

**Yellow Card Centre Wales**

**ANNUAL REPORT  
YEAR 2014-15**

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

**YEAR 2014-15**

**1. STAFF**

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**2. SUMMARY**

The Yellow Card Centre (YCC) Wales spent 2014-15 consolidating the Yellow Card Hospital Champion Scheme and launching Yellow Card reporting as a National Prescribing Indicator for General Practitioners in Wales.

The Yellow Card Hospital Pharmacist Champion Scheme was launched in March 2013 when each Health Board in Wales nominated a minimum of one hospital pharmacist or hospital pharmacy technician to act as a Yellow Card Champion. The aim of the role is promotion of the yellow card scheme through education and training on pharmacovigilance and the Yellow Card scheme. The scheme had a very successful first year and YCC Wales has continued to support the champions throughout 2014-15.

Yellow Card reporting was launched as a National Prescribing Indicator for General Practitioners in 2014-15 via the All Wales Medicines Strategy Group. This has been associated with a 168% increase in submission of GP when compared to the previous year. GP's are now the highest reporting group in Wales.

**3. YELLOW CARD DATA**

A total of 1460 reports of suspected adverse drug reactions originated from the YCC Wales region in 2014/2015. This represents an increase of 24% when compared to 2013/14 (1177). Figure 1 shows the total number of yellow card (YC) reports over time.

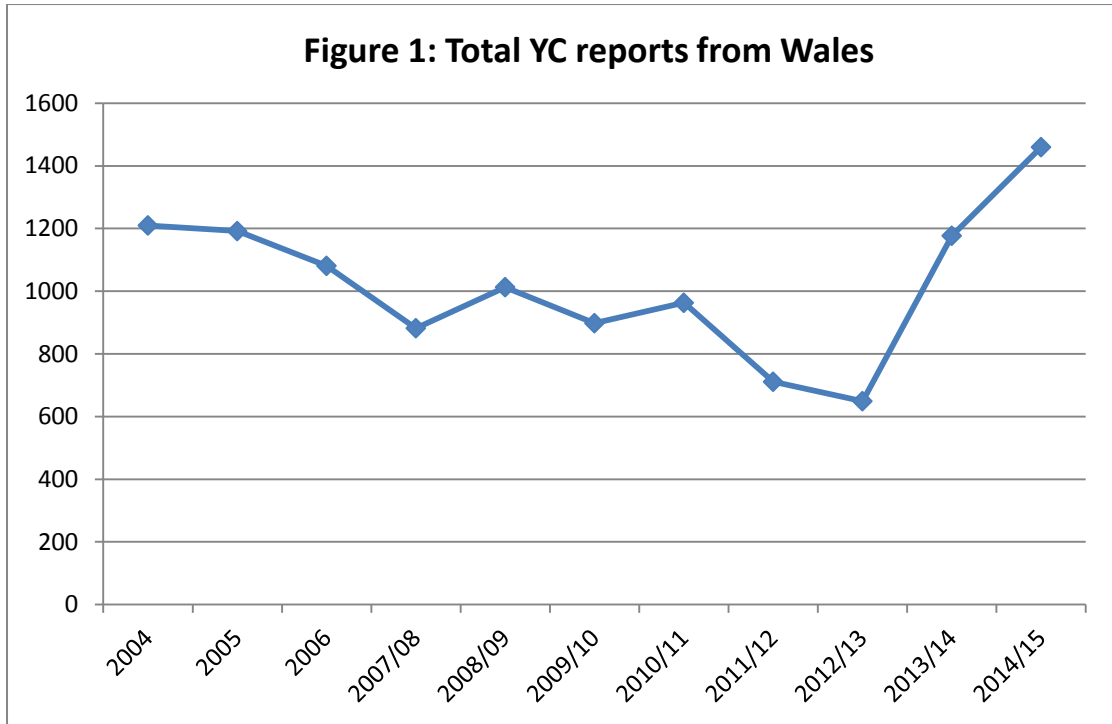


Figure 2 indicates that there is variation in the reporting rates between Health Boards throughout Wales.

