



Sharing field experiences on new vaccine delivery approaches

**Robert Steinglass
John Snow, Inc. (JSI)**

**Developing Countries Vaccine Manufacturers Network
VACCINES, OUR SHARED RESPONSIBILITY**

**15th Annual General Meeting
27-29th October 2014 – New Delhi**

Age groups targeted to receive vaccines



Infants



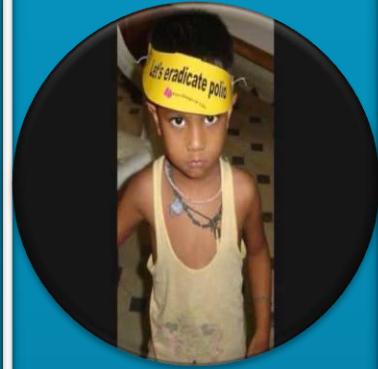
Young children
(e.g.,
measles 2nd
dose)



Pre-
adolescents
(HPV)



Women of
child-
bearing age
(tetanus
toxoid)

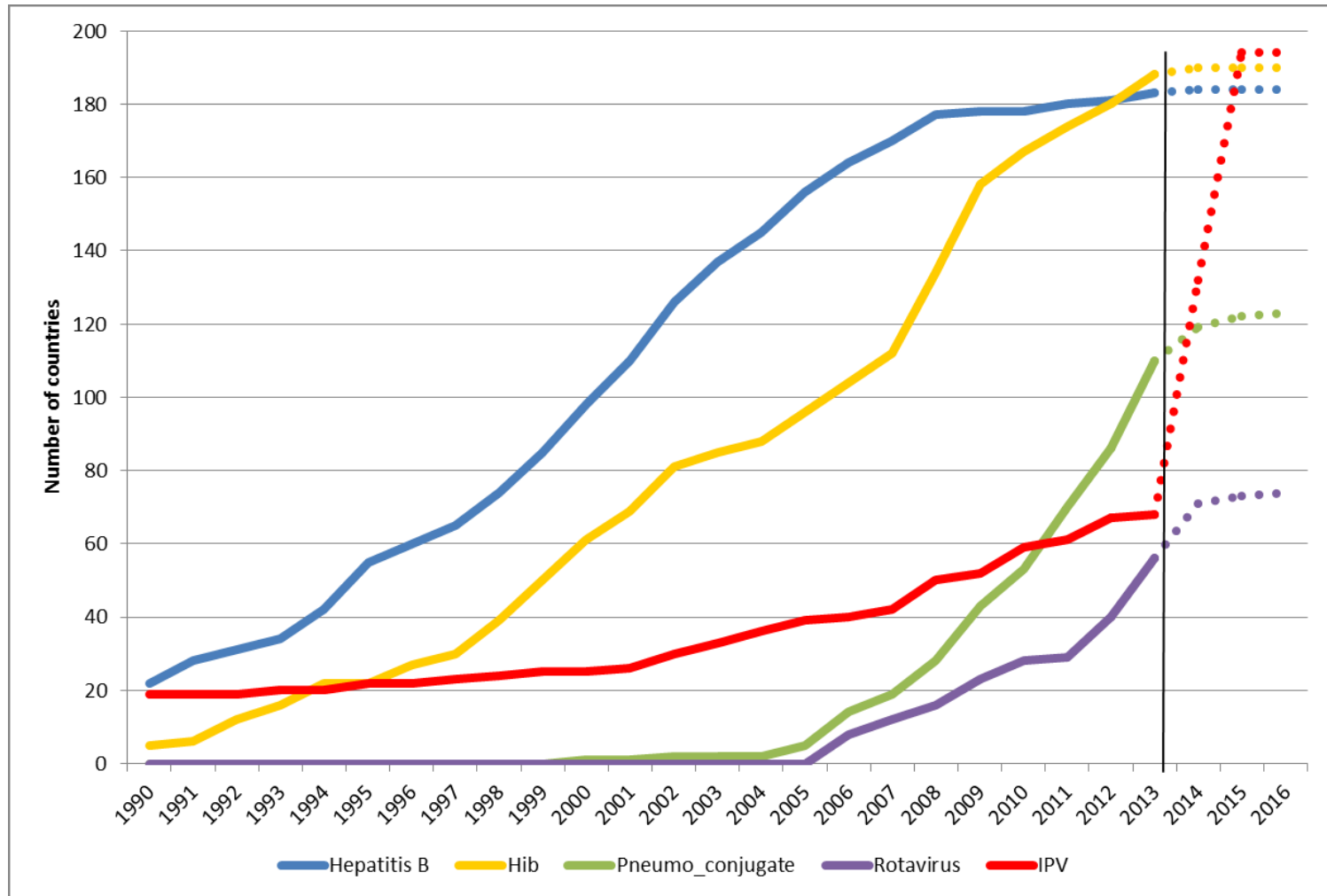


Expanded
age groups
during
campaigns
(e.g. *polio*,
measles,
meningitis A)

Age groups

New vaccine introductions

Overview 1991-2013 of introduction status and 2014-2016 projections



Source: WHO/IVB Database as of 18 October 2013

Date of slide: 18 October 2013

New vaccines have brought new challenges

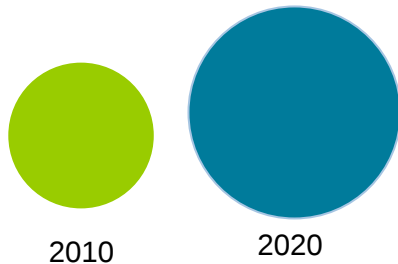
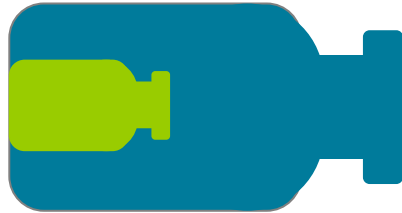
- Increase in number of vaccines (6 → 12-15)
- Age restrictions (Rotavirus vaccine upper age limit)
- New target age groups (HPV: adolescents) requiring new service delivery channels
