Administration of Radioactive Substances Advisory Committee

Minutes of the 83rd Meeting (by teleconference) held on 24 November 2022

Present:
Chairman: Professor K Bradley

Members:
Ms K Adamson
Ms S Aldridge
Dr C Beadsmoore
Dr M Cooper
Dr A Craig
Dr M Gaze
Mr D Graham
Dr J Dickson
Dr K Dixon
Dr N Hartman
Dr P Julyan
Professor I Lyburn
Mrs C Moody
Dr G Petrides
Dr S Rasul
Dr N Singh
Dr T Szyszko
Dr S Wan
Dr T Westwood

Secretariat:
Mrs L Fraser (UKHSA)
Dr A Powell (UKHSA)
Miss K Stonell (UKHSA)
Miss L Burns (UKHSA)

Observers:
Mr M Ager (Welsh Government)
Ms S Peters (DHSC)

Item 1: Welcome and apologies for absence

1.1 The Chairman welcomed members to the 83rd meeting.

1.2 Apologies have been received from Dr Nabil Hujairi, Professor John Wadsley and Mrs Nasreen Parkar.

1.3 This is the first meeting for Dr Simon Wan and Dr Thomas Westwood who joined the Committee in July 2022. No applications were submitted for the Committee Consultant Oncologist post, and this will therefore be re-advertised in 2023.

[Action: All]

Item 2: Declarations of members interests

2.1 The Chairman advised that members interests are published on the members page of the ARSAC website.

2.2 Members were asked to declare any changes to their interests since the last meeting. Members should inform the ARSAC secretariat of any changes between meetings.

Item 3: Minutes and notes of previous meeting

3.1 The Chairman asked members for corrections to the minutes from the previous meeting

3.2 The minutes were accepted as an accurate record of the meeting with the following amendments, and will be published on the ARSAC website:

- Paragraph 7.2: amend option '3' to option 'c'
- Paragraph 10.5: insert space after 'committee'

Item 4: Matters arising

a) Updated practitioner and employer application forms

4.1 The Chairman drew members' attention to the draft renewal application form for practitioners and employers. The practitioner licence renewal application form has been updated to include a statement regarding conducting continual medical education appropriate to hold a practitioner licence. The employer application forms (new and renewal) have also been updated to include details of the wider scientific support (in addition to MPE) available at the site.

b) HRA Update

4.2 CTIMP applications involving ionising radiation are required to use two IRAS systems. The new ionising radiation module set to be released by the HRA to remedy this has been put on hold with no planned date of release. There is no interim change to the documentation submitted to ARSAC prior to the final process implementation.

[Action: Secretariat]

c) Workforce issues

4.3 Workforce issues have been identified for both MPE's and practitioners. In response to the identified shortage of MPE's, the employer licence application form has been updated for applicants to include the availability of wider scientific support. An email has recently been sent to the DHSC by the Secretariat on behalf of ARSAC to highlight members concerns regarding nuclear medicine departments being under resourced in terms of both equipment and staffing to perform dosimetry for molecular radiotherapy procedures. The Secretariat will share the response with Committee members in due course.

[Action: Secretariat]

Item 5: Revoking licences

5.1 Mrs Fraser summarised the prohibition notice served by CQC which led to the first a revocation of an employer licence by ARSAC.

Item 6: Pregnancy/breastfeeding checking procedures

6.1 Dr Powell drew members' attention to ARSAC 11-22 and reflected on the current guidance in the Notes for Guidance (NfG). In light of the guidance published by the Society of Radiographers (SoR), members were asked to consider whether ARSAC should provide specific guidance on how to enquire about pregnancy and breastfeeding. Members were also asked to consider whether ARSAC should provide specific guidance on the methodology of checking pregnancy status prior to therapeutic administrations.

6.2 Members discussed this at length and questioned who was best placed to provide advice. Members reflected on local procedures, and offered the following comments:

- Provide a broad framework with examples proportionate to risk, allowing practitioners to decide on the level of risk and appropriate standard operating procedures to be developed locally within that framework
- Identify high risk procedures where there should be an obligation to exclude pregnancy and be explicit on how it is excluded using more than one method i.e. date of last menstrual period, blood test, urine test, patient declaration
- This is broader than ARSAC for NM and consideration should be given to what research trials are doing, patients with chemotherapy etc.
- Review international guidance – Ireland published some guidance this year. Mrs Fraser advised members that the UKHSA is intending to update the guidance jointly published by HPA, RCR and CoR in March 2009, next year.

