1. Opening and Introduction

Dr Shelley Deeks (chair) opened the meeting. Dr Christopher Morgan from the Burnet Institute in Melbourne Australia and Dr Jean-Marc Olivé, an independent consultant, were welcomed as new IPAC members. Dr Jean Marc Olivé was unable to attend this meeting. Dr Osman Mansoor from UNICEF was welcomed as an observer, replacing Dr Jos Vandelaer. Dr Shelley Deeks' term as Chair of IPAC was extended and she has agreed to chair the IPAC meetings for the next two years.

The minutes of the previous IPAC meeting were approved unanimously, without changes.

Diana Chang Blanc, WHO Technical Officer returning from UNICEF secondment, was introduced as EPI staff person newly appointed to support the IPAC Secretariat.

2. Finalisation of visual cue

2.1 Report of the visual cue sub-group to select final pair (Robert Steinglass, IPAC)

The visual cue has been discussed at all three previous IPAC meetings. One recommendation from the April 2011 meeting was for the Visual Cue Sub-group (VCSG) to collaborate with industry to further refine the chosen visual cue pair, in order to ensure maximum readability and feasibility of print. As a consequence, the VCSG members, in collaboration with vaccine manufacturers, deliberated over seven graphic features of the chosen pair and reached consensus on the final design features.

VCSG proposed for acceptance by IPAC the preferred icons to discard the vaccine 6 hours after opening the vial, alongside its alternate of 8 hours, as illustrated below:
The preferred icons to discard 28 days after opening the vial with the alternate for discarding 14 days after opening are illustrated below:

![Preferred Icons](image)

The VCSG proposed to IPAC members that the preferred icons, as displayed above, be accepted as the final visual cues for use in the field-pilot. The dimensions of the visual cue for the 6 hour icon was proposed to be 7 mm (height) and 5.4 mm (width), and the dimension for the 28 day icon 3.8 mm (height) and 8 mm (width).

Vaccine vials with mock labels which included the visual cues were circulated among meeting participants by Rudi Eggers.

**Discussion**

An observation was made that the preferred icons appear different to Pair A which had been agreed upon by IPAC members in April. However, as the task of the sub-group was to improve readability and feasibility of print, it was believed that the group stayed within the boundaries of its assignment. The proposed preferred icons were chosen unanimously among the subgroup members and industry as improvements on the legibility, especially with respect to the small print size.

Industry offered to assist by printing the visual cues on actual labels in printable formats prior to launching the field-pilot test, after remarking that the mock labels would not be acceptable under standard guidelines as the visual cues were situated too close to the labels' edge. This offer was acknowledged and welcomed. The proposed dimensions of the cue were based on the parameters of the Vaccine Vial Monitor (VVM) (7 mm x 7 mm). The calendar icon needed to be slightly increased from this reference point to improve legibility. Discussion was held on the type of label that would be used for testing and the positioning of the visual cue, particularly in relation to VVM placement. Industry requested very clear directives on this matter.

Suggestions were made to run a legibility test among 'naive' subjects (i.e., not health workers) as a preliminary step; this was deemed acceptable but unnecessary since legibility will be queried by health workers during the pilot. It was also suggested to align the pilot test with principles articulated in the initiative from Vaccine Presentation and Packaging Advisory Group (VPPAG) on standardizing vaccine labels, such as minimum font size and type or expiry date format. To the extent possible, the recommendations of VPPAG on standardization of labels can be applied, but not at the expense of delaying the visual cue pilot.

Concern was expressed that the calendar image was not completely intuitive, particularly the alternate of 14 days.

In response to the mock labels, meeting participants were generally positive about the appearance of the visual cues. It was suggested to increase the size of the number 6 on the
turned hours sample and to leave some space between the arrow and the "X" to increase legibility; to permit where possible adequate space for health workers to write the time/date of the opening of the vial, in accordance with the multi-dose vial policy; and to ensure adequate training of health workers to interpret the visual cue.

**IPAC recommendations and decisions**

1. The preferred icons proposed by the VCSG are accepted as the final visual cues for the field pilot. (*Vote: 10 members in favour and 1 abstention*)

2. The target dimensions should be guided by 7 mm by 7 mm (VVM dimensions), but the exact specifications should be subject to a legibility and printability assessment. (*Vote: unanimous consensus*)

3. Jon Colton and industry will collaborate on designing and printing the visual cues on a complex label (i.e., multiple language and VVM included).

4. The VCSG will review the visual cue labels after printing and decide on the format to be pilot-tested. VCSG requested genuine vials with printed labels rather than email attachments for deliberation.

**2.2 Progress with visual cue field piloting (Rudi Eggers, WHO)**

It is difficult to find the appropriate country / vaccine combination that would fit this pilot. The 10-valent pneumococcal conjugate vaccine (PCV-10) is an option but introduction is already underway in Kenya and Ethiopia. The 13-valent PCV (PCV-13) introduction is not an option because it is a single dose vaccine. Rotavirus vaccine is not an option because it is a mono-dose oral presentation. Human papillomavirus (HPV) vaccine targets a completely different age group (adolescents) and/or settings (school programmes) different to routine childhood immunisations.

One suitable candidate is the typhoid vaccine; WHO has identified typhoid as one of the priority communicable diseases to be controlled. Several countries have already introduced typhoid vaccine, particularly in the Asia-Pacific region. One could expect that if GAVI eventually supports typhoid vaccine, its uptake by countries could be more wide-spread.

The Typhoid vaccine (TYPHIM Vi) candidate is a Sanofi-Pasteur product that has been pre-qualified since the 1st of June 2011. It is a liquid injectable vaccine which contains phenol as preservative, comes in a 20 dose vial with a VVM30, and is labeled to be discarded 6 hours after opening.

