MEDICAL GAS CONTROL

The increased risk to patients from the under-reported problem of home oxygen fires in Europe

Is the EU Medical Device Vigilance System fully protecting patients by identifying the scale and severity of the issue?

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Executive Summary

Each year, home oxygen fires cause a significant number of avoidable deaths and severe burn-related injuries in Europe. However, despite a requirement for serious incidents that involve home oxygen devices to be reported under medical device regulation in the European Union (EU), new analysis of media reports in France and Italy suggests that many such incidents are not being captured.

Without knowing the true scale of the problem, the industry cannot work together effectively to prevent further harm. Given this new evidence that serious incidents are slipping through the cracks in the current Medical Device Vigilance System, this paper questions the need for consistent, comprehensive reporting and clear guidance on risk control requirements.

Part 1: Reporting requirements and challenges

Our research suggests a lack of consistency in how home oxygen fire incident data is being captured. Ambiguity about who is to report safety incidents and to whom – coupled with inconsistent communication between healthcare stakeholders, emergency services and home oxygen installers may be a cause. Patients may not even report less serious incidents, leaving installers unaware that they have ever happened. It is therefore inevitable that some events will be missed, meaning decisions about fire safety policy and practice will be based on incomplete data.

A lack of clarity around reporting, alongside incomplete data, prevents regulators and industry from understanding and addressing the issue and therefore helping to keep home oxygen patients and their communities safe.

Part 2: Reducing the risk: cooperation, risk assessment and engineering solutions

Only when the scale of the problem is properly understood, can the industry focus on solutions. This includes consistent incident reporting, along with a culture of cooperation between stakeholders, a strong risk assessment process, and the use of low-cost risk control measures such as patient education, smoke alarms, and solutions to prevent fire spreading.

There are already requirements in place to reduce the risk from home oxygen fires. In recognition of the long-standing problem, the International Organisation for Standardisation (ISO) has introduced risk control measures into some standards. Meanwhile, Medical Device Regulation 2017/745 (MDR)[1] requires that all medical devices 'reduce risk as far as possible' in line with the 'state of the art'.

However, while these standards are currently followed to the letter in some European countries, in others they are not. In some cases, safety devices are only installed for so-called high-risk users. In other cases they are fitted on oxygen concentrators but not on other modalities (compressed gas cylinders and liquid oxygen).

A key objective of the MDR is:

> "to establish a robust, transparent, predictable and sustainable regulatory framework for medical devices which ensures a high level of safety and health whilst supporting innovation.

This paper questions the need for Competent Authorities and/or the Medical Devices Coordination Group, as appropriate, to take action to reduce death and serious injury by:

a) clarifying the reporting requirements for home oxygen-related fires; and

b) clarifying whether, under the MDR, solutions to prevent fire from spreading should be fitted to all oxygen modalities.

Introduction:
The burning issue of home oxygen-related fires

Home oxygen therapy (HOT) allows patients with chronic respiratory conditions to breathe more easily, while improving arterial blood oxygen saturation. Typically, oxygen is delivered via a nasal cannula attached to:

- an oxygen concentrator (COX), a device that extracts and separates oxygen from the surrounding air;
- a liquid oxygen system (LOX), a compact storage vessel containing large quantities of oxygen in liquid form; or
- a pressurised oxygen cylinder (GOX), containing relatively high volumes under extremely high pressure.

While HOT enhances patients' lives, it's also a major risk in the presence of a naked flame or other source of ignition.

Many patients who develop lung conditions do so after a lifetime of smoking cigarettes. Unfortunately, due to nicotine's addictive nature, quitting can be a significant struggle. Estimates suggest that up to half of patients with chronic obstructive pulmonary disease (COPD) continue to smoke while using HOT.[2] Smoking poses a huge risk of house fire: a 2018 report by the European Fire Safety Alliance found that while just 5% of house fires in Europe in the previous ten years were caused by smoking, **25% of fatal fires were caused by smoking.**[3]

The combination of concentrated oxygen and a lit cigarette is what sparks most severe home oxygen fires. Heat from the cigarette can ignite the nasal cannula, causing a flash fire around the patient's nose and mouth, or in their lap if they've removed the cannula. The flames will burn down the tube towards the oxygen source, potentially causing a whole house fire if not extinguished.

