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What Constitutes Neuroradiology Diagnostic Quality and How Does It Affect Coverage Decisions?

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The importance of diagnostic imaging, and specifically neuro-radiology, has never been greater as recent simulation modeling suggests enhanced global access to diagnostic imaging would substantially improve patient outcome.¹ Some studies estimate that nearly \$100 billion was spent on diagnostic imaging in 2019, and this amount will continue to increase as new clinical trials (eg, Alzheimer disease) are more reliant on neuroimaging for monitoring for treatment side effects.^{2,3} The increasing costs will be borne predominantly by purchasers and payers who are faced with the important challenge of balancing patient access to care and costs while ensuring employees have access novel diagnostic testing which can improve outcome.

The Leapfrog Group (Leapfrog) is an independent national watchdog organization of employers and health care purchasers whose mission is to make health care safer and improve quality. Leapfrog conducts an annual survey of hospitals to collect data on quality of care, which is publicly reported and used in a variety of pay-for-reporting and pay-for-performance programs nationwide. Over 2300 acute care hospitals participate in the Leapfrog Hospital Survey annually, representing approximately 78% of all acute care inpatient beds nationally.⁴ Leapfrog recently conducted interviews with leaders of various health care organizations responsible for substantial “purchases” of diagnostic imaging to better understand how payers and purchasers define “diagnostic quality” (DQ) and make coverage decisions on new forms of diagnostic imaging. These decisions affect the payment rates of current neuroimaging studies and help determine the likelihood that future neuroimaging studies will be reimbursed. These organizations included:

National health plan (NHP), an entity responsible for paying for their members’ health care expenses, subject to various annual limits and co-pays, typically as part of an employer-sponsored health insurance benefit conditional on employment.

State-based Medicaid department (SBMD), responsible for administering an individual state’s health insurance program primarily aimed at low-income people and people with disabilities. Eligibility varies from state to state and is set as a percentage of the federal poverty limit. Individual state Medicaid plans charge very limited copayments or coinsurance costs to limit out-of-pocket expenditures from enrollees.

State-based business health coalition (SBBHC), representing the collective interests of large for-profit and nonprofit corporations, unions, and the public sector in a single state or otherwise limited geographic area. Business health coalitions collectively advocate for affordable and high-quality health care, as well as price transparency initiatives.

National purchasing group (NPG), including a variety of models that purchase health care across many different states, such as a large multistate for-profit or nonprofit corporation or an aggregate of state or regional business health coalitions.

Large public payer (LPP), of which there are several in the United States with purchasing and a service delivery model that varies based on their constituency. Some examples are the US Department of Veterans Affairs, which focuses on discharged members of the US military, or the Indian Health Service and Medicare, divisions of the US Department of Health and Human Services, which focus on members of federally recognized tribes and citizens over age 65, respectively.

The organizational representatives agreed to participate in the interviews under the condition of anonymity. Interviews were conducted individually by the authors in 2023 in single sessions with written electronic follow-up to supplement responses.

DEFINITION OF DIAGNOSTIC QUALITY?

The Agency for Healthcare Research and Quality (AHRQ) has defined a diagnostic safety event⁵ as the occurrence of 1 or both of the following (whether or not the patient was harmed):

- Delayed, wrong, or missed diagnosis: There were one or more missed opportunities to pursue or identify an accurate and timely diagnosis (or other explanation) of the patient’s health problems based on the information that existed at the time.
- Diagnosis not communicated to patient: An accurate diagnosis (or other explanation) of the patient’s health problems was available, but it was not communicated to the patient (includes the patient’s representative or family as applicable).

This definition is itself a synthesis of prior definitions, including ones articulated in diagnostic quality and safety literature, as well as by the National Academies of Sciences, Engineering, and Medicine (NASEM).⁶ This definition and others it is based on do not explicitly cite excessive costs or inefficient use of diagnostic resources as a possible diagnostic error. However, “overdiagnosis” and cost considerations have long been considered by researchers.⁷ We anticipated that our interview subjects would expand the definition of diagnostic quality to go beyond the avoidance of harmful events and emphasize cost considerations.

There was good consensus regarding how the purchaser and payer community defined DQ regarding neuroimaging. Good DQ is a test or service that is safe, appropriate, accessible, cost-effective, and performed in a timely manner with accurate results that are conveyed to the patient and physician. This accurate information results in the proper diagnosis and treatment, improves patient outcomes, and eliminates the avoidable direct and indirect costs associated with incorrect, missed, or delayed diagnosis.

Poor DQ negatively affects patient care or results in unnecessary costs. Specifically, poor DQ includes imaging that is inappropriate, inaccessible, duplicative, or provides incorrect or unreliable results. Poor diagnostic imaging quality is also characterized by correct results that are not communicated to the patient or provider in a

timely manner, which contributes to wrong diagnosis or incorrect or delayed treatment, which negatively affects patient outcome.

