U.K. Radiopharmacy Group

UKRG Guidance for Radiopharmacies during the Covid-19 Pandemic

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Background

The Covid-19 outbreak continues to be a very fast moving situation and updates to this guidance will be made as required.

The British Nuclear Medicine Society (BNMS) has issued guidance to departments for infection prevention and control in nuclear medicine settings during the Covid-19 crisis. The BNMS guidance is updated regularly. The following are links for infection control and recovery phase guidance which can be found on their website:

https://cdn.ymaws.com/www.bnms.org.uk/resource/resmgr/news_&_press_office/news/new_060420_nuclear_medicine_.pdf

https://cdn.ymaws.com/www.bnms.org.uk/resource/resmgr/news_&_press_office/news/covid-19_recovery_phase_guid.pdf

This involved ensuring patients who urgently need their Nuclear Medicine scan or treatment could still get it, whilst at the same time ensuring people who didn't need to come to hospital urgently could stay at home. As a result, both Nuclear Medicine and Radiopharmacy workloads are likely to have reduced temporarily.

With the initial country-wide lockdown easing and clinics re-opening, departments are now working to reduce the backlog of patients waiting for appointments.

However, although the guidance around shielding has been paused by the government, many of our patients are elderly or have underlying health conditions, and as such may be reluctant to come to hospital. And a second wave may lead to a reintroduction of prioritisation of patient appointments, particularly if there is another full lockdown. Both these scenarios present challenges to departments trying to reduce the number of waiting patients whilst continuing to see those who urgently require their scans or treatments.

However, Nuclear Medicine and Radiopharmacy departments now have the benefit of experience, and are well versed with how to care for their patients and protect and manage staff within the confines of a pandemic. This is vital as it would seem highly unlikely that routine hospital services will be shut down again, even in the event of a significant second wave.

But although contingency arrangements will hopefully have been established, there is still a potentially significant impact from staff absenteeism going forward. This could be as a result of a staff member developing symptoms, a household member

developing symptoms, staff being asked to self-isolate because of a track and trace contact, or because of childcare issues should their children be sent home from school to self-isolate. Holiday arrangements will also have to be considered, as there is the potential for staff to be required to quarantine if they have been to a country which is not on the government exemption list.

In order to reduce the risk of staff developing Covid-19 infection from contact at work and to reduce the number of staff who would need to self-isolate should another member of staff develop symptoms, social distancing, frequent hand washing and use of PPE, particularly masks, remain a part of everyday working life. Whilst handwashing and PPE are inherent in the Radiopharmacy operation, social distancing in particular can create some challenges.

This document gives guidance on how the many impacts of the Covid-19 pandemic may continue to be managed going forward.

Infection Control

Departments must comply with local policy and recommendations for prevention of infection. Workflows in the Radiopharmacy should be reviewed so they permit staff to maintain sufficient distance from each other where possible. If it is not possible to maintain a 2 metre distance from other staff member, staff should wear a non-sterile mask. It should be noted that a distance of 1m should still be maintained under these circumstances unless this is for less than 15 minutes. Therefore wearing a mask whilst moving around the Radiopharmacy will be acceptable if distance cannot be maintained, but if sitting in an office with other staff members, proximity should still be assessed even if wearing a mask. Working from home for office work could also be considered.

Access to the Radiopharmacy by non-Radiopharmacy staff (such as drivers and Nuclear Medicine staff collecting radiopharmaceuticals) should be restricted to limit spread of any potential viral contamination. Door handles should be cleaned regularly, and this should be documented. Staff should be instructed to wash their hands regularly, and especially as they are entering the department from outside.

PPE

As the number of infected and potentially infected patients presenting in hospital starts to increase again, hospital staff will be required to wear Personnel Protective Equipment (PPE) in order to look after them safely. More cleaning materials will be

required to sanitise staff, facilities and equipment and although supplies of PPE are now more effectively managed, there is still the chance that some PPE and cleaning materials will once again be in short supply and may not be available to use in the Radiopharmacy. Implementation of a strategy for their use may again be necessary with contingencies in the event they are not available.

Any contingencies around PPE and cleaning materials, such as use of non-sterile masks in Grade B clean room for example, must be documented and risk assessed. The local QA Pharmacy specialist should be contacted for advice on this.

