

YCC West Midlands

ANNUAL REPORT

2011/12

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

2011/12

1. STAFF

Professor R E Ferner – Director

Dr J J Coleman – Honorary Consultant Physician

Mr C Anton – Administrative Co-ordinator

Dr A R Cox – Pharmacovigilance Pharmacist

Ms M Robinson – Clerical Officer

2. SUMMARY

Our priorities for the year remain focused on teaching, providing information, and understanding adverse drug reactions. We have continued to teach nursing, pharmaceutical and medical staff from students to consultants. We have reminded GPs of the existence of the Yellow Card scheme and distributed patient Yellow Cards about the region.

The number of reports from the region rose, as did the percentage of serious reports

3. YELLOW CARD DATA

Number of reports

There were 974 reports in 2011/12.

There have been 453 reports in the first two quarters of 2012/13

| Year | Number of reports | as %age of national reports | Source |
|---------|-------------------|-----------------------------|-----------|
| 2011/12 | 974 | 7.4% | from MHRA |
| 2010/11 | 879 | 7.2% | |
| 2009/10 | 915 | 7.7% | |
| 2008/09 | 1137 | 8.0% | |
| 2007/08 | 1149 | 9.1% | |

Serious reports

There were 544 (56%) serious reports in 2011/12.

There have been 243 (54%) serious reports received in the first two quarters of 2012/13

| Year | Number of serious reports | as %age of total reports |
|---------|---------------------------|--------------------------|
| 2011/12 | 544 | 56% |
| 2010/11 | 481 | 55% |
| 2009/10 | 494 | 54% |
| 2008/09 | 623 | 55% |
| 2007/08 | 824 | 72% |

Fatal reports

| Year | Number of fatal reports | as %age of total reports |
|---------|-------------------------|--------------------------|
| 2011/12 | 29 | 3% |
| 2010/11 | 34 | 3.9% |
| 2009/10 | 18 | 2% |
| 2008/09 | 22 | 1.9% |
| 2007/08 | 35 | 3.0% |
| 2006/07 | 28 | 2.3% |

Age bands

| Age range | %age of reports | %age of reports | %age of reports | %age of reports | %age of reports |
|--------------|-----------------|-----------------|-----------------|-----------------|-----------------|
| | 2011/12 | 2010/11 | 2009/10 | 2008/09 | 2007/08 |
| <18 | 9% | 13% | 17% | 16% | 13% |
| 18-24 | 6% | 6% | 7% | 3% | 4% |
| 25-34 | 9% | 9% | 9% | 8% | 9% |
| 35-44 | 10% | 13% | 12% | 10% | 11% |
| 45-54 | 16% | 11% | 12% | 14% | 14% |
| 55-64 | 13% | 14% | 14% | 16% | 18% |
| 65-74 | 17% | 13% | 13% | 13% | 14% |
| 75-84 | 10% | 13% | 7% | 9% | 8% |
| >85 | 3% | 3% | 2% | 2% | 2% |
| unknown | 6% | 6% | 6% | 8% | 7% |
| Total | 974 | 879 | 915 | 1137 | 1149 |

Source of report

| Reporter qualification | 2011/12 | 2010/11 | 2009/10 | 2008/09 | 2007/08 |
|---|----------------|---------|---------|---------|---------|
| Carer | 7 | 5 | 6 | 10 | 12 |
| Community Pharmacist | 44 | 24 | 34 | 42 | 40 |
| Consumer or other non health professional | | | 2 | | |
| Coroner | | | | | 2 |
| Dentist | 3 | 3 | 3 | 4 | 4 |
| GP | 229 | 190 | 192 | 257 | 302 |
| Healthcare Assistant | 2 | | | | |
| Hospital Doctor | 191 | 184 | 143 | 177 | 202 |
| Hospital Health Professional | 63 | 51 | 63 | 92 | 80 |
| Hospital Nurse | 68 | 66 | 67 | 65 | 44 |
| Hospital Pharmacist | 68 | 36 | 57 | 58 | 76 |
| Nurse | 102 | 105 | 140 | 157 | 126 |
| Optometrist | | 1 | | | |
| Other Health Professional | 45 | 63 | 36 | 63 | 67 |
| Parent | 10 | 8 | 15 | 7 | 6 |
| Patient | 84 | 90 | 97 | 155 | 140 |
| Pharmacist | 28 | 12 | 29 | 20 | 21 |
| Physician | 12 | 39 | 31 | 29 | 34 |
| Radiographer | 21 | | | | |

