HSIB

HEALTHCARE SAFETY INVESTIGATION BRANCH

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SUMMARY REPORT

DESIGN AND SAFE USE OF PORTABLE OXYGEN SYSTEMS

I2017/013

Independent report by the
Healthcare Safety Investigation Branch

November 2018 Edition


HSIB
HEALTHCARE SAFETY
INVESTIGATION BRANCH

PROVIDING FEEDBACK AND COMMENT ON HSIB REPORTS

At HSIB we welcome feedback on our investigation reports. The best way to share your views and comments is to email **enquiries@hsib.org.uk**

When we receive your feedback, we will share it with the most appropriate person to provide a response and you can expect to be contacted within five working days.

The decision to conduct a national investigation is based on specific criteria. More detail about this criteria can be found on our website **www.hsib.org.uk**

All information provided to HSIB is collated and may provide inform other investigations.

Thank you for taking the time to read this investigation report and we look forward to receiving your feedback and comments.

ABOUT HSIB

The Healthcare Safety Investigation Branch (HSIB) began operating on 1 April 2017. The HSIB offers an independent service for England, guiding and supporting NHS organisations on investigations and conducting independent safety investigations.

HSIB aims to improve patient safety through effective and independent investigations that do not apportion blame or liability. This is delivered through:

- Learning for improvement – by using findings to deliver practical solutions, address contributory factors and provide support to increase the capability within local NHS systems.
- Diffusing learning – through effective communications and engagement with the wider health and social care system.

HSIB's investigations are conducted by a team of professional investigators from a range of safety-critical backgrounds, including the NHS, transport and the military. The HSIB also draws on additional expertise when required, including Human Factors advisors.

HSIB investigates up to 30 safety incidents each year to provide meaningful safety recommendations and share learning across the whole of the healthcare system for the benefits of everyone who is cared for by it and works in it.

HSIB works with patients and their families and carers, healthcare staff, Trusts, hospitals and other healthcare providers across England.

HOW HSIB DECIDES WHAT TO INVESTIGATE

Safety risks for potential investigations can be shared by individuals, groups or organisations. The decision to start an investigation could relate to a single event, a series of events or a risk discovered through current, ongoing investigations.

An HSIB investigation does not replace the local investigation of a patient safety incident. Instead, the aim is to identify national learning from these events to consider the wider systems and processes involved.

The following three criteria are used to determine whether the HSIB will commence an investigation:

OUTCOME IMPACT

Assessing the impact, or potential impact, on people is a crucial part of the process. It helps identify the most serious risks as these usually involve significant physical and emotional harm.

HSIB also considers the impact on services, and whether the safety risk(s) have, for example, reduced the ability to deliver safe and reliable care. In addition, the HSIB also looks at whether an incident has caused a loss of confidence in the healthcare system.

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SYSTEMIC RISK

The systemic risk is reviewed; that is, how common or widespread is the risk? Does it occur in different areas of healthcare and/or across multiple sites?

LEARNING POTENTIAL

HSIB will consider whether an investigation has the potential to reduce risk through meaningful, influential and effective safety recommendations.

INVESTIGATION APPROACH

Investigations conducted by the HSIB do not attribute blame or liability; their purpose is to provide lessons for future safety and identify wider opportunities for systemic learning.

Although funded by the Department of Health and hosted by NHS Improvement, the HSIB is operationally independent. The HSIB is also independent from regulatory bodies like the Care Quality Commission (CQC).

HSIB's independent status ensures that its investigations are not conducted on behalf of the families, staff, organisations or regulators. Following an investigation, Safety Recommendations, Safety Observations and Safety Actions taken may be identified.

Safety Recommendations are directed to a specific individual or organisation for action. They are based on information derived from the investigation or other sources such as safety studies, and are made with the intention of preventing future, similar events.

Safety Observations are made for wider learning within the NHS and may be directed to a specific individual or organisation for consideration. They are made when there is insufficient or incomplete information on which to make a definite recommendation for action, but where findings are deemed to warrant attention.

Safety Actions are actions taken during the investigation as a response to the issue under investigation.

A NOTE OF ACKNOWLEDGMENT

HSIB recognises the possible anguish an investigation can bring to those families affected and although we always welcome family involvement, we understand the importance of this being a choice. At the time of publication, the family of the patient referred to in this report have not taken up our invitation to talk to us about this investigation; we would welcome a request to meet with them at any time in the future.

EXECUTIVE SUMMARY

The reference event

An 83-year-old man was admitted to hospital via the Emergency Department. He complained of feeling unwell for the previous few weeks, decreased appetite, vomiting after eating, loose stools and abdominal discomfort. A medical history of type 2 diabetes, rheumatoid arthritis, hypertension (high blood pressure) and high cholesterol were recorded.

The following day the patient was transferred to the Acute Medical Unit with a diagnosis of hyperglycaemia (high blood sugar) and acute kidney injury; he was later transferred to a diabetes and endocrinology ward.

Eleven days after being admitted, the patient had recovered enough for a discharge plan to be made to allow him to return home. However, on day 12 his clinical condition unexpectedly began to deteriorate, and this progressed to the extent that over the course of a few hours he became unresponsive.

A nurse began cardiopulmonary resuscitation (CPR) and a resuscitation trolley was brought to the bedside by a care support worker. The resuscitation team arrived, and the patient's breathing was supported using a bag-valve-mask, with a reservoir bag attached, connected to a portable oxygen supply with a standard valve.

