Certificate in Hyperbaric Medicine (United Kingdom)

Quality Assurance in Hyperbaric Medicine

Quality Assurance in hyperbaric medicine refers to the systematic processes and activities designed to ensure that all aspects of hyperbaric treatment delivery meet established standards of safety, efficacy, and regulatory compliance. It encompasses planning, implementation, monitoring, and continuous improvement of clinical, technical, and administrative functions within a hyperbaric facility. The primary goal is to protect patients, staff, and equipment while maintaining high-quality therapeutic outcomes.

Quality Control is a subset of quality assurance that focuses on operational activities used to verify that specific processes and outputs meet predefined criteria. In the hyperbaric context, quality control activities include routine checks of chamber pressure, oxygen concentration, and temperature, as well as verification of patient monitoring equipment. While quality assurance is proactive and strategic, quality control is reactive and operational, providing the data needed to assess whether the system is performing as intended.

Standard Operating Procedure (SOP) is a documented, step-by-step set of instructions that describes how to carry out a particular task consistently and safely. SOPs in hyperbaric medicine cover a wide range of activities, from patient intake and pre-treatment screening to chamber pressurisation, decompression protocols, and emergency evacuation. A well-written SOP includes the purpose, scope, responsibilities, required equipment, detailed steps, safety precautions, and criteria for acceptance. For example, an SOP for "Chamber Leak Test" might specify the use of a calibrated pressure gauge, the target pressure (e.G., 2.0 Bar), the duration of the test (e.G., 10 Minutes), and the acceptable pressure drop (e.G., ≤0.02 Bar). Regular review and revision of SOPs are essential to incorporate new evidence, technology updates, and regulatory changes.

Calibration is the process of adjusting and verifying the accuracy of measurement instruments against known standards. In hyperbaric medicine, calibration applies to pressure transducers, oxygen analyzers, temperature probes, and gas flow meters. Calibration schedules are typically defined by manufacturers, national standards bodies, and regulatory agencies. For instance, a pressure transducer used to monitor chamber pressure may require calibration every six months, with a traceable reference standard that has an uncertainty of ±0.01 Bar. Failure to calibrate instruments can lead to erroneous readings, potentially compromising patient safety during treatment.

Validation refers to the documented evidence that a system, process, or equipment consistently produces results that meet predetermined specifications. Validation in hyperbaric medicine includes the validation of treatment protocols, software used for treatment planning, and the performance of the hyperbaric chamber itself. A common validation activity is the "Decompression Validation Test," which demonstrates that the chamber's decompression schedule reliably achieves the target pressure reduction without exceeding safe ascent rates. Validation records must be retained and reviewed during audits to confirm that the processes remain fit for purpose.

Accreditation is formal recognition by an external body that a hyperbaric facility meets defined standards of practice. In the United Kingdom, accreditation may be granted by organisations such as the British Hyperbaric Association (BHA) or the Care Quality Commission (CQC). Accreditation processes involve comprehensive assessments of clinical governance, staff competence, equipment maintenance, and documentation. Achieving accreditation demonstrates a commitment to high standards and can enhance patient confidence, facilitate referrals, and provide a framework for continuous improvement.

Audit is a systematic, independent examination of processes, records, and performance data to determine compliance with internal policies, SOPs, and external regulations. Audits can be internal (conducted by the facility's own quality team) or external (performed by accrediting bodies). Typical audit elements in hyperbaric medicine include review of patient records, inspection of equipment maintenance logs, verification of calibration certificates, and assessment of incident reports. Findings from audits are used to develop corrective actions, which are then monitored for effectiveness.

Incident Reporting is the formal documentation of any unexpected event, near-miss, or adverse outcome that occurs during hyperbaric treatment. The purpose of incident reporting is to capture information that can be analysed to identify trends, root causes, and opportunities for improvement. An incident report should contain the date and time, description of the event, personnel involved, immediate actions taken, and any patient impact. For example, a "Minor Leak" incident might be recorded when a pressure gauge indicates a deviation of 0.03 Bar from the set point, prompting an immediate investigation and corrective maintenance.

