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Entonox® System Loss Mitigation and Management Technical Update

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Recommended Health	Health Board Chief Executives; Heads of Midwifery;			
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Distribution:	Gastroenterology; Clinical Directors of Pain			
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Document Information

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Health board reporting and auditing schedules:	Annual Delivery Plans (ADPs) Public Bodies Climate Change Duties Reporting, annual National Sustainability Assessment Tool (NSAT), biennial Statutory Compliance and Risk Tool (SCART), ongoing Environmental Management Systems (EMS), under development		
External evaluation, monitoring and reporting:	Quarterly tracking of nitrous oxide emissions by Health Infrastructure and Sustainability Division, Scottish Government Scottish Government, annual climate duties reporting		
Key documents:	Scottish Health Technical Memorandum (SHTM 02- 01) Nitrous Oxide Mitigation Implementation Plan Evidence-Based Policy Report: Reducing Environmental Emissions attributed to Piped Nitrous Oxide Products Monitoring strategies for toxic substances (HSG 173) Methods for the determination of hazardous substances (MDHS 88) NHS Scotland (NHSS) nitrous oxide data (health boards to email data requests to <u>nss.nppharmacy@nhs.scot</u>) Nitrous oxide analytics dashboard (under development)		
Purpose:	This is a technical document created to facilitate a leaner physical provision of Entonox® within NHSS sites and improve indoor air quality by minimising occupational exposure to Entonox®.		

Executive Summary

Entonox® is a 50:50 mix of nitrous oxide and oxygen. It is a valuable analgesic agent used across a wide range of clinical services including emergency medicine, pain management, palliative care, colonoscopy and maternity. It is inexpensive, can be self-administered over prolonged periods, is well tolerated by nearly 70% of patients, and is relatively safe if used within therapeutic limits. In maternity, its versatility is of note and there remains no comparable pharmacological analgesic intervention that supports such independence and mobility of a mother in labour.

However, Entonox® is a nitrous oxide product and nitrous oxide is a potent greenhouse gas contributing to climate change. Within NHS Scotland, Entonox® alone is responsible for an emission footprint similar to that of 18,000 flights from Frankfurt to New York. Additionally, chronic exposure to Entonox® can compromise vitamin B12 function and lead to the development of associated anaemia in NHS staff.

The challenge for NHS Scotland is to minimise these environmental and occupational health risks of Entonox® while continuing to utilise this analgesic agent and without compromising patient care.

This briefing draws on a growing body of evidence that indicates that a significant amount of Entonox® used at NHS sites is lost via outlets or valves or is wasted through poor stock management. It suggests processes that will help minimise Entonox® loss, waste and occupational exposure. Entonox® system loss mitigation and management is an evolving area of work and all NHS Scotland sites are encouraged to contribute to future iterations of this briefing by sharing their experiences in minimising risks associated with Entonox® supply.

1. Background

- 1.1 NHSS, through its climate emergency and sustainability strategy, is working to become a net-zero emissions health service by 2040 or earlier if possible [1]. This requires significant reductions in NHSS greenhouse gas emissions.
- 1.2 Nitrous oxide (N₂O) is a potent greenhouse gas with a global warming potential 298 times that of carbon dioxide over a 100-year period and is the dominant ozone depleting substance globally [2]. As a medical gas it is exhaled by the patient virtually unchanged into the environment and finds its way into the atmosphere, where it remains stable for up to 115 years [3]. In addition to its deleterious climate effects, it is a substance regulated by COSHH¹. Chronic occupational exposure has been shown to depress vitamin B12 function, leading to associated anaemias in healthcare staff [4]
- 1.3 In 2018/19, medical nitrous oxide products used by NHSS amounted to 28,274 tonnes in carbon equivalents (tCO₂e), of which **17,899 tCO₂e** was attributed to Entonox® (50% oxygen/50% nitrous oxide gas mixture).

¹ Control of Substances Hazardous to Health.