The impact can be devastating. Not only does the patient face severe burn-related injuries or even death, but family members and pets are also at risk. Major incidents can endanger neighbours and emergency services. Property damage and medical treatment can incur significant financial costs.

All stakeholders, including regulatory bodies, home oxygen device manufacturers, home oxygen installers, their trade associations, and clinicians, are aware of the issue. In fact, there was sufficient concern about the problem to prompt international action in 2012 to amend the ISO standard to include additional risk controls.

What is not known, however, is how far this problem extends. If the incident rate is under-reported through existing vigilance mechanisms, regulatory authorities will be prevented from acting accordingly on patient safety.

Part 1:
Reporting, requirements and challenges

The lack of consistent data on fire incidents in Europe has been widely recognised.[4,5] The European Commission funded a pilot project aimed at closing the gaps in fire data more generally. A recent progress report for the EUFireStat project noted that:

"There is no single approach to fire incident data collection by countries within and outside the European Union. Differences in data collection methodologies may be influenced by a variety of factors, including distribution of administrative authority, data collection traditions, available technologies, size and distribution of the population, levels of funding, and other factors. The achievement of more harmonised data among fire data collection systems in the European Union will be substantially influenced by the consistency and completeness of information produced by the data collection systems of member states."[6]

"There is no single approach to fire incident data collection by countries within and outside the European Union.

However, this project does not explicitly include data points that would help determine the prevalence of fires involving home oxygen equipment.

What are the current reporting requirements around home oxygen fires?

There is an existing reporting mechanism that ought to capture this information. As of 26 May 2021, the MDR requires serious incidents involving medical devices, which includes home oxygen therapy related equipment, to be reported to Competent Authorities. It assigns specific reporting responsibilities to the manufacturers, importers and distributors of medical devices. For example, under this regulation:

- **Article 13** requires importers of medical devices to keep a register of complaints and share this with the manufacturer, authorised representative and distributors to allow investigation of complaints.
- **Article 14** requires distributors of medical devices (which means home oxygen installers under the Economic Operator supply chain described in the MDR7) to keep a register of complaints and inform manufacturers (or the authorised representative and importer if the manufacturer is outside the European Union) when advised of suspected incidents by healthcare professionals, patients or users.
- **Article 87** sets out various requirements for manufacturers regarding the reporting of serious incidents involving medical devices to the relevant Competent Authorities.

There are also provisions relating to EU Member States, who are required to take appropriate measures to raise awareness among healthcare professionals, users and patients about the importance of reporting incidents. National Competent Authorities should inform manufacturers of suspected serious incidents and must follow up accordingly. The MDR also provides for a central electronic database to record such incidents (EUDAMED), and the European Commission is expected to provide systems and mechanisms to monitor vigilance reporting to identify trends that may reveal potential safety risks.

Lack of clarity leads to under-reporting

In principle, the provisions exist to ensure a joined-up flow of information between the various economic operators involved in the manufacture, supply and use of medical devices such as home oxygen therapy equipment.

In practice, there may be variation in how these provisions are interpreted. For example, in the event of a residential fire involving home oxygen, should the installer notify the manufacturer of the tubing, the nasal cannula, or the oxygen concentrator, or all three? Do provisions relating to system assembly apply, when installers believe that they're merely putting individual devices in service?

Given the ongoing debate around definitions, roles and responsibilities with incident reporting, it seems highly likely that many incidents could go unreported. If reporting requirements are unclear, or if too many reporting decisions are left to individual judgement, could the result be a patchy approach to incident reporting and investigation?

