

LOOKING AHEAD – THEMES THAT WILL INFLUENCE THE R&D AGENDA

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SO MANY THEMES – LINKING THEM ALL TO UPTAKE AND IMPACT

- We all have the potential to address some of the greatest challenges and inequities
- Immunization environment changing at a rapid pace
- More important than ever to take a wide lens to understand the larger ecosystem and think from the perspective of those procuring and delivering vaccines in order to get to impact we all want

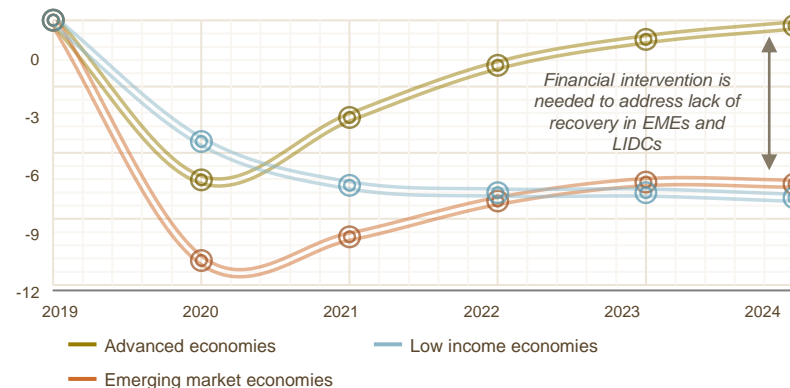


TWO TRACK RECOVERY – FISCAL SPACE TIGHT IN MANY ECONOMIES

COVID-19, inflation and public debt have precipitated economic crises in an era of declining ODA

Early signs point to a sharp disparity in GDP recovery, with risk of major economic scarring outside advanced economies

Deviation from pre-COVID projections (avg % of GDP)¹



Recovery gaps may be wider and the IMF is calling on policymakers to “shift to measures that aim to reverse scarring from the crisis”

- ~25% of original Gavi countries transitioned by 2025; 35% by 2030
- Low-income economy governments have less to invest in health
- Rising interest payments will constrain capacity of countries to spend on health
- At the same time development assistance for health is not expected to rise commensurately
- Ability to pay (co-pay, vaccine cost) a concern

Sources: OECD CRS, Development Initiatives, and Center for Global Development; “Kurowski, Christoph; Evans, David B; Tandon, Ajay; Eozenou, Patrick Hoang-Vu; Schmidt, Martin; Irwin, Alec; Salcedo Cain, Jewelwayne; Pambudi, Eko Setyo; Postolovska, Iryna. 2021. From Double Shock to Double Recovery : Implications and Options for Health Financing in the Time of COVID-19. Health, Nutrition and Population Discussion Paper; © World Bank, Washington, DC. <https://openknowledge.worldbank.org/entities/publication/d964eff2-d6b8-5aea-96d5-c0a628a13706> License: CC BY 3.0 IGO.”

¹ Chart based on projections from April 2021 WEO. Estimates from the January 2022 WEO show LICs suffered higher losses in 2021 than previously expected; ²World Bank (unpublished research). Health prioritization is measured as the share of the approved government health budget to the total central government budget approved. The number of AMC countries registering a decrease in per capita health spending with respect to pre-pandemic levels went from 9 to 18 between 2019 and 2020.;



IMPACT OF ADDITIONAL NEW VACCINES: COUNTRY EXAMPLE

Seven new and emerging vaccines would increase countries' burden on the financial cost to the healthcare system, healthcare worker labor needs, and storage capacity.

Vaccine Adoption

One platform per each new and emerging vaccine was selected^{1,2}



new
vaccines

Child: Malaria, Shigella

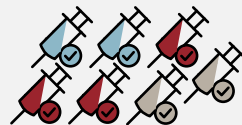
Adult: HIV, TB 2nd Gen, COVID-19

Maternal: RSV, GBS

Additional

Vaccine cost per FVP

Weighted average for \$5/dose and 1 dose for each new and emerging vaccine³



+\$12.10

↑ **~90%**
Increase
from
baseline

Additional

Delivery cost per FVP

Weighted average for \$1.87/child dose and \$2.15/adult and maternal dose⁴

+\$5.10

↑ **~15%**
Increase
from
baseline

Additional

Total annual cost to country and GAVI

Country is responsible for 20 cents/dose for vaccine cost and entire delivery cost^{5,6}