Fiscal year	Piped Entonox®	Portable Entonox®	Piped nitrous	Portable nitrous
2018/19	14,287	3,612	9,586	789
2019/20	14,677	3,511	9,385	790
2020/21	14,078	2,775	7,764	392
2021/22	14,666	3,350	6,717	733
2022/23	14,506	3,345	6,486	988

Table 1. Emissions of nitrous oxide product in carbon dioxide equivalents (determined from BOC data)

- 1.4 NHSS is evaluating its N₂O mitigation against its 2018/19 baseline. Mitigation is already observed against piped anaesthetic nitrous oxide. Discussions have now turned to minimising system loss and waste of Entonox®.
- 1.5 Entonox® is supplied by either a piped system or portable cylinders within NHS sites.
- 1.6 A piped supply that is correctly sized, well maintained and serviced is an ideal system for delivering analgesic Entonox®. If well managed, it will generate far less waste, operate at a lower cost, and avoids the risks² associated with managing portable cylinders.
- 1.7 Repeated loss analysis indicates that diminished integrity of piped systems is a significant driver of system loss [5, 6]. Early evidence from piped Entonox® mitigation projects suggests that such losses are driven by leaks from permanent mechanical joints or temporary joints including cylinder connections and demand valves; with secondary losses or waste attributed to poor security or stock management³.
- 1.8 With respect to portable cylinders, at least one study indicated that portable cylinders are often returned to the medical gas supplier before being optimally utilised [7]; this will impact negatively on NHSS emissions because medical gas suppliers vent all remaining gas within a cylinder, in alignment with MHRA batch control requirements.
- 1.9 Chronic system loss of Entonox® can lead to an accumulation of background N₂O in the work environment and become an occupational health concern. Recent cases in NHS England's Princess Alexandra Hospital in Harlow⁴ and Basildon Hospital⁵ have demonstrated that delivery suites can breach COSHH occupational exposure levels for N₂O due to persistent leaks of Entonox® into clinical areas, coupled with inadequate ventilation arrangements.
- 1.10 Within a health board, Medical Gas Committees hold responsibility for the governance and management of these agents and include representatives from all the key stakeholder groups involved in the supply, management and administration of Entonox®. These include piped medical gas authorised persons, soft facilities designated porter leads, pharmacy services, clinical engineers, and clinical and managerial leads from various teams who rely on the use of Entonox® in their practice.

⁴ Reporting by Theresa Hughes (Quality Assurance Specialist).

² Risks include medicine depleting mid case, trip and injury hazards from falling cylinders, increased frequency of manual handling, and the additional storage space and security required (Theresa Hughes, Quality Assurance Specialist).

³ Hull University Teaching Hospitals NHS Trust; Princess Alexandra Hospital, Harlow; Basildon Hospital; King's College Hospital Trust, London; and St John's Hospital (NHS Lothian).

⁵ Reporting by Michael Ralph (Principal Engineer, NHS England now NHS Assure).

1.11 Maintenance of piped systems and minimisation of system loss are expectations of the <u>SHTM 02-01</u>. Appropriate governance and management of the piped medical gas system are required to ensure that the systems function as required and that system loss is kept to a minimum.

2. Scope

- 2.1 This document aims to clarify process, and reparative and preventive actions, with respect to minimising system loss and waste of, and occupational exposure to, Entonox®.
 - Section 3 Minimising system loss and waste of piped Entonox® systems
 - Section 4 Minimising system loss and waste of portable Entonox®
 - Section 5 Minimising occupational exposure to Entonox®
- 2.2 Within this document, green technologies designed to destroy the N₂O molecule are considered secondary to establishing rigorous system loss and waste mitigation protocols. As services move towards a leaner supply of Entonox®, this assists in determining the type of N₂O mitigation solution that is needed.
- 2.3 These green technological solutions are being assessed against posology, utility, infrastructure compatibility and emission reduction capability versus cost (including life cycle analysis).
- 2.4 Clinical alternatives with a potentially lower carbon footprint to that of Entonox® are outside the scope of this document. It is noted that some emergency departments and paramedic services have introduced methoxyflurane (Penthrox®) as an alternative to Entonox®. Penthrox® has a 100-year global warming potential of 4, compared with 298 for N₂O. However, it can be used only in small volumes over a short period of time and is therefore not suitable for administration to a mother in labour.

3. Minimising System Loss and Waste of Piped Entonox® Systems

3.1 Improvement Approach

- 3.1.1 A well-maintained piped supply is an ideal system for delivering analgesic Entonox®, generating less waste and operating at a lower cost than portable cylinders and avoiding the risks⁶ associated with managing portable cylinders.
- 3.1.2 It is recommended that a quality improvement (QI) approach is taken to minimise loss of this agent. NHS sites should establish a project team with a project lead and with subject matter experts. These should include piped medical gas authorised persons, soft facilities designated porter leads, pharmacy services representatives, clinical

⁶ Risks include medicine depleting mid case, trip and injury hazards from falling cylinders, increased frequency of manual handling, and the additional storage Space and security required (Theresa Hughes, Quality Assurance Specialist).

engineers, and clinical and managerial leads from various teams who rely on the use of Entonox® in their practice, such as midwifery. Where available, support can be provided by QI advisers within a health board.

