotiate with the insurance company for inclusion of that particular procedure.

Durable Medical Goods

Durable goods, such as IUDs, may be stocked by an office if they are used on a frequent basis. It is always best to check with a patient's insurance company prior to performing a procedure and, if possible, to arrange with that insurance company to assist with the provision of a device. If a patient cannot or will not wait for that to occur, it is always important to have the patient sign an Advance Beneficiary Notice ("ABN") stating that she is willing to pay for the procedure and the durable goods prior to performing the procedure. If the office is providing the device, the clinician needs to bill the specific HCPCS or "J code" associated with the device as well as billing the code for the procedure itself. Not to do so will mean that the office will absorb the cost of a very expensive device. Many offices order the device when the patient comes in for a consultative visit prior to the procedure. The IUD is then sent

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to the office in the patient's name; when it is received, the patient is called so that insertion can be scheduled. In this case, the provider will bill the procedure code but not bill for the device. There are organizations that will assist women advocating with their insurance to get one, such as the National Women's Law Center "Cover her" project [6].

Charity Care Procedures

Charity care services also may be available for procedures such as IUD insertion or implantable devices. For instance, the Arch Foundation was established as a not-for-profit institution to help low-income women who have no insurance coverage for the levonorgestrel intrauterine systems manufactured by Bayer. Primary Care residencies who participate in charity care programs for teaching learners how to insert or implant contraceptive devices may in some cases be able to access devices from manufacturers. Physician preceptors who oversee learners must be present for the entire procedure in order to bill for the procedure.

Cosmetic Surgery Billing

Most cosmetic surgery is not covered by insurance companies and is considered an "out-of-pocket" expense for the patient. Most clinicians who provide cosmetic surgery will stipulate that the patient pays prior to the actual procedure being performed. It is best to do a consultation prior to the procedure and to clearly provide the price of each procedure both verbally and in writing. Having the patient sign an ABN prior to the procedure is helpful.

Summary

Appropriate coding and billing improves women's access to important health procedures, as practitioners are more likely to continue doing procedures for which they can be paid. Due to the coding specificity, tracking payment and improving the process of payment are relatively easy tasks for any clinician's practice. Familiarizing oneself and one's billing staff with coding for procedures by type of procedure and by type of payment by specific insurance company will increase the likelihood of payment, thus rewarding the clinician for providing services that are requested by the patient or necessary for good clinical care.

Questions for Learners

- What are the pros and cons of stocking devices within an office setting?
- How would you streamline the authorization process?

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Additional Resource

Websites

http://www.archfoundation.com/.
The Arch Foundation: http://www.archfoundation.com.
https://larcprogram.ucsf.edu/coding.

Chapter 3 Legal Aspects of Office-Based Women's Health Procedures



David E. Kolva

Introduction

As primary care practitioners face increasing liability risk in this litigious society, careful planning and timely consultation with your competent legal advisor are critically important to reduce your exposure to lawsuits or misconduct sanctions. The conviction of former Michigan State University, US Olympic Committee, and US Gymnastics national team physician Dr. Larry Jassar on several hundred sexual assault charges in 2018 has sent shock waves throughout the medicolegal policymaking world. There will be future far-reaching investigations (and litigation) into the failures of these institutions to protect young female athletes from predation and abuse. The facts will help shape how to correctly respond to accusations in the future. It is imperative that all practitioners who provide health care to females go beyond the institutional written policies and fully adopt a "culture of safety" to avoid invasions of patient privacy or physical boundary violations.

Since the regulation of medical practice is largely an individual state activity, and laws vary widely by locality, this chapter is not intended to provide personal legal advice. When your practice makes decisions about new policies or procedures, they should be clearly recorded in a practice policy and procedure manual. A user-friendly manual, in print or electronic form, will standardize policy and procedure throughout a medical practice and facilitate training of new employees. The clinician leader of the practice must be the role model for establishing a safe culture to protect and respect every female patient.

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Office Physical Plant Concerns

Local zoning laws regulate the use of the office building premises for provision of medical services. If your existing practice location is in complete compliance with local zoning law requirements, none of the procedures described in this book should require additional special permits or variances since they fall into the category of usual medical diagnostic and therapeutic services for licensed physicians.

If you are adding colposcopy or electrosurgery services to your practice, you should consult with an electrician to evaluate your electrical service requirements. Equipment manufacturers will provide the detailed specifications to ensure safe operation.

The decision whether to purchase or lease your new equipment has important tax implications. Consultation with your accountant is mandatory before any large practice expense. For example, the cost of a new colposcopy suite may easily surpass 15,000 dollars. The cost of necessary physical plant electrical, plumbing, and storage improvements should be budgeted carefully. Remember to review your office/business property insurance policy to include the new equipment and leasehold improvements.

