



Practihc 14- 17 April 2004 project meeting in Maputo

## **Practihc minutes Maputo**

Present: Signe Flottorp, Andy Oxman, Astrid Dahlgren , Shaun Treweek, John Lavis, Michel Grignon, Gill Walt, Dave Sackett, Erasmo Huertas Tacchino, Eduardo Bergels, Merrick Zwarenstein, Susanne Doepfmer, Godfrey Woelk, Jimmy Volmink, Chris Seebregts, Carl Lombard, Simon Lewin, Karen Daniels, Juan Manuel Lozano, Ubaldo Farnot, Lelia Duley, Edgardo Abalos, Juan Manuel Nardin, Cecilia Stålsby Lundborg, Vinod Diwan, Max Petzwold + Mozambiqian partner researchers and guests

### **Wednesday 14th April**

#### **The reorganisation of Practihc (by Shaun Treweek)**

- The response from the commission so far has been encouraging.
- Two partners have withdrawn: University of Oxford, UK. and University of the Orange Free State, South Africa.
- Coordination of Practihc has moved to Oslo.
- Responsibility for the scientific component of the Oxford's Practihc contribution has moved to the University of Leeds.
- The project start date was confirmed to be 1/12/2001 by the commission and the previous cost-statements were rejected. Next money transfer will depend on the approval of the cost-statements that were submitted in February 2004.
- The budget has been revised favouring more workshops and each partners travel category; all unspent money from year 1 and 2 will be transferred to year 3.
- We will apply for a six-month extension.

#### Action item:

All partners should sign the letter applying for a 6-month extension.

#### **Protocol support clinic and mentoring- (by Susanne Doepfmer)**

- The clinic has only had a few requests, some of low quality.
- The goal should be to have about 20 ongoing protocols, with each Practihc member mentoring at least one person.
- The mentor will obtain help from specialists (e.g. statisticians) should such help be required.
- The workshops will be a natural place to market the Protocol support clinic.



Action:

- Susanne will allocate individuals submitting requests to a mentor. Susanne will base her choice on the list produced at the meeting.
- A form made available through the Web Page and by email, containing a few questions that interested individuals need to answer prior to getting support. Drafts of these were developed during small group work and Shaun will take this further.

**Presentation Clinical trial simulator (CTS) (by Eduardo Bergel)**

- The CTS can help individuals to plan RCTs and it can be used for teaching. It does this through allowing the user to vary factors such as sample size, loss to follow-up and compliance.
- It can help with the analysis and reporting of RCT results (according to CONSORT statement).
- There is now a CTS website ([www.randomization.org](http://www.randomization.org)), which gives the current version for download.

Action:

- Everyone should comment on the CTS by using the discussion forum laid out as a link in the tool, or directly to Eduardo.
- The CTS was also piloted in small group discussion during the next session and feedback was given directly to Eduardo.
- A cluster trial version of the CTS will be available for the next meeting (probably around Easter 2005).
- Eduardo's PowerPoint presentation of the CTS can act as part of the teaching material together with the CTS. A library of samples should also be developed for this purpose.

**Website- Chris Seebregts**

- The website should change from being a tool that serves the project group to a site that presents the project and it's resources to the public.



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Action:

- A new draft of the website was developed in a small group session. Chris will take this forward.
- We should attempt to get Practihc flagged by search engines.
- We should also try to get other sites to link to our web page. Dave will talk to some of his contacts (e.g. at the BMJ, JAMA). Eduardo will also talk to his contact at WHO about this.

**Other small group work:**

- An article/news item should be drafted for the new journal on RCTs, 'Clinical Trials'. Andy has the draft and will take this further.
- A short statement to appear on the website and in the trial protocol tool was developed.

**1600- Presentation Methodology Overview (by Andy Oxman)**

- The objective is to prepare an overview of systematic methodology reviews relevant to conducting and reporting a) pragmatic RCTs and b) systematic reviews of RCTs.
- The search includes Cochrane Methodology Reviews, UK HTA methodology reports and Cochrane methodology register.

Action:

- Abstracts and commentaries will be ready by summer and made available through Cochrane Methodology Group, the trial protocol tool and publications.
- Eduardo was added to the workgroup.



## Thursday 15th of April

### Update of progress with protocol tool (by Edgardo Abalos, Shaun Treweek)

- the name of the tool has changed from PST to Trial protocol tool.
- we now have a complete version of the trial protocol tool in both English and Spanish.
- we plan to break up the tool so that it can be delivered in a range of sizes.
- the tool could support customisation. This would allow a user to download extra content that is not part of the core tool.
- a British charity, eTalc, is interested in distributing our materials, at no cost, via their networks in developing countries.

#### Action:

- The two versions of the trial protocol tool were evaluated during the small group session. The group developing the tool will take this further.

