2022 represents a significant milestone for the SNMMI Value Initiative: five years of partnering with our volunteer leaders and industry partners to advance nuclear medicine, molecular imaging, and radiopharmaceutical therapy.

In these five years, I’ve seen our volunteer leaders embrace their strategic role in driving positive change. I’ve seen tremendous growth, collaboration, and participation from our industry partners. I’ve seen recognition of the critical role and value of SNMMI in supporting the profession. Thanks to these partnerships and tireless efforts, we have:

- Bolstered SNMMI’s focus on precision medicine with the creation of the Radiopharmaceutical Therapy, AI, and Dosimetry Task Forces
- Created and held multiple therapeutics-specific conferences
- Launched new SNMMI resources, including the ‘Radiopharmaceutical Therapy Central’ and ‘Resident and Medical Student’ websites, and the ‘One’s to Watch’ recognition program
- Successfully advocated to retire FDG F-18 PET for infection and inflammation beginning in 2021 and the exclusionary language for non-oncologic PET in 2022
- Along with our society partners, succeeded in maintaining the training and experience requirements for Authorized Users
- Provided a forum for start-up companies with the creation of the Small Business Pavilion on the exhibit floor at SNMMI’s Annual Meeting
- Saw the approval of new radiopharmaceuticals, including Lutathera (Lu177-dotatate); Azedra (I131-iobenguane); Ga68-dotatoc (U of Iowa); Pylarify (F18-DCFPyL); Ga68-PSMA (UCSF and UCLA); Tauvid (F18 flortaucipir); Cerianna (F18-FES); and Illuccix (Ga68-PSMA kits)

In recognition that our initiatives are achieving positive outcomes, we have seen a steady increase in industry support, with participation increasing from 5 industry alliance companies in 2018 to 37 (and counting) in 2022. This tremendous support powers the engine that will drive transformative change.

An Interview with Tiffany Olson

Tiffany’s passion is to make a difference in the world. She is a thought leader, advisor, and speaker with a goal of inspiring companies to bring their teams to the next level of connection and leadership. She recently retired as President of Cardinal Health Nuclear & Precision Health Solutions. Currently she serves on company boards and has started her own business in consulting, speaking, and advising.

Tell us about your leadership journey in nuclear medicine.

When I was five, I had my first lemonade stand and knew that I wanted to run a business one day. In pursuit of this goal, I acquired a business degree and began working in pharmaceuticals. Working in this industry, I found my passion for helping patients. In 2009, I was recruited to Eli Lilly to develop and lead a diagnostic strategy. It was here that I was the champion for the Avid Radiopharmaceuticals (Amyvid™) acquisition. This was my first entry into nuclear medicine and prompted my move to Cardinal Health. This allowed me to continue my passions of business and helping patients while also working at one of the largest nuclear companies in the world. In my role as president, millions of patients were served every year, and with the help of my team, developed and brought attention to the power and the promise of nuclear medicine.

How do you differentiate between leadership and management?

Managers manage things. Leaders lead people. Managers build systems and processes. Leaders build relationships. Managers plan. Leaders dream! As a leader, you still need to have good management skills and use them; however, inspiring change takes the ability to grab not only the minds but also the hearts of your team. It is about letting your vision of the future be known.

What advice do you have for women as they aspire to leadership roles?

Trust your gut and use your intuition to gather and interpret subtle interpersonal messages. Hearing what isn’t being said helps you understand what the team really needs.

Keep learning about leadership. Many women in science keep up their science learning but don’t realize that leadership education is just as important. Being good at leadership is about self-reflection and gaining new skills to continue to grow.

And find a mentor! Having a mentor, male or female, has helped me grow as a leader.

What were some examples of difficulties you ran into and how did you overcome them?

When I was asked to be the VP for Roche Molecular, I knew nothing about PCR. Now it’s a household name. They wanted me for my business background, not my science understanding. When meeting the team, I was worried about how I would bring value. This job was about leading people responsible for specific areas where I lacked the technical expertise; my skills were in strategy, team building, and markets. I let the team know my vulnerability and asked for their help to teach me about the science involved. Developing trust, relying on experts, and bringing my own unique value made a strong team bond. It wasn’t always easy! But over time, we learned the importance of diversity of all kinds, including experience and thought, and the team along with the business excelled in bringing transformational programs to market.

What are you most proud of?

My relationships with my family, my friends, and my colleagues. We all know there are struggles in life, but it’s the quality of your relationships that get you through them. I am particularly proud of the transformation of Nuclear & Precision Health Solutions. We pivoted from leaders in preparing and delivering radiopharmaceuticals to leaders in partnering with innovators for developing, manufacturing, and commercializing. And we did this mammoth job, laughing, eating pizza, pulling our hair out, and with the utmost respect for each other. Once again, it’s the relationships.

Continued on page 10. See An Interview with Tiffany Olson.
The AI task force of SNMMI was formed in the summer of 2020. Comprised of nearly 20 members, including nuclear medicine physicists and physicians, engineers, computational imaging scientists, statisticians, and representatives from industry and regulatory agencies. The task force has aimed to make recommendations, educate, and enable new opportunities and capabilities towards effective integration of AI in nuclear medicine and molecular imaging, including translation to routine clinical practice. So far, the task force has created 4 main reports (published [1] or undergoing journal review), on:

(1) **Opportunities, challenges, and responsibilities in nuclear medicine towards creating trustworthy AI ecosystems**: This report aims to help establish and maintain leadership in AI by envisioning and motivating concerted efforts to promote the rational and safe deployment of AI in nuclear medicine, including effective engagement of all stakeholders.

