

YCC West Midlands

**ANNUAL REPORT
2016/17**

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

2016/17

1. STAFF

Professor R E Ferner – Director
Professor J J Coleman – Honorary Consultant Physician
Dr J K Aronson – Honorary Consultant Physician
Mr C Anton – Administrative Co-ordinator
Mrs K Badyal – Pharmacovigilance Pharmacist
Dr A R Cox – Honorary Pharmacovigilance Pharmacist
Mrs T J Ahmad – Information Scientist

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 student nurses to consultants. We have continued to expand our network of ADR Champions and now have a champion in each of the acute Trusts. Work is continuing to recruit Champions in community and mental health trusts.

The number of reports from the region rose for the fourth year in a row with the total numbers up by 8%. There was an increase of 9% in reports from hospital pharmacists and 33% from community pharmacists. The number of patient reports increased and they now comprise 26% of all our reports. Reports from GPs fell. Few GPs in the region have electronic systems capable of submitting Yellow Cards directly. Electronic reports rose again and now comprise nearly 90% of our reports.

3. YELLOW CARD DATA

Number of reports

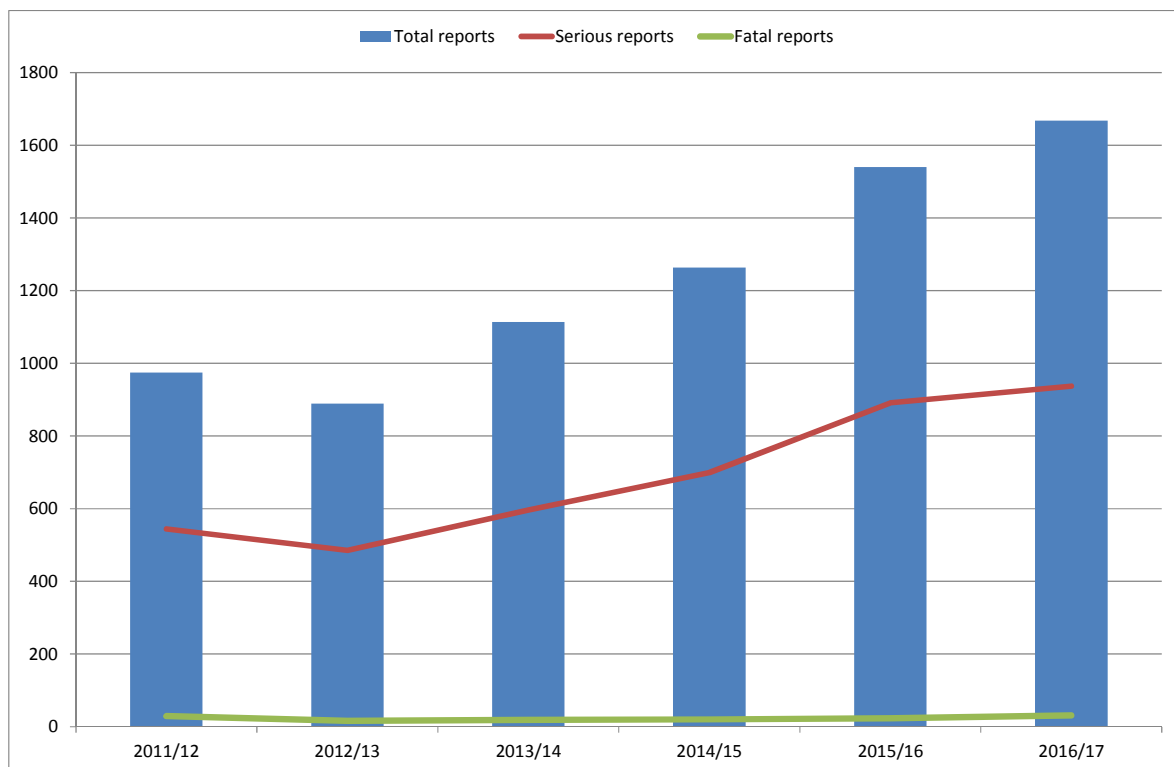
Year	Number of reports	As a percentage of national reports
2016/17	1668	6.2%
2015/16	1540	6.6%
2014/15	1263	6.5%
2013/14	1114	6.4%
2012/13	889	6.2%

Serious reports

Year	Number of serious reports	As percentage of total reports
2016/17	937	56%
2015/16	891	58%
2014/15	699	55%
2013/14	596	54%
2012/13	485	55%

Fatal reports

Year	Number of fatal reports	As percentage of total reports
2016/17	31	1.9%
2015/16	23	1.5%
2014/15	20	1.6%
2013/14	19	1.7%
2012/13	16	1.8%



