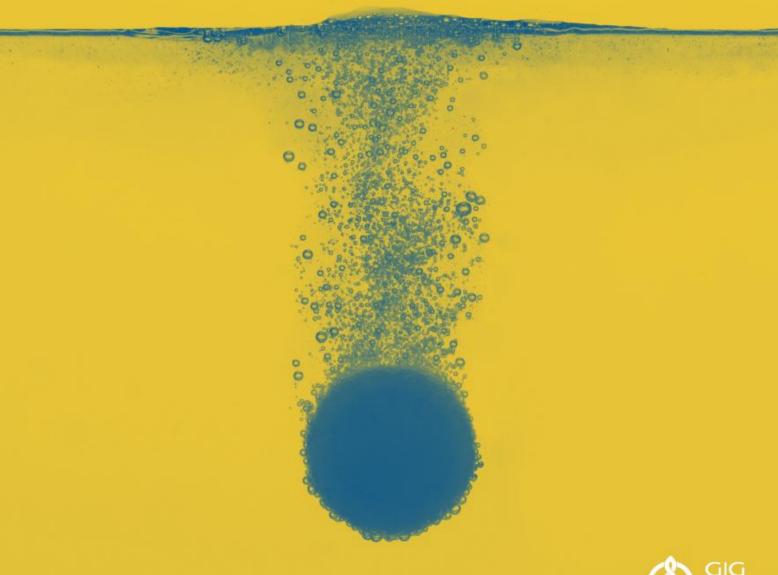


Annual Report 2015-2016









YELLOW CARD CENTRE WALES ANNUAL REPORT TO MHRA

Date: 2015-16

1. STAFF

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2. EXECUTIVE SUMMARY

Yellow Card Centre Wales (YCC Wales) has continued to promote adverse drug reaction reporting via the Yellow Card Scheme to healthcare professionals and patients throughout 2015/16.

During the financial year 2015/16, 1,817 Yellow Card reports were received from reporters based in Wales by the MHRA. This is a 24.5% increase on 2014/15 and continues an upwards trend from the past 3 years. This increase has been largely due to a 24% increase in reports from GP's and is likely to be, at least in part associated with the adoption by the All Wales Medicines Strategy Group of a National Prescribing Indicator for Yellow Cards now in its third year.

YCC Wales has continued to support local Yellow Card (YC) Champions and extended the scheme to include YC community pharmacy champions. YCC Wales hosted a successful training day in March 2016 to train new champions and act as a refresher course for those already in post.

Work has been ongoing to develop a new website and social media presence. The new website is due to be launched in Autumn 2016 together with a YCC Wales Twitter account.



3. YELLOW CARD DATA

a. Total numbers

A total of 1817 reports of suspected adverse drug reactions originated from the YCC Wales region in 2015/16. This represents an increase of 24.5% when compared to 2014/15 (1460). Figure 1 shows the total number of yellow card (YC) reports over time.

Year	Number of reports	Percentage change on previous year
2015/16	1817	+24.5
2014/15	1460	+24
2013/14	1177	+81
2012/13	649	-9
2011/12	711	

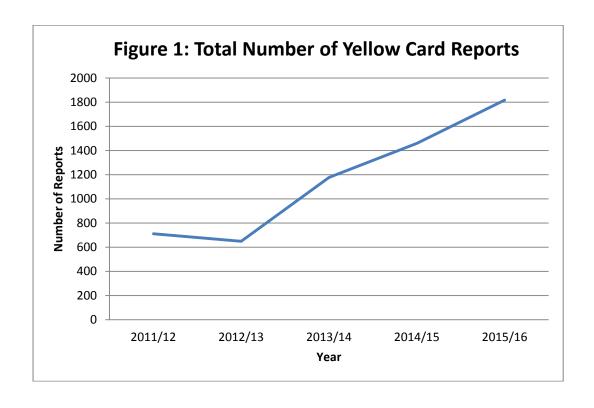






Figure 2 shows the seven Health Boards in Wales. Chart 2 shows the number of reports from each region from the past five years.



