

Yellow Card Centre Wales

**ANNUAL REPORT
2011/12**

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

1. STAFF

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2. SUMMARY

As in previous years, members of YCC Wales have continued to encourage the spontaneous reporting of suspected adverse drug reactions from both healthcare professionals and members of the public. Lectures, workshops, poster presentations and seminars on pharmacovigilance have been given throughout Wales. We continued to explore other mechanisms to encourage reporting.

In 2011/12 the reporting rate in the YCC Wales decreased by twenty six percent compared with the previous year. There was a twenty eight percent increase in the number of reports from community pharmacists but a decrease in reports from all the other reporter types. The highest reporter type was hospital pharmacists.

Sixty six percent of all reports were of serious suspected reactions, with hospital pharmacists reporting the highest percentage of these, as in previous years. Twenty three percent of the reports were reactions to black triangle drugs

Members of YCC Wales continue to contribute to the work of the All Wales Medicines Strategy Group in Wales. Drug safety is a major theme in the Medicines Strategy for Wales and YCC Wales, by encouraging spontaneous reporting of suspected adverse drug reactions by health professionals and patients in Wales, has an important role in achieving the optimal use of medicines and thus the best outcomes for patients.

. 3. YELLOW CARD DATA

A total of 711 reports of suspected adverse drug reactions originated from the YCC Wales region in 2010/2011. Comparative data for the previous four years are shown in Table 1. There was a 26% decrease in the total number of reports over the previous year.

Table 1. Number of reports received 2011-12 with previous 4 years for comparison

Year	Total number of reports	Percentage change on previous year
2011/12	711	- 26
2010/11	963	+7
2009/10	898	-11
2008/9	1013	+15
2007/8	882	-8

Chart 1 indicates that there is a considerable variation in the reporting rates throughout Wales. There was increased reporting from Cwm Taf, but a decreasing rate of reporting from the other health boards.

