2023 Noninterpretive Skills

Study Guide

ABR | American Board of Radiology

This study guide is to be used in preparation for all Diagnostic Radiology Qualifying (Core) and Certifying exams administered through calendar year 2023.

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Screening of Patients before Contrast Media Administration

Safe administration of contrast media begins with a focused patient history to identify the factors that may increase the likelihood of an adverse reaction to contrast media.

The likelihood of an allergic-like contrast reaction may be reduced by premedication.

Premedication

Premedication may be considered for patients who are at increased risk of an acute allergic-like reaction to contrast media. The ACR Manual on Contrast Media (2020) suggests consideration of premedication only for patients who have had a prior allergic-like or unknown-type reaction to the same class of contrast media as that to be administered. However, policies vary by site, but it is generally agreed in the United States that premedication is indicated at least in patients who have had a previous moderate or severe allergic-like reaction to the same class of contrast media. Surveys have shown that some, but fewer, institutions administer premedication to patients with a history of a mild allergic-like reaction to the same class of contrast media, to patients with a history of allergies to substances other than contrast media, or to patients with a history of asthma.

The most widely accepted premedication regimens, or "preps," involve the use of oral corticosteroids, with the first dose administered 12 to 13 hours before contrast media injection. One common adult regimen involves oral administration of 50 mg of prednisone 13, 7, and 1 hour(s) before contrast media injection, and oral administration of 50 mg of diphenhydramine (Benadryl®) 1 hour before injection. Another common regimen involves oral administration of 32 mg of methylprednisolone 12 and 2 hours before contrast media injection. While a 12- or 13-hour oral regimen has been proven effective, and a 1- or 2-hour oral regimen has been proven to be ineffective, the precise minimum effective time for premedication is not known.

Premedication can also be administered to children who have had prior allergic-like contrast reactions. One recommended regimen calls for administration of 0.5-0.7 mg/kg of oral prednisone at 13, 7, and 1 hours prior to contrast injection, up to a maximum of 50 mg, with one dose of oral diphenhydramine (Benadryl ®) one hour prior to injection, at a dose of 1 mg/kg, up to a maximum dose of 50 mg.

In some situations, patient health can be seriously jeopardized by having the patient wait 12 or more hours before a contrast-enhanced study. In these situations, "rapid" corticosteroid regimens may be utilized, with the understanding that limited evidence supports this approach. The ACR Manual on Contrast Media (2020) suggests using one of these regimens in inpatients and Emergency Room patients. One of the more commonly used rapid preps consists of intravenous (IV) administration of 200 mg of hydrocortisone every 4 hours until the study is performed, preferably deferring imaging until at least two doses of hydrocortisone have been administered. In this rapid prep, 50 mg of diphenhydramine is also administered 1 hour before contrast media injection. In the rare emergency situation where a contrast-enhanced examination must be performed immediately, the contrast media may have to be administered without premedication.

The only proven benefit of corticosteroid premedication regimens is a reduction in the number of mild reactions. Studies showing the reduction in the number of mild reactions after premedication did not have sufficient numbers

of patients with moderate, severe, or life-threatening reactions to draw statistically significant conclusions about the ability of premedication to reduce those reaction rates. Thus while there is no definite evidence that premedication protects against moderate, severe, or life-threatening reactions, it is typically assumed that there is a positive effect. The rarity of severe reactions makes it difficult to prove a benefit of premedication in this setting.

Premedication likely reduces the risk of a contrast reaction in high-risk patients, but it does not eliminate it. A contrast reaction that occurs despite premedication is called a "breakthrough reaction."

Even with appropriate use of an accepted premedication regimen, breakthrough reactions occur in a small number of high-risk patients. When they do occur, they are of similar severity to the initial reaction about 80% of the time, less severe about 10% of the time, and more severe about 10% of the time.

A patient who has had an allergic-like reaction to contrast media despite steroid premedication can be reinjected in the future after being premedicated again, if clinical circumstances require reinjection. Many such patients will not have a repeat reaction, and if a repeat reaction occurs, it will most likely be of the same severity as the previous breakthrough reaction (e.g., mild subsequent breakthrough reaction if the previous breakthrough reaction was mild).

The greatest risk of corticosteroid premedication to patient health is probably the delay that it causes in the performance of an imaging study (which can delay disease diagnosis, increase cost, and, in inpatients, expose patients to the additional risk of hospital-acquired infections for longer periods of time). For such patients, use of the "rapid" prep has been recommended. While transient hyperglycemia can occur from three doses of corticosteroids, it is usually mild and is rarely clinically significant. Other complications from a short burst of corticosteroids, such as exacerbation of infection and peptic ulcer disease, steroid psychosis, and tumor lysis syndromes, have been reported, but are very rare.

Postcontrast Acute Kidney Injury and Contrast-induced Nephropathy

Postcontrast acute kidney injury (PC-AKI) is a general term used to describe a sudden deterioration in renal function that occurs after the intravascular administration of iodinated contrast media (with clinical onset detectable within 24 to 48 hours as creatinine accumulates in the serum). Such injury may occur whether or not the contrast medium is determined to have caused the deterioration in renal function. PC-AKI is a correlative diagnosis, meaning that AKI can be correlated to, but not proven to be caused by, the administration of IV contrast.

Contrast-induced nephropathy (CIN) is defined as a sudden deterioration in renal function caused by intra- vascular administration of iodinated contrast media. CIN is a subset of PC-AKI, that is, those cases of PC-AKI in which iodinated contrast media is proven or known to be the cause of the AKI; CIN is more of a statistical concept because it is difficult in practice to identify which individual cases of PC-AKI can be proven to be due to the contrast media. For example, if a group of patients who are administered iodinated contrast media have a higher rate of PC-AKI than a properly chosen control group of patients not receiving iodinated contrast media, then the excess rate is due to CIN, but it is not generally not possible to identify which patients have PC-AKI from CIN and which have PC-AKI from causes other than contrast media.

Nearly all papers published on CIN before

2006, and many afterwards, considered all PC-AKI to be CIN. This error has led to substantially inflated estimates of the rate of CIN. It is now known that most PC-AKI is not due to CIN.

CIN was previously believed to be common, because a clear majority of published studies that came to this conclusion did not include control groups of patients who did not receive contrast media. For this reason, distinction between CIN and PC-AKI was not possible in these studies. Additionally, many previous publications studied patients who had undergone arteriography rather than IV contrast media injections. Catheter angiography may be associated with additional risks to the patient that could also affect renal function, including catheter manipulation in the abdominal aorta (i.e., atheroemboli) and exposure of the kidneys to more concentrated contrast media.

With the recent performance of several large propensity-adjusted controlled retrospective studies, it is now understood that true CIN is much less common than previously thought, and if CIN occurs at all, it is most likely to develop in patients who have severe CKD (estimated glomerular filtration rate [eGFR] < 30 mL/min/1.73 m^2) or AKI. CIN occurring in patients with an eGFR of 45 mL/min/1.73 m^2 or higher is very unlikely, and in patients with an eGFR between 30 and 45 mL/min/1.73 m^2, it is questionable. As a result, special precautions for administering intravascular iodinated contrast media are advised only for patients with severe CKD or AKI. Administration of large or multiple doses of contrast media within 24 to 48 hours may also be a risk factor for AKI, although precise risk thresholds are not well defined and likely vary by patient condition, and whether the contrast medium is administered intra-arterially or intravenously.

This dose-toxicity relationship has been consistently shown after coronary arteriography, but has not been conclusively shown for IV administrations.

The historical definition of PC-AKI refers to an absolute increase in serum creatinine from baseline of at least 0.5 mg/dL, or a 25% to 50% increase in the baseline serum creatinine. The Acute Kidney Injury Network (AKIN) has suggested that, regardless of the cause, AKI should be diagnosed whenever there is 1) an absolute serum creatinine increase of at least 0.3 mg/ dL; or 2) a percentage increase in serum creatinine of at least 50% (1.5-fold above baseline); or 3) a reduction in urine output to 0.5 mL/kg/h for at least 6 hours.

The usual clinical course of PC-AKI (including CIN) is a rise in serum creatinine beginning within 24 hours of contrast media administration, peaking at about 4 days and then usually returning to baseline by 7 to 10 days. Most affected patients do not have oliguria. Permanent renal dysfunction is unusual.

In addition to severe renal dysfunction, other previously identified diseases or conditions may predispose patients to develop AKI, but most likely, in and of themselves, they do not specifically predispose patients to develop CIN. These include diabetes mellitus, dehydration, cardiovascular disease, diuretic use, advanced age, multiple myeloma, hypertension, and hyperuricemia.