### Country level progress

#### **Argentina activities (by Edgardo Abalos):**

##### WP4- workshops and advocacy to policymakers

- Two RCT workshops with a total of 63 participants
- Five EBM workshops with total 93 attendants
- Interactions with policymakers:
  - Advocacy by publications, disseminations, identification of key policymakers, norms & guidelines
  - Implementation through Corrientes City, Corrientes Province, NMH and Rosario City.
  - Evaluations by identification of facilitators and barriers

##### WP5 : RCT's & SR's

- Calcium supplementation trial.
- Timing for umbilical Cord Clamping after delivery.
- Treatment of asymptomatic bacteriuria during pregnancy.
- Multiple long- term follow up.

#### At protocol stage



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- Protocol under development: Antihypertensive drugs for HT during pregnancy.
- Protocol under development: Contribution of the components of the active management of 3rd stage of labour.
- Protocol under development: Early discharge of hospital after delivery.

#### WP3- Tools

- Contribution to Trial protocol tool contents
- Translation performed by experienced translators specialised in medicine working in close cooperation with the Rosario group and a scientific (physician) editor. The process includes back- translation done by separate group.
- Translation of a couple of pages for the website will be done using the same resources.

#### **Canada ongoing activities (by Merrick Zwarenstein):**

- An application was sent to the Canadian Health Research Council: funds were granted by the Global Health Research Initiative to collaborate with Practihc. Jeremy Grimshaw, Dave Sackett, Eduardo Bergel and Merrick Zwarenstein are being funded for a period of 1-2 years.
- Erasmo and Eduardo were funded to participate in a training course at the TROUT centre. Together they produced an application together with Bill Fraser (an obstetrician) for a multi-center study between development countries and Canada on the topic "Core clamp", which is similar to the topic of Edgardo's project. A full protocol is now being produced for applying for funds to do the actual study
- Systematic review on RCTs in Canada.
- Systematic review on "large scale" randomised trial in the world.
- Application for a study on knowledge translation including three randomised trials
- Further collaboration with Practihc on Trial protocol tool.

#### **Cuba activities 2003/ 2004 (by Ubaldo Farnot):**



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- Havana Practihc workshop Feb 9th-12th, 2003
- Havana Practihc workshop Feb 13th-15th, 2003.
- Publication and distribution of Practihc RCT course.
- Provincial Training Workshops planned to be held in June and October
- Magpie follow- up.
- WHO global data system for maternal and prenatal health (ongoing).
- PAHO maternal mortality in Cuba, a case study from 1950-1999 case study.
- Association between socio-demographic risk factors and cervical and vaginal infections during pregnancy. Study by WHO (ongoing).
- Protocol under development: Intervention for psychosocial barriers to sexual transmitted infection treatment.
- Protocol under development: RCT to compare 2 educational interventions about the use of emergency contraception.
- Provincial training workshop on RCT planned to be held in 2004: 27th-28th April, 23rd-24th July and 29th-30th October. The Havana workshops include policymakers
- WHO global data system for Maternal and Prenatal health.
- Maternal morbidity.
- Intervention for psychosocial barriers to sexual transmitted infection treatment.
- RCT to compare 2 educational interventions about the use of emergency contraception.

**Mozambique activities 2003/ 2004 (by Julie Cliff):**

- Preparations for Practihc's 3rd annual meeting
- Planning and preparations for workshop April 2004. Around 50 people will be attending.
- One of the people from Mozambique who were attending the Cape- Town course is in Melbourne, Australia doing his PhD, and the other is in Barcelona doing her Masters.
- Started a study on policymakers' use of evidence with Godfrey Woelk (Zimbabwe), Simon Lewin (South Africa) and Andy Oxman (Norway).



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**Canada/ CLAP activities 2003/ 2004 (by Eduardo Bergel/ Erasmo Heurtas):**

- Workshops by Canadian/ Eduardo/ Erasmo (each lasting 1 week)
- Two RCT workshops
- Six EBM workshops
- Three guideline development workshops.
- Hoping to raise the quality of routine data collection in the region to be able to run multi-centre RCTs.
- A cluster-trial to promote the use of evidence based care and how this may change practice in hospitals.
- Developing a cluster-trial version of the clinical trial simulator.

**Zimbabwe activities 2003/ 2004 (by Godfrey Woelk):**

- Started a study on policymakers' use of evidence with Julie Cliff (Mozambique), Simon Lewin (South Africa) and Andy Oxman (Norway).
- Workshops are on the planning stage and will probably be conducted in October 2004.

**South Africa activities 2003/ 2004 (by Carl Lombard/Jimmy Volmink):**

- Jimmy Volmink has joined as new collaborator based at the MRC in Cape Town.
- Training workshop in Pretoria April 2004.
- Jimmy Volmink is participating in a training course financed by MRC and will be held in June.
- A cluster trial on lung diseases.
- Chris Seebregts is updating the Practihc website.
- The south African partner has also been supporting the Clinical trial simulator and the trial protocol tool.
- Started a study on policymakers' use of evidence with Godfrey Woelk (Zimbabwe), Julie Cliff (Mozambique) and Andy Oxman (Norway).
- Practihc's final annual meeting is planned to be held in Cape town, probably around Easter 2005.