Fig. 2: Health Boards in Wales

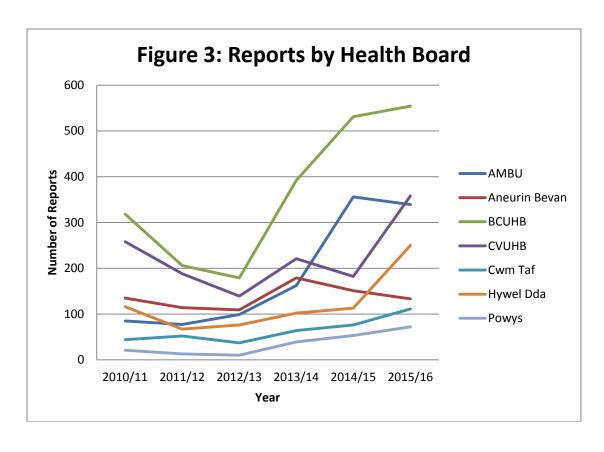
ABMU = Abertawe Bro Morgannwg

University Health Board: BCUHB = Betsi

Cadwaladr University Health Board:

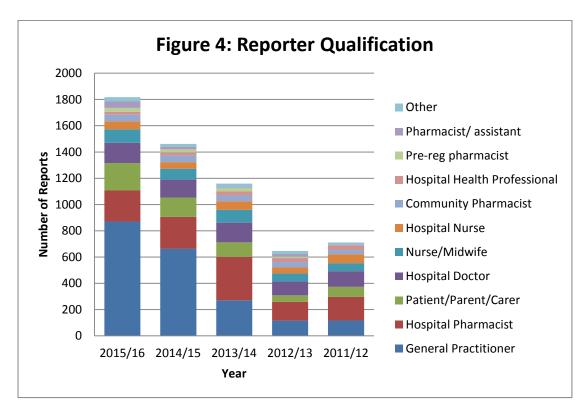
CVUHB= Cardiff and Vale University

Health Board:





b. Reporter qualifications



Other reporter qualifications: paramedic, optometrist, dentist, coroner, radiographer, chiropodist, medical student

Reporter	2015/16	2014/15	2013/14	2012/13	2011/12
General Practitioner	870	665	271	116	117
Hospital Pharmacist	237	241	330	144	179
Patient/Parent/Carer	208	147	111	49	77
Hospital Doctor	155	137	150	104	119
Nurse/Midwife	103	83	98	61	62
Hospital Nurse	61	50	65	46	68
Community Pharmacist	49	49	44	42	32
Hospital Health Professional	22	25	31	30	36
Pre-reg pharmacist	31	23	26	12	0
Pharmacist	39	15	6	19	2
Pharmacy assistant	10	6	0	0	0
Other Health Professional	20	5	7	15	10
Radiographer	4	5	8	0	0
Dentist	3	4	8	5	5
Medical student	0	3	4	2	0
Physician	2	2	0	1	4
Chiropodist	0	1	0	0	0
Coroner	0	1	0	0	0
Optometrist	1	0	0	0	0
Paramedic	2	0	0	0	0



c. Serious reports - table of serious reactions over last five years

Year	Number of serious reports	Percentage of total reports	Percentage change on previous year
2015/16	908	50	-4
2014/15	789	54	+28
2013/14	308	26	-39
2012/13	422	65	-1
2011/12	468	66	

d. Fatal reports - table summarising fatal reports over last five years

Year	Number of fatal reports	Percentage of total reports	Percentage change on previous year
2015/16	22	1.2	-0.4
2014/15	23	1.6	+0.2
2013/14	17	1.4	0
2012/13	9	1.4	-0.3
2011/12	12	1.7	