- New messages (syndromes, partial protection)
- Integrated approaches to disease control
- Cost of new vaccines
- Cold chain/logistics challenges (bulk and waste disposal)



Most new vaccines require a well-functioning routine immunization program.

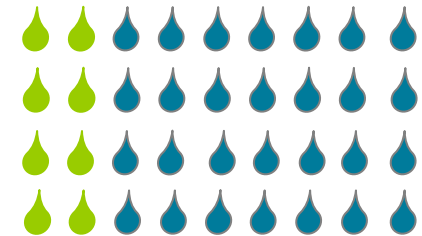
Challenges to the immunization supply chain

Growing volume (cm³)
to vaccinate per child



Introduction of more
expensive vaccines

Increasing number
of doses



Increase in stock keeping
units

■ 2010 ■ 2020

Note: All figures relate to GAVI-funded vaccines

1. UNICEF Supply 2012 Financial report, WHO data for Pneumo and Rota vaccines, and HPV (only for girls); 2. 2010: GAVI Shipment Data; 2020: GAVI SDF Forecast; Including volume for GAVI future graduated countries; 3. Comparison based on 2013 Price; 2020 Vaccines include: Rota, Pneumo; HPV; 2010' vaccines include: YF, Measles, DPT, OPV (UNICEF SD); 4. GAVI Background SDF Information; 2010": estimates based on 2009 data; 2020: estimates based on 2013 forecast

