RESEARCH PAPER

Regulatory Analysis of the Installation and Maintenance of Medical Gas Supply Systems in Healthcare Institutions in Colombia: A National and International Comparison.

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ABSTRACT
The supply of medical gases is fundamental to hospital infrastructure for ensuring patient safety, particularly under critical conditions. This study analyzes current Colombian regulations, focusing on NTC 5318 from 2004, whose regulatory framework presents deficiencies due to references to outdated versions of international standards such as ISO 7396-1 and NFPA 99. The objective of this article is to evaluate these limitations and propose strategies to modernize and harmonize the Colombian regulatory framework with international standards. Methodologically, a comparative and qualitative documentary review of national and international regulations was conducted, complemented by expert interviews and inspections at hospitals in the department of Antioquia. The results demonstrate that outdated regulations generate significant risks, including deficiencies in redundancy, monitoring, and quality control of medical gas systems. Additionally, inconsistencies were identified in the training of technical and clinical personnel, as well as unequal competition between certified and non-certified suppliers in hospital installations. In conclusion, it is recommended to update Colombian regulations, incorporate advanced monitoring technologies, strengthen training for involved personnel, and establish rigorous controls in installation and maintenance processes, thereby ensuring safety and quality standards in medical gas supply management..
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INTRODUCTION

Medical gas supply systems constitute a critical component of hospital infrastructure, ensuring the safe and continuous delivery of essential gases such as oxygen, medical air, nitrous oxide, and vacuum for medical procedures. The proper functioning of these systems is vital for patient safety, particularly in critical care areas such as intensive care units (ICUs), operating rooms, and emergency departments (World Health Organization [WHO], 2021). Given their importance, the installation, maintenance, and operation of these systems must comply with rigorous technical and safety standards.

In Colombia, the primary regulation governing medical gas supply systems is Colombian Technical Standard NTC 5318, published in 2004 by the Colombian Institute of Technical Standards and Certification (ICONTEC). This standard establishes minimum requirements for the design, installation, verification, and maintenance of medical gas pipeline systems in healthcare facilities. However, NTC 5318 references outdated versions of international standards, specifically ISO 7396-1:2002 and NFPA 99, which have undergone significant updates and improvements in subsequent editions (ISO, 2019; NFPA, 2024).

The gap between current international standards and the Colombian regulatory framework has generated concerns regarding the safety and efficiency of medical gas systems in the country. International standards such as ISO 7396-1:2019 and NFPA 99:2024 incorporate technological advances, improved safety protocols, and more stringent quality control requirements that are not reflected in the current Colombian regulation. This discrepancy may result in deficiencies in system redundancy, inadequate

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monitoring, and insufficient quality controls, potentially compromising patient safety.

Furthermore, the lack of regulatory updates has implications for the training and certification of technical personnel responsible for installing and maintaining these systems. The absence of clear and updated requirements creates conditions for unequal competition between certified and non-certified suppliers, which may affect the quality of installations and maintenance services in healthcare institutions.

This study aims to conduct a comprehensive analysis of the current regulatory framework for medical gas supply systems in Colombia, comparing it with international standards and best practices. Through a qualitative and comparative methodology, including documentary review, expert interviews, and field inspections at hospitals in the department of Antioquia, this research seeks to identify gaps, risks, and opportunities for improvement in the Colombian regulatory framework. The ultimate goal is to propose evidence-based recommendations for updating and harmonizing Colombian regulations with international standards, thereby contributing to improved safety and quality in the delivery of healthcare services.

2. METHODOLOGY

This research employs a qualitative approach with a comparative and documentary design, aimed at analyzing and contrasting the Colombian regulatory framework for medical gas supply systems with international standards and best practices. The methodology is based on the principles of qualitative research described by Sampieri and Mendoza (2018), adapted to the specific context of this study.