Although patients with end-stage renal disease who are on chronic hemodialysis could experience additional renal function compromise (resulting in a further decrease in any remaining urine output that might be helpful for managing electrolyte balance), such a risk is theoretical. Many nephrologists agree to inject these patients with intravascular contrast media if a contrast- enhanced study is

necessary. There is also a possibility that such patients, if their fluid status is brittle, could develop fluid overload as a result of the administration of even a relatively small volume of hyperosmolality contrast media.

Because iodinated contrast media have no significant toxicity if retained in the body after injection, there is no requirement that chronic hemodialysis be timed to occur either immediately before or immediately after contrast media administration.

Some nephrologists advocate more caution in administering potential nephrotoxins such as intravascular iodinated contrast to patients on peritoneal dialysis because the urine output of these patients may be more important to their well-being than for patients on chronic hemodialysis.

There is some controversy concerning screening of patients' renal function before contrast media administration if no recent serum creatinine level/eGFR level is available. Suggested indications for obtaining a serum creatinine, from which an eGFR can be determined, have included a history of renal disease (including dialysis, renal transplant, solitary kidney, renal cancer, or renal surgery), hypertension and diabetes mellitus. If a potentially at-risk patient's condition is stable, a creatinine value within 30 days of contrast administration is generally considered sufficient.

In patients with severe CKD or AKI who are considered at increased risk of developing CIN, several prophylactic strategies should be considered. Since most iodinated contrast media are currently administered intravenously for CT scans, alternatives include performing only unenhanced scans or using other modalities such as ultrasound or MR (note that contrast-enhanced MR performed with certain MR contrast media is associated with a risk of nephrogenic systemic fibrosis [NSF] in patients with severe CKD or AKI —see separate section on NSF). When iodinated contrast media administration is deemed necessary in high-risk patients, the lowest possible dose needed to perform a diagnostic study should be used.

The most widely accepted strategy for minimizing the risk of PC-AKI in at-risk patients is IV volume expansion with isotonic fluids, such as 0.9% saline or Lactated Ringer's solution. Some suggested volume expansion protocols have included administration of volumes of 100 mL/h for 6 to 12 hours before contrast administration and continued for 4 to 12 hours after contrast administration. Volume expansion with sodium bicarbonate solution instead of saline or Lactated Ringer's solution has been used, but it is not clear that this solution is any more efficacious.

Several other prophylactic agents have been suggested, but there is no consistent proof that any of these are effective in preventing PC-AKI or CIN. Administration of N-acetylcysteine has been widely studied and is now thought to be of no value. Other agents, such as mannitol, furosemide, theophylline, etc., have been discredited.

It has recently been shown that prophylactic administration of high-dose statins appears to be effective in reducing the risk of PC-AKI after cardiac catheterization.

Metformin

Metformin-containing drugs are prescribed as oral agents of choice for treating many patients with diabetes mellitus. Metformin is contraindicated in patients with severe renal dysfunction because a very small percentage of these patients develop lactic acidosis, leading to a reported 50% mortality rate.

There is no direct interaction between iodinated contrast media and metformin; however, if a patient receiving metformin develops AKI, the

possibility of developing lactic acidosis exists. The American College of Radiology Committee on Drugs and Contrast Media currently recommends that no precautions are necessary in diabetic patients taking metformin, unless the patient has CKD and the eGFR is < 30 mL/min/1.73 m^2 (in which case the patient should not be taking metformin anyway), the patient has AKI, or the patient is undergoing arterial catheterization with the risk of emboli to the renal arteries. In the latter instances, the drug should be withheld for 48 hours after contrast media administration and only reinstituted if the renal function is reassessed and found to be acceptable.

Thus, metformin itself is not a risk factor for the development of CIN, but patients who develop renal failure while taking metformin are at risk of developing lactic acidosis.

Iodinated Contrast Media in Pregnancy

Although iodinated contrast media cross the placenta, there is no evidence that maternal exposure to intravascular iodinated contrast media is harmful to the fetus. Specifically, there is no evidence that fetal exposure to iodinated contrast media increases mutagenesis or fetal cancer risk or affects fetal renal function.

Iodinated Contrast Media in Women Who Are Breastfeeding

Only 1% of maternally administered contrast media enters the milk of breastfeeding mothers and, of this, only 1% of the contrast media in breast milk is absorbed through an infant's gastrointestinal tract.

This represents less than 1% of the recommended infant dose of iodinated contrast media that could be used for a contrast-enhanced imaging study on that infant.

There is no evidence that this tiny amount of absorbed iodinated contrast media has any adverse effect on the infant. Although it is generally accepted that no precautions need to be taken, it is recommended that a lactating mother be informed that studies assessing the risks to an infant are limited. If concerned, the mother can abstain from breastfeeding for 12 to 24 hours after a contrast-enhanced study is performed and pump and discard breast milk that is produced during this time.

Extravasation

Extravasation of IV-administered iodinated contrast media is an occasionally encountered complication of intravascular contrast media administration, usually occurring during CT. The reported overall rate of extravasation with power injection for CT ranges from 0.1% to 1.2%. While extravasations are more likely to occur when poor catheter insertion technique is utilized, they can be encountered even when proper technique is employed.

Patients are believed to be at increased risk for extravasation when more peripheral access sites are used (such as the hand, wrist, foot, and ankle) rather than the antecubital fossa, when utilized indwelling lines have been in place for more than 24 hours (in which case some degree of phlebitis may be present), and when there are multiple punctures into the same vein. Certain risk factors are believed to be associated with an increased volume of extravasated contrast, including inability of the patient to communicate (as is the case with infants, young children, and patients with altered consciousness), severe illness, and debilitation.

Immediately after extravasation of contrast media occurs, most patients complain of swelling or tightness and/or stinging or burning pain at the site of extravasation. Edema, erythema, and tenderness may be found on physical examination. Ninety-eight percent of extravasation injuries resolve with no adverse sequelae. In the remaining 2% of injuries, some

patient morbidity develops because contrast media can damage adjacent tissue, likely due to a combination of direct toxic effects and its hyperosmolality. Adverse effects are usually self-limited, most commonly consisting of prolonged pain or swelling.

Severe extravasation injuries occur in < 1% of patients with extravasations. The most common and most potentially devastating severe injuries after extravasation of nonionic contrast media are compartment syndromes, which result from mechanical compression. Skin ulceration and tissue necrosis are less commonly encountered. Other complications, including lymphedema and reflex sympathetic dystrophy, are extremely rare.

Compartment syndromes are more likely to develop when large volume extravasations occur, especially into smaller compartments such as the hand, wrist, or foot, but even large-volume extravasations most often resolve without any adverse effects. The risk of a severe extravasation injury may also be increased in patients with arterial insufficiency or compromised venous or lymphatic drainage.

Severe symptoms may not be evident immediately after the extravasation occurs. They may develop gradually over time. For this reason, patients should be monitored to assure that minor symptoms remain stable or that minor or more significant symptoms are resolving or improving. When a symptomatically stable or improving patient is discharged from the radiology department, he or she must be given clear instructions concerning what new or recurring symptoms may indicate a severe injury and where and how to seek prompt additional treatment if necessary.

Little can be done to mitigate the effects of contrast extravasations after they occur. Elevation of the affected extremity above the level of the heart is recommended to decrease capillary hydrostatic pressure. This may promote resorption of the extravasated contrast media. Cold compresses or ice packs can be applied to the site of extravasation. Attempted aspiration of the extravasated contrast media and injection of medications into the extravasation site (such as corticosteroids or hyaluronidase) are ineffective.

Surgical consultation should be obtained after an extravasation whenever there is concern for a developing compartment syndrome or for tissue necrosis. Ominous symptoms that indicate the need for prompt surgical consultation include progressive swelling or pain, decreased finger mobility, altered tissue perfusion (manifested by decreased capillary refill), change in sensation, or skin ulceration or blistering. In some instances, it may be difficult to recognize the early signs of a compartment syndrome. Symptoms concerning for severe extravasation injury include worsening pain or failure of existing pain to improve; decreasing arm, wrist, or finger motion; loss of sensation or paresthesia in the affected extremity; and skin breakdown.

In general, however, the earliest and most reliable sign of a severe injury is severe or progressive pain. It should be noted that there is no extravasation volume threshold above which surgical consultation is considered mandatory.

4.2.2 Gadolinium-based Contrast Media (GBCM)

Classification of GBCM

Most contrast agents used for MRI contain gadolinium bound within a chemical moiety called a chelate.