6.3 Members were also asked to consider whether ARSAC should be providing guidance on inclusive terminology for both pregnancy and breastfeeding. Members offered the following comments:

- The SoR guidance is very comprehensive and is being used across entire Trusts. If ARSAC issues guidance that differs from this, it will confuse an already complex issue

6.4 Members concluded that the NfG should signpost to the SoR guidance.

6.5 Curium has updated their Summary of Product Characteristics (SpC) for 131I-iodide and state that conception should be avoided for 6 months, due to the lifespan of a sperm cell. Furthermore, the SpC states that thyroid cancer patients should be advised not to become pregnant within 6 to 12 months following treatment. Members are asked to consider whether the ARSAC NfG should be updated to reflect the duration of avoiding conception and pregnancy stated in the Curium SpC for 131-I iodide treatments. Members agreed that the NfG should be updated to match the SpC information.

[Action: Secretariat]

Item 7: ARSAC Notes for Guidance

7.1 Mrs Fraser drew members' attention to ARSAC 11-22. There are minimal changes proposed for the next update, of particular note:

- Guidance on transitional arrangements in IR(ME)R has been removed as all certificates issued under the MARS Regulations will have expired by 7th February 2023
- Information required to be submitted in employer applications for therapy procedures, consistent with guidance issued in Newsletters in 2022 has been updated
- Information on the role of scientific support other than that provided by the MPE
- Research trials that do not require ARSAC approval have been clarified
- Minor amendments to the procedure tables.

7.2 Members offered additional suggested typographical corrections

[Action: Secretariat]

7.3 Dr Julyan and Dr Dickson will review the DRLs specifically around PET and activity per kg in time for the next revision in 2024. Mrs Fraser noted that the information in the NfG is consistent with the EANM guidelines but is happy to set up a meeting to review it.

[Action: Secretariat/Dr Julyan/Dr Dickson]

7.4 Members are asked to send any further comments to the Secretariat. The NfG will be published in February 2023 to coincide with the anniversary of licensing.

[Action: All]

Item 8: Trends and issues on applications

a) Use of 18-FDG PET CT for bone imaging in research

8.1 The Chairman drew members' attention to ARSAC 13-22. A number of research applications for oncology trials have been received recently for 18-FDG for bone scanning. There is not a procedure code for bone scanning using 18-FDG and therefore this is not authorised for use in the UK. For such applications, ARSAC have requested updates to the PRA and PIS to reflect the use of 18-FDG for 'whole body tumour imaging'.

8.2 Members were asked to consider whether any further guidance is required and gave the following comments:

- ARSAC should continue to act in the best interests of the patient and challenge the information on the PIS where it is not deemed to be correct.
- For international trials, there is likely to be a standard PIS and it is the responsibility of the local teams to reword information sheets where appropriate
- The UK chief investigator has a vested interested and should be contacted.

b) Applicants for practitioner licences who are not on the specialist register

8.3 The Chairman drew members' attention to the letter at Annex A from Dr Rachel Cooper at the RCR regarding the guidance in the NfG.

8.4 The NfG states that to hold a practitioner licence, applicants are usually expected to be on the specialist register and in a substantive post. However, where the normal standard criteria are not met, ARSAC can approve applications for exceptional cases where appropriate justification is provided.

8.5 Members discussed this at length and agreed that ARSAC should maintain the position in the NfG. The Chairman will draft a reply to Dr Cooper advising that ARSAC has discussed this at length and maintains its approach that under normal circumstances, people will be on the specialist register and in a substantive post but explaining that guidance allows for non-consultant grades and locums to apply for a practitioner licence if they are able to demonstrate appropriate exceptional circumstances.

[Action: The Chairman]

c) 18F-PSMA applications

8.6 Members were asked to consider whether separate ARSAC procedure codes should be issued for each version of fluorinated PSMA coming to market.

8.7 Dr Hartman reflected on the review of all radiopharmaceuticals with the Secretariat to rationalise them. According to the principles applied to this process, Dr Hartman suggested standardisation under PSMA. Members agreed but suggested that the different doses are listed.

8.8 Members discussed the training requirements and whether existing training translated between tracers. Clinicians who would hold the licence for this should ensure the reporters have the requisite skills and are suitably qualified and experienced to report the studies.

8.9 Members also reflected on tracer supply being a real issue and some ability to be flexible with the use of tracers is a big advantage. Applying a separate code could be very disruptive to workflow and departments. The sensitivity for different bone lesions is an issue, but experienced reporters are likely to have some insight into that.

d) 177Lu-PSMA applications

8.10 The Chairman drew members' attention to the April newsletter but noted some applications are being received where the applicant has no direct mentored experience.

