### Trends in Imaging Usage

Smith-Bindman, from the University of California San Francisco, and authors from across the United States and Canada published an article in the September issue of *JAMA* (2019;322 [9]:843–856) on "Trends in use of medical imaging in U.S. health care systems and in Ontario, Canada, 2000–2016." The authors assessed annual and relative imaging rates for CT, MR, ultrasound, and nuclear imaging by country, health system, and patient demographic factors. A total of 135,774,532 imaging studies were included. As expected, imaging rates were significantly higher in 2016 than in 2000 for CT, MR, and ultrasound but with a slower pace of growth in the most recent years. Nuclear imaging, however, was the 1 modality that experienced a downward trend in usage over the study period, showing the greatest decline in adults ≤65 y of age and in children.

As an example of usage increases cited in the article, CT imaging rose from 56 per 1,000 person-years in 2000 to 141 in 2016; MRI from 16 to 64 per 1,000 person-years, and ultrasound from 177 to 347 per 1,000 person-years. During the same period, nuclear medicine usage decreased from 33 to 25 per 1,000 person-years. Figures were similar in Ottawa. For older adults (>65 y old), nuclear medicine usage fell from 94 to 64 per 1,000 person-years in the United States, with a comparable decline from 87 to 74 in Ottawa. The study made no assessments of whether the observed imaging utilization was appropriate or associated with improved outcomes, and the authors did not suggest reasons for the decline in nuclear medicine use. The article contains a wealth of data and analyses that merit further exploration by the nuclear medicine community.

*JAMA*

### NIH-Sponsored Trials and Clinical Cancer Care

In an article published on September 4 in *JAMA Network Open*, Unger and colleagues from the SWOG Cancer Research Network Statistics and Data Management Center (Seattle, WA), the Fred Hutchinson Cancer Research Center (Seattle, WA), Columbia University Medical Center (New York, NY), and the Oregon Health and Science University (Portland) offered data indicating that 82 of 182 phase 3 clinical trials led by SWOG or by other National Cancer Institute Clinical Trial Network (NCTN) groups with SWOG participation were "practice influential." To be considered as practice influential, the trials must have been completed with published results and have been associated with guideline care through effects on National Comprehensive Cancer Network (NCCN) clinical guidelines or U.S. Food and Drug Administration (FDA) approvals in favor of a recommended treatment.

According to a press release about the article released on September 18 by the National Cancer Institute (NCI), the study results suggested that NCTN trials add value regardless of whether findings were positive or negative. In addition, the authors also found that the cost of a U.S. FDA approval from an NCTN trial was much less than the costs incurred in a trial run by pharmaceutical companies. "We found that the NCTN program contributes clinically meaningful, cost-effective evidence to guide care of cancer patients," said Joseph Unger, PhD, a health services researcher and biostatistician for SWOG at the Fred Hutchinson Cancer Research Center. "These trials are largely funded by the public, which is getting good value for their investment."

The data included the records of 148,028 patients treated on phase 3 cancer trials at multiple institutions between 1980 and 2017 led by SWOG or other NCTN groups with SWOG participation. Of the 82 practice-influential trials, 70 influenced NCCN guidelines, 6 influenced new FDA drug approvals, and 6 influenced both.

Of note, the number of practice-influential trials was 47 of 65 (72.3%) among those with positive findings and 35 of 117 (29.9%) among those with negative findings. A surprising 42.7% of practice-influential results were based on studies with negative findings, with nearly half of these studies (17 of 35; 48.6%) reaffirming standard of care over experimental therapy. The total federal investment spent in conducting the trials was $1.36 billion, a rate of $7.5 million per study or $16.6 million per practice-influential trial.

The authors also estimated that total federal investment supporting the trials in the study was $1.36 billion. This suggests that for 182 trials, average costs were $7.5 million per completed phase 3 trial (all trials), $16.6 million per practice-influential trial, and $123.6 million per new drug approval. In a review of 10 studies of the cost of new drug approvals by industry, the researchers found that the mean inflation-adjusted cost for a single new drug approval was $1.73 billion.

Despite some limitations in variables assessed, Unger noted that "The take-home message from the study is that NCTN studies provide a lot of clinically meaningful evidence for patients that influences their care routinely and does so at a relatively cost-effective level. It's important that people appreciate just how valuable these trials are in terms of benefit to patients with cancer."

