

CSM Scotland Centre for Adverse Reactions to Drugs (Scotland)



Minutes from Advisory Group Meeting Wednesday 23 June 2004 at 2.30pm In Seminar Room 5, 1st floor, Chancellor's Building, NRIE

Present: Professor D Webb, Professor of Clin Pharmacol, University of Edinburgh (Chair)

Dr N Bateman, Medical Director, SPIB and CARDS, RIE Melinda Cuthbert, Senior Pharmacist, CARDS, RIE

Jane Harris, Academic Team Leader for Public Health & Primary Care Nursing,

School of Nursing & Midwifery, University of Dundee Professor N Lannigan, Trust Chief Pharmacist, LUHD

Anne Lee, Principal Pharmacist, Medicines Information, Glasgow Royal

Infirmary

Dr R Taylor, Senior Lecturer, Dept General Practice in Primary Care, Aberdeen

1 Apologies for absence

Apologies were received from Dr Maxwell, Dr D Alexander, Professor S Hudson, Professor T MacDonald and H Purves.

2 Minutes of previous meeting

J Harris noted that in item 3.2 it should be 'extended nurse prescribing course' not 'nurse practitioners course'. No other errors or omissions were noted and the minutes were accepted as a true record.

3 Matters Arising

3.1 Progress with contacting NES to take forward incorporating BPS curriculum redesign recommendations into post-grad curriculum

M Cuthbert reported in Dr Maxwell's absence that he had arranged a meeting with Ms Elgin-Shartou at NES for mid July. J Harris pointed out that Ms Elgin-Shartou was actually the professional educator for nursing and might not be the most appropriate person to meet with. J Harris said she would contact Dr Maxwell directly to discuss this. Professor Webb will also take this up with him.

ACTION: J HARRIS/ PROFESSOR WEBB

Professor Lannigan suggested that Rose-Marie Parr, NES Director of Pharmacy, might be a useful contact as well.

3.2 Circulating ADR PowerPoint Presentation to all MI sites and to J Harris for extended nurse prescribing course

M Cuthbert reported that the PowerPoint presentations had been circulated. J Harris indicated that the nurse prescribers were very please with the ADR package and would be circulating it for use in their own areas.

3.3 Letter to Charlie Knox regarding access to the equivalent of GPASS in secondary care.

Professor Webb reported that a letter had been sent to Charlie Knox and a reply had been received (Appendix 1 and 2). Subsequently Professor Webb received a draft copy of the Hospital Electronic Prescribing and Medication Administration (HEPMA) systems and it was circulated for comments to the Advisory Group. No comments were received in response. Professor Webb will keep the group up to date on any further correspondence received.

3.4 Summary list of attendance at launch seminar

M Cuthbert reported that the list had been circulated (Appendix 3) and was for information for the group. Professor Webb enquired what the biggest impact of the meeting had been. Dr Bateman suggested that it was probably with representatives from the MHRA since the people that were in attendance from Scotland were already "converts".

Dr Bateman suggested that we should think about doing another national seminar in the future but with a more educational component. It was suggested that the symposium on toxicology could be used as a platform for this. Dr Bateman suggested that a symposium for general physicians might be beneficial. Professor Webb suggested that it be more aimed at the multidisciplinary group, perhaps under the aegis of the Royal College of Physicians and broader publicity could be given this time. Dr Bateman to write to Professor Webb about this.

ACTION: DR BATEMAN

3.5 Link from SMC website to CSM Scotland web site

Professor Webb and M Cuthbert confirmed that links to each site are now present in both web pages.

3.6 Letter to ASTCP to obtain names of local ADR "champions"

Professor Lannigan reported that the letter had been sent (Appendix 4), and the group accepted it with enthusiasm. They would identify candidates via their local D&T committees or pharmacy departments and advise.

