IPAC BULLETIN

April 2016

QUARTERLY UPDATE OF THE IMMUNIZATION PRACTICES ADVISORY COMMITEE

Volume 2, Issue 1 **WORLD HEALTH ORGANIZATION**

A note from the Chair:

Dear IPAC members and observers,

Welcome to the April 2016 IPAC bulletin, written at an historic time in global immunization – the tOPV to bOPV 'switch'.

We need you to "hit" us more! As we provide advice to WHO, we do need all members (and observers if they wish) to actively use the IPAC Discussion Forum hosted on the TechNet21 site for document review and discussion. I'm encouraged that recent posts by Anna-Lea, such as the draft IPAC strategy structure received 23 hits as people download and 6 replies as people give public comment; this compares to the zero hits received by some posts in November- so must represent some improvement!

Please especially note posts/ emails with the subject REVIEW REQUESTED and use the TechNet21 Discussions tab (under the Applications tab). If at all possible, please also provide brief comments in the discussion related to that document so others on the committee can see and react to what you think. If TechNet21 log-in is impossible for some reason – do please provide comments by email, and let Anna-Lea know you are still involved.

While logged in on downtown Yangon's dodgy internet, I've also noticed how often work presented to IPAC in the past re-emerges on other sections of TechNet21. Three examples over the past few months: the new annotated bibliography of **home based records** running out of Swiss Tropical Institute; new guidance on **solar vaccine fridges and freezers;** planning and supply chain for **outreach services;** and the final report of the "**Briefing on WHO Tools and Guidance on Immunization Data Quality and Vaccination Coverage Surveys**".

On IPAC's behalf, I attended the **SAGE meeting** – it was good to see a few other members there as well. Once again, SAGE spent a large amount of time dealing with issues highly relevant to immunization practices such as missed opportunities, second year of life and health systems integration. I have provided a brief summary from a practice perspective in this bulletin and you can also see the web-report at: http://www.who.int/immunization/sage/meetings/2016/april/SAGE_April_2016_Meeting_Web_summary.pdf and look for the formal report in the WER.

Thanks to all for your work through IPAC – look forward to seeing you online and via teleconference soon!

Chris Morgan

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Inside this issue:

New IPAC Call for Nominations launched.

As you may recall, we initially launched this process back in December 2015, when we posted an IPAC Call for Nominations with a deadline in early February. Our objective had been to fill the two seats vacated by Robert Steinglass and Shelley Deeks with persons who could bring new varied skills and experience to IPAC, better reflecting the broadening scope of the Committee's agenda.

Much to the IPAC Secretariat's dismay, the response to that call for nominations did not yield the calibre of applicants we were seeking and it was determined that it would be in the best interests of the Committee to refrain from selecting out of the February pool of candidates, in favour of a new, better targeted launch this Spring. The revised Call for Nominations was therefore published and circulated earlier this month (available also through the IPAC Discussion Forum) and carries a ***new application deadline of May 31st.***

In view of two more members (Jon Colton and Robin Biellik) reaching the end of their terms during the next quarter, we will be aiming to select four new members through this current round of nominations. It is therefore more critical than ever that you help us get the word out and not hesitate to propose appropriate candidates.

The Secretariat is looking for two types of new member:

a) Experts in target areas such as **new technologies for vaccine delivery** (injection devices or others), **regulatory pathways** for new vaccine technologies, **immunization program management reform** *or* **immunization policy**; and

b) Experts with deep engagement with **national or regional immunization programs**, and the **field realities of providing immunization services**.

Nominations from any geographic regions will be considered, but as you know well, we particularly could use experts with expertise in the South Asian and Western Pacific regions, and for increased female membership. We are also very interested in nominees with experience in applying implementation science or health systems research tools to immunization program issues.

> "We will be aiming to select **four** new members through this current round of IPAC nominations."

We are very mindful that Jon and Robin will be leaving some big shoes to fill. We look forward to your suggestions and to announcing the outcome of this round of nominations in the next IPAC Bulletin.

