

PRACTIHC Workshop

9 – 11 December 2001
Monkey Valley, Noordhoek, South Africa

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1. Executive summary

The first PRACTIHC (Pragmatic Randomised Controlled Trials in Health Care Systems) Workshop was held at Monkey Valley, Noordhoek, South Africa from 9 – 11 December 2001.

PRACTIHC is an international research and technology development network to facilitate information for action on priority health problems, funded by the European Commission.

The main business of the Workshop was to inaugurate PRACTIHC, and to establish working relationships and administrative and communication patterns, along with guidelines for the initiation of the Work Packages (WPs), through which the project will be realised.

The meeting was structured with plenary and focus group discussions, from which the following outcomes resulted:

- The Work Package lead partners were confirmed, and partners indicated the deliverables to which they wish to contribute (Section 2).
- Facilitators and barriers to the use of pragmatic random control trial (RCT) information were identified based on the individual perceptions of Workshop participants (3.2.1), the perceptions of groups on specific studies (3.2.2), and a systematic review of decision makers perceptions (3.2.3), with the main common facilitators being personal contact with policy makers and the timeliness and relevance of the research, while also cost effectiveness is important. Three projects were identified as case studies of developing country RCTs (3.3).
- Parameters and issues to be determined from an analysis of developing country RCTs, to be identified from the Cochrane register, were discussed (Section 4).
- Criteria for the strategy for identification, exclusion, evaluation and prioritisation of tools to assist in the conduct of RCTs were identified, and specific tools in the areas of design, conduct, analysis/reporting, and training were prioritised (Section 5).
- Partner experiences of policy support initiatives were reviewed (Section 6.1) and action plans for the dissemination of PRACTIHC were developed for Colombia, Mozambique, South Africa and Zimbabwe (Section 6.2).
- The first PRACTIHC RCT course (a 3-day course held immediately before the Workshop), was reviewed (Section 6.3).
- Guidelines for the operation of Work package 5 were established (Section 7.1) and partners indicated service support areas (Section 7.2).
- Guidelines for the management and general and financial administration of PRACTIHC, centralising the administrative function in Oxford, were established (Section 8.1), and the workshop was evaluated (Section 8.2).

2. PRACTIHC: Work packages, Deliverables, Partner participation

The first PRACTIHC (Pragmatic Randomised Controlled Trials in Health Care Systems) Workshop was opened by Merrick Zwarenstein, who welcomed the partners present (all except Ubaldo Farnot, ..., Cuba).

PRACTIHC is an international research and technology development network to facilitate information for action on priority health problems, funded by the European Commission. Its general objectives are:

- To improve partner countries' health systems by increasing their capacity to evaluate health care delivery systems, specific health policy, public health and clinical choices and identify those options which are effective.
- To develop the global science of *pragmatic* randomised controlled trials (RCTs) and promote inclusion of their findings as an element in health care decision making.
- To promote research and technology development co-operation internationally by consolidating a network of established centres with expertise (in RCTs), and to extend this network to support the achievement of scientific excellence and real world health system decision making relevance in neighbouring countries.

The specific scientific and technological objectives are:

1. To study up to 100 partner experiences in pragmatic RCTs for high priority health problems to develop guidelines for improving their quality, relevance and decision making use. The study will identify ways to prioritise, assess the feasibility, acceptability and usefulness of such trials as part of the decision making process, and ways to simplify, speed, systematise and reduce the costs of such trials.
2. To systematically review the published literature on conduct of RCTs of interventions for high priority health problems in developing countries, in order to develop guidelines for improving the quality, relevance and decision making use of this potentially valuable tool.
 1. To locate or develop tools and resources to support the development and use of pragmatic trials (linked to the guidelines, based upon needs identified in objectives 1 and 2), and make these guidelines, with their tools and resources accessible to people planning evaluations of important health care interventions.
 2. To reinforce the capacity of developing countries to conduct high quality trials relevant to health care decision making in close co-operation with decision makers by developing and piloting a programme of trial development workshops/training events in the design and conduct of randomised trials.
 1. To promote the science of pragmatic randomised trials through dissemination workshops and publications and by extending training and support to neighbouring countries.
6. To reinforce scientific and technological co-operation between researchers in developing countries and in the European Community by collaborating in the development of tools, trial resources, planning and teaching of workshops, and new joint research.

These will be realised in a set of Work Packages, each of which in turn have a series of “deliverables”. These are critical in the performance of the programme and the contract with the funder.

The break-down of the project, with corresponding lead partners and contributors, is detailed in Table 1 (below).

WP	Deliverable	Lead partner	Contributors
1.1	Workshop 1. Initiation workshop, Workshop report on web site	SA MRC Merrick Zwarenstein	All
1.2a	Case studies of the use of pragmatic RCTs in DCs	OSLO Andy Osman	Eduardo Bergel Martinho Dgedge Simon Innver Cathy Mathews Tesse Tan- Torres Edejer Mari Trommald Godfrey Woelk Merrick Zwarenstein
1.2b	Qualitative policy analysis of use of pragmatic RCTs in DCs	OSLO Andy Osman	Max Bachmann Eduardo Bergel Martinho Dgedge Vinod Diwan Simon Innver Cecilia Stalsby Lundborg Tesse Tan- Torres Edejer Mari Trommald Godfrey Woelk Merrick Zwarenstein
1.2c	Overview of methodological studies on pragmatic RCTs, both to be published on web site and in scientific literature	OSLO Andy Osman	Lelia Duley Craig Ramsay Merrick Zwarenstein
2.1	Database of DC RCTs, accessible through web site, and one or more partners, updated regularly	OXFORD Lelia Duley	Barbara Farrell Chris Seebregts
2.2	Analysis of DC RCTs from database, published on web site and in scientific literature, updated as required	OXFORD Lelia Duley	Barbara Farrell Simon Lewin George Swindler Tesse Tan-Torres Edejer Godfrey Woelk Merrick Zwarenstein
2.3	Workshop 3: Database analysis will be reported as main input item on agenda, with a review and update on barriers work, review and updating of tools package, report back on progress with protocol development, and report back on progress with national and	OXFORD Lelia Duley	All
	regional action plans		