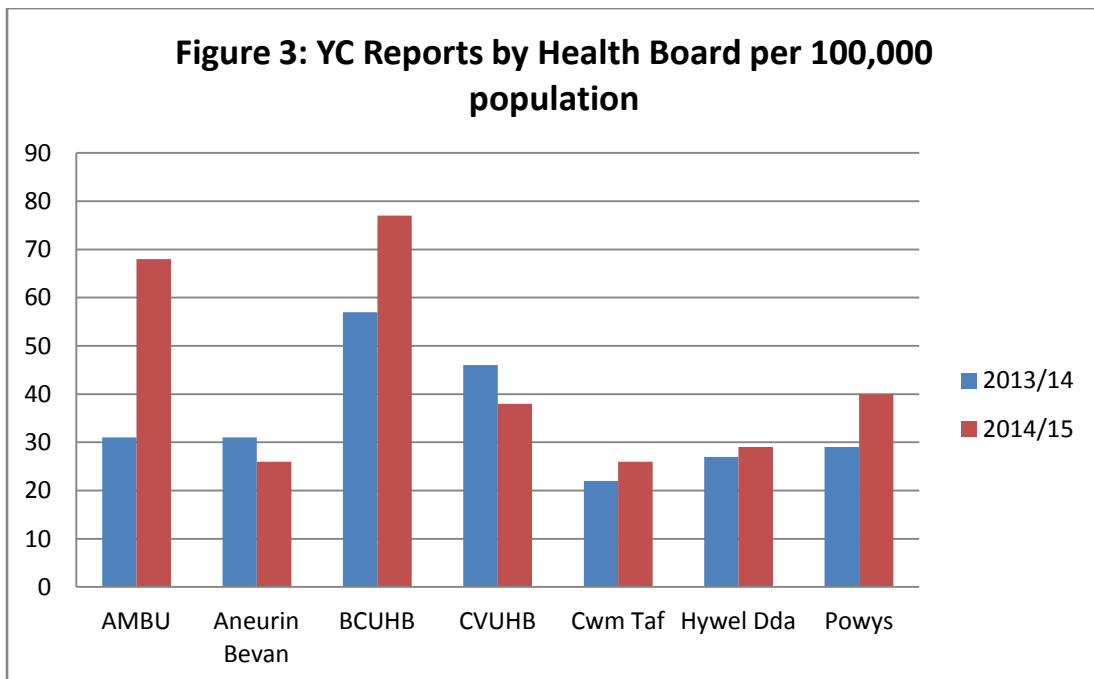
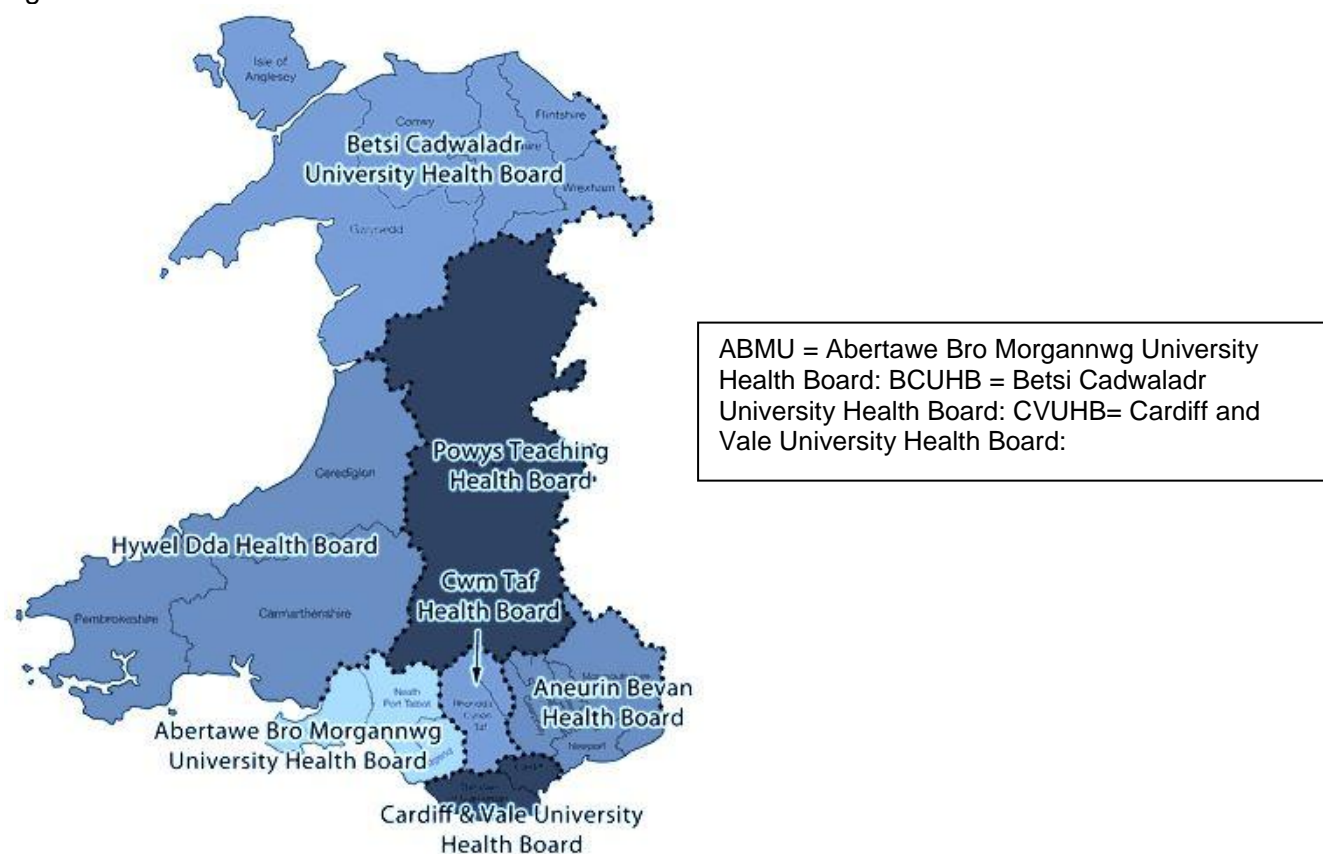


Figure 4 The Seven Health Boards in Wales



**Table 1** Total number and percentage of YC reports from reporter groups in 201 with comparative percentage changes from 2013/14.

Reporter qualification	Number of reports 14/15	Number of reports 13/14	% of total reports 14/15	% change from previous year
General Practitioner	665	271	46	+162
Hospital Pharmacist	241	330	17	-27
Patient/Parent/Carer	147	111	10	+24
Hospital Doctor	137	150	9	-11
Nurse/Midwife	83	98	6	-15
Hospital Nurse	50	65	3	-23
Community Pharmacist	49	44	3	+10
Hospital Health Professional	25	31	2	-19
Pre-reg pharmacist	23	26	2	-12
Pharmacist	15	6	1	+60
Pharmacy assistant	6	0	<1	+600
Other Health Professional	5	7	<1	-29
Radiographer	5	8	<1	-38
Dentist	4	8	<1	-50
Medical student	3	4	<1	-25
Physician	2	0	<1	+200
Chiropodist	1	0	<1	+100
Coroner	1	0	<1	+100

Figure 5 shows the number of reports by GPs per 100,000 population. There continues to be a large variation in reporting rates between the Health Boards.