Age banding

Age range	Percentage of reports 2016/17	Percentage of reports 2015/16	Percentage of reports 2014/15	Percentage of reports 2013/14	Percentage of reports 2012/13
<18	11%	11%	13%	12%	8%
18-24	7%	6%	6%	4%	6%
25-34	9%	9%	9%	8%	9%
35-44	11%	10%	9%	11%	11%
45-54	11%	13%	12%	14%	12%
55-64	15%	12%	12%	14%	14%
65-74	16%	17%	18%	16%	20%
75-84	11%	13%	11%	13%	11%
>85	4%	5%	4%	2%	5%
unknown	6%	4%	5%	4%	5%
Total	1668	1540	1263	1114	889

Source of report

Reporter qualification	2016/1	2015/1	2014/1	2013/1	2012/1	2011/1
Reporter qualification	7	6	5	4	3	2
Carer	13	7	11	9	6	7
Community Pharmacist	111	83	47	90	61	44
Coroner	1		2	1	1	
Dentist	1	4	5	8	1	3
GP	252	325	279	248	236	229
Healthcare Assistant	2		1	3		2
Hospital Doctor	189	174	176	155	144	191
Hospital Health Professional	28	16	36	31	48	63
Hospital Nurse	141	97	128	85	60	68
Hospital Pharmacist	250	230	121	92	98	68
Nurse	112	181	115	131	91	102
Other Health Professional	51	20	47	39	26	45
Parent	58	49	22	24	11	10
Patient	355	301	254	135	77	84
Pharmacist	25	14		16	8	28
Pharmacy Assistant	11	7				
Physician	12	3	7	11	8	12
Pre-reg Pharmacist	32	16				
Radiographer	24	9	7	11	10	21

Report type

Report type	2016/17	2015/16	2014/15
eYC	1219	988	768
Paper	198	214	275
GP systems	6		117
TPP	104	297	61
MiDB	46	41	37

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)

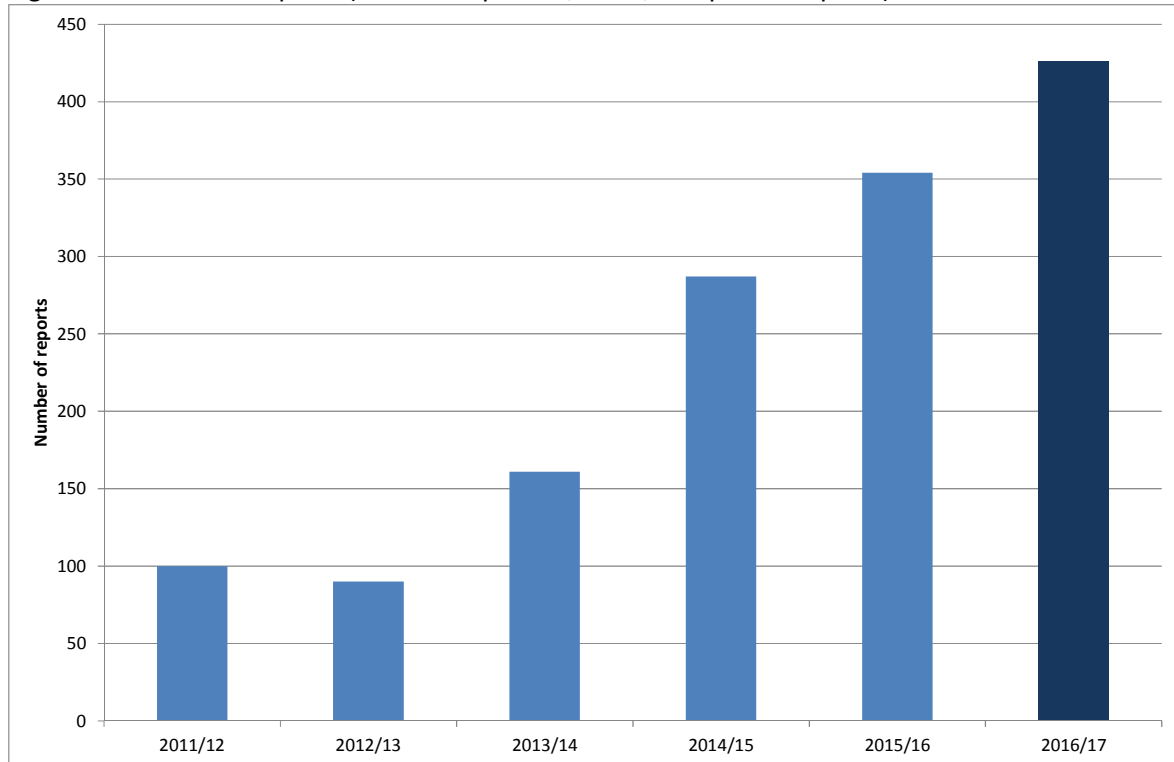


Figure 2: All hospital Reports (Combination of hospital doctor, hospital nurse, hospital pharmacist & hospital other healthcare professional)