Risk Management is a structured approach to identifying, assessing, and controlling hazards that could affect patient safety, staff health, or equipment integrity. In hyperbaric medicine, risk management begins with a hazard analysis, such as a failure modes and effects analysis (FMEA), which evaluates potential points of failure in the chamber system (e.G., Pressure valve malfunction, oxygen enrichment, fire risk). Risks are then ranked according to likelihood and severity, and mitigation strategies are implemented. Effective risk management reduces the probability of adverse events and supports compliance with health-care regulations.

Root Cause Analysis (RCA) is a method used to investigate the underlying factors that contribute to an incident or non-conformance. RCA techniques include the "5 Whys," fishbone diagrams, and fault tree analysis. The outcome of an RCA is a set of actionable recommendations aimed at preventing recurrence. For instance, an RCA of a "Oxygen Toxicity" incident may reveal inadequate patient monitoring during a high-dose treatment, leading to a recommendation to revise monitoring SOPs and provide additional staff training.

Corrective Action is a step taken to eliminate the cause of a detected non-conformance or undesirable situation. Corrective actions are documented, assigned to responsible individuals, and tracked for completion. In hyperbaric medicine, a corrective action might involve replacing a faulty pressure sensor, updating an SOP, retraining staff, or modifying a treatment protocol. The effectiveness of corrective actions is verified through follow-up audits or performance monitoring.

Preventive Action differs from corrective action in that it is taken to prevent the occurrence of a potential non-conformance before it happens. Preventive actions are often identified during risk assessments, audits, or trend analysis of incident data. An example of a preventive action could be the introduction of a “Pre-Treatment Checklist” that includes verification of oxygen concentration, patient consent, and equipment status, thereby reducing the risk of treatment errors.

Documentation Control ensures that all quality-related documents, such as SOPs, work instructions, calibration certificates, and training records, are reviewed, approved, updated, and archived in a controlled manner. Document control systems may be paper-based or electronic, but they must provide traceability, version control, and access restrictions. Proper documentation control prevents the use of outdated procedures and supports regulatory compliance during inspections.

Training and Competency are critical components of quality assurance. All personnel involved in hyperbaric treatment, including physicians, nurses, technicians, and support staff, must demonstrate competence in their respective roles. Training programmes typically cover topics such as hyperbaric physics, patient selection criteria, emergency response, equipment operation, and infection control. Competency is assessed through written examinations, practical demonstrations, and periodic re-certification. For example, a hyperbaric technician may be required to complete a “Chamber Operation” competency assessment annually, with a minimum passing score of 85 %.

Equipment Maintenance encompasses scheduled preventive maintenance, unscheduled repairs, and routine inspections of hyperbaric chambers and ancillary devices. Maintenance programmes are based on manufacturer recommendations, regulatory requirements, and risk assessments. Key maintenance activities include pressure vessel integrity testing, valve lubrication, seal replacement, and cleaning of oxygen-compatible components. Maintenance logs must record the date, performed tasks, personnel involved, and any findings or corrective actions.

Environmental Monitoring in a hyperbaric facility involves tracking parameters such as ambient temperature, humidity, oxygen concentration, and fire detection systems. Maintaining an appropriate environment reduces the risk of fire, corrosion, and equipment degradation. For instance, oxygen concentration in a treatment area must be kept below 23 % to prevent combustion hazards, and continuous monitoring devices should trigger alarms if thresholds are exceeded.

Infection Control is essential in any health-care setting, including hyperbaric units where patients may be immunocompromised. Infection control measures include hand hygiene, use of personal protective equipment, regular cleaning of chamber interiors, and sterilisation of reusable medical devices. Documentation of cleaning cycles, disinfectant concentrations, and validation of cleaning efficacy must be part of the quality system.

Patient Safety is the overarching principle that guides all quality assurance activities. Specific patient-safety measures include thorough pre-treatment screening, verification of contraindications, real-time monitoring of vital signs, and clear communication of treatment plans. Safety checklists, such as the “Time-Out” before chamber pressurisation, help ensure that critical steps are not omitted.

