Chief Pharmacist Responsibilities: Medical Gases – clinical oversight of storage, supply and usage

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The first stop for professional medicines advice

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1. Introduction

Medical gases are medicinal products and are supplied for patient use either via medical gas pipeline systems or medical gas cylinders. As with all medicinal products, the governance of medical gases within a hospital is the responsibility of its Chief Pharmacist. This includes ensuring that there are written policies and Standard Operating Procedures (SOPs) in place for the management and safe use for all aspects of medical gas supply and administration.

The COVID-19 pandemic highlighted the importance of medical gases in treatment protocols and the need for all relevant healthcare professionals to understand their particular roles and responsibilities in delivering safe and effective care.

It is essential for the Chief Pharmacist to have and maintain oversight of the safe and continuous supply of medical gases, in particular oxygen, during periods of increased usage.

Effective links are required between appropriately qualified practitioners from Pharmacy, Estates, Facilities, Health and Safety and clinical teams etc.

In particular, due to the engineering elements associated with safe supply of these medicines, the Chief Pharmacist must form strong and sustained relationships with local Estates Directors and their teams. Increases in oxygen demand presents significant challenges in terms of safety and continuity of supply to meet patient needs. EFA alert NHSE/I-2020/003 issued November 2020 describes actions to be taken to mitigate and manage risk to patient care.

This advice note provides guidance to the Chief Pharmacist in the effective application of their role.

2. Key Chief Pharmacist Responsibilities

The unique nature of medicinal gases and their delivery / dispensing systems gives the Chief Pharmacist additional responsibilities to those already in place for other medicinal products used within the Trust /organisation.

2.1 Medical Gas Committee

HTM 02-01 ((s)HTM 02-01 in Scotland) states that it is fundamental for each Trust / Organisation to have a Medical Gas Committee, on which pharmacy is represented. It is recommended by the NHS Pharmaceutical Quality Assurance Committee's Medical Gas Sub Group that Chief Pharmacists take a lead role within their Medical Gas Committee, either directly or via appropriate delegation to a member of pharmacy with sufficient authority and knowledge to act.
This is substantiated by "*The COVID-19 Pandemic and actions necessary to mitigate its effect on the performance of Healthcare Cryogenic Liquid Oxygen System*" produced by the NHSI
COVID-19 Working Group, which advocates that the Chief Pharmacist takes the role of Chair.

Responsibilities of the **Medical Gas Committee** would normally include:

- Development and maintenance of organisational medical gas policies and procedures
- Assessment of the location of cryogenic, cylinder and other installations
- Health and safety associated with staff, patient and delivery areas
- Assessment of supply and demand including monitoring abnormal usage
- Continuity of supply & system back-up (duplex/triplex capability)
- Emergency responses and contingency planning
- Security (of storage and distribution)
- Maintenance and testing of pipeline systems
- Training of staff involved in the safe and secure handling of medical gases
- Investigation of all incidents relating to medical gas use and supply
- Compliance with regulations and HTM 02-01 ((s) HTM 02-01)

The COVID-19 pandemic has augmented the need to effectively manage these activities and to ensure that systems are put in place to conserve oxygen supplies. Local 'good housekeeping' guides to support the provision of simple messages and approaches to preserve supplies and effectively manage medical gases have been developed. Turning off and removing oxygen flowmeters which are not in use is a simple but effective way of reducing wastage.

2.2 Medicines Management:

An additional role of a Medical Gas Committee would be to oversee the clinical safety and efficacy of medical gases within its Trust / Organisation. Of particular importance to Chief Pharmacists would be:

- Safe clinical use of gases as medicines
- Systems to assure correct and safe use of administration and monitoring equipment
- Safe prescribing policy
- Minimised use of cylinders in patient areas
- Training of all staff who have a role in the safe and secure handling of medical gases
- Monitoring of clinical incidents

The requirement for high level responsibility for governance in the use and provision of medical gases reflects the fact that these medicines (especially oxygen), are amongst the most commonly used therapeutic agents in the hospital environment. They are indicated in many critical conditions, and there is the potential for serious harm and even death if not administered and managed appropriately.

