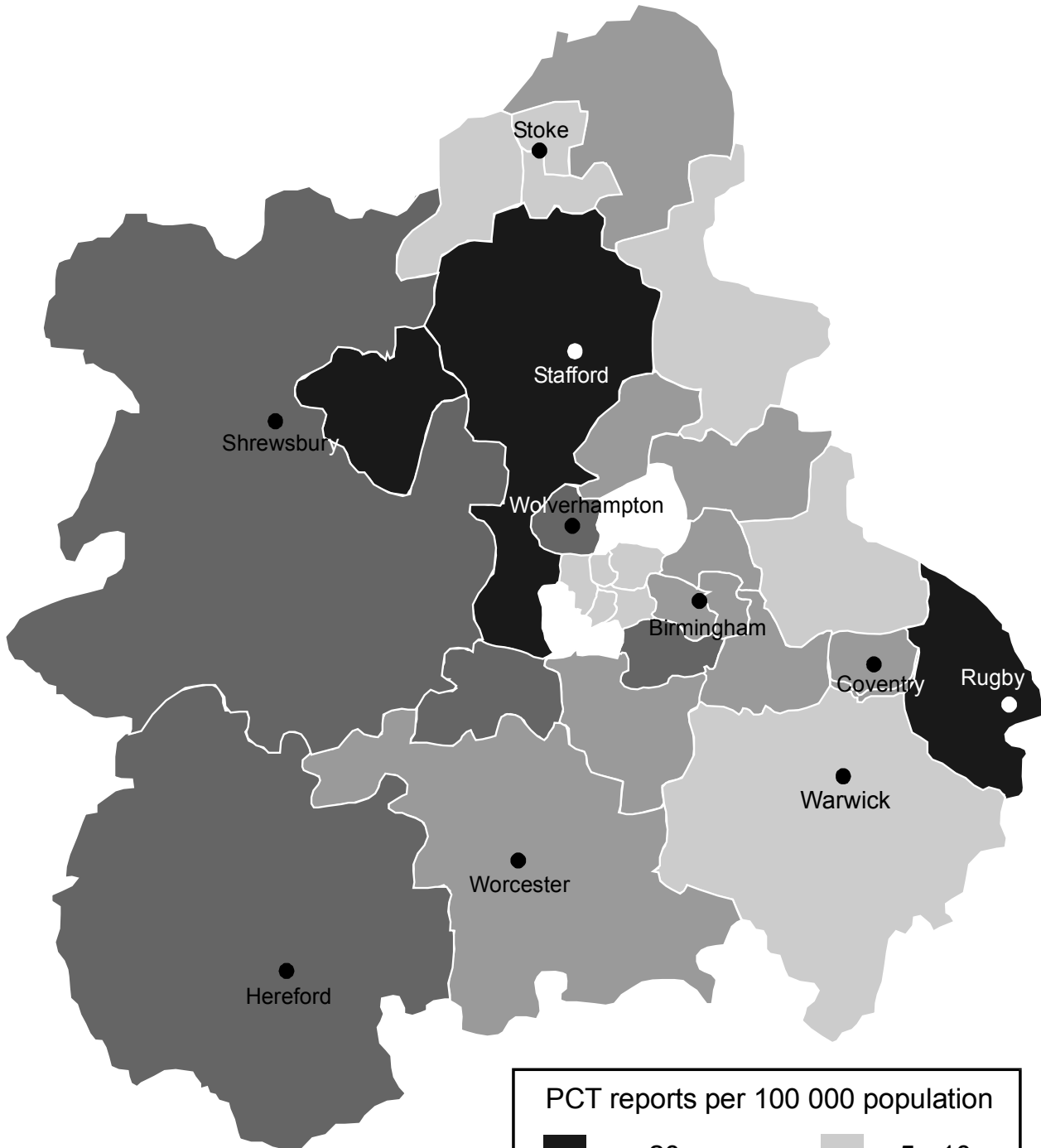




CSM West Midlands Annual Report 2003



ANNUAL REPORT OF REGIONAL MONITORING CENTRES,
MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY

WEST MIDLANDS CENTRE FOR ADVERSE DRUG REACTION REPORTING

2003

1. Centre Staff

Director - Dr R E Ferner
Specialist Registrar - Dr N J Langford
Administrative Co-ordinator - Mr C Anton
ADR Pharmacist - Mr A R Cox
Clerical Officer - Mr D Handy

