

Priority Setting for Health R&D

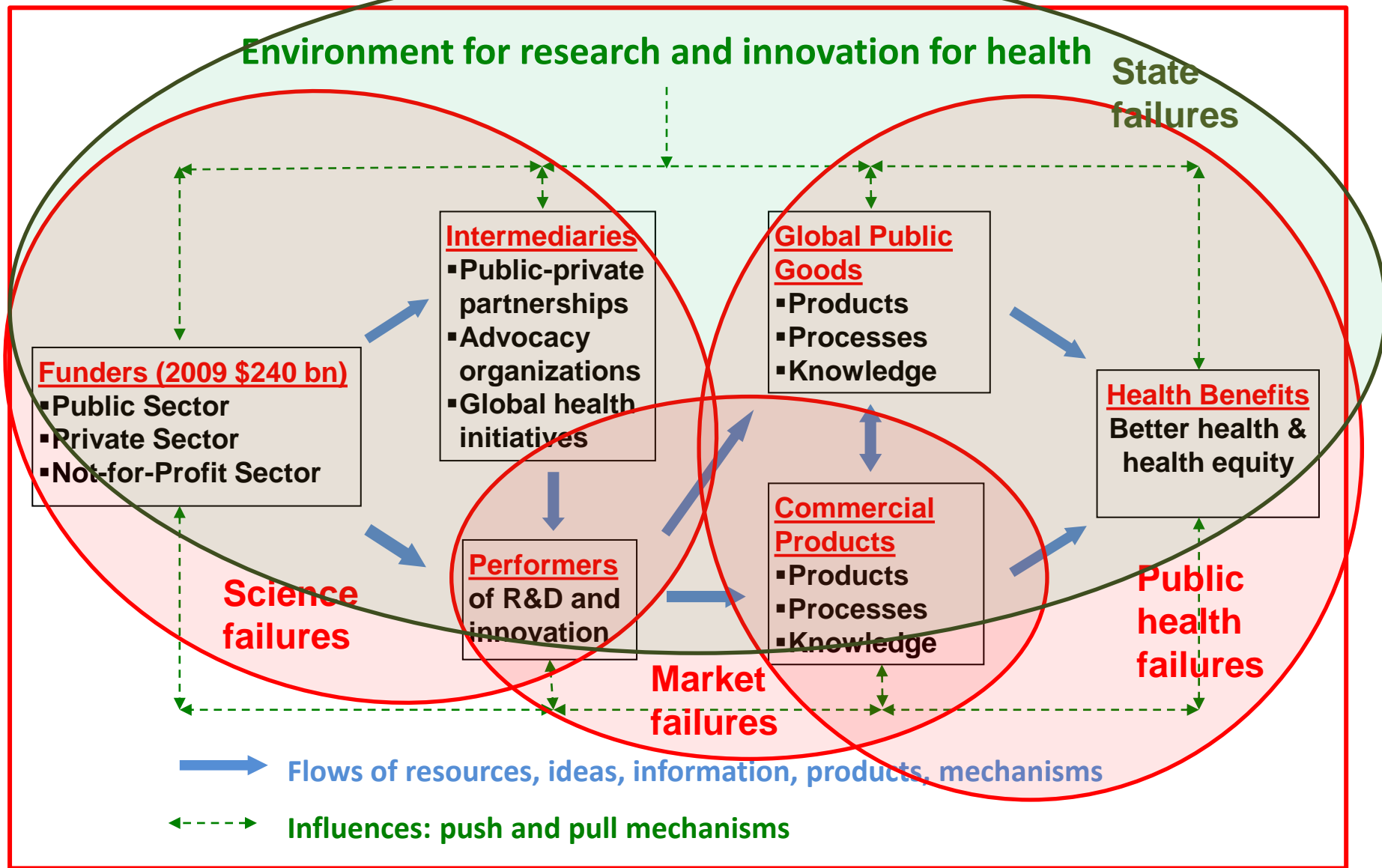
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Symposium and Workshop: 24 April 2013
Health R&D as a Global Public Good

