
Minutes from Advisory Group Meeting
Wednesday 29 January 2003
in the meeting Room, Old Residency, RIE

Present: Professor D Webb, Professor of Clin Pharmacol, University of Edinburgh (Chair)
Dr N Bateman, Medical Director, SPIB and CARDS, RIE
Dr N Lannigan, Trust Chief Pharmacist, LUHT
Dr R Taylor, Senior Lecturer, Dept General Practice in Primary Care, Aberdeen
Dr S Maxwell, Senior Lecturer, Dept Clinical Pharmacol, University of Edinburgh
Sheena Kerr, Principal Pharmacist, Medicines Information, RIE
Melinda Cuthbert, Senior Pharmacist, CARDS, RIE
Professor S Hudson, Dept Pharmaceutical Sciences, University of Strathclyde
Professor T MacDonald, Deputy Director of MEMO, Ninewells Hospital, Dundee

1 Apologies for absence

Apologies were received from Mrs A Lee, and Mr H Purves

2 Minutes of previous meeting

Minutes from the meeting held on 30 October 2002 were accepted as a correct record.

3 Matters Arising

3.1 Launch Seminar

After much discussion it was decided that the autumn of 2003, likely the month of October, would be the best time. The Minister of Health wishes to attend the launch of the Centre so we shall have to ensure that the date is in keeping with his diary.

It will be a whole day event that will involve presentations on adverse drug reactions to promote pharmacovigilance as well. The suggested venues put forward were Stirling Royal Infirmary or the Stirling Management Centre.

A guest list will need to be compiled and further discussion regarding this will take place at the Management Board Meeting to be held on Tuesday 4 February 2003.

ACTION: MANAGEMENT BOARD MEMBERS

3.2 Membership of Advisory Group

The community pharmacist, Hugh Purves, has been appointed to the Advisory Group on the recommendation of the RPSGB. However, to date no non-academic GP or nurse representation have been appointed.

The non-academic GP representative should be ratified through the BMA and a recommendation for appointment will be sought from John Garner.

ACTION: Dr Maxwell/Dr Bateman

Two nurse representatives will be sought, one of which should preferably have a background in training and education. It was suggested by Professor MacDonald that the Kirkcaldy Nursing College or the Caledonian University in Glasgow would be two places from which a representative could come. Dr Lannigan suggested that the Scottish Education Board should be involved and their recommendation for representation on our Advisory Group should be sought.

ACTION: M Cuthbert

3.3 Education & Training

As discussed at the previously meeting, the 4 schools of Clinical Medicine in Scotland (ie, Aberdeen, Dundee, Edinburgh, and Glasgow), and the 2 schools of pharmacy (ie Robert Gordon's University and the University of Strathclyde) should be contacted to see if their curricullae currently includes any training in adverse drug reaction reporting.

M Cuthbert sent letters to both of the heads of the schools of pharmacy. To date one reply has been received from Professor Terry Healey from the School of Pharmacy at Robert Gordon University. In this letter he confirmed that within the pharmacy undergraduate programme there is undergraduate training in adverse drug reactions. It is covered in the second year, under legislation and licensing in the pharmacy practice 2 module. As well as, in the 4th year under risk to public health in the public health module. A one hour slot is allotted to each of these lectures in both the 2nd and the 4th years, and the lecturers who teach these components are Brian Addison and David Pflieger. M Cuthbert is still awaiting a reply from the University of Strathclyde.

The BPS are still currently developing new guidance for curriculum design and it is thought that it will be released in April or May of 2003. The Group will wait for this new guidance being launched before sending out letters to the 4 schools of clinical medicine in Scotland. Dr Maxwell will advise of this date.

ACTION: Dr Maxwell/Dr Bateman

Currently at the University of Edinburgh School of Medicine there is one session of adverse drug reactions training in year 3. Currently within Lothian there is a major concern of prescribing problems with new doctors which was sparked by an audit carried out by the Medicines Policy Committee. Professor MacDonald reported at the school of medicine in Aberdeen there is not much practical training given on prescribing or on the reporting of adverse drug reactions. However, at present the McLeod interactive specialist modules have been launched and it does involve sessions on adverse drug reaction reporting. It was suggested by Professor MacDonald that contact be made with Mary Jo Mcleod to obtain copies of these modules.

ACTION: M Cuthbert

Professor MacDonald also suggested that adverse drug reaction slides are available from the MCA for presentation purposes and they could be obtained from the secretary of the sub-committee of pharmacovigilance, Bridget Jennings.

ACTION: M Cuthbert

As well, the ISP have teaching slides that can be obtained, Professor MacDonald advised M Cuthbert the contact person is Mark Epstein.