IPAC was requested to give guidance on the purpose/objectives of the pilot and the potential vaccine chosen. It was also requested to provide input into the Request for Proposals that will need to be developed for the field evaluation and the end-point criteria of acceptance.

Rudi Eggers made a request of regions, countries and vaccine manufacturers to support the pilot study.

**Discussion:**

It was noted that testing of the visual cue on the typhoid vaccine will only test ‘one-half’ of the proposed visual cues -- the six hour limit. For testing the calendar image, another vaccine and perhaps a second country will have to be identified. Prioritization thus far has been on testing the six-hour visual cue; this is based on the rationale that if health workers erroneously keep a vaccine that must normally be discarded after six hours, the practice is dangerous for the infant. In contrast, discarding a vaccine prematurely, when it could potentially be kept for 28 days, is wasteful but does not present a risk to the child.

It was queried as to why a 'new' vaccine needs to be used for the field pilot and suggested that the pilot be conducted in a country that might soon be implementing the Multi-Dose Vial Policy
(MDVP) with an existing vaccine. This idea was dismissed because it would primarily test 'compliance' rather than the utility of the visual cue—i.e., are the health workers doing what they should be doing. Another idea offered was to label all vials with the visual cue in a country already applying the MDVP, but this was considered to primarily measure the reinforcement of existing and familiar practice. Furthermore, negotiating relabeling of all vaccines with relevant vaccine suppliers was considered logistically complex.

Group discussion then shifted to the key purpose and objective of the study. Suggestions on the pilot included measuring whether the visual cue prompts behaviour change, or leads to correct behaviour, and/or whether that behaviour is durable over time. This discussion prompted queries of whether a control group (vials with no visual cue, or vials with the VVM) would then be necessary and ultimately, what actions would be taken if the pilot were to 'fail'. A plea was made not to test the visual cue in complete isolation, but also to test whether it is a helpful tool in enforcing the application of the MDVP.

Finally, it was proposed that the visual cue be considered a piece of necessary information on a vaccine label, such as an expiry date or vaccine type. In that case, the study design would evaluate the programmatic aspects of introducing and using the visual cue, including whether health workers could interpret the visual cue and understand the meaning behind it. This idea was received positively by members.

There was consensus that a sub-group be established to provide input into study design.

**IPAC recommendations and decisions**

1. IPAC affirms that the ultimate purpose of the study is to evaluate the programmatic aspects of introducing and using the visual cue.

2. A Visual Cue Pilot sub-group (VCPS) composed of IPAC members and regional representation will be formed to provide input into the pilot design. The members are Xavier Bosch-Capblanch, Folake Kio-Olayinka, and Christopher Morgan, as well as Richard Mihigo (AFRO) and Oommen John (SEARO), with the focal point of WHO to be decided.

3. The terms of Reference of the sub-group will need to be drafted.

**2.3 Next steps with revision of the Multi Dose Vial Policy (Diana Chang Blanc, WHO)**

The current WHO Policy Statement on the use of opened vials of vaccine in subsequent immunization sessions was issued in 2000 (WHO/V&B/00.09) and articulates that opened multi-dose vials of a specified group of vaccines can be used in subsequent immunization sessions for up to a maximum of 4 weeks provided that the expiry date has not passed and certain cold chain and sterility conditions are met. For vaccines that are reconstituted, vials must be discarded at the end of each immunization session or after six hours, whichever comes first. Over the course of the past decade, health workers have generally interpreted the policy to mean that all liquid vaccines can be kept for 28 days and that all reconstituted vaccines must be discarded after the session.

This multi-dose vial policy (MDVP) is now outdated and provides incomplete guidance to health workers in the current environment. This is due to the greater diversity of vaccines in EPI, the variance of presentations of the same vaccine type, and the introduction of new vaccine formulations in non-traditional formats such as PCV-10 (Synflorix) and HPV (Cervarix). These latter two vaccines are two-dose liquid products with no preservative.

It should be recognised that revision of the MDVP requires the convergence of three streams of work:

1. **Visual Cue.** A visual cue which is 'universal' to all health workers, will be easy to interpret, irrespective of any specific vaccine, manufacturer or presentation, provide signals about the action to be taken, and provide reassurance to the health worker.
It should be noted that WHO Performance Quality and Safety specifications and verification protocol for vaccine vial monitors (VVMs) was revised in 2011. This now requires that the VVM appears on the label of the vaccine regardless of its type (liquid or freeze-dried), if the vaccine can be kept in subsequent immunization sessions\(^1\). All vaccines with VVMs on cap or on the neck of an ampoule will be discarded at the end of the session, regardless if of liquid or freeze-dried formulation. This revision on VVM placement reinforces IPAC’s previous decision on the utility of the VVM as a secondary visual cue.

2. **Programmatic Suitability for Prequalification (PSPQ).** While preferences in vaccine presentation are not strictly part of the MDVP, PSPQ will facilitate common understanding among vaccine manufacturing, regulatory and pre-qualifying components regarding which vaccine characteristics are preferred or critical in EPI.

3. **Filling Data Gaps.** Additional scientific evidence may be required to back up the components of a new policy, such as criteria-setting of the time thresholds for MDVP categorization (e.g., rationale for establishing six hours and 28 days as the timeframe for using vaccines before discard).

The final revision to the MDVP will depend on advances made in the above areas of work. In the meantime, a broader framework for a vaccine handling policy, of which MDVP is a part, could be developed and newly prequalified vaccines could be classified on a case-by-case basis.

IPAC was requested to dissolve the IPAC visual cue sub-group in favour of an MDVP sub-group and to identify an IPAC focal point and 1-2 additional members for the working group.

**Discussion:**

There was consensus among IPAC members that there is a critical need for MDVP revision. It was noted that policy revision is a complex undertaking, and would require a dedicated WHO focal point assigned to the task. It was also observed that while revision to the MDVP required finalization of the visual cue and PSPQ guides, these activities did not have to occur sequentially; some work could be done in parallel to accelerate the outcome. Instead, WHO was encouraged to consider revising the MDVP as soon as possible.