**Sweden upcoming events (by Vinod Diwan):**



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- One or two workshop are planned to take place in India in October 2004. Participants come with a protocol idea and will encouraged to complete it during the ten-day course.

**Studies of the use of evidence in policy making in WHO, South Africa, Zimbabwe and Mozambique (by Andy Oxman, Michel Grignon, John Lavis, Gill Walt and Simon Lewin)**

- Evidence is often not used for policy making when it exists.
- Andy's and colleagues' interviews with WHO department heads has found that WHO has no formal process in place for the use of evidence and it does not give much thought to local factors when developing guidelines.
- An additional study to be done chiefly in Mozambique, South Africa and Zimbabwe has as its objective to describe the use of evidence in WHO recommendations, focusing particularly on evidence of effects, and explore ways in which the use of such evidence might be improved. This will be done by semi-structured interviews, document analysis and literature reviews.
- Presentation (John Lavis): on how to enhance the contribution of research Knowledge to health policy.

Action:

- The policy group will continue working on these studies and will come back to the group for support when appropriate.

**Database of developing country trials (by Lelia Duley)**

- The Leeds partner has done a "quick and dirty search" in Central
- About 4200 references have been identified and about 80% of these will be possible to retrieve by Leeds themselves. The retrieved articles will be available on disc with the help of the Cochrane Schizophrenia group.

Action:

- Lelia distributed a list with the 20% of the search that Leeds would have problems to retrieve. Lelia asked all partners to go through this list and see if they have access to any of the journals. The data extraction form was piloted and discussed in small groups during the next session and feedback was given directly to Lelia.



### **Other**

- The European and Developing Countries Clinical Trials Partnership (EDCTP) is a program funded by the European Commission. The fund is primarily for trials on drugs for Malaria, TB and HIV/AIDS. Of interest to Practihc are EDCTP's potential support for:
  - Support training for people who will do trials with special interest in developing a specialised TST aimed at Malaria.
  - Knowledge translation.
  - Register of trials.

### **Friday 16th of April**

#### **Presentation of training courses and curricula (by Juan Manuel Lozano)**

- Training materials will be pitched at different levels depending on the audience.
- Two workshops have been designed based on the Cape Town/Havana workshops.
- Materials are available in both English and Spanish. Translations are performed in association with Argentina.
- Copies of pdf files are distributed with references and the slides from the lectures.
- The plan is to make all material available via the website.

#### Action:

- The training materials were discussed in small groups and feedback given to Juan. Further feedback will be sent after the meeting.

#### **Presentation of two tools (by Chris Seebregts)**

- Handheld Personal Interview (HAPI) Application. HAPI is a data collection tool for rapidly managing trial data electronically using Palm Pilots. By using a palm Pilot it is possible to collect data in a systematic way and the data can then be sent directly to the server by email for collection. One



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device can hold up to 6000 questionnaires at one time. The cost is about half of the ordinary paper-based data collection.

- Email-based web-browsing. This system, developed in Cape Town, will allow users who do not have access to Internet be able to receive web pages via email.

## **Saturday 17<sup>th</sup> April**

### **The future of Practihc (by Andy Oxman)**

Why should we apply for Practihc II?

- To build on our work, products and network, implementation of results from Practihc I, expansion of Practihc I and sustainability.
- The objectives will be
  - to do trials
  - sustainable support for trials
  - support for existing networks (eg. Eclampsia/ Magpie, EDCTP, Malaria/ TB/ AIDS, Adherence/ health services etc)
  - support policy makers.
- Possible trials include: Adherence to ARVs, Corticostreoids for TB, DOT vs SAT, Hypertension in pregnancy, Maternal Mortality Prevention, Reserpne for hypertension.

### Other suggestions for trials:

- Antibiotic use (Cecilia)
- Preterm delivery (Erasmus)
- Guidance re use of placebos/ withholding effective drugs (Dave)
- Economic evaluation, follow up strategies, assessment of newborn health, consumer involvement (Lelia)
- Include more social scientist/ qualitative methods (Ubaldo)

### How should Practihc II be funded?

Possible sources are EC, national agency's, and EU network of excellence.

### Action:

- Andy will send out a copy of the published article on trial support units.



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- Oslo will distribute John Lavis' Push-Pull presentation on how to involve policymakers.

### **Publishing policy and plans (by Merrick Zwarenstein)**

- A report is under planning for the journal of controlled trials or Lancet
- Trial protocol tool - two articles
  - Why the tool is useful - a more general article in BMJ
  - A technical article in Biomed Central
- Trial simulator- a possible place for publication can be in the Journal of Clinical Trials.
- Presentation at Health Information Forum, London. This is a network that aims to distribute health educational materials in developing countries.
- We should have a short flyer that we can distribute to key groups, eg. funding agencies.
- We can publicise the Protocol support clinic through our workshops.
- A one-day conference/ scientific meeting in Cape Town with focus on trials in development countries.
- The tools can be sent for review to journals, together with some descriptive material on the CD that we produce with eTalc.
- Distribute the Etalc CD to universities.
- A press release for Practihc.