



WORLD HEALTH ORGANIZATION IMMUNIZATIONS, VACCINES AND BIOLOGICALS

IMMUNIZATION PRACTICES ADVISORY COMMITTEE (IPAC) 2-3 October 2012

Final meeting report and recommendations

Opening and Introduction	1
Session I. Controlled Temperature Chain for Meningococcal A vaccine (MenAfrivac®)	1
Session II. SAGE Polio Working Group.....	2
Session III. Global Updates.....	5
Session IV. Solar Refrigeration Systems	6
Session V. Time Temperature Indicators for Vaccines.....	11
Closing.....	12

Opening and Introduction

Dr Shelley Deeks (chair) opened the meeting and welcomed Dr Samir Sodha from the US Centers for Disease Control and Prevention as an observer, replacing Dr Vance Dietz. Dr Sodha is Team Lead of the Routine Immunization Team (RIT) in the Global Immunization Division. On behalf of Dr Soepardi, Dr Deeks expressed Dr Soepardi's regrets on her meeting absence. All other members and observers were present.

IPAC Members present:

Shelley Deeks (Chair)
Robin Biellik
Xavier Bosch-Capblanch
Jonathan S. Colton
Francois Gasse
Najwa Khuri-Bulos
Folake Kio-Olayink
Sanath Lamabadusuriya
Christopher Morgan
Jean Marc Olivé
Robert Steinglass

Session I. Controlled Temperature Chain for Meningococcal A vaccine (MenAfrivac®)

The session began with an introduction by Mr Michel Zaffran, who highlighted the groundbreaking progress made with MenAfriVac®, which will be the first EPI vaccine licensed for use in a controlled temperature chain (CTC). In 2012, the license for Serum Institute of India's Meningitis A vaccine, MenAfriVac®, will be changed based on a thorough review of scientific data by regulatory authorities as well as WHO to allow for use of the vaccine for a period of up to four days at temperatures of up to 40°C, in a CTC. After reconstitution, the vaccine may be kept in CTC up to 6 hours, after which it must be discarded. Mr Zaffran expressed his hope that this leap forward will break the cycle of small pilots being used to deliver vaccines out-of-the-cold-chain; historically, these pilots have not been successful in scaling up due to lack of support from National Regulatory Authorities (NRAs) in-country, and subsequently concerns of manufacturer or immunization programme liability. Licensing the use of this vaccine for four days at temperatures up to 40°C is an important first step in setting precedent, and may extend the possibility of CTC application to other vaccines.

A. Update on CTC: Progress and plans for MenAfriVac®, and a glimpse into the future (Simona Zipursky, Optimise)

Ms Zipursky provided an overview of the work ongoing to license vaccines - primarily those delivered through campaigns or special strategies - to reflect their true stability and enable their use in a CTC. In addition to the ongoing work on MenAfriVac®, as outlined above, updates were shared on other key initiatives, including the development of guidance for regulators on how to license vaccines for CTC use, which are being developed through the mechanism of WHO's regulatory collaborating centres. Additionally, other collaborations with

several vaccine manufacturers through the Gates Foundation CEO roundtable were referenced (hepatitis B, Yellow Fever, and HPV, among others).

B. MenAfriVac® CTC Guidance: Updates and questions for IPAC (*Francois Gasse, IPAC and working group member*)

This is the final review of the document by IPAC prior to the planned field testing during the MenAfriVac® campaign in Benin in November 2012, where one district will use the vaccine in a CTC. After the field testing has been conducted, the revised final guidance document will come back to IPAC for endorsement in 2013. Dr Gasse provided a summary of the working group's activities and posed specific questions to frame the plenary discussion.

Discussion:

Overall, IPAC members were satisfied with the updated document and the direction taken by the working group in contributing to its revised form. Members remarked that the field guidance improves each time it is presented and the document is now quite clear and useful.

Several comments were made on clarifying and highlighting concepts in the guidance before finalization. These included introducing the concept of the threshold indicator earlier in the document, highlighting the need to consider elevated temperatures during transport, emphasizing the benefits of CTC, and clarifying storage conditions for diluents. Specific proposals were offered on how to design a decision-making tree.

