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Supplement Article

Use of evidence and negotiation in the review of national standard treatment guidelines and essential medicines list: experience from Ghana

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Abstract

Understanding how countries review their national standard treatment guidelines (STGs) and essential medicines list (EML) is important in the light of ever-changing trends in public health and evidence supporting the selection and use of medicines in disease management. This study examines the 2017 STGs and EML review process, the actors involved and how the list of medicines and disease conditions evolved between the last two editions. We examined expert committee reports, stakeholder engagement reports and the last two editions (2010, 2017) STGs and EML. The review process occurred in both bureaucratic and public arenas where various actors with varied power and interest engaged in ways to consolidate their influence with the use of evidence from research and practice. In the bureaucratic arena, a national medicines selection committee inaugurated by the Minister of Health assessed the 2010 edition through technical sessions considering the country's disease burden, hierarchical healthcare structure and evidence on safety and efficacy and expert opinion. To build consensus and ensure credibility service providers, professional bodies and healthcare managers scrutinized the assessed guidelines and medicines list in public arenas. In such public arenas, technical discussions moved towards negotiations with emphasis on practicability of the policies. Updates in the 2017 guidelines involved the addition of 64 new disease conditions in the STG, with the EML including 153 additional medicines and excluding 56 medicines previously found in the 2010 EML. Furthermore, the level of care categorization for Level 'A' [i.e. community-based health planning and services (CHPS)] and Level 'M' (i.e. midwifery and CHPS with a midwife) evolved to reflect the current primary healthcare and community mobilization activities for healthcare delivery in Ghana. Ghana's experience in using evidence from research and practice and engaging wide stakeholders can serve as lessons for other low and middle-income countries.

Keywords: Essential medicines list, evidence-based medicine, policy review process, standard treatment guidelines

Introduction

Ghana first published its national treatment guidelines and medicines list policy in 1988 and since then the guidelines and medicines list have evolved. The Ghana National Drugs Programme (GNDP), a pharmaceutical policy unit of the Ministry of Health (MoH), coordinated the review process from 2000. The MoH published the 1988 edition titled 'Essential Drugs List and National Formulary with Therapeutic Guidelines' (Ministry of Health, 1988).

Key Messages

- Stakeholders within health systems space have varied interest and power to influence what gets on to or out of the national standard treatment guidelines (STGs) and essential medicines list (EML).
- Consensus building among stakeholders and agreement on what evidence from research and practice to use for selecting treatment options are critical for the STGs/EML review process.
- National STGs and EML policies are clinically relevant for service delivery at all levels of care and their timely review is therefore critical.

Subsequently, two further editions of the documents with the same title were published in 1993 and 1996 (Ministry of Health, 1993, 1996). However, in the year 2000, the Essential Drugs List and National Formulary with Therapeutic Guidelines developed into two separate books titled *Standard Treatment Guidelines* (STGs) and *Essential Medicines List* (EML) (Ministry of Health, 2000a,b). Since then the GNDP has published the 2004, 2010 and 2017 STGs and EML editions (Ministry of Health, 2004a,c; 2010a,b; 2017a,c). Over the years, a national medicines selection committee (NMSC) of locally based specialists have provided technical support for the review processes towards publications of newer editions.

In 1977 when World Health Organization (WHO) introduced the EML concept, less than a dozen countries had EML. Now, at least 135 countries have their own therapeutic manuals and formularies, which provide health professionals with up to date, accurate and unbiased advice on the rational use of medicines (WHO, 2007). The WHO essential medicine list is reviewed every 2 years. However, country-specific EML review period vary, e.g. Bhutan has 2007, 2009, 2011 and 2012 editions with an average review period of <2 years. Ethiopia has 2001, 2008, 2010 and 2015 editions with a 5-year review gap for the last two editions (WHO, 2019). WHO selection criteria for medicines have evolved with a change from experience-based to evidence-based approach (Laing *et al.*, 2003). Countries may have specific criteria for medicines selection, and these may include elements of experience-based and evidence-based approaches. In Tanzania efficacy, safety, availability and affordability influenced selection decisions although these were largely based on experience rather than evidence (Mori *et al.*, 2014).

National medicines selection is important as it informs availability of essential medicines, medicines procurement, quality of care, treatment cost and access to medicines. In Ghana, healthcare providers use either the national STGs and/or EML as a guide to diagnose, prescribe medicines and manage common disease conditions. In addition, healthcare managers use the STGs and EML to guide treatment costing, development of institutional EMLs, procurement of medicines and National Health Insurance reimbursement at the three different levels of care delivery, namely, primary, secondary and tertiary. The EML confines circulation of essential medicines to specific and appropriate levels of care in Ghana. Healthcare providers deliver services through a hierarchy of hospitals, clinics, health centres, maternity homes and community-based health planning and services (CHPS) posts that reflect their human resources employed and capabilities to provide services (Ministry of Health, 2007).

Due to the ever-changing trends in public health and evidence supporting the selection and use of medicines in disease management, regular evidence-based and transparent reviews of existing national STGs and EML is essential. This in turn requires timely use of evidence-based treatment recommendations by stakeholders and consensus building to ensure credibility and acceptance (World Health Organization, 2002; Sinclair *et al.*, 2013; Perumal-Pillay and Suleman, 2017). Despite the importance of understanding how countries review and reconsider their national STGs and accompanying EML policies and use evidence from research and practice for the processes, documentation of this aspect has received little attention. The Ghanaian STGs/EML policy review process is not documented, and little information is available to stakeholders and policy change advocates who wish to understand how disease conditions and essential medicines are selected and how policymakers and advocates use evidence from practice and research to inform decisions. This article therefore aims to fill the gap and describes the review processes of how disease conditions and medicines get to be added or removed; the actors involved and their negotiations and use of evidence from research and practice in selecting common diseases treatment options and essential medicines for the 2017 edition of the STGs and EML for Ghana.

Materials and methods

Data collection and analysis

This study employs a case study design that allows for in-depth investigation of complex and context-specific events such as the STGs/EML review process, within a real-life context. It allows the use of multiple sources of evidence and triangulation to provide data-rich explanation of a phenomenon (Yin, 2009).

We present data drawing on our retrospective recollection of the review process as active participants and content analysis of the NMSC output, stakeholder meetings reports and the 2010 and 2017 STGs/EML editions. Disease conditions and medicines from the 2010 and 2017 STGs/EML editions were itemized and analysed to document how listed disease conditions and medicines evolved between the last two editions. Additionally, we purposively selected and studied all meeting reports, outputs and attendance of NMSC, management meetings, inauguration and publication launch and stakeholder engagement between 10 January 2014 and 4 October 2017 (Table 1) to trace and map the review process including specific timelines, activities, attendees and decisions. The inauguration and publication launch events as well as management group meetings were half-working day sessions while all other meetings were held for full working days. The data were then tabulated and systematically grouped based on different periods of the review process. The data were coded on four main themes: evidence, stakeholders, process and disease conditions. Evidence was categorized as being drawn from clinical experience and studies. Stakeholders categorized as practice, academia and management. Process categorized as STGs/EML pre-review, review and post-review processes. Under disease condition, there were two categories: 2010 disease conditions and 2017 disease conditions.

Active participation and observation enable one to describe the setting observed, the activities that took place in that setting, the people who participated in those activities and better understand

Table 1 STGs and EML review process meetings reports and outputs

Meetings reports	Number of meeting reports/outputs	Dates
Inauguration of National Medicines Selection Committee report	1	10 June 2014
Management Group report	10	10 January 2014–17 February 2015
National Medicines Selection Committee Workshops report	7	24 February–11 June 2015
Stakeholder Consensus Workshop report	4	6 October 2015–13 September 2017
Evidence summaries group report	7	21 October 2015–8 January 2016
Editorial Committee output	40	November 2015–10 April 2017
Launch of STGs and EML report	1	4 October 2017

and capture the context within which people interacted (Patton, 2002). We drew on our experiences to interpret findings from the document analysis. Further analysis involved chronologically restructuring how the GNDP coordinated the review process, how the 2010 edition STGs and EML disease conditions and medicines evolved, and how various actors influenced the 2017 edition list of disease conditions and medicines with use of evidence and negotiations. We acknowledge the challenges involved in mapping the exact sequence of events and providing full explanations of events as they unfolded. To minimize this, we drew from varied meeting reports and outputs and our experiences of the review process. We present our analyses in three main stages: pre-review, review and post-review.

