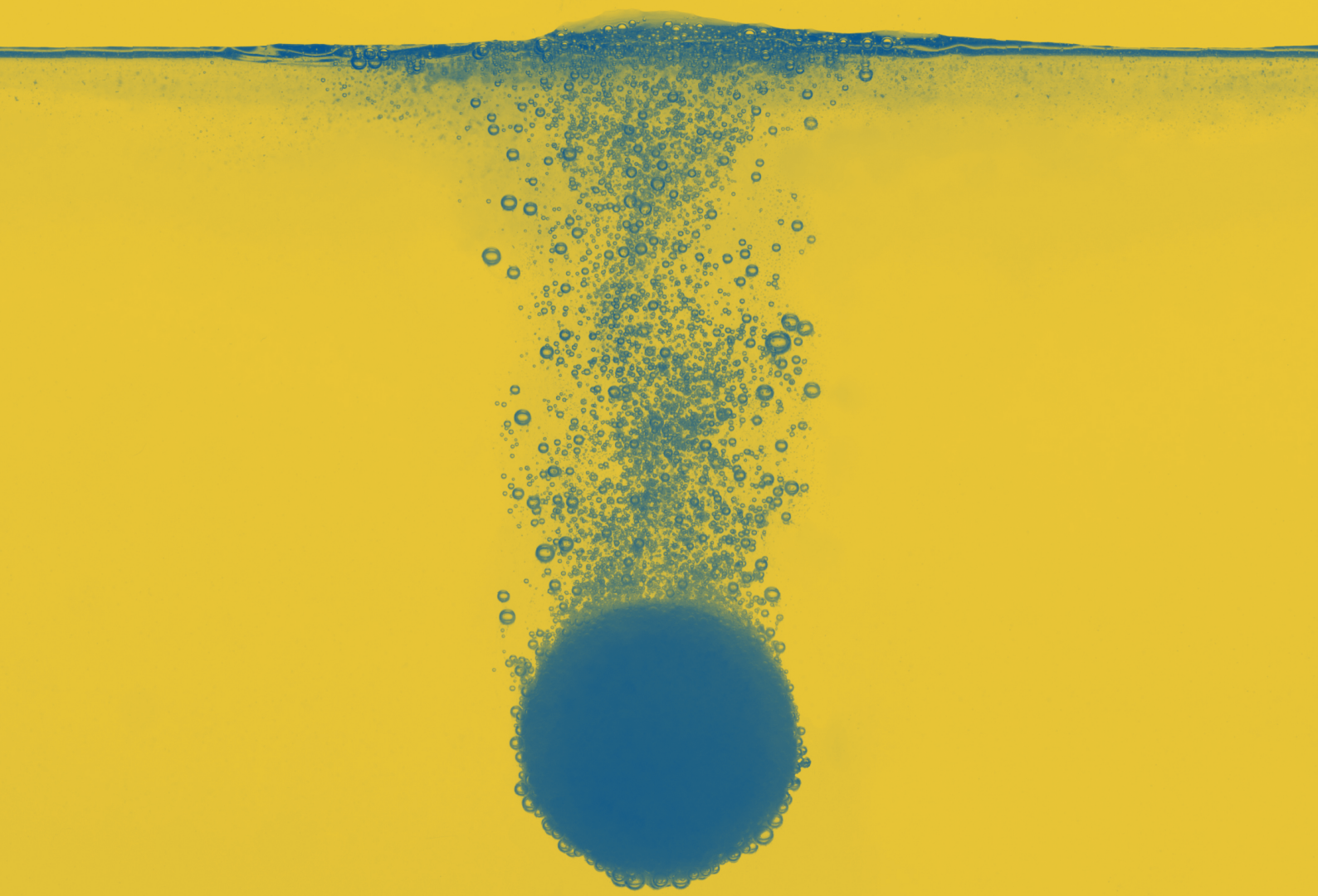




Annual Report 2013-2014



Annual Report of Yellow Card Centre Wales to the Medicines and Healthcare Products Regulatory Agency

Year 2013-14

Staff

Dr A M Thomas	Medical Director
Professor P A Routledge	Associate Medical Director
Dr J P Thompson	Senior Lecturer in Clinical Pharmacology
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Mrs F J Woods	Director, Welsh Medicines Information Centre
Mrs A Adams	Senior Information Pharmacist
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Summary

The Yellow Card Centre (YCC) Wales spent 2013-14 working on a number of high profile initiatives to improve the Yellow Card reporting rates for General Practitioners, Hospital Pharmacists, Community Pharmacists and Hospital based reporters in general.

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 to promote the Yellow Card Scheme through education and training on pharmacovigilance. It was postulated that this would improve reporting rates amongst hospital based reporters, particularly hospital pharmacists.

YCC Wales has worked in collaboration with the Welsh Medicines Resource Centre (WeMeReC) at the All Wales Therapeutics and Toxicology Centre (AWTTC) to produce a Pharmacovigilance module that was issued in May 2013 and completed by 411 GPs.

YCC Wales also worked in collaboration with Cardiff University in a study on the attitudes of community pharmacists to Yellow Card reporting. The questionnaire was followed up with a nationwide Yellow Card promotional mail campaign in September 2013.

This targeted promotional work has been associated with an increase in the number of Yellow Cards submitted by Wales based reporters.

Further developments include the adoption in 2014-15 of Yellow Card reporting as a National Prescribing Indicator by the All Wales Medicines Strategy Group (AWMSG) and the continuation of the Yellow Card Hospital Champion Scheme.



Yellow Card Data

A total of 1177 reports of suspected adverse drug reactions originated from the YCC Wales region in 2013/2014. This represents an increase of 81% when compared to 2012/13 (649).

Chart 1 shows the total number of reports over time.