IPAC's specific changes to the document prior to its pilot application were as follows:

1. Provide a step-by-step flow chart early in the document, to allow countries to assess if CTC is appropriate for use in their context;
2. Clarify that there are two key decisions that need to be made at different levels, both addressed by the guidance document:
 - a. For national level to decide whether to pursue CTC (political, technical decision);
 - b. For regional/district level to decide where and how to implement; and
3. Consider dividing the guidance into two sections in accordance with point 2 above.

While it was acknowledged that the possibility of using Menafrivac under CTC is a key and encouraging step for future developments of the CTC, IPAC members highlighted the importance of keeping a holistic perspective of long-term programmatic implications if other vaccines would be considered for CTC implementation.

Recommendations and Decisions by IPAC

1. IPAC recommended against the integration of MenAfriVac® in a CTC with other activities (vaccines and other health interventions) to limit additional complexity in management of the CTC.
2. IPAC recommended that vaccines used in a CTC should be discarded at the end of the four-day CTC period and not be returned to the cold chain after CTC use, even if the VVM and threshold indicators are not expired. This will allow for worst-case scenario assessment of wastage, which should be reviewed after the pilot.
3. IPAC stressed the importance of developing a strong guidance evaluation plan for the pilot.

Session II. SAGE Polio Working Group

Dr Rudi Tangermann (WHO HQ) described the background of activities leading to the IPAC session, which included the recent declaration by the World Health Assembly of polio eradication as a global public health emergency. The WHA requested WHO to finalize a

comprehensive polio endgame plan, including a switch from trivalent oral polio vaccine (tOPV) to bivalent oral polio vaccine (bOPV) for routine immunization - the progressive cessation of OPV use, starting with oral poliovirus type 2 (OPV2) cessation.

The issue of OPV2 cessation has been reviewed by SAGE since its November 2010 meeting. In April 2012, based on evidence presented by the SAGE Polio Working Group (WG), SAGE reaffirmed the need for progressive removal of OPV serotypes, starting with type 2 (i.e., synchronous replacement of tOPV with bOPV for routine immunization, or OPV2 cessation), and, to mitigate possible associated risks, recommended for countries to consider introduction of one dose of inactivated polio vaccine (IPV) into their routine immunization schedules prior to OPV2 cessation. SAGE noted that the current intramuscular (IM) injectable inactivated polio vaccine (IPV) was not affordable for many low and middle income countries, and stressed the importance of making a low cost IPV option available.

SAGE requested that WHO undertake further consultation with countries and regions to document the policy and programmatic implications of introducing an IPV dose (whether IM, IM adjuvanted dose, or intradermal [ID]) as part of the strategy to switch from tOPV to bOPV and to facilitate individual country decision-making. The SAGE Polio WG has been tasked to guide the ongoing work to prepare for the 'polio endgame', including the cessation of OPV and preparation of post-eradication immunization policy.

Dr Tangermann summarized interviews conducted with EPI managers from India and two small African countries with relatively well-performing immunization programmes. Managers were queried on their reaction to adding IPV as an ID dose at the 14-week contact for routine immunization. The main programmatic implications were cited as follows:

- **Service delivery:** all trained vaccinators expected to deliver IM dose without problems, using standard 23-25 gauge needle; IM injection unlikely to interfere with compliance of client or service provider; ID injection, requiring 0.1 ml BCG-type syringe with 26-27 gauge needle (BCG dose is 0.05 ml), is technically much more challenging for vaccinators; possible programmatic errors, increase in AEFIs and decreased seroconversion rates if ID doses given incorrectly by IM route; possible compliance issues for both vaccinator and client - more painful injection.
- **Cold chain - logistics:** for IM delivery ('full' 0.5 ml dose) wastage will be variable, depending on vial size; use of 0.5 ml dose (IM) will require more cold chain space than with fractional ID dose as each IM dose represents up to 5 times the volume per dose; wastage could be considerable (no single ID dose option); and no multi-dose policy is currently applicable for to either option.
- **Management, training, supervision:** The introduction of a 1-dose IPV policy, irrespective of application mode, will require the entire range of efforts associated with introducing any new vaccine; the more complex service delivery of ID IPV (see above) will significantly increase needs of management, training and supervision.

