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

Geneva, 26–27 May 2008

The Initiative for Vaccine Research
thanks the following for their support during 2006–2007 (in alphabetical order):
the Bill & Melinda Gates Foundation, the Canadian International Development Agency, the US Centers for Disease Control and Prevention, the UK Department of Health, the US Department of Health and Human Services, Finland, the Fondation Mérieux (France), Fraunhofer Institut (Germany), the GAVI Alliance, the Global HIV Vaccine Enterprise, the International AIDS Vaccine Initiative, the International Vaccine Institute, Japan, the Johns Hopkins Bloomberg School of Public Health (USA), Merck Vaccines, the Netherlands, the Program for Appropriate Technology in Health, the Public Health Agency of Canada, the Serum Institute of India, the Department for Research Cooperation of the Swedish International Development Cooperation Agency, the United Nations Children's Fund, the Joint United Nations Programme on HIV/AIDS, the US Agency for International Development, and the Wellcome Trust.

This document was produced by Ms Kay Bond for the Initiative for Vaccine Research, and is available at www.who.int/vaccine_research/documents/en/.

1. Opening Session

Professor Peter Ndumbe opened the meeting as Chair of the IVR Vaccine Advisory Committee (IVAC) and welcomed participants to the seventh meeting of the group. He reminded member of the role and functions of IVAC, presented the agenda of the meeting, and invited participants to present themselves to the group. Given the close link between the IVR progress report and the IVR external evaluation, discussion followed the first two presentations outlined below.

2. IVR Report 2006–2007

Dr Marie-Paule Kieny presented major highlights of the work of IVR during 2006–2007, contained in the full biennial report provided to each participant.[1] The results and challenges were presented within the framework of the comments and recommendations made at the previous IVAC meeting in April 2007.

Dr Kieny noted that the 2006–2007 workplan had to take on board the unexpected pandemic influenza project, as well as a reduction in the level of staff to carry out the activities. Since these staff will not be replaced, it was important for IVR to be even more efficient.

The presentation summarized the global vaccine R&D scenario as it stands today, and IVR's role and functions within this framework. The three-pronged approach of knowledge management, product research and development, and implementation research had been put into effect, largely to reinforce the cross-cutting functions of the Initiative.

Successful projects included the Target Product Profile for pneumococcal vaccines, increasing the potential supply of pandemic influenza vaccine, the meningococcal A conjugate vaccine trials (which led to a US$370 million GAVI Investment Case for vaccine introduction in Africa), the Global Adjuvant Development Initiative on downstream adjuvants that have already shown pre-clinical efficacy in man, and the new guidelines on economic evaluation of immunization programmes.

Finally, Dr Kieny summarized IVR's expenditure over the last biennium, its priorities for 2008–2009, and requested advice from IVAC on

- how to improve the profile and visibility of IVR
- how to attract funding for core functions
- how to clarify IVR's role in capacity strengthening compared to other global mandates such as TDR
- the orientation of the IVR Strategic Plan 2010–2020.

[1] *IVR Report 2006–2007*. Geneva, World Health Organization, 2008 (WHO/IVB/08.11).

3. IVR external review 2007–2008

Mr Nicolaus Lorenz of the Swiss Centre for International Health presented a summary of the rationale, methodology, results and recommendations of the independent evaluation of IVR, commissioned by the Initiative in October 2007.

The review sought to assess the relevance, effectiveness and impact of IVR since its inception and against its stated mission. Interviews were carried out with key stakeholders and a detailed, confidential questionnaire returned by 159 collaborators from all sectors.

Overall, it was estimated that IVR was doing very well, and the leadership and performance of the team was widely appreciated. The core functions were unanimously recognized – if not funded – while IVR's role in product development remained controversial. IVR was seen to be highly successful in promoting partnerships, sustaining its reputation and credibility, and facilitating landmark projects. It was felt, however, that IVR could involve developing countries more in setting priorities, and exercise caution if expected to be "referee and player" at the same time.