Study limitations

The in-depth personal engagement of a participant observer yields rich and 'thick' descriptive material and insights, but it is also its weakness. This is because, the participant's view of the process may be clouded by their biases and sentiments and their influence on the processes may not be objectively assessed (Agyepong and Adjei, 2008). In addition, the challenge of recollecting information through active participation and observation is the ability to combine active participation and observation so as to become capable of understanding the review process as an insider while describing the process for an outsider (Patton, 2002; Robson, 2011). To minimize this weakness as noted by Agyepong and Adjei (2008), we provided no value judgments as to 'good' or 'bad', 'success' or 'failure' but rather focused on analysis and description.

Results

Pre-review stage

The pre-review period included activities undertaken by the GNDP prior to assessing the 2010 STGs and EML. The Minister of Health in consultation with the GNDP and director pharmaceutical services nominated a chairperson to oversee technical discussion of the review process. A consultant physician and university academic with a background in internal medicine and therapeutics who had been a member of three previous STGs/EML expert committees and had previously directed the review process of the 2010 edition of the STGs/EML was nominated. The chairperson was to lead technical discussions related to treatment options and medicines selections based on local context, public health safety, efficacy, clinical and cost-effectiveness.

STGs/EML management group

With a chairperson in place, the GNDP constituted a management group to oversee day-to-day operations of the review process in January 2014. This comprised of the chairperson, GNDP technical officers (3), director pharmaceutical services and two representatives of the National Health Insurance Authority (NHIA) and a WHO country office representative. The NHIA representatives were included to guide align the STGs and EML to the national health insurance benefit package. The director pharmaceutical services represented the Minister of Health and were to ensure the STGs and EML alignment to national health strategies and plans. Finally, the WHO national programme officer for Essential Drugs and Medicines was included to provide technical guidelines on global best practices and lessons from other health systems as well as guidance on WHO model list of medicines and the WHO classification of antimicrobials.

With the management group in place, the GNDP collated all disease review documents from the MoH, Ghana Health Service, Christian Health Association of Ghana to ascertain disease pattern of the country. The management group in turn recruited reviewers. Curriculum Vitae of review members with long history on the STGs/EML review committees were solicited and their availability assessed. New recruits recommended by existing reviewers and nominated by the management group were approached based on their expertise, years of experience and availability. In total, the management group recruited 40 local reviewers with expertise on the identified disease patterns to form the NMSC (Figure 1).

To align the STGs/EML to existing public health programme treatment protocols, the GNDP collated current country-specific treatment protocols for expanded programme on immunization, eye care programme, buruli ulcer, national acquired immune deficiency syndrome/sexually transmitted infection control programme, national malaria control programme, national tuberculosis programme, national yaws eradication and reproductive health programmes. In addition, the GNDP collated relevant documents such as national health insurance benefits package, the WHO model list of essential medicines for both adults and children, submissions from stakeholders on inclusions and deletions to the EML as resources for the reviewers.

To supplement funds from the Government of Ghana, the GNDP requested financial support from the European Union Commission, WHO and United Kingdom Department for International Development to compensate reviewers for their time and print copies of the STGs and EML.

Conflict of interest, STGs format and terms of reference

The management group developed conflict of interest form, terms of reference (TOR) and STGs outline format for the reviewers to facilitate the review process. All reviewers and persons closely involved in selecting treatment options and medicines disclosed any circumstance that could represent a potential conflict of interest at the beginning of all technical meetings. GNDP documented the conflict of interest forms and in case any interest was declared the reviewer would have been exempted from the meeting. However, no conflict of interest was declared during the review process. The TOR and

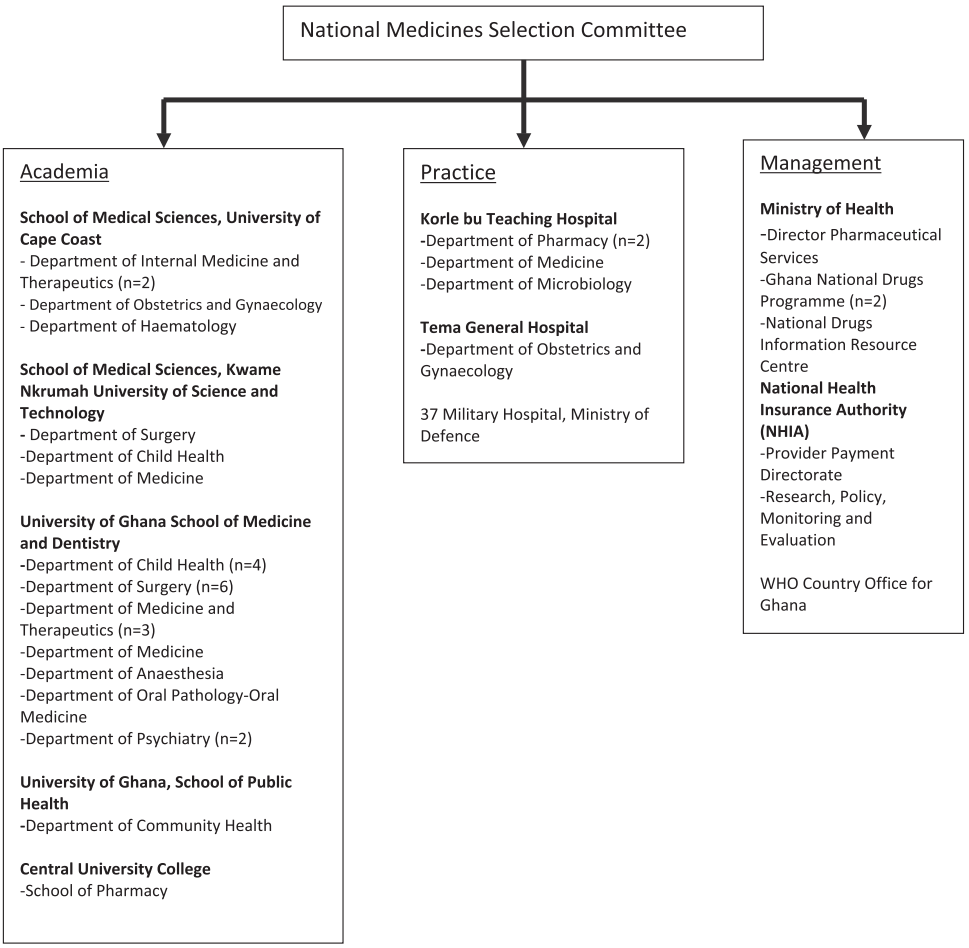

Figure 1 Composition of National Medicines Selection Committee.

criteria for medicine selection to guide the review process and functioning of the NMSC are summarized in Box 1.

To ensure uniformity in assessment and recommendations from NMSC members, the management group designed an outline format for the presentation of content on each disease condition. The outline included—Preamble; Causes; Symptoms; Signs; Investigations; Treatment objectives; Non-pharmacological treatment; Pharmacological treatment; first-line treatment; second-line treatment (where applicable); Evidence rating; Cautions/contraindication/alternative(s); Referral Criteria and Treatment summaries in the form of flowcharts or tables where possible.

Review stage

The GNDP placed a public announcement on 10 June 2014 in a national newspaper—The Ghanaian Daily Graphic—with a title 'Committee to review essential medicines list' (Appiah and Omaboe, 2014). The public announcement coincided with inauguration of the NMSC by the Minister of Health. The Minister tasked the committee to work with the GNDP to attain objectives of the review process. The review process is summarized in Figure 2.

NMSC assignment and plenary sessions

The management group in September 2014, assigned specific disease conditions from the 2010 edition STGs and priority disease conditions to NMSC members based on their expertise. NMSC members worked independently according to the pre-established STGs outline and criteria. To facilitate a plenary session and subject individual work to peer review, the management group further assigned NMSC members to specific groups (Table 2) based on clinical areas and cross-cutting disease conditions. A mix of expertise from child health, pharmacy, public health and policy, surgery and internal medicine constituted each group. Experts reported on disease conditions assigned and recommended new treatment options in their field using the agreed STGs outline format.

