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TOPICAL DEBATE

Patient hospitalisation for radionuclide therapy should be the exception and not the norm

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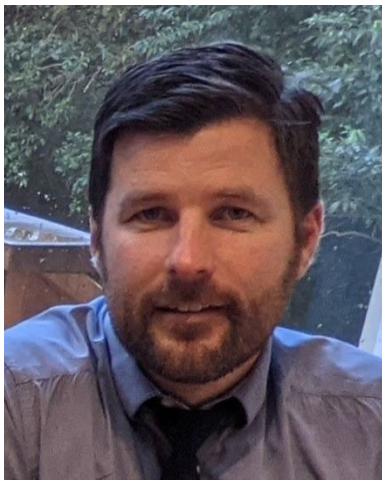
Introduction and overview: Clive Baldock, moderator

With an increasing growth worldwide in the medical use of ionising radiation for diagnosis and treatment of disease, an important consideration is that the exposure of patients from ionising radiation requires procedures be justified and optimised so that the appropriate radiation dose is delivered to the patient in order to achieve the required clinical objective. In the case of a diagnostic procedures, radiation doses should be minimised to that required to provide the necessary diagnostic information and, in the case of treatment procedures, radiation doses should be delivered to the tissue of interest whilst minimising exposure of non-target tissue.

In general, radionuclide treatments are administered to patients either as an inpatient in a hospital or as an outpatient. For each approach to treatment, there are well established and accepted standards of radiation protection that are applied with consideration given to the safety of the patient, family members, associated carers, staff and members of the public.

In this topical debate, Nicholas Forwood and Nick Hille debate whether patient hospitalisation for radionuclide therapy should be the exception and not the norm in Australia and New Zealand.[1]

Arguing for the proposition is Nicholas Forwood. Nicholas is a Senior Medical Physics Specialist at Concord Repatriation General Hospital. He has worked in clinical nuclear medicine physics for more than 14 years having previously worked at Royal North Shore Hospital and St Vincent's Hospital in Sydney. His research interests are in clinical radiation safety and has hands on experience in consulting patients on radiation safety and dealing with contamination.



Nicholas Forwood

Arguing against the proposition is Nick Hille. Nick was born and educated in Brisbane receiving a Bachelor's degree in experimental physics and a Master's degree in medical physics. After securing a position in nuclear medicine at St. Vincent's Hospital in Sydney (1986), Nick worked there until leaving for some adventure in Saudi Arabia, where he helped install several nuclear medicine facilities within the Ministry of Defence and Aviation.

Nick then travelled north to Townsville and helped establish the nuclear medicine facility and radiation oncology service in Far North Queensland. In 2001 Nick re-joined NSW health when he took up a position at John Hunter Hospital, primarily as a nuclear medicine physicist but also

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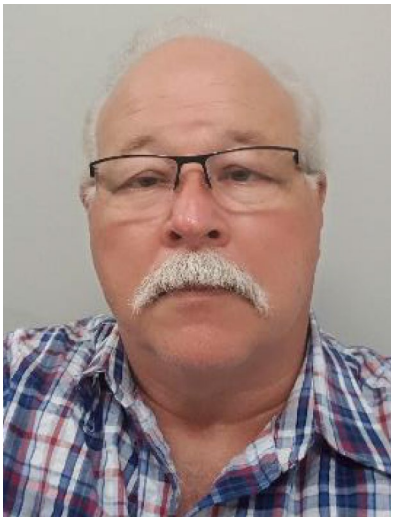
[1] Contributors to Topical Debates are selected for their knowledge and expertise. Their position for or against a proposition may or may not reflect their personal opinions.

as the radiation safety officer for, the Hunter New England Local Health District (HNELHD). Nick has been a member of the NSW HURSOG (Hospital and University Radiation Safety Officer Group) and has served as both the Secretary (mostly) or Chairman of HURSOG for a number of years until December 2020. Nick is currently the Chief Physicist at HNELHD.



