

# Patient Requests for Office-Based Imaging

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The rising cost of health care affects our economy and can impact the health of our citizens. Costs can be divided into direct costs, which are incurred in the provision of services and procedures, and ancillary costs, such as labs and imaging. While ancillary services greatly assist providers in diagnosing and treating medical conditions, they can be overused or inappropriately used and can lead to adverse events. All providers should work to order the most appropriate imaging and tests and to protect patients at all times.

The use of advanced imaging enhances the clinician's ability to more quickly and accurately diagnose a wide range of conditions. However, increases in the availability, use, and public awareness of such imaging have had unintended consequences for patients, clinicians, and the entire health care system. The proliferation of online medical information makes it easier for patients to create their own differential diagnoses and to request studies they believe are needed to evaluate their concerns. As a result, use of office-based imaging is on the rise [1, 2]. A patient's demand for imaging, however, can put the clinician in a difficult position if it conflicts with what the scientific evidence says is appropriate.

A driving principle in medicine is *primum non nocere*—"first, do no harm." The current challenge with imaging is to do what is right while minimizing the risk to the patient and avoiding overuse of limited resources. All too often, patients do not understand the true risks or consequences of imaging, whether it is performed for diagnostic or screening purposes. This lack of understanding can have both direct and indirect effects, including physical or psychological problems, potential strain on the doctor-patient relationship, and significant costs for the entire health care system.

As family physicians with many years of practice experience, my partners and I deal regularly with requests for imaging. To address these, we must determine why a patient is making the request and whether the imaging is necessary (or potentially harmful), figure out what to do when clear guidelines are not available, and decide how to respond to patients and educate them so that they can make informed decisions. The nature of these issues highlights the importance of an established doctor-patient relationship that is founded on mutual trust and respect.

## Applying Evidence-Based Guidelines

Advances in technology are progressing at a rapid pace; information is more accessible, both to clinicians and to the public; and studies frequently provide new information about the effectiveness of screening tests and treatments and their impact on outcomes. Physicians have a responsibility to strive to provide services that are beneficial to patients while weighing the risks of any test or intervention. To accomplish this goal, we must know what is most effective and how treatments or interventions might cause harm. The US Department of Health & Human Services, through the Agency for Healthcare Research and Quality (AHRQ), defines this balancing of risk and benefit as *comparative effectiveness*. According to AHRQ, research in this area is "designed to inform health-care decisions by providing evidence on the effectiveness, benefits, and harms of different treatment options" [3].

Often clinicians are not fully aware of the latest guidelines for the appropriate use of imaging in screening or diagnosis, or they do not know how such guidelines may relate to a particular patient's situation. Even with this information, clinicians face many questions: Will the screening test alter the course of the disease or its effect on this patient? How can we adequately inform patients of the risks of a test, and will patients truly understand these risks? How do we use statistical information from populations when treating a single individual? In a health care system that puts the patient at the center and judges providers based on patient satisfaction, how do we balance what is right versus what the patient wants? How do we balance limited system resources with some patients' belief that they are entitled to whatever tests they desire?

The good news for patients is that, more than ever, the health care system is focusing on them rather than just on their conditions or diseases. The model of the patient-centered medical home, a concept developed years ago—and in 2007 endorsed by all the major primary care professional societies [4]—is now widely accepted and supported by the

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# Keepsake Prenatal Ultrasound: Pros and Cons of Non-Medically Indicated Imaging

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Having a prenatal ultrasound is usually an enjoyable event that combines medical care and family celebration. Ultrasound imaging is often performed during a prenatal exam to confirm gestational age, to screen for fetal abnormalities, and to assess other aspects of fetal well-being. However, ultrasound is sometimes performed when it is not medically indicated. Patient demand for “keepsake” prenatal images has arisen because of a confluence of factors: 4-dimensional (4D) imaging now allows sonographers to capture 3-dimensional (3D) images in real time; the mother may want to “show” her baby to family members who are not present during the medical exam; and practitioners are sometimes reluctant to provide copies of ultrasound images because of medicolegal concerns. Thus, commercial 3D/4D ultrasound studios are becoming increasingly common.

Elective prenatal ultrasound has been promoted as a means of enhancing parent-child bonding. Although studies have not shown 3D/4D ultrasound to be any more effective than 2-dimensional ultrasound when it comes to improving bonding scores or reducing parental stress and anxiety [1], elective ultrasound sessions may allow greater involvement of siblings and other family members and may provide more time for the ultrasound than would be possible in a busy sonography unit.