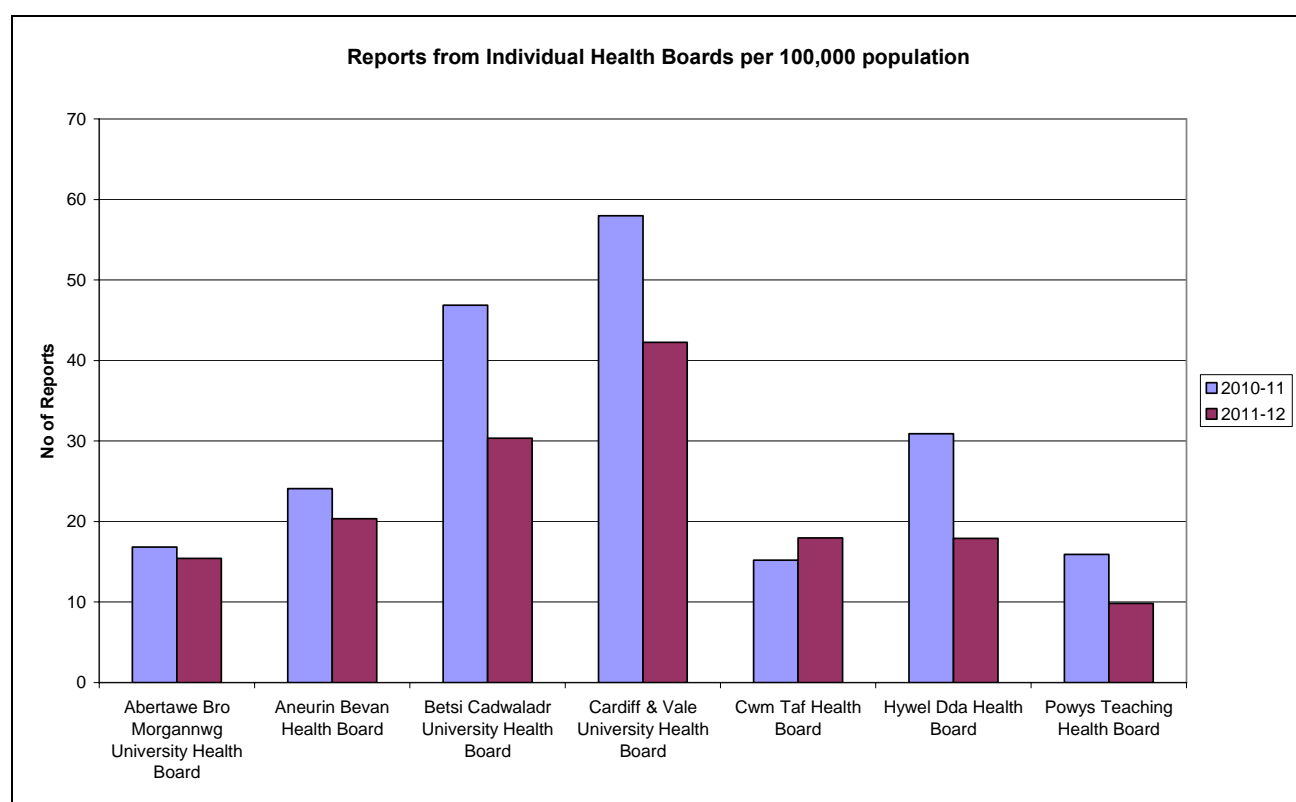


Chart 1

Table 2 highlights the total number and percentage of reports from reporter groups in 2011/12 with comparative percentage data for 2010/11. The highest reporting as in previous years was from hospital pharmacists.

Table 2 Total number and percentage of reports from reporter groups in 2011/12 with comparative percentage changes compared with 2010/11.

Source of reports

Reporter qualification	Number of Reports	Number of reports previous year	Percentage of total reports	Percentage change on previous years
Hospital Pharmacist	179	286	25	-37
Hospital Doctor	119	131	17	-9
General Practitioners	117	163	16	-28
Patient/Parent/Carer	77	79	11	-3
Hospital Nurse	68	84	10	-19
Nurse	62	65	9	-5
Hospital Health Professional	36	97	5	-63
Community Pharmacist	32	25	5	+28
Other Health Professional	9	30	1	-70
Dentist	5	2	<1	+250
Physician	4	0	<1	+400
Pharmacist	2	0	<1	+200
Healthcare Assistant	1	0	<1	+100
Total	711	963		

The following charts show the differing reporting patterns geographically throughout Wales.