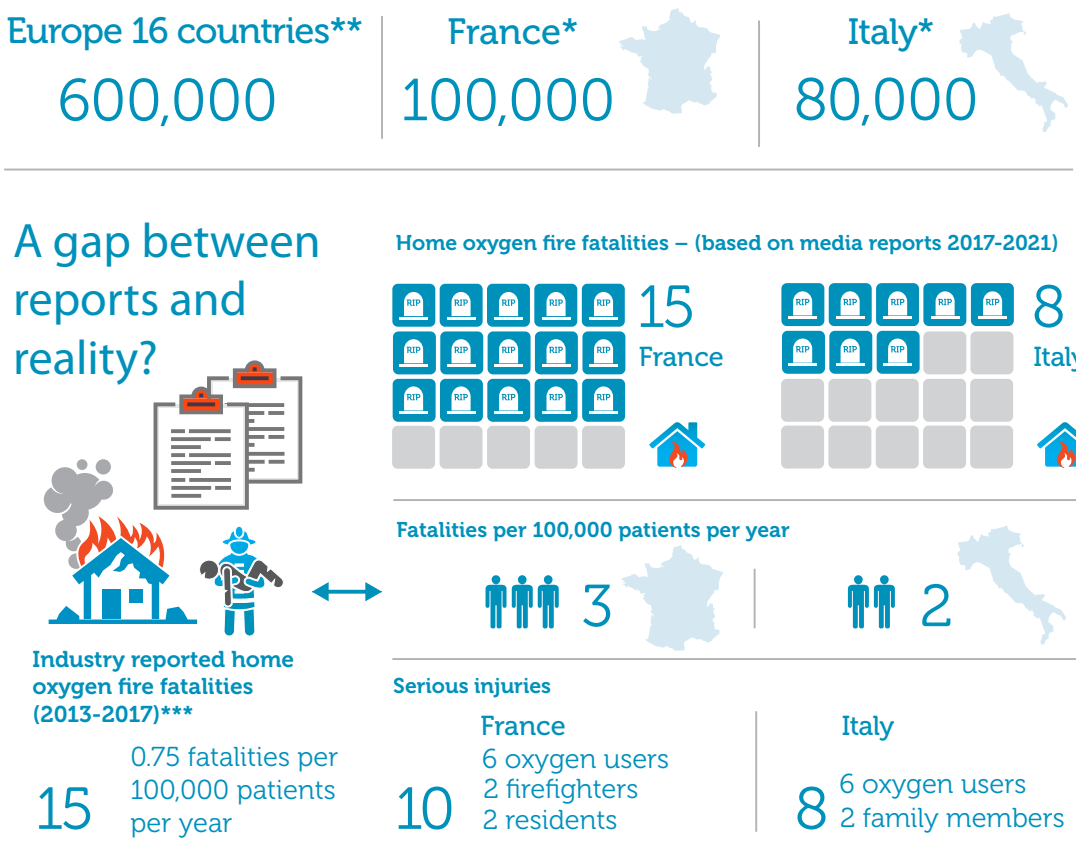
Attempts have been made to clarify the regulations: BPR Medical published a white paper[8] on the status of home oxygen service providers in 2017, and an EIGA Technical Bulletin published in March 2021 summarised key requirements for home care service providers.[7] Yet clearly there remain outstanding questions about these definitions and responsibilities. This speaks to the need for a standardised interpretation of Medical Device Regulation specifically in relation to home oxygen installations, leading to clear guidance on reporting requirements and mechanisms.

If an incident results in a fatality or serious injury, and a medical device was involved, that incident should be captured through vigilance reports or trend reports according to Articles 87 and 88 of the MDR.

What is a reportable incident?

As well as greater clarity around the process of reporting home oxygen fires, a better understanding of when an incident should be reported would benefit all those involved in supporting patients on home oxygen. Anecdotal reports suggest that a patient who experiences a minor fire or injury that does not require hospitalisation will not report the incident to their provider or clinician, sometimes through fear of having their equipment removed.

Meanwhile, the fact that more serious incidents appear not to have been reported, suggests that other stakeholders, including fire and emergency services, family doctors, specialist clinicians, and social services, may be unaware of what types of incident should be reported and to whom.



