

19 October 2021



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

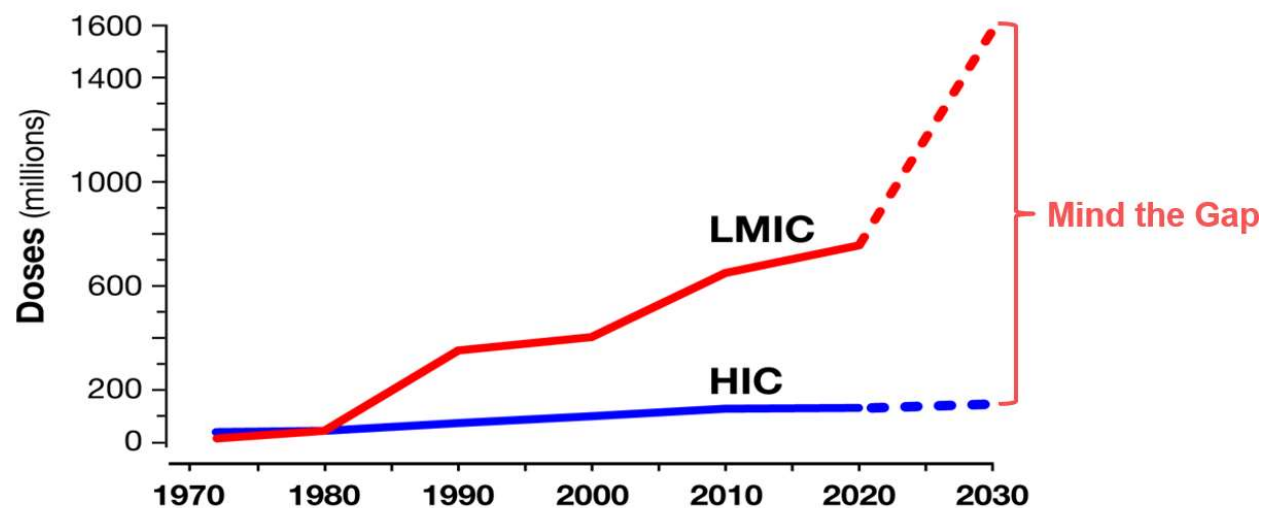
New Challenges: **IA2030** “*leave no one behind*”



Before the pandemic...

From presentation at 2019 DCVMN AGM, Rio de Janeiro

Next decade of vaccine



Rappuoli et al., *Sci. Transl. Med.* 11, eaaw2888 (2019)
<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...

