



(REVIEW ARTICLE)



ISO CERTIFICATION AND STANDARDISATION SYSTEMS IN DENTAL PUBLIC HEALTH POLICYMAKING AND GOVERNMENT-BASED DENTAL SYSTEMS: A GLOBAL NARRATIVE REVIEW

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Global Journal of Research in Medicine and Dentistry, 2026, 05(04), 070–077

Publication history: Received on 25 August 2026; revised on 30 September 2026; accepted on 02 October 2026

Article DOI: <https://doi.org/10.58175/gjrmd.2026.5.4.0111>

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ABSTRACT

Background: Oral diseases are the most widespread noncommunicable diseases, and governments are being urged to progress towards universal health coverage for oral health. Quality assurance and standardisation are increasingly discussed as enabling mechanisms, yet the role of International Organization for Standardization (ISO) systems in dental public health policy has not been synthesised. Objective: To review how ISO standards and certification are used in dental public health policymaking and in government-based dental systems globally, and to identify gaps in the evidence. Methods: A narrative review was undertaken using targeted searches of open-access biomedical literature and of official ISO, World Health Organization (WHO) and FDI World Dental Federation sources. Findings were synthesised thematically. Results: ISO influence operates through four domains: (i) product and technical standards developed by ISO/TC 106 Dentistry; (ii) terminology and data standards; (iii) environmental instruments, such as amalgam-separator requirements supporting implementation of the Minamata Convention; and (iv) quality management system certification, principally ISO 9001 and its predecessors, applied to dental facilities and to government health-ministry functions. Evidence on dental facilities is dominated by descriptive reports and recommendations rather than outcome data, is concentrated in high-income settings, and no national dental programme-level evaluation of ISO certification was identified in the sources reviewed. Conclusion: ISO systems are established infrastructure for dental product safety and offer a credible governance tool for process consistency, but their contribution to population oral health outcomes and equity remains unproven. Certification should complement, not replace, outcome-based quality measures, and evaluative research in public-sector and low- and middle-income settings is a priority.

Keywords: ISO standards; Quality management systems; Dental public health; Oral health policy; ISO 9001; Health system governance.

1 INTRODUCTION

Oral diseases are the most widespread noncommunicable diseases, affecting an estimated 3.5 billion people, or 45% of the global population, across the life course [1]. Their economic toll is substantial: in 2015, dental diseases were estimated to cost US\$356.80 billion in direct treatment expenditure and US\$187.61 billion in productivity losses worldwide [2]. In response, the World Health Assembly adopted a global strategy on oral health in 2022 with a vision

of universal health coverage for oral health for all individuals and communities by 2030 [1,3]. Delivering that vision will depend not only on financing and workforce, but also on the systems that make dental care safe, consistent and measurable.

Quality management in oral healthcare, however, is a young field. A recent systematic review concluded that research is still concerned largely with defining quality and establishing metrics, and that quality in oral healthcare is less clearly defined than in general medicine [4,5]. An international working definition has proposed seven domains of oral healthcare quality: patient safety, timeliness, patient-centredness, equitability, efficiency, effectiveness and accessibility [4,6]. Against this background, governments and dental organisations frequently turn to internationally recognised standards as a shared language for safety, consistency and accountability.

The International Organization for Standardization (ISO) is an independent international standard-setting body whose voluntary consensus standards reach dentistry in several ways. Some are technical specifications for dental products; some are terminology and data standards; and others are management-system standards, notably ISO 9001, against which organisations may be independently certified by accredited third-party certification bodies. Each of these has different implications for public policy, yet they are seldom discussed together in the dental public health literature.

The objective of this review was therefore to examine how ISO standards and certification systems are used in dental public health policymaking and in government-based dental systems globally, to appraise the strength of the evidence for their value, and to identify priorities for policy and research.

2 MATERIALS AND METHODS

2.1 Study design

This was a narrative review with structured, targeted searching. A narrative design was chosen because the topic spans heterogeneous evidence types, including peer-reviewed studies, standards-body documents, intergovernmental reports and government announcements, which are not amenable to meta-analysis or a conventional systematic protocol.