Chart 1: Total reports from Wales

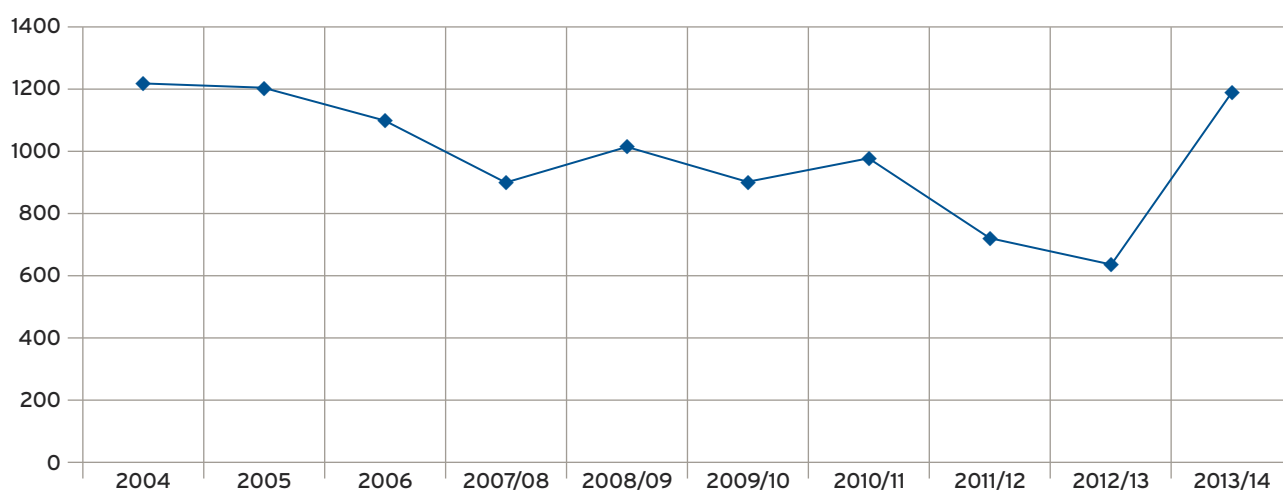


Chart 2 indicates that there is variation in the reporting rates between Health Boards throughout Wales. However, each Health Board (HB) has shown an increased Yellow Card reporting rate in the past year when compared with 2012/13.

Chart 2: Reports by Health Board per 100,000 population

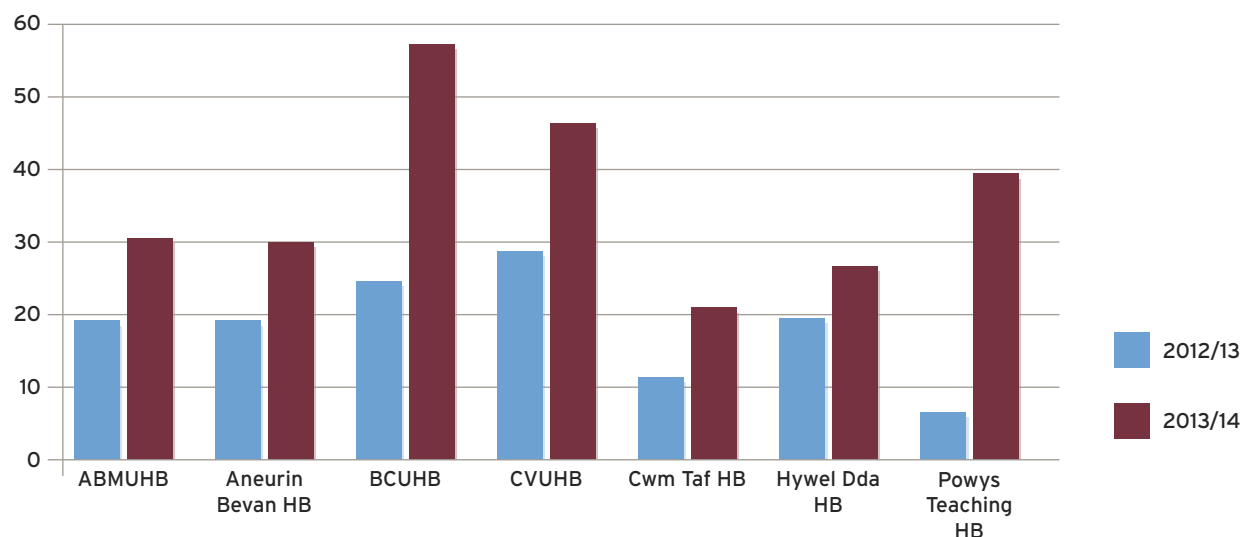


Illustration 1 shows the Health Boards in Wales for reference.

- Betsi Cadwaladr University Health Board
- Hywel dda Health Board
- Powys Teaching Health Board
- Abertawe Bro Morgannwg University Health Board
- Cwm Taf Health Board
- Aneurin Bevan Health Board
- Cardiff & Vale University Health Board



Table 2 Total number and percentage of reports from reporter groups in 2013/14 with comparative percentage changes compared with 2012/13.

Table 2: Source of reports

Reporter qualification	Number of reports 12/13	Number of reports 13/14	% of total reports 13/14	% change from previous year
Hospital Pharmacist	144	330	28	+129
Hospital Doctor	104	150	13	+44
General Practitioner	116	271	23	+134
Patient/Parent/Carer	49	111	10	+127
Hospital Nurse	46	65	6	+41
Nurse/Midwife	61	98	9	+61
Hospital Health Professional	30	31	3	+3
Community Pharmacist	42	44	4	+5
Other Health Professional	15	7	<1	-53
Dentist	5	8	<1	+60
Physician	1	0	0	-100
Pharmacist	19	6	<1	-68
Pre-reg pharmacist	12	26	2	+117
Optometrist	2	0	0	-100
Medical student	2	4	<1	+100
Radiographer	0	8	<1	+800

Chart 3 shows the number of reports by GPs per 100,000 population. Each Health Board shows an increase in the reporting rate when compared to the previous year. However, there is still variation between the reporting rates depending on the Health Board.

