

# Public health emergency archetypes: a framework to guide efforts to ensure equitable access to medical countermeasures

Paul A Wilson <sup>1</sup>, Ian Thornton <sup>2</sup>, Gian Gandhi <sup>2</sup>

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<sup>1</sup>Mailman School of Public Health, Columbia University, New York, New York, USA

<sup>2</sup>Supply Division, UNICEF, New York, New York, USA

## Correspondence to

Dr Paul A Wilson;  
pw2101@columbia.edu

The international response to the COVID-19 pandemic, despite important successes, has highlighted profound inequities in access to medical countermeasures (MCMs), with many low-income and middle-income countries (LMICs) receiving life-saving products, especially vaccines, months or years after high-income countries (HICs).<sup>1</sup> Many efforts are now underway to absorb the lessons from the COVID-19 experience and to build a stronger infrastructure for ensuring fair access to MCMs in future disease outbreaks. There have been more than 30 reviews and evaluations of the COVID-19 response, negotiations have begun on a pandemic accord, WHO is developing an MCMs 'platform', and both the G7 and G20 will focus on pandemic preparedness and response this year.<sup>2-7</sup> Although there is not yet a clear consensus on the way forward, several themes have emerged, including the need for greater regional autonomy in pandemic response, rapidly accessible funding, greater emphasis on technology transfer, and more inclusive governance of international responses.<sup>8-10</sup>

While understanding and remedying what did not work well in the response to the COVID-19 pandemic is crucial, there is also a danger of focusing too much on public health emergencies that closely resemble this one, that is, of fighting the last war. Infectious disease outbreaks come in many kinds and the differences among them have important consequences for efforts to ensure equitable access. We outline here a simple framework, based on characteristics of outbreaks relevant to availability and supply of MCMs, and highlight some important implications for approaches to ensuring supply to LMICs.

Disease outbreaks and the pathogens that cause them differ in many ways, including the type of pathogen and mode of transmission,

## SUMMARY BOX

- ⇒ Infectious disease outbreaks and epidemics vary enormously in scale, frequency and geographical focus, and these differences have crucial implications for ensuring equitable and timely access to medical countermeasures in low-income and middle-income countries. International initiatives to improve preparedness and response must not only learn the lessons of the COVID-19 response but prepare for outbreaks of very different types.
- ⇒ From the perspective of the availability of medical countermeasures in low-income and middle-income countries, outbreaks and outbreak pathogens can be classified along two dimensions: the typical scale of the outbreaks and the impact on high-income countries on one hand and the status of medical countermeasure development and supply on the other. Taking these two dimensions together, we define nine health emergency 'archetypes'.
- ⇒ Different types of outbreaks are characterised by different supply challenges. These challenges in turn have implications for the relevance or effectiveness of the market-shaping levers and supply strategies that regional and international agencies can deploy to promote equitable access to medical countermeasures.
- ⇒ The framework presented here can inform current efforts to improve the international infrastructure for health emergency preparedness and response.

the location of the outbreak and health system capacity to respond. A number of organisations, including WHO, Africa Centres for Disease Control and Prevention (Africa CDC), US National Institutes of Health, the European Commission's Health Emergency Preparedness and Response Authority and the UK Vaccine Network, have categorised and prioritised pathogens in various and valuable ways.<sup>11-15</sup> In our work with UNICEF Supply Division, the world's largest procurer of vaccines and a key supply partner in health emergencies, our focus is on access to MCMs.

From this perspective, we believe that the critical characteristics of pathogens are the typical size and frequency of the outbreaks they cause and the likelihood that they will strongly affect HICs. The latter is important because of HICs’ disproportionate role in research and development (R&D) investment, the importance of their markets to commercial incentives for product developers and manufacturers, and their ability to lock up supply of scarce MCMs. On this basis, we propose a simple division of disease outbreaks into three categories or tiers, each associated with a particular supply challenge.

