The role of government agencies and other actors in influencing access to medicines in three East African countries

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Abstract

The WHO Model List of Essential Medicines (MLEM) has since 1977 helped prioritize and ensure availability of medicines especially in low- and middle-income countries. The MLEM consists mainly of generic medicines, though recent trends point towards listing expensive on-patent medicines and increasing global support for medicines against non-communicable diseases. However, the implications of such changes for national essential medicines list (NEML) updates for access to essential medicines has received relatively little attention. This study examined how government agencies and other actors in Kenya, Uganda and Tanzania participate in and influence the NEML update process and subsequent availability of prioritized medicines; and the alignment of these processes to WHO guidance. A mixed study design was used, with qualitative documentary review, key informant interviews and thematic data analysis. Results show that NEML updating processes were similar amongst the three countries and aligned to WHO guidelines, albeit conducted irregularly, with tendency to reprioritization during procurement stages, and were not always accompanied by revision of clinical guidelines. Variations were noted in the inclusion of medicines against cancer and hepatitis C, and the utilization of health technology assessment (HTA). For medicines against diseases with high global engagement, such as HIV/AIDS and TB, national stakeholders had more limited inputs in prioritization and funding. Furthermore, national actors were not influenced by the pharmaceutical industry during the NEML update process, nor were any conflicting agendas identified between health, trade and industrial policies. Hence, the study suggests that more attention should be paid to the combination of HTAs and NEMLs, particularly as countries work towards universal health coverage, in addition to heightened awareness of how global disease-specific initiatives may confound national implementation of the NEML. The study concludes with a call to strengthen country-level policy and procedural coherence around the process of prioritizing and ensuring availability of essential medicines.

Keywords: Model list of essential medicines, national essential medicines list, health policy, actors, Uganda, Kenya, Tanzania, access to medicines

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- Evidence around governance issues on access to medicines remains scarce, relative to what is known about breakthroughs in biomedical technologies. The WHO Model List of Essential Medicines (MLEM) and national essential medicine list development, update and implementation is one such policy and governance issue. The process for the essential medicines list development and implementation takes place within a national policy space in which national key stakeholders deliberate and choose their policy options to determine availability and access to medicines at point of care.
- The national policy-level analysis of essential medicines lists development suggest that prioritization and availability are two sides of the same coin and benefit from being analysed as such and essential medicines lists represent an important interface between demand, and supply-side factors, however, this interface varies according to medicines that come into play with new and more expensive medicines tampering the balance between demand and supply. The differences in content of Essential Medicines Lists amongst countries are a constellation of actors and elements within the process.

Introduction

Evidence around governance issues regarding access to medicines remains scarce, relative to what is known about breakthroughs in biomedical technologies (Simao, 2018), and yet medicines account for a large proportion of national health expenditure (WHO, 2011). The concept of essential medicines advanced by the World Health Organization (WHO) in 1977 has been adopted as a global practice (Laing et al., 2003). Essential medicines are defined as those meeting priority health care needs of the population (WHO, 2002). However, considerations of essential medicines also include evidence of efficacy and safety, and both comparative costs and cost-effectiveness (Magrini et al., 2015). WHO revises the model list of essential medicines (MLEM) biennially, providing additional guidance for developing and implementing NEML (Magrini et al., 2015). The usefulness of the list has been tagged to its adaptation by member states as they develop national lists (Laing et al., 2003). The governance aspects of updating national essential medicines lists (NEML) is subject to limited systematic comparison, and especially in low- and middle-income countries (LMICs) (Mori et al., 2014). A common assumption that needs to be critiqued, is that once a select list of medicines is prioritized, e.g. through the NEML, there is improved access, higher quality of care, and rational and safe use of such medicines (WHO, 2002; Mugiraneza, 2009). Even though essential medicines policies are found to be associated with quality use of medicines, there is a stated need for better data about the co-implementation of medicine-related policies as well as the interaction between public and private sectors (Holloway et al., 2020). The national policy space and discourse where key domestic stakeholders deliberate and choose their policy options, often in collaboration with international partners, is a key determinant related to the availability and access to medicines at point of care (Mugiraneza, 2009). Therefore, more attention needs to be paid to how governance and financing at both global and national levels affect the availability of essential medicines (Bernstein and Cashore, 2012; Shaffer and Ginsburg, 2017). Greater engagement of health policy makers and systems research actors on issues of access to medicines in LMICs is necessary to fill current gaps in published literature (Adam et al., 2011).

The WHO MLEM mainly includes off-patent medicines, which are generally affordable for most countries. However, in 2001, the WHO Executive Board (EB) indicated that absolute treatment cost should not disqualify a proposed addition to the model list, as long as a particular medicine meets the criteria for benefit and public health relevance. The issue of affordability, the EB argued, should be considered as a consequence to be managed after the list is developed (Magrini et al., 2015). Subsequently, in the past 15 years, the inclusion of these on-patent medicines on the MLEM has fuelled discussions within the global health community and among countries about what should be regarded as an ‘essential’ or ‘cost-effective’ product (Laing et al., 2003). Following the 2015 revision of MLEM, many new or relatively new and expensive medicines to treat cancer, hepatitis C and multidrug-resistant tuberculosis were added to the list (Magrini et al., 2015). The extent to which these aforementioned medicines become part of the access norm, through inclusion in revised editions of NEMLs, remains to be established (Ferrario et al., 2018).