2. Summary

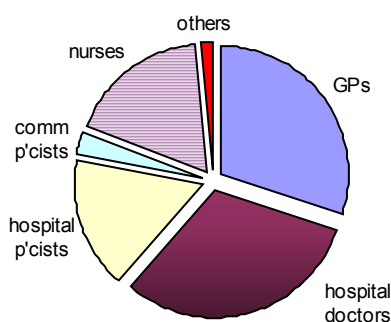
The number of reports received by the Centre during the year increased by 34%. This increase was seen across all reporter groups apart from community pharmacists and GPs. Nurse reporting, which began in autumn 2002, has started well, and their reports are of a consistently high standard and appropriateness; we have been to many of the PCTs lecturing to nurses about the Yellow card scheme and their new role as reporters. The proportion of serious reactions reported to the Centre has risen to its highest level of 55% and the number of serious reactions reported higher than any time except the year of the meningitis C campaign. The MHRA now provides us with frequent and detailed data on regional reports received directly by them and this very helpful innovation has allowed us to integrate these reports into our database. These reports are included in this annual report. We are concerned at the drop in the number of reports from GPs from over 60% in 1997 to fewer than 30% in 2002 and have started a randomised controlled trial to investigate if stimulating GPs into reporting serious reactions has any effect. We will publish our results next year.

3. Number of reports received

3.1 Table 1 shows the number of reports received in 2003 and the previous five years for comparison. In this table, and all subsequent ones, figures in parentheses refer to all the reports from the Region including those which bypass the Centre.

Year	Total number of reports received	Change on previous year (%)
2003	1245 (1488)	+34 (+31)
2002	926 (1135)	-30 (-29)
2001	1317 (1588)	-50 (-50)
2000	2654 (3149)	+103 (+105)
1999	1306 (1538)	0 (+4)
1998	1306 (1484)	+6 (+6)

Table 1



3.2 Table 2 shows the number of reports received from Primary care doctors (GPs and doctors at child health, mental health clinics etc which are managed by primary care trusts).

Table 2

Year	Total No of reports received from GPs	Percentage of total reports	Change on previous year (%)
2003	372 (492)	30% (33%)	-14 (-7)
2002	435 (527)	47% (46%)	-39 (-40)
2001	716 (873)	54% (55%)	-31 (-30)
2000	1032 (1249)	39% (40%)	+44
1999	719	55%	-5
1998	765	59%	+8

3.3 Table 3 shows the number of reports received from hospital doctors.

Table 3

Year	Total No of reports received from hospital doctors	Percentage of total reports	Change on previous year (%)
2003	393 (450)	32% (30%)	+35 (+27)
2002	292 (354)	32% (31%)	-14 (-10)
2001	341 (395)	26% (25%)	-9
2000	376 (434)	14%	+4
1999	362	28%	-9
1998	411	31%	-6

3.4 Table 4 shows the number of reports received from hospital pharmacists.

Table 4

Year	Total received from hospital pharmacists	Percentage of total reports	Change on previous year (%)
2003	206 (212)	17% (14%)	+161 (+152)
2002	79 (84)	9% (7%)	-11 (-13)
2001	89 (97)	7% (6%)	-16
2000	106 (125)	4%	+16
1999	91	7%	+63
1998	56	4%	+100

