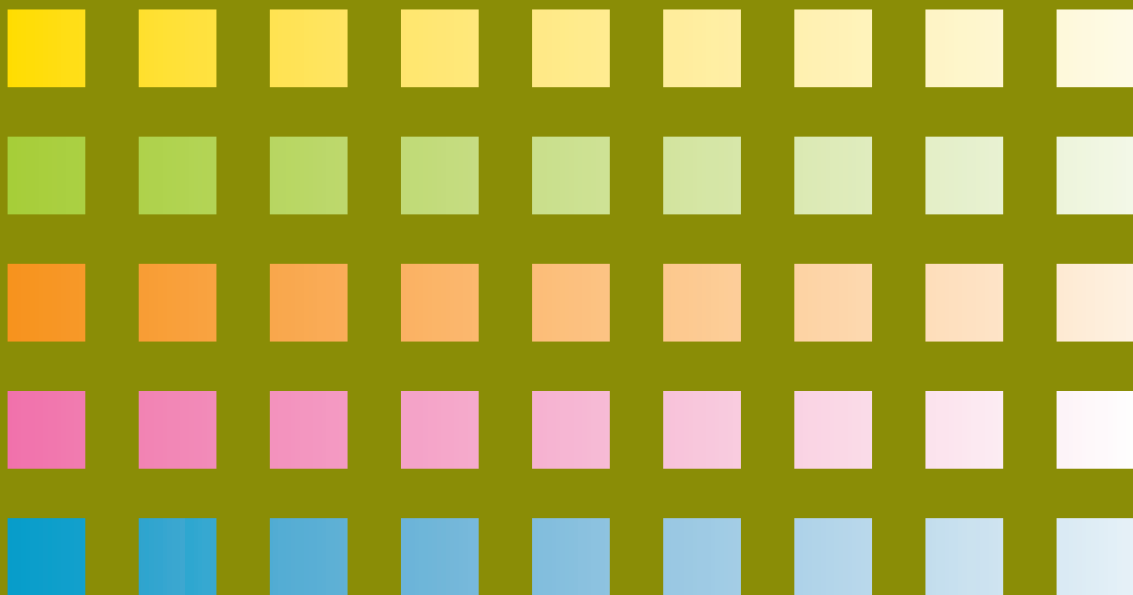


Identifying priorities for child health research to achieve Millennium Development Goal 4

Consultation Proceedings

Geneva, 26–27 March 2009



World Health
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Acronyms

ARI	Acute respiratory infection(s)
ARVs	Antiretroviral drugs
CAH	Department of Child and Adolescent Health and Development
CHERG	Child Health Epidemiology Reference Group
CHNRI	Child Health and Nutrition Research Initiative
DHS	Demographic and Health Survey(s)
Hib	<i>Haemophilus influenzae</i> type B
IMCI	Integrated Management of Childhood Illness
MDG	Millennium Development Goal
ORS	Oral rehydration solution
ORT	Oral rehydration therapy
PCV	Pneumococcal conjugate vaccine
RHS	Recommended home solution

Summary of proceedings

Background

Close to 25,000 children die every day, mostly due to pneumonia, diarrhoea and newborn problems.¹ These three main causes of child mortality, which represent 70% of all deaths in under-five children, receive very minimal research funding. Of current research funding, 97% focuses on the development of new interventions, with the potential to reduce child mortality by 22%, while the remaining 3% of funding goes to optimize the delivery of existing technologies, with the potential to reduce child mortality by 60%.² Re-visiting research priorities may help to galvanize support towards work with greater potential to contribute to achieving Millennium Development Goal (MDG) 4, over the 6 years left before 2015.

Objectives of meeting

The Department of Child and Adolescent Health and Development (CAH) in WHO convened a meeting of researchers, representatives of donor agencies and institutions in Geneva from 26 to 27 March 2009 with the objectives of identifying:

1. A selected subset of priority research issues as the ones to be addressed as of highest priority by the participants and WHO CAH;
2. Sources of support for the various research priority issues identified.

The list of participants at the meeting is presented in **Annex 1**, and the proposed agenda is in **Annex 2**.

WHO's research work and vision

WHO has a long history of research policy development and cooperation, with a vision that **"decisions and actions to improve health and enhance health equity are grounded in evidence from research"**. As the lead global public health agency, one of WHO's six core functions is to shape the research agenda and stimulate the generation, translation and dissemination of valuable knowledge. The Organization has unique strengths for performing this function: convening power to bring together the best scientists from many institutions and ministries of health of member states; experts' willingness to contribute; and independence and neutrality.

Within WHO, CAH has one of the four largest research programmes, supporting research projects focusing on the major killers of under-five children (acute respiratory infections, diarrhoea and newborn issues), in low- and middle-income countries. WHO's framework for describing the priorities in programmes is applied in CAH as follows:

¹ *The global burden of disease: 2004 update*. Geneva, World Health Organization, 2008.

² Leroy JL et al. Current priorities in health research funding and lack of impact on the number of child deaths per year. *American Journal of Public Health*, 2007, 97(2):219–223.

- Measurement of the problem: CAH is the Secretariat for the Child Epidemiology Reference Group (CHERG) that works for quantifying the burden of ill health;
- Understanding the causes/determinants of problems: CAH supported and disseminated findings from research to understand causes to inform the development of interventions to address problems;
- Development of solutions: CAH has promoted and supported the development and testing of improved solutions for the management of childhood illnesses (diarrhoea, acute respiratory infections, neonatal health, etc.);
- Translation and delivery of the solution: CAH has promoted and supported the development and evaluation of new, improved delivery strategies;
- Evaluation of the impact of the solution: CAH has promoted and supported large-scale evaluation of improved interventions.

CAH aims to use its position to identify research priorities, and promote and support research on them. An example of this work concerns newborn health, where priorities were identified at a meeting in 2001. Based on these priorities, formative research for intervention design was carried out, and simplified diagnostic and clinical algorithms defined. Research focused on the priorities of improving careseeking, and the effectiveness of community intervention packages. The information derived from research CAH supports is nearly always published in widely circulated peer-reviewed journals and also disseminated in other ways. The information is turned into guidelines and policies at country level and facilitates implementation of programmes.

CAH is now endeavouring to look at priorities again, in order to direct questions and investments to address how more children can be reached by the interventions they need to survive.

Identifying research priorities

The Child Health and Nutrition Research Initiative (CHNRI) has developed a methodology for setting priorities in health research investments. The work began in 2005, and has been documented through a series of articles.