(2) **Best practice for algorithm development**: This document aims to educate the community and to provide

Continued on page 10. See Nuclear Medicine & Artificial Intelligence.
How Point-of-Care Imaging is Changing Radiology Departments

MARTY SHIRLEY, CNMT — DIGIRAD

Most hospitals utilize portable x-ray and portable ultrasound daily. The ability to provide point-of-care diagnostic imaging is an invaluable way to reduce costs, help patients, and increase the overall quality of care.

Advancements in technology have made delivering portable nuclear imaging as easy as ultrasound or X-Ray. Which begs the question: Why in the world are hospitals and technologists not leveraging portable nuclear imaging in the same way?

Point-of-care nuclear imaging is safer for patients, improves care, and helps to protect the hospital from costs associated with HAI’s (healthcare-associated infections) and readmittance.

Additionally, the Coronavirus pandemic has caused many hospitals to take a fresh look at their processes, procedures, staffing, and equipment needs. We’ve seen firsthand how easily “department-centric” imaging can grind to a halt.

How Point-of-Care Testing Is Shaping Radiology

There are obvious benefits in implementing portable radiology technology in hospital settings. By harnessing its potential, you can improve patient satisfaction, quality of care, and even hospital revenue.

Impacting Studies

Adding point-of-care (POC) testing to your departments can significantly increase the number of studies you can perform.

Without portable imaging, there are certain settings where studies are too risky or complicated to perform. In contrast, POC tests allow you to bring imaging to the patient, which can allow for successful and transformative clinical research that can’t be performed outside of the hospital.

This unique opportunity is coupled with increased efficiency, as POC technology can be completed quickly and requires no patient transport. This can significantly boost not only the potential for studies but the amount you can perform in a given time period.

Many nuclear medicine departments are using Digirad’s Ergo camera to perform POC imaging and have reported an increased number of studies in:

- Brain Viability
- Intraoperative Imaging
- Lymphoscintigraphy
- GI Bleed
- Lung Perfusion
- HIDA
- MUGA
- Bone Flow/Blood Pool

Reducing Risk Factors Associated with Patient Transport

Patient transport is a significant risk factor in hospital settings. According to one review, some risks associated with patient transport are:

- Potential for infectious exposure
- Ventilator-acquired pneumonia
- Hypoxemia
- Pulmonary complications
- Tachycardia
- Cardiac arrest
- Arrhythmia
- Equipment dislodgement
- Interruption of therapy or care
Could a Cost-Effectiveness Study Lead to More Appropriate Payment for Diagnostic Radiopharmaceuticals?

THOMAS GUSTAFSON, PHD, SENIOR POLICY ADVISOR, ARNOLD & PORTER
WITH THE ASSISTANCE OF PAUL RUDOLF, MD, JD; JOHN MCINNES, MD, JD; AND AMANDA CASSIDY, MPH

Uptake of newer, promising diagnostic radiopharmaceuticals (DxRPs) has been inhibited by CMS’ policy under the Outpatient Prospective Payment System (OPPS), which pays hospitals for facility expenses. Since 2008, CMS has “packaged” the cost of DxRPs in the payment it makes for the diagnostic imaging service. At the time this policy was introduced, DxRPs were generally relatively inexpensive, with small variance in costs. Since then, a number of new DxRPs with more sophisticated technical characteristics and costs several times those of the older products have been introduced.

Under the OPPS, payment rates are defined for groupings of services called Ambulatory Payment Classifications (APCs). An APC’s payment rate is a volume-weighted average of the estimated mean cost across all services assigned to the APC. When the majority of DxRPs used are the old-cheap ones, they bring the average down, and the overall payment made to the hospital for the diagnostic imaging APC may not be close to covering hospital costs for scans using the new, higher cost DxRPs. Many of the new DxRPs were paid separately for a short period because they qualified for transitional pass-through payments, but when these payments expired, they fell into the otherwise applicable APCs with the old-cheap products.

CMS’ current policy accords with the agency’s general preference for packaging items and service whenever appropriate. In this instance, CMS determined that performance of any diagnostic nuclear medicine scan inevitably requires a DxRP, so the agency classified DxRPs as supplies that must be furnished incident to the scans, ceased making separate payment for the DxRPs, and packaged payment for the DxRPs in the payment for the scans. Despite objections from stakeholders over many years, CMS has resolutely maintained its policy.

The payment-rate problem results from a bi-modal distribution of costs of radiodiagnostic services by volume, as shown in stylized fashion in Figure 1. Differences in service costs can be largely attributed to the differences in the DxRPs used in the services grouped into the APC. The APC's payment rate, based on an overall average, in this example mis-pays both high-cost and most low-cost services. Removing the high-cost scans from the APC would result in more accurate payments.

How can this be done? One approach, repeatedly urged on CMS, would be for Medicare to pay separately for DxRPs costing more than a specified threshold, as it does for other pharmaceuticals, including therapeutic radiopharmaceuticals. CMS has refused, arguing that regardless of cost the DxRPs act as supplies that are integral to the procedure, so separate payment is inappropriate.