O.S.H.A. Concerns

In 2001, the federal Occupational Safety and Health Administration (OSHA) substantially revised the 1991 compliance standards for employers to prevent employees' exposure to bloodborne pathogens [1]. Your practice must have an exposure control plan to reflect these standards, and it must be "reviewed and updated" at least once a year. The employer is responsible for staff training and compliance as well as proper documentation of these activities. Practitioners and assistants who perform these women's health procedures should have serological documented immunity to hepatitis B. The practice must have a written protocol that clearly outlines proper handling, storage, and disposal of "sharps" (needles and blades), toxic chemicals (acetic acid, Lugol's and Monsel's solutions), and regulated medical waste. Personal protective equipment and emergency eyewash stations must be provided by the employer.

The practice must create engineering controls that allow for the proper ventilation of waste nitrous oxide gas from certain cryosurgical instruments if this equipment is used for cryosurgery of cervical or vulvar lesions. Similarly, a smoke evacuation system should be available for electrosurgical procedures to minimize aerosolized tissue inhalation.

Promotion of Services

If the practitioner is providing outpatient women's health procedures for patients outside of the practice's enrolled panel on a referral basis from other practitioners, then state and federal "anti-kickback" laws prevail. These laws, Anti-Kickback

Statute (42 U.S §1320a-7b(b)) and Physician Self-Referral Law (Stark) (42 U.S.C. § 1395nn), prohibit self-referrals, fee-splitting arrangements, and other types of activity between business entities [2]. You must consult an attorney who is knowledgeable with this technical area of the law before promoting or advertising your services to patients outside of your group practice.

Individual States regulate the scope and content of advertisement of physician's services. Fraudulent or misleading advertisement is considered professional misconduct in most states and may negate your malpractice insurance coverage for these services if results are guaranteed or falsely solicited [3].

Credentialing Concerns

While surgery performed in facilities licensed under state Public Health Laws (such as hospitals or ambulatory surgery centers) is subject to regulatory standards established under such law, procedures performed by primary care practitioners in private offices are not subjected to the same standards. The practitioner's authority to perform office-based procedures is derived from the license to practice medicine issued by the states. States are increasingly establishing clinical guidelines for office-based surgery [4]. The practitioner should become familiar with his state's guidelines for definitions of standards of care and quality (see http://lawatlas.org/datasets/office-based-surgery-laws accessed June 6, 2018). These guidelines can serve as a good resource template for creating your office policy concerning staff education and training for individual procedures.

One of the most important rules of risk management is that the practitioner must be able to prove competency in the performance of these outpatient procedures. Procedure-specific competence should include education, training, experience, and evaluations of performance. Proof of competence should include documentation of procedures performed during postgraduate residency programs and/or proof of satisfactory completion of approved didactic courses offered as continuing medical education (CME). The American Academy of Family Physicians offers a Continuing Medical Education syllabus in colposcopy and outlines methods to facilitate credentialing [5]. Your practice should have a system to record the ongoing number of procedures performed by each practitioner and have a formal "re-evaluation of competency" policy in place.

The practitioner must research the terms of coverage of the practice's professional malpractice policy to make sure that the planned procedures are covered under the existing policy. Unlicensed personnel should not be assigned duties or responsibilities that require professional licensure [4]. The practice should have a formal "in-service" instruction program for office assistants involved in these procedures and document successful completion in the personnel record. This program should also address the knowledge needs of telephone-triage or advice nurses who are most likely to receive telephone calls for postoperative care concerns from patients.

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Informed Consent

Informed consent is a process of communication with a competent patient about the planned procedure in sufficient detail to allow a decision whether to proceed with the intervention [6]. The key legal components of informed consent have evolved over the last 50 years in the United States. Not only is this process an ethical obligation, it is now a legal duty of professional conduct as described in statutes and case law in all 50 states. Informed consent is also a key component of the "shared decision-making" process that is replacing the "paternalistic" practice of medicine [7].

For the procedures described in this book, informed consent must include the following components:

- 1. Information on the patient's pathology or current medical condition.
- 2. Other scientifically valid treatment options.
- 3. Rationale for the chosen procedure.
- 4. Anticipated beneficial outcomes of the procedure.
- 5. Potential harmful complications or consequences of the procedure.
- 6. Consequences of *not* having the procedure (informed refusal).

There can be no deliberate or willful misrepresentation of facts in these discussions with patients. In addition, the discussion must be in a language that is understandable to the patient in terms of education level and native tongue. Certified medical interpreters should be provided for patients whose native language is discordant with the practitioner. Many studies have shown a higher medicolegal risk when using family members as "ad hoc" interpreters [8].