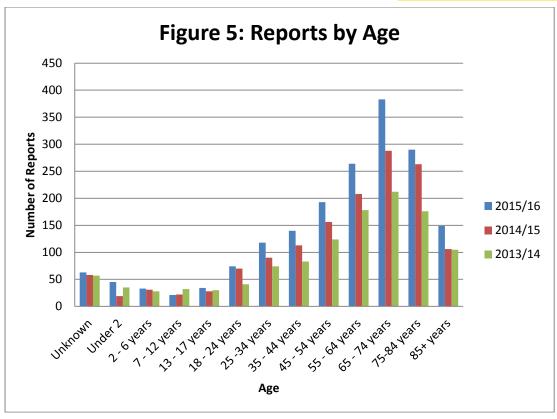
It is extremely important to note that suspected ADRs are associations only and there is not necessarily a causal link between any of the medicines reported on a particular yellow card and the fatal outcome.

e. Age breakdown - table and clustered bar graph

Age band	2015/16	2014/15	2013/14
Unknown	63	58	57
Under 2	45	19	35
2 - 6 years	33	31	28
7 - 12 years	21	22	32
13 - 17 years	34	28	30
18 - 24 years	74	70	41
25 -34 years	118	90	74
35 - 44 years	140	113	83
45 - 54 years	193	156	124
55 - 64 years	264	208	178
65 - 74 years	383	288	212
75-84 years	290	263	176
85+ years	149	106	105
Total	1817	1460	1177







f. Top 10 suspected medicines - comparison of last two years

Drug name	Number of reports (2015/16)	Number of reports (2014/15)
Rivaroxaban ▼	107	53
Dapagliflozin ▼	49	26
Influenza vaccine* ▼	44	33
Apixaban▼	42	21
Gabapentin	32	14
Sertraline	30	27
Ramipril	29	47
Amlodipine	27	25
Citalopram	26	16
Trimethoprim	25	22

^{*}multiple brands

[▼] medicine subject to additional monitoring



g. Sources of reports - detailed breakdown

5 .	201	5/16	201	4/15	2013/14	
Reporter	Number	% of total	Number	% of total	Number	% of total
Carer	6	0.3	5	0.3	4	0.3
Parent	29	1.6	16	1.1	21	1.8
Patient	173	9.5	126	8.6	86	7.3
Community Pharmacist	49	2.7	49	3.4	44	3.7
Hospital Pharmacist	237	13	241	16.5	330	28
Pharmacist	39	2.1	15	1	6	0.5
Pharmacy Assistant	10	0.6	6	0.4	0	0
Pre-reg pharmacist	31	1.7	23	1.6	26	2.2
Hospital Nurse	61	3.4	50	3.4	65	5.5
Nurse	102	5.6	83	5.7	98	8.3
GP	870	48	665	45.5	271	23
Hospital Doctor	155	8.5	137	9.4	150	12.7
Physician	2	0.1	2	0.1	0	0
Coroner	0	0	1	0.06	0	0
Dentist	3	0.2	4	0.3	8	0.7
Midwife	1	0.06	0	0	0	0
Optometrist	1	0.06	0	0	0	0
Radiographer	4	0.2	5	0.3	8	0.7
Hospital Healthcare Professional	22	1.2	25	1.7	31	2.6
Healthcare Assistant	0	0	0	0	0	0
Other Healthcare Professional	20	1.1	5	0.3	7	0.6
Medical Student	0	0	3	0.2	4	0.3
Unknown	0	0	0	0	0	0
Total	1817	100	1460	100	1177	100





h. Type of Reports

Report Type	Number of reports (2015/16)	Percentage of total reports
EYC	1227	67.5
Paper	536	29
APP	14	0.5
MiDatabank	40	2

4. DISCUSSION OF YELLOW CARD DATA

There has been a further increase in the number of reports from Wales in 2015-16, increasing by 24.5% (1817) when compared to the previous year (1460). The highest number of reports was from General Practitioners, whose reports contributed 48% of the total received this year (870). This is an increase of 31% on the previous year and builds on the progress made when reporting rates increased in line with the launch of Yellow Card reporting rates as a National Prescribing Indicator in the community in 2014-15.

