Ad Hoc Immunization and Vaccine related Implementation Research (IVIR) Advisory Committee working group meeting – Summary Points

Geneva, 17-18 June 2014

Immunization, Vaccines and Biologicals (IVB)

World Health Organization
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Meeting objectives

- Objective of the meeting was to crystalize the individual research themes in terms of main knowledge gaps, identifying the research questions and to identify the optimal research designs, methods and studies to be presented at the full IVIR-AC meeting 17-19 September 2014 in Geneva.

- During the discussions participants were reminded to identify these gaps, questions etc. against the background of concrete recommendations to inform decision and policy making.
Session 1 Missed opportunities

- According to literature review and DHS data analysis main reasons for missed opportunities are related to on-going health system practices, perceived contra-indications, logistics rather than behavioural and attitude issues of vaccine recipients such as awareness, beliefs, knowledge, attitudes of parents and caregivers.

- Remaining knowledge gaps and research suggested:
  o Categorize knowledge:
    ▪ Analyse evidence according to methods used to promote existing WHO standard protocols for data collection and analysis.
  o Attitude:
    ▪ Document the working attitude of health care providers with regard to how they communicate with parents and/or caregivers regarding fever, respiratory or diarrheal illnesses as contraindications for vaccination. Experiences from the former Soviet Union from the 90ties on contraindications are worthwhile to study.
    ▪ What is the attitude of end users towards missed opportunities?
    ▪ Training is needed/medical curriculum of HCWs (e.g. nurses and midwives) on attitude and communication needs to be adapted.
  o Policies:
    ▪ How to improve coverage through better and more clear immunization policies e.g. to improve existing guidelines on open vial policies are required.
  o Research:
    ▪ Exit interviews such as based on WHO protocols in the Americas and longitudinal data analysis in PNG were proposed.
    ▪ Defining quality of research in terms of performance indicators.
    ▪ Research needs to be done on what strategies are successful in different settings and increased opportunities e.g. through integrated care (provision through contacts with Vit A, bednet, deworming etc.) or use of campaigns.

- Next steps:
  1. To present the an update of the generic WHO protocol to assess missed opportunities.
  2. To present a plan for studies for priority studies in low and middle income countries.
  3. To present draft proposal of tool summarizing successful interventions

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Session 2: Integration of care with immunization programmes

- Remaining knowledge gaps:
  - Existing research studies still minimal for the complete answer.
    - Yet question is no longer whether but how, when and where to integrate.

- Research questions suggested:
  - How does integrated delivery impact on quality of service provision?
  - Does integration lead to cost-savings and other efficiencies in organization and use of human resources?
  - How is the success or failure of integrated delivery affected by contextual factors (e.g. health system strength; stigma) within the service setting and community?
  - How do we ‘optimize’ integrated service delivery via patient flow measures, thoughtful packaging of services, ensured confidentiality of services and acceptable workloads?

- Challenges identified:
  - Community acceptance of integration.
  - Stigma and unintended consequences e.g. HIV stigma influenced immunization coverage uptake.
  - Immunization outcome measures not always useful or meaningful for other interventions.
  - Complexity of delivery at the working floor in terms of patient flow.
  - Integration may have additional benefits (e.g. co-morbidity) and risks (e.g. equity i.e. “those who misses integrated care misses everything”).

- Lessons learned:
  - Challenges are related to limited capacities of the health system as a whole in terms of limited availability of human resources, supplies etc:
    - Health systems strengthening is required in terms of vital registration, birth registration, supply chain strengthening.
  - Integration is not the magic bullet – better planning is required:
    - Management issue: how to combine interventions and delivery them effectively
      - Better understanding integration from provider perspective:
        - Should we “de-integrate”?
        - Why are current services not integrated?
      - How to integrated requires local solutions:
        - “Pick the right intervention package in the right context”
      - Also understand the history of vertical programs and their rationale for being vertical before integrating. E.g the example of Nepal: despite limited resource availability they have relative good preventive services (reached the MDG goals). Why?
  - Community based services such as home base delivery of vaccines.
• Research methods/approaches suggested:
  o Since how and when to integrate depends on where it happens it was suggested that one recipe does not fit all and training only would not suffice. Instead providing a menu of solutions/strategies with a help desk for technical assistance would be more useful.
    ▪ The menu should be age/stage specific, what could offered etc to address different needs. What is the current status? The help desk should guide the user through the menu of options. Examples from mental health and TB (DOTS) should be looked at including their Policy Briefs.
  o Design approach for community involvement of integrated care:
    ▪ Focus Group discussions of residents who know their community.
    ▪ Open questions/surveys.
  o What is the scope of the study?
    ▪ What actions and strategies help us to increase immunization coverage?
  o Propose within a 2 year time line a selective approach should be proposed two study integration at two levels; service delivery and management level:
    ▪ Few sites should be selected in terms of both successes and unsuccessful approaches.
    ▪ Knowns and unknows should be better documented.
    ▪ BRICS middle-upper income countries should be selected.
  o Country programme managers should be involved in research from several regions.
  o Volunteers for IVIR-AC Working Group: Rachel, Rob, Mitchell, Cherry, Chris, Aaron, Joseph and Mary.

