

Minutes: 2nd Meeting of the PRACTIHC Concerted Action Havana, Cuba 9th-12th February 2003

List of Attendees: Lelia Duley (Oxford), Merrick Zwarenstein (Canada), Carl Lombard (South Africa), Kirsty McCormack (UK), Marion Campbell (UK), Craig Ramsay (UK), Edgardo Abalos (Argentina), Julie Cliff (Mozambique), Ana Maria Novoa (Mozambique), Godfrey Woelk (Zimbabwe), Susanne Doepfmer (Germany), Andy Oxman (Norway), Shaun Treweek (Norway), Signe Flottorp (Norway), Max Petzold (Sweden), Cecilia Stalsby Lundborg (Sweden), Richard Allen Dale (Sweden), Farnot Ubaldo (Cuba), Juan Carlos Vazquez (Cuba), Goerge Swingler (South Africa), Eduardo Bergel (Uruguay), Juan Manuel Lozano (Columbia), Dave Sackett (Canada), Elba Gomez (Cuba), Georgina Rojas (Cuba), Alejandro Velazco (Cuba), Simon Lewin (South Africa), Chris Seebregts (South Africa), Zosa De Sas Kropiwnicki (UK).

Workpackage 1: Policy and Methodology

Sunday preplanning

The policy group of Practihc attempted initially to identify cases of evidence implementation into policy decision-making, but this proved impractical. Therefore they took opportunity to follow-up implementation of Magpie Trial result, which had just been published.

Some background information on barriers to implementation of this evidence was collected at a Magpie Trial Collaborators Meeting. It seemed that in middle-income countries the main issues were guideline development and implementation rather than any policy related barrier to the drug, and so further efforts were focussed on low-income countries. For low-income countries the group developed a survey to look at barriers to access in these countries. It has proven surprisingly difficult to define these barriers, as there is no way to access national information sources, which can reliably and simply report on these and answer the survey. WHO networks have proven to be inadequate as an entry portal to the national sources of information. The survey was piloted in 12 countries, but not all could be completed due to the difficulties of accessing the right people in each of the target countries.

Results suggest that the drug (magnesium sulphate) is generally licensed in low-income countries, but problems exist in distribution. May not be useful to do a longer survey, as key issues seem to be more local, perhaps requiring guideline implementation.

Policy Case Studies: - No progress yet

Tessa's idea was to undertake a case study to investigate evidence base of policy development in WHO. No progress has been made on analysing policy making in WHO in terms of how they do and do not use pragmatic trials. Need to discuss whether this task still seems relevant and do-able.

Julie Cliff will present recent policy case study work from Mozambique and South Africa to facilitate a discussion on whether case study methodology is an approach

that Practihc could use.

Possible case studies:

- TB prophylactics for patients with TB.-DOTS
- Mozambique Malaria trial on bed nets versus spraying.
- Could also consider a reanalysis of existing case studies, e.g. TB and DOTS.
- Studies in Vietnam and Laos from Karolinska

What needs to be done during meeting?

- Further discussion on ways forward and main conclusions from the work that has already been done.
- Lelia: may need to focus on specific regions in which magnesium sulphate access is still a problem e.g. Africa and certain parts of Asia. Also availability – distribution issues.
- There is agreement that work to date should be written up - draft papers might be prepared during the meeting.

Methodology Reviews:

Overview of existing systematic reviews (SRs):

About 20 SRs from NHS Research and Development (Health Technology Assessment) exist. Others exist on the Cochrane library. Need to develop a protocol for this project at this meeting, identifying questions/issues relevant to Practihc group.

Plenary Session: Policy: Monday Morning 0900

Andy Oxman

Three deliverables will be discussed:

- Overview of reviews of methodology
- Case studies of evidence to policy transfer
- Systematic review of studies of qualitative studies of evidence to policy interventions

Methodological overview: Andy Oxman has the resources in his group to make an index of existing systematic reviews and to highlight methodological studies that are not included in reviews. Within 2 months he will circulate the protocol for comment, and will complete the work within a year.

Interest in overview of methodology reviews: Edgardo Abalos, Juan Manual Lozano, Richard Allen Dale, Lelia Duley, Signe Agnes Flottorp, Andy Oxman, Merrick Zwarenstein. Shaun Treweek is interested in putting it or part of it into the protocol simulator tool.

Evidence to policy- prospective case study of Magnesium Sulphate:

- The first Magpie policy study has been completed (Barriers and facilitators for implementation of Magpie Trial Results: Trial Partner Perceptions)
- Trialists may not be in a position to identify barriers. Many are unable to identify key policy makers.
- Half of it is in English and the other half is in Norwegian so needs to be translated and circulated for review (date?).

- The second pilot study: Is magnesium sulphate available for women with pre-eclampsia in low-income countries?
- Focus: on policy decisions related to licensing, supplying and distribution (although WHO prefers to focus on clinical decisions).

