YellowCard * Centre Scotland

Centre for Adverse Reactions to Drugs (Scotland) Helping to make medicines safer.



Annual Report April 2014 to March 2015

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

2014-2015

1. STAFF

Professor Simon Maxwell – Consultant Clinical Pharmacologist, Medical Director YCC Scotland

Mrs Melinda Cuthbert - Lead Pharmacist Medicines Information / YCC Scotland

Dr James Dear, Consultant Clinical Pharmacologist, Deputy Medical Director YCC Scotland

Professor Angela Timoney – Director of Pharmacy, NHS Lothian

Mrs Sheila C Noble – Senior Pharmacist Medicines Information / YCC Scotland

Mrs Anne MacKay – Information Officer Medicines Information / YCC Scotland [Retired 31st March 2015]

2. Executive Summary

YCC Scotland has been working closely with the Scottish Government Pharmaceutical Division, NHS Education for Scotland, Healthcare Improvement Scotland, NHS National Services Scotland and the MHRA to take forward medicines governance and safety aligned developments during 2014/15.

Members of the YCC Scotland team have again been engaged in national strategic development and delivery of initiatives to support the work of the Yellow Card Scheme and patient safety with medicines across Scotland through liaison with the Scotlish Government, Health Improvement Scotland (HIS) and Incident Reporting and Investigation Centre (IRIC) to develop an integrated platform encompassing medication error, faulty medication devices and pharmacovigilance. In addition there has been ongoing work to integrate the electronic Yellow Card with both primary and secondary care electronic prescribing systems through engagement with HEPMA and VISION

Following the development of the NES/YCC Scotland eLearning modules during the previous year, in 2014/15 these modules were officially added to the core learning for pre-registration pharmacists and FY1 doctors as well as being added to the LearnPro platform for all healthcare professionals and incorporated into blended learning for non-medical prescribers in Napier and Dundee universities. Between the launch and the end of March 2015 there have been 549 modules completed via the NES and NHS LearnPro websites.

Members of the YCC Scotland management board were actively involved in the Yellow Card 50th Anniversary Event held in Edinburgh on 20th March 2015. This event was well received and included the presentation of the first Dunlop Award for the "First report of a major new drug association" to two Scottish doctors, Dr David Hunt and Dr Oliver Flossman, who identified a link between recombinant interferon-beta and a potentially fatal disease of small blood vessels (i.e. thrombotic microangiopathy). The identification of this serious adverse drug reaction led to the world-wide implementation of measures to reduce risk to patients.

Members of the team continue to support and deliver educational sessions and have provided 21 ADR specific presentations and 4 invited lectures to different groups of professionals and students.

For the second year running Yellow Card reporting has continued to increase in 2014/15 with a 6% uplift compared with the previous year. The Scottish increase is lower than the 11% increase in ADR reporting over the UK as a whole although it should be noted that in 2013/14 the Scottish increase in reporting had been 37% compared with the whole of the UK reports increasing by 21%. The percentage of ADRs from Scotland compared with the whole of the UK is 6.3%, slightly lower than the 7% achieved in 2013/14. For the first time the patient reporting group (incorporating patients, carers and parents) has produced the highest volume of reports exceeding those coming from GPs and hospital doctors. Most other reporter groups have also demonstrated an increase in reporting with the exception of GPs, hospital nurses and 'others'.

Members of the YCC Scotland team have invested considerable effort into the promotion of patient reporting by contacting and providing short presentations and interactive sessions at a variety of patient support groups and this may have contributed to the marked increase in patient reporting.

3. Yellow Card Data Analysis

Year	Number of reports	Percentage change on previous year
2014/15	1242	+6%
2013/14	1173	+37%
2012/13	858	-6%
2011/12	914	-9%
2010/11	1008	

Table 1 – Yellow Card reporting for Scotland 2010/11 to 2014/15

3a Total Scottish Reports

Table 1 above shows the total Scottish Reports increased by 6% from 1173 in 2013/14 to 1242 in 2014/15. Figure 1 shows the reporting trend for Scotland since 2010/11. A steady rate of decline had been observed from 2009/10 until 2013/14 with a reversal in trend observed from there onwards.