Global Health Research and Innovation System



Global Health Research and Innovation System

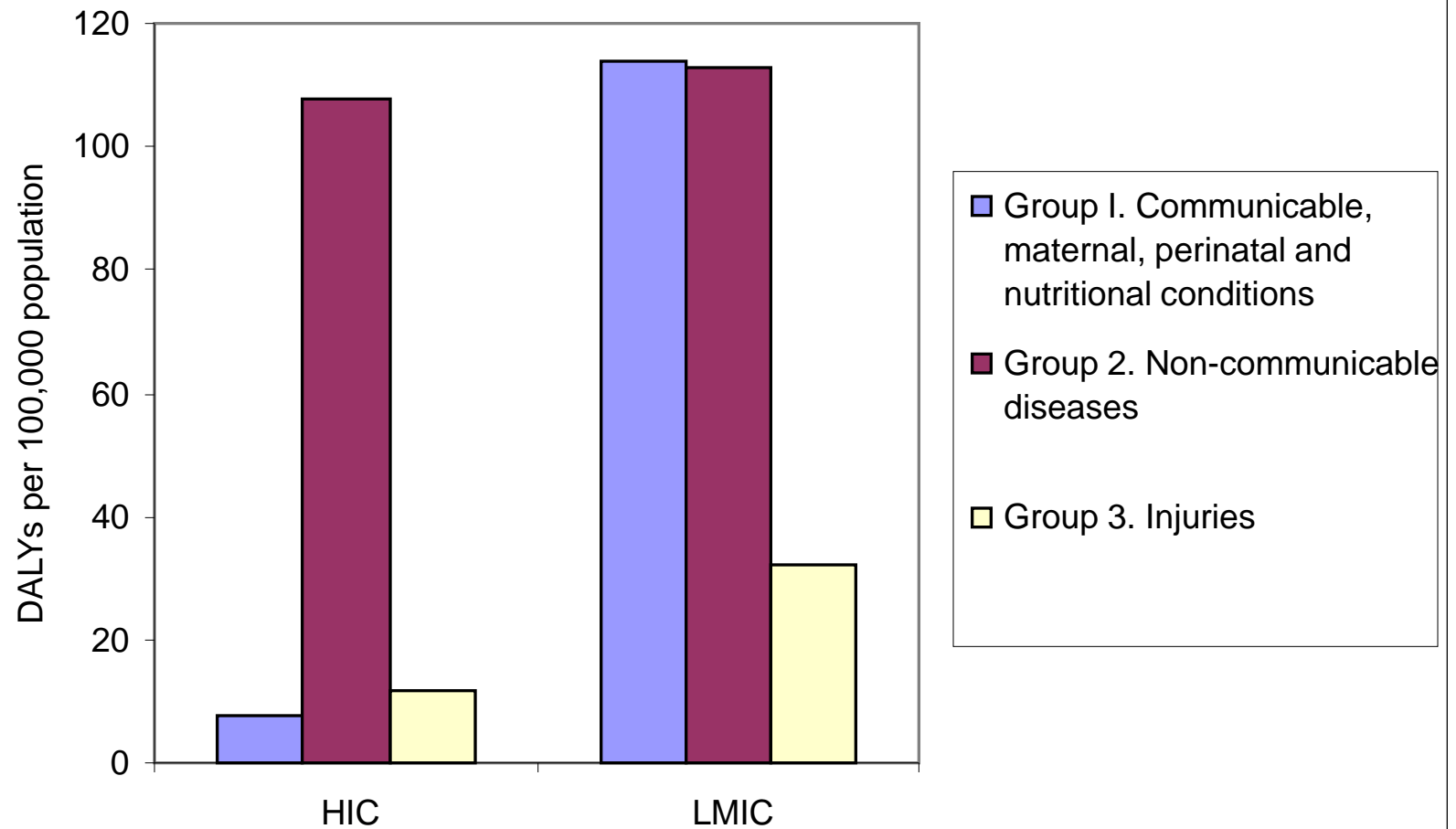
Efforts to overcome failures to address health conditions found in LMICs must consider how to organize and finance R&D for:

- **Type III diseases:** burden lies overwhelmingly or exclusively in poor countries
- **Type II diseases:** predominance of the burden lies in poor countries
- **Some Type I diseases:** burden is similar in poor and in rich countries

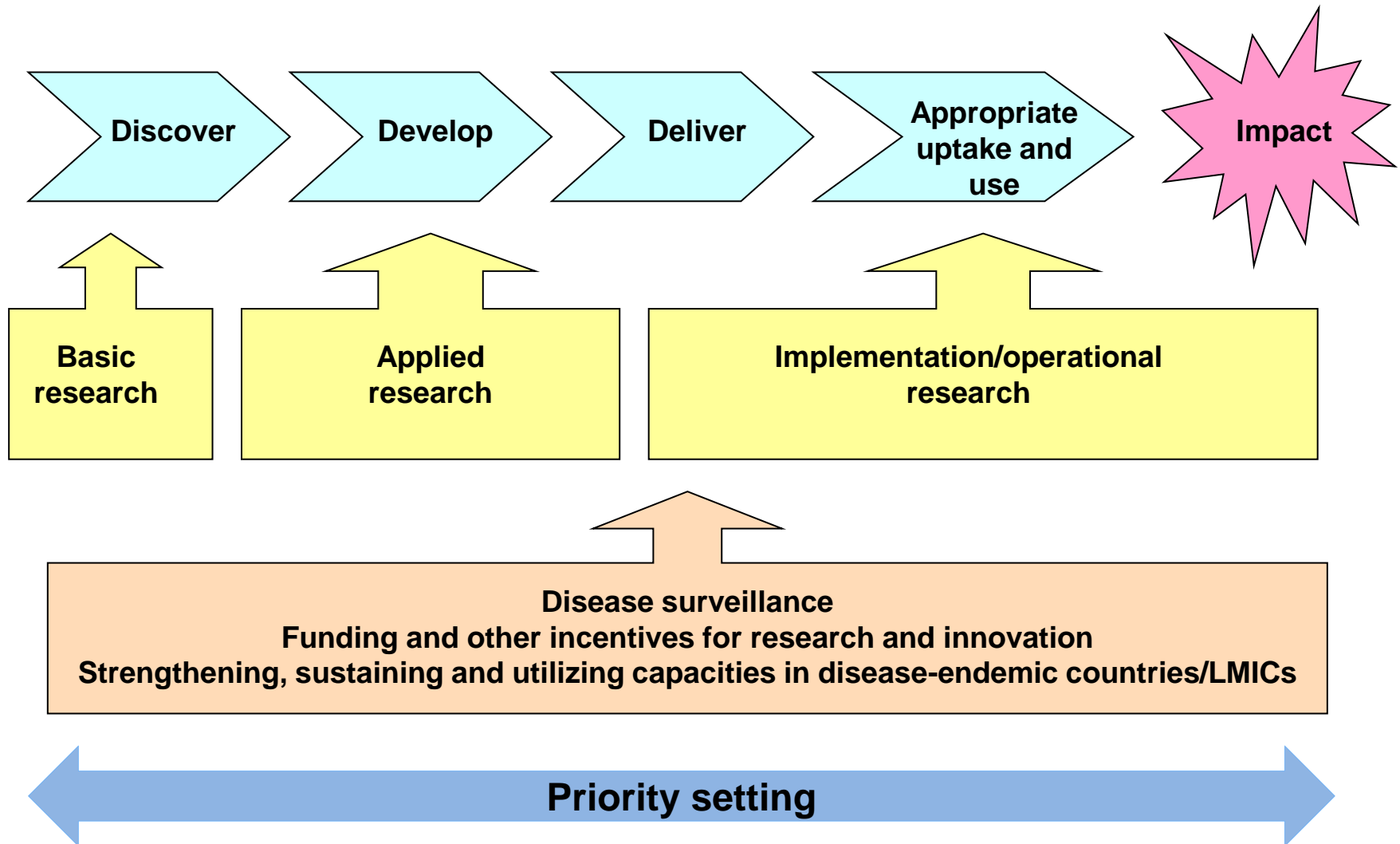
Commission on Macroeconomics and Health. WHO, 2001