Problems Encountered:

- The WHO's list of drug information officers is not up-to-date and high levels of variability on who is on that list
- It has been difficult to identify people who can answer questions on availability, licensing etc.
- Problems encountered when researching availability/distribution of drug in developing countries. Answers were unreliable because they were influenced by specific local conditions. Some of the people targeted with the questions only work in clinical care or, if in policy, only in one area and thus find it difficult to answer questions at the national level. Variability of answers in terms of geographical location and whether public/private practice.
- We therefore lack reliable information on availability of the drug, but it is clear that it is a complex problem e.g. rural/urban divides; public/private; expense.

Need to decide whether it is worthwhile to invest more resources to pursue this study further when it appears that the most reliable information can be obtained from drug information officers and not from obstetricians.

Possible suggestions from the floor:

- Go through pharmacist organisation.
- Contact 'INRUD' (International Network for Rational Use of Drugs) which have studies on drug availability.
- Alter methodology: Utilise case-study approach. Choose 2/3 countries that provide unique perspectives
- Get information from producers and importers (i.e. their gross estimates on sales)

Questions to consider:

- To what extent do we want to collaborate with other groups such as Central Medicine Programme (?) which provide research on pragmatic trials (?)
- Do we abandon our 'pilot' study design because it is too expensive to do on a wider scale?
- Do we abandon this particular medical problem and move on to another?
- Do we stop doing more case studies but test key hypothesis from existing case studies?
- Collaboration with the Alliance for Health Policy and Systems Research was considered, in order to get more resources to continue the pilot study design on a wider scale. They address the extent that policy makers utilise research, in particular in the sphere of health care. They have prepared a pilot of a questionnaire, which they send to policy makers. On the one hand it is worthwhile because they have experience/ideas/resources. On the other hand, they may only have 'core-responsive' resources. More discussion and thought is needed.

Emphasised that our interest for this part of the Practihc project is in changing outcomes at a policy level rather than on changing practice at a clinical level.

Julie Cliff Presentation:

The study in Mozambique was done with the London School of Hygienic and Tropical Medicine. Attention was placed on the policy process (not on implementation).

Addressed 2 policies:

- DOTS for tuberculosis
- Syndromic management for STDs in South Africa and Mozambique

The team consisted of 3 policy analysts from London school and four in-country researchers. 3 workshops have been held (pre, mid, post phase) and there is the possibility of holding another workshop in the future.

Utilised standard interview forms and taped and transcribed interviews.

Focus on history of policy and theory (Bennett model).

Worthwhile? At the international level it was seen as worthwhile, as it provided valuable insights. But may get criticism when published. At country level seen as worthwhile because it is self-affirming (showed that that they have a role in decision making)

Problems with case study approach:

- Time: great deal of time spent on interviewing and transcribing. It also took up the time of policy makers.
- In-depth policy analysis needed to enrich the study.
- Case study approach has limited conclusions. Cannot generalise.
- Difficulties in deciding which countries to use. Need to link perceived needs of the country with specific needs of project.

How can the Practihc policy group produce policy that is useful to developing country trialists?

Need to take particular country needs into account:

- In some countries (e.g. Uruguay) national policies are ineffective so need interventions at clinical level.
- In Uruguay: people often do not follow national guidelines. A mixed strategy is needed at hospital and national levels, particularly since the large hospitals have great influence over smaller health centres
- In Cuba by contrast, policies are effectively implemented, so it is useful to focus on ensuring that evidence influences policy makers at a national level.
- In other countries, we also need to look at the interests of the insurer (the one paying for services outside of the government system) as a route to increasing the influence of evidence.
- Need parallel but different workshops with clinicians on the one hand, and administrators /policy makers. Andy Oxman described a series of workshops he helped conduct in South Africa, where it was clear that these target audiences had different interests.

Discussion of differences between developing and developed countries:

In developed countries a focus on policy makers may be appropriate, whereas in developing countries we may need to focus on clinicians at the hospital level. Alternatively, there may only be differences of degree between developed and developing countries. In developed countries such as Canada decision-makers have more skills needed to absorb evidence but there is no vast difference in the way they act on evidence. There are also great variations in styles of interventions with policymakers. Informal non-imposition (e.g. syndromic management people in Mozambique) versus imposition (e.g. Dots).

Conclusions:

- Need to address the particular needs of developing countries
- Need to account for a wide audience and a spectrum of policy makers stretching from the micro to the macro level
- Certain individuals are influential. Need to identify them and/or their institutions bearing in mind that their involvement can have a positive/negative impact on outcomes of the research.
- Need to look at the issues surrounding the transfer of results from developed to developing countries

Andy Oxman Presentation: Systematic review of qualitative studies of evidence use by policymakers

Found 24 mostly retrospective studies, including a total of 2041 interviews.

Findings:

- Importance of personal contact
- Research must have a brief clear summary with recommendation
- Timeliness and relevance of research
- Good quality
- Confirm current policy/self-interest
- Community pressures

Barriers:

- Mutual mistrust/naivety of policy makers and scientists
- Lack timeliness and relevance of research
- Power and budget struggles
- Absence of personal contact
- Political instability and high turnover of staff

Researchers should:

- Use personal and two-way communication
- Provide brief summary
- Include effective data
- Ensure perceived as timely, relevant and high quality
- Avoid trying to intervene in areas where there are severe power/budget-struggles and high turnover of decision-makers (if possible!)