Subsequently, a consultation session on the 'polio endgame' and OPV2 cessation was conducted at the Eastern Mediterranean Regional (EMR) EPI manager's meeting with EPI managers of all Member states. Among EMR, 10 countries have already introduced at least 1 dose of IPV, and two (Tunisia, Morocco) are about to introduce IPV. Of the non-IPV-using countries, 3 countries (Egypt, Iran, and Pakistan) had general concerns about introducing IPV, but the seven remaining countries (all GAVI-eligible) would introduce IPV, pending partner financial support.

EPI managers raised programmatic issues similar to those listed above and were concerned about ID injection for 2 main reasons: a) limited field staff capacity to deliver a proper ID injection, and b) that an incorrect ID injection would be ineffective. Only one country - Tunisia - would prefer ID over IM.

IPAC members were requested to further advise on the programmatic advantages and disadvantages of a routine dose of IPV given by the ID versus IM route, and highlight additional measures which programs should undertake in these scenarios.

Discussion:

IPAC members appreciated the information relayed from the recent consultation held on the 'polio endgame' and OPV2 cessation with country EPI managers in WHO's Eastern Mediterranean Region, and encouraged that similar discussion be held in all WHO Regions. WHO informed IPAC that similar meetings have already been scheduled in the Americas (late October), in the African and the South-East Asian Regions. The main difficulty with an IPV ID delivery strategy is that intra-dermal vaccination of BCG typically is executed in hospitals, not health facilities; there would therefore be enormous training implications.

Participants noted that in countries that have employed a "combined" IPV-OPV schedule, the IPV was usually given before OPV in order to create humoral immunity to eliminate the risk of vaccine-associated paralytic poliomyelitis (VAPP). It was clarified that the main reason for recommending IPV at 14 weeks was the better efficacy of the vaccine at that age. This was needed because of the wider objectives of using IPV in the context of OPV2 cessation to prevent paralytic polio (due to circulating type 2 vaccine-derived poliovirus [cVDPV2]); to improve the immunological response in IPV-vaccinated individuals when receiving mOPV2 vaccination given in response to a type 2 polio virus outbreak post OPV2 cessation; and to boost immunity against wild poliovirus type 1 and 3. However, it was noted that a "combined" schedule with 2 or 3 doses of OPV given before IPV would likely not eliminate VAPP.

IPAC members queried the availability of global vaccine supply given the timeline for introduction, and were informed that WHO anticipates to have multiple suppliers coming into the market over the next five years. However, no IPV vaccine is currently licensed for intra-dermal use; in addition, even though the most recent published clinical data provide interesting information, these are not considered as sufficient to support the licensure of IPV with the ID route of administration. It was also noted that current auto-disable syringes for intra-dermal use are not marked 0.10 ml (IPV ID use), but only 0.05 ml, an issue that would need to be addressed.

IPAC members referred to the progress made towards using low-cost 'needle-free' devices / jet injectors to deliver the fractional ID IPV dose, and queried whether these needle-free devices might become available within the proposed time-frame for OPV2 cessation. Collaborative efforts with the manufacturers of needle-free injection devices have been ongoing for several years, which have resulted in the engineering of two new ID devices that are currently being investigated in clinical trials. If successful, these devices could be used to administer fractional-dose IPV intradermally; however, it remains unclear how long it will take for the devices to be mass-produced, licensed, and made available on a large scale.

Several IPAC members commented that the introduction of IPV into OPV-using immunization programmes will require considerable efforts, training and financial resources; in addition to assuring a sufficient supply of IPV, resources will be needed to train and supervise health workers at all levels.

IPAC members noted the introduction of IPV in this context will pose the same problems and challenges as the introduction of any other new vaccine; whether a country decides to adopt intramuscular (IM 'full' dose or IM 'adjuvanted' dose) or ID fractional dose, the necessary support for preparing for the introduction, the introduction itself, as well as for evaluating the coverage and quality of service delivery achieved will need to largely follow existing guidelines for the introduction of new vaccines into routine immunization programmes.