Gadolinium-based contrast media (GBCM) are classified as linear or macrocyclic, and ionic or nonionic. In general, macrocyclic GBCM, in

which the gadolinium ion is surrounded by a chelate ring, have more stable binding of the gadolinium ion within the chelate than do linear agents, in which the chelate is not in the form of a ring. Among the linear agents, the nonionic agents are less stable than the ionic agents. Table 4.1 summarizes the gadolinium-containing contrast agents currently available for use in the United States.

Agent	Ionicity	Linear or macrocyclic
Gadopentetate dimeglumine (Magnevist®)[1]	Ionic	Linear
Gadobenate dimeglumine (MultiHance®)[2]	Ionic	Linear
Gadoxetate disodium (Eovist®)[3]	Ionic	Linear
Gadodiamide (Omniscan®)[1]	Nonionic	Linear
Gadoteridol (ProHance®)[2]	Nonionic	Macrocyclic
Gadobutrol (Gadavist®)[2]	Nonionic	Macrocyclic
Gadoterate meglumine (Dotarem®)[2] (Clariscan®)[2]	Ionic	Macrocyclic

Table 4.1. *Characteristics of approved gadolinium-containing contrast agents.*

[1]Indicates agents that have a higher risk for nephrogenic systemic fibrosis (NSF)
[2]Indicates agents that have a lower risk for nephrogenic systemic fibrosis (NSF)
[3]Indicates agent with limited evidence regarding association with nephrogenic systemic fibrosis (NSF)

Acute adverse reactions to GBCM occur approximately two to four times less frequently than acute adverse reactions to iodinated contrast media. In general, the physiologic and allergic-like reactions that occur after GBCM administration are similar to those that occur after injection of iodinated contrast agents. For this reason, treatment of contrast reactions to GBCM is similar to that of contrast reactions to iodinated contrast media (see separate section on treatment, to follow).

A clear majority of GBCM reactions are mild and non-allergic-like (i.e., physiologic), including coldness at the injection site, nausea with or without vomiting, headache, warmth or pain at the injection site, paresthesias, and dizziness. Rash, hives, and urticaria are the most frequent allergic-like symptoms; however, respiratory and cardiovascular reactions can occur. Fatal contrast reactions have been reported but are exceedingly rare.

A unique physiologic side effect of gadoxetate disodium (Eovist®) is transient tachypnea, which can cause motion artifact on arterial-phase MRI. It is more common with high volume, off-label administrations.

Patients at highest risk for adverse reactions to GBCM are those who have had previous

reactions to these agents (even to different GBCM). Lesser risk factors include other allergies and asthma. A history of a prior allergic-like reaction to iodinated contrast media is not believed to increase the risk of an allergic-like reaction to GBCM above that of other allergies.

Some preventive measures can be considered in patients who have experienced previous adverse reactions to GBCM. This includes using a different gadolinium compound for reinjection. It should be noted that the FDA-approved package insert for one GBCM (gadobenate dimeglumine [MultiHance®]) states that use of this GBCM is specifically contraindicated in patients who have had prior allergic-like contrast reactions to ANY GBCM. Another preventive measure is premedicating patients with corticosteroids and antihistamines (using a regimen identical to that used for prophylaxis of adverse reactions to iodinated contrast media) before injection. The effectiveness of premedication before GBCM has not yet been determined, but premedication is still often performed, based on evidence extrapolated from experience with iodinated contrast media.

GBCM in Pregnancy

GBCM have been classified by the Food and Drug Administration as pregnancy class C drugs (no adequate and well-controlled studies in humans have been performed, although animal reproduction studies have shown an adverse effect on the fetus) and are therefore relatively contraindicated in pregnant patients. These agents pass through the placental barrier and enter the fetal circulation. They are then filtered by the fetal kidneys and excreted into the amniotic fluid, where they may remain for a prolonged period. Prolonged presence of the agent in the amniotic fluid could theoretically increase the risk of dissociation from the chelate of the potentially toxic gadolinium ion (see separate section on nephrogenic systemic fibrosis, to follow). For this reason, GBCM should only be administered to pregnant patients in carefully selected situations in which the benefit is thought to outweigh the potential risk.

GBCM in Women Who Are Breastfeeding

Only tiny amounts (0.04%) of administered GBCM are excreted into the milk of breastfeeding mothers, and only a tiny percentage of this (1%) GBCM is absorbed through an infant's gastrointestinal tract. This is much less than the allowed GBCM dose, when a contrast-enhanced imaging study is needed in an infant. There is no evidence that the tiny amount of absorbed GBCM has any adverse effect on a breastfed infant. Therefore, there is no need for a mother to stop breastfeeding after a GBCM-enhanced study. However, as with the administration of iodinated contrast media, if the mother is concerned, she can stop breastfeeding for 12 to 24 hours after the study, and pump and discard any milk produced during this time.

Nephrogenic Systemic Fibrosis (NSF)

Nephrogenic systemic fibrosis (NSF) is a fibrosing disease most evident in the skin and subcutaneous tissues, but it also may involve other organs, such as the lungs, esophagus, heart, and skeletal muscles. Initial symptoms typically include skin thickening with plaque formation. Symptoms and signs may progress rapidly, with some affected patients developing contractures and joint immobility. Occasionally, the disease may be fatal. There is no known effective treatment.

NSF occurs nearly exclusively in patients with severe CKD (eGFR < 30 mL/min/1.73 m^2) or in patients with AKI who have been exposed to GBCM. Symptom onset can occur from days to

years after GBCM administration. Identification of the GBCM responsible for the precipitation of this disease is sometimes difficult, because many patients have received multiple different MR contrast agents. GBCM agent exposure is considered to be "confounded" in patients with NSF who have been exposed to multiple GBCM; the exposure is considered to be "unconfounded" when a patient with NSF has only been exposed to one agent.

NSF has been encountered almost exclusively after patient exposure to several specific linear GBCM, with the high-risk agents being gadodiamide (Omniscan®), gadoversetamide (OptiMark®, no longer manufactured), and gadopentetate dimeglumine (Magnevist®). Higher doses and multiple doses of the higher risk GBCM are believed to increase the likelihood of NSF, although cases have occurred after only a single administration of a standard dose of GBCM.

Few, if any, cases of unconfounded NSF have been reported with the lower-risk agents, which include gadobenate dimeglumine (MultiHance®), gadobutrol (Gadavist®), gadoterate meglumine (Dotarem® and Clariscan®), and gadoteridol (ProHance®). Gadoxetate disodium (Eovist®) is a newer agent with limited information about its association with NSF; however, the risk of NSF developing after gadoxetate disodium administration is probably very low.

Because most patients with severe CKD who are exposed to NSF-associated GBCM do not develop NSF, other factors are believed to be required for disease development. Additional suggested risk factors for NSF have included metabolic acidosis or medications that predispose patients to acidosis; increased iron, calcium, and/or phosphate levels; high-dose erythropoietin therapy; immunosuppression; vasculopathy; an acute pro-inflammatory event; and infection. Unfortunately, no consistent relationship between these factors and NSF has been identified.

The mechanism of NSF is unknown, although many experts have speculated that it may result from dissociation of the gadolinium ion from its chelate in vivo, with subsequent precipitation of gadolinium in tissue. This mechanism has been suggested because the three high-risk GBCM have lower stability of gadolinium ion binding to the chelate than do most of the nonimplicated GBCM. With high-risk GBCMs, a different ion is thought to be able to replace the gadolinium ion within the chelate more easily, thereby freeing up the toxic gadolinium atom. This replacement process is referred to as transmetallation.

In response to the emergence of NSF, radiologists have instituted a number of precautions that have been effective in nearly eliminating this disease. The most important precaution is avoiding the high-risk GBCM (gadodiamide [Omniscan®], gadoversetamide [OptiMark®], and gadopentetate dimeglumine [Magnevist®]) in any patients requiring contrast- enhanced MRI who might have severe CKD (eGFR < 30 mL/min/1.73 m^2) or AKI. At institutions where high-risk GBCM are used, patients referred for contrast-enhanced MRI should be screened for renal disease (which may include obtaining eGFR levels in any patient with a history of a solitary kidney, kidney transplant, or renal neoplasm; or hypertension or diabetes mellitus). The three high-risk GBCM are absolutely contraindicated by the Food and Drug Administration when the eGFR is less than 30 mL/min/1.73 m^2.

There is no proof that immediate post-MRI dialysis reduces the risk of NSF in any high-risk GBCM- exposed patients.

Gadolinium Retention

Some administered gadolinium remains in the body after GBCM administration. It has long been known that this retention occurs in the skeleton and is greater with linear than macrocyclic agents.

More recently, investigators have found that gadolinium is also retained within the brain (particularly in the globus pallidus and dentate nucleus). This occurs even in patients with normal renal function. The amount of gadolinium accumulation is proportional to the amount of GBCM that a patient has received. It is not clear in what state the gadolinium is retained. As with retention in the bones, retention in the brain is greater with linear than with macrocyclic agents.

