

Report of the Eighth Meeting of the
(IVR) Vaccine Advisory Committee
(IVAC)

Geneva, 20-21 May 2009

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Abbreviations and acronyms

BMGF	Bill and Melinda Gates Foundation
CE	Cost-Effectiveness
CS	Capacity Strengthening
EC	European Community
GCP	Good Clinical Practices
HPV	Human Papilloma Virus
IP	Intellectual Property
IVAC	Initiative for Vaccine Research Vaccine Advisory Committee
IVB	Department of Immunization, Vaccines & Biologicals, WHO
IVI	International Vaccine Institute
IVR	Initiative for Vaccine Research, WHO
KPI	Key Project Indicators
MVP	Meningitis Vaccine Project (WHO - PATH)
NIH	National Institutes of Health
NRA	National Regulatory Authorities
NTD	Neglected Tropical Diseases
PATH	Programme for Appropriate Technology in Health
QSS	Quality and Safety of Vaccines Team, WHO
SAGE	Strategic Advisory Group of Experts
SEARO	WHO Regional Office for South East Asia
TDR	UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases
TPP	Target Product Profile
WHO	World Health Organization

Introduction

Dr Kiény welcomed IVAC members and thanked her colleagues for the hard work they did to enable the IVAC meeting to be held.

Dr Peter Ndumbe presented the agenda, which was adopted.

1.1 Progress with the implementation of IVAC's 2008 recommendations

Dr Kiény provided the status of implementation of last year's recommendations (see PowerPoint presentation in Annex 1).

Question for IVAC members:

Are there any critical recommendation(s) that were not implemented and merit additional IVAC's consideration?

The Chair acknowledged that most of the 2008 recommendations have been implemented and that the core IVR functions seem well in line with WHO strategies.

Some clarification was requested on the difference between capacity building and strengthening. Dr Kiény answered that capacity building is when there is no system in place and strengthening when you improved the existing structure.

Prof Ganguly asked that IVR liaise with companies producing adjuvants to facilitate access for developing country vaccine manufacturers. He also made a plea for maintenance of enteric vaccines in IVR portfolio, Dr Kiény answered this is an area where IVR relies on partners (IVI and PATH mainly) and tries to interact with developers and SAGE, like for typhoid and cholera for example.

Finally, there was general agreement on the fact that IVR value was on research to enable policy and encouraged the team to keep the hands on science.

1.2 IVR Strategic position within the WHO context

Dr Kiény presented the Context for IVR strategic plan 2010-2020 (see PowerPoint presentation in Annex 2)

Question for IVAC members:

Does IVR positioning within other WHO components appear appropriate?

There was a general consensus among IVAC members that IVR strategy should be coherent with the broader WHO approach on research for health and innovation. Prof Ganguly underlined that Poverty related vaccines should be one of IVR main focus.

Several members of IVAC enquired about monitoring and evaluation of IVR activities, and Dr Kiény asked IVAC advice on this important and challenging area.

1.3 Overview of IVR's activities over the last 12 months

Dr Kiény presented the Successes and Lessons learnt (see PowerPoint presentation in Annex 3)

Questions for the IVAC members:

- *How well do the last 12 months activities reflect 2008 IVAC recommendations?*
- *Is more alignment needed?*

IVAC members congratulated IVR on a very productive 12 months, with lots of achievements. Although there was agreement that IVR should not engage into too many different projects, the committee acknowledged that fact that IVR should engage where there is a need. Prof Ganguly further commented that research could remain dynamic and flexible.

Some discussion was held on the need to proceed more rapidly on some key projects (e.g. the measles aerosol project, soon to begin pivotal clinical trial). Due to the small size of the team, IVR should clearly define what they will not do in order to avoid engaging into low-impact projects.

It was also noted that IVR is increasingly assuming a dual role, in that it acts as scientific body to SAGE, and promotes and conducts innovative research.

A couple of general conclusion were drawn, which included then acknowledgment that partnerships with clearly defined roles based on the strengths of the partners work well, that defined and technical projects can effectively have broader impact, and finally that a small multi-disciplinary as represented by IVR can make substantive contributions to vaccine and immunization research.