ACTION: M Cuthbert

A PowerPoint presentation has been written by M Cuthbert for the purpose of adverse drug reaction training to nurses. It was suggested by Prof MacDonald that this presentation be reviewed by the Advisory Group at the next meeting.

ACTION: M Cuthbert

With regard to distance learning, SCPPE currently does an education pack on adverse drug reaction training. It was felt by the Group that the Scottish Education Board should be approached to see if they could become involved in the dissemination of packages for post-graduate training. Dr Lannigan suggested that an audit of teaching at present should be undertaken with nurses to see what they are currently doing and then from there we can see how we can share with them to develop their training needs. Chief Pharmacists have been approached for to assist with nurse training for adverse drug reaction within Lothian.

3.4 Article based on pre-launch report

A paper is currently being written by Dr Maxwell and M Cuthbert from the data compiled in the preliminary analysis of the CSM data for Scotland from 2000 and 2001. It is hoped that this paper will be finished in the near future. It initially had been hoped that prescribing data from ISD could have been obtained to answer the question posed by Professor Webb as to whether or not the low prescribing of new drugs and the Lothian Joint formulary may have had some impact upon the reporting trends seen in the preliminary analysis data. However, to date this has not been possible. Dr Bateman recently met with Richard Clark from ISD to discuss this since he is interested in this analysis as part of his MSc. M Cuthbert will pursue this with R Clark.

ACTION: M Cuthbert

It was also suggested that a BJCP editorial letter to announce the launch should be pursued.

ACTION: Dr Bateman/Dr Maxwell

3.5 Letter to Scottish Medicines Information Pharmacists and Trust Chief Pharmacists

A letter has been prepared and sent to all of the Scottish Medicines Information Pharmacists and all Trust chief Pharmacist within Scotland. (Enclosure 1)

3.6 Research

The centre must develop a cohesive way of dealing with and seeking funding for research initiatives, since there are a number of professionals within Scotland who would be interested in research into pharmacovigilance.

Scotland has great potential for the development of a pharmacovigilance system due to its size and the opportunity which will arise from the anonymised data from The Scottish Health Informatics Centre in Tayside. This centre will link ISD data and health care reports to make anonymised data available for research purposes. CSM Scotland should be able to obtain access to this data.

The ABPI is having an increasing influence in Scotland at present. It was suggested by Professor MacDonald that we might want to look into a partnership between Industry and the NHS whereby they might be willing to do research within our system and pay for it. The group was undecided upon this idea but it was agreed that a representative from ABPI from within Scotland would be invited to speak to the Advisory Group Committee about this point.

ACTION: Dr Bateman

Also Richard Copland from ISD should be invited to come to speak to the group to see how they can work with CSM Scotland on any future research initiatives.

ACTION: Dr Bateman

3.7 Electronic reporting

As discussed during the previous meeting the electronic yellow card reporting direct to London is of great concern to the group. For the period of October 10th to the end of December 2002, 178 reports were reported direct to the centre but 155 reports bypassed the centre during the same period. However, we do not know whether these 155 reports were due to electronic reporting or due to the use of old BNF cards with the London.

The AGM for CSM will be held on February 28th in London and at this point Dr Bateman will discuss these issues with the group. It was suggested by Professor Webb that informally Dr Bateman should make contact with Alistair Breckenridge or Martin Kendall to informally discuss these issues prior to the meeting.

ACTION: Dr Bateman

4 Quarterly report October – December 2002

The quarterly report for the centre for October – December 2002 (enclosure 2) summarises the reports received during that period. Greater Glasgow, Lothian and Tayside were the three geographical areas with the greatest percentage of reports, but Lothian was ranked number one. Hospital pharmacists accounted for 71% of these reports from within Lothian, with 41% of the reports actually coming from the oncology pharmacists at the WGH Edinburgh. Professor MacDonald suggested it may be useful to compare the overall reports for the United Kingdom for oncology medications to those for reports received from Scotland. M Cuthbert will try to gather this information together for a report to the next meeting.

ACTION: M Cuthbert

5 Dundee Health Informatics Initiative

Peter Davies is the head of the Health Informatics Centre, University of Dundee. The centre will transform data into information that can be used for research and audit. It will facilitate interdisciplinary research and improve access for researchers nationally and internationally.

6 Website Design and e-mail address

The website for CSM Scotland is currently being prepared. Dr Bateman circulated a copy of the home page for the site. Prof MacDonald suggested that CARDS should be changed to CSM Scotland at the top of the web page to avoid confusion over the identity of the centre. He also requested that the e-mail address be changed from CARDS to CSM Scotland. S Kerr agreed that this change can take place.

