Title:

Implementation considerations for the WHO Essential Diagnostics List with insights from
the Essential Medicines List: A scoping review protocol

Authors:

*Moriasi Nyanchoka ¹, Mercy Mulaku ^{1,2}, Simon Kariuki ¹, Feiko ter Kuile ³, Taryn Young ², Paul Garner
³, Eleanor Ochodo ^{1,2}

Authors Affiliation:

¹ Centre for Global Health Research, Kenya Medical Research Institute, Kenya

² Centre for Evidence-based Health Care, Division of Epidemiology and Biostatistics, Faculty of
Medicine and Health Sciences, Stellenbosch University, South Africa

³ Department of Clinical Sciences, Liverpool School of Tropical Medicine and Hygiene, United Kingdom

***Corresponding author: Moriasi Nyanchoka** moriasi.nyanchoka@outlook.com

ABSTRACT

Background: Access to medicines and technologies is a key building block of the WHO health systems framework. In 2018, the World Health Organization (WHO) published the first Essential Diagnostics List (EDL) to address the need for countries to make essential diagnostics more accessible and affordable to patients in low-and-middle-income countries and to complement the more established Essential Medicines List (EML). The effective implementation of the WHO EDL is vital to ensure its impact on improving health outcomes. This scoping review aims to map literature on the implementation, uptake and evaluation of the WHO essential lists in African nations in order to guide the effective implementation and evaluation of the WHO EDL.

Methods: This review will map literature on the implementation and evaluation of the WHO's essential diagnostic list (EDL) and essential medical list (EML), using the Joanna Briggs Institute guidelines for scoping review. The implementation considerations we will review include, study designs used in the evaluation of the WHO essential lists, and the outcome measures, findings, gaps and limitations highlighted in the included articles. We will review both primary and secondary quantitative and qualitative literature evaluating the WHO essential lists. A comprehensive search strategy, developed with an information scientist, will be used to identify relevant sources. The database to be searched include: MEDLINE (Pubmed), CINAHL, the Cochrane Library, the Health Technology Assessment database, EMBASE, Health systems evidence, African Index Medicus, Web of Science, Science Direct, Scopus and WHO library databases. Grey Literature will be accessed by searching for policy documents, diagnostic guidelines, and reports of ministry of health, health agencies through their websites and links published in the last three years from selected African countries. Searches, study selection and data extraction will be conducted using the covidence platform by two independent reviewers. The Mixed Method Appraisal Tool (MMAT) version 2018 will be used to assess the quality of included studies. The findings will be analysed using the thematic content analysis approach and the results presented narratively and graphically.

Discussion: We anticipate finding relevant literature on the implementation considerations for WHO's essential diagnostic and medicines list in Africa. This review is likely to reveal implementation considerations, challenges, gaps, which could guide future evaluation, implementation, policy development, and development of practice tools to support the wider adoption of the WHO essential diagnostic list in Africa.

Dissemination: We plan to publish our findings in a peer-reviewed journal and develop useful and accessible summary of the results.

Keywords: Essential Diagnostic Lists, Essential Medical Lists, Diagnostics, Medical Devices, Africa

Background

Diagnostic tests are an essential component of healthcare system ¹⁻³. It is well acknowledged that diagnostic tests contribute significantly to delivery of quality healthcare, and it makes up 5% of a hospital's budget but leverage 60-70% of all critical decision-making such as admittance, discharge, and medication ¹. As a consequence there is provision of objective information that enables patients to be diagnosed, treated and/or monitored precisely and swiftly ^{1,4,5}. Diagnostic tests further aid in recognizing complications such as drug resistance, enhances epidemiological surveillance for early disease detection and monitoring, as well as research and development ³⁻⁵.

Access to diagnostics is a key challenge in developing countries, posing challenges in effective and timely treatment, management and preventions of both communicable and non-communicable diseases. As a result of poor access, populations in low-income-and-middle-income countries (LMICs) have frequently received treatment without the support of essential diagnostic tests, compromising patients care, leading to underdiagnosis and misdiagnosis and ultimately poor health outcomes ^{6,7}. The Sustainable Development Goal (SDG) 3.8 sets to achieve universal health coverage, including financial risk protection, access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all ^{8,9}. Access to diagnostic tests remains a key component in the achievement of SDG 3.8. and universal health coverage ^{8,10}. Without access to essential diagnostics at all healthcare levels, achievement of the SDGs, including Universal Health Coverage (UHC) will not be achieved as targeted.

