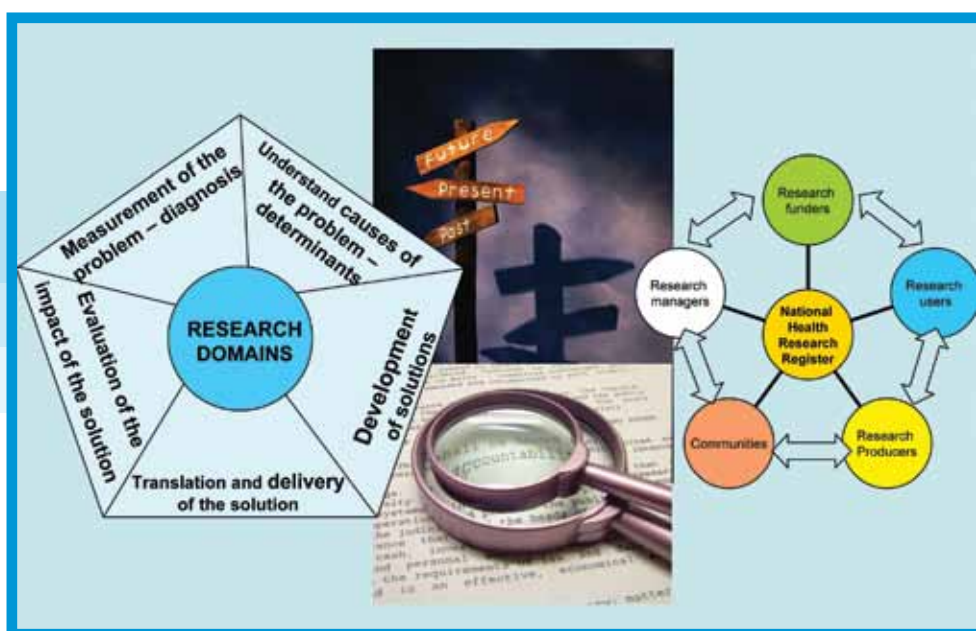


## Expert Consultation on Improving Health Research Management, Governance and Data Sharing in the Western Pacific



15 to 17 August 2011  
Manila, Philippines



EXPERT CONSULTATION ON IMPROVING HEALTH RESEARCH MANAGEMENT,  
GOVERNANCE AND DATA SHARING IN THE WESTERN PACIFIC  
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REPORT

EXPERT CONSULTATION ON IMPROVING HEALTH RESEARCH MANAGEMENT,  
GOVERNANCE AND DATA-SHARING IN THE WESTERN PACIFIC

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## NOTE

The views expressed in this report are those of the participants of the Expert Consultation on Improving Health Research Management, Governance and Data-Sharing in the Western Pacific and do not necessarily reflect the policy of the World Health Organization.

This report has been prepared by the World Health Organization Regional Office for the Western Pacific for governments of Member States in the Region and for participants of the Expert Consultation on Improving Health Research Management, Governance and Data-Sharing in the Western Pacific, which was held in Manila, Philippines from 15 to 17 August 2011.

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### Key words

Health services research – organization and administration / Research / Registries/ Data collection / Information Dissemination
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## List of acronyms

ANZCTR	Australia and New Zealand Clinical Trials Registry
ChiCTR	Chinese Clinical Trials Registry
COHRED	Council on Health Research for Development
CDC	Centers for Disease Control and Prevention
CIOMS	Council for International Organizations of Medical Sciences
CRIS	Clinical Research Information Service
CTR	Clinical Trials Register
DFG	Deutsche Forschungsgemeinschaft
DHS	Demographic and Health Surveys
DOH Philippines	Department of Health, Philippines
DOST Philippines	Department of Science and Technology, Philippines
EBM	Evidence-based medicine
ESRC	Economic and Social Research Council (UK)
EVIPNet	Evidence-informed Policy Network
FERCAP	Forum for Ethical Review Committees in Asia and the Western Pacific
FNRERC	Fiji National Research Ethics Review Committee
HIV	Human immunodeficiency virus
HRSA	Health Research Systems Analysis
HRWeb	Health Research Web
ICTRP	International Clinical Trials Registration Platform
IT	Information technology
KNIH	Korea National Institute for Health
MOH	Ministry of Health
NCD	Noncommunicable diseases
NGO	Nongovernmental organization
NIH	National Institute for Health
NHMRC	National Health and Medical Research Council of Australia
NHRR	National Health Research Register
HRCNZ	Health Research Council of New Zealand
PNHRS	Philippine National Health Research System
REC	Research Ethics Committee
UNICEF	United Nations Children's Fund
USAID	United States Agency for International Development
WB	World Bank
WHA	World Health Assembly
WHO	World Health Organization
WHO STEPS	WHO STEPwise approach to surveillance

## SUMMARY

An Expert Consultation on Improving Health Research Management, Governance and Data-Sharing in the Western Pacific was held at the WHO Regional Office for the Western Pacific in Manila, Philippines from 15 to 17 August 2011.

The objectives of the meeting were:

- (1) to review the organizational structures, status and practices in governance and management of health research in the Western Pacific Region and suggest potential goals and targets to monitor the progress;
- (2) to review the policies for data archiving and access for health research in the Western Pacific Region and reach consensus on desirable goals; and
- (3) to recommend key actions that may be undertaken by Member States and by the WHO Regional Office for the Western Pacific to improve management, governance and data archiving and access for health research.

The Expert Consultation discussed the current neglect of governance and management of health research at the national level leading to inefficiencies, and poor access and use of health research. It then considered a few selected tools and specific areas of action that can have substantial returns in improving the efficiency and effectiveness of health research. These included prospective research registration, systematic data archiving and access, and research ethics review systems.

The Expert Consultation discussed governance and management functions that are essential. These essential functions included effective monitoring and direction of national health research activities and investments; development of systems to ensure access to and use of research outputs; systematic actions to build research capacity in the country; and oversight to ensure research meets agreed ethical and technical standards.

National Health Research Registries (NHRR) were discussed as a support tool to facilitate governance and management in health research by providing a whole picture of national research activity. NHRRs build on the concept of Clinical Trial Registers by requiring prospective registration of all types of health research. Presentations from China, the Republic of Korea and Malaysia described those countries' experiences with research registries, and a presentation by the Council on Health Research for Development described the Health Research Web. The Expert Consultation acknowledged the challenges involved in establishing NHRRs especially in low- and middle-income countries but considered them to have considerable potential.

The Expert Consultation discussed the potential for systematic archiving of health research data and increased access to data for use by the wider research community to improve the effectiveness, efficiency and transparency of health research. Presentations from Australia, Japan, Malaysia, New Zealand, the Philippines and Viet Nam described the current status of data archiving and access in those countries. The Wellcome Trust described its efforts to improve archiving and access to data for the research that it supports as well other ongoing global efforts. A presentation on the work and history of the Demographic and Health Surveys, which is funded by the United States Agency for International Development (USAID), described how different cultural, technical and infrastructural barriers were overcome in ensuring access to data from surveys conducted in over 70 developing countries since the 1980s.

The Expert Consultation discussed governance and management of the ethical review and oversight of research, and whether the role of Research Ethics Committees could be expanded beyond ethical review. Presentations from Cambodia, Fiji, the Lao People's Democratic Republic, Mongolia and the Philippines described the current status and potential of Research Ethics Committees in those countries, which vary widely from highly developed national systems to very poorly resourced systems at an early stage of development. The Expert Consultation underlined the need for the support and development of more consistent systems to ensure ethical standards and technical quality in research.

Through detailed discussion and consensus, the Expert Consultation developed combined recommendations that reflect the views expressed during the meeting relating to the improvement of research governance and management, the development of NHRRs, systematic data archiving and access, and the governance and development of Research Ethics Committees.

Overall recommendations included:

Recognizing and performing essential health research governance and management functions to ensure effectiveness and efficiency of health research

(1) Appropriate bodies should be identified or created within Member States and assigned responsibility for the following essential health research governance and management functions:

- effective monitoring and direction of national health research activities and investments;
- oversight, support and development of systems to ensure ethical standards and technical quality in research;
- development and oversight of systems to ensure efficient data archiving and wider access to data for health research; and
- ensuring that the value of national research outputs is realized and communicated to policy-makers.

(2) The human and financial resources required to discharge these functions should be recognized and supported as legitimate research costs.

*National health research registries*

(3) Member States should acknowledge the importance of National Health Research Registries in improving the governance and management of health research.

(4) Appropriate bodies should develop and implement time-bound plans to establish and operate national or subregional health research registries covering at least health research requiring prior ethical approval.

*Archiving and access to health research data*

(5) Each Member State is encouraged to develop and implement data archiving and wider access policies with time-bound goals and targets.

(6) Member States should encourage the active collaboration and cooperation of diverse research stakeholders in the implementation of data archiving and access policies.



*Research ethics*

(7) Member States should set ethical standards for health research that are in line with international standards and guidelines. These standards should be monitored and enforced by systems of adequately trained and resourced Research Ethics Committees.

(8) Mechanisms that can realize the potential of Research Ethics Committees to contribute to wider research governance functions such as prospective research registration and data archiving should be explored.

*WHO Regional Office for the Western Pacific*

(9) WHO will advocate the importance of effective governance and management of health research and in partnership with Member States will coordinate the sharing of learning and experience in the development of policies, standards, methods and technologies.

The Expert Consultation suggested the following plans and follow-up mechanisms to ensure implementation of the recommendations:

(1) National-level consultations involving broad groups of stakeholders within countries could be held to raise awareness of the issues and to hear their views. Stakeholder groups may include researchers and research institutions, national and international health research funders, and other relevant organizations in the health and science sectors.

(2) WHO could play an active role in raising awareness and supporting national consultations by involving their country and subregional offices.

(3) A follow-up subregional meeting for Pacific islands countries and areas could be organized.

(4) At the international level, mechanisms could be pursued to encourage and facilitate collaboration and shared learning in the development of policies, infrastructures, methods and materials for use in the governance and management functions discussed at the Expert Consultation. This could include the development by WHO of an online repository for resources such as national policies, guideline documents and training materials.

(5) Support could be mobilized from developed countries for less-developed countries. It was also suggested that countries with more highly developed and well-resourced health research systems could share their skills, either by placing skilled personnel in developing research systems or by hosting researchers from developing countries.

(6) Regional follow-up and monitoring mechanisms could be established under the auspices of the WHO Regional Office for the Western Pacific.



## 1. INTRODUCTION

An Expert Consultation on Improving Health Research Management, Governance and Data-Sharing in the Western Pacific was held at the World Health Organization (WHO) Regional Office for the Western Pacific in Manila, Philippines from 15 to 17 August 2011. The consultation was organized by the WHO Regional Office for the Western Pacific with financial support provided by the Japan Voluntary Contribution and the Wellcome Trust.

### 1.1 Objectives

The objectives of the workshop were:

- (1) to review the organizational structures, status and practices in governance and management of health research in the Western Pacific Region and suggest potential goals;
- (2) to review the policies for data archiving and access for health research in the Western Pacific Region and reach consensus on desirable goals; and
- (3) to recommend key actions that may be undertaken by Member States and by the WHO Regional Office for the Western Pacific to improve management, governance and data archiving and access for health research.

### 1.2 Organization

The Expert Consultation was convened by the Health Information, Evidence and Research (IER) unit of the Division of Health Sector Development (DHS), WHO Regional Office for the Western Pacific. Dr Manju Rani, Senior Technical Officer, Health Research Policy, served as the responsible officer from the Secretariat. Chairpersons and rapporteurs were selected for the different sessions. Annex 1 provides the meeting agenda and detailed programme.

### 1.3 Participants and resource persons

Excluding the WHO Regional Office for the Western Pacific secretariat and consultant, there were 24 participants, including 18 temporary advisers from 14 Member States (Australia, Cambodia, China, Fiji, Japan, the Lao People's Democratic Republic, Malaysia, Mongolia, New Zealand, the Philippines, the Republic of Korea, Singapore USA and Viet Nam) and 6 observers (Department of Health, Philippines; International Organization for Migration; Korea Health Industry Development Institute; Philippine Council for Health Research and Development; Wellcome Trust, UK). The list of temporary advisers, consultant, observers and the secretariat is attached as Annex 2.

### 1.4 Opening ceremony

Dr Shin Young-soo, WHO Regional Director for the Western Pacific, welcomed the members of the Expert Consultation and other meeting participants and observers.

He commented that the importance of health research will be reflected in the next *World Health Report*, which will be titled "No Health Without Research". He questioned whether research was as effective and credible as it could be in producing the evidence needed to inform

health policies and programmes. He reflected that while it was important to increase spending on health research, it was equally important to produce quality research to ensure the best use of funds.

Dr Shin stressed that better governance and management of health research offers the potential to achieve maximum returns on investment in health research in terms of improved health services and outcomes. This can be done through efficient monitoring of national research activity, identification of appropriate research priorities, prevention of duplication and utilization of research findings in the development of policies and guidelines.

Dr Shin expressed his hope that the Expert Consultation would not only examine governance and management of health research, data archiving and access and ethical conduct in research, but also produce practical recommendations that could be implemented by the Member States in the near future.

The full text of Dr Shin's message is attached as Annex 3.

## 2. PROCEEDINGS

### 2.1 Session 1: Setting the scene: governance and management of health research *Chairperson: Dr Maimunah Hamid, Rapporteur: Dr Graham Roberts*

#### 2.1.1 Introduction – Governance and management of research: the issues and status

Mr Robert Terry presented an overview of important issues and functions in the governance and management of health research, with governance aiming to improve transparency, accountability and efficiency in health research.

He explained why improved governance and management of health research is needed. Most notably, the amount of health research conducted and reported has been growing rapidly to the point of “information overload”, with some 75 clinical trials and 14 systematic reviews of research evidence published daily. However, many systematic reviews and policy-makers argue that there is still not enough evidence to inform important clinical decisions and policies. This can be due to health research being aligned with donor-driven agendas instead of national priorities, poor access to research results because of the high cost of subscriptions, and results presented in inaccessible formats and languages. Selective publishing and reporting and other misconduct in research including fraud and manipulation of results also affect the credibility of the evidence. There are substantial inefficiencies in health research due to duplication or overlapping, and repeated “me too” research.

Furthermore, there are now multiple local, regional and global initiatives in public health, making the coordination of research efforts even more complex. This is especially true for countries without a structured system for research governance and management. In many countries it is difficult to answer very important questions: How much is spent on health research in a country? Who is doing what research? Who is monitoring research activities and outputs? Is the evidence generated by research being put to use?

The question then arises: Who should be responsible for the governance and management of health research? Again, this is affected by the very complex research environment in which many stakeholder groups interact – local, regional and international funders, researchers,

research users and publishers, legal and regulatory bodies – all with their own rules and regulations and agendas and ways of interacting with one another. Hence, it is important to designate specific organizations at the national level to be responsible for the governance and management of health research and clearly specify what the essential governance and management functions are.

Mr Terry described some work that is being conducted globally to develop tools and approaches that are used to describe and manage the complex area of health care and research. In 2009, WHO developed a global strategy on research for health that focuses on four areas: priorities, capacity, standards, and translation. The lack of a common approach or standards for research classification is another challenge that complicates the coordination and comparison of research globally. As such, a framework has been developed to describe health research along five dimensions: measurement of the problem; understanding the cause of the problem; developing solutions that may involve medicines or guidance; translation and delivery of the solution; and evaluating the impact of the solution. The framework allows those commissioning research to visualize the areas where the research gaps lie. This framework will be discussed further in the upcoming WHO *World Health Report*.

He also alluded to other initiatives at the global level, such as the Health Research Web by the Council of Health Research for Development; an initiative for strengthening health systems research by The Alliance for Health Policy and Systems Research; and the development of checklists and other work in research priority setting by WHO.

