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GLOBAL TRENDS AND APPLICATIONS OF ISO CERTIFICATION IN DENTAL PRACTICE MANAGEMENT AND DENTAL ACADEMIA: A NARRATIVE REVIEW

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ABSTRACT

Objective: International Organization for Standardization (ISO) standards are increasingly referenced across healthcare delivery, yet their specific penetration into dental practice management and dental academia remains poorly characterised as a unified body of evidence. This narrative review synthesises the available literature and organisational documentation on the application, impact, and global distribution of ISO certification within dentistry, spanning private and institutional practice as well as dental education.

Methodology: A narrative literature review was undertaken using PubMed/MEDLINE, Scopus-indexed journals, and the official repositories of the International Organization for Standardization, the FDI World Dental Federation, the Commission on Dental Accreditation, and relevant national regulatory bodies, including South African authorities. Search terms combined "ISO", "quality management", "dental practice", "dental education", and related standard designations (ISO 9001, ISO 13485, ISO 21001, ISO/IEC 17024). English-language sources published up to September 2026 were included, with priority given to systematic reviews, empirical studies, and authoritative policy statements.

Results: ISO/TC 106 (Dentistry) underpins product and materials standardisation, while ISO 9001 is the most widely adopted management-system standard in dental practice, with documented associations with patient satisfaction, safety culture, and operational efficiency, though the underlying evidence base remains methodologically limited. ISO 13485 governs dental device and prosthetic manufacturing quality systems. In dental academia, ISO's role is emergent rather than dominant, operating alongside specialised accreditation bodies through instruments such as ISO 21001 for educational organisations and ISO/IEC 17024 for personnel certification. Global uptake is uneven, concentrated in Europe and high-income settings, with structural barriers reported in low- and middle-income countries, including parts of Africa.

Conclusion: ISO certification offers a structured, internationally recognised framework for quality management in dentistry, complementing rather than replacing profession-specific accreditation. Broader, dentistry-specific, and low-resource-setting research is required to strengthen the evidence underpinning its adoption.

Keywords: ISO Certification; Quality Management Systems; Dental Practice Management; Dental Education; ISO 9001; Oral Healthcare Standards

1 INTRODUCTION

The International Organization for Standardization (ISO) is an independent, non-governmental federation of close to 175 national standards bodies that develops voluntary, consensus-based international standards spanning virtually every sector of economic and professional activity [1,2]. Standards, specifications, and guidelines exist to secure reliable, comparable, and high-quality outcomes by defining agreed methods, terminology, and criteria [1]. Within dentistry, standardisation has a long history: dental-specific international standards have been developed since the 1960s, predominantly under the auspices of ISO Technical Committee 106 (ISO/TC 106, "Dentistry"), which now oversees close to 200 published standards addressing terminology, performance and safety specifications for dental materials, instruments and equipment, and clinically relevant laboratory test methods [2,3].

Beyond product-level standardisation, a distinct and increasingly visible application of ISO standards concerns the management of dental services themselves. Quality management system (QMS) standards, most notably ISO 9001, and sector-specific derivatives such as ISO 13485 for medical devices, have been adopted by hospital dental departments, private clinics, dental laboratories, and, less commonly, by dental schools and continuing-education providers seeking to formalise administrative, clinical, and educational processes [4-7]. In parallel, dental education has historically relied on profession-specific accreditation systems, such as the Commission on Dental Accreditation (CODA) in the United States, rather than generic ISO management-system certification, although newer ISO instruments targeting educational organisations and professional certification bodies are beginning to intersect with this space [8-11].

Despite this growing footprint, the literature on ISO certification in dentistry is fragmented across disparate disciplines, health management journals, dental-specific publications, and organisational grey literature, with no single synthesis addressing both dental practice management and dental academia across global contexts, including under-represented low- and middle-income settings such as sub-Saharan Africa. This review therefore aims to (i) characterise the principal ISO standards relevant to dental practice management and dental academia; (ii) synthesise the available evidence on their implementation and impact; and (iii) examine patterns of global and regional variation, including barriers to adoption, in order to inform practitioners, educators, and policymakers considering ISO-based quality frameworks in oral healthcare.

