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Time to inclusion of selected medicines for priority diseases in National Essential Medicines Lists compared with the WHO Model List

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Based on this study, a rapid response was published in the BMJ entitled 'The current relevance of the World Health Organization's Model List of Essential Medicines'. Moreover, an abstract from the 5th PPRI conference 2024 entitled 'Selection of novel medicines for acute conditions versus chronic conditions on National Essential Medicines Lists compared to the WHO Model List', based on part of this study, is published in the Journal of Pharmaceutical Policy and Practice. Finally, another abstract from the Combined University of KwaZulu-Natal, Utrecht University and Journal of Pharmaceutical Policy and Practice Symposium, based on this study, will be published as a supplement to a journal (awaiting editor's decision).

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ABSTRACT

Introduction The WHO maintains a Model List of Essential Medicines, which guides countries in developing their National Essential Medicines List (NEML) to improve access to medicines. We aimed to assess the time it took for countries to adjust their NEMLs when medicines were added or deleted from the WHO Model List and if this differed between priority diseases.

Methods We extracted medicines added or deleted from the WHO Model List (2007–2021) for selected priority diseases: diabetes, hepatitis C, HIV, oncology and tuberculosis. These medicines were compared with NEMLs from 20 countries; reimbursement lists (RLs) were used in the absence of an NEML. The time to inclusion in NEMLs/RLs and the percentage of included medicines in the most recent NEML/RL were assessed.

Results 90 medicines were added, and 15 medicines were deleted from the WHO Model List. Low-income and middle-income countries (LMICs) mostly included medicines in NEMLs after their addition to the WHO Model List (median: 1 year), and high-income countries prior to addition (median: –9 years). Medicines for HIV (62%) and tuberculosis (59%) were most frequently included in the most recent NEML/RL. High-income countries included the most medicines for diabetes (86%) and oncology (67%).

Conclusions The WHO Model List may be a guiding tool for selecting medicines in LMICs, although it is applied differently between the priority diseases included in the present study. More medicines could be included in NEMLs for non-communicable diseases, which impose a large health burden on LMICs, as a first step to ensure their sustainable access.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ The WHO's Model List of Essential Medicines (the WHO Model List) is a guide for countries to develop a National Essential Medicines List (NEML). Existing literature indicates variable availability and listing of medicines in NEMLs across communicable and non-communicable diseases, highlighting challenges with access to medicines in low-income and middle-income countries (LMICs).

WHAT THIS STUDY ADDS

⇒ Unlike previous studies that compared NEMLs with the WHO Model List cross-sectionally, this study assessed the time it took for countries to adjust their NEML when the WHO Model List was amended and if this differed between priority diseases. It is important to understand how long it takes before medicines are included in NEMLs after their addition to the WHO Model List because long delays in inclusion could hinder timely access to these essential medicines and eventually impact patient outcomes.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ Our study showed that the WHO Model List is a useful guiding tool for LMICs, especially for medicines to treat communicable diseases. However, as fewer medicines for non-communicable diseases were included in NEMLs, these findings point to the urgent need to include more of these medicines earlier in NEMLs because non-communicable diseases impose a large health burden on LMICs. Especially since delaying the inclusion of medicines in NEMLs increases waiting times, impacting the health of patients with no alternative treatments available for non-communicable diseases.

INTRODUCTION

In 2015, the United Nations established 17 Sustainable Development Goals (SDGs).[1] SDG 3 advocates to 'ensure healthy lives and promote well-being for all at all ages', for which universal health coverage must be achieved.[1] For health systems to function with universal health coverage, it is critical for everyone to have affordable access to quality medicines and medical devices.[2] SDG 3.3 targets communicable diseases while SDG 3.4 targets non-communicable diseases (NCDs).

Table 1 A summary of the basket of medicines, which were added or deleted from the WHO Model List for diabetes, hepatitis C, HIV, oncology or tuberculosis between 2007 and 2021

Additions to the WHO Model List						
Disease area	**Diabetes**	**Hepatitis C**	**HIV**	**Oncology**	**Tuberculosis**	**Total**
Medicines added n	7	12	12	48	11	90
Year medicines added (n)	2013 (1) 2021 (6)	2013 (4) 2015 (5) 2017 (1) 2019 (1) 2021 (1)	2007 (4) 2015 (2) 2017 (5) 2019 (1)	2009 (3) 2011 (4) 2015 (16) 2017 (3) 2019 (14) 2021 (8)	2007 (1) 2009 (1) 2015 (5) 2017 (1) 2019 (1) 2021 (2)	
Deletions from the WHO Model List						
Disease area	**Diabetes**	**Hepatitis C**	**HIV**	**Oncology**	**Tuberculosis**	**Total**
Medicines deleted n	1	1	9	0	4	15
Year medicines deleted (n)	2013 (1)	2019 (1)	2009 (1) 2015 (3) 2017 (3) 2021 (2)		2013 (1) 2019 (3)	

HIV, human immunodeficiency virus; WHO, World Health Organization.