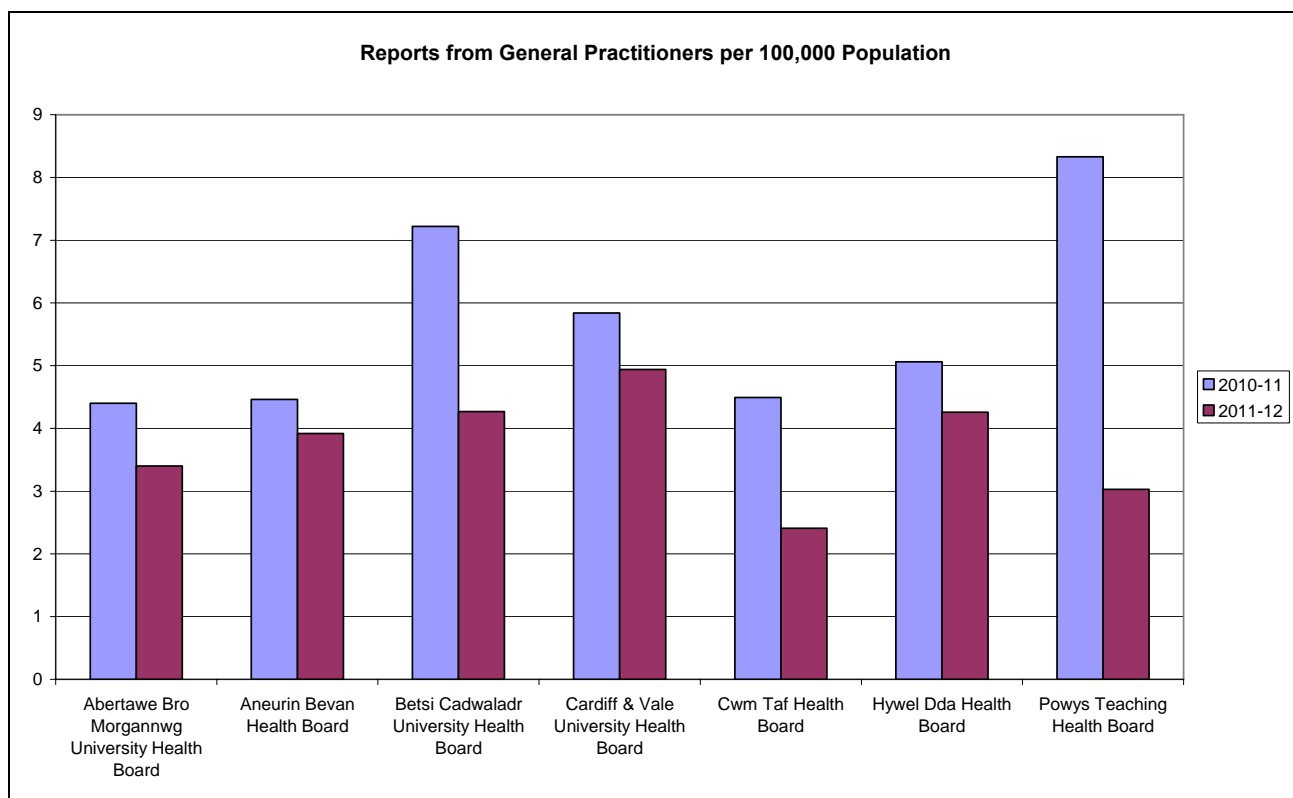


Chart 2

The highest number of community based reporters was from the Betsi Cadwaladr University Health Board followed by Cardiff & Vale and Aneurin Bevan.

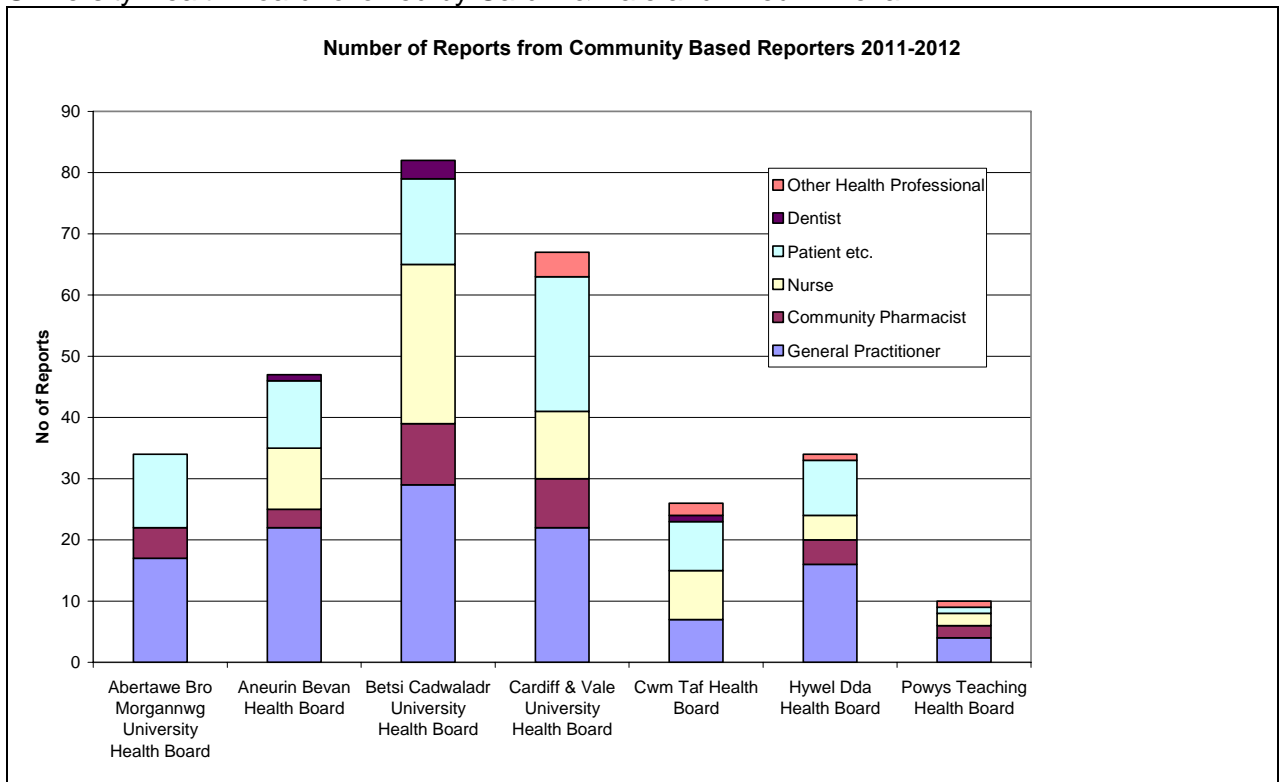


Chart 3

The highest number of hospital based reporters were as in previous years from Betsi Cadwaladr followed by Cardiff & Vale.