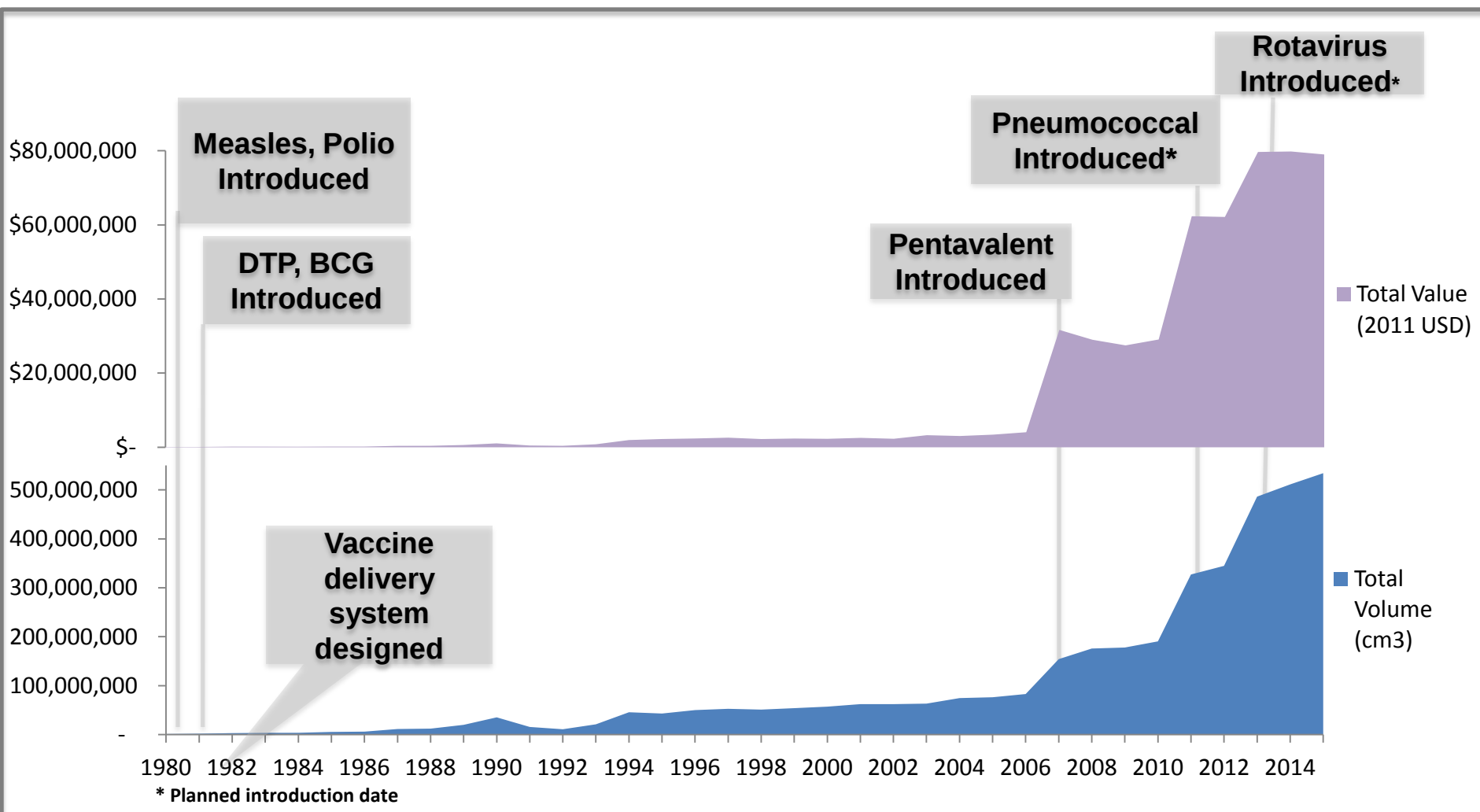
Immunization challenges: cold chain and logistics management



Examples of impact of increasing vaccine volumes on developing country supply systems, 2007



Cumulative value and volume of vaccines used in routine childhood immunization: Ethiopia



What have decision makers mostly focused on before introducing a new vaccine?

- Disease burden (incidence, mortality, morbidity, disability)
- Vaccine efficacy, effectiveness
- Vaccine safety, reactogenicity
- Fits with existing immunization schedule (e.g., timeliness issues)
- Simultaneous administration possible?
- Combination with other antigens into single product possible?
- Current and future price, stability and security of vaccine market
- Trade-offs with other investments
- Immunogenicity
- Expected health gains
- Health care cost savings
- Care-related productivity gains
- Outbreak potential
- Public perception of the disease
- How to communicate about the disease/syndrome
- Willingness to give/accept more than one injection on same visit

But what other things are informed decision makers increasingly concerned about?

