Annals of Agricultural and Environmental Medicine
www.aaem.pl

Medical gas management in healthcare – safety systems, legal liability, and 'Never Events' risk analysis

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Ćwik K. Medical gas management in healthcare – safety systems, legal liability, and 'Never Events' risk analysis. Ann Agric Environ Med. doi:10.26444/aaem/220372:

Abstract

Introduction and Objective. Medical gases are indispensable in contemporary healthcare. Their dual status as medicinal products and medical devices generates specific clinical, legal, and organizational risks. The aim of this review was to summarize current knowledge of medical gas management.

Materials and Method. A narrative review of literature was conducted retrieved from databases such as PubMed and Google Scholar using the key words, legal regulations and documented case reports of medical gas–related incidents. The 'Swiss cheese' model was applied as a conceptual framework for identifying systemic vulnerabilities.

Brief description of the state of knowledge. The literature indicates that severe medical gas incidents are predominantly caused by system-level failures rather than isolated human error.

Conclusions. Medical gas systems should be recognized as life-critical infrastructure requiring integrated risk management, and clearly defined interdisciplinary responsibilities.

Key words

patient safety, risk management, healthcare system, safety culture, legal responsibility, medical gases, healthcare facility manager, 'never events', Swiss cheese model

INTRODUCTION

The management of medical gases in healthcare is one of the most complex and yet underestimated areas of critical infrastructure management, where the line between effective treatment and an adverse event with potentially fatal consequences is extremely thin, yet the issue remains marginalised. It should be emphasised that the proper supervision of medical gases is directly related to patient safety [1]. Medical gas systems are used in almost all areas of the hospital and in such issues as surgery, trauma, heart failure, asthma, pneumonia and maternal and child care [2]. In everyday clinical practice, oxygen, nitrous oxide and medical air are treated as media that occur naturally in the therapeutic space, but their dual nature – as medicinal products and high-pressure technical media – generates unique challenges for the safety of patients and staff.

This analysis demonstrates that supervision in this area is systematically marginalised, which, under the current Polish legal provisions, leads to a dangerous asymmetry between the scope of actual knowledge and the burden of responsibility resting on the manager of the healthcare entity.

OBJECTIVE

The aim of the study is to examine medical gas management as one of the most complex and underappreciated areas of critical infrastructure management in healthcare, where the line between effective treatment and an adverse event with potentially fatal consequences is extremely thin. The study aims to demonstrate that oversight of this area is systematically marginalized, which in the current Polish legal model leads to a dangerous asymmetry between the scope of actual knowledge and the burden of responsibility resting with the manager of a healthcare facility.

MATERIALS AND METHOD

The review utilizes a qualitative and interpretive approach, integrating normative and legal analysis with insights drawn from practical experience in healthcare management and participant observation. The research material comprises a systematic review of three primary source categories: the legal and normative framework, including national Acts (such as the Pharmaceutical Law, Medical Devices Act, and Labour Code), European Union directives, and technical safety standards (notably ISO standards), as well as scientific literature and technical documentation which involved a review of medical, engineering, and management databases concerning patient safety and medical gas infrastructure. Clinical and operational data, including case studies of clinical incidents, actual failures, and accidents in medical facilities, were analyzed through the Root Cause Analysis (RCA) procedure and the High Reliability Organizations (HRO) framework.

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Received: 10.01.2026; accepted: 02.04.2026; first published: 20.04.2026

RESULTS

Medical gases as critical substances – from antiquity to the modern pharmacopoeia. Medical gases have long been known and widely used in medicine and for a wide range of medical applications. For many years, they were treated as ordinary technical products, and their marketing was not given much attention [3]. The most commonly used medical gases, not only in hospitals but also in home therapy, include medical oxygen, nitrous oxide, and compressed air. The early use of these gases for therapeutic purposes was both innovative and risk-laden. In the 19th century, Sir Humphry Davy experimented with nitrous oxide, known as laughing gas, initially used for entertainment it quickly gained recognition for its anaesthetic properties, paving the way for the development of anaesthetic gases.

