

Dengue vaccination: critical issues for future vaccine introduction

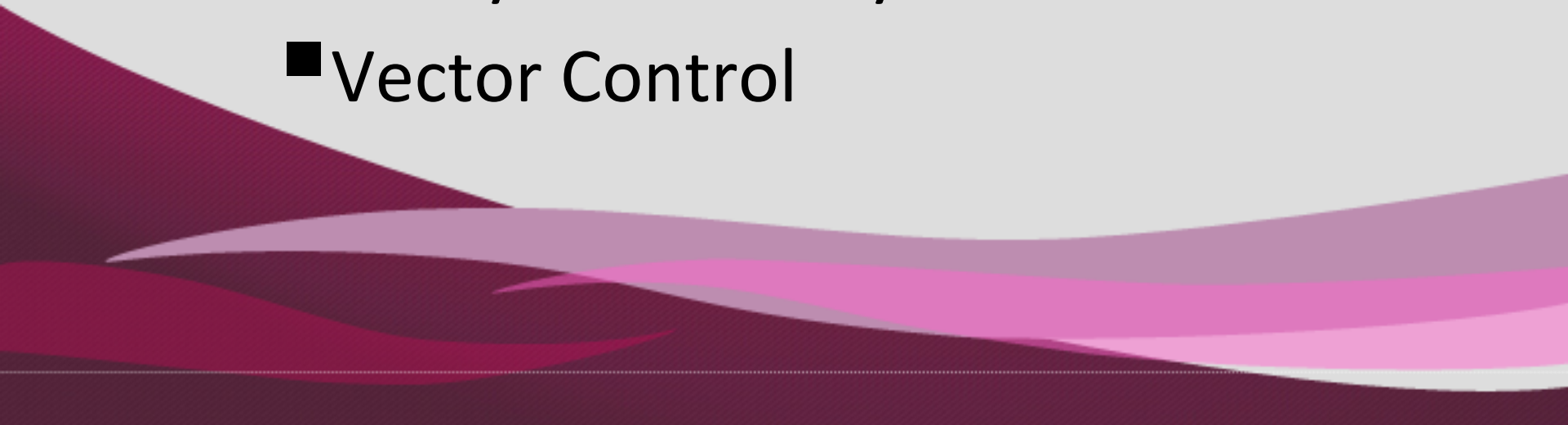
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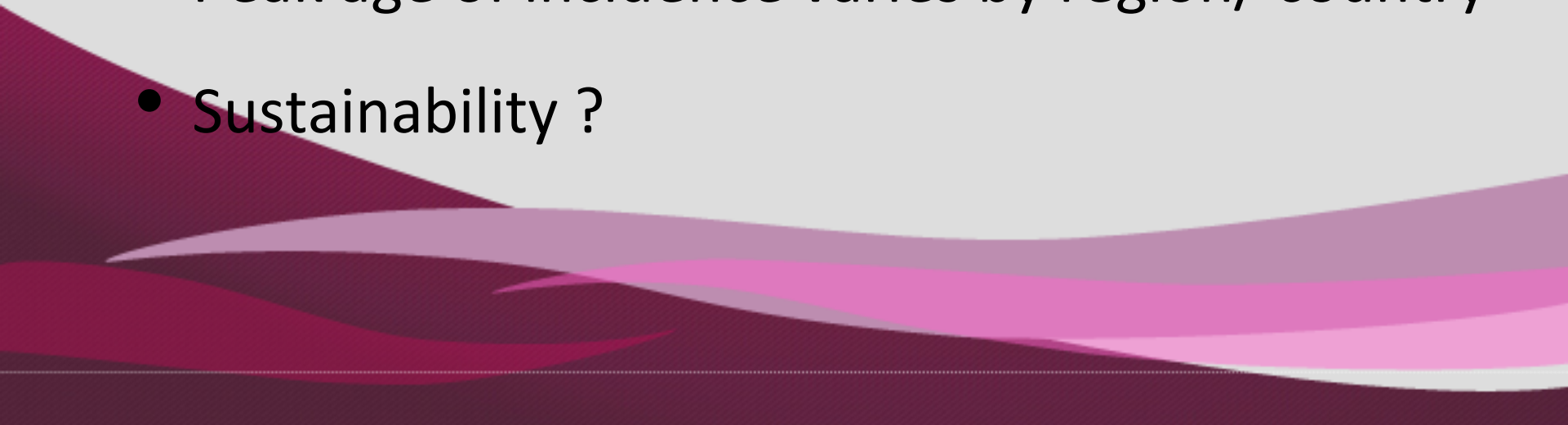
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Outline