It was noted that the controlled-temperature chain (CTC) work that has previously been presented to IPAC, as well as the VPPAG’s work on label re-formatting and standardisation was also relevant to the revision of the MDVP.

A query was made on the initiative of the United Nations Environmental Programme (UNEP) to reduce mercury-containing products, and as a consequence, the implications of using thiomersal as a preservative. WHO’s Global Advisory Committee on Vaccine Safety (GACVS) has determined that there is no evidence of toxicity in infants, children and adults exposed to thiomersal in vaccines. Thiomersal is seen as a negligible contributor to the environmental damage caused by mercury-based products.\(^2\) While there is on-going exploration by industry of the use of alternative vaccine preservatives, there is no timetable for such alternative products.

**Recommendations and Decisions by IPAC**

1. IPAC strongly recommends that the current MDVP be revised in a timely manner.

2. IPAC recommends that human and financial resources within WHO are prioritized to complete this work. *(Vote: unanimous consensus)*

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\(^1\) VVMs are not currently a requirement of MDVP implementation

3. IPAC members agree that the current visual cue subgroup can transition to a MDVP sub-group. Additional members include Robin Biellik, Thierry Gastineau and Martha Velandia (PAHO).

3. **Finalization of Programmatic Suitability of Vaccine Candidates for WHO Prequalification criteria and process**

The PSPQ process has been discussed at all three previous IPAC meetings. IFPMA and DCVMN representatives were requested to provide to IPAC final formal input outlining outstanding concerns, and it was agreed at the previous IPAC meeting that the final draft would be submitted to IPAC for approval at this September meeting.

3.1 **Final comments from industry on PSPQ process**

(Thierry Gastineau, IFPMA and Reinaldo de Menezes Martins, DCVMN)

Detailed written feedback was provided by industry in the final draft of the document "Assessing the Programmatic Suitably of Vaccine Candidates for WHO Prequalification." Their key areas of concern are grouped as follows:

**A. Implications if PSPQ criteria are applied to already pre-qualified vaccines**

Industry underlined its concerns that a vaccine’s loss of prequalification status due to non-adherence to programme suitability criteria could lead to the risk that health authorities and procuring agencies would not consider it viable for purchase, even though the product is safe and effective, and that this would have negative implications for global vaccine security. In addition, some national regulatory authorities consider U.N. prequalification as a necessary step for granting local licensure, and the de-listing of a prequalified vaccine could inappropriately signal to the international community that something is flawed with the product in terms of quality, safety and efficacy.

The industry recommended prioritizing new vaccines for prequalification rather than re-reviewing already pre-qualified products. Industry also suggested further consideration of a transitional time-frame for vaccines which are reaching late stages of development.

**B. Implications if PSPQ criteria are revised every three years**

Applying, getting and maintaining prequalification status is a time and resource intensive process that involves many stakeholders. If every three years the criteria for PSPQ are reviewed and altered, it is possible that pre-qualification will not be viewed as an adequate incentive. This is particularly true if pre-qualification status can be revoked for reasons which are not driven by quality, safety or efficacy.

**C. Anti-microbial preservative (mandatory & critical criteria)**

Industry is concerned that the condition of demonstrating anti-microbial efficacy for a duration of 28 days is not triggered by scientific reasons but for supply reasons (wastage), and is not consistent with a flexible approach as has been discussed in previous IPAC meetings.

Queries were made on the application of PSPQ for multi-dose vaccines which are intended for campaign use (e.g., flu vaccine); how equity will be ensured for all dossiers when testing approaches are reviewed on a case by case basis; why the criteria is mandatory for ready-to-use presentations and critical for reconstituted presentations; and how to apply the criteria on single-dose presentations which can be fractionated into multiple doses. Industry urged that the generic protocol be formally reviewed and published by WHO.

Industry proposed language to amend the standard defined for anti-microbial efficacy.
**D. Antigenic stability after reconstitution (critical criteria)**

Similar comments apply to the standard on antigenic stability after reconstitution as to the anti-microbial efficacy test. Industry believes this criterion should not apply to live vaccines and proposed moving this characteristic to “Preferred”, at least until there was resolution on the technical details.

Industry proposed language to amend the standard defined for antigenic stability.

**E. The appeal procedure**

Industry requested that an appeal procedure be instituted, should the product not pass PSPQ screening. This exists in most regulatory processes, and would permit oral dialogue with WHO QSS to promote exchange and understanding.

**F. Miscellaneous**

Industry requested that, as agreed at previous IPAC meetings, WHO issue official minutes of consultations conducted between PQ Secretariat and industry, and suggested language to this effect.

**3.2 Review of industry comments and pre-qualification team responses**

*(Rudi Eggers, WHO)*

Detailed written feedback on industry comments was provided by WHO in a meeting document "WHO response to Vaccine Manufacturer comments on PSPQ paper (version 30 August 2011)".

Dr Eggers' presentation at IPAC addressed industry's key areas of concern as follows:

**A. Transitioning of non-compliant products**

WHO reaffirms that the priority in the document is on addressing future vaccine pre-qualifications.

WHO did not state a date of final compliance for all vaccines (as was requested by IPAC), but rather will engage with vaccine manufacturers on a one-to-one basis to negotiate the terms of PSPQ compliance that would be mutually acceptable.

WHO believes the current approach illustrates cooperation with vaccine manufacturers and is consistent with previous IPAC recommendations to strive towards universal PSPQ compliance. Language changes will be made in PSPQ text to clarify seemingly conflicting statements.