In the same century, the therapeutic effects of oxygen were discovered, and its medical applications were intensively studied in the following decades. The history of oxygen, from its discovery to its clinical application in patients with chronic lung disease, has been a long journey one. Early researchers not only discovered oxygen, but also recognised the importance of oxygen for life and its role in respiration, yet it took several centuries for oxygen to be used in chronic lung disease [4]. Understanding the contemporary challenges associated with medical gases requires an analysis of their evolution from purely technical products to life-saving medicines.

The historical perspective of oxygen shows that this process lasted from ancient times to the 18th century. The concepts of Galen (born around 130 A.D.) and Erasistratus (born around 304 B.C.) formulated a "pneumatic" theory of respiration, followed by Ibn al-Nafis' discovery of pulmonary circulation in the 13th century, and finally the modern concepts of Servetus (1511–1553) and Mayow (1641–1679), which linked blood flow through the lungs to gas exchange and metabolic processes. The breakthrough came in the 18th century thanks to the experiments of Scheele (1742–1786) and Priestley (1733–1804), which led to the identification of oxygen as a gas essential for breathing and life. Analysing these results in the second half of the 18th century, Lavoisier (1743–1794) introduced the term "oxygen" and linked it directly to respiration and oxidation processes, which led to the refutation of the phlogiston theory and established the foundations of modern respiratory physiology, the pathophysiology of gas exchange and the clinical significance of oxygen in medicine [5].

Figure 1. Historical perspective of oxygen

Currently, medical oxygen is considered to be one of the most important medicines in the world, as evidenced by its inclusion on the WHO List of Essential Medicines for acutely ill patients and those with chronic diseases causing hypoxaemia [6]. In Polish law, the status of gases as medicinal products requires compliance with the rigours of the Pharmaceutical Law regarding the production, supervision of trade, and supervision of the safety of its use.

Medical gases are a special type of specialist gases, and working with them requires non-standard technical solutions, both with respect to transmission systems and handling of containers and steel cylinders. Compressed gas equipment (containers, fittings, automation), storage, equipment ensuring occupational safety, fire and explosion safety, types of personal protective equipment, and other related health and safety issues, are regulated by European Union directives, national legislation, standards, relevant instructions and regulations of institutions producing and using compressed gases [7].

The operation of medical gas cylinders and the medical gas pipeline system (SRGM) is governed by multiple legal frameworks: ranging from the Pharmaceutical Law [8], through the Medical Devices Act [9], the Technical Inspection Act [10], ISO standards (including 7396, 9170, 13348), to implementing regulations. All of this means that the topic of medical gases is often a point of contention between the technical department, the medical equipment department, and the pharmaceutical department [1].

Framework legal and normative regulations for the supervision of medical gases. Modern medicine makes extensive use of advanced technologies and specialised substances, among which medical gases occupy a position of strategic importance. From oxygen essential for sustaining vital functions and nitrous oxide used in anaesthesiology, to medical air and carbon dioxide in laparoscopic procedures. Nevertheless, despite their widespread use and fundamental in saving lives, the supervision of medical gases poses an extremely complex regulatory and operational challenge.

As has been pointed out, this problem stems from the dual nature of medical gases. On the one hand, according to the Pharmaceutical Law, they are treated as medicinal products. On the other hand, their delivery to the patient involves complex technical systems – from cylinders and tanks, through central piping systems, pressure regulators and dispensers, to end-use medical devices, such as masks and cannulas. These infrastructure elements are subject to regulations resulting from the Medical Devices Act, the Technical Supervision Act and numerous international standards, such as the ISO.

Moreover, in the context of occupational safety, the universal principles set out in the Labour Code [11] and in implementing regulations on occupational health and safety [12] are also crucial. They provide a framework for ensuring safe working conditions for personnel operating medical gases and their installations. The lack of a consistent and rigorous approach to the supervision of these substances and systems, however, can trigger disastrous consequences.

The Pharmaceutical Law is the key Act regulating the status of medical gases, which classifies oxygen, nitrous oxide, and medical air as medicinal products. This classification requires production which is in compliance with Good Manufacturing Practice (GMP) principles – including production standards, quality control, and appropriate infrastructure and staff. Trade is strictly regulated and limited to licensed entities and supervised by the Pharmaceutical Inspectorate. Marketing requires authorization from the President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products (URPLWMiPB), and once introduced, pharmacovigilance applies which obliges hospitals to monitor and report adverse reactions to the District Pharmaceutical Inspectorate (WIF). Storage conditions are regulated by implementing regulations.