3.1.3 Piped Entonox® systems are serviced by 211-G and 211-EW BOC cylinders. NHSS health boards can email requests for monthly nitrous oxide product data updates (email: <u>nss.nppharmacy@nhs.scot</u>). The team should consider this data, system logs and potentially utilise other QI tools such as process mapping to understand the granular management of this agent at a site and identify the problem(s) within a local context.

3.2 Planned Preventive Maintenance

- 3.2.1 Loss through the pipeline infrastructure is more likely at terminal units (wall outlets) but is not uncommon at the manifold and other junctures, including the area valve service unit (AVSU).
- 3.2.2 All sites' authorised persons should carry out a system loss assessment of piped Entonox® within three (3) months of receiving this document. Thereafter, in accordance with planned preventive maintenance, all terminal units, the manifold, and all mechanical connections in the system are checked regularly for leakage. The estates or operation and maintenance team have ownership of this and must choose the best course of action considering the frequency of use and age of the system.
- 3.2.3 Demand valves should be removed from wall outlets when not in use. System loss is increased by leaving demand valves in situ when there is no clinical usage^{7.} The demand valve left in an outlet increases the risk of damage to the outlet, and poor connectivity between the demand valve and the wall outlet may result in a leak. Furthermore, a functioning demand valve can leak 2 litres per minute and faulty valve may exceed this without audibility⁸. The responsible clinician must ensure that demand valves are not left in situ, and suspected damage to outlets or demand valves should be reported to estates and medical physics, respectively.
- 3.2.4 Manifolds should be checked regularly for leakages and faults. Logbooks should be maintained for both cylinder changes and leak tests. This maintenance should occur when a bank of cylinders is changed as well as weekly, as a precaution. Soft facilities management teams should perform and log these checks as they are carried out.
- 3.2.5 An increase in frequency of cylinder bank changes should be reported by soft facilities to the estates authorised person for medical gases, for investigation.

3.3 Stock Management

- 3.3.1 Waste minimisation can be facilitated through prudent procurement and stock management, to ensure that correct supply arrangements are in place. Such arrangements include cylinders being rotated from the emergency reserve supply into the active banks.
- 3.3.2 Security of large cylinders 211-G and 211-EW has been a problem at some NHS England sites. Theft should be considered if system loss cannot be accounted for;

⁷ For example, Hull University Teaching Hospitals NHS Trust.

⁸ Reporting by Michael Ralph Principal Engineer (NHS England now NHS Scotland Assure).

this should be recorded on Datix and escalated by the Medical Gases Committee to the Director of Pharmacy and the site's Chief Executive Officer.

3.4 Termination or Minimisation of Piped Entonox®

- 3.4.1 A piped supply that is well maintained and serviced to minimise system loss and waste is an ideal system for delivering analgesic Entonox®. However, sites may find that superfluous outlets or low demand for Entonox® as a clinical agent can mean that the presence of a piped supply may be surplus to need and create a management burden and/or an unnecessary leak risk.
- 3.4.2 Sites should actively question the validity of an Entonox® piped supply in its entirety or in part where:
 - a) there is no clinical demand for a piped supply (e.g. no maternity unit)
 - b) the number of maternities is less than 200 per annum⁹
 - c) the clinical area has a piped Entonox® supply that is not utilised
 - d) the detection or repair of system leak(s) has proved expensive or disruptive¹⁰.
- 3.4.3 Where the project group has determined that a piped Entonox® system is redundant, a formal request to decommission an Entonox® manifold should be issued (email is suitable) by the Clinical Director of Anaesthesia and the Head of Midwifery to the Director of Estates within a given health board. All relevant stakeholders should be copied into the correspondence, including the Authorising Engineer for the site, the Chair of the Medical Gases Committee and the Director of Pharmacy.
- 3.4.4 When a segment of the piped Entonox® supply has been deemed redundant, the same request procedure should be followed. The redundant piped supply can be terminated at the AVSU.

