

Global standards, local impact:

How ISO 7101 is transforming
hospital care in India

A BSI case study

India's healthcare challenge

India's healthcare sector is undergoing significant transformation as providers work to improve quality, consistency, and access across a highly fragmented system^{1,2}. Despite rapid growth and increasing private sector investment, the sector continues to face several entrenched challenges—including inconsistent standards between public and private providers, workforce distribution gaps, poor staff retention, and limited access to continuous professional development.

Weak governance models and hierarchical management structures in many healthcare settings further inhibit the delivery of truly patient-centered care¹. These factors, combined with limited financial resources, have historically restricted the ability of hospitals and health systems to invest in sustainable quality improvement and staff training.

However, there is growing recognition—particularly among leading healthcare networks—of the need for a more integrated, people-centered approach to quality. This shift is not only essential for improving health outcomes domestically but also presents a strategic advantage as India continues to attract international patients through medical tourism^{2,3}.

Ensuring consistent, high-quality, and efficient care across all touchpoints is now seen as critical to building trust, strengthening system resilience, and unlocking the full potential of India's healthcare economy.



Introducing ISO 7101

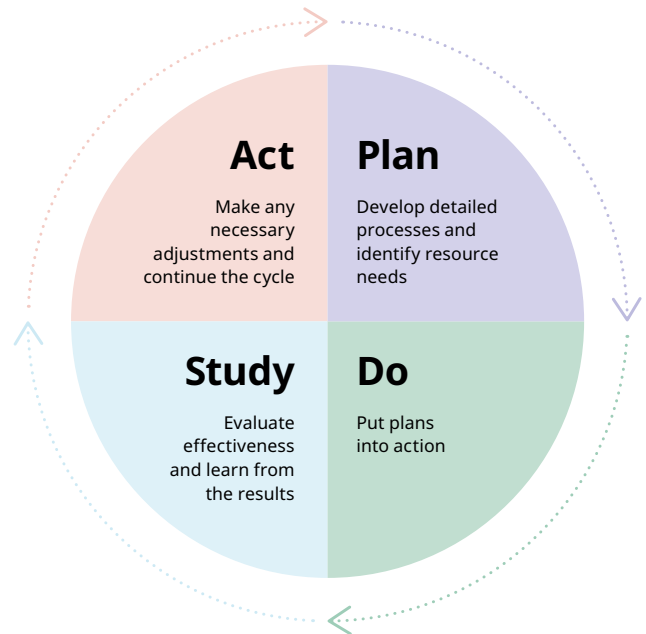
A key part of their solution lies in ISO 7101:2023, Healthcare Organization Management, the first international consensus-based standard designed to improve the experience of patients by embedding a culture of quality across a healthcare organization.

Founded on similar principles to the iconic, but generic, ISO 9001 quality management standard, ISO 7101's key difference is that it directly addresses healthcare organizations' specific service delivery challenges.

Co-created with stakeholders and healthcare leaders from around the world, ISO 7101 provides a roadmap for a systematic approach towards enabling high-quality, sustainable, safe healthcare services. It offers a universal set of requirements applicable to healthcare organizations of all sizes and types seeking to elevate the quality of their healthcare service delivery or overarching management system.

Importantly, BSI certification to the standard requires healthcare organizations to continually improve, refining their systems and identifying new areas for quality improvement through the:

Plan-Do-Study-Act (PDSA) cycle





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ISO 7101 is a performance- focused management system purpose-built for healthcare; empowering staff, enhancing accountability, and delivering measurable improvements in patient and operational outcomes. Unlike traditional compliance models, ISO 7101 focuses on optimizing performance and accelerating impactful patient and organizational outcomes.

Majid Zahoor, Sector Director, Healthcare, BSI

Pioneering the solution

BSI collaborated with the Consortium of Accredited Healthcare Organization (CAHO) setting out to understand the impact of ISO 7101 by funding implementation in a small number of healthcare organizations across India. The aim of this pilot program was to determine the opportunities, challenges and value additions of the standard in strengthening the hospitals' quality management systems.

Among the organizations that wanted to take part in the pilot were Dr Mehta's Hospitals, Chennai, and Annai Velankanni Hospital, Tirunelveli, in the southern Indian state of Tamil Nadu. Having attended a BSI course on ISO 7101 in Chennai, leaders from the two hospitals recognized the new standard as a potential solution to the quality challenge. They could see that the goal of effective quality management depends on continual improvement, driven by patient needs, together with clear assessment criteria and defined roles for all hospital staff.

Founded in 1933, Dr Mehta's Hospitals has 500 beds across two Chennai campuses and employs more than 600 practitioners covering some 80 medical specialties. While its long history, relatively large size and clinical complexity have led it to acquire several safety, quality and care certifications from accredited industry bodies (including NABH, NABL and QAI), such certifications are focused primarily on clinical outcomes, with little emphasis on management processes.

Annai Velankanni Hospital, established in 1977 and now with 110 beds, is also multi-specialty, but is best-known for its expertise in obstetrics and gynaecology. As a newer, smaller organization than Dr Mehta's Hospital, it has relatively little experience of quality and care certification processes.

The two hospitals have been taking part in BSI's ISO 7101 pilot program since mid-2024.