The CHNRI methodology is intended to systematically and transparently take into account the main issues to assist priority setting. It depends on inputs from:

- investors and policy makers, to define the context and criteria for priority setting;
- technical experts for listing and scoring research investment options; and
- other stakeholders for weighing the criteria according to the wider societal system of values.

The method compares a larger list of systematically defined competing research options and assigns a quantitative research priority score to each of the options, based on technical experts' assessment of the likelihood of each option to address each of five criteria:

- answerability;
- effectiveness;
- deliverability;
- equity; and
- impact on disease burden.

The advantages of the CHNRI methodology include involvement of different stakeholders; transparency; treating all inputs equally; possibility of feedback; ability to compare all types of health research and many ideas in the same framework; clear exposure of the strengths, weaknesses of each idea and points of controversy; inclusion of the values of stakeholders and the general public; and a simple, intuitive, quantitative and easily communicated final outcome.

In collaboration with CHNRI, CAH has embarked on using this methodology. The context defined by CAH is global, focusing on children under five, with a time frame of up to 2015, to fit with the MDG date. Key initial areas of research were identified by the department based on the main causes of under-five deaths: birth asphyxia; diarrhoea; newborn infections; pneumonia; and pre-term/low birth weight. Within the general areas, experts were then asked to specify the most important research questions (sometimes formulated as options or issues). After refinement of these, experts were further asked to give scores to each of the research questions identified. The questions were then ranked according to the scores. The top ten for each of the research areas are in **Annex 3**.

Identifying sources of support for priority research

To take the priorities identified and measure their funding attractiveness, meeting participants were provided with the five lists of priorities, and asked to individually identify those that were most likely to receive funding support. The work was anonymous, with only the type of organization identified. Funding attractiveness was measured by both a rank score indicating how likely a question was to receive support under an organization's current investment policies and practices; and also by the distribution of a theoretical US\$100 among those questions that seem realistically fundable. The purpose of the exercise was to learn what makes a research question attractive or unattractive for funding support from donors; whether there are large differences between different categories of donor agencies in their current investment policies; and which of the identified priority research questions would be most realistic candidates for funding support by donors.

Sixteen participants scored the research priorities, and their responses were categorized into four groups (ministries; bilateral organizations; not-for-profit foundations; non governmental organizations). The combined average rank given by participants to the various research issues ranged from 3.7 to 7.2, and the average US dollar amount assigned ranged from \$2.5 to \$20.1. There was general consistency between the ranking of the questions and the US dollars assigned by the different groups, with some exceptions. The ministry group assigned a US dollar value to all questions, while all the other groups gave \$0.0 to some, an indication that they would not financially support studies to answer those specific questions. The group of nongovernmental organizations gave slightly higher rank ranges than the others. Although there was some variation between groups in the priority they gave to specific questions, five research questions stood out from the others as prioritized by all groups. They may provide a starting point where CAH can concentrate its efforts:

- Evaluate the quality of community workers to adequately assess, recognize danger signs, refer and treat acute respiratory infections (ARI) in different contexts and settings.
- What are the barriers against appropriate use of oral rehydration therapy (ORT) and zinc and how can they be addressed to increase population coverage of this intervention?
- What are the health system interventions that would increase population coverage of key maternal, newborn and child health interventions – (i) at least four antenatal care visits (ii) skilled care at birth (iii) two postnatal care contacts in the first week of life (iv) exclusive breast-

feeding for the first six months of life (v) immunizations (vi) care seeking for pneumonia and (vii) ORT for diarrhoea?

- What are the feasibility, effectiveness and cost of scaling up routine home visits for initiation of good care practices and early detection of illness in the mother and newborn?
- What are the feasibility, effectiveness and cost of different approaches to promote the following home care practices: breastfeeding, cord/skin, care seeking, handwashing?

Additional discussions were held in disease/condition-specific groups to review further the lists of priority questions. Participants found it useful to have the opportunity for researchers and potential funders to sit together to have research questions and their implications explained. They recognized that criteria may be different when researchers and funders prioritize questions: clarity and specificity of questions, value for money, linkages to broader issues and competitiveness are attributes particularly valued by funders.

Observations on the methodology

The sample size for this exercise was small, and various factors influenced the ranking, including the different knowledge levels and investment strategies of institutions. Decisions on assignment of funds were affected by whether it was known that funding was already being provided for this area of research, and the total amount that would be needed to carry it out. Some of the questions were phrased in a way that required additional background information to understand the implications and scope of the research required. Community-based questions were more likely to be ranked highly than those related to hospital care.

Participants also felt that, as staff working on research in donor agencies have widely different backgrounds, it would be helpful if a short statement explaining the background and implications of each priority research question to be considered were available.

An important point in the discussion, and related to the funding of questions, was that often researchers and potential donors, especially in the private sector, speak different languages. Researchers need to be clear on what it is they are planning to do, and communicate this in more readily-understood terms.

The way forward

However imperfect the exercise, the Department felt it was useful to have an insight into the ranking of the research questions by outside agencies and have them engaged as a group in the definition of priorities. The methodology can be refined by CHNRI and CAH, and used with different, possibly larger, groups.

The highest-ranked priorities provide CAH with ideas on areas to focus attention that will be most likely to meet with donor support, allowing faster implementation of studies. CAH will need to think about the different directions to look for possible funding for other questions that may also be of priority but that are less likely to obtain immediate donor support. The process also indicates where there are needs for greater advocacy for areas that CAH feels are important, but where at the moment funding is unlikely.

On the basis of the discussions, CAH will work with CHNRI to:

- Develop the final list of 15–20 research priorities for MDG4 taking into account “funding attractiveness”;

- Track funding and research output for those 15–20 research priorities;
- Support and monitor changes in policy in response to results of the implementation of studies addressing those 15–20 research priorities.

CAH will also look to create mechanisms to:

- Communicate to a broad audience the identified research priorities;
- Ensure continued work with the group of participants; and
- Work together with others to generate resources and direct resources to answering priority questions.

Details of the presentations and discussions of the meeting are given in **Annex 4**.

