

Yellow Card Centre Scotland Centre for Adverse Reactions to Drugs (Scotland)



Minutes from Advisory Group Meeting Thursday 15 June 2006 at 2pm Meeting Room, Royal College of Physicians of Edinburgh

Present: Professor N Bateman, Medical Director, SPIB and YCC Scotland, RIE (Acting Chair)

Sheena Kerr, Principal Pharmacist, YCC Scotland, RIE Melinda Cuthbert, Senior Pharmacist, YCC Scotland, RIE Sheila Noble, Senior Pharmacist, YCC Scotland, RIE Professor N Lannigan, Chief Pharmacist, WGH

Dr R Taylor, Senior Lecturer, Dept General Practice in Primary Care, Aberdeen Dr S Maxwell, Senior Lecturer, Dept Clinical Pharmacol, University of Edinburgh

Jane Harris, Teaching Dean, School of Nursing & Midwifery, University of

Dundee

Asgher Mohammed, Community Pharmacist, Glasgow representing RPSGB in

Scotland

Janice Watt, Principal Pharmacist Glasgow Royal Infirmary, representing

ASMIP

1 Apologies for absence

Apologies were received from Professor D Webb, Professor T MacDonald, Professor S Hudson and Dr D Alexander. In the absence of Professor Webb the meeting was chaired by Professor Bateman.

Professor Bateman welcomed Sheila Noble, Janice Watt and Asgher Mohammend to their first meeting of the group.

2 Minutes of previous meeting – 25 May 2005

Dr Maxwell commented that in section 4.1 of the previous minutes the title should be renamed to 'Progress with NES in spreading ADR education to health professionals' instead of 'Progress with contacting NES to take forward incorporated BPS curriculum redesign recommendations into post graduate curriculum'. With this change the minutes were accepted as a true record.

3 Matters Arising

3.1 Post graduate education regarding ADRs

Dr Maxwell reported that progress with the medical side is currently underway via DOTS (Docotors On-line Training System). DOTS is a national programme for all junior doctors in FY1 and 2. It is administrated by Dr Hazel Scott at Hairmyres Hospital but is a national programme under the umbrella of NES.

Under this programme all trainees must demonstrate on-line core competencies in certain areas, some of them involving medicines. Dr Maxwell has been in discussion with Dr Scott regarding the addition of an ADR DOTS package. Initially it was anticipated that it would be in

the August roll-out however, M Cuthbert reported that correspondence from the pharmacist in charge, Helen Barclay, indicated that due to a lack of funding at the moment it may be pushed back to the winter of 2007. However Dr Maxwell was confident that if the package was completed soon we might be able to still achieve the August roll-out. Therefore, it was requested that M Cuthbert complete the package ASAP and forward to Dr Maxwell for review.

ACTION: M CUTHBERT/DR MAXWELL

Once completed it will be sent to the group for comments and feedback before it is rolled out.

ACTION: ALL

Once the package is ready Dr Maxwell will contact Dr Scott to pursue the August roll-out.

ACTION: DR MAXWELL

J Harris enquired whether any non-medical personnel could access the DOTS package. Dr Maxwell reported that at present it is only the junior doctors who are able to access this programme due to passwords, however, there is a possibility that it would be generically useful for other professions. J Harris suggested that AHPs, nurse and pharmacists might also benefit from this programme once the DOTS platform is complete.

Dr Maxwell said that some of institutions had virtual learning for undergraduate medical students. So if we could get the ADR package working within DOTS then we could possibly then share the package with University learning programmes.

Professor Lannigan suggested that we should involve NES if we are going to roll-out the DOTSpackage to pharmacists, nurses or AHPs. Professor Bateman supported this idea.

3.2 Link from YCC Scotland to GPASS

Professor Bateman reported that he had received correspondence from Kenneth Harden who was optimistic that the Yellow Card Reporting icon on GPASS could be fully functional and switched on in the near future. Asgher Mohammed enquired whether an electronic yellow card could be incorporated into the EMIS IT link which is being rolled out to all community pharmacies in Scotland under the new contract.

Professor Lannigan said that Alison Strath would be the person to contact at the Scottish Executive Health Department, Pharmaceutical Division because she was personally responsible for the roll out of the EMAS system. This had been previously discussed at the YCC Management Board meeting and M Cuthbert is to pursue a meeting with Alison Strath to discuss.

ACTION: M CUTHBERT

3.3 Patient reporting

Dr Maxwell reported that currently with patient yellow card reporting small numbers are being received. More information is still required about the quality of the information that is being received on these yellow card reports. Dr Maxwell, Professor Bateman and Dr S Thomas (Newcastle) currently are preparing a proposal for research into patient yellow card reporting.