+\$13M
(\$1M vaccine cost & \$12M delivery cost)

↑ **~15%**
Increase
from
baseline

+\$28M
(vaccine cost only)

↑ **~120%**
Increase
from
baseline

Additional

Total volume across all FVP

Average volume per dose is assumed to be 0.03 liters^{7,8}

+176K liters

↑ **~15%**
Increase
from
baseline

* Please see speaker's notes for detailed assumption and primary data sources

Note: 1. The hypothetical (Kenya-like) country used in this scenario is assumed to be in a preparatory transition; baselines are based on Kenya data

“GETTING SHOTS IN ARMS IS GETTING HARDER”



CHALLENGES IN VACCINE IMPLEMENTATION: FIRST YEAR OF LIFE EXAMPLE

Routine immunization Schedule – Oral, Parental (upper arm, thigh)

Polio 0 – at birth
 Polio 1 – 6 weeks
 Polio 2 – 10 weeks
 Polio 3 – 14 weeks



BCG – at birth



YF – 9 mos



Malaria – ~7 mos



PCV 1 – 6 weeks



PCV 2 – 10 weeks



PCV 3 – 14 weeks



IPV – 14 weeks



Hep B – at birth



Vitamin A > 6 mos
 Rota 1 – 6 weeks
 Rota 2 – 10 weeks
 Rota 3 – 14 weeks



Measles – 9 mos



Malaria – ~5 mos



Malaria – ~6 mos



Men A – 9 mos



Penta 1 – 6 weeks



Penta 2 – 10 weeks



Penta 3 – 14 weeks



- Fear of multiple injections (no more real estate)
- Soreness and adverse events can affect return
- **Presentation matters for impact**
 - Combos reduce # of injections
 - Lyophilized vaccines can lead to error/take up cold chain
 - # of doses/vial affects coverage
 - Cold chain needs confusing (-80°, -20°, 2-8°, stable at room temp for x number of hours)
 - Secondary and tertiary packaging
 - Vaccine Vial Monitor ensures potency
- Optimize schedules
- Competing priorities beyond immunization

If you're interested in these topics go to session P7!

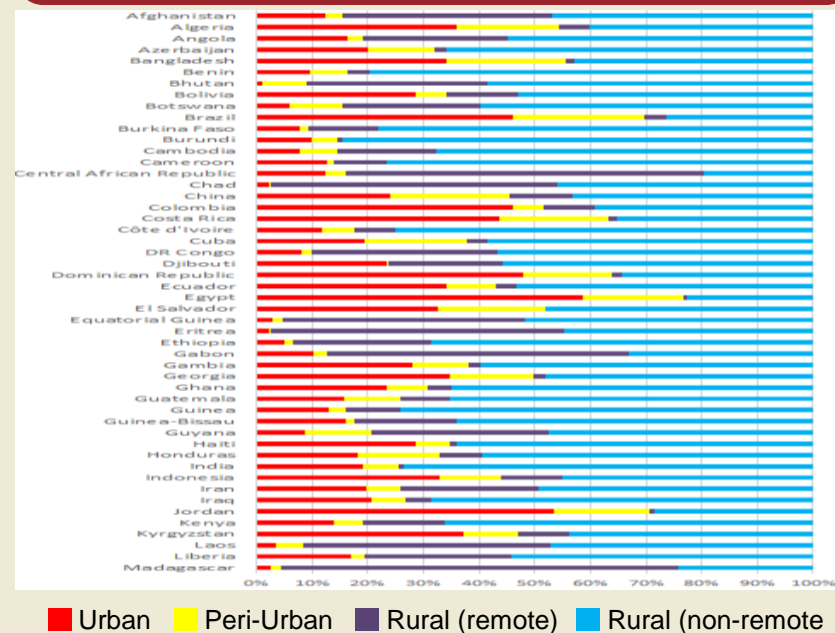
WITHIN COUNTRY VACCINE INEQUITY – ZERO DOSE CHILDREN

If you're interested in these topics
go to session P5 & W9!

Majority of 0-dose children live within 1 hour of a town/city

In Gavi focus countries	% of all 0-dose kids
Urban (incl. slum)	15%
Peri-urban	6%
Rural non-remote (<3hr to town/city)	66%
<1 hr	46%
<2 hrs	13%
<3 hrs	6%
Rural remote (>3 hr to town/city)	14%
Conflict-affected	6-15%

0-dose geographic contexts vary by country



WHY ARE SARA'S CHILDREN NOT VACCINATED?

