



HEALTHCARE

RISK MANAGER

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Cumulative Radiation Exposure: Experts urge physicians to consider the risks to patients

Dear Risk Manager:

A referring urologist requested a CT of the abdomen and pelvis with and without contrast on an 18 year old patient. The radiologist told me he was practicing "CYA" medicine. However if we complete this consultation, the young man will have received 60-80 milliseiverts (mSv) doses of radiation, along with having been exposed to the risks of a reaction to the contrast dye. How can a consultant physician appropriately communicate concerns to referring physicians about balancing patient safety without compromising good quality diagnostic work?

- John Doe, MD, Diagnostic Radiologist

Answer:

The downside of advances in radiological technology is that Americans are being exposed to record amounts of ionizing radiation, the most energetic and potentially hazardous form of radiation. According to a recent paper from the American College of Radiology, "It is worth noting that many CT scans and nuclear medicine studies have effective dose estimates in the range of 10 to 25 mSv for a single study, and some patients have multiple studies. It would not be uncommon for a patient's estimated exposure to exceed 50 mSv." The International Commission on Radiological Protections has reported that CT doses can indeed approach or exceed levels that have been shown to result in an increase in cancer.

Ways consultative physicians can help colleagues and patients:

1) Educate referral physicians – Referring physicians should be familiar with the radiology college index of appropriateness criteria, which rates the imaging procedures for more than 200

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Updated Guidelines Address Prevention of Second Stroke

By Georgette Samaritan, BSN, Senior Risk Management Consultant

In 2006 the American Heart Association (AHA), the American Stroke Association (ASA) and others created updated guidelines to prevent second strokes in patients who experienced an ischemic stroke or transient ischemic attack (TIA)¹. An important departure from earlier guidelines is that "stroke" and "TIA" should be treated interchangeably.

According to the authors, survivors of a TIA or stroke have an increased risk of another stroke, which can cause further disability or death. Nearly one third of the estimated 700,000 strokes occurring each year in the United States are recurrent strokes, and the risk for secondary strokes in survivors of stroke and TIA approaches 40 percent within five years.

Epidemiological studies help to identify the risk and determinants of recurrent stroke, and clinical trials have provided the data to generate evidence-based recommendations to reduce this risk. The recommendations below focus primarily on the prevention of stroke among these two groups.

Guidelines Summary

- Modifiable risk factors for stroke include eliminating smoking, limiting daily alcohol consumption to no more than 2 drinks for men and 1 for women; reducing obesity and encouraging physical activity.
- Comorbid diseases, such as hypertension and diabetes, should be aggressively managed according to known practice guidelines.
- Medical options include anticoagulants and antiplatelet agents.
- Interventional measures include CEA or carotid balloon angioplasty or stent (CAS) or extracranial-intracranial bypass surgery.
- Blood Pressure (BP) lowering should follow recommendations of the Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC-7); benefit has been demonstrated with a reduction of ~10/5 mm Hg. More than 1 antihypertensive agent may be required to prevent stroke. The JNC-7 has defined normal BP levels as less than 120/80mm Hg.
- For patients with elevated cholesterol or comorbid cardiovascular disease, the recommendations of the National Cholesterol Education

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medical conditions. They should also provide the rating for a given condition—scores range from 1 to 9. If the number turns out to be 1 or 2, the radiologist may recommend another exam.

2) Promote facility accreditation – Accreditation by the American College of Radiology is voluntary. Accreditation means the machines are surveyed and calibrated to use the correct level radiation and the technologists are certified. It also means the images are likely to be of higher quality, reducing the likelihood of having to repeat a procedure and suffer additional exposure.

3) Educate patients – Patients should be provided information that encourages them to ask questions like, “*Do I really need this exam?*” and “*Are your machines routinely inspected by a medical physicist?*” Women should tell the doctor or technician if they might be pregnant. Generally, women, children and young people should try to avoid scans.

4) Keep Scans – If patients are given a CD of their scan, along with the interpretation, they should hold onto it, to avoid having to repeat a procedure. People who are undergoing multiple studies may be encouraged to keep a record tracking all the radiological procedures they have had, and inform their physicians of their history.

5) Types of scans – Full-body CT scans should be avoided unless there is a good medical reason.