Furthermore, there is a critical need to further plan, design, and evaluate appropriate and effective advocacy and communication strategies related to the introduction of IPV as part of OPV2 cessation - to assure compliance of health workers and of clients / families / caretakers; on the importance of efficient and large-scale training and communication efforts, in order to successfully implement OPV2 cessation. In addition, it was remarked that the frequent changes in polio immunization policies in themselves may lead to loss of public trust, so a strong public communications strategy is critical.

Recommendations and Decisions by IPAC

1. IPAC members recommended further detailed review of existing literature and data on the relationship between quality of ID injections and vaccinator/health worker training. This would encompass a review of the 'BCG literature', including existing estimations of the proportion of ID injections that do not deliver the vaccine into the skin but are given too superficially ('wet') or too deeply, resulting in sub-cutaneous injections. There is a need to estimate the extent to which the expected injection errors will impact on sero-conversion.
2. IPAC members noted the importance for the GPEI to develop feasible options for the use of needle-free jet injection devices for ID application of IPV (e.g., availability, licensure, and eventual cost).
3. IPAC stressed the importance of gaining public acceptance of the end-game strategy by developing a strong communication framework which clearly explains to communities, country immunization programme managers and other EPI stakeholders, the rationale for progressive OPV2 cessation, the tOPV-bOPV switch, and the introduction of IPV.
4. IPAC strongly recommended the development of programmatic materials to address how health workers should deliver IPV including how to handle errors in administration (i.e., if IPV ID is given sub-cutaneously, or if 0.05 ml is administered instead of 0.1 ml), and cautioned against under-estimating the significant resources required to train health workers at all levels on the practical aspects of implementation.
5. IPAC emphasised the need for GPEI to address potential negative public and political perceptions generated by the adoption of 'full' 0.5 ml doses of IPV in industrialized and upper middle-income countries that can afford them, whereas dose-sparing options (adjuvanted IM or fractional dose ID) are considered as the only financially viable choice for low/lower middle income countries.

Session III. Global Updates

A. Updates from Global Advisory Committee on Vaccine Safety (*Madhava Balakrishnan, WHO HQ*)

Dr Balakrishnan reported on the topics reviewed during the Global Advisory Committee on Vaccine Safety (GACVS) meeting conducted in June 2012. The conclusions are reported in WER No 30, 2012, 87, 277-288. The topics included the safety of thiomersal; the safety of aluminium adjuvants; the safety profile of influenza vaccines during pregnancy, safety of immunization during pregnancy and lactation; causality assessment for serious individual cases of adverse events following immunization (AEFI) and the core variables for AEFI monitoring.

The overall benefits of multidose vials with thiomersal in the broader context of resource limited settings and the need to address the issue of public awareness about the safety of thiomersal was deliberated. The need for disseminating the 22 core variables for AEFI reporting and the application of the AEFI causality assessment classification in developing country settings was also discussed.

B. Update from UNEP Inter-governmental Negotiating Committee Meeting (David Wood, WHO HQ)

Dr Wood informed IPAC on the outcomes of the 4th Intergovernmental Negotiating Committee Meeting (INC4), convened by the UN Environment Programme and composed of all UN Member States, which is preparing a global legally binding instrument on mercury reduction. INC4 ended without resolution on policy options for “Products and Processes” which is part of the treaty that will specify provisions, if any, for vaccines that contain thiomersal or use thiomersal during manufacture. A decision will be made at the next meeting (INC5) which is scheduled to be held in January 2013. Dr Wood updated on work in progress to address equity/moral justice questions, research on alternatives to thiomersal, and to promote coherence in government decision-making. IPAC has previously agreed that, for the long-term, the global community must develop and articulate an agreed vision of future vaccine presentations that facilitate delivery of effective, affordable and safe vaccines, especially to populations most in need.

Discussion:

IPAC members remarked on the lack of detail reported in the WER and requested improved and increased flow of information between GACVS and IPAC, as the summaries in the WER do not always provide sufficient detail for persons external to the meetings. Specifically, IPAC members requested information on the substance of the core variables for AEFI reporting deliberated by GACVS. It was requested that in future GACVS updates, issues relevant to IPAC be reviewed in further detail than captured in the WER publication so that members were alerted to issues with programmatic implications.

