MEDICAL GASES

GOOD HOMECARE PRACTICE FOR OXYGEN THERAPY

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Amendments from 158/09

Section	Change
	Editorial to align to new format
	Since the previous version of this document some content has been taken out and described in more detail in separate documents. Where this is the case, there is a reference to the new document.

1 Introduction

The supply of oxygen therapies to patients at home is a specific activity and service. It is performed within individual and varying environments from one patient to another.

Patient safety, quality of therapy and patient education are the prime objective of the Homecare Service Providers (HSP).

The HSP organises activities in compliance with the European and national legislation related with manufacture and supply of medicinal products and medical devices. This includes:

- Good Manufacturing Practice (GMP) [1][1]
- Good Distribution Practice (GDP) [2]
- General Data Protection Regulation (GDPR) [3].

In addition to the European and national legislation, the HSP will specifically act in accordance to the documented therapy prescription and contractual agreements and following industry guidelines including those in EIGA publications.

As an overview, this publication combines and refers to the elements above and provides guidance for HSPs on Good Homecare Practice for Oxygen Therapy.

2 Scope and purpose

2.1 Scope

This publication applies to the delivery of medical oxygen and related services by HSPs using:

- compressed oxygen cylinders
- transportable liquid oxygen systems
- oxygen concentrators
- oxygen self-fill systems.

2.2 Purpose

The purpose of the publication is to provide guidance for all HSPs for the supply of oxygen therapy.

The publication provides best operating practices for the supply of medical oxygen but does not cover all the relevant applicable national regulations that could apply in some countries.

The basic requirements include, but are not limited to:

- Services and supply of products are assured to each patient in compliance with the therapy prescription and according to the terms of the contract including installation, maintenance and removal of the equipment.
- Service and supply processes are clearly defined, systematically reviewed in the light of experience and shown to be capable of consistently delivering services and products.

[1] References are shown by bracketed numbers and are listed in order of appearance in the reference section.

- Each patient or carer is adequately trained in the safe and correct use of the therapy related products.

- Relevant service and supply processes are risk assessed to ensure the safety and health of personnel and patients.

3 Definitions

3.1 Publication terminology

3.1.1 Shall

Indicates that the procedure is mandatory. It is used wherever the criterion for conformance to specific recommendations allows no deviation.

3.1.2 Should

Indicates that a procedure is recommended.

3.1.3 May and Need not

Indicate that the procedure is optional.

3.1.4 Will

Is used only to indicate the future, not a degree of requirement.

3.1.5 Can

Indicates a possibility or ability.

3.2 Technical definitions

3.2.1 Base unit

Mobile device that is vacuum insulated intended to store oxygen and maintain it in the liquid state to refill portable units and that includes an internal vaporiser and a flow control valve for the direct supply of gaseous oxygen to the patient.

3.2.2 Basic maintenance

Maintenance according to the user manual.

3.2.3 Carer

Person (for example a relative or friend) who can assist the patient with their therapy.

3.2.4 Oxygen cylinders

Transportable pressure receptacle of a water capacity not exceeding 150 litres.

3.2.5 Equipment

Oxygen therapy related medical devices.

3.2.6 Homecare Service Provider (HSP)

Organisation that provides the medical oxygen and the medical oxygen equipment for treatment of patients either in their home or supplied directly to the healthcare facility treating the patient.

3.2.7 Homecare Service Provider facilities

Any sites involved in the supply chain and field operations managed by the HSP.

3.2.8 Oxygen concentrators

Medical device that produce flow of oxygen enriched air for patient use by separating the oxygen and nitrogen in atmospheric air by passing it through a molecular sieve. Concentrators can be divided in three families: stationary concentrator, transportable concentrator and portable concentrator.

3.2.9 Oxygen cylinder filling system (self-fill system)

System consisting of a medical oxygen concentrator with a compressor (integrated or in a separated unit) to fill an oxygen cylinder.

3.2.10 Portable concentrator

Concentrator that weighs less than 4 kg, it can be carried on the shoulder in an appropriate bag or pulled by a trolley.

3.2.11 Portable unit

Portable device including a vacuum insulated cryogenic vessel to maintain liquid oxygen at cryogenic temperatures, an internal vaporiser and a flow control to provide gaseous oxygen to the patient. The portable unit can be filled from the base unit by the patient.