ACTION: M Cuthbert

7 Promotion of Adverse Drug Reaction Reporting

The centre will develop a slide package which can be used by members of the management group to make presentation to any interested parties.

8 Year one objectives

The suggested list of objectives for CSM Scotland was reviewed by the group and prioritisation of short-term, medium-term and long-term was assigned (Enclosure 3).

9 CSM Scotland representation on SCOP

Professor MacDonald, spoke to June Rayne of the CSM regarding this issue. At present there is fair Scots representation on the Committee and they need to re-balance with representation from within the UK. Prof MacDonald suggested he should have a deputy from within the advisory group who would be willing to attend any meetings of SCOP he was not able to attend. He will however need approval further from SCOP. He will write to June Rayne to obtain permission.

ACTION: Professor Macdonald

10 CSM Committee Members

Ross Taylor, who sits on the CSM Committee will check with A Breckenridge and M Kendall if he is able to share the confidential information from the CSM Committee meetings with the CSM Scotland Advisory Group.

ACTION: Dr Taylor

11 Date and time of next meeting

The next meeting will hopefully be held at the end of May on a Wednesday or Thursday from 1-4pm, with date and venue to be arranged. M Cuthbert will circulate suggested dates shortly.

ACTION: M Cuthbert

**CSM Scotland
Centre for Adverse Reactions to Drugs (Scotland)**

Royal Infirmary of Edinburgh
1 Lauriston Place
EDINBURGH
EH3 9YW

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Fax 0131 536 2827
E-mail: CARDS@luht.scot.nhs.uk
Your Ref:
Our Ref: csm Scotland\circular



02 December 2002



COMMITTEE ON SAFETY
OF MEDICINES

Dear Colleague

As recommended in the "Right Medicine - a Pharmaceutical Plan for Scotland", the Centre for Adverse Reactions (Scotland) [CARDS] has been established. The role of this centre will be to administer the yellow card scheme and promote pharmacovigilance in collaboration with the Committee on Safety of Medicines.

The centre started to process yellow card reports a few weeks ago but an official launch has not yet taken place. You will be advised of the details of this event in due course. However, a launch letter with an accompanying yellow card should have already been sent to you. Therefore, from this point forward all yellow cards should be forwarded to CARDS. It would be appreciated if you could ensure that your fellow colleagues are aware of this, and are encouraged to participate in the yellow card scheme.

Yellow cards with our address on it are available in the 44th edition of the BNF, and are also available from CARDS if required. If the yellow cards you currently do not have our address on them, they can still be submitted to CARDS by sending them to the address below. Please contact the centre to request a supply of yellow cards.

As you may already be aware from the recent insert which accompanied "Current Problems", nurses and midwives have been added to the list of professionals who can now report to the yellow card scheme. A very useful summary of the yellow card scheme was included in their launch which is enclosed for your information. You may circulate or photocopy as your needs necessitate.

Thank you for your assistance in this matter. We look forward to forging a partnership with you to promote pharmacovigilance in Scotland.

Yours sincerely

Sheena Kerr
Pharmaceutical Advisor
CARDS

Melinda Cuthbert
Senior Pharmacist
CARDS

Please address correspondence to yellow card reports to:
CSM Scotland
Centre for Adverse Reactions to Drugs (Scotland)
FREEPOST SCO 7777
Edinburgh
EH3 0BR

CSM Scotland

Centre for Adverse Reactions to Drugs (Scotland)

October – December 2002

Prepared by Melinda Cuthbert January 2003

The Centre for Adverse Reactions to Drugs (Scotland) [CARDS] officially opened on October 10, 2002. During this short time the centre has received 178 reports from Scotland. During this same period 155 reports have bypassed the centre by being submitted directly to the CSM/MCA London. The following summary details the reports received by CARDS directly.

Table 1 – Total reports received October to December 2002

Month	Number Received	Black Triangle	Serious Reactions
October	40	14	26
November	56	16	38
December	82	24	55
Total for Quarter	178	54 (30%)	119 (66.8%)

The breakdown of these reports by geographical area can be seen in Table 2.