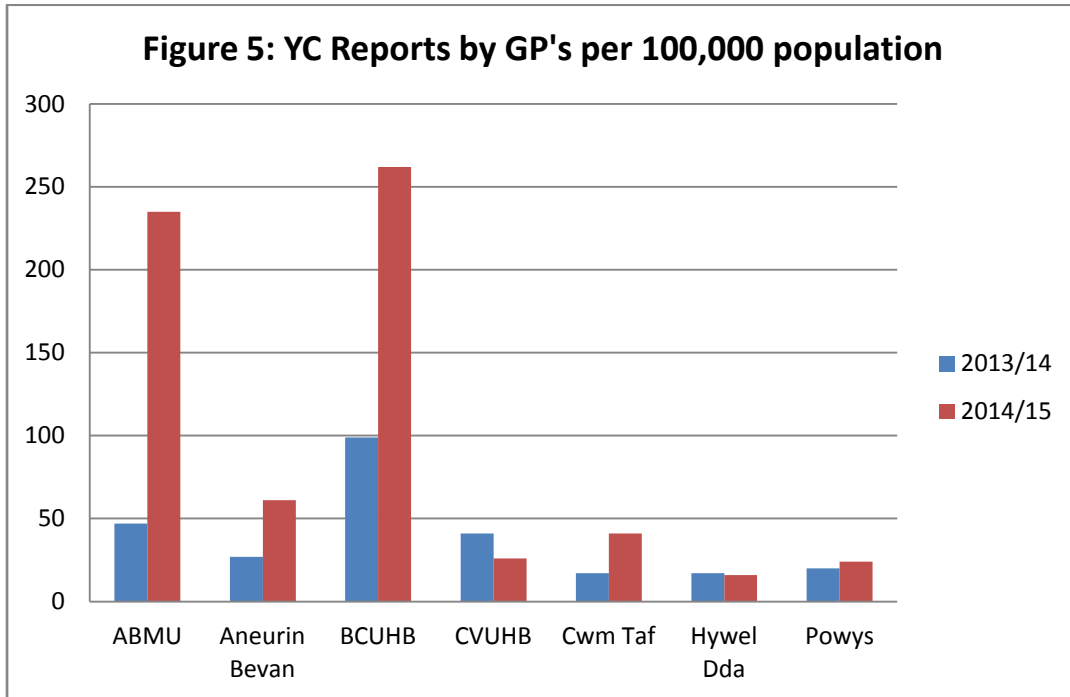


Figure 6 shows the number of reports submitted by community based reporters by Health Board. The chart shows that GPs are the largest reporter group in each Health Board in all but one (Cardiff and Vale) Health Board.