Mr Terry concluded his presentation by drawing attention to the 2012 *World Health Report*, which will be titled “No Health Without Research”. In association with the publication of the *World Health Report*, the online journal *PLoS Medicine* will publish a series of papers on themes such as translation of health research, health systems research and health systems governance.

#### 2.1.2 Group work 1: Identifying essential research governance and management functions and challenges

Participants worked in three groups to discuss essential functions involved in the governance and management of health research. The groups considered the following: functions of governance and management and why they are important for improving research effectiveness, transparency and quality; whether systems to perform the functions are already in place in their countries; how the functions might best be performed; and what barriers or challenges may exist. The key functions considered were as follows:

- (1) monitoring the overall health research activity in the country in terms of topic, research completion, and reporting of research results;
- (2) overseeing health research in the country to ensure it is conducted ethically;
- (3) monitoring levels and trends in health research funding and taking actions to achieve balanced allocation of funds in an accountable and transparent manner;
- (4) identifying appropriate national research priorities and coordinating adherence to them;
- (5) monitoring, building, strengthening and sustaining national human and physical capacity to conduct health research;

- (6) undertaking actions to increase access to research results to inform health policy, health practice and public opinion; and
- (7) defining and articulating a national health research strategy.

### 2.1.3 Feedback from group work 1

Rapporteurs for the three groups, Dr Brian Buckley, Dr Asmaliza Ismail and Mr Robert Terry, presented feedback from the three working groups.

- (1) *Monitoring overall health research activity:* All three groups considered this function essential to use existing resources and capacity effectively, to align research with national priorities and to identify gaps in research activity, and to assess returns on national research investments. However, national capacity to monitor research activity was not regarded as strong. Not all countries have national bodies in place to monitor health research activity, and where such bodies are in place, they often monitor only government-funded research. Even then, monitoring is not considered to be comprehensive. Incomplete final reporting of research was reported as a common problem. In Cambodia, a single national Research Ethics Committee (REC) could potentially play a monitoring role since all research is prospectively registered; however, incomplete reporting once research has started was reported as a problem.

Barriers to effective monitoring of research activity include insufficient infrastructure, lack of human and financial resources and undeveloped capacity. In addition, research independently initiated by international- donors and research organizations and commercial sponsors, which constitute a majority of research activity in some lower-income countries, presents problems for ongoing monitoring. Currently, research funders in many countries carry out ongoing monitoring for the research funded by them. The multiplicity of research funding sources makes it difficult to achieve a comprehensive overview of national research activity.

Several factors were agreed as vital in improving monitoring of health research activity. Leadership was seen as a key issue. Better liaison between national bodies with responsibility for research governance and international donors, research organizations and commercial sponsors was seen as offering potential for improved monitoring. Groups reported that no single system for coordinated and comprehensive oversight and monitoring of national health research activity was likely to be appropriate globally, but rather that context-specific systems should be developed that were appropriate for each country.

- (2) *Setting and ensuring national standards for ethical conduct:* This function was accepted by all participants as being of high importance. Existing systems and practices for the ethical review of research varied widely between countries: (a) the Philippines reported having an extensive and well-regulated system in place; (b) Viet Nam reported having a number of RECs affiliated with many institutions within the Ministry of Health and with other institutions including hospitals, but with uncertain oversight of individual institutions' practices; and (c) Cambodia and the Lao People's Democratic Republic reported having a single national Ethics Review Committee with which all research is required to register, but with limited capacity to maintain ongoing oversight following initial review.

Establishing consistent standards in ethical committee practice was seen as important but challenging. Although compliance with international guidelines on the ethical conduct of

research was agreed as fundamental, context-specific ethical issues relating to the involvement of indigenous populations were also highlighted. Sustaining the monitoring of ongoing research was another challenge identified.

(3) *Monitoring health research funding*: This function was acknowledged as being important for governance and management but was reported as being challenging in all countries. In more developed countries, such as Singapore, coordination of domestic funding agencies is practised to avoid duplication. However, even in well-developed countries, where the majority of research is domestically funded, potential for monitoring commercial or international research funding is limited. In lower-income countries, where external sources fund the majority of research, the challenge is greater. Better liaison between national bodies with responsibility for research governance and state research funders, international donors and commercial sponsors was seen as an important factor.

(4) *Setting national research priorities*: The Chinese expert in particular advocated the potential value of setting health research strategies and priorities at the global level, with national bodies coordinating associated national activities. The value of research prioritization at the national level was recognized as a way to ensure that research addressed evidence gaps of national importance. However, the identification of national research priorities is not commonly practised. Malaysia and the Philippines reported systematic research priority-setting at the national level, but both acknowledged limited resources and mechanisms to ensure adherence. Lack of national influence over research funded by international donors and commercial sponsors affects the ability of countries to implement comprehensive national research strategies and to pursue national research priorities, in particular in lower-income countries. Groups reported discussion on the need for balance between setting and encouraging compliance with national research priorities and strategies and allowing research to flourish in undefined or non-prioritized areas: governance should “guide rather than dictate”.

(5) *Monitoring, building, strengthening and sustaining human and physical capacity to conduct health research*. This function was seen as being vitally important, but it was generally acknowledged that it was not being done in a coordinated way in any country. In lower-income countries in particular there were reports of a “brain drain” in health research. Non-clinician researchers such as statisticians and data managers may start their career in research but often transfer to commercial or financial sectors for better salaries or career prospects. In countries where private practice forms the larger part of clinicians’ earnings, many do not pursue research as a major element in their career and may be reluctant to devote time to governance roles or membership of ethical committees.

(6) *Developing systems to facilitate research use*: The fundamental purpose of health research is to achieve better health in individuals and populations. As such, the importance of making the best use of research results was underlined by the discussions. However, concerns were expressed that the results of research were often not well disseminated and not well communicated to policy-makers or the public. The view was expressed that researchers too often neglect wider dissemination of their work to influence the behaviour or decisions of their target audience and consider their job done when papers are published in scientific journals. However, many of these scientific journals are not easily accessible to the target audience. In addition, a large volume of research is never published or reported anywhere. The Philippines and Viet Nam reported collaborating to some extent with the Evidence-informed Policy Network (EVIPNet) for better translation of evidence into policy. This resource offers potential benefits for all countries; however, the activities under this initiative remain rather limited.

(7) *Developing a national strategy for health research:* The potential value of well-defined health research strategies to guide the direction of research and development of research capacity was acknowledged. However, many participants also indicated that sometimes too much time is spent on developing formal strategies. A concise vision and mission, therefore, are needed to guide the work. National research strategies were reportedly not in place in most countries. Where strategies do exist they often relate only to government-funded research.

## 2.2 Session 2: Improving governance and management of health research: discussing and agreeing on the way ahead

*Chairperson: Dr Tran Huu Bich, Rapporteur: Dr Graham Roberts*

### 2.2.1 Setting up national health research registries – introducing the concept

Dr Manju Rani outlined the concept of national health research registries (NHRRs) as a tool to facilitate effective governance and management of health research as well as some of the regulatory and other challenges associated with establishing registries.

*The challenges in health research governance:* The governance and management of health research poses unique challenges because of the complex environment with multiple stakeholders, each with their own agendas and practices. Multiple research stakeholders – national and international funders, researchers and research organizations, health service providers and individual health programmes, health research publishers and editors and RECs – pursue their own agendas and are bound by their own regulations and practices. The group work highlighted the fact that although the governance and management of health research needs to be more coordinated, it would be neither practical nor desirable to try to establish central control with a managed type of organizational structure. So, a relatively non-intrusive system is needed to bring all the stakeholders together by transparent information sharing and by which knowledge of current and past research activity can be charted and monitored without the necessity for centralized control or management.

*The concept of NHRR:* Dr Rani suggested that web-based NHRRs in which all research on humans must be prospectively registered may provide at least part of the solution. Prospective registration of key metadata by researchers and public accessibility of these data are defining features of NHRRs that will lead to greater transparency and accountability in research practice. The creation of a database that provides an overview of national research activity, both past and present, can be used for better research governance and planning.

Clinical trial registers (CTRs), which provide the “proof of concept” for NHRRs, have been set up in many countries. The first CTR was established in the United States of America in 2000 ([www.clinicaltrials.gov](http://www.clinicaltrials.gov)). CTRs sprang up largely because of concerns surrounding publication bias and because of failing public confidence in research conduct – researchers in both the public and private sectors had been suspected of concealing adverse events and not reporting negative trial results. CTRs are mandated to register only clinical trials. However, since the registration of other forms of research has been acknowledged as equally important, CTRs in some countries including the Australia-New Zealand, United States of America and Germany are already registering a broad range of research types. The American CTR accepts registrations from any country, including countries in the Western Pacific Region, not all of which are clinical trials. A search for studies about the management of diabetes in the Philippines on [ClinicalTrials.gov](http://ClinicalTrials.gov) reveals that three of the first four studies on the list are observational studies. The German CTR has started to register epidemiological and observational studies. The Malaysian National Medical Research Register (NMRR) has been expanded to include all



research conducted by Ministry of Health personnel or in Ministry of Health facilities or funded by the Ministry of Health.

Since 2005, WHO has been involved in coordinating the development of CTRs through the International Clinical Trials Registration Platform (ICTRP) and has defined a 20-item minimum data set that researchers should complete when registering their study with a CTR. Currently the German CTR requires the same metadata for observational studies as for clinical trials. However, for maximum governance potential of NHRRs, it may be necessary for countries to expand the registration data set required of studies. For example, information about the estimated total research cost may help in monitoring the national health research investment.

Thus, there is evidence that the registration of all forms of health research is possible and can be used to improve research governance.

NHRRs are comprised of information technology (IT) elements as well as management and policy elements. The IT elements need to be developed properly: the platform must be secure and user-friendly and reliable; and human and financial resources are needed to manage, maintain and implement quality control measures to ensure the completeness and quality of data. Policies need to be developed that define the remit of the register in terms of scope of research to be registered. The minimum data set for required registration needs to be defined so that it provides optimal governance potential while presenting as little burden as possible to researchers. Policies need to be developed to determine which data beyond the 20 minimum data fields can be made publicly accessible and which can be made accessible only to defined stakeholders. Policy will also be required to determine how compliance with registration can be encouraged. Information about registration requirements and methods will need to be disseminated.

NHRRs can assist research governance by providing a “whole picture” of national research activity. This can be of use in national research priority-setting, as seen in Malaysia where the NMRR has been used to define national medical research priorities, and in Australia where analysis of current and past cancer trials has been used to identify gaps in cancer research activity. NHRRs can also assist in managing the work of RECs, several of which may operate quite independently within a single country. Researchers can be required to state which REC they intend to apply to for ethics review and subsequently to upload the ethical approval letter or number when available. This type of system has already been put into place in the Indian CTR and the German CTR. With further development, NHRRs could be used as a portal through which ethics applications are submitted and forwarded to RECs for review, as is being done by the NMRR in Malaysia. Changing the focus from researcher to REC, NHRRs have the potential to monitor the work of RECs in terms of workload, approval rates and even development, training or resource needs.

In all research systems, a major problem is the non-reporting of research outcomes. NHRRs can provide a mechanism to track ongoing research and to assess how many and what types of research have been successfully completed and reported. NHRRs can also provide a mechanism to monitor and assess a country’s financial investment in research if total research costs are included. At present, most CTRs ask for the source of funding but not for the amounts.

In conclusion, Dr Rani suggested that NHRRs offer the potential to improve transparency, accountability and efficiency in research and to connect all the diverse stakeholders. Without controlling stakeholders, a whole picture of national research activity can be publicly available to assist in effective governance and management. However, existing challenges will need to be addressed if NHRRs are to be implemented and to be effective.

To ensure compliance with mandatory registration of research, a regulatory framework will be necessary and several approaches can be explored. In the absence of a single organization controlling all research activity, a system of diverse mechanisms and bodies can be used to ensure registration. Registration can be a condition for ethical review, or can be required by funders before release of funds, by regulatory bodies for registration of a product or by publishers for publication of research papers. Each of these approaches has been successfully implemented for clinical trials.

The geographical scope of NHRRs – global, regional or national – is an issue that needs to be considered. ClinicalTrials.gov contains studies from 174 countries and has demonstrated that registers can be global in their coverage. On the other hand, some countries have successfully established national CTRs, and regional registers may be an efficient option for groups of countries. Another model may be the affiliation of groups of smaller countries with larger, well-resourced countries; for example, Pacific island countries could affiliate themselves with the Australia and New Zealand Clinical Trials Registry (ANZCTR). However, although shared registers may offer economies, they may offer little opportunity for countries to design the registration data set so that it best serves their own research governance and planning functions.

Not the least of the challenges involved in establishing NHRRs is the need for policy-makers to be aware of and to take action on current failings in research governance and management. Beyond that, issues such as who should establish, fund and maintain NHRRs need to be clarified. However, the potential benefits offered by NHRRs in terms of more effective and efficient research systems with less wastage and duplication of effort may outweigh any costs associated with them.

## 2.2.2 Current country experiences with clinical trial registers

In subsequent presentations, participants described experiences with research registers in their own countries.

### 2.2.2.1 Malaysia

Dr Asmaliza Ismail described the National Medical Research Register (NMRR) in Malaysia ([www.nmrr.gov.my](http://www.nmrr.gov.my)). The NMRR was established in response to the international practice of requiring the registration of clinical trials in publicly accessible databases in order to ensure transparency and improved conduct in research, and therefore increase public confidence, and to facilitate clinician, researcher and public awareness of ongoing research.

The NMRR is an online system that facilitates key research policy and governance requirements:

- It is a publicly accessible database that stores the registrations of all research involving Ministry of Health personnel, conducted in Ministry of Health facilities or funded by the Ministry of Health.
- It is a one-stop shop for online submission of technical and ethical reviews and research approvals by the relevant Ministry of Health entity, applications for Ministry of Health research grants by researchers, and supporting review processes by technical reviewers or Medical Review and Ethics Committee members.
- It allows online submission of research reports and publications for review and approval by the National Institute for Health (NIH) and the Ministry of Health.
- It allows monitoring of Ministry of Health-related research activities and progress.

Planned future developments for the NMRR include post-approval monitoring of research progress, patient enrollment, adverse event reporting.

The NMRR was developed originally as a research management tool for the Clinical Research Centre of the NIH. Its role was expanded in 2007, when the Ministry of Health began requiring the registration of all Ministry-funded research. The NMRR has been operating in its present form since 2008. The National Pharmaceutical Control Bureau, which provides clinical trial import licenses or exemption, joined the NMRR system as a way of monitoring the ethical approval of pharmaceutical trials. To date, 3783 research projects have been registered, including 1917 clinical trials and a growing number of all types of research since 2007.

The NMRR has improved the efficiency of research review and approval processes and has also improved transparency in research practice. Researchers and research managers can see what research is ongoing and avoid duplication, while patients can find studies in which they may want to enroll. A particular strength of the NMRR, which has been of value in research governance and management, is its capacity to produce statistical reports about the nature and funding of ongoing research, which has helped in overall research planning, research prioritization and financial control.

*Discussion point:* Dr Graham Roberts commented that students undertaking research in Fiji are required to register their research for ethical approval, thereby adding to the pressure of delivering completed research projects on time. He noticed that the Malaysian NMRR required registration by students and asked whether this had added to the time pressure. Dr Ismail responded that the system allows for expedited registration and approval of student applications, which makes the process quicker. At first, compulsory registration had caused difficulties, but processing by the NMRR had become quicker and registration was now accepted as part of the student research pathway.

#### 2.2.2.2 Republic of Korea

Dr Hyun-Young Park described the Republic of Korea's Clinical Research Information Service (CRIS). CRIS, a publicly accessible web-based research registry was developed in 2009 with the approval of the Department of Health. An application submitted to WHO in 2009 to make CRIS a "primary registry" for ICTRP was approved in May 2010. The system became "live" in early 2010.

