

Development of Research Proposal on Communicable Diseases

*Report of an Informal Consultation
Kolkata, India, 23-24 December 2010*



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Executive summary

An Informal Consultation on Development of Research Proposal for Communicable Diseases was organized by the World Health Organization, Regional Office for South-East Asia (WHO-SEARO), at the National Institute of Cholera and Enteric Diseases, Kolkata, India, on 23 - 24 December 2010.

The meeting was attended by 10 participants from different countries like Bangladesh (2), Bhutan (2), Maldives (2), Indonesia (2) and observers (2) from India. Participants from DPR Korea and Timor-Leste could not attend. The main theme of the consultation was how to develop valid and robust project proposals to address the key health-related problems in this part of the world and obtain competitive funding from external agencies.

At the opening session, besides introduction of participants, the objectives of the consultation were described. It was emphasized that sessions should be interactive. All doubts should be clarified. The Technical Session started with a presentation on Issues and Priorities for Research on Communicable Diseases, at which the limited fund allocation for research on neglected communicable diseases of poverty in the developing world was emphasized. In view of this, disease burden estimation should guide identification of research priorities. Participants identified acute respiratory infections and acute diarrhoeal diseases as priority areas in almost all countries in the WHO South-East Asia (SEA) Region.

Detailed discussions were held about how to develop a good research proposal, as well as about the elements (e.g. title, name of investigators, affiliations, and research priorities, introduction of research methodology, epidemiological and statistical concepts, administrative issues, ethical issues and dissemination of research findings) that should form the general format of the proposal. Statistical concepts encompassing data management and analytical approaches were discussed at length. The sessions were highly interactive. Ethical issues involving human subjects were discussed at length. Informed consent and ethical review are the two pillars of safety. Post-trial benefits were also discussed, along with examples. Technology transfer was emphasized. Transfer of biological samples and the administrative and ethical procedures involved were discussed.

Administrative approvals should follow scientific scrutiny and for foreign collaboration any special clearance required must be obtained.

Participants were encouraged to develop protocols and present them at the plenary. For that purpose, they were divided into two groups, one group developed a community-based observational study to estimate the prevalence of diarrhoeal disease among under-5 children in a rural community of Bangladesh and the other group designed an observational study to estimate the mortality among under-5 children due to acute respiratory tract infections in Bhutan. The two groups were assisted by facilitators. They were taught how to find out the disease burden of each country by using search engines like Google and Yahoo. Emphasis was given on sample size calculation, data entry, data cleaning and data validation. It was suggested that the title of the protocol may be given after developing the entire protocol. A bio-statistician helped them to learn the preliminary bio-statistics that are needed for proposal development. Protocols were critically discussed by the entire faculty and participants. They were encouraged to submit such proposals for “small grants” from TDR-SEARO. However, they were advised to check the announcements not only for “small grants” but also for other funding sources. Each agency has its own priorities for funding.

Participants felt that they were in a better position to develop good research proposals as a result of discussions. They were encouraged to compete for award of Small Grant SEARO-TDR. Participants also urged that such workshops should be organized by SEARO, and that they should be of longer duration. It was emphasized that more funding should be made available for capacity building in research in various countries in the Region.

1. Opening session

Dr A.P.Dash, Regional Adviser, Vector-borne and Neglected Tropical Diseases, Regional Office for South-East Asia, welcomed the participants on behalf of the WHO Regional director for South-East Asia Region, Dr Samlee Plianbanchang.

Research is an active, diligent and systematic process of inquiry in order to discover, interpret or revise facts, events, behaviours, or theories, or to make practical applications with the help of such facts, laws or theories. The term "research" is also used to describe the collection of information about a particular subject. Health research can be of various types, viz., clinical, epidemiological, operational, implementation, basic and applied, etc.

The SEA Region is at high risk for new and emerging infectious diseases and has become a hotspot for many zoonoses, drug-resistant pathogens and vector-borne diseases. Better understanding of the epidemiology and the broader social, economic, cultural, environmental, ecological and political dimensions are some of the challenges for today's research in communicable diseases.

Research is essential for the development of new tools and interventions, and should be geared towards the development of evidence-based policies and interventions to increase efficiency and effectiveness of programme development and management of health promotion and diseases prevention and control.

The need for research as a part of strategic information and evidence base for developing effective and efficient disease interventions that contribute to the scaling up and sustaining of interventions that work, cannot be underestimated. In the face of the financial crisis affecting countries, priority-setting becomes important, in order to carry out research for health problems that target groups or populations such as the poor, vulnerable, marginalized and the underprivileged.

Undoubtedly, the environmental, ecological, social, economic and cultural aspects in disease control require partnerships and networking with social scientists, environmentalists and health economists, both in developing research proposals and conducting research.

Besides old challenges, research should address new challenges such as climate change and its impact on health. As a cross-cutting issue, research agendas in this area would include study of host factors, environmental and sociocultural factors, and also health systems leading to developing policies and strategies and ensuring optimal health service delivery systems.