New technological advancements are continuously being developed in many areas of diagnostic testing, which include new innovations in radiology (high field magnets, PET-MRI, theranostics, etc). The focus of the purchaser and payer community was expeditiously arriving at the correct diagnosis versus focusing on the most advanced equipment, provider qualifications, or practice setting.

WHO IN YOUR ORGANIZATION HELPS YOU MAKE DECISIONS ABOUT DIAGNOSTIC QUALITY?

The response to this question varied widely among purchasers and payers. The health care purchaser organizations reported competing priorities that de-emphasized focusing on diagnostic imaging. Their focus is on high-cost medical conditions, such as cancer and low back pain, as opposed to specific imaging modalities, despite neuroradiology being a critical component of timely and effective diagnosis and treatment. In general, NHP and SBBHC tend to be focused on the volumes of diagnostic tests performed as opposed to the costs of individual tests, the type of equipment, or the experience of the radiologist interpreting the neuroimaging study.

However, the interest in medical imaging by the SBBHC we interviewed may not be representative of others nationally. The specific SBBHC we interviewed has a medical director with expertise in neuroradiology and medical imaging. This specific coalition is also in a state-regulated certificate of need (CON), which covers services such as CT, MRI, and PET-CT. However, many other SBBHCs do not have a medical director with neuroimaging expertise or are in a state that regulates imaging under CON.

The NHP considers several factors when making decisions regarding medical imaging, including the approval of new medical imaging modalities by the US Food and Drug Administration. The NHP we interviewed routinely performs literature reviews of the best available evidence and has both internal and external review committees to ensure the diagnostic efficacy of the study is maintained. The NHP emphasized that coverage decisions for medical imaging are based on clinical efficacy and independent of costs.

Various health care professionals and coders overseen by a governance committee comprised the SBMD Office of Medical Directors. The SBMD predominantly relies on state legislative mandates to determine coverage for specific diagnostic tests, including radiology. Coverage decisions are based on diagnostic testing codes approved by the state legislature. There is an internal process to determine coverage for diagnostic imaging that has not been mandated by a state statute, which includes input from the state's medical benefits office, medical directors, and governance committee.

The LPP views assessing DQ as a very difficult task and does not have good measures to assess it adequately. They are currently partnering with different national organizations and physician experts to help them make better decisions on DQ.

DOES YOUR ORGANIZATION CURRENTLY HAVE ANY INITIATIVES IN DEVELOPMENT OR BEING IMPLEMENTED FOCUSING ON IMPROVING DQ FOR YOUR BENEFICIARIES AND COVERED LIVES?

The SBBHC does not have specific quality initiatives pertaining to diagnostic imaging. The NPG recently established criteria that members should request from their payers and providers to ensure their employees receive a minimum level of diagnostic quality for medical imaging. The specific recommended criteria are:

- Require annual physics testing of radiation dose for equipment that requires radiation to create images
- Clinical peer review for physicians who interpret medical imaging
- Appropriate utilization for advanced imaging (CT, MRI, PET-CT)
- Establish oversight of cone-beam CT
- Optimize the patient experience

Several large purchasers have created Center of Excellence (COE) models for evaluating high-spend conditions such as back pain and oncology. These COE models are focused on the total cost of care, which focuses on the appropriate utilization and interpretation of neuroradiology studies by subspecialists. One large purchaser suggested that nearly 50% of back surgeries were unnecessary because of incorrect interpretation of lumbar spine MRIs.⁸ Some large corporations and payers are now partnering with independent companies that have created proprietary assessment tools to determine the quality of radiology facilities and interpretations. Some large purchasers and payers now use these companies to actively steer patients to centers deemed as "high quality" for neuroimaging.⁹

The NHP is launching a new diagnostic quality initiative that relates to appropriate utilization, specifically focused on neuroimaging studies that are "compressible." The most performed diagnostic tests are routine bloodwork, which is low-cost and challenging to manage ("noncompressible"). The NHP understands the importance of neuroimaging. However, there is growing concern regarding appropriate utilization, and the NHP is exploring opportunities to ensure patients receive the most appropriate advanced neuroimaging studies to optimize outcomes while avoiding unnecessary costs.

The SBMD relies on state legislation to determine covered imaging studies based on approved codes and does not have any independent initiatives focusing on DQ.

The LPP has several initiatives to improve medical imaging. The LPP is currently investigating how clinical decision support can improve DQ by ensuring the appropriate medical imaging test is ordered. Artificial intelligence (AI) directly affects the medical imaging DQ value chain. AI algorithms have the capability to reduce imaging time, decrease radiation dose, lower the amount of intravenous contrast, improve diagnostic accuracy, automatically triage patients with emergent imaging findings (intracranial hemorrhage, acute stroke, fractures, etc), and improve the quality of diagnostic reports. AI is also currently being used to identify patients with diabetic retinopathy, which could help identify patients at higher risk of stroke. The LPP is closely assessing the impact of AI on DQ with future coverage decisions based on

improved patient outcome as opposed to solely relying on testing accuracy. The LPP has recently implemented several temporary new technology payment classifications for innovative AI products, which are felt to improve the quality of care by avoiding invasive procedures or decreasing the utilization of additional imaging studies.⁵

WHICH OF THE FOLLOWING LEVELS OF EVIDENCE DO YOU RELY ON FOR DECIDING ON REIMBURSEMENT OR PAYMENT FOR A NEW DIAGNOSTIC TECHNOLOGY OR INTERVENTION

Level 1 (lowest)–Technology or intervention has been successfully implemented in a few health systems and shown to improve diagnostic outcomes (i.e., timeliness, accuracy, communication of diagnosis, etc), or technology or intervention is recommended by a benefits manager or third-party administrator (TPA).