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

Figure 1: All Patient Reports (combined patient, carer, and parent reports)

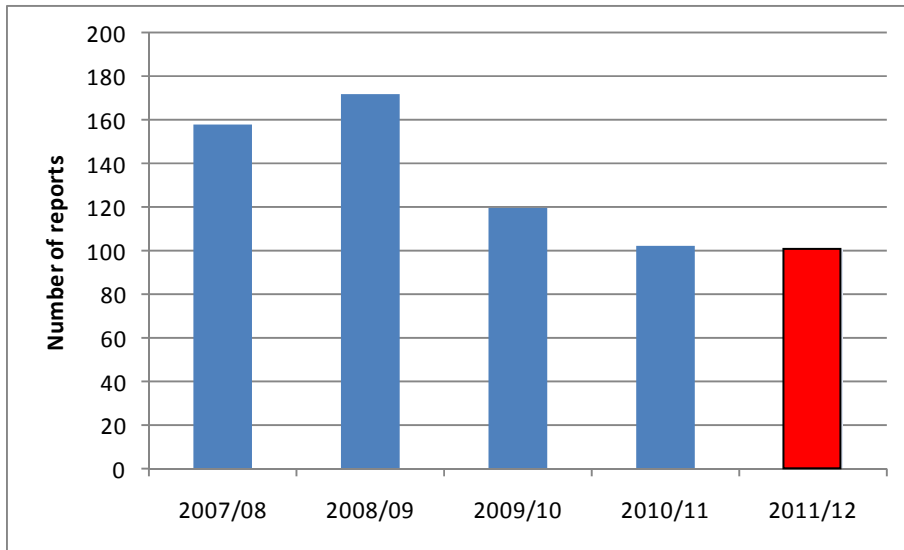


Figure 2: All hospital Reports (Combination of hospital doctor, hospital nurse, hospital pharmacist & hospital other healthcare professional)

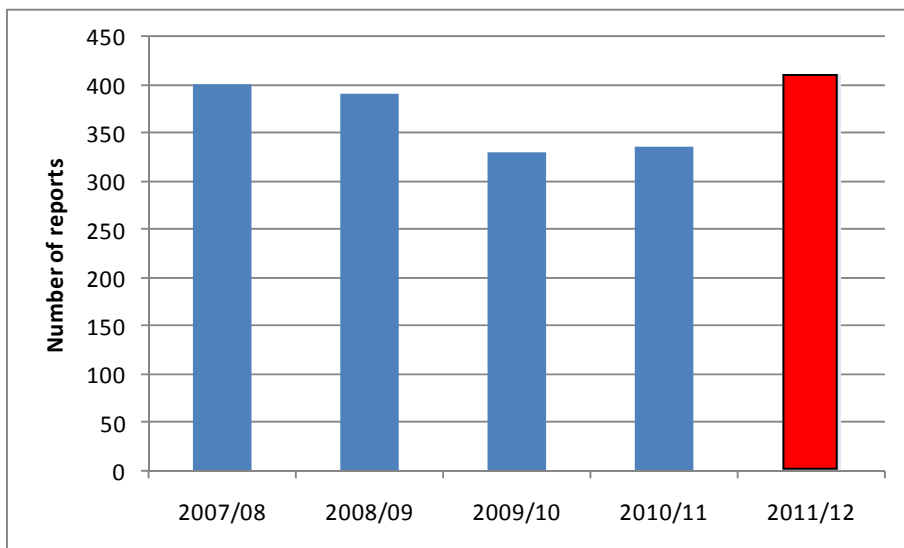


Figure 3: All Pharmacist Reports (Combination of pharmacist, community pharmacist, & hospital pharmacist).