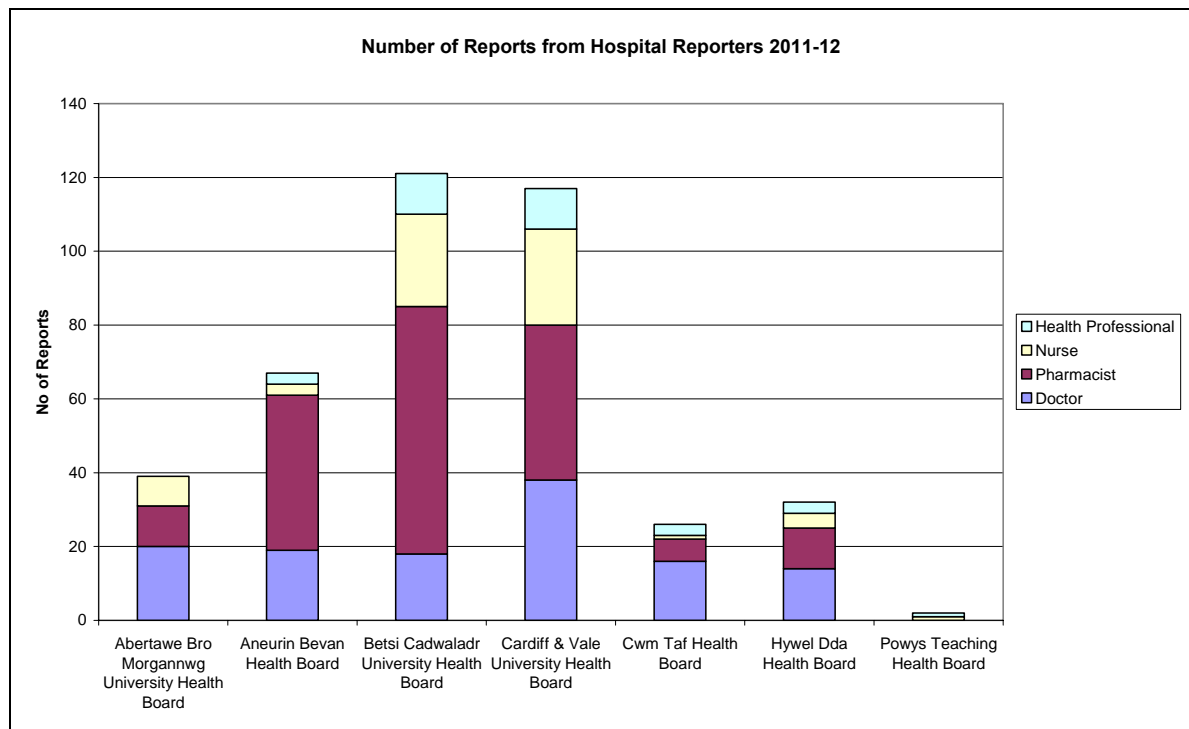


Chart 4

4. Serious Reactions

The total number of reports of serious reactions received in 2011/12 and comparative data for the previous 4 years is shown in Table 3.

Table 3. The total number of reports of serious reactions received in 2011/12 and comparative data for the previous 4 years

Year	Number of Serious Reactions	% of Total Reports	% Change (on previous year)
2011/12	468	66	-20
2010/11	588	61	42
2009/10	413	56	-20
2008/9	514	51	-18
2007/8	626	70	-9

Table 4 highlights the number and percentage of serious reactions per reporter group in 2011/12 with comparative percentage data in 2010/11.

Table 4. The number and percentage of serious reactions per reporter group in 2011/12 with comparative percentage data in 2010/11

Reporter Qualification	Number of Serious Reports	Percentage of Serious Reports/Total Reports by reporter type 2011/12	Percentage of Serious Reports/Total Reports by reporter type 2010/11
Hospital Pharmacist	154	86	84
Hospital Doctor	87	73	65
Patient/Parent/Carer	61	79	72
General Practitioner	54	46	48
Hospital Nurse	37	54	33
Hospital Health Professional	24	67	56
Nurse	23	37	34
Community Pharmacist	15	47	48
Other Health Professional	5	56	30
Dentist	3	60	50
Pharmacist	2	100	
Physician	2	50	
Healthcare Assistant	1	100	-
Total	468		

5. Reports of reactions to Black Triangle Drugs

The total number of reports related to black triangle drugs received in 2011/12 together with comparative data from the previous 4 years are shown in Table 5.