** Estimates*

*** Estimated patient population in 16 EU countries covered by the European Industrial Gases Association (EIGA) member survey. EIGA estimates that there were 2 million patients over the course of its 5 year survey.*

**** In a survey of its members, EIGA found 15 fatalities resulting from home oxygen-related fires in 16 countries in the EU between 2013 and 2017. TB/36-20, Analysis of Fire Incidents in Homecare Oxygen Therapy Based on Data Review and Literature (July 2020)*

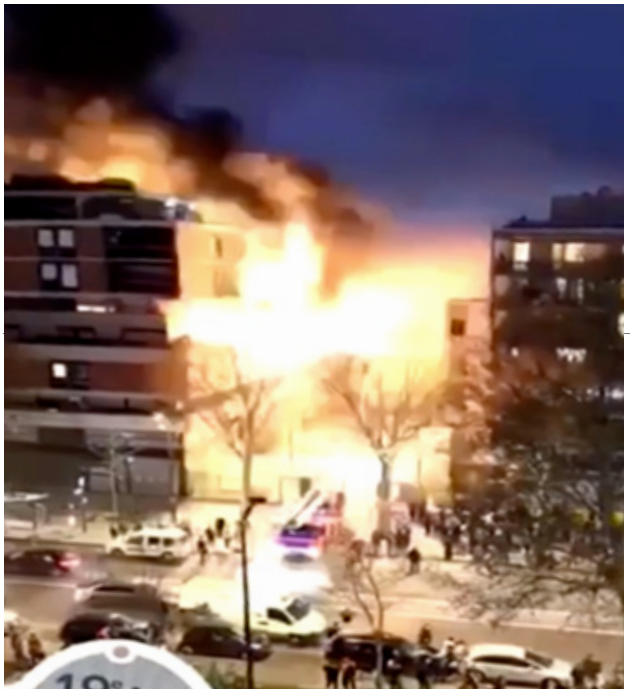
Understanding the scale of the problem

Preventing home oxygen fires begins with understanding their prevalence. Data on the number of residential fires involving home oxygen are not routinely recorded in all European countries, and central reporting is extremely challenging.[4]

In response to the issue, the European Industrial Gases Association (EIGA) conducted a survey among its members and found that between 2013 and 2017, there were 15 fatalities resulting from home oxygen-related fires in 16 countries in the EU.[9] This equates to around 0.75 fatalities per 100,000 HOT patients, based on estimates of patients receiving home oxygen therapy services from EIGA members. However, data collated elsewhere often suggest much higher fatality rates. For example, home oxygen fires are thought to cause 3.3 deaths per 100,000 HOT patients in Japan,10 and at least 6.6 deaths per 100,000 patients in the US.[11] It seems unlikely that the number of fatalities would be significantly lower in European countries, where safety measures are not widely adopted and informal reports from stakeholders in different countries suggest some incidents are not being captured. In addition, the EIGA Bulletin did not include data on the number of home oxygen fires and the number of serious injuries caused – both essential data points for appropriate risk management.

An absence of reports does not mean there is an absence of incidents. To test the hypothesis that many home oxygen fire-related incidents are not being captured by the vigilance system, BPR Medical undertook its own analysis. Using a similar methodology to that used in our recent US study,[12] we found that, in contrast to arguments put forward by some in the sector, home oxygen fires present a significant public health challenge in France and Italy.

In this report, we aim to shed light on the problem of under-reporting, so that industry and regulators can take the action needed to reduce the impact of home oxygen fires. We provide evidence that home oxygen fires in France and Italy are much more prevalent than previously thought. We raise several specific questions for regulators to consider when it comes to the issue of fire safety for home oxygen users.



A smartphone captures the moment an explosion rips through a residential apartment in the 19th arrondissment in Paris in April 2019. Home oxygen cylinders are thought to have caused the fire.

Recognising the problem: Prevalence of home oxygen fires in France and Italy

To gauge whether a gap between reported and actual numbers of incidents exists, BPR Medical is conducting an ongoing research project to identify, analyse and record media reports of home oxygen fires in Italy and France. Reports are identified using Google Alerts, as well as active online searches, and are assessed by native Italian and French speakers. This report covers a period of five years between January 2017 and December 2021. Incidents are included if a fire occurred and home oxygen was present. We recognise that this method of data collection has limitations; the number of incidents may well be greater than that reported and, while many reports state that cigarette use may have started the fire, we cannot be sure of the causal factors in every case.