The purpose of CRIS is to provide greater transparency and accountability in research undertaken in the Republic Korea and to make information about ongoing research available to the public. Since 2005, the International Committee of Medical Journal Editors (ICMJE) has been requiring researchers to prospectively register all clinical trials as a precondition for publication in its member journals. Since 2007, ICMJE has accepted registration in any ICTRP primary registry. In order to increase international usefulness and accessibility, CRIS is presented in both Korean and English. CRIS provides data on all registered research to the WHO ICTRP on monthly basis.

CRIS is entirely funded by the Korean National Institute of Health (KNIH), Ministry of Health and Welfare. There are four full-time staff (one coordinator, two internal reviewers and one IT professional) and six external advisers. The approximate cost per financial year is US\$50 000 for maintenance and promotion, not including salary costs.

The process of registration involves a number of key stages:

- A researcher applies for an account.

- Once an account is created, the researcher enters data about the study – 40 items, including the 20 items included in the WHO minimum data set.
- Internal reviewers review the data to ensure methodological quality and appropriateness, REC approval and accuracy of study type, aims, interventions and outcomes.
- Once reviewed, data are made available publicly.

Data must be reviewed and updated every six months, with reminder e-mails being sent to researchers.

As there is no statutory requirement for registration of research in the Republic of Korea with CRIS, the registry is promoted through contact with stakeholders such as researchers and academic societies, RECs and medical journal editors. In 2011, the Korean Food and Drugs Administration also recommended registering trials with CRIS. It is likely that policy requiring mandatory registration of government-sponsored research will be in place by the end of 2011.

Since CRIS is still in its early stages, only a small proportion of research conducted in the Republic of Korea has been registered, but the numbers are growing. A quarter of the registered studies are observational in design and the rest are interventional clinical trials. Many Korean studies continue to be registered only with ClinicalTrials.gov partly because it requires data to be entered only in English.

#### 2.2.2.3 China

Professor Li Youping described the Chinese Clinical Trials Registry (ChiCTR), which was originally established in 2004 by the Chinese Evidence-based Medicine Center and Chinese Cochrane Center at the West China Hospital, Sichuan University. The software was developed and became operational in 2005. The Chinese Ministry of Health assigned ChiCTR as the national registry in 2007. It was approved as a WHO ICTRP primary registry in the same year. A good deal of work has been done to raise awareness of ChiCTR among researchers in China and to promote trial registration to ensure transparency in the research process. Awareness-raising articles published in medical journals and textbooks and presentations made at conferences have been facilitated by joint action by evidence-based medicine networks in leading universities and the establishment of a ChiCTR-focused medical journals network.

To date, 1453 trials have been registered, 562 prospectively, with 48% sponsored by the Government, 32% self-funded and 15% pharmaceutical-industry sponsored. The rate of registration with ChiCTR is increasing, but many researchers continue to register instead with ClinicalTrials.gov because of a belief that registration with an international registry may improve the potential for publication. ChiCTR is housed by the West China Hospital under the auspices of the Chinese Evidence-based Medicine Center and Chinese Cochrane Center. The staff of ChiCTR includes a director, administrator, and four other medically qualified staff members specially trained for this work. Potential staff members are developed by the training of Master of Science students in the ChiCTR registration process, and the register is supported by West China Hospital IT staff and an advisory board. Personnel and maintenance costs are covered by West China Hospital.

The Chinese Ministry of Health is developing regulatory policies for ChiCTR. The ChiCTR-focused medical journals network published a statement recommending registration, but registration is not yet mandatory. Journals are not uniformly applying a policy of prior registration as a precondition for publication because an insufficient proportion of Chinese trials

are registered: 30 000–50 000 studies involving humans are published in 1300 Chinese journals per year and only 1% of these are registered.

The data collected by ChiCTR have been used extensively by stakeholders in Australia and the United States of America, but less so in China. However, emerging policy by the Ministry of Health on health technology assessment means that ChiCTR will be increasingly used as a resource domestically. ChiCTR in consultation with the Ministry of Health will undertake further work to make registration a requirement of publication in journals and review by RECs. ChiCTR could be extended to become an NHRR. Key national research projects are already registered, and ChiCTR has been asked by the Ministry of Health to prepare the regulatory framework for mandatory registration of all new medical technology and clinical studies. The registry can already be used as a publicly accessible portal for searching for studies and for monitoring their progress.

Professor Li Youping explained that only a small proportion of trials in China are registered in any CTR because ethical approval is required for registration and there is a shortage of RECs nationally. At the end of 2009, China had 19 729 hospitals and fewer than 400 RECs.

*Discussion point:* Mr Robert Terry commented that the small percentage of research with any ethical oversight (also observed in the Russian Federation and Central Europe) points to the importance of the issues being addressed by the Expert Consultation. Appropriate ethical governance of health research requires not only efficient research registries but also adequate REC systems, associated policy and regulation frameworks to require registration and mechanisms for monitoring and enforcing compliance.

#### 2.2.2.4 Health Research Web

Mr Robert Terry described the Health Research Web (HRWeb) on behalf of the Council on Health Research for Development (COHRED), based in Geneva. As a point of information, he stated that his presentation did not mean that HRWeb was endorsed by WHO.

HRWeb ([www.healthresearchweb.org](http://www.healthresearchweb.org)) is not a registry for individual trials, but rather an open access platform on which information can be presented and shared both within countries and internationally about health research systems and governance. Its software is open source so that it can be used and adapted by any registered user. The information that is presented and accessed on HRWeb includes many of the research governance issues discussed in the Expert Consultation: descriptions of health systems, health research systems and funding, priority setting, RECs, etc.

HRWeb is primarily designed as a resource that can be used by countries to present and share information at the national level, but it can be adapted and used at subnational and institutional levels also. It is of particular value in low-income settings where the resources to develop such a platform nationally may not be available. HRWeb has been used extensively by countries such as Tanzania, where the Council of Science and Technology has used the platform to record, present and make accessible a great deal of information about health research activities, needs and potential. Since the appearance of HRWeb can be adapted by users, the Tanzania portal appears to be a website of the Council of Science and Technology, and yet the database, software and platform are HRWeb. HRWeb has also been used very effectively by Senegal to communicate information about its health research system, funding, key topics and outputs.

Since the Expert Consultation aimed to consider approaches and tools that may be useful in improving health research governance and management, it was in this context that HRWeb

was viewed. It was noted that the platform is in the early stages of development and that many countries have not yet uploaded information about their health research systems. Thus, it is solely a source of information about health research in those countries that use it effectively. Ultimately, if country research profiles are managed properly and populated by data by appropriate national bodies, HRWeb could be used to benchmark, compare and contrast health research systems and activities between regions, countries and research topics, providing a potentially very useful global health research governance tool. To date, uptake has been mostly limited to Africa and the Americas, where considerable effort has been made to ensure that countries register and use the resource. HRWeb was proposed as a platform that may be of use to record, compare, contrast and improve health research governance activities in the Western Pacific Region.

2.3 Session 3: National health research registries to improve governance and management: feasibility and options

*Chairperson: Dr Tran Huu Bich, Rapporteur: Dr Graham Roberts*

2.3.1 Group work 2: NHRRs – responsibility, scope and function, compliance

Participants worked in three groups to discuss the potential benefits and challenges associated with the establishment of NHRRs. Participants considered issues such as: the type and level of organization that should oversee the development and operation of NHRRs; the challenges that may be faced in establishing NHRRs; the extent to which NHRRs might assist various areas of health research governance and management; the type of research that should be included in NHRRs; the data that should be collected for each study; and how compliance with registration might be achieved.

2.3.2 Feedback from group work 2

Rapporteurs for the three groups, Mr Robert Terry, Mrs Mere Delai and Dr Lim Eng Kok, presented feedback from the three working groups. The key issues included the following:

- (1) *Potential of NHRRs*: All three groups agreed that in principle NHRRs have potential to improve health research governance and management. In particular, they were seen as having potential to improve monitoring and assessment of health research activities; to promote transparency and accountability in research; to facilitate financial monitoring, identification of research priorities, monitoring of compliance with research priorities and strategies; and to some extent facilitate use of research results.
- (2) *Organization that should oversee operation of NHRR*: It was felt that support and leadership may be needed at government level to establish NHRRs and to ensure adequate legal and regulatory frameworks. Ideally, the Ministry of Health, national research councils or other Ministry of Health-mandated organizations that have the resources and the power to put in place necessary legal and regulatory frameworks should establish NHRRs. It was felt that rather than starting at institutional level, it may be best to focus on advocating for NHRRs and building governmental support at the national level. In doing so, it would be important to emphasize the benefits offered by NHRRs in terms of ongoing effective monitoring and evaluation of national health research activities and investment and the potential to ensure best use of resources and of research outputs in the national interest.
- (3) *Challenges: human and financial resources*: The challenges involved in establishing and operating NHRRs may be considerable, varied and country-specific. Doubts were raised about the availability of adequate human resources in many countries

to establish an NHRR; therefore, capacity-building would be important. The financial implications of establishing and operating NHRRs were also discussed. It was suggested that it may be more efficient if national REC monitoring systems and NHRRs were developed as one and the same thing so that registration happens at the same time as application for ethical approval. In Cambodia, the existence of a single national REC presents an opportunity for the development of an NHRR, but the REC is under-funded. Although the ongoing maintenance costs were not seen as a serious difficulty, the development and start-up of an NHRR would be beyond the REC's current capabilities. Ideally, NHRRs should be developed and funded by national governments, but it was felt that international donors could assist with funding because of the potential that NHRRs would offer in terms of monitoring and evaluation of research and measuring of research impact. The issue was raised as to whether it would be appropriate to charge for registration.

(4) *Scope of the research to be registered:* It was felt that the simplest starting point for defining the types of studies to be registered would be to include all research that needs ethical approval as per national standards, although this would introduce national differences. It was pointed out, however, that this definition would not include some nationally and internationally valuable research activities such as meta-analyses, systematic reviews and health technology assessments. Views were expressed that the mandatory registration of all research may result in considerable resistance and technical challenges in the early stages. Several staged approaches were suggested as alternatives, including: (a) encouragement of voluntary registration for all research, with compulsory registration of studies over a certain scale, and with the gradual expansion of criteria that determine if mandatory registration is required; and (b) focus on clinical trials in the early stages and then expansion to all study types. However, it was pointed out that frequent changes in policies regarding the registration of research may be difficult to communicate and may require additional resources for dissemination. It may also create confusion among researchers and reduce compliance. It may be best to set the desired policy at the onset and then implement measures slowly to increase the coverage, acknowledging that the registration coverage may be suboptimal in the initial years.

(5) *Minimum registration data set:* A minimum data set for studies would need to be identified. The 20 data points required by ICTRP could be considered a starting point, to which other data types for non-trial research would be added. Some data might need to be kept confidential so as to encourage registration from the private sector. Concerns were expressed that there may be a temptation to use NHRRs for unintended purposes, for example, to evaluate the research performance of individual institutions or individuals.

Countries may want NHRR registration data sets to include data required for specific national research governance and management needs. In addition, NHRRs may be used to deposit or link research outputs including published papers and reports in addition to simple metadata at time of registration, though experience is limited in this regard. Only ClinicalTrials.gov currently requires submission of summary clinical trial results on registry.

(6) *National or shared NHRRs:* The issue was raised as to whether all countries produce sufficient amounts of research to require national registries or whether in some circumstances shared regional or subregional registries would be appropriate. Some experts felt that it is important for each country to establish and run its own registry of national research activity. Although only one Pacific island state was represented, the view was supported by other Australasian experts that issues of national sovereignty relating to NHRRs were of considerable and justified importance.

2.4 Session 4: Round-table discussion: finalization of recommendations  
*Chairperson: Dr Maimunah Hamid, Rapporteur: Dr Graham Roberts*

Draft recommendations relating to research governance and management and to national health research registries, based on the discussions and presentations, were presented to the committee. The following recommendations were reached on consensus.

2.4.1 Recommendations regarding governance and management of health research

- (1) Member countries should acknowledge that effective governance and management systems of national health research are essential to ensure optimal effectiveness and efficiency of health research.

Essential governance and management functions include:

- effective monitoring of national health research activity and financial investments;
- national oversight of ethical and technical quality in research; and
- development of systems to ensure wider access to and wider use of research results.

- (2) Appropriate bodies should be identified or created and assigned responsibility for the discharge of these essential health research governance and management functions.

- (3) The cost of human and financial resources required to perform these essential functions should be acknowledged as legitimate research costs by national and international funding agencies. Options should be explored to mobilize or channel these funds from the research funding agencies to appropriate agencies responsible for governance and management functions.

2.4.2 Recommendations regarding national health research registries

- (1) National health research registries should be acknowledged by member countries as mechanisms with potential to improve the governance and management of health research, leading to more relevant, transparent, efficient, and quality research.

- (2) All Member States should be encouraged to identify/designate local agencies to develop and implement time-bound plans to establish and operate a national health research registry that covers at least the health research requiring ethical approval. Joint subregional or regional development of shared hosting of national data may be considered for smaller Member States along the lines of the joint Australia and New Zealand Clinical Trials Registry.

- (3) In partnership with the WHO Regional Office for the Western Pacific, countries should:

- work together and share experiences as they develop NHRRs in order to avoid duplication of efforts; and
- collaborate on the technical aspects of developing appropriate formats and minimum data requirements for NHRRs.



2.5 Session 5: Setting the scene: data-sharing in public health research (rationale, issues, potential challenges)

*Chairperson: Professor James Best, Rapporteur: Dr Lim Eng Kok*

2.5.1 Data-sharing and the Wellcome Trust

Dr David Carr from the Wellcome Trust began his presentation by posing three questions to researchers:

- Have you ever wondered about the truthfulness of research findings?
- Have you ever lamented the fact that key research data languished on someone else's computer and were unavailable to answer important health questions?
- Have you ever wished you had access to data collected many years ago so that they could compare with their own current data to examine health trends?

The Wellcome Trust feels that data sets that can be of use in public health research should be made more widely available to researchers so that their capacity to contribute to better health in individuals and populations can be realized.

*Wellcome Trust and data access:* The Wellcome Trust is a charitable foundation that supports biomedical research in the United Kingdom of Great Britain and Northern Ireland and in many low- and middle-income countries. It aims to support high-quality research that is timely and widely used, transparent and available to all. It aims to avoid duplication in research and to extract best value from funds invested in research by ensuring that data sets can be used more widely, can answer several questions and are preserved for future use. The Trust has played a leading role in ensuring that key data sets are made available to the research community, in particular in recent years in the area of genomics. It has been a leading advocate of open-access publishing and has introduced a policy that requires data from Wellcome Trust-funded research to be made available to other researchers with as few restrictions as possible.

*Why wider data access?:* The process of analysis and reporting of health research is often slow and incomplete. Lack of access to data limits the capacity for comparative analysis or accuracy checking. Full potential of the data is not utilized, addressing only immediate research questions. Duplication in data collection is commonplace and data archiving is poorly coordinated. Data-sharing practices in other areas demonstrate that this need not be the situation. For example, in the field of genomics, routine sharing of data has resulted in international collaboration and rapid advancements in science. Open access to geophysical data is provided through the World Data Center system and many social science and economic data sets are shared as a matter of course.

*Challenge in data-sharing:* Dr Carr acknowledged, however, that routine sharing of data in public health research may be challenging, especially in lower-income countries. Routine sharing of data may lead to a situation where a great deal of the work in collecting the data may be done by researchers in lower-income countries, while the better-resourced researchers in other countries analyse the data and publish the results. In a research culture where peer-reviewed publication is a measure of research success, this will lead to tensions and inequity between researchers in developed and developing countries. In addition, the human and technical infrastructures required for systematic data preservation and access will have costs in terms of time and money.

There is a perception that increased data-sharing may lead to increased ethical risks: the risk of breach of confidentiality for research participants; the “stretching” of original consent;

and the risk of stigmatization of small communities. However, these ethical risks must be balanced with other ethical imperatives: the need to ensure best use of scientific data to improve health; the need to make best use of taxpayers' and funders' investments; the need to avoid research fatigue in populations by avoiding duplication in data collection; and the need to ensure policies and investments in health are informed by all available information.