A change in law could require CMS to pay separately. The Facilitating Innovative Nuclear Diagnostics (FIND) Act promoted by SNMMI would require CMS to unpackage DxRPs where the per-day cost exceeds $500 and to pay for those DxRPs separately. However, the fate of this bill is uncertain in the current gridlocked political environment.

The question has been raised whether a cost-effectiveness analysis of new DxRPs that demonstrates that their use reduces overall spending sufficiently to compensate the system for their higher costs might persuade CMS to make separate payment for them.

Such a cost-effectiveness study would presumably have to provide comparative information on the overall costs attendant on use of a particular DxRP, set of DxRPs, or platform versus diagnostic alternatives. It would optimally follow patients for some time, perhaps several years, taking account of changes in costs of care, including therapies dependent on the diagnostic

Continued on page 15. See Could a Cost-Effectiveness.
Broadening the Scope of a Pharmaceutical Company to the Benefit of Patients

Despite its many challenges, the last two years have been immensely inspiring. We have witnessed the triumph of science over doubt and seen an unparalleled collective effort help soften the impact of what is certainly one of the most severe crises we have faced as a global community in decades. For companies in the pharmaceutical industry like ours, that have been focusing on bringing promising new technologies to the market for the benefit of patients worldwide, the past few months have been a validation of everything we do. Perseverance does pay off and new technologies will get adapted at a rapid pace once they are able to showcase what they can do. Only through industry-wide collaboration will we be able to bring forward new treatment concepts in a timely manner.

The technology we at ITM have been focusing on for more than 15 years, Targeted Radionuclide Therapy (TRT), is a concept used in precision oncology that has been studied intensively over the last decade and beyond. ITM itself has contributed heavily to the development of industrial scale production methods for specific therapeutic radioisotopes such as no-carrier-added lutetium-177. Methods we have not only introduced but used to establish our own production facilities to bring TRT to as many patients as possible. Much like what we saw in the vaccine space over the last two years, TRT has the potential to revolutionize cancer treatment.

With a broad pipeline of radiopharmaceuticals in both preclinical and clinical phases we are currently developing various “theranostic” pairs — candidates that can be adapted for both therapy and diagnostics — for several types of cancers. Our lead candidate ITM-11 (n.c.a. \(^{177}\)Lu-edotreotide) is currently undergoing evaluation in two separate phase III clinical trials. COMPETE for patients with grade 1 and grade 2 gastroenteropancreatic neuroendocrine tumors (GEP-NETs), COMPOSE for patients with high grade 2 and grade 3 GEP-NETs. ITM-11 consists of the medical radioisotope no-carrier-added lutetium-177 (n.c.a. \(^{177}\)Lu) linked to the targeting molecule edotreotide, a somatostatin analogue that targets SST-receptors highly expressed by GEP-NETs. Its diagnostic counterpart \(^{68}\)Ga-edotreotide has already received market authorization in Austria, Germany, and France. In addition to GEP-NETs our pipeline is also investigating the potential of TRT for glioblastoma, prostate cancer, ovarian cancer, non-small-cell-lung cancer, osteosarcoma and osteoblastic bone metastases. ITM-41 (n.c.a. \(^{177}\)Lu-zoledronate) for example, a radiopharmaceutical candidate in preclinical development, binds to the bone material hydroxyapatite, which accumulates in bone with malignant bone disease, and thus may offer therapeutic properties.

As well as the beta emitter lutetium-177, we are also looking at the therapeutic potential of alpha emitters against prostate cancer or FR\(\alpha\)+ tumors such as ovarian cancer and non-small-cell-lung cancer. Here, our focus is particularly on actinium-225 and we are eager to build upon our initial preclinical work. For FR\(\alpha\)+ tumors, specifically developed targeting molecules have shown promising dosimetry and imaging results in a phase I study when labeled with fluorine-18, the diagnostic companion to actinium-225 in our research activities.

But despite their many promises, development and research have not been the sole focus of ITM in the recent months. In fact, one aspect, which has proven itself vital for the pharmaceutical industry over the last two years, we have been cultivating from the very beginning of the company: collaboration. Right from the start, we knew that only by working together with academic and industry partners would we be able to provide state-of-the-art treatments to those in need quickly and efficiently.

One of the pillars to the success of ITM is providing best-in-class radioisotopes to numerous industry-leading pharmaceutical companies through long-term supply agreements. This not only ensures the timely development of promising treatment options for various indications outside our scope of operations, but also helps to grow our business to support our very own pipeline of precision oncology candidates more effectively. Recently we have even entered into an exclusive licensing agreement with a Chinese partner to provide our radiopharmaceuticals in a region with a growing patient population in need of precision oncology treatments even more effectively.

In parallel to our various collaboration efforts, we continue to expand our presence in key markets such

NorthStar Medical Radioisotopes is poised to become the first-in-class production supply chain for the future of therapeutic radiopharmaceuticals. In September 2019, the company broke ground on a 30,000 ft. building that now houses the company’s first pair of electron beam accelerators. This past September 2021, the company celebrated the successful installation of the accelerators as well as all the equipment installed in an adjoining building, which will serve as the dissolution, processing, and filling facility. During our celebratory event this past September, we invited investors, customers, members of local and federal government and special guests to take a tour of these buildings. The feedback was so positive and garnered so much interest in our facilities that we decided to share the highlights with the membership of SNMMI. The following is an interview with James McCarter, PhD, Manager, Irradiation and James Harvey, PhD, Senior Vice President & Chief Science Officer, who have been leading the accelerator program at NorthStar.