ANNEX 1

List of Participants

Dr Narendra Arora , INCLEN, New Delhi, India

Dr Emmanuel Baron, EPICENTRE, Paris, France

Dr Nancy Binkin, UNICEF, New York, NY, USA

Dr MK Bhan, Department of Biotechnology, Ministry of Science and Technology, New Delhi, India

Dr Robert Black, Johns Hopkins Bloomberg School of Public Health, Department of International Health, Baltimore, MD, USA

Dr Neal Brandes, USAID, Washington DC, USA

*Dr Mickey Chopra, Health Systems Research Unit, MRC, Western Cape, South Africa

Dr Téa Collins, Global Forum for Health Research, Geneva, Switzerland

The Honorable J. Fontana, Chair of Executive Committee, Trinity Global Support Foundation, Kitchener, Canada

Dr Elsa Giugliani, Ministério da Saúde, Brasília DF, Brazil

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*Dr Lindsay Hayden, Children's Investment Fund Foundation, London, United Kingdom

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Dr Carole Lanteri, Mission Permanente de la Principauté de Monaco, Geneva, Switzerland

Dr Sanderson Layng, Trinity Global Support Foundation, Kitchener, Canada

*Dr VM Mukonka, Public Health and Research, Ministry of Health, Lusaka, Zambia

Dr David Marsh, Save The Children, Westport, CT, USA

Dr Saul Morris, Bill and Melinda Gates Foundation, Seattle, WA, USA

Dr Kim Mulholland, London School of Hygiene and Tropical Medicine, London, United Kingdom

Dr Rintaro Mori, Osaka Medical Center and Research Institute for Maternal and Child Health, Izumi, Osaka, Japan

Dr Sue Kinn, DFID Research, UK Department for International Development, London, United Kingdom

* Unable to attend

Dr Lars-Ake Persson, Women's and Children's Health, International Maternal and Child Health, University Hospital, Uppsala, Sweden

Dr Igor Rudan, Department of Public Health, University of Edinburgh, Medical School, Edinburgh, Scotland, United Kingdom

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Dr Catharine Taylor, Maternal Child Health & Nutrition, PATH, Washington DC, USA

*Dr Linda Wright, National Institutes of Health, Bethesda, MD, USA

Secretariat

Mrs Daisy Mafubelu, Assistant Director-General, WHO/FCH, Geneva

Dr Rajiv Bahl, Medical Officer, WHO/CAH, Geneva

Dr André Briend, Medical Officer, WHO/CAH, Geneva

*Dr Olivier Fontaine, Medical Officer, WHO/CAH, Geneva

Dr Jose Martines, Coordinator NCH, WHO/CAH, Geneva

Dr Elizabeth Mason, Director, WHO/CAH, Geneva

Dr Shamim Qazi, Medical Officer, WHO/CAH, Geneva

Dr Nigel Rollins, Medical Officer, WHO/CAH, Geneva

WHO Departments

Dr Andres de Francisco WHO/PMNCH

Dr Monir Islam WHO/MPS

Dr Suzanne Hill WHO/PSM

Dr Mike Mbizvo WHO/RHR

Dr Jean-Marie Okwo-Bele WHO/IVR

Dr Rob Terry WHO/RPC

Dr Melba Gomes WHO/TDR

Dr Abha Saxena WHO/ERC

* Unable to attend

ANNEX 2

Agenda

THURSDAY 26 MARCH

8:30–9:00	Registration	
9:00–9:30	Welcome	ADG/FCH
	Introduction and Objectives of the Meeting	Director CAH
9:30–9:40	Overview of the Agenda	Dr J. Martines
9:40–9:50	WHO Research Strategy Framework	Dr R. Terry
9:50–10:05	The Bill and Melinda Gates Foundation Maternal and Neonatal Health Strategy	Dr S. Morris
10:05–10:10	Discussion	
10:10–10:30	CAH: Responses to Priority Research	Dr J. Martines
10:30–11:00	COFFEE BREAK	
11:00–11:15	How research can help in accelerating the achievement of MDG4	Dr M.K. Bhan
11:15–11:45	The CHNRI process for identifying research priority issues	Dr I. Rudan
11:45–12:30	Panel Presentation of the lists of issues identified Introduction • Neonatal problems • Diarrhoea • Pneumonia	Dr J. Martines Dr R. Bahl Dr J. Martines Dr S. Qazi
12:30–13:00	Discussion	
13:00–14:00	LUNCH BREAK	
14:00–14:15	Research needs: a pharmaceutical lens	Dr S. Hill
14:15–15:00	Discussion	
15:00–15:30	COFFEE BREAK	
15:30–16:00	Proposed process to reflect participants' views of funding priorities	Dr I. Rudan
16:00–17:30	Allocating resources according to priority level:	Individual work
18:00–20:00	Reception	WHO Restaurant

FRIDAY 27 MARCH		
9:00–9:30	Presentation of the results of the analysis of individual work outputs	Dr I. Rudan
9:30–10:30	Discussion	
10:30–11:00 COFFEE BREAK		
11:00–12:30	Discussions and agreement on a list of selected priority issues for funding	Chairperson
12:30–14:00 LUNCH BREAK		
14:00–15:30	Discussion on how we can get the selected priority issues addressed, with mobilization of resources and commitments.	Chairperson
15:30–16:00 COFFEE BREAK		
16:00–17:00	Conclusions of the meeting and closing	ADG/FCH & Director CAH

ANNEX 3

List of priority research questions, by cause of mortality

PRETERM/LOW BIRTH WEIGHT

What is the effectiveness of approaches to increase the use of interventions such as antenatal corticosteroids in preterm labour and antibiotics for premature prolonged rupture of membranes in resource-poor settings?

What is the effectiveness of approaches to improve access to care for the subset of low-birth-weight infants born at home who need hospital care?

What are current home care practices, and barriers and supports for optimal practices in different contexts and settings?

What is the effectiveness of approaches to improve quality of care of low-birth-weight infants in health facilities?

What is the effectiveness of approaches to achieve early initiation of breastfeeding, including feeding mode and techniques for those unable to suckle directly from the breast?

Development and evaluation of new simple and effective interventions for providing thermal care to low-birth-weight infants, if Kangaroo Mother Care is not acceptable to the mother.

What is the effectiveness of approaches for identification of low-birth-weight infants within 24–48 hours of birth for additional care at home or in a health facility?

What is the effectiveness of approaches to increase the proportion of low-birth-weight infants who receive additional care before discharge among those born in a hospital?

What is the effectiveness of Kangaroo Mother Care and alternative methods of keeping the low-birth-weight infant warm in community settings?

