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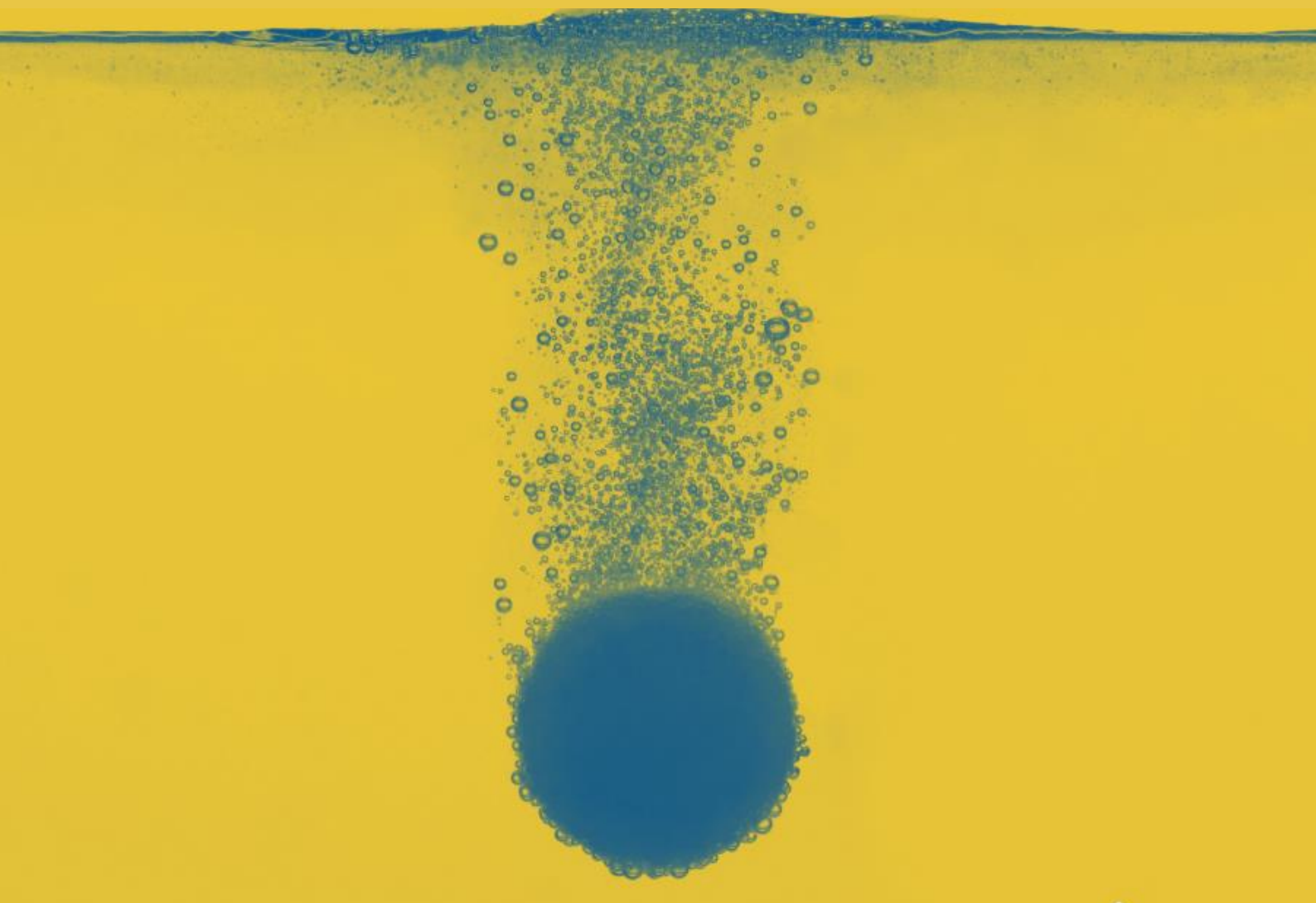
 **YellowCard**
Making medicines safer



YCC Wales

Yellow Card Centre Wales
Canolfan Cerdyn Melyn Cymru

Annual Report 2016-2017





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YELLOW CARD CENTRE WALES ANNUAL REPORT TO MHRA

Date: 2016-17

1. TEAM

Dr A M Thomas	Medical Director
Prof P A Routledge	Associate Medical Director
Dr J P Thompson	Senior Lecturer in Clinical Pharmacology
Dr C V Krishna	Consultant Clinical Pharmacologist/Toxicologist
Dr J M Coulson	Senior Lecturer in Clinical Pharmacology
Dr R Bracchi	Primary Care Advisor, AWTTTC
Dr L Gray	Specialist Registrar in Clinical Pharmacology
Mrs F J Woods	Director, Welsh Medicines Information Centre
Mrs A Adams	Principal Pharmacist, Welsh Medicines Information Centre
Mrs E Carey	Specialist Information Pharmacist
Mr J Hayes	Director, Welsh Medicines Resource Centre

2. EXECUTIVE SUMMARY

Yellow Card Centre Wales (YCC Wales) had a productive year. The centre continued to promote the reporting of suspected adverse drug reactions (ADRs) via the Yellow Card Scheme to healthcare professionals and patients throughout 2016-17.

The number of reports from Wales rose from 1817 in 2015-16 to 2330 in 2016-17, an increase of 28%. This continued the upward trend in reporting rates that had been seen over the last 4 years. GP reporters remained the highest reporting group and an increase of 12% was seen in the number of reports submitted by GPs compared with the previous year. An increase was also seen in the number of reports submitted by pharmacists, community pharmacists and members of the public (456%, 133% and 44% respectively).

Improving reporting rates within Aneurin Bevan was a particular focus for YCC Wales during 2016-17. The provision of four large-scale training events and recruitment of five new Yellow Card Champions across the health board resulted in an impressive increase of 241%.

The decision by the All Wales Medicines Strategy Group (AWMSG) to maintain Yellow Card reporting as a National Prescribing (reporting) Indicator in Wales for a third year may have been a factor in the increase of reports submitted.

YCC Wales continued to support local Yellow Card Champions in the health boards across Wales and the scheme was expanded to include general practice pharmacists. The third successful YCC Wales Yellow Card Champion training day was held in March 2017.

