







Malawi newborn and childhealth national clinical practice guidelines A landscape analysis









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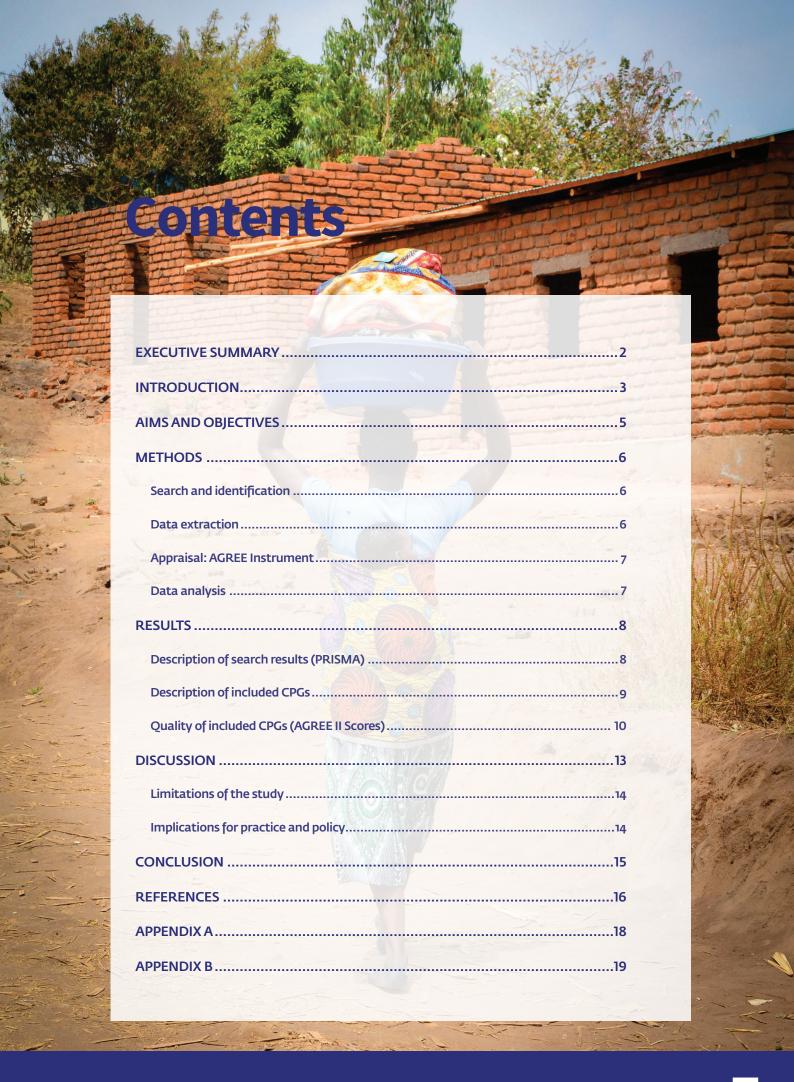
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Conflict of interest

All authors declare that they have no conflict of interests.

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Executive summary

In sub-Saharan Africa (SSA), Malawi is acknowledged as one of the few countries to meet the Millennium Development Goals (MDGs) of reducing under-five mortality by two thirds between 1990 and 2015. However, Malaria, HIV, Tuberculosis, acute respiratory infections and diarrhoeal diseases remain the leading causes of death in the under-five-year-old Malawian children. However, in resource-limited settings such as Malawi, there are many challenges involved in the provision of care. Clinical practice guidelines (CPGs) are evidence-informed recommendations intended to optimise patient care and have the potential to improve quality of care. With collaborative efforts from key external organisations, experts and stakeholders, the World Health Organization (WHO) develops high-quality global level CPGs for use in low-resource settings which cover all key infectious conditions aligned with the burden of disease. However, these CPGs have not consistently been adopted, updated or adapted in SSA countries such as Malawi. This scoping review aimed to identify the available national CPGs for newborn and childhealth topics developed between 2017 and 2022, describe their scope and appraise the quality using the AGREE II tool. Following a comprehensive search, we identified 322 records in Google Scholar,

