

YCC West Midlands

**ANNUAL REPORT
2009/10**

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

2009/10

1. STAFF

Professor R E Ferner – Director
 Dr N J Langford – Honorary Consultant Pharmacologist
 Dr N Arulanantham – Honorary Specialist Registrar
 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 focused on teaching and providing information and we have continued our programmes for all grades of staff from nurses to consultants, and have begun to make progress in communicating with patient groups.

The number of reports from the Region fell again, and this was particularly so for reports from GPs. Patient reports also fell. The proportion of serious reports has not changed from last year.

3. YELLOW CARD DATA

Number of reports

Year	Number of reports	as %age of national reports	Source
2009/10	915	7.7%	from MHRA
2008/09	1137	8.0%	
2007/08	1149	9.1%	
2006/07	1217	9.3%	

Serious reports

Year	Number of serious reports	as %age of total reports
2009/2010	494	54%
2008/09	623	55%
2007/08	824	72%
2006/07	837	69%

Black triangle reports

Year	Number of ▼ reports	as %age of total reports
2009/10	-	-
2008/09	-	-
2007/08	264	23%
2006/07	271	22%

Fatal reports

Year	Number of fatal reports	as %age of total reports
2009/10	18	2%
2008/09	22	1.9%
2007/08	35	3.0%
2006/07	28	2.3%

Age banding

Age range	%age of reports 2009/10	%age of reports 2008/09	%age of reports 2007/08	%age of reports 2006/07
<18	17%	16%	13%	13%
18-24	7%	3%	4%	4%
25-34	9%	8%	9%	8%
35-44	12%	10%	11%	9%
45-54	12%	14%	14%	13%
55-64	14%	16%	18%	16%
65-74	13%	13%	14%	14%
75-84	7%	9%	8%	8%
>85	2%	2%	2%	4%
not specified	6%	8%	7%	12%
Total	915	1137	1149	1217

Source of report

Reporter qualification	2009/10	2008/09	2007/08	2006/07
Carer	6	10	12	5
Community Pharmacist	34	42	40	13
Consumer or other non health professional	2			2
Coroner			2	
Dentist	3	4	4	1
GP	192	257	302	314
Hospital Doctor	143	177	202	137
Hospital Health Professional	63	92	80	26
Hospital Nurse	67	65	44	45
Hospital Pharmacist	57	58	76	85
Nurse	140	157	126	108
Optometrist				3
Other Health Professional	36	63	67	139
Parent	15	7	6	11
Patient	97	155	140	202
Pharmacist	29	20	21	23
Physician	31	29	34	114

We have created a number of additional graphs to examine some local trends in reporting.

Figure 2: All Patient Reports (combined patient, carer, and parent reports)

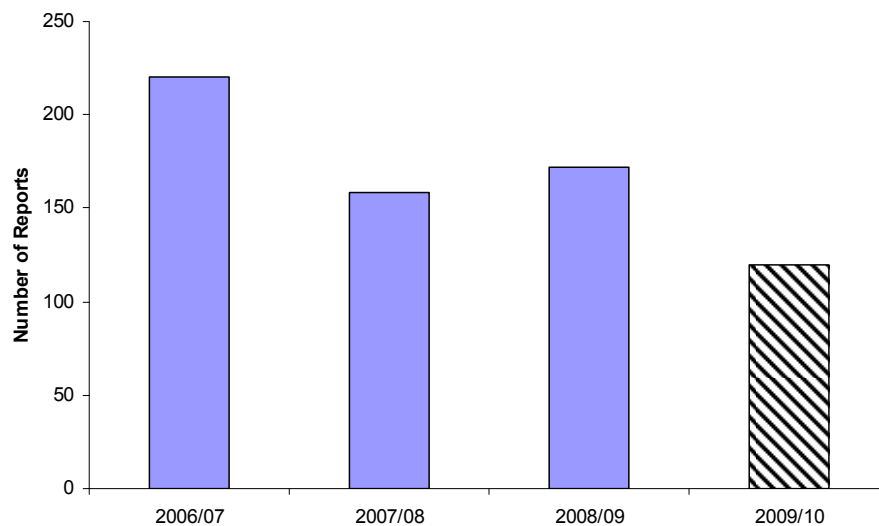


Figure 3: All hospital Reports (Combination of hospital doctor, hospital nurse, hospital pharmacist & hospital other healthcare professional)