It is likely that the number of incidents will vary in other European countries, depending on local fire safety practices. However, without clarity around formal reporting processes, this exercise helps to demonstrate that there is a significant difference between the industry's current assessment of the number of incidents and the likely number of home oxygen-related fires.

Reported incidents, deaths and serious injuries: what has been reported?

According to EIGA, 15 fatalities resulting from home oxygen-related fires were recorded across 16 countries in the EU between 2013 and 2017.[9]

BPR Medical contacted the National Agency for the Safety of Medicines and Health Products in France (ANSM) and the Italian Ministry of Health to see what official data were available as a comparison, but neither provided current figures on the number of serious incidents or fatalities arising from home oxygen-related fires. The Italian authorities did confirm that all incidents where there has been a trigger or a fire involving oxygen-containing devices are to be considered "serious accidents" based on the definition provided by the European regulation.

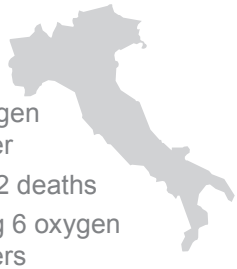
This raises the question of whether the incidents we found have been captured under the Medical Device Vigilance System.

Media reports of incidents, deaths and serious injuries

In France, between January 2017 and December 2021, the media reported:

- 15 fatalities, including 13 home oxygen users and 2 residents
- 10 serious injuries, including 6 oxygen users, 2 firefighters and 2 residents

In Italy, between January 2017 and October 2021, the media reported:



- 8 fatalities including 7 oxygen users and 1 family member
- 1 incident that resulted in 2 deaths
- 8 serious injuries including 6 oxygen users and 2 family members

Is there a gap between reports and reality?

There is a clear difference between the incidence figures used by many in the industry and what seems to be the real-world incidence rate. EIGA's review found 15 fatalities in 16 countries over a five-year period, while the analysis of media reports found the same number in France alone over a similar timeframe. There may be good reasons for some variation in the figures, but these data suggest that EIGA's analysis has not picked up on the true scale of the problem of home oxygen fires in Europe.

While these may not be huge numbers, any death that could have been avoided is one too many. France and Italy account for around one fifth of the EU's population, so if similar trends are found in the rest of the EU (noting that additional risk control measures are used in some countries), the number of fatalities could be five times higher than the numbers listed here. If there are solutions to prevent these patients and their families from being seriously affected by home oxygen fires in future, the MDR requires medical device manufacturers to act.

There is therefore an urgent need for stakeholders to consider the following questions on how best to achieve consistent and accurate reporting.

> "Seven years ago my article raising awareness of the danger posed by home oxygen fires was published in the hope it would guarantee the future protection of all patients. In light of this, I am surprised to find the close surveillance of home oxygen domestic fires and subsequent safety measures have not been widely implemented across Europe. The UK remains ahead of other countries when it comes to patient safety and home oxygen, using a range of measures – including fire-breaks – to drive down the rate of fatalities and serious burns. Hopefully this initiative will help to achieve the safety levels our patients on home oxygen across Europe deserve.
>
> ***Dr Brendan Cooper,*** *Respiratory Physiologist and President of the Academy for Healthcare Science*

Part 1: Questions

1. What measures can be taken by Competent Authorities to ensure that 'serious incidents' are recorded in line with the vigilance procedures set out in the MDR?
2. How can home oxygen service providers and healthcare stakeholders work together to ensure that all incidents are recorded and reported to the relevant economic operator(s) via the Medical Device Vigilance System?
3. What guidance can be provided to standardise the requirement to report serious incidents to Competent Authorities across EU member states?
4. What clarity can be provided on who the manufacturer is in the case of a home oxygen system and who is responsible for investigating the cause of incidents?

Part 2:
Reducing the risk: cooperation, risk assessment and engineering solutions

Once the scale of the problem is known, the home oxygen industry can work together to develop and implement effective solutions, built around a consistent multidisciplinary approach. As well as mandatory incident reporting, a culture of stakeholder cooperation is needed, together with a strong risk assessment process and the use of low-cost risk control measures, such as patient education, smoke alarms and engineering solutions to prevent fire spreading.