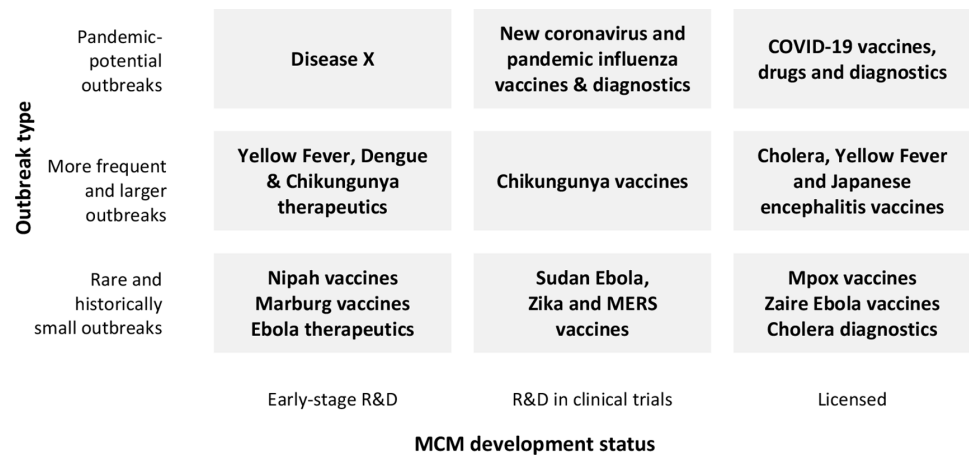
- 1. Rare and historically small: This category includes pathogens such as the Ebola, Marburg and Nipah viruses, which, at least to date, have caused outbreaks of hundreds or at most thousands of cases and pose little realistic threat to HICs. The volume of MCMs required for these diseases is so small—and in many cases, the ability of affected populations and states to pay for them so limited—that the fundamental supply challenge for these outbreaks is the almost complete lack of commercial incentives to develop or manufacture these products.
- 2. More frequent, larger and semiendemic: This category includes pathogens such as cholera, yellow fever, bacterial meningitis, and perhaps dengue and chikungunya, which cause more frequent and larger outbreaks and may be endemic in some countries. Like the rare and historically small outbreaks, these pose little current threat to HICs. Although the location and timing of these outbreaks is unpredictable, the required volumes of MCMs, averaged over year-to-year fluctuations, are sufficient to support a commercial market. Here, the main challenge is to stabilise demand enough to ensure reliable and sufficient commercial supply.
- 3. True pandemics: COVID-19 and a potential global influenza pandemic are the canonical examples of this upper tier of outbreaks, which affect hundreds of millions or even billions of people, including those in HICs as well as LMICs. For these outbreaks, scope

and duration and hence demand for MCMs remain unpredictable, but there is a potential for large commercial returns to product developers and manufacturers. Critically, there is every expectation that HICs will invest large sums in R&D and in creating attractive markets for suppliers. Thus, for LMICs and organisations acting on their behalf, including regional bodies, the fundamental challenge in these cases is to secure adequate and timely supplies of MCMs in the face of competition from HICs, as the struggle for COVID-19 vaccines demonstrated.

This division into three tiers based on the characteristics of pathogens can be complemented by a second axis based on the status of particular countermeasures, with its own implications for market-shaping priorities. For some outbreak pathogens, we have no MCMs of needed types and R&D is at a very early stage. For others, some MCMs have advanced to clinical trials and enough safety data is available to move to an efficacy trial when an outbreak occurs. Finally, adequate MCMs already exist for some pathogens—in these cases the emphasis can be on ensuring adequate supply available to LMICs.

Combining these two dimensions, we arrive at a three-by-three matrix of categories, which we call health emergency archetypes. Figure 1 displays the nine archetypes, with illustrative examples of pathogen–MCM combinations corresponding to each. This framework was developed primarily on the basis of experience with vaccines, but we believe it should be useful for medicines and, with modification, for diagnostics as well.