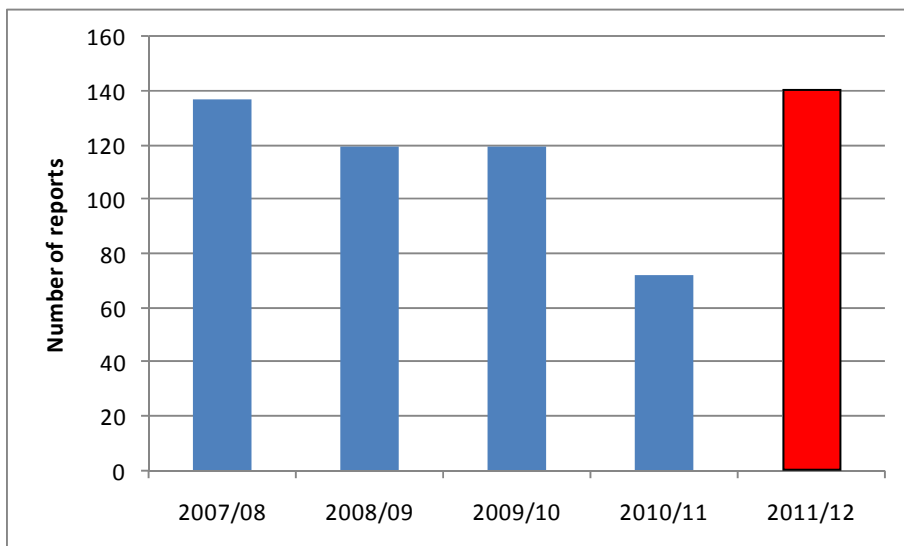


Figure 4: Hospital Doctor Reports

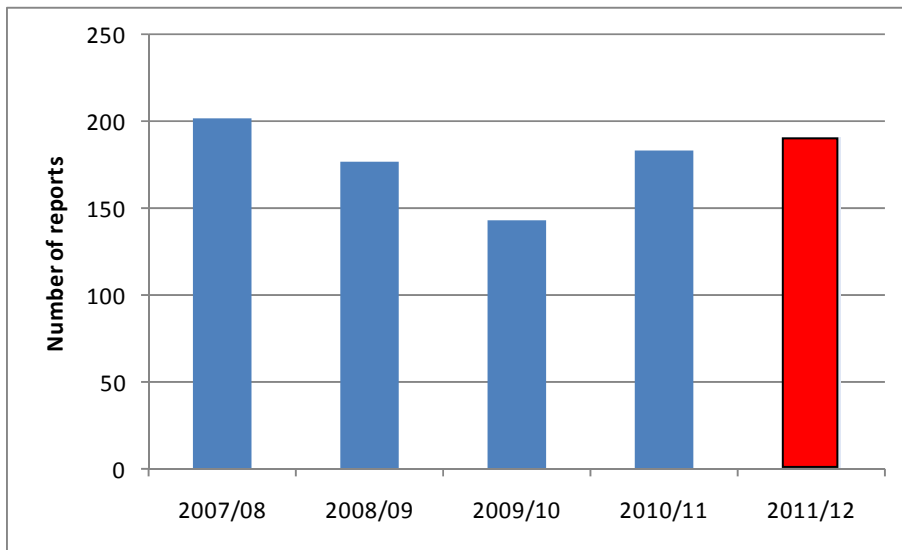


Figure 5: All Healthcare Professional Reports