IPAC's strategic framework under development

The IPAC Secretariat remains committed to addressing the seven recommendations which emerged from the recently completed external evaluation of IPAC's functions, operational structure, and future potential. Among the most important recommendations was the Development of a 2-year IPAC strategic plan which presents more clearly the framework in which IPAC operates and deals with the outcomes of the evaluation, such as by spelling out a communications plan for the Committee and Secretariat, an agenda reflecting IVB subject priorities, as well as a clear set of performance benchmarks for the Committee.

> *The Committee's feedback next month on this draft document will be critical.*

As was announced through the IPAC Discussion forum, Burke Fishburn– who headed up the external evaluation team- has been commissioned once again to support IPAC by developing the initial draft of this strategic framework document. We believe he is best suited for this task, given his familiarity with the Committee, both in terms of history and evolution, as well as purpose and objectives.

The agreed timelines for the document's development are as follows:

1. ***Inception***—April 2016
2. ***Desk review*** — late April / early May 2016
3. ***Draft framework document*** — mid-May 2016
4. ***IPAC review of draft document***—mid-May 2016
5. ***Final report/framework document*** —late May 2016

VPPAG Transition - by Debra Kristensen, Dmitri Davydov, and Anna-Lea Kahn

To build on the successes of VPPAG, and in recognition of the significant changes recently implemented to the structure and functioning of IPAC, as well as the recommendations from IPAC's external evaluation with respect to clarifying and streamlining the Committee's functions and relationship with other advisory groups, WHO has been aiming to restructure the VPPAG's work streams to allow for stronger and more effective impact and reporting lines.

The VPPAG has served as a unique forum for public sector agencies and industry to discuss and reach consensus on vaccine presentation, packaging, and delivery issues in order to effectively support the development of products suited to low- and middle-income country contexts. The VPPAG also has responded to requests from industry, vaccine development groups, IPAC and other relevant agencies for consultations and guidance on specific product issues.

The VPPAG has largely been an independent entity to date that has reported progress to IPAC on a regular basis. In addition, the recommendations from the VPPAG's Generic Preferred Product Profile for Vaccines (gPPP) document have informed guidance and requirements within WHO's Assessing the Programmatic Suitability of Vaccine Candidates for Prequalification (PSPQ) document and process.

The following steps have been agreed on by the IPAC Secretariat and Chair, the VPPAG Secretariat and Chair, and relevant units within WHO:

a) **Consolidating the broader roles of VPPAG into IPAC**. IPAC, directly or through its respective subgroups, will now serve as the source of general information for vaccine industry members about immunization programme progress and issues, through existing IFPMA and DCMN representation.

b) **Moving the Delivery Technologies working group directly under IPAC**. This working group is dealing with primary container and delivery technologies and the recommendations from this working group can continue to inform the PSPQ which also reports to IPAC. The Delivery Technologies working group (DTWG) will also take on the role of providing initial informal consultations to stakeholders on specific delivery technology and primary container issues.

c) **Moving the Packaging working group under WHO's Essential Medicines and Health Products (EMP) department's oversight**, under the continued leadership of Denis Maire. This working group is focused on recommendations that will feed into WHO's Guidelines on the International Packaging and Shipping of Vaccines currently under review by the vaccine prequalification team within EMP. This working group will continue to include and work closely with industry to ensure strong communication and exchange of ideas and issues.

It is recognized that these changes will require some adjustments to facilitate a smooth transition. Working group memberships may need to be modified to ensure that all appropriate agencies and skills are brought to bear on the issues. The latter effort will be coordinated by the respective chair-persons. New working groups, such as one focused on the Con trolled Temperature Chain (CTC) will be formed as needed on a case by case basis through IPAC. While the existing gPPP stands as a relevant document for vaccine developers and may influence future versions of WHO's PSPQ, new recommendations from the working groups will flow directly into the PSPQ and relevant WHO guidance documents.

The transition process is to be considered complete at the end of April 2016.