*Global initiatives around wider data access:* Dr Carr described global initiatives aimed at encouraging and facilitating the sharing of research data. For example, the Organisation for Economic Co-operation and Development has issued principles and guidelines that advocate maximized access to and use of research data generated by publicly funded research. Funders such as the United States National Institutes of Health have established data-sharing policies, as have leading research universities and institutions.

Notable international initiatives to reach consensus on data-sharing started in earnest in 2008 and were supported in principle at the Global Ministerial Forum on Research for Health in Bamako in 2008. Principles and guidelines were developed further in the following years. In 2010, key statements on data-sharing were made by the World Bank and the H8 group of leading research organizations. In January 2011, 17 international research funding organizations published their joint statement of purpose on sharing research data to improve public health, accompanied by a commentary in *The Lancet*. The signatories are committed to working together to expand the availability of data resulting from research funded by their organizations. The joint statement set out three principles to guide conduct in data-sharing and seven goals.

The three principles dictate that the sharing of data should be equitable, ethical and efficient:

- (1) *Equitable:* Any approach to the sharing of data should recognize and balance the needs of researchers who generate and use data, other analysts who may want to reuse those data, and communities and funders who expect health benefits to arise from research.
- (2) *Ethical:* All data-sharing should protect the privacy of individuals and the dignity of communities, while simultaneously respecting the imperative to improve public health through the most productive use of data.
- (3) *Efficient:* Any approach to data-sharing should improve the quality and value of research and increase its contribution to improving public health. Approaches should be proportionate and build on existing practice and reduce unnecessary duplication and competition.

The seven goals set out immediate objectives and longer-term aspirations:

- (1) *Data management standards support data-sharing.* Standards of data management are developed, promoted and entrenched so that research data can be shared routinely and re-used effectively.
- (2) *Data-sharing is recognized as a professional achievement.* Funders and employers of researchers recognize data management and sharing of well-managed data sets as an important professional indicator of success in research.
- (3) *Secondary data users respect the rights of producers and add value to the data they use.* Researchers creating data sets for secondary analysis from shared primary data are

expected to share those data sets and act with integrity and in line with good practice – giving due acknowledgement to the generators of the original data.

- (4) *Well-documented data sets are available for secondary analysis.* Data collected for health research are made available to the scientific community for analysis, which adds value to existing knowledge and leads to improvements in health.
- (5) *Capacity to manage and analyse data is strengthened.* The research community, particularly those collecting data in developing countries, develop the capacity to manage and analyse data locally, at the same time contributing to international analysis efforts.
- (6) *Published work and data are linked and archived.* To the extent possible, data sets underpinning research papers in peer-reviewed journals are archived and made available to other researchers in a clear and transparent manner.
- (7) *Data-sharing is sustainably resourced for the long term.* The human and technical resources and infrastructures needed to support data management, archiving and access are developed and supported for long-term sustainability.

*Ongoing work at the global level:* To further the implementation of the statement of joint purpose, the signatory organizations have formed three cross-funder working groups to address some of the pressing challenges in order to facilitate wider data-sharing. Issues associated with capacity and skills will be examined by the Doris Duke Charitable Foundation, the Medical Research Council (UK), the Wellcome Trust, the United Nations Children’s Fund (UNICEF), the Hewlett Foundation and NHMRC (Australia). Culture and incentives within research, organizations and countries that affect data-sharing will be considered by the United States Centers for Disease Control and Prevention (CDC), the Medical Research Council (UK), the German Research Foundation (DFG), the Bill & Melinda Gates Foundation and the United States Agency for International Development (USAID). The infrastructure and tools that may be required for data-sharing will be considered by WHO, the Medical Research Council (UK), the Economic and Social Research Council, DFG (Germany), NIH (United States of America), the World Bank and NHMRC (Australia).

*Joint statement of purpose and invitation to other Member States and organizations to join:* Dr Carr stressed that the joint statement, originally made by 17 organizations, was not intended to form a closed or defined group of stakeholders. WHO, UNICEF and the South African Medical Research Council have indicated their support and other organizations are welcome to become signatories or to join discussions.

*The good practice examples in data-sharing:* The purpose of the joint statement is to promote the idea that data-sharing should become widespread and routine. Dr Carr also pointed to some well-established and long-standing examples of wider public access to health research data that illustrate the benefits. National initiatives include the national health and nutrition studies that have been conducted in the United States of America for many years. International collaborative initiatives include the USAID-supported Demographic and Health Surveys (DHS), which have been conducted in many countries since the 1990s, UNICEF’s Multiple Indicator Cluster Survey, and the World Bank’s International Household Survey Network. These surveys can be contrasted with the WHO-supported surveys for surveillance of noncommunicable diseases (WHO STEPS), whose data have largely not been systematically archived and shared with wider group of researchers and may now be difficult to retrieve.

*Policies on data-sharing at the Wellcome Trust:* The Wellcome Trust has introduced a policy for its sponsored research that requires data to be made available to other researchers with

as few restrictions as possible. Upon application for funding, research proposals must include data management and data-sharing plans that indicate how data will be archived and made available for other researchers. The Trust undertakes to support costs for data-sharing included in research proposals. A review of the Wellcome Trust's data management and data-sharing policy found that researchers were not entirely clear about the purposes of the data-sharing requirement and that they needed more support in implementing data management and data-sharing plans. Consequently, the Trust published further clarifications and guidelines to assist researchers with data management and data-sharing. The strategies for increasing access to data vary between research fields. Since it is often not appropriate for data to be made publicly accessible, some controls or checks are needed. But whatever the level of access provided, mechanisms for accessing data or restricting access should be proportionate, transparent and consistently applied and they should be aimed at maximizing legitimate research access in a timely manner.

*Barriers to data access:* Several barriers to data-sharing have been encountered. These include developing and sustaining the infrastructure required for long-term data storage and curation, changing the "research culture" to include incentives and recognition for researchers who share their data, developing data standards and the platforms needed for inter-operability, improved training and career development of data specialists and bio-informaticians, and ethical guidelines to protect the confidentiality of research participants.

*Discussion point:* Dr Maimunah Hamid enquired whether the signatories of the international joint statement envisaged data-sharing to be increased initially at the international level with international data sets or within countries. Dr Carr responded that the signatories had no particular agenda or preferences on such matters and did not prioritize increased data-sharing at one level over another. Dr Manju Rani commented that whereas the drive for increased data-sharing and best practice in this regard may be coming from international bodies, it would be of particular importance for Ministries of Health to promote data-sharing to realize maximum returns from the resources that they invest in health research. Dr Rani also stressed the vital role that increased access to data at the national level can play in the research experience of students, and that increased access to data could be a key factor in strengthening the capacity of researchers in lower-income countries to undertake their own analysis and publication.

## 2.5.2 Data-sharing in public health research: current status, experience and policies (countries and organizations)

### 2.5.2.1 Australia

*Australian Code for Good Practice in Research and data-sharing:* Professor James Best described data management and access issues in Australia from the point of view of the National Health and Medical Research Council (NHMRC), the major national research funder. NHMRC and the Australian Research Council, which funds non-medical research, developed the Australian Code for Good Practice in Research. The Code includes sections that are of relevance to data preservation and sharing. Research institutions are required to have policies on data retention, long-term archiving and access by the wider research community unless there are ethical reasons for restricting access. Institutions are encouraged to have institutional repositories for data rather than multiple departmental practices. It is also recommended that full reports of all research findings are published as broadly as possible. The "Group of Eight" major universities in Australia has a policy of data-sharing that requires wider access of stored databases to researchers.

*Existing examples of data-sharing:* Professor Best presented a number of examples of the data-sharing policy in practice. The Western Australian Data Linkage System at the University of Western Australia collects information about notifiable and infectious diseases, and includes a

cancer registry, which is widely accessible and used by researchers. The Australia and New Zealand Clinical Trials Register has registered over 3000 trials at a rate of just over 100 per month. The Australian Institute of Health and Welfare maintains an accessible database that contains data on key health indicators, cancer and noncommunicable disease risk factors, alcohol and drug use, disability and mental health. The Australian Bureau of Statistics provides access to data on births and deaths and on the health status of indigenous populations. However, accessing these data sets can be difficult and the NHMRC views the policies in place to guard privacy as disproportionate to the actual risks. Consequently, although it is possible for researchers to access individual-level anonymous data, the process is unnecessarily difficult.

*Ongoing and future work:* Professor Best expressed the view that Australia is on the threshold of some exciting developments that will link up existing data sets, improve long-term archiving and facilitate greater access to and use of data. In particular, capacity will improve in the linking of data sets, which hitherto had been very difficult. The Government has provided funding for several initiatives in e-Research. A central register of existing databases is expected to be created and will include a network of data storage, access and transfer tools that will facilitate collaboration and secure transfer of large data sets.

*NHMRC and the joint statement of purpose on data-sharing:* The NHMRC is one of the first 17 signatories of the joint statement on sharing research data to improve public health. It has a policy that requires open publication and sharing of data from any research that it funds unless reasons for limiting access to data can be demonstrated. The NHMRC has participated in data-sharing for genomic research and has recently joined other major international research funders in the Global Alliance for Chronic Diseases to come up with a common data set for research into hypertension in low- and middle-income countries, to be collected and shared to facilitate international comparison.

#### 2.5.2.2 New Zealand

*Current practices in data-sharing:* Dr Robin Olds of the Health Research Council of New Zealand (HRCNZ) described data-sharing as being a story with two parts: good practice on the one hand, and poor practice on the other. Good practice is illustrated by New Zealand's established history of national health surveys; data from these surveys are available in several formats, from aggregate summary data describing prevalence of factors and indicators to files containing the raw "microdata". In some cases, small fees are charged to access certain kinds of data, but in general, access is easy and widely available. On the other hand, where investigator-initiated research such as hypothesis-driven academic research is concerned the story is very different. Dr Olds felt that while researchers expect to have access to high-quality data sets such as the national surveys, they are very reluctant to share the data generated by their own research.

*HRCNZ and the joint statement of purpose on data-sharing:* Like NHMRC, HRCNZ is a signatory of the joint statement on data-sharing. Dr Olds described a framework by which implementation of data-sharing policy may be achieved.

A policy statement has been drafted as follows:

"The HRC considers research data generated with public funding to be a valuable resource, representing both a significant investment and a source of knowledge which may assist in efforts to improve the health of New Zealanders.

The HRC is committed to ensuring that there is timely sharing of this data with the research community and that it is reused in a responsible manner.

We expect all Project and Programme applicants to consider the case for a data-sharing strategy. Where applicable, applicants should outline their plans to maximise the availability of final research data to valid second users, with as few restrictions as possible.

Where required, applicants will need to outline the specific argument as to why data cannot be shared or the data-sharing strategy is limited in any way.”

Data-sharing strategies and associated costs will be considered by the HRCNZ during the funding recommendations process.

*Future plans:* Starting in 2012, broad consultation with national stakeholders will be organized with two goals: (1) to hear the views of stakeholder organizations, and (2) to raise awareness of the data-sharing policy. Stakeholders will include researchers and research institutions, national health research funders and other bodies in the health and science sectors. Initially, it will only be suggested that funding applications address data storage and data-sharing plans, but subsequently it will be required (or an explanation for why it is not appropriate or possible).

The HRCNZ also feels that it is essential to encourage the sharing of good examples that illustrate the value of data-sharing and methods for achieving it, to conduct ongoing reviews of the funding and infrastructure implications of data storage and sharing, and to advocate for the creation and sharing of high-quality data sets as a valuable research activity.

*Challenges and potential solutions:* Dr Olds outlined challenges to data-sharing that overlapped with those already acknowledged by other speakers: research culture issues such as perceived researcher ownership of the data sets; the need for defined standards; and the need for increased resources and infrastructures. He highlighted two ethical considerations: (1) the well-developed New Zealand REC system has a fundamental principle of consent for single specified data use, and this presents a considerable challenge for data-sharing that must be discussed; and (2) among Maori populations individual data may be considered the property of neither individuals nor funders, but rather of family or community groupings, which means that slightly different approaches to consent need to be explored thoughtfully. He proposed the concept of “guardianship” rather than the “ownership” of the data.

*Discussion point:* Mr Robert Terry commented that rather than approach the ethical, cultural and technical challenges that had been highlighted from the data-sharing perspective, it may be best to start with the emphasis on data management. Explaining more fully, he suggested that the first steps might be about the efficient collection and secure storage of research data and then about the development of further understanding of how data can be more widely accessed. He commented that there may be perfectly good reasons for a range of levels of access to data (from publicly accessible to confidential) and that these considerations should be retained in discussions.

### 2.5.2.3 Philippines

*Philippine National Health Research System:* Dr Jaime Montoya of the Philippine Council for Health Research and Development described the Philippine National Health Research System (PNHRS) and highlighted opportunities and challenges in the country for improved data archiving and access. The PNHRS system, established in 2003, is comprised of four core agencies: the Department of Health, the Department of Science & Technology, the Commission on Higher Education and the National Institutes of Health at the University of the Philippines Manila. The PNHRS provides a framework of human, technical, financial, research and development facilities and logistical resources to implement the PNHRS Plan and the National

Unified Health Research Agenda. The overall aim of the PNHRS is to provide an enabling environment for health research and promote the importance of evidence-based health care and health policy.

*Current status:* A national repository for health research information, Health Research and Development Information Network (HERDIN), records the activities and publications of researchers. Currently, HERDIN offers free access to an online searchable bibliographic database of papers published in 150 Philippine health journals from 1906 to 2010. The next pursuit for HERDIN will be the development of a national health research registry, in collaboration with research, ethics and health publisher stakeholders, which will register the research studies prospectively.

The archiving of research data is currently institution-based. No central agency has the capacity or remit to archive these data sets. Databases created for national surveys are usually archived by the implementing institutions such as the National Statistics Office the Philippine College of Chest Physicians (National Chronic Obstructive Pulmonary Disease Survey) and the Food and Nutrition Research Institute (National Nutrition and Health Survey). Aggregate data are available on the institution websites in the form of published survey reports, and micro-data may be available from the institution by request.

*No systematic national policy for data archiving:* No national policy exists on data-sharing. Regulations relating to data are part of the ethical regulations relating to research. A pending freedom of information Bill will apply to research results and will likely put pressure on the regulatory authorities to develop and implement guidelines on access to databases generated through research. The PNHRS is currently considering requiring government-funded research projects to submit their raw data to the funders as part of the research completion requirements, with the added condition that if research results are not published within a certain time, the funder will have the right to publish them. These developments represent a move towards increased access to research data, but there is not an overall policy or strategy with that goal explicitly stated.

*Potential challenges:* Dr Montoya highlighted a number of challenges that must be addressed to increase data-sharing and to make databases publicly available in the Philippines. The issue of data ownership – whether owned by the funding agency, investigator or research institution – needs clarification. Confidentiality may be an issue in technology-based studies with resulting technology or product development. Researchers and institutions may have concerns about preserving a competitive advantage in research that may be lost by making their data available. There are few incentives to encourage data-sharing and a lack of perceived advantages offered by data-sharing. There is also a lack of accepted and easily usable mechanisms for data-sharing and a lack of agreed standards for databases. Another factor that restricts enthusiasm for data-sharing is a lack of interaction between researcher or institutions with the end users of shared databases, and hence a lack of awareness of the demand and the potential uses for data.

#### 2.5.2.4 Demographic and Health Surveys

Dr Kia Reinis gave a presentation on the Demographic and Health Surveys (DHS), a project funded by USAID that started in 1984 ([www.measuredhs.com](http://www.measuredhs.com)). To date DHS has conducted 290 surveys in 89 countries around the globe, principally in countries that receive American financial aid in Central and South America, Africa and Asia. DHS provides support, coordination and technical assistance to agencies in host countries that wish to conduct surveys. Data are collected through face-to-face interviews with individuals in nationally representative samples that have ranged in size from over 3000 households to over 100 000 households in an Indian survey. The survey collects data on fertility and family planning, maternal and child

health, infant and child mortality, adult morbidity and mortality, key health indicators and risk factors, and socioeconomic and education status.

