The Joint Commission Journal on Quality and Patient Safety 2026; 000:1–10

ORIGINAL RESEARCH

Prospective Failure Mode and Effects Analysis to Support Implementation Readiness for a New Hyperbaric Oxygen Therapy Service

Loay Zaknoun, RN, MN; Moshe Kulikovsky, MD; Einav Atzmona Rosh, RN, PhD; Mazal Ben Hayoun, RN, MN; Salman Zarka, MD, MPH, MA

Background: Launching a clinical service is a vulnerable phase in which latent risks may emerge before care processes stabilize. Hyperbaric oxygen therapy (HBOT) is a high-risk, technology-intensive service requiring infrastructure, equipment control, procedures, emergency preparedness, and cross-departmental coordination. The role of failure mode and effects analysis (FMEA) in supporting pre-launch implementation readiness has been less clearly described.

Methods: The authors conducted a prospective, multidisciplinary patient safety improvement project during pre-implementation of a hospital-based HBOT service in northern Israel. FMEA linked risk identification with mitigation planning, accountability, operational controls, readiness activities, and early post-launch review.

Results: The FMEA mapped 13 process stages and identified 114 failure modes. High-priority risks extended beyond in-chamber treatment to maintenance, patient preparation and transfer, discharge planning, equipment control, and fire and electrical safety. The highest risk priority number (RPN) was 504 for use of a non-approved external electrical device; RPNs were prioritization aids rather than precise risk estimates. Of the 10 highest-priority failure modes, mitigation actions for 7 were implemented before launch, while 3 underwent additional reinforcement during early follow-up. All core launch-facing staff completed preparation, and three operational checklists were deployed. By February 2026, 347 treatment sessions had been completed, with no patient harm events identified in the reviewed top-risk categories. This was treated as an early operational observation, not evidence of reduced harm.

Conclusion: Prospective multidisciplinary FMEA helped structure implementation readiness by linking risk identification with mitigation ownership, operational controls, readiness review, and early post-launch learning. This single-center project did not evaluate whether FMEA reduced patient harm or improved clinical outcomes. FMEA or a comparable prospective hazard-assessment method may be considered in pre-launch planning for selected high-risk clinical services.

The introduction of a new hospital-based clinical service is a vulnerable organizational phase during which latent risks may emerge before care processes become stable and reliable.[1] This is particularly important for services that depend on complex infrastructure, multidisciplinary coordination, specialized equipment, emergency preparedness, and careful patient selection.[2] In such settings, readiness for implementation depends not only on bedside clinical decision-making, but also on how the service is designed, governed, operationalized, and reassessed before and immediately after the first patients receive care. For high-risk, technology-dependent services, prospective identification of system vulnerabilities may therefore support implementation readiness and safety governance.[2,3]

Hyperbaric oxygen therapy (HBOT) is one such service. HBOT involves administration of approximately 100% oxygen under increased atmospheric pressure in a hyperbaric chamber and is used for a range of emergency and nonemergency indications.[4,5] Although HBOT is generally considered safe when appropriately delivered, its provision depends on reliable referral pathways, careful patient selection, equipment readiness, physiologic monitoring, trained staff, emergency response capability, and coordination across hospital systems.[6,7] It is also associated with recognized adverse effects, including middle ear barotrauma, ocular effects, hypoglycemic events in some patients with diabetes, and, more rarely, oxygen toxicity seizures.[7] Establishing an HBOT unit should therefore be understood not only as a clinical undertaking, but also as an implementation-readiness and safety-governance challenge.

In the present case, a new hospital-based HBOT service was established in northern Israel, a peripheral region with limited local access to advanced hyperbaric care. Anticipated patient groups included individuals with diabetic

1553-7250/$-see front matter

https://doi.org/10.1016/j.jcjq.2026.08.003

foot ulcers and other complex wound conditions for whom HBOT may be considered as an adjunctive treatment in selected cases.[8] Expanding local access to such care was clinically important. However, opening a new HBOT service also required prospective attention to operational vulnerabilities across clinical, technical, environmental, and organizational interfaces.

Failure mode and effects analysis (FMEA) is a structured prospective method for mapping processes, identifying potential failure modes, and prioritizing preventive action before harm occurs.[2] In healthcare, FMEA has been applied to a range of high-risk processes, and process mapping combined with FMEA has also been described as a useful approach for identifying and prioritizing implementation barriers.[2,3,9] These features make FMEA suitable for pre-launch contexts in which local adverse event data are not yet available and risks must be anticipated prospectively across a planned care pathway.

