YCC Scotland Centre for Adverse Reactions to Drugs (Scotland)

ANNUAL REPORT 2007/08

ANNUAL REPORT OF THE YCC SCOTLAND YELLOW CARD CENTRE TO THE MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY

2007/08

1. STAFF

Professor D Nicholas Bateman – Professor of Clinical Toxicology, Consultant Physician and Medical Director of YCC Scotland

Mrs Melinda Cuthbert – Senior Pharmacist Medicines Information / YCC Scotland

Miss Sheena Kerr – Pharmaceutical Advisor, Principal Pharmacist Medicines Information / YCC Scotland (until August 2007)

Dr Simon Maxwell – Senior Lecturer in Clinical Pharmacology, Deputy Medical Director YCC Scotland

Mrs Sheila C Noble - Senior Pharmacist Medicines Information / YCC Scotland

Dr Ruben Thanacoody – Consultant Physician, Royal Infirmary of Edinburgh.

2. SUMMARY

With the advent of the new contract between YCC Scotland and the MHRA, the role of YCC Scotland is to promote the appropriate use of the Yellow Card system through education, training and promotional materials and activities. YCC Scotland continues to follow up Yellow Cards which have been submitted by reporters in Scotland and for which further details are required.

YCC Scotland has been very proactive throughout 2007/2008. A total of 15 presentations, lectures and training sessions on ADR reporting have been given throughout the year to a wide range of audiences as detailed in section 5.

In addition to the provision of lectures, an updated online training module for FY1 doctors throughout Scotland has been completed and following a needs assessment a generic training package for use by educational establishment for teaching ADR reporting has been compiled and sent to all relevant universities and colleges.

The major promotional campaign has been the Patient Yellow Card Reporting campaign which was rolled out nationally in February 2008. In liaison with the Scottish Government and in collaboration with the MHRA, YCC Scotland had developed a Scottish poster and information card for community pharmacists to be incorporated into the Scottish community pharmacists' health promotion campaign which actively encouraged all Scottish community pharmacies to display the posters and hold campaign materials during a six week period in Spring 2008. A research

project to assess the impact of the promotion is currently awaiting Independent Science Advisory Committee (ISAC) approval.

A separate poster has been developed for nurses and is currently being distributed to all nursing establishments throughout Scotland. This poster is being adapted so that it is appropriate for all healthcare professionals.

YCC Scotland has been working with the Association of Scottish Medicine Information Pharmacists both to promote Yellow Card reporting by arranging Grand Round sessions and to promote Drug Safety Update awareness by encouraging all Health Boards to have hyperlinks on their hospital intranet sites.

There has been liaison with the Scottish Medicines for Children network to promote the reporting of side effects in children as part of an ongoing study.

YCC Scotland has been processing data to produce individual reports on Yellow Card Reporting to all the Scottish Health Boards.

In addition to processing 38 Yellow Card follow-ups with a response rate of 74%, YCC Scotland has also dealt with 31 Legacy Yellow Cards throughout the year.

There have been meetings of both the YCC Scotland Management Board and the YCC Scotland/CARDS Advisory Group and members of YCC Scotland have attended the MHRA conference in February 2008, the meeting on the Development of a Communications Strategy for Patient Reporting on 17th May 2007 and the Medical Director has attended 9 PEAG meetings.

Sheena Kerr left for a new post in August 2007 and her presence and expertise is greatly missed.

3. YELLOW CARD DATA
(See Appendix 1 for Breakdown of Scottish reports by quarter)

	2006/7	%Of UK total	2007/8	% of UK Total	% increase or decrease on previous year
(3.1)TotalUK Reports (exc MAH holders)	13030		12713		2.4% decrease
(3.2)Total Scottish Reports	1149	8.8%	1214	9.5%	5.7% increase
		% of Scottish Total		**% of Scottish Total**	
(3.3)Serious Reports Scotland	842	73%	878	72%	4.3% increase
(3.4)Black Triangle Reports Scotland	232	20%	196	16%	15.5% decrease
(3.5)Fatal Reports Scotland	n/a	n/a	38	3.1%	n/a
(3.6)Age Banding Scotland					
Child <18	146	12.7%	127 (130)*	10.5%	13.0% decrease
18-24	n/a	n/a	41	3.4%	n/a
25-34	n/a	n/a	108	8.9%	n/a
35-44	n/a	n/a	160	13.2%	n/a
45-54	n/a	n/a	186	15.3%	n/a
55-64	n/a	n/a	217	17.9%	n/a
65-74	n/a	n/a	192	15.8%	n/a
75-84	n/a	n/a	99	8.2%	n/a
>85	n/a	n/a	29	2.4%	n/a
Age not specified	n/a	n/a	53	4.4%	n/a
Total Reports by age			1212		

n/a = data not available

* Data received by age banding indicated 127 reports for under 18s however when collating reports for children over the same time scale, 130 reports were recorded.