Consultative Expert Working Group on Research and Development: Financing and Coordination. WHO 2012

Burden of disease (2002) by income and cause group



R&D pipeline for medicines to prevent and treat diseases



Priority setting

Primary objective:

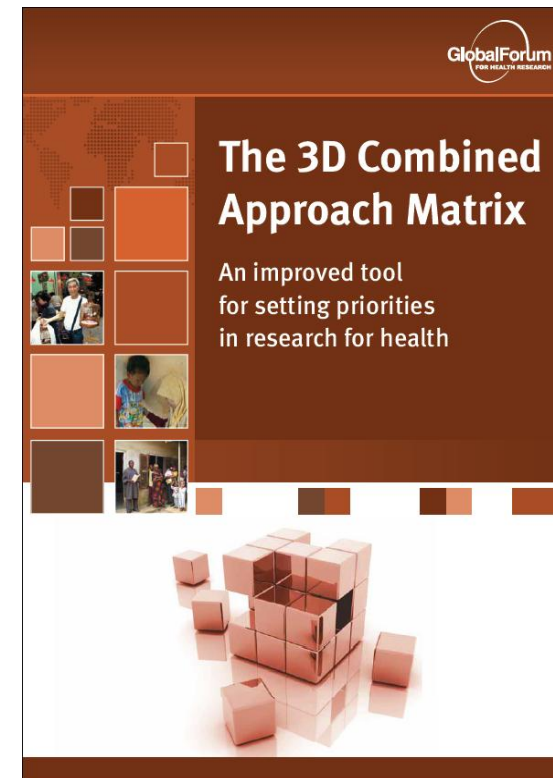
- to ensure that new drugs, vaccines and diagnostics needed to treat diseases prevalent in LMICs are developed and
 - are safe, effective, affordable and suitable to the conditions in which they will be used;
 - contribute to better health and health equity globally.

Secondary objectives could include:

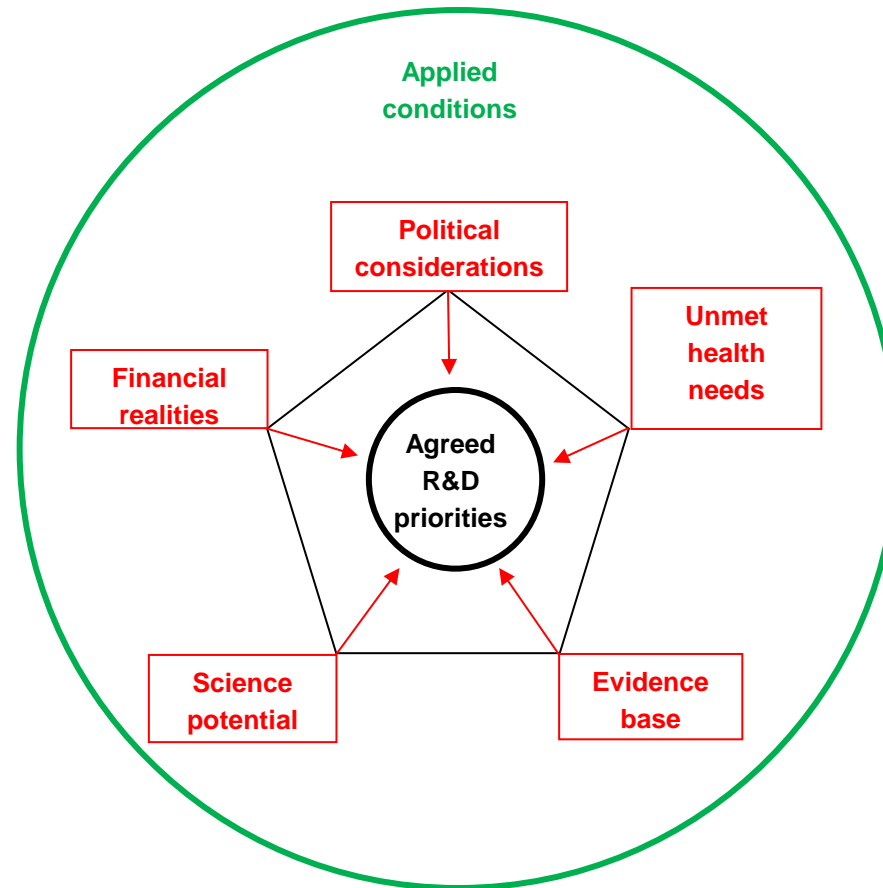
- avoiding unnecessary duplication of effort
- avoiding waste of funding
- encouraging equity-enhancing investments
- enabling priority efforts to be directed to urgent or neglected areas by assisting policy makers and funders in :
 - setting and management of global priorities
 - selecting the most productive areas for attention along the innovation
- facilitating cooperation between public and private sector actors;
- promoting inclusion of a wider range of actors in the R&D process – e.g. ensuring involvement of LMIC researchers in developing solutions to problems in their own countries; and/or R&D capacity building in LMICs.