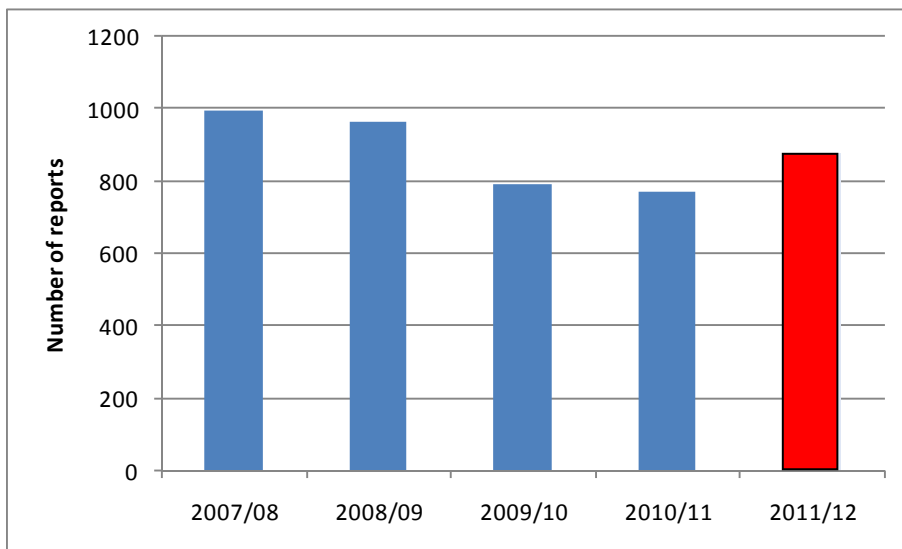


Figure 6: All Nurse Reports (Nurse, and Hospital Nurse)

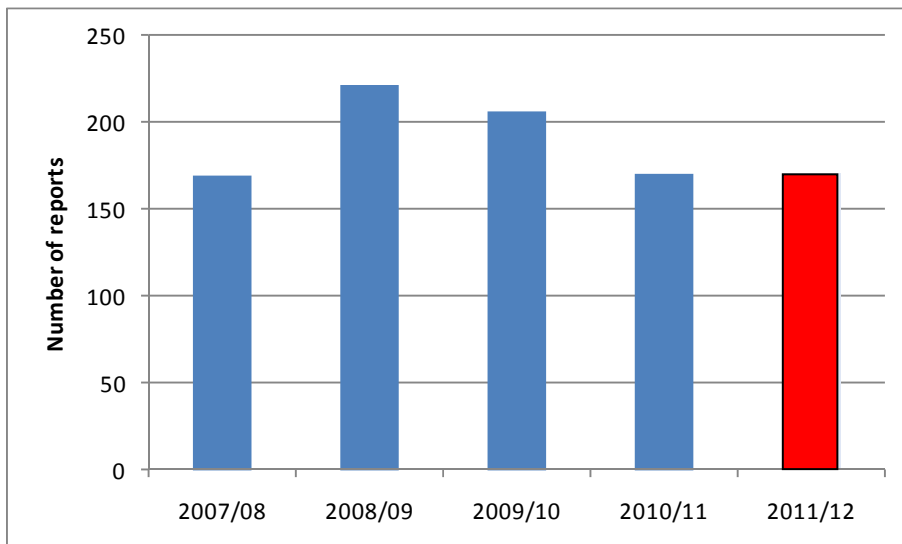
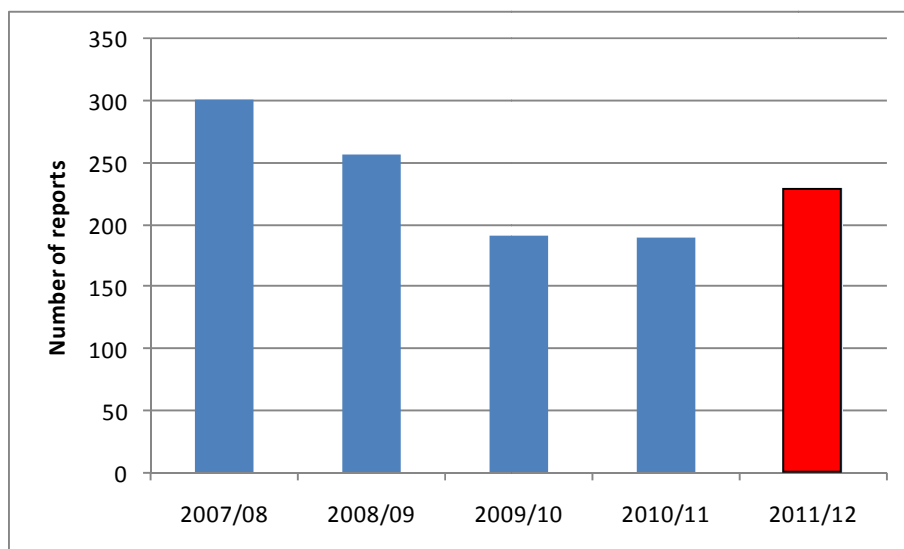