3.7 Sources of Yellow Card Reports

Source of Reports	Reports in 2006/7	% of 2006/7 total	Reports in 2007/8	% of 2007/8 total	% increase or decrease on previous year
Carer	13	1.1%	8	0.6%	38.5% decrease
Parent	7	0.6%	9	0.7%	28.6% increase
Patient	131	11.2%	145	11.9%	10.7% increase
Community Pharmacist	24	0.20%	34	0.27%	41.7% increase
Hospital Pharmacist	165	14.2%	125	10.2%	24.2% decrease
Pharmacist	37	3.2%	39	3.2%	5.4% increase
Dentist	3	0.3%	3	0.2%	No change
GP	330	28.3%	353	28.9%	7.0% increase
Hospital Doctor	131	11.2%	178	14.6%	35.9% increase
Physician	107	9.2%	31	2.5%	71% decrease
Hospital Nurse	10	0.86%	34	2.8%	240% increase
Nurse	78	6.7%	83	6.8%	6.4% increase
Hospital HCP	24	2.1%	77	6.3%	220.8% increase
Other HCP	102	8.7%	100	8.2%	2.0% decrease
Optometrist	4	0.3%	2	0.2%	50% decrease
Literature	0	0%	1	0%	n/a
SUM	**1166**		**1222**		**4.8% increase**

HCP = Health Care Professional

3.8Top Ten Drugs reported 2007/2008

Ranking	Scotland Drug Name	Number Of reports	UK Drug Name	Number Of reports
1	Varenicline	226	Varenicline	1966
2	Aspirin	145	Aspirin	1209
3	Simvastatin	109	Simvastatin	1125
4	Omeprazole	104	Omeprazole	667
5	Levothyroxine	67	Paracetamol	582
6	Co-codamol	64	Salbutamol	572
7	Paracetamol	58	Ramipril	562
8	Atorvastatin	57	Atorvastatin	520
9	Salbutamol	56	Lansoprazole	473
10	Furosemide	53	Amlodipine	463

3A. INTERPRETATION

3A.1 Total UK Reports (excluding MAH holders)

Without access to other National data it is not possible to interpret the reason for the 2.4% decrease in Yellow Card reporting (excluding MAH holders) nationally other than the fact that this follows a general trend over the past few years where reports excluding those from MAH holders have decreased while those from MAH holders have continued to increase.

3A.2 Total Number of Scottish Reports

In contrast to the UK national trend there was a 5.7% increase in Scottish reports in 2007/8 compared with the previous year.

According to the Office of National Statistics in August 2007, the population of Scotland is 8.4% of the total UK population. In 2007/8 the Scottish reports comprised 9.5% of the UK total reports thus indicating that Scottish reporters are themselves submitting more reports per head of population than the UK average.

For the first three quarters of 2007/8 the average reports per quarter was 268 and this increased by 53% to 411 reports in the period January to March 2008 (See Appendix 1 for details). This correlates to some extent with the increase in Patient Reporting from an average of 18 patient reports for the first three quarters to 91 patient reports (400% increase involving 73 more reports per quarter) in January to March 2008. There was also a marked increase in Parent and Carer reporting in the final quarter of the year (average of 1.7 reports per quarter for Parents and Carers combined in the first three quarters compared with 12 Parent and Carer reports in the final quarter).

These data suggest the possibility that at least some of the increase in Yellow Card Reporting in Scotland may be directly attributed to the Patient Reporting Promotional Campaign which was launched on 17th February 2008.

Nationally the number of Patient (plus carer and parent) reports doubled from 250 to 500 i.e. 100% increase during the course of the Patient Reporting Campaign. In Scotland for the fourth quarter (January to March 2008) there were 103 reports compared with 45 over the same period the year before .e. 129% increase. This suggests that the Scottish arm of the Patient Reporting campaign was at least as effective, if not slightly more effective than the UK – wide campaign. Whether this hypothesis stands will be addressed by the “Assessment of the impact of a Scottish community pharmacy campaign on Patient Yellow Card reporting – Spring 2008” Research Project currently awaiting ISAC approval.

Varenicline reporting appeared to have increased nationally following the original “Hot Topic” entry in the December 2007 issue of Drug Safety Updates, the subsequent Update on Varenicline in the February 2008 Drug Safety Update issue and extensive media coverage. Without access to Varenicline figures on a quarterly basis it is not possible to determine to what extent Varenicline reporting boosted reporting in the fourth quarter in Scotland.

3A.3 Serious Reports (Scotland)

There has been a 4.3% increase in the number of serious reports received from Scotland compared with the previous year. In 2007/8 serious reports comprised 72% of the Scottish total compared with 73% the previous year. This is in line with the reporting trend overall.

3A 4 Black Triangle Reports (Scotland)

The number of reports for Black Triangle drugs in Scotland has decreased from 232 in 2006/7 (20% of the Scottish total) to 196 (16% of the Scottish total).

Of the drugs in the Top 10 drugs reported both nationally and in Scotland, only Varenicline (Champix) and Paracetamol in its intravenousl formulation (Perfalgan) currently have Black Triangle status. It has not been possible so far to identify which paracetamol reports were for the intravenous route.

3A.5 Fatalities (Scotland)

There were 38 reports (3.1% of the Scottish total) of ADRs associated with a fatal outcome from Scotland in 2007/8. Without access to national data or data from previous years it is not possible to draw any conclusions.

3A.6 Age Banding

Based upon the available data there was a 13% reduction in reporting for children in 2007/8 (130) compared with the previous year (146).

The age group for whom there have been the most reports is the 55-64 year age group with 17.9% of all Scottish reports. This is likely to reflect the epidemiology of prescribing as many adults start to develop illnesses such as cardiovascular disease and Type 2 diabetes within this age range and therefore require medication which may then result in an ADR. Although patients in the 65-74 demographic are likely to be using even more drugs and are thus more at risk from ADRs, according to statistics from the General Register Office for Scotland, the population over this age range decreases significantly resulting in fewer ADR reports overall.

3A.7 Source

GPs continue to be the group most likely to submit a Yellow Card with 353 reports submitted comprising 29% of all Yellow Cards submitted in Scotland. The number of **GPs and Hospital Doctors** combined submitting a Yellow Card in Scotland in 2007/8 had increased by 65 compared with the previous year however the number of Yellow Cards from **Physicians** declined by 76. There may therefore have been an element of differing classification rather than a significant change in actual reporting.

Dentist reporting continued to be very low at 3 per year and YCC Scotland is trying to address this issue by actively offering training to Dental Students on ADR reporting.