Chart 3: Reports from GP's per 100,000 population

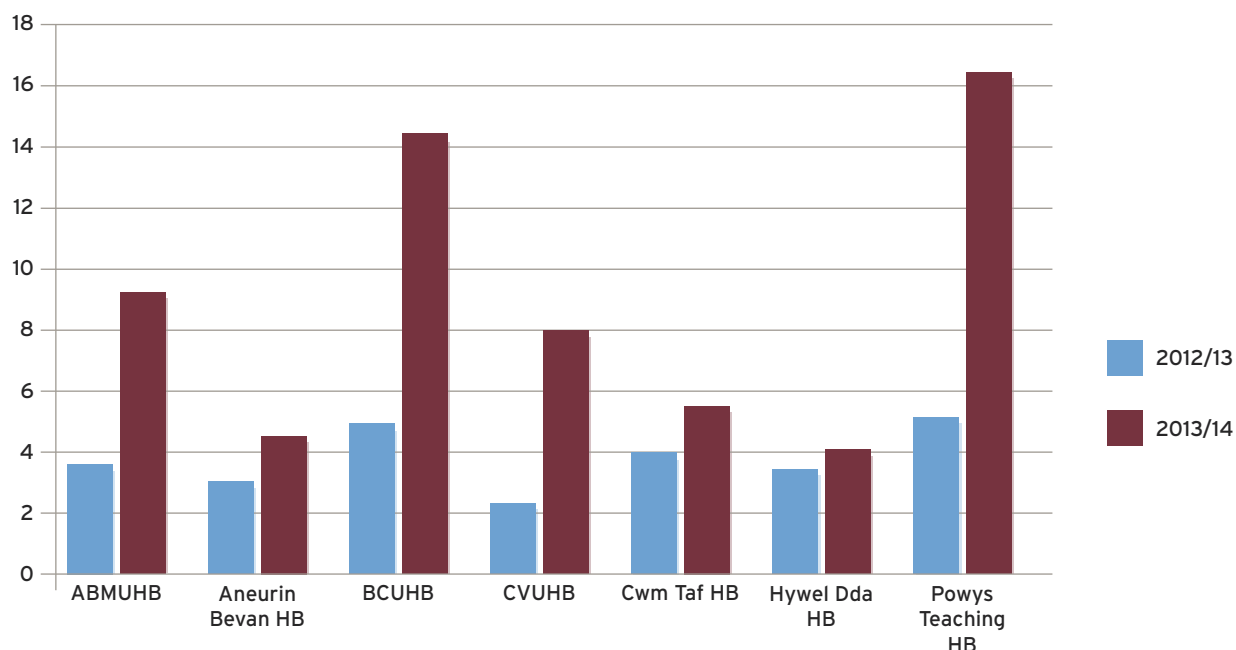


Chart 4 shows the number of reports submitted by community based reporters by Health Board. The chart shows that GPs are the largest reporter group in each Health Board.

Chart 4: Reports from Community Based Reporters

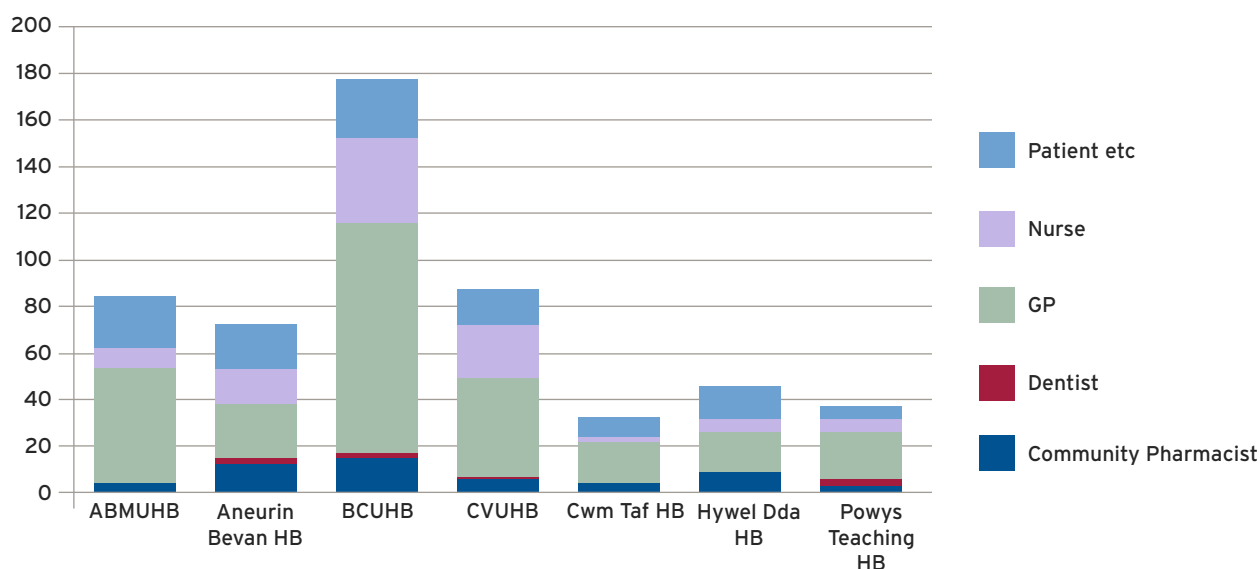
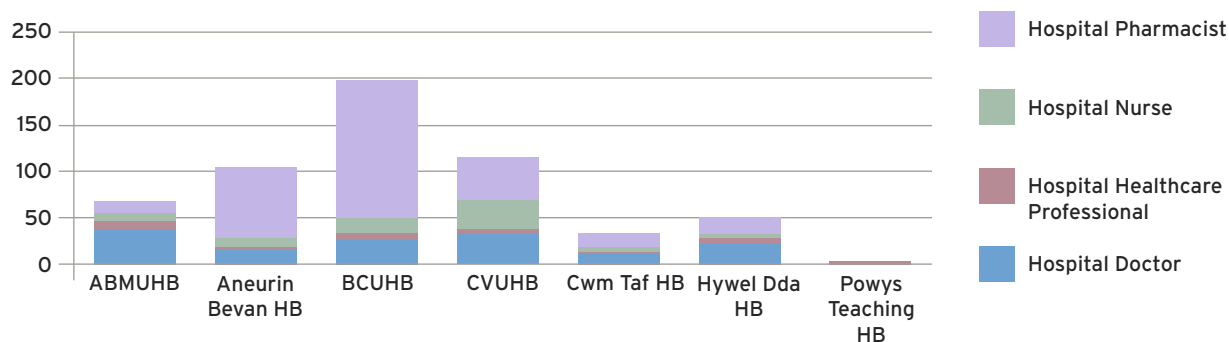


Chart 5 shows the number of reports submitted by hospital based reporters. Hospital pharmacists represent the largest reporter group in all but one Health Board.

Chart 5: Reports from Hospital Based Reporters



Serious Reactions

Table 3 The total number of reports of serious reactions received in 2013/14 and comparative data for the previous 4 years.

Year	Number of Serious Reactions	% of Total Reports
2013/14	758	64
2012/13	422	65
2011/12	468	66
2010/11	588	61
2009/10	413	56

Serious Reactions *continued*

Table 4 The number and percentage of serious reactions per reporter group in 2013/14 with comparative percentage data in 2012/13.

Reporter Qualification	Number of Serious Reports 2013/14	Percentage of Serious Reports/ Total Reports by reporter type 2013/14	Percentage of Serious Reports/ Total Reports by reporter type 2012/13
Hospital Pharmacist	308	93	90
Hospital Doctor	116	77	78
General Practitioner	111	40	54
Patient/Parent/Carer	94	85	84
Hospital Nurse	31	48	50
Nurse/Midwife	33	34	30
Hospital Health Professional	14	45	60
Community Pharmacist	19	43	40
Other Health Professional	4	57	27
Dentist	5	63	100
Pre-reg pharmacist	19	73	55
Radiographer	2	25	0
Medical student	2	50	100

Reports of 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 intensive monitoring.

Table 5 The total number of reports concerning medicines subject to additional monitoring received in 2013/14 together with comparative data from the previous 4 years.