Table 5. The total number of reports concerning black triangle drugs received in 2011/12 together with comparative data from the previous 4 years

Year	Number of reactions to ▼ drugs	Percentage of total reports	% Change (on previous year)
2011/12	168	23	-22
2010/11	216	22	-11
2009/10	243	33	-34
2008/9	370	37	+90
2007/8	194	22	-5

Table 6 highlights the number and percentage of black triangle reports per reporter group in 2011/12 with comparative data for the previous year. General practitioners reported the highest number of reports to black triangle drugs.

Table 6. The number and percentage of black triangle reports per reporter group in 2011/12

Reporter Qualification	Number of Black Triangle Reports	Percentage of Black Triangle Reports/Total Reports 2011/12	Percentage of Black Triangle Reports/Total Reports 2010/11
General Practitioner	47	40	36
Hospital Pharmacist	38	21	20
Hospital Nurse	18	26	29
Hospital Doctor	24	20	15
Nurse	15	24	29
Patient/Parent/Carer	8	10	8
Hospital Health Professional	6	17	21
Community Pharmacist	5	16	24
Other Health Professional	3	33	17
Pharmacist	2	100	0
Physician	2	50	0
Total	168		

6. Fatal Reports

The total number of fatal reports received in 2011/12 together with comparative data from the previous 4 years are shown in Table 7. There was a 43% decrease in the number of fatal reports reported in 2011/12. It is important to note that suspected ADRs are associations only and the absolute numbers of fatal outcomes are still small as a proportion of total reports.

Table 7. Total number of fatal reports received in 2011/12 together with comparative data from the previous 4 years

Year	Number of fatal reports	Percentage of total reports	Percentage change on previous years
2011/12	12	1.7	-43
2010/11	21	2.1	31
2009/10	16	2.2	-43
2008/9	28	2.8	+155
2007/8	11	1.2	-27

7. Age Banding

Table 8 highlights the number of reports per age band in 2011/12 and comparative data for the previous year. It will be noted that in 2011/12, as in the previous year the highest number of reports were in the 65-74 age group. Chart 5 is a graphical representation of this data.

Table 8. Number of reports per age band in 2011/12 and comparative data for the previous year

Age range	Number of reports 2011/12	Number of reports 2010/11
<18	82	114
18-24	39	41
25-34	49	67
35-44	65	84
45-54	81	105
55-64	100	135
65-74	127	177
75-84	81	116
>85	38	59
not specified	49	65
Total	711	963