The total number of direct UK reports increased from 17463 in 2013/14 to 19466 in 2014/15 demonstrating an increase of 11%. The increase in Scotland was less compared with the whole of the UK and with the previous year, however Scotland has not yet benefited from GP computer system eYellow Card reporting and it is anticipated that when this becomes available in line with much of the rest of the UK, figures should improve further.



Figure 1 - Total Yellow Card reports from Scotland 2010/11 to 2014/15

Figure 2 demonstrates that the average number of Yellow Card reports per 100,000 population in Scotland is just over 23, which is an increase from 22 the previous year.

While most of the health board areas have demonstrated an increase in reporting from the previous year per 100.000 population. Highland, Grampian, Orkney and Dumfries and Galloway had a lower number of reports compared with the previous year. Although NHS Lanarkshire is still below the Scottish average, their reporting rate has improved considerably from 12 reports per 100,000 in 2013/14 to 16 reports per 100,000 in 2014/15. It is of interest to note that patient reporting had increased in Lanarkshire from 16% to 28% of all reports and this therefore had a significant impact on their overall reporting.

Figure 2 – Comparison of Yellow Card reports per 100,000 population by Health Board April 2014 to March 2015



Comparison of Yellow Card reports per 100,000 population by Health Board

3b Sources of Yellow Card Reports (Scotland)

Figure 3 demonstrates the rate of increase in ADR reporting for the majority of the main reporter groups that contribute to the Yellow Card Scheme. The groups showing any decline in reporting were GPs, hospital nurses, the generic terms "other healthcare professionals" (i.e. professional affiliation not specified on the report) and "others" (i.e. dentist, healthcare assistant, optometrist, medical student, radiographer, chiropodist, midwife, pre-registration pharmacist). While the decline in the generic terms is expected due to more professional choices being available on the electronic Yellow Card, it is disappointing to note that both GPs and hospital nurses reports have declined It is, however, very encouraging to note that patient, parent and carer reporting has increased significantly.

Figure 3 – Scotland total Yellow Card reports by reporter 2013/14 and 2014/15



*Other – dentist, healthcare assistant, optometrist, medical student, radiographer, chiropodist, midwife, preregistration pharmacist

The main points of note are as follows:

Healthcare Professionals submitted 957 reports (a 4.5% decrease of 45 reports compared with 1002 the previous year). Healthcare professional reporting comprised 77% of all Scottish reports while **Patient Groups** submitted 285 reports (reflecting an overall increase in patient reporting from 171 reports the previous year) making up the remaining 23%.

GPs reporting decreased by 13% from 231 in 2013/14 to 200 in 2014/15. In Scotland during 2014/15 the awaited addition of electronic Yellow Card reporting to the GP computer system is still in development. The most frequently reported drugs from GPs were rivaroxaban, mirabegron influenza vaccines and the varicella zoster vaccine. Mirabegron and the intranasal influenza vaccines both had Black Triangle (BT) status indicating good reporting practice.

Hospital Doctors reporting increased from 253 in 2013/14 to 265 in 2014/15 showing a modest 4.7% increase and involving 12% of all Yellow Card reports. For the third year running Hospital Doctor reports have exceeded GP reports. The most commonly reported drugs were warfarin followed by rivaroxaban and ticagrelor. This may reflect the ongoing YCC Scotland promotion of Yellow Card reporting provided at both undergraduate and postgraduate level.

Nurses, who incorporate all community nurses, reporting increased from 106 in 2013/14 to 119 in 2014/15, a 12% increase. The most frequently reported product was Fluenz, the Black Triangle (BT) status intranasal influenza vaccine for which they submitted 38 reports comprising 32% of all nurse reports. Only 5 of the Fluenz reports were considered serious which is in keeping with the BT status of the product.

Hospital Nurse reporting decreased by 19% from 81 reports in 2014/14 to 66 in 2014/15. The most frequently reported product was the BT intranasal influenza vaccine with 5 reports. **Hospital pharmacist** reporting increased slightly by 3% (i.e. from 119 to 123). With rivaroxaban and apixaban being associated with the greatest number of reports (7 and 5 reports respectively). Of the 123 Hospital Pharmacist reports, 21 (17%) were submitted via the UKMi network electronic database (i.e. MiDatabank).