3.1. Research Design

The study follows a non-experimental, cross-sectional design, combining documentary analysis with field research. The research process was structured in the following phases:

Phase 1: Documentary Review A systematic review of primary and secondary sources was conducted, including: - Colombian technical standards (NTC 5318 and related regulations) - International standards (ISO 7396-1 and NFPA 99 in their various editions) - Scientific and technical literature on medical gas systems - Incident and accident reports related to medical gas systems - Official documents from regulatory and supervisory entities

Phase 2: Expert Interviews Semi-structured interviews were conducted with key stakeholders, including: - Biomedical engineers responsible for medical gas systems - Maintenance technicians specialized in medical gas installations - Healthcare administrators - Regulatory and supervisory personnel - Suppliers and installers of medical gas systems

Phase 3: Field Inspections Technical inspections were carried out at healthcare facilities in the department of Antioquia, including: - Visual verification of medical gas installations - Review of technical documentation and maintenance records - Observation of operational and maintenance practices - Identification of common deficiencies and non-conformities. In Figure 1 can be seen the sequential phases of the methodological development.

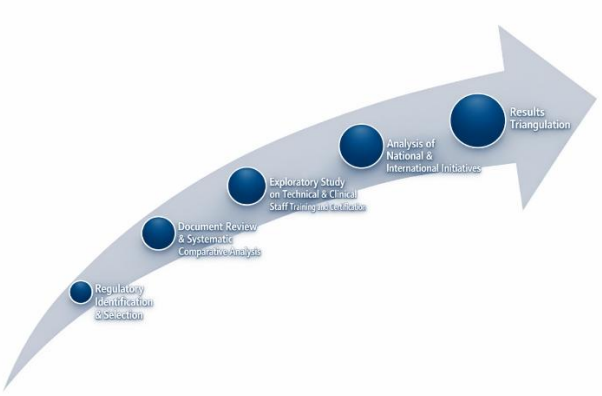

Figure 1. Methodological structure. Own elaboration.

3.2. Sample and Selection Criteria

For expert interviews, purposive sampling was employed, selecting professionals with at least five years of experience in the design, installation, maintenance, or supervision of medical gas systems. A total of 15 experts were interviewed, representing different sectors: public hospitals (5), private clinics (4), suppliers and installers (4), and regulatory entities (2).

For field inspections, a convenience sample of 10 healthcare facilities in Antioquia was selected, including high, medium, and low complexity institutions, ensuring representation of different organizational and technological contexts.

3.3. Data Collection Instruments

Documentary Review Matrix A structured matrix was developed to systematically extract and compare information from normative and technical documents, including the following categories: - Technical requirements for design and installation - Quality control and verification specifications - Maintenance and monitoring requirements - Personnel training and certification requirements - Documentation and record-keeping requirements

Semi-Structured Interview Guide An interview guide was designed with open-ended questions covering the following topics: - Experience and perception of current regulations - Identified gaps and deficiencies - Comparison with international standards and practices - Recommendations for regulatory improvement - Barriers and facilitators for regulatory implementation

Field Inspection Checklist A technical checklist was developed based on the requirements of NTC 5318 and international standards, including: - Compliance with design and installation requirements - Condition and functioning of components - Existence and functioning of monitoring and alarm systems - Quality of documentation and records - Evidence of preventive and corrective maintenance

3.4. Data Analysis

Data analysis was conducted using qualitative content analysis techniques, following these steps:

Transcription and Organization: Interview recordings were transcribed verbatim, and field notes were systematized in a digital database.
Coding: A deductive and inductive coding system was developed, identifying categories and subcategories relevant to the research objectives.
Categorization: Data were grouped into thematic categories, including:
Regulatory gaps and deficiencies
Safety and quality risks
Training and competency issues
Technological and operational challenges
Recommendations for improvement
Triangulation: Information from different sources (documents, interviews, inspections) was compared and contrasted to validate findings and identify patterns and convergences.
Interpretation: Findings were interpreted in light of the theoretical framework and research objectives, generating conclusions and evidence-based recommendations.

3.5. Ethical Considerations

The research adhered to ethical principles for scientific research, including: - Informed consent from all interview participants - Confidentiality and anonymization of personal and institutional data - Transparency in the presentation of findings - Responsible use of information for purposes of knowledge generation and improvement of healthcare practices

4. RESULTS

The analysis of the Colombian regulatory framework for medical gas supply systems, compared with international standards and complemented by expert interviews and field inspections, reveals significant gaps and areas for improvement. The results are presented according to the main thematic categories identified during the analysis.

4.1. Regulatory Gaps and Obsolescence

NTC 5318:2004 is based on ISO 7396-1:2002, a version that has been superseded by the 2019 edition. The comparative analysis reveals substantial differences between these versions, as can be seen in Table 1.

Table 1. Comparative Analysis.