Despite growing use of FMEA in healthcare, less attention has been paid to its role as a practical implementation-readiness framework during the pre-launch introduction of complex new clinical services. In the HBOT literature, most published work has focused on indications, mechanisms, adverse effects, and patient outcomes rather than on the organizational conditions required to prepare a new service for routine operation.[6,7] This leaves an important practical gap: how prospective risk analysis can be translated into mitigation ownership, operational controls, readiness verification, and early post-launch reassessment.

We therefore conducted a prospective multidisciplinary FMEA before launch of a new hospital-based HBOT service. The objective was to examine how FMEA could support implementation readiness by linking prospective risk identification with mitigation planning, assigned accountability, readiness controls, and early post-launch learning. The project was not designed to evaluate whether FMEA reduced patient harm or improved clinical outcomes. Figure 1 illustrates the implementation-readiness and safety-governance framework used in this project and its timeline from pre-launch planning through early post-launch review.

METHODS

Study Design and Setting

We conducted a prospective patient safety improvement project during pre-implementation of a new hospital-based HBOT service at a general hospital in northern Israel. The project was reported with reference to SQUIRE 2.0 principles.[10]

The new HBOT service was based on a multiplace hyperbaric chamber consisting of two treatment compartments with an interlock between them. During the study period, the service operated as an ambulatory elective service from 7:00 A.M. to 3:00 P.M., with an expected daily treatment capacity of approximately 12 to 36 sessions. Although the chamber was built and technically prepared to support emergency treatment, emergency HBOT was not part of routine service activity during the period evaluated. As is typical for multiplace systems, the chamber was compressed with air, while patients breathed oxygen primarily through masks and, when needed, through hoods. Patients were accompanied inside the chamber by a trained tender during treatment and during entry or exit through the interlock. Tenders were nurses, paramedics, or physicians and were required to complete a comprehensive medical evaluation before beginning work in the chamber environment.

The prospective FMEA process began in April 2025 and continued through the pre-launch period. The HBOT service opened in mid-October 2025. Structured post-launch reviews were conducted in late November 2025 and again in February 2026. Additional later-phase oversight reviews were planned as part of ongoing service governance. The implementation context was shaped by the launch of a high-risk, technology-intensive service in a peripheral general hospital, with dependence on cross-departmental coordination, new infrastructure, vendor-supported technical setup, and limited prior local HBOT operational experience.

Rationale for Selecting FMEA

FMEA was selected because the service had not yet opened, local adverse event data were unavailable, and a proactive, process-based method was needed to anticipate hazards before routine patient care began. FMEA was considered suitable for this pre-launch context because it enabled the multidisciplinary team to map the planned care pathway, identify potential failure modes, prioritize risks, assign mitigation ownership, and link identified vulnerabilities to readiness actions. Other prospective hazard-assessment approaches may also be appropriate in different settings; in this project, FMEA was chosen as a practical method for structuring implementation readiness and safety governance before service activation.

Team Organization and Governance

The project was initiated by the Director of Patient Safety and Risk Management together with the hospital director and was operationally led by the patient safety unit in partnership with HBOT service leadership. The multidisciplinary team included HBOT medical and nursing leadership, patient safety personnel, infection prevention and control staff, fire and infrastructure safety personnel, biomedical and medical engineering staff, and maintenance, procurement, logistics, emergency preparedness, ambulatory services, appointment scheduling, nursing administration, and quality personnel. HBOT leadership also contributed prior operational experience from another hyperbaric service. The chamber vendor's technical and oper-