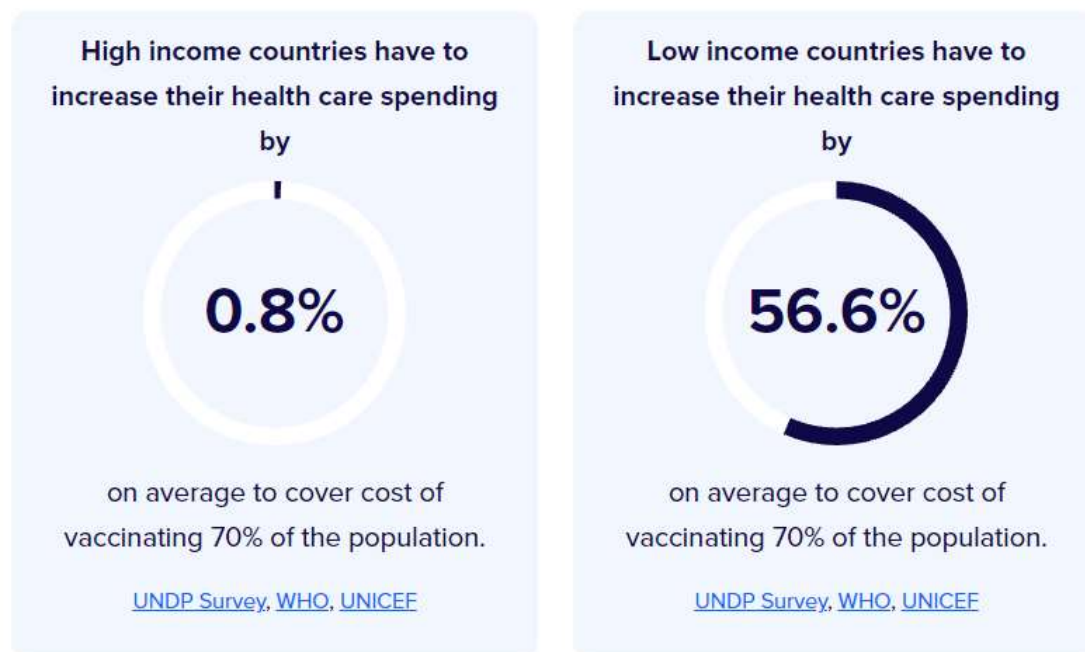


Source: <https://data.undp.org/vaccine-equity/> accessed 16 OCT 2021

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



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



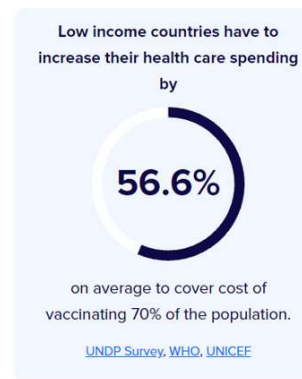
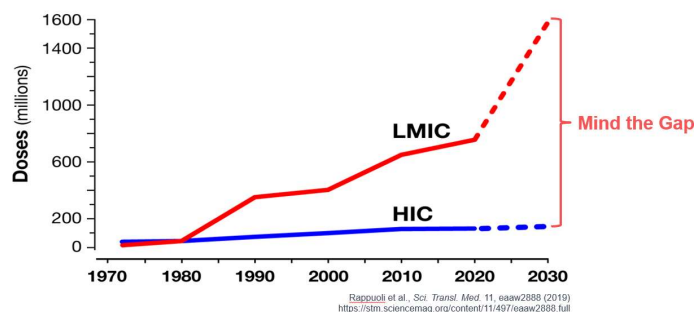
Source: <https://data.undp.org/vaccine-equity/> accessed 16 OCT 2021

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



The new challenge goes beyond existing supply global access principles and sustainability, it includes “absorptive capacity” gaps....

Next decade of vaccine









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)...

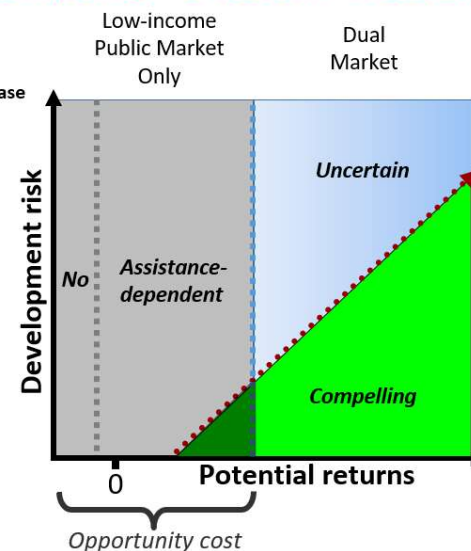
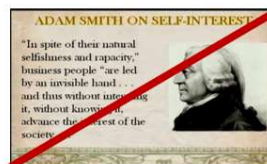
From presentation at 2019 DCVMN AGM, Rio de Janeiro

	excludable	non-excludable
rivalrous	Private good  (e.g., private vehicle)	Common good  (e.g., timber)
non-rivalrous	Club good  (e.g., internet access)	Public good  (e.g., national defense)

Four Vaccine Business Cases Compelling—Uncertain—Assistance—No

Assistance-dependent business case (LMIC only; Outbreak)
 (e.g., LMIC: Cholera, Malaria, Men A, Shigella; Outbreak: Ebola, MERS, Nipah, Lassa Fever)
 Solutions:

- Public funding
- Priority Review Vouchers
- LMIC Manufacturers
- Push & Pull mechanisms



Uncertain business case (LMIC ↔ HIC)
 (e.g., Grp A Strep, Grp B Strep, TB)
 Solutions:





- Reverse tiered pricing
- Push & Pull mechanisms

Compelling business case (HIC → LMIC)
 (e.g., HBV, HiB, HPV, PCV, RSV, Rota)
 Solutions:


- Tiered pricing
- Push & Pull mechanisms

New Paradigms: Vaccines as “public goods”

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

	excludable	non-excludable
rivalrous	Private good  (e.g., private vehicle)	Common good  (e.g., timber)
non-rivalrous	Club good  (e.g., internet access)	Public good  (e.g., national defense)

United Nations
A/RES/74/306


General Assembly
Distr.: General
15 September 2020

**Resolution adopted by the General Assembly
on 11 September 2020**

[without reference to a Main Committee (A/74/L.92)]