Compliance refers to adherence to legal, regulatory, and professional standards that govern hyperbaric practice. In the United Kingdom, relevant legislation includes the Medical Devices Regulations, the Health and Safety at Work Act, and the Controlled Drugs Regulations where applicable. Compliance is demonstrated through documentation, audits, and reporting to authorities. Non-compliance can result in penalties, loss of accreditation, or legal action.

Performance Indicators (KPIs) are measurable values used to assess the effectiveness of quality-assurance activities. Common KPIs in hyperbaric medicine might include the number of incidents per 1,000 treatment sessions, equipment downtime percentage, patient satisfaction scores, and audit completion rates. KPIs should be regularly reviewed, and trends analysed to drive continuous improvement.

Continuous Improvement is a core tenet of quality assurance, emphasizing the ongoing effort to enhance processes, outcomes, and patient experiences. Techniques such as Plan-Do-Check-Act (PDCA) cycles, Lean methodology, and Six Sigma can be applied to hyperbaric workflows. For example, a PDCA cycle could be used to optimise the patient intake process:
Plan – identify delays in paperwork;
Do – implement an electronic pre-registration system;
Check – measure reduction in wait times;
Act – standardise the new process across all treatment rooms.

Traceability ensures that every component, medication, or consumable used in hyperbaric treatment can be linked back to its source, batch, and expiry date. Traceability is vital for managing recalls, investigating adverse events, and maintaining regulatory compliance. Bar-coding or RFID systems can facilitate rapid identification and tracking of items such as oxygen cylinders, wound dressings, and patient-specific devices.

Supplier Management involves evaluating, selecting, and monitoring external vendors who provide equipment, consumables, or services to the hyperbaric facility. Supplier performance is assessed based on criteria such as product quality, delivery reliability, regulatory compliance, and response to corrective actions. Contracts should include clauses that require suppliers to provide calibration certificates, safety data sheets, and evidence of quality-management systems.

Regulatory Reporting is the mandatory submission of specific data to governmental or professional bodies. In hyperbaric medicine, required reports may include adverse event notifications, equipment safety notices, and annual performance summaries. Timely and accurate reporting supports public health surveillance and demonstrates the facility’s commitment to transparency.

Clinical Governance is the framework through which organisations are accountable for delivering high-quality clinical care. It integrates risk management, audit, staff appraisal, patient feedback, and policy development. In a hyperbaric setting, clinical governance ensures that treatment protocols are evidence-based, that staff maintain competence, and that patient outcomes are systematically reviewed.

Documentation Review is the periodic evaluation of all quality-related documents to confirm that they remain current, accurate, and aligned with best practice. Review cycles are typically defined by document type – for example, SOPs may be reviewed annually, while policy documents may be reviewed every two years. Changes resulting from new research, technological advances, or regulatory updates must be incorporated and re-approved.

Change Management is the structured approach to transitioning individuals, processes, or systems from a current state to a desired future state. In hyperbaric medicine, change management may be required when introducing a new chamber model, implementing a revised treatment protocol, or adopting a new electronic health record system. Effective change management includes stakeholder engagement, training, communication of benefits, and monitoring of implementation outcomes.

Validation of Software used for treatment planning, patient monitoring, or data management is essential to ensure that the software functions correctly and reliably. Validation activities include requirement specification, installation qualification, operational qualification, and performance qualification. Documentation of software validation must include test cases, acceptance criteria, and results.

Decompression Schedules are scientifically derived algorithms that dictate the rate at which pressure is reduced during a hyperbaric session. These schedules are based on models such as the US Navy tables, the Royal Navy tables, or the European Consensus Guidelines. Quality assurance ensures that the selected schedule is appropriate for the treatment indication, depth, and duration, and that it is correctly programmed into the chamber control system.

Oxygen Toxicity Monitoring involves tracking the partial pressure of oxygen (P_O2) delivered to patients, as excessive exposure can lead to central nervous system (CNS) or pulmonary toxicity. Monitoring devices must be calibrated, and treatment protocols should limit P_O2 to ≤ 1.4 Atm for exposures longer than 30 minutes. Documentation of oxygen exposure, including cumulative dose, is part of the patient record and aids in risk assessment.