The other regulatory pillar governing the use of medical gases is the Medical Devices Act, which covers the equipment used to administer them, even though the gases themselves remain medicinal products. Pipeline installations, cylinders, regulators, dispensers, concentrators, respirators and accessories are classified as medical devices and must meet essential safety and performance requirements, confirmed by CE marking – European Conformity *(Confirmité Européene).* Manufacturers are required to carry out conformity assessments, while hospitals are required to participate in medical product vigilance, including reports on medical incidents and failures to the President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products. These regulations are complemented by ISO standards, which constitute the technical backbone of medical gas installation safety. For example, the ISO 7396–1:2016 standard is fundamental for the design, installation, operation, and maintenance of medical gas pipeline systems (SRGM) in healthcare facilities.

Even the design and construction stages of technical installations have a direct impact on the quality of medical gases. For example, compressed air must meet the current requirements of the European Pharmacopoeia and the PN-ISO 8573–1 standard. During final acceptance of the installation, it is necessary to conduct not only pressure tests but also system validation. Confirmation that the installation was completed in compliance with the technical documentation is provided by IQ (Installation Qualification) and OQ (Operational Qualification) qualifications, which confirm that the system operates according to its functional assumptions and achieves the required parameters.

The Technical Inspection Act is also a crucial element of the legal framework. The provisions of this Act apply to the pressure equipment, including tanks and cylinders for medical gases and certain components of central gas installations. The Office of Technical Inspection (UDT) supervises them, requiring regular technical inspections, which include checking the technical condition, tightness and operational safety. The employer's obligations under the Labour Code and occupational health and safety regulations are crucial for the supervision of medical gases in a hospital. According to Article 207 of the Labour Code, the employer is obligated to ensure safe working conditions, which includes identifying and minimizing hazards associated with the storage, transport, and use of medical gases. Their responsibilities include maintaining the technical efficiency of installations and equipment, providing personal protective equipment, and implementing occupational health and safety training, including on-the-job training (Article 237^3 of the Labour Code). Occupational risk assessment (Article 226 of the Labour Code) and informing employees about hazards are also essential. In the event of an occupational accident (Article 234 of the Labour Code), the employer implements post-accident procedures, including securing the scene, preparing documentation, and – in serious or fatal cases – notifying the appropriate authorities.

In the circumstances described, the supervision of medical gases in a hospital is a multi-level and interdisciplinary process, requiring close cooperation between various departments and specialists (Technical Department, Medical Equipment Department, Pharmacy Department or Hospital Pharmacy) [1].

Risk management, pathophysiology of errors and 'Never Events'. The main paradigm of risk management in the field of medical gases is prevention of 'Never Events', critical errors that should never occur in a safe healthcare system. A review and analysis of the literature has shown that the most serious of these is gas mix-up, technically referred to as *cross-connection*.

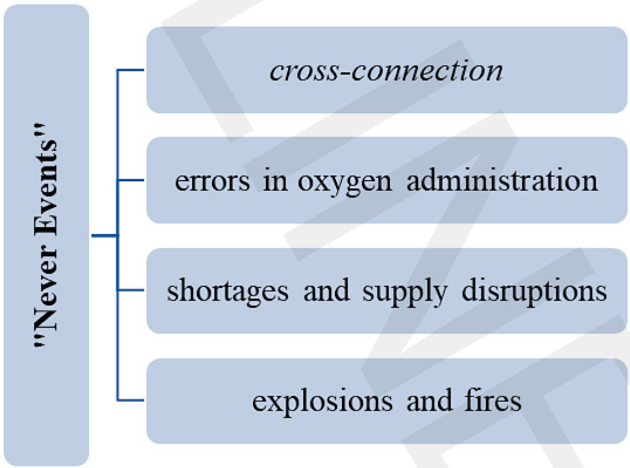

Figure 2. Classification of 'Never Events'

Table 1 provides a description and classification of adverse events and 'Never Events' in the field of medical gases, and emphasizes the causal links between failures and clinical outcomes.