Nick Hille

Opening statement—Nicholas Forwood

It has become an unshakeable tenet of nuclear medicine in Australia that a radioactive patient is a dangerous hazard when the radiation emanating from them is greater than 25 μSv per hour, but once it falls below that threshold, the patient becomes instantly safe. This is based on a misreading of the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) 20 year old document, *Discharge of Patients Undergoing Treatment with Radioactive Substances* [1]. The guidelines actually state that a patient may be discharged when an estimate of the dose to the other people from the patient has been found to comply with the relevant constraints. When no estimate is available, the threshold of 25 μSv per hour can be applied. The threshold concept was not mentioned in ARPANSA's more recent publication, *Code for Radiation Protection in Medical Exposure* [2], which only discusses the constraint requirement. If the constraint is the only goal, then we must ask whether these patients should be hospitalised as inpatients at all.

On this topic, the literature has an abundance of high-quality studies which show that in almost all cases, the radiation dose to members of the patient's family is far less than whatever constraint is imposed. Similar studies have been conducted in the USA [3, 4], Belgium [5, 6] and Mexico [7]. In this series of studies which looked at the radiation dose to family members of thyroid cancer patients after radioactive iodine was administered, out of 219 family members who were monitored, only 14 (6%) exceeded the constraint of 1 mSv. Each institution in this series of studies used a different timeframe for hospitalisation and for social distancing at home and yet there was no real-world difference between the results. This would suggest that the hospitalisation protocol used by the institution was not the critical difference. Research has shown that the significant difference is between those who have excellent facilities for isolating at home and those who have very poor facilities for isolating at home [7, 8]. In fact, when Iodine was administered as an outpatient procedure it was almost always possible to fit within the constraints required and this was especially the case in more developed countries [4, 7].

I argue that a correct interpretation of the ARPANSA guidelines would involve almost all patients who receive radioactive Iodine for thyroid carcinoma avoiding hospitalisation. Instead the medical physicist would consult with the patient and discuss their living situation and then use population based quantitative methods to estimate the radiation dose. The informed patient (and their carer if necessary) would be made aware that the estimate was lower than whatever constraint was applied with the patient not having to stay in hospital. It has been shown that the specific instructions from the medical physicist have a significant impact on the dose to family members [8]. There will of course always be outliers, particularly around patients with small children at home or where facilities are inadequate. However, in most cases the analysis will show that, given the correct radiation safety advice, the dose to the public should be well within the constraints needed, freeing a hospital bed for someone who is more acutely unwell.

Opening statement—Nick Hille

To begin the discussion, it is pertinent to make some attempt at definitions in order to guide the debate.

Radionuclide therapy tends to lead us into thinking about the oncological pathway of treatment. The various cancers, tumours and 'something-omas' that we have become most familiar with. However, we should also consider other uses of radionuclides that may be used for palliation or pain relief in certain circumstances. At any rate, radionuclide treatment entails the application of an unsealed radioactive source to a patient in order to effect a medical outcome.

It should also be borne in mind that hospitalisation may not necessarily mean an overnight admission of a patient into the hospital itself, but may also can be taken to mean an attendance to a hospital day clinic, nuclear medicine

department or even an outpatient clinic. In fact, ARPANSA RPS4 [1], clearly states that "discharge of the patient means the return of the patient into the community, and applies equally to the patient who has been admitted to a hospital for the treatment and to the patient who has been administered the treatment as an outpatient". Therefore, in this context any presentation to a hospital can be defined as 'hospitalisation'. It is also in the context of RPS4 [1] that we can further apply the general recommendations found therein.

The premise of hospitalisation of patients undergoing such a treatment is to reduce or minimise the radiation dose to others (members of the public) who may be exposed either by the external dose rate to such patients or by contamination from an unsealed radioactive substance that may be excreted by these patients.

It should be noted that the term 'discharge' may hold particular meaning to administrative types, i.e. discharge only applies to a hospital admission, which in some circumstances involves an overnight stay. But in the broader sense of the term, discharge may mean a 'release' back into the public domain away from the hospital(isation) and free to wander at will. Thus, public safety and ALARA becomes the focus.

It has been seen that while from an administrative perspective and perhaps also from a socio-economic perspective, outpatient treatment of, for example, radioiodine ablation for thyroid cancer may at first appear an attractive mode of treatment, it has been proven to be problematic with poor patient compliance (~ 35% conformity) [9]. While estimated doses to members of the public, or indeed, other members of the family, may have been below accepted dose limits or constraints, it remains a relevant observation that a simple hospitalisation of 48 h would have had a more dose constraint/limit compliant outcome [9].