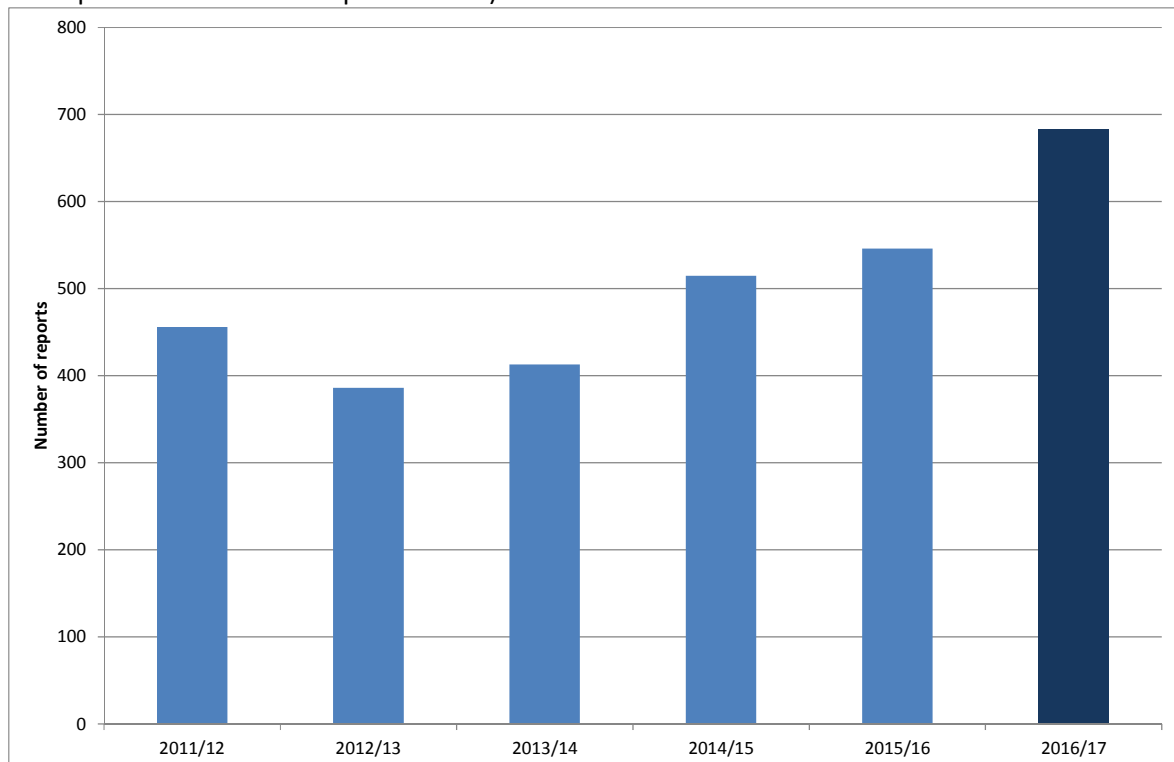


Figure 3: All Pharmacist Reports (Combination of pharmacist, community pharmacist, & hospital pharmacist).

