Primary Container Decisions and Impact on Coverage, Safety and Affordability

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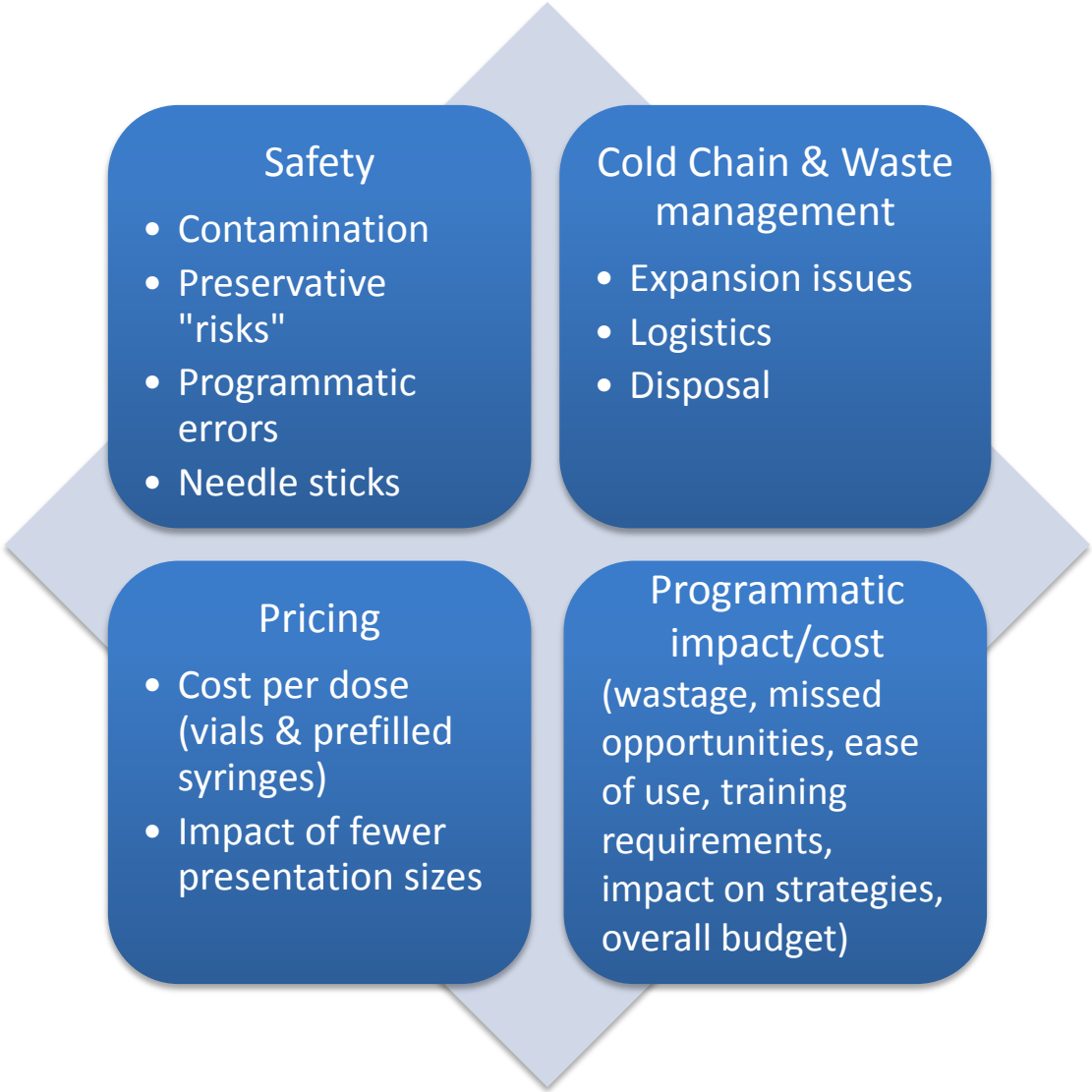
Outline