Not enough time to discuss
her concerns with doctor

Is not aware of
the schedule

Wanted to do it, but
never got around to it

Does not believe measles
is a serious disease

Believes vaccination
may cause autism

Did not like the picture on
the pamphlet she
received

Opening hours not
convenient and waiting
time too long



The waiting
area is too
crowded

Community
resistance against
vaccination

Does not trust
her doctor

Does not trust
national
health
authorities

Religious
concerns

If you're interested in these
topics go to session P5 & W9!

... and what to do about it?

EMERGING GLOBAL AND ECOSYSTEM COMPLEXITIES & OPPORTUNITIES



ECOSYSTEM SHIFTS IN VACCINE MARKETS POST COVID-19

PRIOR DECADE

NEXT DECADE

Products

Blockbuster products with dramatic price reductions and coverage improvements (e.g. Rota, Penta, PCV)

Niche products for sub populations – with higher prices and smaller population sizes

Buyers

Coordinated global markets and consolidated buyers

Potential fragmentation of global buyers and ecosystem with interest in regional and bilateral procurement

Pipeline

Tight R&D pipeline of vaccines with highest impact

Burgeoning R&D platform with a wide range of products and spend increasing overall

Countries

Country preference and price sensitivity had low impact on Gavi product portfolios as options were few

Increasing importance of country preference and price sensitivity with multiple presentations to choose from

Suppliers

~Dozen vaccine manufacturers

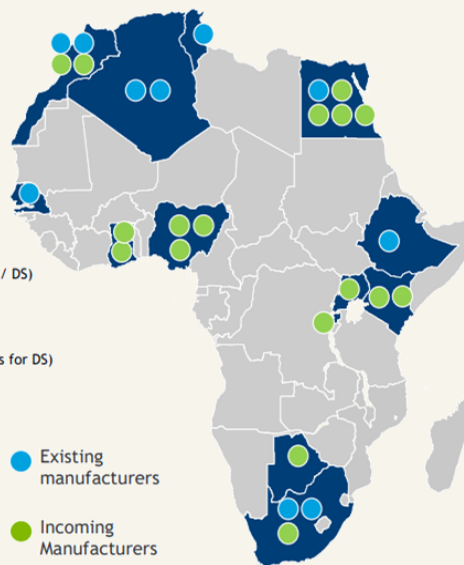
Increasing diversified manufacturing base leading to loss in economies of scale



GLOBAL VACCINE MANUFACTURING/INTRODUCTION EQUITY

Map of current and planned vaccine manufacturing on the African continent, including ownership structure and value chain capabilities

Existing manufacturers

-  Institut Pasteur Algeria (Non-profit / DS)
-  Sidal (State Owned / F&F)
-  Vacsera (State Owned / F&F)
-  Institut Pasteur du Maroc (Non-profit / Pack.)
-  Sothema (Publicly Listed / F&F)
-  Institut Pasteur de Tunis (Non-profit / DS)
-  Ethiopian Public Health Institute (State Owned / DS)
-  Institut Pasteur de Dakar (Non-profit / DS)
-  Biovax (Public-Private Partnership / F&F → Plans for DS)
-  Aspen Pharmacare (Publicly Listed / F&F)



-  Existing manufacturers
-  Incoming Manufacturers

Incoming manufacturers

-  Minapharm (Publicly Listed / F&F)
-  Biogeneric (Private / F&F)
-  Eva Pharma (Private / F&F)
-  Mevac (Private)
-  Sensyo Pharmatech (Public-Private Partnership / F&F)
-  Galencia (Private / F&F)
-  DEI Biopharma (Private / F&F)
-  Moderna (Private / F&F)
-  Biovax (State Owned / DS)
-  Rwanda Biomedical Centre (State Owned / DS)
-  Atlantic Biotech (Private / F&F)
-  DEK (Private / F&F)
-  Biovaccines (Public-private partnership / F&F)
-  Innovative Biotech (Private / DS)
-  NIBI (Private / F&F)
-  NantBotswana (Private / DS)
-  NantSA (Private / DS)

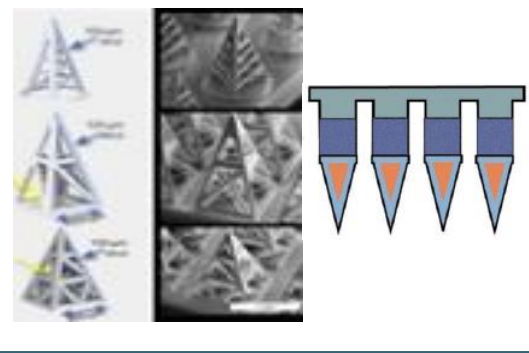
If you're interested in this topics go to session W3!