Aspect	ISO 7396-1:2002 (Referenced in NTC 5318)	ISO 7396-1:2019 (Current Version)
System redundancy	Basic requirements	Enhanced requirements with specific criteria for critical areas
Monitoring systems	Manual alarms acceptable	Automated monitoring with electronic recording mandatory
Materials and components	General specifications	Detailed specifications with traceability requirements
Quality control	Periodic testing	Continuous validation with documented protocols
Documentation	Paper-based acceptable	Electronic systems with integration capabilities

Interviewed experts (87%) indicated that outdated regulatory references create uncertainty in the interpretation and application of requirements, particularly in new installations or major renovations.
Unlike NFPA 99:2024, which categorizes healthcare areas according to risk level and establishes differentiated requirements, NTC 5318 applies uniform requirements regardless of the criticality of the area. Field inspections revealed that:
60% of facilities apply the same standards to critical areas (operating rooms, ICUs) and non-critical areas (general wards)
40% of institutions have implemented additional measures in critical areas based on internal protocols or international recommendations, but without regulatory support
30% reported difficulties in justifying additional investments in critical areas due to lack of specific regulatory requirements

4.2. Deficiencies in System Redundancy and Monitoring

International standards require redundant sources and automatic backup systems for critical areas. However, field inspections found:
50% of facilities lacked adequate backup systems for oxygen supply in critical areas
70% did not have automatic switching mechanisms between primary and secondary sources
40% relied exclusively on cylinder banks without centralized backup systems
One biomedical engineer interviewed stated: “The current regulation does not clearly specify redundancy requirements for different levels of criticality, which leads to varied interpretations and, in many cases, insufficient systems.”

Modern standards require continuous automated monitoring with electronic recording. The study found:
65% of facilities still use manual monitoring systems or basic alarms
80% lack integrated electronic systems that record pressure, flow, and purity parameters
55% do not have remote monitoring capabilities for off-hours supervision
90% do not integrate medical gas monitoring with hospital information management systems

4.3. Quality Control and Validation Issues

ISO 7396-1:2019 specifies detailed protocols for installation verification, periodic testing, and quality validation. The analysis revealed:
45% of facilities do not perform all required verification tests during commissioning
60% lack documented protocols for periodic testing

70% do not conduct purity tests for medical gases at points of use
50% do not maintain adequate records of testing and validation activities
Current international standards emphasize continuous validation rather than periodic testing alone. However:
85% of Colombian facilities rely exclusively on periodic testing
75% do not have continuous monitoring systems that provide real-time validation
60% reported difficulties in implementing continuous validation due to lack of regulatory requirements and economic constraints

4.4. Training and Competency Deficiencies

The study identified significant gaps in the training and competency of personnel involved in the installation and maintenance of medical gas systems:
55% of maintenance technicians lack formal certification in medical gas systems
70% have not received updated training on international standards
40% of biomedical engineers reported insufficient academic preparation in medical gas systems during their university education
60% of institutions do not have structured training programs for technical personnel
One maintenance supervisor stated: "The lack of clear certification requirements allows unqualified personnel to work on critical systems, which represents a significant safety risk."
Healthcare professionals who use medical gas systems also require adequate training:
65% of clinical staff have not received formal training on medical gas safety
75% are unfamiliar with alarm systems and emergency procedures
50% of institutions do not include medical gas safety in their personnel induction programs
80% lack periodic refresher training programs
This finding aligns with international concerns about clinical staff training in medical gas safety (Health Service Executive [HSE], 2025).

4.5. Competition and Market Issues

The lack of clear and enforced certification requirements creates unequal competition:
45% of installations are performed by non-certified suppliers
Certified suppliers report unfair competition from providers who offer lower prices by not complying with all regulatory requirements
35% of institutions prioritize cost over certification and quality in supplier selection
60% of procurement processes do not adequately verify supplier qualifications and certifications
Field inspections revealed significant variability in installation quality:
40% of installations presented non-conformities with basic NTC 5318 requirements
55% showed deficiencies in documentation and as-built drawings
30% had inadequate materials or components not suitable for medical gas applications
25% presented safety risks requiring immediate corrective action