3.2.12 Products

Medical oxygen and/or equipment.

3.2.13 Services

Can mean any combination of:

- Installation or removal and replacement, maintenance and technical verification of equipment;
- Supply of products;
- Providing training, support, advice, and follow-up to the patient; and
- Providing feedback to prescribers.

3.2.14 Stationary concentrator

Concentrator that weighs more than 9 kg, installed in a fixed position.

3.2.15 Transportable concentrator

Concentrator that weighs between 4 and 9 kg, it can be pulled by a trolley.

3.2.16 Transportable liquid oxygen system

Comprising of the base unit and the portable unit.

4 Personnel

4.1 Principle

All HSP personnel dealing with oxygen therapy homecare services shall be trained and qualified in accordance with a defined programme incorporating this publication.

4.2 General

Training requirements shall be the same whether the work is carried out by employees or is sub-contracted to external companies. HSP personnel shall be trained using a referenced training document/package, including both theoretical & practical training.

4.3 Training requirements for operational personnel

4.3.1 HSP personnel providing oxygen therapy services at patients' home

Basic training shall cover:

- oxygen risks, including fire, cryogenic hazards, oxygen enriched atmosphere, high pressure;
- installation of the therapy equipment;
- removal of the therapy equipment;
- patient/carer training;
- preliminary risk assessment at patient home;
- basic maintenance of equipment;
- basic clinical understanding of oxygen therapy and patient empathy;
- principles of traceability and recall;
- administrative requirements;
- incident and emergency procedures;
- customer complaint procedures;
- hygienic operations;
- safety principles;
- driving skills;
- manual handling skills;
- GDP;
- GDPR; and
- regulatory requirements.

4.3.1.1 Specific training when handling liquid oxygen (LOX)

HSP personnel shall be trained on:

- working principles of transportable liquid oxygen system including accessories and cryogenics and high-pressure hazards;
- cryogenics hazards of lox including effects on other materials;
- lox transport and compatibility of goods;
- lox storage on HSP facilities, in vehicles and at patients' homes;
- transportable liquid oxygen system installation and related checks;
- base units handling; and
- base and portable unit filling.

4.3.1.2 Specific training when handling gaseous oxygen (GOX)

HSP personnel shall be trained on:

- working principles including accessories and high-pressure hazards;
- cylinder storage on HSP facilities, in vehicles and at patients' homes;
- cylinder installation and related checks;
- cylinder handling;
- working principle of pressure/flow regulation; and
- cylinder transport and compatibility of goods.

4.3.1.3 Specific training when handling with oxygen concentrators

HSP personnel shall be trained on:

- oxygen concentrator working principles;
- concentrator transport;
- concentrator storage on HSP facilities, in vehicles and at patients' homes; and
- concentrator installation and related checks.

4.3.1.4 Specific training when handling oxygen self-fill systems

HSP personnel shall be trained on:

- working principles including accessories and high-pressure hazards;
- oxygen self-fill systems installation and related checks;
- cylinder handling;
- working principle of pressure/flow regulation;

- cylinder transport and compatibility of goods;
- oxygen concentrator working principles;
- concentrator transport and storage conditions; and
- concentrator installation and related checks.

4.3.1.5 Specific training when handling other oxygen therapy related equipment

HSP personnel shall be trained on each specific device.

For further detail please consult EIGA Doc 89 *Medical Oxygen Systems for Homecare Supply* [4].

4.4 Training requirements for customer service personnel

The customer service personnel, who handle all types of communication with home oxygen patients, clinicians and other customers, shall be trained on general customer service and specifically on:

- basic clinical understanding of oxygen therapy and patient empathy;
- oxygen risks, including fire, cryogenic hazards, oxygen enriched atmosphere, high pressure;
- the modalities of oxygen supply;
- basic function and principles of operation of each of the devices in use;
- The information to collect and elements to record before setting up of a new therapy;
- GDPR compliance;
- Incident procedures;
- Customer complaint procedures; and
- Principles of traceability and recall.

5 HSP facilities

5.1 Principle

Facilities shall be located, designed, constructed, adapted and maintained to suit the operations according to GMP, GDP, Medical Device Regulations, and applicable national regulation.