In summary:

Radiologists do not want to scare people away from having scans and exams when necessary, but they want physicians and patients to carefully evaluate the benefits and risks. It is also important to be sure the procedure is appropriate and to keep track of cumulative exposure levels. Radiologists should partner with primary care physicians, as well as patients, in order to track the numbers of radiological procedures ordered over time.

References:

www.Radiologyinfo.org

The Doctors' World, Radiology Was Young, and So Was I, Lawrence K. Altman, MD, NY Times, June 19, 2007.

With Rise in Radiation Exposure, Experts Urge Caution on Tests, Roni Caryn Rabin, NY Times, June 19, 2007.

Updated Guidelines Address Prevention of Second Stroke (continued from page one)

Program III (NCEP III) should be followed for target lipid levels, and treatment with statins to reduce the overall risk for vascular events. The target low-density lipoprotein cholesterol level is <100 mg/dl for those with coronary heart disease or symptomatic atherosclerotic disease and <70 mg/dl for very high-risk persons with multiple risk factors.

- Weight reduction to maintain goal Body Mass Index (BMI) between 18.5 and 24.9 kg/m² and a waist circumference of less than 35 inches for women and less than 40 inches for men recommended.
- At least 30 minutes of moderate intensity physical exercise on most days for those capable of engaging in physical activity is recommended.

Medical Recommendations

- For patients with stroke or TIA with persistent or paroxysmal atrial fibrillation anticoagulation with adjusted-dose warfarin with target international normalized rate (INR) of 2.5 (range, 2.0 - 3.0) is recommended, and aspirin may be used for those who cannot tolerate warfarin.
- In those in whom stroke or TIA is caused by myocardial infarction with left ventricular intramural thrombus anticoagulation with INR of 2.0 to 3.0 for at least 3 months is reasonable, and aspirin up to 162 mg daily should be used concurrently for ischemic coronary disease.
- For those with dilated cardiomyopathy, either warfarin with INR of 2.0 to 3.0 or antiplatelet therapy may be considered.
- For those with rheumatic mitral valve disease, either warfarin with target INR of 2.5 and aspirin at 81 mg daily are suggested.
- For those with mechanical prosthetic valves, an INR target of 3.0 is recommended, and 75 to 100 mg/day of aspirin may be added.
- Compared with aspirin alone, both the combination of aspirin and extended-release dipyridamole and clopidogrel are safe. Aspirin with extended-release dipyridamole is recommended over aspirin alone.
- However, the addition of aspirin to clopidogrel increases the risk for hemorrhage and is not routinely recommended for ischemic stroke or TIA patients.

Surgical Recommendations

- Patients with recent TIA or ischemic stroke within 6 months and ipsilateral severe (70% - 99%) carotid artery stenosis should receive carotid endarterectomy (CEA) by a surgeon with a morbidity and mortality of less than 6%.
- Patients with recent TIA or stroke with moderate carotid stenosis (50% - 69%) may have CEA depending on comorbid factors, whereas CEA is not recommended for those with less than 50% stenosis.
- When CEA is recommended, surgery should be performed within 2 weeks.
- In those with symptomatic severe stenosis greater than 70% in whom stenosis is difficult to assess, CAS is not inferior to CEA and may be considered.
- Among patients with symptomatic carotid occlusion, extracranial-intracranial bypass is not routinely recommended.
- Endovascular treatment of patients with symptomatic extracranial vertebral stenosis may be considered when patients are having symptoms despite

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Calculate Your MRI Suite Safety Score

- Tobias Gilk, MRI-Planning, Imaging Design Specialists

For years, hospitals and imaging facilities considered MRI accidents inevitable. Sooner or later a floor polisher, a fire extinguisher or ubiquitous health care appliances like a wheelchair would crash into the MRI. Perhaps they would damage coils, phantoms or other components, but this was just the cost of doing business' in Magnetic Resonance Imaging. However, following a tragic MRI death several years ago, the radiology community recognized that MRI safety is more important than ever before.

With the exploding growth in diagnostic imaging and rapid adoption of 3.0 T (Tesla) machines, the stakes for patient safety grow every day. Governing safety regulations, including accreditation for MRI providers from the Joint Commission for Accreditation of Healthcare Organizations (JCAHO) and the American College of Radiology (ACR), have not kept up. Although updates and alerts from these organizations address growing safety concerns and provides guidelines, each practice must take precautions to prevent accidents.