• Next steps
  1. IVIR-AC working group to propose elements of the menu of solutions on the integration of care with immunization programs.
  2. Propose within a 2 year time line a selective approach should be proposed two study integration at two levels; service delivery and management level.
  3. Identify network of social scientist in different disease areas including country managers to be involved in implementation research.
Session 3: Decade of Vaccine Economics

- Remaining knowledge gaps:
  - Since 2006-2015 GIVS costing no update has been estimated on the global and regional costs, financing and financing gaps of vaccination programmes in LMICs for decade of vaccine horizon 2011-2020.
  - Specifically a user-friendly, transparent and readily updatable tool to fill in the gaps in the previous GIVS exercise including scenario and sensitivity analysis designed to link with economic benefits is lacking.

- Challenges identified:
  - Data sources such as cMYP and GAVI demand forecast are based on aspirational goals – how realistic are the projections? How will they be validated.
  - To increase the transparency of the cost analysis more specific, detailed and transparent documentation is needed on the CFF methods, assumptions, regression and extrapolation methods and data sources for the full IVIR-AC meeting in September 2014.

- Research suggested:
  - The extrapolation of the 10% for the last child to be reached using linear relations is a major assumption. This needs to be addressed in the scenario/sensitivity analysis.
  - For routine service delivery costs: details of the regression method and assumptions to impute costs from 63 countries to remaining 31 countries need to be further explained including the model specifications.
  - For the supply chain mechanistic model rationale behind the four reference countries and extrapolation methods should be clarified. More specific reference materials should be provided with regard to the HERMES models (currently a flyer is provided on the model).
  - Table 2 of the DOVE-FCC Model Conceptual Framework should be expanded with a column with regard of the grading of the evidence with regard to the data sources.

- Next steps
  1. In order to answer the key questions to IVIR-AC (i.e. the appropriateness of the data and methods used) more specific, detailed and transparent documentation is needed on the CFF methods, assumptions, regression and extrapolation methods and data sources for the full IVIR-AC meeting in September 2014.
  2. Specifically, more background information needs to be provided on the regression method and assumptions for estimating the routine service delivery costs.
  3. More specific information needs to be provided on the HERMES model including the supply chain mechanistic model.
Session 4: Reasons for vaccine non-acceptance

- **Remaining knowledge gaps:**
  - In understanding the barriers regarding the uptake vaccines the community views and perception have been grossly ignored.
  - The terms “non-acceptance” and “hesitancy” have been used interchangeably during the discussion. It was proposed that a better wording/terminology is required for future discussions e.g. non-vaccination.

- **Lessons learned:**
  - Experiences from AFR:
    - Lessons learned from Onchocerciasis program:
      - Invest in community driven delivery of treatment.
      - Training and retraining of HCW.
      - Close linkages between frontline health providers and community structures.
      - Operations research to inform program implementation.
    - Lessons from Polio in Pakistan are unique because of political tensions:
      - Primary strategy: negotiated access – involvement and engagement of religious and tribal leaders.
      - Opportunistic vaccination strategies: permanent points of vaccinations, self vaccination and restoring routine EPI.