5.2 General

Facilities shall be laid out to allow for separation between returned products and products ready to supply patients. There shall be a logical flow between incoming and outgoing products to ensure that operations are safely and effectively carried out.

All products shall be secured and protected against adverse weather conditions.

Lighting, temperature, humidity and ventilation shall be appropriate and such that they do not adversely affect the storage or functioning of products.

A preventive pest control programme should be in place according to GDP guidelines.

Measures shall be taken to prevent unauthorised people from access to the premise and specific zones, such as production, storage and quality control areas.

5.3 Storage areas

Storage areas shall be clean and of sufficient capacity to allow orderly storage of the various categories of products: new, quarantined, released, rejected, returned or recalled.

Storage areas shall be kept clean and dry.

Storage areas for medicinal oxygen shall have:

- no combustible material e.g. oil and grease adjacent;
- no heat sources in the vicinity;
- ventilation to maintain the oxygen concentration below 23.5% in the ambient air;
- space and access for “first expired, first out” stock rotation; and
- marked separation of full, empty and non-conform containers.

Reception areas shall be designed and equipped to allow incoming products to be segregated and, where necessary, cleaned before storage.

Segregated areas shall be provided for the storage of non-conform, recalled or, returned products.

6 Vehicles

6.1 Principle

Vehicles used to transport products required in a Homecare oxygen therapy service shall comply with safety design rules and operations.

6.2 General

For guidance on minimum vehicle design and operational safety requirements for Homecare Therapy Service please consult Doc 128 *Design and Operation of Vehicles Used in Medical Oxygen Homecare Deliveries* [5].

7 Documentation

7.1 Principle

Documentation should be an integral part of the quality management system of the HSP personnel: procedures, checklists, work instructions and manufacturer’s user manuals.

Any patient related data shall be managed in compliance with the GDPR and national laws.

7.2 Essential documentation

Documents and records may be either paper or electronic version. Archiving requirements should comply with GDPR and local regulation. The essential documentation includes, but is not limited to:

- personnel training records;
- standard operating procedures (SOPs);
- SOP related checklists;

- user and technical manuals of equipment;
- batch records for products;
- traceability of products;
- maintenance and repair history of equipment;
- patient data file;
- patient instructions about safety and usage; and
- documented therapy prescription record.

8 Operations

8.1 Principle

Operations shall be performed according to the requirements described below.

8.2 General

It is the responsibility of the HSP to provide the services and products in accordance with the documented therapy prescription and contractual agreements, and the necessary safety and usage instructions.

The appropriate response to patient's calls is ensured according to a pre-established procedure. This procedure shall be effective 24 hours per day, 7 days per week or as specified in a contractual agreement.

It is essential that the HSP's personnel have the appropriate skills and training to handle patients/carers' needs regarding oxygen therapy.

EIGA Doc 89 [4] and EIGA Doc 98 *Safe Supply of Transportable Medical Liquid Oxygen Systems by Homecare Service Providers* [6] provide information on the most common supply methods for oxygen therapy.

8.3 Setting up of a new therapy

In the process of setting up a new therapy the following information shall be collected:

- personal patient data - name, address, phone (s), email address (if any), patient social security number;
- invoicing data - contact name, address;
- prescriber data - where required - contact name, address, function;
- documented therapy prescription;
- therapy parameters - oxygen flow, hours/day, duration;
- therapy equipment - devices, accessories and disposables needed;
- access conditions to and within patient's facilities; and
- timeframe for the first installation service, if specifically written in the documented therapy prescription.

8.4 Operation process

For detailed guidelines about operation process please refer to EIGA Doc 89 [4] and EIGA Doc 98 [6].

Following procedures/instructions are of specific notice:

- initial set up of the oxygen therapy supply systems;
- homecare environment risk assessment at the patient's home;
- patient instructions about safety and usage;
- basic maintenance of medical oxygen therapy equipment;
- medical oxygen therapy supply systems: storage, handling and usage;
- storage of the transportable liquid oxygen systems; and
- transfilling of the portable unit.

8.5 End of oxygen therapy

As soon as the HSP has been authorised to remove all products an appointment shall be made with the patient and/or carer. Sensitivity and respect shall be exercised by the HSP personnel.

The HSP personnel shall verify if the collected products are the same as recorded in patient file. If a product is missing an internal procedure should be followed. The same applies for non-conforming products.