The number of **Hospital Health Care Professionals** submitting reports trebled from 24 in 2006/7 to 77 in 2007/8 as non-nursing hospital healthcare professionals took on prescribing roles as independent prescribers, supplementary prescribers or via Patient Group Directions (PGDs) and thus received training on and increased awareness of ADR reporting.

The number of reports from **Hospital Pharmacists** dropped by 40 from 165 in 2006/7 to 125 in 2007/8. Some of this could be attributed to other HCPs being able to report ADRs themselves where the pharmacist may have felt obliged to complete the report previously. According to a recent article by Professor Lannigan in the Pharmaceutical Journal on 28th June 2008, many Scottish hospitals seem to be running with a deficit of clinical pharmacists and this too may have had an impact upon the level of ADR reporting.

Community Pharmacist reports increased by 10 from 24 to 34 compared with the previous year while **unspecified Pharmacists** marginally increased from 37 to 39.

Hospital Nurse reporting increased from 10 in 2006/7 to 34 in 2007/8 and **unspecified Nurses** also increased their reporting from 78 to 83. This is to be expected as more nurses train in prescribing or supply medicines under PGDs and are thus more aware of the importance of ADR reporting.

Patient reporting increased by 14 from 131 in 2006/7 to 145 in 2007/8, an increase of 10.7%. Looking at 2007/8 patient reporting by quarters (Appendix 1), for the first three quarters there averaged 18 reports per quarter and this increased to 91 reports in the final quarter. This 400% increase can probably be attributed to the Patient Reporting Promotional Campaign.

In previous years the level of patient reporting had been consistently quite high with 131 patient reports submitted in 2006/7 however this had diminished by the beginning of 2007/8

The majority of **Parent and Carer** reports were submitted in the final quarter of 2007/8. In the first three quarters of 2007/8 there was an average of 1.7 parent and carer reports per quarter. In the final quarter there were12 parent and carer reports. Again this correlates with increased reporting in response to the Patient Reporting campaign. It is again interesting to note that during the previous year there was a total of 20 parent and carer reports whereas the total number for 2007/8 was only 17 i.e. a reduction of 3 reports. The reason for the higher level of parent and carer reporting in the previous year merits investigation.

Optometrist reporting remained low. Four reports had been submitted in 2006/7 and this reduced to two in 2007/8.

Other Health Care Professionals had submitted 102 reports in 2006/7 and this remained almost identical with 100 Yellow Card reports in 2007/8

Summary

These data might suggest that the educational and other promotional activities undertaken by YCC Scotland may have had a positive impact on Yellow Card reporting resulting in an overall increase in reporting at a time when nationally the figures have been dropping. Although Patient, Parent and Carer reporting had been significant in 2006/7 this had declined substantially in the early part of 2007/8 to be boosted by the Community Pharmacy Patient Reporting Campaign early in the final quarter.

3A.8 Top Ten Drugs Reported in 2007/8

These data show that there were no major differences between the top ten drugs reported from Scotland compared with the national trend.

Varenicline, the most highly reported drug, is a Black Triangle drug under intensive surveillance and there have been a number of concerns associated with psychiatric side effects which have been well documented in Drug Safety Updates as well as the media.

The other Black Triangle drug in the Top Ten for Scotland and the UK was **Paracetamol** (Perfalgan IV). As paracetamol itself is rarely associated with serious ADRs when taken at therapeutic doses we might assume that the high level of ADR reporting is due at least in part to the launch of the IV formulation. This is however only an assumption as we have not been able to identify the actual routes of administration for paracetamol Yellow Card reports in Scotland and other factors may be involved.

The remaining Top 10 Scottish drugs are all frequently prescribed drugs and the frequency of ADR reports appears to be directly proportional to the number of times these drugs are prescribed and used. Aspirin, simvastatin, omeprazole, oral paracetamol and co-codamol are all available Over the Counter (OTC) in addition to being prescribed which further increases the potential exposures and may increase the likelihood of Patient Reporting for these drugs

Aspirin is very widely used however it considered to be one of the most common causes of hospital admission due to ADRs including GI bleeds and exacerbation of asthma.

Simvastatin and **atorvastatin** are both associated with dose related ADRs including hepatic disturbances, myopathies and rhabdomyolysis. The risk of such ADRs developing is increased when taken with interacting drugs or foodstuffs.

Salbutamol is again very frequently prescribed by inhalation however association with serious side effects tends to develop at higher doses resulting in cardiac, psychiatric and CNS disorders.

Furosemide is again associated with more serious ADRs such as electrolyte disturbances at higher doses.

Omeprazole is very widely used and has been associated with a variety of serious reactions including psychiatric disorders, CNS, hepatic and skin reactions.

The codeine component of **co-codamol** can cause a number of potentially serious ADRs including dose related respiratory depression and severe constipation.

Levothyroxine is a well established and commonly prescribed drug however it is not normally associated with a range of serious adverse reactions when used at therapeutic doses. Some of the more significant ADRs which may have been reported this year include psychiatric disturbances and drug interactions. Of all the drugs in the Scottish Top Ten, this is the one which is the most surprising.

4. FOLLOW-UP REPORTS 1st April 2007 – 31st March 2008

Reports followed up	38
Responses received	28
Null Returns	10
Response still active	0
Response Rate	74%

5. PROMOTIONAL ACTIVITIES

5.1 Presentations:

"The Role of YCC Scotland/CARDS". A 15 minute presentation given to Lothian Area Drug and Therapeutics Committee by Sheena Kerr on 13th April 2007.

"Delivering Local Reporting" A 30 minute presentation given at the MHRA Annual Conference by Professor Nick Bateman on 4th February 2008.