There is no evidence of any adverse neurologic effects of this accumulation (even after millions of GBCM administrations throughout the world); however, further study is necessary to determine long-term effects, if any, that gadolinium deposition in the brain may have.

4.2.3 Treatment of Acute Contrast Reactions

When an allergic-like reaction occurs, rapid recognition, patient assessment, and diagnosis are important so that appropriate treatment can be instituted rapidly.

A responding radiologist should assess the patient quickly. A brief discussion with the patient and any present healthcare providers, when possible, should provide the following information: the reason for the imaging study, a description of the patient's current symptoms, and a summary of the patient's health problems and medications. Vital signs should be obtained promptly. IV access should be secured. A pulse oximeter should be available. Oxygen should also be available and, if administered, should be given at high doses.

The examining radiologist should quickly determine the level of patient consciousness, the appearance of the skin, the quality of phonation, and the presence or absence of respiratory and cardiovascular symptoms.

Mild reactions usually resolve within 20 to 30 minutes and do not require medical treatment; however, some patients with moderate and severe reactions may initially develop only mild symptoms. For this reason, all patients should be monitored until their symptoms have improved.

The management of a contrast reaction depends on the nature of the reaction and its severity. Treatments recommended in the *ACR Manual on Contrast Media* (2020) for different types of reactions in adults are condensed and summarized below.

Hives (Urticaria)

- No treatment is needed in most cases.
- If symptomatic, administer diphenhydramine (Benadryl®), 25 to 50 mg orally (PO), intra- muscularly (IM), or intravenously (IV). Alternatively, use fexofenadine (Allegra®), 180 mg PO.

Diffuse Erythema

- Preserve IV access, monitor vitals, and use a pulse oximeter.
- Give O_2, 6 to 10 L/min (via mask).
- If the patient is normotensive, no further treatment is usually needed; note that antihistamines should be administered with caution, as they may exacerbate existing or developing hypotension.
- If the patient is hypotensive, give 1 L of IV fluids rapidly, either 0.9% normal saline or Lactated Ringer's solution.
- If hypotension is profound or does not respond to IV fluids, consider

epinephrine IV (1 mg/ 10 mL) (1:10,000), 1 mL (0.1 mg) slowly into a running infusion of IV fluids. Repeat as needed at 5- to 10-minute intervals up to 10 mL total. In the absence of IV access, consider epinephrine IM (1 mg/mL) (1:1000), 0.3 mL (0.3 mg), or IM EpiPen or equivalent (0.3 mL, 1:1000 dilution fixed). IM epinephrine may be repeated up to 1 mg total.

- Consider calling an emergency response team or 911 based on the severity of the reaction and the completeness of patient response to treatment.

Laryngeal Edema

- Preserve IV access, monitor vitals, and use a pulse oximeter.
- Give O_2, 6 to 10 L/min (via mask).
- Give epinephrine IM (1:1000), 0.3 mL (0.3 mg), or IM EpiPen or equivalent (0.3 mL, 1:1000 dilution fixed), or, especially if hypotensive, epinephrine IV (1:10,000), 1 mL (0.1 mg) slowly into a running infusion of IV fluids.
- Repeat epinephrine as needed up to a maximum of 1 mg.
- Consider calling an emergency response team or 911 based on the severity of the reaction and the completeness of patient response to treatment

Bronchospasm

- Preserve IV access, monitor vitals, and use a pulse oximeter.
- Give O_2, 6 to 10 L/min (via mask).
- Give beta-agonist inhaler albuterol, 2 puffs (90 mcg per puff); can repeat up to three times. In cases in which bronchospasm is severe and/or unresponsive to an inhaler, consider adding epinephrine IM (1 mg/mL) (1:1000), 0.3 mL (0.3 mg), or IM EpiPen or equivalent (0.3 mL, 1 mg /mL 1:1000 dilution fixed), or epinephrine IV (1 mg/10 mL) (1:10,000), 1 mL (0.1 mg) slowly into a running infusion of IV fluids.
- Repeat epinephrine as needed up to a maximum of 1 mg.
- Consider calling an emergency response team or 911 based on the completeness of patient response to treatment.

Hypotension, Any Cause (systolic blood pressure < 90 mm Hg)

- Preserve IV access, monitor vitals, and use a pulse oximeter.
- Elevate legs at least 60 degrees (Trendelenburg position).
- Give O_2, 6 to 10 L/min (via mask).
- Consider rapid administration of 1 L of IV fluids, 0.9% normal saline or Lactated Ringer's solution.

Hypotension with Bradycardia (pulse < 60 bpm) (Vagal Reaction)

- If mild, no additional treatment is usually needed beyond that listed above for any cause of hypotension.
- If severe (patient remains unresponsive to above measures), give atropine, 0.6 to 1.0 mg IV, into a running infusion of IV fluids. (Note: lower doses of atropine may exacerbate bradycardia.)
- May repeat atropine up to a total dose of 3 mg.
- Consider calling an emergency response team or 911.

Hypotension with Tachycardia (pulse > 100 bpm) (Allergic-like Reaction)

- If hypotension persists after the basic treatment listed above for any cause of hypotension, give epinephrine IV (1 mg/10 mL) (1:10,000), 1 mL (0.1 mg) slowly into a running infusion of IV fluids. Can repeat as needed up to 10 mL (1 mg) total. Alternately, IM epinephrine (1 mg/mL) (1:1000) could be given, 0.3 mL (0.3 mg), or IM EpiPen or equivalent (0.3 mL, 1 mg/mL 1:1000 dilution fixed). IM epinephrine may be repeated up to 1 mg total.
- Consider calling an emergency response team or 911 based on the severity of the reaction and the completeness of patient response to treatment.

Unresponsive and Pulseless

- Check for responsiveness.
- Activate emergency response team or call 911.
- Perform CPR per American Heart Association protocols.
- Defibrillate as indicated if equipment is available.
- May administer epinephrine IV 1 mg/10 mL) (1:10,000), 10 mL (1 mg), between 2-minute cycles of CPR.

Reaction Rebound Prevention

- IV corticosteroids are not useful in acute treatment of any reaction.
- However, IV corticosteroids help prevent a short- term recurrence of an allergic-like reaction and may be considered for a patient having a severe allergic-like reaction before transportation to the emergency department.
- Give hydrocortisone, 5 mg/kg IV over 1 to 2 minutes ,or methylprednisolone, 1 mg/kg IV over 1 to 2 minutes.

Hypertensive crisis, pulmonary edema, seizures or convulsions, and hypoglycemia are uncommon reactions. If these occur, the radiologist should refer to standard treatment sources, including the *ACR Manual on Contrast Media.*

Pediatric Dosing

Pediatric dosing for some of the interventions/medications utilized for treating allergic-like contrast reactions are provided as follows:

- Isotonic fluid: 10-20 mL/kg of 0.9% normal saline or Lactated Ringers up to a maximum volume of 500-1,000 mL
- Diphenhydramine (Benadryl ®): 1 mg/kg up to a maximum of 50 mg
- Beta agonist inhaler (Albuterol ®): 2 puffs (90 mcg/puff) for a total of 180 mcg; can repeat up to three times
- Epinephrine:
  - IM dosing: (up to 30 kg): epinephrine autoinjector (EpiPen Jr®) single dose of (0.15 mg)
  - IM dosing: (over 30 kg patient weight): use adult autoinjector; or 0.01 mL/kg (0.01 mg/kg) of 1 mg/mL or 1:1000 dilution (maximum single dose of 0.3 mL [0.3 mg]); repeated every 5-15 minutes needed up to a maximum dose of 1 mg (1 mL)
  - IV dosing: 0.1 mL/kg (0.01 mg/kg) of 1 mg/10 mL or 1:10,000

dilution (maximum single dose of 1 mL [0.1 mg]), repeated every 5 – 15 minutes, as needed up to a maximum dose of 1 mg (10 mL)

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Chapter 5: Reimbursement, Regulatory Compliance, and Legal Considerations in Radiology

5.1 Reimbursement and Regulatory Compliance

5.1.1 Coding, Billing, and Reimbursement

Appropriate reimbursement for healthcare services involves a series of complex and interconnected steps that often vary depending on the payer. A number of generalizable principles based on Medicare rules should guide best practice efforts to optimize revenue and compliance activities. These principles of reimbursement are also important to understand as they often serve as the basis for how third-party payors structure their reimbursement. Traditionally, physician services and procedures are reimbursed on a fee-for-service basis. Although this fee-for-service system of reimbursement forms the basis for physician reimbursement today, it is important to recognize that especially with primary care models, there is a clear shift away from a volume-based form of reimbursement (i.e., fee-for -service) towards more value-based payments requiring attainment of certain quality measures.