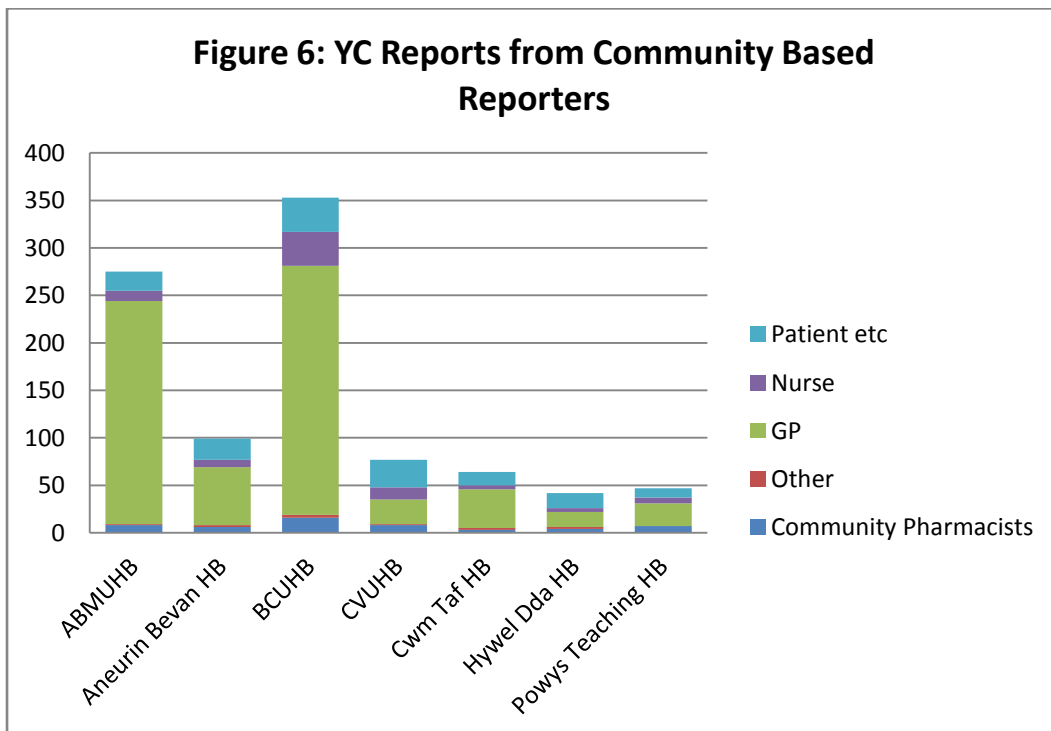
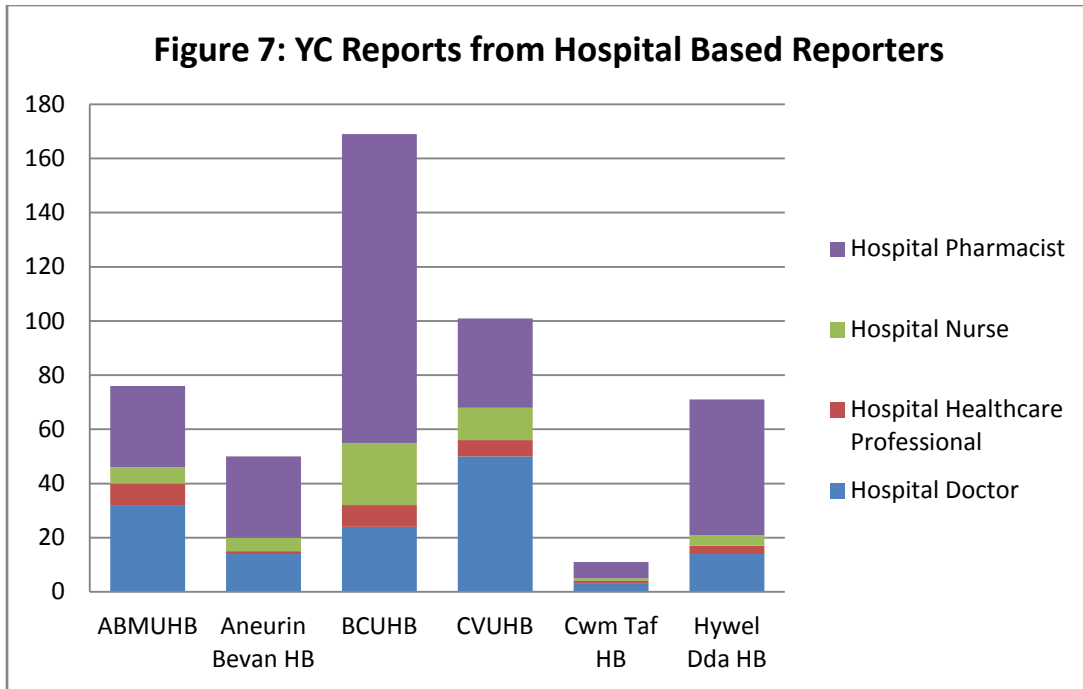


Figure 7 shows the number of YC reports submitted by hospital based reporters. Hospital pharmacists represent the largest reporter group in all but one Health Board.



#### 4. SERIOUS SUSPECTED ADVERSE DRUG REACTIONS

The total number of reports of suspected serious adverse drug reaction YC reports received in 2014/15 and comparative data for the previous 5 years is shown in Table 3.

**Table 2.** The total number of reports of suspected adverse drug serious reaction YC reports received in 2014/15 and comparative data for the previous 5 years

Year	Number of Serious Reactions	% of Total Reports
2014/15	789	54
2013/14	308	26
2012/13	422	65
2011/12	468	66
2010/11	588	61
2009/10	413	56

**Table 4.** The number and percentage of suspected serious adverse drug reaction YC reports per reporter group in 2014/15 with comparative percentage data in 2013/14

Reporter Qualification	Number of Suspected Serious YC Reports	Percentage of Suspected Serious YC Reports/Total Reports by reporter type 2014/15	Percentage of Suspected Serious YC Reports/Total Reports by reporter type 2013/14
Hospital Pharmacist	233	89	93
Hospital Doctor	94	69	77
General Practitioner	268	40	40
Patient/Parent/Carer	98	67	85
Hospital Nurse	21	41	48
Nurse/Midwife	19	23	34
Hospital Health Professional	18	67	45
Community Pharmacist	20	38	43

#### 5. YC REPORTS OF SUSPECTED REACTIONS TO MEDICINES SUBJECT TO 'ADDITIONAL MONITORING'

Medicines that are being monitored particularly closely by regulatory authorities in the European Union (EU) are described as being under 'additional monitoring'. These were previously known as 'black triangle drugs'. All medicines are carefully monitored after they are placed on the market. If a medicine carries the Black Triangle symbol, this means that it is subject to more intensive monitoring.

**Table 5.** The total number of reports concerning medicines subject to additional monitoring received in 2014/15 together with comparative data from the previous 5 years

Year	Number of reactions associated with ▼ drugs	Percentage of total reports
2014/15	239	16
2013/14	128	11
2012/13	153	24
2011/12	168	24
2010/11	216	22
2009/10	243	33

## 6. YC REPORTS OF SUSPECTED ADVERSE DRUG REACTIONS ASSOCIATED WITH FATALITY

The number of YC reports associated with a fatal outcome, received in 2014/15 with comparative data from the previous 5 years are shown in Table 6.

**N.B. It is extremely important to note that suspected ADRs are associations only and there is not necessarily a causal link between any of the medicines reported on a particular yellow card and the fatal outcome.**

It is also important to note that the reports associated with a are a very small proportion of the total yellow card reports (generally less than 2%)..