*Data-sharing and DHS:* The principle of data-sharing is the cornerstone of the DHS ethos. DHS sees collecting data as an integral component in policy formulation, programme planning, decision-making and monitoring and evaluation. Hence, data sets are made freely available to responsible researchers and other users. Free data-sharing is a requirement for a country's participation in the DHS programme. Dr Reinis explained that the key reason for the willingness of countries to share their data is trust – DHS has established a relationship of trust with the participating countries over the years. She credited a portion of the trust that countries have in the DHS concept to its predecessor, the World Fertility Survey, established by the International Statistical Institute (ISI) in London in the 1970s, which saw the value of researching health trends with well-designed, well-managed and accessible longitudinal data from nationally representative samples. Other aspects important in maintaining trust between DHS and host countries include honouring agreements, never misusing the data and never sharing data until the country's final survey report has been released, national dissemination seminars have been held and a formal letter of approval of data release has been received from the national organization implementing the survey.

Fostering and reinforcing host country ownership of data collection, analysis, presentation and use are fundamental. After data collection, DHS works with the host organization and provides technical assistance in the analysis and interpretation of the data and writing the report. Tools and assistance are also provided to enable countries to make best use of the data in informing policy and decision-making at local and national levels, further increasing country ownership of the surveys. Countries are confident as a result of DHS's experience that the data are of high quality and also that DHS reviews all applications to use the data after its release to ensure that only bona fide researchers with legitimate reasons to use the data are granted access.

The trust of individual research participants is also important. DHS ensures that each participant is fully informed, that their data remain confidential and that their identification is protected. DHS is governed by USAID Regulations for Protection of Human Research Subjects (22 CFR 225) and monitored by an Institutional Review Board. All data files are anonymous, making it impossible to identify respondents. Anonymity, however, precludes any follow-up cohort studies unless they are planned in advance and consent is requested for contacting households again. Where GPS data are coded, they are randomly displaced slightly to ensure that they cannot identify individuals or communities while retaining their usefulness of geographical analysis.

Specific ethical implications have been associated with the measurement of HIV status in recent surveys. HIV has been determined from blood drop samples sent to laboratories following face-to-face interviews. Although HIV status is therefore established for each person in the survey, the identity of the individuals is at that stage unknown. This means that the data are confidential, but also that DHS cannot inform individuals of their HIV status. Respondents are informed of this arrangement at time of consent.

*Actions to facilitate data use by users:* Dr Reinis went on to explain that the databases produced by DHS are not only accessible, but also easy to use. Many different kinds of data files are produced to ensure maximum usability and are presented in the three major data analysis applications: STATA, SAS and SPSS. Users are also provided with background documentation such as standard recode manuals, an editing and imputation manual, and country-specific survey documentation. In addition, ready-made reports are produced for users who do not need or want to conduct their own analyses.



*Procedures to access data sets:* Researchers who want to gain access to the data sets must register with DHS, must submit a description of their planned study, and must agree not to share the data. Data will not be supplied for commercial or marketing research. Researchers are requested to supply a copy of their research report or publication to the DHS archive. More strict conditions are applied to the release of HIV status or GPS data and these are only supplied if a research need for them can be demonstrated.

*Statistics on use of DHS data:* DHS data files are used extensively, demonstrating the increased value that can be realized from collected data if they are made available. In 2010 alone, DHS received 3915 requests for data and 133 314 data files were downloaded. Nearly half of all requests for data during the period 2006–2010 came from users registered in North America, but a proportion of these requests may have been made by foreign postgraduate students in America requesting data about their own countries, so that the usefulness of DHS data in the training of worldwide research and analysis skills is likely to be significant. In the period 2003–2011, 713 peer-reviewed papers based primarily or wholly on DHS data were published in 222 journals in 59 countries.

*No negative experience with wider use of data:* Dr Reinis reported that no negative experience or consequences have been noted by any stakeholder as a result of the public access policy for DHS data. She concluded by acknowledging the support of USAID for over 25 years and by applauding the countries who have demonstrated such foresight by their willingness to share data for the benefit of the world's health.

*Discussion point:* Dr Maimunah Hamid expressed interest and some concern about the arrangements relating to HIV status and queried whether an ethical dilemma was created by the inability of DHS to inform individuals of their HIV status, especially if they test positive. Dr Reinis acknowledged the issue and said that the same question had often been asked of DHS. However, Dr Reinis pointed out that the surveys were not intended as screening programmes. She stressed that the rapid tests used by DHS increased the possibility of false-positive tests and assured the Expert Consultation that all participants give consent to the arrangements. Dr Reinis also clarified that DHS surveys undergo ethical review both in the United States and in the host country.

Dr Maimunah Hamid also asked if any statistics could be provided to demonstrate the extent to which DHS, when working on a survey in a country, had improved that country's capacity to conduct its own research and analysis based on its own data. Dr Reinis responded that although she could not present any objective evidence of capacity-building, she was certain that the work DHS does in terms of partnering and workshops in survey analysis and reporting improves national research, analysis and interpretation capacity.

Dr Reinis was asked whether there were criteria or procedures used for selecting the countries in which DHS works. She responded that the countries were those that receive international assistance from USAID, but also confirmed that other countries could invite DHS to conduct surveys but they would not receive USAID funding.

Dr Vonthanak Saphonn stressed the importance of trust. Developing countries need to feel confident that they are full partners in the process of data-sharing. They should not be sidelined as data collectors and providers while researchers in developed countries remain the principal interpreters of data and publishers of research papers. He expressed concern that this should be the case in all data-sharing transactions, not just DHS surveys, and underlined the necessity of building this culture if data-sharing was to succeed.

The Chairperson agreed that these were very important comments and that true partnership and collaboration between developed and developing worlds and real benefits in terms of improved research capacity and use of data to improve health and health care were vital considerations.

Dr Manju Rani commented that one way to see the benefit of the DHS shared-database approach was to consider the case of Cambodia, where multiple national health surveys had been conducted by national agencies in addition to the DHS surveys. She explained that while DHS data were made available to researchers, data from the other surveys were not. A search on PubMed for papers from Cambodia using survey data identifies papers based upon DHS data but few using other data sets, thereby illustrating the value of DHS data in both informing policy and developing research skills and activity. Dr Maimunah Hamid encouraged DHS to record the nationality of researchers downloading data as well as their location so as to better assess capacity-building among researchers from developing countries. Dr Montoya observed that low awareness of DHS data availability among researchers might be a reason why requests for data from Asia are lower than expected. He suggested that DHS and national research governance and education bodies should increase awareness of the research opportunities.

In closing, Dr Reinis reminded the Expert Consultation that although the data-sharing and secondary analysis aspects of the work of DHS were important, and were the topic of her presentation, the primary analysis of the data immediately after the surveys was of crucial importance in informing national health policies.

#### 2.5.2.5 Malaysia

*Current status:* Dr Maimunah Hamid made a presentation outlining the experience of Malaysia relating to data archiving and access. Malaysia has conducted National Health and Morbidity Surveys every 10 years since 1986, along with a number of other national surveys, such as the 1996 National Health Expenditure Survey, the 2002 World Health Survey and nutritional and dental surveys. Other health data sources include electronic data sources based upon hospital and dental care records, disease registries, census, household surveys and labour force surveys.

Dr Hamid expressed her concern that although a great deal of money is used to collect data, the degree to which the data have been used in research to improve health care and policy was less than encouraging. Although no specific policies are in place for data-sharing in Malaysia, the intention to make best use of data to improve research and health care is an intrinsic part of many policies.

*Potential challenges:* Dr Hamid outlined some of the challenges faced by Malaysia as it tries to increase use and sharing of data. To begin with, there is a need to develop a governance framework including policy, guidelines, standards and safeguards for data archiving and sharing. Another governance challenge is securing funding for the infrastructure and systems required. In terms of human and technical resources and infrastructure, there exists a shortage of institutional capacity to support data management, secure archiving and data access. With regards to specific skills, Dr Hamid felt that the weakest element in many surveys was data management and that this is an area in which capacity-building is needed in all surveys. Capacity may also be needed in terms of skills in secondary data analysis and methods for exploiting existing data to inform policy and practice. Dr Hamid suggested that Malaysian researchers shared some of the same cultural attitudes that previous speakers had mentioned, such as a perceived ownership of data and a lack of incentive to share.

*Progress made, ongoing and future plans:* Dr Hamid described some areas in which significant progress of relevance to data archiving and access has been made in Malaysia recently. In the latest National Health and Morbidity Survey, much more work has been done on establishing data management and documentation roles and assigning data coordination roles and responsibilities. A Centre for Epidemiological Studies has been created that acts as an advisory resource and a repository for epidemiological studies and seeks to increase the value gained from epidemiological work by facilitating the archiving and linking of data sets. Policies have been devised for the use of data from epidemiological surveys that guarantee exclusivity of use to the principle investigators for two years, beyond which time the data sets can be used by anyone who applies and is approved by the Director General, Ministry of Health. Proposed research that will use the data sets must be registered in the Malaysian NMRR, must be approved by MREC, must acknowledge the source of the data, and finally must be approved by the Director General of Health for publication.

Plans are in progress to bring all the National Institutes for Health under one umbrella, in one facility complex, and with that move, to establish a central data warehouse for health research databases. Nationally, a Malaysia Health Data Warehouse (MyHDW) is being planned to provide access to reliable health data and to serve as a platform for the standardization and integration of health data from multiple sources. Drafting of guidelines and database blueprints are currently under way.

*Discussion:* Professor Best commented on the balanced approach that is illustrated by the two-year period of exclusive use of data for principle investigators and asked how that time period had been decided upon. Dr Hamid responded that it was a reasonable time frame for principle investigators to publish their primary report and to do further analysis on the database. Dr Latsamy Siengsouhthone asked for more information about the Ministry of Health's data ownership and archiving at the Centre for Epidemiological Studies. Dr Hamid explained that the Centre for Epidemiological Studies was established because of concerns about the conduct of some previous surveys and about duplication. Researchers intending to do new surveys are asked to submit their proposals to the Centre for Epidemiological Studies to receive advice about appropriate sampling frames, to check that the data they seek do not already exist, and to see whether the questions they want to ask can be incorporated into a survey that is already planned, including data linkages within and between surveys, so that resources are used wisely.

#### 2.5.2.6 Japan

*Overall health research systems:* Dr Suzuko Tanaka described the health research system and the present situation relating to data archiving and access in Japan. The Minister of State for Science and Technology and the Council for Science and Technology Policy oversee the science and technology elements of the work of all government ministries. The Ministry of Health, Labour and Welfare oversees research aimed at the development, safety and effectiveness of health technologies and epidemiological research. Japan develops a general science and technology plan every five years that forms the basis for the governance and direction of research and development (finalization of the next plan has been delayed because of the Great East Japan Earthquake, but it will be implemented in the coming months).

*Current status of data-sharing:* There is no specific policy on data-sharing, but the current research plan does include stated objectives of efficient development and use of data and data infrastructures. In the draft of the forthcoming plan, objectives include promoting intellectual infrastructure and developing and integrating life science databases. Researchers must submit the final report of any research funded by public funds and the ministries operate a publicly accessible and searchable database that houses these reports (<http://mhlw-grants.niph.go.jp/index.html>).

Although research reports are collated and searchable, this is not true of research data sets. Many high-quality databases exist in Japan, but they are scattered among institutions and are inconsistent in their structures, making it difficult to locate and combine databases for further analysis. Once funding for a research project ends, the support for data management also ends so that these valuable databases receive no further attention.

*Ongoing and future plans:* To address the above problems, a five-year Integrated Database Project was initiated in 2006, with the aim of integrating multiple research databases in order to produce a major data resource for life science research in Japan. The Integrated Database Taskforce was established in the Council for Science and Technology Policy in 2008 to discuss the development of the planned database. Based on the discussions of the Taskforce, the National Bioscience Database Center (NBDC) was established in the Japan Science and Technology Agency in 2011 to take over the life science database integration project.

*Challenges:* The Integrated Database Taskforce identified a number of challenges in establishing the integrated database, including the need for efficient mechanisms to register and transfer of research data sets and incentives for researchers to collaborate. In addition, there are ethical issues related to data confidentiality, in particular protecting the identity of participants who have contributed human specimens.

In conclusion, Dr Tanaka reiterated the Japanese Government's intentions to promote efficient and effective use of research data and collaboration between researchers and institutes. Some of the challenges related to data archiving and increased data access and use echo those experienced in other countries: technical challenges, ethical issues and a need to change the culture of researchers relating to data-sharing.

*Discussion:* Dr Maimunah Hamid inquired as to whether the Japanese ministries presented data and research results in English as well as in Japanese. Dr Tanaka confirmed that the online databases were available in English as well as Japanese. Professor Best and Dr Hamid acknowledged this extra linguistic challenge for many countries in relation to data-sharing and collaboration in research. Professor Best asked whether Japan planned a national approach to the ethical issues associated with shared or integrated data and Dr Tanaka confirmed that currently ethical approval of data collection was institution-based and that this presented a problem for a central data repository that will have to be addressed by the Council for Science and Technology Policy.

#### 2.5.2.7 Viet Nam

Professor Pham Nhat An began his presentation by clarifying that Viet Nam currently has no policy or strategy on data-sharing. He discussed the situation relating to clinical research in Viet Nam and issues relating to data archiving and sharing. The process of conducting clinical research in Viet Nam usually starts with a researcher identifying a research question, writing a study proposal and then submitting the proposal to a research committee in an institution or ministry. The research committee at the Ministry of Health will consult with other committees nationally and determine which proposals should be funded and which institutions should conduct the research projects. Once data collection and analysis is completed, the final research report must be submitted to the host research committee. In addition, researchers must provide progress and final reports and reports on budget usage to the Ministry of Health or institutions, depending upon the location of the host research committee. In addition to this process, research committees can commission research from institutions. There is no single system for overseeing research activity in Viet Nam, and projects can be managed by bodies at different levels. Greater uniformity and improved governance is required.

As yet there is no formal policy or practice relating to data-sharing. Professor An acknowledged the value of the Expert Consultation as an opportunity for countries to share their knowledge and experience in this area in order that progress can be made. Currently, research reports and data are collected and archived in many different places including the Central Medical Library and the new Medical Informatics Institute as well as in individual institutions and professional associations. While national health survey databases are archived, awareness of them and access to them needs to be improved. Professor An highlighted the issue of misuse of fully accessible databases such as national health surveys and census data, which have been exploited by the non-scientific media to produce misleading news stories.

Although potential exists in Viet Nam to develop clearer structures within its health research system for data archiving and sharing, Professor An felt that it may involve some of the same challenges identified by other countries. There exists a need for clear policy and governance that can oversee efficient archiving and increased data access and use. In addition to a lack of capacity, skills, mechanisms and infrastructure to support data archiving and sharing, there may be a lack of willingness or incentives for researchers to comply.

## 2.6 Session 6: Data-sharing: next steps, time line and recommendations

*Chairperson: Dr Robin Olds, Rapporteurs: Dr David Carr and Dr Lim Eng Kok*

### 2.6.1 Group work: Data archiving and access – discussion of the issues

Participants worked in three groups to discuss the potential benefits and challenges associated with data archiving and access. Discussion notes were provided that suggested areas that the groups might consider in three general areas: culture and incentives; capacity and skills; and infrastructure and skills.

### 2.6.2 Feedback from group work 3

Rapporteurs for the three groups, Dr Vonthanak Saphonn, Ms Merlita Opena and Dr Vicente Belizario, presented feedback from the three working groups.

