Report of the Immunization Practice Advisory Committee (IPAC) to SAGE

Dr Shelley Deeks, IPAC Chair

5 November 2013

World Health Organization

IPAC Overview

- **Meeting Summary: 17-18 October 2013**
  - Immunization Supply Chain and Logistics
  - Immunization Management Group (IMG)
  - Vaccine Wastage Modelling
  - Programmatic Suitability of Prequalified Vaccines (PSPQ)
  - Visual Cue Icon

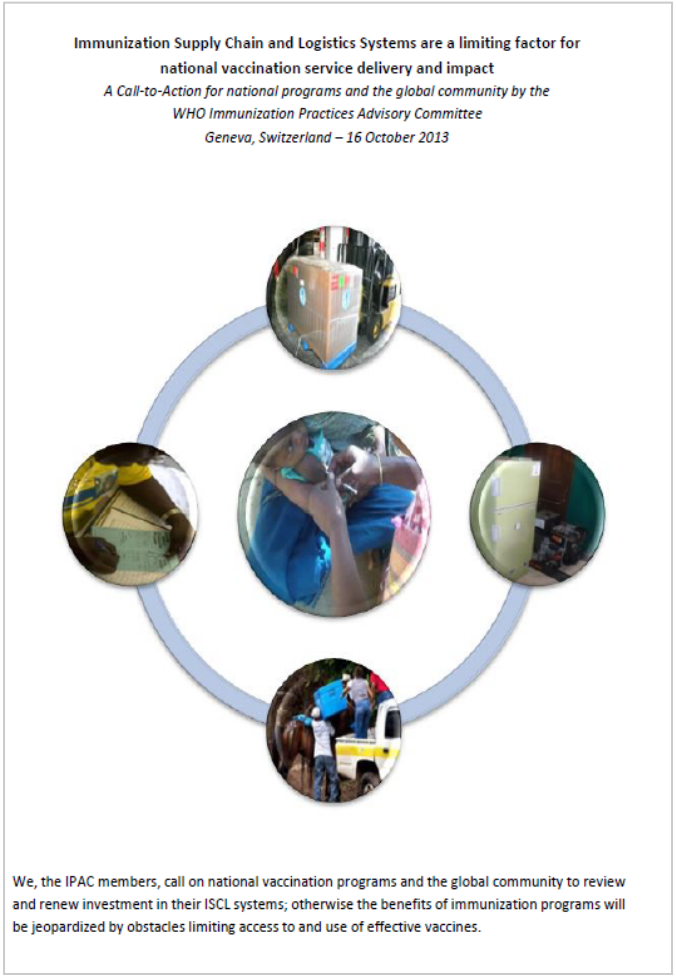
- **Next F2F meeting**
  - June 2014
  - New Chairmanship: Chris Morgan

Immunization Supply Chain and Logistics (iSCL)

- Reviewed the challenges faced by the iSCL systems of national immunization programmes due the acceleration of new vaccine introduction
- Broad consensus that this is a critical area of work that has been neglected and needs urgent attention
- IPAC reviewed and commented on several draft documents which highlight the urgency of the issue, including WHO-UNICEF Joint Statement on Effective Vaccine Management

Immunization Supply Chain and Logistics (iSCL) (2)

- IPAC reviewed and endorsed in principle an early draft of ***"IPAC Call to Action" for national programmes and the global community***
  - To be presented to SAGE in 2014
- IPAC reviewed and provided feedback on the ISCL Key Challenges presentation for the November 2013 SAGE meeting



Immunization Supply Chain and Logistics Systems are a limiting factor for national vaccination service delivery and impact

A Call-to-Action for national programs and the global community by the WHO Immunization Practices Advisory Committee

Geneva, Switzerland – 16 October 2013

We, the IPAC members, call on national vaccination programs and the global community to review and renew investment in their ISCL systems; otherwise the benefits of immunization programs will be jeopardized by obstacles limiting access to and use of effective vaccines.

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Immunization Management Group (IMG)

- Addresses Objective 2 of the Polio Eradication & Endgame Strategic Plan 2013 – 2018: "*Immunization Systems and OPV withdrawal*"
- IPAC updated on workstreams of IMG including issues around IPV forecast demand, country readiness, and communication strategy
- IPAC were appreciative of the comprehensive update and posed many queries around operationalizing IPV (dose scheduling, number of injections at visit, AEFIs)

Vaccine Wastage Modeling (1)

- In the absence of reliable data on vaccine wastage rates, many countries use the WHO indicative wastage rates when forecasting their vaccine needs
- IPAC reviewed work conducted by EPI to date which illustrates a methodology to help countries better estimate their opened vial wastage rates
- Using country level data from 4 countries (Bangladesh, Ethiopia, Burkina Faso, Cambodia) it was illustrated that under certain assumptions, **session size distributions are governed by binominal statistics**

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Vaccine Wastage Modeling (2)

- The initial analysis suggest that for a given facility the expected distribution is determined by 2 parameters:
  - The number of doses administered per year
  - The number of sessions per week conducted (⇒ per year).

