

Coming-of-age: The ImageGuide™ Registry at three

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Received Sep 4, 2018; accepted Sep 4, 2018

doi:10.1007/s12350-018-1442-1

The ImageGuide™ Registry has celebrated an important birthday, it has turned three! It has been an exciting three years of progress for the registry and one of attaining significant milestones that were set forth during the initial conversations regarding the mission and goals of the registry. Drs. Shaw, Williams, and Tilkemeier outlined a number of these goals in the early articles describing the philosophy, goals, and structure of ImageGuide™.¹⁻⁴ The ImageGuide™ Registry remains the first of its kind in cardiovascular imaging, as it currently provides an integrated platform for laboratories to document quality, safety, efficiency, and clinical care delivery. The strong foundation that was built-on, in collaboration with the Duke Clinical Research Institute and its leadership, including Drs. Tracy Wang and Pamela Douglas, remains central to the diverse functionality of this registry. As ImageGuide™ was born and has thrived, it has started to provide clinical data feedback to participating laboratories. Indeed, we are hearing many anecdotes regarding the impact this has had on quality and performance measures within participating laboratories, which was clearly one of the pivotal goals of the registry.

Perhaps most important to the development and maturation of the ImageGuide Registry™ is the new partnership between the American Society of Nuclear Cardiology (ASNC) and the American Society of

Echocardiography (ASE). Through this partnership, ASE developed and launched in September 2017 an echocardiography arm of the registry, known as ImageGuideEcho™. This addition provides an opportunity for physicians across the United States who perform both nuclear and echocardiographic studies to submit data in a single interface through the ImageGuide Registry™ platform, and also allow physicians who perform solely echocardiography to participate independently. Harnessing the power of “big data” in ImageGuideEcho™, will not only demonstrate the utility of echocardiography, but also identify opportunities for improvement and highlight best practices. ImageGuideEcho™ was created to assess specific quality metrics and patient outcomes as a vehicle to drive echocardiography applications for the benefit of all stakeholders, including patients, physicians, and researchers, through analysis of echo-specific registry data. Currently, ImageGuideEcho™ collects information on transthoracic echocardiography, including: patient demographics and clinical characteristics, indications, the technology used (e.g., 3D, strain), left ventricular size and systolic function via a global and 17-segment model, left ventricular diastolic function, pulmonary artery pressures, right ventricular size and function, the pericardium, and valvular structure and function, as assessed qualitatively and quantitatively. Within the echo module, much as in the nuclear module, physicians can submit their data and compare their performance on echo-specific quality measures against institutional and national aggregates. Thus, a laboratory can use registry data to identify an opportunity for improvement regarding a certain quality metric,

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J Nucl Cardiol 2019;26:72–5.

1071-3581/\$34.00

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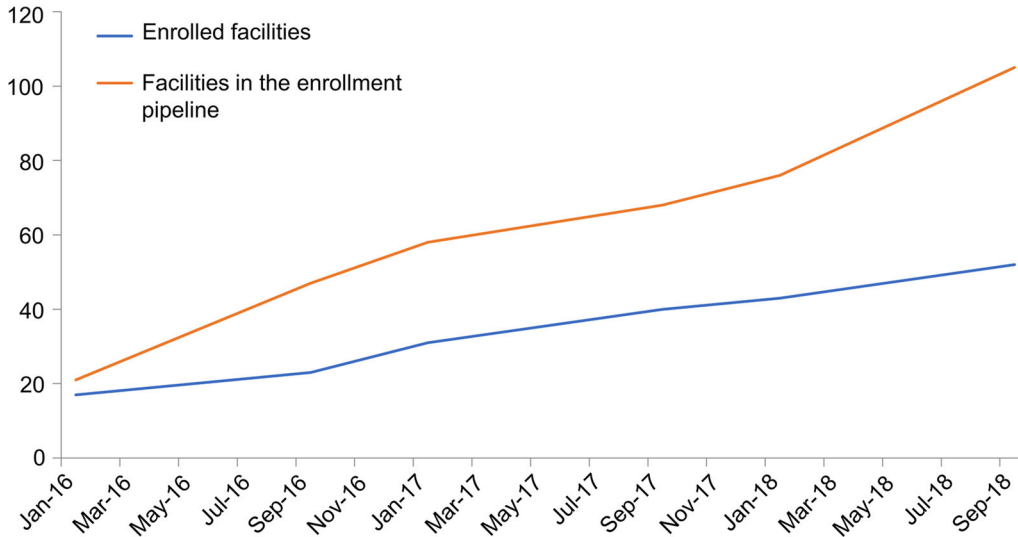