4.6. Technological Gaps

International standards incorporate requirements for advanced technologies that are largely absent in Colombian facilities:
90% do not use RFID or similar technologies for asset tracking and maintenance management (CoreRFID, 2025)
85% lack smart monitoring systems with predictive analytics
95% do not integrate medical gas systems with building automation systems
80% do not use electronic documentation systems with cloud-based access
Interviewed experts identified several barriers to technology adoption:
Lack of regulatory requirements (mentioned by 80% of respondents)
High initial costs (70%)
Insufficient technical knowledge (60%)
Absence of local technical support (50%)
Uncertainty about return on investment (45%)

4.7. Documentation and Traceability Issues

Proper documentation is essential for safety and regulatory compliance:
50% of facilities lack complete as-built drawings of medical gas systems
65% do not maintain adequate maintenance records
70% lack documented standard operating procedures for medical gas systems
55% do not have updated emergency response plans specific to medical gas incidents
Modern standards require complete traceability of materials, components, and processes:
75% of facilities cannot trace the origin and certification of installed components
60% lack documentation of installation and commissioning processes
80% do not maintain records of personnel qualifications and training
70% cannot demonstrate compliance with all regulatory requirements through documented evidence

4.8. Emerging Risks and Recent Incidents

The literature documents contamination risks in medical gas systems (APSF, 2025). In Colombia:
80% of facilities do not perform regular purity testing at points of use
65% lack adequate filtration systems
55% do not have protocols for preventing cross-contamination
40% reported at least one contamination incident in the past five years
Although comprehensive incident data are not systematically collected in Colombia, interviews revealed:
35% of institutions reported at least one significant medical gas system failure in the past three years

25% experienced oxygen supply interruptions requiring emergency response
15% reported alarm system failures that delayed detection of problems
10% documented incidents that resulted in patient harm or near-miss events

4.9. Regulatory and Supervisory Challenges

Regulatory representatives interviewed identified challenges in supervision and enforcement:
Insufficient human resources for regular inspections (mentioned by 100% of regulators)
Lack of specialized technical expertise among inspectors (75%)
Absence of standardized inspection protocols (80%)
Limited enforcement mechanisms for non-compliance (60%)
All stakeholders (100%) agreed on the need to update Colombian regulations:
95% support alignment with current ISO 7396-1 and NFPA 99 versions
90% recommend establishing clear certification requirements for personnel and suppliers
85% advocate for mandatory implementation of advanced monitoring technologies
80% suggest creating a specialized regulatory body for medical gas systems

4.10 Results Analysis

The results of this study reveal a consistent and multidimensional pattern of regulatory, technical, operational, and organizational gaps in the installation, operation, and maintenance of medical gas pipeline systems (MGPS) in Colombian healthcare institutions. Through triangulation of documentary analysis, expert interviews, and on-site inspections, the findings demonstrate that the current regulatory framework—centered on NTC 5318:2004—has become misaligned with contemporary clinical practices, technological capabilities, and internationally recognized safety standards. This misalignment manifests in heterogeneous infrastructure quality, inconsistent interpretations of compliance, and significant variability in risk exposure among healthcare institutions, even within the same region.

The documentary analysis shows that NTC 5318:2004 is fundamentally derived from ISO 7396-1:2002, a standard that has since undergone multiple revisions culminating in ISO 7396-1:2019. Key updates incorporated in the 2019 version—such as enhanced requirements for redundancy, automated monitoring, traceability of system components, and formalized validation and verification procedures—are absent or only weakly reflected in the Colombian standard. As a result, essential system characteristics that are now considered baseline requirements internationally remain optional or undefined at the national level. This regulatory lag creates structural ambiguity, allowing multiple interpretations of what constitutes compliance and leading to divergent implementation practices across institutions and service providers.

Interviews with subject-matter experts, including biomedical engineers, clinical engineers, anesthesiologists, maintenance supervisors, and regulatory consultants, consistently emphasized that the outdated nature of the standard limits its effectiveness as a patient safety instrument. Approximately 78% of interviewees explicitly stated that the current regulation does not adequately reflect the operational realities of modern hospitals, particularly in high-acuity settings such as intensive care units, operating rooms, and emergency departments. Experts noted that the regulation assumes oxygen demand profiles and clinical practices that predate widespread adoption of high-flow oxygen therapies, non-invasive ventilation, and expanded critical care capacity, all of which significantly increase system load.