Encouragingly, there was also a further increase in the number of reports from patients and work is planned to improve this in 2016-17. 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 in the next year.

There has been growth in the number of reports from practice based pharmacists this year, probably reflecting the new cluster pharmacist posts (covering several practices in an area). YCC Wales ran a training session at the WCPPE cluster pharmacist training course in 2015/16 to support Yellow Card submission as part of this new role.

Five of the seven Health Boards in Wales had an increase in reporting rates in 2015-16. YCC Wales will be focused particularly on improving reporting rates in Aneurin Bevan HB during the next year.

The percentage of serious suspected YC reports decreased by 4% in 2015/16 when compared to last year. The percentage of serious reports from GPs was 32%.

The most frequently reported treatment was rivaroxaban with 107 reports. The top three reported medicines in Wales in 2015/16 are all on the list of medicines subjected to additional monitoring. The highest number of reports was in the 65-74 age band but there has been an increase in reports across all age groups.



5. PROMOTIONAL ACTIVITIES

a. Training delivered to healthcare professionals and their respective groups

Audience type	Session type	Duration (hours)	Number of sessions	Total audience numbers	Total hours training
Hospital Pharmacists	Lecture	1	1 EC	24	1
Cluster Pharmacists	Lecture	2	1 EC	30	2
Pharmacists	Conference	1	1 EC	50	1
GPs, practice nurses	Lecture	1	1 EC	12	1
Medicines Safety Officers	Lecture	1	1 EC	15	1
Hospital Champions	Teleconference	2	1 EC	14	2
Practice nurses	Lecture	1	1 EC	60	1
YCC Wales Champions	Lecture	6	1 EC/JH	30	6
Velindre Hospital Staff	Concourse stand	5	1 EC	60	5
Community Pharmacists	Lecture	3	3 RB	300	9
Diploma pharmacists	Lecture	2	1 AA	30	2
GPs	Seminar	1.5	4 JH	20	6
Dentists	Workshop	2.5	4 JH	60	10
Non-medical prescribers	Workshop	2.5	5 JH	90	12.5
Non-medical prescribers	Workshop	3	6 JD/PAR	240	18
Medics	Workshop	2	2 AT	600	4
Medics	Lecture	2	3AT	60	6
Toxicologists	Lecture	1	3 PAR	200	3
Hospital Doctors	Lecture	2	2 PAR	50	4

b. Training delivered to patients and their respective groups

Audience type	Session type	Duration (hours)	Number of sessions	Total audience numbers	Total hours training
Velindre Hospital Visitors	Concourse stand	5	1	40	5
Patient And Public Involvement Group	Lecture	1	6 RB/AT/EC	60	6
Public Understanding of Science	Lecture	0.5	1 PAR	100	0.5

c. Training delivered to undergraduates

Audience type	Session type	Duration (hours)	Number of sessions	Total audience numbers	Total hours training
Medical Students	Lecture	1	4 RB/PAR	300	4
IPL (pharmacy and medical students)	Workshop	2	8 JH/PAR	150	16
Dental Students	Lecture	1	2 AT/PAR	60	2
Medical students	Lecture	1	AT	100	1
BSc Pharmacology	Lecture	1	7 PAR	150	7



d. Materials developed for YCS promotion

Further to the Yellow Card Champions Training Day in February 2016, all training materials have been updated and redistributed.

YCC Wales continues to use promotional materials including pens, post-it notes and lanyards at conference events and training sessions.

6. PUBLICATIONS

Khangura K.; Adams A.; Anton C.; Bracchi R.; Carey E.; Thomas A.; Ferner R. Enforcing the habit-the role of champions in pharmacovigilance education. Drug Safety. Conference: 15th ISoP Annual Meeting "Cubism in Pharmacovigilance" Prague Czech Republic. Conference Start: 20151027 Conference End: 20151030. Conference Publication: (var.pagings). 38 (10) (pp 947), 2015. Date of Publication: October 2015.