Other suggestions:

- Give policymakers a stake in the research so that they are more likely to

implement it (although this may have negative implications for the outcomes).

Key message: we should build these findings into the tools Practihc is developing.

Small Group Meeting: Policy: Monday Morning 1130

Present: Allen Dale, Andy Oxman, Merrick Zwarenstein, Ana Maria Novoa, Julie Cliff, Godfrey Woelk, Cecilia Stalsby Lundborg, Lelia Duley, Simon Lewin, Elba Gomez, Ubaldo Farnot, Georgina Rojas, Signe Flottorp

Suggested agenda:

- Magpie study.
- Develop tools/resources based on what we already know
- Case studies?

Magpie Follow-Up:

The pilot was helpful re identifying barriers to implementation. What are the experience-based lessons learnt? For future trials it would be useful to have a checklist to offer to trialists, that they could include in their protocol including items such as:

- Include stakeholders early on in the process.
- During visits to multicentre trial sites, do not focus only on the trial clinicians, but speak to the decision-makers as well.

The checklist and results of SR of health policy can be included in tools.

Draft of Magpie health policy study will be circulated to Practihc group and collaborators.

Should Practihc do some Country-based case studies of evidence use?

Divided opinions and ambivalence in the group.

Disadvantages:

- Unless collaborate with a senior person in the country concerned enthusiasm is generally lacking.
- Too costly in terms of financial resources and manpower. Should just use information in existing case studies.
- (But a possible sources of funding for this project in Southern Africa is GTZ - German Technical Development, which provides small grants (approx US\$ 7000 for HSR studies.)

Advantages:

Case studies can be used to engage policy-makers. They can be used as a form of intervention, as the research itself raises awareness and influences policy (e.g.-anti tobacco projects have used this tool).

If there is a health service partner helping with design and if there is collaboration with aid agencies and others, it may increase the resources available and the influence.

Possible case studies:

- A case study of WHO. Might result in concrete recommendations.
- Possibly look at Cuba, Mozambique and Zimbabwe for the purpose of learning

and intervention. Focus on the extent to which evidence from developing country trials is used.

Action Plans:

1. Magpie study

It was agreed that, despite major limitations with the data that were collected, both the study undertaken in Oxford with the Magpie trialists and the pilot survey on the availability of MgSO₄ provided useful information. Andy Oxman, Simon Lewin et al will prepare a draft report to circulate and publish. This will include some important lessons learned from the Magpie study regarding questions to ask during site visits. It was also agreed that the survey of low-income countries would be unlikely to yield sufficient information relative to its cost and it will not be completed.

2. Case studies in partner countries

Godfrey Woelk developed a first draft of a protocol, which was discussed and will be circulated.

3. WHO case study

Andy Oxman will prepare a first draft of a protocol and circulate this

4. Tools for improving the use of RCTs by policy makers

Andy Oxman will take the lead on developing policy-related tools for PST. He will circulate a first draft outlining possible tools and plans for identifying/developing these. Possible tools might include examples, strategies for involving policy makers in formulating questions, strategies for presenting results to policy makers, a checklist

Workpackage 2: Developing country RCT Database

Sunday preplanning

- Possibility of using Cochrane CENTRAL (a register of all RCT's identified on Medline and by the Cochrane Collaboration) to identify and describe RCTs in 'developing' countries
- Not much progression on this so far
- A 3-page protocol and data extraction sheet has been drafted. Possibility of 20,000 relevant trials
- Need to know what to search what data to extract and whether to look at all or sample.
- Possible collaboration: Mike Clark, Euro mental health project
- Interested in this project: George Swingler, Merrick Zwarenstein Richard Allen Dale, Cecilia Lundborg Stalsby

Plenary: DC RCT database: Monday afternoon 1400

Lelia Duley presentation

Key issues to consider:

- Sample size? large/small sample
- How can one make it easier to extract information on clinical problems across the broad spectrum?
- How will interventions on clinical problems be extracted if the coder lacks clinical experience?
- What outcome measures?

George Swingler presentation:

- African trials register developed by the South African Cochrane Centre. It is a resource to study the epidemiology of African trials.
- Initial aim: extract basic data on all trials utilising health conditions and methodological quality as criteria.
- Constraints:
 1. Time and resource constraints
 2. Difficulties in data extraction and operational definitions: what does 'African relevance' really mean?
- Study 1: relationship of RCTs to the burden of disease in Africa. Very focused and quick. Only needed the number of participants in the trial and the health conditions, which are available in the abstracts. Mainly use electronic abstracts.
- Study 2: address associations of non-African collaboration with Africans and whether this affects the relationship positively or negatively. Used the 'clean' database from Study 1. Utilised case control design. Require the hard copy of the trial, which takes longer than data extraction and increased cost. The database needed updating.

Tension: between doing in-depth look at a small sample and a bigger 'quick and dirty' sample. With the quick and dirty approach one can never be sure that it is a randomised clinical trial but one can get a rough idea. It depends largely on what

question one wants to address.