Recommendations of the review fell within four categories:

1. Develop a long-term strategic plan
2. Increase attention in developing countries
3. Learn from success stories
4. Refocus the portfolio.

A summary of the results of the external review is available in Annex 3.

Discussion on items 2 and 3

The Chair congratulated Dr Kieny and her team for an impressive report, and suggested that an executive summary could be considered for wider circulation. The following points were raised:

Funding
There had been a 40% shortfall in the planned budget for the entire department of Immunization, Vaccines and Biologicals, and not just for research. Some concern was expressed that cuts in funding should not affect IVR projects such as the measles aerosol vaccine and prioritization of vaccine introduction in developing countries. Since the department receives very few recurrent resources from the WHO regular budget, IVAC members were requested to make recommendations on how to raise the profile and core funding of IVR. IVAC considered that the global vaccine R&D community needed to be better informed of IVR's lack of core funding, especially since donors may believe mistakenly that IVR receives part of their direct contribution to WHO unspecified funds. These, and potential funders need to be identified and targeted to fill this gap.

IVR core functions and improved visibility

Related to the above issue of funding was the chronic problem of how to "sell" core functions. GAVI, for example, invests considerable resources into immunization, but does not fund research. It was remarked that since funding tends to go to new initiatives rather than core activities, IVR should focus on improving its advocacy. Other suggestions were to review the priorities and select the highest profile projects to attract larger funds; and to integrate the core functions into project funding (e.g. TPPs, immunization schedules). However, the most urgent recommendation was to delineate and spotlight the unique core functions of IVR and critical gaps that non-funding of these would entail for the global vaccine R&D community. This last point is particularly relevant in the development of a ten-year strategic plan. In summary, IVR must acquire communications support, such as that provided by PATH for the successful MVP project, and elaborate a solid communications strategy if it is to raise its profile. This may best be achieved by outsourcing – already widely used by IVR – and by taking more advantage of existing communications staff within WHO.

Capacity strengthening

IVR is active in this area and has gained excellent experience and outcomes *through* the projects it supports, not as an academic training centre. Moreover, there is a knock-on effect where countries can apply the new capacity to other areas of health research. IVR also participates actively in workshops and annual training courses for developing country scientists in immunology and vaccinology, organized by various partners. It was recommended that the success stories from the MVP, pandemic influenza, measles aerosol and other projects be pulled together into a compelling advocacy presentation.

Results of the evaluation

It was considered a positive move to seek and reflect on feedback from stakeholders on IVR progress, although the focus of the review on individuals had led to some surprising, even conflicting recommendations. Attention was drawn to the WHO label under which IVR is uniquely able to provide credible and neutral advice, without judgement, as long as it does not play researcher and referee at the same time. Clearly, an element of competition existed in roles within the vaccine R&D community, although collaboration should reduce this.

IVR priorities 2008–2009 and 10-year strategic plan

The list of priorities presented for the forthcoming biennium was approved, with the addition of the introduction of pneumococcal vaccines into national immunization programmes (see box). It was agreed that the pilot TPP for pneumococcal vaccines had been a useful and thorough exercise, but should be factored into implementation research at a much earlier stage for future studies.

IVR priorities for 2008–2009

- Pandemic influenza technology transfer project, including validation of the hub paradigm
- New Target Product Profiles
- Global Adjuvant Development Initiative
- Measles aerosol registration
- Introduction of meningitis vaccine, including impact assessment
- Introduction of pneumococcal vaccines
- Immunization schedules
- Independence and replication of AAVP
- Regulatory and ethical research, including capacity strengthening
- Ten-year Strategic Plan

The longer time frame for the next IVR Strategic Plan was welcomed by IVAC members. Many of the issues and recommendations made during this meeting, including the outcome of the external review, should be addressed in such a plan. It was agreed that IVR would seek the help of a consultant and develop a substantive draft for presentation and discussion at the next IVAC meeting.

