

YCC West Midlands

**ANNUAL REPORT
2008/09**

ANNUAL REPORT OF YELLOW CARD CENTRE WEST MIDLANDS TO THE MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY

2008/09

1. STAFF

Professor R E Ferner – Director
Dr N J Langford* – Honorary Consultant Pharmacologist
Dr T F Butt* – Honorary Specialist Registrar
Mr C Anton – Administrative Co-ordinator
Dr A R Cox – Pharmacovigilance Pharmacist
Miss S E McDowell – Research Officer
Ms M Robinson – Clerical Officer

2. SUMMARY

Our priorities for the year remain on focussing on teaching and information and we have continued our programmes for all grades of staff from nurses to consultants. We have continued to expand our website to provide a valuable resource for the region, and more widely.

There was a slight fall in the number of reports from the region and this was seen particularly from GPs. The number of reports from patients has seen an increase. The proportion of serious reports has fallen but many of the reports to human papilloma vaccine were non-serious. The proportion of reports to black triangle drugs has increased and half of the top 14 drugs were black triangle drugs.

3. YELLOW CARD DATA

Number of reports

Year	Number of reports	as %age of national reports	Source
2008/09	1137	8.0%	from MHRA
2007/08	1149	9.1%	
2006/07	1217	9.3%	
2005/06	1396 [†]		direct reporting to CSMWM and bypass data
2004/05	1643		

[†] total does not include bypass data from 1/1/06 to 31/3/06

Serious reports

Year	Number of serious reports	as %age of total reports
2008/09	623	55%
2007/08	824	72%

2006/07	837	69%
2005	859	57%
2004	963	58%

* data on seriousness of reports by financial year are not available because of anonymisation of our database

Black triangle reports

Year	Number of ▼ reports	as %age of total reports
2008/09		
2007/08	264	23%
2006/07	271	22%
2005/06	362	26%
2004/05	512	31%

Fatal reports

Year	Number of fatal reports	as %age of total reports
2008/09	22	1.9%
2007/08	35	3.0%
2006/07	28	2.3%
2005/06	33	2.4%
2004/05	32	2.0%

Age banding

Age range	%age of reports 2008/09	%age of reports 2007/08	%age of reports 2006/07	%age of reports 2005/06
<18	16%	13%	13%	8%
18-24	3%	4%	4%	3%
25-34	8%	9%	8%	8%
35-44	10%	11%	9%	9%
45-54	14%	14%	13%	11%
55-64	16%	18%	16%	15%
65-74	13%	14%	14%	17%
75-84	9%	8%	8%	16%
>85	2%	2%	4%	6%
not specified	8%	7%	12%	6%
Total	1137	1149	1217	1396