The YCC Wales website underwent a complete redesign. The new website was incorporated into the new All Wales Therapeutics and Toxicology Centre (AWTTTC) website and was launched in October 2016.



3. YELLOW CARD DATA

a. Total numbers

A total of 2330 reports of suspected adverse drug reactions originated from the YCC Wales region in 2016/17. This represents an increase of 28% when compared to 2015/16 (1817). Figure 1 shows the upward trend in total number of Yellow Card (YC) reports from Wales over the last 5 years.

Year	Number of reports	Percentage change on previous year
2016/17	2330	+28
2015/16	1817	+25
2014/15	1460	+24
2013/14	1177	+81
2012/13	649	

Figure 1: Number of Yellow Card Reports

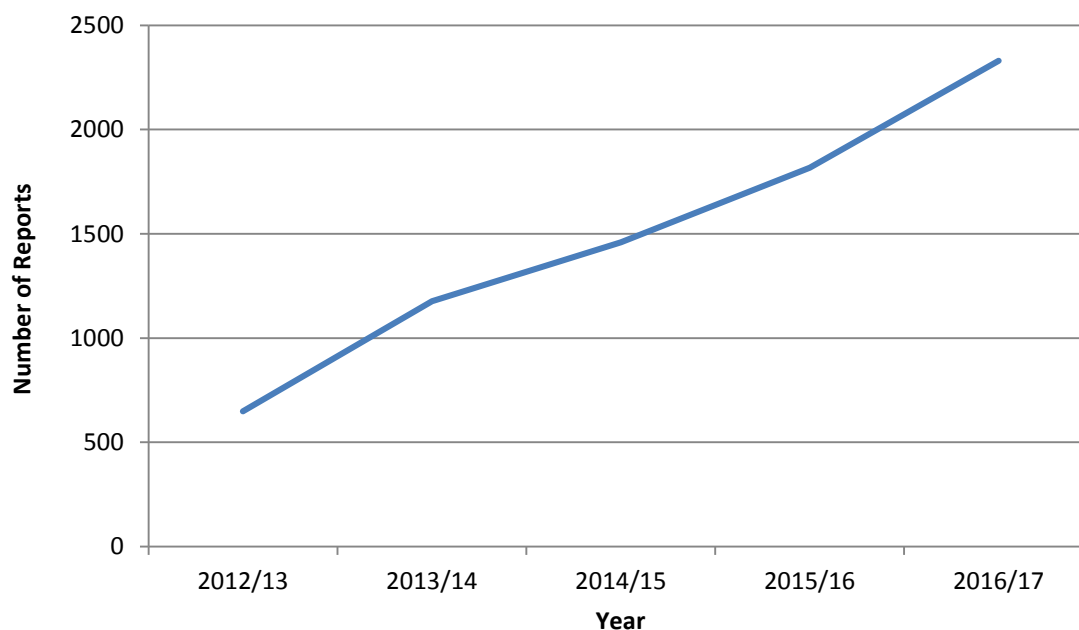




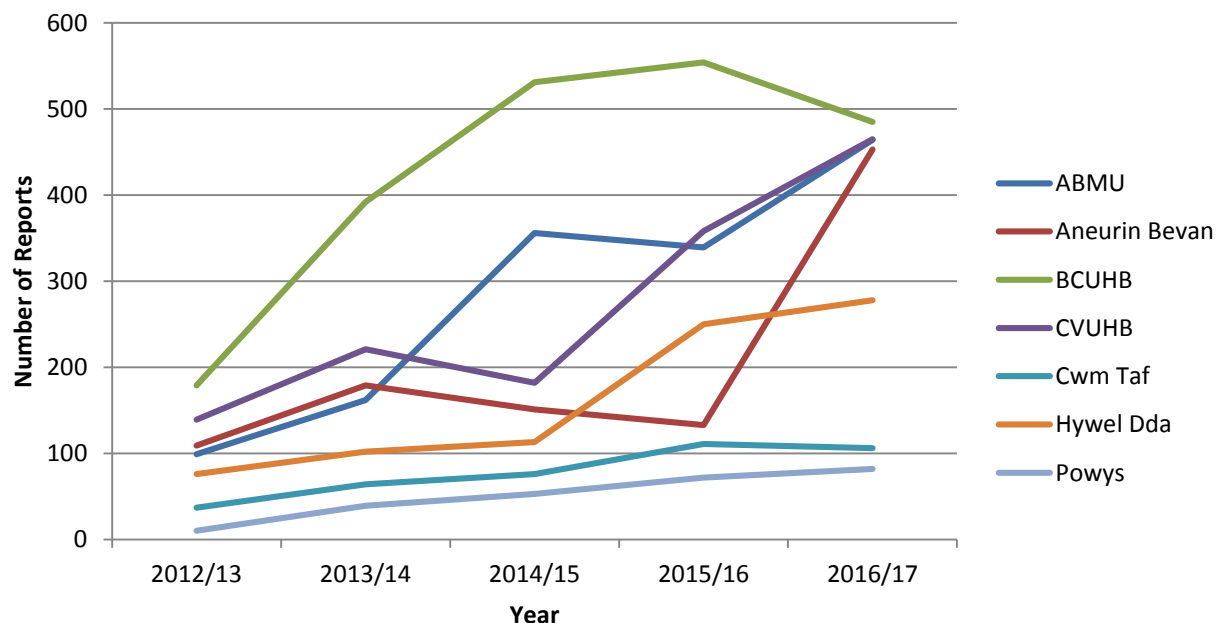
Figure 2 shows the seven health boards in Wales.

Figure 3 shows the number of reports from each health board over the past five years.