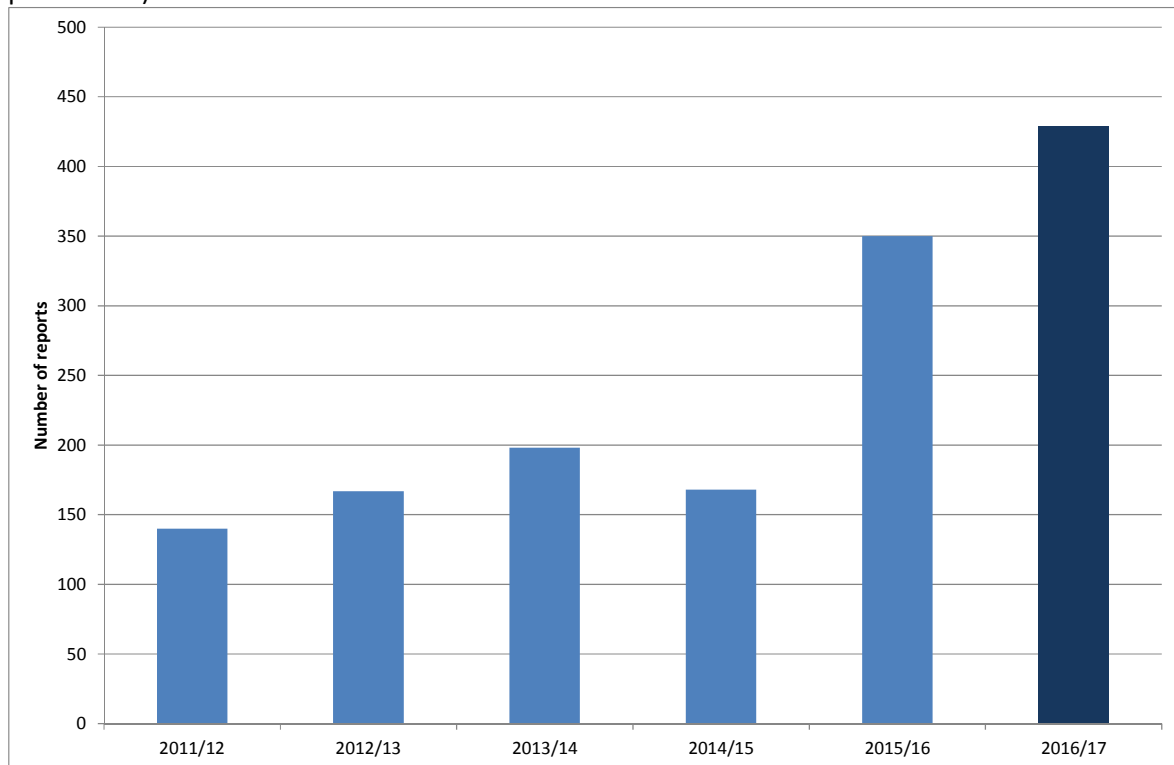


Figure 4: Hospital Doctor Reports

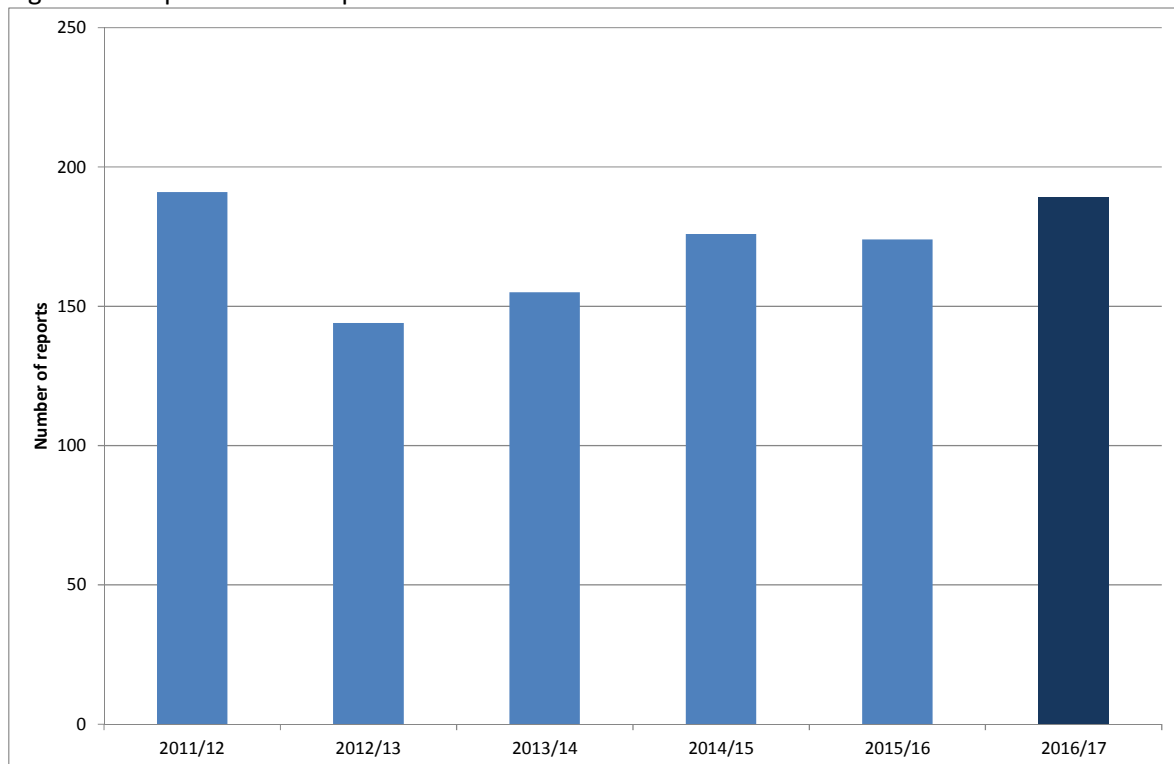


