Sessions 3 and 4

Costs, storage and waste

- World thiomersal production is about 2,500 kg, 64% of which goes to vaccines, possibly from one single producer
- Development costs and time are substantial and the increased storage volume requirements are of the order of a 2 to 3-fold
- Waste management implications are of the order of a tripling of impact.
- Cheaper vaccines have a disproportinately greater impact

Operational implications of preservative-free (no multi-dose)

- Workload implications for many cadres of staff noting an Optimize time-motion study shows single dose as 38% slower
- Potential for interruption to vaccine coverage
  - "Campaign" style operations likely to be compromised, whether for influenza, pandemic preparedness, meningococcal vaccine, or routine intensification activities
  - Other routine settings may be compromised, if storage and supply is disrupted

Country and procurer perspectives

- Included China, Sri Lanka, UNICEF, PAHO
- Confirm continued demand for multi-dose vaccines
  - Driven by operational uses and also by need to accommodate newer vaccines
  - Requests for thiomersal-containing vaccines are not declining
- A ban on thiomersal would disproportionately affect the 'basic' vaccines and diseases of significance to adult and child survival in LMICs
- Case study from Chile on "a political problem requiring a technical solution" resulting in a shift to thiomersal free vaccines, and other changes in formulation

Manufacturer perspectives

- Confirm large investment of time and money that would be needed to seek an alternative preservatives, or a switch to preservative-free
- Switch to single dose formulations may decrease manufacturing capacity, commercial viability and ultimately vaccine supply
- Call for evidence-based policy, balancing public health risks and long-term planning if any switch is contemplated
- Veterinary vaccines are also highly regulated, need to account for food chain issues, and are provided in settings where single-dose formulations are not feasible

Decisions have consequences: coordinated communication is essential to maintain public confidence

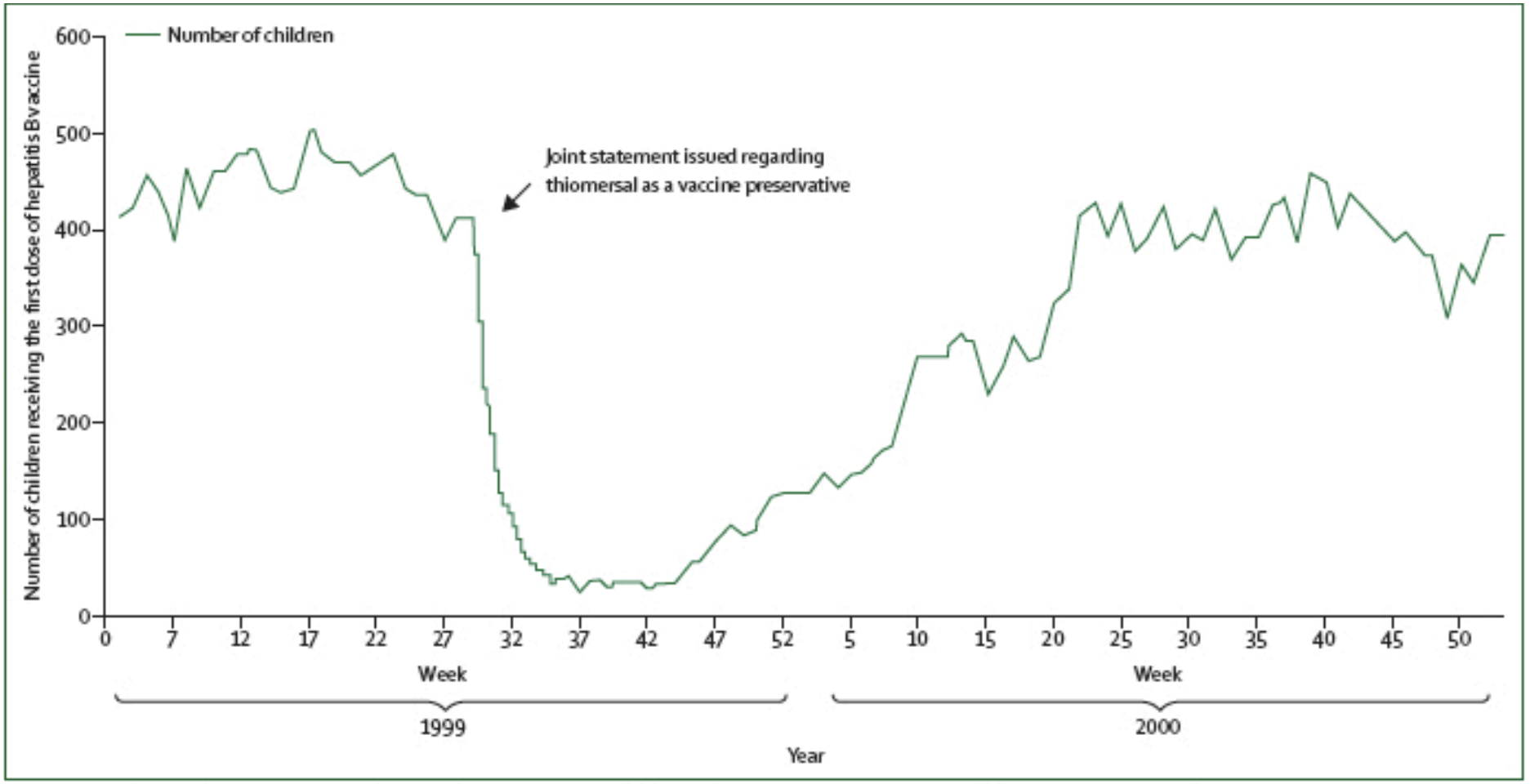

***Figure 1*: Number of children who received the first dose of hepatitis B vaccine less than 5 days after birth (USA, 1999–2000)**
Data from the US Centres of Disease Control and Prevention's morbidity and mortality weekly report.[38]

From Larson et al, Lancet 2011; 378: 526–35

Session 3 and 4 conclusions

- A shift to preservative-free vaccines would have major implications including:
  - Multi-fold increases in costs of vaccines, storage and waste
  - Potential disruptions to supply of vaccines
  - Other operational disruption with potential for fewer children vaccinated
- Need for multi-dose formulations will continue
  - Strengthen support for current preservative supply
  - ? Continue long-term search for alternative preservatives as part of 'due diligence' in light of anticipated increased regulation of thiomersal
- Communications need careful coordination to emphasise
  - Country and agency concerns expressed in this meeting
  - Work for a unified position rather than country by country
  - That the position on safety remains unchanged, although monitoring will continue