IPAC BULLETIN

April 2015

QUARTERLY UPDATE OF THE IMMUNIZATION PRACTICES ADVISORY COMMITEE

Volume 1, Issue 1 WORLD HEALTH ORGANIZATION

A note from the Chair:

Dear IPAC members and observers,

Welcome to the first IPAC newsletter – I do hope this message finds you well and thriving in your many varied roles in global health. Both 2014 and 2015 are years of transition for the type of advisory service that IPAC provides to WHO and to global immunization more broadly. It is encouraging that there is continued commitment to ensuring high level advice on what represents good practice or useful innovation in the implementation of immunization programmes. This commitment is reflected in the support we receive from our WHO secretariat of Anna-Lea Kahn, Diana Chang Blanc and Giselle Richardson, working under Michel Zaffran's leadership in EPI, and in the renewed funding from the Bill and Melinda Gates Foundation.

IPAC members are increasingly called upon to serve as members or contributors to other working groups, often those formed to advise SAGE, as you'll see in other reports in this newsletter. I think that it is crucially important that such groups hear the viewpoints of practitioners such as yourselves whose expertise has been forged in the field: whether through managing, implementing or researching quality improvement of immunization programmes – especially those striving to provide services under difficult resource constraints. It is my hope that the "IPAC voice" is one that helps such groups consider any innovation's operational feasibility, acceptability to staff and clients, likelihood of benefit to vulnerable or unreached populations, and any likely impacts (either good or bad) on routine immunization and the broader primary health care system.

It is also my hope that, as a group, we will continue to make increasing use of rigorous public health evidence, especially in the fields of implementation science and health policy and systems research, and that we will have a role in stimulating more research into programme implementation. One example: several years ago, SAGE commissioned research into the effects of new vaccine introduction on health systems in general and immunization programmes in particular. This evidence went beyond the published systematic reviews (as all evidence should!) to inform an IVB guidance document *"Principles and considerations for adding a vaccine to a national immunization programme"* (that many of you may know). I've appreciated the annex that pulls the evidence together into a short summary of some examples of how vaccine innovation can be used to help strengthen health systems, based on solid programmatic evidence.

Our contributions to global immunization go beyond working groups and the IPAC meeting coming up this October. We often provide review and comment on a variety of draft guidelines or evidence reviews. Many thanks to all of you who manage to overcome the tyranny of overflowing in-boxes to respond in a timely way to emails and requests for document review. These highly valued inputs are important contributions that IPAC members are making alongside those other WHO advisory bodies that support immunization – safety, biological standards, implementation research, new product development, and SAGE.

I hope you enjoy reading through this newsletter, and please do feel free to contact me or the WHO's Secretariat on any topic at any time.

Kind regards,

Chris Morgan

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Inside this issue:

"We are delighted to welcome to IPAC: **Craig Burgess**, **Brad Gessner,** and **Adelaide Shearley**."

Three New Members join IPAC

Throughout January and the first half of February 2015, the IPAC Secretariat received numerous responses to the IPAC Call for Nominations that was circulated widely through the global immunization community and published on the WHO/IVB website, the TechNet announcement forum, and in the Global Immunization Newsletter, released monthly by WHO.

Following a rigorous review of the applications by a WHO Selection panel which included senior EPI staff, the IPAC Secretariat and IPAC Chair, the three most highly qualified candidates were issued invitations by Dr Okwo-Bele, IVB Director, to join IPAC as official members.

We are delighted to welcome to IPAC: **Craig Burgess**, **Brad Gessner,** and **Adelaide Shearley**.

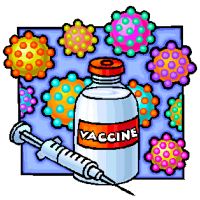
A brief biography of each will soon be made available on the IPAC page of the WHO/IVB website and these new members should shortly be joining the IPAC Group on TechNet through which you can dialogue with them.

From the Working Group frontlines

Robert Steinglass on the *Immunization Systems Management Group* (IMG) WG:

The main suggestion of our review of the Communication Planning Guide for IPV Introduction and Routine Immunisation Strengthening was that the guide point out that each country's communications plan and activities reflect its specific situation, since the levels of planning and scope of the suggested communication activities seemed too ambitious and/or too extensive for the needs of many countries. In a country with high coverage and no significant vaccination hesitancy, the communications efforts can be relatively modest: provide basic information on the change and the reason, and prepare health workers and others to respond to any questions or concerns of parents of others (assuming the formative research does not reveal any major resistances). In a country with low coverage, the introduction can be an opportunity to promote RI in general in a big way. In a country with a lot of anti-vaccination sentiment, the communication effort would need to be much more intensive and extensive. The final version does reflect this suggestion.