Figure 5: All Healthcare Professional Reports

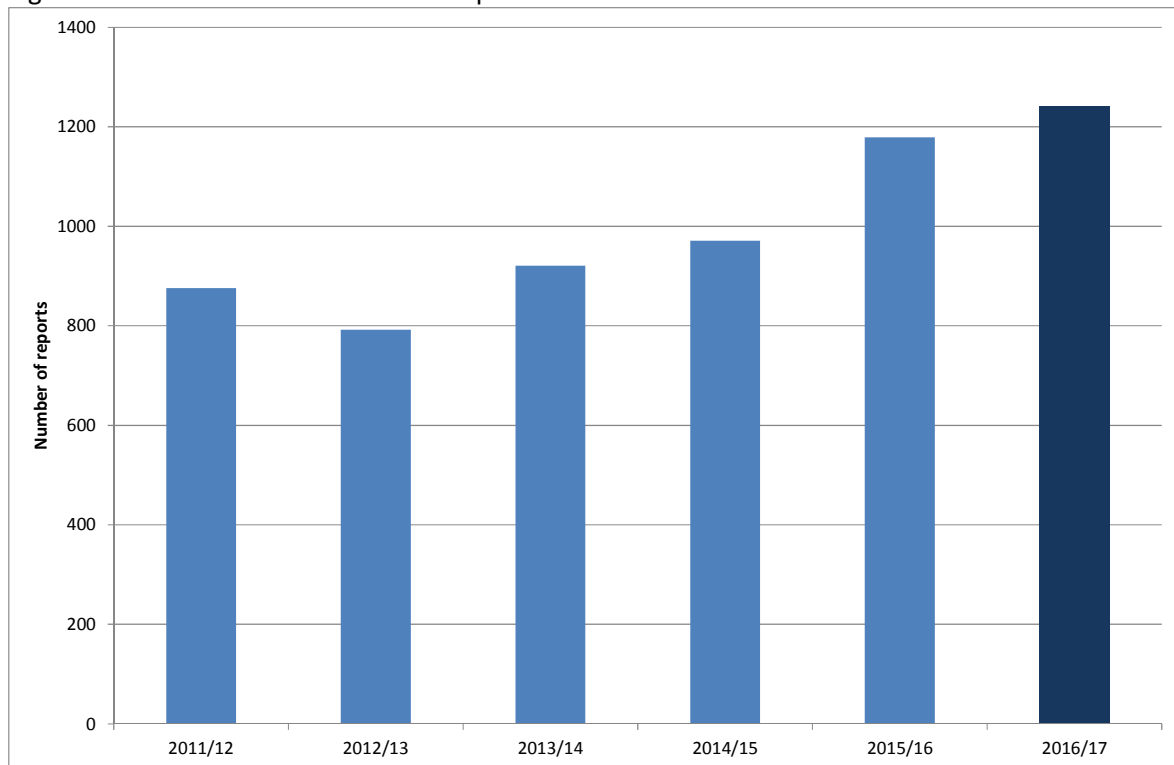


Figure 6: All Nurse Reports (Nurse, and Hospital Nurse)