3.5 Table 5 shows the number of reports received from community pharmacists.

Table 5

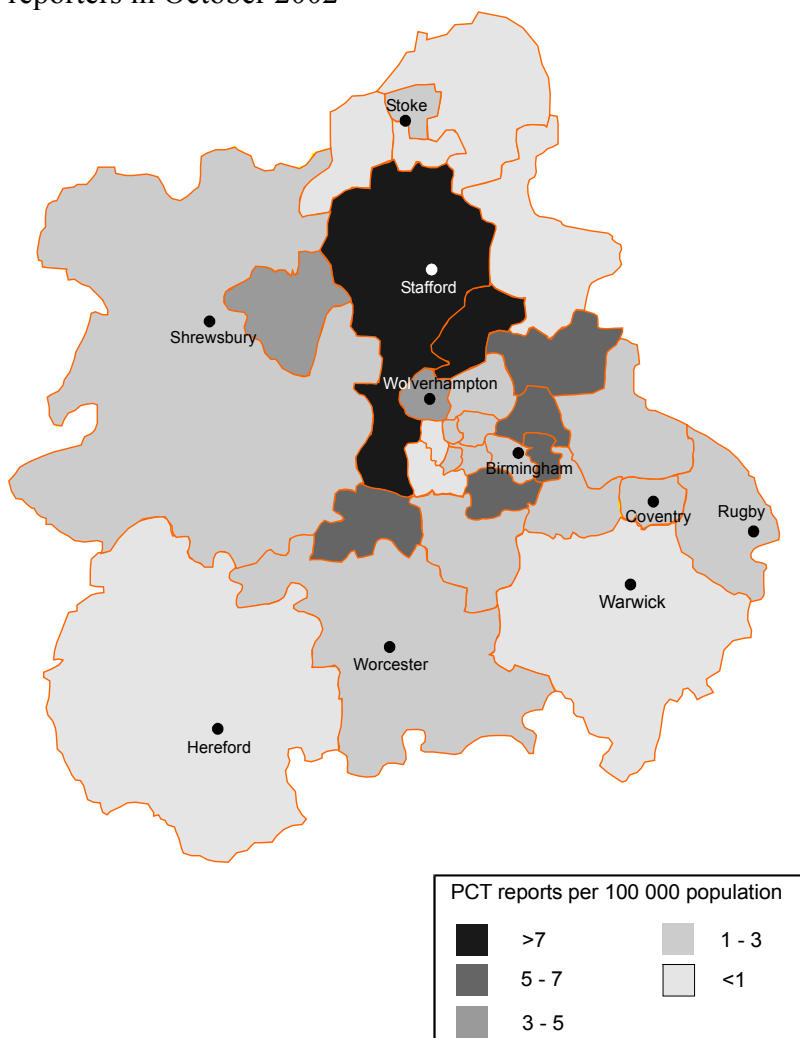
Year	Total received from community pharmacists	Percentage of total reports	Change on previous year (%)
2003	35 (46)	3% (3%)	-13 (-13)
2002	40 (53)	4% (5%)	0 (+13)
2001	40 (47)	3% (3%)	+60
2000	25 (32)	1%	+56
1999	16	1%	-62
1998	42	3%	+24

3.6 Table 6 shows the number of reports received from nurses.

Table 6

Type or reporter	Total received	Percentage of total reports	Change on previous year (%)
Practice/School nurse	134 (151)	11% (10%)	+173 (+138)
Hospital nurse	73 (78)	6% (5%)	+387 (+420)
Health visitor	14 (14)	1% (1%)	+180 (+180)

Nurse reporting varied markedly throughout the region. The map shows the reports from practice and school nurses and health visitors since nurses were added as reporters in October 2002