Access to medicines and technologies is a key building block of the WHO framework for health systems performance ¹¹. In 2018, in an approach to curb the gaps between diagnosis and essential medicines and bring standardization in diagnosis, the World Health Organization (WHO) published the first edition of the Essential List of in vitro Diagnostics (EDL) ¹². The list was developed to complement the more established essential medicine lists introduced now more than 40 years ago and promote greater equitable access to quality and affordable diagnostics at all levels of healthcare delivery system ¹³. Three model lists of the EDL have been published to date with the latest third model containing a list of more than 122 test categories for communicable and non-communicable diseases ^{12,14,15}. Further, national EDLs adapted from the WHO EDL could clarify priorities for policymakers and encourage setting common goals regarding diagnostic testing, paving the way toward improved health care delivery and ultimately better patient outcomes.

This scoping review, therefore, aims at mapping evidence on the implementation, uptake and evaluation of the WHO's essential lists in African countries in order to guide the effective implementation and evaluation of the new WHO EDL. Lessons learnt in the evaluation and implementation of the WHO EML introduced about 40 years ago may shed light on implementation considerations of the WHO EDL. This review is likely to reveal implementation considerations, challenges, gaps, which could guide future evaluation, implementation, policy development, and development of practice tools to support the wider adoption of the WHO essential diagnostic list in Africa.

Objective

The objective of this scoping review is to systematically map the evidence on implementation, uptake and evaluation of the WHO essential lists in Africa in order to guide the effective implementation and evaluation of the newly introduced WHO EDL.

Methodology

Study Design

The Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) and protocols ¹⁶ will be used to guide this scoping review protocol write-up in line with review objectives (Additional file 1). A map literature on the implementation of the WHO's essential diagnostic list (EDL) and essential medical list (EML) will be conducted using the Joanna Briggs Institute guidelines for scoping review ¹⁷. The methodology involves the following: identifying the research question, identifying relevant sources of evidence, study selection, charting the data, collating, summarizing, and reporting the results.

Defining the research question

The scoping review will use the Population-Concept-Context (PCC) framework designed by the Joanna Briggs Institute to formulate the primary research question ¹⁸. It will also be utilized to define the scoping review question as shown in Table 1.

Table 1: PCC framework for defining the eligibility of the studies for the primary research question

PCC Framework for defining the eligibility of the studies for the primary research question	
P – Population	Population at risk or suspected of disease
C – Concept	Implementation of the WHO EML and EDL
C – Context	Health facilities in African settings

The primary research question is what are factors that influence the implementation, uptake and evaluation of the WHO essential lists in African nations?

The sub-questions for the proposed scoping review are:

- What are the implementation and evaluation strategies of EMLs in African settings?
- What are the implementation and evaluation strategies on EDLs in African settings?

Search strategy and study selection

A comprehensive search strategy, developed with an information scientist, will be used to identify all relevant studies on the implementation of the WHO EDL published in English globally, and WHO EML published in English in Africa. The terms used in the search will be broad and will include “Essential lists”, “WHO essential lists”, “WHO essential diagnostics list or WHO EDL”, “WHO essential medicines list or WHO EML”. The search strategy, including all identified keywords and index terms, will be adapted for each included information source. The databases to be searched include: MEDLINE (Pubmed), CINAHL (EBSCO), the Cochrane Library, the Health Technology Assessment database, EMBASE, Health systems evidence, African Index Medicus, Web of Science, Science Direct, Scopus and WHO library databases. There will be no publication date limit on the electronic databases. An example of the search strategy tailored for MEDLINE is shown in appendix 1. A convenience sample of grey Literature will be accessed by searching for Global and National policy documents on EML and EDL, diagnostic guidelines, and reports of ministry of health, health agencies through their websites and links published in the last three years from selected African countries. The reference list of all identified reviews, reports and articles will be screened for additional studies. If deemed necessary, experts in the essential lists will also be contacted for additional articles.

Study selection will be conducted using the covidence platform by two independent reviewers. Disagreements will be resolved through discussion or by consulting a senior reviewer.

Study selection and eligibility criteria

The following eligibility criteria will guide the inclusion of eligible articles.

Study designs

- All study designs reporting on the implementation, uptake and evaluation of the WHO essential lists (EDL AND EML) will be included, such as primary experimental and observational studies, primary qualitative studies as well as systematic reviews and literature reviews. We will include conference abstracts that have sufficient information on themes related to the implementation,

uptake and evaluation of these lists. We will exclude study protocols, editorials and personal opinions papers.

Population

We will include articles about populations at risk or diseased populations regardless of age or gender. We will not limit our review to any disease condition.

Concept

We will include any article that discusses the evaluation, uptake and implementation of the WHO essential lists as well as their acceptance and feasibility.