What is the effect of a package of interventions (e.g. including delaying first pregnancy, birth spacing, anti-malarial therapy, dietary interventions and micronutrients) on the incidence of pre-term birth and growth retardation?

DIARRHOEA

What are the acceptability and effectiveness of the new reduced osmolarity ORS in the clinic as well as in the community?

Among children who were given zinc for treatment of diarrhoea, what is the proportion who continue to receive the full course of zinc for prevention after cessation of the diarrhoea episode?

What are the barriers against appropriate use of ORT?

What is the effectiveness of zinc supplementation on the outcome and incidence of diarrhoea in the community?

What is the impact of the strategy of Integrated Management of Childhood Illness (IMCI) implemented at facility and community level in different population groups on timely identification and treatment of acute diarrhoeas (ORS and zinc)?

Develop and evaluate interventions to increase early initiation of breastfeeding and exclusively breastfed infants up to six months of age.

Comparative assessment of indicators to determine effectiveness of IMCI in treatment of diarrhoea and in term of reducing disease burden.

Assess cost effectiveness of outpatient treatment of diarrhoea with zinc and ORS.

Design and evaluate locally-adapted training programmes to orient health workers on IMCI.

Assess proportion of cases with diarrhoea that get appropriate outpatient treatment in different contexts and settings.

PNEUMONIA

Evaluate the quality of community workers to adequately assess, recognize danger signs, refer and treat ARI in different contexts and settings.

What are the key risk factors predisposing to the development of severe pneumonia and identifying children who require hospitalization?

What is the capacity of health systems to provide (and main barriers to increase) availability of oxygen in health facilities?

Can the coverage by antibiotic treatment be greatly expanded in a safe and effective way if administered by community health workers?

What are the main barriers specifically to increasing the compliance with vaccination with available vaccines in different contexts (including Hib and pneumococcal vaccine)?

What are the main barriers to health care seeking and access for children with pneumonia in different contexts in developing countries?

What is the effectiveness of new conjugate pneumococcal vaccines in reduction of childhood pneumonia morbidity and mortality in different settings?

What are the key bacterial and non-bacterial pathogens associated with childhood pneumonia morbidity and mortality at the global level in HIV and non-HIV infected children?

What are the main barriers to increase coverage of available vaccines (including Hib and pneumococcal vaccine) in different contexts, and what is their relative importance?

Evaluate different mechanisms for cost reduction of conjugate vaccines in different contexts and settings.

BIRTH ASPHYXIA

What is the effect of low-cost, robust, simple fetal heart monitors in improving fetal heart rate monitoring and reducing stillbirths and asphyxia related outcomes?

What is the effectiveness of the actions of community health workers (e.g. social support, accompanying woman to facility during labour, danger recognition/referral)?

What is the effectiveness of community participation to improve recognition and acting on simplified danger signs for mothers in labour (including transport/communication)?

What is the effectiveness of simpler/cheaper/more robust technology for neonatal resuscitation and for training (e.g. bag and mask, suction devices, mannequins)?

Development and evaluation of methods for early detection of specific maternal complications with higher risk of unfavourable asphyxia related outcomes.

Does the presence of a supportive companion or family member at facility births increase acceptance/use of facilities for births as well as provide the benefits of supportive companionship?

What is the effect of simpler clinical algorithms for recognition and management of babies who require resuscitation at birth on met need for resuscitation at birth?

What is the effectiveness of perinatal audit in improving adherence to clinical standards for intrapartum care (e.g. partograph, fetal heart monitoring, resuscitation) and reducing adverse asphyxia related outcomes?

Does the use of standard protocols and training (including "fire drills" audit) to increase quality of intrapartum monitoring and speed of intervention reduce the incidence of birth asphyxia?

What is the effectiveness of strategies for increasing demand for skilled birth attendance, e.g. conditional cash transfers?

NEWBORN INFECTIONS

What are the feasibility, effectiveness and cost of different approaches to promote the following home care practices:

- Early initiation and exclusivity of breastfeeding
- Hygienic cord and skin care
- Prompt care seeking for illness from an appropriate provider
- Hand washing of caregivers

What are the feasibility, costs and effectiveness of setting up newborn care corners in first referral units and district hospitals?

What are the feasibility, effectiveness and cost of approaches to increase coverage of clean delivery practices in facilities and in homes?

What are the feasibility and effectiveness of approaches to increase quality of care in hospitals, such as using standardized protocols for management of common conditions in hospitals?

What is the role of local application of disinfectants in the prevention of umbilical infections and sepsis?

What are the feasibility, effectiveness and cost of approaches to increase tetanus toxoid immunization coverage?

What are the effectiveness and cost of implementing IMCI guidelines, including inpatient care where applicable using WHO guidelines, in health facilities?

What are the feasibility and effectiveness of approaches to improve aseptic practices in labour rooms, maternity, paediatric wards and nurseries?

What are the feasibility, effectiveness and cost of a scheme of routine home visits for initiation of supportive practices, detection of illness and newborn survival?

What are the feasibility, safety, effectiveness and cost of managing severe neonatal infections in community settings?

ANNEX 4

Summary of presentations and discussions

Welcome

Dr Elizabeth Mason, Director, CAH, WHO HQ and Ms Daisy Mafubelu, Assistant Director-General, Family and Community Health Cluster

Dr Mason and Ms Mafubelu welcomed the participants. Ms Mafubelu reminded them that there are only six years before the deadline of 2015 for the achievements of the MDGs. Last April, a meeting on the Countdown to the Goals looked at progress towards targets, and found that 68 priority countries, mostly in Africa, accounting for 98% of child deaths were not likely to meet MDGs 4 and 5. However, there are encouraging trends in some countries, such as Bangladesh and Tanzania.

Countries do not appear to be on course because of low coverage of interventions, even though the types of interventions needed are known, and addressing just three priority areas would help a great deal. Ms Mafubelu hoped that this group would help us to focus on the priorities, and perhaps help with research on increasing coverage.

She noted that about 97% of research is on new technologies, with the possibility of reducing child mortality by 22%. Only about 3% is on optimizing existing technologies, even though this could reduce child mortality by 60%. She asked what the appropriate balance might be. She hoped that this group would identify priorities to facilitate WHO's work, and share information and expertise to help WHO to give guidance to countries.

Objectives of the meeting

Dr Jose Martines, Coordinator, Newborn and Child Health team, CAH, WHO, Geneva

Dr Martines reminded the group of the objectives for the meeting:

1. To identify a selected subset of the priority research issues as the ones to be addressed as of highest priority by the participants and WHO/CAH;
2. To identify sources of support for the various research priority issues identified.