Figure 1. Growth in facilities enrolled in ImageGuide™.

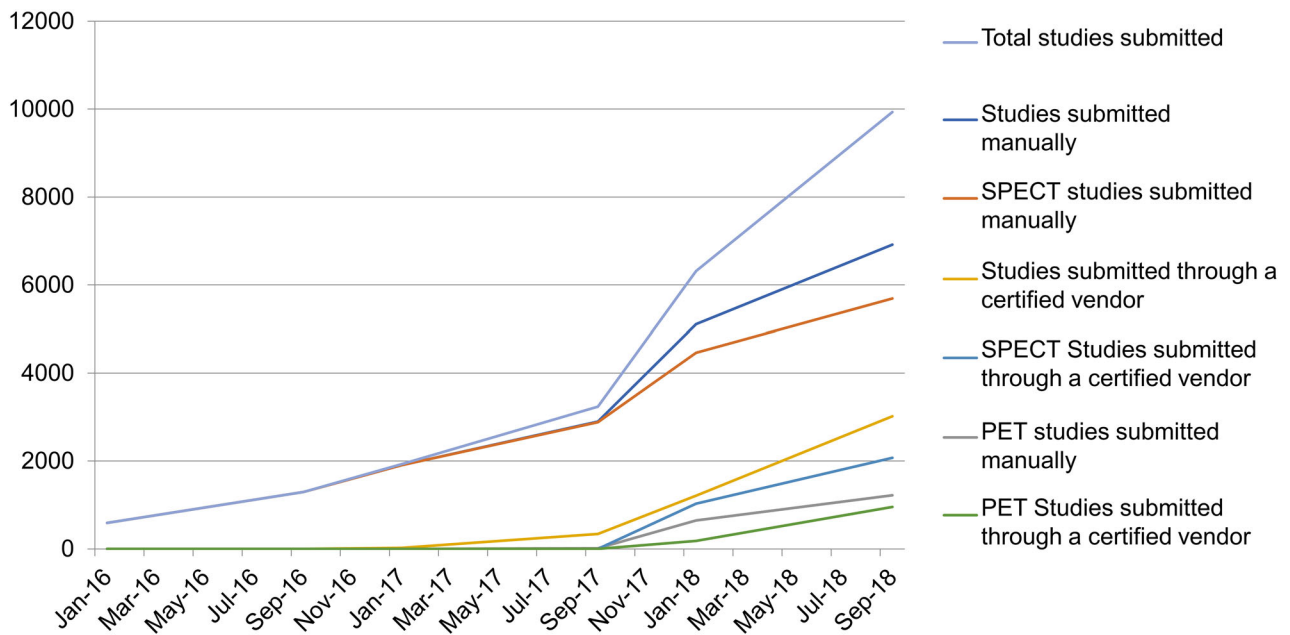


Figure 2. Patient studies submitted to ImageGuide™ by study type and submission method.

implement change, and subsequently evaluate the impact of the intervention on the performance metric with the ultimate goal of improving quality and overall patient outcomes.

Additionally, partnerships with nuclear cardiology software vendors have been formed. Mechanisms have been put in place to certify submissions from these software applications to the registry. In fact, several

vendors have reached accreditation status with the registry, which allows clinical, imaging, and interpretation data entered or generated using these software applications to flow seamlessly into the registry. Similarly, ImageGuideEcho™ data can be pushed automatically from the laboratory's certified structured reporting software and PACS systems into the registry's knowledge base. This is a significant milestone for both

modalities, as it enables laboratories to report their data through an automated mechanism at the time of report completion. Alternatively, information can be entered into both nuclear cardiology and echo modules via a web-based data collection form.

