

ASF-EV-001

Standards Evidence Bibliography

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Approved by	Prof. Giorgi Pkhakadze, MD, MPH, PhD President, Accréditation Sans Frontières
Purpose	Evidence base supporting the development and ongoing validity of ASF accreditation standards across all facility types; submitted as part of the ASF ISQua EEA application package
Related documents	ASF-GOV-001 Standards Development Methodology · ASF-EV-002 Stakeholder Consultation Summary · ASF-EV-003 Pilot and Field Validation Summary · ASF-EV-004 ISQua EEA Crosswalk
Supersedes	ASF-EV-001 V1.0 (2026-09-30)
Next review	At each major standards revision cycle

Version History

Version	Date	Nature of change	Approved by
V0.1	2025-04-01	Initial working bibliography — internal use only	—
V1.0	2025-07-15	Published: 48 key references organised by domain	Prof. G. Pkhakadze, ASF President
V2.0	2026-04-10	Expanded to 80+ references; 8 evidence domains; evidence grading notes added	Standards Development Committee
V3.0	2026-09-30	Full annotated bibliography; ISQua EEA alignment notes per domain; approved for ISQua EEA package	Prof. G. Pkhakadze, ASF President

1. Purpose and Scope

1.1 This document constitutes the Standards Evidence Bibliography (SEB) for ASF's accreditation standards. It provides the evidentiary foundation that underpins the development of ASF's criterion sets and demonstrates that ASF standards are grounded in current scientific evidence, international best practice, and the published experience of established healthcare accreditation programmes worldwide.

1.2 The SEB is organised into eight evidence domains, each corresponding to a cluster of ASF accreditation criteria. For each domain, key references are listed with brief annotations explaining their relevance to the criterion set. The bibliography is a living document, reviewed and updated at each major standards revision cycle (see ASF-GOV-001, §4.1).

1.3 The bibliography covers the Hospital Accreditation Standard as the primary submitted standard. Evidence for the Ambulatory Clinic, Long-Term Care, and Fitness and Wellness standards draws on the same literature base, supplemented by domain-specific references for each facility type where relevant.

2. Evidence Methodology

2.1 References in this bibliography were identified through: (a) systematic searches of PubMed, Cochrane, and Embase using accreditation-relevant MeSH terms and free-text terms; (b) hand-searching of the reference lists of key systematic reviews and meta-analyses; (c) review of the published standards, guidelines, and policy documents of ISQua, JCI, Accreditation Canada, ACHS, and HQACI; (d) review of WHO and OECD quality of care frameworks; and (e) grey literature searches targeting national and regional health quality agencies.

2.2 The bibliography prioritises: (a) systematic reviews and meta-analyses over single studies; (b) studies published in the preceding 10 years over older literature, except for foundational texts; (c) evidence directly addressing the link between the criterion area and patient safety or quality outcomes; (d) international applicability over single-country studies, where both are available.

2.3 Where the evidence base for a criterion area is primarily expert consensus rather than high-quality primary evidence — as is the case in some infrastructure and governance domains — this is noted in the domain annotation, and the relevant consensus guidelines are cited.

3. Evidence by Domain

Domain 1 — Governance, Leadership and Strategic Management

Evidence supports the direct relationship between healthcare governance quality and clinical outcomes. Key sources establish that board oversight of quality, clear organisational accountability, and strategic quality planning are associated with better patient safety performance.

Ref	Citation	Relevance to ASF criteria
[1]	Jha AK, Epstein AM. Hospital governance and the quality of care. <i>Health Affairs</i> . 2010;29(1):182–187.	Governance structure (board quality oversight) directly associated with clinical outcomes — basis for ASF

Ref	Citation	Relevance to ASF criteria
		Critical governance criteria
[2]	Braithwaite J, Travaglia JF. An overview of clinical governance policies, practices and initiatives. Aust Health Rev. 2008;32(1):10–22.	Clinical governance frameworks — foundation for leadership accountability criteria
[3]	WHO. Governance for Health in the 21st Century. WHO Regional Office for Europe, Copenhagen, 2012.	WHO governance framework — cross-references to governance criteria in Hospital and LTC standards
[4]	Dixon-Woods M et al. Explaining Michigan: developing an ex post theory of a quality improvement program. Milbank Q. 2011;89(2):167–205.	Leadership culture and safety outcomes — basis for leadership commitment criteria
[5]	The Kings Fund. Leadership and Engagement for Improvement in the NHS. London: The Kings Fund, 2012.	Board-level engagement in quality — essential criteria for strategic quality planning

Domain 2 — Patient Rights and Ethical Framework

Evidence base draws on international human rights instruments, medical ethics frameworks, and empirical studies linking patient rights implementation to outcomes, satisfaction, and trust.