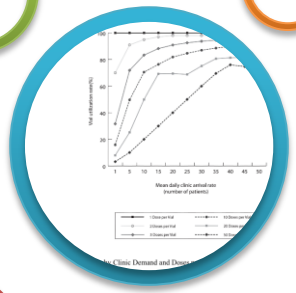
- Understanding impact of primary containers
- Primary container roundtable
- Country examples using the HERMES model:
  - Detailed computational simulation model of a country's vaccine supply chain.
- Quantifying the impact on a larger scale
- Need for better decisions: role for manufacturers

Issues related to containers are varied

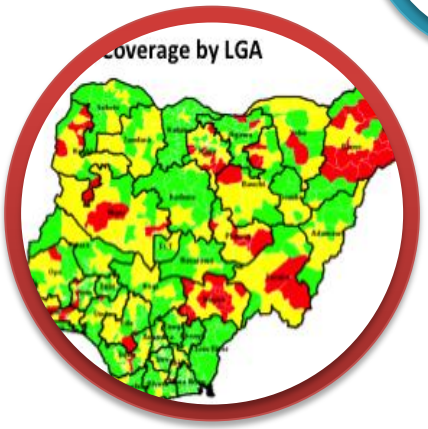


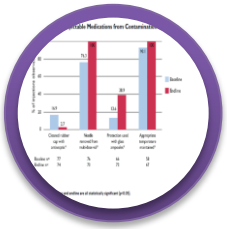
Impact can be described in 3 components

Coverage



Affordability





Safety

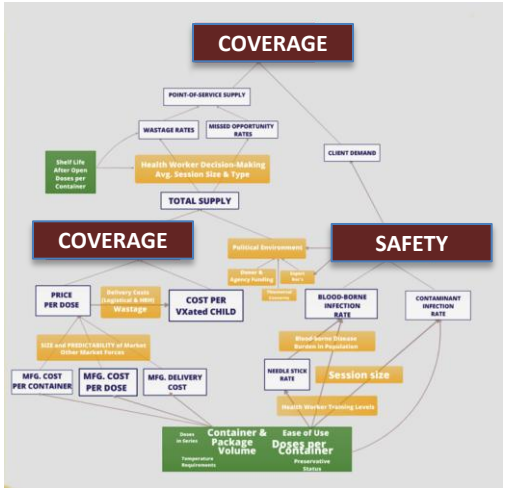
Primary container roundtable

Co-chairs: Orin Levine (IVAC/now Gates) & Robert Steinglass (JSI)

Participants from Bangladesh, Jordan, Nigeria, India, SII, Crucell, BD, Merck, Novartis, PATH, JSI, UNICEF, WHO, PAHO, AMP, USAID, GAVI, PDPs, academic institutions, consultants, IPAC and VPAGG