BSI's impact pilot program

The project has provided the hospitals with a clear, systematic approach to meeting the requirements of ISO 7101 through improved patient care, service delivery and workforce wellbeing. It focuses on continual quality improvement, effective leadership, risk management, effective monitoring and evaluation of health outcome indicators, and comprehensive information management.

The program encompasses a comprehensive process that includes conducting a gap analysis, implementing necessary changes based on identified gaps, a timeline for implementation, and resources required to achieve compliance.

Hospital implementation

Dr Mehta's Hospital and Annai Velankanni Hospital applied six key steps required to meet the requirements of ISO 7101, with BSI providing independent assessment, once the hospitals, with the help of CAHO experts completed the process:

- Understanding the ten clauses of the standard
- Engaging leadership, ensuring they champion the quality agenda
- Communicating clearly, sharing quality goals and indicators, so that everyone applies the standard effectively
- Building the capabilities of staff in quality management, in line with the standard's requirements
- Documenting processes and keeping detailed records to track progress
- Prioritizing people through initiatives on inclusivity, diversity, co-production, and wellbeing.



Benefits of ISO 7101 for the hospitals

ISO 7101 has already helped both the pilot hospitals to improve their healthcare management processes. Benefits already observed include:

Stronger leadership and more collaborative decision-making

Transitioning from a rigid 'command and control' model to a participative management approach has fostered better clinical governance, improved communication, and a culture of continuous improvement.

Enhanced quality and risk management

Dr Mehta's Hospital, for example, now conducts more comprehensive audits, covering infection control (hand hygiene compliance, PPE adherence), facility maintenance (cleaning protocols, biomedical waste disposal), and clinical safety across both its locations, ensuring a proactive approach to patient safety.

Improved patient safety and infection control

Strengthened sterilization protocols and rigorous hygiene standards have resulted in better infection prevention. Annai Velankanni Hospital, for example, has reported a significant reduction in hospital-acquired infections (HAIs) in its Central Sterile Services Department (CSSD).

Greater employee engagement and accountability

The implementation of quality circles and multidisciplinary committees has empowered healthcare teams, increasing staff participation in decision-making while ensuring adherence to documented protocols and best practices.

Advanced workforce training and competency development

Structured training programs have enhanced clinical skills, improving patient interactions, continuity of care, and overall staff motivation.

Regulatory compliance and standardization

Alignment with national and international healthcare regulations has been streamlined, ensuring consistent adherence to quality, safety, and sustainability standards.

Operational efficiency and resource optimization

Reduced administrative bottlenecks, improved interdepartmental coordination, and better resource allocation have enhanced service delivery, minimizing delays and maximizing patient throughput.

Key trends in hospital improvement

Dr Mehta Hospital:

- ↑ Improved regulatory compliance
- ↓ Reduced readmission rates
- ↑ High and stable compliance in laboratory safety
- ↑ Improved mock drill variations – indicating better emergency preparedness
- ↑ High and stable patient satisfaction.

Annai Velankanni Hospital:

- ↑ Consistently good regulatory compliance
- ↓ Significantly reduced readmission rates
- ↓ Decreasing medication 'stock outs' – indicating robust inventory management
- ↑ Improved employee satisfaction
- ↓ Low medication errors
- ↑ Improved blood issue turnaround time
- ↑ High patient satisfaction.



Looking to the future

For Dr Mehta's Hospital and Annai Velankanni Hospital, the implementation of ISO 7101 – and, ultimately, BSI certification to this new healthcare quality standard – offers a robust foundation to deliver superior healthcare and helps them meet statutory and regulatory requirements. It ensures there is the opportunity both to enhance the patient experience during care and to continually improve clinical outcomes.

By contributing to the well-being of patients, the standard also enhances the two hospitals' reputation, positioning them as reliable, resilient, high-quality service providers in the competitive medical tourism market.

CAHO's Dr Agarwal, sums up, "Participation in BSI's impact pilot project in India has supported these hospitals to become early adopters of the standard, helping to build patient trust in the healthcare industry."

He concludes,

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We're happy to be working alongside BSI towards hospitals achieving ISO 7101 certification, which demonstrates their commitment to continuous improvement and the pursuit of excellence in healthcare delivery."

Dr Vijay Agarwal, President of Consortium of Accredited Healthcare Organizations (CAHO)

Why BSI for the healthcare industry?

BSI is a business improvement and standards company and for over a century BSI has been recognized for having a positive impact on organizations and society, building trust and enhancing lives.

Today BSI partners with more than 77,500 clients in 195 countries and engages with a 15,000 strong global community of experts, industry and consumer groups, organizations and governments.

Utilizing its extensive expertise in key industry sectors such as healthcare, BSI delivers on its purpose by helping its clients fulfil theirs.

BSI provides organizations with the confidence to grow by partnering with them to tackle society's critical issues – from climate change to building trust in digital transformation and everything in between – to accelerate progress towards a better society and a sustainable world.

References

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3. Madhur M. "We expect India's medical tourism market to achieve a compound annual growth rate of more than 20% between 2023 and 2027 to more than US \$35bn." HFS, global research and advisory firm, October 2023. <https://www.hfsresearch.com/research/india-medical-tourism/#:~:text=India's%20medical%20tourism%20has%20grown,as%20the%20US%20and%20UK.>

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