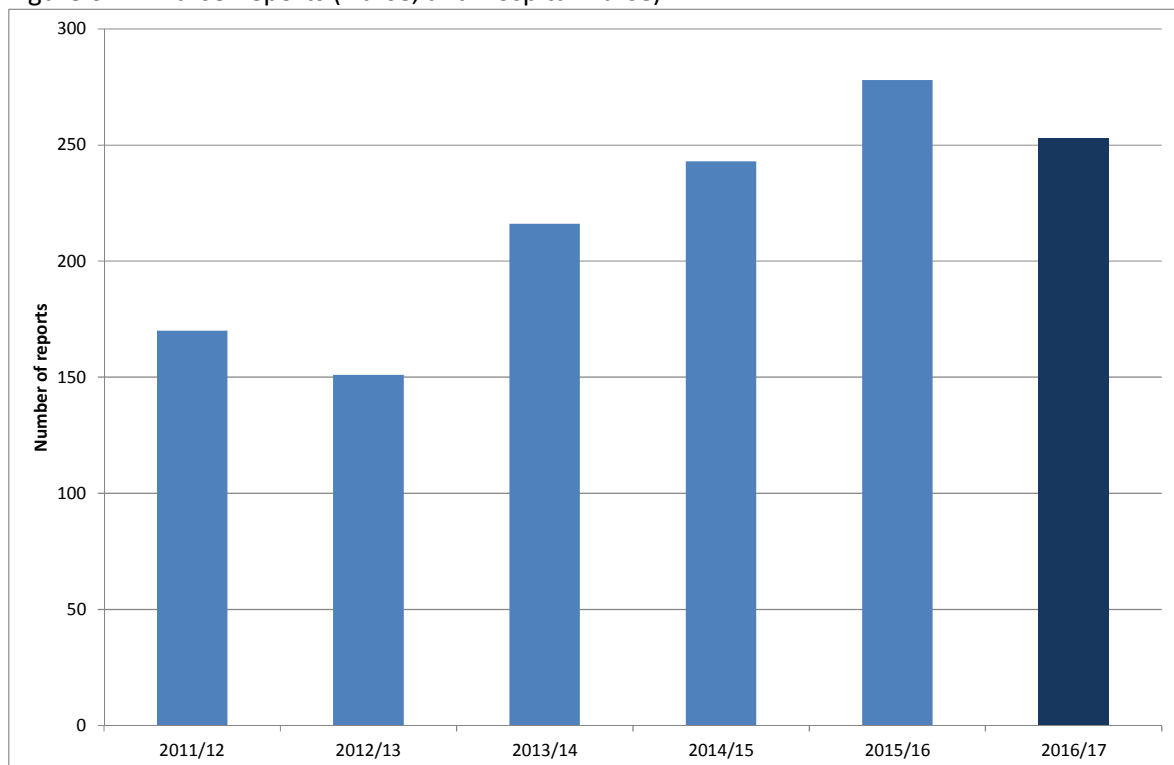
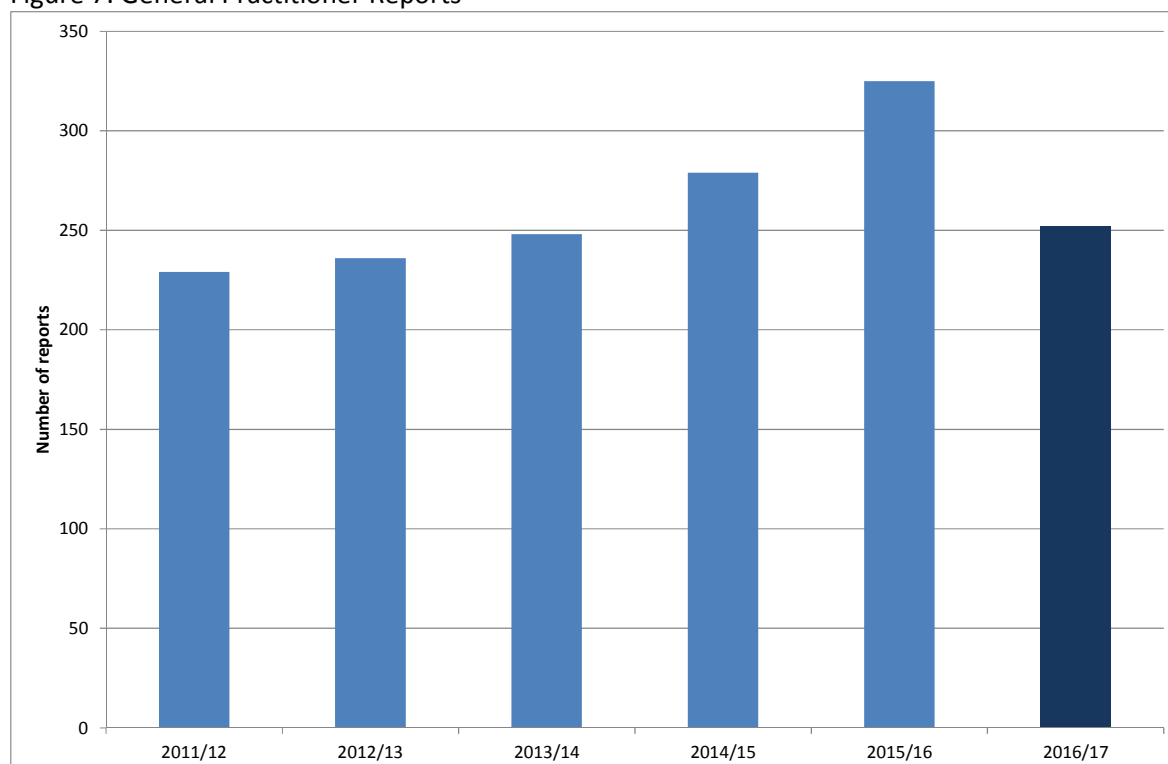


Figure 7: General Practitioner Reports



Top 10 drugs

The top 10 drugs listed as suspect drug are shown below

Drug	Total
rivaroxaban ▼	60
meningococcal group B vaccine ▼	55
apixaban ▼	40
phenoxymethylpenicillin	31
ibuprofen	29
omeprazole	24
influenza virus ▼	24
atorvastatin	24
nitrofurantoin	24
dapagliflozin ▼	22

4. PROMOTIONAL ACTIVITIES

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

Meetings

Professor Coleman attended meetings of PEAG and deputized on occasions for Professor Pirmohamed as Chair, and also at CHM.

Professor Coleman is the Vice Chair of the European Association of Clinical Pharmacology and Therapeutics and Chair of the Clinical Pharmacology and Therapeutics Specialist Advisory Committee.

ADR Champions

We have now recruited ADR Champions at all the acute Trusts in the region and held a study day for them in October together with a follow-up teleconference.

Work is continuing to recruit Champions in mental health and community Trusts and in GP practices and CCGs.