Thomas A.; Routledge P.; Bracchi R.; Carey E.; Adams A. Yellow card champions to help increase reporting of adverse drug reactions. Clinical Pharmacist. 8 (2) (no pagination), 2016. Date of Publication: February 2016.

Routledge PA, Allgeier R, Ives R, James K, Oretti R, Smith J, Hill R and Coulson JM. (November 2015). Tramadol Report. http://gov.wales/topics/people-and-communities/communities/safety/substancemisuse/governance/advice/current-work/?lang=en

Named lecture:

Routledge PA: Fourth Annual Shirley Norton Lecture "Pharmacovigilance with an accent on the E" MHRA, London, October 20th 2015.

7. YCC WEBSITE

a. Website updates

The YCC Wales website will be included in the new All Wales Therapeutics and Toxicology Centre (AWTTC) website due to be launched in Autumn 2016.

AWTTC is an organisation that includes the Welsh National Poisons Unit (WNPU), the Welsh Medicines Resource Centre (WeMeReC), the Welsh Analytical Prescribing Support Unit (WAPSU), the Patient Access to Medicines Service (PAMS) and YCC Wales.

This redesign included a review of all the content on the YCC Wales website and the design of a new logo.



b. Number of website hits (optional)

This function has not been available up to the present time but will be possible with the launch of the new website.

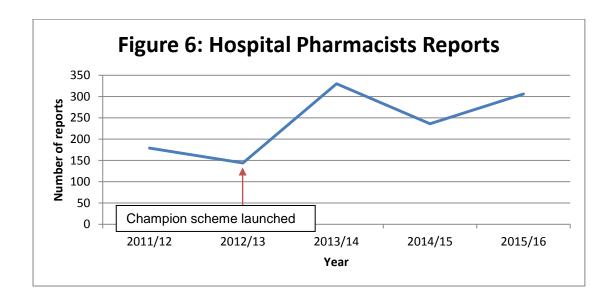


8. RESEARCH AND ONGOING INITIATIVES

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



The number of YC reports submitted by hospital pharmacists remained stable in 2015/16. The aim of the next financial year is to increase the number of reports by hospital pharmacists.



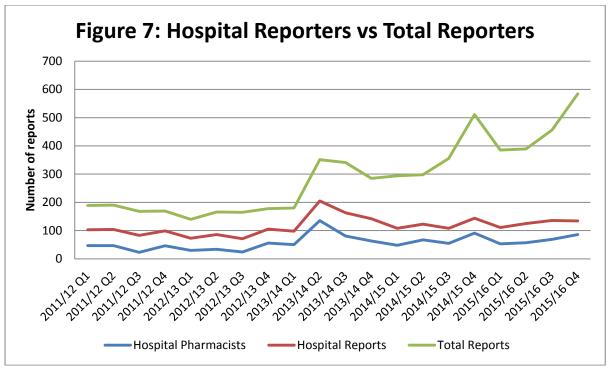


Fig. 7 shows that the number of reports from secondary care has not increased to the same extent as for primary care over the past two years. The YC champions have extended their role in the past two years to train healthcare professionals from primary and secondary care and, due to the other initiatives YCC Wales are running, it is difficult to ascertain the direct impact on reporting that the champions have.

Of note, Aneurin Bevan HB did not have a YC champion in post during 2015/16 and this health board reported a reduced number of Yellow Card reports in that period. A new champion has now been recruited and this Health Board will be an area that YCC Wales will target in 2016/17.

YCC Wales hosted a second Yellow Card Champions Training Day on 2nd February 2016 and invited all the hospital pharmacist champions along with three community pharmacy champions from Lloyds Pharmacy. The programme for the day included sessions on factors affecting community pharmacists reporting ADRs, presentation skills and a session on what happens to a Yellow Card amongst others. YCC Wales received excellent feedback on the content and presentation standard of the day and will run a training day annually from now on.

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 2015-16 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.