During the first plenary session (24–27 February 2015), NMSC members peer-reviewed individual work to ensure practical relevance of treatment options, applicability to the Ghanaian healthcare service delivery system, best current evidence, consistency of recommendations, as well as uniformity based on agreed STGs outline format. NMSC members reviewed individual work as per assigned group and presented agreed evidence rating for proposed treatment options for disease conditions stated in the 2010 edition and new common disease conditions.

The GNDP compiled inputs from the first plenary session and arranged the content in alphabetical order of 'body systems'. The draft report was sent to NMSC members for further review of their individually assigned disease conditions. After, 3 months of individual work, the NMSC reconvened for a second plenary session (9–11 June 2015) to further peer review, build consensus on treatment options for the listed disease conditions and generate a draft STGs for a broader stakeholder engagement. During these technical workshops, reviewers discussed evidence rating from practice and

Box 1: Terms of reference for NMSC

1. To review the diseases listed in the 2010 STG based on current trends in conditions of common occurrence in Ghana
2. To review the medicines listed for the treatment of such diseases in the EML
3. To recommend medicines for reimbursements in the National Health Insurance Medicines List through evidence for efficacy, safety and cost effectiveness.
4. To define list of medicines for specialist care and programme drugs.
5. To define a list of medicines for medical emergencies based on a defined list of emergency medical conditions

Criteria for selection of essential medicines are:

- Drug selection should be based on the results of efficacy and safety evaluations obtained in controlled clinical trials and epidemiological studies, and on the performance in general use in a variety of medical settings.
- When several drugs are available for the same indication, only the drug and the pharmaceutical form that provides the more convenient benefit/risk ratio should be selected.
- When two or more drugs are therapeutically equivalent, the selection should fall on:
  - The drug that has been more thoroughly investigated.
  - The drug with the most favourable pharmacokinetic properties.
  - The drug with the lowest cost, calculated on the basis of the whole course of treatment.
  - The drug with which health workers are already familiar.
  - The drug for which economically convenient manufacturing is available in the country.
  - The drug which shows better stability at the available storage conditions.
- A fixed dose combination should be accepted only if clinical documentation justifies the concomitant use of more than one drug, and the combination provides a proven advantage over single compounds administered separately in therapeutic effect, safety patients' compliance or cost.

Evidence rating:
NMSC members were to rate selected treatment options on the following basis. First, evidence rating A—requires at least one randomized control trial as part of a body of scientific literature of overall good quality and consistency addressing the specific recommendation. Second, evidence rating B—requires the availability of well-conducted clinical studies but no randomized clinical trials on the topic of recommendation. Third, evidence rating C—requires evidence obtained from expert committee reports or opinions and/or clinical experience of respected authorities.

scientific study, and decisions were made to suit the local country context in terms of efficacy, safety, cost, availability and use.

Stakeholder engagement for draft STGs

The GNDP organized a stakeholder meeting on 6 October 2015 with the objectives to consult stakeholders on the revised STGs, develop ownership amongst stakeholders and build consensus on the NMSC recommendations. To facilitate pre-reading and prior comments, the GNDP sent draft STGs copies to invited stakeholders 2 weeks before the meeting. The 62 participants are summarized in Figure 3 and their decisions in Box 2.

Evidence summaries group

During feedback session of the NMSC and the stakeholders meeting, there were elements of contestation on weight of evidence to support treatment options. As a result, the chairperson and NMSC members decided to reconstitute an evidence summaries group to validate contested evidence presented to support a treatment option.

An evidence summaries group previously trained by a specialist from Liverpool School of Tropical Medicine in the retrieval, appraisal and interpretation of systematic reviews (Sinclair *et al.*, 2013) therefore supported the NMSC work. The evidence summaries group investigated conflicting issues over treatment options and weight of evidence for contested treatment options and reported to the NMSC. For example, the evidence summaries group provided information on use of Widal test in confirming typhoid fever. To prevent ambiguity a note—'Diagnosis of typhoid fever is based on a strong clinical suspicion backed by; Blood cultures, positive during first 10 days of fever; Stool cultures, positive after 10th day up to 4th or 5th week; Urine cultures, positive during 2nd and 3rd week. The stated tests are superior to the Widal test, which is unreliable and rarely useful in confirming a diagnosis of typhoid fever'—was therefore included in the 2017 edition (Ministry of Health, 2017c).

How the STGs content evolved

Based on country-specific conditions of high prevalence and public health importance, the 2010 edition content evolved in terms of disease conditions. First, terms of some disease conditions presented in the 2010 edition were modified in the 2017 edition. For example, 'Hepatitis' revised as Acute Hepatitis and Chronic Hepatitis to reflect their different pharmacological and non-pharmacological treatments. Table 3 summarizes the disease conditions and 'body systems' revision. Finally, the 2017 edition incorporated 64 more disease conditions such as drug-resistant tuberculosis and topics such as 'medicines use in the elderly and local anaesthetic agents'. Table 4 summarizes the new disease conditions and topics.

Essential medicines list

The GNDP compiled a second draft of the STGs based on NMSC updated version and stakeholder consensus and generated a list of all essential medicines with their international non-proprietary names in line with practice, National Medicines Policy (Ministry of Health, 2004b) and level of care (Table 5). Due to new developments in terms of disease priorities, value for money and safety, efficacy and use of medicines, the 2017 EML increased by 153 medicines (Table 6) and 56 medicines (Table 7) that were listed in the 2010 EML excluded.

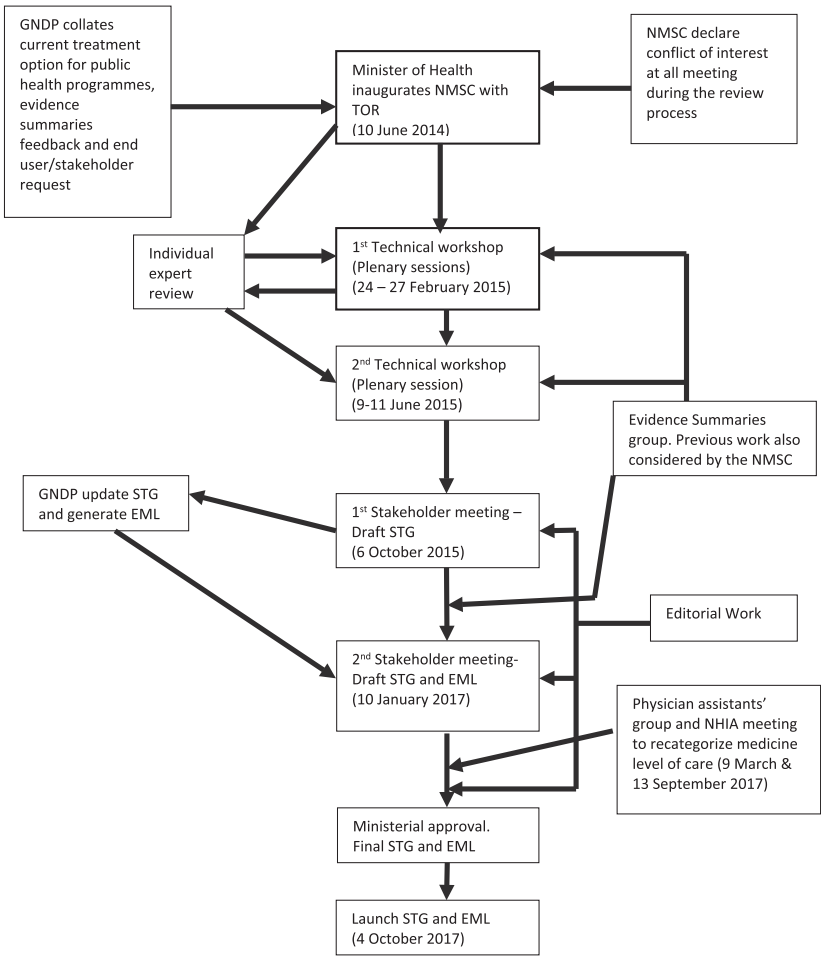

Figure 2 STGs/EML review process.