"Side Effects of Medicines". An interview on BBC Radio 4 Case Notes involving Professor Nick Bateman on 29th January 2008.

5.2 Training Sessions and Lectures

Lecture to 3rd Year medical students at Edinburgh University on ADRs and ADR reporting. (1 hour). 21st September 2007. Dr Simon Maxwell.

Lecture to 4th Year medical students at Edinburgh University on ADRs and ADR reporting. (1 hour). 5th June 2007. Dr Simon Maxwell.

Lecture on ADR Reporting to pharmacy pre-registration graduates in Glasgow. (1 hour). 22nd August 2007. Sheila Noble.

Lecture to 4th year pharmacy students at Robert Gordon University, Aberdeen. (1 hour). 17th March 2008. Melinda Cuthbert.

Lecture and workshop session on ADR Reporting for pharmacy pre-registration graduates in Edinburgh. (3 hours). 25th October 2007. Melinda Cuthbert.

Lecture and workshop session on ADR Reporting for nurse and other independent and supplementary prescribers at Queen Margaret University, Edinburgh. (3 hours). 19th December 2007. Sheila Noble.

Lecture and workshop session on Drug Interactions for nurse and other independent and supplementary prescribers at Queen Margaret University, Edinburgh. (2 hours). 12th March 2008. Ruben Thanacoody.

Lecture on ADR reporting for MSc Podiatrists at Queen Margaret University, Edinburgh. (1 hour). 6th October 2007. Sheila Noble.

Lecture on ADR reporting for undergraduate podiatry students. (1 hour). 14th January 2008. Sheila Noble.

Training session and workshop on ADR reporting for GP registrars in Lothian. (3 hours) 13th November 2007. Professor Nick Bateman and Sheena Kerr.

Training session for Lothian GP Retainers Group. (1 hour). 20th February 2008. Sheila Noble.

Training session on Patient Reporting and the Spring Promotion Campaign to a group of Lothian hospital pharmacists. (1 hour). 13th February 2008. Melinda Cuthbert.

A 9 hour package providing information and experience regarding the activities of YCC Scotland was provided for a 3rd Year medical student who wished to further his understanding of the role of YCC Scotland as part of his SSC project. This was spread over 3 days from 18th – 21st December 2007. The report produced by the student identifies that he now has a good understanding of the service provided by the centre and had found the experience very useful and enlightening. It is anticipated that this may be repeated in the future.

In 10/13 training sessions the generic training package was used as a basis for the training session tailored to the requirements of the group.

5.3 Meetings

YCC Scotland / CARDS Advisory Group meeting. There has been one meeting of the Advisory Group within the past year held in Edinburgh on 1st October 2007.

YCC Scotland Management Board. Four meetings of the Management Board have been held on 31st May 2007, 24th September 2007, 26th November 2007 and 28th January 2008.

As detailed above, presentations and training sessions have been given at meetings of the Lothian Area Drug and Therapeutics Committee and the Lothian GP Retainers Group.

A paper on Electronic Yellow Card reporting was written by Melinda Cuthbert and presented to Lothian Health Senior Management Team Clinical Board at their meeting on 18th March 2008 by Mrs Patricia Murray, a member of the YCC Scotland Advisory Group.

5.4 Promotional Materials

A poster aimed primarily at nurses has been designed and is currently being disseminated to all nursing establishments throughout Scotland. (See Appendix 2).

A similar generic poster aimed at all Health Care Professionals in Scotland is currently being completed.

A poster and accompanying information card for community pharmacists on Patient Yellow Card reporting were designed and distributed to all community pharmacies throughout Scotland as part of the Scottish Government Health Promotion Campaign. (see Appendix 3). This promotion was conducted in collaboration with the MHRA.

These posters and other educational materials were also distributed to hospital pharmacies throughout Scotland via the Association of Scottish Medicines Information Pharmacists to ensure that Scottish hospital pharmacists were aware of the community pharmacist led campaign and had access to materials.

A generic training package has been developed including a Powerpoint presentation, workshops and a resource pack providing links to key websites primarily for use by educational establishments for teaching and promoting ADR reporting. This has been sent to key personnel in all the universities and colleges in Scotland involved in training doctors, pharmacists, nurses, dentists and other allied healthcare professionals.

The Doctors Online Training System (DOTS) module on ADR reporting for FY1 doctors has recently been updated by YCC Scotland and is now a mandatory component to their training.
YCC Scotland is currently in liaison with NHS Education in Scotland NES to identify if there is a requirement for a similar module for FY2 doctors.

Meeting with members of the Scottish Medicines for Children network on 23rd January 2008 to promote participation in the “Side Effects fo Medicines in Children” study.

5.5 YCC Scotland Website

Due to problems in obtaining IT support, the YCC Scotland website is still awaiting update. The areas requiring update and the new hyperlinks have been identified. Contact has now been made with an IT expert at NHS Lothian to enable Melinda Cuthbert and Sheila Noble to receive training to allow them to undertake the work themselves and it is hoped to have this task completed in the near future.

5.6 Other Promotional Activities

Arrangements are being made with the assistance of the Association of Scottish Medicines Information Pharmacists for the provision of Grand Round talks on ADR reporting at all the major teaching hospitals throughout Scotland.

YCC Scotland has been actively promoting Drug Safety Updates hyperlinks via NHS Scotland Intranet sites and on NHS e-Library.

6 PUBLICATIONS

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7. RESEARCH

1. Assessment of the impact of a Scottish community pharmacy campaign on Patient Yellow Card reporting – Spring 2008

This study is currently awaiting approval from ISAC

It is proposed that Yellow Card reporting data will be compared over a timescale before and after the Patient Reporting Campaign to identify any changes in the reporters, the number of reports and the type of reports. It is also planned to compare results with matched YCCs in England and Wales to identify if the Scottish promotion, which was actively supported by the Scottish Government Health Promotion Campaign, had the same impact as other regions or if there were any differences.