Community Pharmacist reporting continued to increase from 54 to 63 reports indicating a 17% rise in reporting. A wide range of drugs were reported although the most frequently reported drug was varenicline, a BT drug, which had 9 reports from community pharmacists in 5 different health board areas and included 3 serious reports.

Patient, Parent and Carer reporting demonstrated a large increase for the second year running from 171 in 2013/14 to 285 in 2014/15 showing a 67% increase.and again there were reports from all Health Board areas. The main contribution to this was again from patients and parents whose reporting increased by 89 and 23 reports respectively compared with the previous year.

The majority of parent reports were concerning the intranasal influenza vaccine which had 44 (67%) reports from parents. Of these intranasal influenza vaccine reports 32 (73%) were identified by the parents as serious reactions.

Patient reports covered a wide range of medicines with the most frequently reported product being the influenza vaccine with 10 reports comprising 5% of all patient reports.

There were 8 reports from carers covering 8 separate medicines, 7 of which were considered to be serious by the reporter.

It is of interest to note that 220 of the 285 reports i.e. 77% from patients, parents and carers were identified by the reporters as serious. (See section 3c for further analysis).

Even if all influenza vaccines are removed from patient, parent and carer reporting data this still leaves 229 reports which is a 34% increase on reports from members of the public compared with the previous year

It is good to note that for all the areas where YCC Scotland provided patient/carer group information sessions, there was a significant increase in reporting. The areas visited included Lanarkshire, GG&C, Forth Valley and Tayside and these showed a 123%, 79%, 88% and 211% increase in reporting from the previous year suggesting a possible association between the YCC Scotland input and the increase in reporting. While we cannot altogether take the credit for these results, they are none-the-less encouraging.

Other Groups

Other groups of particular note are **Radiographers** whose reports increased from 4 in 2013/14 to 9 in 2014/15. Of their reports, 8 involved iodinated contrast media, 2 of which were considered serious reactions and one was concerning gadoteric acid, another contrast agent. Radiographer reports came from 3 different health boards.

Health board	I otal Reports	Hospital reports	% of Board's Total	% of Board's total
	2014/15	2014/15*	Reports 2014/15	reports 2013/14
			= Hospital reports	=Hospital reports
NHS Ayrshire &	106	49	46%	37%
Arran				
NHS Borders	28	11	39%	43%
NHS Dumfries &	28	16	57%	56%
Galloway				
NHS Fife	83	25	30%	35%
NHS Forth Valley	59	29	49%	28%
NHS Grampian	100	29	29%	36%
NHS Greater	252	100	40%	50%
Glasgow				
& Clyde				
NHS Highland	105	44	42%	42%
NHS Lanarkshire	102	46	45%	46%
NHS Lothian	228	118	52%	49%
NHS Orkney	5	1	20%	22%
NHS Shetland	11	3	27%	10%
NHS Tayside	123	35	28%	38%
NHS Western Isles	12	6	50%	0%

Table 2 - Reports from hospitals 2014/15

Hospital Reporting by Health Board

Table 2 shows the number of reports received from hospitals by health board. NHS Dumfries and Galloway, NHS Lothian and NHS Western Isles had the highest proportion of reports from hospitals with at least 50% of all reports via this route.

3c Serious Reports (Scotland)

Table 3 and Figure 4 show that the number of serious reports from Scotland increased from 683 in 2013/14 to 719 in 2014/15 showing a 5% rise. In both 2013/14 and 2014/15, 58% of all Scottish reports were classified as serious. Thus the proportion of serious reports has remained constant despite a marked increase in Black Triangle drugs being reported which might be expected to be accompanied by an increase in non-serious reporting. It is noted that 220 of 285 Patient/Parent/Carer reports were considered to be serious i.e. 77% and this will have influenced the overall serious reports.