3.1a	PRACTIHC web site A moderated e-mail methodology discussion list server, to enable partners and other interested parties to review published articles and learn by exchange	SA MRC Merrick Zwarenstein	Eduardo Bergel Chris Seebregts Shaun Treweek
3.1b	Existing tools Annotated library of examples of trial protocols. To be made available as guide book in hard copy, through web site, partner web sites and other electronic media Evaluation of existing randomisation and trial entry hardware and software P	ABERDEEN Marion Campbell CREP Edgardo Abalos	Eduardo Bergel Vinod Diwan Bo Eriksson Barbara Farrell Carl Lombard Juan Manuel Lozano Cecilia Stalsby Lundborg Craig Ramsay Tesse Tan-Torres Edejer Shaun Treweek Merrick Zwarenstein Vinod Diwan Lelia Duley Barbara Farrell Cecilia Stalsby Lundborg
	rotocols for different types of pragmatic RCTs, as word processor templates and linked to trial design tools. To be updated annually and made available on project and partner web sites and on other electronic media Teaching: Programme for workshops for t		Mari Trommald
	rialists to facilitate design and conduct of trials, for different potential user audiences for pragmatic RCTs such as policy makers, managers and trial coordinators		
3.1c	Specifications for new tools Develop specifications for commissioning new software, if required, for computerised central telephone, computerised telephonist operated and decentralised palmtop computer randomisation and trial entry software	ABERDEEN Marion Campbell CREP Edgardo Abalos OSLO Andy Osman	Max Bachmann Eduardo Bergel Vinod Diwan Lelia Duley Bo Eriksson Barbara Farrell Simon Innver Carl Lombard Juan Manuel Lozano Cecilia Stalsby Lundborg Craig Ramsay Chris Seebregts Tesse Tan-Torres Edejer Shaun Treweek Mari Trommald Godfrey Woelk Merrick Zw

3.1d	Translation into Spanish Partner on WPs 3.1b, c, d 3.1b Library, existing tools, teaching, new tools Moderator for LA	CREP Edgardo Abalos	Eduardo Bergel Juan Manuel Lozano
3.2	'E-mail trial protocol clinic' to provide easy and prompt access to advice on trial protocol developments, open to all users	LUBECK Susanne Doepfmer	Max Bachmann Lelia Duley Simon Lewin Carl Lombard Juan Manuel Lozano Cathy Mathews Andy Oxman Chris Seebregts Godfrey Woelk Merrick Zwarenstein
3.3	Workshop 2: Appraisal and selection of tools and resource items will be main content	CREP Edgardo Abalos	All
4.1	Iterative cycle of action plans, activities and progress reports for each DC partner country, to be incorporated into annual review of network progress, on web site with updates. Activities will be locally designed, based on tools designed as part of WP3	SA MRC Merrick Zwarenstein CREP Edgardo Abalos	Edgardo Abalos Max Bachmann Cathy Mathews Tesse Tan-Torres Edejer Merrick Zwarenstein
4.2	Support for action plan at country level eg support for training workshops to raise awareness of need for RCTs amongst allied health professionals, such as midwives and nurses, support for workshops with journalists to raise level of mass media coverage o	SA MRC Merrick Zwarenstein CREP Edgardo Abalos	Fatima Abacassamo Max Bachmann Eduardo Bergel Marion Campbell Julie Cliff Vinod Diwan Lelia Duley Bo Eriksson Simon Innver Carl Lombard Juan Manuel Lozano Cecilia Stalsby Lundborg Cathy Mathews Andy Oxman Mohsin Sidat Tesse Tan-Torres Edejer Mari Trommald
	f health policy decision making on effectiveness		Godfrey Woelk

5	Pragmatic RCT and associated systematic review protocols, submitted for peer review and analysis	LUBECK Susanne Doepfmer	Edgardo Abalos Eduardo Bergel Lelia Duley Simon Lewin Juan Carlos Lozano Cathy Mathews Godfrey Woelk Merrick Zwarenstein
6	Project co-ordination and management	OXFORD Lelia Duley	Merrick Zwarenstein Barbara Farrell Nina Armstrong

3. Work Package 1: Facilitators and barriers to the use of pragmatic trial information

Work package 1 (of which this Workshop forms a part) identifies the main barriers to wider use of rigorous evaluations (pragmatic RCTs) of health policy, health care and public health interventions, especially in developing countries, based on review and qualitative analysis of partner experiences and an overview of the existing methodological literature on health services research and pragmatic trials.

0.1. Workshop and summary report

The holding of Workshop 1 and the completion of this summary report (and supplementary minutes) constitute two of the elements of deliverable 1.1 (the remaining ones being their distribution on the PRACTIHC web site in English and Spanish).

3.2 Identification of facilitators and barriers

Facilitators and barriers to the use of pragmatic trial information were identified in three ways: a survey of the perceptions on an individual basis of the Workshop participants, a survey of group perceptions of specific studies, and a systematic review of decision maker perceptions. (The full results are listed in Appendix 1.)

3.2.1 Individual perceptions

Participants felt that the main factors that had facilitated the appropriate use of their research were personal contacts/meetings with policy makers (scored by 10/29) and its timeliness (5/29). Conversely the main factors that were regarded as having restricted the use of research were lack of adequate knowledge at all levels/lack of dissemination (8/29), political interest/preconceived ideas of its use, lack of funding/resources and lack of personal contact (all 3/29).

3.2.2 Group perceptions

The groups felt that the main information policy makers would need to make a decision on the policy were costs (scored by 7/8) and availability of alternative treatments/interventions (3/8). They also felt that the main reasons policy makers might find the results of the trial useful in making health policy decisions or in providing advice were its cost effectiveness and its importance as a problem (both 3/8). Conversely the main reasons why policy makers would not find the results of the research useful were that it contradicts other evidence, is not relevant and a lack of knowledge/skill (all 2/8).