In addition to the increasing number of expensive on-patent medicines to the MLEM and specific guidance by WHO on the update process, the last two decades have witnessed changes in pharmaceutical markets with increasing importance of emerging country manufacturers, together with a growing density of global health governance arrangements designed to assist LMIC in adopting and delivering at point of care medicines against key infectious diseases, particularly HIV/AIDS and tuberculosis (WHO 2001a; Laing et al., 2003; Bigdeli et al., 2013; Hill et al., 2018). As a result, national authorities have to contend with increasing number of actors with interest in the development and implementation of national policies relevant to medicines access. Furthermore, country commitments to the sustainable development goals, which sought to reposition access to quality essential medicines as part of efforts towards universal health coverage (UHC), adds to this complexity (Bigdeli et al., 2015). A rising global concern for increased prevalence of non-communicable diseases and hence the case for equitable access to these medicines points towards the possibility of a more inclusive global agenda. Evidently, however, understanding these dynamics and their implications for the national policy processes requires a broader conceptual view (Bigdeli et al., 2013).

There is limited evidence on how countries manage these governance situations, including coordination of multiple stakeholders, funding sources and procurement organizations, and various supply chains within a single national policy environment to support and facilitate access to essential medicines (Kraiselburd and Yadav, 2013; Simao et al., 2018). Therefore, in this study we sought to examine how government agencies and other actors, including non-state actors and international partners in Kenya, Uganda and Tanzania participate in and influence the process of updating their NEML and making prioritized medicines available. In addition, we examined the extent to which the processes in the three countries...
were aligned to the WHO guidance, paying particular attention to
new addition to the 2015 MLEM with focus on tuberculosis, hepa-
titis C and cancer medicines. This group of medicines formed the
bunked of the new addition to the 2015 MLEM. In balancing a wide
scope with small-scale empirical data, the study is suited as an initial
building block for exploring policy-options and further paths for in-
quiry. The comparative design, examining the policy-processes in
three settings, further strengthens the methodological approach we
adopted.

**Methodology**

A mixed method case study approach was used, relying mainly on
qualitative data, collected using semi-structured interviews and a
document review guide. Documents for the review were searched
from four electronic databases (Allied and Complementary
Medicine, Embase, MEDLINE and PsycINFO). Google scholar and
websites of Ministries of Health, National Medicine Regulatory
Authorities (NMRAs) and national medicines procurement agencies
of Kenya, Uganda and Tanzania were also searched to supplement
what was obtained from the above databases. The choice of the
study sites was informed largely due to the timeframe and the avail-
able resources. However, the data generated, and findings is ade-
quate, and likely the same picture holds for countries of similar
contextual environment; the LMIC.

Searching databases involved the use of standard Boolean opera-
tors. Search on the databases, Google scholar and websites of
NMRAs, Ministries of Health yielded 512 documents. Given time
restraints the title and abstract review for the initial screening was
completed by one reviewer (EP). The final documents used in the
analysis were 42 after limiting to broad relevance to study objec-
tives; and availability of full-length articles. The 42 documents also
included the three countries’ NEMls, national pharmaceutical
(medicines/drug) policies, national health strategic plans, national
health policies; and WHO MLEM 2013 and 2015. The document
review was conducted to provide context and empirical literature
on discourses in NEMl, as well as facilitate identification of the new
medicines added to the WHO 2015 MLEM and of those, which
ones the countries added to their national lists.

To complement information from the documentary review, key
informant interviews were conducted between May and July 2018.
The selected participants were senior officials at national level and
had partaken in or had knowledge of the most recent NEMl update
process. Study participants were from Ministries of Health (MOH),
NMRAs, Medical Procurement agencies, WHO country offices,
Country offices of The Global Fund and non-governmental organi-
zations. A 45 min in-person interview on average was conducted
with each of the 20 purposely selected participants (Uganda 8,
Kenya 7 and Tanzania 5). None of the invited study participants
deprecated the invitation for interviews. We did not specifically set out
to pilot test the interview guide, the authors (WDO, KIS and YD)
discussed and revised the question guide. We also used the first two
interviews to highlight additional probes to employ during succes-
sive interviews given that the questions were already broad and
open ended. Interviews were digitally recorded and subsequently
transcribed verbatim. The interviews complemented the documen-
tary review by eliciting perspectives from key stakeholders on main
drivers and barriers as countries consider adapting WHO revisions
to their NEMl. (Supplementary data S1: Interview guide). The infor-
mation from interviews was extracted by two authors; WDO and
KIS. Where there were disagreements, it was addressed through
discussion and consensus. In addition, eight (n = 8) of the study par-
ticipants took part in a 2-day validation workshop with members of
the research team in Mombasa, Kenya, in March 2019, during
which preliminary findings were presented and a focus group discus-
sion on select issues requiring clarification were addressed.