Photo: Unicep - Blow-Fill-Seal Unit Dose

From the Working Group frontlines

Gitte Giersing:
A briefing from the new Delivery Technologies Working Group (DTWG)

On 7 April 2016, it was announced that the DTWG will report directly to IPAC, rather than through VPPAG. The DTWG evaluates novel primary container and vaccine delivery technologies, and where appropriate will collaborate with PSPQ to form recommendations for IPAC. The DTWG, co-chaired by PATH and WHO, is composed of global public health partners, vaccine manufacturers, device/technology developers, funders, PDPs and NGOs.

In the brief time since its inception in December 2015, the group has developed a Target Product Profile (TPP) for measles-rubella microarray patches (MAP), convened a workshop to discuss MAP product development including regulatory pathways and cost modeling, considered the optimal design for blow-fill seal (BFS) primary containers and integrated needle designs and is currently developing and evaluating a qualitative and quantitative framework to inform and aid decision making with regard to prioritization of novel delivery and packaging technologies. The group is currently providing feedback to BFS container developers and defining the critical characteristics for this types of packaging. In the coming months, the DTWG will be seeking feedback from IPAC on the MAP TPP, as well as PATH's technology prioritization framework, and the total system effectiveness framework that is currently under development to provide a comparative evaluation of the commodity and system costs for the current vaccine/technology presentation compared to a new presentation.

Reflections from SAGE April 2016 - by Chris Morgan

Some high level themes I noticed:

"global health security" is increasingly used as a concept to frame many discussions; **vaccination in emergencies** or conflict have challenged existing plans but also enabled innovation; recurring discussion on **stockpiles** and rapid response plans provoked by outbreaks and by global vaccine shortages; that the technical blueprint for **rapid research response** in emergencies is now more mature; and an iterative discussion in the chairs' meeting on the **private sector** as a group increasingly important as immunization provider, source of information, and potential disrupter in resource-constrained settings.

Two new vaccines were discussed. Prevention of **respiratory syncytial virus** infection is arguably the most active research pipe-line of relevance to WHO. The different types of vaccine and immunological products under development have wide variation in implementation strategy, ranging from maternal immunization, newborn/birth-dose administration, to provision alongside the primary schedule. These vary in efficacy, so future decision making will need to balance this with programmatic considerations.

On **dengue,** SAGE discussed the implications of phase 3 trials in 10 countries in Asia and Latin America, and modeling of potential impact of the CYD-TDV (Dengvaxia®) product, now licensed in 5 countries and introduced in Philippines. This needs to be given in children over nine-years of age – accessing the emerging 'adolescent platform' –and more data is to come on co-administration with other vaccines designed for this age group. SAGE recommended that countries consider introduction in populations where seroprevalence is high (70+%, or at least 50+%).

April 2016 SAGE - WHO/C. Corsini

Implementation research and health systems integration had a dedicated session, and were mentioned throughout SAGE, with a stronger call to embed this in all new vaccine research. I emphasized the need to clarify which research tools are most useful to research rigor in implementation evidence, and links to good programme evaluation. More evidence is going to be needed for newer vaccines on implementation feasibility and cost-effectiveness, especially when they require new "immunization platforms": such as the adolescent platform. For example, it seems that some countries find that school-based vaccination is an expensive a way to deliver HPV and need alternatives.

Work on the **second year of life platform**, essential to measles second dose (and other new vaccines such as the malaria RTS,S) is much more advanced than when we reviewed it last October, and I am especially keen to see this coming back to IPAC for review over the next month or so. Some SAGE members saw this platform as needing an explicit linkage back to comprehensive primary health care. (*A more detailed summary of this session by Rudi Eggers appears below.)*

SAGE also heard an update on work on **missed opportunities** for vaccination. The new strategy documents include a planning guide, revised assessment protocol, and intervention handbook – a very structured data-driven process. Case studies illustrated testing of the approach including, from Malawi, the contribution of home-based record as a health passport required for all consultations. (*A more detailed summary of this area of work by Ike Ogbuanu appears on page 5.)*

The session on **global vaccine shortages** soberingly noted roughly 60% vaccines in shortage or at risk of shortage – especially "older" vaccines, and with the example of IPV fresh in everyone's mind. All partners in the room, including industry were calling for increased global discussion on supply and demand issues. The *Linksbridge* tool for the Global Vaccine Market Model - developed in 2015, is soon to be publicly available to help improve transparency and forecasting of vaccine needs. I found encouraging the conclusion that the OPV switch can proceed despite IPV shortages, and the demonstration of the key global coordination role of UN agencies – in this case by the prioritization of countries on the basis of infection risk rather than markets.