Q. Why don’t you start with an introduction, and tell us what your role is at NorthStar.

JM: I am James McCarter, Manager of our Irradiation team at NorthStar. Our Irradiation Group has a blended focus on nuclear physics and engineering, providing support throughout various processes along the production pathway. Our team is responsible for NorthStar’s production of Molybdenum-99 using electron accelerators and applying the same accelerator technologies to future radioisotope programs.

JH: I am James Harvey, NorthStar’s Senior Vice President and Chief Science Officer. I work with NorthStar’s engineering, manufacturing and development teams to bring new products to the company in a Business Development capacity. I have been in this role at NorthStar since the inception of the Company more than 17 years ago.

Q. How does NorthStar currently produce Mo-99?

JM: Mo-99 is currently produced in partnership with The University of Missouri Research Reactor, or MURR®, as we call it. This process involves the addition of a neutron to naturally occurring Mo-98 to create Mo-99. Our new electron accelerators will create electron beams that produce x-rays that will knock neutrons off, known as neutron knock-off. This process takes a naturally occurring and abundant natural resource, Molybdenum-100, knocking off a neutron to create the radioactive Mo-99. In summary – we currently add a neutron to Mo-98 in the MURR® reactor; additionally, in the future, we will remove a neutron from Mo-100 using the electron accelerators.

Q. When thinking of new ways to produce domestic, non-uranium Mo-99, how did you and your team begin to think about electron accelerator technology? What were the goals you had in mind or issues that you thought through to solve using accelerator technology?

JM: The Program was already underway when I joined NorthStar. I come from a background of accelerator physics. I have my PhD in Engineering Physics that I received through the University of Virginia and Thomas Jefferson National Accelerator Facility, working on accelerators for many years at a few different companies before coming to NorthStar.

I have always been interested in the space and am aware of the many ways that accelerators can help society and have meaningful impact. When I learned of NorthStar’s approach to use accelerators to produce Mo-99 and pursue other medical radioisotopes, I was intrigued. When I learned about the accelerator project, how NorthStar operated, and its management team and resources, I decided this was the place I wanted to pursue my career and advance the growth of a domestic Mo-99 supply chain.

JH: We knew as far back as the first major shortage of Mo-99 after Canada’s National Research Universal (NRU) reactor at Chalk River outage in late 2007 that we had something special – the technology that has become the FDA approved isotope separation platform known as the RadioGenix® System. We also understood then that we could combine this technology with two different non-uranium production technologies, either reactor neutron capture or electron accelerator neutron “knock-out” to produce a domestic, non-uranium, non-HEU Mo-99 at a commercial scale. We knew we needed to establish two distinctly separate production technologies that could provide dual production pathways – sourcing Mo-99 that would be reliable for our customers and most importantly, for the patients they serve.

Continued on page 12. See NorthStar.
Personalized Dosimetry is Essential for NETs

LYDIA RAM, MSC; ERIN ROSS, PHD — UNIVERSITY HOSPITALS BIRMINGHAM NHS FT, UK
HELENA MCMEEKIN, MSC — HERMES MEDICAL SOLUTIONS, SWEDEN
FREDERIK L. GIESEL, MD — UNIVERSITY HOSPITAL DUSSELDORF, GERMANY

Peptide receptor radionuclide therapy (PRRT) is a powerful tool in the fight against neuroendocrine tumors (NETs). But the complexities of tailoring the treatment to each individual patient present a challenge to both clinical departments and software companies. In this article we describe a multi-disciplinary effort to overcome the challenges and deliver the optimal treatment for patients.

Lydia Ram, Erin Ross, and a multi-disciplinary team at University Hospitals Birmingham NHS FT in the UK, with the support of Hermes Medical Solutions, are undertaking a project to evaluate the dose delivered to patients receiving the fixed treatment regime of 4 cycles of 7.4GBq Lu-177 DOTATATE. The aim is to build a tumor dose-response relationship and determine dose limits for organs at risk (OARs), facilitating a personalized activity prescription on an individual patient basis rather than a standardized ‘one size fits all’ regime. Here we report initial results from 19 patients.

Using the state-of-the-art Voxel Dosimetry™ and vendor-neutral quantitative SPECT reconstruction software from Hermes Medical Solutions, post therapy SPECT images acquired on day 0, day 1, day 4, and day 7 were combined into a 3D voxel dose distribution facilitating detailed dosimetric analysis. Voxel Dosimetry™ employs full Monte-Carlo simulation for the photon component of the radionuclide, which is essential when evaluating OAR dose when a high uptake tumor is close by. Indeed, 18 out of 19 patients in the cohort received less than the 23 Gy assumed mean kidney dose limit summed over the four treatment cycles; for the one patient exceeding this limit a kidney-adjacent high uptake tumor was the cause.

Wide variation was found in the mean absorbed dose to the 37 analysed NETs: mean dose 14.4 Gy with a standard deviation of 10.2 Gy. Analysed NETs included those in the mesenteric nodes, abdominal nodes, liver, and bones. NET and OAR doses vary significantly between patients, highlighting the need for individualized dosimetry.