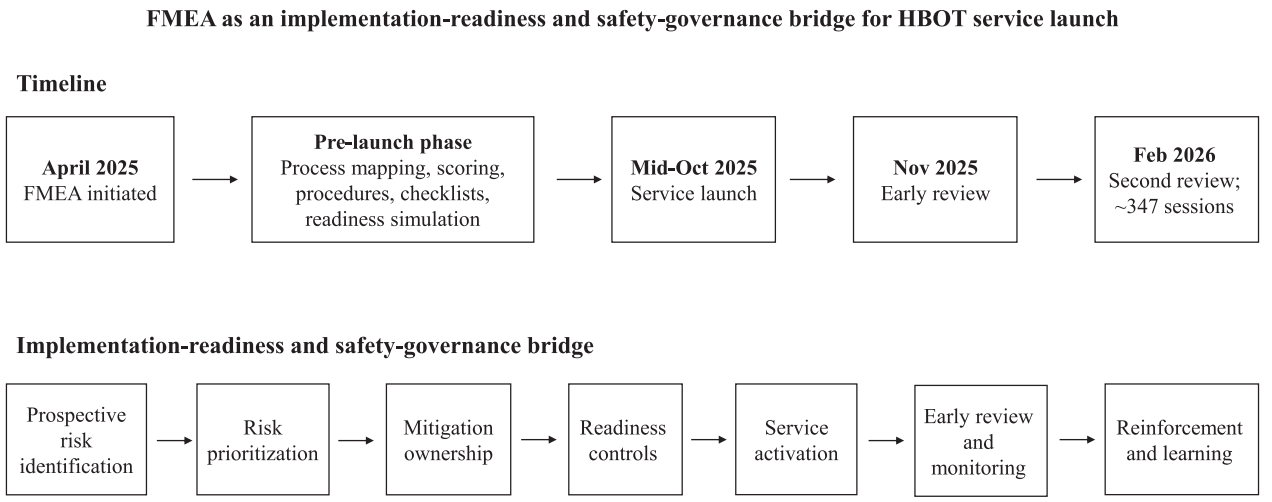

Figure 1: This figure summarizes how prospective failure modes and effect analysis (FMEA) linked pre-launch service design with early routine operation, from FMEA initiation in April 2025 through service launch in mid-October 2025 and early post-launch reviews in November 2025 and February 2026. It illustrates how FMEA connected prospective risk identification, mitigation ownership, readiness controls, service activation, and early post-launch learning. HBOT, hyperbaric oxygen therapy.

ational support team accompanied the opening phase and the first month of service activity.

The pre-launch phase included eight structured multidisciplinary meetings. The patient safety unit coordinator documented process maps, failure modes, scores, mitigation actions, responsible owners, and follow-up items. Mitigation tracking was conducted through meeting records, assigned action items, readiness documentation, and post-launch review materials.

Process Mapping, Failure Mode Identification, and Scoring

The team mapped the anticipated HBOT service pathway and identified potential failure modes across 13 principal stages: referral and scheduling, arrival and access, reception and check-in, pre-treatment preparation, transfer to and entry into the chamber, treatment delivery, post-treatment exit and observation, equipment and technical support, procurement and supply chain management, sterile supply and instrument processing, emergency preparedness and response, environmental and infection control, and post-treatment follow-up and discharge coordination.

For each stage, the team identified potential failure modes, likely causes, possible consequences, a responsible owner, and a corresponding preventive mitigation action. In total, 114 potential failure modes were identified. The complete FMEA matrix, including all identified failure modes, causes, consequences, and mitigation actions, is provided in Supplementary Table 1 (available in online article).

All failure modes were scored using the standard FMEA domains of Severity, Occurrence, and Detection on a 1–10 scale adapted for healthcare applications and supported by predefined scoring anchors in Supplementary Table 1. Detection reflected the likelihood that a failure would not be recognized before causing harm. Each failure mode was independently scored by at least three domain-relevant participants, followed by multidisciplinary discussion until consensus was reached. Not all team members scored all failure modes; rather, scoring was performed by participants with relevant clinical, technical, operational, or safety expertise for the process stage under review. A risk priority number (RPN) was calculated as Severity × Occurrence × Detection. RPNs were used as pragmatic prioritization aids rather than precise or validated quantitative estimates of risk magnitude. Failure modes were ranked according to RPN, with higher Severity used to order ties. Scores were not recalculated after mitigation; implementation status and follow-up actions were tracked separately.

Development and Implementation of Mitigation Actions

For prioritized failure modes, the team developed mitigation actions across clinical, technical, and organizational domains. These included procedure development or revision, workflow redesign, clarification of referral and eligibility criteria, communication pathways, equipment and maintenance controls, emergency preparedness measures, staff training, and environmental or infrastructure modifications.

Specific implementation tools included three operational checklists—intake, pre-entry, and discharge—a fire and electrical safety readiness review, and a formal readiness simulation. Readiness for launch was assessed on the basis of completion of key implementation elements, including staff preparation, equipment verification, checklist availability, procedural readiness, environmental and signage preparation, emergency preparedness activities, and review

of unresolved or reinforced mitigation items by service leadership and relevant operational stakeholders. No formal numeric launch-readiness threshold was prespecified; readiness for service activation was determined through multidisciplinary leadership review by HBOT service leadership, hospital leadership, quality and patient safety personnel, and relevant operational stakeholders, based on core controls, unresolved or reinforced mitigation items, and planned post-launch monitoring.