SAGE supports 2YL guidance - by Rudi Eggers

Information was presented to SAGE on creating guidance to national programmes to establish routine healthy child visits during the second year of life (2YL). There are multiple benefits to establishing a strong platform for immunization and other interventions in the 2YL. Firstly, it provides for an additional routine contact for vaccination in the 2YL to delivery primary vaccination doses, booster doses and second doses. Secondly, a routine visit in the 2YL will allow an opportunity to deliver missed vaccine doses offered in the first year of life through catch-up vaccination. Thirdly, such a routine visit creates opportunities to integrate with multiple other health interventions, and reinforces good Primary Health Care (PHC) practice.

The presentations outlined the planned project to develop guidance, gathering experiences and learnings from two countries (Zambia and Senegal), describing the challenges Zambia faced with the introduction of the routine measles second dose, and the process it followed in identifying shortcomings and defining additional strategies to improve the programme delivery. The Zambian Ministry of Health initiated a process to address these challenges, focussing on the development of policies and guidelines, improvement of data collection and recording tools, assuring the availability of the necessary commodities at the point of service delivery (including the non-vaccine commod-

2YL update - *continued from page 4*

ities required to deliver a comprehensive healthy child service) and community engagement and communication.

The global landscape analysis and literature review provided insights into experiences from many countries on routine visits in the 2YL, highlighting the gap between doses given by the end of the first year of life and those delivered beyond. While many countries have introduced a 2YL visit, it is found that there is a large vaccination drop-out to doses given in the first year of life, opportunities of catching-up missed doses are a major cause of lower 2YL coverage, frequently vaccines are given at different times during the 2YL, not together and frequently other health interventions in the 2YL are poorly integrated with the vaccination visit. SAGE supported the development of this guidance, highlighting the need that this work is strongly supportive of a continued revitalization of a comprehensive Primary Health Care approach, ensuring that the immunization service requirements are firmly imbedded into a broader delivery of health services appropriate for this age group. The increasing complexity of the schedule requires better guidance to health workers on how to decide on eligibility of vaccines, especially for children that had missed earlier doses. While WHO has developed recommendations to deal with "interrupted or delayed schedule", countries should be supported to develop easy to understand job-aids or decision flow charts to deal with such event, allowing the health worker to make appropriate vaccination catch-up decisions. Recording and reporting tools should be revised to assure that data are collected adequately, and the forms do not communicate false policy directions. Finally the expansion of electronic immunization registries would greatly facilitate the proper understanding of the programme in the second year of life. SAGE requested that the final guidance developed for this work to be reviewed by the Immunization Practices Advisory Group and then sent to SAGE for endorsement.

Reducing Missed Opportunities for Vaccination: A concrete strategy to improve coverage and equity - by Ikechukwu Ogbuanu, IVB

Concerned about stagnating immunization coverage, during its October 2014 review of the GVAP Progress Report, SAGE recommended studies to understand how opportunities to vaccinate people are being missed by health-care workers and their systems, and action to markedly reduce their incidence. [1]

A missed opportunity for vaccination (MOV) occurs when a person eligible for vaccination, and with no valid contraindication, visits a health service facility and does NOT receive all recommended vaccines. The number of MOVs in some countries is huge, and globally the pooled prevalence of MOV was estimated at round 32% for children.[2,3] With relatively very little effort or cost (compared with reaching children who have no access to the health system), ensuring that all visitors to health centres are vaccinated can have an important impact on raising coverage of national immunization programmes.