*Acceptability of data-sharing:* Groups discussed whether increased data-sharing would be acceptable for all stakeholders and found that the answer was unlikely to be straightforward. It was felt that they needed to be realistic in terms of aspirations and to acknowledge that the natural tendency of many bodies, especially government bodies, was to be reluctant to release data. It was observed that when large surveys are undertaken, for example, the final report containing aggregate data is published, but the database of individual-level data remains unavailable. Other challenges to wider data-sharing are associated with intellectual property issues: while the data may theoretically not be the property of researchers or their institutes, it was felt that the rationale underlying data collection and the database's potential for knowledge generation may be factors that lead some researchers to feel they can claim ownership. Among some stakeholder groups, there may be poor understanding of the benefits offered by systematic data archiving and wider access, and hence advocacy is needed on this issue. In such a context, the concept of wider public access to such data sets is likely to face challenges from many directions. At the same time, the possibility was raised that groups may have diverse motivations for supporting increased data access and some checks and balances may be needed to ensure responsible conduct and use of data.

*Candidates for wider access:* A comparison was made of the rationales for data-sharing from different types of research databases. Whereas the rationale and justification for increased access to databases generated by "large" nationally representative surveys may be quite easy to demonstrate, due to their "potential" value in many areas of research, it may be more difficult to

demonstrate the need for increased access to databases designed and generated for more narrowly focused, research-question-based studies as these may have more “limited” value to other research. The commercial sensitivity of some databases was acknowledged in the discussions. The idea of a period of protected data use may be particularly relevant in investigator-driven research, with data archiving and data-sharing only required after that period. Longer periods of protected data use or even exemption from sharing requirements may be justified in certain circumstances. Hence, there is an implicit need to define what constitutes a “large” sample and what determines the “potential” or “limited” value of a database in terms of access.

It was felt that achieving increased data archiving and access would necessitate changes in existing research cultures. The recognition of database generation and data management as worthwhile research activities should be encouraged in academic contexts. Conventions and mechanisms need to be developed to acknowledge the creators of databases in publications of secondary analyses and also to track the usage of databases so that their contribution to knowledge creation might be evaluated. Codes of conduct for responsible research may need to be developed or revised in order to ensure compliance with requirements for data archiving and access, and also to ensure responsible secondary use of databases.

*Capacity and skills for data-sharing:* In terms of capacity and skills, the groups felt that a lot of work was needed in many areas. In particular, it was felt that many countries would need to build capacity in the area of data management. Dedicated data management posts and career paths, with financial commitment from governments or research funding institutions to support them, were recommended. The development of institutions’ training capacity in data management and analysis was seen as important so that data management departments and posts could be maintained without dependence upon individuals. The development of standards and training tools in the area of data preservation and coding may be especially beneficial. For data users, it was suggested that databases of raw research data should be accompanied by a “manual” that highlighted the nature of the data and data collection methods.

Concerns were raised about the governance of data archiving and access. Most countries have not identified who is responsible for overseeing these activities and have not yet put policies or regulations in place. Beyond policy and governance, most countries need to develop appropriate administrative infrastructures for data archiving and access.

The archiving of databases was felt to present little in the way of ethical difficulties as long as the data were rigorously checked for anonymity prior to archiving and the databases were generated by studies that had already been reviewed and approved by RECs. That said, discussion and clarification or alteration of ethical guidelines may be needed to ensure consent obtained from research participants allowed for archiving and secondary use.

Some participants suggested that governance and management of data archiving and access might be overseen by research ethics systems given considerable overlaps in terms of the administrative tasks and ethical implications involved. It was further suggested that NHRRs and data archiving have many functions in common and that a systems approach may be devised that linked the three research management activities.

Data archiving and access may require the development of technical infrastructures, data standards, data quality control, data exchange protocols and data security systems. It was felt that the development of guidelines in this area may be appropriately addressed by major donor organizations such as WHO. For optimal interoperability of databases, standards for database architecture and data labelling and measures would be needed, but this may not be fully achievable. In addition to mechanisms and technologies for the archiving of databases, systems

may be needed for searching for and locating databases if their potential to the wider research community is to be realized.

The financial implications of data archiving and access was a matter of concern for many countries and they felt these costs should be recognized as important elements of the research process and supported by funders. The processes by which costs are calculated and funds are transferred would need to be considered. The idea that secondary users of databases may also contribute to the costs of archiving and access was also discussed.

Knowing that some stakeholders may be reluctant to pursue or comply with increased requirements for data archiving and access, advocacy on the subject will be needed to achieve consensus among stakeholders. Widespread consultations with stakeholders may be necessary in order to clarify the potential benefits associated with archiving and access, as well as the checks, balances and assurances that would be put in place to safeguard the interests of primary researchers and data collectors. Raising stakeholders' awareness of best practices in data archiving and access may serve to increase understanding of the associated benefits and issues.

It was felt that although increased access to and use of data may be the ultimate goal of developments in this area, placing emphasis on data-sharing in the early stages of advocacy may be counterproductive. Rather, it may be more productive to concentrate on the importance of systematic secure archiving of data in order to prevent loss of data and preserve its scientific potential, with increased access to and use of data as a longer term goal to be achieved in stages.

In conclusion, participants were supportive of improved archiving of and access to research data but recognized many challenges. Advocacy is needed on the benefits involved and considerable work is needed relating to the governance, infrastructures and methods that are necessary for improved archiving of and access to research data.

### 2.6.3 Finalization of recommendations with consensus

Draft recommendations relating to data archiving and access based on discussions and presentations were presented to the committee. The final agreed recommendations are as follows:

- (1) All Member States and research stakeholders should support efficient data archiving and wider and more effective data use for public health research.
- (2) Each Member State is encouraged to identify mechanisms for developing, overseeing and ensuring compliance with data archiving and access policies.
- (3) International agencies, donors and Member States should support proactive initiatives to encourage and facilitate collaboration and cooperation among stakeholders involved in data archiving and access.
- (4) Development work should be supported and agreements should be pursued on common data formats and database architectures.
- (5) Organizations that fund research should acknowledge the cost of data archiving and access as legitimate research costs.
- (6) WHO should advocate the importance of data archiving and access.

2.7 Session 7: Research Ethics Committees: gateway for health research governance  
*Chairperson: Dr Jaime Montoya, Rapporteur: Mr Robert Terry*

2.7.1 Setting the scene: Research Ethics Committees: key issues

Dr Manju Rani began her overview of the key issues that affect the work and organization of RECs by reviewing some of the notable historical research events that led to international agreements and guidelines on ethical standards in medical research. Two such events were the Nuremberg Trials of doctors who had conducted research in concentration camps in the Second World War and the American Tuskegee study of the natural history of syphilis. Such events demonstrated that research was sometimes conducted without respect for the safety of participants, and that researchers could not always be trusted to work in a responsible and accountable manner.

Beyond extreme examples of ethical abuses, it is also the case that researchers can have multiple interests driving their research ranging from personal career considerations to financial incentives, and while many of these drivers can be legitimate, they can be perceived as undermining the validity of research. Other issues can have a bearing on whether research is “worthwhile” or whether it is “valueless”. For example, studies may be poorly designed so that their results are not valid or not generalizable to wider populations, or may be unnecessary because the question they are addressing has already been answered. In such cases, subjecting participants to risk or even to minimal inconvenience is indefensible.

In such a context, there has emerged a need for independent review of research proposals and activity to ensure the public that research is well-designed and has potential to create new knowledge, and that the new knowledge created is not gained by the abuse of participants. To fulfil this need, committees have been formed to review research proposal prospectively to ensure that proposed research is of sufficient technical or methodological quality and is ethically sound and respects the safety and the rights of all individual participants. Several names have been used to describe these committees, including Research Ethics Committees, Independent Ethics Committees and Institutional Review Boards.

Ethical and technical reviews of research proposals are performed by well-organized systems of RECs in many countries. However, this is not the case universally. In many lower- and middle-income countries, awareness of the need for these key research governance functions is low. In others, capacity and resources to conduct ethical and technical reviews are lacking, with a shortage of trained reviewers often working voluntarily on their own time. Among many researchers, the concept of technical and ethical reviews is not well accepted, often regarded as a burdensome and unnecessarily bureaucratic procedure.

Building capacity for ethical and technical reviews is a multidimensional challenge. An efficient and effective REC system requires significant investment in training, resources and expertise. Members of review committees require sufficient expertise in many aspects of research – ranging from scientific experience to lay perspectives. In addition, researchers require training on ethical requirements in research. A review system also requires considerable infrastructural resources to support the review process: the secretariat must be able to manage the submission, review and archiving of research proposals and the ongoing review of research projects once approved.

In most countries, the process of ethical and technical reviews is decentralized, with RECs working at places such as research institutions, hospitals and professional associations. Many countries do not have national guidance and regulatory frameworks to determine what research needs to be reviewed and how it should be done. Decentralized systems with poor regulatory



frameworks can lead to inconsistency in the standards and practices of RECs, and to lack of clarity regarding what research needs to be reviewed and by which committee.

Hence, the need for governance to ensure consistent standards and practices between committees and to oversee and guide their work must be examined. Specifically, who should be responsible for governance? What ways might governance be organized and what should it aim to do? How might the governance of RECs be efficient and not involve unnecessary and expensive bureaucracy?

A further consideration is whether a well-organized system of RECs may undertake roles other than ethical and technical reviews of research. RECs are in a unique position in that they receive and archive information about a great deal of research involving human participants, in some cases all such research within a country. This raises the issue of whether, with further support and infrastructure, RECs may be in an ideal position to play a role in the operation of NHRRs and in data archiving and access.

## 2.7.2 Research Ethics Committees: Country experiences and status

### 2.7.2.1 Philippines

Dr Vicente Belizario described a well-developed and well-organized system of ethical and technical reviews in the Philippines. Standards for ethical review of research are set out in the National Ethical Guidelines for Health Research, 2006, which describe the processes of ethical review, the principles of ethical conduct of research and the national network of RECs in the Philippines. The guidelines are currently being updated. The Philippine Health Research Ethics Board (PHREB), part of the Philippine National Health Research System, is mandated to formulate guidelines for both the ethical conduct of research and the establishment and management of RECs. It also monitors the performance of RECs and provides advice to national and institutional bodies relating to ethical issues in research.

Currently, 103 RECs are registered with PHREB, close to 50% of which are in the National Capital Region. Despite this number, more than 50% of institutions conducting research do not have an REC. The network includes both “institutional RECs”, which operate in institutions and conduct substantial amounts of health research, and “cluster RECs”, which are shared between institutions that may lack the level of research to justify an institutional REC. The scope of RECs’ work includes the prospective research review and approval, post-commencement review and ongoing approval of all research involving human subjects.

PHREB is linked to and advised by the Forum for Ethical Review Committees in Asia and the Western Pacific (FERCAP), a regional accreditation organization for RECs that follows WHO guidance on conduct and evaluation. Accreditation is voluntary and only four RECs in the Philippines are currently recognized by FERCAP. PHREB operates a national database of RECs that requires registration and annual reporting (although compliance is uncertain) and is planning a national accreditation scheme.

Beyond the initial review and approval or rejection of research, RECs in the Philippines monitor the progress of the research and require final reporting. RECs also require reporting of adverse events for clinical trials.

Training is offered in both conducting ethical review and preparing research for ethical review, aimed at REC members, researchers and academics, department heads, policy-makers and sponsors. Training initiated by sponsors ensures that researchers involved in their projects are trained in the ethical conduct of research and good clinical practice. Institutions may also

initiate training to ensure proper research conduct by their staff. The National Institutes of Health in the University of the Philippines Manila has established a Training Center for Health Research Ethics and Good Clinical Practice, which works closely with the Departments of Health and of Science and Technology.

Dr Belizario described some challenges in ensuring the conduct of ethical review of research: (1) a lack of awareness of the importance of ethical review among the directors of research institutions, who do not prioritize establishment or activities of REC; (2) a perception that ethical review and oversight of research is an unnecessary bureaucratic burden; and (3) a shortage of well-trained REC members and lack of incentives for them to be involved in ethical review. Despite a relatively well-organized system of ethical review, Dr Belizario felt that the situation could be improved by stronger guidelines – including, perhaps, penalties for allowing the conduct of research that has not been reviewed and approved – and continued capacity-building and training. Dr Belizario concluded that it remains difficult to estimate the proportion of research that undergoes review and to assess the quality of review without mandatory registration and accreditation of RECs.

#### 2.7.2.2 Cambodia

Dr Vonthanak Saphonn reported on the situation relating to ethical review of research in Cambodia. The National Ethics Committee for Health Research (NECHR) was established by the Ministry of Health in May 2002, and mandated by the Prime Minister in 2004. Ministry of Health developed the Ethical Guidelines for Health Research Involving Human Subjects in 2002. In addition Ministry of health developed the standard operating procedures for NECHR in 2002, which were revised in 2006. NECHR is also a member of FERCAP and is aiming for recognition by Recognition Program of the Strategic Initiative for Developing Capacity in Ethical Review (SIDCER)—a public-private partnership project supported by WHO-TDR. All NECHR members participated in training on Human Participant Protection and Good Clinical Practice conducted by FERCAP (with financial support from WHO).

Currently, NECHR is the only REC in the country that reviews all health research conducted in the country. However, plans are under way to establish institutional RECs that will operate according to NECHR guidelines.

Beyond the initial review of research proposals, NECHR requires continuing review and final reports, conducts site monitoring visits, receives and addresses feedback and queries from research participants, and processes adverse event reports.

Dr Saphonn explained that a substantial number of researchers in Cambodia have also participated in the Human Participant Protection and Good Clinical Practice training programme offered by NECHR, as well as the Fogarty Training Program and the Human Subjects Protection Training Program offered online by the United States Department of Health and Human Services.

Dr Saphonn highlighted two challenges related to ethical review: (1) lack of capacity to provide continuing training of NECHR members, researchers and investigators; and (2) lack of an overall national health research strategy. Despite not having an official remit for the overall governance and management of national health research activity or resources to fulfil such a function, the NECHR receives many inquiries regarding national research and this is an additional burden.

In closing, Dr Saphonn concluded that given the NECHR's position and current activities, it may make sense to seek resources and a mandate to develop a formal role in national research

governance and management. Building upon the NECHR's existing database of national research, it may also be possible, given the resources and mandate, to develop a Cambodian NHRR.

#### 2.7.2.3 Lao People's Democratic Republic

Dr Latsamy Siengsounthone reported that the Lao People's Democratic Republic has only one fully pledged REC, the National Ethical Committee for Health Research (NECHR), created by the Ministry of Health in 2002, with members appointed by the Vice-President. The NECHR is located within the offices of the National Institute of Public Health. There is no national guideline for ethical review, but the NECHR operates according to the WHO Operational Guideline for Ethics Committees that Review Biomedical Research, which has been translated into the Lao language. The scope of the document has been expanded to include all health-related research including biomedical, social science, epidemiological, operational and health systems research. The University of Health Sciences operates an institutional REC for student research, but all professional research is submitted to the NECHR. As yet, the Lao People's Democratic Republic does not maintain a database that records the work of the REC and has no system in place for their accreditation.

Since the NECHR does not receive funding, it charges a minimal fee (less than US\$ 40) to review submissions. Capacity-building is needed in terms of human resources and infrastructure, but funding is a perpetual problem. REC members have received training in bioethics, and the NECHR has offered training to researchers, which was well-received. However, continued training would be desirable for NECHR members as they come from diverse backgrounds from various institutions and their skills in research ethics are varied. The NECHR is seeking support for ongoing training from the Ministry of Health and international bodies.

Dr Siengsounthone shared her opinion that ethical review of research in the Lao People's Democratic Republic needed to be enhanced. Even though the number of studies submitted yearly is small (approximately 60 per year), the lack of resources and time makes reviewing these proposals a challenge for NECHR members and the quality of reviews is inconsistent. The NECHR is as yet unable to ensure follow-up monitoring and evaluation of ongoing research. The research submitted for review by the NECHR represents only a portion of the total research being conducted in the country; as such, some research must be conducted without any ethical review.

