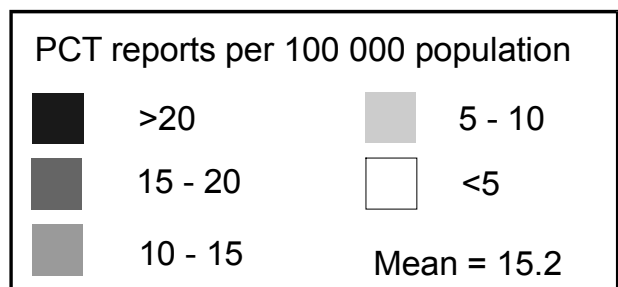
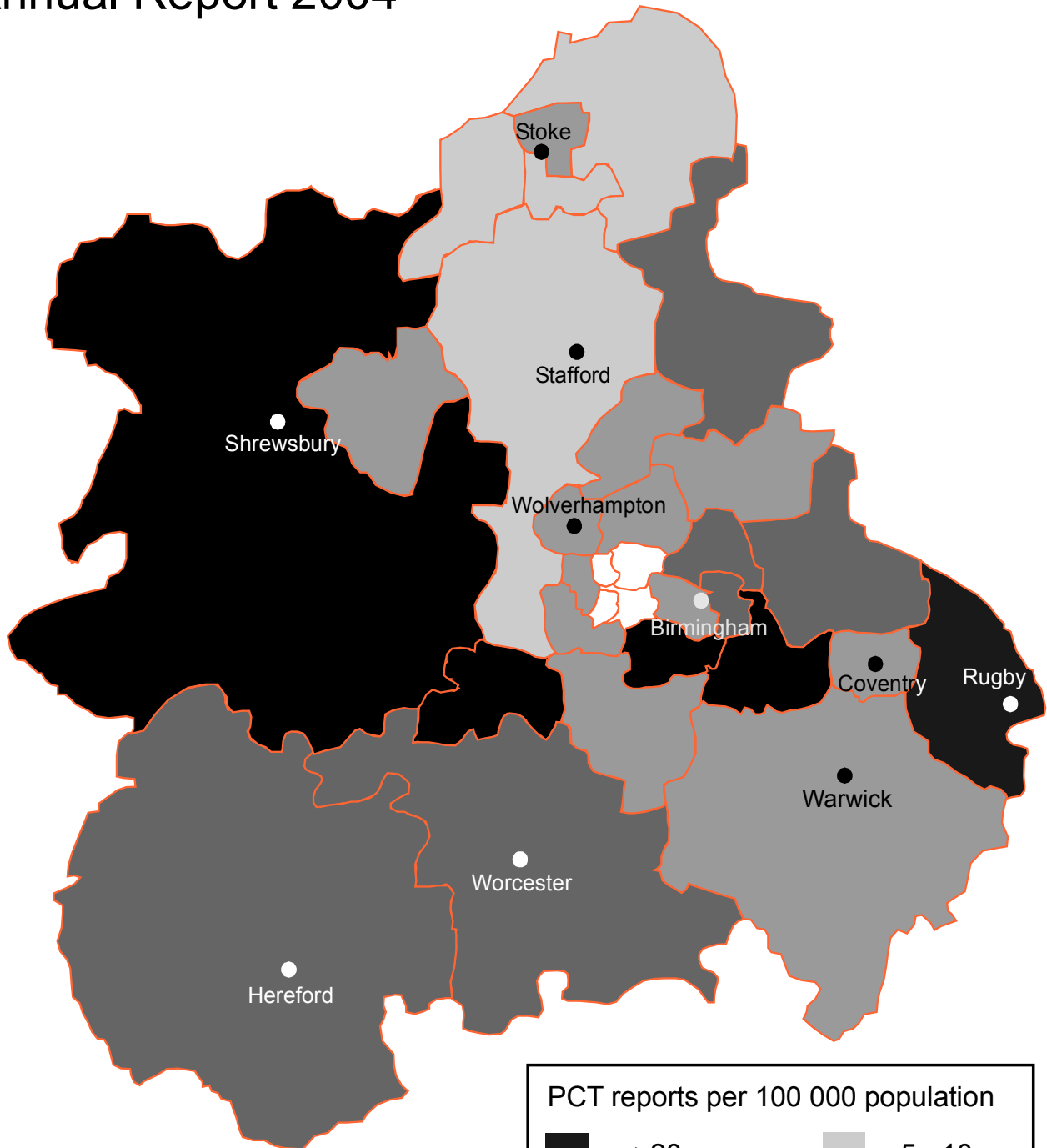




# CSM West Midlands Annual Report 2004



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

WEST MIDLANDS CENTRE FOR ADVERSE DRUG REACTION REPORTING

2004

1. Centre Staff

Director - Dr R E Ferner  
 Honorary Consultant Physician - Dr N J Langford  
 Specialist Registrar - Dr J J Coleman  
 Administrative Co-ordinator - Mr C Anton  
 ADR Pharmacist - Mr A R Cox  
 Clerical Officer - Mr D Handy (until October)