Stakeholder engagement for the second draft STGs and accompanying EML

The GNDP organized a stakeholder meeting for the draft STGs and EML 10 January 2017 to build consensus, ownership and legitimize the outcome. A broader stakeholder of 95 participants (Figure 3) subjected the second draft STGs and accompanying EML to further review. Since the EML informs the NHIA medicines list, public procurement and use at different levels of care, discussions on EML attracted large participants. During the meeting, service providers contested some proposed level of care and requested changes (summarized in Table 8). At stakeholder engagements, the NMSC and GNDP did not exert their influence on service providers and stakeholders rather collective decisions were made based on information from research and practice adapted to reflect Ghana's healthcare structure needs.

Negotiations with an interest group and institution

After the stakeholder meeting in January 2017, the GNDP and NMSC further negotiated with an organized professional health group and representatives of the NHIA who sought to consolidate their influence and preserve their interest. First, the Ghana Physician Assistants Association requested a meeting with the GNDP to negotiate an increase in the number of medicines allowed at their level of care (Level B1). The physician assistants group representatives could not attend the January 2017 stakeholder meeting but later made suggestions to the GNDP for consideration.

Table 2 NMSC plenary grouping based on cross cutting diseases

Group 1	• Disorders of the Gastrointestinal Tract • Disorders of the Liver • Nutritional Disorders • Haematological Disorders • Malignancies
Group 2	• Childhood Immunisable Disease • Problems of the Newborn • General Emergency • Antibiotics Prophylaxis in Survey • Structured Approach to the Seriously Ill Child
Group 3	• Endocrine and Metabolic Disorders • Obstetric Care and Obstetric Disorders • Gynaecological Disorders • Disorders of the Kidney and Genitourinary System
Group 4	• Eye Disorders • Ear, Nose and Throat Disorders • Oral and Dental Conditions • General Management of Poisoning
Group 5	• Disorders of the Skin (Fungal Skin Infections, Viral Skin Infections, Non-Specific Skin Infections) • Sexually Transmitted Infections • Infectious Disease and Infections • Disorders of the Musculoskeletal System • Local Anaesthetic Agents • Trauma and Injuries • Management of Acute Pain

Figure 3 Summary of key stakeholder engagements participants.

At the meeting on 9 March 2017, the physician assistants argued that as trained prescribers, they usually manage health centres in the rural areas and current EML places limits on their service delivery capabilities. Taking into account the hierarchical structure of the health system and the gatekeeper system where lower levels health facilities are to provide basic primary care and refer clients to higher level if necessary, the NMSC made some concessions. Table 8 summarizes the physician assistant's request and NMSC decisions.

The NHIA provider payment directorate recommended few changes to the final draft EML and requested a meeting with the GNDP officials to discuss their concerns. The NHIA concerns related to management of possible side effects, reimbursement cost

Box 2: 6 October 2015 stakeholder meeting

- Labelling and classifying disease conditions. For example, juvenile rheumatoid arthritis was revised to juvenile idiopathic arthritis and gout moved from endocrine and metabolic disorders section to disorders of the musculoskeletal system section.
- Concomitant use of same class of medicine for pain relief. A service provider noted an increase use of the same class of analgesic in different formulation for pain relief, for example the concurrent use of oral, topical and injection diclofenac. To minimize this practice, a note—'Different groups of drugs can be used together to treat pain. This increases the effectiveness of pain relief, as there is a limit to the dosage of each drug that can be given. This limits its effectiveness when used alone'. Recommended combinations include: (1) paracetamol and opioid (2) paracetamol and non-steroidal anti-inflammatory drug (NSAID) and (3) paracetamol and NSAID and opioid'—(Ministry of Health, 2017c) was include under management of pain section of the STGs.
- Clear difference between the causes of 'acute diarrhoea' and 'chronic diarrhoea' made as different pharmacological and non-pharmacological treatments were required.
- Stating dosage by age and weight in a consistent and uniform manner. Four clinical and child health pharmacists and a family physician were co-opted to align child specific dosage regimen by age and weight.
- GNDP set up 11-member editorial committee

Table 3 Disease conditions presented in the 2010 edition but modified for the 2017 edition

2010 Edition	2017 Edition
Disorder of the Liver	Disorder of the Liver
• Hepatitis	• Acute Hepatitis
	• Chronic Hepatitis
Eye Disorders	Eye Disorders
• Conjunctivitis	• Neonatal conjunctivitis
Haematological Disorders	Haematological Disorders
• Multiple Myeloma	• Plasma Cell Myeloma
• Lymphoma	• Malignant Lymphoma
Psychiatric disorders	Psychiatric disorders
• Alcoholism	• Alcoholic Delirium Tremens
Childhood Immunisable Diseases	Immunisable Diseases
• Hepatitis B	• Hepatitis
Disorder of the Cardiovascular System	Disorder of the Cardiovascular System
• Cardiac Arrhythmias	• Arrhythmias
• Rheumatic Fever	• Acute Rheumatic Fever
Disorder of the Central Nervous System	Disorder of the Cardiovascular System
• Dizziness and Blackout	• Dizziness and Blackout
Disorder of the Respiratory System	Disorder of the Respiratory System
• Asthma	• Bronchial Asthma
Common Malignancies	Disorder of the Kidney and Genitourinary
• Bladder Cancer	• Bladder Cancer
• Carcinoma of Prostate	• Carcinoma of Prostate
Common Malignancies	Disorder of Liver
• Hepatocellular Carcinoma	• Hepatocellular Carcinoma
Common Malignancies	Gynaecological Disorders
• Carcinoma of the cervix	• Carcinoma of the cervix
Endocrine and Metabolic Disorders	Disorder of Musculoskeletal System
• Gout	• Gout
Disorders of the Musculoskeletal System	Disorders of the Musculoskeletal System
• Juvenile Rheumatoid Arthritis	• Juvenile Idiopathic Arthritis
• Low Back Pain	• Back pain
General Emergencies	Trauma and Injuries
• Shock	• Shock
Oral and Dental Conditions	Oral and Dental Conditions
• Gingivitis	• Acute Necrotizing Ulcerative Gingivitis

and access to essential medicines especially in hard to reach areas usually served by CHPS posts (Table 8).

Post-review stage

The editorial committee proofread the draft STGs and EML to ensure standardized format and accuracy. The NMSC members then signed off the edited STGs and EML for ministerial approval. As per the national procurement law (Act 663), the GNDP sought invoices for three publishing companies. The procurement and supplies directorate of the MoH awarded a contract to Yamens Press Limited to print copies of the STGs and EML.

The Minister of Health officially launched the documents on 4 October 2017 in Accra. During the launch, the chairperson proposed creation of a 'standing committee' or technical advisory committee in selected institutions to constantly evaluate and disseminate new data in between major national STGs and EML review process and advocated for adherence to the guidelines and essential medicines policies. In addition, the chair asked government and development partners to provide funds for STGs/EML review promptly to avoid rather long process because of insufficient funds and sporadic funding arrangement. The NMSC dissolved after the Minister of Health launched the published 2017 STGs and accompanying EML.

Discussion

The Ghanaian national STGs and accompanying EML review process is predominately evidence-based drawing on information provided by the NMSC, evidence summaries group and GNDP, and then adapted to reflect Ghana's healthcare structure needs as informed by experts, stakeholders, service providers and professional groups. The review process involved actors with varied power sources who in different arenas influenced the process and how the content of the previous edition evolved. The review process occurred between bureaucratic (committee plenary sessions, management group meetings) and public arenas (stakeholder engagements) (Grindle and Thomas, 1991) where varied actors whether NMSC members or service providers influenced decisions.