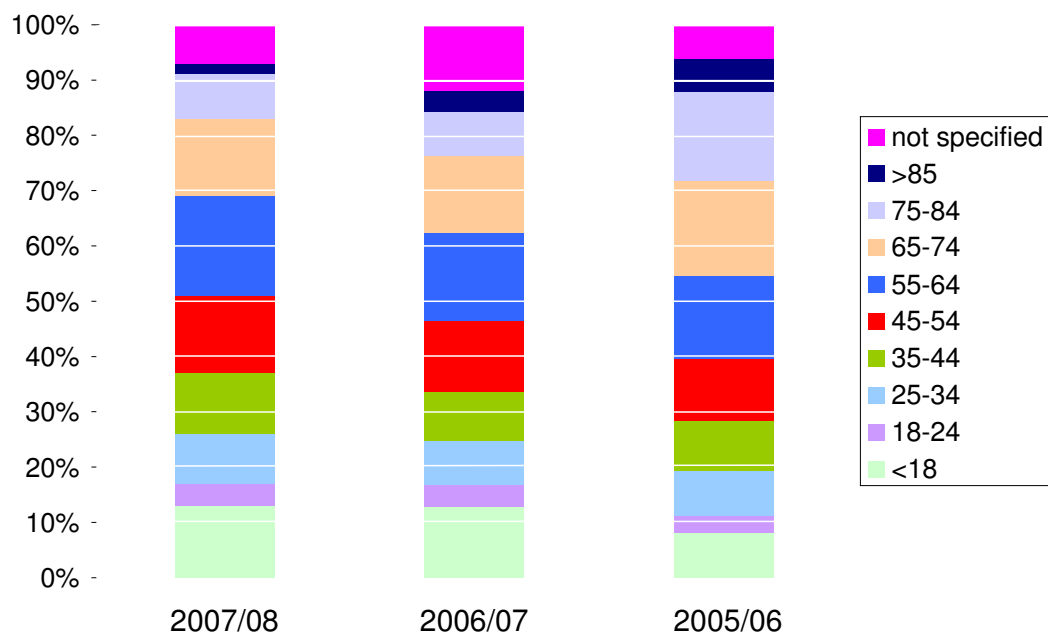


Figure 1: Proportion of reports by age of patient

Source of report

Reporter qualification	2008/09	2007/08	2006/07	2005/06
Carer	10	12	5	
Community Pharmacist	42	40	13	52
Consumer or other non health professional			2	1
Coroner		2		1
Dentist	4	4	1	4
GP	257	302	314	318
Hospital Doctor	177	202	137	346
Hospital Health Professional	92	80	26	
Hospital Nurse	65	44	45	60
Hospital Pharmacist	58	76	85	220
Nurse	157	126	108	61
Optometrist			3	
Other Health Professional	63	67	139	333
Parent	7	6	11	
Patient	155	140	202	
Pharmacist	20	21	23	
Physician	29	34	114	

Type of report

Source	2008/09	2007/08	2006/07	2005/06
Paper	data not available	923	data not available	1328
Electronic		220		68
Telephone		6		

Top 14 drugs

The top 14 drugs listed as suspect drug are shown below

rINN	Total
human papilloma virus ▼	93
varenicline ▼	76
etanercept ▼	33
simvastatin	27
adalimumab ▼	20
citalopram	18
exenatide ▼	17
pneumococcal vaccine	17
atorvastatin	13
diclofenac	11
olanzapine	11
pregabalin ▼	11
ramipril	11
rimonabant ▼	11

4. FOLLOW UP OF REPORTS

We were asked to follow up 33 reports on behalf of the MHRA, of which three had a fatal outcome.

The response rate to follow up is 56%. The average interval from the date of the report to our being asked to follow it up was over 40 days.

5. PROMOTIONAL ACTIVITIES

We have promoted the scheme with various talks and lectures during the year. Details of them are listed below.

Teaching

Meeting	Time	Number of participants	Number of sessions
Regional Medicines Information pharmacists	1 hour	20	2
Aston University pharmacy students – signal detection	1 hour	12	1
Birmingham University medical students –	half day	70	6

OSCE			
FY2s study day	whole day	100	2
University of Hertfordshire MSc in Pharmacovigilance – classifying ADRs	1 hour	30	1
FY1s – safe use of medicines	half day	40	1
University of Birmingham roadshow to 5 th year medical students	whole day		1
MHRA SpR training day	whole day		1
Birmingham University MSc lectures in toxicology	4 hours		1
Birmingham University medical school – safe prescribing lecture	3 hours		1
Drug Safety Induction talks	1 hours	10-30	26
HOB PCT update	4 hours	250	1
Overseas Pharmacy Programme	3	40	1
4 th Year Pharmacists specialist Option	3	12	5
2nd year pharmacy students – introduction to pharmacovigilance	1	160	1
Keele Clinical Diploma – ADR section revised	Distance learning material	25	1
Warfarin interactions and Yellow Card scheme: Birmingham University Primary care unit	2 hours	15	6
Yellow Card scheme update: Kidderminster General Practitioner and nurses	1 hour	50	1
Yellow Card scheme update: Bromsgrove General Practitioners and Nurses	1 hour	50	1
Royal Pharmaceutical Society of Great Britain. Birmingham Region	2 hours	40	2

Lectures given

Pharmacovigilance. UK Clinical Research Network/Medicines for Children Network.
Pharmacovigilance. Nanomedicine MSc. Cranfield University.