**Table 6.** Total number of YC I reports of suspected ADRs associated with a fatal outcome received in 2014/15 together with comparative data from the previous 5 years

Year	Number of fatal reports	Percentage of total YC reports
2014/15	23	1.6
2013/14	17	1.4
2012/13	9	1.4
2011/12	12	1.7
2010/11	21	2.1
2009/10	16	2.2

## 7. AGE BANDING

The numbers of YC reports involving patients in each pre-specified age band are shown in table 7, Although the highest number of reports concerned patients aged from 65 to 74 years (as in the previous year), these numbers have not been corrected for the distribution of different ages in the population of Wales.

**Table 7.** Number of YC reports involving patients in each pre-specified age band in 2014/15 and comparative data for the previous year.

Age range	Number of YC reports 2014/15	Number of YC reports 2013/14
<18	108	127
18-24	70	41
25-34	90	74
35-44	113	83
45-54	156	124
55-64	208	178
65-74	288	212
75-84	263	176
>85	106	105
not specified	58	57
<b>Total</b>	<b>1460</b>	<b>1177</b>



## 8. TOP TEN MEDICINES

**Table 8.1** Top Ten Medicines appearing on YC reports from Wales via the YC scheme in 2014-15l

	<b>Medicine</b>	<b>Number of YC reports</b>
1	Rivaroxaban	53
2	Ramipril	47
3	Influenza vaccine	33
4	Warfarin	28
5	Sertraline	27
6	Dapagliflozin	26
7	Amlodipine	25
8	Dabigatran	24
9	Herpes zoster vaccine	23
10	Furosemide	22
10	Naproxen	22
10	Trimethoprim	22

**Table 8.2** Top 10 medicines appearing on YC reports from Wales via the YC scheme in 2014-15 from carers/patients/parents

<b>Medicine</b>	<b>Number of YC reports</b>
Influenza vaccine	8
Cerelle	5
Atorvastatin	4
Simvastatin	4
Cerazette	3
Erythromycin	3
Morphine Sulphate	3
Pregabalin	3
Sertraline	3
Trimethoprim	3

**Table 8.3** Top 10 medicines appearing on YC reports from Wales via the YC scheme in 2014 from General Practitioners

<b>Medicine</b>	<b>Number of YC reports</b>
Rivaroxaban	27
Dapagliflozin	19
Ramipril	18
Sertraline	17
Amlodipine	16
Dabigatran	16
Atorvastatin	14
Nexplanon	14
Omeprazole	13
Warfarin	13

**Table 8.4** Top 9 medicines appearing on YC reports from Wales via the YC scheme in 2014 from Hospital Doctors

Medicine	Number of YC reports
Levetiracetam	6
Rivaroxaban	5
Alendronate	3
Aspirin	3
Denosumab	3
Fluoxetine	3
Mirtazapine	3
Naproxen	3
Sugammadex	3

**Table 8.5** Top 9 medicines appearing on YC reports from Wales via the YC scheme in 2014 from Hospital Pharmacists

Medicine	Number of YC reports
Ramipril	25
Furosemide	20
Warfarin	13
Spironolactone	13
Rivaroxaban	11
Naproxen	10
Trimethoprim	8
Bendroflumethiazide	7
Methotrexate	6

N.B. Table 8.4 and 8.5 have top 9 only as after this no single drug fitted the 10<sup>th</sup> category.

## 9. INTERPRETATION OF FINDINGS

There has been a further increase in the number of reports from Wales in 2014-15, increasing by 24% (1460) when compared to the previous year (1177). The highest number of reports was from General Practitioners, who displayed a 168% increase on the number of reports made in 2013-14. This increase is closely associated in time with the launch of Yellow Card reporting rates as a National Prescribing Indicator in the community in 2014-15.

Encouragingly, there was a further increase in the number of reports from patients and further work is planned to improve this further in 2015-16. In 2013-14 YCC Wales saw an 81% increase in the number of yellow cards reported. It is encouraging that other reporter groups maintained their reporting rates this year but additional support is required to consolidate this and further improve reporting rates.

All Health Boards in Wales except two had an increase in reporting rates in 2014-15. YCC Wales will be focused particularly on improving reporting rates in Aneurin Bevan HB and Cardiff and Vale UHB in 2015-16.

The percentage of serious suspected YC reports increased in 2014-15 to 54%. Interestingly, the number of serious reports submitted by GPs remained the same at 40%, indicating that the National Prescribing Indicator was not associated with an increase in the proportion of non-serious reports and thus by definition, decline in the proportion of YC reports of suspected serious ADRs.

The percentage of reports involving medicines requiring additional monitoring, previously known as black triangle drugs, increased in 2014-15. The most frequently reported treatment was Rivaroxaban with 53 reports. The highest number of reports was in the 65-74 age band but there has been an increase in reports across all age groups.

## **10. PROMOTIONAL ACTIVITIES**

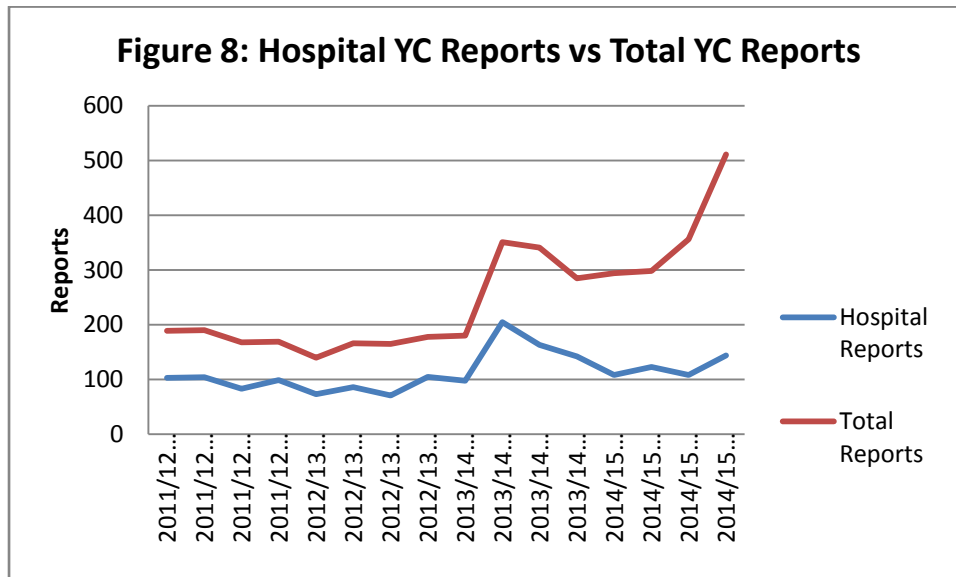
### Yellow Card Hospital Champion Scheme