IVR 2008-2009 budget implementation

Dr Kieny explained that IVR has enough funds available to get to the end of the 2008-2009 biennium, but that the main threat was due to the lack of flexible funding (Annex 4).

Dr Rabinovich mentioned that IVR should be cautious for engaging into new projects, and that no much new funding should be expected from the BMGF in the short term. The need to broaden the funding base was considered priority.

1.4 IVR addressing country level needs

Dr Hutubessy presented Guidance on the value and use of various Cost-Effectiveness (CE) models and other tools for vaccines decision making (see PowerPoint presentation in Annex 5)

Questions for IVAC members:

- *Is the role and value of IVR's contribution to the development and use vaccine decision making tools at country level clear?*
- *Does IVAC agree with this?*
- *Can IVAC recommend other roles and contributions from IVR?*

It was mentioned that African countries should access this information and that capacity strengthening on the use of CE tools is needed. Academic institutes should be involved in training on CE in collaboration with Ministry of Health due to the high turn over in Ministries. Prof Ndumbe requested IVR to investigate on how to involve Ministries of Health to collaborate with Academic institutes.

Furthermore IVR has to emphasize on how to use CE s information in particular on the interpretation of results for vaccine decision making.

The issue was raised that harmonization efforts of CE modelling tools do not exist at the international level and IVR could initiate the standardization of CE tools. There is a need of improving the quality of data in particular on cost data. There is a lack of practical guidelines on collecting costing information for CE analysis and cost-of-illness studies. Make it a discipline as tightly adhered to good practice as clinical trials.

CE analysis poses challenges to companies as information resulting from these analyses is necessary to “sell” their products. However, practice this CE information is not always used in their decision making process. The problem is to know who should pay for this, the user or the company selling the vaccine. In addition, Ministry's own CE analysis could also be biased towards negative results not to introduce new vaccines due to limited resources.

Decisions at country level are for the time being related to competition between companies. In this issue, the economic analysis interpretation is important.

The issue was raised on the comparators in performing economic evaluations. It is not always a matter of comparing the cost and benefits of one vaccine against the other. Economic evaluations ideally should be done as a package of preventive interventions where the vaccine is just one of them. The advantage is that synergies between both the costs and benefits of scaling up interventions in combination will be taken into account which comes more close to reality and more useful for priority setting decision making. Finally the issue raised on transparency was raised - the example of the HPV vaccine not being cost-effective in Thailand was the assumption of the vaccine price per dose i.e. more than US\$50. Another study by Harvard School of Public Health showed the opposite but the vaccine price was assumed to be less than US\$5 per dose in their analysis.

2.1 IVR's strategic plan 2010-2020

Joachim Hombach presented the IVR 10 year Strategic Plan. (see PowerPoint presentation in Annex 6)

Questions for IVAC members:

- *Is the strategic emphasis clear?*
- *Does the plan provide a distinct role for IVR?*
- *Does it meet IVR's implementation capacities?*

IVAC members congratulated IVR for having embarked on developing a long-term strategy for IVR.

In relation to priority setting, IVR was reminded of the implications and accountabilities emerging from priority setting exercises, such as the development of target product profiles. This fact was acknowledged, and mechanisms must be put in place to assure inclusiveness and quality of the process. In addition, taking the example of the development of TPP's, priority setting should be considered a living process, that needs to be revisited regularly, to account for the development of science. Specifically, a question was raised on the value and strategic fit of some developing country vaccine candidates, that respond to product profiles recommended by WHO, such as lower valency pneumococcal vaccines, and IVR iterated that such vaccine would likely find a market if adapted to regional epidemiological profiles, and vaccine price and supply were adapted.

In relation to the planned focussing of IVR's portfolio, IVAC stressed the continued importance of advisory committees to cover neglected diseases and diseases that affect the poorest. Care should also be taken to consider integrated approaches for disease control, and vaccine development efforts should not lose sight of the potential of drugs and diagnostics. Opportunities to liaise within WHO should be seized, and the involvement in TDR's disease reference groups is advisable.

