Dear IPAC members and observers,

Welcome to the July IPAC Bulletin! I’m writing within earshot of a rushing stream, looking out on a misty tree-covered hillside in the highlands of Papua New Guinea. As we try to design an immunization services assessment, my aspirations to use good research processes constantly come up against the unpredictable transport disruptions, political strife, community disengagement, multiple stock-outs, and any number of system failures. They provide an unwelcome reminder of the daily realities that confront many of the immunization program managers and staff whose interests we serve. I believe it is essential that we (mentally at least) spend some of our time in the seat of the local health manager confronted by alarming resource constraints. I know from personal experience that this is the viewpoint taken up by Robin Biellik and Jon Colton, who provided such helpful and pragmatic contributions to IPAC, and whose terms expired last month.

The IPAC operational plan is now in near final form; for those new to IPAC it provides a helpful summary of our mandate, relationships and mode of operating. Perhaps most important is the listing of priority topics we need to focus our attention on. This list is broad (though not as broad as the myriad challenges facing our local manager) and includes topics such as: new delivery technology, integration of immunization services, missed opportunities for immunization, vaccination in the second year of life, needle and syringe practices, strengthening community engagement, supporting polio programme transition planning, health worker training, and the concept of Total System Effectiveness.

First among these is the work on the Controlled Temperature Chain – thanks to all who helped hone the TORs for this group. A specific working group is being formed, but their deliberations will come back to IPAC as a whole for your review and comment. This issue seems to entail a not-uncommon balance of evidence and pragmatism: the challenge of providing guidance to national programs that is both usable and scientifically sound.

This list of topics demands a range of expertise and I’m delighted to welcome four new members to IPAC: Kelly Moore, Michael Free, Masa Hachiya, and Nora Dellepiane. Our new members add to our breadth; spanning innovative technologies, program-oriented research, licensing and accreditation, first-hand knowledge of the juggling act that is immunization program management, and the value of sharing lessons across countries and regions. Please read their bios when those are published so you can start to get to know them.

The advice IPAC needs requires not just expertise but also the willingness to consider how any new approach will practically support field programmes, both new and those to come. We are eager to see the variety of members’ inputs, which all come from different perspectives, on the questions before us. Please do continue to log into TechNet21 regularly and respond to the email requests to view Discussions on that site. Remember to select the item labelled Discussions under the Applications section of the menu to see recent discussions, for review. The secretariat now mark completed discussions in green as ‘Resolved’ to help us see which to focus on. I have just tested the ability of PNG’s erratic internet and found myself able to log on (as long as my phone is as close as possible to the window looking out on those misty mountains).

Chris Morgan
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Appreciation of Departing Members by Chris Morgan

My first encounter with Robin was six years ago in the midst of a high-level discussion on promotion of hepatitis B vaccination at birth - a collaboration that endured through his role on that IPAC working group; the resonance from this is still felt in global guidance issued this year. Since then, in his contributions to IPAC and to WHO more generally, I have appreciated Robin’s commitment to global immunization as an integral part of essential health care - his has often been the voice asking us to take a wholistic view, to see it from the health workers’ viewpoint, and above all to be practical. He is a strong advocate for the needs of routine immunization and the value of the programmatic perspective - seen in his leadership of the work group bringing the neglect of Integrated Supply Chain and Logistics to SAGE’s and other partners’ attention. This contribution is also clear in Robin’s role in the Programmatic Suitability for Pre-Qualification standing committee, which he now chairs. It is great to know that even after he steps down from IPAC he will continue to support PSPQ and we will continue to interact with him in that role. I recall and value Robin’s quiet mentorship of many, his keen-ness to disentangle WHO bureaucracy, and his ability to ensure we do not forget the lessons of whatever we were discussing and ensure what was proposed would make sense in practice. We appreciate his contributions to the new developments in vaccine packaging and labelling, to ideas for a new visual cue indicating when to discard multi-use vials, and to other work contributing to WHO’s current Multi-Dose Vial Policy; an essential tool for resource-constrained immunisation programs. Beyond that, I note his willingness to share from the breadth of his expertise and interests - introducing us to new technologies in temperature monitoring, zero net energy warehousing, and a raft of fascinating ideas for humanitarian design on which he leads his students at Georgia Tech. Jon’s service to this corner of WHO started before IPAC on the Technologies and Logistics Advisory Committee; I am very grateful he was able to serve also on IPAC and to give us such valuable input over these past years.