WHO has recently updated the protocol and tools for conducting MOV assessments, as well as the guidance for follow-up interventions. These consist of a Planning Guide outlining the 10-step process; a detailed MOV Assessment Protocol; and an Interventions Handbook. In collaboration with WHO Regional Offices, MOV assessments have been undertaken in the Dominican Republic, Panama, Peru and Colombia (Bogota), Chad and Malawi and are in the planning stages for several more. This effort to re-launch and expand the use of MOV strategy has generated interest from a number of partners, and WHO has convened a partner coordination framework to support the scale-up of the MOV strategy and amplify its impact.

Malawi MOV focus group - WHO/I. Ogbuanu

The data accumulated so far show compelling evidence that children attending health facilities for vaccination, clinical care or other reasons were not offered the opportunity to receive all the vaccines they need (up to 57% for all clinic attendees; up to 25% for children attending for vaccination and up to 89% among those attending for medical consultation). The reasons for MOVs were mostly attributed to health workers (above 60%), as well as to caregivers (27%) and health services (11%). Lack of integration of services was highlighted by the very high proportion of children attending for treatment who were never referred for vaccination. Related to this is the importance of vaccination records. Home-based records/child health cards in use can affect the ability to verify vaccination status (child health passports which must be brought to every clinic visit vs. child vaccination cards used for immunization services only). A key feature of the new MOV strategy is that data collection is designed to lead to action through the identification of locally appropriate solutions and the development of work plans to reduce MOVs. To ensure sustainability these are accompanied by supervision and long-term impact monitoring and should be part of health system strengthening plans and applications.

References

1.Meeting of the Strategic Advisory Group of Experts on immunization, October 2014 – conclusions and recommendations. Weekly epidemiological record, 2014;50 (89):561-579.

2.Hutchins, et al., Studies of missed opportunities for immunization in developing and industrialized countries; Bulletin of the World Health Organization, 1993;71 (5):549-560

3.Sridhar, et al. A systematic literature review of missed opportunities for immunization in low- and middle-income countries. Vaccine 2014; 32:6870–6879

Dose per Container Partnership (DPCP) launched - by Craig Burgess, JSI

The issue: Multi-dose containers are used to offer lower prices, higher supply volumes, and minimize cold chain storage and distribution requirements. As new, more expensive, vaccines are introduced in multi-dose presentations, maximizing the use of every dose in a container increases in importance. HCWs need to be more strategic about when to open a container; diligent about how they care for open containers, and potentially more active with communication and community outreach to ensure optimal attendance and timely vaccination of every child. Thus, the number of doses per container (DCP) may also impact on health systems in terms of timely, safe and equitable vaccination coverage, supply and cold chain, wastage rates, cost and HCW behavior.

Immunization stakeholders need information and tools to assess which dose per container presentations are appropriate for a country's specific context and priorities.

Initial 2015 response: With Bill & Melinda Gates Foundation (BMGF) funding, JSI Research & Training Institute, Inc. (JSI) helped identify evidence gaps by interviewing key stakeholders and analyzing existing research. An informal network of partners interested in advancing this work was created after a consultative meeting in July 2015.

Launch of the partnership: The Dose Per Container Partnership (DPCP) was launched in March 2016 as a project, funded by the BMGF and implemented by JSI in partnership with PATH, Agence de Médecine Préventive (AMP), Clinton Health Access Initiative (CHAI), HERMES modeling team and the International Vaccine Access Center (IVAC) / Johns Hopkins University. The DPCP aims to address the complexity of vaccine product and program decision-making to include DPC considerations. Understanding and assessing the trade-offs between cost and health impact allows better informed decisions about the impact of the dose per container selected.

DPCP objectives and work streams: The DPCP project will run from February 2016 – December 2017, guided by a Technical Advisory Group (TAG), and aims to achieve two objectives:

i. To gain a deeper understanding of the decision making processes, trade-offs, data and tools used to assess DPC decisions at global and national levels in order to recommend process improvements;

ii. To provide guidance and tools including trade-offs to be considered by countries and facilitate;

iii. sharing of best practices for country level decision makers.