2. Summary

The Centre received more reports during the year than ever before (discounting the year of the meningitis C campaign). The total number of reports from reporters in the West Midlands increased by 12%. All reporter groups apart from practice nurses and health visitors increased their reporting rate. GP reporting, which had been declining for some years rose by 19%. We have been providing reporters with targeted follow-up information during the year and reported on this study to the International Society of Pharmacovigilance (Appendix 1). The percentage of reporters who requested a DAP is significantly lower ( $p < 0.001$ ) than in previous years and perhaps a DAP does not now satisfy reporters' needs for extra information. The proportion of serious reactions reported to the Centre has risen to its highest ever level of 60%, and the number of serious reactions reported increased by 17%. We have continued to integrate the regional reports received directly by the MHRA into our database, although it is not possible to allocate these reports to individual Trusts or PCTs in all cases. These reports are included in this annual report.

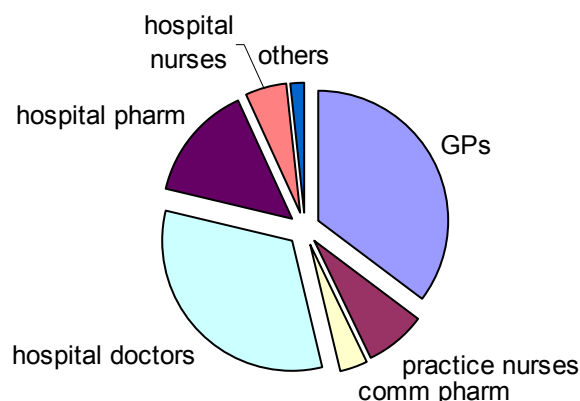
3. Number of reports received

3.1 Table 1 shows the number of reports received in 2004 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 go direct to the MHRA)

Year	Total number of reports received	Change on previous year
	CSMWM (all WM reports)	
2004	1318 (1661)	+6% (+12%)
2003	1245 (1488)	+34% (+31%)
2002	926 (1135)	-30% (-29%)
2001	1317 (1588)	+1% (+2%)
2000*	1309 (1553)	+0% (+1%)
1999	1306 (1538)	0% (+4%)

\* discounting meningitis C reports

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
	CSMWM (all WM reports)		
2004	373 (587)	28% (35%)	0% (+19%)
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%

3.3 Table 3 shows the number of reports received from hospital doctors. This is the highest number of reports received from hospital doctors in any year.

Table 3

Year	Total No of reports received from hospital doctors	Percentage of total reports	Change on previous year
	CSMWM (all WM reports)		
2004	484 (535)	37% (32%)	+23% (+19%)
2003	393 (450)	32% (30%)	+35% (+27%)
2002	292 (354)	32% (31%)	-14% (-10%)
2001	341 (395)	26% (25%)	-9% (-9%)
2000	376 (434)	14%	+4%
1999	362	28%	-9%

3.4 Table 4 shows the number of reports received from hospital pharmacists. This is the highest number of reports received from hospital pharmacists in any year.

Table 4

Year	Total received from hospital pharmacists	Percentage of total reports	Change on previous year
	CSMWM (all WM reports)		
2004	227 (240)	17% (15%)	+10% (+13%)
2003	206 (212)	17% (14%)	+161% (+152%)
2002	79 (84)	9% (7%)	-11% (-13%)
2001	89 (97)	7% (6%)	-16%
2000	106 (125)	4% (4%)	+16%
1999	91	7%	+63%

3.5 Table 5 shows the number of reports received from community pharmacists. This is the highest number of reports received from community pharmacists in any year.

Table 5

Year	Total received from community pharmacists	Percentage of total reports	Change on previous year
	CSMWM (all WM reports)		
2004	50 (63)	4% (4%)	+43% (+37%)
2003	35 (46)	3% (3%)	-13% (-13%)
2002	40 (53)	4% (5%)	0% (+13%)
2001	40 (47)	3% (3%)	+60%
2000	25 (32)	1% (1%)	+56%
1999	16	1%	-62%

3.6 Table 6 shows the number of reports received from hospital nurses. This is the highest number of reports received from hospital nurses in any year.