Summary of Sage Global Measles and Rubella Technical Meeting by Jean-Marc Olive

During the meeting I chaired the session on “Cross-cutting measles, rubella and routine immunization priorities”. The objective of the session was to:

1. Provide an overview of activities that mutually benefit RI and measles elimination
2. Learn about country experiences for establishing and tracking a 2YL child health visit.
3. Inform Participants on guidance for monitoring 2YL vaccinations and activities under the Dose per Container Partnership.
4. Share examples and illustrations of measles vaccine wastage scenarios.

India and Ghana country managers on 2YL platform implementation

Discussion focused on:

1. The operationalization of MSD with a clear target age and interval policy.
2. Catch-up policy for missed antigen.
3. Importance of communication to promote the second year of life visit, and convey that children are not fully vaccinated against measles until they have received 2 doses.
4. The importance to plan ahead to revise data reporting and recording tools.
5. The Sage recommendation requiring a minimum MCV1 of 80% before introducing MCV2 was also discussed and suggested to be reviewed.
6. School entry screening and MenA introduction were also mentioned as approaches to reinforce 2YL and to improve MSD coverage.

Other presentations at the meeting

A presentation focused on alleviating wastage as a barrier to vaccination by providing an overview of the Dose per Container Project (DPCP) in Tanzania and Senegal. A study in Ethiopia is planned to measure differences in coverage determined by a pre/post household coverage survey. A new mobile tool app for estimating wastage based on session size and other variables was also presented and will need to be piloted. The tool will provide utility and flexibility in a wide variety of settings. Other wastage studies from Nigeria, Cambodia and Fiji were presented providing more arguments on the potential benefits of a change in vial size on measles vaccination coverage and missed opportunities.
Gitte Giersing:
A briefing from the Delivery Technologies Working Group (DTWG)

Since the last report, the DTWG has surveyed manufacturers and end-users to provide collated input on the optimal design of blow filled seal containers to a major developer. Potential designs which are currently being evaluated for suitability include polymer blow-fill-seal vials, ampoules, and compact prefilled auto disable devices (cPADs). Other alternative primary containers which may be available in the future include integrated reconstitution technologies, in which the dry vaccine and diluent are packaged together or as an integral system and mixed within the device before delivery, potentially simplifying the logistics of transportation, the process of preparing vaccines and reducing the risks of reconstitution errors that can result in adverse events.

The group has also reviewed and provided feedback to Gavi on the Vaccine Innovation Lexicon that they have developed in collaboration with PATH. More recently, a prioritization framework tool that has been developed by PATH, WHO and the BMGF that aims to provide a tool for policy makers, technology developers, manufacturers, and purchasers to assess and identify potential new vaccine/technology pairings is in the process of being evaluated. Alignment of global level stakeholders on important technology attributes and priority vaccine needs and requirements will allow for focused prioritization and de-prioritization of technologies for consideration and use in LMIC. Short (0 to 2 years), medium (3 to 5 years) and long term (6 to 10 years+) timeframes are being considered with regards to vaccine technology pairing and prioritization as well. Complementary to this qualitative tool, PATH with support from WHO and BMGF are also spear-heading the development of a quantitative program delivery health economic analysis to assess the vaccine technology pairings, and plan to introduce this concept to the WG within the coming weeks.

Both PATH and WHO, as chairs of the WG, collectively advised the Bill and Melinda Gates Foundation on the Request for Proposals for microarray patch (MAP) delivery of measles and rubella vaccine (MR). The proposal review process is currently underway. PATH and WHO are also contributing to a background paper on the background and current state of ID fractional dose delivery in context of both fIPV and the current yellow fever outbreak.

The two DTWG chairs and the secretariat of IPAC had the opportunity to hold a workshop on the ‘Challenges of vaccine delivery for Low and Middle Income Countries’ at the Vaccines Against ETEC and Shigella conference in Washington DC from 28-30th June, where they were able to present and discuss some of the programmatic considerations and WHO prequalification for vaccines that are in preclinical or clinical development.
Background: Between 1988 to 2015, Neonatal Tetanus (NT) deaths decreased by 94% (787,000 to 49,000) and between 2000 and 2015, 38 countries achieved Maternal Neonatal Tetanus Elimination (MNTE). This was achieved through the implementation of strategies to strengthen the health systems that facilitated increase in skilled birth attendance rates as seen in China, India and Rwanda among others, the implementation of the high risk approach and surveillance for neonatal tetanus. Countries claiming elimination were validation using the Lot Quality Assurance – Cluster Sampling survey that also collects additional coverage data on clean delivery, cord care practices and immunization with Tetanus Toxoid (TT) vaccine.