8.11 Members noted that post COVID, there is opportunity to attend in-person training but the number of centres currently doing PSMA means they are inundated and unable meet the demand of the number of people wanting to attend.

Item 9: UKHSA update

a) Clinical imaging and nuclear medicine errors

9.1 Dr Powell advised members that there is currently no national reporting and learning system specifically intended to learn and analyse from errors in nuclear medicine in the UK. The CIB recognises the value of this and supports the national data collection and analysis of diagnostic imaging and nuclear medicine error and near miss events. This work is being co-ordinated by UKHSA through a Working Party. It is recognised there are variations in how NM imaging and molecular radiotherapy (MRT) are delivered across the UK and the Working Party has raised where errors from MRT should be reported, there are three potential proposals:

- Updating the Clinical imaging error taxonomy to include errors from MRT so that all errors from nuclear medicine are reported in this single system
- Updating the Radiotherapy error taxonomy to include errors from MRT, with errors from diagnostic nuclear medicine reported through the clinical imaging error taxonomy. Nuclear medicine error data would be reported through two different systems
- Develop a bespoke error reporting system specific to MRT, with errors from diagnostic nuclear medicine reported through the clinical imaging error taxonomy. Nuclear medicine error data would be reported through two different systems.

9.2 The Chairman noted ARSAC has not been asked for input officially and suggested a watching brief is maintained. An update will be provided by the

Secretariat in due course. Members should contact the Secretariat if further information is required in the meantime.

[Action: All]

b) New database

9.3 Dr Powell advised members that a new Web Server based database to replace the MS Access version is being tested by the ARSAC Secretariat and Support Unit to manage and log specific details from each application and to generate licences, research approval documents and other reports including proc prints. The introduction of this system will not affect how service users or Committee members submit and review applications to ARSAC.

c) JIRA progress

9.4 Dr Powell advised members that testing is underway for submitting notifications to ARSAC through JIRA. This will be launched early 2023.

d) ARSAC application processing timescales

9.5 Dr Powell drew member's attention to the data provided by JIRA for processing times for all applications. The data shows that the average resolution time for research applications is greater than employer and practitioner applications, this is likely to be a result of delays in responses from applicants, and payment delays.

Item 10: Nuclear medicine items from other committees/meetings

a) RCR

10.1 Nothing of relevance to NM to report.

i. **Clinical Oncology**

10.2 Dr Gaze advised members that there is a new organisation being developed called MRT Consortium. The inaugural meeting took place at the RCR recently. The consortium will bring various stakeholders together including patients, industry and professionals to advocate for MRT as an important treatment and try to ensure there are appropriate resources made available nationally. Individuals are being invited to put names forward for election. Dr Gaze has been put forward. A further update will be provided in due course and consideration given to whether this becomes a standing agenda item.

[Action: Dr Gaze]

b) RCP

10.3 Mrs Fraser will circulate notes for the MSc development at Brighton.

[Action: Secretariat]

c) ICSC

10.4 Nothing of relevance to NM to report.

d) UKRG

10.5 Nothing of relevance to NM to report.

e) **BNMS**

10.6 Nothing of relevance to NM to report. The Chairman advised members that the BNMS is trying to produce a short publication to advise on licensing of new PET tracers and evaluation of new PET tracers.

f) SCoR

10.9 Nothing of relevance to NM to report.

g) EANM physics committee

10.12 Nothing of relevance to NM to report.

Item 11: Date of next meeting

11.1 The next meeting is scheduled for 11th May 2023. It is hoped this will be a face-to-face meeting. This will be confirmed in due course.

[Action: Secretariat]

Item 12: Any other business

12.1 The BNMS Spring meeting in May 2023 has been moved by a week and is in Harrogate instead of Liverpool.

12.2 Dr Gaze drew members' attention to the huge problems during the summer with the supply I-131 MIBG for therapy from GE. This has severely affected some patients in international clinical trials who have not been able to receive the treatment they were allocated. An imaging diagnostics importer has been in contact with the DHSC pharmacy team and MHRA to provide the product. GE has cited a wide variety of reasons for lack of supply including inadequate reactor capacity for producing raw material for I-131 which may affect the ability for anyone to import it.

12.3 Dr Craig advised members that the BIR SIG raised a question about ARSAC providing some guidance for training of practitioners. They are organising a course for radiation synovectomy because people are struggling to get enough experience or training.