Year	Number of reactions associated with ▼drugs	Percentage of total reports	% Change (on previous year)
2013/14	128	11	-13
2012/13	153	24	0
2011/12	168	24	+2
2010/11	216	22	-11
2009/10	243	33	Data not available

Fatal Reports

The number of fatal reports received in 2013/14 with comparative data from the previous 4 years are shown in Table 6. Despite the percentage of serious reports reducing this year, the percentage of fatal reports has remained the same. It is 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 fatal reports are a very small proportion of the total Yellow Card reports.

Table 6 Total number of fatal reports received in 2013/14 together with comparative data from the previous 4 years.

Year	Number of fatal reports	Percentage of total reports	Percentage change (on previous year)
2013/14	17	1.4	0
2012/13	9	1.4	-0.3
2011/12	12	1.7	-0.4
2010/11	21	2.1	-0.1
2009/10	16	2.2	Data not available

Age Banding

Table 7 Number of reports per age band in 2013/14 and comparative data for the previous year.

Age Range	Number of reports 2013/14	Number of reports 2012/2013
<18	127	73
18-24	41	25
25-34	74	38
35-44	83	52
45-54	124	81
55-64	178	80
65-74	212	146
75-84	176	83
>85	105	33
not specified	57	39
Total	1177	649

Top Ten Medicines

Table 8.1

Top Ten Drugs Reported overall

Drug	Number of reports
Influenza vaccine*	36
Rivaroxaban	29
Warfarin	28
Amoxicillin	22
Zostavax	20
Ciprofloxacin	20
Gardasil	18
Co-amoxiclav	16
Simvastatin	16
Varenicline	16

*multiple brands

Table 8.2

Top 10 Drugs from carers/patients/parents

Drug	Number of reports
Influenza vaccine*	10
MMR vaccine	6
Alendronate	3
Amlodipine	3
Cerazette	3
Levothyroxine	3
Mirtazapine	3
Omeprazole	3
Tamoxifen	3
Zostavax	3

*multiple brands

Table 8.3

Top 5 Drugs from General Practitioners

Drug	Number of reports
Rivaroxaban	16
Zostavax	11
Varenicline	10
Influenza vaccine*	8
Sertraline	7

*multiple brands

Table 8.4

Top 4 Drugs from Hospital Doctors

Drug	Number of reports
Co-amoxiclav	4
Influenza vaccine*	3
MMR vaccine	3
Quetiapine	3

*multiple brands

Table 8.5

Top 4 Drugs from Hospital Pharmacists

Drug	Number of reports
Warfarin	19
Amoxicillin	16
Ciprofloxacin	14
Trimethoprim	9

Interpretation Of Findings

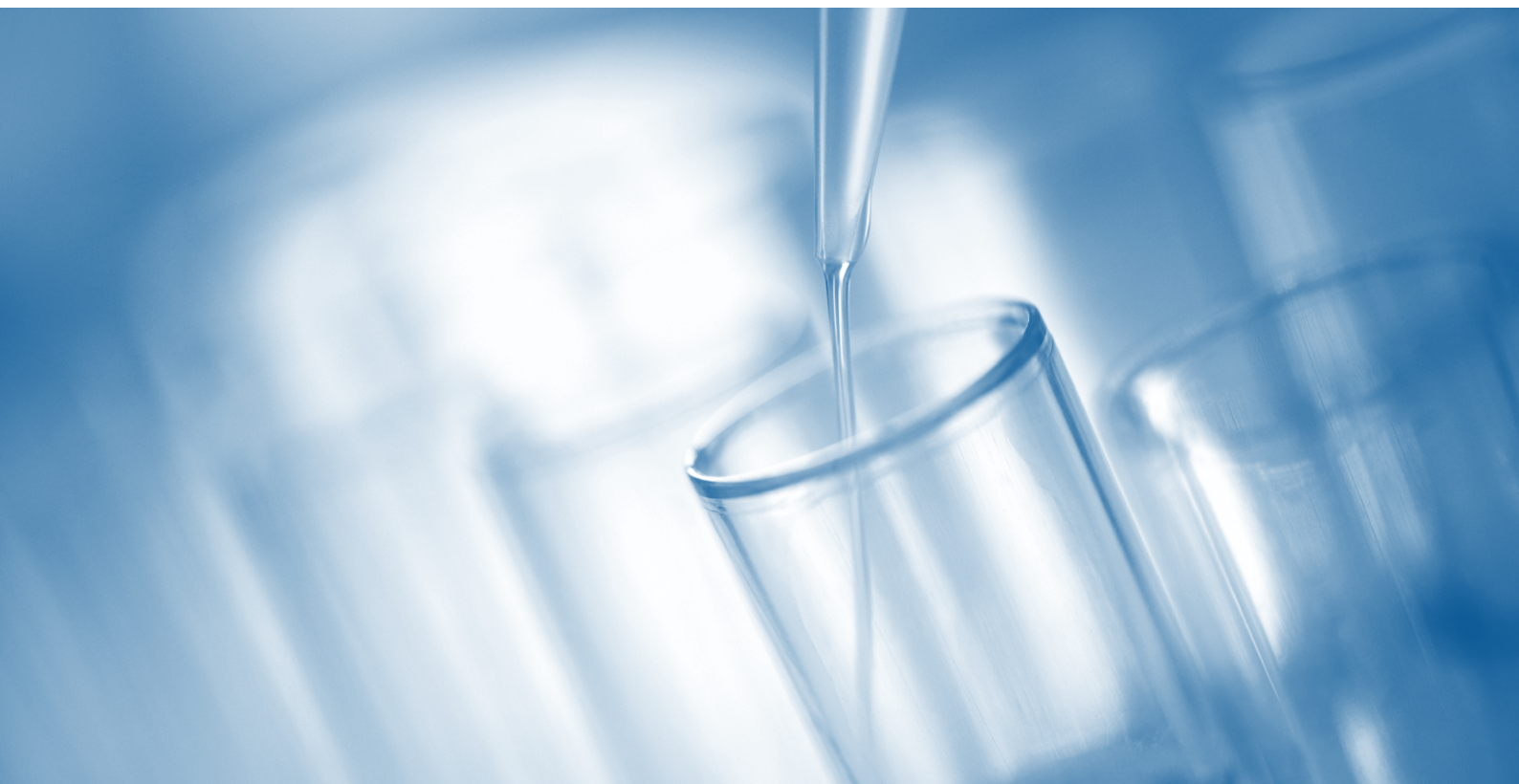
There has been an encouraging increase in the number of reports from Wales in 2013-14, increasing by 81% (1177) when compared to the previous year (649). This represents the highest number of reports in a year since 2005. The highest number of reports was from hospital pharmacists, who displayed a +129 increase on the number of reports made in 2012-13. This increase is closely associated temporally with the launch of the Yellow Card Hospital Champion Scheme.