Ref	Citation	Relevance to ASF criteria
[6]	United Nations. Convention on the Rights of Persons with Disabilities. New York: UN, 2006.	Disability-related rights — basis for accessibility and adaptation criteria
[7]	WHO. Declaration on the Promotion of Patients' Rights in Europe. Copenhagen: WHO/EURO, 1994.	Patient rights framework — foundational source for the patient rights criterion cluster
[8]	Beauchamp TL, Childress JF. Principles of Biomedical Ethics. 8th ed. Oxford University Press, 2019.	Four-principle ethics framework (autonomy, beneficence, non-maleficence, justice) — structures the informed consent and ethical framework criteria
[9]	Levinson W et al. Not all patients want to participate in decision making. J Gen Intern Med. 2005;20(6):531–535.	Shared decision-making evidence — calibrates patient involvement criteria
[10]	European Parliament. Directive 2011/24/EU on the application of patients' rights in cross-border healthcare. Official Journal of the EU, 2011.	EU cross-border patient rights — relevant to criteria for non-national patient management

Domain 3 — Clinical Care and Patient Safety

The most extensively evidenced domain. Evidence links specific clinical care processes — hand hygiene, medication safety, surgical safety, deteriorating patient identification — directly to preventable harm reduction.

Ref	Citation	Relevance to ASF criteria
[11]	WHO. Patient Safety: Making Health Care Safer. Geneva: WHO, 2017.	WHO patient safety evidence compendium — cross-references to all Clinical Care domain criteria
[12]	Allegranzi B et al. Burden of endemic health-care-associated infection in developing countries. <i>Lancet</i> . 2011;377(9761):228–241.	Healthcare-associated infection burden — basis for Critical HAI prevention criteria
[13]	WHO. WHO Surgical Safety Checklist. Geneva: WHO, 2009.	Surgical safety checklist evidence — basis for perioperative safety Critical criteria
[14]	Haynes AB et al. A surgical safety checklist to reduce morbidity and mortality. <i>N Engl J Med</i> . 2009;360(5):491–499.	Landmark RCT demonstrating checklist impact — direct evidence for perioperative Critical criteria
[15]	Bates DW et al. Incidence of adverse drug events and potential adverse drug events. <i>JAMA</i> . 1995;274(1):29–34.	Medication error evidence — basis for medication management Critical criteria
[16]	National Patient Safety Foundation. Free from Harm: Accelerating Patient Safety Improvement. Boston: NPSF, 2015.	Comprehensive patient safety improvement framework — shapes the patient safety criterion cluster
[17]	Flodgren G et al. Interventions to improve professional adherence to guidelines for prevention of device-related infections. <i>Cochrane Database Syst Rev</i> . 2013;3:CD006559.	Evidence for infection prevention guideline adherence — Essential-tier criteria support

Domain 4 — Workforce and Human Resources

Evidence links staffing levels, credential verification, continuing education, and workforce wellbeing to patient outcomes. Key sources establish minimum staffing thresholds and the role of professional development in safety culture.

Ref	Citation	Relevance to ASF criteria
[18]	Aiken LH et al. Nurse staffing and patient mortality, nurse burnout, and job dissatisfaction. <i>JAMA</i> . 2002;288(16):1987–1993.	Landmark staffing-outcomes study — basis for Critical nursing staffing criteria
[19]	Aiken LH et al. Nurse staffing and education and hospital mortality in nine European countries. <i>Lancet</i> . 2014;383(9931):1824–1830.	European multi-country staffing evidence — international applicability for staffing criteria
[20]	Pronovost PJ et al. Physician staffing patterns and clinical outcomes in critically ill patients. <i>JAMA</i> . 2002;288(17):2151–2162.	ICU physician staffing evidence — Critical criteria for intensive care
[21]	ACHS. Credential Verification for Health Professionals. Sydney: ACHS, 2019.	Credential verification standards — basis for workforce verification criteria

Ref	Citation	Relevance to ASF criteria
[22]	WHO. Health Workforce 2030: A Global Strategy for Human Resources for Health. Geneva: WHO, 2016.	Global HRH framework — contextualises staffing criteria for LMICs

Domain 5 — Infection Prevention and Control

Strong evidence base from RCTs, systematic reviews, and surveillance data linking IPC programme components to reduced healthcare-associated infection rates.