General discussion: RCT database:

Purpose of database: It cannot be a register (as this implies a long-term commitment to be kept up to date). A database is a term used to describe a collection of studies that have been done to date, with no implication of long-term maintenance and updating. It will describe the epidemiology of RCTs in low and middle-income countries. . It forms the building blocks for systematic reviews. It highlights where evidence has come from and the setting in which studies have been conducted. It will be placed on the web.

Problems with this approach:

- It does not clearly highlight which trials take a pragmatic approach.
- Problems of developing countries may not only be clinical ones, but organisational problems as well, and so there is a need for fields on the data extraction sheet to allow for studies of organisational change interventions.
- Many trials are based in both developed and developing countries. The multi-centre nature of some trials needs to be captured
- Depending on the size of the database it will require a great investment of resources (time/financial). But need to be wary of restricting it too much
- Need to clearly identify what are the priority questions. Three examples:
- Is it intended to shame agencies that have performed poorly or congratulate those who have done a better job?
- Can we learn any lessons from it to build into the protocol training tools?
- Can we use it to find exemplary examples, which can be made available when there is a need for teaching or research? Need a clear objective and sampling strategy.
- The work does not need to be carried out by a skilled researcher and not by someone with content-expertise (can't afford a skilled, content area expert anyway due to financial constraints). However, a level of skill is necessary to answer questions on the data extraction sheet e.g. medical terminology/question of quality?
- Larger samples would require more language skills. Need to decide whether to limit it to English, Spanish and Portuguese studies. (Call for French speakers).

Value:

- The broad-brush approach is a powerful form of advocacy. In-depth work could take place at a later stage.

Small Group Discussions on DC RCT Database: Monday afternoon 15:00

Small Group 1:

Questions which should be addressed:

- How many trials have been done since year 2000 by country?
- How many trials have been supported by particular funders?
- What proportion of trials have been pragmatic?

- What are 'good' examples?

Method for each:

1. Trials: examine all trials on the CENTRAL database since 2000 extracting only country of conduct and year of publication (also tag. If multinational/multicentre) – this can be done electronically.
2. Trials by funder: from a small (200-300) representative sample of these trials identified in 1 above. Need to extract funding source (as on data form) and funding agency (specify if international).
3. What proportion are pragmatic – use same representative sample identified in 2 above. Collect: clinical problem or organisational area; randomised; allocation concealment; cluster; crossover; experimental intervention; control intervention (as per original form) and add fields for 'relevance' and whether 'pragmatic' or not.

Definitions:

- Relevance: if a clinical problem classify relevance according to global burden of disease. If non-clinical/organisational classify as relevant.
- Pragmatic: Essential elements are: * practical intervention; * useful to developing countries * clinically important outcome (Use the schema outlined by Dave Sackett to help guide this)

Good Examples:

From the sub-sample identify 'good' examples purposively. This needs someone with a basic level of competency to address this.

Small Group 2:

Assessment of quality of trials in developing countries

Key questions:

- What are the objectives of this database?
- Pragmatic RCT's or RCTs?
- How this information will contribute to Practihc?
- Using all possible trials or just a sample?
- Only the last 10 years or everything?
- Who will decide on the methodology?
- What do you want to know about pragmatic RCTs? Survey among researchers in developing countries.
- Need a database with all possible RCTs from developing countries but analysis must be limited to a sample of them
- Need to assess the quality of RCTs (may need a skilled researcher)
- Need to decide what we want to know exactly.

Small Group 3

- Present: Godfrey Woelk, Eduardo Bergel, Ana Maria Novoa, Chris Seebregts, Cecilia Lundborg Salsby, Simon Lewin
- According to overall description, this group needs to be of local relevance and useful in terms of decision-making. The inclusion criteria include trials where

- participants are from developing countries
- Possibility of involving multinational pharmaceutical companies. More involvement from people from developing countries is needed.
 - Multistage sampling:
 - need electronic information
 - weighted sampling strategy
 - Need to decide what kinds of focus do these clinical trials have and who are the participants. Need to address clinical and other interventions
 - ATLAS: use the process to find the key words
 - Quality = standardised
 - Relevance to DC: need to address topics of high priority, top ten of burden of disease
 - Pragmatic or not: sub-sub-sub sample
 - Funding: methodology. Difficulties of obtaining hard copies.
 - Collaborative/one-country
 - Setting: community/hospitals
 - Main outcome measures: how to create a typology of outcomes
 - Time trends
 - Perceived use: oral/advocacy

Workpackage 3: Tools Group

Sunday preplanning

Action Points:

- Shaun Treweek gave a presentation on the Protocol Support Tool.
- Carl Lombard will send a number of South African RCT protocols to the tools group. The protocols may be available as hard copies only. Chris Seebregts offered to scan these and convert into electronic copies if necessary.
- One partner from each of the developing countries could provide details of particular issues in that particular country, that needs to be taken into account in RCT design. This could help future trialists to overcome country specific hurdles.
- Only content developed by Practihc will be translated into Spanish.
- The content will be sent to CREP section by section for translation.
- The management group needs to decide who has editorial responsibility. This will need to be decided in Cuba.
- Concerns re the scope of what type of trials were raised. A section will be added to the PST stating which type of trials the tool will help with.
- The tools group will focus on two-arm individually randomised trials. However, guidance will be provided for other study designs. This could link up with a bibliography.
- It was suggested that a hyperlink to a glossary should be included in the PST.
- Distribution – It was suggested that a compact disk could be distributed to ministries and hospitals. They could then replicate and distribute to potential trialists.
- Where no individual has been named the PIG group has joint responsibility for these actions.
- The Clinical Trial Simulator (CTS) was briefly discussed and it was decided that a CTS sub-group meeting in Cuba was required. Chris Seebregts, Eduardo Bergel and Dave Sackett will take responsibility for this.