IVR should balance effort to focus on few projects. Nevertheless, in particular through its priority setting function, IVR could provide advice on a broader number of subjects or diseases. As a public service IVR, needs indeed to be responsive to Member states needs.

Capacity strengthening was mentioned to be particularly critical in relation to national regulatory authorities, and collaborating centres should be exploited more systematically for that purpose. IVR could have also a catalytic function in addition of the capacity building functions which are core functions.

IVAC reminded IVR that priority areas should be selected on criteria related to public health needs and the role IVR could play to advance the field, and should not be opportunistic in relation to potential funding opportunities. It was highlighted though that occasionally high value research and coordination activities of IVR remain unfunded, despite their demonstrated utility. An example here is IVR's work on policy recommendations for Malaria. As IVR now got staff is seconded from EC to help on the malaria project, IVR can continue to work on the project despite funding problems.

Collaborating centres should be used more systematically for the implementation of IVR's activities. IVR confirmed that very productive work relationships have been established with some of them. However, IVR has not always the same priorities for the proposed/potential new ones.

The gap in regulatory affairs and development of clinical dossiers tailored to developing country needs was mentioned. Here IVR could play a role, and the target product profiles could provide very useful guidance much ahead of the prequalification process. There is indeed intense collaboration on that subject, such as the work being done on dengue vaccine evaluation, that now will be included into written standards. Similarly, a complete review on correlates of protection is planned by IVR.

Several questions related to the management of IVR under the new plan. It was clarified by the secretariat that the categories presented in the plan do not necessarily represent management structures, but are a way to group and strategize activities. It was also clarified that many of IVR's current projects can be mapped into the categories. In that context, IVAC recommend to remove the category of "other" projects.

It was also noted that projects, as they mature move out of IVR to other programmes, such as EPI, as this will be soon the case for MVP.

Finally, IVR was reminded that the vocabulary used in the plan should be self explanatory so that it is clear for everyone.

2.2 How will the strategic functions be implemented?

Dr Fruth presented the IVR vision and strategy 2010-2020, Strategic Function: Priority Setting (see PowerPoint presentation in Annex 7)

Priority setting: IVR's role in ensuring that research needs are identified and gaps are appropriately targeted

Questions for IVAC members:

- *Are the proposed approaches in support of IVR's priority setting goal both appropriate and relevant?*
- *How could IVR, in the priority-setting arena, become a more efficient interlocutor for other entities which sponsor global vaccine development?*

IVAC members requested additional clarifications on the proposed role of IVR the area of priority setting and in particular on the process that will be used to assign the degree of IVR's involvement, e.g. assessment vs. facilitation vs. development/improvement of tools and technologies. The rationale for this priority setting exercise should be clear and shared with the research community.

IVAC members agreed that IVR's input is crucial in defining the key challenges in vaccine research and development. To this end, it was suggested to define a list of priority vaccine development targets and research questions, e.g. in the form of a "top-ten list" to guide the global vaccine research community. Not all these topics needed to be necessarily to be address by IVR itself. In this context, a clear definition of areas of IVR's comparative advantage would help to differentiate between those that only need to be flagged and those where a more active role of IVR was required. Ideally such a list should be constructed with inputs from key vaccine research stakeholders. In setting set a list of priorities, IVR should devote attention to issues that are relevant to regions or groups of countries. In addition, IVR should consider to include some "low hanging fruits" in the list of priorities. IVAC members agreed that the list of priorities should be reviewed regularly and be revised as part of an evolving process.

IVAC members also stressed the need to clearly define how the progress will be assessed. They encouraged IVR to set wider more ambitious goals and set the selected priority areas within this ambitious agenda with clearly define objectives, milestones and implementation plans. In doing so, IVR should attempt to define a "brand name" that encompasses its priorities and comparative advantages.