**B. Antimicrobial preservative**

The anti-microbial preservative requirements in the PSPQ paper cover three different categories for multi-dose vials:

<table>
<thead>
<tr>
<th>Vaccine Category</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Category A</td>
<td>These vaccines will be excluded from pre-qualification. In the current context, multi-dose vials with more than 2 doses per vial which are ready-to-use and are not, or are inadequately, preserved are considered dangerous to the vaccination programme.</td>
</tr>
<tr>
<td>Category B</td>
<td>This is an interim category. A vaccine of this category was recently pre-qualified, under certain conditions regarding training and AEFI surveillance, and with the proviso that follow-up data from two pilot countries (Kenya and Ethiopia)</td>
</tr>
<tr>
<td>(2-dose vial, ready-to-use)</td>
<td></td>
</tr>
</tbody>
</table>

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will be evaluated.

The criteria in the PSPQ document will be reviewed once the country pilots have clarified the operational risk of such formulations. If the risk is too great, category B vaccines will become un-pre-qualifiable. The Director-IVB / PQ Secretariat will decide if the pre-qualification of this vaccine will be upheld.

<table>
<thead>
<tr>
<th>Category C</th>
<th>Reconstituted multi-dose vaccines which are inadequately preserved are at lower risk because health workers following their current training and experience would discard these vials at the end of an immunization session. As some risk remains, this has been termed a critical characteristic, requiring review by the PSPQ Standing Committee.</th>
</tr>
</thead>
<tbody>
<tr>
<td>(all multi-dose vials, requiring reconstitution)</td>
<td></td>
</tr>
</tbody>
</table>

C. Testing for preservative efficacy

The WHO generic protocol is an adaptation of the preservative efficacy protocol articulated by the European Medicines Agency (EMEA). However, instead of a single inoculation ("spike") of potential pathogens, WHO requires a multiple-challenge test, which better simulates the actual conditions of a vial in the field.

Alternative testing approaches chosen by the manufacturer may be acceptable and will be reviewed on a case by case basis. Manufacturers can design the protocol to best demonstrate that the preservative contained in the formulation is efficacious against several spikes conducted over 28 days.

The final decision on whether to establish a new category of vaccines (beyond 6 hour discard and 28 day discard) based on anti-microbial preservative rests with the WHO QSS pre-qualification team. If WHO QSS enables additional categories in the future, these criteria would consequently be adapted and new visual cues would be developed to accommodate the change.

D. Antigenic stability

The rewording of the criteria has made antigenic stability a requirement only for those multi-dose vaccines that are adequately preserved. The ability to keep multi-dose vaccines for subsequent sessions is the resulting outcome of the vaccine formulation, not a criterion for PSPQ.

The antigenic stability should be shown by the manufacturer using an appropriate test of their choice to show stability for 28 days after reconstitution at temperatures between +2°C and +8°C. This requirement does not relate to aberrant field conditions but to the assumption that vaccine is kept under recommended conditions.

E. Appeal procedure

As yet, WHO has no formal appeal mechanism for prequalification; however, there is a conflict-resolution procedure. Vaccine manufacturers of vaccines where prequalification has not proceeded can engage directly with the PQ Secretariat or the Director of IVB for reconsideration or to bring additional evidence to light.

Dr Eggers concluded his presentation with specific clarifications and/or revisions to several language and editing suggestions to the PSPQ document.

3.3 Implications of PSPQ implementation on vaccines in prequalification process
(Carmen Rodriguez Hernandez, WHO)
Vaccines that have received WHO prequalification prior to January 1, 2012 will not be required to comply with the PSPQ guidelines at this time. Any vaccine dossiers already submitted to WHO, for which the prequalification process has not yet been completed by January 1, 2012 are initially exempt from PSPQ review.

All currently pre-qualified vaccines, as well as vaccines that were in the process of being pre-qualified, will be screened against the PSPQ criteria by the PQ secretariat before the end of 2012.

Following the PSPQ Standing Committee report, the PQ secretariat will contact manufacturers and discuss, on a one-on-one basis, the identified concerns and required changes in order to bring the product into compliance, along with a negotiated timeframe to do so.

It is estimated that less than 10% of the currently 130 pre-qualified vaccines will need review by the PSPQ committee. The main issues identified during the preliminary scan are: oral products requiring reconstitution, multi-dose lyophilized products that are not live-attenuated and containing no preservative, and the antigenic stability of reconstituted products with preservative and preservative efficacy.

There will be an initial meeting of the PSPQ Standing Committee on 3 October to establish a working relationship and discuss the application of the PSPQ process. The Committee will conduct a trial review later in 2011 of three existing pre-qualified products to understand process issues; it is not a formal dossier review. The intent is to solidify group operations and identify steps in its functioning that may need further refinement.

Vaccines that are not yet prequalified but in late stage of development will need to adhere to PSPQ guidelines. Manufacturers are encouraged to contact WHO vaccine prequalification team (WHO/QSS) as early as possible to discuss potential concerns on a one-on-one basis.

**Discussion:**

The PSPQ process is generally recognized as a useful mechanism and a positive step forward in promoting appropriate vaccine products for developing countries.

Dr David Wood, WHO/QSS explained that WHO is initiating a general policy to guide all pre-qualification activities at WHO. Furthermore, Dr Wood reassured industry that de-listing a vaccine product (e.g., taking it off the prequalified list) is a step that is not taken lightly by WHO. Accurate communications around such an unlikely event would be handled professionally and the public health implications of such a decision would be carefully weighed beforehand. There was a short discussion on the need to define or clarify 'public health' relevance, as this would bring together different perspectives and engage value judgements.

Industry acknowledged that while the process of the PSPQ development was very collaborative, interactive and collegial, the wording in the document in places is not aligned with that approach. A request was made to adjust the tenor in certain areas of the document to be more 'friendly'.

Concern was expressed about the safety of keeping vaccines for 28 days after opening because field conditions may be more extreme than laboratory conditions and the newer preservatives may be less likely to provide preservative efficacy for such duration.