He reviewed the agenda, pointing out that it had been recently revised to give more time for participants to give feedback to the organizers on the process. Participants asked if it would be useful to review progress in setting priorities since 2002, and also wondered whether there were other methodologies to be discussed, besides the CHNRI one to be presented. They also expressed a wish to look at how to implement interventions, and not just what interventions should be implemented. Dr Martines explained that he would be reviewing progress in setting priorities and responding to priority questions, and also that this meeting was focusing on this methodology because we were hoping to see the priorities from the perspective of those who may influence funding research.

WHO Research Strategy Framework

Dr Rob Terry, Department of Research Policy and Cooperation, WHO, Geneva

Dr Terry explained WHO's strategy on research for health. The vision is that "decisions and action to improve health and enhance health equity are grounded in evidence from research". The five goals were described briefly as: "priorities", to champion research that addresses priority health needs; "capacity", to support the development of robust national health research systems; "standards", to promote good research practice; "translation", to strengthen links between policy and practice; and "organization", to strengthen the research culture across WHO.

Types of health research were classified into four "Ds": epidemiological, which gives a "description" of the burden of disease; health systems and policy, providing information on "delivery"; research to improve existing interventions, for "development"; and development of new interventions, or "discovery".

The framework for describing the priorities in WHO programmes involves:

- Measuring the magnitude and distribution of the problem;
- Understanding the diverse causes or the determinants of the problem, whether they are due to biological, behavioural, social or environmental factors;
- Developing solutions or interventions that will help to prevent or mitigate the problem;
- Implementing or delivering solutions through policies and programmes;
- Evaluating the impact of these solutions on the level and distribution of the problem.

WHO is expected to give guidance on priorities; build capacity; set standards; and translate the results into implementable programmes. The latter area and evaluation are areas where funding is lacking.

Dr Terry then illustrated how this framework is reflected in individual department's work, using CAH, Research and training in tropical diseases, Reproductive Health and Research and Food-borne disease burden as examples. WHO's framework for describing the priorities in programmes is applied in CAH as follows:

- Measurement of the problem: CAH is the Secretariat for the Child Epidemiology Reference Group (CHERG) that works for quantifying the burden of ill health;
- Understanding the causes/determinants of problems: CAH supported and disseminated findings from research to understand causes to inform the development of interventions to address problems
- Development of solutions: CAH has promoted and supported the development and testing of improved solutions for the management of childhood illnesses (diarrhoea, acute respiratory infections, neonatal health, etc.);
- Translation and delivery of the solution: CAH has promoted and supported the development and evaluation of new, improved delivery strategies;
- Evaluation of the impact of the solution: CAH has promoted and supported large-scale evaluation of improved interventions.

The Bill and Melinda Gates Foundation Maternal and Neonatal Health Strategy

Dr Saul Morris, Bill and Melinda Gates Foundation, USA

Dr Morris of the Bill and Melinda Gates Foundation announced the recent approval of the new Maternal and Neonatal Health Strategy. The strategy focuses on reducing neonatal mortality through new, adapted, and existing interventions delivered at home and community levels in South Asia and sub-Saharan Africa. More details will be forthcoming at the official strategy launch, expected to take place during the second quarter of 2009.

During the discussion on the previous two presentations, participants raised issues such as whether there is the capacity to train and support numerous front-line workers. Many countries have already trained front-line workers of one kind or another, and in any case first-level facilities will also be covered. Some wondered about the Gates Foundation apparent decision to focus on home and community, given the evidence that many interventions to prevent newborn morbidity and mortality do not work in the first days of life, and effective interventions may be too intensive to go to scale. There was emphasis on the need for operational research on delivery of interventions. However, it is difficult to obtain funding for the inter-sectoral type of research that is often needed.

CAH: Responses to priority research

**Dr Jose Martines, Coordinator, Newborn and Child Health team,
CAH, WHO, Geneva**

Dr Martines talked about CAH's work, and how the department has taken previous recommendations regarding research directions into account. As the lead public health agency, one of WHO's six core functions is to "shape the research agenda and stimulate the generation, translation and dissemination of valuable knowledge." The organization has unique strengths for performing this function: convening power to bring together the best scientists from many institutions and ministries of health of member states; experts' willingness to contribute; and independence and neutrality.

Within WHO, CAH has one of the four largest research programmes. While resources are limited, they are multiplied by the use of WHO's mandate and partnerships – through cooperation with scientists, universities and governments, and collaboration with donors. CAH aims to use this unique position to identify research priorities, promote and support research on them.

An example of this work concerns newborn health, where priorities were identified at a meeting in 2001:

- Formative research for community-based intervention design;
- Simplified clinical diagnostic and treatment algorithms;
- Recognition and management of sepsis when referral is not possible;
- Prevention and management of birth asphyxia and meconium aspiration;
- Improving careseeking;
- Effectiveness of community intervention packages.

Based on these priorities, formative research for intervention design was carried out, and simplified diagnostic and clinical algorithms defined. Dr Martines gave examples on newborn health from various settings where action on these priorities has been carried out.

As new knowledge is acquired, it is disseminated and put into use. For example, 95% of CAH-supported studies lead to publication at national or international level, in addition to presentations at meetings and distribution to offices around the world. Guidelines and policies are adapted at country level into nationally appropriate policies and programmes. To facilitate the implementation of programmes, instruments such as training courses, planning guides, manuals, assessment and evaluation tools are prepared and their use promoted in order to translate new information into more effective ways of saving child lives.

Despite these efforts, many key child health interventions only reach up to about 30–40% of children. There is a need to better direct our questions and our investments to address how more children can be reached by the interventions they need in order to survive.

During discussion, it was noted that child health research had been more active during the 1980s, but declined greatly during the 1990s, after scientific working groups convened by WHO had been discontinued. The groups were useful for new ideas, support and advocacy, but the resources were no longer available to support them. Several groups were required, and they met more than once per year, creating a substantial financial burden. Thus, a more flexible system of advisers was instituted.