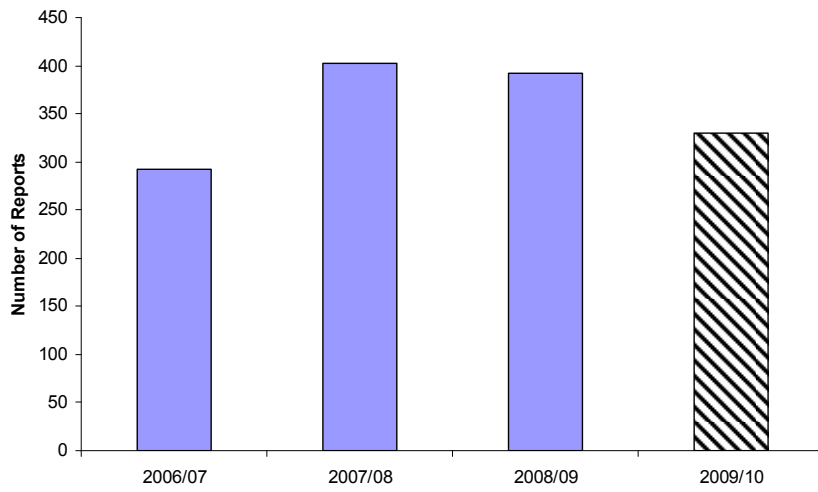


Figure 4: All Pharmacist Reports (Combination of pharmacist, community pharmacist, & hospital pharmacist).