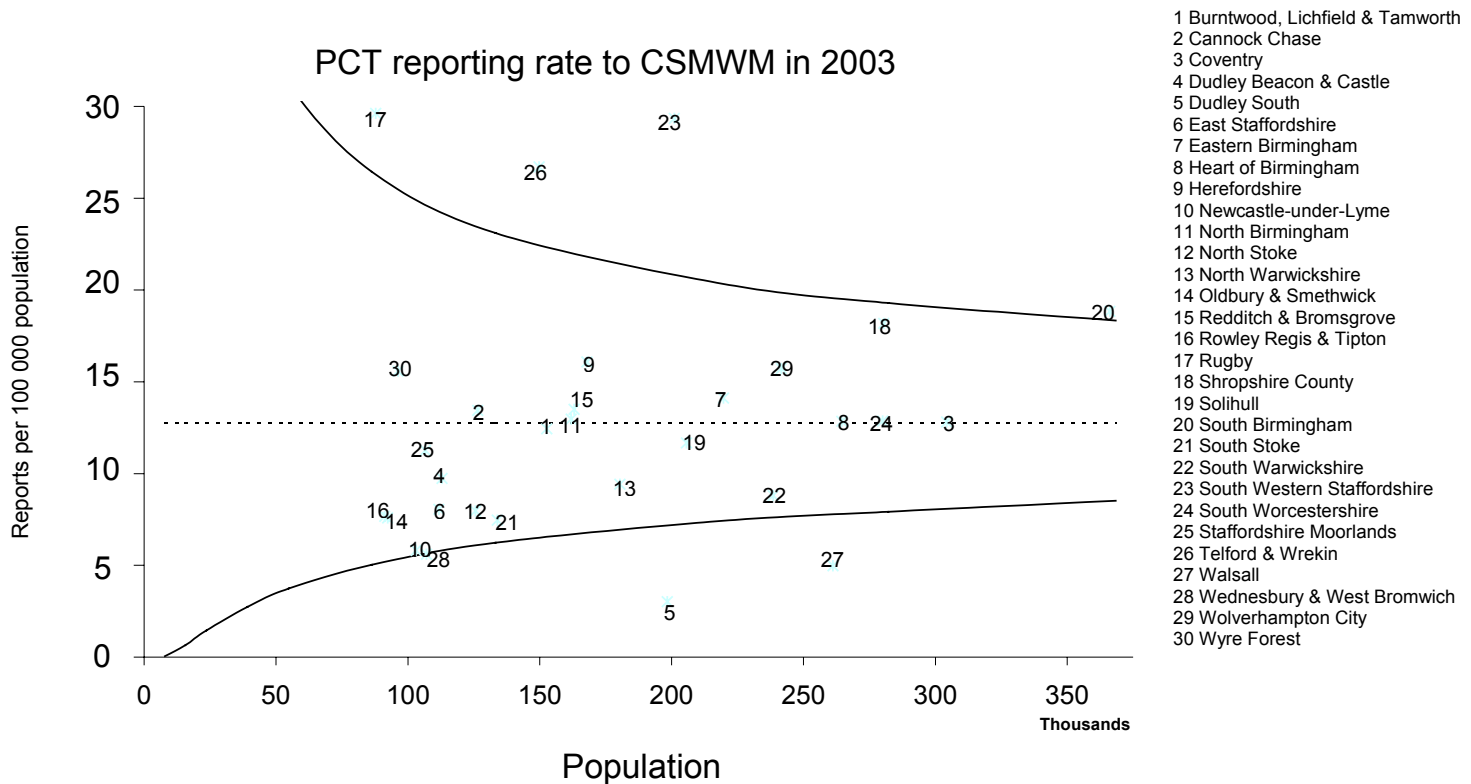


3.7 Table 7 shows the number of reports received from other sources

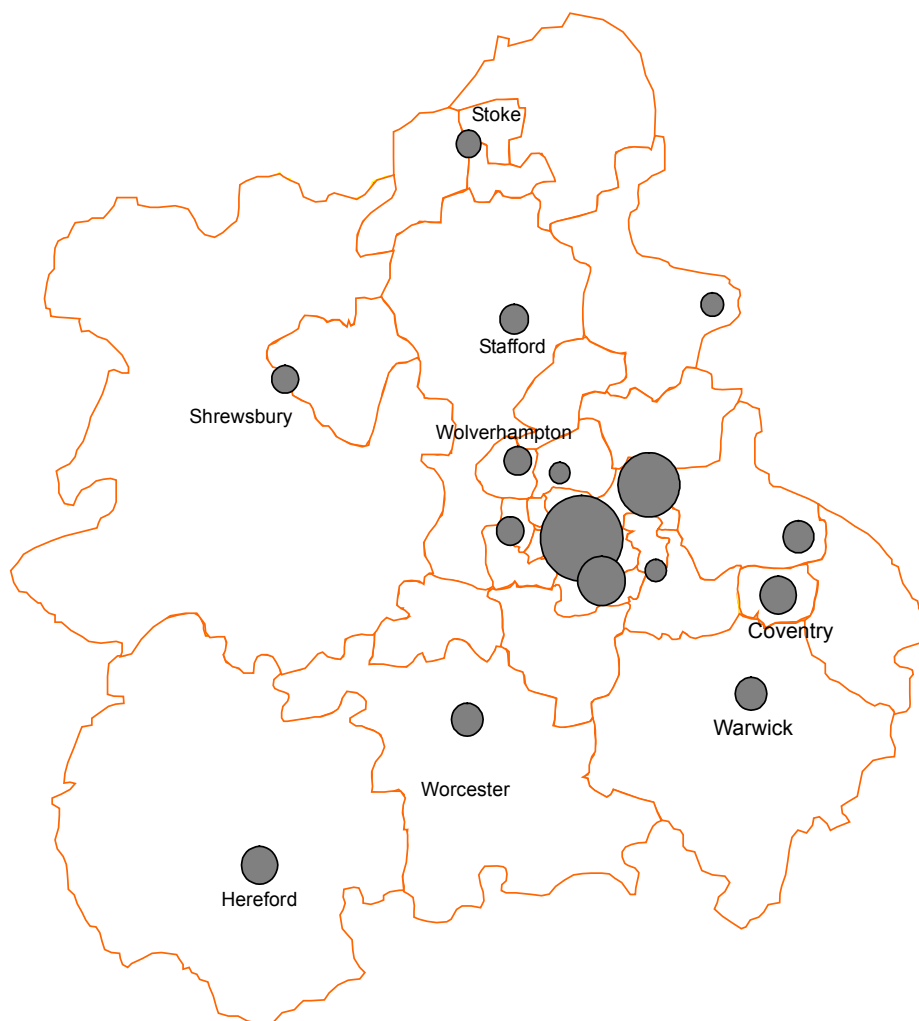
Table 7

Type of reporter	Total received
Coroner	0 (1)
Dentist	3 (7)
Other health professional	4 (26)
Patient	1 (1)
Not ascertainable	10 (10)

The disparity between the PCTs and the hospital trusts remains and are illustrated in Figure 1. The upper and lower control limits (solid lines) approximate to the 95% confidence intervals. The regional mean is marked by the dashed line.



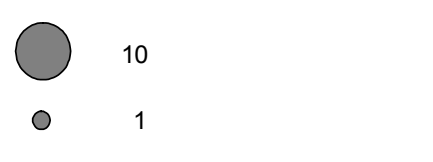
The large disparity in reporting between hospital trusts persists and is illustrated in the map below. The area of the circle corresponds to the reporting rate per 10 000 FCEs for each of the acute trusts in the Region.



Regional Hospitals



Reports per 10 000 FCEs

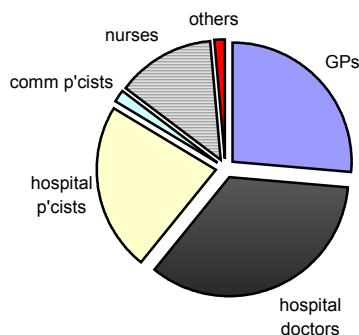


4. Serious reports

4.1 We received 681 (55%) reports which were classified as serious by the ADROIT medical dictionary. The data are shown in table 8. There were 23 (3%) reports with a fatal outcome.

Table 8

Year	Total No of serious reports received	Percentage of total reports	Change on previous year (%)
2003	681 (803)	55% (54%)	+40
2002	485	52%	-27
2001	665	50%	-23
2000	856	32%	+44
1999	595	46%	+5
1998	565	43%	+6



4.2 The number of reports of serious reactions from GPs is shown in Table 9.

Table 9

Year	Total No of serious reports received	As percentage of GP reports
2003	179 (234)	48% (48%)
2002	200	46%
2001	318	44%
2000	303	29%
1999	292	41%
1998	263	34%

4.3 The number of reports of serious reactions from hospital doctors is shown in Table 10.

Table 10

Year	Total No of serious reports received	As percentage of hospital doctor reports
2003	235 (271)	60% (60%)
2002	194	66%
2001	216	63%
2000	223	60%
1999	219	60%
1998	236	58%

4.4 The number of reports of serious reactions received from hospital pharmacists is shown in Table 11.

Table 11

Year	Total No of serious reports received	As percentage of hospital pharmacist reports
2003	155 (160)	75% (75%)
2002	61	77%
2001	67	63%
2000	72	60%
1999	69	60%
1998	40	58%