- Dengue epidemiology/surveillance/challenges
 - Vaccine introduction
 - Pharmacovigilance
 - Policy & advocacy
 - Vector Control
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Dengue Epidemiology-challenges for vaccine introduction

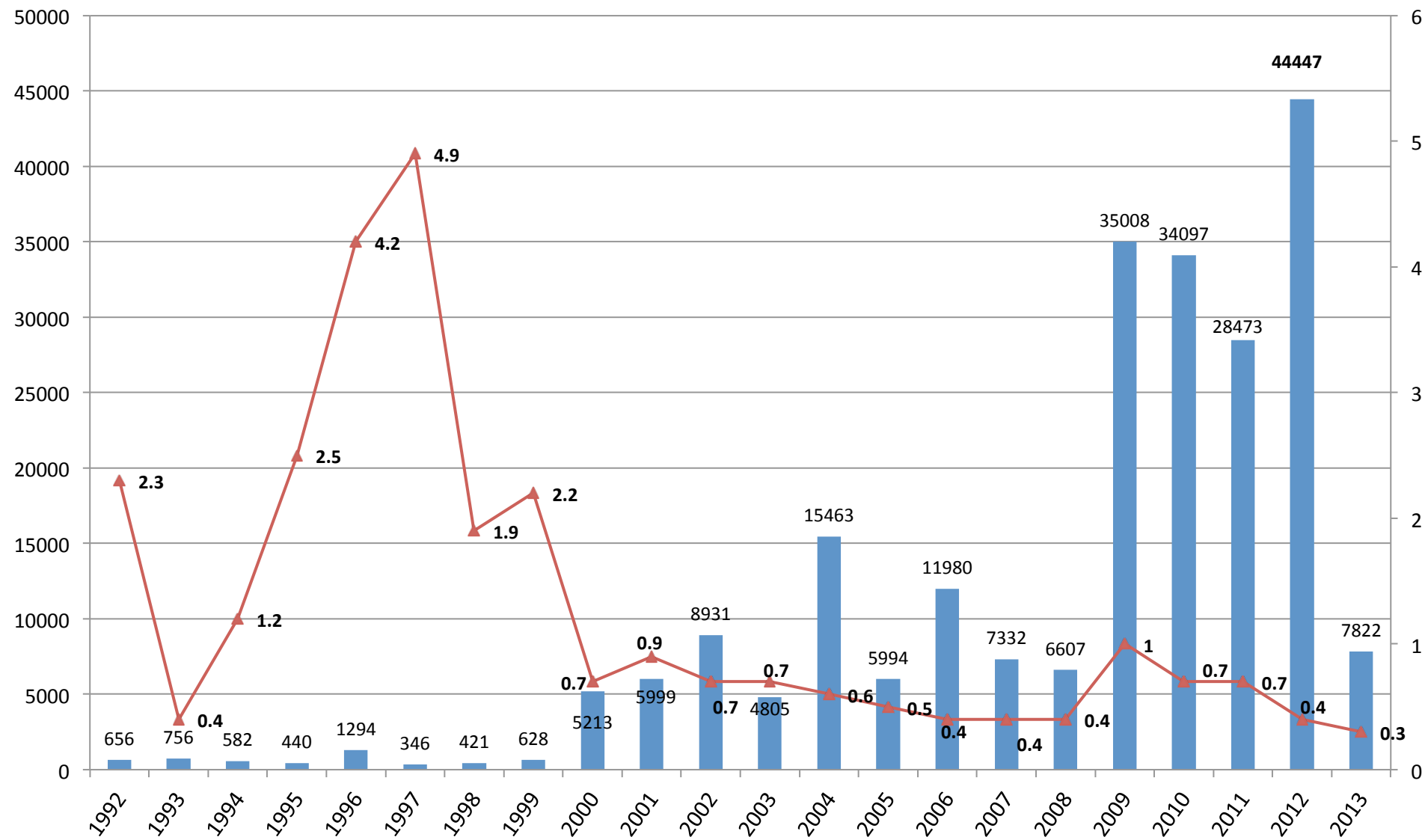
- Surveillance for febrile illnesses to detect dengue
 - Multiple virus types (serotypes)
 - Incidence: high endemicity + periodic epidemics
Early detection and prediction of outbreaks
 - Peak age of incidence varies by region/ country
 - Sustainability ?
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Dengue surveillance needs