In 2021, BPR Medical published a white paper that showed how a holistic approach to fire safety, including collaboration, risk assessment and the use of engineered solutions, could improve patient safety in the event of a home oxygen fire. That report showed that while firebreaks do not eliminate the risk of fire, they could potentially reduce the death rate from home oxygen fires in the US from 100-150 per year to just 5 per year.[12] It also showed that the risk of death in a home oxygen fire is far lower in other countries where they are installed.[13]

Differences in national and local fire safety practices also influence the scale and impact of a home oxygen fire, such as the use of home inspections, fitting of smoke alarms, patient education, coordinated safety reporting, and the type of home.

While these structural mechanisms can be difficult to change, firebreaks are a relatively straightforward way to make home oxygen therapy safer for patients. But their use in Europe is mixed. They have been mandatory in England and Wales since 2006, and in Germany since 2012. Other countries, including France and Italy, tend to install them for high-risk patients only. Uptake in Spain and Portugal has been very strong, but adoption is slow in much of the rest of Europe. EIGA considers patient education a more effective approach to home oxygen safety. However, its own reports point to incidents where patient education has clearly failed.[14]

The experience elsewhere in Europe

In the UK, reporting of adverse events is routinely carried out through the National Health Service. In England there are 20 times fewer fatalities per 100,000 patients compared to the US, and 10 times fewer fatalities than in Japan.[11] This low level of fatalities is likely due to the combined effect of coordinated risk assessments by fire safety officers, and a multidisciplinary approach to patient education involving fire safety and health professionals, and mandatory firebreak use.[15] Of course, reliable comparisons can only be made where there is robust reporting.

> “Up until 2006, the frequency of fires in patients’ homes was unacceptable. At that point, the UK government took proactive steps to improve safety utilising a national change in contracts in the NHS. A clear reporting process and a multidisciplinary approach – including local fire authorities, who were informed about all new installations – along with the introduction of firebreaks – has led to a drop in reported serious incidents to the point where they have become a very rare event indeed.
>
> ***Dr Declan Weldon,*** *former General Manager for UK and Ireland Healthcare, Air Products*

Is fire risk a 'user problem'?

For many installers, the key to reducing fire risk is patient education. Why don't home oxygen users simply stop smoking? Nicotine is highly addictive. Giving up is easier said than done though, especially when cigarettes are one of the few small pleasures left in life for patients with chronic illness.

Supporting patients to give up smoking and educating them on the dangers of smoking while using home oxygen therapy are essential pieces of the fire safety puzzle. However human beings are notoriously bad at assessing risk. When oxygen is a colourless, odourless gas that is already in the air we breathe, it is potentially difficult to imagine the danger and there is often a built tendency to think "that won't happen to me". When coupled with the cognitive impairment caused by oxygen deprivation16 and the increasing prevalence of dementia, the effectiveness of patient education diminishes even further. The fact that so many patients continue to smoke and there is still a high number of home oxygen fires indicates that these risk controls are insufficient on their own.

Estimates suggest that 52% of patients continue to smoke while using HOT.[2] Many patients worry about confessing to continuing to smoke, so this number may well be higher. Research shows discrepancies between the number of patients who say they continue to smoke, and the number of home oxygen fires involving cigarettes. For example, 89% of US veterans who experienced flash burns while using HOT said they had given up smoking, yet 92% of those fires occurred because of smoking.[17]

Given that so many patients appear to continue smoking, the risk of flash burns remains high. Other fire safety measures should therefore be considered in conjunction with patient education to ensure home oxygen users who smoke do not pose a risk to themselves and others.

What do the regulations say about firebreaks?

European regulations require that all home oxygen installations with an oxygen concentrator must be fitted with means to reduce the extent of the propagation of fire if ignition occurs. EN ISO 80601-2-69:2020 provides that:

i. The accessories (nasal cannula and tubing or mask and tubing) shall be provided with a means to extinguish a tubing fire and isolate the oxygen flow. This should be fitted close to the patient.

ii. A means to prevent propagation of fire into the oxygen concentrator outlet shall be provided. The means can also stop the flow of oxygen, but it doesn't have to. If a bubble humidifier is fitted to the concentrator, the means must protect the bubble humidifier too.