The Americans with Disabilities Act requires the provider of medical services to provide appropriate means for hearing-impaired patients to function in the medical environment. Because informed consent discussions are of the highest importance, only medically certified interpreters should be hired by the practice to serve in this function with hearing-impaired patients. The cost of this service must be absorbed by the practice and not billed to the patient.

The informed consent discussion should be performed by the practitioner in the office setting. This discussion should be recorded in the patient's medical record, with care to mention the use of any drawings or audiovisual aids [9]. Many practices have preprinted informational brochures that are part of the informed consent discussion. The patient's signature authorizes the procedure *only at the successful conclusion of the informed consent process*. If the patient refuses to have the intervention after this discussion, this refusal should be documented with a discussion of the repercussions fully acknowledged by the patient.

The increasingly popular usage of electronic medical records (EMR) has allowed groups to create standardized electronic consent systems and forms. The use of these new standardized systems has improved the documentation accuracy of the informed consent process [10]. New practice models for primary care introduce more complex rules concerning informed consent and release of information

procedures, treatment and warm hand-off protocols, documentation and electronic record keeping, agreements with other providers, and billing [11].

Rights of Minors

While primary care physicians provide the majority of health care to adolescents, there is "significant evidence that both physicians and adolescents are uninformed of adolescent's legal rights to confidential reproductive health care" [12]. The Guttmacher Institute (https://www.guttmacher.org/state-policy/explore/overviewminors-consent-law) sponsors an online reference source that is updated monthly to provide information on key issues affecting these rights indexed by each individual state [13]. The practitioner AND the office staff must be knowledgeable about their own state's law concerning consent and confidentiality when treating minors. In general, the law recognizes special conditions where the minor child may consent to diagnostic and treatment activities without parental approval or knowledge in matters concerning sexually transmitted infections (STIs), contraception, and reproductive (pregnancy) health including abortion [14]. When the practitioner consents to perform these gynecological procedures on minors, there are practical clinical concerns that may arise in the office with regard to billing, scheduling, telephone calls, and medical records privacy. The practice's policy and procedure manual should anticipate these potential breaches and detail the proper method of handling each issue. If your practice participates in the federal Title X Family Planning Program or the State Children Health Insurance Program (SCHIP), you must be knowledgeable about the confidentiality and consent rules for these programs. The major specialty organizations have all published policy statements regarding health care for adolescents [15]. These comprehensive guides should require reading by practitioners who perform these gynecological procedures.

Use of Chaperones

There is no *uniform* national legal requirement mandating the use of a chaperone during female pelvic examinations or procedures. Even though all medicolegal risk managers recommend the routine use of chaperones, there is wide variation in this practice between American physicians [16] and their European counterparts [17]. The American Medical Association has addressed this deficiency by publishing a Policy Compendium stating, from the standpoint of ethics and prudence, the protocol of having chaperones available on a consistent basis for patient examinations is recommended [18]. A recent study showed that the characteristics of physicians convicted of sexual misconduct involved a combination

of five factors: male physicians (100%), older than the age of 39 (92%), who were not board certified (70%), and practicing in nonacademic settings (94%) where they always examined patients alone (85%) [19].

In April 2006, the Federation of State Medical Boards adopted a policy that defines physician sexual misconduct and provides recommendations for physician education [20]. When reviewing the definitions of sexual impropriety and sexual violation in this publication, it is clear that most false accusations or misunderstandings can be avoided with the proper use of a *medically trained* chaperone *always* when performing these women's health procedures. The practice policy and procedure manual should state this clearly. It is also a good investment to avoid the emotionally wrenching experience of a false sexual misconduct charge. For most of the procedures described in this book, a chaperone is the beneficial "second pair" of hands to assist the operator in the completion of the procedure. Most experts recommend that the chaperone be the same sex as the patient; thus, a male physician should have a female chaperone for a female patient.

Patient Preprocedure Preparation Concerns

Solutions to prevent health-care errors were unveiled in May 2007 by the World Health Organization's (WHO) Collaborating Centre for Patient Safety Solutions. Two of the solutions deal with office-based procedures: patient identification and performance of correct procedure at the correct body site. Your practice should adopt the "Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery" as standard office policy [21]. It is the responsibility of the practitioner to verify the adequacy of the informed consent process and double-check the patient's identity and planned procedure. The office should have an adequate privacy area to allow for patient disrobing and gowning.