Programmatic characteristics of competing products:

- heat stability
- storage temperature
- number of doses per vial
- wastage rate
- storage volume
- volume of waste for disposal
- acceptability by health staff (e.g., # injections on same day)
- ease of use (preparation and administration)
- volume of dose administered

Rotarix™ and RotaTeq® snapshot (2013)

	Rotarix™ (GSK)	RotaTeq® (Merck)
Type of vaccine	Live, liquid vaccine	Live, liquid vaccine
Method of administration	1.5 ml for Oral use	2 ml for Oral use
Presentation and vial size	Mono-dose, liquid tube	Mono-dose, liquid
Target age group	Infants <32 weeks of age, first dose no earlier than 15 weeks	Infants <32 weeks of age, first dose no earlier than 15 weeks
Number of doses	2	3
Schedule	Co-administered with Penta1 and Penta2	Co-administered with Penta 1, Penta 2, Penta 3
VVM type	14	No Vaccine Vial Monitor (VVM) technology has been validated for use
Packaged volume per dose	17.1 cm ³ in 50 dose carton	46.3 cm ³ in 25 dose packaging

Single dose versus multi-dose trade-offs

Comparison of the Major Programmatic and Economic Advantages of Single- Versus Multi-Dose Vaccine Containers ^a		
	Single-dose	Multi-dose
Production	Eliminates use of thiomersal	Faster filling rate
Packaging		Cheaper packaging costs
Distribution	Simplified logistics	Smaller and lighter for transport
Cold chain		Smaller cold chain volume
Safety	Less risk of contamination Ensures more accurate dose delivery	
Syringe usage (for injectable vaccines)		Requires fewer reconstitution syringes (for lyophilized vaccines)
Vaccine wastage	Significantly less vaccine wastage	
Coverage rates	Facilitates innovative outreach strategies Prevents missed opportunities due to reluctance to open a multi-dose container for small sessions	
Medical waste		Smaller medical waste volume ^b

^a Adapted from Drain PK, Nelson CM, Lloyd JS. Single-dose versus multi-dose vaccine vials for immunization programmes in developing countries. Bull World Health Org 2003; 81 (10): 726-31.

^b Compact prefilled autodisable syringes (Uniject) have less waste volume than multi-dose vials with syringes.

Fear of vaccine wastage using some larger multi-dose vials leads to delayed protection

Policies/Practices

Measles vaccine on specific days to increase session size (weekly or monthly)