In the bureaucratic arena, the NMSC chair and members, evidence summaries group and GNDP reviewed the 2010 edition STGs/EML and considered the country's disease burden, public health relevance, hierarchical health service delivery and evidence

Table 4 New topics and disease conditions included in the 2017 edition

1. Disorders of the Gastrointestinal Tract • Rotavirus Disease and Diarrhoea	2. Medicines Use in the Elderly • Medicines use in the Elderly	3. Local Anaesthetic Agents • Local Anaesthetic Agents	4. Immunisable Diseases • Pneumococcal Disease • Rotavirus Disease	5. Disorder of the Liver • Vomiting • Drugs and the Liver
6. Eye Disorders • Exposure Keratopathy • Strabismus • Sickle-Cell Disease—Retinopathy • Endocrine and metabolic disorders with eye complications	7. Disorders of the Musculoskeletal System • Fibromyalgia • Idiopathic inflammatory myopathies • Management of the Hot Swollen Joint • Pseudo-gout (chondrocalcinosis)	8. Gynaecological Disorders • Abnormal Vaginal Discharge • Acute Lower Abdominal Pain	9. Infectious Disease and Infestations • Drug resistant tuberculosis • Seasonal Malaria Chemoprevention	10. Obstetric Care and Obstetric Disorders • Sickle-Cell Disease in Pregnancy • Severe Pre-eclampsia and Imminent Eclampsia
11. Psychiatric Disorder • Substance Use Disorders • Autistic Spectrum Disorder	12. Ear, Nose and Throat Disorders • Acute Epiglottitis	13. Structured Approach to the Seriously Ill Child • Structured approach to the seriously ill child	14. Problems of the Newborn (Neonate) • Retinoblastoma • Wilms Tumour	15. Endocrine and Metabolic Disorders • Diabetes in Pregnancy • Treatment-Induced Hypoglycaemia
16. Sexually Transmitted Infections (STI) • *Mycoplasma genitalum* • STI-related Ano-rectal Related Syndromes • Sexually Transmitted Infections in Children • STI-related Neonatal Conjunctivitis (Opthalmia Neonatorum)	17. Management of Specific STI and STI Syndromes in Children • STI-related Urethral Discharge Syndrome in Children • STI-related Vaginal Discharge Syndromes in Children • STI-related Lower Abdominal Pain or Pelvic Inflammatory Disease Syndrome in Children • STI-related Genital Ulcer Syndrome in Children • STI-related Ano-Rectal Related Syndromes in Children	18. Trauma and Injuries • Abdominal Trauma • Closed Fractures • Open Fractures • Dislocations • Acute orthopaedic infections • Cellulitis • Chronic Osteomyelitis and Chronic Septic Arthritis • Necrotizing Fasciitis • Hand Infections • Tuberculosis in orthopaedics • Rickets and Osteomalacia • Scurvy • Osteoporosis • Sickle-cell Vaso-occlusive Crisis • Avascular Necrosis • Osteogenesis Imperfecta	19. Oral and Dental Conditions • Bacterial Endocarditis and Prophylaxis in Dentistry • Acute Bacterial Sialoadenitis • Ludwig's Angina/ Cervico-Facial Abscess • Chronic Periodontal Infections • Mouth Ulcers • Odontogenic Infections • Oral Squamous Cell Carcinoma • Temporo-mandibular Joint dysfunction and masticatory muscle dysfunction • Trigeminal Neuralgia	20. Disorders of the Kidney and Genitourinary System • Anaemia in Chronic Kidney Disease • Medicines and the Kidney • Persistent or Recurrent Urethral Discharge • Retention of Urine

from research and practice on the safety, efficacy and cost-effectiveness of the treatment options. To build consensus and ensure credibility and acceptance (World Health Organization, 2002), treatment options and list of essential medicines generated from the STGs were subjected to discussions in public arenas. During these stakeholder engagements, whether organized as part of the scheduled review process or a request by specific groups such as the physician assistants group, service providers subjected the recommended treatment options and medicines list to further scrutiny. Service providers considered their experience from practice and how the new guidelines would impact their practice. In such public arenas, technical discussions move towards negotiations between the policymakers and implementers with emphasis on effect of changing health service delivery in terms of tasking shifting and continuous training of health professional to provide additional care and the practicability of the policy. Therefore, training of health professionals to provide reproductive healthcare at the lowest level of care (i.e. CHPS posts) and challenges of irrational use of medicines such as the concomitant use of same class of medicine for pain relief were some issues that influenced medicines categorization and notes for treatment options, respectively.

Additionally, medicines for specific treatment options aligned to levels of care within the Ghanaian hierarchical health system. Aligning treatment options and medicines to level of care according to the National Medicines Policy (Ministry of Health, 2017b) aims to promote responsible use of medicines and encourage referral and adherence to the gatekeeper system where lower levels health facilities are to provide basic primary care and refer clients to higher levels if necessary. The categorization of medicines for 'Level A' and 'Level M' evolved to reflect national strategic plan for reproductive health and human resources training at the lowest level of the health system (Ministry of Health, 2016a,b).

One may question whether findings and description of the Ghanaian process of reviewing its 2010 STGs/EML are generalizable. However, when you look at other studies (Laing *et al.*, 2003; Mori *et al.*, 2014; Perumal-Pillay and Suleman, 2017;

Table 5 Level of care categorization for EML 2017

2017	Comment
Level A—Community based Health Planning and Services (CHPS)	The current categorization reflects primary healthcare and community mobilization activities for healthcare. 2010 edition categorized Level 'A' as Community
Level M—Midwifery and CHPS with midwife	Level 'M' category arose from the fact that some CHPS posts had midwives as well as community health officers with training in Integrated Management of Neonatal and Childhood Illness. 2010 edition categorized Level 'M' as Midwifery
Level B1—Health centre without a doctor	Same as 2010 edition
Level B2—Health centre with a doctor	
Level C—District Hospital	
Level D—Regional/Teaching Hospital	

Osorio-de-Castro *et al.*, 2018), there are fundamental similarities and context-specific difference in how STGs/EML policies are reviewed. The review process of EML for Ghana, South Africa, Brazil, Tanzania and the WHO model list has similarities in the following aspects. One, the medicine selection expert members are multidisciplinary and are appointed or inaugurated or established by a higher authority such as the Minister of Health, MoH or Director General in the case of WHO. Two, all expert members declare potential conflict of interest during the review process. Three, evidence-based considerations on safety, efficacy, cost-effectiveness as well as expert opinions and experiences influenced medicines selection. Although the approach and level of evidence from research and practice may differ, there are some evidence-based considerations. Finally, the recommended medicine lists of the expert members are subjected to stakeholder comments and scrutiny and this is to accommodate different stakeholder perspectives (Laing *et al.*, 2003; Mori *et al.*, 2014; Perumal-Pillay and Suleman, 2017; Osorio-de-Castro *et al.*, 2018).

The review process in Ghana differs from South Africa in terms of expert members' nomination. In South Africa, a notice of call for nomination is advertised at provincial and departmental levels, department of health intranet, national department of health internal and external webpages and in newspapers. Criteria for selection include a practitioner in a public sector hospital with an expertise in one of the following: internal medicine, psychiatry, pharmacology, public health, rational use of medicines, evidence-based medicines, health economics and bioethics. Field, capacity and geographical mix in provincial representation of each individual is considered (Perumal-Pillay and Suleman, 2017). While in Ghana, nominations are not widely advertised rather Curriculum Vitae of pervious experts are solicited and the management group on recommendations from existing NMSC members nominates new experts based on their availability and expertise on the country's disease pattern and emerging public health trends. Additionally, the national EML committee of South Africa has four subcommittees, which are the technical review committees for primary healthcare, adult hospital