The main barriers to implement the results of the research were felt to be lack of funding/costs (4/8), that results contradict current policies, their availability/capacity and non-acceptance/no incentives (all 2/8), while the main actions that might be taken to facilitate the implementation of the results were the dissemination of the results and demand by consumers/opinion leaders/media (both 3/8).

3.2.3 Review of decision makers

The main facilitators were personal contact, the timeliness and relevance of the research (both scored by 13/24) and research that includes a summary with clear recommendations (11/24). The main barriers were an absence of personal contact (11/24) and lack of timeliness/relevance of research (9/24).

3.2.4 Discussion

The agreement between Workshop participants and decision makers on the most important facilitators was noted, although the participants may be a 'biased' sample. The distinction was also noted between "personal contact" and "personal connection", with the latter probably being more important in developing countries. In a snap survey, approximately half the participants indicated disappointment in the uptake into policy of their research results.

3.3 Action plan (Deliverable 1.2a)

Three projects were identified as case studies of developing country RCTs:

1. The Magpie study (being co-ordinated by Lelia Duley).
2. Case study of WHO, evaluating trials across different disease groups (eg malaria, eclampsia, TB/DOTS etc).
3. Trials that have been completed within the last 5 years or that will be completed before the end of 2002, to be identified within the PRACTIHC network, and from which a sequential sample will be set up with one or two to be studied initially and others added as experience is gained.

3.3.1 Discussion

The Oslo group will initiate and co-ordinate all actions, and will also support partners doing methodological reviews but will not undertake such reviews itself. In general developing country partners could 'twin' with developed country partners for capacity building.

4. Work Package 2: Developing country RCTs: Database and analysis

Work package 2 is a descriptive analysis of developing country RCTs, based on the co-ordination and completion of efforts to develop a database of RCTs in developing countries.

4.1 Action plan

The Cochrane Controlled Trials Register will be searched to identify a sample of trials conducted in developing countries. These can then be surveyed, with the range of issues and information that would be of interest to evaluate identified as pertaining to: where the trial was undertaken; when it was undertaken; by whom it was undertaken/funded; what method/critical appraisal was used; why it was undertaken; and the means of publication to (full list in Appendix 2).

4.2 Discussion

What is the main thrust of the survey: To confirm suspicions? To improve methods? To identify gaps in expertise/knowledge? To compare with developed countries? This cannot be identified at present as these are very broad issues. However, refer to objective (1, Section 2) “to develop guidelines for improving [RCT] quality, relevance and decision making use”. This is a huge and labour-intensive research agenda, which others can also pick up on, and all agreed it to be worthwhile. The African trials register (George Swingler) could serve as a pilot.

5. Work Package 3: Location and development of tools

Work package 3 covers the development (or location, if any already exist) of a set of resources to simplify the conduct of pragmatic RCTs in developing countries, and ensure that researchers in developing countries have access to current knowledge on these study designs and their conduct.

The four areas identified in which tools are needed are:

- _ Design of trials
- _ Conduct of trials
- _ Analysis/reporting of trials
- _ Training materials

For each of these a set of identification criteria (comprising Strategy, Exclusion, Evaluation, and Prioritisation) were developed, and based on these a list of tools were identified and a subset prioritised in each category. (Full list of identification criteria and tools identified in Appendix 3.)

5.1 Tools prioritised

5.1.1 Design of trials tools

- _ Checklists eg rationale, trial management, protocol sub-sections, stakeholder groups, elements of pragmatic design
- _ Examples eg protocols, informed consent forms, data collection forms etc.
- _ Budgeting tool
- _ Sample size calculators
- _ Protocol templates

5.1.2 Conduct of trials tools

- _ Search information/tool
- _ Protocol checklist
- _ Basic stats package
- _ Randomisation methods
- _ Data management checklist
- _ Analyses and publication
- _ Examples
- _ Useful reading/links

5.1.3 Analysis/reporting of trials tools

- _ Review of simple stats packages (EPI-INFO)
- _ Sample size calculator
- _ Examples of common analysis problems

5.1.4 Training materials tools

- _ Year 1 – 3-5-day course for trial participants (possibly to trial pre-Workshop 2 in Argentina)
- _ Year 2 – 1-5-hour course for policy makers

5.2 Discussion

Resources will be available in both English and Spanish, although it probably won't be possible to translate everything into Spanish. The target audience must be considered very carefully as the tools seem to be aimed at a "low level", but policy making is a "high level" activity. PRACTIHC was conceived with "multiple entry points", one being to increase the number of people in low income countries doing RCTs. With exposure to PRACTIHC, policy makers should begin to realise the need to contribute to it. The deliverables of this WP3 will begin to appear probably only after month 12.

6. Work Package 4: Country-level dissemination

Work package 4 aims to increase the number and improve the quality of pragmatic RCTs conducted by others besides partners themselves. Partner countries will prepare an action plan for promoting the conduct of pragmatic trials and their use in decision making in their own and neighbouring countries, largely through workshops aimed at training trialists and trial co-ordinators, as well as decision makers in the policy, public health or health care fields.

6.1 Developing country experiences of policy support initiatives

6.1.1 Essential national health research – South Africa (Merrick Zwarenstein)

The ENHR initiative is intended to orient the research agenda so that it is appropriately balanced across the diseases and other health problems in a country, and in particular to increase research in developing countries on health systems. Many meetings have been held involving the national Health department, universities, funders and other players and the jargon has come to be widely used, but there has been no apparent change in the research structures or research agenda.

6.1.2 Health systems research initiative – Zimbabwe (Godfrey Woelk)

This initiative had its origins in the mid-1980s in a workshop on research protocols for mid-level researchers and managers from the region organised by the Canadian IDRC and later continued with funding from the Dutch Ministry for Development Cooperation. From this several manuals were developed and workshops were held throughout the region, and subsequently the manuals have also formed the basis for a similar initiative in Asia. From the perspective that an initiative that started as a regional one has developed an international perspective, it can be considered successful. However, probably fewer than half of the research projects undertaken as a result of the initiative have led to policy/health practice changes.