Fire Prevention is a critical safety priority because oxygen-rich environments increase fire risk. Key fire-prevention measures include using oxygen-compatible materials, maintaining oxygen concentrations below 23 % in occupied areas, prohibiting smoking, and conducting regular fire-drill exercises. Fire-extinguishing equipment must be appropriate for oxygen-enriched settings (e.G., CO_2 extinguishers) and inspected annually.

Emergency Procedures are detailed plans that outline actions to be taken in the event of an adverse incident, such as a rapid decompression, fire, or patient collapse. Emergency SOPs should specify roles (e.G., Chamber operator, medical officer), communication protocols, evacuation routes, and equipment needed (e.G., Emergency oxygen masks, defibrillators). Regular drills, with documented debriefings, help maintain staff readiness.

Patient Consent is a legal and ethical requirement that ensures patients are fully informed about the benefits, risks, alternatives, and procedures associated with hyperbaric treatment. Consent forms must be clear, written in plain language, and signed by the patient or a legally authorised representative. The consent process should be documented in the patient's record, and any questions answered before treatment commences.

Data Integrity refers to the accuracy, completeness, and reliability of data captured during hyperbaric treatments. Maintaining data integrity involves using validated electronic systems, implementing access controls, and performing regular data audits. Errors in data can lead to incorrect dosing, misinterpretation of outcomes, and regulatory non-compliance.

Patient Records must be kept confidential, secure, and readily retrievable for clinical and audit purposes. Records typically include medical history, screening results, treatment parameters, monitoring data, and post-treatment assessments. Retention periods are defined by legislation (often a minimum of eight years), and records must be disposed of securely when no longer required.

Risk Assessment is a systematic process of identifying potential hazards, evaluating their likelihood and impact, and determining control measures. In hyperbaric medicine, risk assessments are performed for activities such as chamber loading, oxygen handling, and patient transport. The outcome is a risk register that prioritises actions based on risk scores.

Hazard Identification is the first step in risk assessment and involves recognising any source of potential harm. Common hazards in a hyperbaric unit include high pressure, oxygen enrichment, fire, electrical faults, and patient contraindications. Tools such as checklists, walkthroughs, and staff interviews facilitate comprehensive hazard identification.

Control Measures are actions taken to eliminate or reduce identified risks to an acceptable level. Controls can be engineering (e.G., Pressure relief valves), administrative (e.G., SOPs, training), or personal protective equipment (e.G., Fire-resistant clothing). The hierarchy of controls prioritises elimination, substitution, engineering, administrative, and finally PPE.

Incident Investigation follows the discovery of an adverse event and involves gathering evidence, interviewing witnesses, and analysing data to determine the sequence of events. The investigation must be impartial, thorough, and documented. Findings inform corrective and preventive actions, and the investigation report is often shared with regulatory bodies.

Safety Culture is the collective attitudes, values, and behaviours that determine an organisation’s commitment to safety. A positive safety culture encourages reporting of near-misses, open communication, and continuous learning. Leadership plays a vital role by modelling safety-first behaviours, allocating resources for training, and recognising staff contributions to safety improvements.

Audit Trail is a chronological record that shows the sequence of activities performed on a system, document, or data set. In hyperbaric medicine, audit trails are essential for tracking changes to treatment parameters, equipment maintenance actions, and user access to electronic records. An audit trail must be tamper-evident and retained for the required period.

Performance Review involves periodic evaluation of the hyperbaric unit’s operational performance against predefined standards and KPIs. Reviews may be conducted quarterly or annually and should involve multidisciplinary teams. Outcomes of the review guide strategic planning, resource allocation, and quality-improvement initiatives.

Benchmarking is the practice of comparing an organisation’s performance with that of peers or industry standards. Benchmarking data can be obtained from published literature, professional societies, or collaborative networks. By identifying gaps, a hyperbaric centre can set realistic improvement targets and adopt best practices.

Patient Outcome Measures are specific metrics used to evaluate the effectiveness of hyperbaric therapy. Common outcome measures include wound healing rates, reduction in neurological symptoms, improvement in radiation-induced tissue injury, and patient-reported quality-of-life scores. Collecting outcome data supports evidence-based practice and informs quality-assurance reporting.