Google and the Ministry of Health (MOH) website and hardcopy versions in the MOH offices using the pre-determined search terms. In addition, we hand searched for eligible CPGs in relevant offices. We identified a total of six CPGs that were eligible for this review. Following data extraction, we found that five CPGs were for managing children from the perinatal period up to older ages. The CPGs were targeted at healthcare providers (n=6), followed by programme managers (n=2) and researchers (n=2). The topics ranged from prevention, screening and diagnosis to management and rehabilitation. The quality of reporting was appraised using the AGREE II tool. Using these quality indicators, we found that reporting was poorly done overall. In particular, reporting on the methodological rigour and editorial independence was poor (i.e. it wasn't clearly stated who funded the CPG and how the interests were managed). Overall, although several recent and relevant CPGs are available, there is scope for improvement on the reporting and standards to benefit newborn and child health. A collaborative effort including the MOH, NGOs, professional associations and researchers in developing and adapting newborn and child-health CPGs could yield large benefits in improving the quality of care of children in Malawi.

O] INTRODUCTION

here has been substantial global progress, in reducing under-five child mortality since 1990, with neonatal deaths decreasing from five million in 1990 to 2.4 million in 2020.2 However, sub-Saharan Africa (SSA) still has the highest neonatal mortality rate in the world accounting for 43% of global newborn deaths.3 Mortality within the first 28 days of life is often preventable and associated with factors such as lack of appropriate postnatal care. In Malawi there has been a slight decline in the infant-mortality rate over the years. For instance, the infant-mortality rate is currently at 34.327 deaths per 1000 live births, representing a 4.85% decline from 2021.4 Malawi is one of the few countries in SSA to meet the millennium developmental goal (MDG) of reducing under-five mortality by two thirds between 1990 and 2015.5 This reduction has been attributed to the increased coverage of health interventions such as antenatal and delivery care, immunisation, distribution of insecticidetreated nets and prevention and treatment of common infectious diseases.⁶ Despite global advances in the prevention and management of infectious diseases, evidence suggests that malaria, HIV, TB, acute respiratory infections and diarrhoeal diseases remain amongst the leading causes of death in children under-five years of age in Malawi.6 In resource-constrained countries such as Malawi, where children succumb to preventable disease due to inequitable access to health services, the WHO recommends the use of evidence-based clinical practice guidelines (CPGs) in primary healthcare to improve the quality of healthcare for newborns and young children.⁵ Recommendations for interventions that have been proven to work and are cost-effective should be a priority to be adapted in the Malawian context.⁷ CPGs are evidence-informed recommendations intended to optimise patient care and a high-quality guideline has the potential to influence care outcomes.8 If developed and implemented according to international standards, CPGs have the potential to improve quality of care by assessing the benefits and harms of alternative care options and reducing unwarranted practice variations. Currently, Malawi has few existing CPGs for newborn and child health.

The development of CPGs in Malawi include defining the clinical problem, assembling a multidisciplinary CPG development group which comprises experts who translate the evidence from a systematic review of the literature to recommendations, critically appraising the CPG, and updating the literature. This process is supported by the Malawi Ministry of Health and mostly funded by Non-Governmental Organisations (NGOs). Although collaborative efforts ensure the effective development of child-health CPGs, there is still more to be done to ensure the adaptation and effective use of the CPGs. Studies have highlighted

challenges in the development of these CPGs including lack of resources to update them, failure to digitise CPGs to facilitate updates, and lack of stakeholder involvement and local context adaptation.¹¹

Development of *de novo* (new) CPGs is resource intensive, requires adequate funding, technical expertise and ample time to complete.⁵ As a result, countries opt for CPG adaptation and contextualisation to local settings or country needs to save costs and resources associated with developing CPGs from scratch. Adoption and local contextualisation of CPGs minimises waste of resources and duplication of efforts. The WHO has developed high-quality, global-level CPGs for use in low-resource settings which cover all key infectious conditions that cause most deaths. However, these CPGs have not consistently been adopted, updated, or adapted in SSA countries.¹² Furthermore, lack of transparency in adaptation methods pose questions on the credibility of the guidelines and recommendations. Therefore, in this review we identify, describe and appraise the quality of the existing newborn and child-health guidelines in Malawi.

This is a sub-study of a larger project, Global Evidence, Local Adaptation (GELA), which aims to increase decision makers' capacity to use global research evidence to develop locally relevant CPGs for newborn and child health. GELA will support decision makers in Malawi, Nigeria and South Africa, and aims to build on and add value to the large-scale programme of global child-health CPG development led by the WHO with adaptation and implementation led by the WHO Afro regional office and national ministries.