After approximately 10 minutes of CPR, it was recognised that the reservoir bag was not inflating between breaths, which was interpreted by the resuscitation team as an indication that the patient was not receiving supplementary oxygen. The resuscitation team concluded that the oxygen cylinder was empty, so the cylinder was replaced, and the oxygen supply checked as being delivered to the patient. Despite further CPR, the patient remained unresponsive and CPR was eventually stopped. The patient subsequently died.

The following morning the medical gases porter arrived on the ward to replace the cylinder that was thought to be empty. Upon examination, the cylinder was found to be full.

The wider investigation

The Trust informed the HSIB about the incident for consideration as a national investigation. After gathering additional information about the reference event and assessing the incident against the HSIB's investigation criteria, the decision was made to progress to a national investigation.

The national investigation focused on:

- reviewing how the design of portable oxygen systems is regulated by the Medicines and Healthcare products Regulatory Agency (MHRA)
- reviewing the design of portable oxygen systems used in other industries to determine if there are appropriate lessons for healthcare

Findings

- Portable oxygen systems currently used across the NHS in England do not provide clear and timely feedback that oxygen is flowing to the patient.
- There are various design issues with current portable oxygen systems that may lead users to interpret that oxygen is flowing when it is not.
- It is unclear how the MHRA's Human Factors guidance document, published in 2017 (MHRA, 2017), is used in practice.
- Devices that contain a medicinal product (such as portable oxygen systems and pre-filled syringes) are regulated as medicines as defined in Article 1 (European Parliament, 2001), and not as medical devices.
- Evidence suggests that design changes, such as updating labelling and instructions for use, are most likely to be made following post-market incident investigations. These are weak solutions for preventing error but can be used to address an issue while long-term solutions are being sought.
- Products used in other industries might improve patient safety and the delivery of portable oxygen but are yet to be tested and implemented.
- Traditional NHS procurement processes thoroughly evaluate the utility and financial feasibility of products to be purchased. There is potential to reduce errors and improve effectiveness and user satisfaction if Human Factors evaluation methods are incorporated into procurement methodology.

SAFETY RECOMMENDATIONS

Safety Recommendations are directed to a specific organisation for action. They are based on information derived from the investigation or other sources, such as safety studies, and are made with the intention of preventing future, similar events.

The HSIB investigation focused on the design and regulation of portable oxygen systems. The responsibility for ensuring the design of portable oxygen equipment is appropriate rests with the MHRA. Accordingly, recommendations made in this report are directed towards that organisation. Future HSIB investigations will look in detail at different parts of the healthcare system that can also help to address the risks highlighted in this investigation.

HSIB MAKES THE FOLLOWING SAFETY RECOMMENDATIONS

Recommendation 2018/021:
It is recommended that the Medicines and Healthcare products Regulatory Agency evaluate how its Human Factors guidance document is used in practice by manufacturers and by Notified Bodies. Based on the review, the MHRA should make any changes necessary to the document or use other mechanisms to improve the implementation of Human Factors in the pre-market approval process.

Recommendation 2018/022:
It is recommended that the Medicines and Healthcare products Regulatory Agency require oxygen manufacturers to submit evidence of Human Factors summative testing of the complete product as part of the market authorisation process for medicinal licence.

Recommendation 2018/023:
It is recommended that the Medicines and Healthcare products Regulatory Agency review its documentation to determine whether more specific guidance is required on how to incorporate Human Factors into post-market adverse event investigations.

Recommendation 2018/024:
It is recommended that, when reviewing manufacturers' Field Safety Notifications, the Medicines and Healthcare products Regulatory Agency discourages the use of weak barriers as defined in ISO 14971 (Risk Management for Medical Devices) particularly as long-term solutions.

SAFETY OBSERVATIONS

Safety Observations are made for wider learning within the NHS. They are made when there is insufficient or incomplete information on which to make a definite recommendation for action, but where findings are deemed to warrant attention.

HSIB MAKES THE FOLLOWING SAFETY OBSERVATIONS

Observation 1:
Staff working within Notified Bodies should have relevant competencies to review Human Factors Engineering reports submitted during the pre-market approval process.

Observation 2:
It would be beneficial if the Medicines and Healthcare products Regulatory Agency initiates market surveillance activities based on a variety of intelligence, and not necessarily require a serious incident.

Observation 3:
It would be beneficial if the Medicines and Healthcare products Regulatory Agency reviews its processes regarding post-market surveillance of drug-combination products to ensure device design is considered.

Observation 4:
Flow indicators have the potential to improve patient safety and provide a clear visual cue that oxygen is flowing to a patient. It may be beneficial if further research, testing and evaluation is conducted to consider these products for use in a healthcare setting.

Observation 5:
Human Factors testing and evaluation criteria should be included as part of the selection methodology used in NHS procurement processes.

Observation 6: It may be beneficial if single action portable oxygen systems are considered as part of the tendering process within the healthcare market.

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FURTHER INFORMATION

More information about HSIB – including its team, investigations and history – is available at **www.hsib.org.uk**.

If you would like to request an investigation then please read our **guidance** before submitting a safety awareness form.

@hsib_org is our Twitter handle. We use this feed to raise awareness of our work and to direct followers to our publications, news and events.

CONTACT US

If you would like a response to a query or concern please contact us via email using **enquiries@hsib.org.uk**. We monitor this inbox during normal office hours - Monday to Fridays (not bank holidays) from 0900hrs to 1700hrs. We aim to respond to enquiries within five working days.

To access this document in a different format – including braille, large-print or easy-read – please contact **enquiries@hsib.org.uk**.