Small Group Discussion: Clinical Trial Simulator Tool: Monday Morning 1130

- Dave Sackett presented the CTS (Clinical Trial Simulator) tool that had been developed and used at McMaster University in Canada in the eighties, and briefly outlined the use and application of this tool.
- Discussion on the priority of this as a training tool followed. It has wider use than only as a training tool
- Three groups expressed interest in contributing to development of the CTS: Eduardo Bergel (Uruguay), Colombia (Juan Lozano), South Africa (Carl Lombard and Chris Seebregts), Dave Sackett as helper.
- Possibility that may need to extend the Practihc budget
- Decision: in principle the tool has support. Basic planning should be done. It was decided that a prototype version would be ready for evaluation by the group by the June report back. Eduardo Bergel has taken responsibility for this action with South Africa adopting a supporting role.

Plenary: Protocol Support Tool: Tuesday Morning 0830

Presentation by Marion Campbell, Kirsty McCormack and Craig Ramsay

- Call for input from other partners to add to Aberdeen's minimum deliverable. Currently deals with 2-arm RCTs in depth and will flag issues for other (esp. cluster) designs. Depending on time, resources, user group and contributions from other partners the tool is open to further development by another format.
- The philosophy underlying its design was that the Protocol Support Tool (PST) should:
 - Function independently from the internet. I.e.: must be used locally.
 - Must expand on what people are familiar with and must be familiar to novices;
 - Must support multiple languages.
 - The chosen design uses the help system that comes with Windows. Plan to make programs executable files that do not rely on an individual possessing particular software.
 - Need to decide what generic resources to include. It is currently 3 meg so do not want to increase the size too much.
- Call for input on what to put in it? How much to put in it? How in-depth and deep to make it? And how to use the library further? Can the HTML format be replaced by a more useful format?
- The skeleton structure is deliberately restricted as Aberdeen awaits feedback.

Future plans:

- Link protocol support tool with didactic training materials.
- Make it possible to use without internet connections.
- Develop it to allow users to: get tools and updates via email, by emailing to an 'anonymous email address'.
- Update content: create an IT tool that allows individuals to have responsibility for updating and modifying parts of the website and protocol support tool.
- Find ways of overcoming university security firewalls, which prevent it being emailed as an attachment.

Time line:

Full first draft version in English and Spanish to be made available for comment by the middle of the year.

Final points:

- Marion Campbell requires more example protocols for the protocol library of the PST, and for use in examples in the PST- these can be sent to her electronically or on hard copy.
- Possibility of translation into other languages (Shaun Treweek has been approached by an Italian colleague): depends on the quality of the translation and whether the translator can update it.
- Issue of copyright: As the tool is produced by Practihc and placed on the net Practihc does not specifically need to register copyright. A disclaimer needs to be inserted that it is a free service and users should not be charged.
- Dave Sackett will help the Protocol Support Team in any way they want.

Workpackage 3b: Training Materials

Sunday preplanning

Discussion points:

Who is our consumer or target audience: it was agreed that there are three main groups who have different training needs:

- People wanting to learn about trials in general
- People with specific research questions who wish to develop a protocol. (This is the group that was identified at the Cape Town meeting as being a priority for training materials design. A second priority was to develop very short training experiences for policymakers, to familiarise them with the advantages of RCTs as sources of evidence for decision-making. Other groups e.g. UK MRC is already developing training materials for trial co-ordinators.
- Trainers

Training approaches for these different groups may need to be different. e.g. content overview for those with generic information needs or problem based learning for those trying to develop specific protocols.

What are the training needs: it was agreed that it would be helpful to discuss training needs with the Practihc members. It was acknowledged that this has been discussed in Cape Town but would usefully be revisited.

Training materials within Practihc: it was acknowledged that a number of Practihc partners already have well-developed training materials. It was agreed that these need to be collated and evaluated for suitability for use in this context. It was agreed that it would be helpful if partners who already have training materials available could present some of their content at the meeting.

Prioritisation of training development: it was agreed that prioritisation of training materials development was necessary. This should be raised with the larger Practihc group.

Responsibility for taking training forward: it was agreed that appointment of a convenor to co-ordinate development of training materials was key. It was agreed that this issue be raised with the management group.

Plenary: Training materials: Wednesday Morning 0900

Edgardo provided background on training materials. At the last management call it was decided that searching within Practihc and its partners was necessary. However, little feedback was received.

Discussion questions: who is interested in leading or joining this group? Where can Practihc find training materials? Who is the target audience? Will the courses be didactic or training based? Are there any other formats for teaching?

Audience: 3 possible audiences were identified:

- Those with generic knowledge
- Those with protocols

- Trainers.