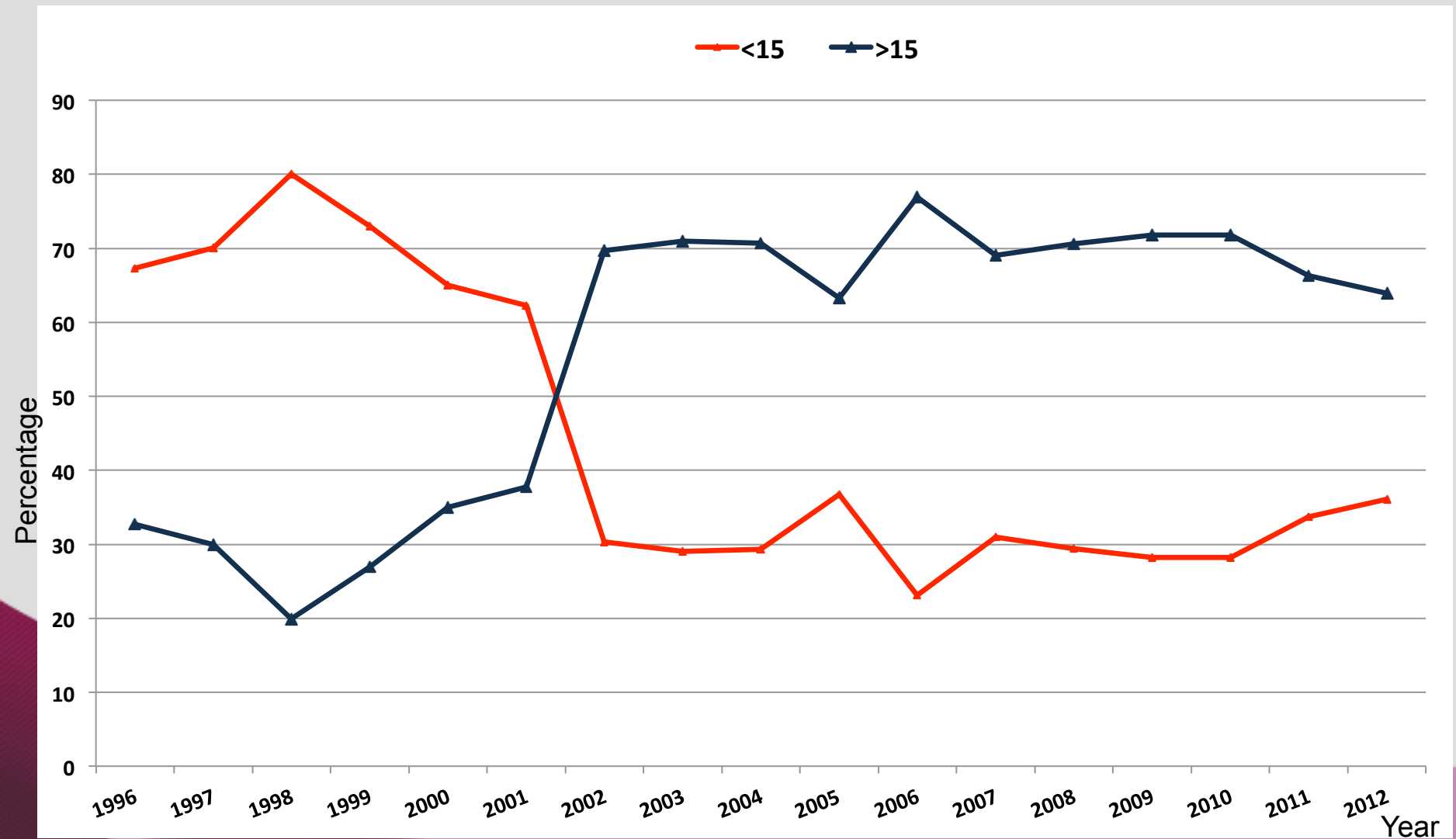
- Reporting to National Surveillance System mandatory
- Laboratory surveillance should be an integral part
- Operational Research-modeling & evaluating vaccine effectiveness

Dengue Trends in Sri Lanka

Cases CFR



Ratio of children : adult dengue in Sri Lanka, 1996 - 2012



Reported mean age changed from 10-15yrs to 20-25yrs between 1996 & 2006

Sero-prevalence among Urban Children

Dengue Surveillance in Colombo, Sri Lanka: Baseline seroprevalence among children