O2 OBJECTIVES



To identify publicly available CPGs for newborn and child-health topics from 2017-2022.



To describe the scope of the identified CPGs, including methods used and the stakeholders involved in the CPG development.



To appraise the quality and reporting standards of identified CPGs using the AGREE II tool for *de novo* CPGs and an adapted AGREE II for adapted CPGs.

03 METHODS

Search and identification

A comprehensive literature search was done by two independent authors (RC and GK) using the following keyword combinations of "guideline" OR "protocol" OR "recommendations" OR "standards" OR "strategies" OR "consensus" AND "newborn health" OR "Infant health" OR "childhood illnesses" OR "perinatal health" OR "newborn illnesses" OR "poverty related diseases" AND "Malawi". We searched Google and Google Scholar for clinical practice guidelines addressing newborn and child health published in Malawi between the years 2017-2022. In addition, we consulted the Ministry of Health departments (i.e. the National Malaria Control Programme, the Department of HIV/AIDS, the TB control programme, the Schistosomiasis programme and more) as well as other relevant stakeholders to assist with identifying published, updated CPGs as well as non-published hardcopy files.

Data extraction

Two authors (RC and GK) independently extracted data using a pre-developed and piloted extraction form (excel sheet) from included CPGs, which included: Title of the CPG, year of publication, CPG scope, topic or condition covered by the CPG, target population, target users of the CPG, responsible developers, stakeholder consultations, CPG development groups, consultation with external reviewers, assessment of overall certainty of evidence (using GRADE, etc.), and a detailed description of the methods used for adapting the CPG.

Appraisal using the AGREE tool

We used the AGREE II tool to appraise the quality of the CPGs. Each guideline was appraised independently by two trained reviewers (RC and GK), and any discrepancies in scoring were resolved by consensus. A third reviewer (NM) resolved any persisting disputes. We evaluated the quality of parent guidelines, developed from 2017 to 2022, that explicitly stated that they were adapted.

Each guideline was appraised using 23 key items divided into six domains and scored on a scale of 1 (strongly disagree) to 7 (strongly agree) for each item.

We calculated standardised domain scores by summing up all the scores of individual items in a domain and by standardising the total as a percentage of the maximum possible score for that domain.

Domain 1. Scope and Purpose (items 1-3) is concerned with the overall aim of the guideline, the specific clinical questions and the target patient population.

Domain 2. Stakeholder Involvement (items 4-6) focuses on the extent to which the guideline represents the views of its intended users. Guideline development should involve all stakeholders whose activities are likely to be covered in the proposed guideline including patient groups.

Domain 3. Rigour of Development (items 7-14) relates to the process used to collect and synthesise the evidence, the methods to formulate the recommendations and to update the guideline.

Domain 4. Clarity of Presentation (items 15-17) deals with the language and format of the guideline.

Domain 5. Applicability (items 18-21) pertains to the likely barriers and facilitators to implementation strategies to improve uptake, and resource implications of applying the guideline.

Domain 6. Editorial Independence (items 22-23) is concerned with the formulation of the recommendations not being unduly biased with competing interests.

Data analysis

We analysed the data descriptively using Microsoft Excel and reported median AGREE II domain scores and associated ranges for all included CPGs.

O4 RESULTS

Description of search results (PRISMA)

In total, 322 records were identified; 272 CPGs in Google Scholar and 50 additional records from the Google search and Ministry of Health documents (Figure 1). After removing five duplicates, we screened 317 titles and abstracts, and then 34 full texts of potentially eligible CPGs. Of the latter, 28 records were excluded for the following reasons: one was a technical report, nine were outdated (i.e. published before 2017), one included an older population (i.e. adult men and women only), four were done at district level, seven were published primary studies, one was a briefing document, one was a systematic review, one was a thesis, and three had the same title but were published in different years, of which we included only the latest version. Thus, six CPGs were included for review.