74/306. Comprehensive and coordinated response to the coronavirus disease (COVID-19) pandemic

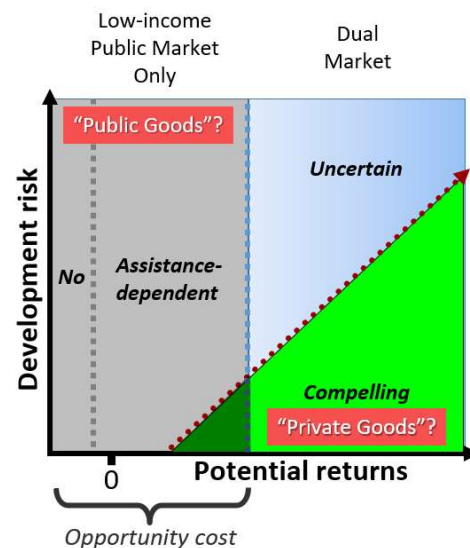
13. *Recognizes* the role of extensive immunization against COVID-19 as a **global public good** for health in preventing, containing and stopping transmission in order to bring the pandemic to an end, once safe, quality, efficacious, effective, accessible and affordable vaccines are available;

Source: <https://undocs.org/pdf?symbol=en/A/RES/74/306>

New Paradigms: Vaccines as “public goods”

What will the new paradigm(s) be?

	excludable	non-excludable
rivalrous	Private good  (e.g., private vehicle)	Common good  (e.g., timber)
non-rivalrous	Club good  (e.g., internet access)	Public good  (e.g., national defense)



If “public goods”, who geographically defines?





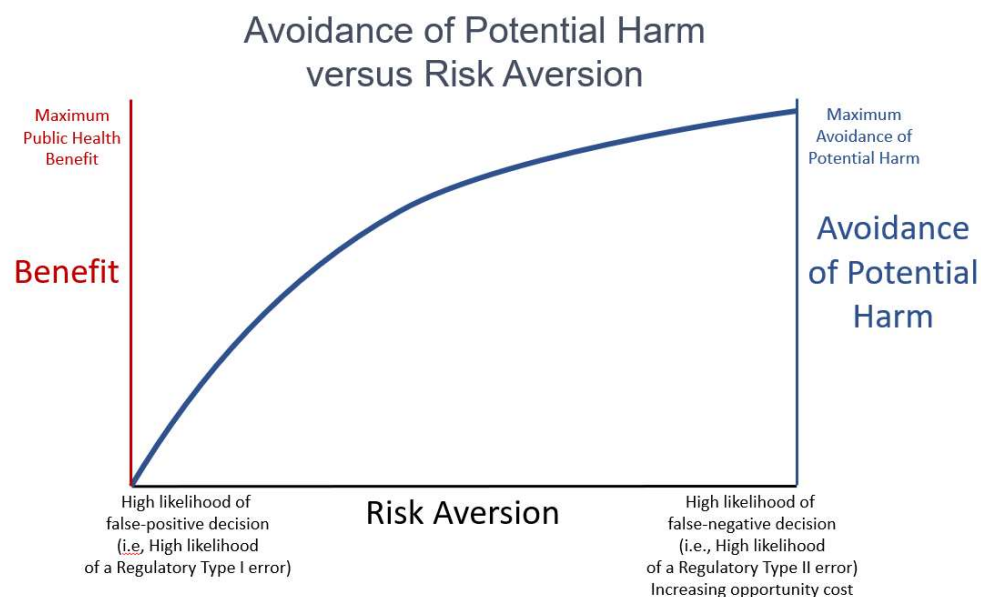
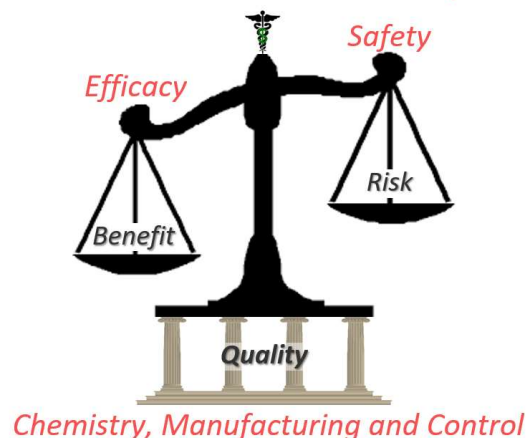
New paradigms (Part 2)

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...

