

ImageGuide™ Update

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The American Society of Nuclear Cardiology (ASNC)'s cardiovascular imaging registry—ImageGuide™—continues to make exceptional progress toward implementation this summer. The culmination of this historic journey has been achieved by involving a broad spectrum of experts in the fields of nuclear cardiac imaging, data registries using outcomes-based research, our industry partners, and, most importantly, ASNC membership. This initiative is the result of a shared vision of what nuclear cardiology's future role will be in impacting patient management. Focused registries were initially considered 15 years ago, and in 2011, ASNC leadership developed a vision for a clinical registry which would function to guide, inform, and partner with physicians, industry, payers, and governmental regulators at their respective agencies. In the last 2 years, there has been significant progress toward achieving this goal. As noted in previous publications led by Drs. Shaw, Williams and Tilkemeier, the registry will be a living project that will evolve over time as the field of nuclear cardiology evolves.¹⁻³

Historically, registries have played an important role in the development and implementation of quality benchmarks—most notably, disease characterization, surveillance of community-based event rates, and real-world evaluation of a test or therapy's clinical benefits, risks, and costs. Other quality metrics have included: (1) assessing adoption and implementation of evidence-based care in the community; (2) providing practices with information so as to effectively track and change their methods of health care delivery based on evolving

standards and health policy decisions; and (3) identifying unmet needs and knowledge gaps. These analyses will aid in the design of future clinical trials and outcomes research. To be stated more simply: Are we doing the right things?, Are we doing the right things right?, and Ares our patients better off for it?

Given this background, the ImageGuide™ mission and goals were identified by the ASNC Board of Directors. The mission of ImageGuide™ is to support nuclear cardiology specialists and laboratories in their efforts to enhance the quality, safety, and value of nuclear cardiology and clinical care locally, nationally, and across the globe. There are five specifically identified goals: (1) provide timely data feedback and tools for nuclear cardiology practices; (2) facilitate fulfillment of regulatory and other reporting requirements; (3) advocate for health policy and reimbursement reform; (4) demonstrate the value of nuclear cardiology; and (5) serve as a platform for research and education. In order to accomplish its mission and goals, the registry requires structured data so as to monitor compliance with current nuclear cardiac imaging acquisition and reporting guidelines and their integration into daily practice. Structured data will also ensure utilization of a "single language" which will allow automation of data entry and analysis, facilitating data flow from laboratories to the registry, and allowing for inter-site comparisons of performance measures.⁴ As an extension of this single language, the permissible values will be derived from structured and standardized sources such as the ASNC nuclear acquisition, reporting, and patient-centered imaging guidelines,^{4,5} the ACC's health policy statement,⁶ and appropriate use criteria documents.⁷⁻⁹ ImageGuide data elements have been built based on structured sources such as the digital imaging in communications and medicine (DICOM),^{10,11} systematized nomenclature of medicine-clinical terms (SNOMED-CT), Integrating the Healthcare Enterprise

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(IHE),¹² and Health Level VII (HL7)¹³ communication standards, such as the new Clinical Data Architecture (CDA).¹⁴ To facilitate the development and oversight of the registry, ASNC has developed a governance structure comprising a main steering committee which will receive recommendations from committees overseeing (1) performance measure development, (2) data harvesting, (3) participating site interactions, and (4) integration of data for research initiatives.

Through an initial partnership with the Duke Clinical Research Institute, the required minimum data elements to successfully report a myocardial perfusion imaging study in a registry format were developed. The expertise provided by Duke galvanized the registry's foundation. Their prior experience in registry development will ensure the compatibility of the ImageGuide™ registry with other cardiovascular registries. This is critical as data from multiple registries will be necessary to "track" a given patient's management through the health care system such as an overview of their clinical care through the Pinnacle registry, interventional cardiac procedures through the NCDR registry, cardiac surgery through the STS registry, and potentially cost of care through individual insurers or the Centers for Medicare and Medicaid Services databases. The initial dataset resulted in the development of approximately 132 data elements grouped into 14 major categories that are aligned with the current cardiovascular data standards and informed by ASNC leadership.⁴ These were additionally harmonized with the European Society of Cardiology standards as well as those of other registries.¹⁵ Metrics for monitoring the demographics of participating registry sites were also developed. The 14 data element categories are study referral information, patient demographics, clinical information, stress testing data, resting electrocardiographic data, imaging parameters, radiation dosimetry, left ventricular perfusion, left ventricular perfusion quantification, stress left ventricular function parameters, resting left ventricular function parameters, study quality, right ventricular parameters, and signature date and time. These data element categories with each of their specific elements should provide a broad-based perspective on current nuclear cardiology practice.