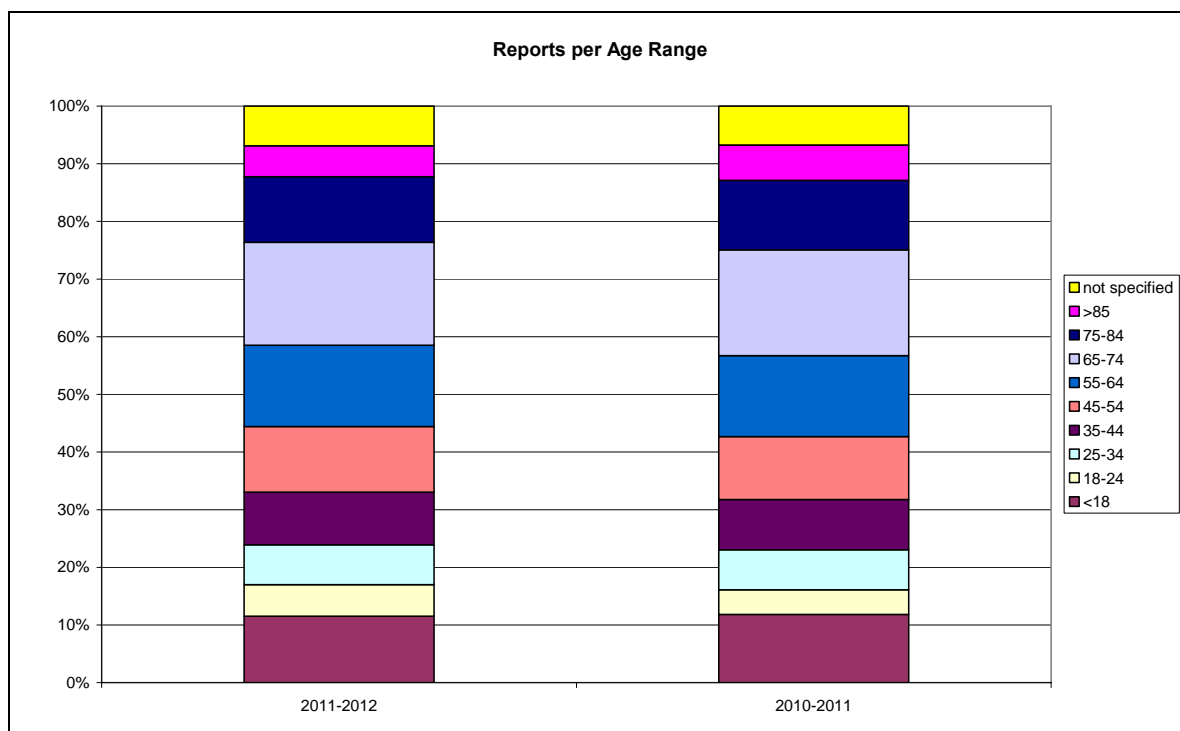


Chart 5

8. Top Ten Medicines

The ten most frequently reported suspect drugs for 2011/12 are shown below in Table 9, together with the number of reports received. For the third year the highest number of reports were to human Papilloma virus vaccine.

Table 9. Ten most frequently reported suspect drugs for 2011/12

Drug/Vaccine	Number of Reports
Human Papilloma virus vaccine	33
Varenicline	22
Influenza Vaccine	18
Rivaroxaban	16
Naproxen	12
Simvastatin	12
Warfarin	12
Alendronic acid	11
Duloxetine	10
Aripiprazole	10
Sitagliptin	10

Table 10 shows the top ten drugs reported to the MHRA in 2011/12 for comparison.

Table 10. Ten most frequently reported suspect drugs to MHRA for 2011/12

Drug/Vaccine
Champix
Cervarix
Omeprazole
Simvastatin
Citalopram
Paracetamol
Aspirin
Ramipril
Mirtazepine
Tramadol

The five most frequently reported suspect drugs by General Practitioners are shown in Table 11. Not surprisingly, the majority of reports of suspected ADRs in association with varenicline were from General Practitioners

Table 11. Five most frequently suspected drugs figuring in reports by General Practitioners

Drug/Vaccine	Number of Reports
Varenicline	13
Duloxetine	5
Sitagliptin	5
Atorvastatin	4
Simvastatin	4

The three most frequently reported suspect drugs from Hospital Doctors is shown in Table 12.

Table 12. Three most frequently reported suspect drugs from Hospital Doctors

Drug/Vaccine	Number of Reports
Aripiprazole	5
MMR Vaccine	3
Tramadol	3

The five most frequently reported suspect drugs from Hospital Pharmacists are shown in Table 13.

Table 13. Five most frequently reported drugs from Hospital Pharmacists

Drug/Vaccine	Number of Reports
Rivaroxaban	11
Warfarin	10
Naproxen	5
Aripiprazole	4
Alendronic acid	4

The four most frequently reported suspect drugs from Carers/Patients/Parents are shown in Table 14.

Table 14. Four most frequently reported suspect drugs from Carers/Patients/Parents

Drug/Vaccine	Number of Reports
Influenza Vaccine	8
Venlafaxine	4
Desogestrel	3
Varenicline	3

The four most frequently reported suspect drugs from Hospital Nurses are shown in Table 15.

Table 15. Four most frequently reported suspect drugs from Hospital Nurses

Drug/Vaccine	Number of Reports
Human Papilloma Virus Vaccine	10
Influenza Vaccine	6
Denusumab	5
Chlorhexidine Gluconate	4

The three most frequently reported suspect drug from community nurses is shown in Table 16.