Radiopharmacy Service Contingency Plans

Contingency plans should be in place for the eventuality there are insufficient staff to run the service. These could also be helpful if there is a serious shortage of PPE and cleaning materials. Close liaison with neighbouring Radiopharmacies could help with this. The first consideration would be to see if the supply could be outsourced. However, outsourcing arrangements are not as simple as they are when there is a problem with the facility, for example. Then an external Radiopharmacy could reliably provide the service; however in this situation all units are equally as susceptible to staff being unavailable to work and therefore the external Radiopharmacy may be facing the same problems.

One suggested solution would be for Radiopharmacies to work together to consolidate their staffing pool. For example, releasers from neighbouring units could be given local training and be accredited to release within the Quality Management Systems. Radiopharmacy staff in other units could be trained to support a 'supply hub' whereby, should there be staffing shortages at any of the units, the workload could be consolidated in one place. The choice of supply hub should take into account location, experience of providing a centralised service and the existence of procedures and systems already in place to support this. Early training should be undertaken to support this proposal and availability of trained drivers must be taken into account. Any contingencies should be risk assessed, and the MHRA should be informed as well as the local HR department.

Another approach could be to revise the roles being carried out by Radiopharmacy staff. Any deviations to usual arrangements for manufacture and independent release must be fully risk assessed and documented, and the MHRA inspector / Regional QA specialist should be consulted.

Increasing Pharmacy Aseptic Capacity during the Coronavirus Pandemic

The first wave of the Covid-19 pandemic has placed increased demand on Pharmacy Aseptics to provide additional services for intensive care wards, for example pre-filled syringes. In some cases there were also knock on effects on other aseptic services such as oncology, central intravenous additive services (CIVAS) or parenteral nutrition as facilities or staff were reallocated to meet the increasing Covid-19 related demands. Whilst these demands reduced as the number of Covid-19 patients being treating in hospital fell, it is reasonably likely that it will again become an issue during a second wave of the pandemic. Depending on the staffing arrangements in the Radiopharmacy, any reduction in non-urgent workload may mean there is spare capacity (either staffing or within the facility as necessary) which could be used to support other aseptic services in the organisation.

There are two different contingencies which could be put in place to help:

1. Radiopharmacy staff working in other areas of Aseptics.

This is the easiest and most likely scenario, since the main issue affecting capacity is likely to be lack of staff. Local policy for redeployment of staff should be followed if necessary and the following should be considered:

- Firstly the capacity of Radiopharmacy staff should be reviewed to see if staff could be released to train and work in Pharmacy Aseptic Units. This should be regularly monitored to ensure it can continue to be supported – for example, if there is Radiopharmacy staff sickness - so that Radiopharmacy services could still be provided to the required standards. The agreement with the Pharmacy must make it clear what action would be taken in this case; i.e. whether staff would need to be called back to Radiopharmacy or whether the Radiopharmacy service will be reduced according to risk
- Identify training needs of staff with the Aseptic Services Manager. Transferred staff will require training in local aseptic unit procedures and processes. Consideration should be given to the type of clean room facility used in both areas and the impact this may have on training. For example, one area may have Grade B clean rooms whilst another may have Grade D.
- Information on the GMP validation of transferred staff must be provided in advance. This may include:
    - Recent broth tests
    - Environmental monitoring e.g. finger dabs, sessional plates etc.

- Transfer disinfection qualification
- Recent competency assessment (where appropriate)
- Training records (where appropriate)

2. Sharing Radiopharmacy facilities.

This is less likely to be needed, but may be required if the workload in Pharmacy Aseptic Units exceeds the capacity in terms of the number of units which can be made in the workstations available. However, it is more complex than moving the Radiopharmacy staff to the Aseptics department.

Where there is more than one clean room in the Radiopharmacy the best approach would be to designate one room for hosting the guest unit's processes only. This will have less impact on the Radiopharmacy. Where there are limited clean rooms in the Radiopharmacy this would result in sharing clean rooms and cabinets.

The following should be considered when preparing to share a Radiopharmacy Facility:

- Regulatory arrangements: depending on the organisation these products may be prepared under one of the following two conditions:
  - Under a Section 10 exemption to the Medicines Act 1968 where all preparation is by, or under, the supervision of a Pharmacist.
  - In an MHRA Specials Licensed unit.

  Different areas within the organisation may operate under one or other of the above, which needs to be taken into account. For brevity the units will be designated as Section 10 or Licensed.