Dr Fruth reiterated that the IVR prioritization exercise was part of a process of development of tools to guide decision making processes at country and regional level, but by no means an exercise to set priorities for all countries in a vertical approach. In this regard, IVR has facilitated one country level exercise (Mozambique) and supported a regional level exercise with SEARO countries. Both experiences have highlighted the need for tools to guide priority setting at country level and the need to promote this exercise as an ongoing open dialogue. In addition, he mentioned a number of specific IVR initiatives such as the Global Adjuvant Development Initiative or regulatory research as a mechanisms where priorities where identified within specific areas.

Capacity strengthening: IVR's role in supporting sustainable research in developing countries (see PowerPoint presentation in Annex 8)

Questions for IVAC members:

- *What do you think should be the priorities for IVR in the area of capacity strengthening: Basic research and training? Clinical trials? Implementation research?*

- *Can you identify specific opportunities for cooperation and collaboration with your own institutions for capacity-strengthening*

IVAC members commented that Capacity strengthening (CS) is recognized by the majority of partners as one of the unique strengths of IVR, in particular targeting to strengthen clinical trial capacities in developing countries. Some basic principles should be kept in mind in prioritization CS activities. Firstly, it is important to broaden the geographical landscape of developing countries be involved in clinical trials with novel vaccines, e.g. Chad, Congo, Brazzaville, Gabon, Central Africa, Tanzania, Uganda, Kenya, Senegal, Côte d'Ivoire. The CS strategy should be based on principles of collaboration and complementarity at regional and global levels with a primary responsibility of host countries in ensuring relevance and sustainability of CS plans for their own country on a long-term basis.

With regard to specific areas of CS, the IVAC members made several suggestions where the contribution of IVR is deemed important, namely:

- Development, evaluation, standardization and development of reagents for basic and newly develop lab assays for evaluation of safety, immunogenicity, efficacy and search of correlates of immune protection

- Training and transfer of novel lab technologies for vaccine trials, so that most of the lab testing could be done on site in the host country which will make the trials less costly and would certainly allow to avoid logistic and ethical problems related to shipment of clinical samples to industrialized countries.

- GCP training was seen as important, but the proposed standard operational procedures will have to be checked in order not to be in conflict with the existing in-country requirements and regulations

- Other potential CS areas could include data management & statistical support for clinical trials, licensing and IP issues

Dr Osmanov, acknowledged the importance of these comments. With regard to selection of countries for CS activities, geographical considerations may be important but those would also need to be considered with other criteria, including disease specific epidemiology relevant for the conduct of different phases of vaccine trials. A special challenge is related to preparation of conduct of large-scale efficacy trials which require some defined pre-existing infrastructures and human resources. It is therefore important to ensure that the CS activities would be implemented in collaboration with all partners working in a particular country, which should be coordinated with other on-going prevention and treatment programmes in the country. The development of National Vaccine Trial Plans which include a component of CS has shown to be a good example, which ensured ownership and sustainability vaccine trial capacity even after one specific trial has been completed.

2.3 Implementing the Strategy: Example of a priority project

Immunization in the Elderly: overcoming immune senescence in the elderly.

Dr Aguado presented "Vaccines for the ageing population: Identifying and addressing gaps in research". The presentation consisted of a very brief overview of a) the problem the growing elderly population represents globally which is still lacking a lot of data in general,

particularly in developing countries, b) a few examples of the types of impaired immune responses in the elderly as compared to younger adults and c) a proposal for a step-wise plan to develop a research agenda leading to immunization policy for healthy ageing, with a few selected immediate activities (see PowerPoint presentation in Annex 9)

Questions to IVAC members:

- *Does the group feel that the area of work is a well-chosen one, regarding the environment and impact?*
- *Is the list of issues to be addressed a complete and focused one?*
- *Are the immediate activities proposed the ones that will provide the go/no go answers?*

The group felt that this was an interesting and relevant new subject, but it could take a big effort for IVR to undertake alone. However, it is well understood that IVR will develop the research agenda, but it will thereafter be a shared task with other relevant WHO departments and partners. The idea is to develop a plan that would gather information in a stepwise manner, analyse it and then move to the next level of activities (measurement of the problem, understanding causes, development of the tools, evaluation of the tool's impact, translating lessons learnt into policy). IVR could help to facilitate the process, although certainly not undertake every activity therein. This should be done in collaboration with the departments in health metrics and ageing at WHO.