4.5 The number of reports of serious reactions received from community pharmacists is shown in Table 12.

Table 12

Year	Total No of serious reports received	As percentage of hospital pharmacist reports
2003	12 (16)	34% (35%)
2002	10	25%
2001	15	38%
2000	10	40%
1999	5	31%
1998	15	36%

4.6 The number of reports of serious reactions reported by hospital nurses is shown in Table 13.

Table 13

Year	Total No of serious reports received	As percentage of hospital nurse reports
2003	35 (37)	48% (47%)
2002	7	47%

4.7 The number of reports of serious reactions reported by practice nurses and health visitors is shown in Table 14.

Table 14

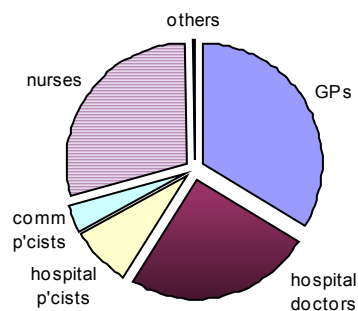
Year	Total No of serious reports received	As percentage of nurse reports
2003	56 (60)	38% (37%)
2002	13	24%

5. Reports to black triangle drugs

5.1 A total of 421 (34%) reports to black triangle drugs were received. The data are shown in Table 15.

Table 15

Year	Total No of ▼ reports received	Percentage of total reports	Change on previous year (%)
2003	421 (503)	34% (34%)	+25
2002	338	37%	-45
2001	613	47%	-70
2000	1996	75%	+246
1999	577	44%	+16
1998	498	38%	+26



5.2 The number of reports of reactions to ▼ drugs from GPs is shown in Table 16.

Table 16

Year	Total No of ▼ reports received	As percentage of GP reports
2003	141 (181)	38% (37%)
2002	195	45%
2001	419	44%
2000	721	29%
1999	336	41%
1998	330	34%

5.3 The number of reports of reactions to ▼ drugs from hospital doctors is shown in Table 17.

Table 17

Year	Total No of ▼ reports received	As percentage of hospital doctor reports
2003	107 (129)	27% (28%)
2002	71	24%
2001	88	26%
2000	158	42%
1999	108	30%
1998	132	32%

5.4 The number of reports of reactions to ▼ drugs from hospital pharmacists is shown in Table 18.

Table 18

Year	Total No of ▼ reports received	As percentage of hospital pharmacist reports
2003	34 (36)	17% (17%)
2002	21	27%
2001	22	25%
2000	34	32%
1999	25	27%
1998	15	27%

5.5 The number of reports of reactions to ▼ drugs from community pharmacists is shown in Table 19.

Table 19

Year	Total No of ▼ reports received	As percentage of community pharmacist reports
2003	15 (18)	43% (39%)
2002	13	33%
2001	17	43%
2000	11	44%
1999	7	44%
1998	15	38%

5.6 The number of reports of reactions to ▼ drugs reported by hospital nurses is shown in Table 20.

Table 20

Year	Total No of ▼ reports received	As percentage of hospital nurse reports
2003	24 (27)	33% (35%)
2002	35	30%

5.7 The number of reports of reactions to ▼ drugs reported by practice nurses and health visitors is shown in Table 21.

Table 21

Year	Total No of ▼ reports received	As percentage of nurse reports
2003	97 (102)	66% (62%)
2002	22	16%

6. Most commonly reported drugs

The 11 drugs most often mentioned in reports are listed in Table 22

Table 22

Drug substance	2003	2002
1 BCG vaccine ▼	97 (105)	12
2 celecoxib	31 (41)	30
3 haemophilus influenzae type B vaccine	28 (34)	22
4 infliximab ▼	24 (29)	13
4 aspirin	24 (26)	9
6 rosuvastatin ▼	21 (28)	0
6 rofecoxib	21 (24)	39
8 sibutramine ▼	19 (22)	28
8 tuberculin PPD	19 (21)	5
10 atorvastatin	18 (19)	12
10 simvastatin	18 (19)	16

If the bypassed reports are included bupropion with 35 reports would be in the top 10.