3.7 Letter to Patrick Waller, DSRU regarding E-PASS approval for ADR on-line modules and reply

M Cuthbert reported that the DSRU did not intend to apply for EPASS accreditation since only 4 GPs within Scotland had completed the on-line ADR package in the previous year. They were open to the suggestion that CSM Scotland could act as an agent for the distance learning modules in Scotland. Their perception of what it might entail is that we would assess the answers submitted by the Scottish GPs, feedback and interact as necessary with

the GPs (generally by e-mail), provide certificates of EPASS accreditation and a joint DSRU/CSM Scotland certificate of completion and provide the DSRU with data regarding the outcome of all completion.

M Cuthbert reported that the cost of EPASS accreditation would be £250 per year for an NHS organisation. Considering that CSM Scotland would be hosting other educational sessions for GPs, it was considered by the group to be worthwhile to obtain EPASS accreditation for CSM Scotland. Dr Bateman enquired as to how much time it would entail to undertake this. It was suggested that M Cuthbert discuss this with the DSRU and report back.

ACTION: M CUTHBERT

3.8 Arrangement for Grand Round Talks in Greater Glasgow

Anne Lee reported that Grand Round talks on ADRs would be a priority for the autumn and it would probably need to be done at 3 sites (i.e. one in the East, West and South). It was suggested by Professor Webb that a local representative such as Professor Gordon McInnes from the West, Dr Ken Paterson from the East and Dr Keith Beard from the South could team up with the CSM Scotland representative in giving these talks. A Lee will advise of dates when available.

ACTION: A LEE

3.9 Adding another representative from an area pharmaceutical committee/community pharmacy to Advisory Group

M Cuthbert reported that H Purves had now officially resigned from the Advisory Group since he no longer had an active role in community pharmacy. He had anticipated that David Thompson would have contacted CSM Scotland to advise of an alternative candidate but to date no letter has been received. Professor Lannigan indicated that he would be speaking to David Thompson in the near future and would take this forward.

ACTION: PROFESSOR LANNIGAN

4 List of topics for research in Pharmacovigilance

Dr Bateman indicated that our main role was not that of research for CSM Scotland but we should help facilitate research projects such as data linkage that would have potential for improving patient safety within the UK. Anne Lee indicated that pharmacovigilance research was tied to the review of the yellow card scheme and should be taken forward under this umbrella. Professor Lannigan indicated that he might be able to help facilitate a liaison with Robert Gordon University now that he was an honorary Chair. He wondered whether we could look at initiatives that measure the impact of what we are doing (i.e. oncology ADR reporting). Professor Lannigan indicated that grant applications should be applied for to take this forward.

5 Review of the yellow card scheme

Dr Bateman indicated that the directors of the RMC had met with Dr Raine on 22 June in London to discuss the review of the yellow card scheme. The consensus was that the review was positive in some areas and negative in others. Pharmacovigilance research that would enable data linkage was considered a positive aspect. The most negative item noted by the group was direct reporting of yellow cards to London bypassing the RMCs. This recommendation held the misconception that even though RMCs have SOPs they may not meet the standards of criteria, and therefore to avoid inconsistencies in the handling of yellow cards all reports should go direct to London. This was viewed by the group as paradoxical and counter productive to RMCs. The possibility of direct inputting of yellow cards at the RMC sites was discussed but obviously due to resources required for hardware and software there would be problems with implementing this. Dr Bateman suggested that this could possibly be overcome by the funding already being provided by industry to address this issue.

Dr Raine had stated that the Minister had accepted the principles of the report but they were yet agreed for implementation. Further input from interested parties was pending prior to a final decision.

M Cuthbert indicated that at the moment the RMCs have no direct access to ADROIT, so if they did proceed with direct reporting to London then RMCs should be given access to ADROIT for direct access to any reports received from their areas.

Professor Webb suggested that a response to the consultation on the report be on behalf of the Advisory Group. Dr Bateman and Professor Webb would collaborate on preparing the draft letter.

ACTION: DR BATEMAN/PROFESSOR WEBB

Professor Webb requested that the draft letter be circulated for comments by 30 June to members of the Advisory Group, and comments be returned to the CSM Scotland by Wednesday 7 July.