A policy analysis approach adapted from Walt and Gilson’s
Policy Triangle Framework guided the analysis. This framework
(Walt and Gilson, 1994) posits that policy research needs to con-
sider not just the content of policies (the NEMl in this instance),
but also the actors, context and process in order to be able to ex-
plain outcomes and assess implementation. The analysis was con-
ducted based on preconceived thematic categories of the Policy
Triangle Framework. This includes the four categories content
(inclusions of the selected medicines on the NEMl), actors, the pro-
cess of updating the list and making medicines available, and finally
the context. On the process, we developed a schema of the WHO
process in order to examine alignment between the national process
and WHO recommendations (Figure 1).

Ethical clearance was obtained from the three countries’
Institutional Review bodies: Kenya’s Kenyatta National Hospital
and University of Nairobi Ethics and Research Committee, Tanzania’s National Institute for Medical Research, and Uganda’s
Higher Degrees, Research and Ethics Committee at Makerere
University School of Public Health. Informed consent of all research
participants was obtained, and their confidentiality and privacy
observed by anonymizing participants. Only synthesized responses
are presented in the results section.

**Results**

Our survey of selected medicines and interviews with country policy
practitioners suggest that the national prioritization of essential
medicines is a task that extends beyond the update of the NEMl,
and is followed by decision-making junctures that are then applied
to further down-select the medicines to be provided by the public
health system. We found that these decisions play out differently
according to medicine groups and contributes to complexity from
the health systems perspective. The results are presented thematical-
ly according to the elements of the policy triangle framework and
summarized in Figure 1 and Tables 1 and 2.

**The process**

The process of updating NEMls can be investigated from the per-
spective of the stages and interactions during each update, or more
broadly, how the practice in each country has developed over time.
While this study considers the former, the initial development of a
national list and the frequency of updates form a backdrop.
Tanzania was the first country of the three to issue an NEMl in
1977, updated in 1981 and 1986 (Munishi, 1995); subsequent
updates in 1991, 1997, 2007, 2013 and 2017 (Munishi, 1995;
Tanzania Ministry of Health, 2017). From 1991, Tanzania NEMl
(NEMLiT) reviews were conducted concurrently with revisions of
the standard treatment guidelines (STG) as recommended by the
WHO (WHO 2013). The first edition of the Essential Medicines
and Health Supplies List for Uganda (EMHSelu) was published in
1991 with subsequent updates in 1996, 2001, 2007, 2012 and
2016 (Uganda Ministry of Health, 2016). Kenya, on the other
hand, developed its first essential medicines list in 1981, with sub-
sequent updates published in 1993, 2003, 2010 and 2016 (Kenya
Ministry of Health, 2016). While there is a consistency in how the
process is implemented, the intervals vary and have at times been as long as 10 years.

For an NLEM update, the WHO recommends the selection of committee members, and the procedure for the structure of interactions and decision-making (WHO 1977, 2001b). Figure 1 summarizes WHO guidance on the process of updating the NLEM based on available literature and the interview data. As depicted in Figure 1, WHO guidance is quite prescriptive and structured for the selection and committee processes until the list is in the publication stage. However, it is not explicit on the implementation stage, as the process enters into the broader practice of making the prioritized medicines available.

Examination of the 2016 (Kenya and Uganda) and 2017 (Tanzania) updates, described in the following section, considered factors that influence actors’ coordination, as well as links between the nature of the process and observed outcomes.

The data show that all three NLEM update processes were coordinated by national medicines and therapeutic committees (NMTC) anchored at a high level within the Ministries of Health, with input from WHO country offices. The committees had representation from a wide range of stakeholders, or consulted other stakeholders not represented on the committees through technical working groups (TWGs), consultative meetings and written submissions (WHO, 2001a, 2002). The number of meetings varied from 10 to 20. Uganda and Tanzania updated the clinical guidelines (STG) and NLEM concurrently. In Kenya, for the update in question, the STG was not concurrently updated with NLEM as recommended, reportedly due to funding constraints. None of the interviewees reported any coordination challenges in terms of involving the recommended stakeholders during the update process of the national lists. In all three countries the activities related to updating the NLEM, including meetings and workshops were largely funded by development partners. The responsible units at Ministries of Health (MOH) budget for this process, however this usually sits amongst MOH’s unfunded priorities.

The main criteria for inclusion and exclusion of medicines on the lists were efficacy, safety, quality, clinical experience, disease prevalence, cost and cost-effectiveness. It is only Tanzania that incorporated cost-effective criteria using the health technology assessment (HTA) during the update. Uganda and Kenya intended to incorporate cost-effectiveness assessment; however, such methods were not used because HTA had yet to be implemented as a policy tool, and difficulties accessing the relevant data to be used for cost-effectiveness calculations. Neither market authorization, nor status of medicine registration in the country was amongst criteria for inclusion or exclusion in all the three countries.