During the COVID-19 pandemic, there have been reports of hospitals declaring critical / major incidents in response to oxygen systems operating at maximum capacity and a need to reduce demand. It is therefore essential that the Medical Gas Committee prepares a site resilience/contingency plan and identifies areas where high oxygen demand can be accommodated. Site plans illustrating this along with areas that have been closed may be helpful. A Standard Operating Procedure detailing action to be taken at strategic points of elevated demand should be prepared. Ensure roles and responsibilities have been identified. "Table top exercises" should be implemented to test the plan before it is needed to identify risks and ensure action is taken accordingly. See https://www.sps.nhs.uk/articles/management-of-oxygen-during-periods-of-high-utilisation/

The NHSI COVID-19 Working Group issued a document in August 2020 that highlighted the tasks and actions needed to create awareness of the medical gas system and detailing practical measures to enable deficiencies to be identified. There is need of a multidisciplinary approach, but the Chief Pharmacist must be well informed and aware because these gases are medicines. This document also stresses that the Medical Gas Committee is instrumental for the safe management of medical gases.

see "The COVID-19 Pandemic and actions necessary to mitigate its effect on the performance of Healthcare Cryogenic Liquid Oxygen Systems" Produced by The NHSI COVID-19 Working Group August 2020)

In November 2020, an Estates and Facilities Alert was issued "Covid-19 Response – Oxygen Supply and Fire Safety" raising awareness of the dangers of high ambient oxygen levels with a real fire risk if oxygen exceeds 23%. It also warned of the risks of loss of pressure if demand drained the piped supply faster than the designed flow rates.

see https://www.cas.mhra.gov.uk/ViewandAcknowledgment/ViewAttachment.aspx?Attachment_id=103712

In April 2020 A National Patient Safety Alert was issued on the risk of harm from the interruption of high flow nasal oxygen (HFNO) during patient transfer.

see https://www.england.nhs.uk/2020/04/interruption-of-high-flow-nasal-oxygen-during-transfer/

In addition there have been several incidents relating to medical gases that have led to the issue of warnings, alerts and rapid response directives within the past decade, for example :-

- In October 2016 NHS Improvement released the Patient Safety Alert, 'Reducing the risk of oxygen tubing being connected to air flowmeters following incidents in which tubing had been connected to the wrong flow meter

  see https://www.england.nhs.uk/publication/patient-safety-alert-reducing-risk-oxygen-tubing-being-connected-air-flowmeters/

- In 2011 an Estates and Facilities Alert was issued following the uncontrolled release of liquid Oxygen from a vacuum insulated evaporator (VIE). This emphasised the importance of ensuring resilience of supply with a medical gas pipeline system, as well as the need to manage the risks of fire.

  see https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/215346/dh_130732.pdf

From a consideration of incidents such as these, plus the findings of local investigations and other sources, some common themes can be identified:

- **Prescribing:** failure to prescribe or wrongly prescribed; clinical pharmacy role to check
- **Monitoring:** patients not monitored, abnormal oxygen saturation levels not acted upon; clinical pharmacy role to check
- **Administration:** confusion of oxygen with medical compressed air, incorrect flow rates, inadvertent disconnection of supply; clinical pharmacy role to check
- **Equipment:** empty or unstable cylinders, faulty and missing equipment; requires monitoring and pharmacy oversight
- **Fires:** affecting patients through mismanagement of oxygen; pharmacy role in observation and awareness training

Misadministration of a medical gas is included in the current National Health Service (NHS) Never Event list in England.
i.e. Unintentional connection of a patient requiring oxygen to an air flowmeter

see https://improvement.nhs.uk/documents/2266/Never_Events_list_2018_FINAL_v5.pdf

2.3 Cylinder Management

HTM 02-01 ((s)HTM 02-01 in Scotland) recommends that regardless of operational infrastructure the Chief Pharmacist should take an active role in the management of medical gas cylinders. This includes ensuring that a system is in place for the procurement, secure storage and use of medical gas cylinders.
(see HTM 02-01 Part B 5.10 p16)

Sound cylinder management is important for the following reasons:

- Inadequate stock management can present problems in maintaining adequacy and continuity of supply. This was highlighted as an important issue during the COVID pandemic when the delayed return of empty cylinders threatened continuity of supply.
- Improper methods of cylinder storage and use may give rise to serious health and safety issues.

Pharmacy procurement teams are responsible for, or should have a close involvement with, the ordering, stock management and safe use of medical gas cylinders.
Ensure that there are instructions for ordering, supply and return of cylinders from wards and departments in place. It may be necessary, if not already undertaken, to carry out a process mapping exercise for cylinder ordering, delivery, intra-site movement and return to the supplier. This should ensure that cylinder processes are efficient and do not create systems whereby cylinders stocks are excessive or not held in suitable locations.
A check for expired and empty cylinders is essential so that these cylinders are returned immediately to the supplier for re-filling. Efficient cylinder turnaround is good practice under normal working situations but is essential during the pandemic. As with other medicines, clinical areas should only hold the number and size of cylinders as absolutely necessary (in accordance with agreed stock list).
Appropriate staff training and/or refresher training on the management of medical gas cylinders will need to be provided.

2.4 Medical Gas Pipeline Systems

The Chief Pharmacist needs to be aware of all developments that may affect the provision of medical gases within their organisation. For example in times of national emergency changes in regulation, guidance / advice or mitigation / derogation may be critical.