The WHO advocates that some medicines are more essential than others through a Model List of Essential Medicines (the WHO Model List) which has been updated biannually by the WHO Expert Committee on the Selection and Use of Essential Medicines since 1977.[3] The WHO defines essential medicines as medicines that should be available within health systems in adequate amounts, in the right dosage forms, with assured quality and adequate information, and at a price the individual and the community can afford.[2]

The WHO Model List is a guiding tool for countries to develop their own National Essential Medicines List (NEML).[2 4] The NEML helps countries improve access to essential medicines; it can be used to guide selecting, purchasing or reimbursing medicines.[4] The WHO Model List caters to both communicable diseases and NCDs. Out of the 194 WHO member states, at least 137 have an official NEML. However, information on how countries select medicines for their NEMLs is limited.[5]

Including medicines on NEMLs can improve access, as the availability of essential medicines is better globally than for non-essential medicines.[6] However, studies have indicated variable availability and listing of essential medicines in NEMLs across disease areas.[7] There are various reasons for the variability in essential medicines selection by countries, including budget impact and non-availability of these medicines in countries.[8] These findings highlight challenges with access to medicines for both communicable diseases and NCDs in low-income and middle-income countries (LMICs).

For several priority diseases, many new medicines have been added to the WHO Model List, of which some are high-priced and/or complex medicines. Some of these additions have been criticised, which has sparked the debate about the WHO Model List as a guiding tool for LMICs.[9–12] Over time, medicines for NCDs such as oncology and diabetes have been added to the WHO Model List, as well as medicines for communicable diseases such as hepatitis C, HIV and tuberculosis.[13] However, these additions were not well adopted by countries.[14–18]

Even though information on the selection of medicines in NEMLs is limited, NEMLs are not well aligned with the WHO Model List as most NEMLs differ from the WHO Model List by more than 200 medicines (range: 85–533).[5] These differences cannot be explained by countries' characteristics, which implies that the process of selecting medicines for NEMLs can be improved. What is not known from previous studies is how long it takes before medicines are included in the NEML after their addition to the WHO Model List. Long delays in inclusion could hinder timely access to these essential medicines and eventually impact patient outcomes.

Here, we aimed to assess the time it took for countries to adjust their NEMLs when the WHO Model List was amended by either adding or deleting medicines. We studied if the WHO Model List is used by countries differently for priority diseases, as we hypothesised that medicines for communicable diseases are adopted into NEMLs more than medicines for NCDs.

METHODS

Selection of medicines

Priority disease areas targeted by SDGs were selected for this study: hepatitis C, HIV and tuberculosis (SDG target 3.3), and diabetes and oncology (as highly prevalent NCDs in SDG target 3.4). We extracted medicines added or deleted from the WHO Model List for these five diseases (for the first time) between 2007 and 2021

Table 2 Overview of the 20 included countries categorised by income level from low to high

Country	Geographical region*	Income group†	Range of NEMLs/RLs	Total NEMLs/RLs	Burden of disease‡, ordered highest–lowest n (% in country) ↑↓ compared with global %
Ethiopia	African	Low	2010–2020	3	Oncology: 1 597 199.02 (4.12) ↓ Tuberculosis: 1 315 587.97 (3.39) ↑ HIV: 983 022 (2.54) ↑ Diabetes: 525 508.17 (1.35) ↓ Hepatitis C: 180 451.61 (0.47) ↓
Rwanda	African	Low	2010–2022	3	Oncology: 241 490.37 (5.35) ↓ HIV: 220 407.48 (4.91) ↑ Tuberculosis: 152 276.86 (3.38) ↑ Diabetes: 70 395.92 (1.56) ↓ Hepatitis C: 34 853.42 (0.77) ↑
Uganda	African	Low	2001–2022	5	HIV: 1 534 875.05 (8.57) ↑ Oncology: 815 666.58 (4.54) ↓ Tuberculosis: 573 778.91 (3.19) ↑ Diabetes: 199 973.22 (1.11) ↓ Hepatitis C: 67 596.05 (0.38) ↓
Zambia	African	Low	2013–2020	3	HIV: 1 328 415.10 (15.96) ↑ Oncology: 416 043.77 (4.95) ↓ Tuberculosis: 160 903.13 (1.92) ↑ Diabetes: 119 718.06 (1.43) ↓ Hepatitis C: 43 305.16 (0.52) ↓
Bhutan	South-East Asian	Lower middle	2007–2021	6	Oncology: 11 717.24 (5.51) ↓ Diabetes: 6180.35 (2.91) ↑ Tuberculosis: 3799.66 (1.79) ↓ Hepatitis C: 1586.31 (0.75) ↑ HIV: 1331.14 (0.63) ↓
India	South-East Asian	Lower middle	2003–2022	4	Oncology: 25 266 390.81 (5.35) ↓ Tuberculosis: 15 624 202.19 (3.31) ↑ Diabetes: 12 899 972.99 (2.73) ↓ HIV: 2 778 465.45 (0.59) ↓ Hepatitis C: 2 150 828.6 (0.46) ↓
Lebanon	Eastern Mediterranean	Lower middle	2010–2018	3	Oncology: 151 921.02 (11.58) ↑ Diabetes: 88 230.95 (6.69) ↑ Hepatitis C: 6565.98 (0.50) ↓ HIV: 2702.41 (0.21) ↓ Tuberculosis: 1597.83 (0.12) ↓
Nigeria	African	Lower middle	2003–2020	4	HIV: 4 233 797.08 (3.36) ↑ Tuberculosis: 2 552 357.68 (2.02) ↑ Oncology: 2 496 076.24 (1.97) ↓ Diabetes: 1 042 956.99 (0.83) ↓ Hepatitis C: 272 338.42 (0.22) ↓
Pakistan	Eastern Mediterranean	Lower middle	2003–2021	5	Oncology: 5 179 830.07 (5.67) ↓ Tuberculosis: 3 139 569.51 (3.44) ↑ Diabetes: 2 040 864.84 (2.23) ↓ Hepatitis C: 753 370.6 (0.82) ↑ HIV: 332 752.68 (0.36) ↓
The Philippines	Western Pacific	Lower middle	2008–2023	4	Oncology: 2 453 583.63 (7.49) ↓ Tuberculosis: 1 125 965.91 (3.44) ↑ Diabetes: 1 100 923.49 (3.36) ↑ HIV: 264 236.5 (0.81) ↓ Hepatitis C: 161 286.36 (0.49) ↓
Brazil	The Americas	Upper middle	2000–2022	11	Oncology: 7 019 741.3 (10.71) ↑ Diabetes: 2 597 848.19 (3.95) ↑ HIV: 744 221.97 (1.13) ↓ Hepatitis C: 311 827.44 (0.48) ↓ Tuberculosis: 226 289.68 (0.35) ↓
Jordan	Eastern Mediterranean	Upper middle	2006–2021	5	Oncology: 143 496.55 (7.04) ↓ Diabetes: 124 245.15 (6.07) ↑ Hepatitis C: 6111.38 (0.30) ↓ Tuberculosis: 1763.05 (0.09) ↓ HIV: 1676.32 (0.08) ↓