The INC5 meeting is scheduled for January 2013. IPAC members discussed strategies for national immunization programmes to facilitate resolution of this issue. This included engaging civil-society to speak to the benefits of vaccination, encouraging MOH counterparts to find out which individuals sit on the INC5 delegation and offer education regarding their national vaccination programmes, drafting editorials in reputable local journals and for WHO to continue developing and disseminating messages about the safety of thiomersal in vaccines.

Session IV. Solar Refrigeration Systems

A. Session overview (*Jonathan Colton, IPAC and working group lead*)

Dr Colton opened the session by stating the purpose and introducing the four speakers and topics. The key purpose was to receive strategic feedback and input from IPAC members on the current draft framework for *Guide for Successful Implementation of Solar Vaccine Refrigerators*, and consider adoption of a statement on solar refrigeration system guidance.

A. Solar Refrigeration: From Present to Future (*Modibo Dicko, WHO/HQ*)

Mr Dicko explained that 20% of the world does not have access to electricity, and that 80% of this burden falls on sub-Saharan Africa. To reach these populations in the late 1970's and early 1980's, immunization programs had no other choice but to set up a cold chain without electricity; at that time, the only viable option was absorption refrigerators (either powered by kerosene or bottled gas). Today more than 60% of cold chain equipment in the developing world is absorption refrigerators. However, experience shows that absorption refrigerators have been faced with several drawbacks: many fuel related problems, high running costs, lack of interest from manufacturers, etc. Since 2010, there have been no pre-qualified absorption refrigerators in the WHO PQS system; furthermore, UNICEF Supply Division is no longer making forward ordering agreements with manufacturers. This means that, in the long term,

absorption refrigerators will not be available. Knowing that electricity grids will not expand quickly to fill the above-highlighted gap, it is imperative to find an alternate solution. Presently, solar refrigeration is the only viable option. To ensure solar success, one must heed the lessons learned and the reasons for failures of past solar projects: poor procurement processes, no quality assurance during installation, inadequate maintenance and spare part supply, system abuses (power diversion, thefts, etc.) and lack of performance monitoring. Next, one must plan and budget for the long-term including maintenance, procuring only qualified equipment and ensuring professional installation, ensuring availability of high quality maintenance services and, last but not least, ensure performance monitoring and active management of inventories.

B. What do we learn from kerosene and solar refrigerator use in the Democratic Republic of Congo? (*Hailu Kenea, WHO/AFRO*)

Mr Kenea described the experience of kerosene and solar refrigerator use in the Democratic Republic of the Congo (DRC). The 2011 national cold chain inventory indicated that there were close to 5,259 refrigerators and freezers used in routine immunization within DRC and that 66% of refrigerators and freezers used kerosene as an energy source. Among all cold chain equipment types available at present, 33% were non-functional due to the shortage of skilled manpower for maintenance, spare parts, or energy supply.

Kerosene driven cold chain equipment faces a number of constraints such as fuel quality and supply problems, high cost of transportation, insufficient funding, high running costs, as well as safety issues. Due to the sheer size of the DRC and its difficult terrain and climate, the cost of transporting kerosene is almost twice its value. Low fuel quality has caused fires and damaged equipment. Due to high cost and shortage of funds, there have been persistent shortages of spare parts and fuel supply, impacting refrigerator reliability. Moreover, refrigerator maintenance costs are high due to access difficulties and inadequately trained staff in proximity of the health facilities. The main limitations faced by operating solar equipment (mostly of the battery type) are associated with high cost of initial investment, high transportation costs, absence of skilled technicians required for installation and maintenance, shortage of spare parts, and lack of guidance in selecting appropriate equipment for use.

Life cycle (i.e., long-term) cost comparisons of a kerosene refrigerator and a solar battery-driven refrigerator in the DRC context indicate that a solar battery-driven refrigerator is 25% cheaper compared to a kerosene refrigerator/freezer unit, assuming a 15 year life-span for each type, while the solar direct-driven refrigerator is almost 35% cheaper.

The advantages of installing solar refrigeration include diminishing problems with quality and fuel supply, reducing running costs, increasing refrigerator reliability and performance, and increased life duration if properly maintained. Outstanding challenges are the initial investment cost, and the need to increase availability of skilled technicians for installation.