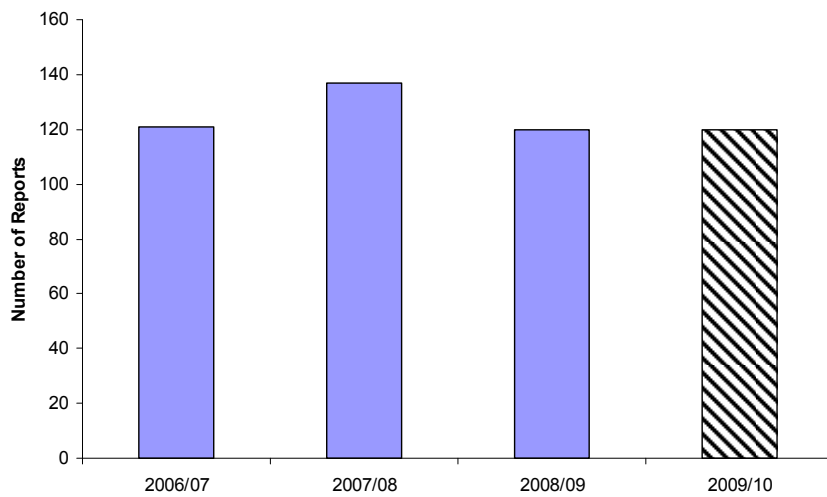


Figure 5: Hospital Doctor Reports

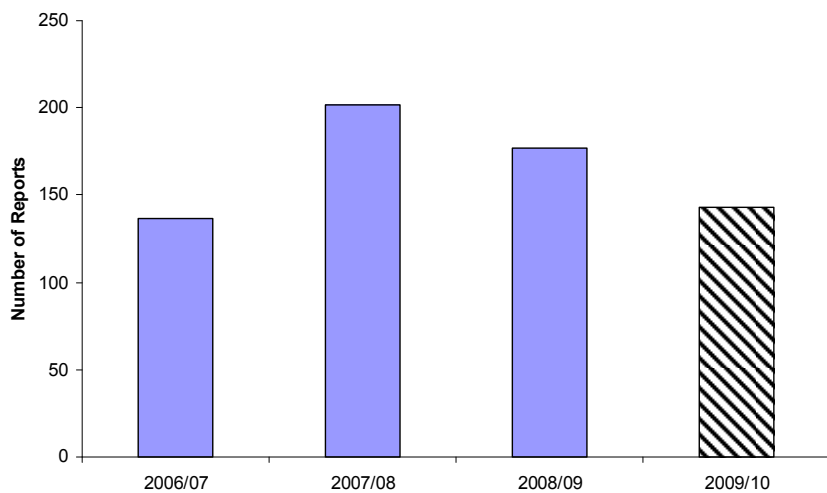


Figure 6: All Healthcare Professional Reports

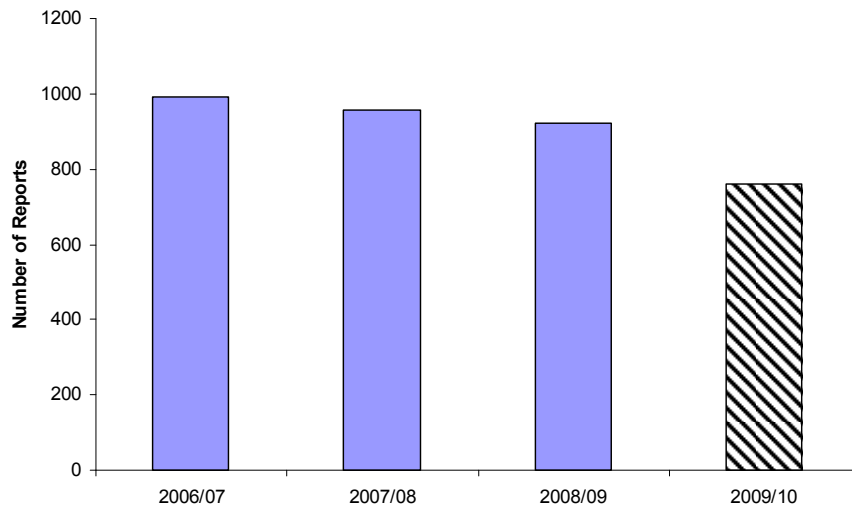


Figure 8: All Nurse Reports (Nurse, and Hospital Nurse)

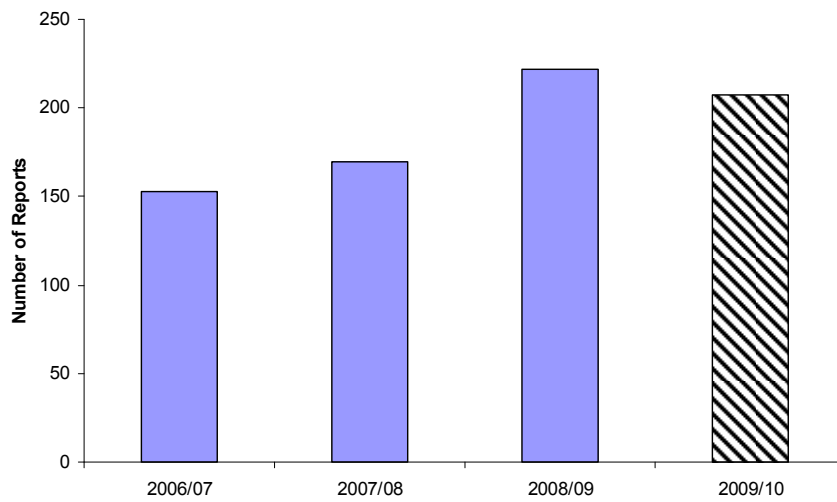
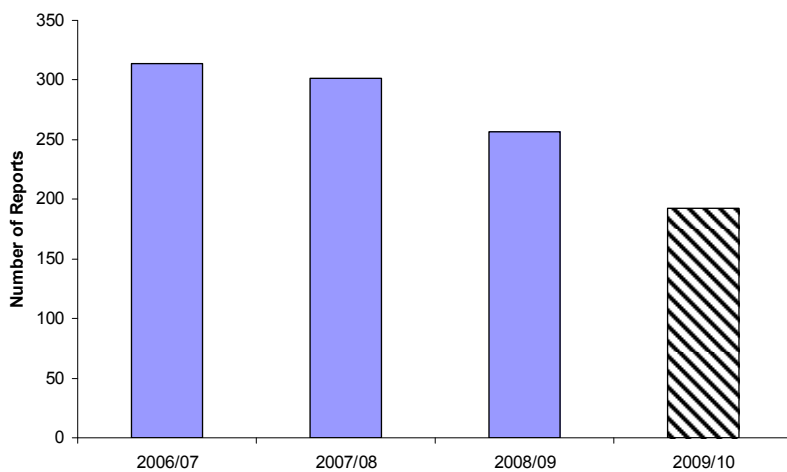


Figure 9: General Practitioner Reports



Type of report

Source	2009/10	2008/09	2007/08	2006/07
Paper	data not available	data not available	923	data not available
Electronic			220	
Telephone			6	

Top 14 drugs

The top 14 drugs listed as suspect drug are shown below

rINN	Total
human papilloma virus vaccine	109
varenicline	64
adalimumab	27
sitagliptin	21
infliximab	18
omalizumab	17
simvastatin	15
exenatide	14
quetiapine	13
atorvastatin	9
diphtheria, tetanus, and poliomyelitis vaccine	9
docetaxel	9
etanercept	9
pneumococcal vaccine	9

Pandemic reports

Pandemic Vaccine / Antiviral	Number of reports	Fatal Reports
Tamiflu®	100	1
Relenza®	1	0
Swine flu vaccines	253	2

4. FOLLOW UP OF REPORTS

We no longer have a role in follow-up.