ACTION: M CUTHBERT/ALL

Dr Bateman indicated that Bill Scott would like to see a draft of the letter, and the final letter would be copied to the CMO, the CPO and Professor K Woods (Chief Executive MHRA).

ACTION: M CUTHBERT

Professor Webb suggested that Professor Neil Douglas be contacted, as President of the RCP in Edinburgh, to add a response supporting CSM Scotland.

ACTION: DR BATEMAN

Professor Lannigan suggested that the RPSGB Scotland should also be contacted to do the same and he would make the necessary contact.

ACTION: PROFESSOR LANNIGAN

Anne Lee indicated that she would be attending a meeting of the United Kingdom Medicines Information Pharmacy Group and she would suggest that a response be prepared on behalf of this group as well.

ACTION: A LEE

6 Patient ADR Reporting

One of the suggestions of the Report of an Independent Review of Access to Yellow Card Scheme was that patient reporting be initiated. Initially the idea was to be piloted in Wales or Scotland as English RMCs were not easily recognisable. However, it was suggested that in Wales it would be difficult to do due to need to print in both Welsh and English. Dr Bateman had indicated that Scotland would be happy to pilot patient ADR reporting but he had discussed this with Professor Scott and there were concerns over cost. Dr Taylor would prefer that Scotland not be the only test site. Dr Bateman will keep the group abreast of any new developments in this area.

7 First Quarterly report 2004

M Cuthbert gave a summary of the 1st quarterly report (appendix 5).

8 Cascading of Urgent Messages from the CSM

Dr Taylor enquired as to whether or not there was anything else that the Advisory Group could do to clarify the cascade of information for urgent messages due to the apparent time lag which exist for GPs/physicians within Scotland in receiving these urgent messages after dissemination from the Scottish Executive. Also it was unclear as to where the cascade began for this group (i.e. did all of the cascades begin with the Chief Pharmaceutical Office or did the Chief Medical Office disseminate to doctors). Professor Lannigan volunteered to contact Pamela Warrington to discuss this and will feed back to the group.

ACTION: PROFESSOR LANNIGAN

9 Any other business

9.1 Publishing of minutes to the web site

Dr Taylor enquired whether the minutes from the Advisory Group meetings were published to the website. M Cuthbert advised that they were not. Much discussion ensued regarding this topic but it was decided the group that the minutes would not be published to website at present. However, it was decided by the group that information on the Advisory Group and its members be added to the website along with dates of meetings, and anonomised agendas. M Cuthbert will facilitate this with web page designer Ben Foster.

ACTION: M CUTHBERT

9.2 Patient representative on the advisory group

Much discussion ensued on this topic. However, it was decided by the Advisory Group that this decision would be postponed until the decision on patient reporting had been confirmed by the MHRA.

9.3 Progress to date of the Advisory Group

Professor Webb enquired if the Advisory Group have been meeting the needs of CSM Scotland. Dr Bateman indicated that an independent reflection of colleagues was always a

useful role and to date some progress had been made on the initial objectives of the centre. However, he indicated that maybe in the future changing the meeting times from every 4 months to a lesser frequency might be warranted. Professor Lannigan indicated that it might be useful to have a longer meeting once a year to discuss key initiatives. The major aims of the group were seen to be education, improving reporting, research, peer review and networking. It was suggested that a remit for the committee should be drafted for addition to the web page but would not be added until after approval by the Advisory Group.

ACTION: M CUTHBERT

9.4 MHRA representation at advisory group meetings

Dr Taylor suggested that at the future yearly work programme meetings it might be useful to invite an MHRA representative such as Dr Raine, and a representative from the Scottish Executive such as Professor Scott, to attend. This will be taken under consideration by the group.

9.5 Letters to ADTCs on reporting data to CSM Scotland

Professor Webb suggested that individual letters be done to the Area D&T committees of the health boards within Scotland giving them information on reporting for their areas to date for 2004. The group agreed that this would be a good idea, but we would anonymise the data except for the health board we were sending the letter to. M Cuthbert will action.