C. Country success and challenges with solar vaccine refrigeration (*Dmitri Davydov, UNICEF HQ*)

Mr Davydov summarised lessons learned from the introduction of solar refrigeration technology. NASA's lessons from the 1980's demonstrated that many solar units only lasted five years as opposed to the 29 year life-cycle that was predicted. Nevertheless, many photo-voltaic (PV) fridges have lasted for more than 10 years. As of 2008, one of the original NASA PV fridge installations in Mali was still functioning (i.e., the fridge lasted for over 26 years).¹ With the maturation of technology, technical issues become minor compared to management

¹ Dicko, Modibo, "The Story of the 'Old Man,'" May 2012; (This fridge was likely an RR-2 model manufactured in Bellingham, WA by Polar Products, one of the three initial manufacturers for the early trials. Polar Products has since become Sea Freeze, and they no longer manufacture vaccine fridges).

issues, where responsibility and accountability for systems needs to be ensured. Key success factors for the future of solar vaccine refrigerators include commitment to sustainability, performance monitoring, and collaboration with industry to ensure quality products and delivery.

To illustrate this point, Mr Davydov presented solar experiences from Haiti, Pacific Island countries, India, Sierra Leone, Gambia, and Kenya. UNICEF obtains equipment performance feedback through Country Offices, partners, consultants, and discussion groups. All complaints regardless of the source are logged and monitored by UNICEF Quality Assurance Centre.

D. Guidance document development: Status and Plans (*Joanie Robertson, PATH Vietnam*)

Ms Robertson provided an overview of the document, the chapter structure, and some information about a few specific chapters. The objective of the document is to provide information to countries and organizations about planning and implementing solar vaccine refrigeration systems that distills lessons learned from past experience and documents best practices as currently understood.

Important points on specific sections include the following:

- Projects should plan for 10-12 year sustainability; funding, training, and maintenance activities all need attention.
- Product selection algorithm reflects WHO and UNICEF move to prioritize solar over absorption options.
- High quality installation is important for good performance; key issues are knowledge and experience of technicians and quality of materials and supplies.
- Performance monitoring is critical and can provide valuable data for refrigerator management and manufacturer feedback. Human resources are needed to ensure monitoring data is processed and analysed.
- Maintenance and repair is key, continuing training is important, as well as spare stock management.

Optimize will coordinate completion of a first draft of the guidance document with input from WHO, UNICEF, other international experts. The target completion date of the final draft is by the end of April 2013.

Discussion:

IPAC members commended the range of presentations and raised the following key issues during the discussion.

<i>Transition from kerosene/gas to solar</i>	<ol style="list-style-type: none"> 1. Stakeholders need to be included to support the shift away from kerosene to solar, and countries need support in their transition plans when phasing out absorption (length and means). 2. Alliances at the local, regional, country and international levels need to be mobilized. Success stories for solar show that community engagement and ownership is critical. 3. In terms of promoting solar energy for EPI, one should be advocating for how solar can save lives in the broader health systems and development context, not just about installing new units.
<i>Installation and maintenance</i>	<ol style="list-style-type: none"> 1. Guidance on the proper installation of solar panels is critical; ease of installation and of establishing the correct orientation must be considered when procuring the equipment.