- As a consequence, opened vial wastage rate may be determined with reasonable certainty if the mean session size is calculated

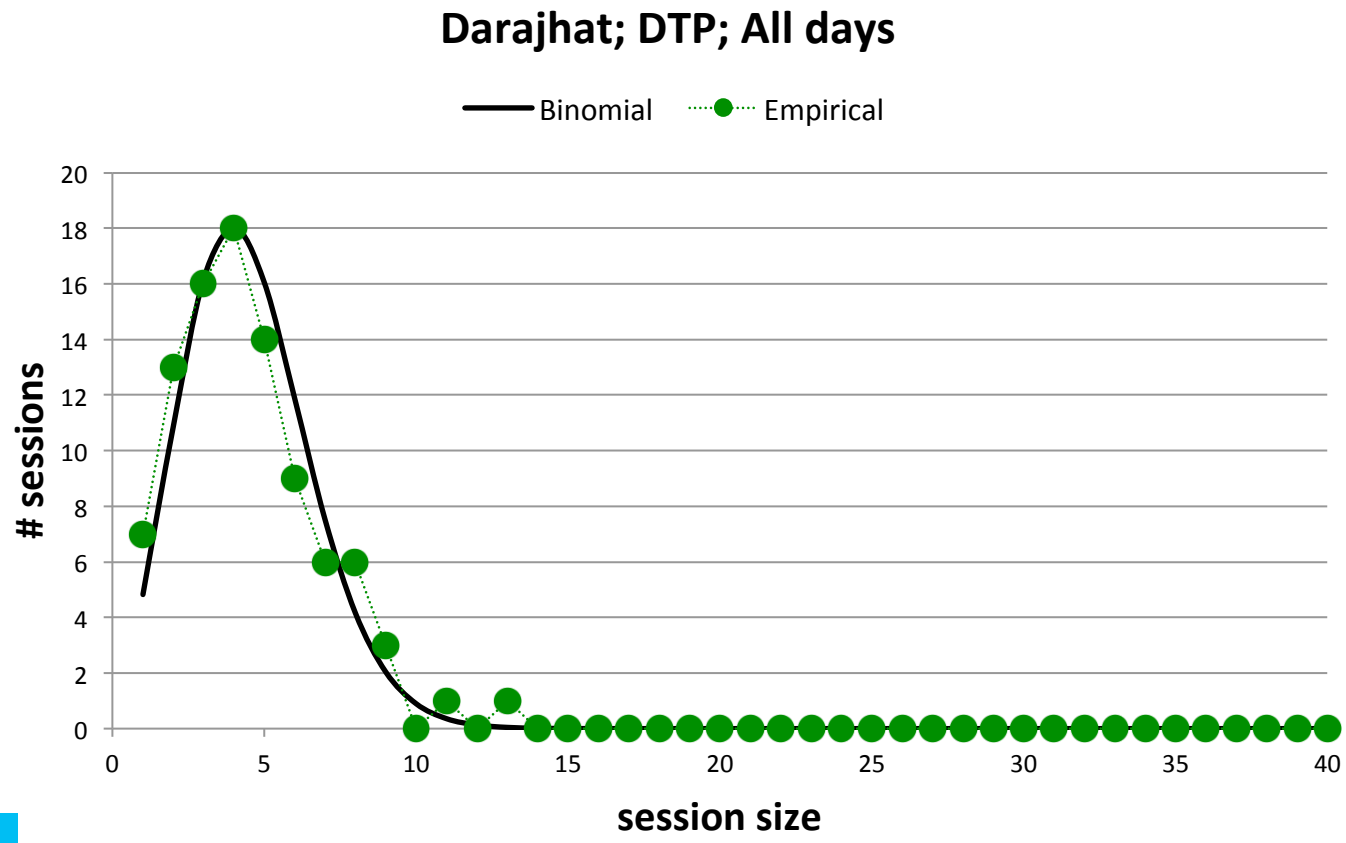
- This knowledge can help countries with improving vaccine forecasting, vaccine monitoring and immunization session planning

Session size distributions: Bangladesh, DTP, 10 dose vial

In 2004 the Darajhat facility in Bangladesh administered 418 doses of DTP Vaccine.
The facility held 94 immunization sessions that year.

