Annex 3

Overall presentation of IVR Strategy

Presentation to the IVR Advisory committee (IVAC)

April 2007

World Health Organization
Outline

- Why does WHO invest in Research & Development?
- What is the Initiative for Vaccine Research (IVR)?
- What is IVR's role?
- What are the new opportunities for IVR?
WHO mandate for Research

The core functions of WHO guide the work of the Secretariat, influence approaches for achieving the strategic objectives, and provide a framework for assuring consistency and output at global, regional and country levels.

The second of the 6 core functions concentrates on research: "shaping the research agenda, and stimulating the generation, dissemination and application of valuable knowledge".
The need for increased investment in vaccine research

- Vaccines are the cornerstone of the fight against communicable diseases

- However, infectious diseases are still responsible for nearly 30% of all deaths worldwide representing over 15 million people of whom 6.7 million are children –every year mostly in low and middle income countries.

- Approx. an additional 1.4 million deaths in children under 5 could be averted if available vaccines were applied universally. Large scale implementation of pneumo and rotavirus vaccines could avert an additional 1.1 million death in this age group.
Global Immunization 1980-2004, DTP3 coverage

Global coverage at 78% in 2005

IVR is a multi-disciplinary team whose task is:

– to facilitate the **development** of vaccines against infectious diseases of major public health importance,

– to **improve** existing immunization technologies, and

– to ensure that these advances are **made available** to the people who need them the most.

IVR is hosted within the WHO Department of Immunization, Vaccines & Biologicals
3 functional groups: clinical research, quantitative implementation research, regulatory research
IVR teams

Tuberculosis Regulatory research
Molecular biology
Economy HIV
Immunology Statistics Modelling
Technologies Adjuvants Vaccine development
Enteric diseases Clinical trials Flaviviruses Molecular biology
Regulatory Influenza Clinical trials
Measles, delivery implementation Malaria, Ethics, Clinical trials
New landscape in Vaccine R&D

- A number of **new vaccines** have been developed & licensed in recent years

- Increased awareness of health issues in the developing world has led to the emergence of several **initiatives & partnerships**

- BUT… for a number of diseases there is still a lack of needed leadership, funding & supportive implementation to bring a vaccine to the market
The vaccines pipeline

Available by > 2011

HIV/AIDS
Malaria
TB

Future

Underutilized Vaccines

Traditional EPI

1960 1980 2000

Diphtheria
Pertussis
Tetanus
YF
Influenza
Polio
Measles
JE Rubella
HepB
Hib (conj)
Typhoid
Cholera
Rotavirus
Pneumo (conj)
Mening (conj)
Dengue
HPV
HIV/AIDS
Malaria
TB

Unfinished agenda

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Unfinished agenda
Highlights of IVR contributions to accelerating availability of new vaccines

- **Rotavirus:**
  - Collection of critical immunogenicity data with the RAPID partnership in the pre-ADIP era;

- **Meningococcal meningitis:**
  - Development of a monovalent conjugate A vaccine with PATH (MVP)
  - Immunogenicity and effectiveness evaluation of PS trivalent vaccine

- **Influenza:**
  - Technology transfer to developing countries;

- **Malaria:**
  - Development of endpoints for clinical trials

- **36 publications in the scientific literature (2006-2007)**
How does IVR support the vaccine research pipeline?

By using a three-pronged approach:

- **Management of knowledge** & provision of guidance & advocacy through effective partnerships to accelerate innovation;

- Support to **research and product development**;