Teaching/Meetings

Venue	Audience	Number	Sector
Thimblemill library	patients	10	Patients
Keele University	undergraduate pharmacists	96	University
Teleconference	ADR champions	5	MHRA
SWBH	nurses, doctors, pharmacists	50	Secondary care
Thimblemill library	patients	15	Patients
SWBH	FY1 doctors at City	20	Secondary care
Dudley	pharmacists	15	Secondary care
MHRA	YCC AGM	20	MHRA
Walsall Manor	pharmacists	10	Secondary care
Moseley Hall	nurses, doctors, pharmacists	20	Secondary care
SWBH	community nurses	20	Primary Care
ISoP	nurses, doctors, pharmacists	100	International conference Secondary care/ primary care
SWBH	NMP forum	40	Secondary care
UHB	FY1 doctors at UHB	50	Secondary care
UHB	FY2 doctors at UHB	35	Secondary care
UHB	CMT doctors at UHB	25	Secondary care
SWBH	nurses, doctors, pharmacists	150	Secondary care
Burton	nurses, doctors, pharmacists	40	Secondary care
SWBH	nurses, doctors, pharmacists	79	Secondary care
Aston University	prescribing course pharmacists undergraduate pharmacists and pharmaceutical science students	18	University
Keele University	undergraduate pharmacists	112	University
Aston University	undergraduate pharmacists	80	University
SWBH	FY1 doctors Sandwell	18	Secondary care
University of Birmingham	MPharm Poster session	50	University Secondary care/ primary care
Coroner's court	Birmingham coroner	1	Primary Care
SWBH	Professor Parle	1	Secondary Care
DGH	FY1 doctors	24	Secondary Care
SWBH	Ulysses meeting	6	Secondary Care
Leicester	Patients and carers	200	Patients
BSC CCG	GP's, nurses, pharmacists	12	Primary Care
BSC CCG	GP's, nurses, pharmacists	15	Primary Care
Telford Hospital	doctors	25	Secondary Care
UHB	nurses, doctors, pharmacists	170	Secondary Care
UHB	Meet pathologist Dr Wharfield RIDR	1	Secondary Care

Lectures given include

Anton C, Badyal K, Ferner RE. Under-reporting of adverse drug reactions quantified by capture-recapture methods in hospital coding databases. Talk at the 2016 ISOP conference in Agra.

Coleman JJ. International Conference on Medication Errors, Erice, May 2016: "Educating medical students and doctors to avoid medication errors"

Ferner RE. International Conference on Medication Errors, Erice, May 2016: "Medication errors, the law, and doctors."

Ferner RE. European Association of Poisons Centres and Clinical Toxicologists, Madrid, May 2016: "Stemming the flow: new hopes [in treating anticoagulant overdose]."

Ferner RE. Centre for Evidence-Based Medicine, Oxford, June 2016: "Evidence of Adverse Drug Reactions."

Ferner RE. International Society of Pharmacovigilance annual meeting, Agra, October 2016: "Medication errors and pharmacovigilance."

Ferner RE. British Association of Physicians of Indian Origin, Birmingham, April 2017: "Medication errors."

Ferner RE. Royal Society of Medicine, Patient Safety, Litigation against Doctors, and Gross Negligence Manslaughter, London, May 2017: "Medication errors in urology,"

6. PUBLICATIONS AND CONFERENCES

Publications for 2016/17 include:

Anton, Christopher. "Adverse effects of laxatives: update." *Adverse Drug Reaction Bulletin* 303, no. 1 (2017): 1171-1174.

Aronson, J. K., and R. E. Ferner. "Unlicensed and off-label uses of medicines: definitions and clarification of terminology." *British journal of clinical pharmacology* (2017).

Aronson, J. K., and R. E. Ferner. "Unlicensed and off-label uses of medicines: definitions and clarification of terminology." *British journal of clinical pharmacology* (2017).

Aronson, Jeffrey K., and Robin E. Ferner. "Biomarkers—a general review." *Current Protocols in Pharmacology* (2017): 9-23.

Aronson, Jeffrey K. "Post-marketing drug withdrawals: Pharmacovigilance success, regulatory problems." *Thérapie* (2017).

Aronson, Jeffrey K., and Robin E. Ferner. "How similar are biosimilars?." (2016): i2721.

Badyal, Karamjit, Christopher Anton, and Robin Ferner. "Adverse drug reactions and urological disease." *Trends in Urology & Men's Health* 8.3 (2017): 21-25.

Breckenridge, Alasdair, Jeffrey K. Aronson, Terrence F. Blaschke, Dan Hartman, Carl C. Peck, and Bernard Vrijens. "Poor medication adherence in clinical trials: consequences and solutions." *Nature reviews. Drug discovery* 16, no. 3 (2017): 149.

Brooks, Hannah L., Sarah K. Pontefract, Hannah K. Vallance, Christine A. Hirsch, Elizabeth Hughes, Robin E. Ferner, John F. Marriott, and Jamie J. Coleman. "Perceptions and Impact of Mandatory eLearning for Foundation Trainee Doctors: A Qualitative Evaluation." *PloS one* 11, no. 12 (2016): e0168558.

Coleman, Jamie J., and Sarah K. Pontefract. "Adverse drug reactions." *Clinical Medicine* 16, no. 5 (2016): 481-485.

Ferner, Robin E., Craig Easton, and Anthony R. Cox. "Deaths from Medicines: A Systematic Analysis of Coroners' Reports to Prevent Future Deaths." *Drug Safety* (2017): 1-8.