Even with such efficient software and such strong evidence for the necessity of dosimetry, the practicalities of scheduling four SPECT imaging time points post-therapy mean dosimetry has been out of reach of the mainstream clinical workflow - until now!

At the SNMMI Virtual Annual Meeting 2021, Hermes Medical Solutions introduced the revolutionizing concept of single time point dosimetry. The novel Hänscheid method calculates doses for Lu-177 PRRT and needs only one imaging time point four days post therapy. Hänscheid and colleagues have validated their method vs multiple time point imaging to within 90% accuracy:

“The absorbed dose from PRRT with 177Lu to NET lesions and relevant abdominal organs can be deduced with reasonable accuracy from a single measurement 4 d after the activity administration... All 177Lu-accumulating tissues showing monoexponential decay with effective half-lives between 38 and 128 h are well represented, with an error of less than 10%.”

As well as the Hänscheid method, the software can model physical or effective half-life for cumulated activity calculation from a single time point.

‘Individual dosimetry will be key to ensure the success of any radionuclide therapy’, argued Frederik Giesel, chairman of the Nuclear Medicine department in University Hospital Dusseldorf, Germany during a webinar hosted...
In 2022, thanks to recent accomplishments and upcoming projects, excitement for the Value Initiative has never been greater.

**Quality of Practice**
- New appropriate use criteria (AUC) for PSMA PET imaging and Musculoskeletal Infection Imaging
- Upcoming launch and pilot phase of the Radiopharmaceutical Therapy Registry (RaPTR)
- Launch of the Radiopharmaceutical Therapy Center of Excellence (RPTCOE), with phase 2 of this program including an option for accreditation
- Recent approval of new procedure standards, including Nuclear Medicine Evaluation and Therapy of Differentiated Thyroid Cancer, Molecular Breast Imaging with Dedicated Gamma-Cameras, Imaging of Pediatric Gliomas, and Use of [18F]FDG PET/CT Imaging During Immunomodulatory Treatments in Patients with Solid Tumors

**Research and Discovery**
- Publication of the recent supplement to *The Journal of Nuclear Medicine* (JNM): "Radiopharmaceutical Dosimetry for Cancer Therapy: From Theory to Practice"
- The initiation of the Mars Shot Fund—supporting innovative research in areas outlined in the Mars Shot for Molecular Imaging paper
- Upcoming summits on Artificial Intelligence in Nuclear Medicine and Patient Access to Nuclear Medicine Procedures including Health Disparities—both organized to bring together high-level stakeholders from FDA, NIH, academia, and industry
- Increased local and national coverage in consumer media to increase the awareness of nuclear medicine and promote research

**Workforce Pipeline and Lifelong Learning**
- Creation and implementation of three new pipeline working groups (physician, scientist, and technologist)
- Creation of a working group to develop educational content/curriculum for residents on radiopharmaceutical therapies and diagnostic procedures
- Increase in awareness of nuclear medicine/molecular imaging as an appealing and rewarding field for students interested in STEM (science, technology, engineering and mathematics) careers by increasing our exposure and participation at events including the Association of University Radiologists; American Medical Student Association; and American Medical Association
- Development and dissemination of information and resources on the SNMMI Approved Family Leave Statement, Implicit Bias Training; and a Best Practice Repository for program directors
- Creation of resources to serve the entire nuclear medicine community, regardless of training pathway, including development of DE&I and wellness websites and connection of early career professionals with professional mentors
- A return in 2022 to in-person roadshows, including a new series on prostate cancer diagnosis and treatment

**Outreach**
- Continued participation and education of referring physicians during session presentations and symposia at several events, including the Pediatric Endocrine Society, American Society for Radiation Oncology, Large Urology Group Practice Association, American Urological Association, and San Antonio Breast Cancer Symposium
- Increased patient involvement in SNMMI virtual fly-ins with congressional staff, media relations efforts, and patient-focused roundtable discussions on disease-specific topics
- Additional growth and collaboration of the SNMMI Patient Advocacy Advisory Board with the addition of two new organizations (Cancer ABCs and Pheo-Para Alliance), bringing total number of members to 14
- Education of patients and patient advocates on the value of nuclear medicine procedures, with the most recent "patient education day" welcoming 223 attendees to the live session, and 1,000+ views of the on-demand sessions to date. A return in 2022 to in-person roadshows, including a new series on prostate cancer diagnosis and treatment

**Advocacy**
- Educating the nuclear medicine community on the bipartisan Facilitating Innovative Nuclear Diagnostics (FIND) Act, including the development of a resource

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What do you see as the most promising aspect of nuclear medicine?

The move from mostly diagnostics into therapeutics and now theranostics is promising. This industry is unique in its ability to provide targeted diagnostics, therapeutics, and imaging, and the information and treatments delivered to physicians and patients are revolutionary. Our industry brings hope.

Tell us about your board work.

I love board work because it is a unique opportunity to work together with people from different backgrounds. The common goal is to provide guidance and recommendations from our diverse perspectives. Recently I joined the ERF, Education & Research Foundation board for nuclear medicine & molecular imagining with special interest in The Curie Fund for Women in Leadership. As part of the founder’s circle for the fund I find it exciting to now be part of the board. I serve on the Langham Logistics board, which brings supply chain solutions. Today, we see how vital the supply chain is for our day-to-day lives in making sure we have the supplies we need. I also serve on the Castle Biosciences board, which does genetic testing for oncology - as a cancer survivor, my heart and soul lie with finding ways to help future patients overcome the disease.