Minimum number of children required to open a vial

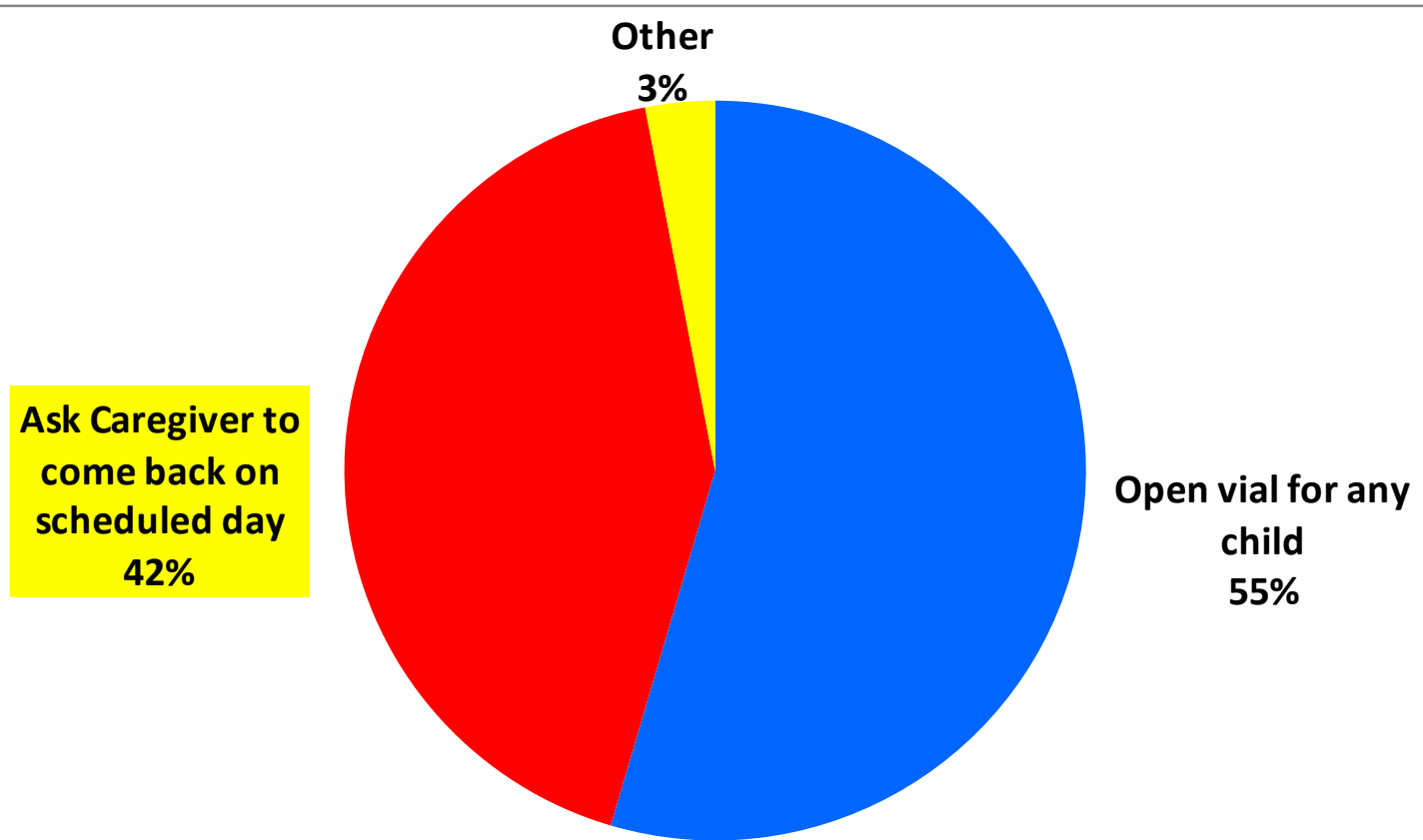
Consequences

Mothers not sure when to come for services

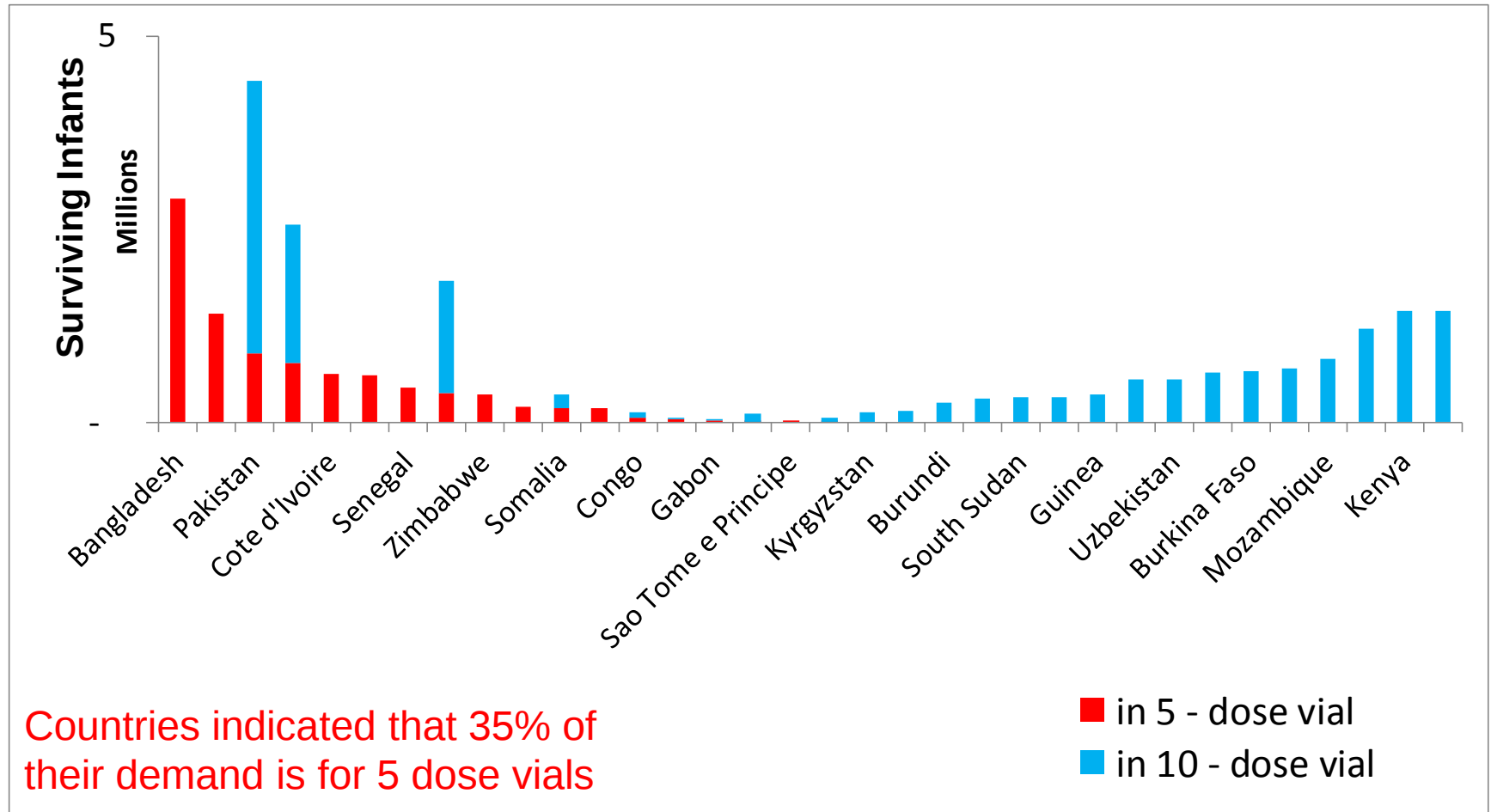
Children are turned away, untimely vaccinated, never vaccinated

Missed opportunities, UNICEF survey, 2012

Countries' policies on opening measles vial (N=33)



Distribution of demand for 5-dose & 10-dose measles vial by country (n=34) procuring through UNICEF (UNICEF survey, 2012)



Practices related to wastage

	<u>Cambodia</u> <u>(95% MCV1 coverage)</u>	<u>Nigeria</u> <u>(57% MCV1 coverage)</u>
Average measles vaccine wastage rate in health centers	58%	19%
Average number of children before opening measles vaccine vial	2.2	6.2
Proportion of parents saying they were turned away for vaccination	4%	30%
Proportion of turned away who never received vaccine	12%	53%
Vaccines missed among turned away	MCV: 63%	BCG: 33% MCV: 26%

How to reduce the threshold to open a vaccine vial?

Source: unpublished data, 2011 Nigeria CDC/WHO/NPHCDA study, 2013 Cambodia WHO/CDC/MOH study in nationally representative samples of health facilities



Centers for Disease Control and Prevention
CDC 24/7: Saving Lives, Protecting People™

Key Messages

- managers have become more informed
- research your market and learn product preferences **directly** from prospective clients
- design more programmatically suitable vaccines
- think downstream earlier in deciding formulation, presentation and packaging
- vaccine presentations influences coverage and equity
- lead the pack, be nimble and responsive to developing country needs

Lessons from USAID's MCHIP on new vaccine introduction

“Bottlenecks and Breakthroughs: Lessons Learned from New Vaccine Introductions in Low-resource Countries, 2008-2013.” MCHIP. 2014.

See the full monograph at: “Achieving Impact at Scale: Lessons from MCHIP collection” at

<http://bit.ly/MCHIPEvent>



Let's make sure every child is a VIP...



***Vaccinated,
Immunized &
Protected!***

Thank You