Continued

Table 2 Continued

Country	Geographical region*	Income group†	Range of NEMLs/RLs	Total NEMLs/RLs	Burden of disease‡, ordered highest–lowest n (% in country) ↑↓ compared with global %
Malaysia	Western Pacific	Upper middle	2008–2023	5	Oncology: 845 723.99 (10.68) ↑ Diabetes: 290 517.14 (3.65) ↑ HIV: 97 068.49 (1.23) ↓ Tuberculosis: 68 544.41 (0.87) ↓ Hepatitis C: 38 274.29 (0.48) ↓
The Russian Federation	European	Upper middle	2012–2023	7	Oncology: 7 904 306.07 (12.97) ↑ Diabetes: 1 518 879.83 (2.48) ↑ HIV: 1 252 939.18 (2.06) ↑ Hepatitis C: 305 047.55 (0.50) ↓ Tuberculosis: 271 133.35 (0.44) ↓
South Africa	African	Upper middle	2003–2022	9	HIV: 5 572 378.66 (20.73) ↑ Oncology: 1 675 994.39 (6.24) ↓ Tuberculosis: 988 245.63 (3.68) ↑ Diabetes: 984 172.62 (3.66) ↑ Hepatitis C: 89 175.23 (0.33) ↓
Suriname	The Americas	Upper middle	1997–2023	4	Oncology: 19 764.39 (9.74) ↑ Diabetes: 13 790.79 (6.77) ↑ HIV: 5362.17 (2.64) ↑ Hepatitis C: 950.13 (0.47) ↓ Tuberculosis: 406.5 (0.20) ↓
Australia	Western Pacific	High	2003–2023	235§	Oncology: 1 107 739.76 (17.19) ↑ Diabetes: 181 678.17 (2.80) ↓ Hepatitis C: 33 739.92 (0.52) ↓ HIV: 4012.14 (0.06) ↓ Tuberculosis: 1648.11 (0.03) ↓
Denmark	European	High	1996–2023	Cont.§	Oncology: 359 619.44 (21.16) ↑ Diabetes: 45 087.27 (2.64) ↓ Hepatitis C: 6755.99 (0.40) ↓ HIV: 1294.56 (0.08) ↓ Tuberculosis: 477.35 (0.03) ↓
Ireland	European	High	2008–2023	179§	Oncology: 217 095.34 (18.24) ↑ Diabetes: 26 676.12 (2.23) ↓ Hepatitis C: 3884.85 (0.33) ↓ HIV: 810.58 (0.07) ↓ Tuberculosis: 514.3 (0.04) ↓
Uruguay	The Americas	High	2006–2020	12	Oncology: 219 907.19 (19.64) ↑ Diabetes: 37 924.43 (3.37) ↑ HIV: 9163.96 (0.82) ↓ Hepatitis C: 4756.85 (0.42) ↓ Tuberculosis: 1810.39 (0.16) ↓