Table 6

Year	Total received from hospital nurses	Percentage of total reports	Change on previous year
	CSMWM (all WM reports)		
2004	74 (87)	6% (5%)	+1% (+12%)
2003	73 (78)	6% (5%)	+387%
2002	15	2%	
2001	24	2%	
2000	7		
1999	4		

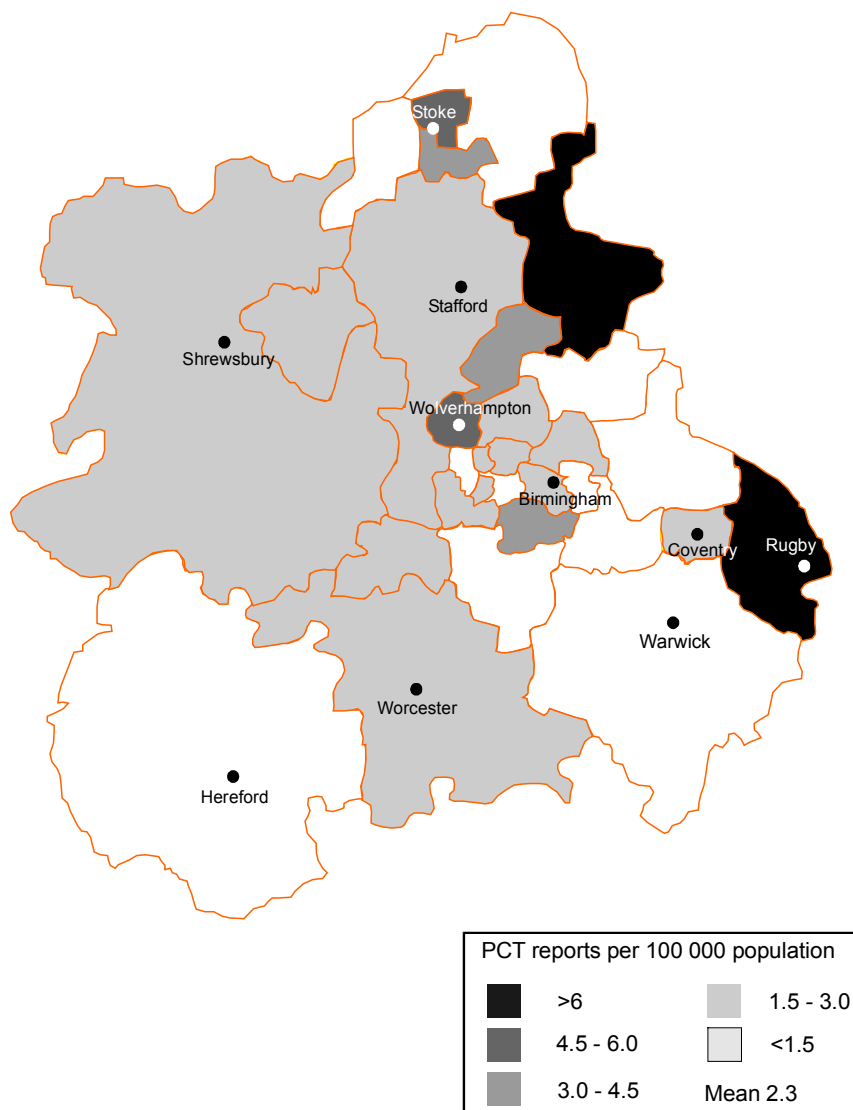
3.7 Table 7 shows the number of reports received from practice nurses and health visitors

Table 7

Year	Total received from practice nurses// health visitors	Percentage of total reports	Change on previous year
	CSMWM (all WM reports)		
2004	93 (122)	7% (7%)	-37% (-26%)
2003	148 (165)	12% (11%)	+174%
2002	54	6%	-27%
2001	74	6%	
2000	885	33%	
1999	94	7%	

Nurse reporting varied markedly within the region. The map shows the reports from practice and school nurses and health visitors during 2004.