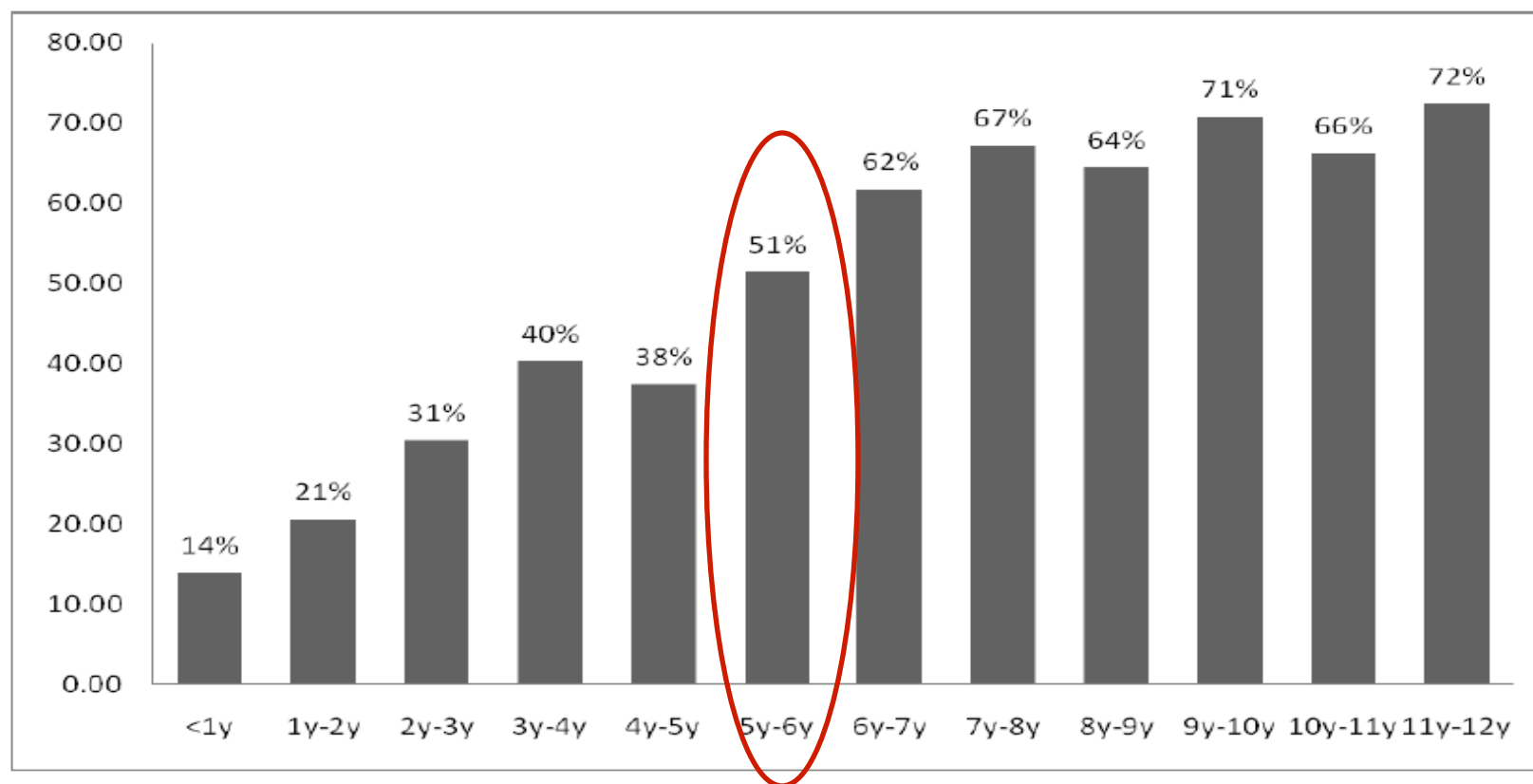
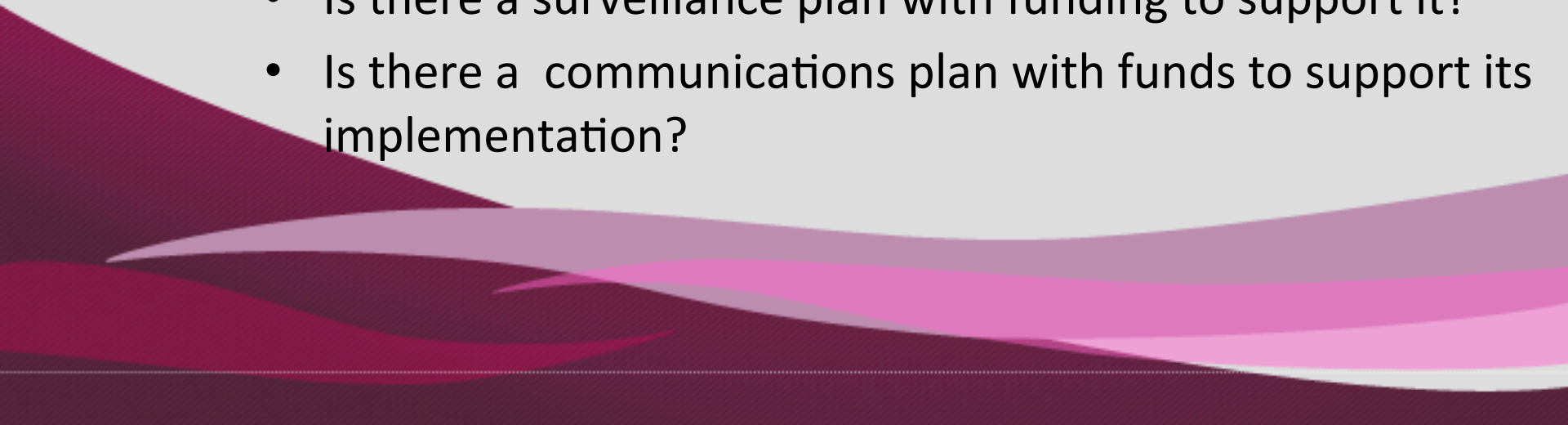


