Understanding WHO SMART Guidelines: Narrative Review of an Innovative Global Digital Health Approach

Martin SABAN[a], Denise ZAVALA[a], Alejandro LOPEZ OSORNIO[a,b], Diego
KAMINKER[c], Martin DÍAZ[a], Adolfo RUBINSTEIN[a], Santiago ESTEBAN[a] and
Daniel A. RIZZATO LEDE [1,a]
[a] CIIPS, IECS, Argentina
[b] SNOMED International, UK
[c] HL7 International, Belgium
ORCiD ID: DA Rizzato Lede https://orcid.org/0000-0003-4670-3046

Abstract. The growing challenges of healthcare systems pose a unique opportunity to leverage evidence-based digital health interventions. The WHO's SMART (Standards-based, Machine-readable, Adaptive, Requirements-based, and Testable) guidelines represent a significant advancement in this domain. This paper aims to summarize SMART guidelines authoring and implementation process, drawing on a comprehensive literature analysis. Our findings highlight critical success factors for national implementation, including stakeholder engagement, customization to local contexts, and leveraging international standards and digital technologies. We conclude with recommendations for countries aiming to implement WHO SMART guidelines, underscoring the need for a multi-disciplinary approach and the potential challenges to be navigated.

Keywords: CDSS, FHIR, guidelines, public health informatics, interoperability.

1. Introduction

In the rapidly evolving landscape of global health, the digital transformation of health systems has emerged as a potential tool to help solve many challenges. Recognizing the potential of digital health technologies, the World Health Organization (WHO) has developed a comprehensive Global Digital Health Strategy [1]. This strategy aims to empower nations with digital health tools to improve the health and well-being of their populations, aligning with the goal of achieving universal health coverage and responding to the health emergencies of the 21st century. Building on this foundational strategy, the WHO, in collaboration with the G20, launched the Global Digital Health Initiative (GDHI) [2] that foster international collaboration in digital health, promote the exchange of best practices, and support the implementation of digital health solutions across countries, thereby advancing the digital transformation of health systems globally.

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[1] Corresponding Author: Daniel Rizzato Lede, danielrizzatolede@gmail.com,CIIPS/IECS Argentina.

The WHO Digital Implementation Investment Guide (DIIG) also orients member states towards planning, costing, and implementing digital health interventions within a digital health enterprise. Amidst these global efforts, a critical challenge remains: the need for standardization and resource reutilization to ensure that digital health interventions are not only effective but also scalable and sustainable. To address this, the WHO advocates for the SMART (Standards-based, Machine-readable, Adaptive, Requirements-based, and Testable) Guidelines approach [3]. This framework is designed to standardize health guidelines in a way that facilitates their implementation across different health systems. By leveraging the WHO SMART approach, countries can enhance the interoperability of health data, improve the quality and accessibility of healthcare services, and accelerate the realization of health system improvements through digital technologies [4].

This framework enhances clinical and epidemiological guideline development and digital healthcare transformation through a structured five-layer approach. This technique ensures that dynamic and evolving guidelines are effectively integrated into digital healthcare systems. The purpose of our paper is to perform a review of the available literature about this WHO initiative for each layer.

2. Methods

We employed a narrative review methodology to synthesize literature on the authoring and implementation of WHO SMART guidelines, focusing on sources published after 2010. The literature search utilized databases such as PubMed, Google Scholar, and direct database searches, encompassing both peer-reviewed and gray literature in English. Keywords included "WHO SMART guidelines," "computable guidelines," "public health informatics," and "DAK", among other variations. Our selection criteria prioritized documents that detailed the authoring, adaptation, and implementation of SMART guidelines, with an emphasis on practical applications and challenges faced. Each document was critically assessed for its relevance, credibility, and scientific rigor to ensure a robust analysis.

3. Results

Our comprehensive literature search yielded 12 peer-reviewed articles and several pieces of gray literature, including policy documents, white papers, and reports from recognized health organizations. Due to space constraints, not every paper is cited. We divided the evidence following the L1 to L5 layers identified in this approach, as seen in Figure 1.
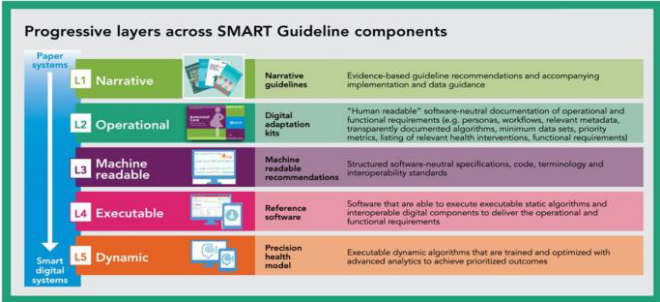

Figure 1. WHO SMART Guidelines L1 to L5 layers (credit: WHO) [3]

The L1 or Narrative layer represents the foundational step where traditional guidelines are enhanced to support digital transformation. It emphasizes the need for uniquely identifying and indexing recommendations that evolve over time. For example, to build the WHO's antenatal care guidelines, the project team collated the most up to date evidence and structured the narrative to allow traceability in subsequent steps and versions [4,5,6].