Based on the classification presented in Table 1, the following section provides an analysis of specific clinical cases that illustrate the mechanisms behind 'Never Events' and their direct impact on patient safety.

The most dramatic 'Never Events' in the medical gas industry involve incorrect connections of pipelines and gas

Table 1. Classification of adverse events and 'Never Events' in the field of medical gases

Category of event	Definition/description	Potential cause	Clinical consequences
cross-connection	Incorrect connection of pipelines or collection points, resulting in the administration of a gas other than oxygen to the patient (e.g., N_2O instead of O_2)	Engineering errors during modernization or maintenance work, lack of validation procedures (IQ/OQ), bypass of Pin Index Safety Systems (PISS) interference by external entities.	Direct risk of death by suffocation, administration of hypoxic mixtures, fatal consequences during routine procedures.
Errors in oxygen administration	Administration of gas with incorrect parameters or concentrations that do not meet the patient's therapeutic needs.	Combination of human error, design and technical deficiencies, and insufficient operational supervision.	Oxygen toxicity (hyperoxia), occurrence of hypoxemia, permanent neurological damage, respiratory failure, failure to sustain vital functions in critically ill patients, interruption of mechanical ventilation, respiratory failure, potential for mass casualty incidents
Shortages and supply disruptions	Unplanned interruption of the medical gas pipeline system (SRGM) supply or exhaustion of cylinder reserves.	Lack of formal emergency procedures (SOP), inventory management errors, monitoring system failures.	Increased morbidity, mortality, and disability, sudden interruption of life-saving therapy.
Explosions and fires	Violent events resulting from the dual nature of medical gases as high-pressure technical media and oxidizers.	Improper operation of cylinders and tanks, lack of fire and explosion safety, technical failures of equipment.	Severe injuries, burns and disfigurement, and direct threat to the life and health of both patients and staff, estruction of medical infrastructure, massive financial and reputational loss

outlets due to engineering errors during modernization or maintenance work, which go undetected due to a lack of validation procedures. The case study described by Bohringer et al. provides dramatic evidence of the consequences of such negligence. The case described involves an 8-year-old boy who, after a routine neck ultrasound under sedation, experienced a sudden drop in saturation and heart rate after being connected to an 'oxygen' mask. The investigation revealed that a newly-hired, inadequately trained technician had cross-connected the nitrous oxide line to the oxygen port. The boy died as a result of the incident [13]. A similar mechanism was at the root of a case at Bankstown-Lidcombe Hospital in Sydney, Australia, in 2016, in which, due to an incorrectly installed gas system in the delivery room, newborn John Ghanem was given nitrous oxide instead of oxygen after birth. In this case, there was gross negligence on the part of the installation company, a lack of verification tests after modernisation, and incorrect labelling of the intake points [14]. Another infant, Amel Khan, suffered permanent injuries. The court ruled that the engineer's actions constituted gross professional negligence [15].

Another mechanism of error concerns both the incorrect selection of oxygen concentration, and administration of an anaerobic or hypoxic mixture to a patient requiring oxygen therapy. Kallet and Matthay describe the mechanisms of hyperoxic lung injury in mechanically ventilated patients. Excessive oxygen concentrations, resulting, among other things, from incorrect ventilator settings and a lack of awareness of O_2 toxicity, led to increased inflammation and structural damage to the alveoli, paradoxically worsening respiratory failure [16]. On the other hand, Ayuk and Nwosu presented a systemic analysis of deficiencies in access to oxygen therapy in Nigeria. The authors point out that each year millions of patients die due to improper management of oxygen resources. The main mistake is the lack of trained personnel capable of operating modern medical gas delivery systems [17]. Both types of errors – hyperoxia and actual hypoxia resulting from improper management of oxygen therapy – should be treated as critical systemic events requiring strict dosing protocols and continuous education of clinicians.

Oxygen supply interruptions constitute another type of 'Never Event', with a high potential for mass casualty. Mostert and Coetzee report an incident at Tygerberg Hospital in Parow, Western Cape, South Africa, where welding work near a leaking oxygen pipeline resulted in an explosion and fire, which interrupted the complete oxygen supply to the entire hospital for approximately eight hours. The staff were forced to manually ventilate numerous ICU patients [18]. In Poland, an incident at a temporary hospital in Poznań (2021) became a symbol of the tragic consequences of delayed logistics. Oxygen needed for critically ill patients ran out, necessitating the dramatic evacuation of 12 people and leading to the death of one patient. The prosecutor's office found out that the oxygen had been ordered too late.