The issue of changing PSPQ criteria every three years was raised again, with a request not to 'always move the goalposts'.

It was mentioned that vaccination schedules vary per country and region, for example influenza vaccine is given at 6 and 7 months of age in AMRO and there is no use of the VVM in that region. One purpose of PSPQ is that future vaccines will be developed to ensure that the number of immunization contacts will not need to be increased. It was proposed to retain the WHO’s recommended EPI schedule as a guideline to Industry, but it is understood that the EPI schedule is adapted by countries or regions. Countries also decide whether they require...
vaccine products with VVMs, however, a vaccine supplied by the UNICEF Supply Division is required to have VVMs affixed. For the PSPQ, the most important issue is that vaccines possess the temperature stability characteristics that enable a VVM to be attached.

The members of the PSPQ Standing Committee include Alan Brooks as Chair, Julie Milstien, and Abdulreza Esteghamati. Two IPAC members sit on the committee: Jane Soepardi and Robin Biellik.

In conclusion, Dr Wood underlined that the development of PSPQ criteria and process represents the formalization of a process that is already in place. The initiative to develop an official system and clearly document those steps is beneficial for both parties.

**Recommendations and Decisions by IPAC**

1. IPAC approves the document entitled “Assessing the programmatic suitability of vaccine candidates for WHO prequalification” with modifications. *(Vote: 10 in favour and 1 abstention)*

2. Modifications include: (a) specification at the beginning of the document that the category “multi-dose vials” includes single dose vials that can be used as fractional doses, and hence function as multi-dose vials; (b) inclusion that dialogue between WHO/Industry will be officially minuted and documented; (c) specification that the visual cue only applies to multi-dose vials; and (d) minor changes in tone and small edits.

**4. Outsourcing of vaccine distribution**

**4.1 Emerging trends and implications (Patrick Lydon, WHO)**

It was argued that with the increasing challenges for government run supply chains to cope with the expansion of the immunization system with new vaccines, more countries are recognizing the benefits of engaging the private sector in supply chain and logistics functions by outsourcing the physical storage and handling of vaccines to private sector logistics operators in-country.

This session presented the trends in supply chain outsourcing for vaccines and the findings from in-depth country case studies conducted under the auspices of project Optimize, with a focus on South Africa. The areas of enquiry included the historical context that led to considering outsourcing as a solution, the decision making process, the contracting process, implementation and monitoring, the clients perceived satisfaction of the outsourced services, the operational performance of the provider, and the economics of outsourcing.

The lessons learned highlight many considerations that should be carefully weighed before any decision is made by a country to outsource their vaccine supply and logistics system. Outsourcing can fail if there is lack of coordination between parties, if poor choices are made on what to outsource, if contracts are drafted with no service level agreement, or if little oversight or regular monitoring of key performance indicators is conducted.

Currently there is little guidance available related to the advantages and disadvantages of outsourcing vaccine supply logistics, the conditions needed for successful outcomes, or how to determine whether it is a viable option for a country. IPAC was queried as to whether WHO should be providing written guidance to countries considering outsourcing.

**Discussion**

Discussion among IPAC members initially focused on the diverse challenges of outsourcing and members shared relevant country experiences that yielded varying results. It was suggested that the quality of evidence supporting the presentation reflected potential biases and that some of the assumptions about the benefits of outsourcing may not hold true. This exchange...
highlighted other important aspects that need to be considered for countries to embark on outsourcing.

It was suggested to document more out-sourcing experiences in difficult settings, although members cautioned against the bias that outsourcing would be advantageous for the MOH. Documentation should provide comprehensive information including challenges and lessons learnt, contractual issues related to outsourcing of vaccine distribution. Support was expressed for the development of a resource library of country-level experiences in public-private partnership of vaccine supply logistics.

**Recommendations and Decisions by IPAC**

1. IPAC members expressed interest in the issue of outsourcing of vaccine distribution; however WHO should decide whether this is a priority to bring back to IPAC for further discussion.

5. **Guidance of programmatic consequences of current rotavirus vaccine age-limitations**

5.1 **Programmatic implications of Rotavirus vaccine age-limitations** *(Rudi Eggers, WHO)*

Rotavirus vaccine coverage may become a key indicator of the performance of an immunization system, on the grounds that the current recommendations on age of administration are operationally complex and therefore require an effective combination of national policy, health worker training, and monitoring and evaluation.

WHO recommends that the first dose of either RotaTeq™ or Rotarix™ vaccines be administered between the ages of 6 and 15 weeks, and the maximum age for administration of the last dose of either vaccine should be at 32 weeks of age. It is recommended that two doses of Rotarix™ be administered at the same time as the first and second doses of DTP rather than with the second and third doses, ensuring maximum coverage and reducing the potential for late administration beyond the approved age.

In many developing countries, up to 80% of infants are vaccinated by outreach services. For optimal coverage of rotavirus vaccination it is important to have regular services with a maximum interval of 9 weeks between sessions for RotaTeq™ and a maximum interval of 10 weeks for Rotarix™. These thresholds ensure that all doses are given before 32 weeks; local level micro-planning is critically important.

Successful and appropriate delivery of rotavirus vaccine will test a programme's ability to deliver vaccine within these limited time-frames but still achieve vaccination coverage similar to that for DPT. It is not possible to deliver rotavirus vaccine adequately through periodic intensification of routine immunization (PIRI) activities, missed opportunities cannot be redressed later due to narrow eligibility windows, and the failure to encourage clients to return on time and regularly will leave children inadequately protected. Hard-to-reach communities and other populations with poor access to health services may therefore suffer low coverage and lack of protection from rotavirus disease unless careful attention is paid to the limited time-frames for vaccine administration.