The second layer (L2, Operational) focuses on translating WHO recommendations into standardized requirements for digital systems, through the creation of dedicated Digital Adaptation Kits (DAK) [6]. WHO has developed a standard operating procedure [7] to set consistencies and alignment in the DAK development process. An example is the HIV DAK [8], which outlines the documentation needed for HIV programs digital tool development, ensuring that health interventions align with WHO standards. This layer bridges the gap between health program managers and software developers, ensuring that digital solutions are grounded in WHO's evidence-based recommendations. Including standardized classifications and terminologies ensures conceptual equivalence and consistency across digital systems [9]. The L2 outcome can be used to inform software development and implementation without a unique format [10,11,12].

At the L3 or Computable layer, recommendations are translated into HL7 FHIR specifications and Clinical Quality Language (CQL) to encode decision logic. The translation of L2 DAK to L3 is a highly demanding process, both in the standard knowledge as in the attention to details of the clinical situations. A dedicated team of subject matter experts, business analysts, clinical terminologists, and FHIR experts can take this job to the next level [13]. The digital certificates implementation guide (DDCC IG) [14] expressed the complexities faced when trying to set a FHIR IG for COVID-19 certificates creation and exchange globally.

The L4 or Executable layer covers reference applications and services, meaning fully functional software applications and/or services that accurately represent WHO recommendations. General mobile or web applications are being developed, and their integration of the FHIR and CQL logic through mechanisms like the Android SDK or CDSHooks allows for code reutilization. They serve as generic starting points for localization, addressing user and health system needs while ensuring data and calculations are embedded within interoperability standards. Integrating these solutions within national digital health platforms [15] is a goal to avoid siloed approaches. The WHO digital ANC module [11,12,16] is an example of a L4 implementation which allows health workers to manage their patients' records with highlighted features like alerts for specific actions, a task list to summarize potentially missed opportunities and additional informative materials for health workers regarding nutrition counseling.

The final layer (L5) is intended to leverage big data and analytics to support precision health, optimizing recommendations for individual or population outcomes. This advanced approach allows an iterative review of global recommendations based on real word data. We did not find published evidence related to this layer.

4. Discussion and Conclusions

WHO SMART Guidelines are a provocative and innovative approach that should be discussed and enhanced both at the global and national levels, promoting distributed projects to gather evidence for supporting its widespread use. Ongoing research in Africa and Asia aims to assess DAK implementation impact on healthcare services [12,17].

There are other methodologies and frameworks aimed at transitioning narrative guidelines into clinical decision support (CDS) systems. Arden Syntax (using FHIR as the data model), Clinical Quality Language, FHIR Clinical Reasoning, US SMART (Substitutable Medical Applications, Reusable Technologies) on FHIR, and CDS Hooks [18], among other CDS engines and tools have been developed and applied in Electronic Health Records. Our research also highlighted comparable efforts like the Centers for Disease Control and Prevention's (CDC) Adapting Clinical Guidelines for the Digital Age (ACG) initiative [19] which promoted a holistic and multidisciplinary approach: established a 12-phase integrated process and model for development and implementation of written and computable guidelines; created and balloted the FHIR Clinical Guidelines Implementation Guide (CPG-on-FHIR IG); among other activities. This CDC-led initiative tried to review and improve the entire system of guideline development and implementation, and then applied the improved approach to specific guidelines. Conversely, the WHO SMART Guidelines approach started applying it to a single domain (antenatal care) [5,6,11,12,16], and then extrapolated the outcomes and lessons learned to the subsequent use cases. The NICE Computable Implementation Guidance project [20] initially tried to create technical implementation standards, but lately focused instead on an intermediate logical model based on the WHO DAK to build technology-neutral specifications of NICE recommendations.

WHO L2 and L3 products usually cover 80% of the general use cases, and should be localized to fulfill countries' needs. The practical application of these methodologies in country-specific contexts, as evidenced in Rwanda and Zambia, showcases the effectiveness of a structured adaptation process [11]. It also emphasizes the necessity of collaborative engagement between health sectors for the successful implementation of digital health care protocols.

Using HL7 FHIR in the SMART Guideline approach might seem to initially limit its adoptability due to the scarcity of trained workforce in LMIC settings, therefore globally scalable educational initiatives should be supported. On the contrary, it is a strength, as similar approaches are being carried out both in high and low-middle-income countries, then the investments and advancements that support one context could help leapfrog many technical difficulties in the other, and vice versa.

Finally, WHO Smart Guidelines have taken a top-down approach with a small amount of global narrative guidelines being transitioned to digital, and afterwards locally adapted and implemented. The huge amount of non-SMART narrative guidelines being created in parallel at WHO, regional offices and member states, might require a different middle-out or bottom-up approach, sharing the methodology and training capabilities for different countries and stakeholders to face such processes on their own. Including a SMART Guidelines statement on current WHO narrative guidelines might help sharing the long-term vision with the broader public health community.