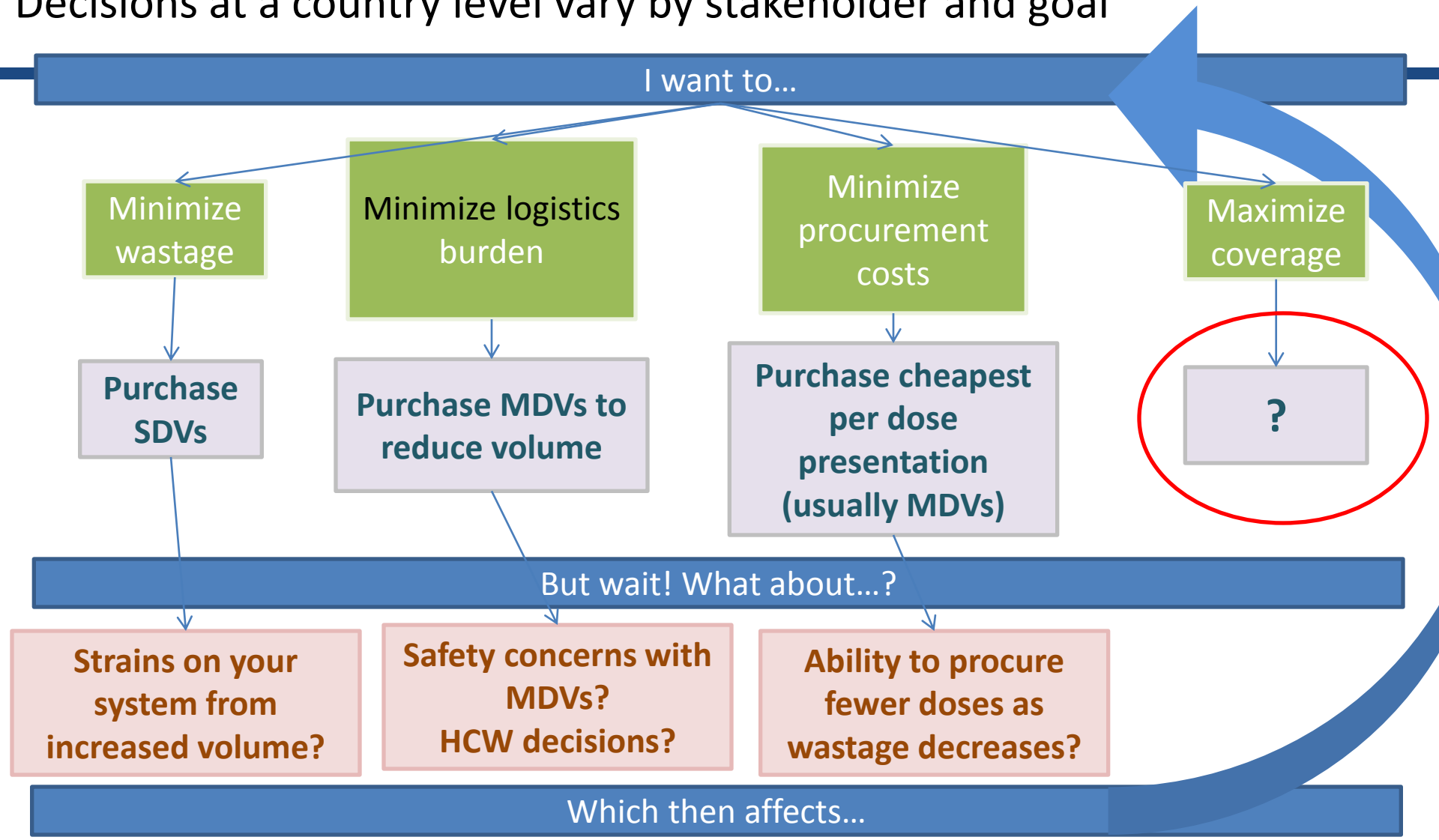
Objectives:

- To review and synthesize the evidence supporting decisions regarding vaccine container size and type and describe the potential impact on the decision making process middle and low income countries.
- To develop a preliminary framework in which data could be considered to support decision making for single vs. multi-dose vials/type of container and the situations in which each may be most appropriate.
- Identify data gaps based on synthesis of evidence and potential framework for evaluation.



Framework exercise

Decisions at a country level vary by stakeholder and goal



In order to make **informed decisions,** we need to **quantify these existing trade-offs**

Getting it right has an impact on…

- Equity
- Price
- Perceived safety
- Ease and cost of delivery and administration of vaccine
- Ability to prevent disease
- Supply (manufacturer capacity)

Roundtable Conclusions

There is a need to consider influencing impact of primary container decisions more systematically for each product in the context of a dynamic environment