Shelley Deeks on the *Global Advisory Committee on Vaccine Safety*:



The following link is to the minutes from the December 2014 meeting of the GACVS. I could not attend in person.

http://www.who.int/wer/2015/wer9004.pdf

The topics included preparing for both dengue (live) and malaria vaccine, as well as safety of Ebola vaccines undergoing clinical trials. Performance indicators for vaccine safety monitoring systems were also discussed (ie globally accepted indicators which could demonstrate the functionality of an AEFI surveillance system). The aim will be for all countries to achieve a minimal threshold of AEFI reporting and then to progressively attain one or more of the more advanced indicators.

The final two items discussed were safety of vaccines used in pregnancy and criteria for assessing websites with vaccine safety content.

Chris Morgan on the *SAGE WG on deployment of new Ebola vaccine candidates:*

This group was established in November 2014 - there have been regular teleconferences and one face-to-face meeting in March 2015. The group, chaired by Helen Rees, is intended to work concurrently with other global coordination and oversight of current vaccine trials in the countries most affected by the outbreak. The aim is to ensure there is a SAGE recommendation on vaccine deployment ready to go once one or more new vaccines are authorised for use, either through formal licensing or under emergency listing provisions. It is a challenge coming up with the formulation of a recommendation while efficacy and safety data are still being collected. It is also a challenge to ensure that we are obtaining sufficient programmatic data to ensure that the recommendation takes due account of the need for vaccine interventions to strengthen, not weaken, other public health and health system initiatives that are essential to the control of the outbreak. The group is still working, and will provide an interim update to the SAGE meeting in April.

Chris Morgan on the *SAGE WG on Japanese Encephalitis Vaccines*:

IPAC preparation for 2014 participation in this WG included collating evidence on the programmatic implications of new JE vaccines under consideration, and we were able to present a short briefing paper on this topic to the working group.

To help organise our data collection we developed a programmatically-oriented analytic framework with key questions for each new vaccine on their potential implications on a) the immunization supply chain, and b) the immunization programme and broader health system (see table). We also conducted a brief literature review on what was published on JE vaccine programme experiences. This was more preparation than is common for WG involvement, but the IPAC secretariat provided some resources, particularly time from a consultant Ryan McWhorter, to help make this possible. The input was appreciated by the SAGE WG and the updated SAGE recommendation was published late in 2014.

Supply Chain questions looked for impact on	*Programme or Health System questions looked for impact on*
Storage Capacity	Service delivery
Supply chain human resources	Human Resources
	Medical technologies
Distribution Capacity	Information Systems
	Vaccine Financing
National receiving and distribution schedules	Leadership & Governance
	Community Engagement

Francois Gasse on the WG on Maternal influenza vaccination:

This WG was aiming at developing/reviewing a draft detailed guidance for programme managers to introduce Maternal Flu vaccine with a specific emphasis on sub-Saharan African countries building those operational guidelines on the SAGE position paper asking to prioritize Flu vaccine for pregnant mothers and on disease burden evidence available. For that meeting, I prepared a 9 page document and a presentation on lessons learned from Maternal TT immunization. My key concluding messages were:

- Endorsed data on disease/death burden was essential for advocacy commitment and ressources mobilization at all levels and that countries and policy makers commitments heavily depends on availability of data (efficacy , safety of the vaccine and cost effectiveness in preventing death.
- Vaccine Delivery schedule and strategies to reach pregnant women had to tailored to country and district situation.
- Having a goal and measuring immunization coverage and impact was critical for long-term effective implementation.
- Crises and false rumors will occur and need to be anticipated and managed.
- Clear responsibilities / accountabilities are required to en sure effective joint implementation and surveillance efforts by MCH, EPI and MNCH.

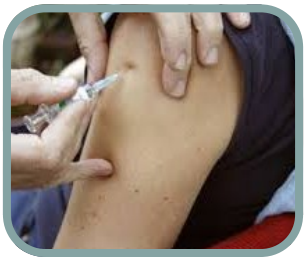
Many of the key element listed above are still unclear but so important programmatically that they have to be on the agenda of the SAGE working group and IPAC members can play a critical role.