Essence of vaccine development



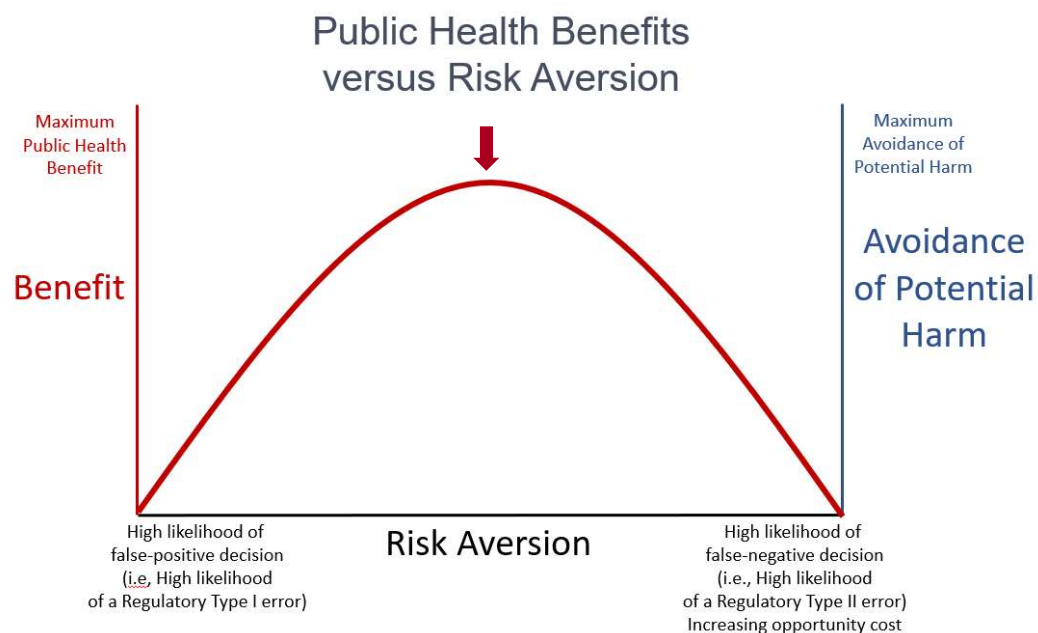
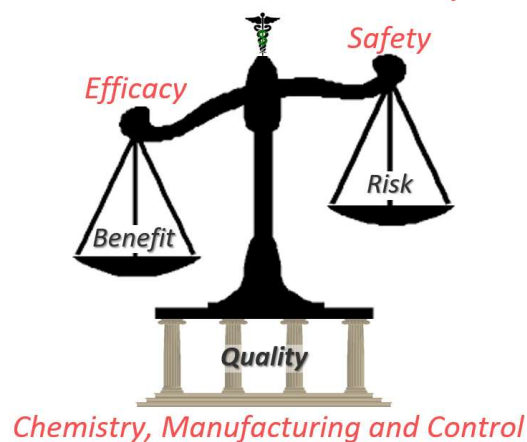
Adapted from: Eichler, H-G et. al. *Nature Reviews Drug Discovery* doi:10.1038/nrd4129

New Paradigms: EUA | EUL regulation for vaccines

Before the pandemic...

How routine vaccine development (regulatory) risk might be optimally managed*...

Essence of vaccine development



Adapted from: Eichler, H-G et. al. *Nature Reviews Drug Discovery* doi:10.1038/nrd4129