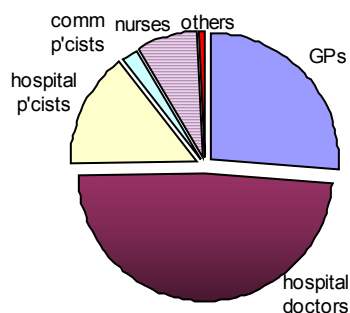
These top 11 drugs accounted for 26% of all reports for 2003 (26% in 2002, 39% in 2001, 67% in 2000, 29% in 1999, 21% in 1998, 26% in 1997).

7. Follow-up of reports

7.1 We requested follow-up information from 114 reporters and the data are given in Table 23.

Table 23

Year	Total No of reports followed-up	As percentage of reports	Follow-up response rate
2003	114	9%	52%
2002	143	15%	62%
2001	171	13%	69%
2000	237	9%	27%
1999	191	15%	40%
1998	230	18%	73%



7.2 To date, we have received further information on 59 reports out of the 114 (52%) where we have requested more information.

8. A total of 340 (27%) reporters requested, and were sent, detailed information from us and the data are given in Table 24. This compares with 27% in 2002, 32% in 2001, 25% in 2000, 29% in 1999, 32% in 1998.

Table 24

Type of reporter	Number of reports	As percentage of reports
GPs	97	26%
Hospital doctors	129	33%
Community pharmacists	15	4%
Hospital pharmacists	31	15%
Hospital nurses	28	38%
Practice nurses/Health visitors	38	26%
Others	2	11%
Total	340	27%

9. Information on the type of card received is shown in Table 25

Table 25

	Number of reports	percentage	Change on previous year (%)
BNF (or copy)	856	69%	+32
AR20 (or copy)	361	29%	+47
FP10	0		
DSC	14	1%	
MIMS	3		
Other	11	1%	

The distribution of the reports which bypassed the centre is shown in Table 26

Table 26

	Number of reports	Percentage of RMC reports
Paper	189	13%
GP electronic	20	1%
HIV	0	
Internet	17	1%
Processed by other RMCs	5	
Total	231	16%

10. We have published 2 editions of *re:Action* (issues 27–28), our occasional bulletin, since the last annual RMC meeting covering:

the fall in the GP reporting rate
 SSRIs and gastrointestinal bleeding
 COX-2 inhibitors and psychiatric reactions
 nicorandil and anal ulceration
 clopidogrel and angioedema
 hepatitis B vaccine and hypoaesthesia
 interactions between drugs and food
 provisional safety of new drugs
 St John's Wort and withdrawal reactions
 adverse effects of drugs bought over the internet

We have produced six editions of the *Adverse Drug Reaction Bulletin*.

A number of publications of adverse reactions and related issues have appeared during the year:

Anton C, Cox AR, Watson RD, Ferner RE. The safety of spironolactone treatment in patients with heart failure. *J Clin Pharm Ther* 2003; **28**: 285-7.

Anton C, Ferner RE. Medication errors detected in infusions. *Arch Intern Med* 2003; **163**: 982

Anton C, Cox AR, Ferner RE. Using trade names: sometimes it helps. *Arch Intern Med* 2003; **162**: 2636.

Anton C. Co-trimoxazole is restricted. *Pharmaceutical Journal* 2003, 271, 612.

Aronson JK, Ferner RE. Joining the DoTS: new approach to classifying adverse drug reactions. *BMJ* 2003; **327**: 1222-5.

Chin BS, Langford NJ, Nuttall SL, Gibbs CR, Blann AD, Lip GYH. Antioxidant

properties of beta-blockers and angiotensin converting enzyme inhibitors in congestive cardiac failure. *Eur J Heart Failure*. 2003; **5**: 171-4.

Cox AR, Langford NJ. Drug induced heart failure. *Adverse Drug Reaction Bulletin* 2003; 220; 843-6.

Cox AR. Manufacturers should make reading labels easier. *Pharmaceutical Journal* 2003; 270: 514.

Cox AR, Anton C. Report all drug reactions with warfarin. *Pharmaceutical Journal* 2003; 270: 366-7.

Cox AR. Advertising: Prescribers need appraisal training programmes. *Pharmaceutical Journal* 2003; 270:154.

Ferner RE. Drugs of abuse. In: Neuberger J, ed. *Horizons in Medicine No. 14*. London: Royal College of Physicians, 2003: 73-84.