Contemporary issues and future challenges in Drug Development - South Asian Chapter of ACCP, Mumbai

Royal College of Physicians of Edinburgh: Medication errors Edinburgh, 2007
Association of Anaesthetists of GB and Ireland: Medical Manslaughter London, 2007
Witness seminar – Clinical Pharmacology - The Wellcome Trust 2007
Contemporary issues and future challenges in Drug Development - South Asian Chapter of American College of Clinical Pharmacology : 'The need for pharmacovigilance' Mumbai, 2007

MSc lectures on toxicology: adverse drug reactions Birmingham, 2007
Post mortem clinical pharmacology Clinical Pharmacology Colloquium Bangor 2008
Medication Errors Royal College - Rational prescribing conference London 2008
MSc lectures on experimental pharmacology: adverse drug reactions Oxford, 2008
Birmingham PCTs Educational Meeting: adverse drug reactions Birmingham, 2008
MSc Lecture on sports science: drugs and athletics Oxford, 2008
Cheltenham Science Festival. Introduction to Sir Michael Rawlins. Cheltenham, 2008

Empirical Medication Errors Research Group Erice: classification of medication errors. Erice, 2008.
RCP Update Meeting - Lecture on Murder by Drugs. Bedford, 2008

Professor Ferner continues as an executive committee member of the British Pharmacological Society and BNF Development Committee, and also as a member of PEAG.

The website has been redeveloped. The Centre's own website is at www.yccwm.org.uk for world related to YCC activity. We also maintain www.adr.org.uk for dealing with aspects of the Centre's work non-related to YCC activity.

We have published 3 issues of our bulletin re:Action (editions 33–35) which is distributed to all pharmacies and GPs' surgeries in the region. Even bulletin reminds reporters to be vigilant of potential ADRs. Topics covered were

Reactions to oseltamivir ▼
Statins and memory impairment
African herbal products
Kelp and thyroid disorders
Antipsychotics and Pisa syndrome
Birth defects and lamotrigine
Upper gastrointestinal bleeding and antithrombotics
Reactions to tablet colourings
Adulterated Ayurvedic medications
Salivary gland enlargement and thiazolidinediones
Adverse drug reaction or side effect? A definition

6. PUBLICATIONS

Publications for 2008/09 include

Alton DM, **Coleman JJ**. The medic's guide to prescribing: What should I know about this drug? *Student BMJ* 2007; 15: 415–6.

Butt TF, Black A, **Ferner RE**. Prescribing, preparing and administering injectable medicines. BMJ Learning 2008. In collaboration with the National Patient Safety Agency (NPSA). Published on BMJ Learning Online Sept 2008.

Butt TF, Cheung BMY. Amlodipine/valsartan combination therapy: It's role in hypertension. *Medical Progress* 2008; 35: 238-242.

Butt TF, **RE Ferner**. Adverse Drug Reactions. *Medicine* 2008, 36 (7), 364 - 368

Cheng K, Masters S, Stephenson T, Cooke R, **Ferner R**, Ashworth M, Nunn T. Identification of suspected fatal adverse drug reactions by paediatricians: a UK surveillance study. *Arch Dis Child* 2007; [Published Online First: 22 June 2007](http://dx.doi.org/10.1136/adc.2006.107789).
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Coleman JJ, **Ferner RE**. Poisoning. In: *An Insider's Guide to the Medical Specialties*. Reckless I, Reynolds J (Eds). Oxford University Press; Oxford, 2006.

Coleman JJ. Antihypertensive Drugs. In: *Side Effects of Drugs Annual 29*. Aronson JK (Ed). Elsevier; Amsterdam, 2007.