	<ol style="list-style-type: none"> 2. The guide needs to emphasize the importance of maintenance issues, as this is a persistent problem regardless of energy source; remote locations make maintenance and the provision of spare parts problematic and costly. 3. The use of solar refrigeration to produce ice for outreach should be clarified. 4. Battery-based solar systems and direct drive refrigeration systems cannot share common solar panels. Similarly, the solar panels used for the direct driver refrigerators cannot be used to power computers, cell phones, lights, etc.
<i>Performance monitoring and documentation</i>	<ol style="list-style-type: none"> 1. The performance of the technology needs to be monitored. Standardization of the monitoring technology (fridge tags, other), the monitored parameters (e.g., temperature, power consumption, how often the doors are opened), and the monitoring protocols should be explored. Similarly, evaluation protocols should be developed and standardized. 2. The guide should help countries document data and provide information to show how direct drive solar refrigerators perform in the field; this is especially important given that this technology is in a very early commercial period. 3. The effects of the introduction of the technology on the system and on health outcomes need to be monitored, documented and shared.
<i>Capacity building and technical assistance</i>	<ol style="list-style-type: none"> 1. Electricians will be needed to install, maintain, and support solar refrigeration systems, so curricula will be needed to train technicians in this area. Training would occur at local technical colleges or universities. 2. It may help countries to cluster installed units in a given area, so as to facilitate training and availability of supervisors and technicians who can provide technical assistance in this concentrated zone.
<i>Costing and financing</i>	<ol style="list-style-type: none"> 1. The cost of vaccines and the cost of the cold chain should be compared and communicated, as it is possible that the value of vaccines exceeds the value of the fridge unit. Estimating the cost to maintain an absorption refrigerator versus the cost of maintaining the solar system is also important data to provide in the guide. 2. Opportunity costs for solar refrigerators fall within the first few years of instalment; preventive maintenance is therefore critical to ensuring the life span of the equipment and benefits of the initial investment. 3. Creative financing for solar infrastructure needs to be explored, such as leasing or potential commercialization of the solar power operations (pay per fee). 4. A market-shaping strategy needs to be developed to sustain healthy markets for these products. 5. The cost of systems will come down when the number of units procured increases. Currently, only a few manufacturers, many small in size, produce the refrigeration systems; this may lead to issues with cost, quality, and availability of the systems and their spare parts.

IPAC members further discussed the broader benefits of solar energy, which can bring added benefits to the community (i.e., lighting, TVs, computers, charging cell phones). EPI should position itself into the bigger picture. One could require extra solar cells be procured to

Meeting Report - IPAC Oct 2012

support the electrification of a community, building community commitment and buy-in, and could lead to local businesses that help maintain the equipment (pay per use fees).

IPAC members provided a range of specific technical inputs into the document:

- *Strengthen title.* This should be guidance for using solar refrigeration for vaccine programs; not simply for using solar refrigerators.
- *Identify audience.* Define the audience for the guidebook, as well as the purpose and use of the guide. Multiple guides, guidance documents or fact sheets for various audiences might be needed.
- *Comparison of technologies.* Provide a comparison across technologies (grid powered, ice lined, absorption, battery solar, direct drive solar, etc.)
- *Selection and procurement.* Provide criteria for equipment and selection of appropriate sites. The section on procurement of equipment should be generic as UNICEF Supply Division's processes are quite specific.
- *Prioritising maintenance.* Place importance on implementing field maintenance, monitoring, and evaluation programs, as a critical part of keeping the equipment operating and extending its life-cycle. Solar systems require more than just cleaning panels. If possible, provide methods on how to determine the true cost of maintenance and use field examples.
- *Sustainability of the system.* Early in the document, add in a section on "building the commitment" and suggest how to build a social infrastructure to support proper care of the units. Link it back to WHO health system analysis, where sustainability is not just about financing, but also human resources.

IPAC members provided a number of other detailed suggestions and were invited to provide further comments in writing.

Recommendations and Decisions by IPAC

The following statement was endorsed by IPAC members (*Vote: 9 yes, 0 no, 2 abstentions*).

1. IPAC welcomes and supports the development of guideline documents regarding solar refrigeration.
2. Evidence-based guidance is needed, for countries and implementing partners, that outline best practices for (a) planning, selection, procurement, installation, long-term maintenance and monitoring of solar refrigerators; (b) transitioning from current refrigeration practices and technologies to solar vaccine refrigeration; (c) addressing vaccine handling practices for outreach strategies; and (d) engaging multiple stakeholders. This guidance should include cost estimation and innovative financing for both procurement and maintenance of the systems.
3. IPAC recommends that WHO continue to promote and support the use of solar vaccine refrigeration through the building of local capacity and the provision of technical resources for countries, both online and through technical consultations; increasing content about solar refrigeration planning and implementation in EPI training programs and resources; and advocating with partners to help ensure solar refrigeration programs are properly designed, funded appropriately for long-term viability, and monitored adequately to provide critical feedback for continuous improvement at both local and global levels. IPAC further recommends an integrated approach to the use of

solar energy for health facilities that includes but is not limited to refrigerators for vaccines.