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	1
Aston University pharmacy students – signal detection	1 hour	12	1
Birmingham University medical students –	half day	70	6

Prescribing Passport Examination			
FY2s study day	whole day	160	2
FY1s – safe use of medicines	half day	105	1
University of Birmingham roadshow to 5 th year medical students	whole day		1
MHRA SpR training day (attended)	whole day		1
Birmingham University MSc lectures in toxicology	4 hours		1
Birmingham University medical school – safe prescribing lecture	6 hours	460	1
Drug Safety Induction talks	1 hours	10-30	26
Overseas Pharmacy Programme	3	40	1
4 th Year Pharmacists Drug Safety	1 hour	140	3
2nd year pharmacy students – introduction to pharmacovigilance	1 hour	160	1
Keele Clinical Diploma – ADR section revised	Distance learning material	25	1
Warfarin interactions and Yellow Card scheme: Birmingham University Primary care unit	1 hour	15-25	6
Hertfordshire University – Pharmacovigilance MSc – Principles of Pharmacovigilance	1 hour	50	1

Lectures given

Pharmacovigilance. UK Clinical Research Network/Medicines for Children Network. A R Cox

Pharmacovigilance. Nanomedicine MSc. Cranfield University. A R Cox

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

We continue to maintain our 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 2 issues of our bulletin re:Action (editions 38 & 39) which is distributed to all pharmacies and GP surgeries in the region. Every bulletin reminds reporters to be vigilant of potential ADRs and promotes our educational service. Topics covered were

- HPV vaccination (Reminder on safety and need for reporting)
- Varenicline (Champix® ▼) (Reminder of MHRA warnings)
- Uncomfortable ulcers? (Nicorandil-induced ulcers)
- CK & you shall find (HMG-CoA reductase inhibitors and myopathy)
- Gd can be bad (gadolinium associated nephrogenic systemic fibrosis)
- Asleep at the wheel (Sleep driving associated with zolpidem)

6. PUBLICATIONS AND CONFERENCES

Publications for 2009/10 include:

Ferner RE, Hughes DA. The problem of orphan drugs. *BMJ* 2010; 341: c6456

Bonnici K, Stanworth D, Simmonds MS, Mukherjee E, Ferner RE. Flowers of evil. *Lancet* 2010; 376(9752): 1616

Ferner RE, Coleman JJ An algorithm for integrating contraindications into electronic prescribing decision support. *Drug Saf* 2010; 33(12): 1089-96

Aronson JK, Ferner RE Preventability of drug-related harms - part II: proposed criteria, based on frameworks that classify adverse drug reactions. *Drug Saf* 2010; 33(11): 995-1002

Ferner RE, Aronson JK Preventability of drug-related harms - part I: a systematic review. *Drug Saf.* 2010; 33(11): 985-94

Aronson JK, Ferner RE Length of treatment. Three questions for prescribers. *BMJ* 2010; 341: c5013

Ferner RE, Lenney W, Marriott JF Controversy over generic substitution. *BMJ* 2010 Jun 1; 340 :c2548

Hughes DA, Ferner RE New drugs for old: disinvestment and NICE. *BMJ* 2010 Feb 25; 340: c572

McDowell SE, Mt-Isa S, Ashby D, Ferner RE. Where errors occur in the preparation and administration of intravenous medicines: a systematic review and Bayesian analysis. *Qual Saf Health Care* 2010; 19(4): 341-5

McDowell SE. Monitoring of patients treated with antihypertensive therapy for adverse drug reactions. *Adverse Drug Reaction Bulletin* 2010; 261: 1003-1006

McDowell SE, Coleman JJ, Evans SJW, Gill PS, Ferner RE. Laboratory monitoring and adverse patient outcomes with antihypertensive therapy in primary care. *Pharmacoepidemiol Drug Saf* 2010; 19: 482-489.