Retail fetal imaging may provide some benefits, but there are also real concerns. Although many ultrasound boutiques employ certified obstetrical sonographers, there is no requirement that these sonographers be certified, nor is there any formal oversight of these units. For example, one company that supports prospective owners in establishing an elective 3D/4D ultrasound business claims that, with their program, 3D/4D ultrasound training can be completed in “around 5 days” for those with no ultrasound experience [2]. In contrast, the education of a certified obstetrical sonographer typically includes 12–48 months of didactic and clinical training in an accred-

ited program, culminating in completion of a credentialing exam [3]. In addition to training sonographers in proper techniques for obtaining fetal images, this education also covers the physics of ultrasonography, the pathophysiology of fetal disorders, and safe use of medical ultrasound. Most clinical obstetrical units also obtain certification from the American Institute of Ultrasound in Medicine (AIUM) for the performance of obstetric ultrasonography. Such certification assures appropriate unit quality and safety, physician oversight and interpretation, and adherence to medical society guidelines. Retail ultrasound facilities lack this certification, which may lead to inconsistent quality of imaging and inconsistent safety practices.

The primary medical harm that can result from ultrasound imaging is incorrect diagnosis, and there is concern about both false-positive and false-negative results. In obstetrical practices, qualified medical professionals review the images obtained during ultrasound exams, and the results are reported to the care provider. In contrast, images obtained in retail boutiques are not reviewed, and there is no communication with the patient’s obstetrical provider. If a keepsake ultrasound does identify a problem, women may have to wait for referral to a clinical obstetrical ultrasound unit, which could lead to significant anxiety. Another concern is that customers may not understand that a keepsake ultrasound does not provide the same information as a diagnostic ultrasound, and they may thus forgo needed prenatal visits.

Obstetrical sonography has an excellent safety record, and it may seem disingenuous for physicians to argue that keepsake sonograms expose the fetus to biophysical harm, while at the same time promoting the safety of medically indicated ultrasound. But it is important to keep in mind that certified sonographers and ultrasound protocols mitigate the risk of biophysical harm by using power settings and exposure times that are “as low as reasonably achievable” (ALARA) [4–6]. Greater intensity or longer exposure

business community and insurers [5]. The patient-centered medical home aims to provide high-quality care at a lower cost and to improve the experiences of both patients and providers by using care coordination and communication.

The most important aspect of outpatient medicine is the establishment of a relationship between a patient and his or her clinician. Medical decisions are best made when there is mutual trust and respect between the parties involved and when an appropriate history and examination have been performed. Knowing a patient’s medical, psychological, environmental, and social history is often helpful when determining the best type of evaluation and the best course of action.

To know which tests are appropriate in which settings, clinicians must stay up to date on the indications, risks,

and benefits of many types of imaging studies and tests. Guidelines and rating systems help clinicians determine the appropriateness of tests and the strength of the evidence in support of screening or other procedures [6, 7]. In recent years, professional societies have also released lists of tests and procedures that current evidence suggests are unnecessary (or useful only under certain conditions) [8]. Once clinicians have gathered this information, they must then educate their patients about the conclusions of such guidelines. When information about a test or procedure is unavailable or inconclusive, clinicians and the public alike should err on the side of protecting the patient—not only from the possibility of a significant pathologic process, but also from the risks of unnecessary screening or diagnostic imaging.

could induce tissue heating and cavitation, which might have adverse fetal effects. Keepsake ultrasounds may include prolonged imaging of the fetal face, which can be seen as a violation of the ALARA principle.

In response to these concerns, the US Food and Drug Administration (FDA) and medical societies have issued statements and regulations regarding “entertainment” ultrasounds [7-10]. The FDA considers keepsake ultrasounds to be an unapproved use of a medical device and states, “exposing the fetus to ultrasound with no anticipation of medical benefit is not justified” [7]. Similarly, the AIUM states that fetal ultrasound should be performed by appropriately trained and credentialed medical professionals with specific training in fetal ultrasound and that all studies should be properly documented in the patient’s medical record [10]. To address providers’ concerns about medicolegal risk while balancing patients’ desires for keepsake images, the AIUM and other societies suggest that it is appropriate to share images taken during an indicated examination with the patient.

Prenatal ultrasound is an excellent diagnostic tool, and its use can contribute to a mother’s bonding with her unborn child. However, performance of prenatal ultrasound solely for the purpose of gender determination or for the acquisition of keepsake images is discouraged. Obstetrical ultrasound providers could better serve patients by providing copies of digital or print images obtained during clinically indicated imaging. If women choose to go to a retail ultrasound vendor, they should know that a keepsake ultrasound is not a medical test and does not replace a clinically performed scan, and they should be advised to inquire about the credentials of the individuals performing the scan. NCMJ

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## Weighing the Risks of Imaging

In my experience, a patient requests imaging for one of several reasons: concern over a particular disorder because he or she has certain risk factors (eg, a history of smoking, a family history of the disorder); concern that a symptom may be related to a significant disorder (eg, cancer); concern arising from a recent diagnosis (eg, heart attack) in someone close to the patient; a wish to use money in a health care savings account while the funds are still available; concern arising from advertisements targeted at the patient; or the recommendation of someone who is not a health care professional.

There are also a number of factors that may cause clini-

cians to feel pressured to order imaging. These include a lack of time to have an adequate conversation about whether a test is warranted; fear of a lawsuit over failure to diagnose various conditions; continued pressure or demand from the patient; and a desire to satisfy the patient, who is often viewed as a “customer” of the physician practice. Patients have the right to refuse any medical treatment or test that a physician recommends, but they do not have the right to demand a particular treatment or test [9]. Explaining to a patient why a test or procedure is not indicated can be difficult and time-consuming, but as clinicians we should educate ourselves and be prepared to have these conversations [10].