2 MATERIALS AND METHODS

This article follows a narrative review design, appropriate to a topic that spans heterogeneous standards, sectors (clinical practice, laboratory manufacturing, and education), and geographic contexts not amenable to a single homogeneous systematic protocol. A structured search was conducted across PubMed/MEDLINE and Scopus-indexed journals, supplemented by targeted retrieval from the official repositories of the International Organization for Standardization, the FDI World Dental Federation, the Commission on Dental Accreditation, the Health Professions Council of South Africa, and the South African National Accreditation System.

Search terms combined the root term "ISO" or "International Organization for Standardization" with "dental", "dentistry", "oral health", "quality management", "dental education", "dental academia", and named standards including ISO 9001, ISO 13485, ISO/TC 106, ISO 21001, and ISO/IEC 17024. Additional searches addressed related constructs, including "hospital ISO certification", "patient safety culture", and "quality improvement low- and middle-income countries", to situate dentistry-specific findings within the broader healthcare quality literature. Reference lists of retrieved systematic reviews were hand-searched for additional primary studies.

Eligible sources comprised English-language, peer-reviewed original studies, systematic and narrative reviews, official ISO and professional-body documentation, and national regulatory publications relevant to ISO certification within dental or closely analogous healthcare and educational settings, published up to September 2026. Sources without verifiable authorship or institutional provenance, and purely promotional or vendor material, were excluded from the evidentiary synthesis, although selected regulatory and standard-body publications were retained for descriptive and contextual purposes. Given the heterogeneity of study designs identified, findings were synthesised narratively and organised thematically rather than pooled quantitatively; no formal risk-of-bias scoring or meta-analysis was undertaken, consistent with the scope of a narrative review. As this review did not involve human participants, animal subjects, or identifiable patient data, no ethical approval or informed consent was required.

3 RESULTS AND DISCUSSION

3.1 The ISO Framework Relevant to Dentistry

ISO/TC 106 (Dentistry) is organised into several subcommittees addressing, among other areas, dental materials, dental instruments, dental equipment, and terminology, and is supported by 31 participating national member bodies and 19 observing members [2]. Its formal scope is the standardisation of terminology, test methods, and specifications applicable to materials, instruments, appliances, and equipment used across all branches of dentistry [4]. The FDI World Dental Federation has formally endorsed collaboration with ISO/TC 106 since 2004, reaffirming in a 2025 policy statement that ISO standards provide a basis for certifying and harmonising dental products, thereby supporting high-quality treatment and improved oral health worldwide, and encouraging national dental associations to reference appropriate ISO standards in national policy [3]. Complementing this product- and materials-oriented normative architecture, Schmalz, Jakubovics and Schwendicke have distinguished standards, specifications, and guidelines as related but distinct normative instruments spanning the full pathway from research methodology and laboratory testing to clinical reporting and device evaluation in oral healthcare, noting the increasing relevance of standardisation to emerging domains such as artificial intelligence in dental research [1].

Distinct from this materials- and device-focused stream, a second and organisationally separate category of ISO standards addresses the management of healthcare organisations themselves, irrespective of clinical discipline. It is this second category, principally ISO 9001 and its sector-specific derivatives, that underlies the concept of "ISO-certified" dental practices, laboratories, and institutions discussed in the remainder of this review.

3.2 ISO 9001 and Quality Management in Dental Practice

ISO 9001:2015, Quality Management Systems – Requirements, is the most widely adopted generic management-system standard globally and the standard most frequently associated with certified dental clinics, hospital dental departments, and dental laboratories [5]. It specifies requirements for a documented quality management system oriented around process control, risk-based thinking, customer satisfaction, and continual improvement, and is applicable without modification to service organisations that have no discipline-specific standard of their own, a category that has historically included general dental practice [5].

Empirical evidence on ISO 9001 in dentistry originates substantially from early single-institution case reports. Kenny, Conway and Johnston described the development of ISO 9002 quality management documentation for Canadian dental practices in the late 1990s, an early example of formal quality-system adoption in dentistry [9], and Casas, Kenny and Johnston subsequently reported a three-year experience of two hospital-based Canadian dental clinics registered to ISO 9002, later transitioning to ISO 9001:2000, finding that registration supported responsive quality systems with an emphasis on patient satisfaction and measurable continuous improvement, although corrective and preventive action processes were underused owing to duplication with separate institutional risk-management systems [8].