A separate group of 'Never Events' result from the physicochemical properties of oxygen related to its role as a combustion accelerator. In 2021, Wood et al. analyze a fire in an Iraqi hospital where an explosion of oxygen cylinders in the intensive care unit killed 82 people. The cause was a combination of improper cylinder storage, system leaks, and the lack of modern detection and control systems for the oxygen atmosphere [19]. Stormont et al. note that approximately 600 fires occur annually in operating theatres in the United States. The typical 'explosive triad' includes high oxygen concentration, an ignition source (e.g., during electrocautery), and flammable materials, resulting in severe respiratory burns, disfigurement – and legal claims [20]. Explosions and injuries can also be purely mechanical in nature, not directly related to the combustion process. Chaljub et al. described a series of five incidents in MRI (Magnetic Resonance Imaging) rooms involving a gas cylinder, including severe craniofacial injuries inflicted on a 60-year-old patient struck by a cylinder that was suddenly drawn into the strong magnetic field. The key error was failure to adhere to the MRI safety zone rules and allowing an unqualified employee to operate the equipment [21].

An analysis of 'Never Events' related to medical gases shows that they are the result of a combination of human error, design and technical deficiencies, as well as insufficient operational supervision. The cases described, including pipeline explosions and fires, cross-connections and hypoxic mixtures, and supply interruptions, confirm that every element of the gas supply chain can become a single point of failure.

The incidents described, above, demonstrate that medical gas safety requires an integrated approach encompassing infrastructure, work procedures, safety culture, and interfaces with other technologies.

Anatomy of a systemic error – the 'Swiss Cheese Model' in medical engineering. Risk is an inherent part of healthcare and it cannot be completely eliminated, Process and causality are very important in operational risk management, as every disruption in an organisation has its causes and effects. One of the methods of building a safety system in the implementation of medical processes is risk assessment, analysis and management, which in healthcare entities should lead to the prevention of adverse events and medical errors [22]. With regard to medical gas infrastructure – including gas sources, piping systems, tapping points, monitoring devices and clinical users – these relationships are of particularly complex nature.

Organizational theories and explanations make relatively frequent use of metaphors. Metaphors allow one experience to be represented in terms of another, and the use of metaphors encourages the search for similarities between the object of study and the reference object [23]. Besides numerous well-known metaphorical theories, such as 'black swans' and the 'domino effect', one of the theoretical concepts used in safety management is the 'Swiss Cheese Model', proposed by James Reason in the 1990s. This is a widely recognized and influential model for understanding and managing complex systems and their associated risks. Reason himself believed that there are two approaches to the problem of human fallibility: the individual approach and systematic approach. Each approach has its own model of error causes and leads to completely different philosophies of error management. Understanding these differences has significant practical implications for coping with the ubiquitous risk of failure in clinical practice.

In medicine, the person-centred approach remains the dominant tradition, but it has serious disadvantages and is not suitable for medical practice. Effective risk management requires a reporting culture based on trust and a just culture, without which recurring error traps will not be detected [21].

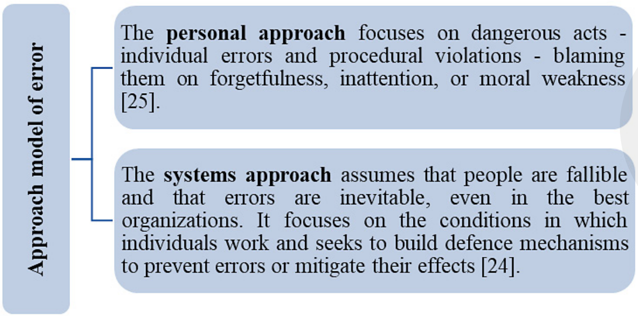

Figure 3. Approach model of error

This model assumes that the security system consists of multiple layers of protection, such as technical solutions, procedures, staff training, organisational supervision, and legal regulations. Each level in the model is often represented as a single layer or slice of cheese. However, each of these layers has potential gaps (holes in the cheese) resulting from active errors and hidden organisational conditions. An undesirable event occurs when gaps in successive layers of the system line up, providing a window of opportunity for an accident or event causing harm to the patient [23]. If the system was completely safe, there would be no holes in the cheese. The cheese would not be Swiss cheese, and the system would be represented by solid slices of cheese, such as cheddar or provolone [25, 26].