5.2 **Health workers training on rotavirus vaccination: case scenarios** *(Jhilmil Bahl, WHO)*

At the April 2011 meeting, a sub group was formed to assist with rotavirus training guidance. This included IPAC members Robin Biellik and Robert Steinglass, as well as Nadia Teleb (EMRO). The sub group members discussed eight case scenarios outlining situations with which the health worker could be confronted, and agreed on potential solutions.
In analysing the scenarios, the sub-group members observed the following guiding principles:

- It is better to vaccinate than send the infant home without vaccination
- All attempts should be made to obtain written documentation - card and register
- Effective interaction between health worker and caregiver is needed to determine eligibility

The training scenarios included unknown birth date, no availability of EPI card, health worker doubts on infant's age based on appearance, suspected prior intussusception, vaccine contraindications, inadequate dosing if the infant spits out the vaccine, and issues related to discarding the tip of the Rotarix™ tube when opening.

These scenarios were presented to IPAC members for discussion, along with the subgroup's recommendation on the action the health worker should be encouraged to take. In general, health workers were encouraged to seek documentation and probe caregivers using different strategies to determine infants' eligibility for the respective dose.

In the case of infants spitting out doses, the subgroup proposed to adhere to the product insert of the vaccine to avoid confusion, meaning that for Rotateq™ a replacement dose is not recommended but for Rotarix™ a single replacement dose may be given.

**Discussion:**

IPAC members observed that major difference in characteristics of the two rotavirus vaccines (with different instructions on the insert), underlined the critical need for adequate health workforce training. There was consensus that obtaining written documentation with the exact date of birth could be a problem in many countries. However, most mothers would know the month of birth of their infant or could be probed to remember a milestone near the infant's birth. The observation was made that the reason behind missing EPI cards is often due to health system failures (e.g., no supply) rather than the lack of retention by caregivers.

Concern was raised by AFRO about the eleven countries that will introduce rotavirus in 2012 and the urgency of proper training at peripheral level for proper implementation, particularly in regard to the age-limitations and precise micro-planning. The need for detailed training on how to deliver these new oral vaccines was highlighted by some members.

With respect to actions to take if a child spits up a dose, the group discussed the inconvenience of having differing guidelines for different products. Again, it will be important to properly orient/train the health worker based on the product adopted.

The variance between industry product package inserts and the WHO SAGE recommendation on age of administration for first and last dose was highlighted as a potential cause of confusion for health workers. The representative from Glaxo Smith Kline emphasized that their package insert recommends that the second (last) dose be given before the age of 24 weeks and therefore, given the minimal interval between doses, that the first dose can be given up to 20 weeks of age.

Regarding the case scenarios, several suggestions were made. They include the following:

- Be consistent about use of weeks for age, rather than months;
- Add a scenario of what to do if the health worker gives a dose to a child outside the recommended age limits;
- Add a scenario dealing with a child that looks younger than his/her age (for example due to malnutrition);
- Demonstrate the vaccine to the mother to differentiate from oral polio vaccine and to prompt recall of administration;
- Limit the number of training scenarios to two or three key situations;
- Delete the scenario on suspected intussusception, as this is extremely rare and unlikely to be accurately diagnosed in a developing country;
• Complement the scenarios with data that would support their selection (e.g. proportion of caregivers that do not possess an EPI card, incidence of intussusception, recall bias for other vaccines, etc.)

A suggestion was made to err on the side of caution and consider not vaccinating a child if there is no EPI card. Others believed this would deprive too many eligible children. It was underlined that the action the health worker needs to take if there is uncertainty about the age needs to be clear. It was subsequently suggested to take into account the parents’ choice as with other vaccines; if parents are fully informed of the risk and choose to take the risk, then the vaccine should be given.

5.3 Sudan: practical experience with rotavirus introduction
(by telephone link with Dr Amani Mostafa, EPI manager, Sudan)

The Ministry of Health in Sudan introduced rotavirus vaccine (Rotarix™) in July 2011, in coordination with UN and international NGO partners, senior paediatricians and civil societies. A detailed implementation plan for all components with monitoring indicators was prepared at national and sub-national levels. The capacity to test for rotavirus and invasive bacterial diseases has been strengthened at the national laboratory and four sub-national labs. After a cold chain gap analysis, additional equipment was installed. Cascade training was conducted including training of trainers (TOT) of 540 central and state EPI officers, who trained 5,298 service providers. Monitoring and evaluation tools and social mobilization materials were updated, printed and disseminated.

During the health worker training, emphasis was placed on the importance of the age limitation and the need to revise the outreach sessions schedule. An algorithm describing the age limitations for vaccine administration was distributed. A brief survey was organized using a special checklist on current vaccine administration practices. From this survey it was concluded that 86% of health workers give OPV before rotavirus vaccine as is recommended, when both vaccines are indicated during the same visit, that none of the children cry during vaccination and that only 1% of the children spit out the dose of rotavirus vaccine.

Extra attention was given to recording and reporting of adverse events following immunization (AEFIs). The AEFI reporting system was expanded from sentinel sites to all immunization sites. There was a retrospective data collection exercise to measure the background incidence of intussusception among infants one to 36 months of age and after 36 months of age, and a post marketing surveillance system was established for active intussusception surveillance at sentinel hospitals in Sudan, supported by CDC and WHO. Seventy cases of intussusception were reported in 2010, and 43 in 2011. Eight of them were reported after rotavirus introduction, but none of the cases had received vaccine because they exceeded the target age.

The programme aims to achieve and sustain coverage of 95% with a complete course of rotavirus vaccine. The main challenge will be to reach the security-compromised areas and special groups (nomads and internally displaced persons) throughout the country. Other challenges include competing activities and the maintenance of high quality surveillance to evaluate impact.

Though it is still early, the rapid survey showed no major problem with implementation of rotavirus vaccine.