The NPI has coincided with an increase in the number of reports submitted by General Practitioners. In the past year, the number of reports submitted by other practice-based staff such as pharmacists and nurses has also increased. From 2016-17, the target has been changed to reflect this and Target A now states that GP practices to submit one yellow card per 2,000 practice population.

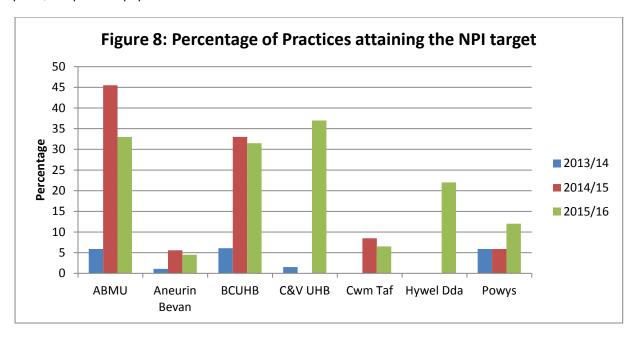


Fig.8 shows that the percentage of GP practices attaining Target A has increased each year since the NPI was launched. This is the first year that all Health Boards in Wales have practices that have achieved the target. The aim for the 2016/17 will be to increase rates further.

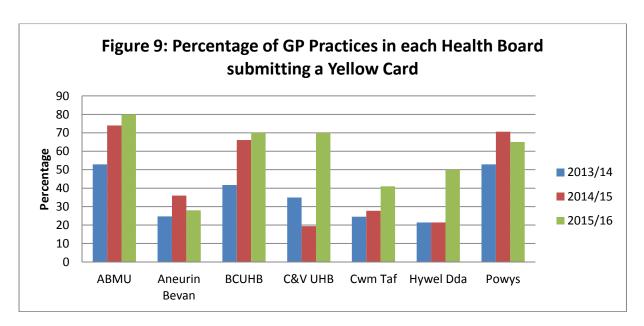


Fig. 9 shows the percentage of GP practices who have submitted at least one Yellow Card. This data can be used to target practices who have not submitted a Yellow Card and offer additional training and support. YCC Wales works with local Yellow Card Champions to offer this support throughout Wales.



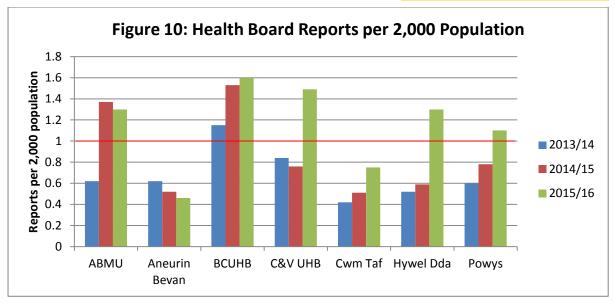


Fig. 10 shows the performance against Target B: Target for each health board- submit yellow cards in excess of one per 2,000 health board population. All Health Boards except two reached this target in 2015-16, in improvement on last year. There continues to be variation in the reporting rates between the Health Boards. YCC Wales will continue to target Aneurin Bevan and Cwm Taf in 2016-17 to help improve their reporting rates further.

9. CONCLUSION

It has been another successful year for YCC Wales. The Yellow Card Champion scheme and National Prescribing are starting to show a sustained increase in the number of reports submitted from Wales.

Our strategy for 2016-17 is to further support the two Health Boards that are not currently achieving the Health Board NPI target, Aneurin Bevan and Cwm Taf, and to support the Yellow Card Champions to increase their promotional work in secondary care.

We look forward to the launch of the new YCC Wales website in Autumn 2016 and to increasing our presence on social media.

10. ACKNOWLEDGEMENTS

YCC Wales would like to acknowledge the contribution made by the following individuals during 2015/16 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 Nia Sainsbury, ABMU

Welsh Analytical Prescribing Support Unit (WAPSU)

Kath Haines Kate Jenkins Chrissie Collier Anne Coles Karen Jones

Cardiff University
Dr Louise Hughes







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