Other reporter groups also showed improvements in the number of reports submitted when compared to previous years. There was a 134% increase in reports from GPs, a 44% increase from hospital doctors, a 41% increase in hospital nurse reports and a 127% increase in reports from patient/parent/carers. Despite targeted promotional work, the number of reports from community pharmacists only showed a modest increase of 5%. Further work is planned to address this.

All Health Boards in Wales had an increase in reporting rates, showing an improvement nationwide. This is in line with the national initiatives that YCC Wales undertook in 2013-14.

The percentage of serious reports was maintained despite a fall in the number of serious reports from GPs from 54% to 40%. The percentage of fatal reports was the same as for the previous year.

The percentage of reports for black triangle drugs decreased in 2013-14. The most frequently reported treatment was for the influenza vaccine. The highest number of reports was in the 65-74 age group but there was an increase in reports across all age groups.



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 with details of all training sessions undertaken

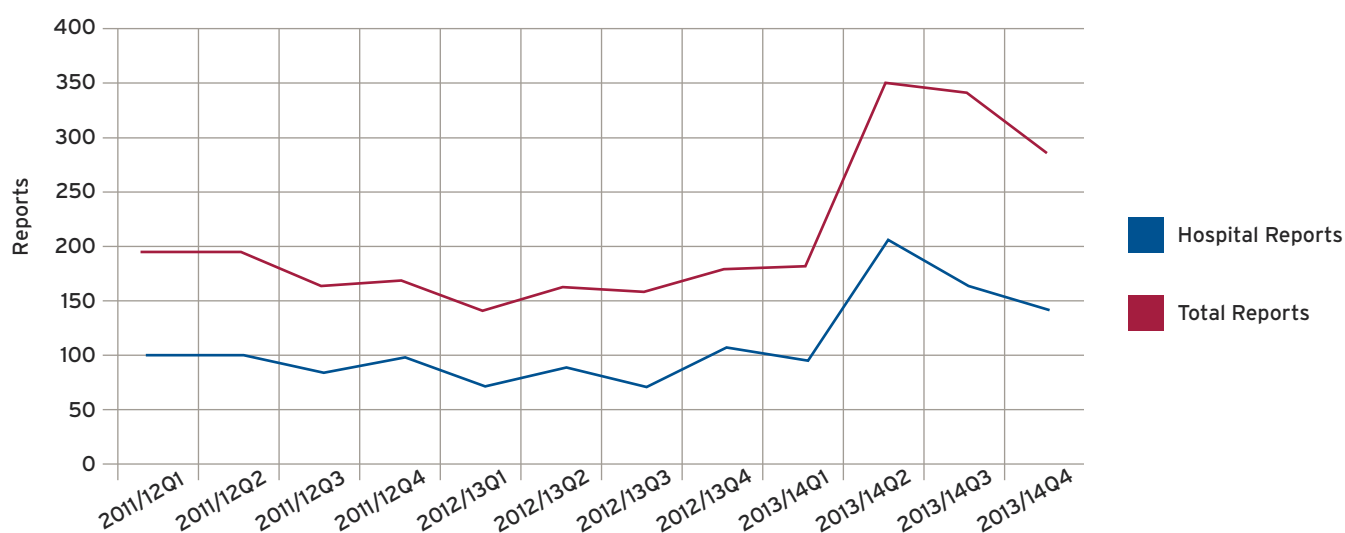
Thirteen hospital pharmacists and hospital pharmacy technicians were appointed representing each Health Board in Wales, Velindre NHS Trust and Public Health Wales.

YCC Wales provided the champions with the following:

- Training to undertake the role at a training day at AWTTTC
- A standard set of PowerPoint presentation slides that could be edited by local Yellow Card Champions to suit their audiences
- Materials such as presentation handouts, information leaflets etc as required
- Updates of legislative changes at the MHRA and EMA
- Communication of important drug safety issues
- Support and advice for Yellow Card Champions whenever necessary

The following chart shows the number of Yellow Cards reported each quarter.

Chart 6: Hospital Reports vs Total Reports

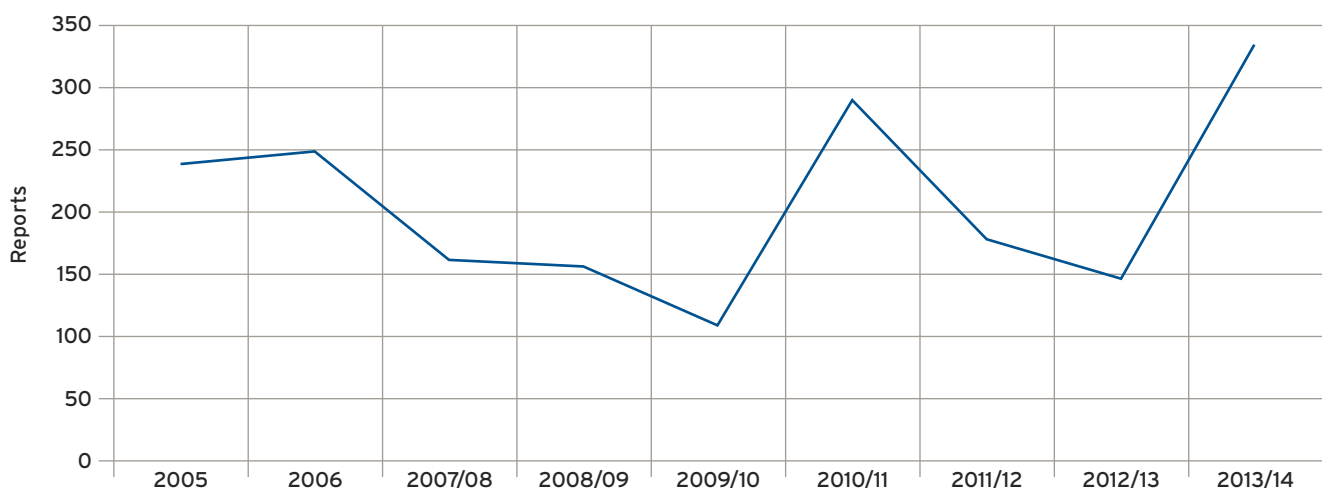




Since the scheme was launched the reporting rate amongst hospital reporters has increased. This has been reflected in the total number of reports submitted.

The following chart shows the number of reports made by hospital pharmacists annually for the past nine years. There has been wide variation in reporting rates. The target for the next year is to further improve reporting by hospital pharmacists.