Workforce Preparation

Pre-launch workforce preparation was treated as a core implementation component. All staff assigned to core HBOT launch-facing roles completed role-specific preparation before service activation, including two physicians, three nurses, one secretary, and two technicians. Training completion was defined according to role and included documented participation in didactic instruction, in-person practical preparation, simulation or readiness exercises, and supervised on-site preparation. In addition, relevant staff completed role-specific observational and practical learning at another hospital-based HBOT unit over approximately three to four months before launch. During the first month after service activation, the chamber manufacturer provided on-site operational accompaniment and reinforcement training. Emergency and fire-safety procedures were refined in coordination with fire-safety requirements and manufacturer guidance. Staff serving as in-chamber tenders also required medical evaluation before beginning work in the chamber environment. Satisfactory completion of preparation was based on documented participation in role-specific training, supervised readiness activities, and completion of the relevant practical components. Simulated readiness exercises included patient entry and exit, checklist use, in-chamber communication, acute clinical deterioration, cardiopulmonary resuscitation, and fire and emergency response procedures. Fire and emergency readiness activities involved HBOT staff together with relevant technical, engineering, and fire-safety personnel.

Evaluation Approach and Early Post-Launch Review

Because the primary aim of this project was to strengthen implementation readiness before launch, the evaluation focused on implementation-oriented and early operational outcomes rather than comparative clinical outcomes. Prespecified evaluation domains included (1) workforce readiness, (2) deployment of key operational safety controls before launch, (3) mitigation status of prioritized failure modes, and (4) early post-launch learning and monitoring.

Implementation status for prioritized mitigation actions was categorized as implemented before launch, reinforced during early post-launch follow-up, or managed through layered controls with continued reinforcement. A mitigation action was considered implemented when the relevant control had moved from planning into operational availability or use, such as an approved procedure, operational checklist, completed staff preparation, verified equipment restriction, completed readiness activity, or another documented safeguard.

Early implementation review drew on multiple routine project and operational data sources, including FMEA meeting records, mitigation tracking logs, procedures and checklists, training documentation, readiness simulation records, structured multidisciplinary review meetings, site walkthrough findings, direct operational observation, and routine incident reporting processes. Structured post-launch reviews were conducted in late November 2025 and February 2026 by HBOT leadership, patient safety personnel, and relevant technical, engineering, and fire-safety stakeholders as applicable. These reviews examined the operational availability and use of checklists, chamber-entry screening, equipment and accessory control, environmental safety, communication and alarm arrangements, emergency readiness, and mitigation progress for prioritized failure modes.

Checklist use was assessed through implementation documentation, managerial oversight, structured review meetings, and site walkthroughs rather than through a formal compliance audit. Because this was an implementation-readiness and safety-governance project rather than a formal comparative study, no baseline comparison, inferential statistical analysis, formal compliance audit, or prespecified balancing measures were included in the evaluation design.

Ethical and Regulatory Considerations

This work was conducted as a patient safety improvement initiative during implementation of a new clinical service. It focused on workflows, operational risks, and preventive mitigation strategies and did not involve patient-identifiable data. The institutional Helsinki Committee, which serves as the hospital's Institutional Review Board (IRB), determined that the project met criteria for exemption from formal IRB review, and the requirement for informed consent was waived.

Patient and Public Involvement

Patients and members of the public were not involved in the design, conduct, reporting, or dissemination planning of this patient safety improvement project.

RESULTS

FMEA Findings and Prioritization

The FMEA mapped 13 stages across the anticipated HBOT service pathway and identified 114 potential failure modes. High-priority risks were distributed across multiple operational domains and were not limited to treatment events inside the chamber. The highest-ranked risks reflected vul-

nerabilities in chamber maintenance and operation, procurement and equipment readiness, patient preparation and transfer, discharge planning, preventive maintenance, chamber-entry screening, emergency supply storage, and fire and electrical safety.

The 10 highest-priority failure modes, together with their principal consequences, key mitigation actions, implementation status, and early post-launch findings or reinforcement actions, are presented in Table 1. The highest RPN was 504 for use of a non-approved external electrical device in the HBOT environment. The second-highest RPN was 400 for mismatch between patient attire or accompanying equipment and chamber safety requirements. These RPNs were used to support prioritization and mitigation planning rather than as precise quantitative estimates of risk magnitude.

Pre-Launch Mitigation and Implementation Readiness

FMEA findings were translated into targeted mitigation actions across clinical, technical, environmental, and organizational domains. These included procedure development, workflow refinement, communication controls, environmental and equipment safeguards, staff preparation, emergency readiness activities, and clarification of mitigation ownership. For identified failure modes, the team documented corresponding preventive actions, assigned responsible owners, and tracked implementation status through the pre-launch and early post-launch phases.

