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Essential medicines lists are for high income countries too

These lists help control costs and encourage rational prescribing

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On 26 July 2023, the World Health Organization published the 23rd edition of its essential medicines list.[1] First devised in 1977, the list comprises medicines "that satisfy the priority healthcare needs of the population." As such, the concept of essential medicines deserves wider attention from high income countries.

Historically, the US has been a consistent opponent of the essential medicines concept.[2] So it is remarkable that, almost unnoticed, on 6 August 2020, US President Biden issued an executive order directing the US Food and Drug Administration to "identify a list of essential medicines ... that are medically necessary to have available at all times in an amount adequate to serve patient needs and in the appropriate dosage forms."[3]

The essential medicine concept is intended to "carve out a core subset of therapeutic substances from the broader universe of commercial pharmaceutical products, and appropriate them into a public health commons."[2] Essential medicines have joined clean water, safe food supply, and adequate housing as necessities whose absence constitutes a basic failure of universal human rights.[4] Access to essential medicines and vaccines is a key component of universal health coverage[5] and central to achieving the sustainable development goal of good health and wellbeing.[6]

Essential medicines are carefully selected on the basis of efficacy, safety, effectiveness, and affordability and incorporation into treatment guidelines for prescribers and patients. The list must be implemented as part of comprehensive national medicines policies that cover licensing, procurement, price regulation, and local manufacturing.

WHO's first list in 1977 contained 187 medicines. By 2017, 137 of the 195 WHO member states had a national essential medicines list.[7] Most of these were low and middle income countries. Fewer than a quarter (21/79) of high income countries had an essential medicines list in 2017,[8] although some (such as Germany, Australia, the UK) prioritise medicines in other ways through local formularies and reimbursement mechanisms.[9]

As pharmaceutical expenditures continue to rise, all countries are seeking to control costs and out-of-pocket expenditure. In the US, the cost of drugs used for chronic, rare, and complex diseases increased by 43% between 2016 and 2021 with expenditure on prescription drugs reaching $603bn (£475bn; $550bn) in 2021.[10] Record out-of-pocket costs were also paid by patients at retail pharmacies in the US in 2019: $67bn up from $61bn in 2015.[7] These increases are primarily driven by new drugs, which often provide only marginal benefits over older or cheaper alternatives.[11] Essential medicine lists may improve availability and reduce healthcare costs and harms by encouraging rational prescribing.[1 12] Direct evidence of improved health outcomes is, however, lacking,[9] so studies evaluating the health benefits for patients and populations should be a research priority.

The US list of essential medicines, launched in response to the vulnerability of medicines supply chains exposed by the pandemic, is mainly targeted at acute care medical facilities specialising in urgent medical conditions and short term treatment; it also includes some pain relief medicines and antibiotics in wider use in the community. The FDA selection centres on medicines "that are medically necessary to have available in adequate supply which can be used for the widest populations to have the greatest potential impact on public health."[3] Affordability is not a consideration.[13] However, the US goes beyond essential medicines policies implemented by many other countries in that the FDA has been directed to coordinate with other partners to minimise the risk of shortages by developing strategies for purchasing, accelerating local manufacture, and monitoring supply chains.[3]

Canada too is moving towards an essential medicines list.[14] Although healthcare services in Canada are generally publicly funded, prescription medicines are not. As in the US, coverage comprises a confusing patchwork of private and public drug insurance plans with a variety of premiums, co-payments, deductibles, and annual limits.[14] In 2019, a government report found that "20% of Canadians have inadequate drug coverage or no coverage at all and must pay out of pocket," and called for "a carefully chosen list of essential medicines" to be publicly funded.[14]

The US's creation of an essential medicines list is a promising development but could also undermine the original WHO concept through pharmaceutical industry lobbying and the real possibility of industry capture of these lists, combined with the global influence of the US. On the positive side, prioritising highly effective medicines over new drugs with only marginal additional benefits could improve training and education of prescribers and reduce harms from inappropriate prescribing: experiences from Sweden's "wise list" highlight the importance of clinician and patient support.[12] Norway's "medical need clause" (given up when it joined the European Economic Area agreement in 1992) was an international exemplar of how to limit registration of irrational or unnecessary medicines, aligning it with the essential medicine concept.[15] An essential medicines list could also

reduce the environmental impact of medicines, helping to reduce water table contamination, antimicrobial resistance,[16] and the potent greenhouse gas effects and ozone depletion caused by some anaesthetic gases, including nitrous oxide.[17]

More high income countries should consider adopting the essential medicines concept and evaluate implementation in a systematic way as part of their national medicines policies.[18] But in so doing, they must ensure that the integrity of this concept is maintained for everyone.

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