The most commonly requested imaging tests in primary

care are magnetic resonance imaging (MRI) studies, computed tomography (CT) scans, ultrasounds, carotid studies, positron emission tomography (PET) scans, coronary calcium scans, and plain-film radiographs. The proliferation of the use of diagnostic imaging in the emergency department [11] and possibly the lack of adequate informed consent [12] may lead patients to overlook the actual short-term and long-term risks of imaging. Clinicians in all settings should be aware of the amount of radiation exposure that will result from any test they order. Compared with the amount of radiation delivered by an anterior-posterior chest radiograph, a CT scan of the lower back delivers 538 times more radiation, a chest or abdominal CT scan delivers 769 times more radiation, and an interventional procedure such as cardiac catheterization can deliver as much as 1,231 times more radiation [13].

Emergency departments often have protocols that rely heavily on imaging and testing based on symptoms, and these imaging studies are often conducted before a clinician takes the patient's history or performs a physical examination. The routine use of CT in the emergent workup of various symptoms (eg, headaches, abdominal pain, pelvic pain) may lead patients to believe that such imaging is the first step in any workup and that it involves little risk; in reality, such imaging is indicated only if a patient's history and/or examination findings suggest significant pathology [8, 14-16].

Although patients and clinicians sometimes are not fully aware of the risks associated with imaging, the radiation delivered during CT scans may have long-term consequences. For example, it has been estimated that a 40-year-old woman receiving a single chest CT scan may have a 1-in-720 lifetime risk of developing cancer from that imaging study; for a 20-year-old woman, the lifetime risk is 1 in 390 [17]. In fact, it has been suggested that as many as 2% of *all* cancers after 2007 in this country may come as a direct result of medical radiation exposure [18-20].

Additional risks of imaging include mild or severe allergic reactions and other risks linked to the use of intravenous contrast material. When intravenous dye is used for imaging, there is a significant risk of kidney toxicity—ranging from 1% to greater than 10% depending on the population and type of imaging procedure [21, 22]. There is also a small but real risk of kidney toxicity contributing to, or directly causing, mortality—ranging from 9 deaths per 100,000 for all CT scans using contrast to up to 0.6% for certain populations scanned in an emergency department [22, 23].

Finally, the most common sequelae of outpatient medical imaging are incidental findings. Up to one-third of all CT scans require some type of follow-up imaging [24-26], which further increases the risks of the reactions noted above and of the patient potentially developing cancer in the future secondary to the radiation from the imaging. Incidental findings can also increase a patient's anxiety and fear, and the evaluation of incidental findings may require that addi-

tional procedures be performed—again exposing the patient to various risks and requiring further investments of time, energy, and money. The cost of additional imaging also strains our health care system [1, 2].

## How to Improve the Use of Diagnostic Imaging

I believe that several changes are needed to improve the use of diagnostic imaging. First and foremost is the development of a trusting and respectful relationship between patients and their clinicians [27]. This relationship should be one in which the appropriateness and consequences of testing are discussed and informed decisions are made collaboratively [28].

We also need a health care system that rewards clinicians for having these tough conversations and for staying abreast of new information. Our current system of payment for medical services often rewards and encourages overuse of procedures and services. Many health care providers are compensated for doing more, not for conversations or for being efficient. Physicians stretched for time in busy practices may find that it is easier for them, and often more satisfying for the patient, if they go ahead and order tests rather than try to explain why imaging may not be necessary. Most physicians are not penalized for ordering unnecessary tests, and there can be secondary gain in taking the path of least resistance.

In emergency departments and other venues, we need to use imaging more selectively, rather than mass screening every patient with a specific complaint. We should try to more precisely determine which patients need imaging by taking an appropriate history and/or performing a physical examination. Limiting imaging can help decrease patients' risk for future health issues related to radiation exposure.

We also must try to find a way for patients to have a greater stake in health care costs. Patients need to understand that having insurance coverage does not entitle them to any test they want. We may also need to look at the private sector and its push to profit from the marketing of imaging screening tests of questionable benefit to the public. Finally, we need to examine the liability issues surrounding all of health care and find a way to decrease the risk of lawsuits, which sometimes prompts clinicians to order unneeded tests.

Our health care system is costly, inequitable, and difficult to navigate—all of which must change. Patients are being moved to the center of the process to improve their care and experiences, and rightfully so. But being at the center of the health care system should come with the responsibility of partnering with a clinician who is trying to provide the highest quality care and to do the right thing, at the right time, for the right reasons [29]. Imaging is a major driver of the rising cost of health care in this country, and although it has many benefits, it also has many drawbacks and risks. As clinicians, we should strive to be thoughtful, compassionate, and informed, and we have a responsibility to inform and



educate our patients. Working together for the benefit of our patients and our communities, we should remember to “first, do no harm.” NCMJ

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