More recent evidence has been synthesised at the level of the broader dental-clinic literature. Crisan, Covaliu and Chis conducted a systematic literature review of 72 sources on quality management initiatives, including ISO-based systems, in dental clinics, applying a Context–Intervention–Mechanism–Outcome framework. They identified five mechanisms through which quality management initiatives operate in dental settings, ranging in complexity from overall quality improvement, through patient satisfaction, service quality, and internal process improvement, to business outcomes, concluding that oral healthcare quality management constitutes a distinct and maturing field within the wider healthcare quality literature [7].

Evidence from the broader hospital literature, while not dentistry-specific, is instructive given the structural similarity between hospital departments and dental clinical units. Yousefinezhadi and colleagues conducted a systematic review of the effect of ISO 9001 and the European Foundation for Quality Management (EFQM) model on hospital performance, identifying seven eligible studies from an initial pool of 121 and concluding that, while the underlying evidence base was limited in robustness and quality, available data suggested ISO 9001 and EFQM implementation could improve hospital performance, with no negative effects identified [10]. A more recent systematic review by Boukhaldi and colleagues, following PRISMA guidance and screening 246 records for studies published between 2014 and 2024, identified 23 eligible studies on ISO 9001 in hospital departments providing direct clinical care. The review found that ISO 9001 adoption was generally associated with improved care quality, patient safety, and organisational efficiency, but that most evidence originated from Europe, with minimal representation from resource-limited settings, and identified limited funding, staff resistance to change, and difficulty adapting an industry-derived standard to clinical practice as recurring implementation barriers, alongside leadership commitment, staff engagement, and external certification-body support as key success factors [11].

Two recent Greek studies illustrate both the mechanisms and the limits of ISO certification's effect on frontline safety culture. Kyriakeli and colleagues conducted a two-phase cross-sectional study comparing ISO-certified and non-certified departments in a tertiary public hospital before and 18 months after certification, using the Hospital Survey on Patient Safety Culture instrument. Certification was associated with statistically significant improvements in supervisor and manager expectations promoting safety, alongside significant changes in teamwork within units and handoffs and transitions, but no significant change in overall perception of safety or non-punitive response to error, suggesting that certification reinforces structured managerial oversight without uniformly transforming frontline safety perceptions [12]. A related analysis by the same lead author examined the Greek experience of ISO and the healthcare-specific EN 15224 standard in public hospitals, situating certification within the broader post-"To Err Is Human" patient-safety movement and framing standardisation as a mechanism for building institutional trust rather than a guarantee of safety outcomes in isolation [13].

Taken together, this literature indicates that ISO 9001 adoption in dental and closely analogous clinical settings is consistently associated with improved documentation, process standardisation, and measurable gains in selected quality and safety-culture domains, but that the underlying evidence base remains dominated by observational, single-institution, and pre-post designs concentrated in European and North American settings, with a corresponding scarcity of dentistry-specific controlled research.

3.3 ISO 13485 and Sector-Specific Standards

ISO 13485:2016, Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes, is a standalone, ISO 9001-derived standard developed specifically for organisations involved in the design, manufacture, and lifecycle management of medical devices, including dental prosthetic and appliance manufacturers, dental implant producers, and in-house dental laboratories [6]. It applies to organisations at any stage of the device lifecycle, imposes heightened requirements for risk management, traceability, and post-market surveillance relative to generic ISO 9001, and underpins regulatory conformity assessment, including CE marking, in the European Union, as well as regulatory recognition in Canada, Japan, Australia, and, since February 2026, incorporation by reference into United States Food and Drug Administration quality-system regulation [6]. For dental practice management specifically, ISO 13485 certification is most relevant where a clinic or associated laboratory manufactures, reprocesses, or maintains reusable medical devices such as implants, orthodontic appliances, or sterilisable surgical instruments, functions that carry device-traceability and sterilisation-validation obligations distinct from, and more stringent than, those addressed by ISO 9001 alone.

Several further ISO management-system standards are cited in professional and industry guidance as relevant, though not core, to dental practice quality frameworks, including ISO 14001 for environmental and biomedical waste management, ISO 45001 for occupational health and safety of dental staff, and ISO/IEC 27001 for information security applicable to electronic patient records. Evidence supporting the dentistry-specific application of these standards remains sparse relative to ISO 9001 and ISO 13485, and their adoption is generally reported as complementary to, rather than a substitute for, a primary quality management system.