All staff assigned to core HBOT launch-facing roles completed required pre-launch preparation before service activation, including two physicians, three nurses, one secretary, and two technicians. Preparation was multimodal and included didactic and practical training, simulation or readiness exercises, role-specific observational and practical learning at another hospital-based HBOT unit over approximately three to four months before launch, and supervised on-site preparation. During the first month of operation, the chamber manufacturer provided additional on-site operational accompaniment and reinforcement training.

Key operational controls deployed before launch included three structured checklists: an intake checklist, a pre-entry checklist, and a discharge checklist or structured discharge guidance process. A formal readiness simulation and a fire and electrical safety readiness review were also completed before service activation.

Of the 10 highest-priority failure modes, mitigation actions for 7 were implemented before launch, and 3 required reinforcement during early post-launch follow-up. Specifically, actions addressing non-approved electrical devices, patient attire or equipment compatibility, treatment-associated in-chamber events, patient transfer and positioning, discharge planning, preventive maintenance, and emergency supply storage were implemented before launch. Actions related to flammable materials during maintenance or operation, screening for sharp metallic items, and fire- and oxygen-enrichment-related chamber-zone hazards were reinforced after early follow-up.

For the fire- and oxygen-enrichment-related failure mode, the revised status clarifies that this was an inherent HBOT risk managed through layered controls rather than an absence of basic fire-safety safeguards at launch. Core controls were in place before service activation, including restriction of unauthorized equipment and accessories, chamber-entry screening, operational checklists, staff training, in-chamber tender presence, fire-safety procedures, and emergency response arrangements. Early post-launch review led to additional reinforcement of these layered controls.

Together, these findings illustrate how prospective risk identification was translated into concrete operational controls, supporting the role of FMEA as an implementation-readiness and safety-governance framework between planned service design and early routine operation. Implementation-readiness indicators and early operational observations are summarized in Table 2. These indicators were used to assess implementation readiness and early operational learning, not to evaluate clinical effectiveness or reduction in patient harm.

Early Post-Launch Learning and Monitoring

The three operational checklists were introduced into routine workflow from service launch. Their early operational use was assessed through implementation documentation, managerial oversight, structured review meetings, site walkthroughs, and direct operational review rather than through a formal compliance audit. By the end of February 2026, approximately 347 treatment sessions had been completed.

Follow-up reviews in late November 2025 and February 2026 showed that, despite substantial pre-launch preparation, additional operational safety needs became visible during early routine use and required reinforcement or refinement. These included strengthening fire preparedness and drills, installing a separating door between the patient waiting area and chamber zone, adding a rear-door telephone/intercom to support communication and response, adding an additional fire alarm activation point accessible to technical staff, and installing emergency call buttons in patient toilet and changing areas.

No patient harm events in the reviewed top-risk categories were identified during this early operational period through routine service oversight, direct operational review, and incident reporting processes. Given the limited follow-up period, the modest early treatment volume, and the implementation-focused design of the project, this finding was treated as an early operational observation and was not

Table 1. Top 10 Prioritized Failure Modes, Principal Consequences, Key Mitigation Actions, Implementation Status, and Early Post-Launch Reinforcement.

Process Stage	Failure Mode	Main Consequence	RPN	Key Mitigation	Implementation Status	Early Post-Launch Finding / Reinforcement
Maintenance and operation	Use of a non-approved external electrical device in the HBOT environment	Fire or electrical hazard with potential patient/staff harm	504	Equipment control policy, supervised approval process, and restriction of unauthorized devices	Implemented before launch	Control maintained through chamber-entry restrictions and equipment oversight
Procurement / chamber readiness	Mismatch between patient attire or accompanying equipment and chamber safety requirements	Ignition risk in an oxygen-enriched care environment	400	Standardized pre-entry screening, approved attire/equipment policy, and checklist-based verification	Implemented before launch	Reinforced through routine use of the pre-entry checklist
Maintenance and operation	Unsafe use of flammable materials during maintenance or operation	Fire, burn injury, and environmental hazard	192	Restriction of flammable materials, maintenance controls, and staff guidance	Reinforced after follow-up	Additional emphasis placed on maintenance controls, staff guidance, and restriction of flammable materials
In-chamber treatment	Treatment-associated in-chamber events, including panic, middle ear barotrauma, or acute clinical deterioration	Patient harm and interruption of treatment	128	Pre-treatment assessment, monitoring protocol, staff preparedness, and emergency response guidance	Implemented before launch	Managed through treatment monitoring, staff preparedness, and emergency response procedures
Pre-treatment transfer and positioning	Inappropriate patient positioning or transfer before treatment	Patient injury or clinical deterioration during preparation or transfer	128	Transfer protocol, staff instruction, and positioning safeguards	Implemented before launch	Incorporated into staff preparation and routine patient-transfer workflow
In-chamber safety	Ignition or explosion associated with oxygen enrichment and unsafe equipment or accessories in the chamber area	Severe patient/staff harm and chamber-related fire event	120	Fire-safety protocol, control of accessories/equipment, chamber-entry screening, staff training, operational checklists, tender presence, and emergency response arrangements	Managed through layered controls at launch	Inherent HBOT risk; layered controls reinforced after early follow-up
Discharge	Inadequate discharge planning for patients with mobility limitations	Fall risk, injury, or unsafe discharge	112	Standardized discharge planning and mobility-related escort/transport procedures	Implemented before launch	Incorporated into discharge checklist and structured discharge guidance