Other general comments
Regarding the link between research policy and research per se, it was clarified that research does not set the policy at WHO, rather it provides evidence for policy.

It was noted that the considerable amount of information disseminated by IVR is integral to its mandate and is well received – some articles receiving best hits. Moreover, information is always disseminated through channels best suited to the different target audiences. Special mention was made of the recently acclaimed ethical guidelines developed by IVR and UNAIDS; the attributes of which might be extracted to build models of success.

The following suggestions were also offered on where developing countries could benefit from IVR assistance, although these were not discussed by the group:

- use the IVR adjuvant platform, to be developed with funding form the Wellcome Trust;
- reduce the time lag to develop and introduce a vaccine by encouraging the evolving manufacturing capacity in developing countries;
- mapping intellectual property rights.

4. Influenza vaccine technology transfer project

The global health security priority of pandemic influenza preparedness led the World Health Assembly to adopt resolution WHA 58.5, which mandated WHO, inter alia, to draw up and coordinate, in collaboration with public and private partners, an international research agenda on pandemic influenza, with a view to increasing the potential supply of vaccine. Dr Teresa Aguado presented IVR's progress within the Global Pandemic Influenza Action Plan.

One avenue to increase influenza vaccine supply to meet the expected pandemic is to build production capacity, particularly in developing countries to redress the current geographical imbalance. The development of adjuvanted vaccines for antigen sparing, the expanded production of live attenuated vaccines and evaluation of the immunogenicity of inactivated whole virus vaccines were also being explored.

Dr Aguado described the six developing country institutes that had received grants to develop influenza production capacity, the specific technologies they had chosen from those eligible through the grant, and the progress they had made to date.

In order to address the difficult challenge of identifying technology transfer partners, and to be able to cope with significant interest from other developing countries, IVR had investigated the option of creating a "technology hub". Such a hub would be able to transfer an IPR-free technology package for a production process, including all relevant documentation. Following an open bid, the Netherlands Vaccine Institute was chosen to act as the hub, developing inactivated whole virion influenza vaccine produced in eggs. It was felt that this solution was of value to the public sector, potentially sustainable and applicable to other fields such as adjuvant formulations.

Discussion

The Chair opened the floor for discussion, noting that avian influenza had brought the pandemic to the fore, requiring a significant increase in supply to meet expected demand, and hence attention to maintaining the highest quality of vaccines and to sustainability.

Members sought clarification on the strategy for selection of the technologies and on issues related to quality, regulation, registration, costs, and WHO involvement in the process. It was agreed that national commitment to the projects was essential and had been secured by the grantees concerned. Regional interests should be respected, and partnerships established with major international agencies.

The concept of the technology hub raised the question of purpose, and fees to developing country customers who could barely afford to fund BCG, let alone influenza vaccine. On the other hand, there was clearly global interest and gain if more countries could access the vaccines.

Some discussion ensued on whether there was in fact a need for more manufacturers, or just more vaccines meeting quality standards. Dr Kieny informed members that at least three of the developing country sites were already on track to produce high-quality products, as attested by an independent field visit report conducted by regulatory experts for Australia and the National Institute for Biological Standards and Control, and an industry production specialist. Moreover, IVR would remain neutral in the production process and would not interfere with prequalification of products generated by the new manufacturers or the technology hub.

Members welcomed the fact that IVR reviewed participation in the project on a case-by-case basis, since not all requests to produce vaccines should be approved. Sustainability issues centred on the vital need to match demand and country needs for seasonal vaccine for fear of an overproduction of unwanted vaccine.

Regarding the choice of technology, there had been no evidence of excess reactogenicity with new generation inactivated whole virus vaccine.

In summary, the technology hub in the Netherlands was considered a praiseworthy option, particularly as it had public sector support from the Netherlands Government and could carry out all the requirements. IVR was advised to incorporate the issues raised in the discussion into future presentations of the Pandemic Influenza Vaccine Technology Transfer Project.