Each service or procedure that a physician provides is given a unique code called a Current Procedural Terminology code (CPT) that in turn is assigned a specific reimbursement amount. The first step in obtaining reimbursement for a new service or procedure is to have it assigned a unique CPT code. The American Medical Association (AMA) CPT Editorial Panel, is responsible for maintaining the CPT code set, including authorizing new codes, modification of existing codes, and deletion of codes no longer relevant. The CPT Editorial Panel is composed of physicians nominated by national medical societies, CMS, and other industry leaders. A separate committee, the AMA CPT Advisory Committee, assists the CPT Editorial Panel by making recommendations regarding new codes and existing codes. The CPT Advisory Committee is composed of representatives nominated by national medical societies. For example, national radiology societies designate representatives to serve on the CPT Advisory Committee who then advocate for radiologists by making recommendations for new or existing radiology CPT codes.

Each CPT code is assigned a value called the Relative Value Unit (RVU) based on the Resource Based Relative Value Scale. This value is relative in that each value reflects its relative value compared to other services or procedures within the specialty as well other medical specialties. The AMA RBRVS Update Committee (also known as "The RUC"), makes recommendations to CMS for RVU valuation for each CPT code, and is predominantly composed of physicians representing various medical societies. The AMA RUC Advisory Committee, supports the RUC by making recommendations just as the CPT Advisory Committee supports the CPT Editorial Panel. National medical societies can nominate representatives to the RUC Advisory Committee who then advocate for their membership by recommending specific RVU valuations to the RUC, which in turn makes its final recommendations to CMS.

Each service or procedure's total RVUs reflect the amount of 1) encounter time, intensity,

effort, and skill (the work RVU); 2) costs of maintaining a practice, such as equipment, supplies, and nonphysician staff (practice expense RVU); and 3) professional liability expenses (malpractice RVU). Work RVU is used by many practices to track physician productivity. Although the Centers for Medicare and Medicaid Services (CMS) ultimately sets the valuation of RVUs, it has historically accepted the AMA RUC recommendations in the vast majority of cases.

Once an RVU is determined for a specific service or procedure designated by its CPT code, a multiplier called the Conversion Factor (CF) is used to determine the actual reimbursement. Thus, to obtain the actual reimbursement for a specific procedure, the RVU for that procedure is multiplied by the CF.

Payment = RVU x CF

The conversion factor is set annually by CMS in Final Rule of the Medicare Physician fee schedule. For example, the CF for 2020 was set by CMS at $36.09 and in 2021 this fell to $34.89.

CMS and private insurers generally pay only for services deemed medically necessary. CMS defines medical necessity as "healthcare services or supplies needed to prevent, diagnose, or treat an illness, injury, condition, disease, or its symptoms and that meet accepted standards of medicine." In practicality, the determination of medical necessity is usually a rules- based administrative exercise performed at the time a claim is submitted to a payer, wherein a CPT service code must match a pre-approved diagnosis code list. Those diagnosis codes must be in the form of the *International Classification of Diseases* (ICD) system, established by the World Health Organization, currently in its 10th revision (ICD-10). ICD-10 codes describe the signs, symptoms, or specific diagnosis of a patient that form the indication for a healthcare service. Terms such as "rule out" or "consistent with" are not capable of being coded by ICD-10, and therefore do not meet medical necessity criteria.

Reimbursement for radiology services is largely predicated on the adequacy of documentation within the physician report. Professional coders, assisted by software tools, extract information from radiology reports to assign both ICD-10 and CPT codes. The Radiology Coding Certification Board is the primary organization that credentials professional medical imaging coders. These individuals extract ICD-10 information from radiology reports using any statements 1) about examination indication and clinical history provided by the referring physician or patient and 2) from any specific diagnostic information located in the findings section or (preferably) in the impression section of the radiologist's report. CPT codes are assigned based on the specific details of the described service. For radiography, more views generally translate to higher complexity codes. For ultrasound, organ inventory "checklists" apply to abdominal, pelvic, obstetrical, and extremity imaging. For CT and MRI, details of contrast administration (i.e., without, with, or without and with contrast) determine the CPT code for a specific body part. Structured template reporting helps radiologists comply with many of these reporting requirements, facilitating appropriate reimbursement and regulatory compliance.

Many private payers, Medicaid plans, and Medicare Advantage (i.e., not traditional Medicare indemnity) payers contract with radiology benefit management (RBM) companies, and require preauthorization (also known as precertification) as a condition for reimbursement for any elective outpatient advanced imaging service. Before performing advanced imaging services such as CT, MRI,

and PET/CT, radiology facilities should determine whether preauthorization is required for a particular service for a particular patient and, if so, whether such preauthorization has been obtained. Although a necessary condition for payment, preauthorization by an outsourced RBM does not always guarantee a subsequent favorable medical necessity determination by the insurer itself when a claim is filed. As a general rule, preauthorization requirements do not apply to emergency department and inpatient services.

The consultation of software for imaging Clinical Decision Support software (CDS) is technically required for all Medicare outpatient and certain ED patients when ordering advanced imaging tests (CT, MRI, and Nuclear Medicine), although payment consequences have not yet been defined. This software further scores appropriateness of imaging orders in 8 clinical priority conditions; Coronary artery disease (suspected or diagnosed), Suspected pulmonary embolism, Headache (traumatic and nontraumatic), Hip pain, Low back pain, Shoulder pain (including suspected rotator cuff injury), cancer of the lung (primary or metastatic, suspected or diagnosed) and cervical or neck pain. These initial 8 clinical priority conditions were designated by the CMS in 2016 with scores now being transmitted on provider claims. The list is likely to grow in future years after the initial operations testing period. These software systems are to use appropriate imaging recommendations from Qualified Provider Led Entities (QPLEs) which include national medical societies. The intent is to guide ordering physicians to the most appropriate studies for their patients, and this approach is being attempted by CMS as an alternative to the pre-authorization process.

The False Claims Act (FCA) protects the government from being overcharged or sold substandard goods or services. A false claim is generally defined as a request for payment for services that a provider knew or should have known was false or fraudulent. While the U.S. Department of Justice does not expect physicians to be experts in all of these nuanced matters, it has set an expectation that radiology practice processes, structures, and cultures be oriented toward optimizing the integrity of revenue cycle operations. Best practice techniques call for formal compliance plans, with a formally designated compliance officer and compliance committee appropriately empowered to oversee these activities. A false claim ruling can result in fines of up to three times the billed amount plus $11,000 *per claim filed*, because each single exam or service billed to Medicare or Medicaid counts as a claim. In 2014, the largest radiology practice settlement occurred for $15.5 Million based upon allegations at a diagnostic testing facility that it falsely billed federal and state health care programs for tests that were not performed or not medically necessary and paid kickbacks to physicians. Multi-million dollar settlements occur almost annually with $5 million being paid in 2020 to resolve allegations of unsupervised radiology services and services provided at unaccredited facilities.

5.1.2 Patient Privacy and HIPAA

Respect for patient privacy is a core responsibility of a medical professional. The Privacy and the Security rules of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) represent a codification of this principle in the law. They provide a set of national privacy standards and bring with them the power of law. As such, compliance activities must prioritize patient privacy. HIPAA rules apply to healthcare providers, plans, and clearinghouses alike.

The Privacy Rule establishes national standards for the protection of individually identifiable health information, referred to as protected health information (PHI). The Security Rule establishes a national set of security standards for securing PHI when held or transferred in electronic form. It operationalizes the protections contained in the Privacy Rule by addressing both technical and nontechnical safeguards that organizations must put in place to secure individuals' electronic PHI (e-PHI). Within the U.S. Department of Health and Human Services, the Office for Civil Rights (OCR) has responsibility for enforcing these rules with civil money penalties.

The major goals of the HIPAA rules are to assure appropriate protection of each individual's PHI while still permitting the flow of information necessary to provide and promote quality healthcare. The following identifiers are included in the definition of PHI: 1) names; 2) geographic subdivisions smaller than a state (except for the first three digits of a ZIP code representing a population greater than 20,000); 3) all elements of dates (except year) related to an individual, such as birthdate, admission date, discharge date, and date of death; 4) phone numbers; 5) fax numbers; 6) email addresses; 7) Social Security numbers; 8) medical record numbers; 9) health plan beneficiary numbers; 10) account numbers; 11) certificate and license numbers; 12) vehicle identification and license plate numbers; 13) device identifiers and serial numbers; webpage universal resource locators (URLs); Internet Protocol (IP) addresses; 16) biometric identifiers such as finger- and voice-prints; 17) full face or similar photographs; and 18) any other unique identifier, characteristic, or code.

