

Ethical considerations related to the provision  
of care and treatment in vaccine trials

A proposed process for  
participatory decision  
on standards of care

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# Consultations and presentations

- Zomba, Malawi, 15-16 April 2005;
- Salvador de Bahia, Brazil, 12-15 June, 2005;
- Karachi, Pakistan, 14-15 February, 2006
- WHO Vaccine Advisory Committee, Gaborone, Botswana, 20 March, 2006.
- St Petersburg, Russia, 7-9 September 2006.
- Bangkok, Vaccine Forum, 3 December 2006

# Why these consultations?

- Vaccine trials in countries with weak health systems are expanding
- Justice, as equality and reciprocity, and beneficence call for access to care by research participants for conditions targeted by vaccine candidate, but:
  - What type, level and duration of care?
  - Are non-participants (screened-out, families...) also eligible?
  - Should also other severe conditions be considered?
  - Who bears the responsibility of providing care?

# Focus on care?

- Prevention standards too, need to be defined in agreement with community and other stakeholders
- Standards of prevention are commonly defined in the scientific design of vaccine trials
- Access to care influences minimally the outcome of vaccine trials
- Access to care is often insufficiently or not defined

## Standards of Care

Specifications for eligibility criteria, including type, level and duration of care, treatment and support

# Some discussion points

1. Facilitation or hampering research?
2. How to interpret and improve the matrix?
3. Best (or good) research governance?
4. What care and treatment?
5. International standard or guidance to countries?
6. A two-tiered system?
7. Sharing the benefits?
8. ...and more

# Establishing standards of care

- Who should benefit from care?
- What type of care?
- What level of care?
- Who should bear the cost of care?

# A matrix approach to map out the questions

	What diseases and conditions?		
Who should benefit from care?			

# Care for whom?

- Trial participants who acquire the disease targeted by the vaccine;
- Trial participants who have severe conditions detected during the trial that are not specifically targeted by the vaccine being tested;
- Individuals considered for enrolment but excluded as a result of pre-enrolment screening for diseases relevant to the trial design;
- Other persons linked to trial participants, but not considered for enrolment in the trial, (e.g. family members or sexual partners); and
- Other members of the community hosting the trial.

# Diseases and conditions for consideration

- Specifically targeted by the vaccine being studied
- Diagnosed as part of the trial design in order to determine levels of protection conferred by the studied vaccine and its possible adverse effects when other diseases or conditions are present
- Unrelated to the purpose of the trial but detected incidentally in a population under surveillance

# Defining standard of care for specific populations and diseases

<b>Populations in the community hosting the trial</b>	<b>Diseases specifically targeted by the vaccine</b>	<b>Diseases diagnosed as part of the trial design</b>	<b>Diseases unrelated to the purpose of the trial</b>
Trial participants			
Individuals excluded after screening			
Other persons linked to participants			
Other members of community			

# Decisions on responsibilities for care and treatment provision in the context of vaccine trials

## Care and treatment for:



Trial participants: care and treatment for target disease

Trial participants: care and treatment for linked diseases

Trial participants: care and treatment of other severe diseases

Non-trial participants: care and treatment for target disease

Non-trial participants: care and treatment for other severe adverse events

1. What care and treatment will be offered through existing services?

2. What additional care and treatment should be provided?

3. For how long? (feasibility study, Phase I, II and III, post-trial)

4. Who will deliver care and treatment?

5. Who will provide the resources?

6. Who will administer the resources?

7. What will be the monitoring and accountability mechanisms?

8. What will be the complaint and arbitration mechanisms?

9. When, under what conditions and how will standards of care be re-evaluated?

# Who are the « stakeholders »?

Volunteers

Participants

Communities

Researchers

Funders

Sponsors

Health systems

Employing organizations

CBOs, NGOs

Care organization

Responsible care professionals

Regulatory authorities

Research Ethics Committee

# Purposes of Good Research Governance

## As an outcome:

- To ensure compliance with international and national scientific and ethical standards
- To achieve a fair balance between community expectations and the provision of care, treatment and support

## As a process:

- To ensure participation in decision making, transparency and mutual accountability
- To document terms of agreement and responsibilities prior to the trial

# Roles and functions of good research governance

Research governance:

- Sets standards
- Defines mechanisms to set standards
- Describes monitoring and assessment arrangements
- Improves research quality and safeguards the public by:
  - Enhancing ethical and scientific quality
  - Promoting good practice
  - Reducing adverse incidents and ensuring lessons are learned
  - Preventing poor performance and misconduct

# Criteria to be considered for decision-making under Good Research Governance

- I. Normative:** Established international and national/local norms and standards.
- II. Factual:** Background evidence relevant to decision making.
- III. Evaluative:** Appraisal of expectations and of the effectiveness of policies, structures and services.
- IV. Prospective:** Projection of resources, mechanisms, resource needs and impact for each optional approach.

# In Summary

- Globally relevant guidance on method, rather than global standard;
- Broad, participatory, transparent, documented process rather than black box;
- Develop user-friendly guidance materials;
- Consider the expansion of this approach to other prevention trials;
- Learn from the practical application of the proposed approach: from rhetoric to practice;
- Capacity building in countries (ERCs, NRAs, health Systems, Researchers, Communities).