Dr Maxwell said that besides this we still have to do more to improve the quality of the reports from patients. Much discussion ensued with regard to how we could take this forward. One suggestion was the SHOW website, however since this venue is not promoted as a public domain this was considered inappropriate. Possible alternatives were:

- 1 NHS 24
- 2 Community pharmacist giving out patient information leaflets and yellow card patient reporting forms to patient directly
- Incorporate an "ADR week" into the community pharmacy poster window displays that money is awarded for under the new community pharmacy contract. Professor Lannigan suggested that we might best take this forward by liaising with Alison Strath.
- 4 Link in with the 'Ask about medicines' week
- 5 Adverts, paper advertising, academic detailing
- 6 Insert information for patients in bags with their medicines at community pharmacies
- 7 Incorporate onto the back of GP10 prescription forms

At present it is unknown which technique would get the most yellow cards with quality information. That is why it is important that the application for the research grant be pursued to see what would be the most successful way of communication ADR information reporting to patients and receiving quality reports.

Professor Bateman said that it would be important not to repeat other initiatives that the MHRA may be taking forward in this area with pilots, therefore we would need to work in liaison with them. However in the interim we would purse a bid for research, explore any contact that could take these suggestions forward and in the interim members could also contribute any ideas for the future.

Professor Lannigan suggested it might be worthwhile contacting Helen McKinnon who is responsible for the patient partnership forum of NES in order to discuss how we may best approach taking forward the patient yellow card reporting.

ACTION: PROFESSOR BATEMAN

4 MHRA new ways of working

Professor Bateman reported that a name change has taken place for the regional monitoring centres (RMCs). This is because the CSM no longer exists, they are now the CHM which is the Commission on Human Medicines. As a result the centre is now called Yellow Card Centre, Scotland. A new way of working is also being introduced for the RMCs which will see a change in function of the centre. This is in part due to

- the review of the yellow card scheme
- the concern of the MHRA to preserve anonymity/identity of patient on yellow card reports
- increased political [pressure because of incidents such as the COX II inhibitors and SSRIs]
- new data handling system called Sentinel

A formal contract has been drafted and is in the process of being signed by the RMCs and the MHRA. The functions of the centre will now be post-graduate education and education to the general public on adverse drug reactions. However, RMCs will still continue to do follow-ups for their area the cover. As a result the centres will no longer receive yellow card reports directly. Currently an ISAC application is pending as to what information will be released back to the RMCs to take forth education and training initiatives and promotion of adverse drug reactions within their areas. A meeting is to take place in July to discuss this application.

Professor Bateman said that YCC Scotland is already unique in that we have an multidisciplinary advisory group who are able to advise on pharmacovigilance training and how might we might best take these initiatives forward in Scotland.

5 Education & Training

5.1 NES post-graduate distance learning

Professor Bateman said that Scotland has a large rural community away from major teaching centres. A key objective isto bring adverse drug reaction training to these individuals, including in particular community pharmacists. Asgher Mohammed reported that NES Pharmacy already has an ADR distance learning package which pharmacists are able to do. Professor Lannigan said that he had also asked NES to add adverse drug reaction reporting to their national pharmacy post-graduate evening training sessions in all of the Health Boards.

5.2 GP registrar training

Professor Bateman had previously made contact with the post-graduate training team at the Lister Institute in Edinburgh to pursue incorporating an adverse drug reaction training session into the GP registrar training year. This suggestion was met with enthusiasm at the time. Professor Bateman has recently re-contacted Dr David Blaney to take this forward.

ACTION: PROFESSOR BATEMAN

5.3 Undergraduate professional training programmes

Much discussion ensued regarding the training content of the undergraduate programmes for AHPs, dentists, pharmacists and doctors. Whilst there is some knowledge of the content for some of the programmes it is unknown for all. Therefore it was agreed by the group that it would be worthwhile getting in contact with all the educational institutions in Scotland to find out if adverse drug reactions was covered in the training programmes and if so what was the content of this training. Dr Maxwell suggested that in the letter we send out we specifically ask "Do your students have to fill out a yellow card in the course?" Once this information has been obtained it will be compiled into a spreadsheet for presentation to the Advisory Group at the next meeting.