Table 6 List of medicines added to the 2017 essential medicines list

	Name	Dosage form	Strength
1.	Abatacept	Injection	125 mg/ml
2.	Actinomycin D	Injection	10 mg/ml
3.	Adalimumab	Injection	10 mg/ml
4.	Adapalene	Cream/Gel	0.1%
5.	Alendronate	Tablet	70 mg
6.	Alfuzocin	Tablet	10 mg
7.	Alprazolam	Tablet	250 µg
8.	Aluminium Hydroxide	Tablet	500 mg
9.	Anakinra	Injection	150 mg/ml
10.	Antacid containing (Aluminium Hydroxide, Magnesium Hydroxide, Simethicone, Calcium alginates)	Mixture	
11.	Atazanavir	Tablet	300 mg
12.	Atomoxetine	Tablet	10 mg, 25 mg, 40 mg
13.	Azathioprine	Injection	25 mg
		Tablet	25 mg
14.	Belimumab	Infusion	120 mg, 400 mg
15.	Calcitonin	Injection	100 units/ml
16.	Capreomycin	Injection	1 g
17.	Carboplatin	Injection	10 mg/ml
18.	Cefixime	Tablet	200 mg
		Suspension	20 mg/ml
19.	Celecoxib	Tablet	100 mg, 200 mg
20.	Certolizumab	Injection	200 mg/ml
21.	Cervedilol	Tablet	3.125 mg, 12.5 mg
22.	Cetirizine	Tablet	10 mg
23.	Chloral Hydrate	Tablet	707 mg
		Oral solution	28.66 mg/ml
24.	Cholestyramine	Oral powder	4 g
25.	Cinnarizine	Injection	15 mg
26.	Citalopram	Tablet	20 mg, 40 mg
27.	Clobetasol Propionate	Cream	0.05%
28.	Clonazepam Hydrochloride	Tablet	500 µg
29.	Clonidine	Tablet	25 µg, 100 µg
30.	Clopidogrel	Tablet	75 mg
31.	Codeine containing cough preparations	Syrup	
32.	Colchicine	Tablet	500 µg
33.	Copper Sulphate	Stone	
34.	Cyclizine	Injection	50 mg/ml
		Tablet	50 mg
35.	Cyclobenzaprine	Tablet	5 mg, 10 mg
36.	Cycloserine	Capsule	250 mg
37.	Cyclosporine	Injection	50 mg/ml
		Oral solution	100 mg/ml
		Tablet	10 mg, 25 mg
38.	D-penicillamine	Tablet	125 mg
39.	Darbepoietin alfa	Injection	250 µg
40.	Denosumab	Injection	60 mg/ml, 70 mg/ml
41.	Desferrioxamine	Injection	500 mg
42.	Desmopressin	Nasal spray	150 µg
43.	Dextromethorphan containing cough preparations	Syrup	
44.	Diloxanide Furoate	Tablet	500 mg
45.	Diphtheria Antitoxin	Infusion	

(continued)

Table 6 (continued)

	Name	Dosage form	Strength
46.	Doxorubucin	Injection	2 mg/ml
47.	Duloxetine Hydrochloride	Tablet	20 mg, 30 mg
48.	E45	Cream	
49.	Econazole	Cream	1%
50.	Entecavir	Injection	50 µg/ml
		Tablet	500 µg
51.	Epoietin beta	Injection	2000 units, 10 000 units
52.	Etanercept	Injection	50 mg/ml
53.	Ethanol	Solution	10%
54.	Ethionamide	Tablet	500 mg
55.	Ferric Sodium Gluconate complex	Injection	62.5 mg elemental iron
56.	Ferrous Gluconate	Tablet	300 mg
57.	Flupenthixol Decanoate	Injection	20 mg/ml, 25 mg/ml
58.	Fomepizole	Injection	5 mg/ml
59.	Fusidic Acid	Cream	2%
60.	Gabapentin	Tablet	300 mg
61.	Glycerol	Suppository	1 g, 2 g, 4 g
62.	Golimumab	Injection	100 mg/ml
63.	Guaifenesin containing experorant	Syrup	
64.	Hydrochlorothiazide	Tablet	12.5 mg, 25 mg
65.	Hydroxychloroquine	Tablet	200 mg
66.	Hydroxymethyl Cellulose	Eye drops	0.3%
67.	Hypertonic Saline	Injection	3%
68.	Imiquimod	Cream	5%
69.	Indomethacin	Tablet	25 mg, 75 mg
70.	Infliximab	Injection	100 mg
71.	Intralipid	Infusion	20%
72.	Ipratropium Bromide	Nebulizer	250 µg
73.	Iron (III) Hydroxide Polymaltose Complex	Suspension	100 mg elemental iron
74.	Kanamycin	Injection	500 mg/vial, 1 g/vial
75.	Lamotrigine	Dispersible tablet	25 mg
		Tablet	25 mg, 50 mg
76.	Leflunomide	Tablet	10 mg, 15 mg, 100 mg
77.	Levofloxacin	Tablet	500 mg
78.	Malathoin	Liquid	0.5%
79.	Mefenamic Acid	Tablet	500 mg
80.	Melatonin	Tablet modified release	2 mg
81.	Methocarbamol	Tablet	750 mg
82.	Methoxy polyethylene glycol epoietin beta (pegylated form of Epo)	Injection	100 µg/ml500 µg/ml
83.	Methylprednisolone sodium succinate	Infusion	500 mg, 1 g
	Methylprednisolone acetate	Suspension for injection	40 mg/ml
84.	Metoprolol Tartrate	Tablet	50 mg, 100 mg
85.	Miconazole + hydrocortisone	Cream	2% + 1%
86.	Milk of Magnesia	Suspension	
87.	Minocycline		100 mg
88.	Mist. Potassium Citrate	Capsule modified release Solution	
89.	Mometasone	Cream	0.1%
90.	Montelukast	Chewable tablet	4 mg, 5 mg
		Tablet	10 mg
		Granule	4 mg, 5 mg
91.	Mupirocin	Ointment	
92.	Mycophenolate mofetil	Capsule	250 mg
		Injection	500 mg
		Suspension	200 mg/ml
93.	Naproxen	Tablet enteric coated	500 mg
94.	Neomycin + Hydrocortisone	Nasal drops	0.5% + 1.5%
95.	Nitrous Oxide: Oxygen	Inhalation	50: 50
96.	Norfloxacin	Tablet	400 mg
97.	Oilatum	Soap	
98.	Ondansetron	Tablet	4 mg, 8 mg
99.	Oxymetazoline	Nasal spray	0.3%
100.	Pamidronate	Injection	6 mg/ml, 15 mg/ml
101.	Pantoprazole	Tablet	40 mg
102.	Para-aminosalicylic acid	Granule	4 mg
103.	Paromomycin	Suspension	125 mg/5 ml
		Capsule	250 mg
104.	Pegylated inteferon alfa-2a	Injection	180 µg/ml
105.	Pegylated inteferon alfa-2b	Powder for injection	50 µg, 80 µg
106.	Permethrin	Lotion	1%
107.	Pneumococcal Conjugate Vaccine 13 (PCV13)	Injection	
108.	Podophyllin	Tincture of benzoin	10–25%
109.	Podophylotoxin	Solution	0.5%
		Cream	0.15%
110.	Polygeline	Infusion	3.5%
111.	Polyvinyl Alcohol	Eye drops	1.4%, 2%
112.	Povidone Iodine	Solution	10%
113.	Pregabalin	Tablet	50 mg, 100 mg
114.	Probenecid	Tablet	500 mg
115.	Prostagladin E1	Injection	500 µg/ml
		Tablet	500 mg
116.	Prothionamide	Injection	250 mg
117.	Purified Factor IX	Injection	
118.	Purified Factor VIII	Injection	
119.	Recombinant Factor IX	Injection	
120.	Recombinant Factor VIII	Injection	
121.	Ribavirin	Tablet	200 mg, 400 mg
122.	Rifaximin	Tablet	200 mg, 550 mg
123.	Rituximab	Injection	10 mg/ml, 119.66 mg/ml
124.	Salt-poor Human Albumin	Solution	
125.	Saxagliptin	Tablet	2.5 mg
126.	Shea Butter	Cream	
127.	Sildenafil Citrate	Tablet	25 mg, 50 mg, 100 mg

Table 6 (continued)

	Name	Dosage form	Strength
128.	Sitagliptin	Tablet	25 mg
129.	Sodium Aurothiomalate	Injection	20 mg/ml, 100 mg/ml
130.	Sodium Thiosulfate	Injection	500 mg/ml
131.	Strontium Ranelate	Granule sachets	2 mg
132.	Sulfasalazine	Suspension	50 mg/ml
		Tablet	500 mg
133.	Tacrolimus	Injection	5 mg/ml
		Tablet	500 µg, 2 mg, 5 mg
134.	Tadalafil	Tablet	2.5 mg, 10 mg
135.	Teriparatide	Injection	20 µg
136.	Tetracaine Hydrochloride	Eye drops	0.5%
137.	Tiotropium Bromide	Inhaler (dry powder)	18 µg
138.	Tizanidine	Tablet	2 mg
139.	Tocilizumab	Injection	20 mg/ml, 180 mg/ml
140.	Tofacitinib	Tablet	5 mg, 11 mg
141.	Tretinoin	Gel	0.01%
142.	Triamcinolone	Injection	10 mg/ml, 40 mg/ml
143.	Triazolam	Tablet	125 µg, 250 µg
144.	Trichloroacetic Acid	Solution	80–90%
145.	Valsartan	Tablet	40 mg, 160 mg
146.	Vancomycin	Injection	500 mg
147.	Verapamil	Tablet	40 mg, 80 mg
148.	Verdanafil	Tablet	5 mg, 10 mg
149.	Vildagliptin	Tablet	50 mg
150.	Vitamin B-Compound	Injection	(High potency)
151.	Vitamin C	Tablet	100 mg
152.	Xylometazoline	Nasal spray	0.1%
153.	Zinc Oxide	Cream	United State Pharmacopeia

level, paediatric hospital level and tertiary/quaternary level. These subcommittees undertake literature review and critical appraisal of evidence for the review of STGs/EML for those levels and make recommendations to the national committee. In Ghana, the GNDP and evidence summaries group support the NMSC with literature review and critical appraisal of evidence. Furthermore, the NMSC categorizes the national essential medicines according to the different levels of care of the healthcare system.