Safety in the MRI suite is both vitally important and unusually challenging to implement because of the invisibility of the threats coupled with the increasingly common presence of objects that MRI's can act upon with disastrous results.

This brief questionnaire will score your facility and determine how effective your current safety practices are. More importantly, it will help to identify ways to improve safety for your patients and staff. We start with the rose-colored presumption that your safety score is a perfect 100 percent, except as modified by the following questions. For every response, subtract the appropriate number.

- 1. Do your referring physicians frequently refer patients with contraindicated implants or patients with unknown medical histories?**
Almost Never - 0
Occasionally - 1
Too Frequently - 2
- 2. Do you pre- screen patients with a telephone appointment confirmation?**
Yes - 0
No - 1
- 3. Do you use standard clinical screening forms or ask only those questions that seem relevant?**
Standard Form - 0
Whatever is Relevant - 3
- 4. Do you have private screening areas for patient interviews?**
Yes - 0
No - 1
- 5. Do you gown your patients?**
Every Patient - 0
Only Some - 2
Street Clothes are Fine - 4
- 6. Do you screen patients and equipment with a ferromagnetic- only detector?**
Yes, at the door into Zone III +3
Yes, at the door to Zone IV +1
No - 1
- 7. Is your waiting room shared between post-screened MRI patients and patients for CT or any other modality?**
No - 0
Yes - 4

9. Do you have a locked door between Zone II and Zone III?
Yes - 0
No - 3
10. Are there any unsecured doors into Zone III or Zone IV, including 'staff only' entrances?
No - 0
Yes - 5 (for each door)
11. Do you use combination or keypad locks for access controls?
No - 0
Yes - 2
12. Does housekeeping or the transport staff have independent access to the MRI suite without MR staff supervision?
No - 0
Yes - 5
13. Does engineering / maintenance or security have independent access to the MRI suite without MR staff supervision?
No - 0
Yes - 4
14. Does any non- MR clinical staff (anesthesiologists, E.R. staff, and cardiology) have independent access to the MRI suite without MR staff supervision?
No - 0
Yes - 3
15. Does the technologist at the console have a direct view of every door entering the magnet room?
Yes - 0
No - 5 (for each door into the magnet room)
16. Does the technologist at the console have a view of the approach to the magnet room door?
Yes - 0
No - 3 (for each door)
17. Does your facility provide partial sedation?
No - 0
No - 1
18. Does your facility image non- emergent fully anesthetized patients?
No - 0
Yes - 2
19. Does your facility image emergent / trauma patients?
No - 0
Yes - 2
20. Does your facility do image- guided biopsies or other minor interventional procedures?
No - 0
Yes - 1
21. Are all incidental, support and transport items appropriately labeled as to their safety in the MRI room?
Yes - 0
No - 2
22. Does your facility provide MR- Safe or MR- Conditional loaner incidental equipment (i.e. wheelchairs, walkers, gurneys)?
Yes - 0
No - 3
23. Are all clinical devices / supplies for use in the magnet room (i.e. medication pumps, patient monitors, ventilators) tested Safe or Conditionally Safe and labeled for that use?
Yes - 0
No - 4
24. If you have more than one magnet with different strengths or formats, is all MR Conditional equipment identified with the safe limits of use?
Yes - 0
No - 2

25. Do your technologists have ready access to implant and medical device safety testing information?

Yes - 0

No - 3

26. Has the cryogen vent (quench pipe) been inspected within the last year?

Yes - 0

No - 2

27. Is the magnet room equipped with an emergency exhaust fan that has been verified

Yes - 0

No - 2

28. Is the magnet room equipped with a passive pressure relief system (not including an out-swinging door)?

Yes - 0

No - 1

29. Do you have an individual designated as your facility's 'MR Safety Officer' as prescribed by the ACR White Paper on MR Safety?

Yes - 0

No - 2

30. Have you met to review MRI safety within the last year with code- teams, fire department, security, police or any other first- responders that might be called to your MRI facility?

Yes - 0

No - 1

31. Have you have emergency resuscitation and contrast reaction equipment and medications readily accessible?

Yes - 0

No - 2

32. Do you have the equipment and staff to quickly remove a coding patient from the magnet room?

Yes - 0

No - 2

33. Have you run a code drill within the last year within your MRI suite?

Yes - 0

No - 2

While every facility should strive to have a score of 100, some facilities, by virtue of built-in limitations or higher-risk applications, simply inherit a higher risk. Some of these factors can be corrected, but if you provide emergent scans, for example, you will always assume a higher risk. Since we're distilling safety down to quantitative values, the next logical step is to share with you the curve for grading the safety scores.