2. Teaching of Adverse Drug Reaction Reporting in Educational Establishments throughout Scotland

Identification of the current status of ADR teaching and the requirement for an updated Generic Presentation and Training Package on ADR Reporting throughout Scottish Higher Educational Establishments training doctors, nurses and pharmacists and other AHPs. See Appendix 4

Improving Standards of Pharmacovigilance in Oncology. M.Phil project currently in progress. M Cuthbert

3. Side Effects of Medicines in Children

Pilot study for monitoring adverse drug reactions associated with paediatric medicines(specifically for the treatment of epilepsy, depression and Attention Defecit Hyperactivity Disorder) in the Aberdeen and Lothian areas. Funded by Chief Scientist's Office.

4. Acute Renal Toxicity and its Detection by the Yellow card Scheme

Research project as part of Master of Science in Clinical Pharmacy undertaken by Katherine Davidson, Senior Pharmacist, Royal Infirmary of Edinburgh.

Appendix 1

YCC Scotland Yellow Card Data 2007/8 by Quarter

	April-June 07	July-Sept 07	Oct-Dec 07	Jan-March 08	Total For Year 2007/08
Total Reports	258	268	277	411	1214
Serious Reports	206	188	200	284	878
Black Triangle	51	57	44	44	196
Fatal	11	8	11	8	38
Child	30	22	30	48	130
Source					
Carer	1	1	2	4	8
Parent	0	0	1	8	9
Patient	12	23	19	91	145
Community Pharmacist	6	9	10	9	34
Hospital Pharmacist	33	26	35	31	125
Pharmacist	8	8	17	6	39
Dentist	1	1	0	1	3
GP	90	85	92	86	353
Hospital Doctor	44	44	34	56	178
Physician	10	3	4	14	31
Hospital Nurse	8	3	12	11	34
Nurse	17	25	20	21	83
Hospital HCP	16	17	20	24	77
Other HCP	16	23	12	49	100
Optometrist	0	0	1	1	2
Literature	0	1	0	0	1
SUM of Sources	262	269	279	412	1222*

*Sum of sources is not the same as total reports as more than one person may have reported the same reaction

Appendix 2

Poster for Nurses

Yellow Card Centre Scotland

Centre for Adverse Reactions to Drugs (Scotland)

YellowCard

NHS SCOTLAND

Adverse Drug Reaction (ADR) reporting by nurses, midwives & specialist community public health nurses

Definition of an Adverse Drug Reaction (ADR)

An ADR is defined as 'an unwanted or harmful reaction experienced following the administration of a medicine or combination of medicines under normal conditions of use and which is suspected to be related to the medicine'. It is important to note that medicines include all over the counter (OTC) preparations and herbal remedies.

Introduction

The Yellow Card Scheme for reporting suspected adverse drug reactions (ADRs) was introduced in 1964, in response to the thalidomide disaster, to aid in monitoring the safety of medicines. Since then over 500,000 reports have been received by the Medicines and Healthcare products Regulatory Agency (MHRA). However under-reporting by all members of the healthcare profession has always been a recognised weakness of the Yellow Card Scheme that can contribute to a time delay in detecting safety issues with medicines.

The monitoring of new medicines is a vital part of ensuring the safety of medicines in clinical use. A new medicine will only have been clinically tested in a few thousand patients, although millions may take the medicine when it is marketed. Therefore not all ADRs (especially the more rare ones) or interactions (with other medicines or concomitant disease states) will be known at the time a medicine is marketed. Reporting to the Yellow Card Scheme can help identify these ADRs and interactions, as well as those medicines for which special precautions may be necessary.

Action that may be taken from information supplied from yellow card reports includes informing healthcare professionals of the new risks, reducing the recommended dose of the medicine, or if the severity and incidence of any adverse effects outweigh the benefits of the medicine, in the most extreme circumstances the withdrawal of the medicine from the market may occur.

Role of nurses, midwives & specialist community public health nurses

Nurses, midwives and specialist community public health nurses were added to the list of healthcare professionals who are allowed to report to the Yellow Card Scheme in 2002. This professional group are well placed to report ADRs associated with all medicines including OTC medicines and herbal products. Further deregulation of medicines and increased clinical and prescribing roles for nurses will enhance these opportunities, increase the level of reporting and yield high-quality information not previously available. Although most nurses, midwives and specialist community public health nurses are aware of the scheme, some may be unclear about what should be reported.

What to report

Table 1 contains a list of what types of ADRs should be reported to the MHRA via the Yellow Card Scheme. Table 2 lists areas of special interest that the MHRA also wish to receive reports for.

It is only necessary for the reporter to reasonably suspect that the medicine has caused the ADR. The MHRA advice is "If in doubt, fill a card out". Diagram 1 gives a flow chart to aid in determining whether it is likely that a patient may have had an ADR due to a medicine.

Diagram 1 - Algorithm to assist in identifying ADRs

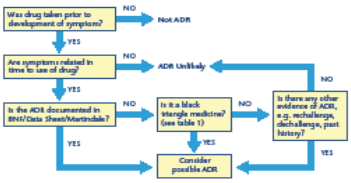

Table 1 - Types of ADRs to report

Black Triangle medicines and vaccines	All suspected ADRs for new medicines (including OTC preparations) and vaccines should be reported. These are identified by the symbol "▼" on the product and in medicines information resources.
Serious ADRs	All suspected serious ADRs for established medicines (including OTC preparations) and vaccines should be reported. The MHRA lists serious reactions as those that are fatal, life-threatening, disabling or incapacitating, result in or prolong hospitalisation, and/or are medically significant.