The collected products should be segregated from the others during transport.

8.6 Travel support for oxygen therapy patients

A specific service for patients is supplying oxygen therapy during their travel. The practical requirements for such service are described in EIGA Doc 141 *Planning Oxygen Supplies for Respiratory Patients when Travelling* [7].

9 Complaints, traceability and recall

9.1 Principle

All complaints and other information concerning potentially non-conform products and services shall be reviewed according to written procedures to allow for continuous improvement and compliance with legal requirements.

A system shall trace products in accordance with national regulation. A procedure shall be in place to recall, if necessary, promptly and effectively products and devices known or suspected to be non-conform.

9.2 Complaints

A structured and documented system shall manage customer complaints including responsibility for investigation, resolution, feedback to the originator and reporting.

Complaints and non-conformances shall be reviewed regularly for any indication of specific or recurring problems requiring attention and possibly the recall of marketed products.

9.3 Traceability

The HSP shall establish documented means including procedures, processes and tools for traceability.

If a non-conforming product is discovered or suspected in a batch, consideration shall be given to checking other batches to determine whether they are also affected.

9.4 Recalls/field safety corrective actions (FSCA)

A person shall be designated as responsible for the management of recalls/FSCA and shall be supported by sufficient personnel to coordinate and execute all the aspects of the recalls with the appropriate degree of urgency.

Recall/FSCA operations shall be capable of being initiated promptly and at any time.

All Competent Authorities of all countries shall be informed promptly of potentially non-conforming products that could have been distributed. They shall also be informed of any recall/FSCA.

The distribution records shall be readily available to the person(s) responsible for recalls/FSCA and shall contain information on wholesalers and directly supplied customers (with addresses, phone and/or fax numbers inside and outside working hours, batches and amounts delivered), including those for exported products.

Recalled products shall be identified and quarantined.

The progress of the recall process shall be recorded, and a final report issued, including reconciliation between the delivered and recovered quantities.

The effectiveness of the arrangements for recalls/FSCA shall be evaluated regularly**.**

10 Self-inspection

10.1 Principle

Self-inspection is part of the operation management system and shall be carried out repeatedly with the aim of checking the implementation of Good Practice guidelines.

10.2 General

Self-inspections shall be conducted according to a procedure written by competent personnel who are designated for this purpose.

These self-inspections are conducted at regular intervals according to a pre-established programme.

The aim of self-inspections is to check:

- conformity of the facilities and products;
- conformity and updating of documents;
- conformity of the training level of personnel;
- compliance with procedures; and
- compliance with good practice guidelines.

The inspections are recorded in a written report that shall include the findings during the self-inspections and, where applicable, suggestions for corrective actions. A system for following up the implementation of the corrective actions shall be set up and formalised.

11 References

Unless otherwise stated the latest revision shall apply.

[1] Good Manufacturing Practice – Regulation No. 1252/2014 and Directive 2003/94/EC, applying to active substances and medicines for human use www.ema.europa.eu

[2] Good Distribution Practice – Directives 2001/83/EC and 2001/82/EC lay down the provisions for distribution of medicines in the EU www.ema.europa.eu

[3] EU General Data Protection Regulation (GDPR) - Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 *on the protection of natural persons with regard to the processing of personal data and on the free movement of such data* www.eur-lex.europe.eu

[4] EIGA Doc 89 *Medical Oxygen Systems for Homecare Supply* www.eiga.eu

[5] EIGA Doc 128 *Design and Operation of Vehicles Used in Medical Oxygen Homecare Deliveries* www.eiga.eu

[6] EIGA Doc 98 *Safe Supply of Transportable Medical Liquid Oxygen Systems by Homecare Service Providers* www.eiga.eu

[7] EIGA Doc 141 *Planning Oxygen Supplies for Respiratory Patients when Travelling* www.eiga.eu

12 Additional references

[1] EIGA Doc 04 *Fire Hazards of Oxygen and Oxygen Enriched Atmospheres* www.eiga.eu

[2] EIGA Doc 193 *Guidance for Safety and Reliability of Oxygen Self-Fill Systems* www.eiga.eu

[3] EIGA Doc 198 *Security and Safety for Homecare Field Personnel* www.eiga.eu