Once NLEMs are confirmed, the next step is the implementation, initial step being sharing the list with the health system at large. In Uganda and Tanzania, interviewees reported that the NLEM was disseminated widely and it is used highly in public and private health facilities. In Kenya, the list has not been disseminated as widely, largely due to limitation in funding. The focus group discussion suggested that the limited dissemination of the list manifests itself as the concept of the essential medicines list not being well understood amongst key stakeholders in both public and private sectors, especially prescribers. On a more general level, the overall demand for and use of the list depends on the general awareness of the essential medicines concept, availability of the list and timely updates.

Following the NLEM update and dissemination, interview data show that funding and procurement are additional decision-making points that prioritize which medicines become available. In all the three countries, the procurement of medicines and other health supplies in the public sector are based on the NLEM; however, final procurement decisions are influenced by the available budget allocated in the year. To a varying extent among the three countries, global initiatives also support procurement of medicines especially the programmatic medicines for HIV, Malaria and TB. However, they require co-funding arrangements with governments as a mechanism of promoting sustainability, and the co-funding is usually drawn from the same source as for other essential medicines, influencing prioritization of government funds for essential medicines (Uganda Ministry of Health et al., 2012).

Actors
In all the three countries, as mentioned above, the process was led by the NMTC. The WHO recommends inclusion of a wide range of stakeholders to the committee (WHO, 2001a, 2002). Documentation and interviews show that Kenya had the least number of committee members 10, compared with 20 each in Uganda and Tanzania. In Kenya, all the members of the NMTC were from MOH (Kenya Ministry of Health, 2016), while in Uganda and

Figure 1 WHO guidance on the process for updating NLEM. Guidance on the process for updating NLEM [based on interview data and literature (Fulone et al. 2016; Albert et al. 2007; Perumal-Pillay and Suleman 2017)].
### Table 1  Thematic summary of findings regarding NEML updates in Kenya, Tanzania and Uganda based on the policy triangle framework

| Country | Content | Actors | Process | Context |
|---------|---------|--------|---------|---------|
| **Kenya Essential Medicines List (KEML)**<br>First published 1981; Most recent: 2016 (5th edition) | • The total number of medicines increased by 46 (to a total of 674)<br>• Medicines grouped as core or specialist<br>• Hepatitis C: did not include 2015 WHO EML additions, but added Pegylated interferon alfa-2a and Ribvarin from the 2013 WHO EML (see Table 2).<br>• List indicates the level of healthcare level in which a particular medicine is to be found | • State and non-state, national and international actors<br>• Clearly prescribed roles under purview of Ministries of Health<br>• National medicines and therapeutics committees lead process<br>• Global stakeholders—DANIDA through Health Sector Programme Support, USAID, Global Fund, UNICEF | • Followed the WHO recommended process<br>• Around 20 meetings of the technical committees<br>• No challenge reaching consensus<br>• The latest update not done concurrently with the revisions of clinical guidelines, as is the norm<br>• Cost-effectiveness findings and challenges with the necessary data means exclusion of its use in decision-making<br>• Fragmentation of medicines funding<br>• Challenges with dissemination mean the list is used less frequently for procurement and clinical practice<br>• Hepatitis C: unknown prevalence, though to be low<br>• Tuberculosis: well-documented prevalence | These common contextual factors were relevant in all three countries<br>• Health sector reforms, especially devolution of health services<br>• Global push for universal health coverage<br>• Limited knowledge and awareness about WHO MLEL and NML concept amongst health workers<br>• Global funding prioritizations and evolving health technologies influence the process and the content of the WHO EML, especially the inclusion of new medicines for the treatment of HIV and TB that are largely funded through global health financing initiatives<br>• Lack of country consultation in the WHO-EML<br>• In the three countries, there is a link between updated national medicines lists and procurement, namely that medicines are classified into subgroups to facilitate reprioritization during procurement. |
| **Tanzania National Essential Medicines List for Tanzania (NEMLIT)**<br>First published 1971; Most recent: 2017 (5th edition) | • Reduced the total number of medicines to 400<br>• Antibiotics classified as access, watch or reserve<br>• List indicates the level of healthcare level in which a particular medicine is to be found | • State and non-state, national and international actors<br>• Clearly prescribed roles under purview of Ministry of Health<br>• National medicines and therapeutics committees lead process<br>• Global stakeholders—WHO, iDSI, PRICELESS; PATH, Swiss Agency for Development and Cooperation and the Global Fund. | • Followed the WHO recommended process<br>• Over 10 meetings of the technical committee<br>• No challenge reaching consensus<br>• The latest list was updated concurrently with revision of standard treatment (clinical) guidelines<br>• HTA integrated in the process, which includes the use of cost-effectiveness findings<br>• Fragmentation of medicines funding<br>• The use of the list for procurement and clinical practice is widespread<br>• Cancer: Lacking reliable data on prevalence;<br>• Hepatitis C: prevalence unknown, though to be high<br>• Tuberculosis: well-documented data on prevalence | |
| **Uganda Essential Medicines and Health Supplies List for Uganda (EMHSLU)** | • The total number of medicines increased by 206 (to a total of 687)<br>• Medicines grouped into Vital, Essential and Necessary | • State and non-state, national and international actors<br>• Clearly prescribed roles under purview of Ministry of Health<br>• National medicines and therapeutics committees as | • Followed the WHO recommended process<br>• Over 10 meetings of the technical committees<br>• No challenge reaching consensus<br>• The latest list was updated concurrently with revision of standard treatment (clinical) guidelines | |
Table 1 (continued)