Figure 2: Health Boards in Wales



Figure 3: Reports by Health Board

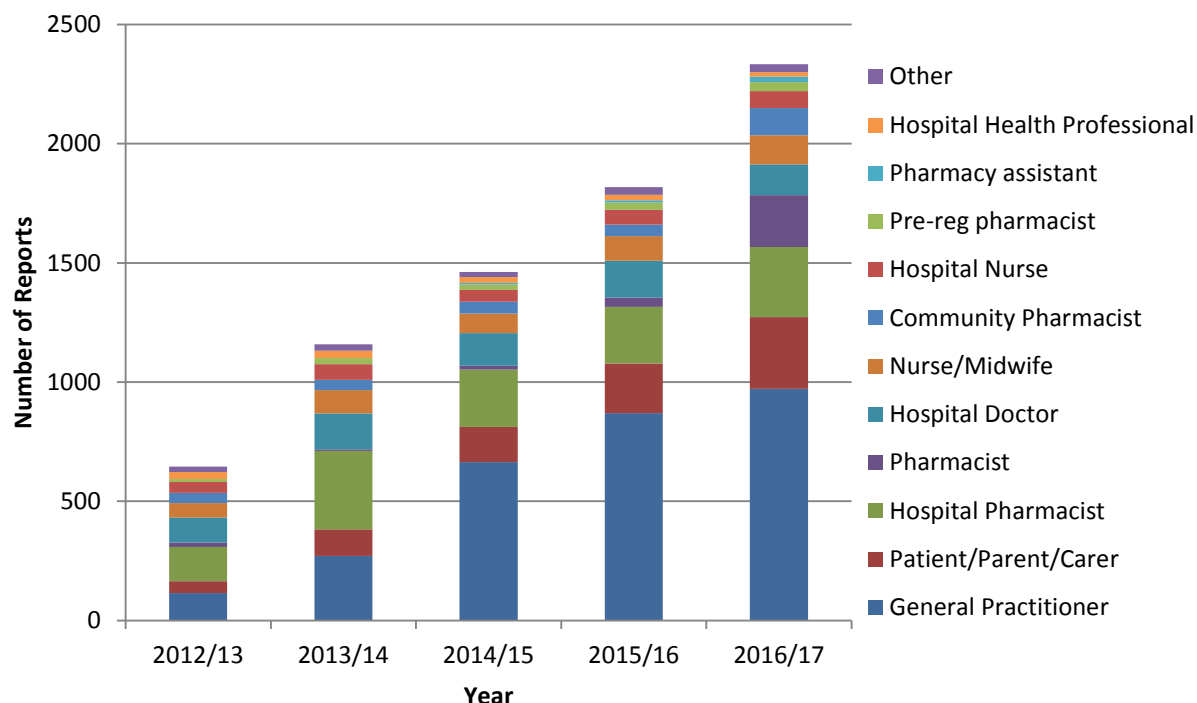


ABMU = Abertawe Bro Morgannwg University Health Board; BCUHB = Betsi Cadwaladr University Health Board; CAVUHB = Cardiff and Vale University Health Board



b. Reporter qualifications

Figure 4: Reporter Qualification



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

Reporter	2012/13	2013/14	2014/15	2015/16	2016/17
General Practitioner	116	271	665	870	972
Patient/Parent/Carer	49	111	147	208	300
Hospital Pharmacist	144	330	241	237	295
Pharmacist	19	6	15	39	217
Hospital Doctor	104	150	137	155	129
Nurse/Midwife	61	98	83	103	122
Community Pharmacist	42	44	49	49	114
Hospital Nurse	46	65	50	61	71
Pre-registration pharmacist	12	26	23	31	38
Pharmacy assistant	0	0	6	10	23
Hospital Health Professional	30	31	25	22	19
Other Health Professional	15	7	5	20	22
Radiographer	0	8	5	4	5
Dentist	5	8	4	3	1
Medical student	2	4	3	0	3
Physician	1	0	2	2	1
Chiropodist	0	0	1	0	0
Coroner	0	0	1	0	0
Optometrist	0	0	0	1	1
Paramedic	0	0	0	2	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
2016/17	987	42	-8
2015/16	908	50	-4
2014/15	789	54	+28
2013/14	308	26	-39
2012/13	422	65	-1

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
2016/17	34	1.5	+0.3
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

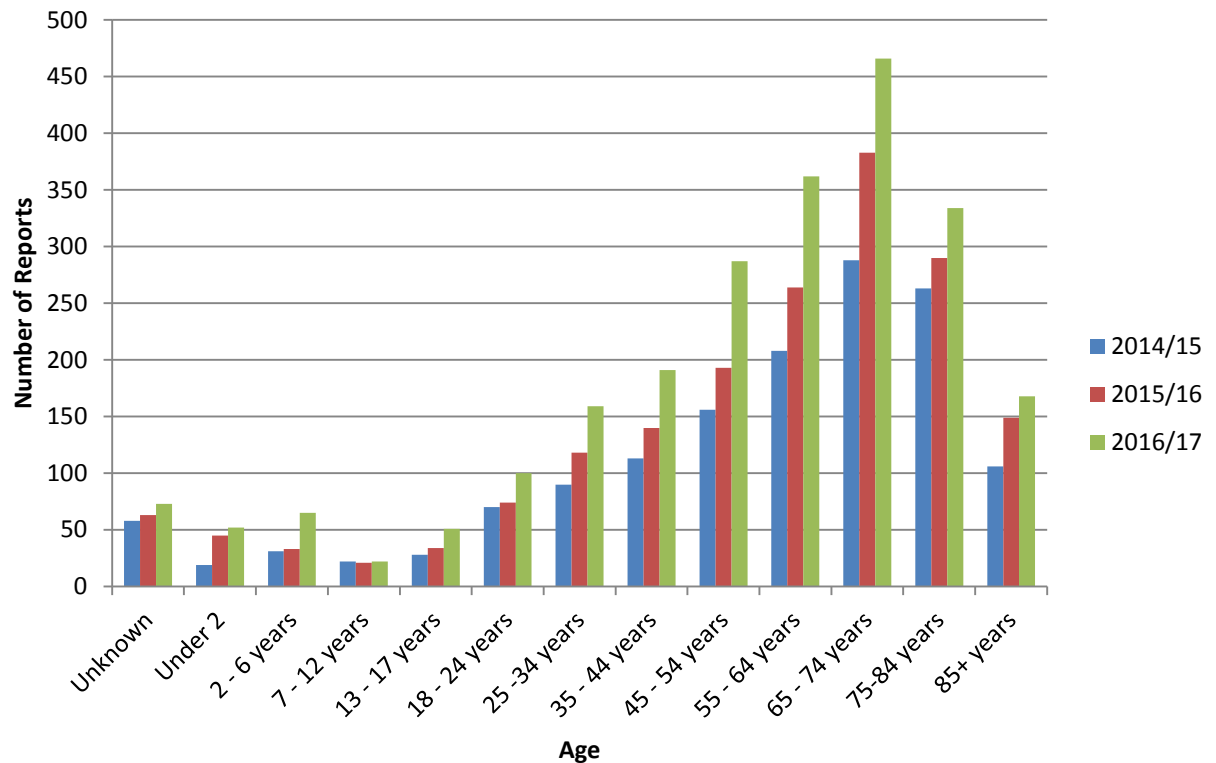
It is important to note that suspected ADRs are associations only and there is not necessarily a causal link between any of the medicines reported on a particular Yellow Card and the fatal outcome.