Ferner, R. E., and J. Aronson. "Medication Errors: Relevance to Pharmacovigilance." In *DRUG SAFETY*, vol. 39, no. 10, pp. 1030-1030.

Ferner, Robin E., and Jeffrey K. Aronson. "Christmas 2016: In the Literature: Nominal ISOMERs (Incorrect Spellings Of Medicines Eluding Researchers)—variants in the spellings of drug names in PubMed: a database review." *The BMJ* 355 (2016).

Ferner, Robin E., and Jeffrey K. Aronson. "The toxicological significance of post-mortem drug concentrations in bile." *Clinical Toxicology* (2017): 1-8.

Fox A, Pontefract S, Brown D, Portlock J, Coleman J. Developing consensus on hospital prescribing indicators of potential harm for infants and children. *Br J Clin Pharmacol.* 2016 Apr 1. doi: 10.1111/bcp.12954

Holland, Michael G., and Robin E. Ferner. "A systematic review of the evidence for acute tolerance to alcohol—the "Mellanby effect". " *Clinical toxicology* 55, no. 6 (2017): 545-556.

Maxwell, Simon RJ, Jamie J. Coleman, Lynne Bollington, Celia Taylor, and David J. Webb. "Prescribing Safety Assessment 2016: Delivery of a national prescribing assessment to 7343 UK final-year medical students." *British Journal of Clinical Pharmacology* (2017).

McCullough, Amanda, Anna M. Scott, Christopher Macindoe, Justin Clark, Malene Plejdrup Hansen, Elaine M. Beller, Jeffrey K. Aronson, and Chris B. Del Mar. "Adverse events in patients taking cephalosporins versus placebo for any indication." *The Cochrane Library* (2016).

Nirantharakumar, K., N. Adderley, T. Marshall, G. Rayman, S. Mallett, S. Ghosh, F. Akiboye, S. Bellary, K. Toulis, and J. Coleman. "External validation of a prediction model that identifies adverse outcomes in hospitalised patients with diabetes." In *DIABETIC MEDICINE*, vol. 34, pp. 6-6. 111 RIVER ST, HOBOKEN 07030-5774, NJ USA: WILEY, 2017.

O'Donovan B, Rodgers RM, Cox AR and Krska J. Patients' use of information sources regarding side effects *Pharmacoepidemiology and Drug Safety*, 2017; 26:15-16 (Prescribing And Research In Medicine Management (Uk & Ireland) Annual Conference 2017, University Of Coventry London Campus, January 28th 2017: "Deprescribing – Is Less More?")

Onakpoya, Igbo J., Carl J. Heneghan, and Jeffrey K. Aronson. "Postmarketing withdrawal of human medicinal products because of adverse reactions in animals: a systematic review and analysis." *Pharmacoepidemiology and Drug Safety* (2017).

Onakpoya, Igbo J., Carl J. Heneghan, and Jeffrey K. Aronson. "Post-marketing regulation of medicines withdrawn from the market because of drug-attributed deaths: an analysis of justification." *Drug safety* 40, no. 5 (2017): 431-441.

Onakpoya, Igbo J., Carl J. Heneghan, and Jeffrey K. Aronson. "Post-marketing withdrawal of anti-obesity medicinal products because of adverse drug reactions: a systematic review." *BMC medicine* 14, no. 1 (2016): 191.

Onakpoya, Igbo J., Carl J. Heneghan, and Jeffrey K. Aronson. "Worldwide withdrawal of medicinal products because of adverse drug reactions: a systematic review and analysis." *Critical reviews in toxicology* 46, no. 6 (2016): 477-489.

Pontefract, Sarah K., James Hodson, John F. Marriott, Sabi Redwood, and Jamie J. Coleman. "Pharmacist-Physician Communications in a Highly Computerised Hospital: Sign-Off and Action of Electronic Review Messages." *PloS one* 11, no. 8 (2016): e0160075.

Seidling, Hanna M., Marion Stütze, Torsten Hoppe-Tichy, Benoît Allenet, Pierrick Bedouch, Pascal Bonnabry, Jamie J. Coleman et al. "Best practice strategies to safeguard drug prescribing and drug administration: an anthology of expert views and opinions." *International journal of clinical pharmacy* 38, no. 2 (2016): 362-373.

Seidling HM, Stütze M, Hoppe-Tichy T, Allenet B, Bedouch P, Bonnabry P, Coleman JJ, Fernandez-Llimos F, Lovis C, Rei MJ, Störzinger D, Taylor LA, Pontefract SK, van den Bemt PM, van der Sijs H, Haefeli WE. Best practice strategies to safeguard drug prescribing and drug administration: an anthology of expert views and opinions. *Int J Clin Pharm* 2016 Apr;38(2):362-73.

We produced and distributed 1 edition of our *ad hoc* Bulletin, re:Action and edited 6 editions of the Adverse Drug reaction Bulletin

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, and medication errors.