| Country       | Content                                                                 | Actors Those involved in the updating and related implementation                                                                 |
|---------------|-------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------|
| Tanzania      | First published 1991; most recent: 2016 (6th edition)                   | The update process of the National Essential Medicines List (EML) involves a number of actors that coordinate the updating of the list. |
|               |                                                                         | These actors include governmental agencies, non-governmental organizations, civil society groups, and private sector actors.       |
|               |                                                                         | The governmental agencies involved in the process of updating the EML include the National Medical Stores Authority (NMSA) in Tanzania. |
|               |                                                                         | The NMSA is responsible for the procurement and supply of essential medicines at the national level.                              |
|               |                                                                         | In addition to the NMSA, other actors involved in the update process include civil society organizations and private sector actors.  |
|               |                                                                         | The update process is coordinated by a national-level technical working group (TWG), which is responsible for the EML.            |
|               |                                                                         | The TWG includes representatives from a wide range of stakeholders, including civil society organizations, private sector actors, |
|               |                                                                         | and governmental agencies. The TWG is responsible for reviewing the list and making recommendations for its update.           |
|               |                                                                         | The update process is also supported by a national-level technical working group (TWG), which is responsible for the EML.      |
|               |                                                                         | The TWG includes representatives from a wide range of stakeholders, including civil society organizations, private sector actors, |
|               |                                                                         | and governmental agencies. The TWG is responsible for reviewing the list and making recommendations for its update.           |
|               |                                                                         | The update process is also supported by a national-level technical working group (TWG), which is responsible for the EML.      |
|               |                                                                         | The TWG includes representatives from a wide range of stakeholders, including civil society organizations, private sector actors, |
|               |                                                                         | and governmental agencies. The TWG is responsible for reviewing the list and making recommendations for its update.           |

The context

The contextual factors affecting update process and ensuring the availability or use of the medicines in the list are similar in the three countries and are summarized in Table 1. Our interview data suggest two broad categories of contextual drivers: firstly, domestic health system changes, which include the transition towards UHC reforms such as devolution of responsibilities from central to district level; and secondly, global health aid funding. Limited information related to changes at the global level and shifting co-financing arrangements challenge governments as they plan medicine procurement budgets. In addition, global initiatives can introduce coordination difficulties if they call for individual medicine updates, initiate parallel procurement and supply chains, or merely conduct negotiations with pharmaceutical industry outside the purview of national stakeholders. Discussion at global level, e.g. between global health financing initiatives and pharmaceutical industries usually do not involve national stakeholders. This has been reportedly so for medicines for TB and HIV/AIDS.

Content

Overall, the latest updates compared with the previous edition indicate there was a net increase of 206 medicines to the 2016 Kenya list (total 687), and 46 to the 2016 Uganda list (total of 674).
In Tanzania, the total number of medicines in the list reduced to 400 compared with >500 that were in the 2013 national list (Uganda Ministry of Health, 2012, 2016; Kenya Ministry of Health, 2016). The increase in Kenya was attributed to the push by the specialist groups, especially the oncologists, whereas the reduction in Tanzania has been attributed to use of HTA.

In reviewing how countries aligned their update with the 2015 MLEM, and with a focus of medicines against tuberculosis, cancer and hepatitis C, the most distinct variations among the countries were those medicines for cancer and hepatitis C. Kenya exceeded the additions to the 2015 WHO MLEM regarding treatments for cancer (21 new anticancer medicines were added to the list) (Table 2) (WHO, 2015). One reason, from interview and focus group discussion is that specialist treatment is more developed in the Kenyan health system compared with the other two countries and that clinicians advocate for enhanced access more.

Regarding hepatitis C, Tanzania added three of the new medicines to its essential list, including sofosbuvir. Kenya and Uganda did not add the new drugs included in the 2015 MLEM. The non-inclusion of hepatitis C medicines in Kenya and Uganda lists was reportedly due to limited information on hepatitis C prevalence.