Role of child health research in achieving MDG4

Dr MK Bhan, Department of Biotechnology, Ministry of Science and Technology, New Delhi, India

Research involves policy and programme design; programme implementation and scale-up; and appropriate technology. There is ample evidence that research has helped to improve interventions, for example with regard to diarrhoeal disease control, it has helped in understanding prolonged diarrhoea, feeding during diarrhoea, improved oral rehydration salts solution, and zinc as an adjunct treatment. However, intervention delivery is still incomplete and coverage inadequate, partly because of inadequate research. This situation is especially true of home care for neonates and young infants.

Intervention development goes through a process starting from establishing efficacy to programme design to scale up. There are gaps in research at various points in this process. Dr Bhan gave several examples of where programme implementation has faltered, because of slow absorption of new solutions; failure to scale up effective pilot programmes; and lack of innovative solutions for unmet needs. He illustrated a Pathway to Survival, taking into account all the steps a child with acute respiratory infection would have to go through in order to receive appropriate care, and the various points at which problems may arise in obtaining the desired care.

The implications for future research of this situation include:

- Focus on finding solutions to the unresolved issues in delivery of interventions to achieve high coverage;
- Continue to support technology development;
- Institutional framework for research;

- People for research – in India, capacity for child health intervention research is decreasing as researchers focus on other areas;
- Top down vs bottom up;
- Partnerships that bring expertise and facilitate research.

In the discussion, it was noted that there are current initiatives (e.g. CHNRI, Global Fund for Health Research) that are attempting to address facilitation of research, exchange of information, funding, etc.

The CHNRI methodology for setting priorities in health research investments

Dr Igor Rudan, Department of Public Health, University of Edinburgh, Medical School, Edinburgh

Dr Rudan gave a brief history of the current initiative in developing a methodology for prioritizing research issues. The work began with a consultation in 2005, followed by further meetings to refine the methodology, and the publication of various papers detailing it, illustrating how it has been used and its potential.

Dr Rudan explained what he considers “health research”, as the process of going from a research question, which then generates new knowledge, which is translated into an intervention and implemented, finally leading to a reduction in the burden of disease. In this process as currently carried out, research questions may be regarded as more attractive because of their novelty, possibility of publications in high-impact journals, media coverage and lobbying. The various types of health research include epidemiological research, which provides a description; health systems and policy research, which deals with delivery; research to improve existing interventions, related to development; and research to develop new interventions, or discovery.

There are various reasons for investing in health research, but the decisions depend on the outlook of the funder. The perception of the return on the investment may be related to a particular area of the world or a particular population, and the yield may be financial benefits or a reduction in the burden of disease.

In the CHNRI methodology, there are various steps in setting priorities for health research. The first one is defining the context, which involves looking at the motivation for the research or return on investment. The next step involves developing criteria for prioritizing. These may include qualities related to the high profile of the research, but also whether the question is answerable in an ethical way; efficacious and effective; deliverable and affordable; has a large potential; and will lead to an equitable reduction in disease. Different contexts require different criteria, and decisions on research investment priorities based on different criteria will necessarily conflict with each other. The third step is evaluation of the research idea, while respecting the context and criteria. This step requires evaluation and discrimination between the different ideas.

Dr Rudan explained that the CHNRI methodology for setting health priorities systematically and transparently takes into account all the issues mentioned to assist priority setting. It initially requires input from investors, that is, government policy makers, private donor foundations, corporations or international organizations, e.g. WHO, to define: motivations for investments and expected returns; investment styles; targets (focus) and population to be addressed; time frame for expected returns; and criteria that would be useful to set research priorities, given all of the above.

The next step requires input from technical experts. The possible research options are systematically listed, according to research instrument and avenues. Experts are then invited to suggest research options and questions by category. These are then circulated for scoring according to the context and criteria agreed. Each research option will receive intermediate scores for each of the criterion.

Input is then sought from other stakeholders. Intermediate scores from experts may be adjusted by setting thresholds and weights based on the values of stakeholders before an overall score is computed.

The outcome of the CHNRI process is a list of research questions with scores for each of the five areas (answerable, effective, deliverable, reduction of disease burden and equitable). These scores measure the collective optimism of technical experts towards each proposed research option in a very structured way. A large number of options can be scored, and through this process the advantages and disadvantages of each research option become transparent.

The advantages of the CHNRI methodology include:

- Full involvement of investors at all stages;
- Transparency over the context and the criteria;
- Transparent input from all those involved;
- Prevention of domination of individuals;
- Replicability of the exercise and internal consistency;
- All stages of the process remain stored and feedback is possible;
- Many types of research and ideas may be compared in the same framework;
- Strengths and weaknesses of each idea and points of controversy become clearly exposed;
- Values of stakeholders and the general public can be introduced;
- Involvement of technical experts and other stakeholders as advisers;
- The final outcome is simple, intuitive, quantitative and easily communicated.

Given the existing lists of priorities, CHNRI is hoping to take this forward and follow up the process by observing implementation and tracking funding, publications and impacts on global policies and on countries.

PANEL PRESENTATION OF THE LISTS OF ISSUES IDENTIFIED

Setting research priorities: Introduction

Dr Jose Martines, Coordinator, Newborn and Child Health team,
CAH, WHO, Geneva

Dr Martines explained the context for setting child health priorities in WHO. The motivation was achieving MDG4; the investment style is balanced; the population of interest is children under 5; the focus is reducing child deaths due to the major causes; and the time frame was 2015. He reviewed the major causes of death in neonates and children under five around the world. From these causes, two groups were established for working on research priorities. Phase I, the conditions with highest mortality, covers pneumonia; diarrhoea; newborn infections; preterm conditions and low birth weight; and birth asphyxia. Phase II will cover malaria, HIV, injuries and undernutrition.

He explained the vision for what was hoped that CAH, working with CHNRI, could achieve:

- Global child health research priorities aimed at reducing child deaths due to major causes by 2015;
- Use of a transparent process to develop the list with technical experts and implementers;
- Reach agreement on the priorities list with major child health research donors;
- Assist in dissemination of the list and implementation of priority research studies;
- Track funding, research output, translation to policy and its implementation in countries while facilitating process.

Setting research priorities to reduce neonatal mortality by 2015

Dr Rajiv Bahl, Medical Officer, Newborn and Child Health team,
CAH, WHO, Geneva

Dr Bahl explained that about 40% of all under-five deaths occur in the first 28 days of life, which means that there are over 3.5 million neonatal deaths per year. Infections, preterm birth and asphyxia account for 84% of these deaths.