6.1.3 Burden of disease initiative – Mozambique (Julie Cliff)

This initiative had its origins in 1993 in a Harvard workshop on DALYs, which gave experience in presentation methods and data analysis, and on the basis of this an analysis was undertaken of the Maputo death register, giving new insight into the death pattern in the city and the taking up of this by government. Subsequently the study has been repeated and now with WHO funding it is to be expanded to include a rural setting. Lessons learned include the length of time that such projects take time to develop, the difficulty of maintaining a “critical mass” of researchers over time, the importance of decision maker contacts, the need for tools, and the need for national courses, as the WHO course has elements that are too difficult for developing country researchers.

6.1.4 Maternal and child health initiatives – Uruguay, Costa Rica (Eduardo Bergel)

An initiative showing that the presence of a midwife during labour and delivery led to a better outcome has resulted in this becoming a legal requirement in Uruguay. In Costa Rica a series of evidence-based courses were initiated at hospital level, resulting in the implementation (currently) of a maternal quality assurance programme to test outcomes. The QA programme stimulates awareness and simple impact measures are required for it.

6.1.5 Maternal and child health initiatives – Argentina (Edgardo Abalos)

CREP’s strategy includes stimulating research participation by creating a critical mass at local level and providing teaching and training short courses. CREP is involved in several trials and has developed a network of hospitals that are participating in these. It is important to understand one’s own country and

identify where interventions can be most effective (in Argentina, at hospital level).

6.2 Developing country action plans

6.2.1 General issues and needs

A low key approach should be adopted initially, and built upon incrementally. Other points include following the development of PRACTIHC tools, identifying feasible intervention (as the first one needs to be successful), identifying key people with research degree training/potential partners and establishing networks. Also time frames and outcome measures for actions needs to be set.

Plans for individual countries/partners were identified as follows:

6.2.2 Colombia

- _ Training at different levels (policy makers/researchers/students)
- _ Distribution of PRACTIHC products through existing networks

6.2.3 Mozambique

- _ Course for a rural centre to support an obstetric trial
- _ Informal consultation service
- _ Module on RCTs in the MPH course at the University of Eduardo Mondlane
- _ Training and support for writing up research results

6.2.4 South Africa

- _ Short course for new staff/students at UFS, Bloemfontein in mid-2002
- _ Inclusion of a critical appraisal session in the Oliver Tambo Programme course at UCT
- _ New tool for sample size calculation, and teaching component on the use of baseline information in trial analysis
- _ PRACTIHC web site, list server and document server development
- _ Country level dissemination plan

6.2.5 Zimbabwe

- _ Workshop on pragmatic RCTs
- _ More training in the MPH programme at the University of Zimbabwe
- _ Multi-centre trial for the region

6.2.6 Discussion

Participants should submit potential research questions for a multi-centre trial in the African region, and a quarterly reporting procedure will be set up to monitor and measures action outcomes of the partner action plans. The Asian region (Vietnam) can be drawn in through the Swedish partner.

6.3 RCT course (6 - 8 December 2001) review

The first PRACTIHC RCT course (6 - 8 December 2001) was conducted by partners over the three days immediately prior to the Workshop for more than thirty participants from southern Africa. Its aim was to

test out strategies for disseminating skills, to make a video record with a view to making “segments” available for use in the classroom and on the web, and to initiate the process of disseminating pragmatic RCT skills in South Africa and in neighbouring countries.

6.3.1 Evaluation

In general the course was regarded as well organised, well managed and useful (full evaluation in Appendix 4). The presentations were regarded as being of a high standard and practically-oriented, although if anything some were felt to have too much content and the statistics were too advanced, and the opportunity to discuss practical issues with experts in the small group context was welcomed. On the balance between presentations and small group discussions, views were mixed, but the need was felt for more plenary report-backs and chaired discussions after presentations. It was also felt the small groups could have been more diversified in terms of background and the distribution of lecture notes in advance would have been appreciated.

The venue was generally liked, although its poor access to shops and city life was felt to be a drawback, and the need was felt for more social time. The tendency of participants to leave before the end was also looked upon negatively.

The mean rating for the course was 7.9

6.3.2 Discussion

This course could form the basis for a 6 – 10 module course, with the preferred format being a 2-day core course covering the basics and a third day with add-ons for self-selection, and the structure based around the structure of a protocol. Students could write down the main elements of a protocol to have something to take away (a tool is needed for a protocol structure) and lecture notes/slides should be distributed. Evaluation is essential for course development and each workshop provides experience for the next.

6.4 Current training activities

The current training activities of partners were listed for reference (Appendix 5).

7. Work Package 5: Systematic review of trials protocols

Work package 5 will include training and protocol development support to network members in the development of their own protocols for funding of pragmatic trials and systematic reviews.

7.1 Guidelines for operation

General guidelines for the management of WP5 were developed, including that access to the co-ordinator should be 'limited' and all requests be submitted through the country partner, which would try to handle it if a local issue. The co-ordinator should be supported by mentors and a list must be drawn up (pairing mentors in developing and developed countries). The co-ordinator should keep a record of all requests submitted and should set up a list of FAQs for the web site. A discussion list could also be moderated on the site. The volume of work and nature of requests should be reviewed at Workshop 2.

7.2 Partner support

Areas in which partners will support WP5 were listed for reference (Appendix 6).

8. Work Package 6: Management of PRACTIHC

Work package 6 was established to encompass the management and administration of PRACTIHC.

8.1 Management guidelines

8.1.1 Administration

The administrative/co-ordinating office will be based in Oxford. The administrative team comprises:

Merrick Zwarenstein – Project Co-ordinator
Barbara Farrell – Financial Manager
Nina Armstrong – Administrative Co-ordinator

Activities of the administrative office will include centralising and maintaining the records, holding and distributing funds, handling queries (or passing on as appropriate), and compiling and distributing reports and newsletters. Regular teleconferences will be held (approximately fortnightly) among the administrative team. Partners should notify the administrative office of their activities for possible co-ordination.