100-92	A (Ahead of the pack)
84-91	B (Better focus on areas for improvement)
76-83	C (Check your liability insurance coverage)
68-75	D (Don't say you weren't warned)
67 or below	Take a long, hard look at your practices!

While there is a long list of potential risk factors to bring you down from your target score of 100, there are also a number of proactive steps you can take to improve safety:

34. Have you conducted a comprehensive MRI suite risk / safety evaluation within the last year?

Yes +5

36. Do you have a written implementation plan for improving MR safety?

Yes: +5

35. Have you developed regular (annual or more often) staff safety training programs for all MR and incidental staff?

Yes: +5

These ‘extra credit’ tasks won’t improve safety by themselves, but can lay the groundwork for significant improvements in the safety of your patients and staff in the months and years ahead. MRI safety is a complicated issue, involving clinical, operational and physical interventions. MR imaging providers often benefit from consultations with safety experts to identify and correct safety lapses that do not interfere with the results or clinical practice.

If your score caught you by surprise, then it’s time to take a close look at your facility, your clinical practices and your operational standards. Particularly if you were unaware of any of the risk factors, it would be wise to bring in outside expertise for a comprehensive MRI Suite Evaluation.

The author, Tobias Gilk, can be reached at: www.MRI-Planning.com for more information.

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Ask A Risk Manager

A patient’s attorney called and wants to chat with me about a matter indirectly related to the care I provided. Should I do it?

Providers are frequently asked by plaintiffs’ attorneys to render an ‘off the record’ opinion. Eager to avoid any appearance of hiding something, physicians often answer the apparently friendly questions verbally or in writing. Inevitably, some regret their decision, when a zealous attorney uses what they have learned to strengthen their client’s position. At that point, the physician’s care may be called into question and they may suddenly find themselves thrown onto the defensive.

In these situations, you should remember that no conversation is truly off the record. What may at first seem totally harmless can lead to completely unexpected allegations. To address the occasions when patients’ attorneys seek an opinion, we recommend that:

1. practices implement a specific policy on the matter;
2. all opinion requests go through a single ‘point-person’ in the practice to ensure consistent compliance with the policy;
3. patient charts be immediately reviewed (by both the provider and point-person) to determine what, if any, liability exists; and
4. most importantly, MAG Mutual’s Claim Department be called to advise how best to respond, based upon the particular circumstances.

The reality is once the words have been uttered (or committed to writing), they are out there and cannot be withdrawn. We therefore strongly recommend consulting with us before communicating with plaintiffs’ attorneys – even where there is no apparent risk to you.

Updated Guidelines Address Prevention of Second Stroke (continued from page two)

medical therapy, the usefulness of endovascular therapy is uncertain.

Since publication of the previous secondary stroke prevention guidelines, the Women's Health Initiative was terminated because of an increase in vascular events associated with hormonal replacement therapy.

¹ Stroke, 2006; 37:577-617.

Physicians Urged to take Advantage of FDA's Electronic Resources

In their quest to move to a paperless environment, the Federal Drug Administration (FDA) is developing a number of electronic tools to assist physicians and other healthcare providers in accessing important safety information on the medical products they use and prescribe.

The new tools will offer timely, science-based and clinically relevant safety information directly to providers and their patients at www.fda.gov/medwatch.

Receive regular updates from the FDA by:

- Subscribing to FDA's MedWatch Listserve notification or RSS news feeds
- Book marking FDA's MedWatch Website safety alert page
- Downloading audio broadcasts (podcasts)

During the past several years, the FDA has worked to provide scientific information utilizing an electronic environment for all of their regulatory activities, including communicating timely safety information to providers and patients. For example:

- In January 2006, the FDA began making updated prescription drug labels available to physicians free of

charge through the National Library of Medicine's DailyMed Web site.

- In March 2007, the FDA hosted a public meeting to explore opportunities for collaborations with private healthcare organizations in order to develop a nationwide electronic network to support rapid access to and analysis of medical product adverse events and to disseminate timely risk communications.