Identification of Clinical Practice Guidelines **CPGs** DENTIFICATION Additional records identified identified through through **Duplicates removed** other sources (Google (n = 5)database plus MOH documents) searching (n = 50)(n = 272)Records excluded (n = 283)SCREENING District-level evidence CPGs screened after duplicates Cross-sectional studies removed Systematic reviews (SR) (n = 317)No child-health outcome Randomised-controlled trials CPGs excluded with reasons ELIGABILITY CPGs assessed for eligibility (n = 28)Technical report = 1(n = 34)Outdated = 9Older age group = 1District level = 4 Cross sectional = 7Brief = 1SR = 1Thesis = 1INCLUDED Of the same title but CPGs included in scoping review outdated = 3

Figure 1. PRISMA flow Diagram

Description of included CPGs

Of the six included CPGs, only one CPG focused on a communicable disease, HIV/AIDS (See Appendix A). Five of the CPGs indicated that the main CPG developer was the Ministry of Health. In the Integrated Management of Childhood Illnesses (IMCI) guideline, the WHO and UNICEF logos are included in the document, however, whether the CPG was adopted from the original, or adapted or whether these organisations had a role in the national development is not reported. Most of the target audience were health practitioners (private/public) (n=6)¹⁶⁻¹⁹ followed by programme managers (n=2)^{18, 19} and researchers (n=2).^{18, 19} Target populations included perinatal (n=3),^{19, 20} prenatal (n=2),^{16, 18} neonates, newborn, infants and young children (n=6)^{19, 20} (Figure 2). The scope covered by CPGs included screening (n=4),^{16, 19, 20} diagnosis (n=4),^{16, 19, 20} prevention (n=5),^{16, 18, 19, 20} treatment (n=4),^{16, 19, 20} and rehabilitation (n=1)¹⁶ (Figure 3). The CPGs were relevant for primary, secondary and tertiary level of care (n=5).^{16, 18, 19, 20} (See Appendix A)

Target population

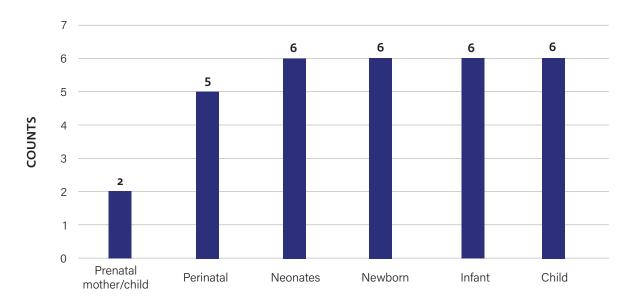


Figure 2. Target populations addressed by recent CPGs addressing newborn and child health in Malawi

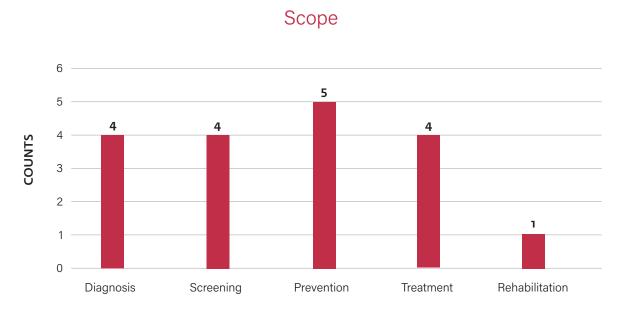


Figure 3. Scope of CPGs in Malawi

Quality of included CPGs (AGREE II Scores)

Table 1 and Figure 4 present a summary of AGREE II scores for included CPGs, which are presented in form of percentages across all domains. The quality of the included CPGs varied. Domains with the lowest median scores were editorial independence [0% (range 0-42%)], and rigour of development [11% (range 3-51%)]. The scope and purpose domain scored the highest [73.5% (range 28-78%)]. All identified CPGs did not report on use of systematic methods to identify or assess certainty of evidence, as well as consultation with external reviewers. Stakeholders were consulted in three of the six CPGs. Assessment of contextual data or CPG acceptability was not described in any of the included CPGs.