*In the WHO regions.
†In the 2022 World Bank classification.
‡Based on the IHME's 2019 Burden of Disease study, in disability-adjusted life-years (DALYs). Percentages of DALYs of total DALYs within the country are also shown, and how this compares to the global average.
§RLs, which were more frequently updated, leading to a high total number.
Cont, continuous updates of the RL; IHME, Institute of Health Metrics and Evaluation; NEMLs, National Essential Medicines Lists; RLs, reimbursement lists.

to create a basket of medicines. For these medicines, we collected the international non-proprietary name (INNs), formulation, dosage and indication. We excluded medicines used only for palliative care. This information was triangulated with the electronic WHO Model EML, Technical Report Series (2007–2021) and a technical document on the additions and deletions on the WHO Model List (used for 2007–2017).[13 19–27]

Countries and NEMLs

We purposefully selected 20 countries based on a variety of World Bank classifications of income groups (4–6 countries from each income group) and WHO geographical regions (2–6 countries from each region). NEMLs were first collected from a repository available on the WHO website, which is no longer available online.[28] To update and complete the collection of NEMLs, websites from the national Ministry of Health and other governmental websites were searched, and search engines were used with the keywords "essential medicines" and "essential drugs" in the country's primary language. Other sources were WHO Country Offices and personal contacts. Countries were selected if they had at least three NEMLs available between 2000 and 2024 and if the most recent NEML was from 2018 or after. In South Africa, the EMLs for Primary Health Care and at the Hospital Level were selected. For Australia, Denmark and Ireland,

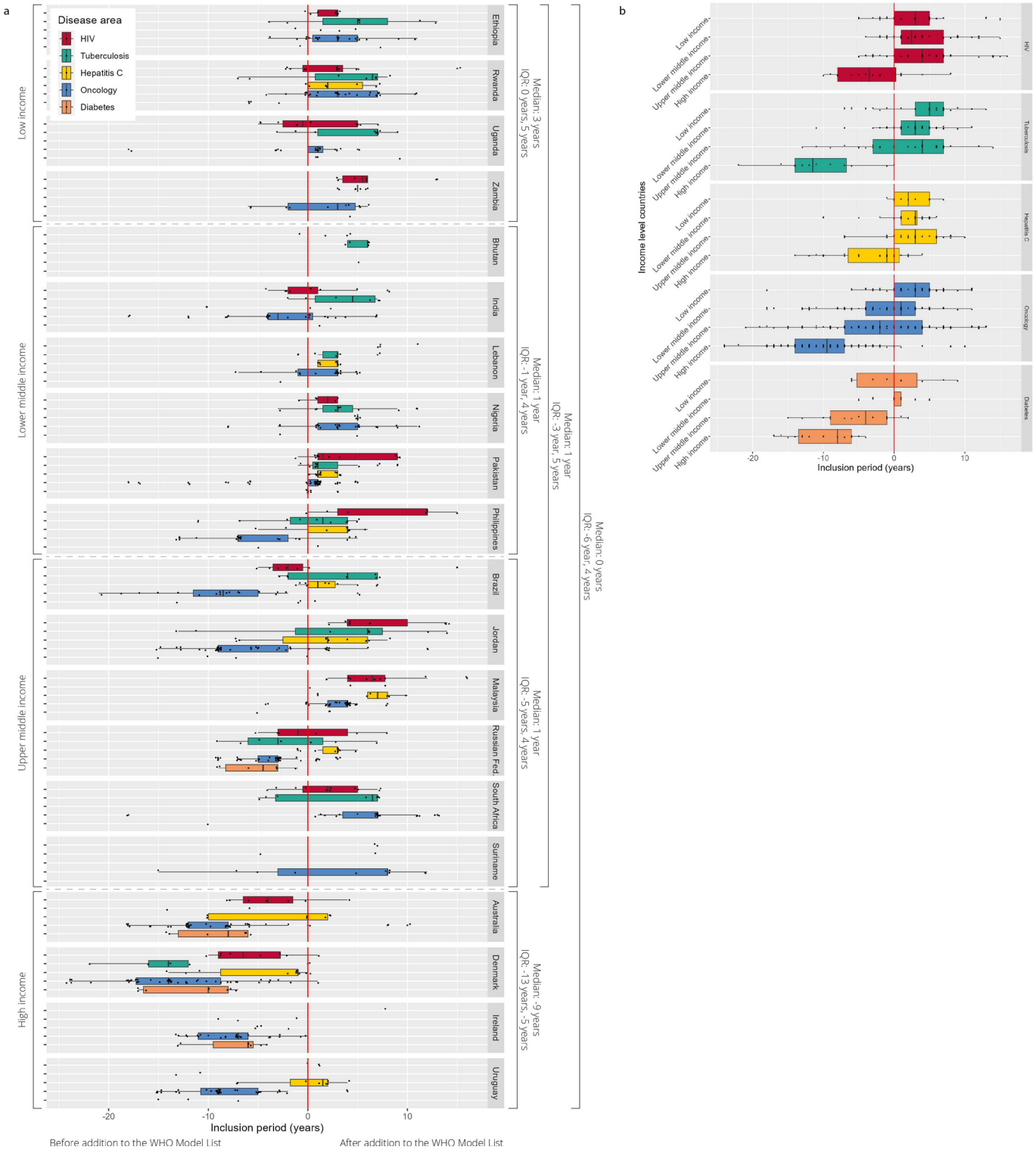

Figure 1 Time to inclusion of a medicine from its addition to the WHO Model List until its inclusion in an NEML/RL: (a) per country and disease area; (b) stratified by disease area and summarised per income group. NEML, National Essential Medicines List; RL, reimbursement list.