Surely a simple observance of a simple recommendation is to be encouraged and thus be the norm in such situations? Therefore, such a simple recommendation (RPS4) [1] that has been referred to in the Safety Guide RPS14.2 [10], an integral component of the Code of Practice RPS14, should be the norm and not the exception.

Rebuttal—Nicholas Forwood

In regulatory 'gobbledygook', all words are flexible including 'hospitalisation'. Medical physicists, however, are bound by empirical measurement and blindly following linguistic trends must be a cause for alarm. ARPANSA RPS 4 [1] was published several years before the release of the iPhone so we should hardly be surprised that its recommendations are out of date in the era of 177Lu and various alpha emitters. Section 1.2 of RPS 4 [1] (titled 'Purpose') makes a clear distinction between a hospital and a clinic. The word clinic is used 17 times and its use indicates that unsealed therapeutic radionuclides can be administered in a non-hospital setting. So, whilst in the vernacular, the word discharge is tightly coupled with the process of being admitted to hospital, for ARPANSA, it is not.

Over time the use of the 25 μSv per hr discharge value has devolved into a non-scientific threshold between safe and unsafe, permissible and forbidden. Indeed, the use of that threshold undermines the use of a constraint in controlling the release of the patient which is the "principal criterion" used by ARPANSA. Far from shying away from the constraints, ARPANSA has elevated the use of constraints from a recommendation to an obligation. The newer code [2] (which should in-time become legally enforceable) enshrines the use of constraints and the process of risk measurement. The previously cited study [9] demonstrates the significant challenge that medical physicists must meet. Far from undermining the proposition, this study actually supports it because it shows that isolating patients in hospital for a certain period until their dose rate crosses a threshold has little impact on exposure to others. The most important issue is to understand the patient's living arrangement and adequately convey the advice. Armed with those skills, clinicians will soon hospitalise patients as the exception rather than the norm.

Rebuttal—Nick Hille

Firstly, let me commend my colleague's arguments for the proposition. However, I consider most of his points, while well thought out, to be optimistic rather than realistic! My colleague speaks of the 'unshakable tenet' in the 25uSv/hr dose rate being applied to radioactive patients as a 'misreading'. I contend that most medical practitioners have never read this at all! The critical gem of information in ARPANSA RPS4 [1] is.

> *Patients may be discharged from hospital or may leave a clinic following treatment with a radioactive substance when an estimate of the effective dose to family members and to members of the general public has been shown to comply with the dose limits and dose constraints given in Section 2.1.*

The relevant dose limits and constraints are respectively 1 mSv for members of the public and 5 mSv for any carer for *each* treatment episode. The 25μSv/hr@1 m is provided to supplement the lack of any reasonable estimate of effective dose to the public (or carer). This is where, I believe, the problem may truly lie. The ability of the practice to provide a reasonable dose estimate may well be beyond their resources (medical physics) or abilities.

We can reference numerous papers stating that outpatient therapy treatments can be 'successfully' undertaken, and my colleague has done this admirably. However, one of the salient points that I glean from such papers [4, 7, 11, 12] is that, yes, outpatient therapies may be undertaken successfully but often there is a caveat detailing some general conditions relating to compliance with radiation safety procedures and guidelines. There is an assumption that such guidelines and procedures are available, in place and/or observed [4, 7, 11, 12]. My colleague, himself, has referred to 'correct radiation safety advice'. Note that nearly all of these procedures BEGIN in the hospital in the first place, and we should ask ourselves why this is.

We all accept and work to the ALARA principal and definitions of 'reasonable' are also up for discussion. However, by and large, the general society in which we find ourselves also accepts, tacitly perhaps, a sweeping concept of 'being reasonable', 'better safe than sorry' and 'prevention is better than cure'.

We can extend this philosophy to radionuclide therapies, and yes, we can monitor these procedures in the home. However, although there may be arguments for this, to me the 'reasonable' approach should prevail, an approach that has the greatest benefit to all.

Therefore, I remain convinced that radionuclide therapies are best suited to in-patient procedures as the norm.

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