5. Immunization schedules

Dr Ana-Maria Henao Restrepo presented the work of IVR to review current immunization schedules for their optimum effectiveness, operational ease and cost, particularly in the light of the many new vaccines that will become available for introduction in the coming years. She underlined that the presentation would make no recommendations, but was intended to share the outcomes of the research carried out and invite discussion.

A thorough review of current practice revealed that new vaccines were being introduced following a traditional vaccine schedule, although even the traditional schedule for DTP presented significant variations among countries. Dr Henao discussed a variety of issues related to the age of vaccination, different dose regimens and the current the funding gap before presenting the introduction of pneumococcal conjugate vaccine as a case study. She summarized the research still needed to define improved immunization schedules for conjugated vaccines, in particular pneumococcal vaccine, in developing countries, and presented IVR's collaboration with partners in this area, along with a time frame for the next steps.

Discussion

IVAC members commended IVR on an impressive and useful project. The research questions being posed in the presentation were relevant, and the timing appropriate for the introduction of pneumococcal vaccines in developing countries.

The need for data from within developing countries on, inter alia, conjugated vaccines, coverage, priorities, different models targeted to different types of developing country, was needed and IVR was encouraged to continue its work in this area.

Dr Henao Restrepo informed the group that, now that initial data had been gathered and analysed, the regional and country offices, including EPI managers, would be consulted to broaden consensus on any future modification to the recommended immunization schedules. IVR was currently looking for opportunities to validate the models and, with experience gained from this first wave, the plan would be to move from models to the collection of surveillance data and carrying out demonstration projects. The long-term goal is for WHO to explore possible scenarios that would offer more choices for schedules in developing countries.

In summary, this was considered an area of research when IVR had a unique role to play to help decision-makers in developing countries, particularly for future vaccines, and should be solidly reflected in the proposed IVR Strategic Plan 2010–2020.

6. Categorization of vaccine-preventable diseases

Dr Uli Fruth summarized the progress made to date on the above project, which had been undertaken in response to an initial request from GAVI. In collaboration with EPI, IVR had categorized, according to public health priorities, diseases for which vaccines were either currently available but not recommended by WHO for routine use, or vaccines that would be licenses by 2012. The aim was to assist the range of immunization players across the world who need to make decisions on which activities to prioritize.

Dr Fruth explained the methodology used to develop the list of 18 diseases, ranked using 10 criteria, and the participants involved in the study. The preliminary results ranked malaria and pneumococcal diseases as the highest priority, with mortality and epidemic or pandemic potential as the most important criteria used.

Finally, following a review of the preliminary results by the Strategic Advisory Group of Experts (SAGE) on immunization, certain flaws in the methodology were identified, and a revised process proposed in order to improve the output and usefulness for decision-makers in developing countries.

It was concluded that this project was still in its early phases and would need to be adapted to regional and country settings. To this end, Mozambique had volunteered to act as a pilot country to test the categorization tool.

Discussion

IVAC members thanked HVI for the presentation. It was clarified that since the project focused on vaccines currently available or expected to be available by 2012, there was no possibility that the project could influence the industry. The project had already had some impact, for example in providing GAVI with evidence that led to the consideration of cholera and typhoid as opposed to hepatitis A and E, for example, in its portfolio.

Concerns were raised regarding the potential efficacy of such a categorization exercise, including its consistency against reliability and accuracy, the assumptions made, its implementation in remote communities, and the fact that industry and others have taken their own lead in this approach.

7. New WHO-wide research strategy

Dr Nirmal Ganguly was invited to make some personal remarks on the process under way to develop the WHO strategy on health research for discussion and adoption at the World Health Assembly in 2009. He reflected how WHO had a clearer research focus in the past, through the Advisory Committee on Health Research, various scientific and technical committees, followed later by the Kobe Centre, among others.