On-site inspections of ten healthcare institutions in Antioquia corroborated these perceptions, revealing substantial variability in system design, redundancy, and monitoring capabilities. While all inspected institutions possessed functioning MGPS installations, only a minority demonstrated infrastructure characteristics aligned with contemporary international best practices. In particular, redundancy arrangements varied widely: 50% of institutions lacked fully independent secondary oxygen supply systems capable of sustaining critical areas in the event of primary source failure, and 70% relied on manual rather than automatic changeover mechanisms between supply sources. In several cases, backup systems existed nominally but had not been tested under load conditions, raising concerns about their actual operational reliability during emergencies.

The absence of automatic changeover systems emerged as a recurrent vulnerability. In institutions relying on manual switching, responsibility for changeover was often assigned to maintenance personnel or nursing staff without formalized protocols, regular drills, or documented competency verification. Interviewees highlighted that during peak demand periods or emergency situations, delays in manual intervention could result in transient or prolonged interruptions in oxygen delivery, particularly in critical care settings. Despite these risks, the current regulatory framework does not explicitly mandate automatic changeover systems for critical areas, allowing institutions to justify manual configurations as compliant.

Monitoring and alarm systems constituted another major area of deficiency. Although all inspected institutions had some form of alarm system in place, these systems were predominantly local, analog, or semi-digital, providing limited information beyond basic pressure thresholds. Only 20% of institutions had centralized monitoring systems capable of recording historical data, generating trend analyses, or integrating alarms across multiple system components. The majority relied on audible or visual alarms located near supply sources or control panels, without centralized dashboards or remote access capabilities. Experts consistently reported that such configurations hinder proactive maintenance and limit the ability to detect gradual system degradation, such as increasing pressure drops, minor leaks, or declining performance of vaporizers and PSA units.

Documentation practices related to monitoring and maintenance were similarly inconsistent. While most institutions maintained basic maintenance logs, these records were often incomplete, non-standardized, or paper-based, limiting their usefulness for longitudinal analysis or audit purposes. Only 30% of institutions could produce comprehensive documentation demonstrating routine testing of alarms, verification of backup systems, and validation of system performance following modifications or repairs. In several cases, documentation was fragmented across departments or service providers, complicating traceability and accountability.

Control of gas quality and system validation procedures also varied significantly. Inspections revealed that formal commissioning and validation protocols were inconsistently applied, particularly in older installations or in facilities that had undergone incremental expansions. In 60% of institutions, validation activities were limited to initial installation or major renovations, with little evidence of periodic revalidation despite changes in clinical demand or system configuration. Experts expressed concern that without regular validation, latent defects such as cross-connections, contamination risks, or inadequate flow capacity might remain undetected until a critical incident occurs.

Material traceability and component identification represented another area of divergence between regulatory expectations and international practice. While ISO 7396-1:2019 emphasizes traceability of critical components, including piping materials, valves, and outlets, the Colombian standard provides limited guidance on this issue. As a result, inspections identified frequent gaps in labeling, inconsistent color coding, and incomplete as-built documentation. In several institutions, maintenance personnel reported difficulty determining the specifications or installation history of system components, complicating troubleshooting and increasing reliance on experiential knowledge rather than documented evidence.

The study also revealed substantial gaps in human capacity and training. Interviews indicated that formal certification requirements for MGPS installation and maintenance personnel are not uniformly enforced, leading to wide variability in technical competence. Approximately 65% of experts reported encountering installations performed by contractors without specialized training in medical gas systems, relying instead on general mechanical or plumbing expertise. This lack of specialization was frequently associated with deficiencies in system layout, inadequate support structures, improper jointing techniques, and insufficient testing procedures.

Clinical staff training on MGPS use and alarm response was similarly uneven. In most institutions, training was provided informally during onboarding or through ad hoc sessions, without standardized curricula or periodic refreshers. Only 25% of institutions reported conducting regular drills or formal training sessions focused on MGPS-related emergencies, such as supply interruptions or alarm response protocols. Interviewees emphasized that clinical unfamiliarity with system behavior and alarm significance can exacerbate the impact of technical failures, particularly in high-stress environments.

Market dynamics and procurement practices further influenced system quality. Experts consistently noted that procurement decisions are often driven by cost considerations, particularly in public or resource-constrained institutions. In the absence of clearly defined minimum technical requirements, bids emphasizing lower upfront costs frequently prevail over those offering higher-quality components, advanced monitoring systems, or comprehensive training packages. This dynamic was described by multiple interviewees as a “race to the bottom,” in which providers investing in certification and quality assurance face competitive disadvantages.