4. Minimising System Loss and Waste of Portable Entonox®

4.1 Improvement Approach

- 4.1.1 Portable cylinders offer mobility of care. Risks associated with portable cylinders that need to be managed include medicine depleting mid case, trip and injury hazards from falling cylinders, increased frequency for manual handling, and the additional storage space and security required.
- 4.1.2 It is recommended that a QI approach is taken to minimise risks and waste of this product. NHS sites should establish a project team with a project lead and with subject matter experts. These should include hard and soft facilities management, pharmacy services representatives, clinical engineers, and clinical and managerial leads from various teams (e.g. pain management teams) who rely on the use of

⁹ There is no definitive rule; however, it may be difficult to justify the risk, cost and maintenance of a piped Entonox® system at sites with such low clinical utility.

¹⁰ King's College Hospital Trust, London, have terminated supply of piped Entonox® where leak detection and reparation have been challenging and moved services to Entonox® EX cylinders (Laura Stevenson, Deputy Chief Aseptic Pharmacist).

Entonox® in their practice. Where available, support can be provided by QI advisers within a health board.

4.1.3 Portable Entonox® cylinders include 211-EA, 211-D, 211-ED, 211-E, 211-F and 211-EX BOC cylinders. NHSS health boards can email requests for monthly nitrous oxide product data updates (email: nss.nppharmacy@nhs.scot). The team should consider this data against site logs and potentially utilise other QI tools, such as process mapping, to understand the granular management of this agent at a site and identify any problem(s) within a local context.

4.2 Stock Management

- 4.2.1 All portable Entonox® gas cylinders should be optimally utilised. To reduce NHS's emission footprint, care is needed to reduce the amount of gas left in Entonox® cylinders after use, because the medical gas cylinder provider is required to vent any returned gas to atmosphere prior to refilling. Where cylinders are fitted with an integral valve (on the ED and EX cylinders), optimising use can be controlled by checking the cylinder contents on the gauge fitted to the valve, making sure that the indicator is as near as possible to the empty mark, these cylinders are at 25% capacity once the gauge indicator enters the 'red zone' allowing ample time for a patient to continue with treatment before a second cylinder is sourced and introduced.¹¹
- 4.2.2 Facilities, pharmacy, and clinical teams must establish safe and secure storage for this product throughout NHS facilities.

5. Minimising Occupational Exposure to Entonox®

- 5.1 Recent cases in NHS England's Princess Alexandra Hospital and Basildon Hospital have demonstrated that delivery suites can breach COSHH¹² occupational exposure levels for N₂O. These safe thresholds were breached due to chronic system loss of Entonox® into clinical areas and/or inadequate ventilation arrangements.
- 5.2 A collaborative approach to minimising these occupational risks, working in partnership with staff side health and safety representatives, should be adopted by Health Boards.¹³
- 5.3 Nationally, to address and minimise these occupational risks, in autumn 2023, NHS Assure alongside the Royal College of Midwives will be establishing a clean indoor air working group to review operations, processes, practice and technologies that can improve indoor air quality for midwives practising in different clinical settings. This working group oversight will inform later iterations of this document.

5.4 Ventilation

5.4.1 Within Scotland, ventilation systems where there is an established Entonox® supply should comply with SHTM 03-01 [8] and HBN 09-02 [9], which specify air supply at

¹¹ entonox-integral-valve-cylinder-instructions_tcm410-675418.pdf (boconline.co.uk).

¹² Control of Substances Hazardous to Health.

¹³ What is Staff Governance? — NHS Scotland Staff Governance

high level with low-level extract (minimum of 10 room air changes per hour); this is to enable N₂O levels (associated with Entonox® supply) to fall within COSHH limits for exposure. Additionally, a scavenging system that removes the exhaled breath containing N₂O may be introduced as adjunctive measure. *These ventilation arrangements should be revalidated by the estate's teams at specified frequencies.*

5.4.2 Portable Entonox® cylinders allow a patient to receive ambulatory analgesia anywhere. This can include home administration, and clinical staff should be mindful of maintaining adequate ventilation either through allowing the entry of outdoor air or increasing the cubic meterage of the internal space by opening a door.

