

The April 2005 meeting of the UK Radiopharmacy Group was held at King's College, London. Items of general interest are summarised below.

WORKFORCE ISSUES

Workforce initiative

The news has finally filtered up to someone at an appropriate level: nuclear medicine is facing a serious staffing shortfall in all specialties, largely due to retirements and an insufficient number of trainees. The need in radiopharmacy is possibly the greatest. A meeting was held in March at which the requirements in all craft groups were discussed. Bev Ellis and Jim Ballinger attended on behalf of UKRG. There were presentations from BNMS (with input from all craft groups), the clinical scientists and techs, and radiographers. In attendance were representatives of the NHS Workforce Review Team, the Department of Health, and ARSAC. Breakout sessions considered diagnostic and therapeutic services separately, though the issues are largely the same. Radiopharmacy emerged as the area requiring most urgent action in terms of training, a career structure, and state registration. The participants left the meeting somewhat encouraged, though there has been little evidence of action in the subsequent three months.

Regional structure

It has been suggested that there be a regional structure of high level radiopharmacy posts via the Strategic Health Authorities or cancer networks. The nuclear medicine physicians have proposed a similar hub-and-spoke model. The recently created Consultant Pharmacist posts may fit the bill. Discussions are ongoing.

National occupational standards / Career pathway

The NOS process continues. The radiopharmacy and nuclear medicine standards have been signed off and have gone upward for approval. The next step is to link the standards to the Knowledge and Skills Framework, but the eventual link to education and training needs remains some way off.

Radiochemistry

A special meeting of the Radiochemistry Group was held at the Royal Society of Chemistry (RSC) in February to look at training issues in radiochemistry, specifically PET. There were two clinical presentations and one each on PET in the pharmaceutical industry and an overview of current training programmes, followed by reports on established or planned courses in nuclear reactor radiochemistry (Birmingham), MRes in biomedical imaging (Imperial College London) and MSc in radiopharmaceutics and PET radiochemistry (King's College London). In particular, with the expanded need for production of FDG and establishment of new cyclotron units, there will be an acute shortage of trained staff. The current expansion of PET in France is expected to mop up any available people. In this country expansion, though slower, is occurring with training being largely provided at foreign locations. While production of FDG via automatic synthesisers (black boxes) may seem routine, there is a need both for experienced people with trouble-shooting abilities and those who can prepare non-routine and/or research products in parallel with FDG. Outcomes of the meeting included initiatives to:

- raise awareness of radiopharmaceutical chemistry as a profession
- obtain support for training (e.g. studentships) from government, agencies (e.g. MRC, EPSRC, Cancer Research UK), associations (e.g. RSC), and European Union programmes.
- obtain industrial support
- obtain endorsement of courses by RSC for accreditation and advertising

REGULATORY ISSUES

Clinical trials / Investigative medicinal product (IMP) licences

There continues to be an enormous degree of confusion over this issue (to quote the opening sentence from the previous Newsletter). In one outstanding case, a major radiopharmaceutical company was initially told by the MHRA that IMP licences would not be required for clinical trials of a new ^{99m}Tc kit, with the interpretation that kit reconstitution was not manufacturing. This decision was later reversed and now all centres must have

an IMP licence to take part, which has resulted in some scrambling.

The issue of Qualified Person (QP) for release of IMPs is also ongoing. One solution is contracting of a QP from a remote site who could release based on electronic transfer of documentation.

A meeting was held at the Royal Pharmaceutical Society of Great Britain in May to look at the clinical trials directive one year after implementation. A presentation from the MHRA is available from the VirRAD web site: click on Library, then SPECT radiopharmacy practice, then Technical notes. The file has the snappy title (according to Paul Maltby) of Phillips 190505.pdf.

<http://community.virrad.eu.org>

Radiopharmacy computer systems

The Veenstra product through Bright Technologies will be beta tested at two European centres beginning in July. The manufacturer intends to link the product with its laminar flow hood complete with touch screen, pneumatic generator handling system, and dose calibrator integrated with the software.