2. Objectives

The objectives of the consultation were:

- (1) To familiarize the participants on how to develop valid and robust project proposals to address the key health-related problems in the South-East Asia Region; and
- (2) How to obtain competitive funding from external agencies.

Dr G. Balakrish Nair, Director, National Institute of Cholera and enteric Diseases (NICED), Kolkata was nominated as the Chairman and Dr Suman Kanungo, Scientist, NICED, as the Rapporteur of the consultation.

3. Technical sessions

Issues and priorities of research on communicable diseases (Dr G. Balakrish Nair)

Communicable diseases continue to pose major public health challenges in the developing world. However, as highlighted by the “10/90 gap”, resources to tackle these challenges are far from adequate. In addition, the distribution of these meager resources also does not follow local public health needs, as the allocations are often based on priorities set through some adhoc decisions rather than evidence-based processes. A systematic

approach to identify the more important diseases in a given setting would be the first and most important step to overcome the challenges. Most of such priority-setting efforts encompass estimating the burdens of prevailing diseases – by measuring DALYs lost due to these diseases or by estimating some other admissible burden indicators – and preparing a list of priorities accordingly. While this approach often serves the basic purpose of identifying diseases to be targeted for control, it continues to be inadequate to identify specific aspects of each disease for further research, so that the disease is efficiently controlled. Moreover, given the resource-constraint scenario, additional considerations of cost-effectiveness of the important target interventions would allow one to take the best possible policy decisions based on evidence. The use of the “Global Forum Combined Approach Matrix” would be immensely helpful in this regard.

Development of a research proposal: structure of a proposal (Dr A.K. Deb)

Every formal research proposal follows some specified structure, mostly guided by the requirements of potential sponsors. Of course, the thinking about the research study does not necessarily follow the order of items put in that structure. It starts with identifying a research question that is valid and relevant for the time, place, and population – mostly within the specific areas of interest of the implementing institution(s). This requires sufficient background information, which should be narrated concisely and simply in a step-by-step fashion – culminating into the rationale of the proposed study. The hypotheses (both conceptual and operational) – need to be stated explicitly, illustrating the one-way or two-way nature of the “null” and the alternative hypotheses. The objectives of the study may be divided into primary and secondary objectives, which it should be possible to test through the study methods described subsequently. The methods should incorporate the study site(s) and populations, the formally estimated sample size and an appropriate sampling technique to recruit study subjects according to eligibility criteria. It is very important to think about the data to be collected – such that they include all necessary variables but avoid any redundant information – and the instruments and approaches to be used (e.g. a questionnaire, some equipment and group discussions, etc.). The methods to enter, check, clean, analyse and finally archive the collected data should be elaborated, including the software requirements. Accomplishing all these procedures will need sufficient resources that

require careful thinking and should be reflected in identifying the study investigators (including the principal investigator), the collaborators, the timeline, and the budget, which again often follow guidelines set by the study sponsors. No study, however, can be conducted unless it is scientifically and ethically valid; these should be carefully considered, addressed in the proposal, and arrangements must be made to obtain them.

Epidemiological concepts for project proposal (Dr Suman Kanungo)

The basic measurements of epidemiology are done to quantify mortality, morbidity and disability, indicating the presence and absence of disease and environmental factors. The basic tools that are used are rate ratios and proportions. To quantify the disease load, the concept of incidence prevalence is very important. To develop a research protocol, proper uses of epidemiological measurements like where can we use the concept of incidence and prevalence are important. Another important aspect is to understand the basic concepts of different study designs through which we can have a validated estimate of disease burden. The hierarchy of epidemiological studies can be divided into two types, observational (descriptive) and analytical. In the descriptive study type, we can describe the disease by time, place or person; conduct ecological, case series or cross-sectional studies to find out the determinants. To find out causal association and estimate the effect of cause we can conduct observational case control and cohort studies. A randomized controlled trial is the most important intervention study where researchers allocate the exposure, usually at random. Different vaccine trials and drug trials are typical examples. During designing or analysis, we need to understand the role of chance, bias and confounding and take appropriate measures to reduce them. Sample size calculation is another important aspect of a good proposal; without understanding that concept, the study results will be erroneous.

Development of research protocol: administrative issues (Dr S.K.Bhattacharya)

All proposals must be subject to scientific scrutiny. Sponsors should be reliable and should not have sponsored studies in areas that are sensitive to the country. Collaboration must be beneficial for the pursuit of research by

the investigator; promotional products should not be investigated. For drug trials, the permission from the Drugs Controller General of the country is essential. The budget should be clearly spelt out. Import of equipment will require the approval of a competent authority. For foreign collaboration in India, Health Ministry Clearance (HMSC) is mandatory. All funds should be disbursed according to the norm of the institution and all documents should be available for audit. All documents should be archived for 10 years after completion of the study.