Francois Gasse on the HIV WG on tetanus post medical circumcision:

This informal consultation on tetanus linked to Voluntary Medical Male Circumcision (VMMC). VMMC has been promoted and implemented in 14 priority countries of East and southern Africa with generalized HIV epidemics. By the end of 2008, an estimated 8 million circumcisions had been performed in male populations aged 15 to 49 years, using traditional surgical procedures and innovative methods using circumcision devices. Nine cases of tetanus occurred post VMMC. WHO's HIV department, along with the prequalification team of Essential Medicine and Health Products (EMP) and the IVB department convened a consultation to advise on the potential risk and risk management of tetanus associated with circumcision.

I was a participant and was asked to make a presentation on the pros and cons of alternative strategies to prevent tetanus, including hygiene, TT vaccination or both, with a particular emphasis on the potential role and limitations of immunizing males doing VMMC with tetanus vaccines. A minimum of 2 doses of TT vaccines one month a apart provide protection if a second dose is administered 15 days, ideally before the intervention , 7 days providing some protection. The major Tetanus immunity gap in male populations compared to female populations was highlighted as males only receive 3 doses TTCV during infant year that provide 5 to 7 years of protection only.

It was advised that tetanus vaccine administered to adolescent and young male adults would reduce the risk of tetanus in unprotected adolescent and adults and to assess and determine effective and practical strategies in the context of male circumcision. In a vaccine-naïve individual, a single priming dose would be inadequate as 2 doses of TT vaccine a month a part are needed for protection. However, it was advised to give a TT booster dose at least 7 days before intervention to allow some development of immunity for primed individuals. The operational challenge in the short term to protect males against tetanus was highlighted and the need to eliminate the immunity gap between males and females through school booster doses was recommended.



IPAC WORKING GROUP PARTICIPATION	
NAME	**WORKING GROUP**
Antwi-Agyei , Kwadwo-Odei	IPV implementation / tOPV-bOPV switch, Pain Mitigation during vaccination.
Biellik, Robin	PSPQ (Programmatic Suitability of Vaccine Candidates for WHO Prequalification)
Colton, John	VPPAG WG on Packaging
Deeks, Shelley	PSPQ, Vaccine Safety
Gasse, Francois	Maternal Immunization against influenza, HIV WG on tetanus post medical circumcision
Morgan, Chris	Ebola, IVIRAC
Olive, Jean Marc	Maternal Immunization against influenza, Measles, Multiple Injections WG
Steinglass, Robert	IMG, SAGE-ISCL, VPPAG
Vizzotti, Carla	Maternal Immunization against influenza

Volunteers for further WG representation are invited to present themselves to the IPAC Secretariat.

New from PSPQ - By R. Biellik

At the last IPAC meeting, (June 2014) the PSPQ SC was tasked to review 6 vaccines that were prequalified before the current PSPQ guidelines were implemented and that are not in compliance with one or more of the PSPQ criteria. For each vaccine, briefing notes were provided by the WHO Secretariat and vaccine supply data were provided by UNICEF Supply Division. The SC has reviewed the first 2 vaccines, recommending that prequalification should be retained for one vaccine and withdrawn for the other. The SC is currently finalizing the review of the next 2 vaccines. It is anticipated that all 6 reviews will be complete by mid-April 2015.

The PSPQ guidelines had been revised in 2014 and the new guidelines are now published and have come into effect from January 2015 onwards. The revised document can be found at:

http://www.who.int/iris/bitstream/10665/148168/1/WHO_IVB_14.10_eng.pdf

The most prominent changes in this revision was a reworking of the preservative efficacy requirement in multi-dose vials, bringing the testing into line with existing international standards.

VPPAG Highlights - by D. Kristensen & D. Davydov

The Vaccine Presentation and Packaging Advisory Group (VPPAG) has updated its generic Preferred Product Profile (gPPP) for Vaccines, which provides evidence-based recommendations for vaccine producers and developers on the presentation and packaging of new vaccines for use by public-sector programs in developing countries. The updated gPPP contains new and updated recommendations on the following topics:

VPPAG Members at the October 2014 Face to Face Meeting in New Delhi, India.