- Cox A, McDowell S.** Changing roles, changing risks — the paradox of pharmacist prescribing. *The Pharmaceutical Journal*. 2007; 278: 46.
- Cox A.** Chimeraphobia. *The Philosophers' Magazine* 2007; 38: 14–6
- Cox AR, Anton C, Marriott JF, Ferner RE.** The paradox of low prescribers who are high reporters: correlates of spontaneous reporting of adverse drug reactions within primary care. *Drug Safety* 2006; 30: 977–8 (Presented at the 7th Annual Meeting of ISoP 2007).
- Cox AR, Kirkham H.** A Case Study of a Graphical Misrepresentation: Drawing the Wrong Conclusions about the Measles, Mumps and Rubella Virus Vaccine. *Drug Safety* 2007; 30: 831–6.
- Cox AR.** Serious ADRs. Recognition and management of drug-induced blood disorders. *Prescriber* 2007; 18: 51–6.
- Ferner RE, Beard K.** Over the counter medicines: proceed with caution. *BMJ*. 2008; 336: 694-6.
- Ferner RE, McDowell S, Cotter A.** Medical Errors and Lessons from Drug-Related Deaths. In: Mann RD, Andrews EB, eds. *Pharmacovigilance*. 2nd ed. Chichester: John Wiley and Son, 2007.
- Ferner RE.** Did the drug cause death? Codeine and breastfeeding. *Lancet* 2008; 372: 606-8
- Ferner RE.** Post-mortem clinical pharmacology. *Br J Clin Pharmacol*. 2008 Jul 15. [Epub ahead of print] PMID: 1863788
- Howard RL, Avery AJ, **Coleman JJ, Ferner RE, Barber N.** Design specification for NHS IT systems to minimise risk of harm to patients from medications. Presented at the *Drug Utilisation Research Group – RSM London 2007*
- Langford NJ, Cox A.** Interactions between Antihypertensive Drugs and Other Medications. In: *Comprehensive Hypertension*. Editors: Lip GHY, Hall JE. Philadelphia, Mosby Elsevier; 2007. 1075–86.
- Langford NJ, Ferner RE.** Adverse effects of methadone in children. *Adverse Drug reaction Bulletin* 2007; 244: 935–8.
- Layton D, **Cox A.** Pharmacovigilance. In: Bond C editor. *Using Medicines Information*. Oxford, Radcliffe Publishing 2007. p. 141–168.
- Martin U, **Coleman JJ.** Drugs and the Elderly. In: *Pharmacovigilance* (2nd Ed.) Mann RD, Andrews EB (Eds). John Wiley and Sons Ltd.; Chichester, 2007.
- McDowell SE, Coleman JJ, Ferner RE.** Rhabdomyolysis and statins – an analysis of spontaneous case reports using a three-dimensional classification scheme. *Drug Safety* 2006; 30: 979 (Presented at the 7th Annual Meeting of ISoP 2007).
- Ormerod S, **McDowell SE, Coleman JJ, Ferner RE.** Ethnic differences in the risks of adverse reactions to drugs used in the treatment of psychoses: systematic review and meta-analysis. *Drug Safety* 2006; 30: 975–6. (Presented at the 7th Annual Meeting of ISoP 2007).
- Quasim S, **Coleman JJ.** Drugs of Abuse – A Review. *CPD Anaesthesia* 2007; 9: 29–36.

Rajakaruna G, **Butt TF**. Drug-induced acute kidney injury. *Adverse Drug Reaction Bulletin* 2007; 245: 939- 942.

Smellie WS, **Coleman JJ**. Pitfalls of testing and summary of guidance on safety monitoring with amiodarone and digoxin. *BMJ* 2007; 334: 312–5.

Smellie WS, Forth J, **Coleman JJ**, Irvine W, Dore PC, Handley G, Williams DG, Galloway PJ, Kerr KG, Herriot R, Spickett GP, Reynolds TM. Best practice in primary care pathology: review 6. *J Clin Pathol* 2007; 60: 225–34.

Tenant R, Mohammed MA, **Coleman JJ**, Martin U. A systematic review of the uses of statistical process control charts to monitor clinical variables in individual patients. *International Journal for Quality in Health Care* August 2007; 19: 187–94

Thomas LJ, **Coleman JJ**. The medic's guide to prescribing: Rational Prescribing. *Student BMJ* 2007; 15: 144–5.

Thomas LJ, **Coleman JJ**. The medic's guide to prescribing: Rational prescribing. *studentBMJ* 2007; 15: 133–68.

7. RESEARCH

We are undertaking a GPRD project looking into the monitoring of patients on antihypertensive medication

We are also undertaking a study into published sources of prescribing guidance.

Dr Cox completed his research into ADR reporting in the West Midlands.