The practical value of this framework is that the different supply challenges associated with each archetype have implications for the approaches that governments, regional bodies and international agencies should take to ensure that LMICs have access to MCMs in an outbreak. To clarify these implications, we analysed the relevance and likely effectiveness for each archetype of a large number of levers available to policy-makers. These levers include purchase modalities such as advance



**Figure 1** Outbreak MCM archetypes. The y-axis distinguishes three tiers of outbreak types, while the x-axis classifies MCMs for these outbreaks by the status of product development and availability. Illustrative examples of pathogen–MCM combinations are given for each archetype. MCM, medical countermeasure; R&D, research and development.

purchase agreements (APAs), measures to promote intellectual property licensing and technology transfer, and changes in regulatory procedures. The right combination of levers varies by archetype, in both preparedness and response.

We highlight some conclusions from this analysis:

- For pathogens that cause rare and historically small outbreaks, creating competitive commercial markets for MCMs is not a realistic goal. Instead, we should use grant or other forms of push funding to bring at least one product through to regulatory approval and to fund production for a small stockpile. Where these products have been shown to be safe in humans, creation and maintenance of a ready reserve of investigational drugs or vaccines is critical both to allowing rapid launch of efficacy trials when an outbreak begins and, where appropriate, use in controlling the outbreak under relevant protocols.
- For pathogens such as cholera causing more frequent and larger outbreaks, our main recommendation is that stockpiles, which in some cases already exist, should be restructured so that they serve to smooth and solidify demand as well as their current purpose of ensuring rapid availability. This might entail making the stockpiles larger, with a commitment to regular replenishment. This should help make these markets more commercially sustainable.
- For true pandemics, the international community should build—and be willing to pay for—the capacity to use a wide range of tools to secure supply, including (1) APAs, (2) expertise, funding and incentives for technology transfer to rapidly expand supply, (3) strengthened regional manufacturing capacity and (4) infrastructure for managing donations, should they materialise. The relative importance of different approaches to supply will depend on characteristics of future pandemics that cannot be predicted in advance, including R&D success rates.
- Broadening the arsenal of supply levers, especially for future pandemics, requires preparedness investments now, including in capacity of regional suppliers and in technology transfer, without which we will find ourselves again with limited options.
- For all potential outbreak pathogens for which adequate MCMs are not available, public investment in R&D is essential, not only to develop and advance product candidates but also to facilitate clinical trials, develop expedited regulatory pathways, and to support simplified and more transferable manufacturing processes. Attaching appropriate conditions to these public investments can help to ensure equitable access to resulting products.
- Investment by international agencies in R&D during pandemics should focus on rapid response and on specific gaps, as any such investment will likely be dwarfed by spending by the USA and other HICs once they engage.

- Rapid access to funding for MCM purchase may be important in pandemics, where LMICs are in competition with HICs for limited supply. For small and rare outbreaks, however, financing may not be the binding constraint if no product is ready for use, as the recent outbreak of Sudan Ebola demonstrated.<sup>16</sup>

- Dose donations are only useful in limited circumstances, especially pandemics, where HIC buying drives commercial supply and may create excess supply. Donations cannot be relied on and can also impede development and use of products more suited to LMICs needs.

We believe that our analysis of outbreak types can be useful to international agencies with a mandate to assist LMICs, including UNICEF and its partners as well as regional bodies such as the Pan American Health Organization (PAHO) and Africa CDC, as they plan for future public health emergencies, by informing approaches to ensuring availability of MCMs in very different kinds of outbreaks. Discussions have already begun with several agencies, including those represented in the project's internal advisory group (see the Acknowledgements section) as well as PAHO. Our analysis also has implications for roles and responsibilities. If certain supply levers, such as push funding for R&D, APAs and stockpiles, are more useful for certain archetypes, it follows that the agencies that deploy these levers may have a larger role in some health emergencies than others.

At a minimum, we argue that the international community should take a more explicitly differentiated approach to preparedness for and response to very different types of public health emergency. We hope that the analysis presented here can be a useful starting point and can inform the various initiatives underway to restructure regional and international pandemic preparedness and response.

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**ORCID iDs**

Paul A Wilson <http://orcid.org/0000-0002-3906-1842>

Ian Thornton <http://orcid.org/0000-0001-8950-8721>  
 Gian Gandhi <http://orcid.org/0000-0002-9630-5866>

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