Discussion

IPAC expressed a high level of interest in Sudan’s presentation. It was observed that a target of 95% rotavirus vaccine coverage might be too optimistic. The Sudan EPI team believes that it is feasible to achieve similar coverage to that achieved with pentavalent3 coverage. Outreach activities and mobile clinics are carefully planned in advance; services are provided weekly, bi-weekly or monthly; and sessions are monitored monthly. So far the maximum interval between two outreach sessions has been two months.
The Sudanese EPI team was asked for their experience related to training of health workers with respect to age limitations. Most Sudanese mothers do not leave the house during the first 40 days after the delivery, regardless of social class. This is an important milestone and can be used by the health worker to probe about the age of the child.

There was lengthy discussion about the balance between safety and practicality and the perceived, potential risks of vaccinating at the wrong age. A query was made about how health workers could be protected from blame should they err in calculating age.

A study in Mexico showed that the incidence of intussusception was higher for the first dose of rotavirus vaccine but was not significantly increased for the second dose. There are also other causes of intussusception beyond rotavirus vaccine, such as the introduction of new foods, usually around the time when the children are due for their second dose. The risk is low compared with the benefits of the vaccine which contribute to the reduction of child mortality due to diarrhoea by 30% globally. The balance of risk-benefit is of different magnitude for developing and developed nations.

IPAC was reminded of the current SAGE recommendation, and that training material needs to be developed immediately to operationalise these recommendations. It is possible that at a later date SAGE will review the age recommendations on the basis of these new data. However, age recommendations are out of scope for IPAC consideration.

**Recommendations and Decisions by IPAC**

1. IPAC stresses the importance of appropriate health worker training to accompany rotavirus vaccine introduction.

2. IPAC recommends that WHO update the case scenarios to incorporate suggestions from the meeting and re-circulate to members for written feedback. IPAC members agreed to provide written feedback to WHO within two weeks of receipt.

3. The rotavirus vaccine working group addressing the programmatic consequences of age-limitations will review the feedback and agree on final case scenarios.

4. The Secretariat will organize an IPAC teleconference to provide further feedback on the training scenarios.

5. IPAC members requested that WHO provide scientific evidence to support the scenarios where available.

6. **Review of rotavirus age limitations through SAGE working group**

6.1 **Overview of preparations for SAGE review (Ana Maria Henao Restrapo, WHO)**

It is necessary for SAGE to decide on the most appropriate vaccination schedules for rotavirus vaccines for children living in different income strata and mortality settings. The evidence that should be considered relates to the epidemiology and clinical characteristics of the disease, the effectiveness and safety of the vaccines, the current pattern of routine health system contacts with infants, challenges for implementation, and cost effectiveness of introduction.

A systematic review of data on rotavirus vaccines will be conducted, compiling evidence from randomised clinical trails, observational studies, and current vaccination schedules, as well as mortality and safety data. The aim is to assemble existing data on rotavirus gastroenteritis in young children in different country settings, to identify data gaps, and to examine the possible implications of alterations to the currently recommended schedule.
An ad-hoc working group has been established to feed data into SAGE deliberations on optimising the immunization schedule for rotavirus. This ad-hoc working group will include subject experts on the vaccines and the disease; methodology experts in epidemiology, systematic reviews, models and cost effectiveness analysis; including members from IPAC, QUIVER and GACVS. In the initial phase, the ad-hoc group will discuss the questions and evidence to consider. Conference calls will be held to review the process and to deliberate about data synthesis and analysis, concluded with an expert consultation on the draft conclusions and recommendations to be presented to SAGE.

IPAC was requested to provide feedback and suggestions on the proposed process, as well as encouraged to share country-data that may be available for further analysis.

**Discussion**

It was clarified that there are two rotavirus working groups in which IPAC is involved: the first focusing on the programmatic implication of rotavirus vaccine and the second on vaccine safety related issues.

It was suggested to include a representative from the Americas Region in the ad-hoc group, as Latin-America has accumulated substantial practical experience from Rotavirus vaccine implementation.

There was discussion on roles and the relationship of this ad-hoc working group to the greater SAGE. It was clarified that this is not a standing working group, and that the outputs of this ad-hoc group will feed information into SAGE's formal decision-making processes.

**Recommendations and Decisions by IPAC**

1. IPAC agrees that an ad hoc expert group to discuss optimizing the impact of rotavirus vaccine implementation is warranted. *(Vote: 10 members in favour and 1 abstention)*

2. IPAC members should provide feedback to WHO regarding operational/health system evidence relevant to the review of the rotavirus vaccination schedule.

3. IPAC agrees to the participation of IPAC representatives Najwa Khuri-Bulos, Robin Biellik and Shelley Deeks on the ad hoc Rotavirus schedule group.

**7. Definitions: Routine or supplemental dose**

**7.1 Criteria to determine if a given vaccination is a routine or a supplemental dose** *(Tracey Goodman, WHO)*

This topic has been discussed at two previous IPAC meetings. With the implementation of PIRI activities the distinction between routine and supplemental vaccine doses has become blurred and the delivery strategy alone can no longer be reliably used to define the most appropriate way to count doses.

The clarification of the definition of the types of dose is important to ensure that the necessary recording practices are planned and properly implemented, and that in turn, the accuracy and reliability of reported routine coverage at all levels are improved. WHO was requested by IPAC to develop the criteria for this purpose. With substantial input from stake-holders and active participation of two IPAC members, a "WHO/UNICEF Guidance Note: Criteria to determine if a given vaccination is a routine or supplemental dose" was developed and presented for endorsement by IPAC.

In summary, three criteria must be met in order for a vaccination to be defined and counted as a "routine dose":
1. Child is screened - for age/vaccination history, etc. and information used in decision to vaccinate or not, per national EPI schedule; AND,

2. Vaccination is Recorded - (vaccine/dose/date) is recorded alongside names on the card and register; and vaccine/dose/date is recorded on session tally sheet and monthly summary; counts towards "fully immunized" status; AND,

3. Dose is reported - in national administrative data collection systems and Joint Reporting Form (JRF) according to specified age categories.