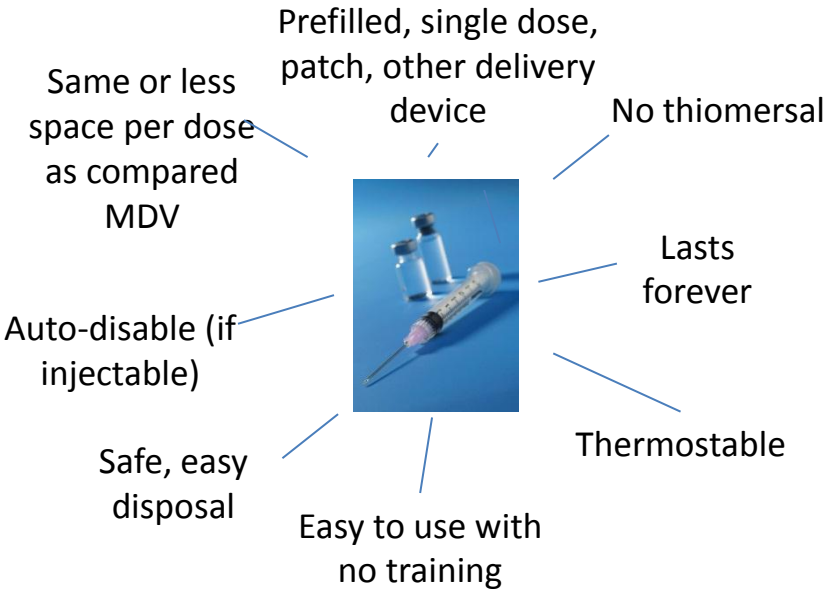
- Country decisions are also impacted by donor and international organizations
- Manufacturers
- Other countries
- The product itself and other product selections, environment within the country

How do we measure a dynamic situation?