Despite the many challenges faced by the under-resourced NECHR, Dr Siengsounthone expressed her hope that it could play a leading role in advocating for better ethical governance and management in research.

#### 2.7.2.4 Fiji

Mrs Mere Delai presented an overview of the Fijian health research system and its ethical review arrangements. The two principle bodies involved in health research are the Ministry of Health and the Fiji National University College of Medicine, Nursing and Health Sciences. The Fiji National Research Ethics Review Committee (FNRERC) is located organizationally between these two bodies. FNRERC is made up of experts from medical and nursing disciplines as well as lay members representing legal, community and religious perspectives. Besides FNRERC, other research committees within the Ministry of Health also play a role in the ethical review of research proposals. For example, the Divisional Research Committee and the National Health Research Committee both conduct technical and ethical reviews and can approve no-risk or low-risk studies. However, all studies that are believed to contain any element that needs consideration from an ethical perspective are forwarded to FNRERC.

No formal national guideline is in place to direct the work of FNRERC, but there are guides that help to inform the processes and procedures for the conduct of health research in the country. The 2007 Health Research Guide for Fiji, an update of a 1999 publication whose development was supported by WHO, includes detailed terms of reference and standard operating procedures for the ethical review of research. A recently developed (2011) Health Information Policy for Fiji also informs some elements of ethical standards in research. While no national system for accreditation of RECs is in place, Mrs Delai reported that the research committees generally follow international guidelines on research ethics, including the International Guidelines for Biomedical Research of the Council of International Organizations of Medical Sciences and the Declaration of Helsinki.

In addition to FNRERC and the Divisional Research and National Health Research Committees, RECs exist within the College of Medicine and at the three hospitals. No national database records REC activity. Recording of REC activity is institution-based and Mrs Delai felt that the information stored may not provide a complete picture of national health research activity. However, work is ongoing to develop a single database at the Ministry of Health level that will record REC activity as well as record the progress and completion of research.

The main challenges facing the further development of RECs in Fiji include a lack of a national health research policy and a shortage of financial and human resources. In principle, the role of the NECHR and other RECs includes tasks beyond the initial review of research proposals such as the ongoing monitoring of current research, but, in practice, this is not possible due to a lack of capacity, staff attrition and low resources. Capacity-building is needed but is entirely dependent upon the availability of funds. Another barrier to capacity-building and training is a lack of awareness of and interest in ethical considerations in research among students and health professionals. However, since medical interns have had to conduct research as part of their training in recent years, NECHR has been involved in training them and their supervisors in research ethics, a development that may result in greater awareness and interest. In conclusion, Mrs Delai felt that while Fiji has the expertise to conduct ethical review of research, more resources and a concerted effort are needed to build capacity.

#### 2.7.2.5 Mongolia

Dr Oyunbileg Janchiv reported on the ethical review of research in Mongolia. A Medical Sciences' Ethics Committee is located at the Ministry of Health and eight other universities and institutes have RECs. Each REC is composed of two elements: a Scientific Committee that grants approval for research methodologies and an Ethical Committee that grants approval for ethical issues. Institutional Ethical Committees are responsible for on-going monitoring and their role is to protect the rights and welfare of all individuals who participate as subjects in human subject research.

There is no single database collecting data on the activities of RECs. Institutional Scientific Committees keep their own records of the minutes of ethical hearings, protocols submitted and review decisions. There is no system for accreditation of RECs in Mongolia, but the Ministry of Health monitors the work of RECs and conducts site visits to ensure compliance with standards in terms of quality of ethical review and of adequate and secure physical and IT infrastructure.

Beyond the initial review of research proposals, RECs endeavour to monitor ongoing research, albeit not regularly. Development is needed in the area of capacity-building and training for RECs. There is no sustained programme for training REC members, only limited training, seminars and workshops. Dr Janchiv reported that as a member of the Medical

Sciences' Ethics Committee of the Ministry of Health and director of a research institute, he had been involved in only one training event on responsible conduct of research and REC processes.

While limited training is available for REC members, Dr Janchiv felt that researchers and heads of institutions should be involved in training programmes because they must ensure that REC approval is obtained before contact is initiated with human subjects in any research project. Researchers need training in developing comprehensive research plans and methodologies that adequately address issues that frequently present ethical difficulties, including data security and recruitment processes and materials.

The challenges facing the expansion of high-quality ethical review of research in Mongolia include a lack of training, a lack of review of REC practices to ensure compliance with latest international guidelines and insufficient sharing of knowledge and experience between RECs nationally and internationally. Dr Janchiv also highlighted the need for raising public awareness and understanding of the ethical aspects of health research.

Following the presentations, Professor Li Youping raised an issue that related to Dr Janchiv's reference to public awareness and understanding of research design and ethics. Professor Li highlighted the importance of raising standards in academic publishing and mainstream journalism relating to health research. Since academic journals continue to publish research that has not undergone ethical and technical reviews, poor quality research results could undermine evidence-based medicine. And since mainstream journalism is allowed to misrepresent the findings and implications of research, the public will continue to be misinformed on important health issues.

Dr Belizario led a discussion in response to a question from Professor Li about the value of case studies in training researchers on research ethics. Dr Belizario reported that case studies of good and bad ethical practices have been successfully used in research ethics training programmes in the Philippines and proposed that a book or collection of case studies from the Region would be a useful resource for training in any country.

Mrs Mere Delai highlighted the importance of publishing examples of best practices for locally conducted research in order to encourage researchers. She reported the existence of a number of journals published in Fiji and suggested that the best examples of student research could be published to aid capacity-building in good research practice.

Professor Pham Nhat An asked for further discussion of issues relating to how the work of RECs and of research ethics training can be financially supported, in particular referring to the experience of the extensive system of RECs in the Philippines. Dr Belizario discussed the financial framework for RECs, which are funded through a combination of institutional support for the secretariat staff and of fees paid by commercial or non-institutional researchers for ethical review. Studies with small budgets and studies conducted within the REC's host institution may be charged either very low fees or no fee for review. Lead reviewers for large proposals and external consultants invited for specific reviews receive honoraria for their work. Members of RECs receive a per diem payment that covers little more than out-of-hand expenses. He also pointed out that members could benefit from the review process as continuing professional training if it was managed well. Other expenses that must be covered include office equipment and consumables needed for administration of the review process. Dr Belizario explained that the training of researchers in the ethical conduct of research is paid for on a course fee basis either by institutions or by research sponsors so that the training programmes are largely self-supporting.

### 2.7.3 Group work 4

Participants worked in three groups to discuss issues relating to RECs. Each group was given a main topic to discuss but was free to discuss other topics as desired. Topics were as follows:

- building capacity and improving performance of RECs: potential options and policies;
- the role of RECs beyond the ethical review of specific research proposals: fulfilling a larger role in health research governance and management; and
- the role of national health governance bodies in monitoring RECs and ethical conduct in research.

## 2.8 Session 8: Feedback from group work 4, draft recommendations on Ethics Review Committees and overall recommendations of the Expert Consultation *Chairperson: Professor James Best, Rapporteur: Mr Robert Terry*

### 2.8.1 Feedback from group work 4

Rapporteurs for the three groups, Dr Vicente Belizario, Dr David Carr and Dr Poonam Dhavan, presented feedback from the three working groups.

*Training and capacity-building for RECs:* It was generally felt that capacity-building was required in the ethical review of research. In considering capacity-building for RECs, it was generally agreed that no matter what the current situation in an REC system, training of REC members should be a continuous and ongoing process. Training on the functions and importance of RECs is also important for researchers who design studies and prepare proposals for submission. The idea of senior researchers mentoring junior researchers was raised. Training modules and materials – including a collection of research case studies – need to be developed to help train REC members and researchers. While training systems have been established in the Philippines, many other countries do not have funds to develop training courses. It was suggested that WHO may want to consider overseeing the development of training materials and workshops.

Decentralized training should be considered to reduce travel. Participants discussed e-Training but expressed reservations about its use in LMICs because of the difficulty of stimulating debate and discussion and the potential for falsified input from students in order to secure accreditation or qualifications.

*Improving efficiency of review process by RECs:* Many countries have complex submission and review processes, with researchers submitting proposals for multi-site research to individual RECs, each with its own paperwork and format requirements. It was felt that options should be considered for the use of existing software – possibly freeware – to enable better management of submission processes and automatic notification to researchers of application status and of the requirement for ongoing research reports. With some work and resources it would be possible and appropriate in the future for systems of web-based central submission and application-tracking to be established. Such systems could ultimately be linked to a NHRR and to other research governance functions.

Simple measures that can facilitate consistent and efficient ethical review were discussed. RECs can use checklists to ensure that reviews are conducted in a structured and consistent manner. Some RECs supply researchers with checklists so that even before submission they can

be sure that their proposals address all the points that the REC will consider. Such strategies allow RECs more time for consideration of more challenging ethical issues or high-risk studies. It was felt that the model of cluster RECs as operated in the Philippines may be appropriate elsewhere in circumstances where individual institutions do not conduct sufficient research to warrant an institutional REC.

*RECs and their role in enforcing compliance with regulatory requirements:* The view was firmly expressed that RECs can and should play an important role in the overall governance and management of national research activities. It was felt that the systems by which studies were submitted for ethical review could play a key role in the prospective registration of studies in NHRs, although concerns were expressed as to whether RECs should play any role in ensuring compliance beyond simply requiring registration as a condition for ethical approval. Where the archiving of data and publication of research results is concerned, it was felt that while REC systems for ongoing monitoring of studies could play a facilitating role, ensuring compliance with these requirements could not be the primary role for RECs. The view was strongly expressed that while these extended registration and archiving functions are of interest and might be usefully explored, in many countries REC systems are in the early stages of development and in such circumstances the core function of ethical review must be the main, if not the only, focus for the foreseeable future. Rather, it was felt that bodies conducting, commissioning, funding and publishing research could take the lead in these areas.

*Organization of RECs in Member States:* Variation between countries was discussed in terms of the separation (or not) of ethical and technical reviews of research proposals. But whether separated or combined, the processes were linked in all countries and served to ensure the quality of research. Variation was also reported in the organization of RECs, as was seen in the presentations from Cambodia, Fiji, the Lao People's Democratic Republic, Mongolia and the Philippines. Japan and the Republic of Korea reported largely decentralized networks of institutional RECs, with common standards and monitoring and a national REC that considered high-risk studies or issues. China reported a complex REC system with different approaches being taken in different areas of research.

*Governance and monitoring of RECs:* A wide range of systems for governance and monitoring of RECs was reported. While some countries have ongoing national oversight and evaluation of RECs and their work, other countries have approaches that are less organized and insufficiently resourced. Different approaches were identified. In some countries, statutory regulation of RECs is in place; in others, a "good practice" model is followed, whereby RECs follow accepted practices and guidelines. Compulsory accreditation is required in some countries but not all. In countries where accreditation among decentralized RECs is not common, accreditation is generally achieved by RECs in the Ministry of Health or at national institutes. The view was generally expressed that accreditation of RECs should be conducted by independent agencies. National standards and guidelines for RECs do not exist in all countries but are common in countries with centrally monitored REC systems.

*Charging a fee for ethical review:* The views on charging for ethical review varied among countries, with some (e.g. Cambodia) regarding it as a necessary and justified approach to financing the work of RECs, and others expressing discomfort in charging for a service that might benefit the public. Payment to REC members was discussed and the consensus was that in developed countries, where professionals had reasonable salaries, payment may be unnecessary, and that in developing countries, where salaries were low and REC membership may mean loss of earnings or opportunities, payment for REC work may be appropriate. Membership in an REC should be recognized as a worthwhile research and academic activity.

*RECs and adverse event reporting:* There was some discussion on the role of RECs in the processing of reports of adverse events.. Although most RECs perform the role of receiving adverse event reports, practices and views varied among countries in terms of what action RECs should take in this context.

*RECs and continued review:* Dr Manju Rani highlighted an earlier mention of RECs in developed countries facings problems in follow-up and ongoing monitoring of studies. Professor Best suggested that it may be better if these ongoing governance and monitoring functions were removed from RECs' burden and were made the responsibility of the local institutions, possibly with a requirement to report to the RECs.

## 2.8.2 Draft recommendations on Ethics Review Committees

*Chairperson: Professor Dr Jaime Montoya, Rapporteur: Mr Robert Terry*

Draft recommendations relating to Ethics Review Committees were prepared in response to the discussions and presentations. These were presented to the committee and discussed in detail. The final agreed recommendations are as follows:

- (1) Appropriate bodies should be identified or created within Member States and assigned responsibilities for the oversight, support and development of systems to ensure ethical standards and technical quality in research.
- (2) The human and financial resources required to discharge these functions should be recognized and supported as legitimate research costs.
- (3) Member States should set ethical standards for health research that are in line with international standards and guidelines. These standards should be monitored and enforced by systems of adequately trained and resourced RECs.
- (4) Mechanisms should be explored that can realize the potential of RECs to contribute to wider research governance functions such as research registration and data archiving.

## 3. CONCLUSIONS AND RECOMMENDATIONS

### 3.1 Overall recommendations of the Expert Consultation

Draft recommendations based on the three-day consultation were presented to the committee and discussed in detail to reach consensus. The final agreed recommendations are as follows:

Recognizing and performing essential health research governance and management functions to ensure effectiveness and efficiency of health research

- (1) Appropriate bodies should be identified or created within Member States and assigned responsibility for the following essential health research governance and management functions:

- effective monitoring and direction of national health research activities and investments;



- oversight, support and development of systems to ensure ethical standards and technical quality in research;
- development and oversight systems to ensure efficient data archiving and wider access to data for health research; and
- ensuring that the value of national research outputs is realized and communicated to policy-makers.

(2) The human and financial resources required to discharge these functions should be recognized and supported as legitimate research costs.

#### *National health research registries*

(3) Member States should acknowledge the importance of national health research registries in improving the governance and management of health research.

(4) Appropriate bodies should develop and implement time-bound plans to establish and operate national or subregional health research registries covering at least health research requiring ethical approval.

#### *Archiving and access to health research data*

(5) Each Member State is encouraged to develop and implement data archiving and wider access policies with time-bound goals and targets.

(6) Member States should encourage the active collaboration and cooperation of diverse research stakeholders in the implementation of data archiving and access policies.

#### *Research ethics*

(7) Member States should set ethical standards for health research that are in line with international standards and guidelines. These standards should be monitored and enforced by systems of adequately trained and resourced RECs.

(8) Mechanisms that can realize the potential of RECs to contribute to wider research governance functions such as research registration and data archiving should be explored.

#### *WHO Regional Office for the Western Pacific*

(9) WHO will advocate the importance of effective governance and management of health research and in partnership with Member States will coordinate the sharing of learning and experience in the development of policies, standards, methods and technologies.

### 3.2 Session 9: Discussion and agreement on plan to follow up on the implementation of outcomes of the consultation

The final session of the consultation was chaired by Dr Maimunah Hamid with co-facilitators Dr Robin Olds and Dr Vonthanak Saphonn. The session explored appropriate follow-up actions and activities required to pursue the recommendations made by the Expert Consultation. The Chairperson commented that the participants should consider what they and their countries might do, and what role WHO might play in order to pursue the realization of the recommendations.

