MEETING OF THE DRUG SAFETY SUB-GROUP OF NRSMG,
ST CATHERINE'S COLLEGE, OXFORD, 27TH MARCH 2001
[Note: the Sub-group has now been renamed ADVERSE EFFECTS Sub-group]

Present: Andrew Boshier (AB), Sheena Derry (SD), Jayne Edwards (JE), David Finnigan (DF), Paul Garner (PG), Andrew Herxheimer (AH), Tom Jefferson (TJ), Yoon Loke (YL), Anne Lusher (AL), Deidre Price (DP), Saad Shakir (SS).

Chair: Saad Shakir

1. The meeting opened with introductions, a brief summary of the DSMG meeting of December 2000, the draft guidelines for handling ADRs in Cochrane reviews and the review on Melatonin for jetlag by Herxheimer and Petrie. It was noted that Alain Li Wan Po and his group had examined how Cochrane reviews had dealt with ADRs and found this patchy and unsatisfactory (Capetown Colloquium abstract; Cochrane Methods Group Newsletter, May 2001).

1.2 The issue of when a review should be updated was discussed - would an update on ADRs happen specially, or just when the review had been due to be next updated? Ideally this should be done as soon as possible, but it will not always be urgent, and often the next update would provide a convenient opportunity.

2. Remit of DSSG:
(a) Improving the evaluation of drug safety, unintended drug effects (serious and trivial) in Cochrane reviews.
(b) Offering guidance to Review Group editors in CRGs and reviewers on the synthesis of reviews. The group aims to contribute a section on this to the Cochrane Handbook.
(c) Considering also that RCTs represent only a part of the work performed in the area of Medicines Safety.

2.2 YL added that estimates of ADRs varied greatly between unblinded case studies, studies in which controls were blinded, and only then RCTs. PG mentioned that WHO review on malaria would attempt to include both effectiveness and safety.

3. It was agreed that ADRs are not adequately dealt with by the CONSORT statement on the reporting of RCTs. The AESG will try to contribute to the next version of the CONSORT statement (AH intends to join the CONSORT Group to contribute to the next version of the CONSORT Guidelines).

3.2 Meanwhile it would be useful to collect examples of ADR evidence in NRS of particular interventions, eg. vaccine studies.

4. Current work. YL and colleagues are attempting to identify trials that contain ADR data. The first study (by SD) was a large task and 25% of the papers were identified only by looking at the full text. SS suggested it would be useful if CONSORT required abstracts of published articles to indicate whether they dealt with ADR's. It

was also commented that the current Medical Subject Headings in MEDLINE (MeSH) do not include adverse effects or side effects, so that they cannot be used for our purposes.

5. Possible tasks for AESG were discussed briefly. A list of action points was agreed:

- Input to the next version of the CONSORT statement (AH).
- Further revise the draft guidelines for the Cochrane Handbook entry. Deadline for comments 1st August 2001.
- AB/AH will present the proposed guidelines for discussion by the NRSMG at its meeting in Davos on 19.04.01. [This was done and led to a useful discussion]
- Develop statistical concepts, including how outliers are dealt with – Professor Stephen Evans is writing a paper.
- Wider involvement - ISoP (Tunis 2001 17-21st Oct) meeting - SS to organise.
- Malaria, YL/SD to collaborate with PG.
- Encourage contributions from colleagues with varying backgrounds to present a workshop on ADRs at the Cochrane Colloquium (9-13th October 2001) of 1.5 to 2 hours of presentations with discussion (AH).
- Develop a list of methods problems and areas for further research: eg, design issues we share with NRSMG, handling pharmacological aspects (AH).