3.4 ISO Standards in Dental Academia

The role of ISO standards in dental academia is comparatively underdeveloped and operates alongside, rather than in place of, profession-specific accreditation systems. In the United States, the Commission on Dental Accreditation employs a collaborative peer-review process, distinct from ISO certification, to evaluate over 1,400 predoctoral, advanced, and allied dental education programmes against discipline-specific standards addressing institutional effectiveness, curriculum, and patient-care quality, with accredited programmes subject to follow-up site review, typically every seven years [14]. CODA additionally offers fee-based consultation and accreditation services to established international predoctoral dental programmes, which are evaluated against the same standards applied to United States programmes [15]. This model, of specialised peer accreditation rather than generic ISO certification, is broadly mirrored by other national and regional dental accrediting bodies internationally.

Nonetheless, two ISO instruments intersect increasingly with dental education. First, ISO 21001:2018, Management Systems for Educational Organizations, provides a discipline-neutral management-system standard emphasising learner-centred processes, stakeholder engagement, and continual improvement, and has been adopted by some universities and professional training providers, including institutions offering dental faculties, as a complement to discipline-specific accreditation rather than a replacement for it [16]. Second, ISO/IEC 17024, Conformity Assessment – General Requirements for Bodies Operating Certification of Persons, sets international requirements for organisations that certify individuals' competence, and has been proposed within dental hygiene professional literature as a mechanism to extend the rigour applied to pre-licensure dental education toward post-licensure certificate programmes and continuing-competence credentials, which currently vary considerably in quality assurance relative to published global standards [17]. Advocates of ISO/IEC 17024 accreditation, typically administered through national

accreditation bodies, argue that it would provide independently verified, internationally recognised assurance of post-licensure competence for allied dental personnel, comparable to models already established in nursing [17].

Overall, the available evidence suggests that ISO's contribution to dental academia is presently supplementary and administrative in nature, most visible in institution-wide management-system certification and emerging personnel-certification frameworks, rather than in direct substitution for specialised programmatic accreditation bodies, which remain the dominant and most clinically authoritative quality assurance mechanism for dental curricula and clinical training.

3.5 Global and Regional Variation

The distribution of ISO-based quality management in dentistry is markedly uneven across regions. European settings account for the largest share of published implementation experience, reflecting both an established regulatory culture of healthcare standardisation and multinational research collaborations such as the Deepening our Understanding of Quality Improvement in Europe (DUQuE) project examining ISO 9001 certification and accreditation across acute-care hospitals in several European Union member states. Country-level examples, including the Greek public hospital experience with ISO 9001 and the healthcare-specific EN 15224 standard, further illustrate a relatively mature regional infrastructure for certification, audit, and outcome evaluation [12,13].

North American experience is characterised by early pioneering adoption in Canadian dental clinics during the 1990s and early 2000s [8,9], but comparatively limited subsequent published literature on ISO-specific certification in United States dental practice, where quality assurance in dentistry has instead been channelled predominantly through professional licensure and CODA accreditation of training programmes rather than generic ISO management-system certification of practices themselves [14].

Evidence from low- and middle-income countries remains markedly scarcer. The systematic review by Boukhaldi and colleagues found that, despite the demonstrated effectiveness of ISO 9001 in numerous high-income healthcare institutions, its application in low- and middle-income countries remains limited by structural constraints, limited resources, and the absence of context-specific implementation strategies, with minimal representation of such settings in the eligible literature [11]. The authors proposed a phased implementation framework, beginning with structured self-assessment, followed by development of an organised quality management system with context-appropriate indicators, and concluding with systematic evaluation and refinement, as a practical route for resource-limited clinical services, including by extension dental services, to build quality management capacity incrementally rather than through direct transposition of models developed in high-income settings [11].