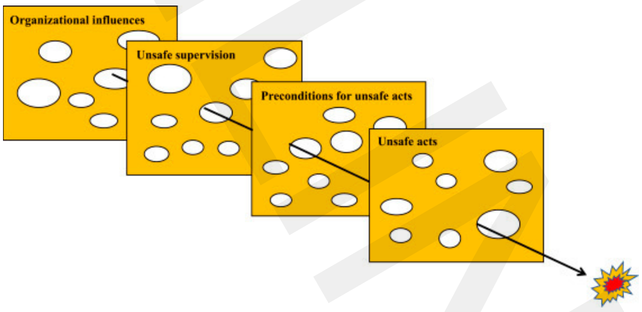

Figure 4. Reason's Swiss cheese model [27]

In 2018, the Organization for Economic Cooperation and Development (OECD) published a report entitled *The Economics of Patient Safety: Strengthening a Value-Based Approach to Reducing Patient Harm at National Level*. The report emphasized that harmful patient incidents during the provision of healthcare services – in addition to the burden of morbidity, mortality, and disability – also results in high financial costs for every healthcare system [22]. The analyses conducted show that systemic risk is exacerbated by department modernizations, which involve interference with SRGM by external entities. Research shows that errors most often occur "behind the wall", in the areas invisible to medical personnel, creating a false sense of security. Furthermore, in the event of an incident, the manager of the healthcare facility, after securing patients, is required to initiate a root cause analysis (RCA). According to the safety guidelines, the incident must be reported to the President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products (URPLWMiPB) as a serious medical incident. The lack of a formal emergency procedure (SOP) and the lack of clarity regarding roles in the supervision of maintenance work are interpreted by the courts as organizational errors by the hospital.

Liability and legal implications. In the legal analysis of an incident or accident involving medical gases in a hospital, it is crucial to identify three potential sources of liability: the manufacturer, the employee and the employer. Each of these sources carries different types of consequences, which may overlap and accumulate, leading to complex legal, financial and reputational consequences. In legal practice, incidents and accidents often result from a combination of causes, leading to an analysis of the responsibility of all three parties. Blame and consequences can be allocated to varying degrees, depending on the specific findings of the investigation and legal proceedings. Analysing an incident or accident involving medical gases requires a detailed investigation to determine the causes and assign blame. It may be that a product defect (manufacturer), an employee's procedural error, and the employer's negligence, all contribute to the incident. In such cases, each party bears the consequences within their own scope of responsibility.

The multifaceted nature of liability in medical gas management, encompassing the manufacturer, the employee, and the employer, is systematized and compared in Table 2, highlighting the distinct legal frameworks and potential sanctions applicable to each entity.

The manufacturer's liability covers defects in medical gas as a medicinal product or medical device that led to the incident. Pursuant to Article 449[1] *et seq.* of the Civil Code [28], the manufacturer is liable for damages on a strict liability basis for a dangerous product, regardless of fault, covering both actual damage *(damnum emergens)* and lost profits *(lucrum cessans).* The result is an obligation to pay compensation and damages for non-material harm. In addition, administrative consequences are possible, including withdrawal of the product from the market, suspension of distribution or financial penalties imposed by supervisory authorities (URPLWMiPB, GIF). In situations posing a direct threat to