To comply with the first of these requirements, manufacturers of oxygen concentrators placed on the European single market include the instruction for use that a means to reduce the risk of fire propagation 'shall' be fitted close to the patient.

The MDR requires that distributors of medical devices must use equipment in accordance with manufacturers' instructions.

Some consider that fitting firebreaks only applies to oxygen concentrators. While the MDR does not refer to them specifically, it does require that medical devices 'reduce risk as far as possible' in line with the 'state of the art'. In the case of home oxygen devices, firebreaks are the 'state of the art', as required under EN ISO 80601-2-69:2020. Not fitting them to the installation tubing on other home oxygen modalities to stem the flow of oxygen in the event of a fire could never be considered as 'reducing risk as far as possible'.

Given the inconsistency in interpretation, it would be helpful for the European authorities to clarify the meaning of the regulations and provide clear guidance.

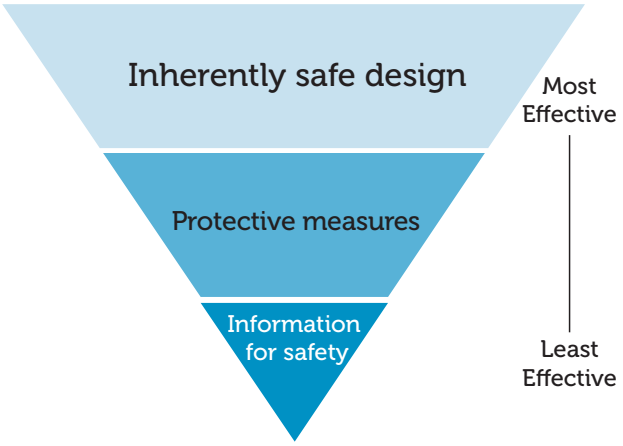
Part 2: Questions

1. How can the Medical Devices Coordination Group clarify the requirements around the use of firebreaks in all oxygen modalities to enhance safety for all patients, not just those using concentrators?
2. What can be done to ensure that the risk control measures in the ISO standard are introduced uniformly across all countries?
3. How can common interpretation of the ISO be reached on the use of a 'means to reduce the risk of fire propagation as far as possible' in other modalities as well as concentrators?

An engineered solution

A hierarchy of controls is often used to assess the effectiveness of different risk management strategies. If this framework were adapted to mitigate the risk of home oxygen fires, patient education would sit some way towards the 'least effective' end of the scale, since it does very little to protect the patient from the hazard. The most effective way to protect home oxygen users would be to eliminate the risk altogether. That's not possible since patients need access to oxygen. However, it is possible to create a barrier between the patient and the risk, in the of form a protective measure.

Risk Control Hierarchy



Source – ISO 14971 – Risk management of medical devices

Germany 2007: a lesson in safety reporting and reform

In 2007, German media drew attention to the fact that 47 patients had undergone total knee arthroplasties, after incorrect use of femoral implants resulted in patient suffering and the need for revision surgery. The case highlighted the problem of existing vigilance systems requiring international and local regulatory stakeholders to coordinate on patient safety. Despite an industry representative from the US manufacturer being present in the hospital, the erroneous surgery using the wrong implant was not reported and therefore was allowed to be repeated.

Given how many patients suffered before the error was spotted or reported, calls were made for a more robust early warning vigilance system. The German Arthroplasty Registry was formed in 2010 to coordinate the collection of data and accurate reporting among industry, clinicians and insurance companies. Similar systems in Sweden and Norway had already led to a halving of surgical revision as well as the early detection of manufacturing faults. The case is particularly relevant for the home oxygen industry as it shows that pre-existing but imperfect vigilance systems can provide 'false reassurance', which compromises patient safety and overlooks the root cause of repeated mistakes.[18]

Conclusion

The medical device industry prides itself on having an evidence-based approach to risk management and we welcome EIGA's determination to identify the scale of the issue of home oxygen fires. But if the system does not capture sufficient evidence – after all, a core intention of the MDR is to ensure a 'high level of safety and health' – we will fail to see problems that could be endangering users, their families, and others and miss the opportunity to improve safety.