The role specification for the Hospital champion scheme was agreed by the All Wales Chief Pharmacist Committee in November 2012 and was:

- To act as an information resource, provide guidance and to deal with local queries on pharmacovigilance and yellow card reporting
- To proactively assist other colleagues in the completion of yellow cards as a result of adverse drug reactions
- To provide education and training sessions on pharmacovigilance and yellow card reporting to HB hospital staff
- To increase local publicity of the yellow card scheme
- To keep up to date with legislative changes at the MHRA and EMA and communicate these and other drug safety issues to the relevant parties
- To attend a training session at YCC Wales
- To provide YCC Wales details of all training sessions undertaken

Thirteen hospital pharmacists and hospital pharmacy technicians were appointed representing each Health Board in Wales, Velindre NHS Trust and Public Health Wales.

Figure 8 shows the number of yellow cards reported each quarter.



Since the scheme was launched the YC reporting rate amongst hospital reporters has increased. This has been reflected in the total number of reports submitted.

The number of YC reports submitted by hospital pharmacists fell 27% in 2014-15 from 330 in 2013-14 to 241. This may in part be associated with the champions being tasked with focussing their training efforts on GP's rather than hospital prescribers in 2014-15 to assist the launch of the National Prescribing Indicator. However this was more than offset by the 162% increase in reports from General Practitioners, so the total number of YC reports rose yet again in 2014-15.

As the scheme entered its second year we have had a number of new champions appointed. A second training day is planned in 2015-16 to ensure that all new champions receive the same training as existing champions in an attempt to improve hospital pharmacist reporting rates further.

#### National Prescribing Indicator

In 2013-14, members of YCC Wales worked with the All Wales Prescribing Advisory Group (AWPAG) to develop yellow card reporting as a National Prescribing Indicator (NPI) in Wales. NPIs are developed annually to promote rational prescribing, balancing both quality and efficiency.

Yellow card reporting was agreed as an NPI for 2014-15 with the following targets set:

- A. Target for GP practice- GPs to submit one yellow card per 2,000 practice population.
- B. Target for each health board- submit yellow cards in excess of one per 2,000 health board population.

**Figure 9** shows the GP reporting figures from 2014-15 for each Health Board. None of the Health Boards achieved target A.

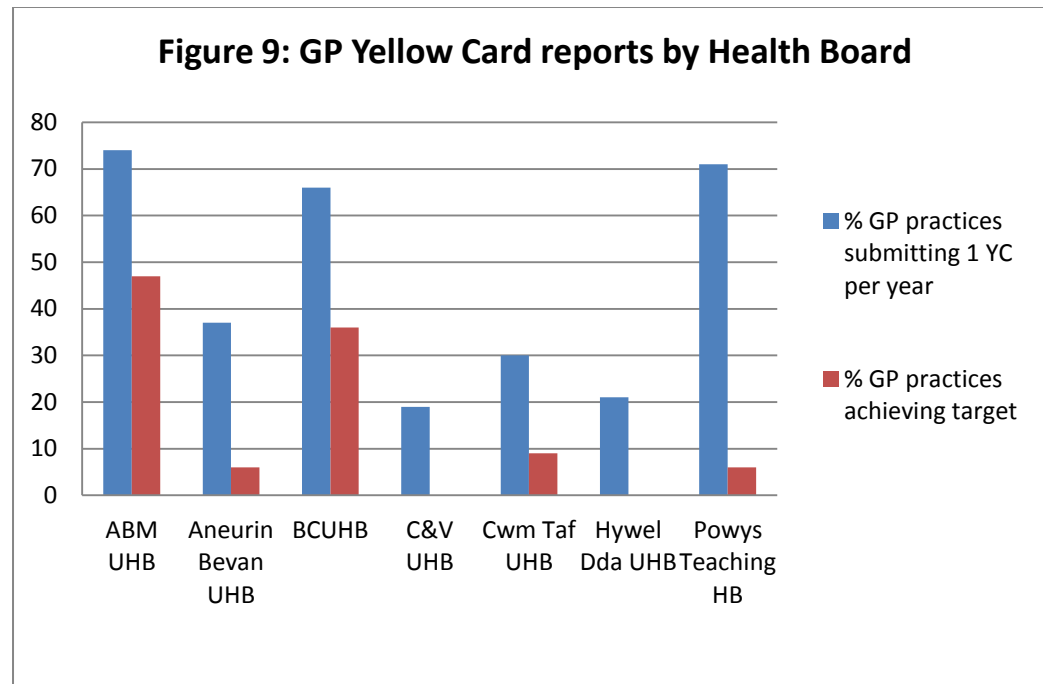
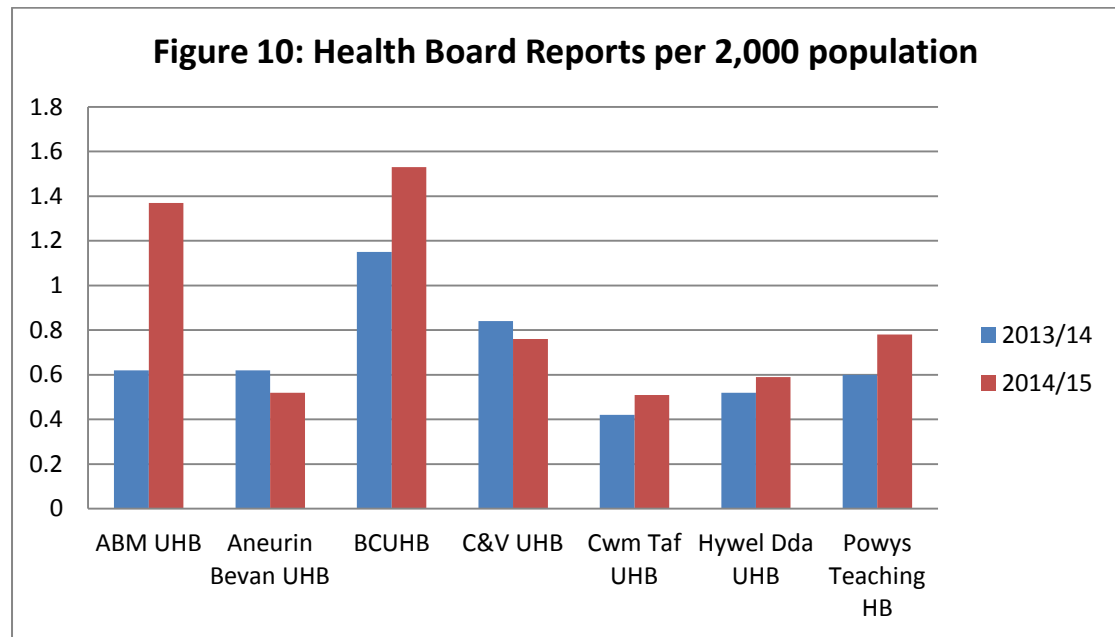