Figure 1: Age stratified seroprevalence among children 0 - 12 in the study cohort

From licensure to programmatic use

- Demands on regulatory authorities
- Needs for post-registration studies
 - Extended safety, in particular longer-term studies
 - Measure vaccine effectiveness, understand impact of pre-existing immunity
 - Assess booster needs
 - Understanding the impact on transmission (herd immunity)
 - Need for coordinated approach between early introducer countries
- Vaccine procurement and supply

Some programmatic considerations

- What strategy is being adopted?
 - Age for routine immunization
 - Catch-up campaign or no catch-up
 - Urban vs rural
 - How will this vaccine be delivered?
 - through EPI or through other mechanisms?
 - Are cold chain and logistics requirements met
 - Are training materials and Job aids ready & available?
 - Is there a surveillance plan with funding to support it?
 - Is there a communications plan with funds to support its implementation?
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Introduction strategies

- Premature to introduce into EPI/NPI – targeted introduction, phase-in manner - intensely follow up for several years
- Most convenient age of introduction -From (modeling) projections it appears that a catch-up campaigns reaching up to 14 years of age seems the best option for the highest impact
 - Amaku et al* showed that with 80% coverage, targeting 3 to 14 years would have the greatest impact
 - Longini** show that a catch-up reaching up to 14 years would have significant impact; reaching up to 44 years while have an impact, the incremental impact gain from reaching just 14 years is not so significant
- Depending on availability and affordability a ‘catch-up’ programme to be considered – few years

*Amaku M. et al., Rev.Inst.Med.Trop.Sao Paulo 2012

**Chao DL et al., PLoS NTD 2012

Ongoing preparatory work: policy considerations and evidence-based decision-making*

- Generating political awareness & support
 - Asia Pacific and Americas "*Dengue Prevention Boards*"
 - Policy studies (opinion-leader surveys, case studies)
- Registration & Licensure (NRA) – WHO prequalification
 - WHO regulatory standards established
 - Technical advice to interested country NRAs
- Vaccine cost, cost-effectiveness, & immunization financing
 - Cost effectiveness of other control methods –vector control
 - Cost estimates and financing strategies studied
 - Demand forecast model developed
- Modeling impact of vaccine intervention/synergies with vector control

*Activities conducted by the "*Dengue Vaccine Initiative*", <http://www.denguevaccines.org/>

Summary on unique challenges for dengue vaccine introduction

- Regulatory & post-licensure: need for coordinated studies on effectiveness and long-term safety in early introducing countries
- Immunization strategies: variable epidemiology, define target age groups & catch up needs, combine operational considerations with modeling studies, immunization schedules & booster needs
- Integration: develop immunization strategies in conjunction with vector control for optimal impact; advocacy and communication
- Evidence for decision-making: cost and cost-effectiveness, vaccine supply and logistics
- Immunization financing (many non-GAVI countries)
- Monitoring & evaluation: needs for strengthened surveillance