Chart 7: Number of reports from Hospital Pharmacists



Promotional Activities *continued*

The following table lists the number of training sessions completed by the hospital champions throughout 2013-14.

Health Board	Date	Audience	Participants
ABMU	March 2013	Hospital Pharmacists	16
	April 2013	Hospital Doctors	9
	June 2013	GPs	17
	June 2013	GPs	20
	July 2013	Hospital Pharmacists	10
	July 2013	GPs	40
	July 2013	Hospital Pharmacists	8
	July 2013	Hospital Pharmacy Technicians	16
	Aug 2013	Hospital Pharmacists	14
	Sept 2013	Hospital Paediatric Team	16
	March 2014	Hospital Palliative Care Team	14
Aneurin Bevan	Sept 2013	Hospital Pharmacists	13
BCUHB - Ysbyty Gwynedd	Aug 2013	Hospital Pharmacists	20
	Aug 2013	Hospital Doctors	20
	Sept 2013	Hospital Pharmacists	25
	Dec 2013	Hospital Doctors	16
	Feb 2014	Hospital Pharmacists	20
CVUHB	April 2013	Hospital Doctors	25
	May 2013	Hospital Pharmacists	2
	May 2013	Hospital Pharmacists	3
	June 2013	Hospital Doctors	3
	Sept 2013	Hospital Pharmacists	5
	Oct 2013	Hospital Pharmacists	5
	Oct 2013	Hospital Pre-registration Pharmacists	3
	April 2014	Patient group	10
Cwm Taf	April 2013	Hospital Pharmacists	5
	April 2013	Hospital Pharmacists	3
	April 2013	Hospital Pharmacists	2
	May 2013	Hospital Doctors	12
Hywel Dda	April 2013	Hospital Pharmacists	6
	April 2013	Hospital Pharmacists	19
	May 2013	Hospital Pharmacists	3
	May 2013	Hospital Pharmacists	7
	May 2013	Hospital Pharmacists	10
	June 2013	Hospital Pharmacists	11
Powys Teaching	April 2013	GPs	10

Testimonials



Pleased to have been involved with a scheme which have some impressive outcomes. Excellent to refresh current knowledge of ADRs and thoroughly enjoyed the 50th anniversary of AWTTC event in Cardiff. Initial reservation from colleagues to engage with the scheme although numbers of Yellow Cards and also numbers of reporters now increasing.



I have really enjoyed the role of Yellow Card Champion. It has been good to have an additional responsibility to my clinical work as a pharmacist in the rotation and I also feel the role has played an important role in my professional development. My personal knowledge and awareness of reporting has increased since taking on the role.

The role has given me the opportunity to network with other pharmacists within the trust and within other health boards (plus with other healthcare professionals). It has also been very rewarding to discover that the Hospital Champion Scheme has had such a positive impact on Yellow Card Reporting. The main challenge is juggling the role of champion with ward & dispensary commitments however I have managed to fit it in so far. Another challenge is encouraging staff to attend sessions that I run as they are usually during lunchtime (particularly the pharmacy technicians)".



Being a hospital champion has been a very rewarding experience. Positives: Able to help other Pharmacist to complete a yellow card. Challenges: Difficult questions on when to report and when not to report, when no clarity is achievable.

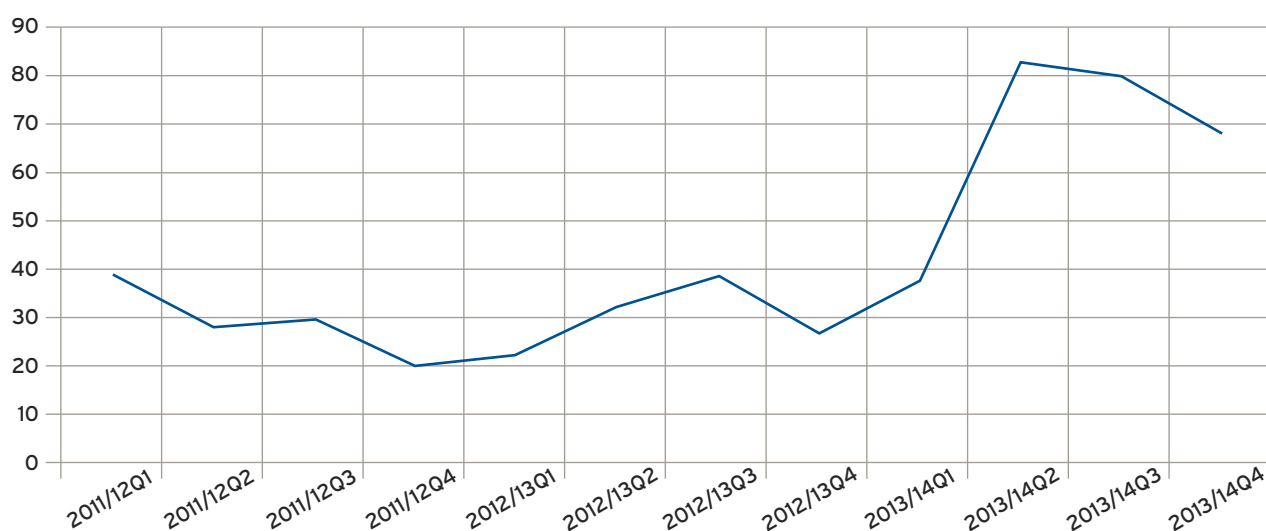


WeMeReC Pharmacovigilance Module

In May 2013, in collaboration with WeMeReC, a pharmacovigilance module was launched. In all, 411 General Practitioners completed the module. The module included questions on attitudes to completing yellow card reports and a separate analysis is currently being undertaken.

Chart 8 shows the association between the circulation of the module and subsequent GP reporting after the module was launched in quarter 2 2013/14.