All three countries included new and expensive treatment for MDR TB, Bedaquiline. All countries also included linezolid for treating tuberculosis, while only Tanzania and Kenya included

### Table 2 New tuberculosis, cancer and hepatitis C medicines on the 2015 WHO Model List vis-à-vis the addition to the latest National EMLs Kenya (2016), Uganda (2016) and Tanzania (2017)

| WHO Model List 2015 Update | Kenya (2016) | Uganda (2016) | Tanzania (2017) |
|---------------------------|-------------|---------------|-----------------|
| **Tuberculosis**           |             |               |                 |
| Bedaquiline               | Bedaquiline<sup>a</sup> | Amikacin      | Bedaquiline<sup>a</sup> |
| Delamanid                 | Capreomycin | Bedaquiline<sup>a</sup> | Delamanid<sup>a</sup> |
| Linezolid                 | Cycloserine | Capreomycin   | Linezolid<sup>a</sup> |
| Rifapentine               | Delamanid<sup>a</sup> | Clofazimine   | Delamanid<sup>a</sup> |
|                           | Levofloxacin| Cycloserine   | Linezolid<sup>a</sup> |
|                           | Linezolid<sup>a</sup> | Ethionamide   |                  |
|                           | Moxifloxacin| Kanamycin     |                  |
|                           | p-aminosalicylic acid | Levofloxacin |                  |
|                           | Prothionamide| Linezolid<sup>a</sup> |                  |
|                           | Rifabutin   | Moxifloxacin  |                 |
|                           |             | P-Aminosalicylic acid |                 |
|                           |             | Prothionamide |                  |
|                           |             | Amoxicillin + Clavulanic Acid |             |
| **Cancer**                |             |               |                 |
| All-trans retinoid acid   | Alendronic acid<sup>b</sup> | Anastrozole<sup>a</sup> | Bicalutamide<sup>a</sup> |
| Bendamustine              | Anastrozole<sup>a</sup> | Bicalutamide<sup>a</sup> | Cisplatin<sup>a</sup> |
| Capecitabine              | Bicalutamide<sup>a</sup> | Capecitabine<sup>a</sup> | Gemcitabine<sup>a</sup> |
| Cisplatin                 | Capecitabine<sup>a</sup> | Dactinomycin | Imatinib<sup>a</sup> |
| Filgrastim                | Diethylstibostrol<sup>b</sup> | Filgrastim | Irinotecan<sup>a</sup> |
| Fludarabine               | Docetaxel   | Fluorouracil  | Oxaliplatin<sup>a</sup> |
| Gemcitabine               | Filgrastim<sup>a</sup> | Gemcitabine<sup>a</sup> | Rituximab<sup>b</sup> |
| Imatinib                  | Gemcitabine<sup>a</sup> | Goserepin | Trastuzumab<sup>a</sup> |
| Irinotecan                | Goserepin<sup>b</sup> | Irinotecan |                 |
| Oxaliplatin               | Ifosfamide  | Mesna         |                 |
| Rituximab                 | Imatinib<sup>b</sup> | Oxaliplatin<sup>a</sup> |                 |
| Trastuzumab               | Irinotecan<sup>a</sup> | Paclitaxel  |                 |
| Vinorelbine               | Methotrexate | Thalidomide  |                 |
|                           | Mesna       | Vinblastine  |                 |
|                           | Oxaliplatin | Rituximab already on |                 |
|                           | Paclitaxel  | the previous national |                 |
|                           | Rituximab<sup>a</sup> | list and retained in 2016 version |                 |
|                           | Tamoxifen   |                 |                 |
|                           | Thalidomide |                 |                 |
|                           | Trastuzumab<sup>a</sup> |                 |                 |
|                           | Vinorelbine |                 |                 |
| **Hepatitis C**           |             |               |                 |
| Sofosbuvir                | Pegylated interferon alfa-2a | Sofosbuvir<sup>a</sup> |                 |
| Simeprevir                | Ribavirin   | Ledpasvir<sup>a</sup> | Ribavirin |
| Daclatasvir               |             |                 |                 |
| Dasabuvir                 |             |                 |                 |
| ledipasvir + sofosbuvir   |             |                 |                 |
| ombitasvir+ paritaprevir  |             |                 |                 |
| + ritonavir               |             |                 |                 |

<sup>a</sup>Medicines that were included in the NEMIs from the 2015 update of the WHO Model List.

<sup>b</sup>Medicines not on the 2015 or 2013 WHO MLEM but on the national list.
delamanda to their lists. The inclusion of expensive, second line anti-TB medicines is, to an extent, driven by global funding available for these medicines through the global financing initiatives, especially the Global Fund to Fight AIDS, TB and Malaria.