ACTION: M CUTHBERT

9.6 Lothian Nursing Clinical Induction programmes

M Cuthbert advised that she had contacted the organisers of the mandatory clinical induction programme and updates within Lothian to enquire if ADR reporting was covered in the programmes now that nurses have been added as official reporters to the Yellow Card Scheme. She received a reply indicating that it was covered but not very much time was allotted to it, due to the full agenda for the day. They indicated that they would not be inclined to increase time for this area unless it were absolutely necessary. M Cuthbert requested a copy of the information presented to the nurses be forwarded. She subsequently received this but it only entailed a photocopy of the initial letter from the MHRA saying they had been officially added as reporters to the yellow card scheme along with a copy of the yellow card on the back. M Cuthbert considered this to be inappropriate.

M Cuthbert said that she would contact them to suggest that alternate ADR education be provided to the nurses. Professor Lannigan indicated that it might be useful to contact Isabel McCallum, Director of Nursing LUHD, and he requested M Cuthbert e-mail him to ensure that this is done.

ACTION: M CUTHBERT/PROFESSOR LANNIGAN

10 Date and time of next meetings

The next meeting is scheduled for 27 October 2004 at 2:00pm in seminar room 5, First Floor, Chancellor's Building, NRIE. However, this date may need to be changed. M Cuthbert will be in touch via email to reschedule if required.

Summary Action List

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Item No	Item for Action	Responsible Individual
3.1	J Harris to contact Dr Maxwell regarding contact person at NES to take forward to BPS Curriculum redesign recommendations into post-graduate curriculum.	J Harris
3.4	Dr Bateman to write to Professor Webb to suggest the symposium on toxicology be used as a platform to do another national ADR event aimed at the multiprofessional group.	Dr Bateman
3.7	M Cuthbert to contact the DSRU regarding commitment time for administering the on-line ADR modules prior to obtaining EPASS approval.	M Cuthbert
3.8	Anne Lee to organise Grand Round ADR talks at 3 sites in Glasgow in Autumn 2004 with local representatives and CSM Scotland representative.	A Lee
3.9	Professor Lannigan to contact David Thomas to obtain name of new community pharmacy representative on Advisory Group	Professor Lannigan
5	Dr Bateman and Professor Webb to draft response to the Report of an Independent Review of Access to the Yellow Card Scheme on behalf of the Advisory Group.	Dr Bateman / Professor Webb
5	Draft letter to be circulated to Advisory Group Members by 30 June 2004.	M Cuthbert
5	Advisory Group members to provide comments on draft letter by July 7.	A 11
5	Draft letter to be copied to Professor Scott	M Cuthbert
5	Final letter to be copied to CMO, CPO, and Professor K Woods (Chief Executive MHRA)	M Cuthbert
5	Letter to Neil Douglas to be done to add a response to Independent Review of Access to the Yellow Card Scheme supporting CSM Scotland.	Dr Bateman
5	Letter to RPSGB Scotland to add a response to Independent Review of Access to the Yellow Card Scheme supporting CSM Scotland.	Professor Lannigan
5	A Lee to suggest United Kingdom Medicines Information Pharmacy Group to write response to Independent Review of Access to the Yellow Card Scheme in support of RMCs.	A Lee
8	Professor Lannigan to contact Pamela Warrington to discuss the dissemination of urgent messages and the origin(s) of the cascades.	Professor Lannigan
9.1	Agendas & dates for meetings of the Advisory Group to be added to CSM Scotland web page.	M Cuthbert
9.3	The remit for the Advisory Group and membership will be added to the CSM Scotland web page once the drafted remit is approved by the Advisory Group	M Cuthbert
9.5	Dissemination of anonymised reporting rates for Health Boards in 2004 to ADT committees.	M Cuthbert
9.6	M Cuthbert to take forward improving the ADR educational material presented to nurses within Lothian. Professor Lannigan to contact Isabel McCallum, Director of Nursing LUHD, to highlight issue.	M Cuthbert/ Professor Lannigan