2.2 Sources and search approach

Searches covered open-access biomedical literature (PubMed and PubMed Central), and the official websites and repositories of ISO (committee pages and standards catalogue), the World Health Organization (including the Global Oral Health Status Report and the global oral health data portal), the FDI World Dental Federation, the Canadian Dental Association, and selected national ministries of health. Search concepts combined ISO standards, ISO 9001, quality management system, certification, accreditation, dental clinics, dental public health, oral health policy and government health services. The reference lists of key reviews were also screened. The most recent searches were completed in September 2026.

2.3 Eligibility

Sources were included if they described the development or content of ISO standards relevant to dentistry, reported on ISO-based certification or quality management in dental facilities, described ISO certification of government health authorities or regulatory functions, or connected standards to oral health policy instruments. Sources in English and Spanish were considered. Commercial marketing material was not used as evidence of effectiveness; where corporate or ministry announcements are cited, they are used only to illustrate that certification has occurred.

2.4 Synthesis

Information was extracted on the type of ISO instrument, the level of application (international, national, facility), the policy function served, and reported outcomes. Findings were synthesised thematically into four domains and appraised against the seven-domain working definition of oral healthcare quality [6]. Because the review was narrative, no formal risk-of-bias tool was applied, and conclusions on strength of evidence reflect the design and outcome reporting of the sources identified.

2.5 Ethical considerations

Ethical approval and informed consent were not required, as the review used only published and publicly available documents and involved no human participants, patient records or identifiable data.

3 RESULTS AND DISCUSSION

3.1 Product and technical standards: the ISO/TC 106 infrastructure

The core of ISO's contribution to dentistry is the technical committee ISO/TC 106 Dentistry, established in 1962 with a scope covering terms and definitions, performance, safety and specification requirements for dental products, and clinically relevant laboratory test methods [7]. Its secretariat is held by the Standards Council of Canada and managed by the Canadian Dental Association [7,8]. The committee took over standardisation work begun by the FDI World Dental Federation, which had produced nine specifications between 1953 and 1958, and FDI remains a liaison member [9]. The committee has published 201 standards [8], compared with 175 in 2017, when it had 44 member economies [10]. Table 1 summarises the subcommittee structure.

Table 1: ISO/TC 106 Dentistry: subcommittees and published standards

Subcommittee	Title	Published standards (n)
SC 1	Filling and restorative materials	25
SC 2	Prosthetic materials	30
SC 3	Terminology	13
SC 4	Dental instruments	77
SC 6	Dental equipment	20
SC 7	Oral care products	12
SC 8	Dental implants	10
SC 9	Dental CAD/CAM systems	9

Source: ISO/TC 106 standards catalogue [11]. Counts are as displayed in the catalogue at the time of access and are subject to change as standards are revised or withdrawn.

These standards are largely invisible to patients and policymakers, but they carry public-health weight. Representatives of the Canadian dental profession describe them as determining the performance requirements for amalgam separators, the colour coding that indicates bur grit, and exposure limits for ultraviolet irradiance from operating lights, and as enabling interoperability, for example between burs and handpieces [8]. For governments, such standards are a ready technical basis for procurement specifications, product regulation and safety inspection, allowing a health ministry to reference an international benchmark rather than to develop its own. The standards catalogue also shows that the system is dynamic: the two-digit tooth designation standard, for example, appears in the catalogue as a withdrawn 1977 edition [11], illustrating that standards are periodically revised and that national policies which cite them must track the current edition.

A limitation for equity is representation. Participation in standard-setting depends on national standards bodies and professional associations having the resources to send experts to committee meetings; the 44 member economies recorded in 2017 [10] represent a minority of the world's countries, and this may shape whose clinical settings and price points the standards reflect. This is an inference from membership data rather than an empirical finding, and warrants direct study.