e. Age breakdown – associated table and clustered bar graph

Age band	2014/15	2015/16	2016/17
Unknown	58	63	73
Under 2	19	45	52
2 - 6 years	31	33	65
7 - 12 years	22	21	22
13 - 17 years	28	34	51
18 - 24 years	70	74	100
25 -34 years	90	118	159
35 - 44 years	113	140	191
45 - 54 years	156	193	287
55 - 64 years	208	264	362
65 - 74 years	288	383	466
75-84 years	263	290	334
85+ years	106	149	168
Total	1460	1817	2330



Figure 5: Reports by Age



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

Drug name	Number of reports (2015/16)	Number of reports (2016/17)
Rivaroxaban ▼	107	121
Dapagliflozin ▼	49	120
Neisseria meningitidis* ▼	18	92
Apixaban ▼	42	73
Ramipril	29	44
Canagliflozin ▼	18	43
Warfarin	23	43
Amlodipine	27	42
Omeprazole	25	38
Sertraline	30	38

*multiple brands

▼ medicine subject to additional monitoring



g. Sources of reports – detailed breakdown

Reporter	2014/15		2015/16		2016/17	
	Number	% of total	Number	% of total	Number	% of total
Carer	5	0.3	6	0.3	18	0.8
Parent	16	1.1	29	1.6	43	1.8
Patient	126	8.6	173	9.5	239	10.2
Community Pharmacist	49	3.4	49	2.7	114	4.9
Hospital Pharmacist	241	16.5	237	13	295	12.6
Pharmacist	15	1	39	2.1	217	9.3
Pharmacy Assistant	6	0.4	10	0.6	23	1.0
Pre-reg pharmacist	23	1.6	31	1.7	38	1.6
Hospital Nurse	50	3.4	61	3.4	71	3.0
Nurse	83	5.7	102	5.6	116	5.0
GP	665	45.5	870	48	972	41.7
Hospital Doctor	137	9.4	155	8.5	129	5.5
Physician	2	0.1	2	0.1	1	0.04
Coroner	1	0.06	0	0	0	0
Dentist	4	0.3	3	0.2	1	0.04
Midwife	0	0	1	0.06	6	0.3
Optometrist	0	0	1	0.06	1	0.04
Radiographer	5	0.3	4	0.2	5	0.2
Hospital Healthcare Professional	25	1.7	22	1.2	19	0.8
Healthcare Assistant	0	0	0	0	3	0.1
Other Healthcare Professional	5	0.3	20	1.1	19	0.8
Medical Student	3	0.2	0	0	3	0.1
Unknown	0	0	0	0	0	0
Total	1460	100	1817	100	2333	100



As can be seen in the table above a total of 2333 reports were analysed. This figure differs from the 2330 reports stated in section 3a above. The reasons for this are:

- Merger of duplicate reports by the Medicines & Healthcare products Regulatory Agency (MHRA) e.g. two reports were merged (one hospital pharmacist and one patient) as they related to the same suspected ADR in the same patient.
- Removal of invalid reports following further investigation by the MHRA.

h. Type of Reports

Report Type	Number of reports (2016/17)	Percentage of total reports
EYC	1650	70.7
Paper	415	17.8
GP systems	188	8.1
App	46	2.0
MiDatabank	34	1.5

4. DISCUSSION OF YELLOW CARD DATA

An increase of 28% was seen in the total number of Yellow Card reports submitted from Wales during 2016-17 (2330) when compared with the previous year (1817).

Five of the seven health boards in Wales had an increase in the number of reports submitted. The highest increase was seen within Aneurin Bevan, where the number of reports rose from 133 in 2015-16 to 453 in 2016-17 (+ 241%). Four large-scale training events were held and five new Yellow Card Champions were trained within the health board during 2016-17. This may have contributed to the rise in number of reports.

The highest number of reports came from General Practitioners (GPs), who contributed 42% (972) of the total number of reports received for the year. This was an increase of 12% on the previous year. The increase in the number of reports from GPs may be related to the continuation of Yellow Card reporting rates as a National Prescribing (reporting) Indicator in primary care and the integration of Yellow Card reporting into the clinical system support which is used in some practices.

The number of reports received from Pharmacists and Community Pharmacists rose by 456% and 133% respectively compared with the previous year. The majority of reports from Pharmacists originated from GP practice addresses and are therefore likely to have been submitted from those working as practice-based pharmacists. They were invited to the Yellow Card Champion Training Day held in March 2017. Five attended and saw pharmacovigilance as part of their role. In addition to this YCC Wales presented at the Advance Practice in GP practice study day.

An increase of 44% was seen in the number of reports submitted by patients, parents and carers compared with 2015-16 (300 in 2016-17, 208 in 2015-16). This is extremely encouraging and YCC Wales is eager to continue building awareness of the Yellow Card Scheme amongst members of the public.



The percentage of serious suspected ADR reports submitted within Wales reduced by 8%. The percentage of serious reports from GPs also reduced from 32% to 26%. The proportion of fatal reports remained comparatively static.

As in the previous year the highest number of reports concerned patients in the group aged 65-74 years. There has been an increase in the number of reports across all age groups.

The most frequently reported suspected medicine was rivaroxaban with 121 reports. Five of the top 10 suspected medicines were on the list of medicines subject to additional monitoring (identified using an inverted black triangle ▼).

The majority (70.7%) of reports were submitted as electronic Yellow Cards. Only 2% were submitted via the app. YCC Wales will continue to advertise the availability of the App more widely.