Development of a research protocol: ethical issues: (Dr S.K.Bhattacharya)

A duly constituted institutional or national ethical committee should review the proposal from the ethical point of view. Such committees should include a clinician, epidemiologist, legal person, lay man, journalist and a subject specialist. There should be a chairman and a secretary. The committee should meet regularly. The investigators are expected to point out the issues of safety or harm to participants expecting to join so that a better review can be done. Informed consent forms should be scrutinized meticulously. Good Clinical Practice (GCP) and Good Laboratory Practice (GLP) should be understood (if required, participants should undergo training) and practised throughout the entire study. The decision of the committee should be communicated in writing. Monitoring and follow-up of the trial should be carried out. All proposals involving human subjects must have the approval in respect of the intellectual property right (IPR) issues. Also it is now very important that transfer of biological materials follows the procedure laid down by the institution and country.

Dissemination of research findings

Research findings should always be disseminated whether it is positive or negative finding. Publication in peer reviewed journal is the best method to reach a large number of readers. Publications could be full paper, short communication or a letter to the editor. Open access journals are now very popular. Some journals have page charges. Reviews and meta-analysis are also published by many journals. Other methods of dissemination are presentation of a paper (oral or poster) in a conference, in the TV programme and also in News Papers and in books.

Group discussions

These discussions were focused on the actual development of a research proposal by participants who were divided into two groups: one group developed the proposal on acute respiratory infection and the other group developed the proposal on acute diarrhoeal diseases. Participants were assisted by facilitators. The proposals were critically discussed at the plenary and improvements were suggested.

4. Conclusions and recommendations

Participants were of the view that they had benefitted by attending the informal consultation and that they would be in a better position to apply for competitive funding from national and international agencies. They recommended that such courses should be of at least 7 days' duration and should be done regularly. This is certainly going to help capacity building of the member countries in SEAR in conducting research.

Annex 1

Agenda

Thursday, 23 December 2010

1. Opening Session
 - Registration
 - Welcome and Objectives of the Meeting
2. Technical session
 - Issues and Priorities of Research on Communicable Diseases
 - Introduction to Research Methodology
 - Development of Research Protocol: Structure
 - Title
 - Investigators with affiliation and contact information
 - Background Information
 - Hypothesis and Research Objectives and generation of hypothesis
 - Study Duration & Timeline
 - Budget
 - Reference
3. Development of Research Protocol
 - Epidemiological Concepts
 - Study Designs (including Randomization and Blinding)
 - Epidemiological Measurements
 - Choice of Population and Study Site
 - Sample Size and Power
 - Statistical Concepts
 - Type of Data and Choice of Variables
 - Data Collection – Procedures and Instruments
 - Data Entry, Checking, Editing, Archiving
 - Data Analysis and Interpretation
 - Statistical Software

- Administrative Issues
 - Study Approvals
 - Collaborators and Sponsors
 - Budget Details and Funds Handling
- Ethical Issues
 - Requirements for Human Subject Research
 - Good Clinical Practices
 - Biomedical Specimen Transfer
 - Intellectual Property Rights
- 4. Dissemination of Research Findings
 - Publications
 - Full Publication, Short communications, Letter
 - Review, Meta analysis
 - Open Access Journals
 - Dissemination through Other Media (Conference, TV, Newspaper, Books etc.)
- 5. General Discussion of First Day Sessions

Friday 24 December 2010

- 6. Briefing of Group Work
- 7. Distribution of Group Work
 - Respiratory Tract Infection
 - Diarrhoeal Diseases
- 8. Group Work
- 9. Plenary Session
 - Group Presentation 1
 - Group Presentation 2
- 10. Research Proposal Development
- 11. Recommendations and Next Steps
- 12. Closing Session

Annex 2

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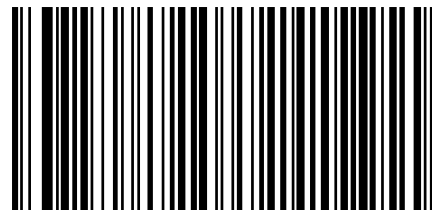
An Informal Consultation for Development of Research Proposal on Communicable Diseases was held in Kolkata, organized by World Health organization, SEARO, New Delhi in Kolkata, at National Institute of Cholera and Enteric Diseases, India, on 23 - 24 December 2010. The meeting was attended by 10 participants from different SEAR countries like Bangladesh (2), Bhutan (2), Maldives (2), Indonesia (2) and observers (2) from India. Participants from DPR Korea and Timor-Leste could not attend. The main theme of the consultation was how to develop valid and robust project proposals to address the key health related problems in this part of the world and obtain competitive funding from external agencies. Detailed discussions were made about how to develop a good research proposal and the elements (e.g. title, name of investigators, affiliations, and research priorities, introduction of research methodology, epidemiological and statistical concepts, administrative issues, ethical issues and dissemination of research findings) that should form the general format of the proposal. Statistical concepts encompassing data management and analytical approaches were discussed at length. The sessions were highly interactive. Ethical issues involving human subjects were discussed at length. Informed consent and Ethical review are the two pillars of safety to the participants.



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