Available data, though incomplete, suggest that home oxygen fires are a material public health issue in France and Italy, and perhaps elsewhere in Europe where risk control measures are not adopted. Clarity over reporting requirements and better incident data are needed to understand and acknowledge the true scale of the problem.

Meanwhile clear requirements on when safety control measures should be fitted – and to which oxygen modalities – is also required. Only then can the industry identify and develop innovative solutions to improve patient safety for home oxygen fire users.

BPR Medical would welcome contact from any organisation that could help to improve the body of knowledge on home oxygen fires, with the aim of increasing awareness and transparency of this problem.

Further Information

If you require clarification on any point in this White Paper, please contact info@bprmedical.com

BPR Medical

BPR Medical is the world's leading supplier of oxygen firebreaks in medical applications. The team specialises in developing successful long-term partnerships with some of the leading medical gas companies and currently exports to 50 different countries. BPR Medical has developed an enviable reputation by delivering on quality at all levels in the business in line with its Zero Defects goal.

Disclaimer

BPR Medical makes no claim as to the legal or regulatory accuracy of the statements in this report and the reader should not rely on anything contained within it when making commercial or other decisions in relation to its operational policies. BPR Medical strongly recommends that independent legal and regulatory advice is obtained before taking any action.

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Appendix 1:
Study Method

The study is based upon responses from a Google Alert query using the keywords “oxygen” and “fire” through the period between January 2017 and December 2021 (60 months). Google Alerts is a content change detection and notification service. The service sends an email to the user when it finds new results—such as web pages, newspaper articles, blogs, or scientific research—that match the user’s search terms.

Each link provided within a daily Google Alerts email was assessed to determine whether it was likely to relate to an oxygen fire. Likely home oxygen fire media reports were visited by following the link provided by Google. If the story was an oxygen fire, then the details were added to a database, recording the relevant information. Where there was ambiguity around the cause of the fire or it was reported as unknown, even though oxygen may have been present, the incident was removed from the records. A PDF was taken of the web site screen and attached to the database to provide enduring evidence, in case the link was subsequently moved or removed by the website owner.

There is little data available as to the coverage and effectiveness of the Google Alerts service. It was effective in uncovering 20 incidents, but it is not known how many media reports it did not find. Many of the incidents had multiple media reports from more than one news agency. The database provides fields for recording the following: geography (city, region); incident date; link to original news story; ignition source; number of cylinders stored; whether cylinders exploded; property (type, degree of damage, neighbouring buildings damaged); if assisted evacuation was needed; were there any injuries; was a working smoke alarm fitted; the number of people displaced; summary of news report. Some of the fields included drop-down choices with associated criteria to improve consistency of judgement.

The study is ongoing, and data continues to be added to the database, with a view to providing reports to the relevant Competent Authorities.

APPENDIX 2:

Appendix 2:
Breakdown of media reports of incidents, fatalities and deaths

Incidents reported in Italy between January 2017 and December 2021

Reported Incidents	Home Oxygen User		Family member / resident / firefighter	
	Fatality	Serious injury	Fatality	Serious injury
1		1		
2	1			1
3	1			
4	1			
5				
6		1		
7		minor		
8				
9		1		1
10		1		
11		1		
12	1			
13		1		
14	1		1	
15	1			
16	1			
Total	7	6	1	2

Incidents reported in France between January 2017 and December 2021

Reported Incidents	Home Oxygen User		Family member / resident / firefighter	
	Fatality	Serious injury	Fatality	Serious injury
1		1		2 (firefighters)
2				
3	1			2 minor
4		minor		2 minor
5		minor		
6	1			
7		minor		
8	1			
9	1			
10	1			
11	1			
12		1		
13	1			
14		1	1	
15	1			
16		minor		
17		minor		
18	1			minor
19	1			2
20		1		minor
21		1		
22	1			2 minor
23		1		
24	1			
25	1			
26			1	
Total	13	6	2	4