Clinical Protocols are evidence-based guidelines that outline the indications, contraindications, dosing, and monitoring requirements for specific hyperbaric indications. Protocols should be reviewed regularly to incorporate new research findings. For example, a protocol for treating diabetic foot ulcers may specify a pressure of 2.5 ATA for 90 minutes, five sessions per week, with a total of 30 sessions.

Patient Selection Criteria define the clinical and physiological parameters that determine eligibility for hyperbaric therapy. Criteria may include age limits, specific diagnoses, comorbid conditions, and contraindications such as untreated pneumothorax or certain chemotherapy agents. Clear selection criteria reduce the risk of inappropriate treatment and improve overall outcomes.

Contraindications are conditions or factors that increase the risk of harm if hyperbaric treatment is administered. Absolute contraindications include untreated pneumothorax and certain types of chemotherapy (e.G., Bleomycin). Relative contraindications, such as chronic obstructive pulmonary disease, require careful risk-benefit analysis and possibly modified treatment parameters.

Oxygen Enrichment occurs when the ambient oxygen concentration exceeds normal atmospheric levels, creating a fire-hazard environment. Monitoring of oxygen levels in the treatment area is mandatory, and ventilation systems must be designed to prevent accumulation. Oxygen-compatible equipment, such as non-spark tools and flame-retardant fabrics, must be used throughout the facility.

Decompression Illness (DCI) is a potential adverse event resulting from the formation of inert gas bubbles in tissues during rapid ascent. Quality assurance measures to prevent DCI include adherence to validated decompression schedules, accurate pressure monitoring, and proper patient education on post-treatment activity restrictions. Immediate recognition and treatment of DCI, typically with recompression, are essential for favourable outcomes.

Recompression Treatment is the therapeutic response to DCI, involving placement of the patient in a hyperbaric chamber at a prescribed pressure and schedule. Protocols for recompression must be readily available, and staff must be trained in rapid mobilisation, patient monitoring, and emergency medication administration. Documentation of the recompression session is a critical component of the patient record.

Equipment Certification verifies that a hyperbaric chamber complies with design, construction, and safety standards set by regulatory bodies such as the European Union’s CE marking or the UK’s MHRA. Certification involves rigorous testing, including pressure-vessel integrity, leak testing, and functional performance. Certification documentation must be retained and made available during audits.

Pressure Vessel Inspection is a mandatory activity that examines the structural integrity of the hyperbaric chamber. Inspections may be visual, ultrasonic, or radiographic, and are typically scheduled at intervals defined by the manufacturer or regulatory guidelines (e.G., Every five years). Findings are recorded, and any identified defects must be corrected before the chamber is returned to service.

Ventilation System in a hyperbaric facility must provide adequate fresh-air exchange, control temperature, and prevent the buildup of excess oxygen. System design should comply with standards such as BS EN 15001, and periodic testing of airflow rates and filtration efficiency is required. Maintenance logs for HVAC components must be kept up to date.

Oxygen Supply Management involves ensuring a reliable source of medical-grade oxygen, proper storage, and distribution to the hyperbaric chamber. Oxygen cylinders must be inspected for corrosion, labeled correctly, and stored in ventilated, fire-protected areas. A log of cylinder use, pressure readings, and replacement dates supports traceability and safety.

Gas Mixing and Delivery systems may be used to provide specific gas mixtures (e.G., Air-oxygen blends) for certain treatment protocols. These systems require calibration, routine maintenance, and validation to ensure the correct composition is delivered. Gas-mixing errors can lead to under- or over-exposure to oxygen, affecting patient safety.

Electrical Safety is vital because many chamber control systems, monitoring devices, and lighting fixtures rely on electricity. Electrical installations must comply with the UK Wiring Regulations (BS 7671) and be subject to regular inspection and testing. Portable electrical equipment used in oxygen-rich areas must be rated as non-sparking.

Patient Monitoring Devices include pulse oximeters, ECG monitors, blood pressure cuffs, and temperature probes. These devices must be calibrated, maintained, and validated for use in hyperbaric environments, where pressure and oxygen levels can affect their performance. Monitoring data should be recorded continuously and reviewed in real time.