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
Poisons Unit staff	Lecture	1	1 (EC)	20	1
Allied Healthcare professionals	Conference stand	7	1 (EC)	100	7
GP & practice staff	Lecture	1	1 (EC)	10	1
AWTTC staff	Lecture	1	1 (EC)	40	1
Pharmacists	Lecture	2	3 (EC)	6	6
Pharmacists	Workshop	2	1 (EC)	20	2
Non-medical prescribers	Lecture	1	1 (EC)	40	1
Hospital Pharmacists	Lecture	1	1 (EC)	20	1
Cluster Pharmacists	Lecture	1	1 (EC)	40	1
Pharmacists	Conference stand	7	1 (EC&AA)	120	7
Pharmacists	Workshop	2	1 (EC)	30	2
GP & practice staff	Lecture	2	1 (DF)	10	2
Parkinson's clinic staff	Lecture	2	1 (DF)	15	2
Toxicologists	Lecture	1	2 (PAR)	45	2
Herbal Medicines Advisory Committee	Lecture	1	1 (PAR)	30	1
National Poisons Information Service	Lecture	1	2 (PAR)	40	2
Doctors, pharmacists and nurses	Lecture	1.5	1 (PAR)	30	1.5

During 2016-17 YCC Wales also provided information and support at meetings for the Welsh Emerging Drugs & Identification of Substances (WEDINOS) Project team.



b. Training delivered to patients and their respective groups

Audience type	Session type	Duration (hours)	Number of sessions	Total audience numbers	Total hours training
Patient and Public Interest Group	Lecture	1	1 (EC)	20	1
Citizen's Jury	Lecture	0.5	1 (PAR)	20	0.5

c. Training delivered to undergraduates

Audience type	Session type	Duration (hours)	Number of sessions	Total audience numbers	Total hours training
Dental Students	Lecture	1	2 (AT)	60	2
Medical Students	Workshop	2	4 (AT)	20	8
Medical Students	Tutorial	3	3 (AT)	25	9
Pharmacy Students	Discussion	1	1 (EC)	3	1
Medical Students	Lecture	1	1 (RB)	50	1
BSc Pharmacology	Lecture	1	4 (PAR)	100	4

YCC Wales has continued to support Cardiff University undergraduate students undertaking projects relating to ADR reporting. During 2016-17 a group of three Pharmacy students undertook a project looking at the role of the Cluster Pharmacists with regards to pharmacovigilance. The findings and recommendations of this project were presented at the Champion Training Day in March 2017 and will be taken forward by the YCC Wales team. Two posters produced by undergraduate students in collaboration with members of the YCC Wales team were submitted to conferences. One was produced by a 4th year Pharmacy student entitled *What do patients know about Yellow Cards?* This won first prize at the UKMi Practice Development Seminar in September 2016. The other was produced by a medical student entitled *Yellow Card? Not for me thank you* and was presented at the 2016 British Pharmacology Conference.

d. Materials developed for YCS promotion

All training materials were updated and redistributed at the Yellow Card Champion Training event held in March 2017.

YCC Wales continues to use promotional materials including pens, post-it notes and lanyards at conference events and training sessions. These have all been updated to include the new YCC Wales logo.



6. PUBLICATIONS

Full Publications

Deslandes PN, Jenkins KS, Haines KE, Hutchings S, Cannings-John R, Lewis TL, Bracchi RC, Routledge PA. A change in the trend in dosulepin usage following the introduction of a prescribing indicator but not after two national safety warnings. *J Clin Pharm Ther.* 2016 Apr; 41(2):224-8. doi: 10.1111/jcpt.12376. Epub 2016 Mar 2.

Abstracts and letters

Thomas AM, Routledge PA, Bracchi R, Carey E, Adams A. Yellow Card Champions to help increase reporting of adverse drug reactions. *Clinical Pharmacist.* Feb 3rd 2016

Islam Z, Deslandes RE, Haines KE, Cannings-John R, Deslandes PN & Routledge PA Benzodiazepine usage in Wales following the introduction of an educational pack encouraging appropriate prescribing in primary care. *Pharmacoepidemiology & Drug Safety.* 2017;26(S1):3-20

Posters

Cassidy C, Adams A, Thomas AM, Hughes L, Carey E. What do patients know about Yellow Cards? [Poster]. Exhibited at UKMi Practice Development Seminar, Birmingham. 2016

Harper L, Adams A, Thomas AM, Tuthill D, Thompson J. Yellow Card? Not for me thank you [Poster]. Exhibited at UKMi Practice Development Seminar, Birmingham. 2016

Named lectures

Routledge PA. *Medicines and Poisons: do your genes matter.* [Lecture] Genetics and Genomics 3rd Generation Conference (Public Understanding of Science), Cardiff, June 22nd 2016

Routledge PA. *High Risk Medications.* [Lecture] WHO, Geneva. August 20th 2016

Routledge PA. *High Risk Medications.* [Lecture] WHO, Florence. September 26th 2016

Routledge PA. *Developing and delivering clinical pharmacology in the NHS; the UK experience.* [Lecture] Società Italiana di Farmacologica, Naples. December 16th 2016

Routledge PA. *European Launch of the WHO Global Challenge in Patient Safety: High Risk Situations in Medication Safety.* [Lecture] WHO, Bonn. March 29th 2017

7. YCC WEBSITE

a. Website updates

The YCC Wales website underwent a complete redesign. The new website was incorporated into the new All Wales Therapeutics and Toxicology Centre (AWTTC) website and was launched in October 2016.



The site includes:

- Information about the YCC Wales team including contact details
- Information for patients
- Advice for healthcare professionals on reporting ADRs
- Links to external educational resources, YCC Wales publications and annual reports.
- Information on our Champion Scheme.

b. Number of website hits (optional)

This function has not yet been activated but will hopefully be for future years.