Any vaccination that does not meet ALL three of the criteria above is a supplemental dose.

The next steps proposed by WHO and UNICEF are to initiate discussions with stakeholders including service providers, national EPI managers, regions and partners to explore the feasibility of implementing these proposed criteria, as well as the usefulness and relevance of the approach. It will be useful to observe the monitoring and recording practices of countries that are currently delivering routine doses using "additional" strategies, otherwise referred to as PIRI. WHO will report back to IPAC after some practical field experience has been gathered.

IPAC was requested to endorse the criteria described in the WHO/UNICEF Guidance Note.³

Discussion:

There was general consensus that the definitions as presented were clear and well-formulated. However, it was noted that instituting such definitions will have wider implications on a range of issues including programming, health systems, human resources, analysis of results based financing, performance rewards, financing, reporting tools, coverage estimations, and those consequences must receive further reflection. WHO acknowledged this as important and reiterated that the establishment of the criteria -- essentially de-linking the dose administration from the delivery strategy used -- was a first step to enable deeper analysis of the implications. The way forward includes consultation with key stakeholders at global, regional and country level to discuss the feasibility and implications of such an approach.

Subsequent discussion focused on how to handle late immunizations, how/where to report supplementary doses, how to consider situations where EPI cards are not provided, and how doses provided at new or temporary service delivery points established during the PIRI could be entered into existing facility-based registers. The proper recording of measles second dose was highlighted as an issue.

It was observed that what matters most is the protection of the child and that the driver behind these proposed criteria is to promote a common understanding across countries, improve data reliability and quality.

It was suggested that references to the term "supplemental dose" be removed in the document, to keep focus only on routine and avoid controversy of comparing routine doses against supplemental doses.

Robert Steinglass offered detailed feedback on the document, which included rationale for keeping the term 'supplemental doses' and will send comments to WHO by email. IPAC members were encouraged to do the same.

Recommendations and Decisions by IPAC

1. IPAC endorses these criteria and definitions with minor modifications. (Vote: unanimous consensus)

2. IPAC requests WHO to update the Committee at a future meeting on practical

³ Version dated 20 September 2011

Meeting Report - IPAC September 2011
experiences with the application of the new definitions.

8. **Report on Global Advisory Committee on Vaccine Safety Meeting and an Overview of Global Vaccine Safety Blueprint**

8.1 **Update from GACVS and Global Vaccine Safety Blueprint** *(Patrick Zuber, WHO)*

The committee was updated on the proceedings of the GACVS June 2011 meeting.

The Global Vaccine Safety Blueprint (GVS) was designed as a framework for collaborative activity in promoting vaccine safety. There is a global responsibility in ensuring that vaccine pharmacovigilance be available so that everyone everywhere is protected by safe and effective vaccines. In addition, vaccine safety crises, whether caused by the vaccine, programme errors or rumours, disrupt immunization programmes. Therefore, it is of high importance to follow adverse events following immunization (AEFI) especially closely, particularly now with the introduction of so many new vaccines, many in countries with weak pharmacovigilance systems. The development of the GVS Blueprint has included many stakeholders and has been an iterative process. The overarching vision is for all countries to implement effective vaccine safety systems, including preparedness, monitoring and prompt response.

The GVS Blueprint is composed of eight strategic objectives which support the achievement of three goals:

- to build effective vaccine safety systems so that all low- and middle-income countries have at least a minimal capacity to ensure the safety of vaccines;
- to ensure an enhanced capacity for vaccine safety activities in countries that introduce newly available vaccines and countries that manufacture and use prequalified vaccines, so that those vaccines can be reliably monitored and appropriate responses provided if required; and
- to foster international collaboration towards a common vision, and establish global mechanisms to ensure that the safety of all vaccines is adequately monitored and that safety information is shared internationally.

The work plan is being devised and will be costed for 2012-2020. WHO will serve as the Secretariat.

**Discussion**

The query was raised on the availability of AEFI data on rotavirus vaccine and programmatic errors, and the role of GACVS especially related to programmatic errors. Dr Zuber explained that the role of GACVS is to assess vaccine risk, with the main focus on vaccine reactions. It is assumed that programmatic errors will be detected through a national monitoring system, once functional.

The GVS Blueprint meeting conducted in September was productive, with feedback provided on improving the document. IPAC members reflected on their role in vaccine safety issues, noting that they would be advising on the programmatic aspects such as vaccine handling and immunization safety, with particular attention to programmatic errors.

Robert Steinglass offered initial feedback on the document and will send written comments to Dr Zuber by email. IPAC members were encouraged to do the same.

**Recommendations and Decisions by IPAC**

1. IPAC members are requested to give written feedback to WHO regarding Global Vaccine Safety Blueprint.
2. IPAC requests WHO to better define IPAC's role regarding vaccine safety in general and in regards to the Vaccine Safety Blueprint.

Concluding Issues

1. Next meeting 17-19 April 2012, followed by 2-4 October 2012.

2. WHO Secretariat to circulate proposed dates for 2013 meeting, which are also proposed to fall in April and October timeframe.

3. Terms of service of members and composition of sub-groups were reviewed and are included in Annexes One and Two, respectively.
9. **Annex One: Terms of service for IPAC members and Observers**

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<tr>
<th>IPAC member</th>
<th>Membership</th>
<th>Start</th>
<th>End (incl.)</th>
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# 10. Annex Two: Sub-Group Composition

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<td><strong>Controlled Temperature Chain</strong></td>
<td>Francois Gasse*</td>
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<td>Robin Biellik</td>
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<td>Robin Biellik</td>
<td>Nadia Teleb</td>
<td>Jhilmil Bahl</td>
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<td>Shelley Deeks</td>
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<td>Vance Dietz</td>
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