

Researchers develop outline that may help weigh benefits of new imaging technologies

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A new article in the February issue of the *Journal of the American College of Radiology* provides a roadmap for imaging manufacturers to navigate the unique and increasingly complex U.S. regulatory and reimbursement environment. "Evidence Requirements for Innovative Imaging Devices: From Concept to Adoption," identifies and addresses the five phases of an imaging procedure's lifecycle and the distinct clinical evidence needs for each phase.

This article is authored by Richard Frank, MD, PhD, Vice President, Global Clinical Strategy and Policy, General Electric, Donald W. Rucker, MD, Chief Medical Office, Siemens Healthcare USA, Michael A. Ferguson, PhD, Global Director, Clinical Outcomes and Translational Research, Philips Healthcare and Terry J. Sweeney, Sr. Vice President, Corporate Quality and Regulatory Affairs, Philips Healthcare.

"We think there is a critical need for this kind of roadmap, given the current mismatch between the pace of advances and the time required to clear regulatory, reimbursement and adoption hurdles," said Frank.

"Only with full adoption does the patient population truly gain access to the benefits of innovation, for example, in reduction of exposure to radiation or increased compliance with screening recommendations and, hence, earlier detection of disease, better outcomes, and reduction in overall cost of [healthcare delivery](#)."

The article closely examines the design, regulatory clearance and approval, early adoption, reimbursement, and full clinical adoption of

imaging technology.

Although the development of [imaging technology](#) is global, the United States has been the largest and most influential adopter of advanced imaging. Therefore, increases in U.S. evidentiary standards may have a global impact on innovation and access to imaging.

"It is our hope that this study will help to foster greater certainty for manufacturers and all stakeholders in navigating the concept-to-adoption pathway so that patients can continue to benefit from these innovative and often life-saving technologies," said Rucker.

"The potential of medical imaging is incalculable, and we need to make sure that the next generation of Americans are able to benefit from transformative imaging technologies in the same ways that we were," added Ferguson. "We believe that the roadmap we have provided is a strong first step to ensuring that manufacturers are able to invest in such watershed technologies and that as a society we are able to achieve this goal."

More information: www.jacr.org/

Provided by American College of Radiology

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