As a general rule, an individual's PHI cannot be disclosed or transmitted to anyone other than the individual without that individual's authorization. Exceptions include information disclosed or transmitted when necessary for 1) the delivery of care or treatment, 2) payment activities, and 3) healthcare operations involving quality or competency assurance, fraud or abuse detection, or compliance. In addition, when required by law, information can be released 1) to public health authorities, 2) during investigation of abuse, neglect, or domestic violence, 3) to oversight agencies, 4) for judicial and administrative proceeding, 5) for law enforcement purposes, and 6) for worker's compensation.

5.1.3 Human Subjects Research

Properly controlled biomedical research involving human subjects is essential to advancing medical knowledge and care. Unfortunately, human cruelty has occasionally been perpetrated in the name of research, and not all human studies have been either justifiable or useful. The discoveries of such abuses during Nazi Germany were the basis for the development of the Nuremberg Code, which represented the first international codification of minimal expectations for the conduct of ethical research involving human subjects. The Code's most important principles were that experiments involving human subjects should occur only with subjects who have freely chosen to participate, and in the context of a clear scientific rationale. The subsequent Declaration of Helsinki, now widely regarded as the cornerstone of human research ethics, has recommended that all research protocols be reviewed by an independent committee prior to initiation.

That recommendation led to the development of the Institutional Review Board (IRB) system currently in place in the United States, wherein appropriately constituted groups, usually at the university or health system level, are formally designated to review and monitor biomedical

research involving human subjects. In accordance with Food and Drug Administration (FDA) regulations, an IRB has the authority to approve, require modifications in order to secure approval, or deny approval for proposed research protocols. These review groups serve important roles in the protection of the rights and welfare of human research subjects.

IRBs are required to ensure a "diversity of members, including consideration of race, gender, cultural backgrounds, and sensitivity to such issues as "community attitudes" and to register with the Department of Health and Human Services (HHS). Institutions engaged in research involving human subjects usually have their own IRBs to oversee research conducted within the institution or by its staff. However, institutions without an IRB are permitted to arrange for an outside IRB to assume oversight responsibilities.

Because the free choice of research subject participation is a fundamental prerequisite to ethical research, an IRB carefully scrutinizes all aspects of consent. The research informed consent process involves 1) providing adequate information about a study to potential subjects, 2) providing an adequate opportunity for subjects to consider all options, 3) responding adequately to all subject questions, 4) ensuring that the subject comprehends all necessary information, 5) obtaining the subject's voluntary agreement to participate, and 6) providing ongoing information as the subject or situation so requires. In some situations (such as many studies involving the retrospective review of imaging), an IRB may waive the requirement for informed consent when the research involves no more than minimal risks to participants, and cannot be practically carried out without such a waiver. IRBs typically provide an exemption from formal protocol review when a project constitutes a quality improvement activity, as long as the primary objective is to improve local practice rather than to create generalizable knowledge. IRB approval is not required for studies that do not meet federal definitions of human subjects research (e.g., studies that utilize open source public datasets).

5.2 Malpractice and Risk Management

5.2.1 General Principles of Malpractice

Malpractice fears have been cited as a cause of physician burnout and distress, including in radiology.

Approximately 7% of all radiologists are named in a medical malpractice lawsuit each year; radiology indemnity payments in malpractice cases average approximately $480,000. The average radiologist spends approximately 19 months of his or her career with an unresolved open malpractice claim. Malpractice concerns have also been identified as a cause of overutilization of services; more than 90% of physicians report that they at least sometimes engage in the practice of defensive medicine.

Malpractice insurance coverage is usually mandated as a condition of state licensure and hospital credentialing. "Claims-made" policies are the most common types of policies and protect physicians from personal financial liability, up to a predetermined policy cap, but only while the policy is in effect. Physicians with claims- made policies thus usually need to arrange for tail insurance when changing jobs or retiring to ensure continued financial protection. "Occurrence" policies cover any claim for an event that took place during the period of coverage, even if a claim is filed after the policy lapses.

Medical malpractice lawsuits are based on the tort of negligence, and require four elements:

1. The physician must have an *established duty* to a patient. For example, duty would exist for a radiologist to provide treatment for a patient undergoing a contrast reaction in the radiology department but not for interpreting the contents of a CT scan on a CD in a patient's purse in her ICU room unless those images were submitted for formal review under established hospital policy.
2. There must have been a *breach of duty*, which usually involves a failure to meet the standard of care. The definition of standard of care varies by jurisdiction, but is generally how a reasonable, prudent, or ordinary physician of a similar specialty would have acted in similar circumstances.
3. *Causation* must exist, in that the breach must have been the proximate cause of injuries. A radiologist, for example, may have negligently missed a lung mass on a chest radiograph, but establishing that as the proximate cause of a hemorrhagic stroke the next day would be difficult.
4. The negligence must result in *damages*. In many jurisdictions, emotional distress, pain, and suffering are frequently considered remunerative damages.

Claims of negligence against radiologists generally fall into 3 categories: 1) diagnostic errors, 2) procedural complications, and 3) communication deficiencies.

5.2.2 Malpractice Related to Diagnostic Errors

The most common cause of malpractice lawsuits against radiologists is for alleged errors in diagnosis. Depending on the clinical indication and modality, the sensitivity of imaging in detecting disease is highly variable, and plaintiff lawyers frequently contend that any false negative interpretation represents medical negligence. In considering a chest radiograph with missed lung cancer, for example, as many as 90% of cancers are identifiable in retrospect; a radiologist's potential legal exposure is not insignificant. Hindsight bias represents the tendency for people with a knowledge of the actual outcome of a case to believe falsely that they would have predicted its outcome. This jury bias makes defending such cases difficult.

Negligent diagnosis claims can be categorized as related to 1) failures of perception (i.e., not identifying a finding), 2) failures of interpretation (i.e., identifying a finding but not appropriately appreciating or adequately communicating its significance), or 3) combinations of both. Diagnostic errors can also be categorized as 1) cognitive errors (e.g., not identifying a lung nodule when interpreting a chest radiograph), which are usually errors of visual perception (scanning, recognition, and interpretation), or 2) system errors (e.g., failure to adequately communicate the presence of that nodule), which are usually attributed to health system issues or context of care delivery problems.

As in other medical disciplines, errors in diagnosis in radiology often result from a combination or interaction between cognitive and system errors, such as preliminary reports by residents that are revised in a final report but not fully communicated to care teams. Certain system factors, such as lighting conditions, shift length, or pace of interpretation, have been shown to increase the likelihood of diagnostic errors. Enhanced awareness of these types of errors helps

radiologists identify areas of diagnostic vulnerability and institute interventions to improve patient care and mitigate their own potential risks.

5.2.3 Malpractice Related to Procedural Complications

Any invasive procedure has a risk of complication. Such complications vary in type and severity based on the procedure, and can similarly serve as the grounds for medical negligence claims. Despite what some plaintiff lawyers might contend, complications by themselves do not indicate negligence. Lawsuits based on procedural complications, however, are more successfully argued in scenarios in which a radiologist did not exercise appropriate care in 1) minimizing the risk of the complication, 2) identifying complication once it occurred, or 3) treating the complication. In the instance of the very common complication of pneumothorax after a lung biopsy, for example, a radiologist's malpractice risk would increase if he or she 1) used an overly large needle or chose a trajectory unnecessarily crossing an aerated lung, 2) did not obtain a postprocedural chest radiograph, or 3) discharged the patient to home in the setting of an enlarging pneumothorax.

Patients and their families are more likely to sue physicians for damages related to complications if they believe that details of their care were withheld. As a result, most risk managers advocate full and prompt disclosure of any untoward events, and ongoing communication about decision-making and treatment. Detailed and contemporaneous documentation of events, discussions, and rationale for decisions in the radiology report and/or elsewhere in the medical record may prove helpful in court.

Engaging patients (and their families, when appropriate) in decision-making before a procedure also helps set realistic expectations. The doctrine of informed consent has been codified in the U.S. courts as a basic right of self-determination: "Any human being of adult years and sound mind has a right to determine what shall be done with his body; and a surgeon who performs an operation without his patient's consent commits an assault." Courts have subsequently expanded that decision to apply to procedures other than open operations and those performed by nonsurgeon physicians. Necessary elements of informed consent are described in Section 3.2.1 of this study guide. Although most hospitals have standard consent forms in place, additional detailed documentation in procedure reports may prove helpful in a claim of negligence.