reimbursement lists (RLs) were used as an alternative to NEMLs. In some cases, such as in Uruguay, the total number of NEMLs included updates to specific parts of the NEML rather than a new edition of the NEML. The final date of data collection was 29 March 2024.

Additional information was obtained to characterise the economic and health landscape of the selected countries. The income group, GDP per capita (purchasing power parity based) and the Gini index were collected from the World Bank (2022), which was the most recent

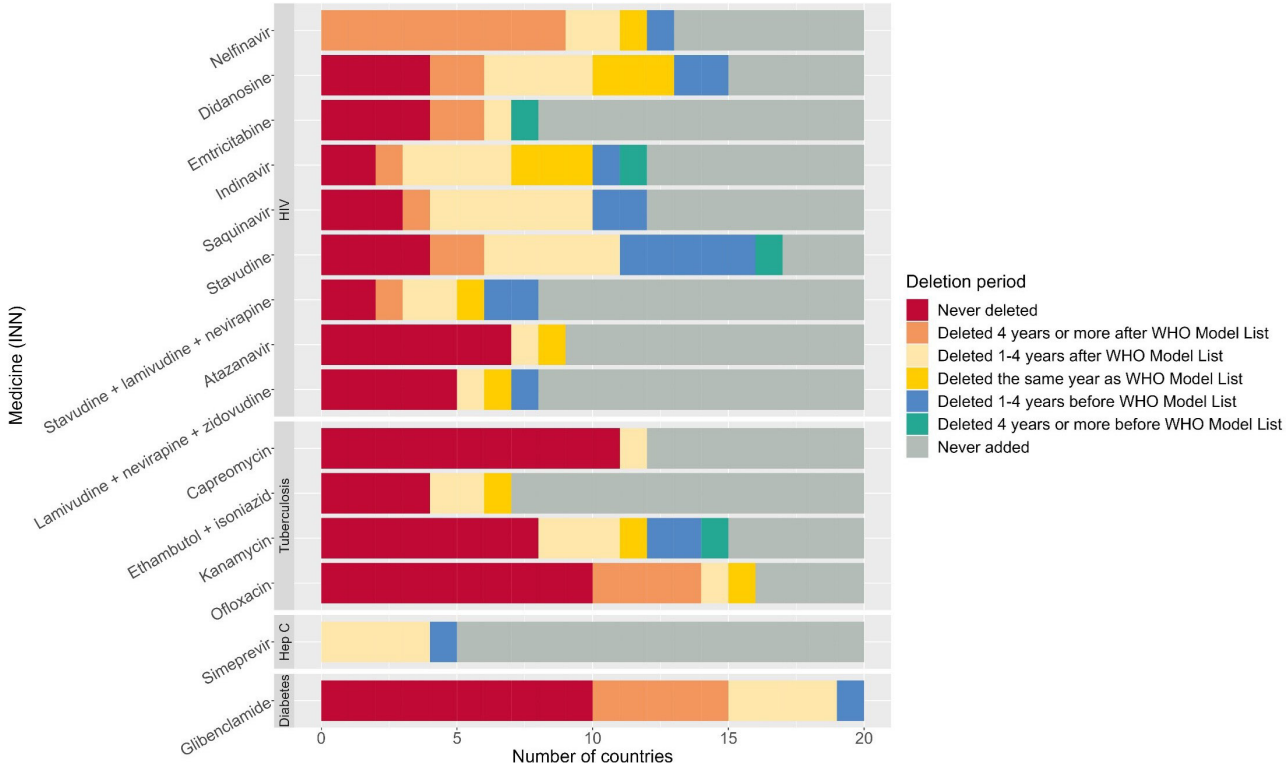

Figure 2 Time to deletion of a medicine from its deletion from the WHO Model List until its deletion within a country from the NEML/RL, categorised by periods. INN, international nonproprietary name; NEML, National Essential Medicines List; RL, reimbursement list.

data at the time.[29–31] The Gini index measures inequality among income, where higher values indicate higher inequality. The geographical regions were obtained from the WHO website.[32] The burden of disease was collected from the Institute of Health Metrics and Evaluation's Global Burden of Disease study (2019), where disability-adjusted life-years were used as a measure of morbidity.[33]

Data analysis

The basket of medicines was summarised by disease area and lists in which year the medicine was added or deleted from the WHO Model List. NEMLs from the selected countries were analysed for the presence of medicines in the basket. Searches in NEMLs were based on INNs listed in the WHO Model List. If a medicine was included in an NEML, the time between its addition to the WHO Model List and inclusion in the NEML was noted.