Figure 7: General Practitioner Reports



Top 10 drugs

The top 10 drugs listed as suspect drug for 2011/12 are shown below

| Drug | Total |
|-----------------------------|-------|
| varenicline ▼ | 47 |
| human papilloma virus ▼ | 23 |
| adalimumab ▼ | 21 |
| simvastatin | 17 |
| citalopram | 14 |
| Nexplanon® implant ▼ | 14 |
| omalizumab ▼ | 14 |
| certolizumab ▼ | 13 |
| etanercept | 13 |
| pneumococcal polysaccharide | 13 |

4. 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 |
|---|-----------|------------------------|--------------------|
| Birmingham University medical students – Prescribing Passport Examination | half day | 70 | 6 |
| University of Birmingham roadshow to 5 th year medical students | whole day | 70 | 6 |
| Birmingham University MSc lectures in toxicology | 4 hours | 40 | 1 |
| Birmingham University medical school – safe prescribing lecture | 6 hours | 460 | 1 |
| Overseas Pharmacy Programme | 1 hour | 40 | 1 |
| 4 th Year Pharmacists Drug Safety | 1 hour | 140 | 3 |
| 2nd year pharmacy students – introduction to pharmacovigilance | 1 hour | 160 | 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 |
| University of Oxford MSc in Experimental Therapeutics – Adverse drug reactions | Half day | 30 | 1 |
| Regional GP trainees | 2 hours | 35 | 1 |

Recent Invited lectures

1. International Congress on Drug-Induced GI Damage: Prevention & Treatment, Treviso, June 2011: ‘Drug-associated Adverse Events: Classification and Evaluation’
2. Innovation in Health Care Technology: Drugs Surgery, Devices and Diagnostics, Erice, June 2011: ‘Orphan Drugs’
3. American College of Clinical Pharmacology - South Asian Chapter, Mumbai August 2011: ‘Pharmacovigilance and Patient Safety–Current Issues in the United Kingdom’
4. Department of Clinical Pharmacology, University of Linkoping, September 2011: ‘Drug-drug interactions’

5. International Society of Pharmacovigilance, Istanbul, October 2011: "Better than cure" Part I: Defining preventability of pharmacovigilance actions of adverse drug reactions'
6. Hong Kong Pharmacology Society, Hong Kong, December 2011: 'The Error Message'
7. Department of Medicine, University of Hong Kong, December 2011: Grand Round— 'Pharmacological Femmes Fatales'
8. European Association of Poison Control Centres and Clinical Toxicologists, London, May 2012: 'Expert evidence in forensic toxicology'

6. PUBLICATIONS AND CONFERENCES

Papers

1. Butt TF, Cox AR, Lewis H, Ferner RE. Patient experiences of serious adverse drug reactions and their attitudes to medicines: a qualitative study of survivors of Stevens-Johnson syndrome and toxic epidermal necrolysis in the UK. *Drug Safety* 2011; 34: 319-28.
2. Butt TF, Cox AR, Oyebode JR, Ferner RE. Internet Accounts of Serious Adverse Drug Reactions: A Study of Experiences of Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis. *Drug Saf.* 2012;35(12):1159-1170
3. Coleman JJ, Hemming K, Nightingale PG, Clark IR, Dixon-Woods M, Ferner RE, Lilford RJ. Can an electronic prescribing system detect doctors who are more likely to make a serious prescribing error? *J R Soc Med* 2011; 104: 208-18.
4. Coleman JJ, Hodson J, Ferner RE. Deriving dose limits for warnings in electronic prescribing systems: statistical analysis of prescription data at University Hospital Birmingham, UK. *Drug Safety* 2012; 35: 291-8.
5. Coleman JJ, McDowell SE, Ferner RE. Dose omissions in hospitalized patients in a UK hospital: an analysis of the relative contribution of adverse drug reactions. *Drug Safety* 2012 Aug 1;35(8):677-83.
6. Coleman JJ, McDowell SE. Clinical Pharmacology: The potential of the internet. *Br J Clin Pharmacol.* 2012 Jun;73(6):953-8.
7. Coleman JJ, Nwulu U, Ferner RE. Decision support for sensible dosing in electronic prescribing systems. *J Clin Pharm Ther.* 2012; 37: 415-19.
8. Coleman JJ, Hodson J, Ferner RE. Deriving Dose Limits for Warnings in Electronic Prescribing Systems: Statistical Analysis of Prescription Data at University Hospital Birmingham, UK *Drug Safety* 2012; 35 (4): 291-298.
9. Ferner R.E. Drug-induced haemolytic anaemia. *Adverse Drug Reaction Bulletin.* October 2012; (276): 1063-1066.