An example is the NHSI COVID-19 Working Group guidance document issued in August 2020: "*The COVID-19 Pandemic and actions necessary to mitigate its effect on the performance of Healthcare Cryogenic Liquid Oxygen System*"

This extensive report examines aspects of liquid oxygen supply and storage, and associated gas distribution system configurations. It also but also provides guidance on oxygen system auditing and critical operational procedures intended to mitigate the effects of exceptional oxygen demands.

Appendix A of the above provided operational protocols for dealing with excessive demands of cryogenic liquid oxygen and directed these be incorporated into the Medical Gas System Operational Policy. It emphasised that the safe management of medical gases and development of the MGPS Operational Policy was the duty of the **Medical Gas Committee**, in which the role of the Chief Pharmacist is key.
seehttps://www.sps.nhs.uk/articles/the-covid-19-pandemic-and-actions-necessary-to-mitigate-its-effect-on-the-performance-of-healthcare-cryogenic-liquid-oxygen-systems/

2.5 Installation, modification and qualification of pipework systems

The installation of any new medical gas pipework, or the modification of existing pipework will normally be co-ordinated by Estates – supervised by a medical gas Authorised Person and carried out under a permit-to-work and will require qualification by an appropriately trained and registered Quality Controller (QC MGPS).
Whenever work is carried out on a medical gas pipeline system, there is a risk that the medical gas quality is compromised. This could be through contamination of the pipeline or cross-over of pipeline systems leading to contaminated or the wrong gas being delivered to patients. Therefore robust systems of quality control need to be in place to ensure medical gas quality is maintained.

The appointment of a QC (MGPS) is formally made by the organisations Chief Executive on the recommendation of the Chief Pharmacist. The Chief Pharmacist must therefore be satisfied with the professional attributes of that person and their acceptance on the register of QC (MGPS).

Note: The COVID-19 pandemic resulted in a significant increase in engineering work carried out on medical gas pipeline systems to improve supply and resilience. This placed additional demands on the services of QC(MGPS) personnel. The Chief Pharmacist will need to be able to access the services of such persons at short notice.

HTM 02-01 (s)HTM 02-01 in Scotland) states

"Only individuals who have been appointed to the Quality Controller (MGPS) register may act as Quality Controller (MGPS)."

"Inclusion on the register will normally be sufficient to qualify an individual to act as QC (MGPS) for any hospital Trust. However, the trust's chief pharmacist may exercise the option to specify, or otherwise limit, those registered as QC (MGPS) who may operate on their site."

Further information regarding the registration of QC (MGPS) can be obtained from 'Registration of Quality Controllers (MGPS), Policy, Guidance and Application form' produced by the NHS QC Medical Gas Subgroup on behalf of the NHS Pharmaceutical Quality Assurance Committee. The current register is published on the SPS website.

2.6 Audit

The Chief Pharmacist shall demonstrate the hospital meets the requirements of key standards in delivery of gases as medicines. This is best achieved through a regular (at least annual) audit of e.g. cylinder stock, location and management; oxygen usage, MGPS maintenance; clinical incidents, etc. The results of which should be reported to the Trust's / organisations Medical Gas Committee. This should also seek to capture issues with ward medical gas practices (e.g. oxygen wastage due to poor housekeeping of flowmeters; expired cylinders; inappropriate use of cylinders etc.)

2.7 Education and training of pharmacy teams

All pharmacy team members, including clinical and ward-based pharmacy teams have a critical role to play in assuring continuity of supply, and safe and effective treatment with medical gases in exactly the same way as they have for other medicines, as an integral part of their routine practice. This is particularly relevant to medical oxygen. Chief Pharmacists have a responsibility to ensure that their team has access to appropriate education and training to support their role.

3. Summary

As for all medicines, the Chief Pharmacist is responsible for ensuring systems are in place to assure the supply, quality, continuity and safety of medical gases within their organisation.

- Ensure a Medical Gas Committee is in place
- Establish links with Healthcare professionals handling / using / maintaining and qualifying medical gases especially Estates
- Ensure continuity of supply through the implementation of “good housekeeping” arrangements
- Ensure their team has appropriate skills and knowledge and understands that their responsibilities including safe and appropriate use of medical gases.

4. Further Information

A “medical gases” resource has been established by the NHS Pharmaceutical Quality Assurance Committee on the SPS website. This contains information to assist Chief Pharmacists in fulfilling responsibilities and will be regularly updated. It is recommended that this is the first port of call for guidance.

Training is available for Chief Pharmacists on their roles and responsibilities with regards Medical Gas’s via the NHS TSET Medical Gas for Service Managers short course run annually via the University of Leeds.
see https://eps.leeds.ac.uk/short-course/994/medical-gases-for-service-managers

5. Bibliography

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   Pharmaceutical Press, July 2019 – **NOTE:** 44th Edn was postponed until **July 2021** due to the coronavirus pandemic.