To enhance clarity of results, domain and overall scores are presented in Table 1 colour-coded according to the description below:



Table 1: Summary of guideline AGREE II scores in percentages

AGREE II Domains	Scope and purpose	Stakeholder involvement	Rigour of development	Clarity of presentation	Applicability	Editorial independence	Overall
Median	73.5	59.5	11	64	35.5	0	50
Range	28-78	3-78	3-51	14-75	19-50	0 -42	42-67
COIN 2022	75	47	51	72	50	0	67
IMCI	56	3	11	56	33	0	58
IYCN Policy	72	75	10	47	19	0	42
BFHI	78	72	3	14	27	42	42
CM_HIV	28	78	38	75	42	0	75
PM_Newborns	75	31	11	75	38	0	42

COIN- Care for Infant and Newborn in Malawi

IMCI - Integrated Management of Childhood Illnesses in Malawi

IYCN Policy - Infant and Young Child Nutrition Policy

CM HIV - Clinical Management of HIV in Children

PM_Newborns - Protocols for Management of Newborns in Malawi

BFHI - Baby Friendly Hospital Initiative



Median domain scores

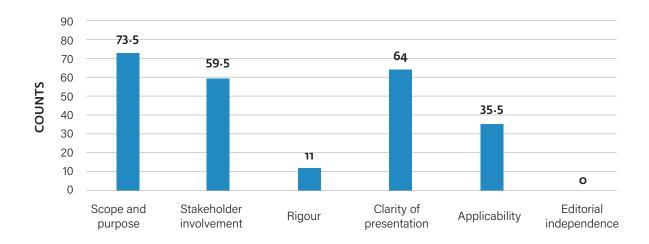


Figure 4. Graphical depiction of domain median scores

05 DISCUSSION

his review has described and evaluated the quality of six national CPGs for child and newborn health in Malawi. Our analysis showed that the Ministry of Health was the primary CPG developer. The majority of the CPGs focused on prevention. Only one focused on HIV/AIDS. Most guidelines were of poor quality; the overall average median score was 50 per cent. The domains with the lowest median scores were editorial independence and rigour of development. Unlike other sub-Saharan African countries, Malawi has a higher burden of infectious disease in the under-five age category.13 Thus, most of the conditions addressed by the identified CPGs do not clearly align with the current disease burden in this population. According to Mill et al (2017), the leading causes of death in under-five children in Malawi are sepsis (85%, of which 28 were neonatal sepsis), lower respiratory tract infection (50%), gastroenteritis (32%), meningitis (30%), and malaria (28%).13 Furthermore, malnutrition (26%) and HIV/ AIDS (38%) also account for most of the childhood-related deaths. However, the scope of the identified CPGs does not align with the current burden, indicating a gap that warrants urgent attention. Thus, there is need for a wider consultation and priority setting prior to further CPG development and updates relevant to these topic areas. It should also be noted that we were unable to identify any CPGs for the care of comorbidities in infants and children. In low-resource environments, diseases like malnutrition, HIV, and TB are likely to co-exist.¹⁴ It may be crucial to consider the emerging burden of communicable diseases in addressing gaps in the current CPG scope.

Despite the poor reporting standards, these CPGs contain useful information and recommendations. Improving the reporting standards is therefore essential in strengthening credibility and implementation of the recommendations. We are unable to rule out a possibility that some recommendations were adopted from the WHO guidelines as some CPG documents such as the IMCI display the WHO and UNICEF logo without transparently stating the role of these organisations in the CPG development process.

In summary, the following are the gaps which need to be addressed:

- CPGs did not clearly report on the methods of CPG development and thus future versions should provide more clarity on this element such as descriptions of the systematic approaches to identifying, selecting, and assessing evidence, or methods used in adaptation from other CPGs such as those from WHO.
- The majority of the CPGs did not clearly report on the funding and how interests of contributors were collected and managed.

- There is potential to increase participation of a range of contributors, such as healthcare providers
 working in the health facilities or the public along with greater consideration of contextual factors
 during the development of CPGs.
- Although it is possible that we did not identify all CPGs, as they were not easily available in a CPG repository, we found that there may be several gaps in available CPGs for informing healthcare for newborn and child health specifically in the fields of malnutrition, HIV/AIDS, and respiratory tract infections.
- It would be advantageous to increase cooperation between the Malawi Ministry of Health and professional organisations in order to reduce duplication of effort, improve CPG development techniques, and streamline attention to the conditions that contribute to the burden of disease in infant and child health.
- A dedicated CPG repository could ease dissemination and identification of CPGs for healthcare providers, programme managers and the public.