10. Ferner R.E. Medication errors. *British Journal of Clinical Pharmacology*. June 2012; 73(6): 912-916.
11. Ferner R.E., Butt T.F. Adverse Drug Reactions. *Medicine (United Kingdom)*. July 2012; 40(7): 366-370
12. Hughes E., Seal R., Davies D., Marriott J., Ferner R., Patel V., Coleman J.. SCRIPT: An innovative e-Learning programme to improve the prescribing of newly qualified doctors in the West Midlands. *British Journal of Clinical Pharmacology*. Conference Publication: (var.pagings). June 2012; 73 (6):998.
13. Karthikeyan VJ, Ferner RE, Baghdadi S, Lane DA, Lip GY, Beevers DG. Are angiotensin-converting enzyme inhibitors and angiotensin receptor blockers safe in pregnancy: a report of ninety-one pregnancies. *J Hypertension* 2011; 29: 396-9.
14. Kshirsagar N, Ferner R, Figueroa BAA, Ghalib H, Lazdin J. Pharmacovigilance methods in public health programmes: the example of miltefosine and visceral leishmaniasis. *Transactions of the Royal Society of Tropical Medicine and Hygiene*. 2011; 105: 61-67.
15. Lorimer S, Cox AR, Langford NJ. A patient's perspective: the impact of adverse drug reactions on patients and their views on reporting. *Journal of Clinical Pharmacy and Therapeutics* 2011;37:148-152
16. McDowell SE, Ferner RE. Biochemical monitoring of patients treated with antihypertensive therapy for adverse drug reactions: a systematic review. *Drug Safety* 2011; 34: 1049-59.
17. Moss C, Ferner RE. British Medical Journal and prescribing of minocycline for acne. *Br J Dermatol*. 2012 Aug 27. doi: 10.1111/bjd.12022. [Epub ahead of print]
18. Nirantharakumar K, Marshall T, Hodson J, Narendran P, Deeks J, Coleman JJ, Ferner RE. Hypoglycemia in non-diabetic in-patients: clinical or criminal? *PLoS One*. 2012; 7: e40384.
19. Nirantharakumar K, Marshall T, Kennedy A, Narendran P, Hemming K, Coleman JJ. Hypoglycaemia is associated with increased length of stay and mortality in people with diabetes who are hospitalized. *Diabetic Medicine* 2012 Aug 31. doi: 10.1111/dme.12002. (ePublished ahead of print)
20. Nwulu U, Nirantharakumar K, Odesanya R, McDowell SE, Coleman JJ. Improvement in the detection of adverse drug events by the use of electronic health and prescription records: An evaluation of two trigger tools. *European Journal of Clinical Pharmacology*. 2012 Jun 17. (ePublished ahead of print)
21. Redwood S, Rajakumar A, Hodson J, Coleman JJ. Does the implementation of an electronic prescribing system create unintended medication errors? A study of the sociotechnical context through the analysis of reported medication incidents. *BMC Medical Informatics and Decision Making* 2011, 11:29.

22. Rosser D, Cowley NJ, Ray D, Nightingale PG, Jones T, Moore J, Coleman JJ. Quality improvement programme, focusing on error reduction: a single center naturalistic study. *JRSM Short Rep.* 2012; 3: 636
23. Thomas SK, Coleman JJ. The impact of Computerised Physician Order-Entry (CPOE) with integrated Clinical Decision Support (CDS) on pharmacist-physician communication in the hospital setting: A systematic review of the literature. *European Journal of Hospital Pharmacy: Science and Practice* doi:10.1136/ejpharm-2012-000110

Case reports

1. Arulanantham N, Anderson M, Gittoes N, Ferner RE. A 63-year-old man with hypomagnesaemia and seizures. *Clinical Medicine, Journal of the Royal College of Physicians of London.* 2011; 11(6): 591-593.