3.2 Terminology and data standards

Policy depends on comparable data. ISO/TC 106 Subcommittee 3 (Terminology), established in 1989, has published 13 standards and has working groups on the harmonisation of dental codes and abbreviations, revision of the dental vocabulary standard (ISO 1942), and terminology for forensic orodental data [12]. These activities are relevant to national oral health information systems and cross-country reporting. The WHO Global Oral Health Status Report, for example, provides country oral health profiles for all 194 Member States drawn from global data sources [1]. Although no source reviewed evaluated whether ISO dental terminology improves the comparability of national surveillance data, standardised vocabularies and codes are a plausible enabling condition for such comparability, and this is an area where evidence would be valuable.

3.3 Environmental policy: amalgam and the Minamata Convention

The clearest example of ISO-type standards intersecting with binding international policy is the Minamata Convention on Mercury. The Convention addresses dental amalgam, which contains approximately 50% elemental mercury by weight, and lists nine measures for phasing down its use [13]. Parties must implement two or more of these measures

[13]. The WHO Global Oral Health Action Plan sets a target that, by 2030, 90% of countries will have implemented such phase-down measures or phased amalgam out [14]. FDI advocates phase-down rather than phase-out, noting that affordable alternatives are not available everywhere and that premature prohibition could harm oral health, and it emphasises prevention, research on alternatives and best practice in amalgam waste management [15].

Technical standards are what make several of these measures operational. Performance requirements for amalgam separators, for example, are set within ISO/TC 106 [8]. It is therefore reasonable to argue that treaty obligations on waste management are only as verifiable as the technical standards that define compliant equipment, although the reviewed sources did not directly evaluate this relationship. For low-resource settings, the interplay is particularly important, because phase-down without accessible alternatives, or waste-management mandates without affordable compliant equipment, may widen inequalities in access to restorative care.

3.4 Quality management system certification in dental facilities

Facility-level certification, principally to ISO 9001 and its predecessor ISO 9002, is the best-known application of ISO to clinical dental services. An early, well-documented institutional example is the Canadian experience. Kenny and colleagues described a ten-month process of adapting ISO 9002 systems to institution-based dental practice, motivated by the wish to consolidate core practice standards and be ready for regulatory practice review [16]. A subsequent three-year report on two hospital-based dental clinics registered to ISO 9002:1994 found that daily equipment and process checks and internal audits formed the backbone of the quality system, and that registration gave the clinics responsive quality systems emphasising patient satisfaction and measurable continuous improvement [17]. The same report noted that corrective and protective actions were underused, partly because of duplication with two institutionally mandated risk-management and incident-reporting systems [17]. This finding matters for policy: where health authorities already impose reporting requirements, an additional certification layer can duplicate rather than add value unless systems are deliberately integrated.

The broader literature is thinner than the prominence of ISO might suggest. A systematic review of quality management initiatives in dental clinics analysed 72 sources published between 1974 and 2020, most of them from Europe and North America, and identified five mechanisms: overall quality, patient satisfaction, service quality, internal process improvement and business outcomes [4]. In that review, system-level quality management, such as ISO practices, was positioned as one stage in an evolutionary maturity model rather than the dominant approach; most initiatives focused on patient satisfaction and process improvement; and only 24 of 72 sources reported real outcomes, while 48 offered proposals only [4]. Programme-based approaches other than ISO certification have also been evaluated in dental practice settings [18].

Evidence from Latin America is similarly limited. A documentary review of ISO 9001 implementation in Ecuadorian dental clinics, drawing on studies from 2018 to 2022, reported a generally positive picture of ISO adoption across organisations, including better collaborative work, fewer errors and better risk mitigation, but also noted cases in which certified organisations did not achieve world-class quality when measured by process defects [19]. Because much of that evidence came from non-dental organisations, it should be read as indicative rather than dental-specific. Corporate dental groups in Spain and Sri Lanka have publicly announced ISO 9001:2015 certification of their clinic networks [20,21], which demonstrates commercial uptake but, as these are announcements rather than evaluations, provides no evidence of effect on patient outcomes.