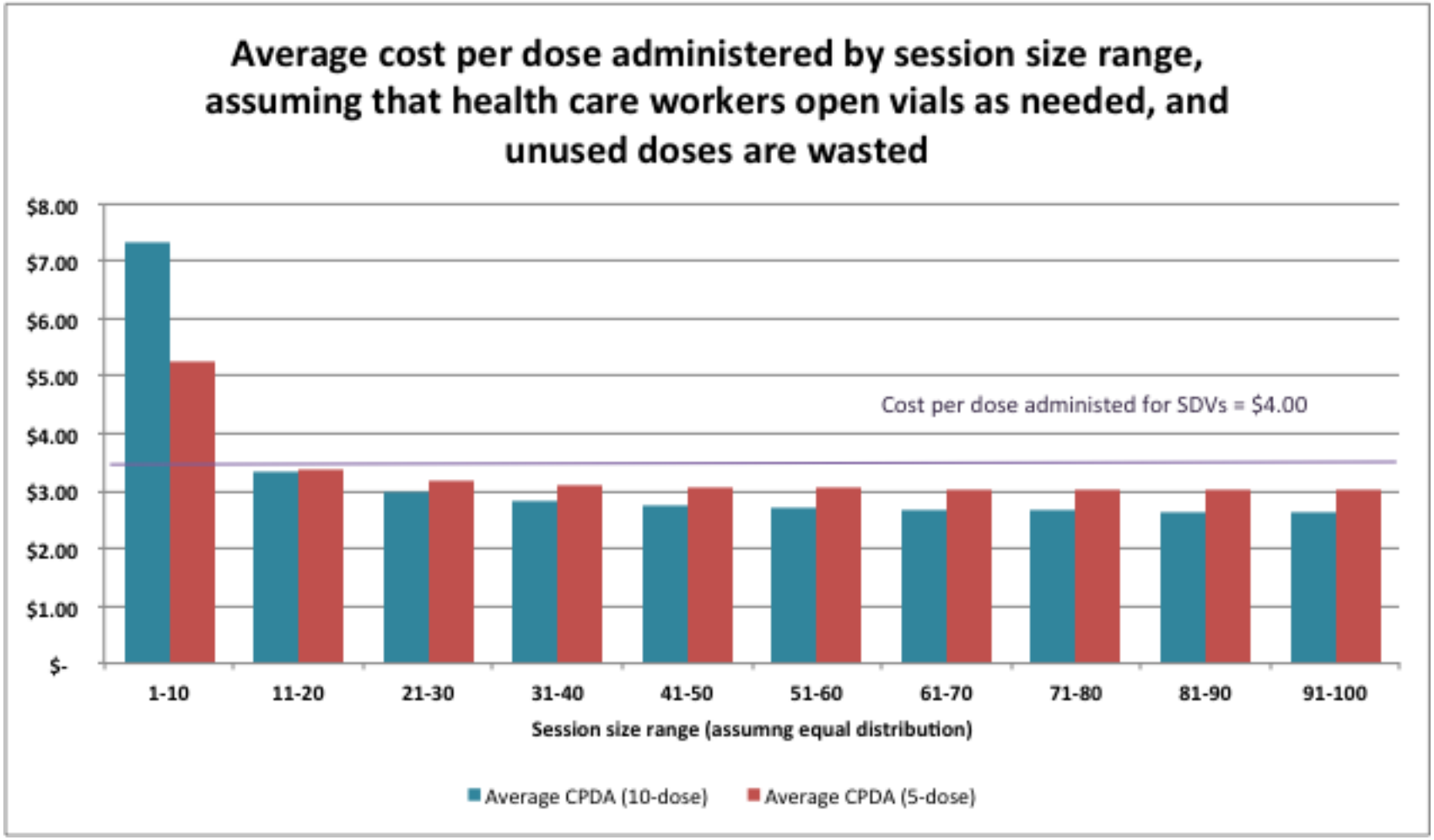
Many competing dynamic tradeoffs

- **What's been modeled so far:** vaccine supply chain from the arrival to the central store all the way to the immunization locations. Limited number of experiments from a sample country
- **What's missing:** safety and compliance, more comprehensive experiments in a greater number of countries, global roll up and impact on equity goals

Moving towards an optimal container

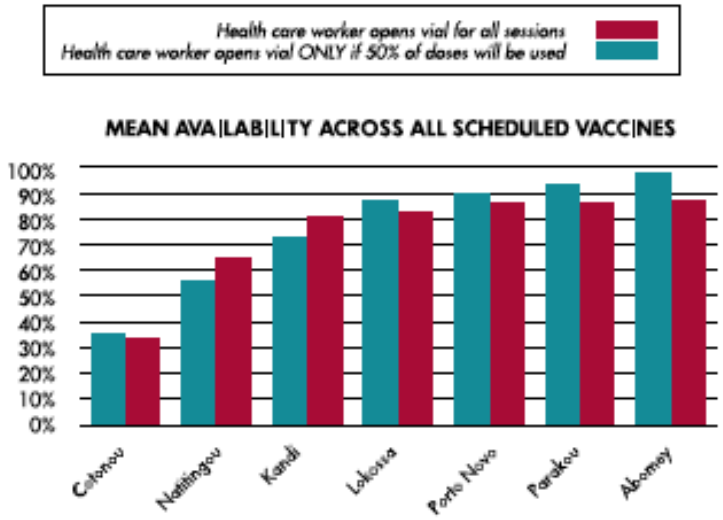


Hypothetical analysis of vial options: modeling vials opened as needed

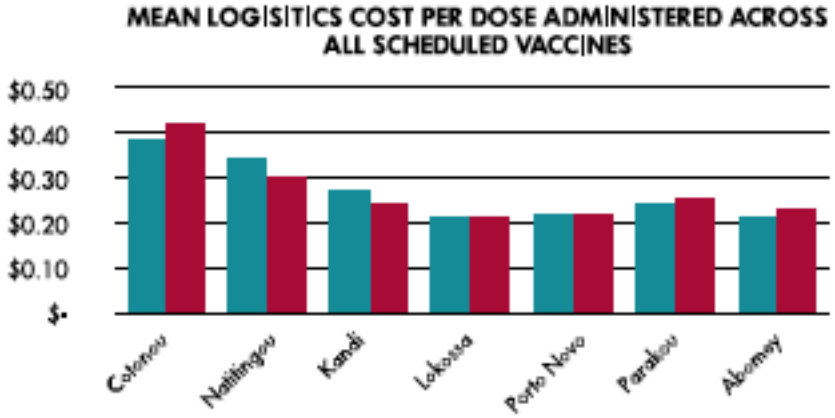


HERMES simulation - sample country's supply chain

Figure 3. Vaccine Availability and Cost per Dose in Benin With and Without a Vial Opening Threshold