Reviews

1. Aronson JK, Ferner RE, Hughes DA. Defining rewardable innovation in drug therapy. *Nature Reviews Drug Discovery* 2012; 11: 253-254.
2. Ferner RE, Butt TF. Adverse drug reactions. *Adverse drug reactions. Medicine (United Kingdom).* 2012; 40: 366-70.
3. Ferner RE, Dear JW, Bateman DN. Management of paracetamol poisoning. *BMJ.* 2011 Apr 19;342:d2218. Review.
4. Ferner RE. Medication errors. *British Journal of Clinical Pharmacology* 2012; 73: 912-16.
5. Ferner RE. Toxicological evidence in forensic pharmacology. *International Journal of Risk and Safety in Medicine.* 2012; 24: 13-21.
6. Ferner RE. What's new in...: Adverse drug reactions. *Medicine.* 2011; 39: 239-241.
7. Langford NJ, Ferner RE. The medicolegal significance of pharmacokinetic interactions with ethanol. *Med Sci Law* (accepted for publication).

Editorials & opinion

1. Ferner RE, Beard K. How should we react to adverse drug reactions? *Postgrad Med J* 2011; 87: 81-2.
2. Ferner RE, Routledge PA, Chew M. The new BMJ series on therapeutics. *BMJ.* 2011; 342: 183.
3. Cox AR, Butt TF. Adverse Drug Reactions: When the Risk Becomes a Reality for Patients. *Drug Safety* 2012;35(11):977-981
4. Cox AR. Should patients report more ADRs. *Prescriber* 2011;22(11):7
5. Cox AR. ADRs: raise your suspicions. *Prescriber* 2011;21(15/16):6-9

Views

1. Ferner RE. Interactions. *BMJ* 2012; 344:e865, 2012
2. Ferner RE. Boundaries. *BMJ* 2012; 344: e2028.
3. Ferner RE. Consequences. *BMJ* 2012; 344: e2859.
4. Ferner RE. Summertime. *BMJ* 2012; 344: e4245.
5. Ferner RE. Susceptibilities. *BMJ* 2012; 345: e6420

Books

1. Richards D, Coleman JJ, Reynolds J, Aronson JK. *Oxford Handbook of Practical Drug Therapy* (2nd Ed). Oxford University Press; Oxford, 2011.

Chapters

1. Krska J, Cox AR. Adverse Drug Reactions. In: *Clinical Pharmacy and Therapeutics*. Walker R, Whittlesea C. (Eds). Churchill Livingstone; Edinburgh, 2012.
2. Ferner RE, McDowell SE. Fatal adverse drug reactions. In: Moore N, Andrews E, Eds. *Mann's pharmacovigilance 3e*. Wiley (In press)
3. Ferner RE, Cox AR. Drug-induced neurological disease. In: *A new textbook of medicine*. Davey P, Spriggings D, Eds. Oxford University Press (In press).
4. Coleman JJ, Cowley NJ, Cox AR. Pharmacology and Safe Prescribing of Drugs. In: *Fundamentals of Surgical Practice* (3rd Ed). Kingsnorth A, Bowley D (Eds). Cambridge University Press; Cambridge, 2011.
5. Coleman JJ, Cowley NJ, Cox AR. Antihypertensive Drugs. In: *Side Effects of Drugs Annual 33*. Aronson JK (Ed). Elsevier; Amsterdam, 2011.
6. Coleman JJ, Cox AR. Antihypertensive Drugs. In: *Side Effects of Drugs Annual 34*. Aronson JK (Ed). Elsevier; Amsterdam, 2012.

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. We conducted a controlled trial to see whether reminding GPs about the Yellow Card scheme improved the reporting rate. These data were presented at the ISOP meeting in 2012. The results showed that reminding GPs about the Yellow Card significantly increases reporting. As a

consequence we are sending reminders to GPs in the region in 2012/13. We see this as a simple and effective way of encouraging reporting.

Anthony Cox and Tehreem Butt have been examining the patient experience of ADRs using qualitative methods. This has taken place in a medical admissions unit, in those suffering severe skin reactions (Stevens Johnson Syndrome and toxic epidermal necrolysis), and via the examination of internet accounts of patients to severe skin reactions. This work has been well received.

Dr Coleman and Professor Ferner have concentrated their efforts on decision support for electronic prescribing to increase the safety of hospital drug use