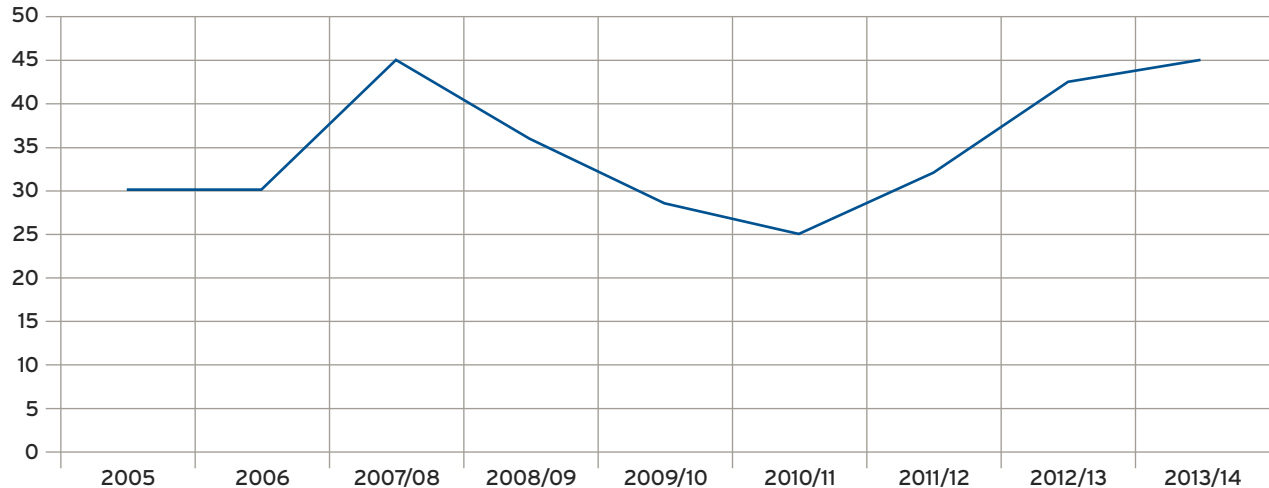
Chart 8: Total GP reports



Community Pharmacist Project

In May 2013, Dr Louise Hughes, School of Pharmacy, Cardiff University, collaborated with YCC Wales to produce a questionnaire on the attitudes of community pharmacists to Yellow Card reporting. This questionnaire was sent to each community pharmacy in Wales and, as a follow up, YCC Wales sent a Yellow Card promotional pack two months later.

The following chart, Chart 9, shows that this mailing was not associated with a significant difference in Yellow Card reporting rates amongst community pharmacists in Wales when compared to the previous year. Further work is planned once analysis of the collected data is completed to identify future strategies to encourage Yellow Card reporting amongst community pharmacists.

Chart 9: Total Community Pharmacist Reports

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.

Chart 10 shows the baseline GP reporting figures from 2013-14 for each health board. None of the Health Boards currently achieves target A.

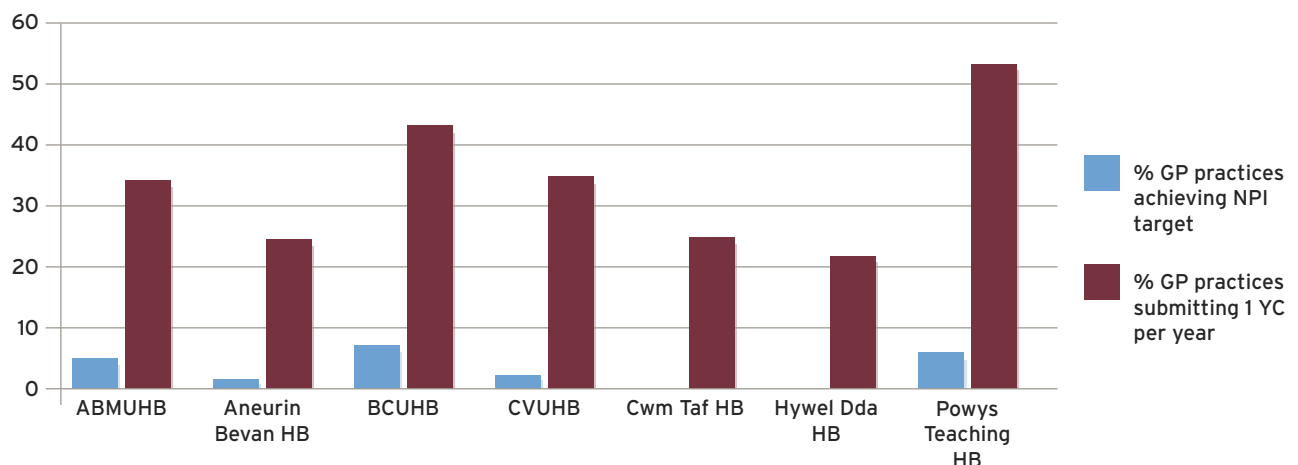
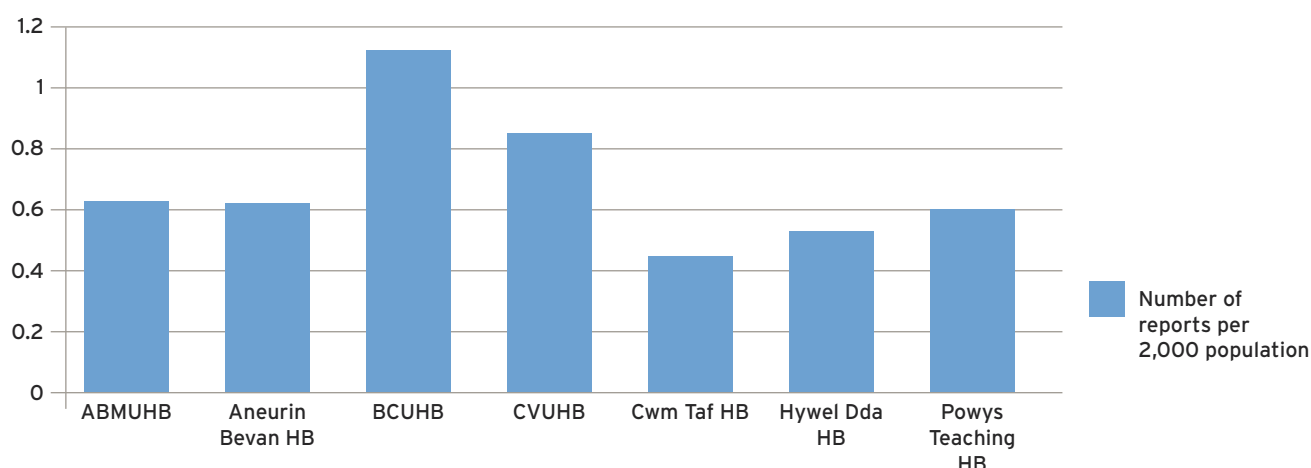
Chart 10: GP Yellow Card reports by Health Board 2013-14

Chart 11 shows the overall Health Board reports for 2013-14. Target B is 1 report per 2,000 population. Only BCUHB achieved this target in 2013-14.

Chart 11: Health Board Reports per 2,000 population



Website

In 2013-14, YCC Wales launched its updated website. The website has been designed to share features with the other AWTTC websites and includes information on how to report as

well as useful links, resources and information on the education and training YCC Wales can undertake. **www.yellowcardwales.org**

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 undergraduates. Regular talks on drug safety have been given to dentists and nurses involved with medicines management. Presentations have been given to non medical prescribers, diploma pharmacists, pre-registration pharmacy graduates, primary and secondary care pharmacy technicians, health visitors and practice nurses.