(*continued on next page*)

Table 1. (*continued*)

Process Stage	Failure Mode	Main Consequence	RPN	Key Mitigation	Implementation Status	Early Post-Launch Finding / Reinforcement
Preventive maintenance	Inadequate preventive maintenance and corrosion monitoring	Equipment malfunction, unsafe operation, or treatment disruption	100	Preventive maintenance schedule, corrosion surveillance, and engineering oversight	Implemented before launch	Continued through engineering and maintenance oversight
Entry screening	Admission of a patient carrying sharp metallic items without adequate screening	Safety hazard in the chamber environment and risk of injury	96	Pre-entry screening and removal check for prohibited personal items	Reinforced after follow-up	Screening reinforced through pre-entry workflow and checklist use
Emergency supply storage/ procurement	Lack of secure storage planning for emergency supplies	Delayed availability of critical items during urgent response	90	Defined storage plan, inventory control, and procure-ment/availability procedures	Implemented before launch	Storage and availability arrangements incorporated into readiness review

RPN, risk priority number; HBOT, hyperbaric oxygen therapy.

Table 2. Implementation-Readiness Indicators and Early Operational Observations.

Evaluation Domain	Indicator	Operational Definition	Data Source	Finding
Workforce readiness	Completion of role-specific pre-launch preparation	Completion of required preparation for staff assigned to core HBOT launch-facing roles	Training and preparation records	All core staff completed required preparation before launch.
Operational control deployment	Deployment of key operational safety controls before launch	Finalization and operational availability of core checklists, readiness review, and simulation activities before launch	Final checklists, readiness records, and meeting documentation	Three core checklists, a readiness simulation, and fire/electrical readiness review were completed before launch.
Mitigation status of prioritized risks	Status of the 10 highest-priority failure modes	Categorized as implemented before launch, reinforced during early follow-up, or managed through layered controls with continued reinforcement	FMEA tracking records and post-launch review documentation	Seven mitigation actions were implemented before launch; three were reinforced during early follow-up.
Early post-launch learning and monitoring	Additional operational safety needs and reviewed harm events during early operation	Identification of residual operational needs and reviewed harm events through structured follow-up and routine oversight	Review meetings, site walkthroughs, incident reporting, and operational review	Additional operational needs were identified and addressed in November 2025 and February 2026; no patient harm events in reviewed top-risk categories were identified during limited early follow-up.

HBOT, hyperbaric oxygen therapy; FMEA, failure mode and effect analysis.

interpreted as evidence of reduced patient harm or sustained safety improvement.

DISCUSSION

This article describes a prospective, multidisciplinary FMEA conducted before the launch of a new hospital-based HBOT service, together with structured early post-launch review. The principal finding is that FMEA functioned not only as a prospective risk-analysis tool, but also as an implementation-readiness and safety-governance framework. The process helped the team identify latent vulnerabilities across the planned service pathway, assign mitigation ownership, deploy operational controls, and reassess selected safeguards during early routine operation. These findings should be interpreted as evidence of structured readiness work and early operational learning, not as evidence that FMEA reduced patient harm or improved clinical outcomes.

The project's main practical contribution is the linkage between prospective risk identification and implementation action. In many applications, FMEA may end with a ranked list of failure modes. In this project, the FMEA was used to support the transition from planned service design to early operationalization by connecting failure modes with responsible owners, mitigation actions, checklists, staff preparation, readiness review, and post-launch reinforcement. This framing is particularly relevant for new high-risk services, where local adverse event data are not yet available and safety governance must rely on prospective identification of vulnerabilities before care begins.[2,3,9] The findings therefore support the use of FMEA as a practical readiness framework, while recognizing that other prospective hazard-assessment methods may also be appropriate in different organizational settings.