MEAN SESSION SIZE = # DOSES / # SESSIONS = 418 / 94 = 4.4

Based on the hypothesis that the session size distribution is Binomial(s; t=418, p=1/94),
the expected session size distribution may be generated…



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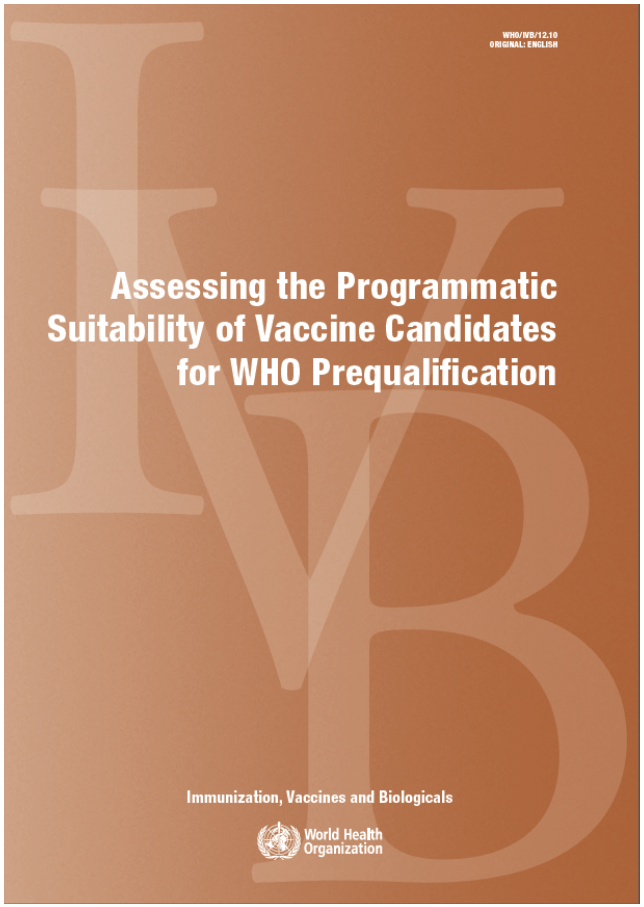
Vaccine Wastage Modeling (3)

- IPAC were cautiously enthusiastic about the potential implications for providing better country field guidance and commended WHO on the innovative work
- Lively discussion among IPAC about the validity of the two underlying assumptions. Specifically, that:
  - Births are uniformly distributed throughout the year
  - Children are immunized according to the national schedule
- IPAC suggested that WHO collect and analyse additional country data to further test the robustness of the hypothesis, particularly for other antigens and in low performing countries

Programmatic Suitability of Prequalified Vaccines (PSPQ)

- Update on implementation of PSPQ process made by Steering Committee since establishment in September 2011
- Evaluation process of Steering Committee reviewed



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Programmatic Suitability of Prequalified Vaccines (PSPQ) (2)

- Nine products with deviations have been reviewed
  - 4 pre-qualified multi-dose unpreserved products (1 liquid, 3 lyophilized/ non-live)
  - 1 pre-qualified single-dose product with poor thermostability and no VVM
  - 1 new single-dose product in pre-filled, non-AD syringe
  - 2 new two-dose unpreserved products
  - 1 new single-dose liquid unpreserved product for which prequalification was requested for fractionated (multi-dose) delivery

- Five of the nine products are previously prequalified products (all vaccines PQ'ed before establishment of process are scheduled for review)

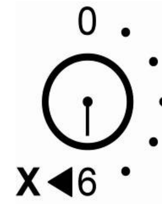
Programmatic Suitability of Prequalified Vaccines (PSPQ) (3)

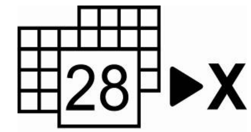
- The (routine) review and revision of PSPQ characteristics and process are underway. To be reviewed and endorsed by IPAC in 2014

Mandatory (4)	Critical (9)	Preferred (7)
- Co-administration with other vaccines - Antimicrobial preservative in multi-dose presentations - Dose volume, injectable - Thermostability / storage	- Vaccination schedule - Auto-disable syringe - Dose volume, injectable - Antimicrobial preservative - Handling - Visual cue regarding handling and discard, primary container* - Heat exposure indicator on primary container (vaccine vial monitor) - Thermostability / storage - Packaging materials	- Maximum packed volume - Dose volume, oral - Doses per primary container - Doses per secondary container - Process of preparation and administration - Thermostability / storage - Packaging materials

*development of a visual cue currently suspended

Visual Cue





- Implementation of field pilot could not be realised
- Subsequent decision by WHO EPI to terminate this initiative as barriers to implementation deemed too high relative to resources required, with uncertain benefit
- IPAC acknowledged the rationale for WHO to curtail further investment but also urged WHO to continue to seek alternative solutions to the problem

THANK YOU