Our review underscores the relationship between technological capabilities, stakeholders' engagement, and supportive policies in the successful authoring and implementation of WHO SMART guidelines. While technological barriers and restricted digital health standards literacy pose significant challenges, tailored strategies are crucial for addressing these obstacles. There is a necessity of robust infrastructure as national digital health platforms, with policies explicitly supporting the integration of WHO SMART guidelines into national health systems. Moreover, this review reveals a significant opportunity for future research, particularly in tracking the long-term effects of WHO SMART guidelines on health outcomes and system efficiencies.

References

[1]   World Health Organization. Global strategy on digital health 2020-2025. WHO. 2021. Available from: https://iris.who.int/handle/10665/344249.

[2]   Global Initiative on Digital Health (GIDH) [Internet]. [cited 2024 Apr 2]. Available from: https://www.who.int/initiatives/gidh

[3]   WHO SMART Guidelines [Internet]. [cited 2024 Apr 2]. Available from: https://www.who.int/teams/digital-health-and-innovation/smart-guidelines

[4]   Mehl G, Tunçalp Ö, Ratanaprayul N, Tamrat T, Barreix M, Lowrance D, et al. WHO SMART guidelines: optimising country-level use of guideline recommendations in the digital age. Lancet Digit Health [Internet]. 2021 Apr;3(4):e213–6.

[5]   Abalos E, Chamillard M, Diaz V, Tuncalp O, Gülmezoglu AM. Antenatal care for healthy pregnant women: A mapping of interventions from existing guidelines to inform the development of new WHO guidance on antenatal care. BJOG An Int J Obstet Gynaecol. 2016;123(4):519-28.

[6]   Barreix M, Lawrie TA, et al. Development of the WHO Antenatal Care Recommendations Adaptation Toolkit: a standardised approach for countries. Health Res Policy Syst. 2020 Jun 22;18(1):70.

[7]   World Health Organization. L2 SOP. In smart-ig-starter-kit Wiki, GitHub. Available from: https://github.com/WorldHealthOrganization/smart-ig-starter-kit/wiki/L2-SOP

[8]   World Health Organization. Digital adaptation kit for HIV: operational requirements for implementing WHO recommendations in digital systems, second edition. WHO. 2024. Available from: https://www.who.int/publications/i/item/9789240085138

[9]   Pretty F, Tamrat T, Ratanaprayul N, et al. Experiences in aligning WHO SMART guidelines to classification and terminology standards. BMJ Health Care Inform [Internet]. 2023 Aug;30(1).

[10] Tamrat T, Ratanaprayul N, Barreix M, Tunçalp Ö, Lowrance D, Thompson J, et al. Transitioning to Digital Systems: The Role of World Health Organization's Digital Adaptation Kits in Operationalizing Recommendations and Interoperability Standards. Glob Health Sci Pract [Internet]. 2022 Feb 28;10(1).

[11] Muliokela R, et al. Integration of new digital antenatal care tools using the WHO SMART guideline approach: Experiences from Rwanda and Zambia. Digit Health. 2022 Feb 2;8:20552076221076256.

[12] NAMAI Research Group. New Antenatal Model in Africa and India (NAMAI) study: implementation research to improve antenatal care using WHO recommendations. Health Res Policy Syst. 2023 Aug 10;21(1):82. doi: 10.1186/s12961-023-01014-5. PMID: 37563619; PMCID: PMC10416399.

[13] Shivers J, et al. Enhancing narrative clinical guidance with computer-readable artifacts: Authoring FHIR implementation guides based on WHO recommendations. J Biomed Inform. 2021;122:103891.

[14] World Health Organization. Digital Documentation of COVID-19 Certificates (DDCC) Implementation Guide, Version 1.0.0. WHO. 2022. Available from: http://smart.who.int/ddcc/ImplementationGuide/who.ddcc.

[15] World Health Organization, International Telecommunication Union. Digital health platform handbook: building a digital information infrastructure (infostructure) for health [Internet]. World Health Organization; 2020. 256 p. Available from: https://iris.who.int/handle/10665/337449

[16] Haddad SM, Souza RT, Cecatti JG, Barreix M, Tamrat T, Footitt C, et al. Building a digital tool for the adoption of the world health organization's antenatal care recommendations: Methodological intersection of evidence, clinical logic, and digital technology. J Med Internet Res. 2020;22(10):1-14.

[17] Digitizing primary healthcare: Implementation research project on Digital Adaptation Kits for strengthening quality of care and accountability [Internet]. ehealthlab Ethiopia. [cited 2024 Apr 3]. Available from: https://ehealthlab.org/nurture/

[18] Strasberg HR, et al. Contemporary clinical decision support standards using Health Level Seven International Fast Healthcare Interoperability Resources. J Am Med Inform Assoc. 2021 30;28(8):1796–806.

[19] Michaels M, et al. Adapted Kaizen: Multi-Organizational Complex Process Redesign for Adapting Clinical Guidelines for the Digital Age. Am J Med Qual [Internet]. 2023 Sep 5;38(5S Suppl 2):S46–59.

[20] Scott P, Heigl M, et al. Modelling clinical narrative as computable knowledge: The NICE computable implementation guidance project. Learn Health Syst [Internet]. 2023 Oct;7(4):e10394.