Today, WHO's three major research departments are on tropical diseases, human reproduction and vaccines. Yet the newer initiatives are being encouraged to focus on health systems research and health policy research, to balance a perceived over-emphasis on clinical research.

Dr Ganguly pointed to the need for IVR to position itself well in this process, to embed itself within health systems using research input as a hallmark of success, and suggested the following ways to achieve this through the new ten-year Strategic Plan were:

1) *Foster collaboration and partnerships*, such as the successful examples with the meningitis vaccine with PATH.

2) *Prioritize*: IVR could collate and analyse data on access to vaccines, surveillance outbreaks, etc., so that even if countries did not consult IVR, it would have played an invaluable role in assisting countries to prioritize since they would still have the data.

3) *Connect policy with research*: IVR has unique access to experts in all vaccine-related fields, ranging from ethical platforms for HPV trials to capacity building in data management, and should capitalize on this pivotal role in further involving developing countries.

4) *Make a difference*: for example by developing measurable indices for vaccines in adolescents or women, that would be fundamental for the Millennium Development Goals.

5) *Regulatory and other research*: focus on demonstration projects, create lines of international standards (e.g. for egg-based pandemic influenza), map intellectual property rights for other vaccines, create matrices for monitoring and evaluation, develop surrogate markers where no protective correlates are known, etc.

The Chair added three points to summarize the situation today regarding research within WHO, namely that: the Organization does not have – and urgently needs – a clear research culture, informed by the best evidence; centrally coordinated research policy had prevailed over mainstreaming research throughout the Organization as this ensures monitoring and evaluation; and there was only one WHO.

Directors IVR and TDR noted that they had been involved since the first steps towards a WHO strategy for health research that would allow Member States to grasp what research the Organization was carrying out, although it was regretted that progress has been somewhat hampered by issues of "structure". In late 2008, following input from an External Reference Group, a prototype of the research strategy will be presented to the Executive Board in January 2009 and then to the Health Assembly in May 2009. IVR, TDR and others will look at how best

to align themselves within this new research strategy and ensure that awareness of the value of the research being carried out is further strengthened.

8. IVR Strategic Plan 2010–2020 and summary recommendations

Director IVR asked IVAC members for their views on the current and projected balance of activities within the Initiative, with particular emphasis on the longer term perspective. The following points and recommendations were made:

- define exactly what the core functions are, illustrate the impact of non-support, and package them within a broader disease or technology project;
- reassess and communicate strengths, e.g. as convenor, interface between developed, developing countries and industry, setting priorities;
- concentrate on fewer projects, with at least a mid- to long-term (4–5 year) perspective and thus avoid (without eliminating) areas of lower impact;
- emulate unique position, e.g. in success stories such as the TPP, MVP and immunization schedules (and implementation research in general)
- clarify niche and assure alignment within partnerships, to ensure harmonized direction and improve visibility and funding opportunities;
- ensure the primacy of scientific over policy research; develop a more proactive perspective for future generation vaccines.

It was felt essential that IVR access communications expertise to improve the visibility of its work and increase its resource base. As a prerequisite, IVR should undertake a fundamental review of its strengths and uniqueness within the current global vaccine arena. Suggestions for communications support included hiring an external consultant, tapping the communications resources within WHO, and requesting the donor partners present to consider support for IVR communications.

Several members felt that the term “knowledge management” was not a useful category to present the work of the Initiative, and IVR agreed to revisit this within the framework of the next Strategic Plan.

Regarding the Strategic Plan 2010–2020, IVR should identify an external consultant to brainstorm and develop the draft, which should be reviewed by IVAC during 2009. IVR partners should be involved in the development of the Strategic Plan to ensure their long-term support.

After 2009, it was agreed that IVAC meetings could take place at 18-month intervals.