  Where a Radiopharmacy unit has been approached by an Aseptic unit the current MHRA inspector or Regional QA Specialist responsible for their EL (97) 52 audit must be contacted to discuss before proceeding any further. The Aseptic unit must also engage their inspecting entity (MHRA/Regional QA) at the earliest opportunity. Note: all Specials Licensed units must work within the confines of the agreed terms stated by the MHRA in their licence.
- Once the agreement of the inspector or auditor has been confirmed, the arrangements to be put in place must be documented in the Quality Management System. A change control form will need to be opened which describes how the arrangement is going to be managed, the impact it will have on running the two departments with a suggested time line for this

arrangement. Assessment on how much of the workload is transferable should be included in the change control. It may be that not all of it can be done in the Radiopharmacy facility because of specialist equipment.

- A risk assessment must be carried out and should consider the following:
    - Capacity impact on the unit - Defining how workload/capacity issues would be managed is important especially if clean rooms are limited in number.
    - Prevention of cross-contamination to radiopharmaceutical products or aseptic unit products made in the facility. Products should be prepared on a 'campaign' basis using appropriate segregation methods so no cross contamination can occur; Radiopharmacy and Aseptic preparation should take place at different times so the product flows are kept separate. Different clean room clothing could be used to differentiate the sessions
- A validation master plan should be drawn up and submitted to the inspector / auditor. Validations already in place should be assessed and further validations carried out for new activity undertaken in the Radiopharmacy and for Aseptics staff working within the unit. Transfer disinfection processes should be risk assessed and adapted as necessary without the need for full validation.
- Staffing requirements and capacity should be considered: for example, whether the work would be undertaken by Radiopharmacy as well as Pharmacy Aseptics staff.
- Clarity on roles and responsibility of staff is required. For example, how staff management will operate, and how deviations or CAPAs, for example, would be reported and managed would need to be agreed.
- A decision needs to be made on whose procedures are going to be followed, and new procedures may be required. Validated procedures that have been demonstrated to be effective in the Radiopharmacy would be required for certain activities in both workstreams, such as gowning and some validation activities. However, Pharmacy Aseptics' own procedures for aseptic manufacturing or preparation activities must be followed for their work. Should deviation to any procedures be required, these should be documented and approved via a planned deviation.
- Consideration should be given to who is responsible for staff training on how to operate in the new facility. Radiopharmacy staff will need training regarding the interaction of the two work streams.

- Assessment of equipment requirements and availability must be undertaken, for example, whether isolators are negative or positive pressure, or whether cabinets are horizontal or vertical laminar flow. Pre-assembled trays and labels may need to be produced. This may have to be done in Pharmacy if the Radiopharmacy department does not have the facility to do it.
- Radiopharmacy units are highly controlled areas due to the storage and use radioactive substances so, as determined by the Ionising Radiations Regulation (IRR17), access to these units is strictly limited to designated staff with appropriate radiation protection training. The RPA should be consulted regarding the arrangements and the Radiation Protection Supervisor is responsible for ensuring good radiation safety is in place throughout this arrangement.
- Radiation protection issues **MUST** be considered – for example, whether generators remain in place. All non-radioactive products made within the Radiopharmacy should be monitored for radiation contamination and a record must be kept of this. Guest staff will need to be familiar with the Radiopharmacy's IRR17 local rules and consideration should be given to developing a specific sub-set of local rules for the proposed arrangement, which all staff would need to sign to confirm they have read and understood.
- Environmental monitoring: which cleaning regimes will be used, who will undertake the cleaning and when will it be done must be agreed, as will how out of specification environmental monitoring results are to be investigated.
- Practicalities on times of each production run need to be discussed.
- Storage: Designated ambient and cold temperature storage of starting materials will be required to maintain segregation of materials to prevent incorrect product selection..
- Waste management from the different activities will also need to be segregated. Pharmacy waste streams may follow different internal waste processes.
- A technical agreement needs to be put in place which defines the detailed plans and agreed processes. It will be signed by the heads of section for the units involved and the Chief Pharmacist. The agreement should include the duration of the arrangement and circumstances where an extension of this arrangement is permissible. If the two departments belong to two different legal entities e.g. different hospital trusts – detailed service level, as well as technical, agreements would be expected by the supervising body

(MHRA/Regional QA) and would need to be signed by the Chief Pharmacists in both organisations

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