5.5 **Personal Exposure Minimisation**

5.5.1 Clinicians' exposure can be affected by their personal positioning within a room, and all practitioners should be cautious of being in the direct path of Entonox® emissions. Recommended actions can include avoiding a patient's direct exhalation of Entonox® or obstructing the room air extract pathway, and practitioners should actively place themselves nearer the fresh air supply delivered into the room.¹⁴

5.6 Nitrous Oxide Environmental Monitoring

- 5.6.1 Environmental monitoring guidance is contained within <u>HSG 173</u> and <u>MDHS 88</u>. These describe both active and passive techniques. Active sampling is preferred as the time stamped data can inform clinical practice. Additionally, active sampling devices also have multifunctional modes that expand utility.
- 5.6.2 N₂O environmental monitoring equipment can help determine personal exposure and background concentration of N₂O and aid leak detection. This equipment can be purchased, but clear arrangements must be in place for servicing and routine calibration; these can be established with the Medical Physics department.
- 5.6.3 N₂O monitoring methodologies must be stipulated for each monitoring function by the Medical Gases Committee. Interpretation expertise can be sourced from pharmacy quality assurance specialists, the Medical Physics department, and estates ventilation engineers or nominees for the health board, along with practitioners who administer Entonox®.
- 5.6.4 COSHH environmental limits relate to personal exposure of N₂O, specifying a UK maximum of 100 ppm over an 8-hour time-weighted average (TWA). Practitioners can routinely wear N₂O monitoring devices to detect their levels of personal exposure. Any data interpretation must be mindful of clinical context and the intensity and duration of Entonox® use before any conclusions are reached.
- 5.6.5 N₂O leak detection can be aided with these technologies. The team at King's College Hospital NHS Foundation Trust, London, utilised the G200 N₂O analyser¹⁵ device, which has three monitoring settings: 1, Person; 2, Area; and 3, Leak. The 'Leak' setting was used to locate leaks in the piped system, from wall outlets to pipework joints, and thereby helped facilitate repair of all faulty valves and isolation of areas of

¹⁴ Theresa Hughes (Quality Assurance Specialist).

¹⁵ https://www.qedenv.com/products/g200-n2o-analyser/.

leaking pipework. Medical Physics departments can enable this monitoring in collaboration with clinical managers and estates.

6. Nitrous Oxide Mitigation (Green) Technologies

- 6.1 Nitrous oxide catalytic cracking technologies are marketed in the form of a mobile destruction unit or a centralised destruction unit (CDU). These devices can reduce the median ambient N₂O levels by up to 70% when excellent patient technique is employed and where system loss of Entonox® has been accounted for. However, there is a cost for these devices and the high heat of catalysis can lead to overheating and unit malfunction. Several manufacturers supply CDUs requiring an N₂O scavenging system, which are not typically present in Scottish maternity units.
- 6.2 These technologies should be considered only once all other waste and loss mitigation measures have been rigorously applied. These green technological solutions are being assessed against posology, utility, infrastructure compatibility and emission reduction capability versus cost (including life cycle analysis) and Health Boards are advised to await the results of this assessment.
- 6.3 Several alternative technologies are under development; however, they will not be available on the UK market until 2025 at the earliest.

7. Financial Implications

- 7.1 Reduction in Entonox® turnover will not deliver significant financial savings. Minimising Entonox® loss and waste will significantly reduce environmental impact and occupational risk associated with this agent.
- 7.2 Environmental sampling devices are available for circa £2,500. At least one device is desirable to monitor N₂O levels in a maternity unit with two or more being preferential in larger units.
- 7.3 Mobile (N₂O) destruction units are available for circa £30,000. A CDU, including infrastructure modification, will cost circa £210,000. This technology should be considered only once all other waste and loss mitigation measures have been rigorously applied.

8. Training Requirements and Facilitators

- 8.1 Specific training is a requirement within the SHTM 02-01 for specialist 'designated porters' who are responsible for moving and replacing cylinders for a piped medical gas system. Medical Gas Committees, within their terms of reference, are obliged to ensure safe handling of all medical gas cylinders by NHS staff and to ensure that the soft facilities directorate understand and comply with all training requirements.
- 8.2 Specific training must be provided for all clinical staff who handle portable cylinders. The Medical Gases Committee must ensure and support such training.
- 8.3 All staff should be made aware that N₂O is a greenhouse gas and that when cylinders are returned to the medical gas supplier for refilling, the surplus residual

gas within them is vented to the atmosphere, under MHRA obligations, and as such forms part of the organisation's emission footprint.

8.4 Process mapping is strongly recommended to articulate the roles of different stakeholders and to identify risks and opportunities and thereby improve processes and communication. Many health boards can provide skilled facilitators via their QI team.

END OF DOCUMENT

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