Alarm Management involves configuring, testing, and responding to alarms generated by pressure, oxygen, and patient-monitoring systems. Alarm thresholds must be set according to clinical guidelines, and staff must be trained to differentiate between critical and non-critical alerts. Documentation of alarm events, including response times and actions taken, supports quality-assurance analysis.

Incident Log is a chronological record of all adverse events, near-misses, and non-conformances. The log should capture essential details such as date, time, description, personnel involved, immediate actions, and root-cause findings. Regular review of the incident log enables identification of recurring issues and prioritisation of improvement initiatives.

Corrective Action Plan outlines the steps required to address a specific non-conformance. The plan includes assigned responsibilities, timelines, required resources, and verification methods. Implementation of corrective actions must be monitored, and effectiveness evaluated through follow-up audits or performance metrics.

Preventive Action Plan is developed from trend analysis of incidents or audit findings that indicate a potential future problem. The plan specifies proactive measures, such as updating SOPs, enhancing training, or modifying equipment, to mitigate the identified risk before it manifests as an incident.

Quality Management System (QMS) is an integrated framework of policies, processes, and procedures that guide the delivery of high-quality hyperbaric services. The QMS incorporates elements such as document control, training, risk management, audit, and continuous improvement. International standards such as ISO 9001 provide a model for establishing a robust QMS.

ISO 9001 specifies requirements for a QMS focused on meeting customer and regulatory requirements and enhancing satisfaction. Adoption of ISO 9001 in hyperbaric medicine ensures systematic documentation, process control, and performance monitoring. Certification to ISO 9001 may be pursued voluntarily to demonstrate commitment to quality.

Regulatory Inspection is an on-site evaluation conducted by an authorised body to assess compliance with legal and professional standards. Inspectors review documentation, interview staff, observe procedures, and examine equipment. Findings are reported in an inspection report, which may include observations, non-conformances, and recommendations.

Non-Conformance is any deviation from a defined requirement, such as a SOP, regulatory standard, or quality-management policy. Non-conformances are recorded, investigated, and addressed through corrective actions. They may be identified during audits, inspections, or routine operations.

Documented Evidence provides proof that processes have been performed as required. Examples include calibration certificates, training records, maintenance logs, and audit reports. Maintaining comprehensive documented evidence is essential for demonstrating compliance during inspections and for internal quality reviews.

Key Performance Indicator (KPI) dashboards provide visual representation of critical metrics, enabling rapid assessment of quality-assurance performance. Dashboards may display trends in incident frequency, equipment uptime, patient-satisfaction scores, and audit completion rates. Regular review of KPI dashboards supports data-driven decision-making.

Statistical Process Control (SPC) uses statistical methods to monitor and control a process. In hyperbaric medicine, SPC can be applied to monitor variables such as chamber pressure stability, oxygen concentration variance, or treatment duration consistency. Control charts help identify when a process is out of control and requires intervention.

Lean Principles aim to eliminate waste, streamline workflows, and improve value for patients. Applying Lean in a hyperbaric unit might involve mapping the patient journey, identifying bottlenecks (e.G., Waiting for chamber availability), and redesigning the process to reduce waiting times and enhance staff utilisation.

Six Sigma focuses on reducing variation and defects to a statistically insignificant level (3.4 Defects per million opportunities). Six Sigma tools such as DMAIC (Define, Measure, Analyse, Improve, Control) can be used to improve specific aspects of hyperbaric service delivery, such as reducing the rate of equipment failures.

Process Mapping visualises the sequence of activities involved in delivering hyperbaric treatment. A typical process map includes steps such as patient referral, eligibility screening, consent acquisition, pre-treatment preparation, chamber loading, pressurisation, treatment monitoring, decompression, and discharge. Mapping helps identify redundant steps and opportunities for standardisation.

Stakeholder Engagement involves involving all parties with an interest in the hyperbaric service, including patients, clinicians, technicians, management, regulators, and suppliers. Engaging stakeholders in quality-assurance activities fosters collaboration, ensures that diverse perspectives are considered, and enhances acceptance of improvement initiatives.