Descriptive data analysis was undertaken. We first compared the time to inclusion of a medicine from its addition to the WHO Model List until its inclusion in an NEML/RL between countries, income groups and disease areas. Additionally, boxplots for the time to inclusion were stratified by disease area and summarised per income group. For the boxplots, we calculated medians with IQRs. A table was also made for the inclusion of individual medicines in NEMLs/RLs between 2010 and 2022 across all countries. For this table, we assumed the same NEML was used by a country until a new edition was published. Moreover, we analysed the time to deletion of a medicine from the WHO Model List until its deletion from an NEML/RL in a stacked bar graph categorised by periods. Additionally, we assessed the percentage of medicines added to the WHO Model List and their inclusion in the most recent NEML/RL overall, per disease area and summarised by either income groups or geographical regions. Bar charts were also made with the percentage of included medicines in the most recent NEML/RL for each disease area overall and summarised by income groups or geographic regions. Finally, R^2 values from scatter plots were assessed for potential correlations between a country's GDP, Gini index and burden of disease with the number of included medicines either overall or for that disease area in its most recent NEML/RL.

Patient and public involvement

Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

RESULTS

Basket of medicines

Between 2007 and 2021, 90 medicines were added to the WHO Model List (table 1), the majority (n=48) being oncology medicines. Only 15 medicines were deleted from the WHO Model List across all disease areas except oncology. See the full list of additions and deletions in online supplemental annex 1.

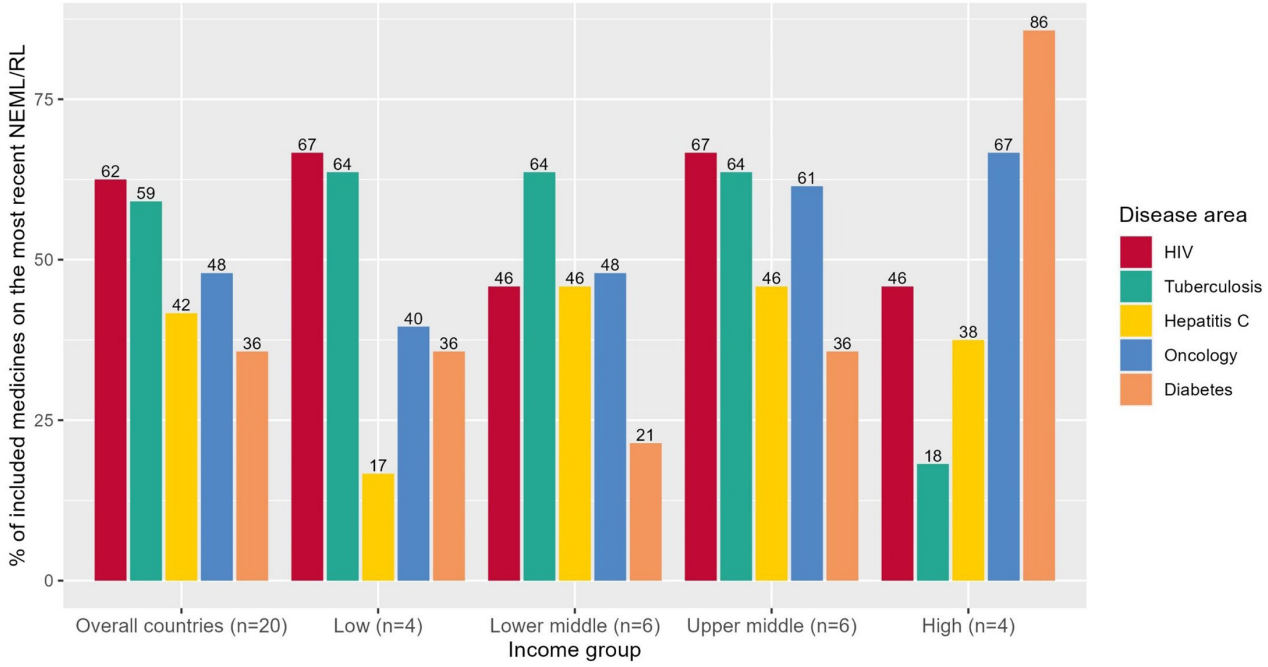

Figure 3 Percentage of medicines added to the WHO Model List and their inclusion in the most recent NEML/RL overall and per income group. INN, international nonproprietary name; NEML, National Essential Medicines List; RL, reimbursement list.

Included countries

20 countries were included in this study: four low-income (LICs), six lower middle-income, six upper middle-income and four high-income countries (HICs) (table 2). There was a large variability in the total number of NEMLs/RLs assessed per country (range 3–235). RLs are more frequently updated, which led to a high number of total RLs. In general, countries from the middle-income group had a higher number of updates to the NEMLs than countries from other income levels. Most countries (16/20) had the highest disease burden within the country for oncology, although the remaining countries (4/20) had oncology in the top three of disease burden. The majority of countries (14/20) also had diabetes in the top three of disease burden.