3.5 ISO certification in government health authorities and public dental systems

At government level, the most detailed published account in the reviewed sources is not dental but regulatory. Health Canada's Biologics and Genetic Therapies Directorate implemented a quality management system based on ISO 9001, integrating requirements from ISO/IEC 17025 for its laboratories, and reported a regulatory system that was more robust, responsive and adaptable, with improved staff involvement, clearer process ownership and a stronger international reputation [22]. Its authors emphasised that ISO 9001 is applicable to government service organisations that do not have customers in the ordinary commercial sense, by substituting stakeholder feedback for customer feedback [22]. That adaptation is directly relevant to public dental services, where the "customer" is a patient, a community and a funder.

Ministries of health elsewhere have pursued certification of central functions. The Sultanate of Oman's Ministry of Health reported ISO 9001:2015 certification of five directorates general, including administrative, financial, pharmaceutical affairs and drug control, private health establishments, and projects and engineering, following a two-year implementation project that trained 50 internal auditors [23]. The United Arab Emirates Ministry of Health and Prevention reported certification of nine central departments to ISO 9001:2015 by an external certification body [24]. In both cases, certification targeted administrative and regulatory processes rather than clinical dental service delivery, and no dental-specific national certification programme was identified in the sources reviewed.

Governments also steer dental quality through non-ISO instruments. Regional and national quality-assurance systems for dental professionals, including initial education and continuing professional development, have been compared across Japan, the European Union and ASEAN [25], and the FDI Quality in Dentistry Policy Statement provides a professional-body framework [26]. These are the mechanisms with which ISO certification must coexist, and policy design should specify how they interact, so that certification supports rather than duplicates professional regulation.

Table 2: Levels at which ISO systems intersect with dental public health policy

Level of application	Principal ISO instruments (examples)	Policy function and status of evidence
Product and technical standards	ISO/TC 106 standards for materials, instruments, equipment, implants, oral care products and CAD/CAM	Safety, performance and interoperability; basis for procurement and regulation. Extensively developed [8,11].
Terminology and data	Dental vocabulary (ISO 1942, under revision); harmonised codes and abbreviations; forensic orodental data terminology	Comparable records and surveillance data. Under development; no evaluation identified [12].
Environmental policy	Amalgam-separator performance requirements	Supports implementation of the Minamata Convention and the WHO 2030 target [8,13,14]. Direct evaluation not identified.
Facility-level quality management	ISO 9001 family (formerly ISO 9002)	Process consistency, internal audit, patient satisfaction. Descriptive evidence, mainly high-income settings [4,16,17,19].
Government and regulatory functions	ISO 9001; ISO/IEC 17025 for laboratories	Reliability of administrative and regulatory processes. Health-ministry examples; none dental-specific identified [22-24].

Source: author's synthesis of the sources reviewed.

3.6 Critical appraisal: what ISO certification can and cannot deliver

Read against the seven-domain working definition of oral healthcare quality [6], management-system certification maps unevenly (Table 3). ISO 9001-type systems are strongest on patient-centredness, through customer focus and satisfaction monitoring, and on process consistency, through process approach, document control, internal audit and continual improvement, which are the qualities highlighted in the facility and government reports reviewed above [16,17,22]. They say little, on their own, about equity or accessibility, and they do not prescribe clinical effectiveness. This is significant for public dental systems, whose central policy problems, according to the WHO, are unequal burden and unequal access among disadvantaged groups [1].

Table 3: Conceptual alignment between the oral healthcare quality domains and ISO 9001-type management systems

Quality domain [6]	Typical alignment	Rationale (author's interpretation)
Patient safety	Partial	Risk-based process control and equipment checks help; product safety depends on ISO/TC 106 standards and clinical governance.
Timeliness	Indirect	Process monitoring can capture waiting and appointment performance if the organisation chooses to measure it.
Patient-centredness	Strong	Customer focus and satisfaction monitoring are core requirements.
Equitability	Not explicit	The standard does not require attention to disparities between population groups.
Efficiency	Partial	Process approach and resource management support efficiency, but cost-effectiveness is not assessed.
Effectiveness	Indirect	Clinical outcomes are not specified by the standard and must be defined by the organisation.