A second important finding was that the highest-priority risks extended beyond direct in-chamber clinical events. Although HBOT is commonly associated with recognized clinical hazards such as barotrauma, hypoglycemia, and oxygen toxicity,[6,7] several of the highest-priority failure modes in this project involved equipment control, patient attire and accessory compatibility, flammable materials, preventive maintenance, discharge planning, and chamber-entry screening. This pattern is consistent with a systems-based understanding of patient safety, in which harm may arise from latent organizational conditions, interface failures, and weaknesses in the work system rather than from isolated frontline clinical decisions alone.[1,11–13] For HBOT implementation, this means that readiness depends not only on chamber operation and clinical expertise, but also on environmental controls, technical infrastructure, workflow design, staff preparation, and cross-departmental coordination.

The fire- and oxygen-enrichment-related failure mode illustrates the importance of precise interpretation of residual risk. Fire and oxygen-enrichment hazards are inherent risks in HBOT practice and cannot be fully eliminated. In this project, the relevant failure mode was managed through layered controls rather than representing an absence of basic fire-safety safeguards at launch. These controls included restriction of unauthorized equipment and accessories, chamber-entry screening, operational checklists, staff training, in-chamber tender presence, fire-safety procedures, and emergency response arrangements. Early post-launch review led to reinforcement of these controls. This distinction is important because implementation readiness does not mean that inherent risks disappear; rather, it requires that such risks are recognized, controlled through multiple safeguards, assigned to responsible owners, and revisited as routine operation reveals additional vulnerabilities.

The early post-launch review also highlights the need to prevent drift between planned controls and routine practice. Although core checklists and readiness activities were deployed before launch, early operation identified additional needs related to fire preparedness, environmental separation, communication, alarm access, and patient-support safeguards. Future implementations should therefore include a structured compliance audit during the first three to six months after launch. Such an audit could combine direct observation of key workflow steps, sampling of checklist completion, review of treatment records, equipment-entry checks, staff feedback, and review of incident reports or near misses. Audit findings should be reviewed by service leadership and patient safety personnel, with rapid feedback to staff and clear ownership for corrective actions. This would strengthen monitoring of implementation fidelity and reduce the risk that new controls decline in use after the initial launch period.

Applying this approach in other settings requires attention to local context and resources. The process described here depended on multidisciplinary participation, leadership support, protected time for structured meetings, access to clinical and technical expertise, cooperation from engineering and fire-safety teams, documentation of mitigation ownership, and capacity for post-launch review. Institutions considering a similar approach should adapt the scope and intensity of FMEA to the complexity of the service, the maturity of local safety infrastructure, available data systems, and the ability to track corrective actions over time. The approach may be most useful for high-risk, technology-intensive services that depend on infrastructure readiness, equipment control, emergency preparedness, multidisciplinary teamwork, and interdepartmental coordination.

Finally, the project should not be interpreted as an effectiveness study of patient safety outcomes. The absence of identified patient harm events in the reviewed top-risk categories during approximately 347 early treatment sessions was a limited operational observation. It was not sufficient to infer reduced harm, sustained safety improvement,

or clinical effectiveness. Longer follow-up, formal compliance auditing, and outcome-oriented evaluation would be needed to determine whether FMEA–informed readiness processes translate into durable improvements in patient safety. Thus, the value of the present project lies in demonstrating how prospective FMEA can structure implementation readiness and safety governance before and shortly after launching a complex clinical service, rather than in proving improved safety outcomes.

LIMITATIONS

This project has several limitations. First, it was conducted in a single general hospital during the launch of one HBOT service, and the specific risk profile, mitigation priorities, and operational controls may not be directly transferable to other institutions without local adaptation. Second, the project was designed as a prospective implementation-readiness and safety-governance initiative rather than as a comparative effectiveness study. It therefore did not include a control group, pre-post outcome comparison, inferential statistical analysis, or formal assessment of patient harm reduction. Third, although structured early post-launch reviews were conducted, early use of the new controls was assessed through documentation review, managerial oversight, structured review meetings, site walkthroughs, and direct operational review rather than through a formal compliance audit. Fourth, FMEA scoring relied on expert judgment and multidisciplinary consensus, and RPNs should be interpreted as pragmatic prioritization aids rather than precise quantitative measures of risk magnitude. Finally, follow-up was limited to the early operational period. Although approximately 347 treatment sessions had been completed by the end of February 2026, longer-term evaluation is needed to assess durability of mitigation measures, fidelity of checklist and control use, and whether FMEA–informed readiness processes are associated with sustained improvements in patient safety.

