

WHO SMART guidelines: optimising country-level use of guideline recommendations in the digital age



WHO publishes clinical, public health policy, and data recommendations to advise countries on health interventions and evidence-based practices for improving the health of individuals and populations. This includes recommendations on who provides health interventions, how they are delivered, and accountability mechanisms. WHO produces international standards for priority indicators, as well as for coding and reporting of data, that include the Family of International Classifications, International Classification of Diseases (ICD), the International Classification of Functioning, Disability and Health, and the International Classification of Health Interventions. WHO and member states recognise that using digital interventions to deliver clinical, public health, and data recommendations has the potential to accelerate and amplify their impact on the health and wellbeing of populations.¹ As countries increasingly invest in digital technologies, WHO will need to build support for digital health across its core functions, to ensure continuing relevance of its norms and standards.

The design, functionality, and content of digital tools and systems that collect, exchange, and use patient data to drive health practices and coordination of care within health systems can ensure adherence to national guidelines and lead to improved quality of care.² To implement WHO recommendations in country settings, governments and technology partners must interpret and then adapt the content in line with local policies, procedures, and digital tools. However, the process of translating, operationalising, and incorporating health and data recommendations into digital systems has been unsystematic, slow, prone to error, and indifferent to technical standards (workflows, classifications, terminologies, identifiers, privacy), resulting in poor transparency and traceability.³ Moreover, many digital solutions are hard-coded, hindering ongoing alignment of content with an evolving evidence base. The lack of specific guidance on both the technology and content levels has resulted in an abundance of digital solutions with data and health content of unknown provenance and merit, which undermines confidence and essential government and donor investment, impedes country localisation, and prevents interoperability essential

for continuity of care, optimised data use, and accountability.

WHO envisions a future where everyone in the world benefits fully and immediately from clinical, public health, and data-use recommendations. SMART guidelines—standards-based, machine-readable, adaptive, requirements-based, and testable—are an operationalisation of this vision for a new WHO-supported approach to facilitate rapid, effective, global implementation of WHO guideline recommendations in the digital age.

WHO SMART guidelines comprise documentation, procedures, and digital health components to steer guideline localisation and implementation through digital systems. This approach instructs guideline developers on how to translate recommendations into specifications and standards; technologists on how to integrate recommendations into updatable digital systems; and countries on how to localise, make interoperable, institutionalise, and update digital systems consistent with evidence-based recommendations. SMART guidelines content is, by design, software-neutral, formulated for adaptation into whichever software platforms a country has elected to use, within an exchanged digital health enterprise architecture.

Expanding on Boxwala's model⁴ and learnings from US health agencies, WHO established a framework for representing different operational components as knowledge layers, developing associated products (eg, enhanced guidelines, digital adaptation kits, machine-readable recommendations, reference software) for country-level adaptation and implementation (figure). The WHO antenatal care (ANC) guideline⁵ served as a test-case for reviewing and refining this framework: products were developed for each of the knowledge layers, with documentation of practical considerations for localisation and implementation into country contexts.

The first knowledge layer (L1: Narrative layer—enhanced guidelines) represents traditional guidelines and guidance, and details how the current guideline development process can be enhanced to better support digital transformation. L1 details a need for registering and

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For the SMART guidelines see <https://www.who.int/teams/digital-health-and-innovation/smart-guidelines/>

For more on WHO and member state recognition of digital interventions see https://apps.who.int/gb/ebwha/pdf_files/WHA71/A71_R7-en.pdf?ua=1

For more on the learnings from US health agencies see <https://www.cdc.gov/ddphss/clinical-guidelines/February-2018-Meeting-Summary.html>