Ferner RE. Accuracy of pharmaceutical advertisements in medical magazines. *Lancet* 2003; 361: 879.

Ferner RE, Daniels AM. Office-based treatment of opioid-dependent patients. *New England Journal of Medicine* 2003; 348: 81-2.

Ferner RE. Adverse drug reactions. *Medicine* 2003; 31: 20-4.

Ferner RE. Is concordance the primrose path to health? *BMJ* 2003; **327**: 821-2.

Ferner RE. Antidotes: principles and clinical applications. *British Journal of Clinical Pharmacology* 2003; **56**: 458

Hughes B, Durran A, **Langford NJ**, Mutimer D. Paracetamol poisoning—impact of pack size reduction. *Journal of Clinical Pharmacy & Therapeutics* 2003; **28**: 307-10.

Kerr KL, Higham C, **Cox AR**, Situnayake RD. A determination of patient awareness of the safety issues surrounding treatment with methotrexate. *The Pharmaceutical Journal* 2003; 271: 900-01.

Langford NJ, Martin U, Elliott S, **Ferner RE**, Krentz S. Severe relapsing sulphonyl-urea induced hypoglycaemia: A diagnostic and therapeutic challenge. *Post-Graduate Medical Journal*. 2003; **79**: 120.

Langford NJ, Aruna RS, Mutimer D, White AC, **Ferner RE**. The impact of pack size legislation on paracetamol (acetaminophen) poisoning in the West Midlands (United Kingdom). *J Tox Clin Tox* 2003; **41**: 419-20

Langford NJ, Good AM, Laing WL, Bateman DN. Reported quinine intoxications to the Scottish Poisons Information Bureau 1997-2002. *Brit J Clin Pharm*.2003; **56**: 576-8.

Langford NJ, Munyame C, Patel H, Hamlyn AN, **Ferner RE**. Mirtazapine overdose and miosis. *J Tox Clin Tox*.2003; **41**:1037-8.

Nuttall SL, Khan J, Thorpe GH, **Langford NJ**, Kendall MJ. The impact of therapeutic doses of paracetamol on serum total antioxidant capacity. *Journal of Clinical Pharmacy & Therapeutics* 2003; **28**: 289-94.

Pirmohamed M, **Ferner RE**. Monitoring drug treatment. *BMJ* 2003; **327**: 1179-81.

Whitaker S, **Cox AR**, Alexander AM. Internet networking for pharmacists: an evaluation of a mailing list for UK pharmacists. *International Journal of Pharmacy Practice* 2003; 11: 25-32.

We continue to educate reporters throughout the region and elsewhere about the Yellow Card Scheme and the importance of reporting adverse drug reactions. Lectures and talks were given to:

Home Office – Coroners’ Continuing Education, Sheffield and Northampton
 Royal College of Physicians College Lecture
 European Association of Poison Control Centres and Clinical Toxicologists meeting
 Royal College of Physicians Study Day
 European Foundation for the Advancement of Healthcare Practitioners meeting.
 Pharmacovigilance: promoting drug safety through collaboration, Mumbai.
 and to Nurses at:

Wyre Forest PCT
North Staffordshire Community Trust
Newcastle-under-Lyme PCT
Oldbury & Smethwick PCT
Staffordshire Moorlands PCT
Birmingham Children's Hospital
Good Hope Hospital
North Staffordshire Hospital

Pharmacists at
Sandwell General Hospital
New Cross Hospital

and the Birmingham Rheumatology meeting

We taught undergraduate pharmacy students at Aston University, undergraduate and medical students at Birmingham University, and pharmacists on the Keele Diploma in Hospital Pharmacy

We ran a study day on ADRs in Diabetes at Warwick University

We also regularly update the Medicines Information pharmacists of the West Midlands and Trent regions on trends in reporting.

Our website at <http://csmwm.org> received over 180,000 hits during 2002 (a 38% increase from 2002).

11. We received visits from Mr He, a pharmacist at Ganju Regional Monitoring Centre, China in March 2003, and from the Rt Hon Clare Short, MP (the centre's MP) in December 2003, and look forward to a visit from the MHRA in March 2004.
12. We continue, as a Centre, to take an interest in errors in the use of medicines.

CA
REF

January 2004