CONCLUSION

Launching a new HBOT service involves not only clinical and technological preparation, but also substantial implementation-readiness and safety-governance challenges. In this project, a prospective multidisciplinary FMEA identified high-priority risks across the planned service pathway, including vulnerabilities related to equipment control, fire and electrical safety, maintenance, patient handling, discharge processes, emergency readiness, and cross-departmental coordination.

The FMEA helped translate prospective risk identification into mitigation planning, assigned accountability, workforce preparation, operational checklists, readiness review, and early post-launch reinforcement. These findings suggest that FMEA can support structured implementation readiness for high-risk, technology-intensive clinical services when linked to concrete controls, mitigation ownership, and post-launch learning.

This single-center project did not evaluate whether FMEA reduced patient harm or improved clinical outcomes. FMEA, or a comparable prospective hazard-assessment method, may be considered as part of pre-launch planning for selected high-risk clinical services, particularly when implementation depends on infrastructure readiness, equipment control, emergency preparedness, multidisciplinary teamwork, and coordination across organizational interfaces.

Acknowledgments. The authors thank the multidisciplinary teams involved in planning, readiness preparation, safety reviews, and early operationalization of the hyperbaric oxygen therapy service. Their contributions across clinical, nursing, engineering, maintenance, safety, logistics, and administrative domains were essential to the implementation process.

Declaration of Generative AI and AI-Assisted Technologies in the Manuscript Preparation Process. During the preparation of this work, the authors used ChatGPT to support language editing and text organization. After using this tool, the authors reviewed and edited the manuscript as needed and take full responsibility for its content.

Conflicts of Interest. All authors report no conflicts of interest.

SUPPLEMENTARY MATERIALS

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.jcjq.2026.08.003.

Loay Zaknoun, RN, MN, are affiliated with Ziv Medical Center, Safed. **Moshe Kulikovsky, MD**, are affiliated with Ziv Medical Center, Safed. **Einav Atzmona Rosh, RN, PhD**, are affiliated with Ziv Medical Center, Safed. **Mazal Ben Hayoun, RN, MN**, are affiliated with Ziv Medical Center, Safed. **Salman Zarka, MD, MPH, MA**, is affiliated with Ziv Medical Center, and the Faculty of Medicine, Bar-Ilan University, Israel. Please address correspondence to Loay Zaknoun, loayz@ziv.gov.il.

REFERENCES

1. Vincent C, Amalberti R. Safer Healthcare: Strategies for the Real World. Cham, Switzerland: Springer, 2016.
2. Ashley L, et al. A practical guide to failure mode and effects analysis in health care: making the most of the team and its meetings. Jt Comm J Qual Patient Saf. 2010;36:351–358.
3. Roseen EJ, et al. Process mapping with failure mode and effects analysis to identify determinants of implementation in healthcare settings: a guide. Implement Sci Commun. 2024 Oct 8;5:110.
4. Ortega MA, et al. A general overview on hyperbaric oxygen therapy: applications, mechanisms and translational opportunities. Medicina (Kaunas).. 2021 Aug 24;57:864.
5. James PB. Indications for oxygen therapy and the Undersea and Hyperbaric Medical Society. Med Gas Res.. 2023;13:219.

6. Zhang Y, et al. Adverse effects of hyperbaric oxygen therapy: a systematic review and meta-analysis. Front Med (Lausanne). 2023 May 18;10:1160774.
7. Heyboer M 3rd, et al. Hyperbaric oxygen therapy: side effects defined and quantified. Adv Wound Care (New Rochelle). 2017 Jun 1;6:210–224.
8. Chen P, et al. Guidelines on interventions to enhance healing of foot ulcers in people with diabetes (IWGDF 2023 update). Diabetes Metab Res Rev. 2024;40:e3644.
9. Vecchia M, et al. Healthcare application of failure mode and effect analysis (FMEA): is there room in the infectious disease setting? A scoping review. Healthcare (Basel). 2025 Jan 4;13:82.
10. Ogrinc G, et al. SQUIRE 2.0 (Standards for QUality Improvement Reporting Excellence): revised publication guidelines from a detailed consensus process. BMJ Qual Saf. 2016;25:986–992.
11. Carayon P, et al. Human factors systems approach to healthcare quality and patient safety. Appl Ergon.. 2014;45:14–25.
12. Antonacci G, et al. Process mapping in healthcare: a systematic review. BMC Health Serv Res. 2021 Apr 14;21:342.
13. Holden RJ, Carayon P. SEIPS 101 and seven simple SEIPS tools. BMJ Qual Saf. 2021;30:901–910.