2. Health Technical Memorandum 02-01 Medical Gas Pipeline Systems (Parts A & B)
   Department of Health, May 2006
see https://www.sps.nhs.uk/articles/medical-gases-health-technical-memorandum-02-01-medical-gas-pipeline-systems/

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see https://www.cas.mhra.gov.uk/ViewandAcknowledgment/ViewAlert.aspx?AlertID=103013

8. Estates and Facilities Alert, NHSE/I-2020/003 Covid-19 Response – Oxygen Supply and Fire Safety NHSI Estates and Facilities 19th November 2020
See https://www.cas.mhra.gov.uk/ViewandAcknowledgment/ViewAttachment.aspx?Attachment_id=103712

9. Professional guidance on the safe and secure handling of medicines - Royal Pharmaceutical Society 2018
see https://www.rpharms.com/recognition/setting-professional-standards/safe-and-secure-handling-of-medicines/professional-guidance-on-the-safe-and-secure-handling-of-medicines

   Specifically refer to:
   - Principle 1: Establish assurance arrangements
   - Principle 3: Seek assurance
   - Appendix A: Storage of medicines in health care settings - supplementary guidance
     - A1 Medicine storage meets national guidance and regulatory requirements.
     - A6 Medical gases in cylinders are stored safely and securely
     - A7 Areas where oxygen is stored or used display appropriate signage

10. Guidance on the security and storage of medical gas cylinders: Issued by NHS Protect 2014
see https://studylib.net/doc/9577653/security-of-medical-gas-cylinders

11. National Health Service (NHS) Never Event list 2018
see https://improvement.nhs.uk/documents/2266/Never_Events_list_2018_FINAL_v5.pdf

12. The COVID-19 pandemic and actions necessary to mitigate its effects on the performance of Healthcare Cryogenic Liquid Oxygen Systems – NHSI COVID-19 Working Group August 2020
seehttps://www.sps.nhs.uk/articles/the-covid-19-pandemic-and-actions-necessary-to-mitigate-its-effect-on-the-performance-of-healthcare-cryogenic-liquid-oxygen-systems/

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Appendix 1 – Key personnel

The **Health Technical Memorandum (HTM) 02-01**[1] **((s)HTM 02-01 in Scotland)** describes the corporate responsibilities held by various officers within an NHS hospital. Working under the overall authority of the Trust Chief Executive, the **Chief Pharmacist** holds significant responsibilities in governance of medical gas pipework systems as described in this advice note.

Chief Executive / Executive Manager - Ultimately responsible for the safe delivery of medical gases [from cylinders, or Medical Gas Pipeline Systems (MGPS)] in their hospital / organisation.

The Head of Estates / Operations Manager - holds responsibility for the maintenance and integrity of the MGPS through the work of the Authorised and Competent Persons (see below).

Authorising Engineer AE(MGPS) – A person with suitable qualifications (for example chartered engineer or incorporated engineer) and sufficient relevant experience to oversee and audit a number of medical gas systems and their associated authorised persons, and who can offer expert technical advice to MGPS managers and users. He/she will also be responsible for recommending Authorised Persons AP(MGPS) for appointment.

AE's working within the NHS are named on a register maintained by the Institute of Healthcare Engineering & Estate Management (IHEEM) www.iheem.org.uk

Authorised Person (AP)MGPS - The person designated by the Executive Manager to be responsible for the day-to-day management of the MGPS at a particular site or sites. This includes the issue of permits in accordance with the permit-to work procedure.

All AP's should be appointed in writing by the Chief Executive / Executive Manager on the recommendation of the AE.

Competent Person CP(MGPS) – The person who carries out the instillation and / or maintenance work on the MGPS. The CP should receive appropriate training and be on a list of CP (MGPS) held by the organisation in which the work is taking place. This list should be held by the AP or project manager.

The Quality Controller QC(MGPS) - The person designated as the quality controller for Medical Gas Pipeline Systems. He/she is responsible for the quality control of the medical gases at the terminal units and manufacturing systems such as medical air compressors, oxygen concentrators and synthetic air systems.

QC(MGPS) working within the NHS are named on a register maintained by the NHS Medical Gas Sub Group on behalf of the NHS Pharmaceutical Quality Assurance Committee. The current register is available on the SPS website.

Designated Medical Officer DMO(MGPS) and **Designated Nursing Officer DNO(MGPS):** The medical or nursing officer designated by the chief executive to act as a focal point for communications related to MGPS in a specified department or departments. Ideally each department will have its own Designated Medical Officer (MGPS) and Designated Nursing Officer (MGPS).

Designated Portering and Security Managers – responsible for security, and cylinder distribution and management.

NHS Specialist Pharmacy Service
www.sps.nhs.uk