

Launch of the *Radioligand Therapy Readiness Assessment Framework*

Meeting report from 9 June, 2021
Virtual ancillary ASCO event

The Health Policy Partnership was pleased to convene a meeting gathering together nuclear medicine specialists, oncologists and patient advocacy representatives to discuss readiness for radioligand therapy and launch the [Radioligand Therapy Readiness Assessment Framework](#).

Dr Suzanne Wait (The Health Policy Partnership) welcomed the attendees and briefly outlined the importance of readiness for innovative cancer therapies like radioligand therapy. She outlined the many policy challenges that cause significant delays in availability and use of radioligand therapy for eligible patients. Professor Ken Herrmann (University Hospital Essen) presented the [Radioligand Therapy Readiness Assessment Framework](#) and his experiences of barriers to wider use of radioligand therapy in the future: the challenge of infrastructure. Professor Herrmann was followed by Josh Mailman (NorCal CarciNet Community), who presented his personal experiences of radioligand therapy through the lens of the readiness assessment framework, and highlighted many learnings from the neuroendocrine cancer community that need to be considered in the future.

Mr Mailman was then joined by Professor Hein van Poppel (European Association of Urology), Dr Diana Paez (International Atomic Energy Agency) and Associate Professor Jolanta Kunikowska (European Association of Nuclear Medicine) for a panel discussion on how to facilitate a ready environment for radioligand therapy.

This international panel was followed by a discussion on clinical readiness in the US with Dr Ronald Ennis (American Society of Radiation Oncology), Dr Richard Wahl (Society of Nuclear Medicine and Molecular Imaging), Dr Ajay Gopal (University of Washington and Fred Hutchinson Cancer Research Center) and Dr Michael Morris (Memorial Sloan Kettering Cancer Center).

Throughout the meeting, many cross-cutting themes emerged:

- The value of multidisciplinary care
- The need for harmonised and updated guidelines and regulations
- The importance of education and accurate communication
- The need to plan for future infrastructure requirements.

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What is a ready policy environment for radioligand therapy? Moderator and panellists (from left to right): Dr Suzanne Wait, Dr Diana Paez, Josh Mailman, Professor Hein van Poppel, Associate Professor Jolanta Kunikowska



The value of multidisciplinary care

During the panel on what makes a ready environment for radioligand therapy, Professor Hein van Poppel acknowledged that decisions around cancer treatment are increasingly complex given the number of treatments available, especially in prostate cancer. Panellists agreed there is significant value in bringing specialists together from different disciplines and sectors to support decision-making around treatment.

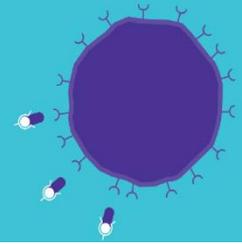
The delivery of radioligand therapy requires a multidisciplinary approach and should systematically involve nuclear medicine physicians, clinical/medical oncologists, radiation oncologists, radiopharmacists, clinical nurse specialists and medical physicists. Dr Ajay Gopal stated that there should be clear 'baton-passing' processes between specialists along the care pathway to facilitate referrals and treatment. Experts in the US case study session noted that referral processes and multidisciplinary care are major challenges. Access to truly multidisciplinary teams can be very variable, especially given that the vast majority of healthcare is delivered in community hospitals. Even when care is provided in academic centres, which are well-equipped to deliver multidisciplinary care, referrals and other processes can be relatively inefficient, Dr Gopal noted.

COVID-19 has forced a paradigm shift towards telemedicine and remote consultations. This provides significant opportunity to improve the efficiency of, and access to, multidisciplinary care. Dr Michael Morris noted: 'Today, a multidisciplinary team does not have to be in your clinic.'

