REGISTRAR PIP

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Imaging Findings - What are Reporting and Data Systems (RADS)?

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Radiology experts rely on the American College of Radiology (ACR) to provide guidance that will ultimately lead to the improvement of radiology care. Since its inception in 1923, the ACR has been the principle contact in matters of legislation and regulation for radiology professionals. In addition, it provides accreditation and lexicons geared toward the implementation, appropriate use and reporting of medical imaging findings.

According to the ACR website (https://www.acr.org/Clinical-Resources/Reporting-and-Data-Systems), ACR developed RADS to provide standardization for both collecting and reporting data in patient imaging. RADS provide standardized terminology, report organization, assessment structure, and classification for data collection and data reporting. ACR developed seven site-specific RADS assessment categories including breast (BI-RADS), colorectal (C-RADS), liver (LI-RADS), lung (Lung-RADS), head and neck (NI-RADS), prostate (PI-RADS) and thyroid (TI-RADS). Some of these assessment categories are further subdivided based on the type of imaging used (e.g., ultrasound, CT, MRI, etc.).

There are a number of questions on the SINQ website asking SEER's position about using RADS schemas as the sole basis to determine reportability for a case. Questions likely arose from a combination of factors including:

- For 2018, where can we find updated information on whether standard setters consider RADS findings diagnostic of a reportable disease process?
- Why does SEER allow registrars to use some of the schemas to establish a date of diagnosis but not others?
- Why isn't the SEER Reportable Ambiguous Terminology list applied consistently across all the ACR site-specific schemas to determine reportability?

Those of you who actively use the SINQ system probably already know the liver schema (Figure 1) was the first RADS schema SEER allowed us to use to determine reportability and the date of diagnosis. SINQ 20160008, which was based on the 2014 American College of Radiology definitions, indicates LR-5 and LR-5V tumors are to be reported as malignant. According to a 2017 update to the ACR definitions for liver cases, the LR-5V category has been renamed LR-TIV. Hence, the date of the LR-5 or LR-TIV scan can be used as the date of diagnosis when it is the first time the malignancy is confirmed.

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Figure 1
Liver CT/MRI LI-RADS Categories

Untreated observation without pathologic proof in patient at high risk for HCC

LR-NC: If cannot be categorized due to image degradation or omission
LR-TIV: If definite tumor in vein (TIV)
LR-1: If definitely benign
LR-2: If probably benign
LR-M: If probably or definitely malignant but NOT HCC specific

Otherwise, use CT/MRI diagnostic table below

LR-3: If intermediate probability of malignancy
LR-4: If probably HCC
LR-5: If definitely HCC

Arterial phase hyperenhancement (APHE)		No APHE		APHE (not rim)		
Observation size (mm)		<20	≥ 20	<10	10-19	≥ 20
Count of the following major features:						
• "Washout" (not peripheral)	None	LR-3	LR-3	LR-3	LR-3	LR-4
• Enhancing "capsule"	One	LR-3	LR-4	LR-4	LR-4/LR-5	LR-5
• Threshold growth	≥ Two	LR-4	LR-4	LR-4	LR-5	LR-5

When SINQ 20170023 was initially submitted and released in May 2017, SEER indicated a standard setter's workgroup was reviewing the use of PI-RADS categories (Figure 2) to determine reportability for prostate cancer. Following their review, this SINQ answer was updated on 3/13/18 and states, "PI-RADS categories 4 and 5 are reportable, unless there is other information to the contrary."

Figure 2
PI-RADS Assessment

A score is given according to each variable. The scale is based on a score from 1 to 5 (which is given for each lesion), with 1 being most probably benign and 5 being highly suspicious of malignancy:

PI-RADS 1: Very low (clinically significant cancer is highly unlikely to be present)
PI-RADS 2: Low (clinically significant cancer is unlikely to be present)
PI-RADS 3: Intermediate (the presence of clinically significant cancer is equivocal)
PI-RADS 4: High (clinically significant cancer is likely to be present)
PI-RADS 5: Very high (clinically significant cancer is highly likely to be present

PI-RADS 4: High (clinically significant cancer is likely to be present) and PI-RADS 5: Very high (clinically significant cancer is highly likely to be present) can now be used to determine reportability. The date of the scan should be used as the date of diagnosis per SINQ 20170023. However, we need to review the medical record for additional information because the SINQ indicates PI-RADS 4 and PI-RADS 5 may be used ***unless there is other information to the contrary***.

