Practical advice for radiopharmacy and nuclear medicine services managing delivery changes due to Brexit

Radiopharmaceuticals are medicines, and the Government has been working with pharmaceutical companies to ensure that Brexit does not result in patients being unable to receive the medicines they need.

With EU withdrawal terms still unconfirmed, UK radioisotope suppliers have now enacted contingency supply measures to mitigate the disruption of a no-deal exit. The Government has confirmed that all UK suppliers are now importing via planned airfreight.

Industry has advised that the changes to total airfreight provision mean some radioactive deliveries may be subject a 24-hour delay, or may only be available on certain days, as a result of these contingencies.

Increased industry overheads may lead to increased costs for individual trusts. We urge trusts to monitor and record these, and the British Nuclear Medicine Society (BNMS) will be surveying members on Brexit-related radioisotope cost rises.

Some industry suppliers have confirmed that altered delivery schedules and costs will be reduced or even reversed if a deal is agreed, or if the UK does leave without a deal but suppliers are able to move products effectively by road.

However, as both contingency operations and a no-deal Brexit could affect the delivery of radioisotopes into the UK, whether temporarily or permanently, it is therefore important services also have their own contingency plans to mitigate against any delays or disruption which may be experienced.

Please note: this does not apply to most PET-CT radiopharmaceuticals, which will continue to be delivered as usual. The vast majority of PET-CT radiotracers are not affected by Brexit as they are manufactured in cyclotrons throughout the UK or are produced from generators that last for many months to years. However, some specialist PET-CT radiotracers may be affected.

It is advised that you liaise directly with your suppliers to find out whether you are likely to experience delays for individual products.

Risk assessment

As already recommended by the BNMS you should carry out a risk assessment on the impact a no-deal Brexit may have on your nuclear medicine service. This should be on the trust/health board risk register, and you should appraise your trust/health board Chief Executive and Brexit lead, if they are not one and the same person.

The following may help to reduce the likelihood of disruption and delays, and should be considered as part of that risk assessment:

Communication

It cannot be overestimated how important this is. Communicate with both suppliers and with other radiopharmacy and nuclear medicine colleagues so that you have factored in the advice contained

in this guidance where applicable. Make sure everyone in your team is aware of the potential for delays.

Local contingencies

Speak to neighbouring radiopharmacies to find out when their generator delivery day is. Where possible, it is advised that different delivery days be arranged, so that back-up supply can be arranged if necessary and possible. Please refer to the guidance produced by the UK Radiopharmacy Group on transfer of Tc-99m eluates and sharing of Mo-99/Tc-99m generators between different hospitals for further information. Please see:

https://cdn.ymaws.com/www.bnms.org.uk/resource/resmgr/guidelines/ukrg_transfer_between_hospit.pdf

Procurement arrangements

Contact your procurement department to explore making arrangements to purchase outside the normal cost envelope if necessary.

If it is likely your generator will arrive later than practical for use on the day of delivery, consider ordering a higher activity generator for the duration of the altered delivery arrangements (one reference activity step higher) to allow for not using it on the usual first day of delivery. A one day delay to delivery would reduce available activity by approximately 20%.

However, a note of caution should be applied here: a lot has been done to streamline the radiopharmacy production process in order to make the most effective use of molybdenum- 99, which can sometimes be in limited supply. Before deciding upon this, speak to the supplier of your generator to ascertain whether delays are actually anticipated.

The Department of Health and Social Care (DHSC) has said it and relevant health agencies will work alongside the BNMS to monitor the costs of radiopharmaceuticals to the NHS in 2019-20. It is hoped that funding will be made available to offset any increased spend.

Appointment booking

Since any delays to deliveries or changes to delivery schedules should now be known in advance and can therefore be planned for, the risk of cancellations of patient appointments for most types of study should be low. As a result, there should not be an impact on waiting times. However, reliance on air freight does bring different risks – for example, if flights are cancelled as a result of the weather. These should be considered as part of the local risk assessment.

If not increasing generator size to offset a delay in delivery, consider booking lower activity tests on your generator delivery day so that you can still fulfil all patient appointments using the remaining delivered generators(s) and schedule higher activity studies for later in the week.