In the South African context specifically, dental practice and dental education operate within a dual regulatory architecture. The Health Professions Council of South Africa (HPCSA) statutorily regulates dental practitioners, dental therapists, and oral hygienists, and, in conjunction with bodies including the Council on Higher Education and the South African Committee of Dental Deans, oversees accreditation of dental education and training programmes [18,19]. Separately, the South African National Accreditation System (SANAS) accredits laboratories, certification bodies, and inspection bodies against international standards including ISO/IEC 17025, ISO 15189, and ISO/IEC 17021, the latter underpinning third-party ISO 9001 certification of organisations including, where pursued, private dental practices and dental laboratories [22]. A four-tier dental workforce comprising oral hygienists, dental therapists, dentists, and dental specialists, trained across four dental schools, currently serves South African oral health needs [20], within a broader national primary healthcare quality assurance culture that has historically emphasised structural, process, and outcome-based standards of care alongside emerging international frameworks [21]. Direct, published evidence specifically documenting ISO 9001 or ISO 13485 certification of South African dental practices or dental faculties was not identified in this review, representing a notable gap given the existing SANAS and HPCSA infrastructure capable of supporting such certification.

3.6 Barriers and Enablers to Implementation

Across the synthesised literature, recurring barriers to ISO adoption in dental and closely analogous clinical settings include the financial and administrative cost of certification and periodic surveillance audits, resistance to change among clinical staff accustomed to informal or discipline-specific quality practices, the perceived mismatch between an industrial, generic management standard and the particularities of direct clinical care, and, in resource-constrained settings, competing priorities for limited infrastructure investment [7,11]. Duplication between ISO-mandated corrective and preventive action processes and pre-existing institutional risk-management or incident-reporting systems has also been identified as a source of underuse of otherwise valuable quality-system components [8].

Conversely, enabling factors reported across the literature include strong and visible leadership commitment to the quality management system, meaningful staff engagement in system design rather than top-down imposition, external support and mentorship from certification bodies, and phased, context-sensitive implementation strategies rather than

wholesale transposition of standards developed for high-resource settings [7,11]. The consistency of these enabling factors across both dentistry-specific and broader hospital literature suggests that successful ISO implementation in oral healthcare depends less on the specific clinical discipline than on organisational readiness, change-management practice, and the availability of sustained external and internal support.

3.7 Quality of the Evidence Base

The evidence underpinning ISO certification in dentistry remains methodologically constrained. Much of the dentistry-specific literature comprises descriptive single-institution case reports, cross-sectional surveys, or narrative and systematic reviews of predominantly observational primary studies, with an absence of randomised or robustly controlled designs, a limitation explicitly acknowledged in systematic reviews of ISO 9001 in both hospital and dental-clinic contexts [7,10,11]. Outcome measures vary considerably across studies, spanning patient satisfaction, safety-culture survey domains, business and operational indicators, and process-compliance metrics, complicating direct comparison and pooled synthesis. Geographic concentration of the available evidence in Europe, together with sparse representation from low- and middle-income countries and from dental academia specifically, further limits the generalisability of existing findings to global dental practice and education. Broader healthcare-quality scholarship corroborates this picture, noting substantial international variation in how healthcare quality is defined, measured, and operationalised, and calling for context-sensitive, rather than uniformly transplanted, quality-system frameworks, particularly in developing-country settings [14].

4 CONCLUSION

ISO certification, principally through ISO 9001 and, where device manufacturing or reprocessing is involved, ISO 13485, provides an internationally recognised, structured framework for quality management in dental practice, with an accumulating body of evidence associating certification with improved documentation, process standardisation, patient satisfaction, and selected dimensions of patient safety culture. Within dental academia, ISO's role remains emergent and largely complementary to established, discipline-specific accreditation systems such as those administered by the Commission on Dental Accreditation, with newer instruments including ISO 21001 for educational organisations and ISO/IEC 17024 for personnel certification beginning to extend standardisation into curriculum management and post-licensure credentialing. Global adoption is markedly uneven, concentrated in European and other high-income settings, with structural, financial, and contextual barriers constraining uptake in low- and middle-income countries, including much of the African continent, despite the presence of enabling national infrastructure, such as South Africa's HPCSA and SANAS systems, capable of supporting such certification. Future research should prioritise dentistry-specific, methodologically robust, and geographically diverse studies, including from under-represented low-resource settings, to strengthen the evidence base guiding practitioners, dental educators, and policymakers in the appropriate and context-sensitive adoption of ISO standards across dental practice management and dental academia

STATEMENTS ON COMPLIANCE WITH ETHICAL STANDARDS

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Disclosure of conflict of interest

The author declares no financial, professional, institutional, or personal conflicts of interest relevant to this manuscript.

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