Priority setting

- **Commission on Health Research for Development (1990)**
Council on Health Research for Development (COHRED)
Systematized approach within country's **Essential National Health Research** strategy:
 - **Planning:** identifying leadership and stakeholders; gathering and analysing relevant information;
 - **Setting the priorities:** preparing the information; determining the process and weighting methods for selecting priorities;
 - **Implementing the priorities:** translating into research portfolios; incorporating into research programmes that are invested in and periodically updated.
- **WHO Ad Hoc Committee on Health Research Relating to Future Intervention Options (1996)**
5-step methodology: involving assessing a set of factors linked to the **public health dimension**:
 - magnitude of burden of disease
 - determinants (risk factors)
 - level of knowledge in relation to interventions
 - cost-effectiveness
 - resources
- **Global Forum for Health Research**
2004 Combined Approach Matrix (CAM)
Combining 5 factors of public health dimension with actors - **institutional dimension**
 - The individual, household and community
 - Health ministry and other health institutions
 - Sectors other than health
 - Macro-economic policies**2009 3D CAM**
Adding **social & economic dimension**; including consideration of
 - **Context:** organizational, political; national, global
 - **Values:** often implicit – personal, institutional, political



Factors to be considered in setting priorities for health R&D for diseases of the poor



Proposal: an option for coordinated priority setting of R&D for diseases of the poor

Structuring multi-stakeholder priority setting

Proposal: Organizing key actors in a two-level process

- **Oversight Group**
to draw together common needs, identify synergies, summarise the global efforts and make final choices among competing priorities.
- **Series of Working Groups**
to address globally the research prioritisation in each problem area comprehensively and systematically, with commonality in approach between the Working Groups
- **Structures and compositions of the groups** designed to address
 - current weaknesses in the existing fragmented approaches, including the paucity of funding for R&D for some 'very neglected' diseases
 - questions of adequate representation by the full spectrum of stakeholders, including funders, experts, disease-endemic countries, the private sector and civil society groups concerned with access, community participation and equity issues.

