

Improving Oncology Patient Safety through Integrated Clinical Audits



Image caption: Medical Team Analysing Data – Healthcare Innovation with Digital Technology

Modern hospital governance increasingly prioritises compliance with international standards to enhance quality and manage risk. This is especially pertinent in oncology, where patient complexity demands rigorous care coordination. At the IRCCS Fondazione Istituto Nazionale dei Tumori in Milan, a revised auditing approach was implemented to move beyond traditional internal assessments. The newly introduced INTegrated Audit Model (INTAM) aligns audit activities with ISO 9001:2015 and Joint Commission International (JCI) standards, placing the patient journey at the centre of the evaluation. By embedding audits into integrated care pathways (ICPs), the model promotes continuous quality improvement and heightened patient safety.

From Internal Checks to Patient-Centred Tracers

Initially, audits at the institute were unit-specific and focused mainly on verifying legal documentation and ISO compliance. While useful, this approach lacked a systemic view of patient care across departments. A comprehensive evaluation between 2016 and 2020 revealed the need for standardisation and a shift from decentralised audits to a holistic model encompassing risk management and clinical governance. In response, the INTAM was introduced, incorporating the JCI's Tracer Methodology and aligning audits with ICPs.

The Tracer approach evaluates the real-world application of clinical protocols by following a patient's care journey across multiple units. In this context, six Tracers were conducted between 2022 and 2023, each focusing on specific oncological pathways such as colorectal, breast and thoracic cancers. The model enabled structured evaluation across departments, helping to identify non-conformities and areas for improvement related to patient identification, medication safety and fall prevention.

Aligning Practice with Standards through Structured Measurement

The INTAM framework follows the Plan-Do-Check-Act cycle and integrates international guidelines, particularly ISO 9001:2015 and JCI standards. During on-site audits, each department's compliance with these benchmarks was examined, with findings documented against 17 key topics. These included documented information management, medication processes, staff training, outcome monitoring and customer satisfaction. A total of 31 units were audited, and reports revealed 11 non-conformities and 46 observations.

Key issues included inconsistencies in documentation, gaps in personnel training and a lack of structured performance reviews. Importantly, each finding was cross-referenced with corresponding ISO and JCI codes, enabling targeted improvement strategies. The use of ICPs ensured that audits reflected actual clinical practices rather than merely procedural compliance. By tracing the patient journey, this model provided a realistic and comprehensive assessment of care delivery, aiding preparation for external audits and strengthening the hospital's clinical governance.

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Building Capacity through Continuous Training and Engagement

A critical success factor of the new audit model has been the investment in auditor training. Between 2019 and 2023, a dedicated programme equipped auditors with skills in risk management, international standards and the Tracer Methodology. Training included simulations and practical exercises to ensure auditors could apply their knowledge effectively. Additional instruction was provided on integrating ICPs into the audit process, reinforcing a multidisciplinary, patient-focused approach.

Auditors reported increased confidence in evaluating interconnected departmental activities and in using the checklist that will be standardised in future audits. Equally, auditees responded positively, noting improved collaboration, clearer insights into operational processes and alignment with accreditation standards. Units involved in the Tracer process appreciated the method's focus on real-world scenarios and its role in fostering a culture of accountability and shared learning. The model also requires compliance with national safety recommendations from the Italian Ministry of Health, reinforcing its relevance and breadth.

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The introduction of the INTEgrated Audit Model has marked a significant advance in quality assurance and risk management at the IRCCS Istituto Nazionale dei Tumori. By embedding audits within the patient journey and aligning them with both international and national standards, the model has enabled a more realistic and effective assessment of healthcare delivery. It has transformed audits from isolated checks into strategic tools for continuous improvement. The structured methodology has identified critical gaps and fostered a culture of engagement among auditors and clinical teams.

Looking forward, the model shows potential for broader application across thematic care pathways such as pharmacovigilance and patient education. Ongoing training, standardised tools and regular feedback will be essential to sustaining and evolving the approach. Ultimately, this model serves as a replicable framework for other institutions aiming to enhance patient safety, clinical integration and operational excellence in oncology care.

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