In 2014, ASNC contracted with FIGMD, a private corporation with expertise in clinical registry development and implementation, to bring the registry to life. Their role will be to implement data harvesting from individual practices via (1) a reverse engineering approach, whereby data are harvested directly from tables in the reporting software or the electronic health record; (2) a direct data entry approach; or (3) from an automated transmission from interpretive software.

Other responsibilities will include the development of meaningful, translatable, and actionable performance reports as well as expertise in providing scalable growth with regard to both volume and scope. There will be no exclusion criteria for patient participation in the ImageGuide™ registry. This is intentional to ensure that the registry reflects the current practice of clinical nuclear cardiology. Additionally, since the ImageGuide™ registry is a diagnostic procedure registry, the relationship between test results and patient outcome is indirect but would potentially be reflected in physician management decisions. By linking ImageGuide with other registries, there is the potential for tracking a physician's response to a particular result and a resultant patient outcome. As the registry matures, data analytics will allow associations among the test indications, results, their effect on care decisions, and ultimately patient outcome. The data generated from the ImageGuide™ registry will be essential in monitoring the pulse of nuclear cardiology in clinical practice and allow for implementation of measures to improve the performance and value of nuclear cardiac imaging using a patient-centered approach.

In parallel to the implementation of the registry structure into practice, the performance measures development group has been working with the leadership of the Centers for Medicare and Medicaid Services to ensure that the ImageGuide™ registry will be recognized as a Qualified Clinical Data Registry (QCDR) for the Center for Medicare services. This process began in January 2015 and, after significant input and work from ASNC leadership and physician participation, culminated in the approval of ImageGuide™ as a

ASNC 2015 Performance Measures

Measure ID	Title
ASNC 1	Cardiac Stress Nuclear Imaging Not Meeting Appropriate Use Criteria: Preoperative Evaluation in Low-Risk Surgery Patients
ASNC 2	Cardiac Stress Nuclear Imaging Not Meeting Appropriate Use Criteria: Routine Testing After Percutaneous Coronary Intervention (PCI)

Measure ID	Title
ASNC 3	Cardiac Stress Nuclear Imaging Not Meeting Appropriate Use Criteria: Testing in Asymptomatic, Low-Risk Patients
ASNC 4	Utilization of Standardized Nomenclature and Reporting for Nuclear Cardiology Imaging Studies
ASNC 5	Single-Photon Emission Computed Tomography (SPECT) Myocardial Perfusion Imaging (MPI) study report turnaround time <24 hours
ASNC 6	Positron Emission Tomography (PET) Imaging Study Report Turnaround time <24 hours
ASNC 7	Nuclear Cardiac Stress Imaging Not Meeting Appropriate Use Criteria
ASNC 8	Laboratory Accreditation for Nuclear Cardiology Imaging Studies
ASNC 9	Physician Reader is CBNC Certified in Nuclear Cardiology
ASNC 10	Nuclear cardiology Imaging Studies Terminated Due to Technical Problems
ASNC 11	Overall Study Quality

QCDR. ASNC submitted the following 11 measures for participation.

There is no requirement for public reporting of the measures in the first year; however, public reporting will be required in 2016. The full parameters of public reporting have yet to be fully defined. Additional measures will be developed as the ImageGuide™ data registry matures and further data elements are added as required. Participation in a QCDR will directly benefit participating practices through the elimination of need to report Physician Quality Reporting System or PQRS measures to qualify for value-based payments.

Additional ImageGuide participation benefits include advocacy-based efforts which will reward clinical improvement activities through recognition of pay for performance-based programs. A number of public payers have expressed interest in a program that helps to identify high-quality labs. Moreover, participation in continuous

quality improvement initiatives should play a significant role in the overhauled maintenance of certification programs (MOC) from the ABIM and others. It is the hope of ASNC that the registry will become a single source of participation in quality measures that will satisfy the requirements for laboratory accreditation, physician certification, maintenance of certification, maintenance of licensure, and continuing education for both physicians and technologists. Participating laboratories will hopefully be seen as regional centers of excellence as we move toward population health, accountable care organizations, and patient choice. ImageGuide™ will ultimately provide a platform for minimizing regulatory oversight and maximizing patient access to the most appropriate test at the most appropriate time.

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