## Nurse/Health Visitor reports 2004

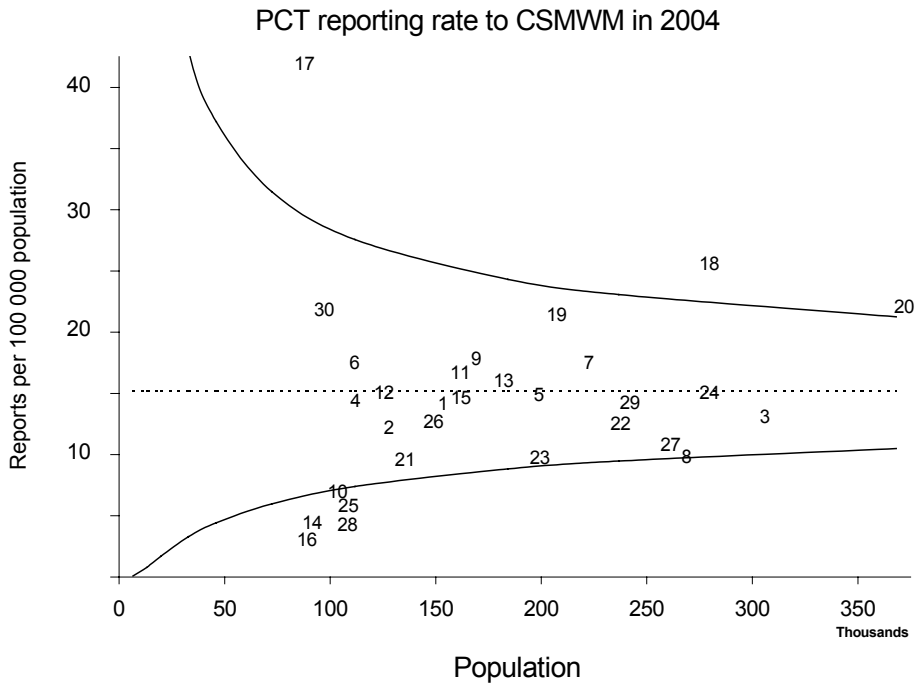


3.8 Table 8 shows the number of reports received from other sources

Table 8

Type of reporter	Total received CSMWM (all WM reports)
Coroner	0 (2)
Dentist	3 (5)
Other health professional	6 (13)
Patient	1 (1)
Not ascertainable	6 (6)

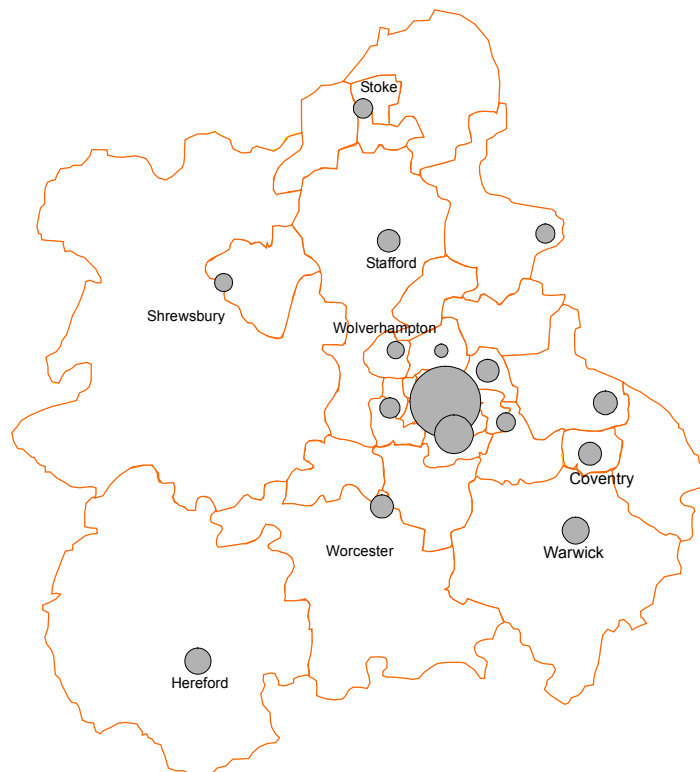
The disparity between PCTs remains and is illustrated below. The upper and lower control limits (solid lines) approximate to the 95% confidence intervals. The regional mean is marked by the dashed line.



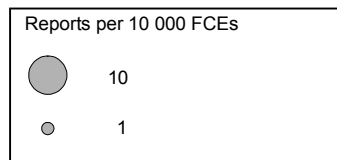
1. Burntwood, Lichfield & Tamworth
2. Cannock Chase
3. Coventry
4. Dudley Beacon & Castle
5. Dudley South
6. East Staffordshire
7. Eastern Birmingham
8. Heart of Birmingham
9. Herefordshire
10. Newcastle-under-Lyme
11. North Birmingham
12. North Stoke
13. North Warwickshire
14. Oldbury & Smethwick
15. Redditch & Bromsgrove
16. Rowley Regis & Tipton
17. Rugby
18. Shropshire County
19. Solihull
20. South Birmingham
21. South Stoke
22. South Warwickshire
23. South Western Staffordshire
24. South Worcestershire
25. Staffordshire Moorlands
26. Telford & Wrekin
27. Walsall
28. Wednesbury & West Bromwich
29. Wolverhampton City
30. Wyre Forest

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.

### Hospital reports in 2004



- Regional Hospitals**
- Children's
  - Women's
  - Royal Orthopaedic

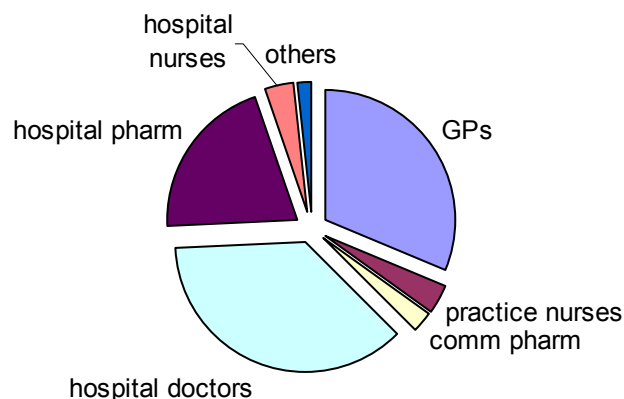


#### 4. Serious reaction reports

4.1 We received 797 (60%) reports which were classified as serious by the ADROIT medical dictionary. This is the highest ever percentage of serious reports received by the Centre. The data are shown in Table 9. There were 33 (4%) reports with a fatal outcome.