5.2.4 Malpractice Related to Communications Deficiencies

Appropriate communication of actionable information from radiologists to clinical caregivers is a critical component of patient care. Both courts and regulatory agencies are increasingly holding radiologists to higher standards of ensuring prompt communication of diagnostic information. In fact, a number of court decisions have focused not only on a radiologist's duty to communicate important or critical findings with referring physicians, but also on communications with patients themselves when their treating physicians may not be available.

Routine Communication

In radiology, routine communication refers to the creation and delivery of written reports. The ACR Practice Parameter for Communication of Diagnostic Imaging Findings outlines suggested formatting for reports, which includes relevant demographic information (e.g., patient name and identifying information, referring physician, facility information), examination details (e.g., type and time of

examination including contrast administration information, time of dictation), and report content recommendations (e.g., findings, impressions, limitations, complications). It is acceptable for demographic information and examination details to be contained in the metadata associated with the report (rather than in the dictated report body itself). Radiology reports are now typically generated and transmitted electronically.

The final report represents the definitive documentation of the results of an imaging examination or procedure. It should be proofread to minimize typographical errors and confusing or conflicting statements. The use of abbreviations or acronyms should be limited to avoid ambiguity. The final report should be completed in accordance with all appropriate state and federal requirements (e.g., Mammography Quality Standards Act). A copy of the final report should be archived by the imaging facility as part of the patient's medical record and be retrievable for future reference. Retention and distribution must be in accordance with all state and federal regulations and facility policies.

Nonroutine Communication

While routine communication is typically carried out through institutionally established final reporting mechanisms, certain circumstances dictate alternative communication mechanisms to ensure timely receipt of important diagnostic information. These include situations warranting preliminary reports and results of an urgent or other significantly important nature.

Occasionally, a preliminary report is issued before the final report, and may be rendered for the purpose of directing immediate patient management (e.g., when old comparison images are not yet available but reporting cannot wait) or to meet the needs of a particular practice environment (e.g., by a trainee in a teaching institution or by a general practice radiologist when a subspecialist radiologist is not immediately available). Such preliminary communications should be archived, since they may have served as the basis of immediate clinical decisions. Institutions are expected to maintain policies for reconciling discrepancies between preliminary and final reports and for discrepancies encountered upon subsequent review of a final report. Any clinically significant variation in findings or impression between a preliminary and final interpretation should be clearly documented and reported as soon as possible and in a manner that ensures receipt by the ordering or treating physician.

Clinical situations that may warrant nonroutine communication include the following:

1. **Findings that warrant immediate or urgent intervention**. These are generally new or unexpected findings on an imaging study that suggest life-threatening conditions or those that may require an immediate change in patient management. Aside from risk management imperatives, The Joint Commission (TJC) requires that professionals "report critical results of tests and diagnostic procedures on a timely basis." TJC-accredited facilities are required to define critical tests and critical results and monitor performance in reporting those results. A critical result is defined as "any result or finding that may be considered life threatening or that could result in severe morbidity and require urgent or emergent clinical attention." Examples include tension pneumothorax, ruptured aortic aneurysm, acute intracerebral hemorrhage, and pneumoperitoneum. Each facility has leeway in defining its own critical tests and critical results; there is no standard list for either category. For all critical results,

communication requires direct contact between the radiologist and the requesting or responding clinician or another licensed healthcare provider responsible for that patient's care. In addition, communication is generally expected to occur within 60 minutes of the time that the observation is made, and it must be documented. When the ordering physician or healthcare provider cannot be contacted expeditiously, it may be appropriate to convey results directly to the patient, depending on the nature of the findings. At some institutions, these critical results are deemed "Level 1 results."

2. **Findings that may not require immediate attention but nonetheless may seriously impact a patient's health, worsen over time, or result in an adverse outcome.** These include the following: 1) New or unexpected findings that could result in mortality or significant morbidity if not treated in a timely manner. Referred to as "Level 2 results" by some institutions, these are less dire than critical results and generally warrant communication within 12 hours. For such findings, the radiologist might call the care team directly, or might request a call service or assistant to call on his or her behalf. Examples include intra-abdominal abscess or impending pathological hip fracture. 2) New or unexpected findings on an imaging study that could result in significant but not immediate morbidity if not appropriately treated. Deemed "Level 3 results" by some institutions, communication is not particularly time sensitive but mechanisms must be in place to ensure that these important or potentially important findings are not overlooked. Examples include a newly identified lung nodule or solid renal mass. These findings may be reported electronically when electronic messaging tracking mechanisms are in place to make sure that information was successfully received and, when necessary, supplemented by telephone confirmation.

Documentation of all nonroutine communication should include the date and time of the communication, the person reporting the information, the person receiving the information, and a summary of or reference to the information that was conveyed.

Informal Communication

Radiologists may occasionally be asked to provide interpretations that do not result in a formal report but are nonetheless used to make treatment decisions.

Such communications may take the form of a "curbside consult" that may occur informally in the reading room or during a clinical conference. These circumstances often preclude immediate documentation and may also occur in suboptimal viewing conditions (e.g., no comparison studies, no original reports, or inadequate incomplete history). Informal communications carry additional inherent risk since the documentation of the clinician initiating the informal consultation may constitute the only written record of that communication. For these reasons, informal communications are largely discouraged; when such communications do occur, radiologists should document them independently from the referring clinician's documentation.

Radiology departments are encouraged to establish processes and policies for reporting studies performed at outside institutions. Radiologists who provide consultations of this nature are encouraged to document any information conveyed, including formal interpretations. Although formal second opinion interpretations are historically non-

payable, Medicare and private payers are increasingly reimbursing radiologists for them when they are medically necessary and are billed in accordance with payer rules.

5.2.5 Discoverability of Communications

In malpractice lawsuits, most communication related to any part of the case—whether written or oral—is considered discoverable and can be used as evidence at trial. However, certain important exceptions apply. The attorney–client privilege is one of the oldest recognized privileges for confidential communications. It encourages clients in all legal matters (not just malpractice cases) to make full and frank disclosures to their attorneys, who should then be better able to provide candid advice and effective representation. Nearly all communication between a client and his or her attorney is protected from discovery. For this reason, physicians involved in lawsuits are strongly discouraged from speaking with any parties other than their attorneys about any elements of their cases.

Most jurisdictions also protect certain peer review activities from legal discovery. Peer review protection laws are designed to provide an incentive for healthcare providers to perform ongoing quality improvement activities without fear of increased tort risk. As a general rule, no person who participates in any approved peer review process shall be permitted or required to testify in any civil action as to the findings, recommendations, evaluations, opinions, or other actions of the peer review process. However, communications are only protected if they occur within established peer review processes; informal conversations with colleagues outside established peer review processes, for example, are typically not protected from legal discovery.

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Chapter 6: Core Concepts of Imaging Informatics

6.1 Standards

DICOM

The Digital Imaging and Communications in Medicine (DICOM) standard (http://dicom.nema.org) is the international standard that specifies protocols for display, transfer, storage, and processing of medical images. The DICOM standard applies to storage of both pixel-based image data and metadata. The metadata, located in the "DICOM header" of the image, contains information about the image, series, exam, patient, imaging facility, and scanner. The data are organized into separate fields, each of which has a unique identifier so that it can be queried directly. DICOM transactions enable data to be queried, retrieved, and transmitted between systems in an organized fashion. They also allow for information about an order to be transmitted between the radiology information system (RIS) and the modality (e.g., the CT, MR, or ultrasound machine) rather than having to be manually entered by the technologist and risking incorrect data entry.

Standard DICOM data elements are required to contain specific information while private data elements can be defined by the vendor. To enable interoperability between systems, vendors who implement products that use DICOM are expected to provide customers with conformance statements that detail their use of the DICOM standard.

HL7

HL7 (http://www.hl7.org) is the international standards organization responsible for developing and maintaining standards for the exchange, integration, sharing, and retrieval of medical information (i.e., nonimage data). The primary HL7 standards are the ones most frequently used to achieve systems interoperability.

The HL7 V2 messaging standard is generally considered to be the most widely implemented healthcare-related standard in the world. This text- based standard facilitates the exchange of medical data by enabling interoperability between many types of electronic medical systems that need to communicate. HL7 V3, while more human-readable, has been less widely adopted in the industry because of its increased complexity. The newer HL7 Fast Healthcare Interoperability Resources (FHIR®) standard allows software developers to use internet transactions to exchange medical data between systems, increasing the potential for data exchange between systems.