Time to inclusion

By the year of their addition to the WHO Model List, half of the medicines were already included in NEMLs/RLs (median: 0 years) (figure 1a). HICs mostly included medicines in their NEMLs/RLs before their addition to the WHO Model List (median: −9 years; IQR: −13, −5 years), while LMICs mostly did so after their addition to the WHO Model List (median: 1 year; IQR: −3, 5 years). This delay in inclusion was even longer for HIV, tuberculosis, and hepatitis C medicines (median: 3 years; IQR: 0, 6 years) versus diabetes and oncology medicines (median: 1 year; IQR: −4, 3 years). Notably, among the LMICs Brazil, India, Jordan, the Philippines and the Russian Federation included some medicines in their NEMLs before their addition to the WHO Model List, mostly for oncology medicines.

LMICs included medicines for HIV, hepatitis C and tuberculosis after their addition to the WHO Model List (figure 1b). Medicines for diabetes and oncology were included by LMICs after their addition to the WHO Model List (median: 1 year; IQR: −2, 3 years), while upper middle-income countries did so before their addition to the WHO Model List (median: −2 years; IQR: −7, 4 years). There was a larger variability in the range of time to inclusion of oncology medicines (range: 37 years) compared with diabetes medicines (range: 26 years) for all income groups. For oncology medicines, HICs included them much earlier (median: −10 years; IQR: −14, −7 years) than LMICs (median: 1 year; IQR: −4, 4 years).

Time to deletion

Medicines for HIV and hepatitis C (simeprevir) were deleted by countries more often than medicines for tuberculosis and diabetes (glibenclamide) before and after their deletion from the WHO Model List (figure 2). Not all tuberculosis medicines deleted from the WHO Model List were included by all countries in the first place. Unlike the diabetes medicine (glibenclamide), which was included by all countries at some point, but was never deleted by half of the countries.

Inclusion of individual medicines

Although overall HICs mostly included medicines in their NEMLs/RLs before their addition to the WHO Model List, while LMICs mostly did so after their addition to the WHO Model List (as shown in figure 1), but for individual medicines, there is no clear pattern of inclusion in NEMLs/RLs over time after their addition or deletion from the WHO Model List (online supplemental annex 2). More information on the number of NEMLs/RLs including individual medicines between 2010 and 2022 can be found in online supplemental annex 2.

Inclusion of medicines on most recent NEMLs

Overall, most medicines from the basket were included in the most recent NEML/RL for HIV (62%) and tuberculosis (59%) (figure 3). LMICs included medicines for these two disease areas more consistently (46%–67%), while medicines for diabetes (86%) and oncology (67%) were included more by HICs than by LMICs. In fact, the lower the income group, the fewer oncology medicines were included (40% for LICs vs 67% for HICs). Hepatitis C medicines were included in similar amounts by middle-income countries and HICs (38%–46%).

Medicines for diabetes and oncology were mostly included in the most recent NEMLs/RLs in European countries (85%–100%) (online supplemental annex 3). Countries in the African and Eastern Mediterranean regions included most medicines for HIV and tuberculosis (64%–83%). Eastern Mediterranean countries also included most medicines for hepatitis C (92%), while countries in the South-East Asian region included the least medicines for diabetes, hepatitis C and oncology (7%–25%). The Russian Federation, Jordan and Denmark included the most medicines in their recently revised NEML/RL, while Bhutan, Suriname and Zambia included the least.

Finally, scatter plots between a country's GDP, Gini index and burden of disease (for the five disease areas separately) did not correlate with the number of included medicines (R^2 values: 0.00–0.40) both overall and for its corresponding disease area in the most recent NEML/RL (online supplemental annex 4).

DISCUSSION

Overall, there are no substantial delays in the inclusion of medicines in NEMLs/RLs as medicines were included in the same year as their addition to the WHO Model List. However, differences in time to inclusions were observed between LMICs and HICs (with the latter being earlier), and medicines for communicable and NCDs (with the latter being earlier). LMICs seemed to be using the WHO Model List as their guiding tool, because medicines were included in NEMLs after their addition to the WHO Model List, especially in the case of HIV, tuberculosis and hepatitis C medicines. This contrasts with HICs, which included medicines in NEMLs/RLs prior to their addition to the WHO Model List. Overall, medicines for HIV and tuberculosis were included more in the most recent NEMLs/RLs than medicines for oncology, hepatitis C and diabetes. In the case of deletions, mostly HIV medicines were deleted by countries before and after their deletion from the WHO Model List.