Table 9

Year	Total No of serious reports received	Percentage of total reports	Change on previous year
	CSMWM (all WM reports)		
2004	797 (963)	60% (58%)	+17% (+20%)
2003	681 (803)	55% (54%)	+40%
2002	485	52%	-27%
2001	665	50%	-23%
2000	856	32%	+44%
1999	595	46%	+5%



4.2 The number of reports of serious reactions from GPs is shown in Table 10.

Table 10

Year	Total No of serious reports received	As percentage of GP reports
	CSMWM (all WM reports)	
2004	198 (301)	53% (51%)
2003	179 (234)	48% (48%)
2002	200	46%
2001	318	44%
2000	303	29%
1999	292	41%

4.3 The number of reports of serious reactions from hospital doctors is shown in Table 11.

Table 11

Year	Total No of serious reports received	As percentage of hospital doctor reports
	CSMWM (all WM reports)	
2004	328 (355)	68% (66%)
2003	235 (271)	60% (60%)
2002	194	66%
2001	216	63%
2000	223	60%
1999	219	60%

- 4.4 The number of reports of serious reactions received from hospital pharmacists is shown in Table 12.

Table 12

Year	Total No of serious reports received	As percentage of hospital pharmacist reports
	CSMWM (all WM reports)	
2004	186 (196)	82% (82%)
2003	155 (160)	75% (75%)
2002	61	77%
2001	67	63%
2000	72	60%
1999	69	60%

- 4.5 The number of reports of serious reactions received from community pharmacists is shown in Table 13.

Table 13

Year	Total No of serious reports received	As percentage of hospital pharmacist reports
	CSMWM (all WM reports)	
2004	18 (23)	36% (37%)
2003	12 (16)	34% (35%)
2002	10	25%
2001	15	38%
2000	10	40%
1999	5	31%

- 4.6 The number of reports of serious reactions reported by hospital nurses is shown in Table 14.

Table 14

Year	Total No of serious reports received	As percentage of hospital nurse reports
	CSMWM (all WM reports)	
2004	30 (35)	41% (40%)
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 15.



Table 15

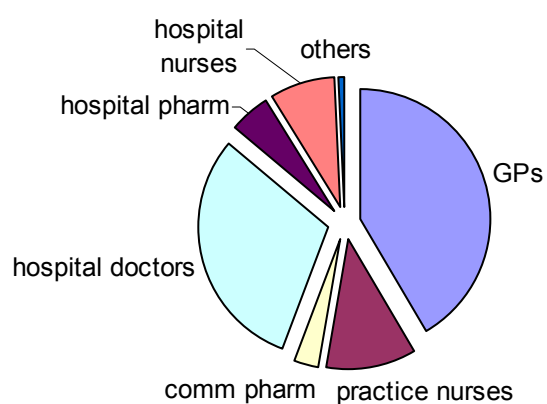
Year	Total No of serious reports received	As percentage of nurse reports
	CSMWM (all WM reports)	
2004	28 (36)	30% (30%)
2003	56 (60)	38% (37%)
2002	13	24%

## 5. Reports of black triangle drugs

5.1 A total of 372 (28%) reports of black triangle drugs were received. The data are shown in Table 16.

Table 16

Year	Total No of ▼ reports received	Percentage of total reports	Change on previous year
	CSMWM (all WM reports)		
2004	372 (501)	28% (30%)	-12% (0%)
2003	421 (503)	34% (34%)	+25%
2002	338	37%	-45%
2001	613	47%	-70%
2000	1996	75%	+246%
1999	577	44%	+16%



5.2 The number of reports of reactions to ▼ drugs from GPs is shown in Table 17.

Table 17

Year	Total No of ▼ reports received	As percentage of GP reports
	CSMWM (all WM reports)	
2004	129 (208)	35% (35%)
2003	141 (181)	38% (37%)
2002	195	45%
2001	419	44%
2000	721	29%
1999	336	41%

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

Table 18

Year	Total No of ▼ reports received	As percentage of hospital doctor reports
	CSMWM (all WM reports)	
2004	133 (152)	27% (29%)
2003	107 (129)	27% (28%)
2002	71	24%
2001	88	26%
2000	158	42%
1999	108	30%

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

Table 19

Year	Total No of ▼ reports received	As percentage of hospital pharmacist reports
	CSMWM (all WM reports)	
2004	22 (25)	10% (10%)
2003	34 (36)	17% (17%)
2002	21	27%
2001	22	25%
2000	34	32%
1999	25	27%

5.5 The number of reports of reactions to ▼ drugs from community pharmacists is shown in Table 20.

Table 20

Year	Total No of ▼ reports received	As percentage of community pharmacist reports
	CSMWM (all WM reports)	
2004	13 (16)	26% (25%)
2003	15 (18)	43% (39%)
2002	13	33%
2001	17	43%
2000	11	44%
1999	7	44%

5.6 The number of reports of reactions to ▼ drugs reported by hospital nurses is shown in Table 21.

Table 21

Year	Total No of ▼ reports received	As percentage of hospital nurse reports
	CSMWM (all WM reports)	
2004	30 (40)	41% (46%)
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 22.