Context/Settings

All studies conducted in Africa (rural or urban) or all eligible publications about the essential lists in Africa will be included. We will consider the implementation of the essential lists in all health care settings or levels.

Outcomes

- Types of studies or study designs about the evaluation, implementation and uptake of the WHO essential lists
- Outcomes of interest guided by the WHO health systems framework ¹¹ for access to medicines and technologies (for example, coverage of intervention, improved health outcomes and equity).
- Reported findings in included studies including effectiveness, acceptance, feasibility, barriers and facilitators of the WHO essential lists
- Limitations and gaps highlighted in included studies

Charting the data

Data will be extracted from studies included in the scoping review by two independent reviewers using a data extraction tool by the reviewers. The data extracted will include specific data about the: study title, study setting, study design, aim of the study, geographical setting, outcomes and relevant findings and themes relevant to the review question. A draft extraction tool is provided in Appendix 2. A data extraction tool will be pre-tested with 10% of the included studies by two reviewers to ensure accuracy and consistency of the extracted content. Feedback from the reviewers will be used to refine the

extraction form before its final adoption. Modification will be detailed in the full scoping review. Any discrepancies that arise between the reviewers will be resolved through discussion or with a third reviewer. Authors of papers will be contacted to request missing or additional data, where required.

Quality appraisal

The Mixed Method Appraisal Tool (MMAT) version 2018 will be used to assess the quality of included studies ¹⁹. The tool will be used to examine selected studies according to the following categories: the appropriateness of the aim of the study, adequacy of methodology, study design, recruitment strategy, data collection, data analysis, the presentation of findings, authors' discussions and conclusions. Scores derived from the MMAT guidelines will be used to determine the quality of the included articles. This will enable reviewers to report on the overall quality of evidence of the included studies.

Collating, summarizing, and reporting the results

We will analyse the extracted data through thematic content analysis and present our results narratively and graphically.

Discussion

Access to diagnostic tests remains sub-optimal in Africa owing to limited human, financial and technical resources that affect various components of the health system. This proposed scoping review will map the existing evidence on implementation considerations for WHO essential lists in the African context, summarize the results as reported in the included studies, and identify gaps for future research in order to guide the effective evaluation and implementation of the new WHO EDL. The Africa Centre for Disease Control and Prevention (Africa CDC) recognizes the importance of essential diagnostics in Africa's health care systems, and in achievement of SDGs and UHC ²⁰. The WHO recommends local adoption of the EDL in development of National lists in line with country specific or regional needs to ensure its impact on health care practice and patient outcomes ^{12,14,15}.

Review results may interest policy-makers and stakeholders involved in implementation of the essential diagnostics and medicines, including health systems and regulation issues to consider. Strengths of this scoping review include a comprehensive assessment of different types of studies and policy documents about the WHO essential lists. We have also followed the PRISMA guidelines for protocols and scoping reviews to guide the reporting of this protocol. Our review is bound to be limited by the paucity of research about the WHO EDL in Africa since it was launched three years ago but this is likely to be mitigated by lessons learnt in reviewing articles about the more established WHO EML.

Ethics and dissemination

The scoping review does not require ethics approval because it is based on publicly available or secondary data. We plan to disseminate the study's findings in peer-reviewed journals and at conference proceedings that focus on implementation research and health systems strengthening.

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Contributors

The study was conceptualized by MN and EO. MN wrote the first draft and MM and EO contributed to the writing and critically reviewed the draft protocol. MN wrote the final manuscript and all authors (MN, MM, SK, TY, PG and EO) approved the final draft.

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Competing interests

None declared

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ⁱ Appendix 1: Pilot search strategy in PubMed database

Date	Database	Keywords
05/05/2021	Ovid MEDLINE(R) and Epub Ahead of Print, In-Process, In-Data-Review & Other Non-Indexed Citations, Daily and Versions(R)	1 Drugs, Essential/ and World Health Organization/ 2 WHO essential medicine list.mp. 3 WHO Model List of Essential Medicines.mp. 4 ("WHO essential diagnostic list*" or WHO essential diagnostic or WHO Model List of Essential Medicines or WHO EML or WHO essential medicines).mp 5 World Health Organization essential medicine*.mp. 6 *Drugs, Essential/ 7 (essential adj2 (drugs or medicines or diagnostic*)).mp. 8 1 or 2 or 3 or 4 or 5 or 6 or 7

Appendix 2: Data extraction form

Items	Description of items	Page No./column
Author(s)		
Year of publication		
Source origin/country of origin		
Study title		
Aim of the study		
Study population and sample size		
Methodology		
Intervention type and comparator		
Concept		
Duration of the implementation		
How outcomes are measured		
Key findings that relate to the review question		
Issues for contacting authors		