At the BNMS meeting in Manchester there was a poster from Ian Murray, Maggie Cooper, and Jane Sosabowski at St Bartholomew's Hospital describing The Radiopharmacist's Friend, an Excel-based system which supports radiopharmaceutical preparation, stock control, and printing of worksheets, labels, and transport documents. See poster P27, *Nucl Med Commun* 2005; 26 (3): 292. It is intended to be distributed as freeware via the VirRAD web site for local customisation and implementation, with the modifications to be fed back and shared.

Finger doses

Also at the BNMS in Manchester, there was a fascinating presentation on finger doses during radiopharmaceutical dispensing from the Royal Surrey Hospital (if finger doses can ever be fascinating). They used a combination of real-time readout fingertip dosimeters and closed-circuit TV to identify the steps at which the highest exposures occurred.

“SENSIBLE ADVICE”

One role of the UK Radiopharmacy Group is to provide “sensible advice” on radiopharmaceuticals to the nuclear medicine community. In this issue of the Newsletter, two areas are addressed. Both were discussed in the Bournville workshop and the UKRG has reached the following consensus.

Radiopharmaceuticals requiring boiling

Several radiopharmaceuticals, including sestamibi, MAG3, depreotide, and some colloids, require boiling for the labelling reaction to take place. The SPCs for the individual products contain diverse and sometimes confusing instructions regarding heating and cooling.

Location of heating

- Either the clean room or support room can be used, providing that adequate attention is paid to the minimisation of potential bacterial growth in water (i.e. use fresh sterile water each day, discard after use, and dry the container)
- In particular, if the kit is to be returned to the isolator or LAFH after boiling, ensure that it has been wiped to remove residual water from boiling or cooling

Heating

- A boiling water bath provides a more efficient transfer of heat than a dry bath
- Adequate time must be allowed for the bath to return to the boil and the product to come to temperature; larger volumes will take longer
- Any change in heating method must be validated
- It is important that the vial be maintained upright and that the rubber bung does not come into contact with boiling water to prevent damage to the bung and possible entry of water through the needle track

Cooling

- Cooling method and timing are largely irrelevant, as long as the product does not scald the patient or user
- However, it would not be wise to use ice-water as the vial may shatter
- Water at room temperature provides more efficient transfer of heat than cooling in air
- The product will likely have cooled down by the time it reaches the clinic anyway

Preparation of nanocolloid for sentinel node studies

There have been several papers on the effect of specific activity (essentially MBq/particle) on the probe counts following injection of ^{99m}Tc-nanocolloid. I reviewed this in a letter to the editor in the *Eur J Nucl Med* 2004; 31 (2): 306. Although there is not total agreement in the literature, the committee felt it would be wise to standardise preparation of ^{99m}Tc-nanocolloid as much as possible using the following principle, with local variations. To maximise the specific activity, prepare nanocolloid at the desired final concentration in the maximum allowed volume. For example, if one wants to deliver 40 MBq in 0.2 mL, the required concentration is 200 MBq/mL or 1000 MBq in the maximum 5 mL.

PRODUCT NEWS

Mebrofenin (Cholecis)

Schering have found an alternative manufacturer who will continue to supply mebrofenin under licence. The new product name is Cholediam and its formulation and instructions are identical to Cholecis (i.e. 4 hour expiry, no antioxidant).

UPCOMING MEETINGS

Myocardial Perfusion Study Day

20 July, City Hospital, Birmingham. Contact: elizabeth.hodgkins@swbh.nhs.uk.

ETH/PSI Symposia on Radiopharmaceutical Sciences

1-3 September, Zurich and Villigen. See VirRAD web site.

International Conference on Radiopharmaceutical Therapy

11-14 October, Cyprus. See VirRAD web site.