Feedback Mechanisms allow staff and patients to provide input on the quality of hyperbaric services. Mechanisms may include suggestion boxes, electronic surveys, focus groups, and post-treatment interviews. Systematic analysis of feedback informs corrective actions and drives patient-centred improvements.

Training Records must capture details of each training event, including the date, content, trainer, participants, assessment results, and competency outcomes. Records are reviewed during audits to verify that staff maintain the required level of competence and that training programmes are effective.

Competency Assessment tools may consist of written tests, practical demonstrations, simulation scenarios, and peer-review assessments. Competency assessments should be aligned with job descriptions and regulatory expectations. Re-assessment intervals are typically set at one- to two-year periods, depending on the complexity of the role.

Simulation Exercises provide a safe environment for staff to practice emergency response, equipment failure scenarios, and patient-care procedures without risking actual patients. Simulations can be tabletop discussions or full-scale drills using a mock chamber. Debriefings after simulations capture lessons learned and inform updates to SOPs.

Patient Education Materials are resources that inform patients about the hyperbaric procedure, expected sensations, safety precautions, and post-treatment care. Materials should be written in plain language, available in multiple languages if needed, and reviewed regularly for accuracy. Effective patient education reduces anxiety and improves compliance.

Record Retention Policy defines how long various types of documentation must be kept and the method of secure storage. In the UK, medical records are generally retained for at least eight years after the last patient contact, but specific policies may require longer retention for research data or legal matters.

Data Protection obligations, such as those imposed by the General Data Protection Regulation (GDPR), require that patient data be processed lawfully, stored securely, and accessed only by authorised personnel. Hyperbaric units must implement technical and organisational measures, such as encryption and role-based access controls, to protect personal data.

Audit Findings are observations made during an audit that indicate compliance, partial compliance, or non-compliance. Findings are categorised by severity (e.G., Minor, major, critical) and assigned to responsible parties for corrective action. Timely closure of audit findings is a key performance indicator for quality assurance.

Management Review is a formal meeting where senior leadership evaluates the performance of the QMS, reviews audit results, assesses resource adequacy, and sets strategic quality objectives. Management reviews ensure that quality assurance remains aligned with organisational goals and that resources are allocated appropriately.

Resource Allocation involves budgeting for equipment purchase, maintenance contracts, staff training, and quality-assurance activities. Adequate resources are essential to sustain compliance, support continuous improvement, and maintain high standards of patient care.

Process Owner is the individual accountable for the performance and improvement of a specific process within the hyperbaric service. The process owner is responsible for defining SOPs, monitoring KPIs, and implementing corrective actions when performance deviates from expectations.

Change Log records all modifications made to SOPs, equipment settings, software versions, or organisational structures. Each entry includes the date, description of the change, reason, authorisation, and impact assessment. Maintaining a change log supports traceability and facilitates audit verification.

Software Updates must be managed carefully to avoid unintended consequences on treatment delivery. Update procedures include reviewing release notes, testing in a non-clinical environment, obtaining regulatory approval if required, and documenting the update process.

Clinical Audit evaluates the quality of patient care against established clinical guidelines or best-practice standards. In hyperbaric medicine, a clinical audit might compare wound-healing rates with published benchmarks, assess adherence to treatment protocols, and identify areas for improvement.

Peer Review involves clinicians reviewing each other’s cases to ensure appropriate patient selection, treatment planning, and outcome documentation. Peer review promotes shared learning, reinforces clinical standards, and can uncover deviations that warrant corrective action.

Incident Trending analyses the frequency and patterns of incidents over time. Trending helps identify emerging risks, such as an increase in equipment-related alarms, and informs proactive interventions. Statistical tools, such as Pareto charts, are useful for visualising incident trends.

Root Cause Identification techniques, such as the “5 Whys,” encourage investigators to probe beyond superficial explanations. By repeatedly asking “why” an event occurred, the investigation can uncover underlying system failures, such as inadequate training, ambiguous SOPs, or design flaws.

Failure Modes and Effects Analysis (FMEA) is a proactive method that evaluates potential failure points in a system and assesses their impact on safety and performance. In hyperbaric medicine, an FMEA might examine the gas-delivery system, identifying failure modes such as valve sticking, and assigning risk priority numbers to guide mitigation efforts.