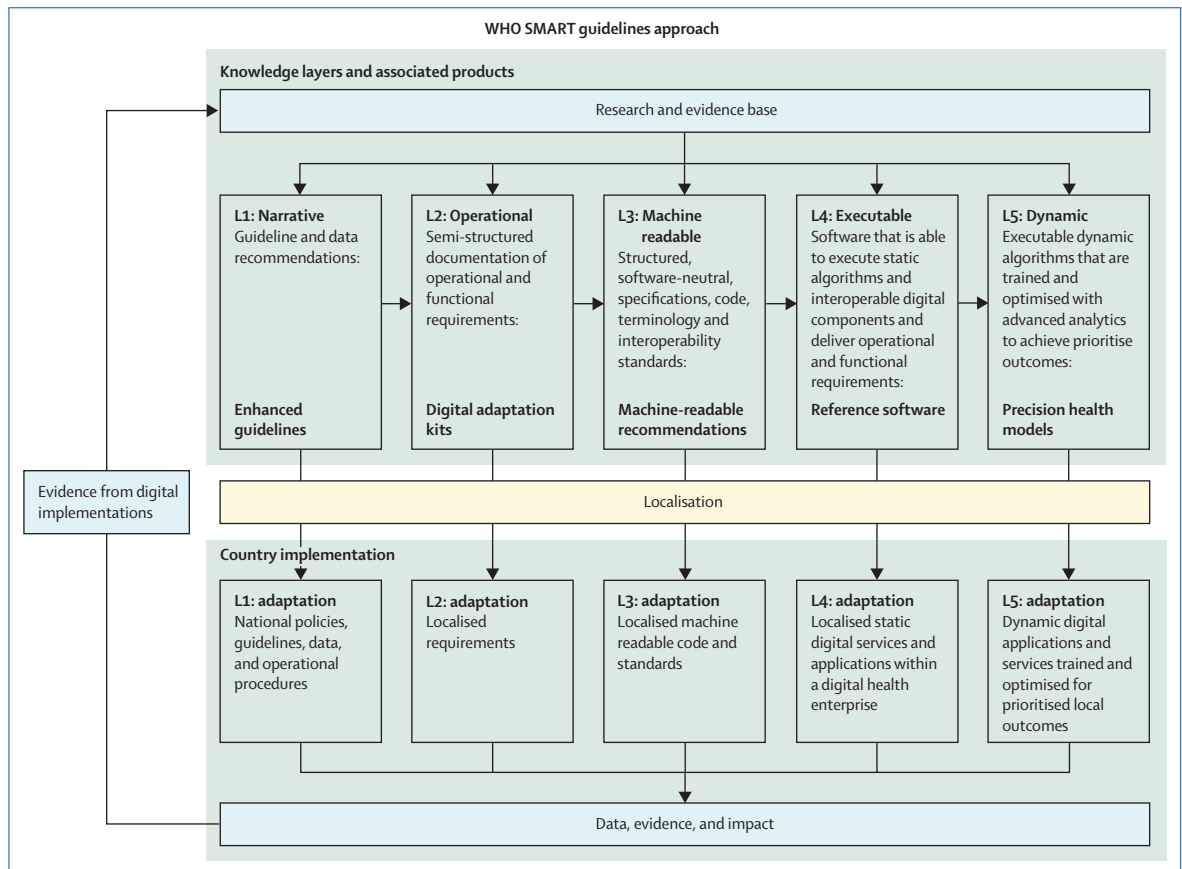


Figure 1: WHO SMART guidelines
 This approach represents a sequence of operational components as knowledge layers (L1–L5), with associated products (eg, digital adaptation kits), for adaptation and implementation at country level. Resulting data and evidence from digital implementations inform iterative cycles of improvement.

For more on the **DAK for ANC** see <https://www.srhr.org/antenatalcare/#Tools>

uniquely identifying recommendations, which are updated as evidence improves over time (living guidelines),⁶ and to which digital solutions can attribute provenance. L1 also recognises the need for increased representation of health informaticians on guideline panels to reinforce adherence to operational and terminology standards. At this level, WHO recommendations on antenatal care for a positive pregnancy experience,⁶ as well as the adaptation toolkit⁷ and monitoring framework⁸ are illustrative tools of ANC L1. The adaptation toolkit and monitoring framework aim to facilitate country adaptation and implementation of the recommendations.