Trends in coverage of interventions that could prevent these deaths are not encouraging. Median baseline coverage for skilled care at birth is 43% in sub-Saharan Africa and 38% in Asia, but the annual increase in coverage is only 0.5% and 1.6% respectively. Similarly, the coverage of initiation of breastfeeding within one hour of birth is 38% in sub-Saharan Africa and 17% in Asia, with coverage increasing 0.9% and 2.6% per year respectively. At these rates, coverage will not increase quickly enough for MDG4 to be achieved.

In order to determine research priorities for neonatal conditions, three expert groups were set up. The group on newborn infections included 13 experts who ranked 61 questions; the preterm and low-birth-weight group included 16 experts and 80 questions; and birth asphyxia had 21 experts ranking 61 questions. The expertise in each group included basic science, epidemiology, clinical science, social science, technology and public health science. On the basis of the group's rankings, the top research questions (see **Annex 3**) were determined.

Dr Bahl summarized the results of the process. Of the 15 top research priorities to reduce global neonatal mortality within the present context, 12 relate to improved delivery of known interven-

tions, and one each to epidemiology, improving known interventions and development of new interventions. Eight relate to community level, five to facility level and two to both levels.

Setting research priorities to reduce diarrhoea mortality by 2015

Drs Jose Martines and Olivier Fontaine, Newborn and Child Health team, CAH, WHO, Geneva

Dr Martines pointed out that trends in the use of oral rehydration salts (ORS) and recommended home solutions (RHS) were not encouraging. ORS or RHS use did not change in countries with two DHS to compare, and ORS use actually decreased by 1%.

With this in mind, a total of 20 experts were asked to contribute to the definition of research questions and options. These experts had expertise in basic science, epidemiology, clinical science, social science, vaccine science or public health science. The top questions identified are listed in **Annex 3**.

The numbers of child deaths caused by diarrhoea has decreased from 4.6 million in 1980 to 1.8 million in 2003. However, diarrhoea is still the second cause of under 5 deaths, representing 18% of child deaths.

The research priorities identified to reduce global mortality from childhood diarrhoea within the present context are dominated by questions aimed at better understanding the barriers towards implementation, effectiveness and optimization of use of available interventions and programmes.

Setting research priorities to reduce pneumonia mortality by 2015

Dr Shamim Qazi, Medical Officer, Newborn and Child Health team, CAH, WHO, Geneva

Pneumonia is the top killer of children under 5, and there are around 2 million under five deaths per year. In sub-Saharan African countries with two DHS for comparison, median baseline coverage for care seeking for acute respiratory infection was 37%, with a median annual change in coverage of 1.4%; in similar Asian countries coverage was 63% with no annual increase.

Similarly, coverage of careseeking and antibiotic prescription for pneumonia in the 28 of 68 Countdown countries with available data, showed that 21% of patients sought care but no antibiotics were given; 33% sought care and were given antibiotics; but in 46% of cases no care was sought. Global coverage of three doses of *Haemophilus influenzae* type B (Hib) vaccine in infants was 26%, but there was a very wide range with 78 countries not yet having introduced the vaccine. Coverage for pneumococcal conjugate vaccine (PCV) is more limited, with only 29 countries including it in the routine immunization schedule in 2008.

During the discussion, participants asked where social contexts, environmental factors and inter-sectoral issues would be taken into account in the priority-setting process. There were also queries related to whether the number and type of people involved in ranking the questions matters. Some participants thought that some questions represented very broad areas of research, while others were much more discrete. It was explained that any of the technical experts involved could pose any question that they wished, and that some inter-sectoral questions had been in the original list but were not prioritized. Weighting of the answers by various criteria did not make much difference to their ranking. While not many people ranked the questions, there are probably only

about 500 experts in each area in the world. Thus, the sample of experts participating was fairly large at about 10% of the total, although a different sample may have ranked differently. When preparing a global list, specificity is lost. The questions point to areas, but they are not yet proper research questions. Some participants wanted challenges of delivering interventions to have come out more clearly as research questions.

Child health research needs: a pharmaceutical 'lens'

Dr Suzanne Hill, Essential Medicines and Pharmaceutical Policies

WHO and UNICEF are working together on a global project to make paediatric medicines a priority. Some of the elements of this plan include adding missing essential formulations to the Model List of Essential Drugs, and advising on doses; developing an essential medicines list for children; updating treatment guidelines; developing paediatric prescribing information; developing effective methods for provision of information at the point of care; collaborating with regulatory authorities to encourage appropriate drug development and approval processes in all regulatory authorities; developing quality standards for paediatric medicines; advocacy for the development of paediatric medicines by the industry; developing a system for enhancing safety monitoring of medicines in children; and providing guidance on procurement and supply of paediatric medicines.

This work has been based on a World Health Assembly resolution on Better Medicines for Children passed in May 2007. In July of that year, there was an Expert Subcommittee meeting that developed the WHO Model List of Essential Medicines for Children. December 2007 brought an initiative on making medicines child-sized. In October 2008, there was an update of the Essential Medicines List for children. Currently, a meeting of the Expert committee is taking place.

The terms of reference for the Subcommittee include:

- To prepare a list of medicines for children, based on their clinical needs and the burden of disease, that the WHO Expert Committee on the Selection and Use of Essential Medicines can use to revise and regularly update the WHO Model List of Essential Medicines to include missing essential medicines for children;
- To determine suitability criteria for dosage forms of medicines for children, with particular attention to conditions prevailing in the developing countries;
- To review the feasibility of manufacturing appropriate formulations for those priority medicines for which no dosage form for children currently exists, specifically considering requirements for use in resource-limited settings and availability of data on efficacy and safety in the appropriate age groups;
- To identify the clinical research gaps regarding safety and efficacy of essential medicines for children in order to improve suboptimal prescribing and dosing, and to facilitate regulatory approval of paediatric formulations;
- To report to the Expert Committee on the Selection and Use of Essential Medicines in 2009.

The approach of the group is to ensure the "rights" of prescribing: patient; diagnosis; medicine; dose, time and route; ensure public health priorities; establish standard criteria for selecting essential medicines; and considerations of sub-populations within the larger group of "children".

As an example of prescribing rights for the right medicine, Dr Hill cited optimal antibiotics for neonatal infection in terms of dosage and form. For dose, among the examples was the appropriate dose for weight, height and age, including in the case of malnutrition. For the optimal dosage

form, examples include how best to enhance administration and adherence. For product gaps, she mentioned specific fixed-dose combinations of antiretroviral drugs (ARVs). With regard to the right drug development methods, there is a call for global standards for clinical trials in children, and determining acceptable short cuts.