Nuclear Medicine & Artificial Intelligence. Continued from page 3.

guidelines on best practices in order to avoid key pitfalls of AI. We have made general recommendations, followed by descriptions on how one might practice these principles for specific topics within nuclear medicine.

(3) Best practices for algorithm evaluation: Specifically, we have introduced the RELAINCE (Recommendations for Evaluation of AI for Nuclear Medicine) guidelines. The goal of this work is to provide best practices to evaluate AI algorithms for different objectives including for proof of concept, technical efficacy, clinical utility, and post-deployment efficacy, in general, and in specific contexts of nuclear medicine imaging.

(4) Ethical contemplations in deployment of AI: this work anticipates potential ethical considerations of widespread, rapidly-evolving AI-based products in medicine. Specifically, viewing these considerations through the lens of health disparities has permitted us to conceive of potential harms to certain groups in the population and to protect against them.

The above 4 efforts are being promoted in our community via conference educational abstracts and organized continuing education (CE) sessions, as well as journal publications.

Furthermore, the valuable discussions in the task force had a direct impact on the structure and approach by editors of two special AI issues (2021, 2022) by the journal PET Clinics, including contributions by many members of the SNMMI AI task force, as directly acknowledged by the journal. In addition, we had representation in a panel towards a “guideline on radiomics in nuclear medicine”, jointly sponsored by the European Association of Nuclear Medicine (EANM) and SNMMI.

Furthermore, significant momentum has been built within the community, and task force members have been actively and closely working with SNMMI in the planning of the upcoming AI summit in March 21-22, 2022 [2].

Finally, two new efforts are currently underway by the task force:

(1) Data infrastructures: AI methods tend to require significant data for training, challenged by data sharing limitations. Our task force seeks to enable improved and effective methods of AI algorithm learning, including possibilities of creating large, centralized databases as well as organization of multiple data challenges, and frameworks for effective model sharing. We are presently working closely with an NSF-sponsored initiative: “Leveraging Data Communities to Advance Open Science” to help make informed decisions in these important directions.

(2) Linking AI and dosimetry towards precision radiopharmaceutical therapy (pRPT): There is increasing enthusiasm in the community towards the significant potential of personalized dosimetry for improved treatment of patients. Nonetheless, dosimetry is often perceived as difficult, cumbersome, and/or in need of improved reproducibility. We believe AI can make significant contributions towards automated and reliable dosimetry applications. This can, in turn, accelerate implementation of dosimetry-based treatment optimization in routine clinical practice.

REFERENCES


Critically ill patients are at the highest risk in these cases and transporting them can be extremely risky. Often, the risk of transporting the patient may even outweigh the benefits. This presents a dilemma for clinicians in the hospital.

But, at times, transportation of patients for imaging is desperately needed. In these cases, patients often require devices like oxygen and a significant labor requirement for transit. Therapists, nurses, transporters, and, sometimes, even more staff must be present for successful intrahospital patient transport.

To truly improve patient care, reducing risks associated with transport is critical. Portable imaging can significantly reduce this risk. Many Digirad Ergo owners have reported great success in both risk reduction and improvements in infection control.

In contrast to labor-laden patient transport, portable imaging only requires one employee: a Nuclear Medicine Technologist (NMT). Best of all, there is absolutely no patient transport necessary. This not only removes the risks associated with patient transport but cuts down on the need for expensive labor that is essential to the process.

Why Point-of-Care Imaging Matters

Now more than ever, portable nuclear imaging is vital for hospitals and imaging centers. Here’s why:

It Will Keep Your Department Running

Portable imaging gives your department flexibility. The COVID-19 crisis has taught us all how the ability to adapt is a critical requirement for hospitals. Being stuck in a single location within the facility limits radiology, and the ability to image throughout the hospital can keep your department running.

It’s Better for Patients and Families

The benefits of portable nuclear imaging to a patient are similar to portable ultrasound and x-ray. Namely, for specific individuals, the process of getting a nuclear medicine scan can be arduous, and the ability to obtain bedside imaging results in far less stress.

The Bottom Line

Does your hospital or imaging facility offer portable nuclear imaging? If not, why?

This technology exists and is being used throughout the country. Cameras such as the Digirad Ergo are available and in use throughout the country. Just like ultrasound or x-ray, hospitals with this nuclear camera can take it where it’s needed.

As we come out of this crisis and look for better ways to serve our patients, you owe it to yourself to explore how portable nuclear imaging could work at your facility.

Personalized Dosimetry. Continued from page 8.

by Hermes Medical Solutions at EANM 2021.

Nuclear medicine is a quantitative diagnostic and therapy modality, and dosimetry software has progressed in leaps and bounds in recent years. Once the preserve of researchers with complicated spreadsheets requiring hours of processing time per patient, dosimetry can, and must, now enter the clinical mainstream. We owe it to the patients to optimise this powerful tool in the fight against cancer.

REFERENCE

Q. How is accelerator technology different from what you are doing now?

**JM:** I think the accelerator technology is different primarily because it gives NorthStar complete control over the supply chain — true vertical integration. We are still fully committed to a long-term relationship with MURR® because it ensures reliability of the supply chain, and at the same time we will have access to that material from start to end; from generation of the raw Mo-100 all the way through to the RadioGenix® System-produced Technetium-99m (Tc-99m) that our radiopharmacy customers use to compound patient doses. Another important added benefit of vertical integration is the ability to adapt our production timelines to meet customer schedules. We will control what days we produce and ship Mo-99. We can increase supply of Mo-99 on short notice and we can produce Mo-99 every day of the week, if that is what customers require, or we can go to a more traditional Sunday production run, adding another day if needed.