Some members considered a very good idea to start "scanning the horizon" for this new immunization area.

Although it was mentioned that some of the vaccines might benefit from some immunomodulators /reformulation, this is a complex matter that could be considered later on. It would also be important to learn from immunization in younger adults, whose outcomes may enlighten the eventual policy for optimal prevention in the elderly.

This new subject was perceived in general, to be a top priority, being particularly important for the developing world where it could raise awareness about this forgotten population, although it is recognized that overcoming immune senescence is quickly becoming a global issue. Models can be adapted into developing country, best practices and best examples. Influenza vaccines should be available to elderly in developing countries and they could provide a first model of performance in this population.

In addition, positioning it with two other forgotten populations, women and adolescents with the goal of diminishing older age problems, like cervical cancer in older women, or vaccinating when the immune parameters are optimal, could raise awareness among new supporters and funders of this area.

Dr Boslego expressed the opinion that it is very important to eventually have tools that work in infants, adolescents and adults, and clearly more needs to be done to prepare the growing field of expanding immunization to other groups. However, for this project IVR should not get involved in scientific studies - there is not that much data available - and those efforts should be undertaken by more appropriate groups. In addition, they might imply a significant involvement and require a level of resources that IVR does not have. Therefore, documentation, e.g. looking at the burden of disease in developing countries would be good, as additional efforts may be premature until more data is gathered.

Members were very supportive of the idea that WHO should be a convenor and facilitator of activities and participate as appropriate in every subsequent step, However IVR should avoid to be an "active actor" in the field. A long-term strategy, 10 or 15 years plan, should be envisaged with recommendations and guidelines. It would be important to assess the impact that such an undertaking could have in the financial load that the elderly management represents.

IVR therefore must work with partners and carefully choose its area of involvement. There is a lot of specific interest from others, including industry which represents an area for funding and support

The Chair summarized that IVAC was advising IVR to gather world-wide figures (disease burden, immune status) that can document the situation and provide information on the way to proceed. IVR should also identify appropriate partners to conduct the work but not to undertake any basic/vaccine research at this point. He emphasized the convenor role of IVR

IVR funding prospects for 2010-2011

Dr Kieny presented the budget (Annex 9) and explained that enough funds should be available to cover salary costs until mid-2010. Moreover, many fundraising options are being explored, notably for new areas of work (e.g. immunization schedules, vaccination of the ageing population).

Recommendations:

- New Strategic Plan:
 - IVAC members agreed that the new proposed strategic emphasis is appropriate for IVR and clearly described in the draft document. However they raised caution about the fact that there may not be enough staff resources in IVR to accomplish what is being proposed.
 - A Monitoring and evaluation section should be added. IVR should define its Key Project Indicators (KPI)
 - Some IVAC members suggested that IVR should focus more on poverty-related diseases, especially on neglected tropical diseases (NTD).
 - Partnerships should be clearly identified which will enable IVR to meet its objectives, and the IVAC members encouraged the team to work as much as possible with and through partners (including WHO Collaborative Centres) in order to avoid unnecessary duplications.
 - As the Strategic Plan is very broad, as it should be as it covers a 10 years period, IVR is encouraged to revise its workplan on a regular basis.
 - Although most IVAC members agreed on the value for IVR and the global vaccine R&D community in the project on immunization for the ageing population, some members considered that this might represent a distraction for the Initiative.
 - A recommendation was made, as in 2008, that IVR should increase the visibility of its activities and acquire a higher profile through better "branding" of its contributions to vaccine R&D.
- Funding of the new Strategy
 - IVAC pointed out that the WHO system imposes constraints on fundraising, and suggested that IVR should hold brainstorm meetings to discuss possible approaches to raising funds. A better visibility of IVR critical role in WHO should be promoted.
 - Dr Heilman pointed that some institutes and companies are willing to co-sponsor meetings. She offered her help for meetings that would be of common interest to IVR and NIH.

Finally, Dr Kieny thanked all IVAC members for their support and advice.

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