Accessibility	Not addressed	Access is a system-level policy matter beyond a facility's management system.
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Table 3 is an interpretive mapping by the author and has not been empirically validated.

Three cautions follow from the evidence. First, the outcome evidence is weak. In the systematic review of dental quality initiatives, most sources offered recommendations rather than measured results, and the evidence base was concentrated in Europe and North America [4]. Second, certification is not a guarantee of excellence: the Ecuadorian review documented certified organisations that still showed process defects [19]. Third, implementation depends on context. Leadership, organisational culture, data infrastructure, prior experience and staff involvement have been identified as factors affecting the success of quality initiatives in healthcare [4,27], and the Canadian dental experience showed that duplication with existing systems can dilute benefit [17]. Measure sets that focus on patient satisfaction while neglecting efficiency and equity, as identified in systematic reviews of dental quality measures [4,28], would leave the very policy priorities highlighted by WHO [1] unmonitored.

There are also cost and burden considerations. The reviewed sources gave little cost information, but the resources committed by ministries (for example, a two-year implementation programme and trained internal auditors in Oman [23]) suggest that certification requires sustained organisational investment. For small private practices and under-resourced public clinics, the documentation and audit burden may be disproportionate unless simplified, shared or subsidised approaches are developed. This remains a hypothesis, since the reviewed studies did not directly compare costs and benefits by clinic size or income setting.

3.7 Implications for policy and practice

On the balance of the evidence reviewed, the following implications are proposed for consideration by policymakers and professional bodies:

- Use ISO/TC 106 standards as the default technical reference for procurement, product regulation and infrastructure standards in public dental services, and track edition changes in national regulations.
- Where certification is pursued in public dental services, integrate it with existing incident-reporting, professional regulation and accreditation systems to avoid duplication, as illustrated by the Canadian clinics [17].
- Do not treat certification as a proxy for quality. Pair it with outcome-oriented indicators covering effectiveness, efficiency, access and equity, in line with the working definition of oral healthcare quality [6].
- Adapt the concept of the "customer" for public systems, using structured community and patient feedback, as the Health Canada example did with stakeholders [22].
- Align environmental standards with treaty commitments, ensuring that amalgam-separator and waste-management requirements are affordable and accessible in low-resource settings [8,13,15].
- Commission evaluative research: controlled or before-and-after studies of ISO certification in public dental clinics; cost analyses; studies in low- and middle-income countries; and assessment of whether ISO terminology improves national surveillance comparability.

3.8 Limitations of this review

This was a narrative review with targeted rather than exhaustive searching, and relevant sources, including those in languages other than English and Spanish, national grey literature and paywalled databases, may have been missed. Ministry and corporate announcements are not evaluations and were used only to show that certification has occurred. Standards counts and committee details change over time. No formal risk-of-bias appraisal was performed. Finally, Tables 2 and 3 contain interpretive syntheses that should be tested in future empirical work.

4 CONCLUSION

ISO systems are already embedded in the infrastructure of dentistry through ISO/TC 106 standards that govern product safety, performance and interoperability, and they intersect with international policy instruments such as the Minamata Convention. Management-system certification, principally ISO 9001, has been adopted by dental facilities and by government health authorities and appears to support process consistency, staff engagement and patient-centred improvement. However, the evidence linking certification to oral health outcomes, equity or cost-effectiveness is thin, largely descriptive and concentrated in high-income settings, and no dental-specific national certification programme evaluation was identified. Policymakers pursuing universal health coverage for oral health should therefore use ISO standards as enabling infrastructure and governance tools, integrate them with professional regulation and outcome-based indicators, and support rigorous evaluation, particularly in public-sector and low- and middle-income settings.

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