Figure 9 also shows that there is great variation between Health Boards in the submission of YC reports by GP's. Two Health Boards, Cardiff and Vale UHB and Hywel Dda UHB, did not have any GP practices achieving the target of one YC report per 2,000 patients and had the lowest percentages of GP practices submitting one YC report per year. These Health Boards will be the focus for further education and training in 2015-16.

Abertawe Bro Morgannwg UHB show the greatest increase in YC reports and now have the highest percentage of GP practices submitting one YC report per year.

**Figure 10** illustrates the overall Health Board reports for 2013-14. Target B is 1 report per 2,000 population. Abertawe Bro Morgannwg UHB and Betsi Cadwaladr UHB both achieved this target in 2014-15.



### Other Promotional Work

Presentations on the Yellow Card Scheme, mechanisms and classification of ADRs have been given to medical students, dental students, nursing students and pharmacy students as well as postgraduate audiences. Regular presentations on medicines safety have been delivered to dentists and nurses involved with medicines management. Presentations have been given to GP's, non medical prescribers, diploma pharmacists, pre-registration pharmacy graduates, primary and secondary care pharmacy technicians, health visitors and practice nurses.

YCC Wales has continued to attend conferences to mount table displays, thus promoting reporting of suspected ADRs by healthcare professionals and members of the general public. Promotional literature has been supplied by YCC Wales for inclusion in delegate packs when high conference fees prohibit the attendance of YCC Wales staff.

Details of some of these these activities are listed below:

#### Presentations (PA Routledge)

- How the All Wales Medicines Strategy Group (AWMSG) is contributing to Antimicrobial Stewardship in Wales at the Antimicrobial Stewardship Forum meeting, Cardiff, April 29<sup>th</sup> 2014

- Drug interactions with Herbal medicines at the joint BPS/ RSM conference, Frontiers in prescribing: Drug interactions: 50 years of progress, held at the Royal Society of Medicine, London, May 7<sup>th</sup> 2014
- Toxicity of Herbal Medicines to the MSc in Experimental Medicine, University of Oxford, Oxford May 14<sup>th</sup> 2014
- Efficacy and safety of herbal and traditional medicines; regulatory implications to the World Congress of Basic and Clinical Pharmacology, Cape Town, South Africa, July 17<sup>th</sup> 2014.
- From Science to Systems in optimising the use of Medicines. North Wales Medicines Research Symposium, Rhyl September 4<sup>th</sup> 2014
- Case Studies in Herbal Medicine to the Diploma in Therapeutics Study Weekend, Cardiff, UK, October 3<sup>rd</sup> 2014.
- The implications of pharmacogenomics to clinical practice in NHS Wales at the The Golden Helix Pharmacogenetics Day, Cardiff , October 10<sup>th</sup> 2014
- Heroes, Villains and the Appliance of (pharmacological) science. 12th Annual ABPI Public Lecture, Cardiff, October 15<sup>th</sup> 2014
- Prudent Prescribing and Antimicrobial Stewardship at the 1000 Lives Prudent Healthcare event in Swansea (European Antibiotic Awareness day), November 18<sup>th</sup> 2014
- “Here, eat this root-Plant poisonings and trends in poisoning in the UK” to the World Plant Toxin Forum, Vienna, Austria, November 10<sup>th</sup> 2014.
- Poisons and Medicines; do your genes matter? At the Wales Gene Park/ Techniquet Sixth Form Conference: Discovering Genomics, Cardiff, December 2<sup>nd</sup> 2014
- Toxicity of Drugs of Abuse in Wales to the Annual Meeting of the Wales External Quality Assessment scheme (WEQAS) User group, Cardiff December 12<sup>th</sup> 2014
- “Toxicity of plants and herbs in the United Kingdom” to the National Poisons Information Service (NPIS) Continuous Professional Development (CPD) Day, Cardiff, UK, March 5<sup>th</sup> 2015.