Table 22

Year	Total No of ▼ reports received	As percentage of nurse reports
	CSMWM (all WM reports)	
2004	43 (56)	46% (46%)
2003	97 (102)	66% (62%)
2002	22	16%

## 6. Most commonly reported drugs

The 10 drugs most often mentioned in reports received by CSM West Midlands are listed in Table 23, and Table 24 includes the reports which go direct to the MHRA (but excluding any clozapine reports sent via the Clozaril Monitoring Scheme).

Table 23

Drug substance	Place	2004	2003	Place
aspirin	<b>1</b>	<b>44</b>	25	3
simvastatin	<b>2</b>	<b>35</b>	18	10
infliximab ▼	<b>3</b>	<b>32</b>	24	3
etanercept ▼	<b>4</b>	<b>23</b>	14	16
bendroflumethiazide	<b>4</b>	<b>23</b>	12	23
diclofenac	<b>4</b>	<b>23</b>	18	13
BCG vaccine ▼	<b>7</b>	<b>21</b>	97	1
etoricoxib ▼	<b>8</b>	<b>20</b>	17	13
rosuvastatin ▼	<b>8</b>	<b>20</b>	21	6
rosiglitazone ▼	<b>8</b>	<b>20</b>	9	43

Table 24

Drug substance	Place	2004	2003	Place
aspirin	1	44	26	6
simvastatin	2	40	19	13
infliximab ▼	3	38	29	4
etanercept ▼	4	31	15	19
BCG vaccine ▼	5	30	106	1
rosiglitazone ▼	5	30	15	19
etoricoxib ▼	7	29	25	7
celecoxib	7	29	41	2
rosuvastatin ▼	9	27	28	4
bupropion ▼	9	27	37	3

These top 10 drugs accounted for 20% of all WM reports for 2004 (26% in 2003, 26% in 2002, 39% in 2001, 67% in 2000, 29% in 1999).

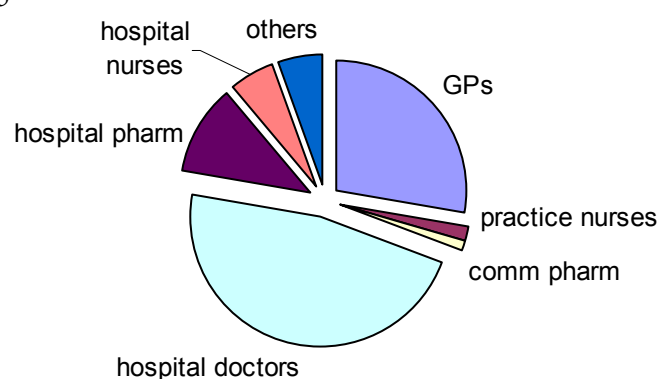
## 7. Follow-up of reports

7.1 We requested follow-up information from 125 reporters and to date have had 70 replies. The data are given in Table 25.

Table 25

Year	Total No of reports followed-up	As percentage of reports	Follow-up response rate
2004	125	10%	56%*
2003	114	9%	52%
2002	143	15%	62%
2001	171	13%	69%
2000	237	9%	27%
1999	191	15%	40%

\* information to date



7.2 The proportion of follow-up information received from various groups of reporters is shown in Table 26

Table 26

Reporter type	No of follow-up requests	Follow-up response rate
GPs	35	57%
Hospital doctors	61	55%
Hospital pharmacists	14	29%
Community pharmacists	2	100%
Hospital nurses	7	86%
Practice nurses	2	0%
Others	6	67%

8. A total of 248 (19%) reporters requested, and were sent, detailed information from us and the data are given in Table 27. This compares with 27% in 2003, 27% in 2002, 32% in 2001, 25% in 2000, 29% in 1999. This is a significantly lower percentage than in any previous year ( $p < 0.001$ ) and we wonder whether reporters feel the DAP is not relevant or unrelated to their needs.

Table 27

Type of reporter	Number of reports	As percentage of reports
GPs	74	20%
Hospital doctors	103	21%
Community pharmacists	10	20%
Hospital pharmacists	12	5%
Hospital nurses	29	39%
Practice nurses/Health visitors	19	20%
Others	1	6%

9. Information on the type of card received is shown in Table 28

Table 28

	Number of reports	percentage
BNF (or copy)	969	74%
AR20 (or copy)	320	24%
Other	29	2%

The distribution of the reports which go direct to the MHRA is shown in Table 29

Table 29

	Number of reports	Percentage of RMC reports	Change on previous year
Paper	182	11%	-4%
GP electronic	129	8%	+545%
HIV	1		
Internet	30	2%	+76%
Processed by other RMCs	1		-80%
Total	343	21%	+48%

10. We have published 3 editions of *re:Action* (issues 29–31), our occasional bulletin, since the last annual RMC meeting covering:

drug-induced hallucinations  
 drug-induced gambling  
 isotretinoin and neuropathy  
 moxifloxacin and bronchospasm

serious adverse drug reactions requiring hospital admission  
drug-induced photosensitivity  
antiretrovirals and pancreatitis  
thiazolidinedione/statin interactions  
40 years of pharmacovigilance  
risk factors for myopathy and rhabdomyolysis with statins  
bupropion and joint pain

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.** Surprise at disdain for conventional medicines. *Pharmaceutical Journal*. 2004; **273**: 114-5.