8. RESEARCH AND ONGOING INITIATIVES

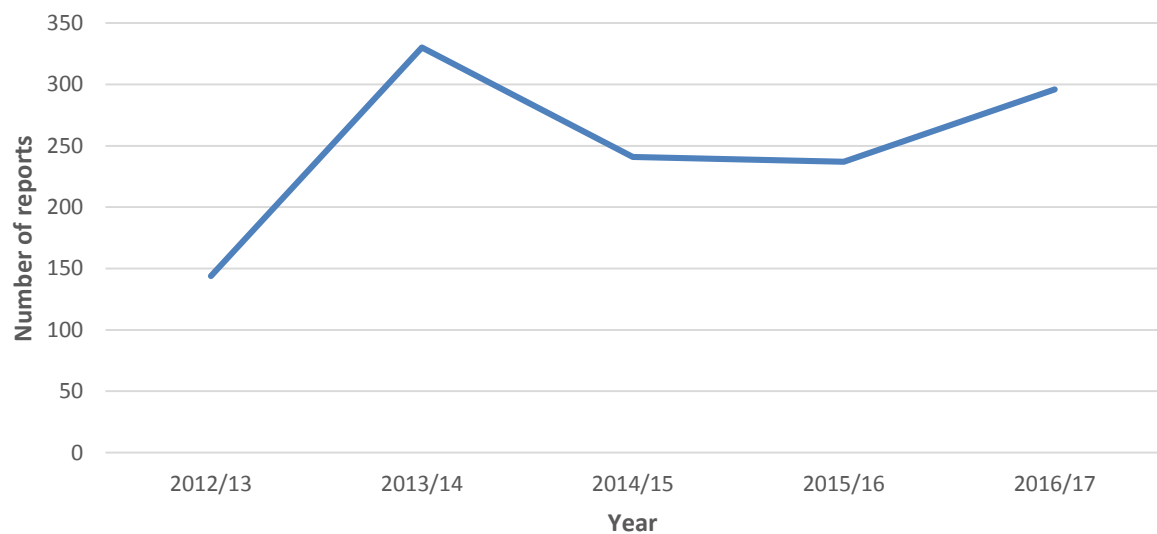
i. Yellow Card Champion Scheme

In November 2012 the All Wales Chief Pharmacists Committee agreed to the implementation of the Yellow Card Hospital Champion Scheme. Whilst the scheme was initially aimed at recruiting hospital pharmacist and pharmacy technician as Champions it has now been expanded. Pharmacists working in other sectors of pharmacy e.g. community pharmacy and general practice have been invited to attend our training days. The role specification for the Champion Scheme remains unchanged to when it was first agreed by the All Wales Chief Pharmacist Committee:

- 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 health board hospital staff
- To increase local publicity of the Yellow Card Scheme
- To keep up to date with legislative changes at the MHRA and European Medicines Agency (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.



Figure 6: Hospital Pharmacist Reports



The number of Yellow Card reports submitted by hospital pharmacists during 2016-17 increased by 11% when compared with the previous year. The aim for the next year will be to further increase the number of reports by hospital pharmacists.

Figure 7: Hospital Reporters vs Total Reporters

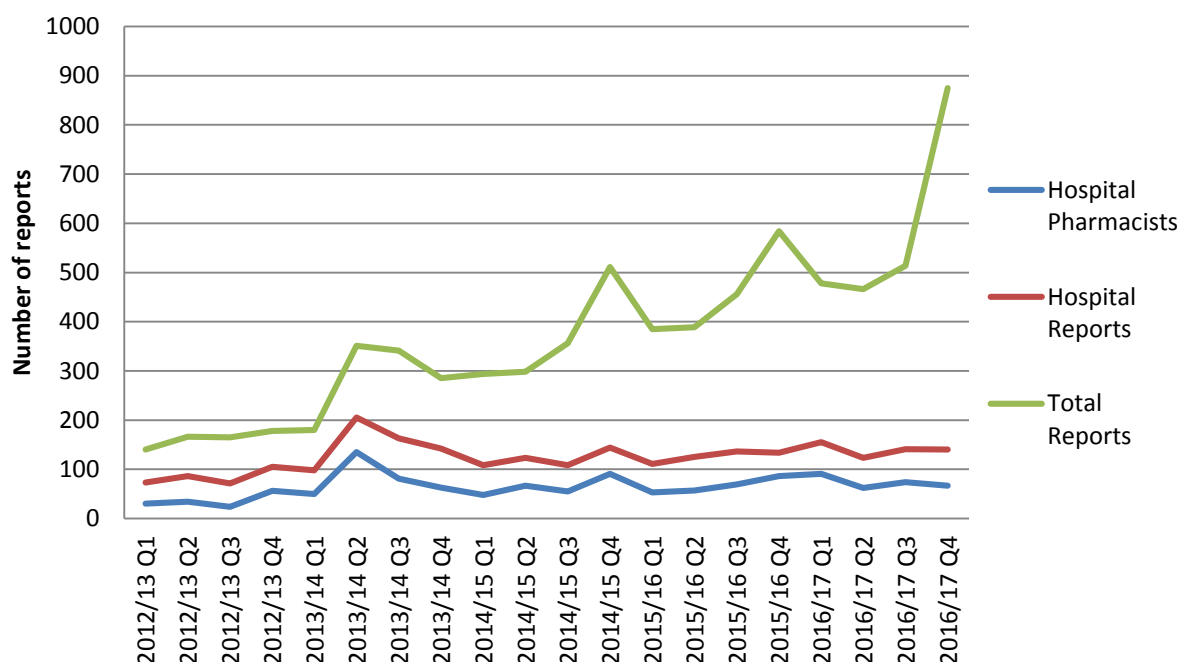


Figure 7 illustrates that the number of reports from secondary care has not increased to the same extent as from primary care sources over the past three years. The Yellow Card Champions have extended their role over this time to provide education to healthcare professionals working within primary and secondary care. Over the past two years we have recruited and trained Yellow Card Champions working in community pharmacies and GP practices.



YCC Wales held its third Yellow Card Champion Training Day on 7th March 2017. All Hospital Pharmacist Champions were invited. The invite was also extended for the first time to pharmacists working within general practice of which five practice pharmacists attended. The programme for the day included sessions on the power of persuasion, how to be a Yellow Card Champion and an update from the MHRA. Students from Cardiff University also presented the results of their projects - 'Cluster Pharmacists project' and 'What do the public know about the Yellow Card Scheme?'. Excellent feedback was received on the content, organisation and presentation standard. The training day will continue to run annually with the next day scheduled for March 2018.

ii. National Prescribing Indicator

In 2013-14 the All Wales Prescribing Advisory Group (AWPAG) agreed to include Yellow Card reporting as a National Prescribing (reporting) Indicator (NPI) in Wales. NPIs are developed annually to promote national prescribing, balancing both quality and efficacy.