However tetanus, particularly neonatal tetanus, remains a hidden disease that has no champions and is often neglected, competing with other health priorities. Several global MNT elimination targets dates have been missed, with 18 countries still to be validated:

1. Ethiopia and the Philippines are conducting the last phase of activities and both are likely to be validated in 2016.
2. Angola, DRC, Haiti, Kenya, South Sudan, and Sudan will complete their planned activities by the end of 2016 and are on target to be validated in 2017.
3. Chad, Guinea, Papua New Guinea, and Somalia will complete their planned activities by the end of 2017 for possible validation in 2018.
4. Afghanistan, CAR, Mali, Nigeria, Pakistan, and Yemen due to insecurity and lack of technology might not be ready for 2020.

Countries that have achieved MNTE
Should sustain MNTE through:
1. Periodic analysis of risk
2. A MNTE sustainability plan (vaccination, clean delivery, and clean cord care).
3. Political commitment, a renewed focus on routine immunization and strong health systems
4. Strengthening monitoring (coverage in all age groups, document individuals) and surveillance (community/facility based, and sero-surveys)

Preparation for October SAGE meeting
A 2016-2020 roadmap was drafted that considered the following elements of work:

Investment case: With key partners, draft an MNTE investment case that would include costing for donors and WHA 2017;

Unject: discuss considering the use of Unject, its licensing and possible market shaping.

Communications that help identify a few champions and reframes the MNTE story in terms of success stories.

Global work: guidelines for country implementation, production of a position paper that may include systematic reviews, review of schedules (2nd year of life, adolescent, school, conflict delivery, age groups) and links with UHC / ANC, opportunities for integration.

Funding gaps: between 2016 and 2020, there is a global $135million short fall to fund validation surveys and implement SIAs and an $80 million shortfall if programs use Unject.

Vaccine controversies: for example rumors spread about reasons for vaccinations;

Insecurity: Hard to reach populations in area of conflict.

Good practices: Good practices of tetanus control were shared from Zambia (focus on SIAs in high risk areas); Indonesia (focus on school based delivery); DRC (focus on improved antenatal care increasing access to TT) and India (focus on integration with holistic RMNCH approaches).

Monitoring and surveillance: The importance of quality monitoring and surveillance was emphasized, with some cases described in Cambodia and the possibility of using tetanus sero-surveys as an adjunct to monitoring unreliable TT and PAB coverage rates. This could possibly help monitor sustainable MNTE programs in future.

The Way Forward
Countries yet to achieve MNTE
1. Should conduct a risk analysis
2. Should produce a national plan of action
3. Create an Implementation timeline
4. Conduct pre-validation Assessments
5. Conduct Validation surveys

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Craig Burgess: A briefing from the Working Group on MNTE

“Tetanus, particularly neonatal tetanus, remains a hidden disease that has no champions and is often neglected, competing with other health priorities.”

Photo: WHO Tetanus
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Reaching Every Child with Valid Vaccinations
by Adelaide Shearley (A Perspective from Zimbabwe)

Red Approach

in 2003 Zimbabwe implemented the Red strategy focusing on poorly performing districts. Implementation was initially in 50 districts, but is currently being rolled out throughout the country. There has been significant progress in increasing national immunization coverage, although there are still pockets of underperforming districts, especially in the hard to reach populations.

According to a study done in countries of the WHO African Region, including Zimbabwe, immunisation services still face various problems including a lack of trained staff to correctly administer vaccinations, as a result, many children in these countries receive inappropriately timed vaccinations. Other studies examining timeliness of vaccinations were dedicated to delayed vaccinations, i.e. vaccinations administered at older ages than recommended, resulting in a longer time of susceptibility for infectious diseases, thus leaving children vulnerable to vaccine-preventable diseases [1]. There is evidence that optimal response to a vaccine depends on multiple factors, including the nature of the vaccine and the age and immune status of the recipient [2]. Recommendations for the age at which vaccines are administered are influenced by age-specific risks for disease, age-specific risks for complications, ability of persons of a certain age to respond to the vaccine, and potential interference with the immune response by passively transferred maternal antibody. Vaccines are recommended for members of the youngest age group at risk for experiencing the disease for which efficacy and safety have been demonstrated.