Table 2. Manufacturer's, Employees', Employer's liability

Comparison Criteria	Manufacturer's Liability	Employees' Liability	Employer's Liability (Healthcare Manager)
Legal basis	Medical Devices Act, Pharmaceutical Law, Civil Code, Penal Code	Labour Code, Penal Code	Labour Code, Civil Code, Penal Code
Type of liability	Product liability, Contractual, Administrative	Disciplinary, Material, Criminal	Organizational, Civil (tort), Criminal
Key violations	Product defects, Non-conformity with ISO standards, Lack of CE marking	Procedural errors, Non-compliance with OHS/BHP instructions	'Behind the wall' errors, Lack of SOPs, Supervisory negligence
Sanctions & Consequences	Financial compensation, Market withdrawal, Administrative fines	Disciplinary dismissal, Professional suspension, Criminal record	Criminal liability, Civil compensation, Reputational loss
Sector-specific focus	GMP/GDP standards, Technical documentation	Proper operation of outlets and terminal units	'Infrastructure hostage', Liability for external contractors and Employees

the life or health of many people (Article 163 of the Penal Code) or the manufacture/marketing of substances harmful to health (Article 165 of the Penal Code), the manufacturer may also be subject to criminal liability [29], including fines and penalties of restriction or deprivation of liberty.

Employees' liability covers violations of occupational health and safety regulations, procedures, or instructions through an act or omission leading to an incident. Under the Labour Code (Article 108 of the Labour Code), an employer may impose disciplinary penalties, including warnings, reprimands, or fines. In the case of a serious violation of occupational health and safety regulations, the employer may terminate the employment agreement without notice due to the employee's fault (Article 52 § 1(1) of the Labour Code). The obligation to comply with occupational health and safety regulations is fundamental (Article 100 § 2(3) and Article 211 of the Labour Code). Employees are also financially liable for any damage caused (Articles 114–122 of the Labour Code), generally up to three months' salary, and in the event of any wilful misconduct, the full amount. Depending on the consequences of the incident and the degree of culpability, an employee may be held criminally liable, including for exposing another person to immediate danger of loss of life or serious bodily harm (Article 160 of the Penal Code), unintentionally causing serious bodily harm (Article 156 § 2 of the Penal Code), or unintentionally causing death (Article 155 of the Penal Code), as well as liability for creating a public threat (Article 163 of the Penal Code). Consequences include fines, restriction of liberty, and even imprisonment.

Employer's liability (as a healthcare provider and his/her managers) is the most complex and comprehensive, encompassing organizational and systemic negligence, lack of supervision, insufficient training, and failure to provide safe infrastructure. It stems from the general obligation to ensure safe and hygienic working conditions (Article 207 of the Labour Code) and other sector-specific regulations. Any failure to comply with the occupational health and safety obligations may result in a fine imposed by the National Labour Inspectorate (hereinafter: PIP) ranging from PLN 1,000 to PLN 30,000 (Article 283 of the Labour Code). Individuals responsible for occupational health and safety in a hospital (e.g., director, technical manager) who fail to fulfil their duties and expose employees to any risk of loss of life or serious bodily harm are subject to criminal liability (Article 220 of the Penal Code), which may result in imprisonment. Similarly, if the employer's negligence led to unintentional death (Article 155 of the Penal Code) or serious bodily harm (Article 156 § 2 of the Penal Code) of patients or employees, or to an event threatening the life or health of many people (Article 163 of the Penal Code).

The employer also bears extensive liability for any damage caused to employees or patients. The consequence is the obligation to pay compensation and damages, covered by civil liability insurance, although in the case of large-scale events, the guarantee sums may prove insufficient. Authorities such as the WIF (District Pharmaceutical Inspectorate), UDT (Office of Technical Inspection) or State Fire Service may impose administrative penalties, order the removal of irregularities, or suspend the activities of individual departments or the use of equipment. An accident or incident involving medical gases can seriously damage the image of a hospital, leading to a loss of trust among patients and staff alike, negative media coverage and, as a consequence, a decline in patient numbers.

On comparing the legal and factual circumstances, it appears that the central point of contention in medical gas management is a gross asymmetry between the statutory requirements for the manager of a healthcare facility, and the actual expectations of the system. In judicial practice, the manager becomes a 'hostage of the infrastructure'. There is a great discrepancy between the formal possibility of delegating tasks to the technical department or hospital pharmacy, and the legal impossibility of delegating responsibility for the consequences of these departments' omissions. Lacking the tools for substantive oversight of specialized engineering work, the manager bears full criminal risk (Article 160 of the Penal Code) and civil liability for any third-party (contractor) errors, which, in the light of the tragic cases described, seems to be a systemic trap.