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

- A. Target for GP practices – GPs to submit one Yellow Card per 2,000 practice population.
- B. Target for each health board – submit in excess of one Yellow Card per 2,000 health board population.

The introduction of the NPI coincided with an increase in the number of reports submitted by General Practitioners. The number of reports submitted by other general practice-based staff such as pharmacists and nurses also increased. Therefore, from 2016-17, Target A was changed to reflect this and now states that GP practices are to submit one Yellow Card per 2,000 practice population.



Figure 8: Percentage of Practices Attaining the NPI target

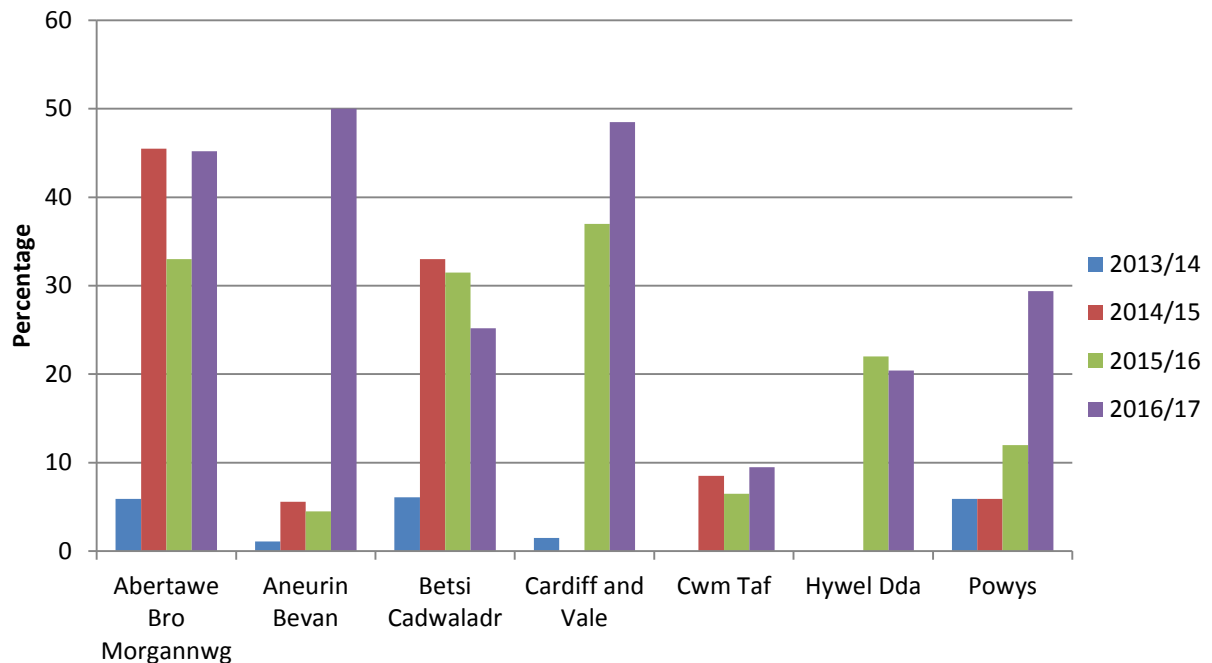


Figure 8 shows the percentage of GP practices achieving Target A has increased each year since the NPI has been in place. For the second year running all health boards in Wales have practices achieving the target. The largest change was within Aneurin Bevan UHB where the percentage of practices attaining the NPI target increased from 4.5% in 2015-16 to 50% in 2016-17. Aneurin Bevan UHB was a main focus for YCC Wales during this year. Four large-scale training events were held and five new Yellow Card Champions were trained.



Figure 9: Percentage of GP Practices in each Health Board submitting a Yellow Card

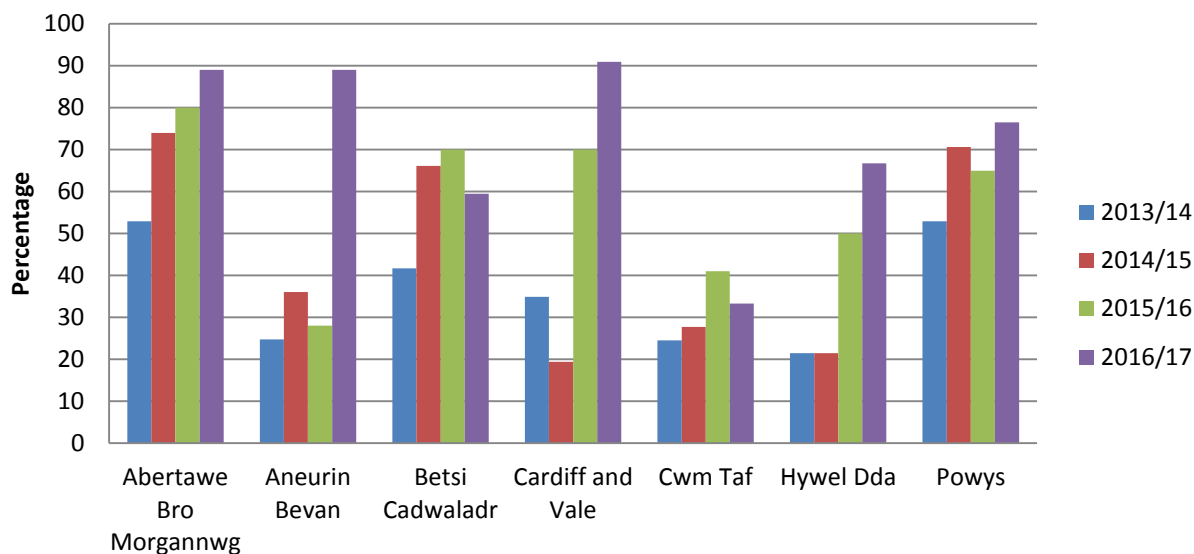


Figure 9 shows the percentage of GP practices who have submitted at least one Yellow Card. Practice level data is cascaded to individual health boards and can be used to target those practices who have not submitted a Yellow Card and offer additional training and support. YCC Wales continues to work with local Yellow Card Champions to offer this support throughout Wales.