It was agreed that Workshop 2, comprising a 3 – 4-day workshop coupled with a 3 – 5-day training course, would be held in Rosario, Argentina between November 2002 and February 2003 and will be scheduled by 28 February 2002.

8.1.2 Management

The management team comprises:

Merrick Zwarenstein – Project Co-ordinator
Edgardo Abalos – Latin America representative
Andy Oxman – Europe representative
Godfrey Woelk – Africa representative

The management team will hold regular teleconferences, and will draw in other partners as needed.

8.1.3 Finances

The following arrangements were made for funding for Year 1:

- _ Funding for personnel for year 1 is guaranteed
- _ Funds for personnel, consumables and travel will be paid quarterly in advance
- _ Funding reallocations necessitated by the budget cut will be re-evaluated after Quarter 1

The funds are envisaged to be available by 31 March 2002. Reimbursements based on a quarterly report will be handled within 30 days (copies of receipts are sufficient for reporting purposes).

8.2 Workshop evaluation

The organisation of the workshop was regarded as good but in general the need was felt for more flexibility in the agenda and for more time for discussions of the work packages and networking during breaks. Participants would be happy to work later into the evening, although less so at a less isolated venue, in which case the workshop would need to be extended to 4 days. Participants would also prefer to select which small groups they participate in. The venue was regarded as nice and while some liked its isolation others would have preferred better access to shops. Internet access is essential.

9. Conclusions

The main business of this Workshop was to inaugurate PRACTIHC, and to establish working relationships and administrative and communication patterns, along with guidelines for the initiation of the Work Packages (WPs), through which the project will be realised.

From that perspective it can be regarded as broadly successful, with all these goals having been realised, as outlined in the preceding pages. However, in general the discussions around the issues were rushed and had to be curtailed due to time constraints and the detail of the majority of the Action plan/deliverables still must be worked out (e.g. the time lines for implementation). Furthermore in conjunction with this – and as with all meetings – a key challenge will be to maintain the enthusiasm and momentum generated at the Workshop after the return of partners to their home institutions. In these respects the lead partners have a particular responsibility, as do the developed country partners as mentors to their developing country counterparts.

In the light of the experience of Workshop 1, the next Workshop, to be held in Rosario, Argentina, will be extended to 4 days to allow adequate time to cover all the business.

Appendix 1. Facilitators and barriers to the use of pragmatic trial information

1. Individual perceptions

What factors have facilitated the appropriate use of your research? (n=29)

- _ Personal contacts/meetings with policy makers (10)
- _ Timeliness (5)
- _ Funding (2)
- _ Publication and dissemination (2)
- _ Commissioned research (2)
- _ Confirms current policy (2)
- _ Relevance (2)
- _ Credibility (1)
- _ High impact journal publication (1)
- _ Low cost (1)

- _ Importance of problem (1)
- _ Controversial intervention (1)
- _ Training of decision makers (1)
- _ Short summaries (1)
- _ Need for a change (1)
- _ Need to get a better instrument to control (1)
- _ Malaria (1)
- _ Links with systematic review evidence (1)
- _ Applicability of results (1)
- _ Strength of the data (1)
- _ Dissemination by local collaborators (1)

What factors have restricted the appropriate use of your research? (n=29)

- _ Adequate knowledge at all levels (lack of dissemination) (8)
- _ Political interest/preconceived ideas of its use (3)
- _ Lack of funding/resources (3)
- _ Lack of personal contact (3)
- _ Capacity of the system to undertake the change (2)
- _ Sensitivity of the topic/results (2)
- _ Unpublished results (2)
- _ Lack of relevance (2)
- _ Language (1)
- _ Lack of training in use of trials (1)
- _ Low priority at national level (1)
- _ Personnel instability (1)
- _ Bureaucratic inertia (1)
- _ Not knowing where to disseminate evidence outside journals/Cochrane (1)

2. Group perceptions

What other information will policy-makers need to make a decision on this policy? (n=8)

- _ Costs (7)
- _ Alternative treatment/interventions (3)
- _ Availability of prescription in periphery (2)
- _ Resistance to change (2)
- _ Logistics (2)
- _ Adverse effects/resistance to antibiotics (2)
- _ Size of the impact (1)
- _ IT system information/software information (1)

- _ Skills development need (1)
- _ Fee structure for consultation (1)
- _ Labour intensive (1)
- _ Replication of study (1)

Why do you think policy-makers might find the results of your trial useful in making health policy decisions or in providing advice? (n=8)

- _ Cost effective (3)
- _ Important problem (3)
- _ No alternative treatments (or too costly) (1)
- _ Simple treatment (1)
- _ Credibility (1)
- _ Essential information (1)
- _ Possible to generalise to other areas (1)
- _ Easy update (software) (1)
- _ Increased capacity (1)
- _ Doctors liked the intervention (1)

Why do you think policy-makers do NOT find the results of your research useful in making health policy decisions or in providing advice? (n=8)

- _ Contradicts other evidence (2)
- _ Not relevant (2)
- _ Lack of knowledge/lack of skill (2)
- _ Resources (personnel/money) (1)
- _ Not necessarily better than alternatives (1)
- _ Too much work for doctors (1)
- _ Contradicts systematic reviews (1)
- _ Too small effect (1)

What barriers might there be to implement the results of your research? (n=8)

- _ Lack of funding/costs (4)
- _ Results contradict current policies (2)
- _ Availability/capacity (2)
- _ Not accepted/no incentives (2)
- _ Logistics (1)
- _ Skills (1)
- _ Still international debate (1)
- _ New drugs coming out (1)
- _ Manual not ready (1)
- _ Interventions not sufficiently tailored to become a programme (1)
- _ System instability (1)
- _ Lack of trust in technology (1)
- _ Longer consultations (1)
- _ Pharmaceutical industry (1)

What actions might be taken to facilitate the implementation of the results of your study by policy makers? (n=8)