Year	Number of serious reports	Percentage of total reports	Percentage change on previous year
2014/15	719	58%	+5%
2013/14	683	58%	+43%
2012/13	478	58%	-1%
2011/12	482	53%	-25%
2010/11	641	64%	-

Table 3 - Serious reports over last five years

Figure 4 – Serious reports as a proportion of total reports from 2010/11 to 2014/15



Total reports - Serious Reports

3d Black Triangle Reports (Scotland)

Table 4 and Figure 5 show that Black Triangle (BT) reporting in Scotland increased from 224 in 2013/14 to 332 in 2014/15 displaying a 48% increase on the previous year. A large proportion of the BT reports were for the intranasal influenza vaccine (Fluenz) which had been introduced in the autumn of 2013 to all children aged 2 and 3 years and was extended in the autumn of 2014 to include all children aged 2,3 and 4 years and of primary school age in Scotland.

Year	Number of Black Triangle reports	Percentage of total reports	Percentage change on previous year
2014/15	332	27%	+48%
2013/14	224	19%	-29%
2012/13	316	37%	+9%
2011/12	289	32%	-20%
2010/11	363	36%	-

Table 4 -	Black	Triangle re	ports over	last five	vears
					J

Figure 5 – Black Triangle reports as a proportion of total reports from 2010	0/11 to
2014/15	



3e Fatal Reports (Scotland)

The number of fatalities reported for Scotland decreased slightly by 8% from 63 in 2013/14 to 58 in 2014/15. This still equates to approximately 5% of the Scottish total, similar to the previous year.

Table 5 shows the number of fatalities reported for Scotland in patients with suspected side effects in association with medicines over the last five years.

 Table 5 - Number of fatalities reported for Scotland in patients with suspected side effects

 in association with medicines over the last five years

Year	Number of fatal reports	Percentage change on previous year
2014/15	58	-8%
2013/14	63	+66%
2012/13	38	+41%
2011/12	27	-20%
2010/11	34	+6%
2009/10	32	-

3f Age Banding (Scotland)

Table 6 and Figure 6 show that, while overall reporting has increased, there have been no major changes in any of the age bands with respect to ADR reporting numbers. Reporting In the under 18s has remained static between 2013/14 and 2014/15. The reporting on some vaccines had reduced although there has been increased reporting regarding the Fluenz intranasal influenza vaccine. This product continues to have BT status and hence still accounts for a high proportion of the reports in this age group (over 45% of all paediatric reports).

Age Banding	Reports in 2012-2013	Reports in 2013-2014	Reports 2014-15
Child <18	101	214	214
18-24	48	49	61
25-34	95	106	97
35-44	105	108	113
45-54	138	154	167
55-64	112	180	164
65-74	122	178	200
75-84	69	139	122
>85	27	51	53
Age not specified	41	39	49
TOTAL	858	1208	1240

Table 6 - Age Banding Reports Scotland 2012-13 to 2014-15

Table 7 - Age	Banding	Paediatric	Reports	Scotland	2014-15
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ICH Age Range	Paediatric Yellow Card Reports	% of Paediatric Yellow Card Reports
Preterm or newborn infants	4	1.9%
Term newborn infants (0-27 days)	2	0.9%
Infants & toddlers (28 days – 23 months)	20	9.3%
Children (2-11 years)	153	71.5%
Adolescents (12-18 years)	35	16.4%
TOTAL	214	

Figure 6 – The percentage of total Yellow Card reports from Scotland, stratified by age group 2012/13 to 2014/15



3g Top Medicines Reported

Tables 8 to 14 details the top medicines reported for Scotland in 2014/15 and 2013/14; top medicines reported for Scotland compared to the UK in 2014/15; top medicines reported for paediatric patients 2014/15 and 2013/14; and top Black Triangle medicines 2014/15 and 2013/14.

Ranking	Drug Name	Number of reports (2014/15)
1	Influenza vaccines	128
2	Varenicline	54
3	Rivaroxaban	38
4	Warfarin	20
5=	Mirabegron	19
5=	Varicella-zoster vaccines	19
7	Ticagrelor	18
8	Diphtheria containing vaccines	17
9	Pneumococcal vaccines	15
10=	Dapagliflozin	13
10=	Measles Mumps and rubella (MMR)	13
	vaccines	
10=	Rotavirus vaccine	13
10=	Apixaban	13

Table 8 - Top Ten Medicines reported 2014-15

Table 9 - Top Ten Medicines reported 2013-2014

Ranking	Drug Name	Number of reports (2013/14)
1	Influenza vaccines	89
2	Varenicline	62
3	Diphtheria containing vaccines	36
4	Rivaroxaban	32
5	Warfarin	28
6	Meningococcal vaccines	24
7	Varicella-zoster vaccines	21
8=	Rotavirus vaccine	20
8=	Ticagrelor	20
10	Pneumococcal vaccines	17