DISCUSSION AND CONCLUSIONS

The considerations on systemic traps and the asymmetry of liability presented in this review find tragic confirmation in the analyzed clinical incident in Warsaw, which serves as a stark reminder of the consequences of neglecting medical gas infrastructure management. The death of a pregnant patient following a routine procedure resulted from the administration of a gas other than oxygen during the procedure. Legal proceedings by the prosecutor in this case are were difficult because they do did not concern a standard medical diagnostic error, but rather a combination of technical, human, service, and procedural errors. This example illustrates that inconsistencies in the management and oversight of a medical gas system can have direct, tragic clinical and legal consequences, justifying the need for comprehensive investigation and immediate corrective action.

An analysis of legal regulations, technical standards, adverse events and risks related to medical gases in hospitals clearly indicates that their supervision is an extremely complex process requiring a holistic and coordinated approach. Medical gases, being both medicinal products and part of the technical infrastructure of a hospital, are subject to numerous regulations in the field of pharmaceutical law, medical device law, technical supervision regulations and, most importantly, strict health and safety rules. The multitude and intertwining of these regulations creates unique challenges for managers of healthcare facilities, medical staff and technical services.

Effective supervision requires not only knowledge and compliance with all applicable laws and standards, but also the creation of a safety culture based on prevention, continuous monitoring, and incident awareness. It is crucial to clearly define the roles and responsibilities of individual departments – from hospital pharmacy, through medical engineering, occupational health and safety services, to clinical staff. Routine inspections, system validations, regular staff training, and effective procedures for reporting and analysing adverse events are the foundation of the safe use of medical gases.

In the light of the potential consequences of inadequate supervision – ranging from criminal liability (e.g. for exposing others to danger), civil liability (compensation), administrative sanctions, loss of public trust, and most importantly, direct threat to the life and health of patients and staff – investing in safe and compliant medical gas management is not just a matter of regulatory compliance, but a strategic priority for every healthcare facility. Only by continuous improvement of quality and safety management systems can hospitals ensure that life-critical medical gases are administered not only effectively, but above all, absolutely safely.

An analysis of legal regulations and technical standards regarding medical gases in hospitals clearly indicates that their supervision is an area full of contradictions, interpretive pitfalls, and blurred responsibility – with the exception of one person: the manager of the healthcare facility. It is this manager, regardless of his or her actual competence and education, who bears the presumption of full, absolute, and non-negotiable responsibility. Interestingly, the legislature does not require hospital directors to have any technical or pharmaceutical knowledge, let alone experience in the field of medical gases – yet they are the ones responsible for knowing, understanding, implementing, and enforcing the entire web of overlapping regulations. It is hard not to notice the irony of a system in which the person formally responsible for the safety of gas pipelines, medication quality, infrastructure compliance with ISO standards, and compliance with pharmaceutical law is simultaneously deprived of any real tools to fulfil these responsibilities without the risk of violating them. Instead of a distributed, shared system of responsibility based on knowledge and procedures, we are facing a centralized model in which every inspection, every ambiguous interpretation, and every incident results in the spotlight and regulations being directed solely at the head of the unit.

Due to the above facts, the question must be emphatically asked: is the current model of managerial responsibility a systemic trap? Should we not – instead of multiplying responsibilities – start building a culture of shared responsibility, in which the scope of knowledge and decision-making is commensurate with formal obligations?

Medical gas management requires an immediate shift away from treating oxygen and pipelines as 'technical media' towards recognising them as 'life-critical systems'. Case studies show that most tragedies result from a lack of communication between engineering, medicine and management. Therefore, the supervision of medical gases requires real cooperation between technical, pharmaceutical and health and safety departments, and management – not just declarative cooperation.

As has been demonstrated, the following conclusion *de lega ferenda* arises: the legal framework should be adapted so that the managers' responsibilities correlates with their actual supervisory powers, while at the same time strengthening the personal responsibility of technical managers for operational errors 'behind the wall', because ultimately, patient safety depends on whether the hospital's 'gas circulation' is managed with the same diligence as the handling of narcotic drugs. Only through evidence-based procedures and technical barriers that physically prevent errors can patients be protected from death by suffocation from the gas that was supposed to save them.

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