Simulating a 50% opening threshold— a rule that vials are only opened when 50% or more of the doses will be immediately used—yields differing results in different areas of Benin. In Natitingou and Kandi, two of the three areas with the lowest vaccine availability at baseline, a 50% opening threshold results in slight increases in vaccine availability and reductions in cost per dose administered. This may indicate that current large vial sizes are reducing overall availability due to open vial wastage. In the higher performing areas, applying a 50% opening threshold had the opposite effect, increasing cost per dose administered and decreasing availability.



Source: IVAC Primary Container Brief. Analysis courtesy of Bruce Lee and HERMES Team

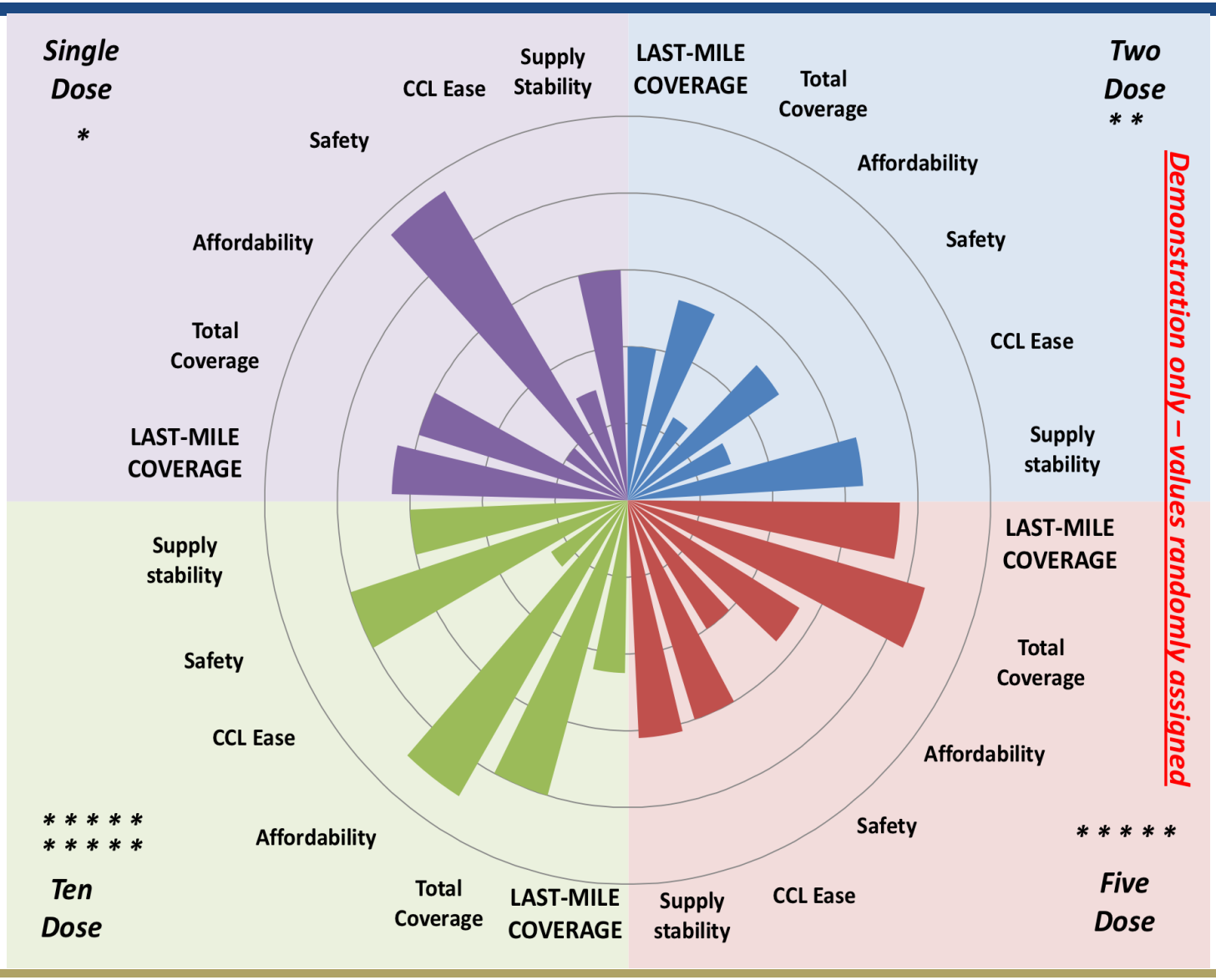
What does this mean for countries?