The WHO publishes clear explanations and evidence for decisions (Laing *et al.*, 2003), similarly in Brazil electronically submitted inclusion proposal for evaluation are made public on the MoH website (Osorio-de-Castro *et al.*, 2018) and this transparency approach is yet to be adopted by Ghana. Additionally, the WHO EML does not necessarily generate from its treatments guidelines because of the apparent disconnect between selection decisions made by WHO expert committees and those made by WHO expert creating treatment guidelines (Laing *et al.*, 2003). However, there are measures by the WHO to coordinate the timing of publication of both WHO guidelines and EML to minimize unintended delays and improve consistency and alignment (World Health Organization, 2017). In Ghana, the national EML reflects treatment guidelines recommended in the STGs to promote access to medicine at all levels of care (Ministry of Health, 2017a,c).

Challenges

The Ghanaian review process had challenges. Since 1988, when Ghana's first Essential Drugs List and National Formulary with

Table 7 List of medicines absent in 2017 essential medicines list

	Name	Dosage Form	Strength
1.	5-Fluorouracil	Injection	50 mg/ml
2.	6-Mercaptopurine	Tablet	50 mg
3.	Atenolol + Hydrochlorothiazide	Tablet	100 mg + 25 mg
4.	Atracurium	Injection	10 mg/ml
5.	Bleomycin	Injection	15 units
6.	Busulphan	Tablet	2 mg
7.	Calcium Carbonate	Tablet	500 mg
8.	Capecitabine	Tablet	500 mg
9.	Cefaclor	Capsule	250 mg, 500 mg
		Suspension	125 mg/5 ml 250 mg/5 ml
10.	Chlorambucil	Tablet	
11.	Crisantaspase	Injection	10 000 units
12.	Crotamiton	Lotion	10%
13.	Cyclopentolate	Eye drops	0.5%, 1%, 2%
14.	Cytarabine	Injection	100 mg
15.	Dacarbazine	Injection	100 mg
16.	Daunorubicine	Injection	50 mg
17.	Didanosine	Capsule	200 mg
		Oral solution	10 mg/ml
		Tablet	100 mg, 150 mg
18.	Docetaxel	Injection	20 mg/0.5 ml
19.	Edrophonium	Injection	10 mg/ml
20.	Ergotamine Tartrate	Tablet	1 mg, 2 mg
21.	Estramustine Phosphate	Capsule	140 mg, 280 mg
22.	Ferrous Sulphate + Folic Acid	Tablet	60 mg + 250 µg
23.	Fluvastatin	Capsule	20 mg
24.	Folinic Acid	Injection	15 mg
		Tablet	15 mg
25.	Gelatin Infusion (Succinylated Gelatin)		
26.	Gentian Violet	Paint	
27.	Halothane	Inhalation	250 ml
28.	Imatinib	Tablet	100 mg, 400 mg
29.	Indinavir	Tablet	400 mg
30.	Isoflurane	Inhalation	100 ml
31.	Ketorolac	Injection	30 mg/ml
32.	Lindane	Lotion	1%
33.	Lodoxamide	Eye drops	0.1%
34.	Mercurochrome	Solution	
35.	Methylcellulose	Eye drops	1%
36.	Mitoxantrone	Injection	2 mg/ml
37.	Natamycin	Eye drops	5%
38.	Nelfinavir	Tablet	250 mg
39.	Neomycin	Tablet	500 mg
40.	Neostigmine	Injection	0.5 mg/ml, 2.5 mg/ml
41.	Noradrenaline (Norepinephrine)	Injection	1 mg/ml (1:1000)
42.	Pancuronium Bromide	Injection	2 mg/ml
43.	Procarbazine	Tablet	50 mg
44.	Propofol	Injection	10 mg/ml
45.	Protamine Sulphate	Injection	10 mg/ml
46.	Ritonavir	Capsule	100 mg
47.	Rocuronium	Injection	10 mg/ml
48.	Rose Bengal Minims	Solution	1%
49.	Rosiglitazone	Tablet	4 mg
50.	Saquinavir	Capsule	300 mg
51.	Stavudine	Capsule	15 mg, 20 mg, 30 mg, 40 mg
		Oral solution	1 mg/ml
52.	Streptokinase	Injection	100 000 units 250 000 units 750 000 units
53.	Suxamethonium Succinylcholine	Injection	50 mg/ml
54.	Tirofiban	Infusion	250 µg/ml
55.	Tuberculin (Purified Protein Derivative)	Injection	20 units/ml
56.	Vecuronium Bromide	Injection	10 mg

Table 8 Request for medicines recategorization by stakeholders during the review process

Request for medicines recategorizations approved at the second stakeholders meeting (10 January 2017)

Medicines	Level of care categorization, 2010	Level of care categorization, 2017	Motivator and rationale for request	Comment
Injection Dexamethasone 4 mg/ml	C	M	A service provider noted that with the provision of equipment for obstetric ultrasound scanning at health centres and some CHPS posts to estimate gestational age and eligibility for Dexamethasone 4 mg/ml injection, Dexamethasone injection be moved to a lower level	Midwives at health centres and CHPS can administer
Injection Metronidazole 5 mg/ml	B2	B1	Service providers advocated use of Metronidazole 5 mg/ml injection at lower healthcare delivery level for pre-referral treatment of pre-term labour	
Injection Magnesium Sulphate 50%	C	M	In order to facilitate pre-referral treatment of severe pre-eclampsia and eclampsia, Ma	
Injection Calcium Gluconate 100 mg/ml	C	B2	As a safety measure for Magnesium Sulphate toxicity	Health centres with doctors to manage Magnesium Sulphate toxicity
Gel Chlorhexidine Gluconate 4%	M	A	To allow access at the lowest healthcare level for other medical procedures	

Request for medicines recategorization approved during negotiations with Physician Assistants (9 March 2017)

Medicines	Level of care categorization, 2010	Level of care categorization, 2017	Motivator and rationale for request	Comment
Tablet Bendroflumethiazide 5 mg Tablet Metformin 500 mg Tablet Glibenclamide 5 mg Injection Metronidazole 5 mg/ml	B2	B1	To improve access to healthcare and medicines especially in the rural areas. Allow physician assistants to management more disease conditions	Physician assistants are to refer patients to higher level health facilities if necessary
Tablet Griseofulvin 125 mg, 500 mg Capsule Tetracycline 250 mg Injection Benzyl Penicillin 1 MU, 5 MU Injection Amoxicillin + Clavulanic Acid 500 mg + 100 mg Tablet Amoxicillin + Clavulanic Acid 250 mg + 125 mg 500 mg + 125 mg Suspension amoxicillin + clavulanic acid 250 mg + 62.5 mg 400 mg + 57 mg Tablet Prednisolone 5 mg				Some medicines for managing chronic conditions such as diabetes (e.g. Metformin 500 mg tablet, Glibenclamide 5 mg tablet) and hypertension (e.g. Bendroflumethiazide 5 mg tablet) moved from Level B2 to Level B1 to improve access to medicines. In addition, some antibiotics categorized by WHO as 'ACCESS' group (World Health Organization, 2017) such as Amoxicillin + Clavulanic Acid and Benzyl Penicillin moved from Level B2 to Level B1
Tablet Omeprazole 40 mg	D	B1		
Tablet Methyldopa 250 mg Clotrimazole Pessary 100 mg Suspension Nystatin 100 000 IU/ml	B2	M		
Clotrimazole Cream 1%, 2%	B2	A		
Tablet Cetirizine 10 mg	Not listed	A		