**Anton C, Langford NJ, Poole CI, Routledge PA, Hutchings A, Bateman DN, Sheehan T, Ferner RE.** Comparison of preparation of infusion bags on the ward or in the pharmacy. National Patient Safety Conference February 2004

**Anton C, Nightingale PG, Adu D, Lipkin G, Ferner RE.** Improving prescribing using a rule based prescribing system. *Quality and Safety in Health Care*. 2004; **13**:186-90.

**Coleman JJ, Langford NJ, Ferner RE, Kendall MJ.** Simulated Practical Therapeutics in an OSCE for final year medical students. Simulation in Medical Education. Association for the Study of Medical Education. January 2004.

**Coleman JJ.** Drug-induced seizures. *Adverse Drug Reaction Bulletin* 2004; **227**: 871-4.

**Cox AR, Langford NJ, Anton C.** Do not forget about the yellow card scheme. *Pharmaceutical Journal* 2004; **272**: 349.

**Cox AR, Langford NJ.** BANs to rINNS. *Journal of Clinical Pharmacy and Therapeutics* 2004; **29**: 491-5.

**Cox AR, Marriott JF, Wilson KA, Ferner RE.** Adverse drug reaction teaching in UK undergraduate medical and pharmacy programmes. *Journal of Clinical Pharmacy and Therapeutics* 2004; **29**: 31-5.

**Cox AR.** Colchicine in acute gout: optimal dose of colchicine is still elusive. *BMJ* 2004; **328**: 288.

**Ferner RE, Aronson JK.** National differences in publishing papers on adverse drug reactions. *British Journal of Clinical Pharmacology* 2005; **59**: 108-111.

Graham-Clarke E, **Langford NJ.** 'All that glitters is not gold'. *Pharmaceutical Journal* 2004; **273**: 284.

Kidd AG, Sharratt C, **Coleman J.** Mobile communication regulations updated: how safely are doctors' telephones used? *Quality and Safety in Health Care* 2004; **13**: 478-9.

Lakie MD, Hayes N, Combes N, **Langford NJ.** Is postural tremor size controlled by interstitial potassium concentration in muscle? *Journal of Neurology, Neurosurgery & Psychiatry* 2004; **75**: 1013-1018.

**Langford NJ, Coleman JJ, Landray M, Martin U, Kendall MJ, Ferner RE.** Teaching final year medical students to avoid errors in prescribing and giving medicines. National Patient Safety Conference February 2004

**Langford NJ, Good AM, Laing WL, Bateman DN.** Quinine intoxications: a continuing problem. *British Journal of Clinical Pharmacology* 2004; **57**: 817.

**Langford NJ, Landray M, Martin U, Ferner RE, Kendall MJ.** Therapeutics OSCE- *Journal of Clinical Pharmacy & Therapeutics* 2004; **29**: 263-6.

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:

- OSCE and Safe prescribing, University of Birmingham November 2004
- Warfarin a temperamental partner, Department of General Practice
- University of Birmingham December 2004
- Caffeine, Stress and Tremor, British Pharmacological Society 2004
- Sandwell and West Birmingham NHS Trust specialist nurses
- Regional palliative care nurses
- A multi-disciplinary study day at Burton Hospital
- Nurses from Coventry PCT
- Clinical Leaders of Thrombosis training day - Drug and Herbal interactions with warfarin
- Drug Packaging and Medication Errors - Pharma Packaging & Labelling Forum, London. October 2004.
- European Symposium on Clinical Pharmacy, Prague
- Update in Medical Toxicology, Cardiff
- Emergency Medicine meeting - Royal College of Physicians
- International Society of Pharmacovigilance annual meeting in Dublin in October 2004.

We taught undergraduate pharmacy students at Aston University, undergraduate and postgraduate medical and dental students at Birmingham University, and pharmacists on the Keele Diploma in Hospital Pharmacy, and participated in the Regional MRCP course.

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

We took part in the consultations arising from Dr Metters's report into the workings of the Yellow Card scheme, the Electronic Yellow Card, and Patient reporting working groups, as well as the EMEA EU experts groups and the National Programme for Information Technology.

Dr Ferner has been Medicines Editorial Advisor to the Concise Oxford English Dictionary, 11<sup>th</sup> Edition.