- **Implementation research**, and development of tools to support evidence-based recommendations.
<table>
<thead>
<tr>
<th>Rank</th>
<th>Child-health themes</th>
<th>Maternal health</th>
<th>Health systems</th>
<th>Community development</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>General newborn care, including prevention and treatment of neonatal sepsis</td>
<td>Skilled birth attendance and intrapartum care</td>
<td>Human resources</td>
<td>Participation and empowerment interventions (eg, women’s groups)</td>
</tr>
<tr>
<td>2</td>
<td>Care of the preterm and low-birthweight infants</td>
<td>Haemorrhage</td>
<td>Quality-improvement interventions</td>
<td>Community models for maternal and newborn care in the home</td>
</tr>
<tr>
<td>3</td>
<td>Immunisation and new vaccines</td>
<td>Family planning, including teenage pregnancy</td>
<td>Scaling-up and sustainability of interventions</td>
<td>Community education in maternal and child health; and cultural acceptability of interventions (joint third position)</td>
</tr>
<tr>
<td>4</td>
<td>Breastfeeding promotion</td>
<td>Unsafe abortion</td>
<td>Getting research into policy and practice</td>
<td>See above</td>
</tr>
<tr>
<td>5</td>
<td>Malaria</td>
<td>Obstructed labour</td>
<td>Organisation and management of services</td>
<td>Food security</td>
</tr>
<tr>
<td>6</td>
<td>Acute respiratory infection</td>
<td>Hypertensive disorders</td>
<td>Evaluation and monitoring methods</td>
<td>Water and sanitation</td>
</tr>
<tr>
<td>7</td>
<td>Weaning, diet, and growth</td>
<td>Antenatal care (eg, screening and birth preparedness)</td>
<td>Appropriate technology</td>
<td>Maternal and children’s rights</td>
</tr>
<tr>
<td>8</td>
<td>Birth asphyxia; intrapartum care and resuscitation</td>
<td>Malaria, anaemia, and other indirect causes of death</td>
<td>Equity, including gender</td>
<td>Working with men</td>
</tr>
<tr>
<td>9</td>
<td>Prevention of mother-to-child transmission of HIV and of HIV in children</td>
<td>HIV in pregnancy</td>
<td>Integration of maternal and child health, and the continuum of care</td>
<td>Social marketing of interventions</td>
</tr>
<tr>
<td>10</td>
<td>Management of the severely sick child</td>
<td>Emergency obstetric care</td>
<td>Health systems governance and accountability</td>
<td>NA</td>
</tr>
</tbody>
</table>

IVR in action: influenza vaccine development

WHO

EPR: selection of potential pandemic vaccine seed strain
EPI: demand & supply landscape; strategies for introduction
QSS: vaccine quality/prequalification

GoJ/US-HHS
Member States
Scientific Advisers & Specialized Research Centres e.g. NIBSC
Other Collaborators? IVI .......

Technology providers
Manufacturers, consultants

Technology recipients
6 developing country vaccine producers

Consultants
IVR budget outlook

Evolution of IVR funding

Major contributors to IVR budget 2006-07 (excluding pandemic flu)

- Gates Foundation 29%
- Core funds 32%
- Others (<1m) 13%
- PATH 5%
- Sweden 5%
- UNAIDS 7%
- CIDA 9%
Monitoring progress: IVR database
Further details on IVR programmes will be presented by:

- Teresa Aguado: Product Research and Development
- Joachim Hombach: Implementation Research
- Saladin Osmanov: cross-cutting, capacity building, legal, regulatory
In the coming years, IVR will continue to encourage increased investment and support for vaccine research by:

- engaging in product R&D in area of comparative advantage -- WHAT ARE THESE?
- facilitating clinical and/or laboratory standards and protocols -- FOR WHICH PRODUCTS? WHAT IS IVR'S COMPARATIVE ADVANTAGE?
- strengthening developing country capacity in the areas of bioethics, regulation and Good Clinical Practice -- HOW CAN WE HELP COORDINATION OF GLOBAL EFFORTS?
- conducting implementation research, including that on future access (cost–effectiveness studies, introduction plans, national decision-making support tools) -- WHICH TOOLS? HOW TO BEST SYNERGIZE WITH ONGOING INITIATIVES?
New Opportunities for IVR?

- Strengthening interactions with global initiatives
  - Development of Best Practices (e.g. cost-effectiveness evaluation)
  - Consensus on optimal Product profiles
  - Monitoring and improving the quality of clinical trials

- Acting upon request of Member States
  - Responses to health security crisis (influenza, meningitis)

- Promoting neglected areas of work
  - Regulatory research (e.g. novel assays and endpoints)
  - Optimization of immunization schedules