Table 16. Three most frequently reported suspect drug from community nurses

Drug/Vaccine	Number of Reports
Human Papilloma Virus Vaccine	18
Influenza Vaccine	5
Varenicline	4

9. INTERPRETATION OF FINDINGS

There were a total of 711 reports from reporters within Wales in 2011/12, the lowest number of reports for over 10 years. There was a 26% decrease in the total number of reports, 66% of the reports were of serious reactions, and 23% were to black triangle drugs. The highest number of reports was from hospital pharmacists, There was a 37% decrease of reports from hospital pharmacists, a 24% decrease from hospital doctors, an 19% decrease in hospital nurse reports, a 3% decrease in reports from patient/parent/carers, a 28% decrease from general practitioners and a 28% increase in the total number of reports from community pharmacists. The continued decrease in reporting from general practitioners is shortly to be met with an intensive promotion of reporting programme.

The most frequently reported drug was Human Papilloma virus vaccine. This drug accounted for approximately 5% of the total reports. The highest number of reports was in the 65-74 age group.

10. PROMOTIONAL ACTIVITIES

As in previous years lectures and workshops on adverse reaction reporting and the Yellow Card Scheme have been given to Foundation 1 and 2 doctors throughout Wales by members of the YCC staff and medicines information (MI) pharmacists. MI pharmacists continue to promote adverse reaction reporting and the importance of the Yellow Card Scheme in their areas, and have contributed via the MiDatabank direct reporting system. Lectures on the Yellow Card Scheme, mechanisms and classification of ADRs have been given to medical students, nurse practitioners and NHS Direct nurses (Bristol/Exeter). Regular talks on ADRs have been given to dentists and nurses involved with medicines management. Talks have been given to non medical prescribers, diploma pharmacists, pre-registration pharmacy graduates, primary and secondary care pharmacy technicians, health visitors and practice nurses. YCC Wales together with YCC North West contributed to the distance learning ADR module available for pharmacists and technicians from CPPE and WCPPE.

YCC Wales has continued to attend conferences to mount table displays thus promoting reporting of side effects to both healthcare professionals and members of the general public. We have continued to work closely with the British Lung Foundation, Diabetes UK Wales, Ileostomy, Crossroads and Arthritis Care patient groups and have given talks in centers throughout Wales. YCC Wales continued to be in communication with coordinators of the Expert Patient Programme, supplying leaflets as required. Promotional literature has been supplied by YCC Wales for inclusion in delegate packs when high conference fees prevent the attendance of YCC Wales staff. The YCC website is currently being updated and will be re-launched shortly.

Communications on drug safety and related issues by members of the YCC Wales team.

Bracchi R

Lecture to Diploma in Therapeutics Cardiff September 2011

Houghton JE

ADR talk to Diabetes Branch Carmarthen April 2011

ADR talk to Diabetes Branch Cardiff April 2011

ADR talk to British Lung Foundation Breathe Easy Group Abergavenny April 2011

ADR talk to Diabetes Branch Vale of Glamorgan April 2011

ADR talk to British Lung Foundation Breathe Easy Group Pontnewydd May 2011

ADR talk to British Lung Foundation Breathe Easy Group Chepstow May 2011

Lecture to nurse prescribers on ADRs Caerleon June 2011

ADR talk to British Lung Foundation Breathe Easy Group Neath July 2011

Workshop for pre-registration pharmacists August 2011

ADR talk to Arthritis Care Group Cardiff September 2011

Lecture to nurse prescribers on ADRs Caerleon September 2011

ADR leaflets inclusion in delegate pack for Update in Medical Toxicology Course Cardiff October 2011

Workshop on ADRs to non medical prescribers Cardiff October 2011

ADR talk to Arthritis Care Group Port Talbot October 2011

ADR talk to British Lung Foundation Breathe Easy Group Bridgend November 2011

ADR talk to South Wales Ileostomy Group Cardiff November 2011

ADR talk to Crossroads Vale of Glamorgan February 2012

ADR talk to British Lung Foundation Breathe Easy Group Merthyr Tydfil February 2012

ADR talk to Diabetes UK Group Tonteg March 2012

Lecture to nurse prescribers on ADRs Cardiff March 2012

ADR talk to South Wales Pharmacy Technicians Group Cardiff March 2012

Poster Display at Non Medical Prescribing Conference Cardiff March 2012

Woods FJ

MSc in Ageing April 2011 - Presentation on Pharmacovigilance

Pre-registration Pharmacist training October 2011- Adverse reactions

Non-medical prescribing course January 2012 – Pharmacovigilance, the MHRA and NPSA