Medicines for diseases targeted by SDG 3.3 (hepatitis C, HIV and tuberculosis) seemed to be included in more NEMLs in LMICs than medicines for NCDs targeted by SDG 3.4 (diabetes and oncology), which was in line with our hypothesis. Due to the traditional focus of health systems on communicable diseases, especially in LMICs, there are often more funding and donation programmes which can explain the higher number of inclusions of medicines for communicable diseases even if these medicines are still high-priced.[34] The low number of inclusions of hepatitis C medicines by LICs (17%) could be due to lower disease burdens, donations bypassing the local health system's processes, or high prices as the direct-acting antivirals are unaffordable in many countries even with price discounts offered to some LICs.[8 35 36] For medicines to treat multidrug-resistant tuberculosis, the burden of catastrophic cost was higher than 80%, which is likely the reason countries did not delete older tuberculosis medicines to replace them with these medicines, even though such newer medicines are still necessary but remain less accessible.[17 18 37]

Despite still being considered high-income conditions, NCDs impose a large and growing health burden on LMICs, which is why it is especially concerning that fewer medicines for NCDs were included in NEMLs in these countries.[38 39] For example, diabetes and oncology medicines were included more by HICs while tuberculosis and HIV medicines were more consistently included by LMICs in NEMLs. As for diabetes medicines, which were mostly included by HICs, six of seven medicines (being insulin analogues) were only added to the WHO Model List in 2021 after their rejection in 2019 due to their higher cost.[40 41] The low number of inclusions by LMICs could first be due to the high prices of medicines, which can have a big budget impact depending on the setting. Moreover, the large variability in year and total number of NEMLs suggests that countries may require more time to update their NEMLs to consider recent updates to the WHO Model List.[41] The same can be true for high-priced oncology medicines, which were included more by countries as their income group increased, implying affordability issues. Newer oncology treatment regimens on the WHO Model List were not affordable in Sub-Saharan Africa because of high out-of-pocket payments.[42] Furthermore, selecting oncology medicines is challenging due to the high level of uncertainty about their added benefit.[43] The WHO has addressed this by forming a Cancer Medicines Working Group and having additional selection criteria specifically for oncology medicines in the WHO Model List. The lack of correlation between disease burden and economic indicators (GDP and Gini index) with the number of included medicines in NEMLs/RLs could be explained by high medicine prices preventing their listing in NEMLs/RLs despite their high disease burden even for HICs.

Very few medicines were deleted from the WHO Model List, with 15 deletions vs 90 additions, and there were no deletions for oncology medicines. Once added, medicines can stay on the WHO Model List for a long time, as shown in this study. WHO has issued an update of the mental health section for the 2023 WHO Model List, which resulted in a series of evidence-based applications for the addition and deletion of medicines developed in consultation with the WHO Department of Mental Health and Substance Use.[44] Such reviews should

be done for other disease sections in the WHO Model List on a regular basis. Countries mostly deleted HIV medicines from their NEMLs, although the sample size for HIV medicines (n=9) was larger than for the other disease areas combined (n=6).

HICs included medicines in NEMLs/RLs prior to their addition to the WHO Model List, which confirms that HICs do not wait for WHO recommendations on the selection of medicines. This supports the argument that there may be more benefit in refocusing the WHO Model List on LMICs.[9] Furthermore, a major driver for manufacturers to submit for marketing approval to regulatory authorities is market forces, especially in emerging markets. In contrast, manufacturers often do not submit for approval in LICs. Manufacturers typically submit more and earlier to regulatory authorities in HICs than in LMICs, which can lead to earlier approval and marketing of medicines. The process by the WHO Expert Committee on the Selection and Use of Essential Medicines waits longer to ensure the robustness of the supporting evidence.[3] Delays in the inclusion of medicines in NEMLs/RLs increase waiting times, which impacts the health of patients especially when there are no alternative treatments available. Such delays can be seen in oncology medicines, which HICs included in NEMLs/RLs ten years prior to their addition to the WHO Model List, while LMICs did so 1 year after.

This study's strength is in its design, which measures the addition and deletion of medicines from the WHO Model List and their inclusion in NEMLs over time, providing a historical perspective on the evolution of NEMLs. Therefore, this analysis has shed further light on how the WHO Model List is used by countries and how this differs between income groups and disease areas as prioritised by the SDGs. Although the sample of countries was quite large and diverse, some regions might be under-represented as not all countries have an NEML, so the potential representativeness of these findings to other countries may be limited. Another limitation is that not all diseases from SDG 3.3 and 3.4 could be included, such as malaria and cardiovascular diseases.

CONCLUSIONS

In conclusion, this study showed that the WHO Model List is a useful guiding tool for LMICs, as these countries include medicines in NEMLs after their addition to the WHO Model List. This is especially the case for medicines to treat communicable diseases such as HIV, tuberculosis and hepatitis C compared with NCDs such as diabetes and oncology. However, more attention needs to be paid to including medicines for NCDs in NEMLs, especially in LMICs. Although their high prices need to be addressed, including a medicine in the NEML is only the first step in ensuring its timely and sustainable access in the country.

Finally, further research is required to explore why medicines for certain diseases were not included in NEMLs and why economic indicators and disease burden were not correlated with the inclusion of medicines in NEMLs. Since NEMLs represent the national priorities, and including medicines in NEMLs impacts their budget, the local context needs to be considered.

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