Coleman JJ, McDowell SE, Evans SJW, Gill PS, Ferner RE Oversight: a retrospective study of biochemical monitoring in patients beginning antihypertensive drug treatment in primary care. *Br J Clin Pharmacol* 2010; 70: 109-117

Cox AR. MMR: a saga of bad science and scare stories that swayed healthcare professionals. *The Pharmaceutical Journal* 2010; 284: 157

Ferner RE, Hughes DA, Aronson JK. NICE and new: appraising innovation. *BMJ* 2010 Jan 5; 340: b5493

Ferner RE, Aronson JK. EIDOS: a mechanistic classification of adverse drug effects. *Drug Saf.* 2010; 33(1): 15-23

Cox AR, Butt TF, Ferner RE. An analysis and comparison of commonly available United Kingdom prescribing resources. *Journal of Clinical Pharmacy and Therapeutics.* 2010; 35(4): 453-464

Cox AR, Anton C, McDowell SE, Marriott JF, Ferner RE. Correlates of spontaneous reporting of adverse drug reactions within primary care: the paradox of low prescribers who are high reporters. *British Journal of Clinical Pharmacology* 2010; 69(5): 529-534

Cox AR, Anton C. Varenicline: evaluation of the utility of spontaneous consumer reports of suspected adverse effects filed on internet sites. *Drug Safety* 2009; 32(10); 903-904; (Presented at the 9th Annual Meeting of the ISoP, Reims, France, 6-9th October 2009)

Anton C, Cox AR, Ferner RE. Improving follow-up rates in spontaneous adverse drug reaction reporting: effectiveness of a targeted letter used by a regional centre in the UK. *Drug Saf.* 2009; 32(12): 1135-40

Cox AR. Patient reporting of adverse drug reactions. *Pharmacovigilance Review* 2009; 3(2): 18-21

Cox AR, Ferner RE. Prescribing errors in diabetes. *The British Journal of Diabetes and Vascular Disease.* 2009; 9(2): 84-88

Ferner RE. The epidemiology of medication errors: the methodological difficulties. *Br J Clin Pharmacol* 2009 ; 67(6): 614-20

McDowell SE, Ferner HS, Ferner RE. The pathophysiology of medication errors: how and where they arise. *Br J Clin Pharmacol* 2009; 67(6): 605-13

Members of EMERGE, Erice Medication Errors Research Group, Agrawal A, Aronson JK, Britten N, Ferner RE, de Smet PA, Fialová D, Fitzgerald RJ, Likič R, Maxwell SR, Meyboom RH, Minuz P, Onder G, Schachter M, Velo G. Medication errors: problems and recommendations from a consensus meeting. *Br J Clin Pharmacol* 2009 ; 67(6): 592-8

Ferner RE, McDowell SE. A model for NICE in the US *BMJ* 2009 ; 338: b2221

Aronson JK, Barnett DB, Breckenridge AM, Ferner RE, Jackson P, Maxwell SR, McInnes GT, Rawlins MD, Ritter JM, Routledge P, Walley TJ, Webb DJ, Williams D, Woods KL. The UK's NHS and pharma: need for more clinical pharmacologists. *Lancet* 2009; 373(9671): 1251-2

Aronson JK, Price D, Ferner RE. A strategy for regulatory action when new adverse effects of a licensed product emerge. *Drug Saf.* 2009; 32(2): 91-8

NJ Langford, K Tonks, M Singh. Out-patient detection of deep vein thrombosis using a combination of risk scoring and strain-gauge plethysmography: a follow-up study. *Acute Medicine* 2009; 8: 134-137

Cox AR, McDowell S. A Response to the article on the Association between Paracetamol/Acetaminophen: Use and Autism by Stephen T. Schultz. *Autism* 2009; 13: 123-124.

McDowell SE, Coleman JJ, Evans SJW, Ferner RE. The Relationship Between Baseline Testing of Serum Electrolytes and Creatinine and Adverse Outcomes in Patients Treated with Antihypertensive Drugs: An Analysis Using Propensity Score Matching Methods. *Drug Safety* 2009; 32(10): 912 (Presented at the 9th Annual Meeting of ISoP Reims, France 6-9 October 2009)

7. RESEARCH

Our current research activity is concerned with adverse drug reactions, including classification, monitoring, and the patient experience of adverse drug reactions and the Yellow Card scheme.

In the summer of 2009 we conducted an internal survey of staff prophylaxis with oseltamivir at City Hospital and Birmingham Children's Hospital. We obtained 34 responses, and discovered a number of previously unreported ADRs .