- (1) *Broad consultation meetings with national stakeholders:* Many participants highlighted the need for in-country consultation with broader national stakeholders to raise awareness, to hear their views and to get their buy-in in the implementation of the recommendations. The in-country stakeholders should include researchers and research institutions, other national and international health research funders, and other relevant organizations (e.g. national statistics bureau) in the health and science sectors. A needs assessment of the current policies, important players and resource situation may be done as part of a national consultation.
- (2) *WHO support in raising awareness and supporting the national consultation:* Participants from low- and middle-income countries in particular strongly voiced the need for continued WHO support in awareness-raising and advocacy at the national and international levels, including support for national consultations.
- (3) *Involvement of WHO country and subregional offices:* WHO involvement was considered important to elicit the support of national ministries and institutions.
- (4) *Shared learning and collaboration with other countries and with WHO:* Regular follow-up meetings could be organized to sustain communication about developments at the national level. Countries may be asked to share their plans of action and progress made.
- (5) *A follow-up subregional meeting for Pacific island countries and areas:* Dr Graham Roberts felt that the Pacific region was in special need of development in health research governance and management and that progress was more likely to be made if WHO was visibly supportive. A suggestion for a follow-up meeting for Pacific countries was made and agreed.
- (6) *Reporting of the Expert Consultation outcomes at an upcoming session of the WHO Regional Committee for the Western Pacific:* A suggestion was made to present the recommendations to top policy-makers at the next WHO Regional Committee meeting. Given the research focus of next year's *World Health Report*, it may be more opportune to present the recommendations to the WHO Regional Committee in 2012. Dr H. Bekedam responded that the most effective plan may be to aim for presenting the recommendations of the Expert Consultation(s) at the session in 2013, as this would allow sufficient time for more work and for the 2012 publication of the *World Health Report*.
- (7) *Support of WHO and other partners in building in-country capacity:* Some members urged WHO to play a leading and coordinating role in developing training methods and materials to support capacity-building for REC members and researchers. The importance of sharing experiences and resources including national policies and guidelines, training materials, etc., across countries was emphasized perhaps by the formation of an online repository of policy and guideline documents that could be used as a resource by all.
- (8) *Mobilizing support from developed-countries for less-developed countries:* Mr Robert Terry suggested that countries with well-developed health research governance systems should share their skills, possibly in terms of placing skilled personnel in countries with less developed systems. These placements could be organized through the WHO Regional Office, but could equally be organized through direct collaboration of individual countries. Dr M Hamid added that it may also be useful if countries with well-developed systems hosted personnel from countries with less developed systems so that they gain relevant experience. Professor Best was pleased to endorse the recommendations

and felt that institutions in Australia would almost certainly want to take part in exchange programmes, especially in the area of research registries.

(9) *Dissemination of consultation recommendations and country experiences:* Countries should learn from one another's experiences in the area of research governance and management, specifically the creation and operation of research registries, data archiving and access, and the ethical review of research. As Editor of the *Journal of Evidence-Based Medicine*, Professor Li urged participants to submit and publish papers to report their country's experiences.

(10) *Establishment of regional follow-up mechanisms:* Dr Manju Rani acknowledged the calls for continued meetings to maintain the momentum of the Expert Consultation. She reflected on the history of the WHO Advisory Committee on Health Research, a committee of appointed members that met every two years until 2007, and compared it with the Expert Consultation for which relevant experts had been selected to discuss specific issues. While one model establishes regularity of meetings and ensures a place for research on the overall WHO agenda, the other allows for more flexibility and ensures that meetings are attended by relevant experts. She asked participants to share their views on what may be the most effective collective regional mechanism to take forward the work of the Expert Consultation. A question was asked whether an Advisory Committee on Health Research would be useful within the WHO Regional Office and if so what form it should take.

Dr Montoya responded that regularly scheduled meetings would help countries adhere to time-tabled development goals and would assist in monitoring progress. Ad hoc consultations on specific themes, although potentially more effective viewed in isolation, would be more difficult for countries to factor into their respective planning.

Dr Maimunah Hamid felt that standing advisory committees and consultations had different roles. Mr Terry urged participants upon their return to their countries to list key people who were already of the issues discussed at the Expert Consultation so that whatever initiatives may be developed – whether meetings, workshops or skill-sharing placements – the task of identifying participants would be less challenging.

Mr Robert Terry commented that whereas committees can be very effective if they have a specific job to do, he was not sure whether a new standing advisory committee would help the WHO Regional Office pursue the agenda discussed at the Expert Consultation. He felt it was most important that the WHO Regional Office continue to obtain advice from and support the expertise and commitment that were evident at the Expert Consultation, and he urged participants to consider what commitment they could offer.

Dr Maimunah Hamid concluded the session by underlining the importance of disseminating the discussions and recommendations of the Expert Consultation. In closing, she repeated the request for WHO to organize follow-up meetings in order to maintain the momentum of the Expert Consultation and acknowledged Dr Bekedam's comments about an Advisory Committee on Health Research.

#### 4. CLOSING CEREMONY

Dr Henk Bekedam, Director, Health Sector Development, WHO Regional Office for the Western Pacific, began his closing remarks by thanking the participants for their enthusiasm, and for the momentum that their discussions had created. He felt that the Expert Consultation had clearly demonstrated that important and exciting discussions about the governance, management and direction of health research still remained.

Dr Bekedam commented that the forthcoming *World Health Report* will be an important one for research, and that work carried out by the WHO Regional Office for the Western Pacific, such as the Expert Consultation, will help to demonstrate that it is aware of the issues and challenges in health research and is ready to address them. He reflected that the Regional Office has concentrated on tasks that are achievable rather than spending too much time on wishful but unattainable tasks. He thanked the Expert Consultation for supporting the Regional Office in this approach, by also focusing on the identification of realistic and achievable goals and activities that can lead to improved governance and management of health research. He felt that with continued commitment the recommendations of the consultation are achievable: that better governance can be achieved, and that data can be better archived and accessed.

Dr Bekedam also emphasized that that use of data to inform policy and practice was a critical area, but that unfortunately the Expert Consultation did not have time to discuss it in full. In closing, he reflected, the most important outcomes are not articles published in medical journals, but rather health outcomes: health research is about people and about serving people better through learning. Dr Bekedam went on to say that although in general the World Health Organization was not always good at working with academic institutions, he proudly reflected that relationships between WHO and academic institutions in this region were very good. He referred to the establishment of the Asia Pacific Observatory on Health Systems and Policies in collaboration with the World Bank and the Asia Development Bank and academic institutions as an example of these good relationships. Dr Bekedam reflected on the importance of linking health research with health policy, and of conveying what we learn to policy-makers so that it can help to create improved health systems and outcomes.

Dr Bekedam commented that while participants are being sent home with tasks to perform, WHO has work to do as well. He reassured participants that the WHO Regional Office was committed to maintaining the dialogue and the work.

Dr Bekedam thanked all the experts, observers and secretariat staff for their excellent input and hard work during the last three days and wished all a safe and pleasant journey home.

**PROVISIONAL AGENDA**

1. Opening session
2. Session 1: Setting the scene: governance and management of health research.  
Group work: Identify essential research governance and management functions and challenges.
3. Session 2: Improving governance and management of health research: discussing and agreeing on the way ahead.
4. Session 3: National health research registers to improve governance and management: feasibility and options.  
Group work: responsibility, scope and function, compliance.
5. Session 4: Round-table discussion: finalization of recommendations
6. Session 5: Setting the scene: data-sharing in public health research (rationale, issue, potential challenges).
7. Session 6: Data-sharing: next steps, time line and recommendations.  
Group work: discussion by issue
8. Session 7: Research Ethics Committees: gateway for health research governance.
9. Session 8: Conclusion 1: revisiting the overall recommendations of the Expert Consultation.
10. Session 9: Conclusion 2: discussion and agreement on plan to follow-up on the implementation of outcomes of consultation.
11. Closing session

## PROGRAMME

### Day 1: Monday, 15 August 2011

Time	Title	Presenter
0800–0830	Registration	
<b>Opening Session</b>		
0830–0835	Welcome	Dr Manju Rani
0835–0845	Opening remarks	Regional Director
0845–0855	Self-introduction of each participant	
<b>Session 1: Setting the scene: governance and management of health research</b>		<b>Chair:</b> Dr Maimunah Hamid
		<b>Rapporteur:</b> Dr. Graham Roberts
0855–0910	Introduction - Governance and management of research: the issues and status	Dr Manju Rani / Dr Robert Terry
0910–0915	Admin announcement	
0915–0925	<i>Group photo</i>	
0925–1000	Group work 1: identify essential research governance and management functions and challenges	
1000–1030	<i>Coffee break</i>	
<b>Session 2: Improving governance and management of health research: discussing and agreeing on the way ahead</b>		<b>Chair:</b> Dr Tran Huu Bich
		<b>Rapporteur:</b> Dr Graham Roberts
1030–1100	Feedback from group work 1	Dr Manju Rani
1100–1130	Setting up national health research registers (NHRR) – introducing the concept	
1130–1230	Current country experiences with clinical trial registers—expanding to NHRR?	Dr Azmaliza Ismail
1145–1200	➤ Malaysia	Dr Hyun-Young Park
1200–1215	➤ Korea	Professor Li Youping
1215–1230	➤ China	Dr R. Terry on behalf of COHRED
	➤ Health research web	
1230–1330	<i>Lunch</i>	
<b>Session 3: National health research registers to improve governance and management: feasibility and options</b>		<b>Moderator:</b>
		<b>Rapporteur:</b>
1330–1500	Group work 2: responsibility, scope and function, compliance	
1500–1530	Feedback from group work 2	
1530–1600	<i>Coffee break</i>	
<b>Session 4: Round table discussion—finalization of recommendations</b>		<b>Chair:</b> Dr Maimunah Hamid
		<b>Rapporteur:</b> Dr Graham Roberts
1600–1700	Round table discussion to finalize the recommendations	
1730–1900	<i>WELCOME RECEPTION hosted by the Regional Director</i>	

**Day 2: Tuesday, 16 August: Maximizing the full potential of public health research data to generate better health**

<b>Session 5: Setting the scene: data sharing in public health research (rationale, issue and potential challenges)</b>		<b>Chair :</b>	Professor James Best
		<b>Rapporteur:</b>	Dr Lim Eng Kok
0830–0915	Data sharing: What? Why? Can we?; experience of Wellcome Trust in data-sharing		Dr David Carr, Wellcome Trust
0915–1000 [10 mins. presentation + 5 mins. discussion]	Data sharing in public health research: current status, experience and policies (countries and organization) <ul style="list-style-type: none"> <li>➤ Australia</li> <li>➤ New Zealand</li> <li>➤ Philippines</li> </ul>		Professor James Best Dr Robin Olds Dr Jaime Montoya
<i>1000–1030 Coffee break</i>			
<b>Session 5: Setting the scene: data-sharing: current status, experience and policies (continued)</b>		<b>Chair :</b>	Professor James Best
		<b>Rapporteur:</b>	Dr Lim Eng Kok
1030–1230 [10 mins. presentation + 5 mins. discussion]	<ul style="list-style-type: none"> <li>➤ Demographic health surveys (DHS/USAID)</li> <li>➤ Malaysia</li> <li>➤ Japan</li> <li>➤ Viet Nam</li> </ul>		Dr Kia Reinis Dr Maimunah Hamid Dr Suzuko Tanaka Prof Pham Nhat Ahn
<i>1230–1330 Lunch</i>			
<b>Session 6: Data sharing: next steps, time line and recommendations</b>			
1330–1530	Group work 3: discussion by issue		
<i>1530–1600 Coffee break</i>			
<b>Session 6: Data-sharing: next steps, time line and recommendations (continued):</b>		<b>Chair :</b>	Dr Robin Olds
		<b>Rapporteur:</b>	Dr David Carr & Dr Lim Eng Kok
1600–1630	Feedback from group work 3		Draft
1630–1730	Finalization of recommendations with consensus		recommendation statement

### **Day 3: Wednesday, 17 August**

<b>Session 7: Research Ethics Committees: gateway for health research governance</b>		<b>Chair:</b>	Dr Jaime Montoya
		<b>Rapporteur:</b>	Robert Terry
0830–0845	Setting the scene: REC/IRB: key issues		Dr Manju Rani
0845–1000	<b>Country experiences/status</b>		
0845–0900	Philippines		Dr Vicente Belizario
0900–0915	Cambodia		Dr Vonthanak Saphonn
0915–0930	Laos		Dr L. Siengsounthone
0930–0945	Fiji		Mrs Mere Delai
0945–1000	Mongolia		Dr Oyunbileg Janchiv
<i>1000–1030 Coffee break</i>			
1030-1200	Group work 4: A. Building capacity and improving performance of REC/IRB: potential options and policies B. Role of REC/IRB: beyond just ethical review of specific research proposals: instruments of health research governance and management C. Role of national health governance bodies in monitoring REC/IRB??		
<i>1200–1300 Lunch</i>			
<b>Session 8: Conclusion 1: revisiting the overall recommendations of the Expert Consultation</b>		<b>Chair :</b>	Dr Jamie Montoya and Professor James Best
		<b>Rapporteur:</b>	Robert Terry
1300–1430	Feedback from group work 4 Draft recommendation on Ethics Review Committee		
1430–1515	<i>Reviewing the final overall recommendations including goals/action plan</i>		
1515–1530	<i>Last opportunity for question and answer</i>		
<i>1530–1545 Coffee break</i>			
<b>Session 9: Conclusion 2: discussion and agreement on plan to follow-up on the implementation of outcomes of consultation</b>		<b>Chair:</b>	Dr Maimunah Hamid
		<b>Co-facilitators</b>	Dr Robin Olds and Dr V. Saphonn
1545–1645	<i>Discussion on follow-up mechanisms to monitor implementation of the consultation outcomes</i>		
1645–1700	Closing session		Closing remarks by Dr Henk Bekedam, Director, DHS



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OPENING REMARKS BY THE REGIONAL DIRECTOR  
AT THE EXPERT CONSULTATION ON IMPROVING HEALTH RESEARCH  
MANAGEMENT, GOVERNANCE AND DATA SHARING IN THE WESTERN PACIFIC  
Manila, Philippines, 15 August 2011

DISTINGUISHED GUESTS, LADIES AND GENTLEMEN.

Welcome to this expert consultation on improving health research management and data-sharing in the Western Pacific.

Let's start by reminding ourselves of two of the core responsibilities of all of us involved in public health work: First, setting norms and standards, and second, identifying evidence-based policy options.

The ability to do either of these is based on the availability of credible research evidence. In fact, the importance of health research is reflected in the next World Health Report, which will be titled "No Health Without Research".

I am sure we all agree on the value of good evidence when we are developing policies and programmes. But is research as effective and credible as it could be?

For years, there have been growing calls for more spending on health research. We are all in favour of that, of course, but we must not lose sight of the need for quality research and better use of funds. Recently there has been substantial increase in the production of new knowledge to the point of "information overload".

Yet, often there is a lack of relevant evidence to inform important clinical and programme decisions. Systematic reviews tell us time and time again that the evidence base is inadequate.

Investment in research is like any other investment: a return is expected. But the returns on health research investments are often poor. And this brings us to the issue of better governance and management of health research.

Most countries, particularly developing countries, have insufficient governance and management systems for health research. This means they cannot manage and fully utilize the investments they have made in research. They cannot guide and monitor research. And they cannot ensure that research addresses the health issues that are most important for their country.

Poor governance and management means a potential for duplication, non-reporting, non-use of research findings and inefficient use of scarce public resources.

Much can be done to improve the overall governance and management of health research and this in turn can improve the credibility, transparency, efficiency and quality of research. The result: better health outcomes.

Another issue for this consultation is the effective use of public health data generated by research programmes. All too often data are treated as the property of individual researchers, or they languish in a computer in a government office.

One initiative that has played a key role in advancing public health in developing countries is the "Demographic & Health Surveys", started by USAID in the late 1980s. The databases generated by these surveys have demonstrated trends in infant and maternal mortality rates over time, highlighted trends in diseases and identified changes in care-seeking behaviours.

What sets the "Demographic & Health Surveys" different from other less successful initiatives is its 'open data policy'. The databases are routinely archived and made freely available to the wider research community. The surveys are seen as the gold standard of research and have helped countless policy-makers and programme managers make smarter decisions.

I hope this eminent body of experts will examine these issues in depth, and produce practical recommendations that can be implemented by all the Member States in the near future.

With this, I officially open this expert consultation and wish you a very productive and successful meeting.

And I hope you have an enjoyable stay in Manila.