- _ Dissemination of results (3)
- _ Consumer demand/opinion leaders/media (3)
- _ Uptake in national drug formulary (2)
- _ Personal contact (2)
- _ Offer support for implementation (1)
- _ Involvement of stakeholders (1)
- _ Possible to generalise to other areas (1)
- _ Collaboration between professionals (1)

3. Review of decision makers

Facilitators (n=24):

- _ Personal contact (13)
- _ Timeliness and relevance of the research (13)
- _ Research that includes a summary with clear recommendations (11)
- _ Good quality research (6)
- _ Research that confirms current policy or endorses self-interest (6)
- _ Community pressure or client demand for research (4)
- _ Inclusion of effectiveness data (3)

Barriers (n=24):

- _ Absence of personal contact (11)
- _ Lack of timeliness or relevance of research (9)
- _ Mutual mistrust, including perceived political naivety of scientists and scientific naivety of policy makers (8)
- _ Power and budget struggles (7)
- _ Poor quality of research (6)
- _ Political instability or high turnover of policy making staff (5)

Appendix 2. Analysis of developing country RCTs

Issues and information to survey in the sample of developing country trials includes:

- Where:
 - Country
 - Institution (private/government/NGO)
 - Care level (hospital/phc/chc)
 - Urban/rural
- When:
 - Year of conduct
 - Year of publication
 - Relation to political/economic situation
 - Timing (social/economic)
- By whom undertaken/funded:
 - Authors/authorship order
 - Country income level
 - Lead institution/countries of authors
 - Professional backer/funding source (international/local/drug company/other)
 - Field worker involvement
 - Male/female
 - Age of researchers
 - Qualifications of researchers
- What method/critical appraisal:
 - Topic/objective
 - Design/context
 - Inclusion criteria
 - Analysis
 - Intervention
 - Results
 - Effect size
 - Validity
 - Outcome measures/relevance
 - Quality measures
- Why:
 - Extent of problem
 - Importance
 - Duplication of results
- Publication:
 - Language of publication
 - Journal impact factor
 - Accessibility (conference abstract/journal)
- Other issues:
 - Time trends in topic/number of trials/authorship
 - Parallel studies published recently, contact authors
 - Methodological grading
 - Proportion of research money/studies/publications in country going to RCTs
 - Proportion of country's abstracts published
 - Proportion of studies that are abstracts
 - Capacity building efforts by centres/over time when link between developing and developed countries
 - Whether centres have favourites
 - When several studies, are these in systematic reviews
 - Comparison with developed countries

Appendix 3. Identification of tools

1 Design of trials tools (Co-ordinator: Carl Lombard)

1.1 Identification criteria

- Strategy:
 - Utilise PRACTIHC network
 - Circulate list to identify specific tools to known people/discussion groups
 - Short questionnaire by e-mail
 - Circulate tool list to networks etc for comment
 - External peer review of tools
- Exclusion:
 - Language (not English/Spanish/Portuguese)
 - Cost
 - Generic software, books, databases for specific settings
- Evaluation:
 - User friendliness
 - Level of knowledge required to use
 - Generalisability
 - Accessibility
 - Cost
 - Specific criteria for each group
 - Criteria-specific evaluation
- Prioritisation:
 - Relevance
 - Usefulness to researchers in developing countries
 - Cost to researcher/PRACTIHC
 - Key for success/failure

1.2 Tools identified

Tools prioritised:

- Checklists eg rationale, trial management, protocol sub-sections, stakeholder groups, elements of pragmatic design
- Examples eg protocols, informed consent forms, data collection forms etc.
- Budgeting tool
- Sample size calculators
- Protocol templates

Other tools:

(Second priority)

- Guidelines for dummy tables for different outcomes
- Project planning tools
- Random number generator
- Tool to help pilot design

(Third priority)

- Guidelines for economic evaluation, process evaluation
- Facilitators/barriers questionnaire
- Links to established trial web sites

(Fourth priority)

- Guidelines on selecting appropriate outcomes
- Guidelines on contracts eg data ownership, collaborator agreements etc.
- Annotated bibliography
- Encyclopedia of terms

2 Conduct of trials tools (Co-ordinator Barbara Farrell)

2.1 Identification criteria

- _ Target audience wider than PRACTIHC
- _ Tools should be developed for all basic IT media. Tools on the Internet should not be dependent on this for their use, and they should also be downloadable for other formats (<1.44 MB, ie floppy disk capacity, in size)
- _ Tools should be available on CD-ROM for limited distribution in developing countries (general postal distribution will not be set up)
- _ Web site should be “minimalist” and can be developed incrementally. The site will probably be sustained after the lifetime of PRACTIHC
- _ From the development aspect, tools have higher priority than the web site
- _ Tools ownership needs clarification. Some tools should be public domain, but others may have IP rights
- _ A publishing strategy can be considered

2.2 Tools identified

Tools prioritised:

- _ Search information/tool
- _ Protocol checklist
- _ Basic stats package
- _ Randomisation methods
- _ Data management checklist
- _ Analyses and publication
- _ Examples
- _ Useful reading/links

Other tools:

- _ Links to trial managers
- _ Checklist on skills mix for running a trial
- _ Budget control/project planning software
- _ Template/checklist on trial conduct
- _ Ideas to maintain enthusiasm
- _ Ownership
- _ Guidelines to manage outsourcing of money
- _ Form design
- _ Audit trails
- _ Communication

3 Analysis/reporting of trials tools (Co-ordinator: Marion Campbell)

3.1 Identification criteria

- _ Strategy – survey partners on what they use/like/hate about analysis packages
- _ Criteria:
 - Low cost (cheap/free)
 - Ease of use
 - Popularity/wide distribution
 - Perform basic analyses only
 - Hardware requirements
 - Languages
- _ Investigate “add-ons” to EPI-INFO

3.2 Tools identified

Tools prioritised:

- _ Review of simple stats packages (EPI-INFO)
- _ Sample size calculator
- _ Examples of common analysis problems

Other tools:

- _ Guidelines for writing papers
- _ Annotated bibliography of useful texts
- _ CONSORT
- _ Translation
- _ Examples of basic types of analyses relevant to different outcomes
- _ Reporting templates eg policy makers, media, lay people
- _ Guide on data cleaning
- _ Links to authorship policies
- _ Links to instructions for authors sites
- _ Lists of units/people who can provide advice
- _ Examples of good methods sections
- _ Links to electronic journal sites

4 Training materials tools (Co-ordinator: Shaun Treweek)

4.1 Tools identification criteria

- _ Strategy:
 - Involve PRACTIHC members/other resources
- _ Exclusion:
 - Not for students
 - Not for drug registration
- _ Evaluation:
 - To fit prioritisation
 - Self-explanatory
 - Focussed/targeted
 - User evaluation
- _ Prioritisation:
 - 3-5-day, 6-10-module course for trial participants
 - 1-5-hour (face-to-face) course for trial co-ordinators
 - 1-5-hour (face-to-face) course for policy makers, and group course if required

4.2 Tools identified

Tools prioritised:

- _ Year 1 – 3-5-day course for trial participants (possibly to trial in Argentina)
- _ Year 2 – 1-5-hour course for policy makers

Other tools:

- _ Register of existing programmes/material
- _ Problem-based set slides
- _ Library of examples good, bad
- _ List/links to people/organisations providing training
- _ Links to training funding sources
- _ Exchange visits – can tool support?
- _ Case studies of what has worked
- _ Material relevant to other levels/courses, eg self learning

Appendix 4. Evaluation of first PRACTIHC RCT course

Evaluations of issues were as follows:

- Small groups:
 - Positive: useful; opportunity to discuss practical issues with experts; well managed
 - Negative: group according to background; plenary report backs; more/less time

- Presentations
 - Positive: different backgrounds of presenters; high standard; "Making it work" highly rated
 - Negative: too much content; stats too advanced (could be streamed); more chaired discussions after presentations

- Organisation:
 - Positive: excellent timekeeping; well organised (Mandy Salomo excellent)
 - Negative: lecture notes in advance; too long/short; more social time; 'finishing school' for protocols; participants leaving early

- Venue:
 - Positive: generally liked
 - Negative: poor access to town/shopping

Appendix 5. Current training activities of partners

Eduardo Bergel	Courses (small group, 1-week) on EBM, guideline development, RCTs
Max Bachmann	Health economics module for MBA
Marion Campbell	Training for masters students, clinicians, trial managers
Susanne Doepfmer	Workshops on EBM
Lelia Duley	Workshops on trial conduct, protocol development
Bo Eriksson	Nordic SPH MPH, DrPH programmes HSR in context of NOP in ... Training related to Epidemiological field laboratory Bavi, Vietnam
Juan M Lojano	Courses (as CMC or MPH in clinical epidemiology) on EBM, research designs, health economics, biostatistics, systematic reviews
Cecelia Stalsby Lundberg	HSR training programme in Laos Course in pharmacoepidemiology
Andy Oxman	Workshops on EBHC, systematic reviews, for policy makers 2002 Cochrane Colloquium
Mari Trommald	Workshops on EBM
Merrick Zwarenstein	HSR courses based on IDRC manual (low to mid-level health workers) Short (1-3-day) courses on RCTs

Appendix 6. Partner support for trial protocol reviews

Eduardo Bergel	Design, analysis
Max Bachmann	Design, analysis, especially primary care professional/training interventions
Marion Campbell	Design, statistics
Julie Cliff	Ethical issues in developing country trials
Vinod Diwan	Trial development in Mozambique and Vietnam
Lelia Duley	Design, conduct, analysis, reporting
Bo Eriksson	Design, analysis
Simon Lewin	Qualitative methods in RCTs; design of training interventions
Juan M Lojano	Design
Carl Lombard	Design, outcomes, sample size, analysis
Cecilia Stalsby Lundborg	Educational interventions, guideline implementation, especially re prescribing practice; practical aspects re cluster RCTs
Cathy Mathews	Behavioural studies; HIV prevention in schools; health education in health services
Andy Oxman	Mentor
Craig Ramsey	Design, analysis
Shaun Treweek	Use of IT; data collection, presentation, storage; database design
Godfrey Woelk	Design, conduct, analysis; ethical issues especially in developing countries
Merrick Zwarenstein	Mentor; design, especially complex interventions related to professional behaviour; qualitative methods in RCTs

Appendix 7. PRACTIHC partners

Fatima Abacassamo

Manhica Health Centre Research, Medicine Faculty, University Eduardo Mondlane, P O Box 257,
Maputo, Mozambique
Tel: +258 1 810-002, Fax: +258 1 810-002, E-mail:

Edgardo Abalos

Centro Rosarino De Estudios Perinatales, Preinatales (CREP), Pueyrredon 985, (2000) Rosario, Argentina
Tel: +54 341 447-2625, Fax: +54 341 448-3887, E-mail: ,

Nina Armstrong

Resource Centre for Randomised Trials, Institute for Health Sciences, Old Road, Headington, Oxford,
OX3 7LF, UK
Tel: +44 1865 227-100, Fax: +44 1865 227-173, E-mail:

Max Bachmann

Department of Community Health, University of the Free State, P O Box 339 (G52), Bloemfontein, 9300,
South Africa
Tel: +27 51 405-3136, E-mail:

Marion Campbell

Health Services Research Unit, University of Aberdeen, Polworth Building, Foresterhill, Aberdeen, AB25
2ZD, UK
Tel: +44 1224 554-480, Fax: +44 1224 554-580, E-mail: m.k.campbell@abdn.ac.uk

Julie Cliff

Department of Community Health, Faculty of Medicine, University of Eduardo Mondlane, CP 257,
Maputo, Mozambique
Tel: +258 1 421-072, Fax: +258 1 425-255, E-mail: jcliff@tropical.co.mz

Martinho Dgedge

Ministry of Health – Mozambique, Faculty of Medicine, University of Eduardo Mondlane, CP 257,
Maputo, Mozambique
Tel: +258 1 421-738, Fax: +258 1 421-738, E-mail:

Vinod Diwan

Nordic School of Public Health and Karolinska Institutet, P O Box 12133, S-40242 Goteburg, Sweden
Tel: +46 31 693-922, Fax: + 46 31 691-777, E-mail:

Susanne Doepfmer

Department of Social Medicine in Luebeck, Lindenstr. 30, 12589, Berlin, Germany
Tel: +49 30 6430-0559, Fax: +49 30 6439-8200, E-mail: doepfmer@snaifu.de

Lelia Duley

Resource Centre for Randomised Trials, Institute for Health Sciences, Old Road, Headington, Oxford,
OX3 7LF, UK
Tel: +44 1865 226-642/227-100, Fax: + 44 1865 227-173, E-mail: lelia.duley@ndm.ox.ac.uk

Bo Eriksson

Nordic School of Public Health, P O Box 12133, S-40242 Goteborg, Sweden
Tel: +46 31 693-943, Cell: +46 704 915-700, Fax: +46 31 691-777, E-mail: bo@nhv.se

Ubaldo Farnot

Cuba

Barbara Farrell

Resource Centre for Randomised Trials, Institute for Health Sciences, Old Road, Headington, Oxford,

OX3 7LF, UK

Tel: +44 1865 227-100, Fax: +44 1865 227-173, E-mail:

Simon Innver

National Institute of Public Health, P O Box 4404, Nydalen, 0403, Oslo, Norway

Tel: +47 2204-2362, Fax: +47 2204-2595, E-mail:

Simon Lewin

Department of Public Health and Policy, LSHTM, Keppel Street, London, WC1E 7HT, UK

Tel: +44 20 7580-4524, Fax: +44 20 7927-2102, E-mail: simon.lewin@mrc.ac.za

Carl Lombard

Biostatistics Unit, Medical Research Council, P O Box 19070, Tygerberg, 7505, South Africa

Tel: +27 21 938-0310, Fax: +27 21 938-0328, E-mail:

Juan Manuel Lozano

Clinical Epidemiology Unit, School of Medicine, Javeriana University, Cr 7 # 40-62, Floor 2, Bogota DC, Colombia

Tel: +57 1 320-8320, ext 2799, Fax: +57 1 285-6981, E-mail:

Cecilia Stalsby Lundborg

Karolinska Institutet, Department of Public Health Sciences, IHCAR, Karolinska Institutet, SE 17176, Stockholm, Sweden

Tel: +46 8 5177-6548, Fax: +46 8 311-590, E-mail:

Bosielo Majara

Department of Community Health, University of the Free State, P O Box 339 (G52), Bloemfontein, 9300, South Africa

Tel: +27 51 405-3625, Fax: +27 51 448-9278, E-mail: gngmbpm@med.uovs.ac.za

Cathy Mathews

Health Systems Unit, Medical Research Council, P O Box 19070, Tygerberg, 7505, South Africa

Tel: +27 21 938-0483, Fax: +27 21 938-0454, E-mail:

Andy Oxman

National Institute of Public Health, SAHT, P O Box 4404, Nydalen, 0403, Oslo, Norway

E-mail: oxman@online.no

Craig Ramsay

Health Services Research Unit, University of Aberdeen, Polworth Building, Foresterhill, Aberdeen AB25 2ZD, UK

Tel: +44 1224 559-296, Fax: +44 1224 663-087, E-mail:

Chris Seebregts

Research Information Systems Division, Medical Research Council, P O Box 19070, Tygerberg, 7505, South Africa

Tel: +27 21 938-0318, Fax: +27 21 938-0526, E-mail: chris.seebregts@mrc.ac.za

Mohsin Sidat

Department of Public Health, University of Eduardo Mondlane, P O Box 257, Maputo, Mozambique

Tel: +258 1 425-227/424-910/428-076, Fax: +258 1 425-255, E-mail: msidat@health.uem.mz

Shaun Treweek

National Institute of Public Health, SAHT, P O Box 4404, Nydalen, 0403, Oslo, Norway

Tel: +47 2204-2271, Fax: +47 2204-2595, E-mail: sht@shdir.no

Mari Trommald

National Institute of Public Health, P O Box 4404, Nydalen, 0403, Oslo, Norway

Tel: +47 2204-2478, Fax: +47 2204-2595, E-mail: mari.trommald@folkehelsa.no

Godfrey Woelk

Department of Community Medicine, University of Zimbabwe, P O Box A178, Harare, Zimbabwe
Tel: +263 4 791-631, Cell: +263 91 232-839, Project: +263 4 791-649, Fax: +263 4 725-166, E-mail: ,

Merrick Zwarenstein

Director: Health Systems, Medical Research Council, P O Box 19070, Tygerberg, 7505, South Africa
Tel: +27 21 938-0247, E-mail: merrick.zwarenstein@mrc.ac.za

Consultants:

Eduardo Bergel

Latin American Centre for Perinatology, PAHO/WHO, CC 627, Montevideo (11000), Uruguay
Tel: +598 2 487 2929, Fax: +598 2 487 2593, E-mail: ,

Tesse Tan-Torres Edejer

Choosing Interventions: Effectiveness, Quality and Costs, Global Programme on Evidence, World Health Organization, Avenue Appia, 1211, Geneva, Switzerland
Tel: +41 22 791-3497, Fax: +41 22 791-4328, E-mail:

Administration:

Nadine Hendricks

Corporate Communication Division, Medical Research Council, P O Box 19070, Tygerberg, 7505, South Africa
Tel: +27 21 938-0346, Fax: +27 21 938-0395, E-mail: nadine.hendricks@mrc.ac.za

Mandy Salomo

Conference Co-ordinator, Medical Research Council, P O Box 19070, Tygerberg, 7505, South Africa
Tel: +27 21 938-0433, Fax: +27 21 938-0395, E-mail:

Minutes/Report:

Jonathan Spencer Jones

P O Box 398, Cape Town 8000, South Africa
Tel: +27 72 297-9925, E-mail: jspencerjones@yebo.co.za