These will be implemented through three technical work streams:

i. A global cross-country review of current DPC-related decision making tools and processes;

ii. Prospective research studies in two African countries will include data collection to improve modeling efforts, economic analysis and see the actual effect on the various systems variables; and

iii. Synthesis of data supporting global level policy and country decisions.

Stakeholders: DPCP aims to inform, support and influence stakeholders at:

a) *Global level,* by providing evidence that fills critical gaps in knowledge, analysis, and policy. This includes ensuring that stakeholders will continue to be informed about sustainable decisions on DPC when considering vaccine products and program designs; and

b) *Country level,* by producing easy-to-use and -understand guides and tools to assess DPC tradeoffs, including cost and systems impact to inform vaccine product selection

Information about the DPCP will be made available through partners engaged with the project, the JSI website, announcements via the TechNet forum and various formal and informal opportunities where immunization practitioners meet globally, regionally or nationally.

(*The first announcement about DPCP on TechNet21 is available through the following link:*

http://www.technet-21.org/en/forums/dose-per-container-partnership-dpcp-launched)

DPCP
DOSE PER CONTAINER PARTNERSHIP

WATCH THIS SPACE: New IPAC Working Group on CTC under development

With a fourth vaccine recently being licensed for use in a **Controlled Temperature Chain (CTC)** and a growing number of countries expressing interest in this innovative approach to cold chain management during the critical last mile, the CTC agenda has been garnering momentum and therefore requires strategic guidance today, more than ever. It has therefore been agreed that a new IPAC subgroup should be established, similar in structure and function to the Delivery Technologies Working Group.

The mission of the CTC WG will be to convene key stakeholders to define a shared vision and strategy for CTC and to increase advocacy for this innovative approach. The working group will serve as a platform to engage in a constructive dialogue with countries, manufacturers and regulatory authorities to identify demand and priorities.

The specific terms of reference are still under development and a draft will be shared with the Committee as soon as available. In the meantime, any IPAC members or observers interested in participating in this CTC Working Group are invited notify Anna-Lea Kahn.

For more information on CTC, please consult the WHO/IVB website at the following link:

http://www.who.int/immunization/programmes_systems/supply_chain/ctc/en/

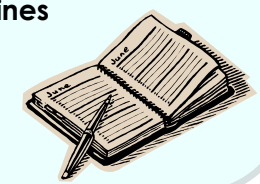
Upcoming Meetings / Events:

⇒ May 4-5, 2016:
Geneva, Switzerland – **Consultation for Guidelines on quality, safety and efficacy of Ebola vaccines**

⇒ May 16-20, 2016:
Rome, Italy - **Vaccine Management and Handling Workshop & WHO/UNICEF iSCL Hub Meeting**

⇒ May 30 - June 1, 2016:
Montreux, Switzerland – **Immunization and vaccines related implementation research advisory committee (IVIR-AC) Meeting**

⇒ June 14-15, 2016:
Geneva, Switzerland – **Expert consultation on implementation of SAGE recommendations on Dengue Vaccines**



A final word from the IPAC Secretariat

A key piece of the Secretariat's efforts in the past three months has been the definition of an **agenda for IPAC** which reflects the priorities of the IVB department and remains aligned with recommendations emerging from SAGE, while still fitting appropriately into the Committee's mandate and capacity. You will shortly be invited to comment on this agenda and the associated potential outputs, as well as the proposed mechanisms by which different subject matter can be tackled by IPAC. This will most likely be followed by the scheduling of a **teleconference in early July.**

In the meantime, many of you continue to query when the Committee will next meet face to face. As you know, under the Committee's new modality, such meetings take place every 12 to 18 months, depending on needs. We still remain confidant that much of our work can be carried out effectively through virtual mechanisms, with a principle one being the IPAC Discussion forum hosted by the TechNet21 website. Nevertheless, we are planning for our **next meeting** to take place during the third week of **February 2017**. Feel free to mark your calendars accordingly and we will notify you of any changes to those plans.

The IPAC Secretariat Team