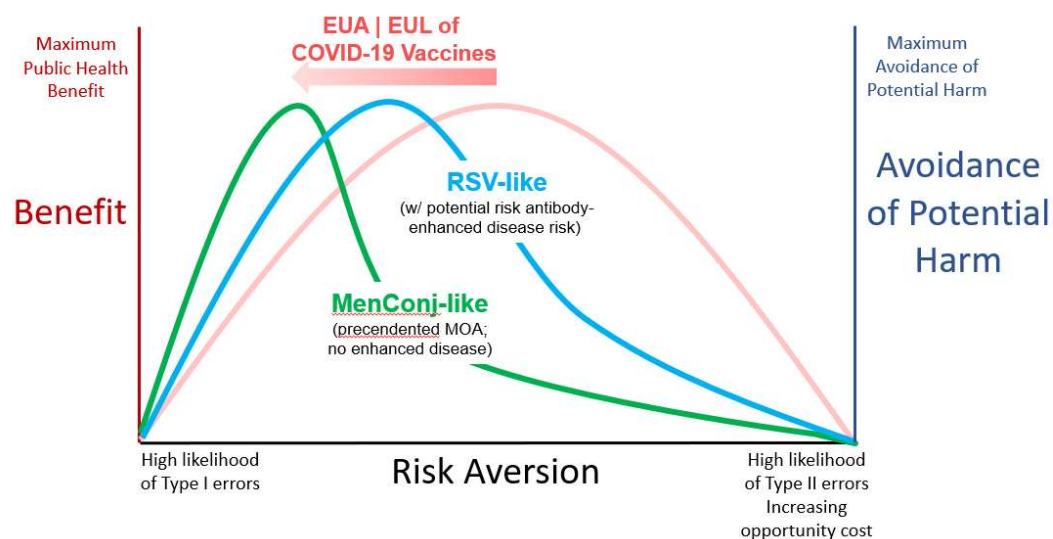
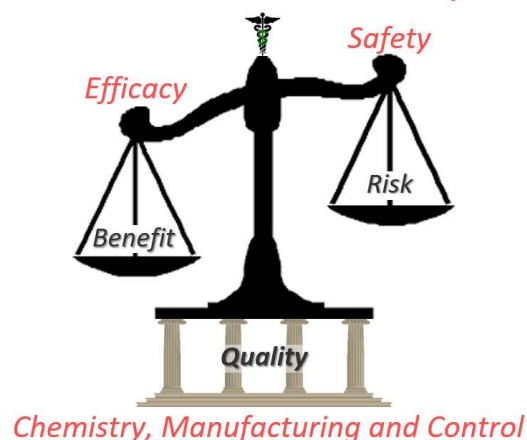
*Black, S et al. *Semin Immunol.* doi:10.1016/j.smim.2020.101413

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



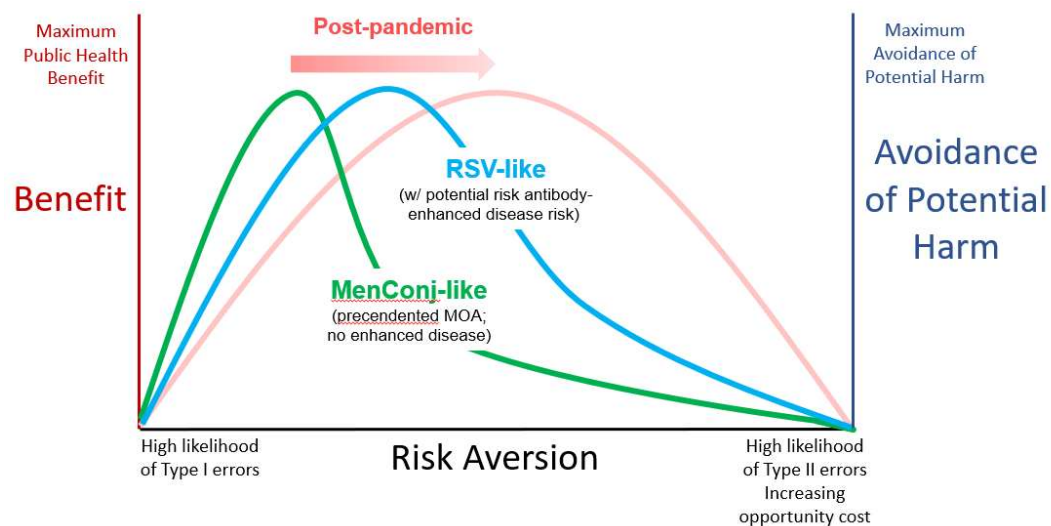
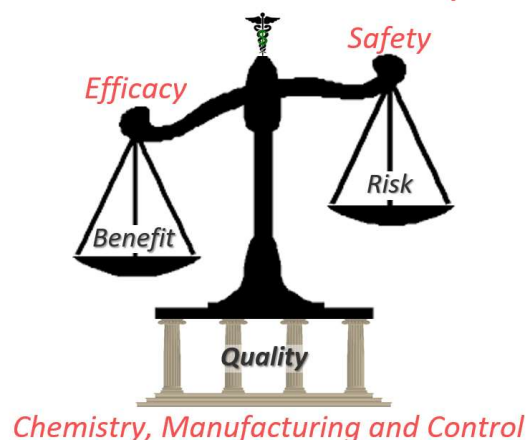
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New Paradigms: EUA | EUL regulation for vaccines

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...

Essence of vaccine development



Adapted from: Eichler, H-G et. al. *Nature Reviews Drug Discovery* doi:10.1038/nrd4129

...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.