Members of YCC Wales have presented at local Quality & Safety sessions, Royal Pharmaceutical Society conferences and patient groups.

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. 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 these activities are listed below:

Dr AM Thomas

- April 2013 Diploma in Pharmaceutical Medicine, Cardiff University
- March 2014 Medical Pharmacology BSc, Cardiff University
- March 2014 BDS Human Disease course, Cardiff University

Professor PA Routledge

- April 2013 Adverse Drug Reactions, Diploma in Pharmaceutical Medicine, Cardiff University
- May 2013 Interprofessional Education - a Cardiff perspective at the 1st Interprofessional Medicine/Pharmacy Conference "Learning and working together to improve safety through better prescribing", Cardiff
- May 2013 Herbal Toxicity: Is There a Problem? To the MSc in Translational Medicine, University of Oxford, Oxford,
- May 2013 Evidence-based Medicine to the Diploma in Pharmaceutical Medicine, Cardiff University,
- July 2013 Prescribing safely, MB BCh (year 5)
- July 2013 Adverse Drug Reactions to MB BCh (year 3) Cardiff University
- July 2013 Documentation and Drug Errors at the European Association of Clinical Pharmacology and Therapeutics (EACPT) Summer School, Edinburgh,
- August 2013 Developing a standardised prescription chart to reduce error at the European Association of Clinical Pharmacology Congress 2013, Geneva, Switzerland,
- August 2013 Safe and Effective prescribing to F1 Induction programme, CVUHB
- August 2013 Safe and Effective prescribing to F2 Induction programme, CVUHB
- September 2013 Advancing Inter Professional Education in the UK at the Annual Conference of the Royal Pharmaceutical Society, ICC Birmingham,
- 1st October 2013 National Prescription Charts and Prescribing Standards at the RCPE Symposium - Safe prescribing and administration of medicines in Scottish hospitals, Edinburgh
- October 2013 Prescribing in Liver and renal disease to BDS, Cardiff University
- October 2013 Pharmacogenomics to Diploma in Non-Medical Prescribing, Cardiff University
- October 2013 Adverse Drug Reactions and Interactions, Diploma in Non-Medical Prescribing, Cardiff University
- November 2013 Herbal medicines, past, present and future to the Teifi Valley and North Pembrokeshire Medical Society, Hammet House, Llechryd, Cardigan, Pembrokeshire,
- November 2013 Clinical Trials and medicines safety, BSc Medical Pharmacology, Cardiff University

- November 2013, Pharmacogenomics, BSc Medical Pharmacology, Cardiff University
- December 2013 Towards safer, more effective medicines and prescribing. Masterclass at Covance Clinical Research Unit Limited, Leeds
- December 2013 Post-marketing Surveillance, BSc Medical Pharmacology, Cardiff University
- January 2014 Adrenal Steroids (safety), BDS, Cardiff University
- February 2014 Pharmacogenomics, MB BCh, Cardiff University
- March 2014. Adverse Drug Reactions and Interactions, MB BCh (year 2), Cardiff University

Dr R Bracchi

- Sept 2013 Diploma in Therapeutics, Cardiff University

Mrs A Adams

- May 2013 Parkinsons Disease Specialist Nurses, Bridgend
- June 2013 NHS Direct Nurses, Exeter
- Feb 2014 Clinical Diploma Hospital Pharmacists, Cardiff University

Mrs E Carey

- April 2013 MSc in Ageing (year 2), Cardiff University
- April 2013 Gofal Service Users Conference-promotional stand
- April 2013 Welsh Immunisation Conference-promotional stand
- May 2013 Cwm Taf Breatheasy patient group
- May 2013 Dermatology Quality & Safety Session, CVUHB
- May 2013 Renal Quality & Safety session, CVUHB
- May 2013 All Wales Hospital Pharmacy Pre-registration Pharmacists, Newport
- June 2013 Age Concern patient group, St Mellons Cardiff
- Sept 2013 5th year medical students, Cardiff University
- Oct 2013 Promotional stand at UHW concourse- 2 days
- Nov 2013 Royal Pharmaceutical Society (Wales) annual conference- promotional stand
- Nov 2013 1,000 lives conference
- Feb 2014 AWTTC Research meeting

Mr J Hayes

- April 25, Royal Collge of GPs Study Day
- May 1st, Dental Prescribing update
- May 9th, Dental Prescribing Update
- July 9th, Medication Review, School of Medicine, Cardiff University
- July 17th, Royal College of GPs Study Day
- August 19th, Patient and Public Engagement Group
- September 10th, Information Mastery, MSc in Palliative Medicine
- September 19th, Information Mastery and

Evidence Based Prescribing, Non-medical prescribers, North Wales

- October 23rd, Influences on Prescribing, Antibiotic Stewardship Forum, Cardiff
- October 25th, Dental Update, Porth
- November 14th, Drug Regulation, Cardiff University
- November 13, 18 & 21, Interprofessional Learning, School of Medicine and School of Pharmacy and Pharmaceutical Sciences, Cardiff
- January 14th, Dental Update, Swansea
- February 19th, UWIC, MSc in Psychology
- March 8th, Evidence Based Prescribing, Diploma Pharmacists, Birmingham
- March 11th, Evidence Based Prescribing, Non-medical prescribers, School of Pharmacy and Pharmaceutical Sciences, Cardiff

Publications

- Gray L, Tuthill D, Thompson JP. Management of Drug Allergy. Paediatrics and Child Health, 24:4, p 177-179
- Hughes D and Routledge PA. A Prescribing Partnership. Public Service Review: Health and Social Care 2013; 35: 65-67
- Routledge PA and Hutchings AD. Therapeutic Drug Monitoring in "The Immunoassay Handbook, Fourth Edition: Theory and applications of ligand binding, ELISA and related techniques". D Wild (ed) Elsevier Science 2013 (pages 945-962)

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Claire Ganderton, Cwm Taf
Susan Huey, CVUHB
Helen Morteo, Cwm Taf
Jayne Price, Powys Teaching
Julie Postle, CVUHB
Helen Richards, ABMU
Nia Sainsbury, ABMU
Joanna Webb, Aneurin Bevan

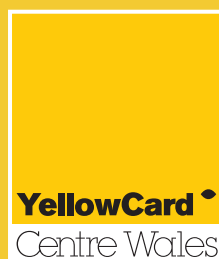
WeMeReC

Andrea Clarke
Jamie Hayes
Simon Wilkins

WAPSU

Kath Haines
Kate Jenkins
Chrissie Collier
Anne Coles

Cardiff University, School of Pharmacy
Dr Louise Hughes



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