REGULATORY PERSPECTIVES

ImageGuide™ is recognized by the Centers for Medicare and Medicaid Services (CMS) as a qualified clinical data registry (QCDR) with 16 approved performance measures for the 2018 reporting year (12 process measures, 3 outcome measures, and 1 efficiency measure). This recognition has provided a pathway for practices to meet their MIPS requirements, which is an important measure of success for the registry and participating practices. In fact, ImageGuide™ leadership is engaged in annual conversations with CMS regarding adopted performance measures that can be met through participation in the ImageGuide Registry™. These measures undergo annual updates, with new measures being introduced to close performance gaps, while high performing measures are retired, thus constantly strengthening the quality and efficiency of cardiovascular imaging.

Moreover, ImageGuide continues to work with the Intersocietal Accreditation Commission (IAC) and other certified accreditation bodies to assure that the data collected aligns with their quality assurance mechanisms and standards. Ultimately, this alignment will allow streamlined data submission to reduce the burden on our practicing physicians and their staff to meet these important criteria regarding Medicare reporting requirements.

GROWTH

Three years after the inception of ImageGuide™, the numbers of participating laboratories and studies submitted continue to grow exponentially (Figures 1, 2). Important events, such as the MIPS deadline, have certainly promoted enrolments and submissions. As we reach a critical mass of studies and diversity of laboratories, the ability to start to address research questions becomes real. ASNC is currently developing a research oversight committee for the registry that is building the pathway and infrastructure for requesting and analyzing registry data to answer pressing research questions. HIPAA compliant processes have been developed for release of data to ensure compliance with ethical and regulatory standards.

THE FUTURE

As the registry comes of age, the opportunities to utilize ImageGuide's™ infrastructure to support new research prospects and new clinical activities are becoming more evident. At the recent ASNC industry forum, there was a robust conversation regarding the development of a registry within ImageGuide™ to allow us to better understand the clinical utilization of technetium pyrophosphate scans in the assessment of suspected transthyretin (TTR) cardiac amyloidosis. Moreover, industry partners have also looked into leveraging ImageGuide™ in phase 3 and 4 clinical trials of new isotopes and imaging techniques. Additionally, the registry will need to be expanded to include the new data elements that were developed as part of the update for the ASNC Reporting Guidelines.⁵ Finally, ASE looks forward to the continued expansion of the echo module through the addition of stress echo, transesophageal echo, and pediatric echo. These expansions are only possible given the strong infrastructure on which the registry is built.

Just like a healthy three or four-year-old child, the ImageGuide Registry™ is meeting all of its developmental milestones. It has come alive and begun to speak, telling stories regarding quality and performance of cardiovascular imaging. It has become nimble and able to move within the field of noninvasive imaging encompassing multiple imaging modalities. It has made “new friends” in the partnerships between ASNC and ASE with the potential to add other imaging societies and industry partners. Finally, it is starting to be able to ask and potentially answer those difficult questions, such as “why is the sky blue?”. By meeting its early developmental goals, the ImageGuide Registry™ has clearly met a number of measures for which it was designed. With continued support and nurturing from the societies and their members, we all look forward to watching it grow into adulthood.

Acknowledgements

ASNC and ASE recognize Joe Reyes, BS, Daniel Lattoz, BS, Kathy Flood, BA, Sarah Beth Bdoyan, MSPH, Kathryn Lyons, BA&Sc, and Robin Wiegerink, MNPL, for their major efforts with ImageGuide™ Nuclear and Echo modules and their critical insight on this editorial.

Disclosures

Rami Doukky has research grant support from Astellas Pharma Global Development (Northbrook, IL). Peter L. Tilkemeier, James N. Kirkpatrick, Milind Y. Desai, and Sherif F. Nagueh have no conflicts to disclose.

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