Other relevant issues include the supply chain, optimizing prescribing (strategies for behaviour change and audit/education/information/guidelines); and identifying, reporting and managing adverse reactions at individual, community/facility settings and programmatic levels. There is need for operations research to help clarify many of these issues.

During the discussion the issue of how to conduct useful and ethical clinical trials on ill children came up, but it was not clear whether any of these were currently in progress. Also discussed was the issue of counterfeit drugs and how they could be prevented and detected. In response to a comment that it was more important to ensure drugs reached children than to be concerned about the precise dose, Dr Hill explained that correct dosages were very important with regards to issues such as resistance in tuberculosis, but may be less important for some other conditions.

Proposed process to reflect participants' views of funding priorities

**Dr Igor Rudan, Department of Public Health, University of Edinburgh,
Medical School, Edinburgh**

Dr Rudan reviewed the proposed CHNRI process for tracking progress after lists of priority research issues are done. He also reviewed the context of the WHO perspective, around which the priority lists were developed, the criteria for setting priorities, and the way that the research questions were evaluated. CHNRI and CAH wished to take this process a step further, and asked each participant to review the lists of the ten top-ranked research questions for the five leading causes of death. While these are the priority questions from the WHO perspective, they may not overlap with investment priorities of donor agencies because of difference in context, targets, motivations, criteria, etc. Therefore, a criterion was added, "funding attractiveness". The aim is to learn from donors what makes a research question more or less attractive for funding support. Dr Rudan therefore requested participants to individually review the lists of questions provided and identify those that are most likely to receive funding support. This was done by ranking with a number the likelihood of receiving funding support under a participant's organization's current investment policies and practices. At the same time, participants were requested to distribute a theoretical US\$100 among those research questions that seem realistically fundable. Through this process, CHNRI and WHO hoped to learn:

- What makes a research question attractive or unattractive for funding support from donors?
- Whether there are large differences between different categories of donor agencies in their current investment policies?
- Which of the 50 research priorities highlighted by this process would be most realistic candidates for funding support by donor organizations?

The follow-up to this exercise is intended to be:

- Development of the final list of 15–20 research priorities for MDG4 taking into account "funding attractiveness";
- Tracking funding and research output for those 15–20 research priorities;

- Influencing and monitoring changes in policy to support those 15–20 research priorities and implementation in countries.

Participants expressed concern about some aspects of the process during the discussion, mainly to do with whether they could accurately reflect the research priorities of their organizations, the confidentiality of their responses, and the difficulty of dealing with the wording of some of the questions.

Presentation of the results of the analysis of individual work outputs

**Dr Igor Rudan, Department of Public Health, University of Edinburgh,
Medical School, Edinburgh**

Dr Rudan reported the results of the individual work on ranking the research questions. Sixteen participants scored the research priorities, and their responses were categorized into four groups (ministry; bilateral donors; not-for-profit foundations; non governmental organizations). The combined average rank given by participants was from 3.7 to 7.2, and the average amount of US dollars assigned ranged from 2.5–20.1. There was generally consistency between the ranks and US dollars assigned by the different groups, with some exceptions. The ministry group assigned a US dollar value to all questions, while the other groups all gave \$0.0 to some. The group of nongovernmental organizations gave slightly higher rank ranges than the others. There was some variation between groups in the priority they gave to specific questions. However, five research questions stood out from the others, and may provide a starting point where CAH can focus attention that will be most likely to meet with donor support, allowing faster implementation of studies:

- Evaluate the quality of community workers to adequately assess, recognize danger signs, refer and treat acute respiratory infections in different contexts and settings.
- What are the barriers against appropriate use of oral rehydration therapy?
- What are the health system interventions that would increase population coverage of key maternal, newborn and child health interventions?
- What are the feasibility, effectiveness and cost of different approaches to promote home care practices (breastfeeding, cord/skin care, care seeking, handwashing)?
- What are the feasibility, effectiveness and cost of a scheme of routine home visits for initiation of supportive practices, detection of illness and newborn survival?

During the discussion, Dr Rudan acknowledged that the sample size for this exercise was small, and various factors influenced the ranking, including the different knowledge levels and investment strategies of institutions. Decisions on assignment of funds were affected by whether it was known that funding was already being provided for this area of research, and the total amount that would be needed to carry it out. Some of the questions were phrased in a way that background was needed to understand the implications and scope of the research. Participants also felt that, as staff working on research in donor agencies have widely different backgrounds, it would be helpful if a short statement explaining the background and implications of each priority research question to be considered were available.

As a general rule, community-based questions were more likely to be ranked highly than those related to hospital care. For some issues that were allocated little funding, participants felt that there is a perception that they were already well-funded, and/or that any research questions had already been answered, when this is not always the case, for example with vaccines. Also, some

areas need a longer time frame than 2015 to make research meaningful, such as on delivery systems. There was a call for more coordination in research between the different funders, and to make research more country-sensitive.

An important point in the discussion, and related to the funding of questions, was that often researchers and potential donors, especially in the private sector, speak different languages. Researchers need to be clear on what it is they are planning to do, and communicate this in more readily-understood terms.

SMALL GROUP WORK

Participants were divided into three groups (neonatal conditions, diarrhoea and pneumonia) in order to discuss:

- What is attractive (or not) about each of the priority research questions?
- Which are appropriate for different agencies?
- How to track progress after this meeting?

Informal feedback from the groups was that the discussions were useful for the opportunity to “unpack” the questions, and see how many of them related to broader issues, such as human resources. It was not always obvious why some of the work was needed, and there was a tendency for the questions to relate to treatment, rather than prevention. It was observed that funders look at different criteria than researchers, such as clarity and specificity of questions, value for money, linkages to broader issues, and competitiveness, and that donors had particular niches for funding. There is value in scientists, donors and implementers sitting together.

Participants raised the issue of whether donors should be part of the technical advisory group, although advisers are meant to act as individuals, not to represent institutions.

There was also discussion on the issue of who should be setting research agendas – should scientists have their own agenda, regardless of donor interests. However, many participants thought that good common ground had been established through this process as long as it was not seen to be restrictive.

A sense of urgency was expressed by many participants, who reminded the group that the deadline of 2015 is very near; while the methodology used was not perfect, it gave a sufficient basis to proceed. At the same time there is need to start thinking beyond that date.

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