Figure 10: Health Board Reports per 2,000 Population

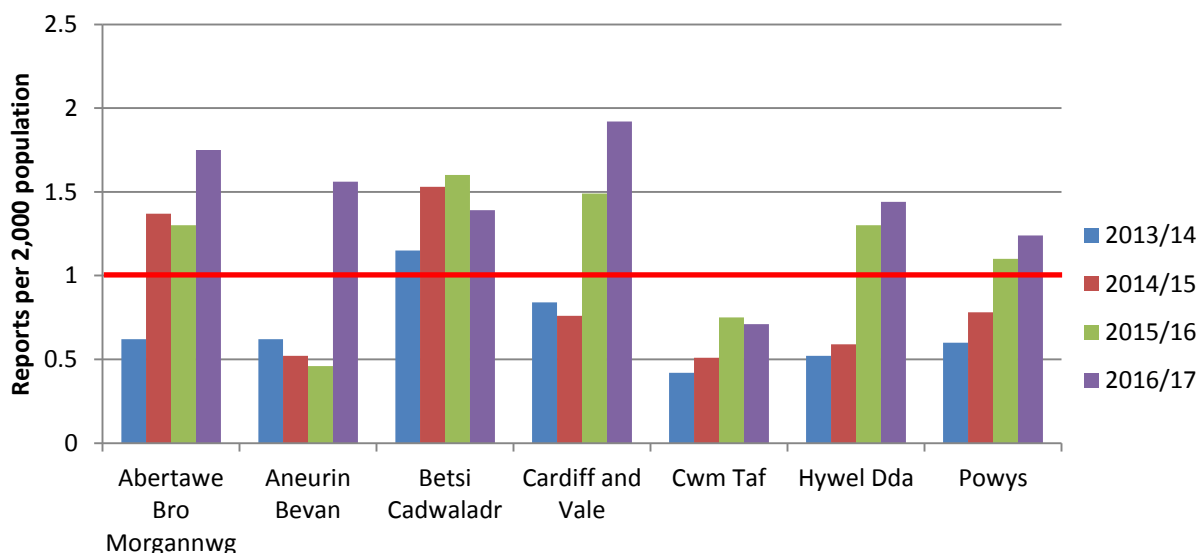


Figure 10 shows the performance of each health board against Target B: Target for each health board – submit in excess of one Yellow Card per 2,000 health board population. An increase was seen in reporting rates in five of the seven health boards in Wales. All health boards except Cwm Taf UHB achieved this target in 2016-17. YCC Wales will support Cwm Taf UHB in addressing this during 2017-18.



The NPIs within primary care have been positively associated with increased numbers of Yellow Card reports submitted from this healthcare sector in Wales. It has been agreed that the NPIs will continue during 2017-18. It has also been proposed that a secondary care NPI be introduced with the aim of increasing Yellow Card reporting rates within the hospital setting.

iii. Social Media

YCC Wales launched its Twitter account in August 2016. Posts are regularly published to encourage Yellow Card reporting amongst healthcare professionals and members of the public. Regular posts were published to inform followers of MHRA developments e.g. launch of RIDR/iDAPS and to publicise YCC Wales activities and initiatives.

Figure 11: Twitter Impressions

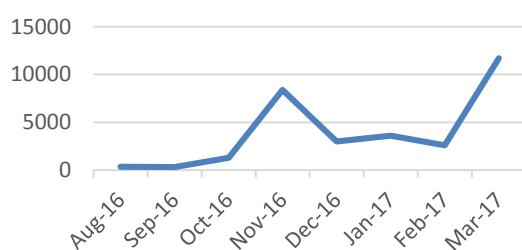
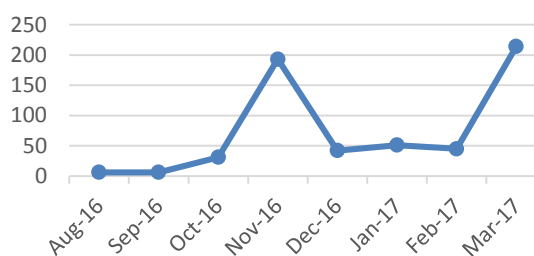


Figure 12: Twitter Engagements



As can be seen in Figures 11 and 12 peak numbers of Twitter impressions and post engagements were achieved during November 2016 and March 2017. These coincided with the SCOPE ADR campaign and the YCC Wales Champion Training Day respectively where YCC Wales were very active on Twitter. During the first eight months of the Twitter page being in place, 61 followers were attained. YCC Wales is keen to build upon its social media platform during the next financial year.

9. CONCLUSIONS

The year 2016/17 has seen further encouraging progress. The continuation and expansion of the Yellow Card Champion Scheme and maintenance of the National Prescribing (reporting) Indicator once again was associated with an increase in reporting rates. The new YCC Wales website has been launched and we are building a social media presence.

Our strategy for 2017-18 will be to:

- Support Cwm Taf University Health Board who did not achieve the NPI target for health boards
- Work closely with our colleagues at AWTTC and AWPAG to finalise details of a secondary care Yellow Card NPI
- Increase awareness of the Yellow Card Scheme and reporting rates amongst members of the public through patient centred initiatives e.g. a Patient Champion Scheme.



10. ACKNOWLEDGEMENTS

YCC Wales acknowledges the contribution made by the following individuals during 2016-17 in helping us to promote and develop our current initiatives:

Yellow Card Hospital Pharmacist Champions

Rosemary Allgeier, Public Health Wales

Vanessa Adams, Velindre

Sue Beach, Hywel Dda

Dianne Burnett, Hywel Dda

Julian Denrico, BCUHB

Emma Jones, Powys

Lauren Jones, ABUHB

Sian Jones, BCUHB

Julie Postle, Cardiff and Vale

Sarah Robinson, ABMU

Nia Sainsbury, ABMU

Debbie Sharp, Cardiff and Vale

Nga Tram, Cardiff and Vale

Bev Woods, Cwm Taf

Practice Pharmacist Champions

Hywel Jones, ABUHB

Lloyd Hambridge, ABUHB

Lucy Higgins, ABUHB

Welsh Analytical Prescribing Support Unit (WAPSU)

Anne Coles

Chrissie Collier

Kath Haines

Kate Jenkins

Karen Jones

Claire Thomas

Cardiff University

Dr Louise Hughes

Welsh Medicines Information Centre

Hannah Evans

Jenna Walker



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