In the three countries, the medicines are classified into subgroups to facilitate prioritization during procurement. In the KEML, medicines have been grouped as either core or specialist. In Uganda, a medicine is vital, essential or necessary (VEN) and in Tanzania, for antibiotics, it has been classified as access, watch or reserve. Medicines considered Vital must always be available (for instance against life-threatening conditions, or first line treatment), while the Essential medicines are against common illnesses, and Necessary medicines are those against minor diseases with limited impact on the population, or high average cost for marginal therapeutic benefit (WHO, 1998; Kenya Ministry of Health, 2016; Uganda Ministry of Health, 2016; Tanzania Ministry of Health, 2017). For all the three countries, the lists indicate the level of healthcare facility in which a particular medicine is to be made available (Tanzania Ministry of Health, 2013, 2017; Kenya Ministry of Health, 2016).

**Discussion**

The three countries’ NEML update processes were similar and showed close alignment to recommended WHO procedures. All countries applied similar criteria for considering changes to the list. However, cost-effectiveness estimations were the most challenging and only Tanzania applied HTA methods through the support of the International Decision Support Initiative (IDSI) (International Decision Support Initiative, 2018). The limited use of HTA in the update process in the region is in line with findings from other studies (Mori et al., 2014; Perumal-Pillay and Suleman, 2016, 2017). Update processes in the studied countries have been largely funded by health development partners, and perhaps the unpredictability that comes with donor funding explains the irregularity in the intervals between updates, ranging from 5 to 10 years.

Another notable feature for the countries included in the study was that many of the medicines have remained on countries NEMLs for a long period of time (Uganda Ministry of Health, 2012; Tanzania Ministry of Health, 2013, 2017; Kenya Ministry of Health, 2016). This is perhaps due to their enduring qualities as safe, efficacious and affordable. However, changes in the local burden of disease and pharmaceutical innovation prompt the need to trade older medicines for new ones, or to consider entire new classes of medicines.

Availability of medicines on the NEML in the public sector rely on government funding allocations to the Ministries of Health (Wirtz et al., 2017). Therefore, financing and affordability are a consideration during the NEML update; whether this is implicitly or explicitly stated. This is reflected in prioritization within the list in terms of medicines classification as either VEN, with available public funding prioritized to vital and essential medicines. As such, even though medicine characteristics and local need represents a potential, its actual availability and accessibility especially in the public sector is inextricably linked to funding.

Further downstream, the link between the updated NEML and procurement planning in the public sector is also the extent to which the Ministry of Health makes the list known to facilities and professionals who procure and prescribe medicines. Once known, its use also depends on it being considered relevant, and not outdated thus requiring the regular updates. However, utilization of the list is likely to work best when the concept of the NEML is integrated as a continuous practice, for instance through professional training, rather than as an implementation or a launch event following each update. Findings by Holloway et al. (2020) indicate that undergraduate training of prescribers in STG is associated with quality use of medicines in comparison to only the biennial updates of the list amongst other NEML implementation enablers.

In developing the NEML, a key objective is that those medicines considered essential will be made available (Lang et al., 2003). Therefore, in the update process, the committee ought to take into account issues of supply chain system including the feasibility of procurement and funding wholesomely. For all of the countries, market authorization was not considered a criterion. According to the WHO, market approval is a regulatory decision on which availability may be conditioned given that it can be a proxy for availability of medicines (WHO, 2002). However, there are regulatory frameworks in the three countries that allow unregistered medicines (non-market authorized) to be brought into the country under special conditions, such as in public health emergencies.

The differences in content of the three countries by way of the essential medicines list updates resulting in a longer or shorter list is likely a constellation of actors and elements within the process. The findings point to a growing dilemma of increasing the number of accessible medicines, for instance against non-communicable diseases such as cancers, and raising the governments’ ability to finance medicines in the public sector. While the process in Kenya appears to have emphasized the former, the introduction of HTA in Tanzania incorporated the latter to a greater extent. However, the present study did not examine the HTA experience in Tanzania beyond publicly available documentation, it cannot detail explicitly how additional economic analyses contributed to the NEML update process outcome (International Decision Support Initiative, 2018). A nascent literature on HTA and priority setting in Africa nevertheless suggests that there is room for discussion as to how economic analysis is carried out, balancing commissioned research with local capacity building (Doherty et al., 2017).

An initial assumption of this study was that coordination between the health and trade sectors at the national policy level represents an obstacle for access to medicines in relation to the NEML. The country perspectives in this study, however, suggest that coordination challenges within the health sector may be more problematic. The reason is the multiple actors within the health sector, especially at the global level with influence or interest at the national level. Apart from the procurement by national medical stores or other national wholesalers, the intersections between national healthcare delivery systems and the pharmaceutical sector occur globally, involving public–private partnerships to incentivize development and introduction of new medicines, conduction of market-shaping activities including bulk procurement, and direct price negotiations. Activities centre around select medicines and may change over time, and country policymakers are poorly represented or rarely directly involved with such initiatives. While these activities of global initiatives may produce substantive gains in terms of access to new and affordable medicines, it conflicts with national ownership, sustainability and the continuation of government funded medicines at the national level (Kusenererwa et al., 2016; Rockers et al., 2018). At the nation level, our finding suggests that there is a window of opportunity to bring in the actors from the trade sector as part of the essential medicine policy development and as a way of engage the sector towards increasing local pharmaceutical production and supplies.
Furthermore, other contextual factors, especially the evolving domestic policies on health systems financing including the establishment of national health insurance schemes and global commitment on UHC influences the process for updating the NEMLS. The way global initiatives support access to medicines varies with disease conditions, yet the update of the NEML is taken as a cross-cutting process at the national level. Therefore, there is a need for better engagement by global health financing initiatives and the country-level stakeholders to ensure smooth introduction of new medicines for programmatic medicines in light of the NEML and associated implementation constraints. Information about the disease prevalence affects inclusion decisions related to medicines on the list, as demonstrated by the case of hepatitis C medicines in the three countries.