Level 2–Evidence of effectiveness in improving diagnostic outcomes has been published in a peer-reviewed journal.

Level 3–Evidence of effectiveness has been demonstrated via a randomized controlled trial (RCT) and published by industry stakeholders (i.e., technology or device manufacturer, or pharma, etc)

Level 4 (highest)–Evidence of effectiveness has been demonstrated via an independent random controlled trial (i.e., NIH).

Most of the purchaser members of the SBBHC make decisions on the coverage of diagnostic imaging based on recommendations from TPAs who are consulted to help design their benefit plans. The member organizations assume the TPA is establishing their recommendations to adopt coverage based on level 3 or 4 evidence and deny coverage based on insufficient evidence. Purchasers also have the option to use utilization management tools to reconcile varying coverage recommendations on specific tests and procedures. The specifics of how different types of neuroimaging studies are obtained and interpreted are not a high priority, as they assume the diagnostic testing results are accurate.

The NPG does not perform its own assessment regarding coverage recommendations for diagnostic testing. They view RCTs as beneficial. However, since RCTs are performed in a tightly controlled setting, the NPG feels the results of RCTs may not be fully applicable in the “real world,” which is fraught with variability that often prevents employees from complying with the study design. Their goal is to identify imaging studies that allow the correct diagnosis to be made earlier, faster, more accurately, and cost-effective on the “front end.” Earlier and more accurate diagnosis would substantially reduce high-cost claims (cancer, cardiovascular, sepsis), which would improve patient outcomes and reduce costs.

The NHP requires level 3 or level 4 evidence when considering coverage of new imaging modalities. The NHP typically does not pay for new technology or processes that improve diagnostic safety and feels hospitals and providers have an obligation to implement these to enhance patient safety. The NHP felt that AI algorithms used to improve neuroimaging quality and enhance efficiency are a practice expense and have no plans to provide additional reimbursement. The SBMD prefers level 3 or level 4 evidence for coverage of new imaging modalities or new

indications for neuroimaging. They also consider assessment by independent organizations and may approve coverage if testing is covered by other Medicaid payers. Their governance committee helps resolve any discrepancies in payment decisions. Costs are factored into coverage decisions, and there must be a strong clinical justification to approve coverage of a new high-cost novel imaging technique or new indication for an existing technique.

This LPP prefers level 4 evidence. However, these decisions are currently being actively investigated by the LPP.

SUMMARY

The results of the interviews showed purchaser and payer stakeholders shared a consensus definition of DQ. However, they had a markedly different understanding of the types of neuroimaging and differing approaches regarding how their organizations make coverage decisions. What they had in common, however, was strong agreement that there is an opportunity for improvement in the diagnostic quality of neurology and that expert opinion will be critical in seizing that opportunity for improvement. As a result, these interviews suggest that neuroradiologists, both as individuals practicing medicine and professional organizations such as the American Society of Neuroradiology, have the opportunity to advocate for diagnostic quality. This advocacy could take many forms, including serving as physician experts for efforts by large payers seeking guidance, conducting the research and analysis to justify innovations in radiologic patient safety by authoring the “business case,” or even serving as quality-of-care experts for organizations developing or evaluating health care performance measures.

The larger purchaser and payer stakeholders we interviewed are also concerned with the adoption of AI in medicine. This new frontier in health care offers a further opportunity for radiologists to participate in setting standards for safe use of these technologies, as radiology has been grappling with computer assistance for decades.¹⁰ Radiologists can communicate the challenges in diagnostic quality and articulate strategies for the safe use of AI, as clinical informaticists have already begun to do.¹¹

These opportunities are worth pursuing for our discipline, which is entrusted with directing some of the most expensive health care. Health care purchasers and payers have a substantial influence on coverage decisions for novel imaging modalities and new indications for neuroimaging. Their influence is apparent in other areas of the health care payment system: renewed emphasis on reference pricing, preauthorization requirements, and surprise billing legislation is directly attributable to efforts by health care purchasers and payers to increase price transparency and decrease costs of various forms of neuroradiology.⁵ Given their expanding influence, it is important to understand the perspective of various decision-making stakeholders. These insights will help create novel strategies to better educate health care purchasers and payers on the essential value of neuroradiology for providing timely, safe, appropriate, accessible, and cost-effective neuroradiology studies that improve the outcome of employers and their employees.

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