#### Publications (PA Routledge)

- James K, Moore S, Ives R, **Routledge P**, Smith J and Parrott A. (MUP Sub-Group on behalf of the Advisory Panel on Substance Misuse [APoSM]). Minimum Unit Pricing: a review of its potential in a Welsh context (2014)  
<http://wales.gov.uk/docs/dhss/publications/140725uniten.pdf>
- **Routledge PA**. Better healthcare outcomes and safer care through Prudent Prescribing (2014)  
<http://www.prudenthealthcare.org.uk/prescribing/>

Dr A M Thomas

- April 2014 Adverse Drug Reactions, BDS, Cardiff University
- April 2014 Adverse Drug Interactions in Dental Practice, BDS, Cardiff University
- April 2014 Adverse Drug Reactions, BSc Medical Pharmacology, Cardiff University
- April 2014 Adverse Drug Interactions, BSc Medical Pharmacology, Cardiff University
- May 2014 YCC Wales- Patient Reporter Activities, Drug Safety In Wales Anniversary Event
- May 2014 Prescribing and how to avoid the pitfalls for finals and beyond, MB BCh
- July 2014 Adverse Drug Reactions for SpRs, GIM Study Day, Wales Deanery
- October 2014 Prescribing in Liver and Renal Disease, BDS, Cardiff University
- February 2014 Patient Compliance, MB BCh
- March 2015 Adverse Drug Reactions, BSc Medical Pharmacology, Cardiff University
- March 2015 Adverse Drug Interactions, BSc Medical Pharmacology, Cardiff University

Mr J Hayes

Jamie Hayes has delivered numerous good prescribing (including pharmacovigilance) workshops to medical, dental, nursing and pharmacist audiences across Wales. This included sixteen prudent prescribing workshops as part of the prudent healthcare agenda.

Zainab Alani

- ADR/Yellow Card Training for Health visitor's October 2014
- ADR/Yellow Card Training for Health visitor's February 2015

Publications

Yellow card blog, 'Yellow is the new black' for Pharma-Cymru by Susan Huey, Yellow Card Champion Spring 2015.

Training delivered by champions on behalf of YCC Wales

- Wednesday 9<sup>th</sup> April ADR/Yellow card training for patients, Cardiff and Vale University Health Board
- Tuesday 22<sup>nd</sup> April ADR/Yellow card training for pharmacists, Cardiff and Vale University Health Board.
- Wednesday 4<sup>th</sup> June ADR/Yellow card training for GP's, Betsi Cadwaladr Health Board
- Wednesday 18<sup>th</sup> June ADR/Yellow card training for GP's, Betsi Cadwaladr Health Board.



- Wednesday 2<sup>nd</sup> July ADR/Yellow card training for pharmacists, Cardiff and Vale University Health Board
- Thursday 16<sup>th</sup> October, ADR/Yellow card training at Patient Safety Wales conference
- Friday 17<sup>th</sup> October ADR/Yellow card training for Paediatric doctors. Cwm Taf Health Board.
- Tuesday 28<sup>th</sup> October - ADR/ Yellow Card Training for medical students, Betsi Cadwaladr Health Board
- Friday 31<sup>st</sup> October ADR/Yellow card training for pharmacists, Cardiff and Vale University Health Board.
- Tuesday Nov 4<sup>th</sup> 2014 – ADR/ Yellow Card Training for Age Connect group, Cardiff and Vale University Health Board.
- Friday 7<sup>th</sup> November – ADR/ Yellow Card Training for pharmacists, Betsi Cadwaladr Health Board
- Thursday 27<sup>th</sup> November - ADR/ Yellow Card Training for GP's Betsi Cadwaladr Health Board,
- Wednesday 21<sup>st</sup> January ADR/ Yellow Card Training for patients Cardiff and Vale University Health Board
- Monday 2<sup>nd</sup> February 2015- – ADR/ Yellow Card Training to patients, Cardiff and Vale University Health Board
- Friday 6<sup>th</sup> March – ADR/ Yellow Card Training for pharmacy technicians, Betsi Cadwaladr Health Board

### Acknowledgements

YCC Wales would like to acknowledge the contribution made by the following parties in helping us to promote and develop our current initiatives:

#### Yellow Card Hospital Pharmacist Champions

Rosemary Allgeier, Public Health Wales

Sue Beach, Hywel Dda

Alison Cox, BCUHB

Sian Davies, BCUHB

Julian Denrico, BCUHB

Vanessa Adams, Velindre

Claire Ganderton, Cwm Taf

Susan Huey, CVUHB

Jayne Price, Powys Teaching

Julie Postle, CVUHB

Helen Richards, ABMU

Nia Sainsbury, ABMU

Jane Basford, Aneurin Bevan

#### Welsh Analytical Prescribing Support Unit (WAPSU)

Kath Haines

Kate Jenkins

Chrissie Collier

Anne Coles

Karen Jones