International Symposium on Trends in Radiopharmaceuticals (ISTR-2005)

14-18 November, Vienna. Further details available on the UKRG and VirRAD web sites. Registration is free but applications must be channelled via the appropriate government agency. For those in the UK this is:

Export Control and Non-Proliferation
Department of Trade and Industry (DTI)
4 Abbey Orchard Street
London SW1P 2HT
United Kingdom
Tel 0207 2150720
Fax 0207 2150722

European Symposium on Radiopharmacy and Radiopharmaceuticals

30 Mar-2 Apr 2006, Pisa. Details to follow.

UPCOMING COURSES

Postgraduate diploma course (PDC) in Radiopharmaceutical Chemistry/Radiopharmacy

Consists of three 2-week blocks over one year, beginning August 2005, held in Frankfurt, Zurich, and Leipzig. See VirRAD web site.

MSc in Radiopharmaceutics and PET Radiochemistry

King's College London, beginning September 2005. One year full-time or two years part-time (day release).

Semester 1:

Module 1, Introduction to radiopharmaceutics

Module 2, Radiopharmacology

Semester 2:

Module 3a, Radiopharmaceutical chemistry or *3b*, Radiopharmaceutical design, formulation, and manufacturing

Module 4a, Cyclotron engineering and nuclear chemistry (with 2-week cyclotron placement)

or *4b*, Radiopharmaceuticals in practice (with 2-week radiopharmacy placement)

Semester 3:

Module 5, Research project

For further information please contact:

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MEETING REPORTS

BNMS, Manchester

There was a good turnout of radiopharmacy types in Manchester – enough for a full table at the banquet during which a remarkable amount of wine was processed. The keynote speaker at the radiopharmacy session was Rob Mairs from the Cancer Research UK Beatson Laboratories in Glasgow, who talked about gene therapy. Those of you who saw his presentation at Bournville last year will know what exciting work he is doing. This was followed by several papers, including the CCTV-in-the-hotlab presentation mentioned above. Overall it was a good meeting and the venue was excellent.

SNM, Toronto

I believe there were only three of us from the UK Radiopharmacy Group in Toronto, and relatively few from the wider nuclear medicine community in the UK. A few general impressions:

- Two areas which have dominated the meeting over the last few years – nuclear cardiology and FDG-PET oncology – appear to have matured into clinical services without the same amount of excitement as previously
- Peptide therapy – and not just somatostatin analogues – is growing by leaps and bounds
- There is a lot of excitement about new tracers for early diagnosis of Alzheimer's disease by detection of amyloid plaque
- Small animal imaging with PET and increasingly with SPECT/CT is becoming widely available and some impressive studies were presented
- We may be on the verge of a paradigm shift in radiopharmaceutical preparation. You are probably aware of initiatives toward micro scale reactions for FDG synthesis (some attempts from Manchester were presented) but there are also novel approaches to carrying out ^{99m}Tc and ^{123}I radiolabelling which may make available some types of compounds which could not previously be labelled.

As a native and former resident of Toronto, let me apologise on behalf of the city to anyone who had the misfortune to fly in via the new Terminal 1. Actually, the new half-finished Terminal 1. If you ever saw the Jacques Tati film *Playtime* you will know what I mean – an airport (in the film a restaurant) that opened before it was ready. But it's not so funny in real life.

^{51}Cr -EDTA SURVEY

Thank you to all who responded to the survey of UK practices for the dispensing of ^{51}Cr -EDTA for GFR determination. More than 30 replies were received. The results are being analysed and will be disseminated in the near future.

PEOPLE

Congratulations to Pei-San Chan who has moved north of the river and taken the radiopharmacy post at the Royal Free Hospital.

Congratulations also to Professor Len Wiebe of the University of Alberta in Edmonton, who is known to many in the UK, on the occasion of his retirement. Steve Mather was able to attend his retirement dinner (though Air Canada did its best to prevent this) and reports that Len received a grand send off.

NOTE FROM THE EDITOR: *The editor apologises for the late running of this Newsletter service, sadly again due to "the wrong kind of stress".* JRB

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This and previous issues of the Newsletter are available from the UKRG web site and are now posted in the library section at www.VirRad.org