The second layer (L2: Operational—digital adaptation kits) focuses on the requirements base, facilitating informed discussion between ministry of health programme managers and software developers. L2 digital adaptation kits (DAKs) include data and health content consistent with WHO data and health service recommendations, generically applicable to many

digital systems. For example, the DAK for ANC follows a consistent format for requirements of documentation needed for developing digital tools: linked health interventions and recommendations; personas; user scenarios; business processes and workflows; core data elements mapped to standard terminology codes (eg, ICD); decision support; programme indicators; and functional and non-functional requirements. These sections of content facilitate consistency and transparency of operationalisation into digital systems.

The third layer (L3: Machine readable—machine-readable recommendations) provides code necessary for software developers to incorporate standardised logic from WHO guidelines into digital systems, testable for conformance to standards including fidelity to recommendations. A standards-based technical implementation guide builds on L2 by mapping L2 content to value sets and Health Level Seven International Fast Healthcare Interoperability Resources

(FHIR) standards. Alongside data standards from L2, this allows for semantic and syntactic interoperability at scale. The logic derived from guidelines, which might include clinical decision support and calculations for performance indicators, is encoded into Clinical Quality Language (CQL). This ensures that key indicators are consistently extracted to support patient care, as well as case surveillance and programme monitoring. In the case of ANC, L3 is represented in an ANC FHIR Implementation Guide for adaptation into countries' digital health service delivery and reporting systems. Digital solutions comprising L3 machine-readable recommendations are in turn testable for conformance to interoperability standards.

The fourth layer (L4: Executable—reference applications and services) focuses on software applications and services within a digital ecosystem. For example, the WHO Digital ANC module⁹ is an executable reference software, which accurately represents the intentions, operational, and functional requirements of the WHO ANC recommendations; addresses user and health system needs; and comprises machine-readable data and calculations within interoperability standards, as documented in the L1–L3 layers. As a fully functional application, it serves as a generic starting point, ready to be localised to the specific operational context of the users, population, and health system within which it is deployed. Additional products at this layer include terminology services to support consistent data representation for interoperability; reusable software libraries including software development kits; application programming interfaces; and function as a service to support updates to FHIR content and capabilities across subscribed digital systems.

The final knowledge layer (L5: Dynamic—precision health models) reflects the use of big data, advanced analytics, and dynamic algorithms to facilitate precision clinical and public health systems. Scaled-up implementation of L4 digital systems will allow for creation of country-specific, as well as globally collated, anonymised, and normalised datasets.¹⁰ Advanced analytics and artificially intelligent technology applied to these datasets facilitate context specificity of globally curated recommendations in countries, optimised for individual or population outcomes. Evidence of improved health outcomes resulting from algorithms trained and optimised

for priority outcomes can inform panels tasked with updating recommendations. Ethical considerations and issues around data ownership will be crucial for this knowledge layer. L5 for ANC will reflect precision models derived from analysis of aggregated datasets consistent with validated methods.¹¹

SMART guidelines offer a pioneering approach towards a systematic, transparent, and testable pathway from narrative global guidelines to localised digital systems at the country level. This approach will facilitate systematic development, curation, and representation of recommendations (data, clinical, public health) in operational, software-neutral interoperable standards; improve global access to software and systems that interoperate across care pathways, facilities, and providers; enforce transparency and traceability of content; and enable pathways for validation of digital solutions. WHO recognises the complexity and comprehensiveness of the systemic change needed and will continue to develop evidence-based guidelines, now augmented with SMART guideline content, for country-level localisation across all knowledge layers. SMART guidelines will be vital to digital health systems transformation, and attainment of universal health coverage and UN Sustainable Development Goals. WHO invites all partners to help deliver this vision.

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For more on **Clinical Quality Language** see <https://cql.hl7.org/2020May/>

For more on the **ANC FHIR implementation guide** see <http://build.fhir.org/ig/who-int/anc-cds>

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