- **Research suggested:**
  - Proposed research framework for non-vaccination of influenza would be useful for the discussion on setting the research priorities.
  - Research on community factors should complement acknowledged priorities of development of efficacious and safe vaccines, and efforts to enhance the capacity and efficiency of health systems, schools and other social agencies involved in vaccine delivery. Attention to community factors relevant for coverage should clarify the role of vaccine awareness, local priority, perceived access and use.
  - Questions of awareness refer to knowledge of the existence and availability of particular vaccines, and awareness of what particular vaccines may have been received in antenatal, paediatric and other health care settings. Questions of locally perceived efficacy and safety should complement professional assessment of available evidence and needed research with regard to vaccine-specific and nonspecific effects. An operational framework of community awareness should be formulated to enhance a sense of community ownership of vaccination interests – developing and validating ways to engage communities, to enlist their support, to foster their sense of responsibility for ensuring local benefits of vaccination, and to harmonize professional and community aims of promoting universal health coverage.
o Community priorities should be examined with regard to vaccine hesitancy, confidence, trust, and with reference to prior experience, anticipated acceptance and prospective study of patterns of use. Clarification of community-perceived access should complement assessment of professional priorities indicated by policy and accessibility of vaccines. The interests of this agenda should be considered with regard to needs pertinent to particular vaccines in particular settings.

o Setting-specific research aims should identify and focus on policy-relevant questions for strategic planning for positive impact in areas of need. The research agenda should also proceed in areas of notably effective vaccine delivery through health systems, educational institutions and/or social agencies, and thereby enable lessons from positive deviance. Elaboration of this IVIR-AC community-based research agenda should be conceived and planned as complementary to consideration of policy and media studies.

- Documentation on what we know in terms of consequences and what we don’t know need to be improved – systematic review LSHTM by Larson et al. Vaccine 2014 is an example to start with.

- Three broad category of research questions for future discussions on research priorities:
  1. Prevalence of non-vaccination according to perception of end-users; among vaccine recipients, HCW, parents etc.
  2. Determinants of non-vaccination e.g. individual vs broader community, by different types of vaccines.
  3. Strategies to address non-vaccination; attitude and communication including media is important.

- Next steps:
  1. Propose research framework including the broad categories of research questions should be presented.
  2. An operational framework of community awareness should be formulated to enhance a sense of community ownership of vaccination interests – developing and validating ways to engage communities, to enlist their support, to foster their sense of responsibility for ensuring local benefits of vaccination, and to harmonize professional and community aims of promoting universal health coverage.
  3. Research agenda should be formulated for specific vaccines and settings.
Session 5: Typhoid burden of disease

- Burden of Disease estimates for typhoid were presented in a detailed, transparent (providing the source data for all assumptions and parameters) and step-by-step manner. Methodological approaches used by a variety of groups were contrasted and compared (based on published methodology where available).

- Knowledge gaps:
  - Several typhoid burden estimation groups have come up with estimates varying from 12-20 million cases globally.

- Challenges identified and specific research questions suggested:
  - Using bootstrapping of input parameters in extrapolating data to other settings should not have been random but according to context specific indicators such as access to water/sanitation. However, the cut-off points of the latter indicator as defined by WHO are not realistic – sensitivity analysis would be appropriate by varying the cut-off points.
  - Quality rating of different studies should be useful.
  - With regard to the selection of studies for inclusion in the final IVI analysis, it should be clear how the relevance of studies for current BOD estimates was decided in terms of timing and context (e.g. link between different hospital settings and CFR).
  - Reviewers for the literature rating should ideally be blinded to the journals in which the papers are published.
  - Can the CFR correction be further refined taking into account prior antibiotic use and health care utilization?
  - It was suggested that the “classic literature” (i.e., pre-antibiotic era) on reported CFRs be reviewed to help determine the correction needed for the CFR.
  - Further adjustments to CFR and blood culture were suggested to take into account variable age-specific sensitivities.
  - The possible effect of the volume of blood for culture should be considered. The presenter noted however that several parameters (including volume of blood, timing of sample collection, culture methods used and history of prior antibiotics) were considered as potentially impacting on the blood culture sensitivity, however, it was not possible to measure their effect given the limited data available.
  - There was some concern about the small number of data points in Africa extrapolated to the whole continent.
  - Recent studies on yellow fever, using an approach to extrapolate data to sites with similar ecological factors (as opposed to geographic proximity for example) may be a good model for typhoid. The committee was also informed that IVI is working on developing a risk prediction model with similar approaches.
  - In terms of future research needs, the following were suggested as possible gaps to be addressed:
- vaccine strategies in context of the characteristics and schedule of other vaccines that typhoid may be co-administered with.
- health system issues in vaccine delivery.

- With regard to Typhoid Burden of Disease meeting organized by Coalition against Typhoid (CaT) in Geneva on 4 July 2014:
  - Ideally IVIR-AC member should attend the meeting.
  - If relevant the 4 July meeting outcomes to be reported to the full IVIR-AC September meeting 2014.