According to Marion Campbell we should start with those with generic knowledge but not lose sight that we will go further. In other words, we should start where we can produce a deliverable.

Dave Sackett's presentation:

- He holds workshops in North Woods for those who want to do particular studies, mainly randomised trials.
- Students apply with a protocol idea (of any length) which they present at the first meeting. They also list their objectives. In the workshop sessions each participant has the opportunity to direct the discussion for 75 minutes.
- The training materials include specific handouts on specific topics. Dave Sackett is currently rewriting the textbook on Clinical Epidemiology. McMaster materials for a course on protocol design are also used, and Practihc is welcome to make use of any of these.
- In terms of teaching, DS combines the formal didactic method with the group solving method.

Small Group: Training Materials: Wednesday Morning 0930

- This discussion group was led by Edgardo Abalos.
- Importance of populating materials with relevant local examples.
- Material needs to be flexible. Flexible in terms of where and how they can be used i.e. allows for long distance learning. Need to combine lectures and problem-based learning.
- Teaching material must be linked to tools i.e. need for increased communication between workpackages.
- Leader of this group needs to have detailed specific tasks
- Need to populate training materials with anecdotes about trials that have failed/succeeded
- Course materials need to be linked to the PST. Require section by section links and one way link to training materials from the PST
- Course will also need to cover some areas not covered in the PST e.g. how to run a trial.
- Want materials for trainers on how to run problem-based learning
- Want course materials to have its own navigation system on the web
- Search strategy: want to get information from Practihc partners
- Current known sources of information on training: CREP, CLAP, Dave Sackett. Cape Town slides, Trial Managers Network

Action:

- Edgardo Abalos and Juan Lozano to coordinate training materials
- First draft of teaching material will be available for contributions from other partners in 6 months time
- Juan Lozano and Edgardo Abalos (and Barbara Farrell) to lead the search for internet and other materials
- Members who will assist the training materials group on specific tasks: Dave Sackett, Juan Lozano, Lelia Duley, Edgardo Abalos, Shaun Treweek, Susanne Doepfmer (especially to provide anecdotes), Cecelia Stalsby Lundborg, George

Swingler, Eduardo Bergel, Juan Carlos Vazquez, Craig Ramsay, Kirsty McCormack and Marion Campbell (help with ensuring linkage with PST)

Workpackage 4: Country Plans

Sunday preplanning

Main agenda for discussions during Cuba workshop:

- Agree on a minimum country-level action plan.
- How to identify relevant groups to support them.
- Should there be active marketing for the training courses (which are the minimum country level activity?)
- How should participants from developed countries contribute to the country level activities of partners from developing countries?
- How to co-ordinate collaboration on a regional cross-country level (to share resources)
- How to involve people from other countries not yet involved in Practihc.

Plenary: Country Level progress: Wednesday Morning 1100

Argentina:

- A number of RCT projects and training courses exist that are not funded by Practihc but are linked to CREP, which is of course a Practihc partner.
- Ready to start translation of PST
- Training materials developed in Argentina are available for use by Practihc
- Training a research fellow in cardiology (supported elsewhere)
- Running RCT funded by WHO
- Protocol funded by UNICEF
- Major collaborator in Magpie Trial Follow Up Study

Colombia:

- Focus on training at different levels and the distribution of Practihc products through existing networks (INCLEN, LatinCLEN)
- Training at Undergraduate level (School of Medicine) and Graduate Students of Clinical Epidemiology.
- Can contribute to teaching materials.

Cuba:

- No national official register of Clinical Trials. Institutions maintain their own registers. Finished and published research is only available. Total of 114 clinical trials were found (1973-2002). Not necessarily pragmatic.
- Workshop on evidence based medicine held on 25/10/2002
- Practihc course 13-15th February 2003.
- Increased links between clinicians and policy makers at provincial level.

Mozambique:

- Sent two participants (Mohsin Sadat and Fatima Abacassamo) on the course in Cape town. They gave full feedback to colleagues on their training there, and will use this training in their further research
- Incorporation into training: MPH course and undergraduate course will now include RCT modules.
- Future plans include more RCT training courses and the creation of an interest

group attached to a Practihc course and a National Health Conference (held every 2 years)

- Need for materials and training in Portuguese (or in Spanish, which is easily understood by Portuguese speakers)
- Possibility of case study on use of evidence by policymakers, and look at how guidelines are based on evidence
- Lelia Duley and Eduardo Bergel to provide contacts

South Africa:

- One Trial protocol from first workshop has been completed and results have been carried out. Another protocol for an RCT on respiratory care has been completed and been funded, and is to be implemented in Free State province primary care clinics in 2003. A number of RCT have been stimulated by the general increase in RCT awareness, arising indirectly out of Practihc but not attributed to Practihc
- Max Bachman did include sections on RCTs in undergraduate courses at the University of Free State, but has now left, and so the future of these training modules is not certain.
- Chris Seebregts has developed and maintained the Practihc website, where both Practihc and non-Practihc sources are used to fund I.T personnel.