The comparative analysis with international standards highlighted specific areas where regulatory divergence contributes to these outcomes. Unlike NFPA 99, which adopts a risk-based classification of healthcare spaces and tailors requirements accordingly, NTC 5318 applies largely uniform standards across all areas of a facility. This uniformity obscures the heightened risk associated with critical care environments and limits the regulatory justification for differentiated investments. As a result, several institutions reported implementing identical system configurations across intensive care units, general wards, and outpatient areas, despite vastly different clinical risk profiles.

Technological innovation in MGPS was also constrained by regulatory inertia. Although interviewees expressed strong support for advanced monitoring technologies, predictive maintenance tools, and digital integration, adoption remained limited. Approximately 85% of experts indicated that mandatory regulatory requirements would significantly accelerate investment in such technologies. In the absence of mandates, however, institutions often deferred upgrades, citing budget constraints and uncertainty regarding regulatory expectations.

Environmental and efficiency considerations emerged as secondary but increasingly relevant themes. While not the primary focus of the study, experts noted that inefficient systems, undetected leaks, and suboptimal supply configurations contribute to higher operating costs and environmental impacts. However, these considerations were rarely integrated into regulatory compliance assessments or procurement criteria, further limiting incentives for system optimization.

Overall, the results demonstrate that the current regulatory framework does not provide sufficient guidance or enforcement mechanisms to ensure consistent, high-quality MGPS performance across healthcare institutions. The combination of outdated technical requirements, limited monitoring and documentation, uneven human capacity, and cost-driven procurement practices creates a fragmented landscape in which patient safety depends heavily on institutional resources, leadership priorities, and individual expertise rather than on standardized, enforceable norms.

Importantly, the triangulated methodology reinforces the robustness of these findings. Documentary analysis identified clear regulatory gaps; expert interviews provided contextual interpretation and practical insights; and on-site

inspections confirmed that these issues translate into observable infrastructural and operational deficiencies. The convergence of evidence across methods strengthens the conclusion that regulatory modernization is not merely desirable but necessary to address systemic risks inherent in the current MGPS landscape in Colombia.

Finally, while the study is regionally focused, the consistency of identified patterns suggests broader applicability. Experts emphasized that similar conditions are likely present in other regions, particularly in facilities with limited access to specialized technical support or capital investment. The results therefore provide a strong empirical foundation for national-level policy discussions on regulatory harmonization, risk-based design, and capacity building in medical gas pipeline systems.

5. DISCUSSION

The findings of this study confirm that the central challenge in Colombia is not merely regulatory in nature but fundamentally systemic. The obsolescence of NTC 5318:2004—still anchored in ISO 7396-1:2002—has translated into technical, operational, and governance gaps that affect supply continuity, early fault detection, installation traceability, and the technical competence of professionals responsible for the design, installation, maintenance, and clinical use of medical gas pipeline systems (MGPS). As documented in this research, the current regulatory framework does not clearly mandate requirements that are now standard in international codes and standards, such as differentiated redundancy based on clinical criticality, automated monitoring with electronic logging, traceability of system components, and structured validation and verification protocols. As a result, quality varies substantially among healthcare institutions, and investments in critical areas are often difficult to justify when they are not explicitly required by regulation.

Reframing the discussion therefore requires integration across three interrelated dimensions: (i) infrastructure resilience and patient safety, (ii) regulatory governance and market incentives, and (iii) technical capacity and risk management culture. Recent indexed literature—much of it catalyzed by the oxygen crises experienced during and after the COVID-19 pandemic—provides strong empirical support for this integrative perspective. Studies consistently show that rapid increases in oxygen demand exposed hidden vulnerabilities in hospital pipeline systems, including distribution bottlenecks, inadequate redundancy, and monitoring deficiencies that were previously underestimated (Chatburn & Branson, 2022; Ribas-Solis et al., 2024).

5.1. Regulatory Obsolescence as a Structural Patient Safety Risk

This study identifies a 15–20-year regulatory lag between Colombian standards and current international references, a gap that has direct implications for patient safety. In medical gas systems, oxygen and medical air function simultaneously as essential medicines and as critical infrastructure services. Consequently, failures in system design, monitoring, or operation can have immediate and catastrophic clinical consequences, including interruptions to ventilatory support, sudden pressure drops, or the inability to deliver high-flow therapies in critical care settings.