Short term changes to the working day could also be considered – for example, if higher activity tests are postponed, or if deliveries arrive later than usual, extended days later on in the week or weekend working should be considered if possible in the short-term.

Delivery arrangements

If there is a possibility that non-technetium radiopharmaceuticals usually delivered to the radiopharmacy could be delivered after the department has closed, consider whether they could be delivered directly to the nuclear medicine department so that they could be drawn up there. This would be subject to their expiry time and would depend on the local facility. This must be first discussed with the relevant radioactive waste adviser to ensure that no Environment Agency Permit conditions are breached.

Reference should be made to the UK Radiopharmacy Group/BNMS document on Safe Drawing up of Radiopharmaceuticals. Please see:

https://cdn.ymaws.com/www.bnms.org.uk/resource/resmgr/guidelines/ukrg_drawing_up_feb-12.pdf

This recommends that drawing up is done in an area supplied with Grade A air. However, if the vial is single dose, this is not necessary.

The exception to this is In-111 Octreoscan, which is subject to further on-site manufacture, which must be carried out in the radiopharmacy.

Practical advice for running a clinical nuclear medicine/radionuclide radiology service with reduced radiopharmaceutical availability

Prioritisation

You should consider how to prioritise requests based on clinical need, should supplies be compromised. In practical terms this will require increased time for vetting and communication with radiopharmacy and referring clinicians.

Consideration needs to be given not only to the clinical urgency of the investigation but the logistics of the entire service, for example associated theatre time for sentinel node surgery.

Administered activity reduction

Activity levels for all investigations can be reduced with a compensatory increase in imaging time. Generally, this will produce a diagnostic investigation; however, this decreases patient experience (due to prolonged scan times), slows work flow and increases movement artefacts.

Imaging tests: considerations and alternatives

Bone scans: All bone scans can be performed using NaF-18 PET-CT subject to costs (commissioning) and logistics. This may be a viable alternative for a small sub section of scans but for the vast majority this not likely to feasible. MRI, whole-body MRI and CT can be used as alternatives for some indications depending on local expertise and capacity.

MUGA/Myocardial Perfusion Scintigraphy: Some of these studies can be substituted with echocardiography and/or MRI depending on local expertise and capacity.

Sentinel nodes: Although methylene blue can be used on its own this offers reduced sensitivity - there are no real alternative imaging tests.

Somatostatin receptor imaging: Ga-68 DOTA-TATE and DOTANOC can be used instead. These PET tracers are only available in a small number of centres with gallium generators.
I-123 MIBG: Consider prioritising urgent paediatric cases.

I-123 DaTScans: For diagnosis of Dementia with Lewy bodies F-18 FDG PET-CT may be helpful. MRI is useful in Parkinson's disease of vascular aetiology and some Parkinson plus syndromes.

DMSA/MAG3 renograms: Although MRI and US can give some of the information, substitution will only be practicable in departments with specialist expertise.

V/Q: In all patients (except severe renal impairment and iodine contrast allergy) CTPA is a viable alternative.

Non-imaging test considerations

With regard to SeHCAT and red cell mass studies there are no viable alternatives.

GFR: If validated, Iohexol GFRs may be done as long as the patient is not allergic to iodine containing contrast.

Radionuclide therapy

As with radioisotopes used for imaging, products used for radionuclide therapy are also now being transported into the UK via air, with the potential for some delays as contingency schedules are established. Therapy radionuclides have longer half-lives and so these offer more scope for managing delivery delays. This may include being flexible in the time and day a radionuclide therapy is given. If this involves Y90 microspheres for SIRT this may also require some flexibility from interventional radiology.

If any product arrives late, expiry time and date should be checked, and available activity checked against the prescribed activity. If an available treatment dose is more than 10% below the prescribed activity the therapy should not be given and your relevant Administration of Radioactive Substances Advisory Committee (ARSAC) practitioner should be informed. Hospital management should be made aware of these issues and an appropriate note placed on the relevant departmental risk register.

You should discuss with ARSAC practitioners how potential delays in treatment could affect the number of days that a patient has been off medication and whether any adjustments will be required to protocols.

As many patients have to organise personal and work arrangements around their scheduled therapy, they should be advised that their day of treatment could potentially change by a day or two at short notice, and that departments will update them as soon as possible if appointments need to be re-arranged.

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