PORTFOLIO OF NEW VACCINE TECHNOLOGIES & PLATFORMS

Moving from multi-step administration to single twist



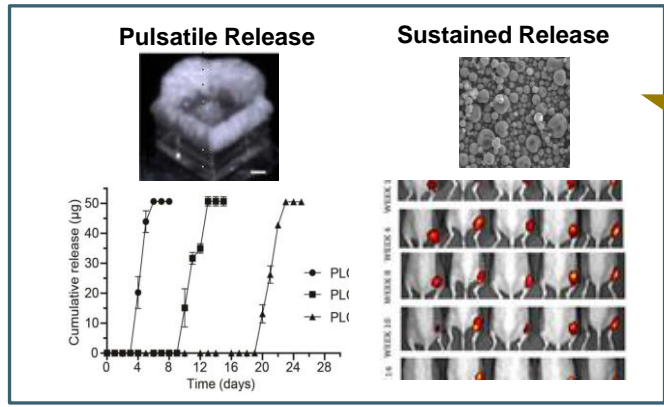
Improved MAP loading & delivery



Improved mRNA thermostability



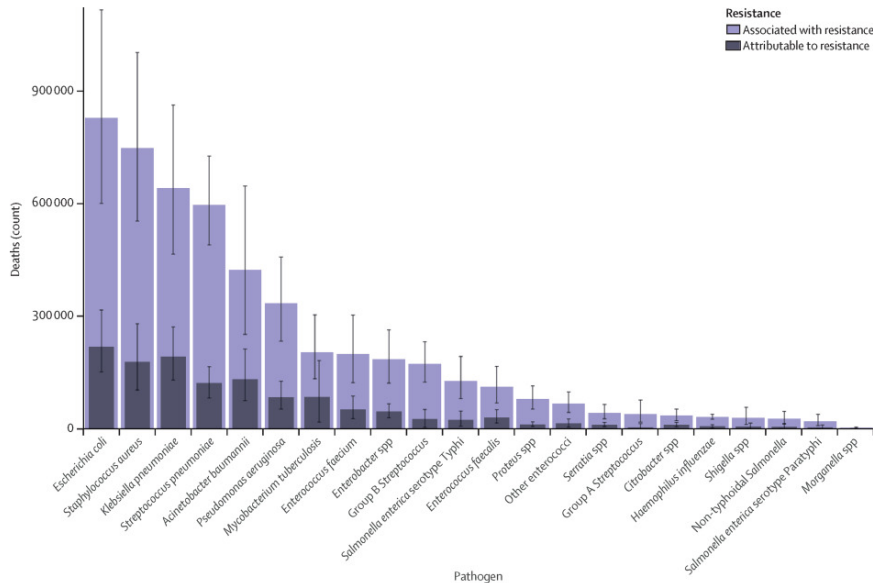
Low-Cost Vaccine Manufacturing



If you're interested in these topics go to session W2 & P6!

ANTIMICROBIAL RESISTANCE (AMR) AND VACCINE-BASED MITIGATIONS

Global deaths (counts) attributable to and associated with bacterial antimicrobial resistance by pathogen, 2019¹



- ~0.7M - 1.27M deaths per year can be directly attributable to AMR
- Estimates suggest this could rise to 10M deaths per year by 2050.^{1, 2, 3}
- Deployment of HiB and pneumococcal vaccines have proven that immunization can reduce AMR.