According to the Zimbabwe DHS (2010) and (2015), as well as the MOHCC EPI Routine Immunization Coverage Surveys of 2010 and 2015, there was a dramatic change in coverage for Fully Immunized Child (FIC), when the criterion of validity was applied. The surveys measured “validity” of the doses given to the child at correct age with proper spacing between doses as stipulated by the national immunization schedule. These doses which are called “Valid doses” are a proxy indicator of health workers’ knowledge as well as the application of national immunization policy in practice. The current Zimbabwe schedule for a fully immunized child comprises BCG (one dose) at birth, Penta, OPV, PCV (three doses each) at six, ten and fourteen weeks, rotavirus vaccine (two doses) at six and ten weeks and measles (one dose) at nine months. With the progression of the programme the definition of “Fully immunized child” will include new antigens as happened with the PCV vaccine which is now a part of the above definition.

Despite the progress which has been made since the last survey (2010) on validity of vaccine doses given in correct age and interval between them, five provinces: Mashonaland Central, Matabeleland North, Matabeleland South and Midlands, are below the overall national rate of 69%. Apparently the need to apply three valid doses of DPT and OPV vaccines with 28 days apart between the doses creates more room for human error than for measles vaccine which is administered in one dose.

There is clear evidence that there is a persistent service delivery deficiency that needs to be urgently addressed in order to improve quality and effectiveness of immunisation services. This is important as the economic implications of repeating invalid vaccinations may be huge, particularly for low-income countries.

The survey results also indicated that what is needed is not only individual training of health care providers administering vaccines, but also general organisation of health care services e.g. with respect to accessibility and constant availability of vaccines, could be other areas for improvement in order to ensure an optimal protection against vaccine-preventable diseases.

In order to address this programmatic deficiency, immunisation supervisors in Manicaland Province have developed a tool / Job aid that aims to assist health workers determine the correct dates for subsequent doses, observing the correct inter-dose spacing. It resembles a pregnancy wheel, where health workers do not have to count the number of days in between doses and instead can use the tool. It is hoped that this tool will go a long way in minimizing invalid doses in Manicaland Province and hopefully be rolled out nationally. This tool will be institutionalized and checking of invalid doses by immunisation supervisors will be part of routine support supervision of the health care providers administering vaccines.

References:


General recommendations on immunization: recommendations of the Advisory Committee on Immunization Practices and the American Academy of Family Physicians. MMWR 2002; 51[No. RR-2]).


WHO Technical Consultation on Maternal Influenza Vaccine Introduction by François Gasse

Summary of Meeting
The WHO developed a manual to support the introduction of maternal influenza vaccination throughout the world, including information and tools to support national decision-making prioritization of health interventions, to inform operational plans for delivering influenza vaccines to pregnant women, (being mindful of local and regional influenza epidemiology, seasonality, and availability of vaccines) and to provide options for service delivery including the incorporation of antenatal care structure in vaccine delivery strategies.

Meeting Objectives
To review a draft of the manual in consultation with experts in international maternal and child health, vaccinology, influenza, and programme implementation and National policy makers will also participate.
To discuss and incorporate conclusions on key aspects of decision making for planning the introduction of influenza vaccination to pregnant women.
To consider options for pilot testing in selected countries of various regions to further improve the manual.

Meeting Outcomes
A Revised manual draft based on meeting discussion and inputs and circulation within the group.
A plan for publishing an online pilot version of the manual and development of an e-learning course to assist implementation.
A plan for piloting and critically evaluating the manual in region: Euro, SEAR, and potentially AFRO (South Africa) to inform national policy development processes and assist with review of existing policies.

Four main topic areas for the introduction of maternal influenza vaccination:
1) Deciding to introduce maternal influenza vaccination 2) Vaccine introduction planning 3) Training and Communications 4) Monitoring and evaluation. Finally, WHO regions highlighted specific regional policy progress, implementation experiences, challenges, and opportunities for maternal influenza vaccination implementation in their region.

2) The current available evidence suggests a range of efficacy of the vaccine varying from year to year depending on the country and circulating influenza prevalence, the vaccine being considered safe and effective but additional high quality data are needed on illness severity, virus and illness seasonality, safety and efficacy, and dissemination strategies.

A variety of economic data on the burden of influenza illness and its societal, economic, and productivity costs, financial burden in terms of direct costs to the health system and indirect costs to society are lacking from low and middle income countries. Weighing strategies for financial sustainability was also discussed.