Proposal: an option for coordinated priority setting of R&D for diseases of the poor

Structuring multi-stakeholder priority setting

Proposal: Organizing key actors in a two-level process

- Oversight Group**

Composition
predominantly
political
representatives, but
with some
participation by
technical
representatives

Establishing a prioritised list of R&D
programmes that are considered the
best choices for funding

- Working Groups**

Composition
predominantly
technical, but with
some participation
by political
representatives

Report for each health problem under
consideration, assessing unmet health
needs, evidence base on current gaps
in treatment, science potential for new
approaches and likely timescales and
costings for proposed R&D

Proposal: an option for coordinated priority setting of R&D for diseases of the poor

Structuring multi-stakeholder priority setting

Proposal: Organizing processes for allocations of work and resources

Option 1

- Combination of Working Groups and Oversight Group take lead role in identifying suitable actors and sites for the conduct of the R&D

Pros:

- Model similar to how Task Forces in TDR and HRP have operated at some time
- Efficient: the groups are intensely knowledgeable about the best places to conduct the work

Cons:

- Apparent conflicts of interest, with the prioritising groups potentially benefiting in some way from their own decisions

Option 2

- Identification of suitable actors and sites for conduct of the R&D made independently by a *Secretariat specially established to manage the whole process* - organization of composition and work schedules of groups involved in prioritization; advertising or commissioning of research activities; distribution of resources; collection of research reports; monitoring and evaluation of entire programme.
- To avoid capture or internal bias, the Secretariat could operate and manage a competitive process involving independent external reviewers. The Secretariat would be overseen by whichever top-level governance mechanism is selected.

Pros:

- Independent, transparent, impartial

Cons:

- Greater bureaucracy and cost

**R&D demonstration projects
to address identified gaps that disproportionately affect poorer countries**

Open-Ended Meeting of WHO Member States 26-28 November 2012

REQUESTS the Director-General:

... to facilitate through regional consultations and broad engagement of relevant stakeholders the implementation of a few health R&D demonstration projects to address identified gaps that disproportionately affect developing countries, particularly the poor, and for which immediate action can be taken

WHO EB Paper 132/21, 7 December 2012
http://apps.who.int/gb/ebwha/pdf_files/EB132/B132_21-en.pdf

**R&D demonstration projects
to address identified gaps that disproportionately affect poorer countries**

Key questions

1. Regard as a stand-alone activity to provide some 'quick wins' while countries continue to debate the merits of global coordination and financing mechanisms for health R&D?

OR

2. Use also to provide a demonstration of key elements of the more comprehensive, global coordinated priority setting process?

AND

3. What mechanism(s) should be used to identify candidate projects and to make the selection from among them of those to be conducted?
 - Should the generation of the entire candidate list ideally be the result of some well-designed, evidence-based and participatory process (for example, it could be run as a pilot version of the proposed Option)?
 - But: some preliminary suggestions for possible high-priority areas that would attract strong and widespread scientific and political support may be extremely valuable to help galvanise action by the global community.

Workshop

Towards a coordinated global process for priority setting for health R&D

1. Consider Option outlined for coordinated priority setting:
 - a. To what extent is it realistic and feasible?
 - b. What are its key advantages and disadvantages as a mechanism for global priority setting?
 - c. Within the broad boundaries of the concept, how could this option be refined and improved?
 - d. What are the key organizational and political hurdles that would need to be overcome to obtain support for the implementation of this option?
2. Consider alternative options that might be used - substantially different from that outlined:
 - a. What are the main distinguishing features of each alternative proposed and to what extent is each such alternative realistic and feasible?
 - b. What are its key advantages and disadvantages compared with the Option outlined?
 - c. What are the key organizational and political hurdles that would need to be overcome to obtain support for the implementation of the alternative option(s) proposed?
3. Regarding selection of demonstration projects to address identified gaps that disproportionately affect poorer countries, consider:
 - a. Desirability of focusing the selection of the projects exclusively around the objective of providing some 'quick wins' which will benefit global health by ensuring the development of needed treatments for neglected diseases; versus option of incorporating additional criteria to also provide a demonstration of key elements of the more comprehensive, global coordinated priority setting process.
 - b. The mechanism(s) that should be used to identify potential demonstration projects and to select those to be conducted.
 - c. Ideas for highly attractive candidates for selection that would be most likely to attract broad international support.

Chair

Rapporteur

- **Assemble summary report for final Plenary Session**
- **Provide a more detailed report of the group's discussions within a few days after the meeting**