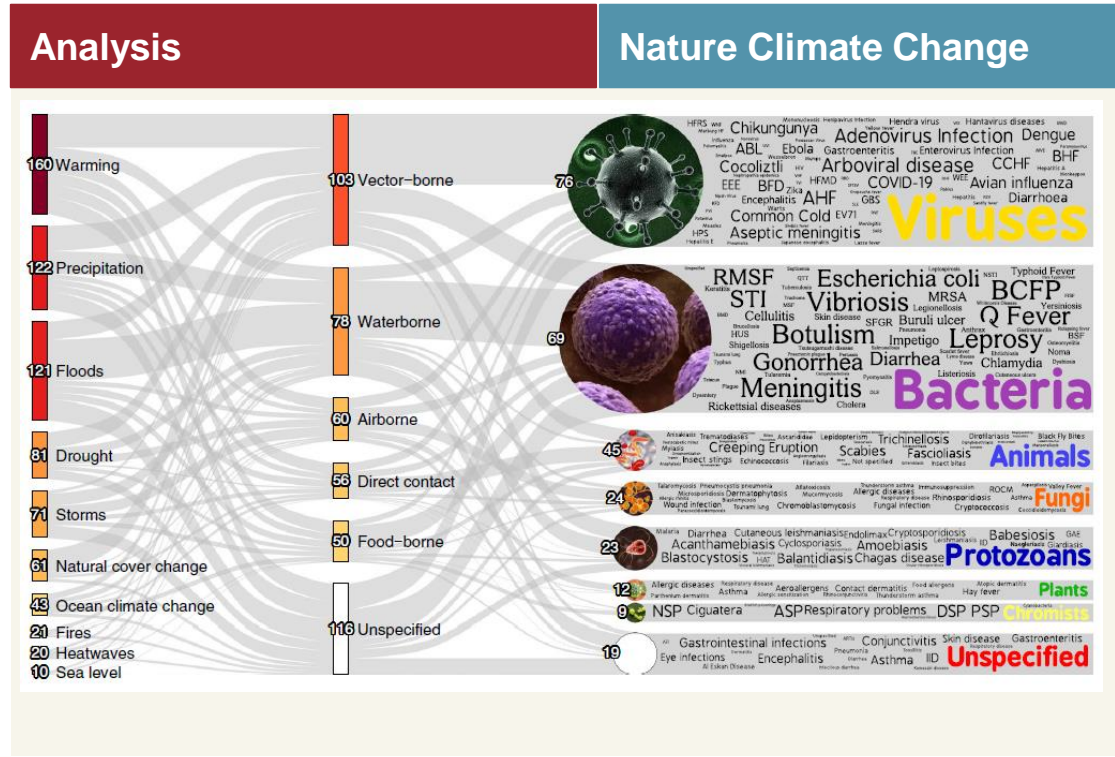
Future opportunities exist to:

- **Directly target AMR pathogens** (e.g. TB, GBS, shigella, klebisella); and
- **Reduce incidence of viral diseases** that drive antimicrobial use (Influenza, RSV)

Reducing AMR burden and emergence in **MIC/LMICs will be essential** to mitigating global risk; products should have **appropriate impact and presentations** to enable wide uptake in these settings.

1) Antimicrobial Resistance Collaborators, Global Burden of antimicrobial resistance in 2019, a systematic analysis (The Lancet, 2022)
 2) O'Neill, J. Tackling Drug-Resistant Infections Globally: Final Report and Recommendations (The Review On Antimicrobial Resistance, 2015);
 3) Jansen, K. Knirsch, C. Anderson, A S. The role of vaccines in preventing bacterial antimicrobial resistance. (Nature Medicine, 2018)

CLIMATE CHANGE AGGRAVATES PATHOGENIC DISEASES



- 58% (218/375) of infectious diseases have been aggravated by climate change
- Over 250 human pathogenic diseases that can be aggravated by human hazards
- Mitigating greenhouse gases is the primary approach to stopping but need to consider arsenal of prioritized vaccines

(1) Over half of known human pathogenic diseases can be aggravated by climate change, Mora, et. al. 2022, Nature Climate Change (2022)

THE NEXT GENERATION OF VACCINES HOLD GREAT PROMISE WHILE NAVIGATING NEW CHALLENGES

Engage your consumers' views

Engage a wide array of perspectives early in development to inform the **vaccine adoption needs and strategies**.

Consider the procurer

Your vaccine is one of many in the pipeline; **value for money important** - increasingly **tight global & country fiscal space**.

Getting shots in arms is harder

Presentation matters – think combos and other innovations to ease delivery and uptake.

Action needed to address zero dose & Vx confidence

These **worrying trends may slow new vaccine adoption** – need to understand drivers and possible responses.

Explore opportunities for equity

Equity in access to manufacturing and technologies may create new pathways to uptake & impact



“The impact of vaccination on the health of the world’s peoples is hard to exaggerate. With the exception of safe water, no other modality has had such a major effect on mortality reduction and population growth” ([Plotkin and Mortimer, 1988](#)).