(continued)

Table 8 (continued)

Request for medicines recategorization denied during negotiations with Physician Assistants (9 March 2017)

Medicines	Level of care categorization, 2010	Level of care categorization, 2017	Motivator and rationale for request	Comment
Injection Artesunate 60 mg Injection Artemether 80 mg/ml Injection Quinine 300 mg/ml Infusion Ciprofloxacin 2 mg/ml Tablet Lisinopril 2.5 mg, 5 mg, 10 mg Injection Aminophylline 250 mg/10 ml Tablet Amlodipine 5 mg, 10 mg Tablet Propranolol 10 mg, 40 mg, 80 mg Tablet Atenolol 25 mg, 50 mg,	B2	B2	To improve access to healthcare and medicines especially in the rural areas. Allow physician assistants to management more disease conditions.	Physician assistants are to refer patients to higher level health facilities if necessary Antibiotics such as injections Ciprofloxacin and Ceftriaxone maintained Levels B2 and Level C respectively, because Ciprofloxacin and Ceftriaxone categorized by WHO as 'WATCH' group (World Health Organization, 2017) must be guarded against potential misuse and abuse
Tablet Atenolol 100 mg Suspension Cefuroxime 125 mg/5 ml Injection Cefuroxime 750 mg, 1.50 mg Tablet Cefuroxime 125 mg, 250 mg	C	B2		
Capsule Azithromycin 250 mg Injection Ceftriaxone 250 mg, 1 g, 2 g	C	C		

Request for medicines recategorization approved during negotiations with NHIA (13 September 2017)

Medicines	Level of care categorization, 2010	Level of care categorization, 2017	Motivator and rationale for request	Comment
Tablet Nifedipine 10 mg, 20 mg (slow release)	B2	B2	Under section 11.1 of draft EML 2017 Anti-anginal Drugs, these medicines with the same strengths and formulation are classified as B2 but under section 11.3 Anti-hypertensive Drugs, these same medicines are classified as M	Nifedipine under section 11.3 moved to Level B2. Methyldopa categorized for Level M can be used at that level of care
Tablet Calcium 500 mg	Not stated	B2	In the draft EML 2017, both Tablet Calcium 500 mg and Calcium + Vitamin D were categorized as M The Calcium Tablet is more expensive (0.50 GHC/tablet) than the Calcium + Vitamin D (0.05 GHC/tablet). Providers, including the maternity homes tend to bill the NHIA with the price for Calcium 500 mg for antenatal care, however, they may have supplied the Calcium + Vitamin D	Calcium supplement is indicated for Rheumatoid Arthritis in the 2017 STG. Calcium 500 mg is moved to Level 'B2' for orthopaedic cases while Calcium + Vitamin D is maintained at Level M
Tablet Calcium 97 mg + Vitamin D 10 µg	C	M		

(continued)

Table 8 (continued)

Request for medicines recategorization denied during negotiations with NHIA (13 September 2017)

Medicines	Level of care categorization, 2010	Level of care categorization, 2017	Motivator and rationale for request	Comment
Gel Diclofenac 1%	A/M	M	The draft EML 2017 categorized Diclofenac 1% gel as B1. The livelihood of most indigenous people is farming, and other heavy duty works. Diclofenac gel would be very useful in alleviating the aches. It should be made available at the lowest level (which is level A) since they are found in the deprived areas.	Moved to Level M (Midwifery and CHPS post with a midwife)
Tablet Co-Trimoxazole 400 mg + 80 mg	B1	A	Looking at the adverse effects of Co-trimoxazole, one may wonder if health personnel at Level A could be able to handle the potential side effects. Adverse effects include seizure, hyperkalaemia, agranulocytosis, hyponatraemia, immune hypersensitive reaction, and Stevens-Johnson syndrome. Recommend recategorization to B1	Maintain at Level A. Decision is based on recommendations from the Ministry of HealthCo-trimoxazole is used at CHPS posts for reproductive interventions
Pessary Clotrimazole 100 mg	B2/M	M	Recommend recategorization to A. To cater for patients with candidiasis in the deprived areas where the only health facility within the closest proximity is a CHPS post	Currently, Level M includes CHPS posts with Midwife. For this reason, Clotrimazole pessary is maintained at Level M
Shampoo Selenium Sulphide 2.5%	C	C	Recommend Levels A or M. Skin infections like Tinea Versicolor, Dandruff and Seborrhoea are usually predominant in the deprived areas where health issues pertaining to personal hygiene and sanitation are high	Selenium Sulphide is maintained at Level C. Another antifungal such as Nystatin cream is available at Level M
Injection Anti-Snake Serum (West African Polyvalent) 1500 IU/ml	B1	B1	Deprived areas have recorded high rates of snake attacks and bites. Anti-snake serum can be very useful at level A to reduce mortality, which may arise due to inability of patients to get to the higher level of care when that facility is far. Health personnel in the lower levels can be trained to prescribe and administer. Storage equipment should be provided as well	Appropriate use and storage facility are important. The current level of care—B1 will have storage facilities and expertise to administer the serum. Anti-snake maintained at Level B1
Injection Pethidine 50 mg/ml	B2	B2	The injectable opioids on the list (e.g. pethidine and morphine injection) at Level B2 should be reviewed upwards to Level C. These injectable medicines have the potential to affect breathing, so patients need to be monitored	Pethidine maintained at Level B2 (Health Centre with a doctor)

Therapeutic Guidelines was published, the average period for the next edition is ~5 years and this is more than twice the National Medicines Policy recommended review period of 2 years (Ministry of Health, 1988, 2004b). The WHO model list of essential medicines, which serves as a guide for the development of national and institutional essential medicine lists is updated and revised every 2 years by the WHO expert committee on selection and use of medicines (World Health Organization, 2002). Additionally, the review process is long due to insufficient funds, intermittent funding flow to the GNDP and securing the availability of potential NMSC members.

Lessons learnt and way forward

STGs serve as one of the means by which quality of care can be provided for patients seeking healthcare as it documents well-established methods of prevention, diagnosis and treatment of common diseases seen in health facilities. The research provides information to service providers and policy change advocates on how reviewers and participating stakeholders interact and discuss issues relating to disease conditions and medicines in Ghana. Selection of medicines in Ghana which engages all relevant stakeholders to arrive at a medicines list that address a majority of common medical conditions affecting the majority of the population is critical given that medicines are categorized on level of care for use and access. The use of multidisciplinary reviewers and varied stakeholders lends to legitimacy and acceptance of the STGs/EML. Although the STGs and EML guide diagnosis, institutional medicines list, public procurement and the NHIA medicines list and benefit package tariff, there is little information on actual use of the STGs in health facilities in Ghana and its impact on rational use of medicines indicators. Studies are therefore required to assess the extent to which service providers use the treatment options stipulated in the STGs and adhere to the EML.

In the future, an NMSC 'standing committee' with clear selection criteria and process, sustained financial support for the review process, evidence-centred database and publicizing the review process are necessary. A future consideration that will potentially increase access, reduce printing costs and allow for a 'living' continually updated STGs/EML is to make the STGs/EML available in an electronic format.

Conclusions

The Ghanaian national STGs and EML review processes are complex and based on evidence and consensus. The NMSC members, evidence summaries group and GNDP influenced the review process and content within bureaucratic arenas through mainly technical discussions. When drafts STGs/EML recommended by the NMSC were subjected to stakeholder discussions, service providers and professional groups influenced the process and content within a public arena mainly through negotiations and consensus building. Understanding the STGs/EML review process, how the content evolved and how stakeholders within a health system space with varied interest and power influenced the process and content are relevant for public policy across other low and middle-income countries. We hope this article contributes to learning in Ghana and beyond.

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