- Session size matters for the country on average, but also when considering reaching the last 20%
- The entire portfolio needs to be considered – not just the product in question
- Safety concerns – real or perceived, need to be brought into the equation – more research is needed to understand which issues may emerge in which countries
- Tools such as HERMES can assist countries in capturing the dynamic trade-offs that will only become more complicated now that more products are entering the system

Equity

- **At the last mile**, where systems are already fragile, **small changes can have big impacts.**
- For eradication**, 80% isn't good enough**.
- Communication around these decisions needs to start now, in order to **give countries and manufacturers time to adjust, react, and provide feedback**.
- We need to **build on current momentum and investments**, otherwise we face more years of more dollars for fewer results.
- There is **no single optimal solution,** particularly when last mile coverage is a key goal.

Quantifying the impact



Quantifying on a larger scale

- Forecasting on a global level (both low and middle income countries) is an imperative
- Countries can be grouped by various characteristics to evaluate needs and arrive at a better thought out forecast (other available products must also be considered)
- Primary container guidance should not only be on a product by product basis, but define the types of countries and situations that have various container needs

Upcoming forecasting considerations and need for guidance

With a number of new vaccines entering national immunization programs in the next few years:

Does a low multi-dose vial offer the right solution?

- Preservative may still matter, cost per dose has impact on wastage, for products like IPV, where disease burden at the last mile may necessitate a different approach, will the same decision making hold?

Will low and middle income countries accept more than one presentation?

How should countries be planning for their future supply chain needs?

What technologies or changes to cold chain requirements will be in place to mitigate the need for cold chain space?

Will safety become more of a concern, particularly in certain countries?

Potential Role for manufacturers

- Demand detailed forecasts considering the dynamic situations of each country
- Work with the global community early to help prepare for inevitable challenges
- Continue to produce a variety of container sizes as one won't fit all
- Help show countries that they can introduce more than one presentation
- Carefully consider safety, even if not a perceived concern today

Summary

- Primary container choice has a wide variety of complex ramifications
- Product specific primary container guidance considering dynamic system characteristics are needed
- More systematic, evidence based approach to forecasting primary container requirements at a country and global level for both low and middle income countries is needed
- Low multi-dose vials may be a compromise, but single dose AND multi-does containers may better address needs and provide lowest cost options – GAVI policy will need to change and countries will need to determine it is feasible
- A framework for decision making is valuable
- Safety (real or perceived) and health worker behavior must be considered in all frameworks

Acknowledgements

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- HERMES Team: Bruce Lee (IVAC and PHICOR), Leila Hardari, Diana Conner, and Angela Wateska (PHICOR) and Shawn Brown at (Pittsburgh Supercomputing Center)
- AMP

http://www.jhsph.edu/research/centers-and-institutes/ivac/projects/primary-vaccine-container-roundtable.html