Q. Why two accelerators?

**JM:** To understand the NorthStar accelerator production process it helps to start with the target. Our target is a series of Mo-100 cylindrical discs, approximately one-inch in diameter. The stack of discs resembles a roll of quarters. To maximize production efficiencies, it helps to shoot the electron beam from both sides. That is the way we can maximize the most efficient production of Mo-99. If we irradiate the starting material from two sides, it makes sense to use two different accelerators instead of trying to use one singular beam, split it in half, then recombine it. That technology would have been even more challenging. With two accelerators, we are

*Continued on page 13. See NorthStar.*
NorthStar’s accelerator production facility houses two custom-built, 24-ton Rhodotron TT 300-HE (High Energy) electron beam accelerators. Each 10’ diameter x 11’ high accelerator weighs 48,000 pounds, or the weight of four African bush elephants. The accelerators were custom-built in Belgium for NorthStar by IBA (Ion Beam Applications S.A., EURONEXT). The accelerators began their 5,700-mile journey in Louvain-la-Neuve, Belgium and were transported via truck to Antwerp. They travelled in separate container ships to Baltimore, Maryland where, after clearing U.S. Customs, they were loaded onto oversized flatbed trucks to travel as a convoy from Baltimore to Beloit. The convoy arrived April 20, 2021 and the vaults and rest of the building were built around them. NorthStar expects equipment qualification and regulatory approvals for aMo-99 production to be completed by the end of 2022 with commercial production beginning in 2023. Up to three additional mirror image, accelerator facilities are planned to support increased market demand for Mo-99 and other radioisotopes.

NorthStar’s unique and proprietary electron accelerator production facility and processes are designed to provide efficiencies throughout the production process, thereby enabling the production of multiple radioisotopes utilizing the same equipment. With this in mind, production of radiochemical grade Copper-67 (Cu-67) is expected in late 2022.

Q. Can you tell us more about the accelerator and the systems required to maintain them.

JM: Our accelerator vault is similar to other accelerator labs, but we have a very high beam power. We have 250 kilowatts of total beam power at 40 MeV of electron energy. To contain that radiation, we built concrete walls that are 7.5 feet-thick of high-density concrete, which is equivalent to 12 to 15 feet of standard density concrete.

In addition, we have local shielding around the target itself, which consists of a series of boxes, similar to Legos stacked on top of each other, and those boxes are filled with a combination of steel pellets and water or steel plates and concrete.

The accelerator facility itself was then built around the vault, which is the center of our process. Our production process also uses very high pressure, high flow helium to cool the target. The facility has a specialized room to house the helium equipment, which ranges from compressors and blowers, to purification and monitoring equipment, all located adjacent to the vault. There is also hot cell space, which the targets are placed into, moved out of the vault and delivered to NorthStar’s adjacent Isotope Processing facility.

The entire accelerator facility is built on a 56-inch concrete foundation, which supports the 15 million pound vaults, the accelerators, and other associated equipment.

Q. The facility must require a lot of power.

JM: The accelerator facility will use approximately 1.5-2.0 megawatts of power to run the accelerators and the associated HVAC and other building systems. It is a lot of power for a very small footprint! You might see that kind of power at a car factory that is spread across several hundred thousand square feet. In comparison, our facility is 25,000 square feet, so it is “energy-dense.” We have a dedicated power substation located adjacent to our facility, which will handle current and future needs including additional accelerators.

Given the enormity of power to dissipate, our chilled water system is very important. The colder temperatures in Wisconsin allow us to utilize a dry cooling system. Similar to how a car radiator works, we pump the water outside to let the cold air of the Wisconsin winter chill the water for us. This provides significant electricity cost savings and helps with sustainability.

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We are equipped through an Uninterruptable Power Supply (UPS) system to handle short power outages. This allows us to safely shut down our accelerators and monitor all equipment and the status of all measurements and instrumentation in our facility. In the event of a power failure, the UPS is able to sustain operations until our facility generators and backup generators turn on.

Q. After the discs are irradiated, can you give an overview of the dissolution, processing, packaging and shipping processes?

JM: To recap, the Mo-100 starting material is pressed into discs, loaded into a holder and irradiated on both sides using our two electron accelerators. The irradiated targets, which are now a combination of Mo-99 and Mo-100, are removed through our hot cells (where we push the targets in and out of the accelerator), placed into a shielded transfer cask and moved from our Accelerator Production facility to our Isotope Processing facility, which is next door. In our Isotope Processing Facility, the discs are removed, and placed into a dissolution chamber where robotic arms are used to remove the discs and process the Mo-99. The material is then moved over to our filling lines, placed in tungsten shielded source vessels, packaged, and then shipped to radiopharmacies across the country.

An important item to note is that any unused Mo-100 is reclaimed and reused. This occurs both at the point of production and any unused Mo-99 that remains in the source vessels that are returned from customers is also reclaimed and reused. This is yet another example of NorthStar’s focus on being an environmentally conscious company.