Table 2 - Areas of special interest that the MHRA wish to receive all ADR reports for

Herbal Medicines	Many people associate 'herbal' with 'natural' and believe that these preparations cannot cause adverse effects. This, however, is not the case and ADRs can occur with herbal preparations and the monitoring of their ADRs and drug interactions is vital. Many herbal remedies are still unlicensed and are purchased from outlets other than pharmacies, including Ayurvedic and Traditional Chinese Medicines.
Children	Children are not just small adults and may have very different reactions to medicines. Also, many medicines are not licensed for use in children and they have not been subjected to clinical trials in those who are under 18 years. Therefore the safety profile in children may not be known.
Elderly	The elderly are at particular risk of ADRs and interactions, particularly during long-term therapy, because of polypharmacy, co-existing chronic disease and a reduced capacity to eliminate medicines.
Other vulnerable groups	Special attention should be given to patients who are pregnant, nursing mothers, or those who have a history of allergies.

Table 3 - Essential Information to Include on a Yellow Card Report

Suspected medicine(s)	The suspected medicine(s), brand name(s) and batch number for vaccines (if known), route of administration, dosage, dates of administration and indication. For herbal products the information required (if available) is: (i) the ingredient(s) (ii) source or supplier (iii) the use to which the remedy was being put Retention of a sample of the product would be helpful in case an analysis is required.
Suspected reaction(s)	A description of the reaction(s) and any treatment given, together with the dates the reaction started and stopped, and whether the reaction was considered to be serious. There are also tick boxes to give information on the outcome, and why the reaction was considered to be serious.
Patient details	Patient's sex and age and their weight (if known). Information that would identify the patient should not be used (for reasons of confidentiality) although their initials and a local identification number are helpful in case it is necessary to refer back to the patient's records. It is not necessary to obtain the patient's consent to report on an ADR.
Reporter details	Name and full professional address of the reporter, so that the report can be acknowledged and contact made for further information, if necessary.

How to submit a Yellow Card Report

Yellow cards can be completed and submitted electronically via the MHRA website at www.yellowcard.gov.uk or via GPASS.

or

Paper yellow cards can be submitted via post (found in the BNF, MIMS, and some other healthcare publications or can be downloaded from the MHRA or YCC Scotland Web sites).

The four critical pieces of information that must be included on the yellow card can be seen in Table 3. However additional information that may be useful includes other medicines taken, and diagnostic test results and known allergies.

Action once yellow card received

Upon receipt all yellow cards are entered into the Sentinel database at the MHRA. The Sentinel system expedites the processing of data and allows for faster detection of any possible drug safety problems, which benefits patient safety within the UK.

An acknowledgement letter is issued, quoting a unique registration number specific to the yellow card report. In the case where follow-up information is required YCC Scotland (previously known as CSM Scotland) may contact you on behalf of the MHRA.

Information about other reactions associated with a medicine can be found in Drug Analysis Prints (DAPs) prepared by the MHRA. These DAPs are available for viewing at: www.mhra.gov.uk

Appendix 3

Scottish Promotional Material for Patient Reporting Scheme

MHRA

NHS SCOTLAND

Do you think you have had a side effect from your medicine(s)?

You now can report any possible side effects to the Yellow Card Scheme, the UK system for monitoring side effects of medicines.

Please see your pharmacist or visit www.yellowcard.gov.uk for details.

YellowCard

Helping to make medicines safer

Adverse Drug Reaction (ADR) Reporting by Patients

Key points

- For patient Yellow Card reporting to be successful, members of the public must be made aware that they are able to report. Community pharmacists are well placed to promote this message.
- Patients only require a suspicion that a medicine has caused the reaction to report.
- Patients should be encouraged to report all suspected serious side effects that were bad enough to interfere with everyday activities and all suspected reactions not listed in the Patient information leaflet for a medicine.
- Patients need not worry that a healthcare professional may have reported the same reaction.
- The MHRA need everyone – healthcare professionals and patients – to tell them about possible side effects they or someone they care for experiences via the Yellow Card Scheme.

Background

Patient reporting of suspected ADRs to the Yellow Card Scheme began as a pilot scheme of the Medicines and Healthcare products Regulatory Agency (MHRA) in 2005. Since then patients have joined healthcare professionals as established reporters to the Yellow Card Scheme.

Reports from healthcare professionals are vital in gaining clinical information and perspective on suspected ADRs. However, patient reporting of ADRs complements healthcare professional reporting in a number of ways, as described below:

1. Patients report directly, cutting out the 'middle man'. That is, for a healthcare professional to consider a Yellow Card report, they must first be informed of a side effect that the patient is experiencing. After discussion with the patient the healthcare professional will then decide if the side effect warrants reporting. If they do decide to report they must then report without changing the meaning of the patient's concerns.
2. Patients tend to report ADRs earlier than their healthcare professional(s), which is particularly important for serious ADRs that require prompt action from the MHRA.
3. Patients provide a more detailed description of side effect(s) and how it affects their quality of life; this is often not provided in reports from healthcare professionals.

For these reasons the MHRA wish to increase patient awareness of this important advancement in the monitoring of the safety of medicines in the UK.

All community pharmacists should be aware, however, that patient reporting is in addition to healthcare professionals' reporting. Therefore the MHRA request that you continue to report ADRs via the Yellow Card as per these criteria:

1. **All** suspected ADRs for new medicines (i.e. those carrying the black triangle (▼) symbol) for which the safety profile in routine clinical use requires further definition.
2. **All** serious suspected ADRs for established medicines and vaccines. The MHRA lists serious reactions as those that are fatal, life-threatening, disabling or incapacitating, result in or prolong hospitalisation, and/or are medically significant.
3. **All** reactions occurring in children.