Corrective Action Verification confirms that a corrective action has been effectively implemented and that the original problem no longer recurs. Verification may involve re-auditing the relevant process, reviewing incident data, or conducting functional tests on equipment.

Preventive Action Verification ensures that a preventive measure has been put in place and is functioning as intended. For example, after introducing a new pre-treatment checklist, verification would involve monitoring checklist completion rates and checking for a reduction in related incidents.

Continuous Monitoring uses real-time data collection systems to track critical parameters, such as chamber pressure, oxygen concentration, and patient vitals. Continuous monitoring enables rapid detection of deviations and supports immediate corrective interventions.

Alarm Threshold Review is conducted periodically to confirm that alarm settings remain appropriate given changes in equipment, clinical practice, or regulatory guidance. Adjustments to thresholds should be documented, and staff retrained on any new alarm responses.

Equipment Lifecycle Management covers the planning, acquisition, operation, maintenance, and disposal of hyperbaric equipment. Effective lifecycle management ensures that equipment remains safe, reliable, and compliant throughout its service life, and that end-of-life disposal follows environmental regulations.

Disposal Procedures for retired chambers and components must comply with waste-management regulations, including the handling of hazardous materials such as compressed gases and electrical components. Documentation of disposal activities, including certificates of destruction, supports environmental compliance.

Supplier Audits evaluate the quality systems of external vendors who provide critical equipment or services. Audits assess supplier capability, traceability, and compliance with contractual requirements. Findings from supplier audits inform decisions on vendor selection and contract renewal.

Contract Management involves monitoring contractual obligations, performance metrics, and service-level agreements with suppliers. Effective contract management ensures that suppliers deliver on time, meet quality standards, and provide necessary support for maintenance or calibration.

Regulatory Change Management tracks updates to legislation, standards, or guidance that affect hyperbaric practice. A systematic approach includes assessing the impact of changes, updating SOPs and training, and communicating revisions to staff. Failure to adapt to regulatory changes can result in non-compliance penalties.

Ethical Considerations in hyperbaric medicine include informed consent, patient autonomy, equitable access to treatment, and confidentiality. Quality-assurance programmes must incorporate ethical oversight, such as ethics-committee review of new protocols or research studies.

Research Governance ensures that any research conducted within the hyperbaric unit complies with ethical standards, data-protection laws, and regulatory requirements. Documentation of research protocols, ethical approvals, and data-management plans is part of the overall quality framework.

Outcome Reporting involves summarising clinical results, safety data, and quality-assurance metrics for internal stakeholders, accrediting bodies, and possibly public reporting. Transparent outcome reporting promotes accountability and supports continuous improvement.

Benchmarking Studies compare the performance of a hyperbaric centre against national or international data sets. Participation in collaborative registries, such as the Hyperbaric Medicine Registry, provides access to comparative data that can drive quality enhancements.

Patient Satisfaction Surveys capture the patient's perspective on the care received, facility environment, communication, and overall experience. Survey results are analysed to identify strengths and areas needing improvement, and action plans are developed accordingly.

Staff Satisfaction Surveys assess morale, workload, training needs, and perception of safety culture. High staff satisfaction is linked to better patient outcomes and lower incident rates. Survey findings guide organisational interventions, such as workload redistribution or professional-development opportunities.

Quality Improvement Projects are targeted initiatives aimed at addressing specific gaps identified through audits, incident analysis, or stakeholder feedback. Projects follow a structured methodology, such as PDCA, and include clear objectives, timelines, and measurable outcomes.

Project Management principles, including scope definition, risk assessment, resource planning, and progress monitoring, support the successful execution of quality-improvement projects. Designating a project manager ensures accountability and coordination across multidisciplinary teams.

Data Analytics leverages statistical software and visualisation tools to interpret large data sets, such as treatment outcomes, incident logs, and equipment performance metrics. Advanced analytics can uncover hidden patterns, predict equipment failures, and inform evidence-based practice.

Key Terminology Summary provides a concise reference list of essential quality-assurance terms, definitions, and context. A well-structured glossary assists learners in mastering the vocabulary and facilitates consistent communication across the hyperbaric team.