Q. Are electron accelerators more environmentally sound than traditional Mo-99 production methods?

JM: Absolutely. NorthStar’s accelerator production technology is more environmentally sound than legacy production using fission methods. The critical distinction is that our process does not use uranium. We do not create uranium fission fragments or any problematic by-products. We have very limited long-term radioactive waste material and a benign chemical waste stream.

NorthStar’s radioisotope production programs rely solely on methods that do not involve use of uranium and the fission process. We believe developing environmentally sound radioisotope production methods is important to the sustainability of nuclear medicine. Radioisotopes we produce now or plan to produce in the future will continue to use non-uranium target material and production processes.

Q. What are plans for expansion at NorthStar? Will there be additional accelerators and what will they be used to produce?

JM: We believe we will have extra capacity with the two accelerators and our current target design. If there are gaps between what the Mo-99 customer base demands and what we can supply in any given time, we are able to ramp up production. However, no additional accelerators are planned at this time.
NorthStar. Continued from page 14.

to use the accelerators for other projects. Those other projects can be improvements to our current design for a more efficient production process, to make more Mo-99 per target, or produce other radioisotopes that serve other markets. Our accelerators are agnostic as to what their target is. They are designed to run 7 days a week, 24 hours a day. For example, if we only need 5 days of Mo-99 production, then there are two days of production that can be used to produce other radioisotopes.

NorthStar will be able to meet our commitment to provide domestic Mo-99 as well as our commitment to future medical radioisotope partners.

Throughout our current commissioning projects we are learning and refining along the way and will apply lessons learned to expand into the therapeutics business. In the near term, we just broke ground on our Actinium-225 Production facility that will house an electron accelerator to produce non-carrier-added Actinium-225 (n.c.a Ac-225).

I think the future of NorthStar and our electron accelerator technology is very bright. In 2023, after receiving all necessary approvals, we will be delivering radioisotopes to the community produced at NorthStar’s own facilities in tandem with the Mo-99 produced from our partners at MURR®. Relying on that expertise will help us bring a dual-sourced domestic, efficient, reliable, and environmentally sound Mo-99 supply. Mo-99 has been the workhorse of the United States nuclear imaging community for years. When we apply the depth and breadth of our knowledge and experience in new and former technologies to the future of radiodiagnostic and radiotherapeutics, you can envision the direct impact that NorthStar will have on the lives of the patients we work so hard to serve.

For additional information on NorthStar’s accelerator technology, and to take a virtual tour of the facilities discussed here, please visit us at www.NorthStarnm.com.

Could a Cost-Effectiveness. Continued from page 5.

outcome and other downstream costs for the underlying disease. For an apt comparison, the analysis would probably have to be disease-specific. It would not necessarily have to be set up as a clinical comparative trial; instead it might be able draw on longitudinal Medicare claims data as a principle source of information, using comparison techniques (for instance, propensity-matched samples) and estimating methodologies. Any stakeholder interested in pursuing such analysis should recognize the need for an expert, sophisticated effort.

Assuming robust, positive results, what good would this do? Surprising as it may seem, CMS does not usually pay much attention to cost-effectiveness. CMS eschews attention to costs in coverage determinations, and the main thrust of payment rate determinations is, within limits, to establish rates that capture the resource requirements of packages of items and services, not on the effects of those services on decreasing — or increasing — overall costs. So, given CMS posture that DxRPs are supplies, a cost effectiveness study may not be the missing link that will impel CMS adopt separate payment for DxRPs.

However, even though CMS does not take costs explicitly into account, its view might still be swayed by evidence pointing to a significant savings potential, and a study with at least moderately robust results could influence the agency’s willingness to provide some accommodation. While the likelihood of CMS wholly abandoning a packaged approach in this instance does not appear high, the agency could conceivably revise the current APCs depending on whether a particular product is used. For example, CMS could split a single APC for diagnostic scans, which is not now differentiated by the DxRP used, into two APCs, one for scans using high cost DxRPs and another for scans using low cost DxRPs. This could allow a higher payment to hospitals for the diagnostic service as a whole in particular instances, while not going as far as providing for separate payment for the DxRP. One stylized example of this is shown in Figure 2.

Further, such a study could help in securing support in Congress for the FIND Act. It may also help with securing more adequate payment rates from capitated plans — Medicare Advantage and many private insurance plans.
As we move forward on these and other critical initiatives, I am eager to meet again soon in person to discuss our strategic priorities and key milestones for the next five years and beyond. I believe we are at the cusp of a unique opportunity to greatly expand the future role of nuclear medicine and molecular imaging in medicine and patient care. Now is the time to harness the power of the Value Initiative to truly elevate the value of nuclear medicine and molecular imaging for generations to come.

Satoshi Minoshima, MD, PhD  
Chair, SNMMI Value Initiative 2.0  
Professor and Anne G. Osborn Chair  
Department of Radiology and Imaging Sciences  
University of Utah

As the United States. There we are currently establishing a structural foundation, that will enable us to scale up our commercial organization quickly and efficiently subject to the favorable outcome of our current Phase III trials and potential market authorization of $^{177}$Lu-edotreotide.

While as an industry we are of course driven by market and business dynamics, pharmaceutical companies must never forget their real purpose: providing care and hope to those in need. Commercial success must serve as a vehicle to enable just that.

Steffen Schuster, CEO  
ITM Isotope Technologies Munich SE
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