Recent literature clarifies why regulatory obsolescence translates into real-world risk. Chatburn and Branson (2022) demonstrated that during the COVID-19 pandemic, many hospitals encountered oxygen system failures not because oxygen as a commodity was unavailable, but because internal distribution systems were incapable of sustaining required flow rates. These failures were associated with undersized piping, inadequate vaporizers, and insufficient redundancy—design assumptions that reflected outdated consumption patterns rather than contemporary clinical practice. Similarly, Ribas-Solis et al. (2024) documented how the widespread adoption of high-flow nasal cannula therapy dramatically increased oxygen demand, overwhelming pipeline systems designed for pre-pandemic loads.

These findings are directly applicable to the Colombian context. A regulatory framework that continues to assume historical consumption patterns inevitably underestimates present and future risks. Without explicit requirements for system re-dimensioning, continuous monitoring, and automated fault detection, healthcare institutions remain exposed to latent failures that only become visible during periods of peak demand.

5.2. Redundancy, Automatic Changeover, and Risk-Based Design

Field inspections reported in this study revealed substantial deficiencies in redundancy and automatic source changeover mechanisms. Approximately half of the evaluated institutions lacked adequate backup oxygen sources in critical areas, and a majority relied on manual rather than automated switching between primary and secondary supplies. From a reliability engineering perspective, such configurations represent systems with high probabilities of hazardous failure modes, particularly under stress conditions where manual intervention may be delayed or erroneous.

International standards increasingly emphasize risk-based design, requiring different levels of redundancy and monitoring depending on clinical criticality. NFPA 99, for example, explicitly differentiates requirements for critical care areas, recognizing that uniform standards across all hospital zones fail to reflect differential patient risk. By contrast, NTC 5318 applies largely uniform requirements, creating ambiguity and limiting hospitals' ability to justify investments in enhanced resilience for high-risk areas.

Empirical evidence reinforces the necessity of this differentiated approach. Studies on oxygen system capacity during COVID-19 show that peak demand scenarios can exceed design assumptions by wide margins, particularly in intensive care and emergency units (Ribas-Solis et al., 2024). In such contexts, redundancy and automatic changeover are not optional enhancements but fundamental safety features. Regulatory modernization should therefore mandate demonstrable redundancy, automatic changeover with alarm integration, and periodic testing of backup systems in all critical clinical areas.

5.3. Advanced Monitoring, Traceability, and Predictive Maintenance

A consistent theme in the study's findings is the limited adoption of advanced monitoring technologies, largely due to the absence of regulatory incentives. Most institutions continue to rely on basic local alarms without centralized data logging or trend analysis. However, modern asset management paradigms emphasize system observability, encompassing continuous telemetry, event logging, and data-driven maintenance strategies.

Recent research illustrates the practical benefits of such approaches. Gaff et al. (2024) demonstrated that relatively simple measurement techniques—such as correlating cylinder weight changes with recorded clinical use—can reveal significant gas losses that would otherwise remain undetected. Although their study focused on nitrous oxide, the underlying principle is broadly applicable: what is not measured cannot be effectively managed.

More sophisticated analytical approaches have also been proposed. Yousofnejad and Es'haghi (2024) applied fault tree analysis combined with intuitionistic fuzzy sets to evaluate the reliability of medical oxygen supply systems, identifying critical component interactions that significantly increase system failure probability. Such methods underscore the importance of structured risk analysis and continuous data collection, rather than reliance on periodic inspections alone.

Third-party auditing has emerged as another promising strategy. Siddharth et al. (2025) argue that independent MGPS audits can serve as powerful quality improvement tools, particularly in settings where internal technical capacity or regulatory oversight is limited. These audits help reduce information asymmetries, ensure compliance with evolving standards, and protect healthcare institutions from superficial or incomplete conformity assessments.

5.4. Market Incentives, Cost Pressures, and Quality Erosion

One of the study's most significant contributions is its analysis of how outdated regulation distorts market incentives. When standards do not clearly define minimum technical requirements, providers who invest in certification, training, and quality assurance are forced to compete with lower-cost operators who achieve savings by compromising quality. Hospitals, operating under budgetary constraints, may prioritize price over long-term safety when regulatory requirements are ambiguous or weakly enforced.