*JAMA Network Open*
*National Cancer Institute*

### DOE Awards 4th Cooperative Agreement for U.S. $^{99}$Mo Production

The Department of Energy (DOE) National Nuclear Security Administration (NNSA) announced on August 28 that it had issued its fourth and final cooperative agreement award in fiscal year (FY) 2019 to Northwest Medical Isotopes, LLC (Corvallis, OR) for the production of $^{99}$Mo without the use of highly enriched uranium. Three other cooperative agreement awards were announced in July to Niowave, Inc. (Lansing, MI), NorthStar Medical Radioisotopes,

LLC (Beloit, WI), and SHINE Medical Technologies (Janesville, WI). The NNSA entered into these agreements with a goal of establishing and maintaining a reliable domestic supply of $^{99}$Mo without the use of highly enriched uranium. To achieve this, the United States is supporting companies that will have the capacity to supply approximately 3,000 6-d curies of $^{99}$Mo per week. The American Medical Isotopes Production Act of 2012 directed DOE to implement a technology-neutral program, in cooperation with nonfederal entities. Congress appropriated $40 million for these awards in FY 2018 and $20 million in FY 2019 and directed DOE to issue a funding opportunity announcement to competitively award cooperative agreements. NNSA will fund each agreement at $15 million and require each awardee to provide $15 million of matching funds. More information on the DOE/NNSA program is available at https://www.energy.gov/nnsa/nnsa-s-molybdenum-99-program-establishing-reliable-supply-mo-99-produced-without-highly.

*U.S. Department of Energy*

### $^{99}$Mo Shortage in Australia

On September 12, the Australian Nuclear Science and Technology Organisation (ANSTO) announced that it had stopped production of $^{99}$Mo because of detection of a valve fault that exposed 2 workers to unsafe levels of radiation. With an uncertain repair timeline, ANSTO immediately began working on alternative supplies. ANSTO operates the Open-Pool Australian Lightwater reactor. In the first days after the shutdown, an ANSTO spokesperson said that "ANSTO has 4 teams working in parallel to progress options to rectify the issue. We thank the nuclear medicine community, and in particular the Nuclear Medicine Working Group, who are helping ensure that the reduced amount of nuclear medicine gets to areas needed most."

Compounding the impact of the shutdown was the prospect of a scheduled 3-week maintenance shutdown of the SAFARI-1 reactor at NTP Radioisotopes SOC Ltd. near Praetoria, South Africa. The ability of ANSTO to bridge supply gaps from already challenged global sources would be constrained. In a September 26 release to its customers, ANSTO indicated that bulk $^{99}$Mo shipments would arrive from NTP on September 27 and 28, with $^{99m}$Tc generators manufactured on September 28 and 29, and generators delivered to all sites by September 30. A similar supply was expected for the weeks of October 7 and 14. Because of NTP's scheduled maintenance shutdown, ANSTO was seeking alternative suppliers for the weeks of October 21, October 28, and November 4. At Newsline press time, no date had been targeted for resumption of domestic production of $^{99}$Mo by ANSTO.

*ANSTO*
*SNMMI*

### Proposed Myocardial PET Cuts

On September 3 SNMMI, along with the American College of Cardiology, the American College of Nuclear Medicine, the American Society of Nuclear Cardiology, and the Cardiology Advocacy Alliance, responded to proposed cuts for myocardial PET imaging in the Centers for Medicare & Medicaid Services (CMS) Medicare Physician Fee Schedule (MPFS) for 2020. These cuts could lead to technical component payment reductions as high as 80% for some services. These revisions resulted from updates to the Current Procedural Terminology codes used to report these services and review of the direct practice expense inputs that inform the calculation for the technical component payment.

One driver of the cuts is a decision by CMS to assume a 90% utilization rate for PET cameras, an assumption that the 5 organizations indicated should be changed. Pricing information for other equipment also may need to be further refined. Although the organizations indicated that they "support the valuation process used to develop input recommendations administered by the American Medical Association's Relative Value Scale Update Committee, payment cuts of this magnitude and on such short notice are not sustainable and could lead to practice disruptions and impact patient access to PET services." In a joint statement, the organizations indicated that if aggressive work to correct the inputs and calculations for the payment formula through the public comment process and communication with policymakers was not successful within the constraints of the rulemaking timeline, they would seek alternative approaches, such as a delay period, to allow further analysis and other efforts to continue.

On September 9 the groups held a webinar on this topic and requested technology cost information from the nuclear medicine community. Public comment to CMS was solicited, although the comment period was short and is no longer open.

The societies on September 23 called for community action and Congressional sign-on to a letter to CMS addressing the cuts and potential patient impacts. The first Congressional signees were Reps. Mike Kelly, (R-PA), Ron Estes (R-KS), and Ron Kind, (D-WI). Members of all 5 societies were urged to write, call, or email their representatives and senators and ask them to sign the letter and voice concerns directly with CMS. The specific goal of this effort was to persuade members of Congress to ask CMS to defer the proposed PET pricing and continue current payment levels while working with stakeholders to ensure that costs are accurately accounted for when setting payment rates for cardiac PET. After the announcement of the proposed cuts, the foci of these groups have been on correcting inputs and calculations for the payment formula through the public comment process and communication with policymakers, and on educating CMS staff and more than 50 Congressional offices, including professional staff from relevant committees.

*SNMMI*