Session V. Time Temperature Indicators for Vaccines

A. Revision of Vaccine Vial Monitor (VVM) Performance Specifications (*Denis Maire, WHO HQ and Jonathan Colton, IPAC and working group lead*)

Mr Maire and Dr Colton lead a facilitated discussion to elicit input from IPAC members concerning the potential revision of the WHO Performance, Quality and Safety (PQS) standards for VVMs. The dialogue has been triggered by a potential new entrant into the VVM product market and information concerning the new technology was presented to IPAC members. The presentation included illustrations of potential designs of the technology and a brief description of its operational characteristics.

In addition to the discussion of the potential new VVM product, a number of new designs for VVMs - including threshold indicators, icons, different colors, and different shapes - were presented to the committee to raise awareness of potential future products and technologies.

Discussion:

An extensive point of discussion surrounded the concern that there is currently only one WHO pre-qualified manufacturer of VVMs. The disruption that could occur by a failure in the fabrication or supply chain was emphasised as a point of vulnerability for EPI. The entry of other manufacturers was perceived as one way to mitigate this risk.

IPAC members, official observers, and meeting attendees from WHO, including regional office representatives, commented on the need for evidenced-based reasoning from the field for any changes to the current VVM performance standards. Given that the current VVM has been used in EPI for 16 years, strong concerns were expressed by many IPAC members that deviations from the design and characteristics of the current VVM should not cause confusion among those working in the current vaccine supply and delivery chain (ministry of health officials, health care workers, health care supervisors, etc.). Furthermore, field observations still demonstrate that lack of understanding persists with interpreting the current VVM; adding a new time temperature indicator may further complicate field compliance and cause immunization errors. Additionally, it was perceived that vaccine manufacturers have already invested in the current VVM procurement, application, and quality assurance/quality control measures and would therefore be unlikely to switch to a new technology given the resources such a switch would entail. They are also unlikely to supply vaccines with different VVM specifications due to the risk of administration errors with multiple VVM interpretations.

Members remarked that if evidence for the need for a change can be demonstrated (e.g., the current VVM is not meeting the needs of country immunization programs), then the design and operation of any new VVM should be based on sound operational research in terms of human acceptance and product operational characteristics. Further gathering of data was encouraged and two sources of existing information were mentioned as references: EVM assessment reports and Project Optimize report (Milstein J., *Vaccine Vial Monitor (VVM) Availability and Use in the African, Eastern Mediterranean, Southeast Asian, and Western Pacific Regions*. Ferney: PATH, World Health Organization; 2010).

The idea of future VVMs that integrate temperature threshold indicators for CTC use or include 2D barcodes (which can contain much more information than 1D barcodes, such as lot number and expiry date) intrigued the audience, and encouragement was shown for exploring innovative designs including new technologies that meet future needs of immunization activities. IPAC suggested that a landscape analysis be performed. One component of this could be the creation of a "call for interest" document to send to manufacturers and designers to gather ideas and technologies for future VVM and vaccine label products.

WHO/QSS will take the IPAC feedback into consideration as they determine whether or not to proceed with revision of the current VVM specifications.

Recommendations and Decisions by IPAC

1. IPAC advised that WHO investigate whether there are short-comings with the acceptability, comprehension, and implementation of the current VVM before embarking on changes to the existing specifications.
2. IPAC recommended the guiding principles that any change to the current VVM (a) should not lead to programmatic disruption and confusion; (b) should not require programmes to manage devices that require different interpretation than the existing VVM by the end-users; and (c) should not require extensive re-training of personnel.
3. IPAC encouraged WHO to seek ways to diversify the supplier base from one single source while keeping the basic design of the product the same.

Closing

Dr Deeks thanked all in attendance and noted that the following individuals have reached the end of their service term as IPAC members: Dr Sanath Lamabadusuriya, Dr Jane Soepardi, and Dr Robert Steinglass. Dr Deeks' term also ends, but she has accepted to be Chairperson until end 2013. All members were thanked for their important contributions and dedication of service.