What a difference a pandemic *should* make…

PATH Center for Vaccine Innovation and Access (CVIA)
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Disclaimers

• The presenter has no financial conflicts of interest to declare.
• The views and opinions expressed in this presentation are those of the presenter and do not necessarily reflect the views and/or opinions of PATH, partners, or donors.
“You never let a serious crisis go to waste... ...it’s an opportunity to do things you think you could not do before.”

Rahm Emanuel

(as President-Elect Obama’s appointed Chief of Staff)
New Challenges: **IA2030 “leave no one behind”**

Before the pandemic…

From presentation at 2019 DCVMN AGM, Rio de Janeiro

Next decade of vaccine

https://stm.sciencemag.org/content/11/497/eaaw2888.full
New Challenges: **IA2030 “leave no one behind”**

COVID-19 pandemic widened not narrowed the gap between high- and low-income countries...

<table>
<thead>
<tr>
<th>High income countries: 1 in 2 people, or</th>
</tr>
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<tbody>
<tr>
<td>62.13% have been vaccinated with at least one dose as of Oct 13, 2021.</td>
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<table>
<thead>
<tr>
<th>Low income countries: 1 in 26 people, or</th>
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<tbody>
<tr>
<td>3.88% have been vaccinated with at least one dose as of Oct 13, 2021.</td>
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New Challenges: **IA2030 “leave no one behind”**

And it’s not just a vaccine supply gap between high- and low-income countries…

<table>
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<tr>
<th>High income countries have to increase their health care spending by</th>
<th>Low income countries have to increase their health care spending by</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.8%</td>
<td>56.6%</td>
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</table>

on average to cover cost of vaccinating 70% of the population.

New Challenges: **IA2030 “leave no one behind”**

The new challenge goes beyond existing supply global access principles and sustainability, it includes “absorptive capacity” gaps....
New paradigms (Part 1)
New Paradigms: **Vaccines as “public goods”**

Before the pandemic, vaccines were managed largely as private goods (i.e., rivalrous and excludable)...

From presentation at 2019 DCVMN AGM, Rio de Janeiro

**Four Vaccine Business Cases**

- **Compelling—Uncertain—Assistance—No**

- **Uncertain business case (LMIC ↔ HIC)** (e.g., Grp A Strep, Grp B Strep, TB)
  - Reverse tiered pricing
  - Push & Pull mechanisms

- **Compelling business case (HIC → LMIC)** (e.g., HBV, HIB, HPV, PCV, RSV, Rota)
  - Tiered pricing
  - Push & Pull mechanisms

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<table>
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<tr>
<th>excludable</th>
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<tr>
<td>Private good</td>
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<td>(e.g., private vehicle)</td>
<td>(e.g., timber)</td>
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<tr>
<td>Club good</td>
<td>Public good</td>
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<td>(e.g., internet access)</td>
<td>(e.g., national defense)</td>
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*The Theory Of Moral Sentiments (Part IV, Chapter 1)*

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**PATH**
New Paradigms: Vaccines as “public goods”

Resolution adopted by the UN General Assembly in response to COVID-19 pandemic …

13. Recognizes the role of extensive immunization against COVID-19 as a global public good for health in preventing, containing and stopping transmission in order to bring the pandemic to an end, once safe, quality, efficacious, effective, accessible and affordable vaccines are available;

Source: https://undocs.org/pdf?symbol=en/A/RES/74/306
New Paradigms: Vaccines as “public goods”

What will the new paradigm(s) be?

If “public goods”, who geographically defines?

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New paradigms (Part 2)
New Paradigms: EUA | EUL regulation for vaccines

Before the pandemic…
Pre-cautionary principle applied as prophylactic vaccine were administered to largely healthy individuals each with a low individual risk of severe outcomes from infection…

Adapted from: Eichler, H-G et. al. *Nature Reviews Drug Discovery* doi:10.1038/nrd4129
New Paradigms: EUA | EUL regulation for vaccines

Before the pandemic…
How routine vaccine development (regulatory) risk might be optimally managed*…


Adapted from: Eichler, H-G et. al. Nature Reviews Drug Discovery doi:10.1038/nrd4129
New Paradigms: EUA | EUL regulation for vaccines

The global COVID-19 pandemic…
Significantly shifted the regulatory risk tolerance curve to the left…

Essence of vaccine development

Adapted from: Eichler, H-G et. al. *Nature Reviews Drug Discovery* doi:10.1038/nrd4129
New Paradigms: EUA | EUL regulation for vaccines

Post-COVID-19 pandemic…
How far the regulatory risk tolerance curve shifts to the right may come down to how manufacturers engage in continuing to assess the benefit-risk post-EUA and post-licensure…

…the more manufacturers “lean into” generating real world evidence, the more likely regulators will risk share …
New opportunities & Key takeaways
Opportunities & Key takeaways

• Challenges in advancing health equity have never been greater as the gap grows between high resource and low resource settings
• The status quo paradigm of vaccines for LMIC public immunization programs as “private goods” have failed to “leave no one behind” and is unlikely sustainable
• New paradigm(s) of vaccine development and vaccines for economically and socially excluded populations as global, regional, and/or national “public goods” are needed to “leave no one behind”
• The COVID-19 pandemic has created new paradigms in vaccine development; Emerging Market Vaccine Manufacturers and DCVMN have an opportunity to make these new paradigms the new norm.