ADR versus Side Effect

The MHRA define an ADR as 'an unwanted or harmful reaction experienced following the administration of a medicine or combination of medicines under normal conditions of use and which is suspected to be related to the medicine'. While a side effect implies some pharmacological basis for the reaction, which may include beneficial effects of a medicine.

Patients may describe their experiences with medicines using different terms compared to healthcare professionals. For instance the term side effect is used synonymously with ADR by most and is likely to be the term most widely used by patients. It is important to be open to the use of lay definitions in use in your discussions with patients.

What can a community pharmacist do to help?

For patient Yellow Card reporting to be successful patients need to be aware that they are able to report. As one of the most accessible of the healthcare professionals, community pharmacists are well placed to inform patients about the Yellow Card Scheme. Pharmacists have a professional responsibility to advise patients on the reporting of any suspected side effects associated with their medicines including over the counter (OTC) medicines and herbal products.

The advice you can offer patients includes helping to think about whether a possible side effect could be due to a patient's medicine; whether the possible side effect meets the MHRA criteria for reporting; and what details to include on the report.

Who can report via the patient Yellow Card?

Anyone can report a possible side effect via the patient Yellow Card. These include those side effects that an individual suspects that they, or a child for whom they are responsible (i.e. as the parent or legal guardian), may have had.

In addition, people can report ADRs on behalf of someone else, such as:

- their spouse/partner
- their adult offspring
- someone who they look after

As long as the person who had the ADR has agreed to this.

Sometimes it is difficult to tell whether a possible side effect is due to a medicine. Patients do not have to be certain a medicine caused a side effect – if they reasonably suspect that this is the case then they should be encouraged to complete a Yellow Card report. Patients should not worry that a healthcare professional may also have reported the reaction; the MHRA can identify duplicate reports.

What should patients report

The MHRA ask patients to follow the guidance listed in **Table 1**.

Table 1 – Types of ADRs for patients to report.

Unknown side effect	All suspected side effects that are not mentioned in the patient information leaflet.
Serious side effect	All suspected serious side effects that were bad enough to interfere with everyday activities.

It is important to note that the MHRA is interested in reports for all prescription and OTC medicines, as well as herbal preparations (licensed or unlicensed). Many herbal remedies are still unlicensed and are purchased from outlets other than pharmacies, including Ayurvedic and Traditional Chinese Medicines. The MHRA would ask you to consider this possibility when patients seek advice on potential side effects. Also it is always worthwhile to consider interactions between herbal preparations (i.e. drug/food, drug/disease and drug/drug) and other medicines, which can possibly lead to side effects.

Areas of special interest

The MHRA is particularly interested in hearing about any side effects occurring in children, the elderly, and other vulnerable groups (e.g. patients who are pregnant, nursing mothers, or those who have a history of allergies). Community pharmacists could encourage patients and carers to make these reports.

Completion of patient Yellow Card reports

Paper Yellow Cards for use by patients have been supplied to all community pharmacists for this promotional campaign. Additional Yellow Cards can be downloaded or submitted electronically from the MHRA website **www.yellowcard.gov.uk**

There are four required pieces of information required from patients when they complete a Yellow Card. These items can be seen in **Table 2**.

Patients can be encouraged to complete as much of the Yellow Card report they can before sending to the MHRA, however, patients should be reassured that the lack of any particular piece of information should not prevent reporting. Some patients may appreciate help in the completion of Yellow Cards.

Action once received

The MHRA will acknowledge each Yellow Card report submitted, and will send the patient a copy of their report for their records. In some cases they may contact the patient requesting additional details regarding the report. This will then aid them in investigating the possible side effect, and taking any necessary action to minimise the risks to other patients taking the same medicine(s).

Additional information

Additional information on Yellow Card reporting for healthcare professionals and patients can be found at **www.mhra.gov.uk**

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Table 2 – Information to include on a patient Yellow Card Report.

Suspected medicine(s)	The name of the suspected medicine(s) must be provided. Further information could include formulation; route of administration; dosage; where medicine was obtained from; dates of when medicine was started and stopped; and indication. For herbal products, additional useful information (if available) could include the ingredient(s); source or supplier; batch number; and the use to which the remedy was being put.
Suspected reaction(s)	The name and/or a description of the reaction(s) must be provided. Further information (e.g. any treatment given, together with the dates the reaction started and stopped, and how bad the reaction was; the outcome of the suspected side effect) is useful but not essential.
Patient details	One of the following pieces of information must be provided: Patient's initials, sex or age at the time of the reaction.
Reporter details	Name and full address of the reporter, so that the report can be acknowledged and contact made for further information, if necessary. Patients should be advised that their personal data are confidential and will be kept secure; and would not be passed to anyone outside the MHRA with their permission.

Please note this information is desirable but patients should not worry if they do not have all this information.

This information sheet was produced on behalf of the MHRA by YCC Scotland, January 2008.

Appendix 4

Teaching of Adverse Drug Reaction Reporting in Educational Establishments throughout Scotland

Introduction

Yellow Card Centre Scotland (YCC Scotland) has been updating a generic Powerpoint presentation covering Adverse Drug Reactions (ADRs) and ADR reporting via the MHRA Yellow Card System. This presentation can be tailored to meet the requirements of a range of educational forums. Prior to promoting and circulating this resource it was decided to identify the current level of teaching on ADRs within educational institutions covering medicine, nursing and pharmacy and to assess the level of interest in the generic presentation.

Method

In January 2007 26 universities and colleges were contacted by YCC Scotland by mail using a questionnaire to ask about their current teaching on ADRs and if they would be interested in the YCC Scotland generic teaching package. The questionnaire (Appendix 1) was sent with a pre-addressed envelope. By mid-March responses had been received from 17 of the 26 establishments giving a 65% response. See table 1.