The need for timely updates to guidelines and clear regulations

New and promising findings from the VISION trial were presented at ASCO, suggesting radioligand therapy will most likely be integrated into clinical guidelines for prostate cancer in the future. However, the panellists noted that amending clinical guidelines requires more than solid clinical trial evidence and clinician support. Associate Professor Jolanta

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Kunikowska stressed the importance of patient engagement in ensuring innovative treatments, like radioligand therapy, are included in clinical guidelines in a timely manner.

Radioligand therapy also requires clear and appropriate regulations and delivery standards. Dr Diana Paez noted that the IAEA has produced a series of standards on radioactive waste management, radioactive material transportation and radiation protection. However, Professor Hein van Poppel pointed out that such international standards are often interpreted differently and subject to varied implementation. The panellists agreed that there is a need for common delivery standards that are followed by all stakeholders to ensure optimal protection of patients, staff and the general public.

Unclear and inconsistent regulations are not just a problem at the international level. Variability in regulations also exist between regions and hospitals in the US. Examples include inconsistency in regulations regarding isolation after radioligand therapy, and limited regulatory requirements for radioactive waste storage. This flexible regulatory landscape may have advantages in supporting wide uptake of radioligand therapies across the US, but may also lead to disparities in use between different centres.

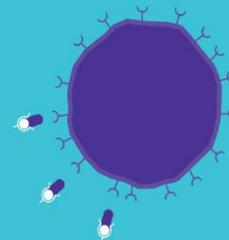
The importance of education and accurate communication

Given the variable approach to delivering radioligand therapy across and within countries, it is vital to educate all people involved in the therapeutic process. This includes regulators, patients and everybody in between. Josh Mailman emphasised the importance of clear and accurate patient education and communication from medical oncologists. Given the technical nature of the approach, clear and accurate information on radioligand therapy is essential – otherwise, we risk the spread of misinformation and incorrect perceptions about radioligand therapy.

What does radioligand therapy mean for patients? Josh Mailman, President, NorCal CarciNET Community

A screenshot of a presentation slide. The slide has a white background with a blue header. The title "Ways to Educate" is in a large, bold, blue font. Below the title, the text "Where we learn and how we share information has changed" is in a smaller blue font. The slide contains two main sections of bullet points. The first section is titled "More hours with the 'University of Google' than with doctors" and includes two bullet points: "Wide variety of misinformation on the NET" and "90% of Wikipedia articles on the ten most costly treatments contain errors". The second section is titled "What we hear from our providers is almost always repeated online in private patient groups" and includes a bullet point "We compare notes" with three sub-bullets: "across providers", "across countries", and "The information world is essentially flat". On the right side of the slide, there is a video inset showing a man with white hair, identified as Josh Mailman, speaking. The video inset has a small logo in the top left corner that says "NorCal CarciNET". The bottom of the slide has a blue bar with a small white icon on the right side.

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Case study: clinical readiness in the US. Moderator and panellists (from left to right): Dr Suzanne Wait, Dr Ronald Ennis, Dr Richard Wahl, Dr Ajay Gopal and Dr Michael Morris



The need to plan for future infrastructure requirements

A surge in interest in radioligand therapy is expected following the positive VISION trial results. This may create challenges around sufficient workforce capacity and infrastructure for delivery and waste management. Professor Dr Ken Herrmann noted that ‘we have no criteria for radioligand therapy centres of excellence’ for prostate cancer. As radioligand therapy is used more widely following the VISION trial results, it is important these criteria are established, and that centres of excellence are distributed appropriately to ensure equitable access to expertise.

Dr Suzanne Wait closed the session with her reflections on the common policy barriers across the various geographies represented in the meeting. She invited people to download the framework and apply it to their own contexts.

For more information and to download the framework and associated user guide, see: www.radioligandtherapy.com/international-framework/

The framework was developed by The Health Policy Partnership in collaboration with a multi-stakeholder International Advisory Group. The group has had full editorial control over all international-level outputs, with national-level groups maintaining editorial control for national outputs. The project is supported with funding by Advanced Accelerator Applications, a Novartis Company, with additional support from Nordic Nanovector.