- heat stability and labelling vaccines for short term higher temperature storage
- prefilled injection devices
- primary container labels
- secondary carton and tertiary packaging labels
- barcoding on secondary and tertiary vaccine and diluent packaging
- package inserts
- dimensional standards for primary, secondary, and tertiary packaging for vaccine products in vials
- packaging materials

These recommendations were reached through a consensus process inclusive of public sector and vaccine industry (both IFPMA and DCVMN) representatives with the intention of ensuring that future vaccine products meet the programmatic suitability needs of developing countries in a manner that is technically and economically feasible for industry.

2015 Agenda

Following its work on the gPPP and PSPQ recommendations, VPPAG members identified 3 priority technical areas for the group's 2015 work plan:

1. Vaccine Packaging (in particular, the bundling of

VPPAG Highlights (cont'd from page 4)

multi-component vials, the future of packaging inserts, and the programmatic and environmental considerations for tertiary packaging);

2. Use of barcoding on secondary and tertiary packaging (containing GS1-standardized GTIN, expiry date and lot data) to support ongoing and future country-level work to strengthen national health management systems, and

3. Delivery technologies and devices.

New VPPAG Terms of Reference.

During a Face to Face Meeting of the VPPAG held in New Delhi, India in October 2014, the governance and operating structure of the group were reviewed and proposed revisions to the TORs agreed on.

The revised TORs can be found on the VPPAG page of the WHO/IVB website.

Other immunization news:

The International Initiative for Impact Evaluation (3ie) will issue a request for proposals (RFP) under its *Breaking through stagnation: testing innovations in engaging communities in increasing immunisation coverage programme* on 21 April 2015. Proposals will be invited to test innovative approaches for engaging communities to increase immunisation coverage and to support formative evaluations and impact evaluations of these approaches.

3ie has posted the draft RFP on its website. This draft RFP will be reviewed at 3ie's consultative workshop on 9 and 10 April in London, where participants' comments will be collected. If you are not one of the attendees of the workshop but wish to comment on the RFP, please send your feedback to tw10@3ieimpact.org by 23:59 GMT, 14 April 2015 mentioning 'Comments on RFP' in the email subject line. 3ie will review all comments by 15 April 2015.

To download the draft RFP click on the link here:
http://www.3ieimpact.org/media/filer_public/2015/04/02/3ie_immunisation_rfp.pdf

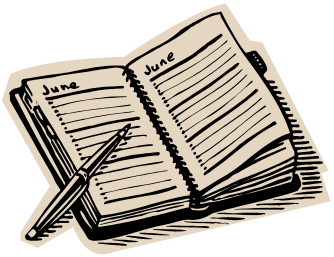
Upcoming Meetings / Events:

⇒ **SAGE Meeting:**
14-16 April 2015
Geneva, Switz.
Draft Agenda

⇒ **14th TechNet Conference:**
12-15 May 2015
Bangkok, Thailand

⇒ **3rd Annual Vaccine Management and Handling Workshop:**
17-20 May 2015
Hua Hin, Thailand

⇒ **WHO Global Meeting on Protect, Innovate, Accelerate (PIA) Immunization:**
23-25 June 2015
Barcelona, Spain



A final word from the IPAC Secretariat

As we adapt to the Committee's format of functioning, you are reminded that an important new component of IPAC's revised modality is to partially replace the face-to-face meetings formerly scheduled twice per year with a more frequent "virtual" dialogue and exchange by way of a dedicated forum on TechNet. To this end, we encourage you to visit this page more often and the few remaining members who have yet to join the group (or TechNet), are invited to do so as soon as possible. Detailed instructions on how to join were shared by email. Please contact Anna-lea Kahn, of the IPAC Secretariat, should you require renewed or further guidance.

The Secretariat is also working on improving IPAC's online presence through revisions to the IPAC page on the WHO/IVB website. Suggestions from the group are most welcome. In the meantime, we are tackling the membership list, which we would like to upgrade with both new bios and recent photos of each member. We would therefore request that you send us a short paragraph and digital passport photo in order to complete this task by the end of April 2015.

Last but not least, your thoughts and feedback on this first issue of the IPAC Bulletin would be most appreciated. The next Bulletin will be published in July 2015.

Sending you all warm Spring greetings from Geneva.

The IPAC Secretariat Team

TechNet-21
http://www.technet-21.org