Limitations of the review

We identified six up-to-date CPGs for newborn and child health, but we anticipate further priority topics may warrant CPGs to guide health practitioners in Malawi. There is a possibility that we might have missed some of the existing CPGs due to lack of a CPG repository. We restricted our search to CPGs created during the last five years (2017 to 2022). It's possible that some CPGs for specific conditions are out of date and in the process of being revised.

Implications for practice and policy

This scoping review has highlighted the need for further collaborative CPG development or adaptation from high-quality, up-to-date CPGs. Most of the existing CPGs have poor reporting quality according to the AGREE II tool or were developed more than five years ago and may be out of date. This review pinpoints some of the gaps in existing CPGs that could facilitate further improvements.

O6 CONCLUSION

his review has described and evaluated national CPGs for child and newborn health in Malawi over the past five years. Our findings reveal that the Malawi Ministry of Health (MOH) was the main CPG developer. Overall, there were several gaps in content covered and reporting standards that warrant further attention. Further research to inform relevant newborn and child-health prioritisation of health topics is necessary, while addressing reporting standards such as systematic approaches to assess evidence and manage transparent disclosure of funding and potential conflicts of interest. The review concludes that strengthening collaborations between the MOH, professional organisations, researchers and other relevant stakeholders may improve CPG development methods and reduce duplication of efforts.

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Appendix A

Eligibility criteria

Documents	Include: CPGs are defined by WHO as "systematically developed evidence-based statements which assist providers, recipients, and other stakeholders to make informed decisions about appropriate health interventions". Documents that put forward actionable recommendations for individual care. The CPGs may be developed <i>de novo</i> (from scratch); or adapted or adopted and refer to a primary CPG or more than one primary CPG.
Focus area	Newborn and child health from birth to 12 years. CPGs that recommend options for health promotion, diagnosis of health conditions or interventions for prevention or management or rehabilitation. Where documents also make recommendations for care of other age groups, e.g. adolescents or mothers/ caregivers, Sections dedicated to healthcare recommendations for newborn and child health were included.
Settings	Malawi National CPGs.
Publication year	From 1 January 2017 – July 2022
Language	English

Appendix B

Characteristics of included guidelines

Title of Guideline (year of publication)	Level of care CPG addressing	Topic	Scope	Target population	Target audience	Guideline developer
Protocols for management of newborns in Malawi (unpublished/2022)	Primary Secondary Tertiary	Management of emergency signs (difficulties in breathing, bleeding and shock)	Diagnosis Screening, Prevention Treatment	Perinatal Child Neonates / infant / newborn	Health practitioners	Ministry of Health
Manual book care for infant and newborn in Malawi (the coin course) participants manual	Primary Secondary Tertiary	Newborn quality care	Diagnosis Screening Prevention Treatment	Neonates / newborn / infant Child	Health practitioners	Ministry of Health
Malawi guidelines for clinical management of HIV in children and adults	Primary Secondary Tertiary	HIV/AIDS	Diagnosis Screening Prevention Treatment Rehabilitation	Prenatal perinatal Neonates / newborn / infants Child	Health practitioners	Ministry of Health
Infant and young child nutrition policy and guidelines	Not applicable	Infant and young child nutrition	Not applicable	Perinatal, Neonates / newborn / infant and Child	Health practitioners Programme managers Researchers	Ministry of Health
How to guide (a guideline on implementing the baby friendly hospital initiative in Malawi)	Primary Secondary Tertiary	Exclusive breastfeeding	Prevention	Prenatal Perinatal Neonates / newborn / Infant Child	Health Practitioners, Programme managers Researchers	USAID, Health policy plus
Integrated management of newborn and childhood illnesses	Primary Secondary Tertiary	Management of newborn and childhood illnesses	Diagnosis Screening, Prevention Treatment	Perinatal Neonates / newborn / infant Child	Health practitioners Parents/ guardians	Ministry of Health, WHO, UNICEF

Countries Clinical Trials Partnership, the GELA Project is a partnership coordinated by Cochrane SA, including the Norwegian Institute of Public Health, the Norwegian University of Science and Technology, Western Norway University of Applied Science, Stellenbosch University, Cochrane Nigeria at the University of Calabar Teaching Hospital, Kamuzu University of Health Sciences, Malawi, Cochrane and the Stiftelsen MAGIC Evidence Ecosystem, Norway. (GELA is part of the EDCTP2 programme supported by the European Union – grant number RIA2020S-3303-GELA

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