ACTION: M CUTHBERT/S NOBLE

5.4 Extended Prescribers

Jane Harris suggested that since supplementary prescribing has already been rolled out to nurses and pharmacists, and will also be rolled out to AHPs, it would be a good time to discuss incorporating ADRs into the clinical management plans which are being developed by the supplementary prescribers. Therefore she suggested we find out what the different supplementary prescribing courses are currently doing and try to initiate this suggestion. She will personally be able to look into the nurse side and the AHPs since they are adopting the nurses programme. However, someone else will have to take forward looking into the pharmacist supplementary prescribing course.

ACTION: J HARRIS/M CUTHBERT/S NOBLE

5.5 Pre-registration pharmacists year

It was suggested by Professor Lannigan that it would be beneficial to contact Stephen Peddie at NES who is co-ordinating the pre-registration pharmacists year for Scotland to ensure that adverse drug reaction training is covered in that year. As well it was suggested by Sheena Kerr that contact be made with the RPSGB in London to ensure it is also incorporated into the training folder for pre-registration pharmacists.

ACTION: M CUTHBERT/S NOBLE

5.6 Grand Rounds in Major Centres

It was suggested by Dr Maxwell that we should get a slot, at least twice a year, to do current topics in pharmacovigilance at the different Grand Rounds for the major centres within Scotland. M Cuthbert suggested that the ADR champions for the local health boards could aid in booking these slots on behalf of the YCC Scotland.

ACTION: M CUTHBERT/S NOBLE

5.7 National Nurse Prescribing Conference

J Harris suggested that a talk on ADRs could be done at this conference in the autumn. A suggested title would be "What nurse prescriber's need to know about ADR reporting". She volunteered to put it on the board agenda for the next nurse prescribers' meeting.

ACTION: J HARRIS

5.8 Education and training strategy development

Professor Lannigan suggested that the team should prepare an education and training strategy for the next meeting.

ACTION: S KERR/M CUTHBERT/ S NOBLE

6 Meeting with the national Medicines Utilisation Unit (MUU) in Scotland

Professor Bateman reported that the MUU had been set up by the Scottish Executive Health Department. The focus of the national MUU is to provide readily accessible information on medicines utilisation across Scotland to underpin evidence based decisions for policy development, planning and service delivery to support patient carers. Within the evolving remit and scope of the unit is the focus on educational research and development including pharmacovigilance within NHS Scotland. To achieve this the national MUU would like to work closely with YCC Scotland to provide appropriate information and to support the Clinical Governance Framework within NHS Scotland.

Marion Bennie and Sharon Hems are the two pharmacists working in this unit and they met with Professor Bateman and S Kerr to discuss this on 28th April 2006. Professor Bateman reported that prescribing data from ISD could potentially be linked to adverse drug reaction reporting reports for use in pharmacovigilance. Currently there is a CSO grant in collaboration with Dundee being pursued. Also they are looking at discharge data with the ICD10 codes and trying to pull out what is coded in there and what is in that data stream that we could use for pharmacovigilance purposes. Dr Ruben Thanacoody is taking this forward.

7 Annual Report 2005 for YCC Scotland

The annual report for the centre was discussed by the group. Professor Bateman said that overall performance nationally was improving and there was an increasing profile of pharmacovigilance in Scotland. Asgher Mohammed noted that a decrease in community

pharmacy reporting was of concern. He suggested that if we implemented a project or initiative we should monitor the effect that that initiative would have on the reporting for that area to see if it was successful.

Professor Bateman told the group that if you have any questions on the report please let us know. He also added that the report is considered confidential and not for circulation and they were not to use any of the data for publication purposes without first obtaining permission from the MHRA.

8 AOCB

8.1 Representation from AHPs on the Advisory Group

J Harris suggested that the group maywant to consider adding an individual that could represent the AHPs interest on the Advisory Group, and thinking strategically Sonia Lam might be a good candidate to invite to join the group. Professor Bateman supported this suggestion and said he would write to invite her to join the group.

ACTION: PROGESSOR BATEMAN

8.2 Scottish Pharmacovigilance Data

Dr Taylor enquired as to whether or not yellow card data would continue to be the main focus of the YCC Scotland, or could we move to using other pharmacovigilance data sources. Presently the MHRA use the GPRD system as the main way of monitoring pharmacovigilance other than the yellow card scheme. There is a very low Scottish input into GPRD though. Professor Bateman thought it might be worthwhile trying to increase the profile of Scottish pharmacovigilance data sources such as MEMO and ISD data sets. He said that a pharmacovigilance strategy will be discussed at the next meeting of the RMC heads with the MHRA in July and he would raise this issue then.

