

**YCC West Midlands**

**ANNUAL REPORT  
2007/08**

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

2007/08

## 1. STAFF

Professor R E Ferner – Director  
Dr N J Langford\* – Honorary Consultant Pharmacologist  
Dr T F Butt\*/Dr J J Coleman\* – 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

This is the first annual report of the Centre under its new contractual arrangements with the MHRA. Our priorities for the year were to focus on teaching and information and we have continued our programmes for all grades of staff from nurses to consultants. We were involved in the launch of patient reporting earlier this year and have distributed a large number of patient reporting packs throughout the region. We have started to make contacts with expert groups of patients. We have continued to expand our website to provide a valuable resource for the region, and more widely.

There has been a fall in reporting rates from the region, but the reporting rate from the West Midlands is still greater than for the UK as a whole. There has, however, been a rise in the proportion of reports submitted which are serious and at 72% this is now the highest in the centre's existence. Reports to black triangle drugs have fallen. There is an unexplained large fall in the percentage and number of reports we receive in elderly patients aged over 65. This is despite many of the drugs in the top 10 being drugs used to treat diseases associated with older age. There have been far fewer varenicline reports than from other regions.

The number of follow-ups processed has been less than we would have predicted. We believe that more timely follow-up – the time for follow-up to be requested was often over 1 month – would result in a higher follow-up rate.

## 3. YELLOW CARD DATA

*Number of reports*

Year	Number of reports	as %age of national reports	Source
2007/08	1149	9.1%	from MHRA
2006/07	1217	9.3%	
2005/06	1396 <sup>†</sup>		direct reporting to CSMWM and bypass data
2004/05	1643		
2003/04	1622		

<sup>†</sup> 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
2007/08	824	72%
2006/07	837	69%
2005	859	57%
2004	963	58%
2003	803	54%

\* 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
2007/08	264	23%
2006/07	271	22%
2005/06	362	26%
2004/05	512	31%
2003/04	532	33%

### *Fatal reports*

Year	Number of fatal reports	as %age of total reports
2007/08	35	3.0%
2006/07	28	2.3%
2005/06	33	2.4%
2004/05	32	2.0%
2003/04	32	2.0%

### *Age banding*

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

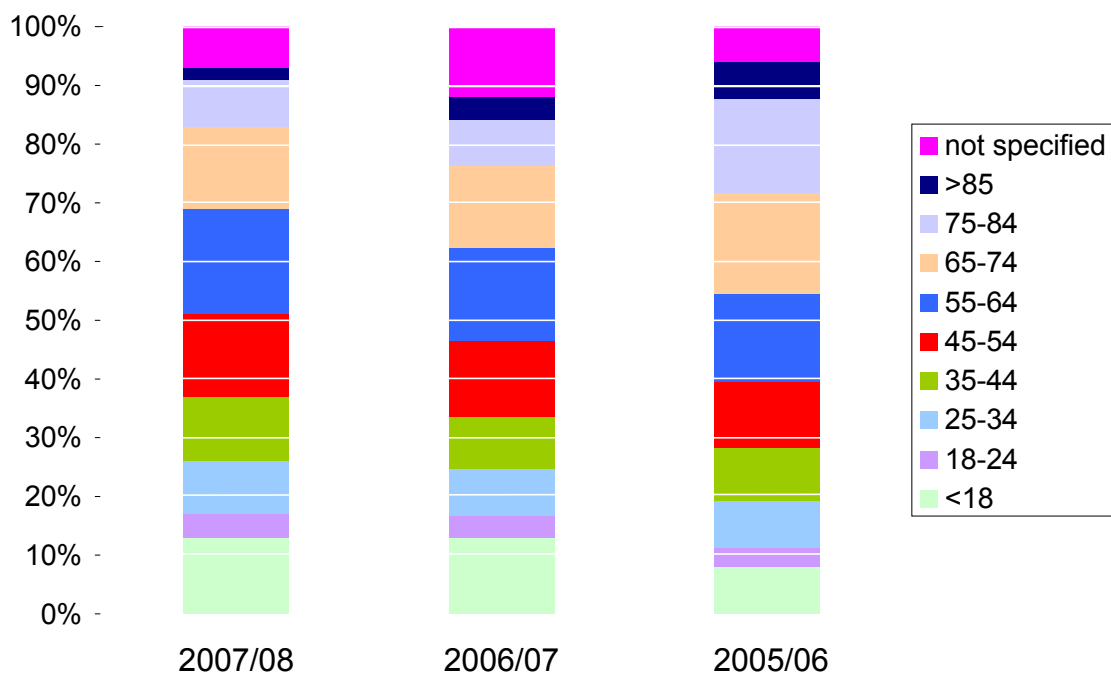


Figure 1: Proportion of reports by age of patient

*Source of report*

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

### Type of report

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

### Top 10 drugs

N.B. these figures provided by the MHRA should be treated with circumspection in light of the total number of reports (718 'top 10' reports compared with 1149 reports for all drugs)

rINN	Total
varenicline▼	118
aspirin	114
simvastatin	101
salbutamol	62
ramipril	62
bendroflumethiazide	56
atorvastatin	54
prednisolone	51
lansoprazole	51
rimonabant▼	49

## 4. FOLLOW UP OF REPORTS

We were asked to follow up 26 reports on behalf of the MHRA, of which 5 had a fatal outcome. A further 38 reports from YCC West Midlands were followed-up directly by the MHRA. This was 2.2% of the total reports from the West Midlands. In the period January-May 2006 before reporting arrangements changed we followed up 13% of our reports. It is not clear why the unit was not asked to follow-up all fatal reports in the region (n=35).

The response rate to follow up is 58%. 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 – OSCE	whole day	12	3

FY2s study day	whole day	30	1
University of Hertfordshire MSc in Pharmacovigilance – classifying ADRs	1 hour	30	1
FY1s – safe use of medicines	1 hour		1
University of Birmingham roadshow to 5 <sup>th</sup> 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
SpR in Neurology training day	1 hour		1
Rugby General practitioners	2 hours	10	1
Drug Safety Induction talks	1 hours	10-30	26
Spring South West Clinical Pharmacology Colloquium	20 minutes	40	1
MHRA Conference Birmingham	30 minutes	150	1
Stafford Hospital – health professionals	1 hour	40	1
UKCRN Paediatrics Forum Birmingham	1 hour	50	1
BPC Manchester	20 minutes	50	1
Birmingham University Warfarin interactions talks (inc ADRs)	1 hour	40	6
Vision gain Pharmacovigilance conference	1 hour	30	1
Warwick Diabetes MSc	2 hours	20	1
HOB PCT update	4 hours	250	1
Overseas Pharmacy Programme	3	40	1
4 <sup>th</sup> Year Pharmacists specialist Option	3	12	5
2nd year pharmacy students – introduction to pharmacovigilance	1	160	1
Keele Clinical Diploma – ADR section	Distance learning material	25	1

### Lectures given

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](http://www.yccwm.org.uk) for world related to YCC activity. We also maintain [www.adr.org.uk](http://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 2007/08 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. doi:10.1136/adc.2006.107789](https://doi.org/10.1136/adc.2006.107789)

**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.