Ref	Citation	Relevance to ASF criteria
[23]	WHO. Guidelines on Core Components of Infection Prevention and Control Programmes. Geneva: WHO, 2016.	WHO IPC core components framework — direct source for ASF IPC Critical criteria
[24]	Pittet D et al. Effectiveness of a hospital-wide programme to improve compliance with hand hygiene. Lancet. 2000;356(9238):1307–1312.	Geneva HHSF study — hand hygiene compliance evidence for IPC criteria
[25]	Proctor ML et al. A targeted multidisciplinary infection prevention programme reduces surgical site infection rates. J Hosp Infect. 2003;54(1):25–31.	Multidisciplinary IPC — basis for IPC committee and programme criteria
[26]	ECDC. European Centre for Disease Prevention and Control. Core Components for IPC Programmes. Stockholm: ECDC, 2019.	EU IPC framework — cross-references to European context IPC criteria
[27]	Allegranzi B, Pittet D. Role of hand hygiene in healthcare-associated infection prevention. J Hosp Infect. 2009;73(4):305–315.	Systematic review of hand hygiene evidence — Essential criteria support

Domain 6 — Information Management, Medical Records and Data

Evidence supports the role of complete, accurate, and accessible medical records in continuity of care, medication safety, and clinical decision-making. Data governance frameworks inform confidentiality criteria.

Ref	Citation	Relevance to ASF criteria
[28]	Committee on Quality of Health Care in America, IOM. To Err is Human. Washington DC: NAP, 2000.	Foundational patient safety text — supports information management critical criteria
[29]	Schiff GD et al. Diagnostic error in medicine: analysis of 583 physician-reported errors. Arch Intern Med. 2009;169(20):1881–1887.	Diagnostic errors linked to information gaps — basis for medical record completeness criteria
[30]	European Parliament. General Data Protection Regulation (GDPR). Official Journal EU, 2016.	GDPR requirements — basis for patient data protection criteria

Ref	Citation	Relevance to ASF criteria
[31]	Black AD et al. The impact of eHealth on the quality and safety of health care. PLoS Med. 2011;8(1):e1000387.	eHealth and quality — supports electronic record management criteria
[32]	WHO. Patient Records Manual. Geneva: WHO, 2006.	WHO medical records guidance — foundational source for Essential-tier records criteria

Domain 7 — Physical Environment, Facilities and Equipment

Evidence links physical environment standards — space adequacy, ventilation, equipment maintenance — to patient safety and infection control outcomes.

Ref	Citation	Relevance to ASF criteria
[33]	WHO. Water, Sanitation and Hygiene in Health Care Facilities. Geneva: WHO, 2019.	WASH standards in health facilities — basis for environmental hygiene Critical criteria
[34]	Ulrich RS et al. A review of the research literature on evidence-based healthcare design. HERD. 2008;1(3):61–125.	Evidence-based healthcare design — supports physical environment Significant criteria
[35]	HTM 07-01: Safe Management of Healthcare Waste. NHS England, 2013.	Healthcare waste management standards — basis for waste management criteria
[36]	WHO. Essential Medicines and Health Products: Medical Devices. Geneva: WHO, 2017.	Medical device management evidence — basis for equipment maintenance criteria
[37]	IEC 60601-1. Medical Electrical Equipment — General Requirements for Safety. Geneva: IEC, 2005.	Electrical safety standards for medical equipment — Critical equipment criteria

Domain 8 — Quality Improvement and Organisational Learning

Evidence base demonstrates that systematic quality improvement processes — incident reporting, clinical audit, performance measurement — reduce adverse events and drive measurable improvement in care quality.

Ref	Citation	Relevance to ASF criteria
[38]	Berwick DM. Continuous improvement as an ideal in health care. N Engl J Med. 1989;320(1):53–56.	Foundational CQI text — basis for quality improvement programme criteria

Ref	Citation	Relevance to ASF criteria
[39]	Donabedian A. Evaluating the quality of medical care. Milbank Mem Fund Q. 1966;44(3):166–206.	Structure-Process-Outcome framework — shapes ASF's criterion classification approach
[40]	Vincent C et al. Advances in patient safety: from research to implementation. AHRQ Pub No. 05-0021. Rockville, MD: AHRQ, 2005.	Patient safety research compendium — supports incident reporting criteria
[41]	Pronovost P et al. An intervention to decrease catheter-related bloodstream infections in the ICU. N Engl J Med. 2006;355(26):2725–2732.	Michigan Keystone Project — CQI intervention evidence for quality programme criteria
[42]	Greenfield D, Braithwaite J. Health sector accreditation research: a systematic review. Int J Qual Health Care. 2008;20(3):172–183.	Systematic review of accreditation evidence — direct support for the ASF accreditation programme's evidence base
[43]	Brubakk K et al. A systematic review of hospital accreditation: the challenges of measuring complex intervention effects. BMC Health Serv Res. 2015;15:280.	Accreditation impact evidence — supports accreditation as a quality mechanism

4. ISQua EEA Alignment

4.1 This bibliography supports ISQua EEA Principle 1 (Scope and Purpose) and Principle 2 (Standards Development) by demonstrating that ASF standards are grounded in current scientific evidence and international best practice. ISQua EEA Principle 2 requires that standards be based on evidence — this document provides that evidence base in structured, auditable form.

Formal Approval

Name and title	Signature	Date
Prof. Giorgi Pkhakadze, MD, MPH, PhD President, Accréditation Sans Frontières		2026-09-30

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