Country experience from India highlighted critical success factors to a successful influenza vaccination program but also challenges encountered such knowledge gaps in influenza disease burden, vaccine availability, seasonal suitability and effectiveness, and program cost and sustainability. The Partnership for Influenza Vaccination Introduction (PIVI) Initiative to support low and middle income countries in creating ae sustainable influenza vaccination programs, country experiences Lao and Nicaragua highlighting the importance of vaccine availability, cost, and sustainability of vaccination programs in pilot countries (Lao and Nicaragua).

Additional data are needed to understand feasibility and benefit to year round delivery strategies and campaign vs provision through antenatal care and optimal choice of vaccine formulation based on seasonality and strains patterns of circulating influenza virus.

Thailand shared the challenges encountered such as low acceptance among health care workers and the population, media disruption of trust when potential adverse events were encountered, and no local vaccine production available.

In Malawi in collaboration with PATH and WHO studied barriers to country uptake of influenza vaccination through an antenatal care integrated vaccine platform.

Lessons learned from UNICEF’s work with MNTE programs, on a comprehensive communication and education strategy were presented highlighting the unique factors related to vaccination during antenatal care that must be in place through training before program roll-out.

In Lithuania, the TIP FLU tool was used to design a successful vaccination campaign training and communication strategy that improved that country’s maternal influenza vaccination rates fifteen fold.

India conducted a pilot in Pune to evaluate a method of educating and engaging physicians in maternal influenza vaccine introduction, that incorporated attitudes from the community on vaccination, and found that physician intervention groups educated and monitored for maternal influenza provision improved vaccination rates for maternal tetanus immunization in addition to influenza vaccination. Monitoring including denominator coverage estimations, adverse event reporting challenges and evaluation of maternal influenza vaccination programs were discussed including a review of considerations for denominator coverage estimation, AEFI surveillance in low resource settings, and Post-introduction evaluation considerations.

Updated global estimates of influenza disease including severe and respiratory illness data from low and middle income countries should be available mid 2017, based on the WHO Burden of Influenza Disease manual estimate methodologies.

Conclusion of the meeting:
The meeting concluded with a summary of the next steps for finalization and release of the manual following the meeting including:
Revision of the manual based on meeting inputs and circulation within the group, with publishing of pilot version online
ii) Development of e-learning course to improve country dissemination and uptake
iii) and pilot use of the manual in regions: EURO, SEARO, and potentially AFRO (South Africa) to inform national policy development processes, to help review existing policies, and to test manual tools and recommendations.
Technical Consultation—continued from page 6

Conclusions drawn from the meeting:

1. There is insufficient data on disease burden evidence and the economic impact the lack of evidence has on LIC and LMIC countries.
2. There is insufficient data on safety during pregnancy leading to vaccine hesitancy from pregnant women and health workers and low general uptake.
3. There are programmatic issues and lack of sufficient information and data evidence to guide decision makers on when to deliver the flu vaccine. Whether it is better to deliver year round or through campaigns. There is a need to take into account the timing of production.
4. There are various challenges in doing adequate monitoring coverage and AEFI/Surveillance for Flu.
5. Financial Sustainability is and will continue to be a big challenge for most countries.

Upcoming Meetings / Events:


⇒ August 17-19 2016: Geneva, Switzerland - 2nd Face-To Face meeting of the SAGE Working Group on MNTE and Broader Tetanus Control

⇒ August 25-26 2016: Geneva, Switzerland - Sage Working Group Meeting on Measles and Rubella

⇒ 18-20 October 2016: Geneva, Switzerland - Meeting of the Strategic Advisory Group of Experts (SAGE) on Immunization

⇒ 17-18 November 2016: Geneva, Switzerland - TAG Meeting WHO/PATH Maternal Influenza Immunization Project

A final word from the IPAC Secretariat

Special thanks are due this month to EPI Program Operations’ summer intern, Greg Lee, who prepared this edition of the IPAC Bulletin. Greg is a graduate student from the University of Southern California, working on his MPH. In addition to taking on the task of editing and formatting this month’s Bulletin, Greg has also been working on an IPAC briefing paper summarizing the current evidence in support of intradermal delivery of vaccines, as well as ongoing related work by WHO and partners interested in this area of work. We look forward to sharing his outputs with you later this summer.

In the meantime, we hope you will each manage to find some time to enjoy a well-deserved break this summer and we look forward to touching base with you in late August, during this year’s first IPAC teleconference. You will have noted that a Doodle-poll was recently sent out to determine the most suitable timing for this call. Please be sure to respond so that we can schedule the teleconference at a time that accommodates the majority of the Committee.

Wishing you all a very pleasant Summer.

The IPAC Secretariat Team