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

Our website at <http://www.csmwm.org> received over 260,000 hits during 2004 (a 44% increase from 2003). We have developed resources for the website including a guide to the pronunciation of drug names and a pharmacovigilance timeline showing the history of pharmacovigilance.

11. The Centre received a visit from the MHRA in April 2004.
12. We continue, as a Centre, to take an interest in errors in the use of medicines.

## Appendix 1

### DOES INFORMING GPs ABOUT COMMON ADVERSE DRUG REACTIONS (ADRS) INFLUENCE ADR REPORTING RATES?

Anton C, Cox AR, Ferner RE

#### Introduction and Aim

Many prescribers are unsure about when to report ADRs to the MHRA, and many never complete a Yellow Card during their career.<sup>1</sup> Additionally, the reporting rate of GPs in the UK has halved in the last five years.

We investigated whether educating GPs about the most common serious reactions, by sending them factsheets had any influence on their subsequent reporting.

#### Method

We identified from our Regional Monitoring Centre database of ADRs the five most common serious reactions (using the MHRA's definition of severity), and produced concise factsheets (about 500 words) on each, describing the reaction, risk factors, and strategies for avoidance.

In 2002 we received reports from 312 individual GPs out of 3157 GPs in the West Midlands region. We randomly selected 198 of the 2845 non-reporting GPs (Group A) and sent them a factsheet each month for 5 months from December 2003. In a second arm of the study we sent factsheets to a randomly selected sample of those reporters (Group B) who reported one of the relevant ADRs ("factsheet reactions") to us to see if this influenced re-reporting rates.

#### Results

During the first six months of 2004 we received 9 reports from 8 of the Group A GPs (4%) who received the factsheets, and 1 from a comparison random sample of 198 GPs (0.5%) (non-reporters in 2002) who did not receive the factsheets. There were 34 reporters in Group B and 6 of these (18%) reported a further reaction subsequent to receiving a factsheet. Seventy-seven other reporters reported a "factsheet reaction" but did not receive a factsheet and only ten of these (13%) have reported a subsequent reaction.

#### Discussion

GPs who received the factsheets (Group A) had a higher reporting rate, compared with a group who did not receive the factsheets [ $P = 0.022$ , Fisher's exact test]. Only about 10% of GPs will report an ADR in any given year; educating non-reporting GPs seems to raise them towards the mean reporting rate. There are insufficient data yet to determine whether factsheets influence re-reporting rates and this arm of the study is ongoing. The factsheets will need updating regularly, but this should be relatively easy. This is a potentially fruitful method of increasing reporting rate from GPs.

#### References

1. Eur J Clin Pharmacol. 1997; 52: 423-7.





## Study design

CSM West Midlands

1. Does reminding GPs about common, serious reactions encourage them to report?
2. Does educating reporters about the reactions they report encourage them to send in further reports?

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## Fact sheets

CSM West Midlands

- we designed fact sheets for our 5 most common serious reactions
  - hepatic ADRs
  - angioedema
  - muscle and joint ADRs
  - hallucinations
  - depression

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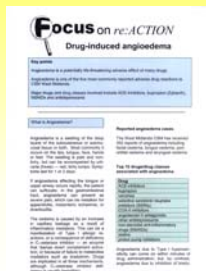
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## Fact sheet design

CSM West Midlands

- 2 sides of A4 (approx 500 words)
- Covered
  - aetiology
  - number of cases
  - most commonly implicated drugs
  - literature review
  - management
  - prescribing advice
  - reporting rationale




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## Selection of recipients

CSM West Midlands

- Arm 1 – GPs
- in 2002, 3127 GPs in our area
  - 312 reporters, 2845 non-reporters
  - intervention group - random selection of 192 of the non-reporters
  - control group – a further random selection of 192 non-reporting GPs

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## Selection of recipients 2

CSM West Midlands

- Arm 2 – reporters of fact sheet reactions
  - intervention group - random selection of all reporters who had reported the relevant reaction
  - control group – all reporters who had reported a fact sheet reaction but who had not received a fact sheet

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## Results Arm 1

CSM West Midlands

- 8 of the intervention group sent in 9 reports
- there was 1 report from the control group
- significant difference ( $P=0.022$ )
- Effects short-lived – none of the intervention group has reported since end of study

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## Results Arm 2

CSM West Midlands

- up to 1/9/04
- 45 reporters had received a fact sheet
  - angioedema (14)
  - depression (1)
  - hepatic (15)
  - muscle (9)
  - hallucinations (6)

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## Results Arm 2

CSM West Midlands

- 45 reporters in the intervention group
  - 8 of these (18%) subsequently reported
- 91 reporters in the control group
  - 11 of these (12%) subsequently reported

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## Conclusions

CSM West Midlands

- effects of intervention short-lived
- insufficient data to determine whether there is a significant effect on re-reporting rates
- more fact sheets will be produced
  - broncospasm, convulsions, withdrawal reactions, GI bleeding, thrombocytopenia

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