- Next steps:
  1. Address and incorporate some of the suggestions listed if feasible within the time frame in the report for the full IVIR-AC meeting in September 2014.
Session 6: Non-specific effects of vaccines

- Remaining challenge
  - Participants agreed that non-specific effects of vaccines should be further investigated and not be ignored in order to have an evidence-driven set of next steps.

- Challenges:
  - Evidence based on observational studies weak; however, observational studies are useful for hypothesis generating.

- Research suggested:
  - The group considered the pertinence of additional observational studies with the inherit risk of bias, the review of existing datasets from demographic surveillance cohorts and whether there is a basis for designing RCTs with the clear objective of assessing non-specific effects of vaccines. These options should be further explored.

- Next steps:
  1. Enumerate the priority research questions that would inform policy decisions (September 2014).
  2. Discuss the kind of studies and study designs that would inform policy questions (2015).
  3. Develop generic protocol(s) and data collection tool(s) (2015).
    a. Identify a pool of suitable sites/locations for potential studies as outlined under item 2 above.
    b. Identify a pool of potential independent investigators.
Annex 1: Agenda

Agenda Ad-hoc IVIR-AC working group meeting
Hotel Crowne Plaza, Geneva, Switzerland
17-18 June 2014

Overall objective:

To discuss details of different implementation research areas and to prepare background materials in preparation to the full IVIR-AC meeting in September

Discussion points for each session:

1. To identify the main knowledge gaps?
2. How to address these gaps in terms of specific research questions? Are these generic or antigen and/or geographically specific issues?
3. What are the data limitations? How to address these in the short/long term?
4. What are the optimal research designs/methods/studies to fill the knowledge gaps and what is feasible within in the near future (within 1-2 years) and longer?
5. What to present in summary to full IVIR-AC meeting in September?

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Tuesday, 17 June 2014

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<th>Time and session</th>
<th>Content</th>
<th>Presenter</th>
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<tr>
<td>08.00-08.30</td>
<td>Registration</td>
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<tr>
<td>08.30-08.45</td>
<td>Introduction</td>
<td>R. Breiman</td>
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Session 1 - Missed opportunities of vaccination

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<tr>
<td>08.45-10.15</td>
<td>• Introduction - 5’</td>
<td>WHO</td>
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<td></td>
<td>• Magnitude of missed opportunities</td>
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<td></td>
<td>o Systematic literature review - 15’</td>
<td>S. Sridar</td>
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<td></td>
<td>o Analysis of data coverage survey – ‘15</td>
<td>A. Clark</td>
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<td>• Plenary discussion – 55’</td>
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10.15-10.45    Coffee/Tea break

Session 2 - Integration of care with immunization programs

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<tr>
<td>10.45-12.15</td>
<td>• Introduction - 5’</td>
<td>WHO</td>
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<td></td>
<td>• Experiences of integrating delivery of maternal and child health services with childhood immunization programs – 20’</td>
<td>A. Wallace</td>
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<td>• Plenary discussion – 65’</td>
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12.15-13.15    Lunch break
**Session 3 - Decade of Vaccines Economics (DoVE)**
13.15-14.45
- Introduction – 15’  
  S. Ozawa
- Q&A through teleconference with S. Ozawa and team – 30’
- Discussion on DoVE Costing, Financing and Funding Gap (CFF) model: methods, data and assumptions – 45’

14.45-15.15 **Coffee/Tea break**

**Session 4 - Reasons for vaccine non-acceptance**
15.15-16.45
- Introduction - 5’  
  WHO
- Experiences and case studies from:
  o African region -15’  
    M. Amuyunzu
  o India –15’  
    M. Weiss
  o Pakistan – 15’  
    H. Jafari
- Plenary discussion – 40’

17.00 **Cocktail**

**Wednesday, 18 June 2014**

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| 08.30-10.00      | **Session 5 - Typhoid burden of disease**  
  - Background – 10’  
    I. Khan
  - Presentation on burden of disease methods, data sources and assumptions – 25’  
    V. Mogasale
  - Plenary discussion – 55’ | |

**10.00 -10.30 Coffee/Tea break**

**Session 6 - Non-specific of vaccines**
10.30-12.00
- Introduction - 5’  
  WHO
- Summary of SAGE discussions and recommendation – 15’  
  WHO
- Plenary discussion – 70’

12.00 **Closure and lunch**
Annex 2: List of participants

Ad hoc Working Group Meeting of the Immunization and Vaccines related Implementation Research Advisory Committee (IVIR-AC)

Hotel Crowne Plaza, Geneva, Switzerland

17-18 June 2014

List of Participants

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