Table 2 - Reports from October to December 2002 by Health Board

Health Board	Number reports	Percentage of total (%)	Population Health Board*	Number Reports per 100,000 population
Argyll & Clyde	8	4.49	531,065	1.5
Ayrshire & Arran	10	5.62	368,149	2.7
Borders	2	1.12	106,764	1.9
Dumfries & Galloway	1	0.56	147,765	0.67
Fife	8	4.49	349,429	2.3
Forth Valley	6	3.37	279,480	2.1
Grampian	12	6.74	525,936	2.3
Greater Glasgow	30	16.85	686,112	4.4
Highlands	9	5.06	250,147	3.6
Lanarkshire	10	5.62	623,283	1.6
Lothian	66	37.08	778,367	8.5
Orkney	0	-	19,245	0
Shetland	0	-	21,988	0
Tayside	12	6.74	389,012	3.1
Western Isles	4	2.25	26,502	15

* figures taken from data in Scotland's Census 2001

The data in the above table illustrates that the largest proportion of reports came from Lothian. This was due to the high number of reports received from hospital pharmacists. Of the 66 reports received from within Lothian, there were 47 (71%) reports from this group, with 27 (41%) of the reports coming from the oncology pharmacists at the Western General Hospital.

Oncology pharmacists at the Western General have been actively reporting all serious adverse reactions to cytotoxic agents for almost 18 months now. This process has been aided by the writing of a standard operating procedure on how to report ADRs, and what to report. This could serve as a model of how to improve reporting of ADRs by pharmacists. Table 3 shows the total reports by reporter group.

Table 3 - - Reports from October to December 2002 by reporter group

Reporter group	Number reports	Percentage of total (%)
Hospital Pharmacist	69	38.7
General Practitioner	67	37.6
Hospital Doctor	26	14.6
Community Pharmacist	11	6.17
Community Nurse	3	1.68
Hospital Nurse	1	<1
Dentist	1	<1
Total Reports	178	

As was seen in the preliminary report for the data for 2000& 2001, community pharmacists reporting still remains a problem area. Efforts will need to be made in aiding this group to improve their contribution to the yellow card scheme, and this should one of the long-term objectives of this centre. A power-point presentation has been prepared by Melinda Cuthbert to be used as a teaching aid for promoting ADR training to pharmacists. However, further initiatives will be necessary.

Nurses, midwives and health visitors were added as reporters to the yellow card scheme in October. A launch package was sent to all of them at that time. A power-point presentation has been prepared by Melinda Cuthbert for aiding in training nurses on ADR training. It will be made available to any individual who should wish to use it for this purpose.

Table 4 shows the top 10 reported medications for this quarter.

Table 4 – Top 10 reported medications from October to December 2002

Medication	Total Reports
Celecoxib ^(∇)	9
Imatinib ^(∇)	5
Citalopram	5
Aspirin	5
Carboplatin	5
Diclofenac	4
Influenza Vaccine	4
Venlafaxine	4
Risperidone ^(∇)	4
Ramipril	3

(∇) = Black Triangle

Table 5 shows the origin of the yellow cards

Origin of yellow card	Total number
A4 Form size	66
BNF	112

There were 25 requests within this quarter for additional information by the reporters. These involved either the furnishing of Drug Analysis Prints (DAPS), or more intensive literature searches to obtain the necessary information.

There were 39 requests made for additional information. To date 28 replies have been received in response to date.

The Annual General Meeting of the CSM/MCA is being held on February 28, 2003. The annual report for the data from Scotland is currently being prepared. It will contain the data collected by the Centre since going live, the bypass data, as well as the reports received prior to going live. A copy of this report will be forwarded to you in the near future.

Contact Details for CARDS

Telephone: 0131 536 2202

E-mail: CARDS@luht.scot.nhs.uk

Website: coming soon

Freepost

SC07777

Scotland

EH3 0BR

Objectives for CSM Scotland & Priority Assignment

Objective	Assigned Priority
Website Design	Short term
Launch Meeting	Short term/ Medium term
Standard Operating Procedures (SOP) for CARDS	Short term
Generic template SOP on how/what to report for ADRs for circulation	Medium term/ Long term
Training on ADRs	
- undergraduate	Long term
- postgraduate	Long term
- grand rounds talks	Medium term / Long term
- Establish link with NHS Education Board Scotland for promotion of ADR training and circulation of material	Short term / Medium term
- Training the trainers	Medium term/ Long term
- Distance learning / web-based learning	Long term
- Academic detailing to lead prescribing advisers, clinical governance representatives	Undecided
- Preparation of ADR promotion packages aimed at community pharmacy	Longterm (maybe in collaboration with NHS Education Board)
- Use networks to promote ADRs (eg. Paediatric pharmacist network, Oncology pharmacists, RCGP, PCTP, etc)	Medium term / Long term
Power point presentation packages for training of nurses and pharmacists	Short term
Development of Bulletin	Long term
Opinions on reporting from the multidisciplinary group of reporters	
- focus groups	Long term
Demonstrate benefit of Yellow Card Scheme in Scotland	Medium term/ Long term