The FDA and its collaborators now face the monumental task of designing a system that integrates information that varies not only in the types of computer programs used and how data are stored but in the very types of information collected.

Many drug and device manufacturers are now turning to electronic methods to disseminate safety information to healthcare professionals in a timely, targeted, and secure manner. The FDA supports the use of electronic methods to disseminate medical product safety information, whether by the industry or through their own resources.

¹ <http://www.fda.gov/medwatch/elist.htm> and <http://www.fda.gov/medwatch/rss.htm>

² <http://www.fda.gov/medwatch/safety.htm>

³ <http://dailymed.nlm.nih.gov>

Ask A Risk Manager

What is your opinion of transferring pregnant patients out of an OB practice?

The American College of Obstetricians and Gynecologists generally encourages the OB to continue treating patients in their second and third trimesters through delivery and post-partum check-up unless very unusual circumstances are described. However, ACOG gives the following recommendations:¹

"What constitutes adequate notice [of termination from the practice] may vary. For gynecologic patients, 30-60 day's notice should be sufficient. Obstetric patients may need more time to find another physician. Physicians should assist their patients in finding other care and provide the name and telephone number of the local medical society so that patients can find other obstetrician-gynecologists in the area or provide the names of other obstetrician-gynecologists. For convenience, the notification can include an authorization form to transfer copies of the patient's records to the physician of her choice. Physicians should retain copies of all correspondence and any authorization forms returned by patients. Only copies of records should be sent, not originals."

¹ "Guidelines for Women's Health Care," 2nd ed., Washington, DC: ACOG; 2002, Liability, pp. 60-61.

Clinical Challenge—Undiagnosed Stroke in a Psychiatric Patient

Clinical Sequence

A long-time psychiatric patient at a community health center presented with a headache, drooling, slurred speech, and stumbling. She was referred to a neurologist at another facility, but did not keep the appointment. Six weeks later, the patient went to the clinic's emergency department, complaining of dysarthria, left-sided weakness, diplopia, and headache. She was seen by a first-year psychiatry resident serving a neurology rotation. He did not have access to previous records, but did document neurological findings similar to her earlier visit to the clinic: abnormal extraocular movements, mild left facial droop, gait disorder and slurred speech. A CAT scan was non-diagnostic. The chief neurology resident examined the patient about two hours later. When he could not reproduce the junior resident's neurological findings, they decided not to order an arteriogram or initiate anticoagulant therapy. Instead they referred her for follow-up to the outpatient psychiatric unit where she underwent another neurological exam.

That examining psychiatrist believed the patient exhibited signs of a classic conversion disorder, the transformation of emotions into physical problems, rather than true neurological symptoms. He also described her in his notes as a "mean, nasty, unpleasant person." The patient requested admission to an inpatient psychiatric unit. When she arrived, physicians at the receiving hospital decided she was not a good candidate for admission and told her to return to the referring hospital. She went home instead.

The next day she was admitted elsewhere with diagnosis of stroke. Her resulting disabilities included memory loss, speech impairment, and partial paralysis.

Claim Sequence and Disposition

The patient brought suit against the two residents, and the

hospital where she was originally seen, for failure to diagnose. The suit was settled in the mid-range (\$100,000-\$499,999) before trial.

Risk Management Discussion Points

- #1 A follow-up call to the patient or neurologist to ensure that she had kept her appointments and that follow-up care was scheduled, may have averted subsequent diagnosis problems. However, the patient had no coordinating physician and the clinic had no system to help with this process. Coordination of care is especially important when care is to be rendered at several different locations.
- #2 Caring for "difficult" or "challenging" patients may be a special liability risk for a number of reasons. In addition, having the patient's record is vital for current providers to assess pertinent history, particularly when the patient is judged to be an unreliable reporter.
- #3 Providers should document new exam findings, especially if these differ from those documented by another provider, and must be addressed. Providers should also document rationale for why a treatment plan is suggested.
- #4 The receiving hospital did not make proper arrangements for the patient's continuing care after it was decided that she was an inappropriate admission to their facility. The patient went home for lack of appropriate referral. When she showed up the next day in another hospital with definitive symptoms of a stroke, previous documentation did not support the decisions to not treat her in a more aggressive manner.

This case was adapted with permission from a case published in the Harvard Risk Management Foundation Forum, March 1998.

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