Uruguay:

- Developed a Trial management system for data management and data quality assurance and transmission
- Building a network of CLAP associated centres, selected by ministry of health in each country with a PAHO/WHO representative. Staff trained on Evidence Based Medicine, evidence based guideline development, designing and conducting RCTs
- 2002 hosted two five-day workshops on Design and conduction of RCTs
- Webpage: working on design of web portal in maternal and child health care
- Published one systematic review and two protocols in Cochrane Collaboration
- Started implementation phase of cluster randomised multi-centre clinical trial

Zimbabwe:

- Godfrey Woelk has integrated issues regarding pragmatic trials in MPH courses
- Plans to have meeting in March/April to discuss and increase awareness

Small Group Discussions: Taking country plans forward: Wednesday Morning 1200

Issues to consider:

- How Practihc can help countries by:
 1. Building capacities in and among countries (region networks)
 2. Training trainers
 3. Distributing materials and tools
 4. Building partnerships
 5. Linking organisations within regions
- Evidence based healthcare VERSUS randomised clinical trials. Need to look at the use of evidence in guidelines. Do we need to develop a protocol on this? Do we require more funds for this?

- What do developing countries need from developed countries?
- How best to utilise the budget for projects within countries?
- Are there alternative methods of communicating information to and between developing countries that are not as problematic as Emails and the Internet? Possibility of a CD? Importance of telephone calls and physical meetings
- Need to reconsider the need for a list-server?
- Should Practihc work towards products?
- Themed teleconference calls, involving different people in different calls
- Development of clinical trials simulator as a useful tool for group training and protocol development
- Issue of credit particularly since Practihc is a concerted action funded by the EU, which is not supposed to fund specific projects but is supposed to support interaction, intensify and extend existing work of Practihc partners. The issue is not about credit, but whether the protocols can help or be helped by Practihc for example, if they can be made available in a library as an example, if their review can provide additional input or value and if teaching materials can be improved through Practihc.

Actions:

- Eduardo Bergel, Juan Manuel Lozano and Chris Seebregts to work on development of clinical trials simulator
- A calendar to be established on Practihc's website listing the partner's travel plans so as to increase the range of possible meetings and workshops.
- Information to be sent to Zosa De Sas Kropiwnicki regarding the type of workshop needed and wanted.
- More focus to be placed on Southern Africa in terms of planning meetings and exchanges with other partners and planned training courses and workshops.
- South Africa to run a workshop on designing protocols and follow up trials by the end of 2003
- Zimbabwe to host a meeting about pragmatic randomised trails by the end of 2003
- In Latin America need to identify which activities will be assisted by Practihc
- Tools to be completed by the middle/end of the year and to be used in workshops
- Merrick Zwarenstein to co-ordinate country plans

Workpackage 5: Co-ordinating Support for Protocol Development

Plenary Session: Wednesday Morning 0830

Susanne Doepfmer presentation

The help service is designed to provide assistance to those developing protocols through Practihc. The goal is to help with any part of the protocol including searching for funding or providing statistical assistance. Partners who are directly in contact with the potential beneficiary are already meeting many such requests for support. This workpackage is designed to help those who, for any reason, are unable to be supported by a Practihc partner nearby. Susanne will act as a clearing-house for such requests, routing them to an appropriate resource, or to an individual who can help. In discussion it was agreed that it is a useful service but there is little awareness from potential users of this service that this kind of help is available

Action:

- Increase awareness of this resource through any RCT workshops that are being conducted by partners.
- The website needs a downloadable and printable section, which provides this description.
- Simon Lewin and Merrick Zwarenstein to assist Susanne in this endeavour.

Workpackage 6: Administration

Partners Meeting: Sunday Afternoon

Merrick gave a thumbnail sketch of developments. He described the governance of Practihc, and the role of the annual partners meeting as the democratic parliament of Practihc. This parliament could appoint another co-ordinator if it so wished. The management group, which ran the overall project, was also accountable to the partner group. Practihc officially began in EU terms only in March 2002. Practihc will run for 36 months from this date.

Co-ordination:

A number of problems were highlighted. These include:

- Groups find it difficult to gain access to skills offered by other partners and have little idea about problems and successes experienced by other partners.
- Some partners are at a standby stage as their workpackages have not yet begun-scheduled for later in the 36 months. These partners feel isolated from Practihc and cannot help other workgroups because they do not know what those groups might need.
- Unclear delegation of responsibility within work packages.
- Infrequent communication within the management group.

It was decided that:

- More communication is needed at 3 levels: inter-group (between workpackages which need to co-ordinate with each other, between countries, between regions), intra-group (within each workpackage group) and general communication.
- Increased communication between the co-ordinator and each workpackage and between the co-ordinator and the wider partners group is needed. More news and information on approaching deadlines needs to be sent between the admin group and the country partners.
- Workpackage leaders need to take more responsibility for the control of their workpackages. It was agreed that they are autonomous within the bounds of their original tasks, and are best placed to decide on how to carry out the goals of that workpackage.
- Workpackage leaders also need to take responsibility for sharing news of their progress, and other information with the network via the administrator (in particular their specific needs).