Annex 1. Programme

MONDAY 26 MAY 2008

14:00	Welcome	Chair
14:10	Presentation of IVR Report 2006–2007	Marie-Paule Kieny
14:30	Presentation of IVR external evaluation report	Nick Lorenz (Swiss Tropical Institute)
14:45	Discussion	
17:30	Cocktail	

TUESDAY 27 MAY 2008

	Discussion on specific IVR programmes	
9:00	Knowledge management: influenza vaccine development and technology transfer	Teresa Aguado Laszlo Palkonyay
9:30	Discussion	
10:15	Refreshment break	
10:45	Implementation research: optimization of immunization schedules with conjugate vaccines	Joachim Hombach Ana-Maria Henao Restrepo
11:15	Discussion	
12:00	Knowledge management: categorization exercise for pipeline vaccines	Saladin Osmanov Uli Fruth
12:20	Discussion	
13:00	Lunch	
14:00	Discussion on WHO research strategy General Discussion	
14:30	Discussion on IVR priorities and Strategic Plan 2010–2020 and proposal for revised 18-month meeting schedule for IVAC	
15:30	Closure	

Annex 2. List of participants

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* replacing Dr Regina Rabinovich

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Dr Robert Ridley, Director

Annex 3. Extracts from IVR survey

What is the role of the IVR?*	**Responses**	**%**
Lead the global vaccine community	40	8.6
Convene the global vaccine community	85	18.3
Guide policy and the global R&D agenda	105	22.6
Set norms and standards	68	14.6
Act as a clearinghouse for information	69	14.8
Bridge vaccine R&D and vaccine availability	79	17.0
Other	19	4.1
**multiple choice*		

How would you assess IVR's overall achievement since 2000?		
Very high	19	12.0
High	100	62.9
Not so high	35	22.0
Low or don't know/can't comment	5	3.1

Has IVR involved developing countries?		
Little or very little	30	18.9
Average	70	44.0
High or very high	47	29.5
Don't know/can't comment	12	7.6

How much public health impact has IVR had?		
None	2	1.3
Small	20	12.6
Some	70	44.0
High or very high	54	34.0
Don't know/can't comment	13	8.1

Is IVR good value for money?		
A waste of resources	4	2.5
Some value for money	52	32.7
Cost-effective	77	48.4
Very cost-effective	22	13.8
Don't know/can't comment	4	2.6

How appropriate are IVR's human resources?		
Insufficient or very insufficient	80	50.3
Average	50	31.5
Adequate or perfectly adequate	24	15.1
Don't know/can't comment	5	3.1

How are IVR's financial resources to achieve its mandate?		
Insufficient or very insufficient	101	63.5
Average	44	27.7
Adequate or perfectly adequate	9	5.7
Don't know/can't comment	5	3.1
How is the global visibility of IVR?		
Poor or no visibility	37	23.3
Average	83	52.2
High or very high profile	36	22.7
Don't know/can't comment	3	1.8
Interest of major donors to invest in IVR?		
No interest	4	2.5
Some or average interest	125	78.6
High investment interest	18	11.3
Very high investment interest	1	0.6
Don't know/can't comment	11	7.0
Is there WHO-in-house competition for funding?		
No competition	16	10.1
Some or average competition	109	68.5
Tough competition	25	15.7
Very tough competition	3	1.9
Don't know/can't comment	6	3.8
How much competition is there with other vaccine R&D initiatives?		
No competition	11	6.9
Some or average competition	77	48.4
Tough competition	50	31.5
Very tough competition	14	8.8
Don't know/can't comment	7	4.4
Should IVR adapt to improve its performance?		
Yes changes are necessary	111	69.8
No changes are necessary	48	30.2
In which area has the IVR's contribution been most effective?		
Implementation research	17	10.7
Product development	14	8.8
Knowledge management	39	24.5
Advocacy and mobilization of commitment	85	53.5
Other or don't know/can't comment	4	2.5
In which area has the IVR's contribution been least effective?		
Implementation research	40	25.2
Product development	68	42.8
Knowledge management	8	5.0
Advocacy and mobilization of commitment	28	17.6
Other or don't know/can't comment	15	9.4