Procedure-Specific Legal Concerns: Cervical Cytology and Pap Smears

Your office should have an established policy for the review of all laboratory reports before the reports are filed into the medical record [22]. The primary care provider must review and acknowledge ALL Pap smear cytology reports. Your office notification system must be fool-proof and have built-in reminders for follow-up of patients with abnormal Pap smear results until diagnostic resolution. Patient risk factors contributing to inadequate follow-up include low-income group, ethnic minority, and low health literacy [23]. Clinical errors occurring that led to Pap smear litigation include failure to notify patients of their abnormal test result, missing or inconsistent follow-up patterns, failure to investigate persistent bleeding following a Pap smear, and failure to biopsy an abnormal cervix given a normal Pap smear

result [24]. Thankfully, the increased utilization of electronic medical records with built-in laboratory results management programs will improve the follow-up process [25]. The practitioner *must* be knowledgeable about the positive and negative predictive values of the Pap smear results to give adequate informed consent.

Procedure-Specific Legal Concerns: Pessary

New self-positioning pessaries are effective, easy to use, and have few complications [26]. The most serious complications from pessary use are attributable to neglected devices in patients lost to follow-up [27]. These rare complications include urosepsis, impaction, vesicovaginal fistulae, and incarceration of cervix and small bowel.

Procedure-Specific Legal Concerns: Contraceptives

When the practitioner discusses the contraceptive needs of the patient, the six key components of the previously discussed informed consent process must be addressed. Elements of the patient's current medical condition that are important in choosing the proper contraceptive method include age, emotional maturity, health literacy, parity, number of sexual partners, cardiac risk profile including hypertension and diabetes, migraines, coagulopathy, history of cancers, history of pelvic inflammatory disease or sexually transmitted infections, HIV and hepatitis B status, tobacco use, street drug or alcohol use, access to medical care follow-up, family history, and latex allergy. The practitioner must also have published information available to compare the relative effectiveness rates of each method [28]. This information should be included in table form on the practice's informed consent forms.

Procedure-Specific Legal Concerns: Diaphragms

"Items that come in contact with mucous membranes or non-intact skin are defined by the CDC as semi-critical. These medical devices should be free of all microorganisms, although small numbers of bacterial spores may be present." Diaphragm fitting rings and pessary fitting kits are considered to be "semi-critical" items for disinfection following use [29]. The manufacturer's recommendations for cleaning and disinfecting must be followed, and this procedure must be part of the practice's OSHA blood-borne pathogens exposure control plan.

Effectiveness of the diaphragm for pregnancy prevention is very dependent on proper inspection of the device prior to use, correct initial fitting on a suitable patient, proper insertion, duration of use post-coitus, and storage of the device [30].

Patient education during the fitting/insertion office visit is critical. The most significant complication of diaphragm use is toxic shock syndrome.

Procedure-Specific Legal Concerns: Long-Acting Reversible Contraception (LARC), IUDs and Implants

The *intrauterine device (IUD)* and the *birth control implant* are long-acting reversible contraception methods. The thought process of a generation of physicians was forever changed by the Dalkon Shield litigation history during the 1970s. It was the largest "defective product" tort case in history and has reduced IUD usage in the United States to the lowest level of any industrialized nation in the world [31]. The new approved IUDs for use in the United States have eliminated the design flaws that plagued the Dalkon Shield. Proper patient selection and post-insertion education and follow-up are important factors to reduce complications and to enhance effectiveness [32]. Contraindications and adverse effects should be included on the informed consent forms. Documentation of absence of pregnancy before insertion is legally critical. The most serious complication of the IUD insertion procedure is uterine perforation with a reported rate of 1 per 1000 insertions for copper IUDs and 2.2 per 1000 insertions for hormone-releasing IUD [33].

Procedure-Specific Legal Concerns: Colposcopy and Loop Electrocautery Excision Procedure (LEEP)

The process of informed consent is of the utmost importance when discussing abnormal Pap smear results with patients and determining who should undergo further procedures. Some patients consider an abnormal Pap smear to automatically indicate cancer and wonder why they are not being managed more aggressively. Even the majority of college educated women do not know the role of HPV in cervical neoplasia [34]. An overlooked communication problem is the confusion between the abbreviations "HPV" and "HIV" and "HSV" when talking with patients. Please be careful!

Recent publications contain excellent consensus statements that summarize the 2012 American Society for Colposcopy and Cervical Pathology Guidelines for evidence-based management of abnormal cervical cytology [35]. These protocol algorithms should be referenced in your informed consent discussion and documentation. The highest medicolegal risk in the performance of a colposcopy is an inadequate examination with inappropriate follow-up. Your office notification system must be foolproof and have built-in reminders for follow-up of patients with abnormal colposcopic findings until diagnostic resolution. A telephone call to a patient before a scheduled recheck appointment has been shown to improve compliance with follow-up. Mail reminders have NOT been found to be helpful to improve compliance but are legally important for documentation purposes.