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- Example 1: If imaging indicates the patient has PI-RADS category 4 disease but subsequent prostate biopsies are negative, do not report the case.
- Example 2: If the managing physician indicates s/he does not consider the patient to have prostate cancer after imaging revealed a PI-RADS 5 lesion, do not report the case.

To summarize, for prostate cases, other indications of non-reportability (e.g., biopsy and/or physician's assessment) will override the imaging assessment of PI-RADS 4 and 5.

While we've been given the green light to use the ACR schemas for liver and prostate, that is not the case for the other five schemas (breast, thyroid, colon, head/neck and lung). Many wonder why the breast schema (BI-RADS) can't be used given the coding definitions seen in Figure 3. To some registrars, the BI-RADS 5 malignancy probability score of 95% appears to be a stronger statement of malignancy than a designation of PI-RADS 5 does for prostate. So why can't we use it? While the likelihood of malignancy percentage is 95%, the current description associated with this category is "highly suggestive" of malignancy, which is non-reportable ambiguous terminology.

Figure 3
BI-RADS Classification of Mammographic Lesions

Category	*Description*	*Likelihood of malignancy*	*Recommendation*
0	Incomplete	Unknown	Special views, US, MRI; comparison with old studies
1	Negative	No evidence of malignancy	Routine screening
2	Benign finding	No evidence of malignancy	Routine screening
3	Probably benign finding	Less than 2% chance of malignancy	Follow-up imaging
4	Suspicious abnormality	2 to 95% chance of malignancy	Biopsy
5	Highly suggestive of malignancy	Greater than 95% chance of malignancy	Biopsy
6	Known malignancy	100% malignant	Definitive treatment

Contrarily, the thyroid (TI-RADS) schema uses reportable ambiguous terminology, but is still unusable to determine reportability or diagnosis date. The latest version of TI-RADS categories, descriptions and definitions has a lot of detail. There are five factors evaluated for thyroid tumors including composition (cystic, spongiform, solid or mixed solid and cystic), level of echogenicity (absent, hyperechoic, hypoechoic, or very hypoechoic), shape (wider than tall vs taller than wide), margin (smooth, ill-defined, irregular, extra-thyroidal extension), and echogenic foci (none or large comet-tail artifacts, macrocalcifications, peripheral calcifications, punctate echogenic foci). Each factor choice has a point score assigned, and then these points are totaled. Scores of 7 points or more are considered "highly suspicious." However, SEER has not approved this schema for our use.

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The colon, lung and head/neck schemas present their own issues. For colon, the highest category (C4) is defined as "colonic mass, likely malignant." For lung, the highest category (L4) is defined as "suspicious." The head and neck schema appears to be used to radiographically evaluate recurrence rather than to establish an initial diagnosis. SEER has not approved these schemas for our use either. It is best to stick with the general guideline that if cancer registry standard setters have not approved the use of specified types of information to establish reportability and diagnosis date, then we cannot use that information.

If we are committed to promoting data accuracy and consistency across all hospital and central registry databases, we need to be patient as we wait for new coding schemas to be developed and released for our use. With medical advances, tests (including imaging) have become more sensitive at correctly identifying patients with reportable diseases and are also more specific in correctly identifying patients who do not have a reportable disease.

We can't fall into the trap of choosing which rules to follow and codes to apply simply because medical advances are occurring faster than this information is being incorporated into our coding schemas. It takes time to accurately reflect population-level test results in coding schemas that will allow us to collect future data consistently and accurately. By exercising patience and following the current rules and guidelines established by standard setters, we will help ensure our regional, state and national data can be interpreted without difficulty.

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