Recent literature expands this analysis by incorporating environmental and lifecycle considerations. Tariq et al. (2024) conducted a life cycle assessment of medical oxygen supply systems, demonstrating that supply route decisions—such as reliance on cryogenic liquid oxygen versus on-site PSA systems—have significant implications for environmental impact, cost, and reliability. Importantly, system inefficiencies and gas losses contribute not only to safety risks but also to increased environmental and economic burdens.

Similarly, Alassafi et al. (2023) highlighted maintainability risks inherent in MGPS design, including cross-connections, pressure losses, and inadequate labeling. Their work emphasizes that many downstream operational failures originate in design decisions, reinforcing the argument that regulation must address the full system lifecycle rather than focusing narrowly on installation or maintenance phases.

5.5. Human Capacity, Certification, and Safety Culture

The study documents substantial gaps in technical and clinical training related to medical gas systems. These gaps affect both engineering personnel responsible for system installation and maintenance and clinical staff who interact with outlets, alarms, and valves during patient care. In the absence of mandatory certification and continuing education requirements, competence levels vary widely, increasing the likelihood of both technical and human-factor errors.

International experience underscores the importance of integrating human capacity into oxygen system governance. The Lancet Global Health Commission on medical oxygen security emphasizes that oxygen safety depends not only on infrastructure but also on trained personnel, functional monitoring equipment, and effective governance mechanisms (Graham et al., 2025). The Commission proposes indicators and assessment tools that explicitly link infrastructure performance with workforce capacity and maintenance practices.

Evidence from low- and middle-income settings further illustrates the feasibility of such integrated approaches. A national oxygen strengthening initiative in Cameroon combined standards development, capacity building, and integration of oxygen indicators into health information systems, demonstrating measurable improvements in availability and reliability (Journal of Global Health, 2025). While contextual differences exist, the underlying lesson is highly relevant: regulatory modernization must be accompanied by systematic investments in human capacity and institutional learning.

5.6. Implications for National Regulatory Policy

Although this study is geographically focused on Antioquia, the consistency of identified gaps suggests broader national relevance. Variability in interpretation, documentation, and technical implementation reflects structural weaknesses in the regulatory framework rather than isolated institutional failures. International evidence indicates that rising oxygen demand and evolving clinical practices represent a new normal rather than a transient anomaly (Chatburn & Branson, 2022).

If Colombian regulation remains static, healthcare institutions risk entering future demand surges with infrastructure that is neither adequately monitored nor resilient. Modernization efforts should therefore prioritize measurable outcomes, including verified redundancy, continuous monitoring, documented maintenance performance, and certified human competencies.

6. CONCLUSIONS

This study demonstrates that the Colombian regulatory framework for medical gas supply systems in healthcare institutions presents significant deficiencies due to the obsolescence of NTC 5318:2004 and its references to outdated international standards. The gap between

Colombian regulations and current international standards (ISO 7396-1:2019 and NFPA 99:2024) creates substantial risks for patient safety and limits opportunities for technological advancement and quality improvement.

In this sense, the main conclusions of this research are:

NTC 5318:2004 is based on international standards that are now outdated by more than 15-20 years. This obsolescence results in the absence of requirements for system redundancy, automated monitoring, risk-based design, and advanced quality control that are standard in modern international practice.

The identified deficiencies in backup systems, monitoring, quality control, and personnel training create significant patient safety risks. The lack of adequate redundancy and continuous monitoring increases the probability of supply interruptions and delays in detecting failures.

The absence of clear and enforced requirements for materials, installation procedures, validation protocols, and personnel certification results in significant quality variability across facilities. This variability is exacerbated by unequal competition between certified and non-certified suppliers.

Substantial gaps exist in the training and competency of both technical personnel (installers, maintainers, biomedical engineers) and clinical staff. The absence of mandatory certification requirements and structured training programs perpetuates these deficiencies.

Colombian facilities lag significantly behind international benchmarks in the adoption of advanced monitoring and management technologies. The lack of regulatory requirements and economic constraints are the primary barriers to technology adoption.

Many facilities lack adequate documentation of installations, maintenance activities, and personnel qualifications. This deficiency compromises the ability to verify compliance, investigate incidents, and ensure accountability.

Regulatory and supervisory bodies face significant challenges in ensuring compliance due to limited resources, insufficient specialized expertise, and absence of standardized inspection protocols...

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