Table 1

Type of establishment	Number Contacted	Number responding	% response
School of medicine	5	4	80%
School of pharmacy	2	2	100%
University/college teaching Nurse Prescribing	7	5	71%
University College teaching Undergrad Nursing	12	6	50%
Total	26	17	65%

Upon receipt of each response the establishment was sent an e-mail acknowledging receipt of the completed questionnaire and one additional question was asked regarding whether or not a Yellow Card was currently being completed as part of the training course. Of the 17 establishments e-mailed 9 responded.

Results

The results of the questionnaire and subsequent e-mail are shown in Table 2.

Table 2

Establishment	Cover ADRs	Core Subject	Hours taught	Copy of Presentation	YCC Tutor?	Complete Yellow Card
Medical						
Dundee	Y	N	20	Y	N	Y
St Andrews	Y	N	2	Y	N	?
Edinburgh	Y	Y	3	Y	?	Y
Glasgow	Y	N	?	Y	Y	?
Nursing U/Grad						
Stirling	Y	N	?	Y	Y	?
Abertay	Y	Y	1	Y	Y	?
Edinburgh Uni	N	N	0	Y	Y	N
QMU	Y	Y	0.5	Y	N	N
Bell	Y	N	?	Y	N	N
RGU	Y	Y	1	Y	Y	?
Nurse Prescribing						
QMU	Y	Y	3	Y	Y	N
Dundee	Y	Y	10	Y	?	?
Napier	Y	Y	3	Y	Y	N
Stirling	Y	Y	?	Y	N	Y
RGU	Y	Y	?	Y	Y	?
Pharmacy						
Strathclyde	Y	Y	3	Y	N	?
RGU	Y	Y	9	Y	Y	N
TOTALS						
Total Yes	16	11	11	17	9	3
Total No	1	6	1	0	6	6
Total Unknown	0	0	5	0	2	8
%/average	94%	65%	4.6	100	53%	33%

Current teaching of ADRs

16 of the 17 educational establishments were already teaching about ADRs to a greater or lesser extent and for 11 it was already part of the core curriculum. Five establishments were unable to estimate the time spent teaching ADRs as it was integrated into other subjects and not taught separately. One medical school indicated that the module on ADRs covered 1-2 weeks so this was estimated as 20 hours whereas other establishments gave times ranging from half an hour to 10 hours. The average time spent on teaching ADRs based on the figures quoted was therefore 4.6 hours with a mode of 3 hours. We currently estimate that the YCC Scotland package with accompanying workshop can be covered in about 3 hours.

Interest in the YCC Scotland Generic Presentation

All 17 establishments who responded to the questionnaire wished to receive a copy of the presentation. Of those 9 were also interested in having a member of the YCC Scotland team presenting the session. One of these 9 was the University of Stirling Undergraduate Nursing Course who indicated that they taught on 3 separate campuses – Stirling, Inverness and the Western Isles and ideally they would like a presentation at each site. Thus there could be a total of 11 sessions requiring to be given by YCC Scotland personnel. Six establishments did not require any teaching input from YCC Scotland as they already had lecturers available who wished to continue presenting the lecture. Two expressed some uncertainty – the first was Dundee University Nurse Prescribing Course and the second was Edinburgh Medical School who stated that Dr Simon Maxwell presented this subject and it would be his decision. Although Dr Maxwell is not an employee of YCC Scotland he is an active member of both the Advisory Board and the Management Board.

Completing Yellow Cards

YCC Scotland considers it important for healthcare professionals to have practice at completing a Yellow Card to instil confidence when the need arises to complete one in reality. A considerable proportion of the presentation covers the completion of a Yellow Card and the accompanying workshop includes a blank Yellow Card to be filled in.

Of the 9 educational establishments who responded to the follow-up e-mailed request about completing Yellow Cards 3 (2 medical schools and one Nurse Prescribing Course) indicated that they were already doing this and the remaining 6 stated that they were not at present.

Discussion

A higher response may have been possible if a second mailing had been conducted to chase up the initial non-responders. Even so, a 65% response is respectable. Of those responding the level of teaching on ADRs varied widely from 0 to 20 hours averaging at 4.6 hours (mode 3 hours) and only a third of those responding were completing a Yellow Card as part of the course however all were interested in receiving the generic presentation.

The next step is to e-mail all the 26 establishments attaching a copy of the presentation in a format which can be personalised and altered to meet individual requirements. The presentation will also be made available on the YCC Scotland website. Workshop materials will also be made available.

Some of the universities and colleges expressing an interest in teaching input from YCC personnel already have the presentation given by us. We would need to discuss the option of presenting the package to the other establishments including remote locations such as the Western Isles. One option may be to prepare a DVD of one of the YCC Scotland staff giving the presentation – a technique frequently employed by NES.

Sheila C Noble
Senior Pharmacist
YCC Scotland
November 2007.

APPENDIX 1 (To appendix 4)

Questionnaire

To enable us to update our records and identify demand for the new presentation, could you please take a few minutes to answer the following questions:

1) Do you currently cover Adverse Drug Reactions in the above course? (Yes/No)

2) In what year of the course is the subject covered?

3) Is the subject of ADRs part of a specific course curriculum? (Yes/No)

4) How much coverage is the subject given (hours of teaching)?

5) Which lecturer(s) teach ADRs?

6) Would you like a copy of the final version of the YCC Scotland Generic ADR Presentation which will be available in spring 2007? (Yes/No)

7) Would you be interested in the presentation being provided by a member of YCC Scotland? (Yes/No)

Thank you for your input.
Please return this form to:

Sheila C Noble
Senior Pharmacist
YCC Scotland
…….

Reply paid envelope provided for your convenience.