Bigdeli et al. (2013) have drawn attention to systemic factors at the national level that influence access, however, their argument largely focuses on going beyond the pharmaceutical sector to other sub-sectors of the health system at all levels; from local to the international. In studying the national policy level—this study suggests that there is still a need to connect demand and supply-side elements within the pharmaceutical area, spanning health and trade sectors. A key limitation of this study is that the exploratory nature of the study combined with modest resources did not allow for a full-fledged systematic review of literature, nor inclusion of additional informants that would be needed for a more in-depth analysis of supply-side factors. Still, the study confirms that by enabling broader representation and perspectives at the national level, the complexity of access becomes apparent, with its priorities, trade-offs, network of global, regional and national stakeholders. This complex system approach is echoed by Ozawa et al. (2019). However, the question remains how this can be best managed. This study suggests that when limited to the specific NEML update process, the three countries are well aligned in following the WHO guidance. In governing the frequency and interlinkages with other policy processes, however, there is a potential for cross-country harmonization and sharing of best practices.

Bigdeli et al. (2013) argue that frameworks for understanding or exploring issue of access to medicines should take into consideration health system dynamics and complexities. For example, when focusing on the health sector, Bigdeli et al. (2013) suggest four constraints on access to medicines, including governance of the pharmaceutical sector (e.g. registration and procurement), prices, overall health sector governance and interaction between private and public services. They also recognize that the international context involves both the market for pharmaceuticals as well as donors’ agenda and funding, but that constraints in this domain is less documented in published literature (Bigdeli et al., 2013). In suggesting that the EML represents an important interface between demand and supply-side factors, this study finds that this interface varies according to medicines that come into play, with new and more expensive medicines tampering with the equilibrium between the two sides. In taking a broader view of health sector governance, one may also see this in relation to the capacity of government to manage actors, networks and institutions, constituting a health sector resilience (Topp, 2020). The remaining question is the extent to which governments are able to steer the engagement of international partners, mobilize own funding and decide on the extent to which new medicines will be offered in the private or public sector.

**Conclusions**

The present study shows that NEML updates tend to follow a structured process aligned to the WHO guidelines and are influenced by prioritization, the procurement planning, and considerations of demand, funding and cost. The national policy-level analysis of the three countries suggests that the implementation of NEMLs should be subject to heightened attention and systematic analysis, as prioritization and availability are two sides of the same coin and benefit from being analysed as such. Furthermore, STG should inform the NEML, this will make the list relevant to the practitioners and improve its use.

Countries in the region need to ensure that health system financing and pharmaceutical policies at the national level promote the implementation of the Essential Medicines concept through building capacities for substantive coherence to ensure complementarity between policy outcomes. Furthermore, national policymakers need to exert their influence over intersections that are currently outside their own policy domains through enhancing global health diplomacy competencies of government officials involved in global pharmaceutical negotiations. In addition, for future research, it is worth further exploring the consequences of adding on-patent drugs for a variety of diseases on the MLEM and thus NEMLs in terms of access and the function of national EMLs.

**Supplementary data**

Supplementary data are available at Health Policy and Planning online.

**Conflict of interest statement.** None declared.

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**References**

Adam T, Ahmad S, Bigdeli M, Ghaffar A, Rottingen J-A. 2011. Trends in health policy and systems research over the past decade: still too little capacity in low-income countries. *PLoS One* 6: e27263.

Albert MA, Fretheim A, Maiga D. 2007. Factors influencing the utilization of research findings by health policy-makers in a developing country: the selection of Mali’s essential medicines. *Health Research Policy and Systems* 5: 2.

Bernstein S, Cashore B. 2012. Complex global governance and domestic policies: four pathways of influence. *International Affairs* 88: 585–604.

Bigdeli M, Jacobs B, Tomson G et al. 2013. Access to medicines from a health system perspective. *Health Policy and Planning* 28: 692–704.

Bigdeli M, Laing R, Tomson G, Babar ZU. 2015. Medicines and universal health coverage: challenges and opportunities. *Journal of Pharmaceutical Policy and Practice* 8: 8.

Doherty J, Wilkinson T, Edoka I, Hofman K. 2017. Strengthening expertise for health technology assessment and priority-setting in Africa. *Global Health Action* 10: 1370194.