Suggested solutions:

- Regular teleconference calls (3/4 a year). They need to be scheduled for the year very soon (end of March)
- A clear agenda is needed, consisting of fewer items and more descriptions.
- These will continue to be run from South Africa to cut costs.
- The minutes of teleconference calls need to be distributed to the entire group. They need to be more explanatory. (At present they only make sense to someone who took part in the discussion- If they are to act as an information source they need to be more narrative).
- The full 6 monthly report to the EU project officer will be circulated to the entire Practihc group, and individual country partner reports will be placed on the web as soon as they arrive.

There needs to be increased follow-up after teleconference calls - Zosha will send out reminders well in advance to anyone who has a scheduled task .

Merrick needs to take on a more hands-on approach in terms of contacting country partners, and in terms of guiding administration activities

Other issues:

- A leader needs to be identified in the tools training group. Edgardo Abalos will take responsibility for the small group discussion on 'training material', as part of the tools workpackage. (In the small group discussion Edgardo and Juan Manuel agreed to co-co-ordinate this part of the Workpackage – see above).
- The website needs to include examples of RCTs that go beyond clinical trials of drugs.
- The design of the website and other tools needs to appeal to a larger audience.
- Marion Campbell is still waiting for protocols to build up the library of protocols.
- In the small groups the tools/protocols that exist need to be presented and priorities need to be set regarding the range of products that Practihc must deliver.
- Further discussion on the issue of materials e.g. PowerPoint slides needs to occur.
- The definition of pragmatic clinical trials needs to be clearly spelt out, in particular the notion of intervention/implementation.

Plenary: Administration issues: Tuesday Morning 1100

Actions:

- Zosa De Sas Kropiwnicki to circulate teleconference call minutes to all partners.
- ZD to follow up actions points.
- ZD to remind partners of deadlines.
- Creation of a brief newsletter to be sent out every 2/3 months, highlighting problems and successes, needs and services offered by partners.
- Partners to provide content of newsletter by keeping ZD updated.
- 6 monthly country reports to be placed on the web site.
- Partners to send country report regularly- reminders from Administrative office will be sent out, but please respond promptly.
- Partners to send financial reports regularly- reminders from Administrative office will be sent out, but please respond promptly.
- The money used for travel and subsistence in Cuba must be covered by Year 1 budget. Quarterly payments will continue, matched to spending of current resources in accordance with responsibilities of each partner. ZD and MZ to have individual discussions with each partner regarding finance and administration.

Partners Meeting: Wednesday Afternoon 1500

- Julie Cliff to investigate the possibility of hosting a meeting and parallel workshop in Maputo, Mozambique. Date provisionally set for second half of April 2004.
- General agreement in favour of the structure of the programme as offered at this Havana workshop. - I.e. one pre meeting preparation afternoon, one full day of meetings, one half day of meetings, one full day of meetings.
- Cuban partners were again complimented for an extremely successful meeting- excellent logistics, accommodation and social activities.
- Partners to inform Zosa De Sas Kropiwnicki and Merrick Zwarenstein of possible

- new projects.
- Payments will be matched to levels of expenditure in SA and in Germany. To be further discussed.

Workpackage description	Lead	Partner,	Milestones
Workpackage 1: Policy and Methodology 1. Case studies of the use of pragmatic RCTs in DCs. 2. Qualitative policy analysis of use of pragmatic RCTs in DCs. 3. An overview of methodological studies on pragmatic RCTs	Andy Oxman		Report : month 4 Update : month 12 Update : month 24 Update : month 36
Workpackage 2: 1. Database of DC RCTs 2. Analysis of trials in DC's from the database	Lelia Duley		Draft : month 6 Report : month 10 Report : month 12 Report : month 18
Workpackage 3: Tools 1. Gather existing tools 2. Specifications for new tools for study design 3. Translation into Spanish	Marion Campbell		Report : month 9 Report : month 15 Report : month 21 Report : month 13 Established : month 30
Workpackage 3b: Training materials 1. Gather existing tools 2. Specifications for new training materials 3. Translation into Spanish	Edgardo Abalos		Report : month 9 Report : month 15 Report : month 21 Report : month 13 Established : month 30
Workpackage 4: Country Plans 1. Action plans for activities in each DC partner country, using tools from wp3, 3b 2. Support for training workshops	Merrick Zwarenstein		Draft : month 12 Report : month 24 Update : month 36
Workpackage 5: Co-ordinating Support for Protocol Development An email 'Trial protocol clinic', to provide easy and prompt access to advice on trial protocol development, open to all users. Pragmatic RCT and associated systematic review protocols, submitted for peer review and funding.			4 protocols : month 18 8 protocols : month 36
Workpackage 6: Administration Project co-ordination and management			Report: month 12 Update : month 24 Update : month 36

Lelia Duley	England
Merrick Zwarenstein	Canada/South Africa
Marion Campbell	Scotland
Gina Joubert	South Africa
Edgardo Abalos	Argentina
Julie Cliff	Mozambique
Godfrey Woelk	Zimbabwe
Susanne Doepfmer	Germany
Andy Oxman	Norway
Cecilia Stalsby-Lundborg	Sweden
Ubaldo Farnot	Cuba
Eduardo Bergel	Uruguay
Juan Manuel Lozano	Colombia
Zosa De Sas Kropiwnicki	Coordinating Centre, Oxford