Ontologies

Ontologies are formal collections of terms and their inherited or causal relationships. RadLex (http://www. radlex.org) is the largest radiology-specific lexicon. It contains more than 68,000 terms that describe imaging anatomy, procedures, and pathology. A special portion of the RadLex ontology, the RadLex Playbook, defines standard imaging exam names, descriptions, and codes. The RadLex Playbook has been merged with LOINC (Logical Observation Identifiers Names and Codes), the international standard nomenclature for health measurements, observations, and documents.

6.2 The Reading Room Environment

PACS

The PACS (picture archiving and communications system) is the radiologist's

primary tool for imaging viewing and interpretation. Basic components of PACS include a workstation, display, short-term storage, and long-term archive. PACS communicates with imaging modalities using DICOM transactions, and with the RIS and/or EMR using HL7 transactions that are translated to and from DICOM. Unlike original PACS implementations that required a physical workstation to run, the modern PACS can be entirely web-based and accessible on mobile devices as well as on desktop thin clients.

VNA

The development of the vendor-neutral archive (VNA) allows data to be stored in a central archive that may support viewers for multiple types of DICOM images (e.g., radiology, cardiology, operating room, etc.), as well as for non-DICOM data, including photographs and pathology slides. Enterprise imaging relies heavily on VNA technology to facilitate dissemination, viewing, and storage of medical imaging data beyond radiology. Determining how best to format and exchange the metadata (e.g., patient information, body part, date of acquisition, etc.) accompanying a non-DICOM image is a major challenge in enterprise imaging.

RIS

The radiology information system (RIS) is a software application that manages all aspects of an imaging exam, including order reconciliation, patient scheduling and tracking, communication with modalities and PACS, reporting, results notification, and billing. The RIS may be a standalone application or a component of the electronic medical record (EMR) application. Both PACS and RIS can be used to drive clinical workflow.

Image Displays

The ACR-AAPM-SIIM technical standard recommends that ideal reading room ambient lighting fall in the range of 25 to 50 lux. This level of lighting is similar to standing under a street light at night in dark surroundings. The maximum gray value luminance for diagnostic monitors is recommended to be at least 350 cd/m^2 for nonmammographic interpretation and 420 cd/m^2 for mammographic interpretation. By way of reference, top-performing flat screen televisions on the market in 2017 have a peak luminance upwards of 400 cd/m^2.

Compression

Compression is used to decrease image file size to speed up transfer and decrease storage requirements. Lossless compression is achieved by decreasing redundant image information (e.g., the black background of a CT image). Because image content is preserved, lossless compression can only reduce image file size by approximately 3:1. Lossy compression allows for more substantial image size compression (on the order of 10:1) by irreversibly discarding unnecessary or minimally important image information without significantly compromising diagnostic quality.

Ergonomics

Like all individuals who spend many hours working on a computer, radiologists are susceptible to repetitive strain injuries (RSI). For example, carpal tunnel syndrome (involving the median nerve) often occurs due to dorsiflexion of the wrist from upward angulation of the wrist while typing. Cubital tunnel syndrome (involving the ulnar nerve) can occur due to RSI at either the wrist or the elbow. And DeQuervain tenosynovitis occurs secondary to RSI of the thumb.

Workstation configurations that promote a neutral body position with the forearm, wrist, and hand parallel to the floor, lumbar support,

and appropriate distance between the user and the display can help to decrease the incidence of RSI among radiologists.

6.3 From Order to Report: Workflow Considerations

Workflow Steps

Medical imaging depends on interoperability between many systems, including PACS, RIS, EMR and imaging modalities, as data are transferred via DICOM and HL7 transactions. The process begins with an order placed in the EMR. HL7 transactions communicate the order to the RIS (if it is a separate system). The RIS communicates order information to the relevant modality via the DICOM Modality Work List, and the modality communicates with the PACS via DICOM transactions. The radiologist views the images on PACS and dictates the report using voice recognition. The reporting software then sends the report to the RIS and EMR via HL7 transactions.

Downtime Procedures

Downtime procedures include disaster recovery (DR) and business continuity (BC) procedures. DR policies direct activities that should be followed in the event of a disaster, such as a large-scale, unexpected, highly disruptive event, whether natural or human in origin.

DR policies typically include a description of off-site data backup systems, including the frequency of backup cycles, and the steps required to restore critical data in the event of a disruption. BC policies refer to the necessary systematic precautions and backups required to continue to care for patients when a system failure (such as a power outage) occurs under otherwise routine working conditions.

Radiology systems are considered to be high-availability (HA) systems. HA systems must have the ability to perform automated recovery and failover operations in the event of service disruption. The uptime expectations of an HA system can be expressed as a "number of nines." For example, PACS is generally expected to perform at "four nines", or 99.99% uptime, which translates to no more than approximately 50 minutes of downtime a year. Fault tolerance (FT) refers to the ability of a system to continue to function if one of its components fails. To avoid single points of failure, redundancy is built into essential components of a system (e.g., servers, network connections, data archives, etc.) to achieve a high FT.

6.4 Data Privacy and Security

De-identification of Images

De-identification involves removing protected health information (PHI), as defined by HIPAA, from an imaging examination such that the identity of the patient cannot be directly determined based on information contained in the images or the metadata. However, de-identified images may contain information that enables an approved entity to identify the patient using a key. In contrast, anonymization involves removing all PHI and other identifiable data from an imaging examination such that the identity of the patient is not revealed and cannot can be re-established in the future. PHI contained in the metadata can typically be removed via automated de-identification processes. In some cases, "burned-in" PHI (such as in ultrasound images) also must be removed to fully de-identify medical images. Because the contours of a patient's face can be reconstructed from CT or MRI of the head, imaging that includes the face is also considered PHI.

De-identification of Report Text

De-identification of report data is less straightforward than de-identification of image data, since PHI is not frequently found in radiology report text. De- identification of report data often requires manual review or application of specialized algorithms.

Tools that have been developed for de-identification of medical text do not work as well for radiology reports, because of the difference in frequencies of PHI in radiology reports compared to medical text such as encounter notes or progress notes.

6.5 Image Post-processing

"Post-processing" refers to image transformations performed after the image has been acquired. These transformations may be performed before image display, interpretation, or quantitative analysis. Post-processing includes techniques such as image segmentation, registration, and iterative reconstruction.

Segmentation involves isolating or extracting a region of interest from an image or extracting a subset of images from an image stack for further analysis. For example, segmentation of gray matter and white matter from MRI of the brain may be the first step to a more advanced analysis of atrophy in neurodegenerative disorders.

Image registration involves aligning one image set onto the coordinate space of another image set to allow a more direct comparison of the two image sets. Deformations can be rigid (translation, scaling), affine (shearing), or elastic. Elastic deformation involves local warping of an image to better align the target image with the reference image. Elastic deformation is one type of image registration that can accommodate changes such as patient position, lung expansion, or soft tissue shape changes in aligning image sets.

Iterative reconstruction is an alternative to filtered back-projection as a method for reconstructing raw CT sinogram data into actual image data. Iterative reconstruction performs several rounds of image reconstruction to optimize the signal and reduce the noise in the resulting images. Noise reduction enables the use of less radiation to acquire the images prospectively, decreasing patient radiation exposure.

6.6 Image Artificial Intelligence

Artificial intelligence (AI) is the field of computer science that gives computers the ability to mimic human intelligence. Machine learning (ML) is a subfield of AI that enables computers to learn a task without being given an explicit set of instructions. Deep learning (DL) uses multi-layered neural networks with weighted connections to analyze images and text.

Unsupervised ML exposes an algorithm to a set of data without pre-defined labels or categories and allows the algorithm to automatically label the data. In radiology, uses of ML are primarily supervised. Supervised ML exposes an algorithm to a set of training data and then evaluates how well the resulting model has "learned" the task using a different set of "test" data. It is important that the testing data are completely separate from the training data, in order to fairly evaluate the performance of the model.

Generating training data for radiology requires experts to label images or text, which is time- and resource- intensive. When training models, a pitfall to avoid is overfitting the model to the data, such that it performs very well on similar

data (e.g., at the organization where it was trained), but is not sufficiently robust to perform well on data that is different (e.g., data from another organization). Labeling images is task specific and can be as simple as assigning a label to an entire image or study (e.g., "normal", "abnormal"), or it may require an expert to use segmentation tools to identify an anatomic structure or disease process. As with de-identification, labeling text data or workflow data requires different tools than labeling image data.

Major challenges in deploying AI for radiology include understanding how the "black box" model produces its results, ensuring that the model performs reliably in all potential applied settings and conditions, and efficiently integrating the model into the clinical workflow. Once deployed, model performance should be monitored to identify data drift, in which model performance degrades over time due to gradual changes in the data it processes. Additionally, the way that radiologists interact with AI should be monitored to guard against automation bias, in which the computer is always assumed to be more correct than the human practitioner.

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