ACTION: PROFESSOR BATEMAN

Professor Bateman also added that there is currently money available thorough DoH that probably could be re-routed for developing or taking forward the pharmacovigilance data sets in Scotland. Professor Bateman suggested that the minutes of the Advisory Group be copied to Dr June Raine to highlight the concern over Scottish data sets not being utilised to aid pharmacovigilance in the UK. Also she should be copied all minutes of this groups meetings in the future.

ACTION: M CUTHBERT

8.3 Pharmacovigilance Seminar

Dr Taylor suggested that it might be worthwhile holding another seminar on pharmacovigilance in which we could highlight Scottish pharmacovigilance data and we could as the MHRA to attend again, such as Dr June Raine and Professor Gordon Duff. Professor Bateman suggested the title of "Current Techniques in Pharmacovigilance" would be a good title for the seminar and we could cover systems such as Sentinel, GPRD, Yellow Card System, and the Scottish pharmacovigilance systems. Dr Taylor suggested that we also invite someone from Scandinavia to speak due to the work which has been taken forward with the Scandinavian systems. Further discussions regarding organising this would take place at the next meeting of the advisory group.

ACTION: ALL

8.4 Audit Scotland Report

The Audit Scotland report that was released in the autumn of 2005 draws attention to the importance of adverse drug reaction reporting and the low reporting rates for the Health Boards within Scotland. As a result various Health Boards have now put adverse drug reaction reporting high on their agenda. Professor Bateman commented that there is a narrow difference between yellow card ADR reporting data for promoting pharmacovigilance as opposed to monitoring performance of ADR reporting. Professor Bateman suggested that it might be worthwhile for Bill Scott to write to the MHRA to highlight the importance of feeding back information to Health Boards on how they are doing with regard to reporting of ADRs and contributing to pharmacovigilance within the UK.

The majority of the Advisory Group had not seen a copy of the Audit Scotland report, therefore it was requested that it be circulated to all members.

ACTION: S KERR

8.5 ADR champions

M Cuthbert reported that we currently have an ADR champion for 6 of the 15 Health Boards within Scotland Professor Bateman explained they could facilitate ADR pharmacovigilance training and education within the Health Boards with YCC Scotland.

9 Date and time of next meeting

M Cuthbert reported that she currently had 3 dates for November and December that would be possible for Professor Webb to chair. Those dates are

Thursday 25th November Thursday 7th December Thursday 14th December

at 2pm. M Cuthbert will circulate these dates to the group to try and arrange the next meeting.

ACTION: M CUTHBERT

Summary Action List

Item No	Item for Action	Responsible Individual
3.1	Complete DOTS ADR package and review	M CUTHBERT/ DR S MAXWELL
3.1	Review ADR DOTS package for comments and feedback to M Cuthbert	ALL
3.1	Contact Dr Hazel Scott to get ADR package added to DOTS for August role-out.	DR S MAXWELL
3.2	Contact Alison Strath to discuss incorporating an electronic yellow card into the EMAS IT platform	M CUTHBERT
3.3	Contact Helen McKinnon to discuss how we might best take forward patient yellow card reporting	PROFESSOR N BATEMAN
5.2	Take forward GP registrar ADR training with Mike Watson	PROFESSOR N BATEMAN
5.3	Contact Scottish educational institutes to see if ADRs are covered in the undergraduate programmes	M CUTHBERT/ S NOBLE
5.4	Contact institutes delivering supplementary prescribers' courses and take forward recommendation of incorporating the reporting or ADRs	J HARRIS/ M CUTHBERT/

	into the clinical management plan	S NOBLE
5.5	Contact Stephen Peddie and RPSGB to ensure ADR reporting is	M CUTHBERT/
	covered in the teaching and training manuals	S NOBLE
5.6	Arrange slots for Grand Rounds talks in major Scottish centres	M CUTHBERT/
		S NOBLE
5.7	Arrange ADR talk to be done at the national nurses prescribing	J HARRIS
	conference	
5.8	Develop education and training strategy for YCC Scotland	S KERR/
		M CUTHBERT/
		S NOBLE
8.1	Write to Sonia Lamb to invite to join the Advisory Group	PROFESSOR N
	· · · · · ·	BATEMAN
8.2	Raise the potential for Scottish datasets in the UK pharmacovigilance	PROFESSOR N
	strategy at the MHRA	BATEMAN
8.2	Copy minutes to Dr June Raine from this point forward	M Cuthbert
8.3	Give thought to a pharmacovigilance seminar for the next meeting	ALL
8.4	Circulate copy of Audit Scotland report to all members of the Advisory	S KERR
	Group	
9	Circulate potential dates for next meeting	M CUTHBERT