Ranking	Scotland Medicine Name	UK Medicine Name
1	Influenza vaccines	Influenza virus
2	Varenicline	Rivaroxaban
3	Rivaroxaban	Human Papillovirus Vaccine
4	Warfarin	Varenicline
5=	Mirabegron	phenoxymethylpenicillin
5=	Varicella-zoster vaccines	simvastatin
7	Ticagrelor	Varicella virus
8	Diphtheria containing vaccines	atorvastatin
9	Pneumococcal vaccines	amoxicillin
10=	Dapagliflozin	trimethoprim
10=	Measles Mumps and rubella (MMR) vaccines	
10=	Rotavirus vaccine	

Table 10 - Top medicines reported for Scotland compared to the UK in 2014/15

Table 11 - Top Five Medicines reported in Paediatric Reports 2014-2015

Paediatric Ranking	Drug Name
1	Influenza vaccines *
2	Diphtheria containing vaccines +
3	HPV vaccines
4=	Fluorides
4=	Rotavirus vaccine

*98 Intranasal influenza vaccines and 4 by injection

Including range of 16 diphtheria, tetanus and pertussis and polio vaccines including 3 with Hib

Table 12 - Top Five Medicines reported in Paediatric Reports 2013-2014

Paediatric Ranking	Drug Name
1	Influenza vaccine
2	Rotavirus vaccine
3	Meningococcal group C conjugate vaccine
4	Diphtheria, tetanus and poliomyelitis vaccine (Revaxis)
5	Pneumococcal polysaccharide conjugate vaccine

Table 13 - Top Ten Black Triangle Medicines 2014-2015

Generic Drug Name	Yellow Card Reports
Influenza vaccines (intranasal)	99
Varenicline	54
Rivaroxaban	38
Mirabegron	19
Dapagliflozin	13
Apixaban	13
Aclidinium Bromide	10
Denosumab	7
Sofosbuvir	6
Ferric carboxymaltose	5

Table 14 - Top Ten Black Triangle Medicines 2013-2014

Generic Drug Name	Yellow Card Reports
Varenicline	62
Influenza vaccines	55
Rivaroxaban	20
Mirabegron	14
Telaprevir	10
Aclidinium bromide	6
Dapagliflozin	4
Etonogestrel	4
Glycopyrronium bromide	4
Ivacaftor	4

Of note from the Top 10 reported medicines:

Influenza Vaccines, for the second year running, were the most frequently reported products in Scotland during 2014/15 with a total of 128 reports (55 serious). Of these 99 reports were for the Fluenz intranasal influenza vaccine which has Black Triangle (BT) status. This was therefore also the most frequently reported BT drug and also the most frequently reported paediatric medicine. In the whole of the UK influenza vaccines were also the most frequently reported products

Varenicline is the second most frequently reported drug in Scotland with 54 reports (16 of which were considered serious). Varenicline remains a BT drug so the high percentage of non-serious reports is to be expected. It is now the second most frequently reported BT drug in Scotland and the fourth most frequently reported drug in the whole of the UK

Mirabegron is a BT drug approved by the Scottish Medicines Consortium (SMC) in May 2013 for urinary frequency, urgency and urge incontinence and was the 5th equal most frequently reported drug in Scotland and the 4th top BT drug with 19 reports (6 considered serious) This is the first time it has been in the Scottish top 10 drugs. It does not feature in the UK top 10.

Dapagliflozin was in 10th equal position with 13 reports. It is also in 5th position the BT top 10 drugs and this is the first time it has reached either top 10 list. It is an antidiabetic drug which was approved by the SMC in January 2013. Five of the reports were considered serious.

Anticoagulant and Antiplatelet drugs

Rivaroxaban was the 3rd most reported medicine in Scotland with 38 reports, an increase on the previous year. Rivaroxaban has BT status and is the third highest reported BT drug in Scotland and the second highest drug in the UK as a whole. Of the 38 Scottish reports, 25 were considered serious and 22 were associated with bleeding. Thus, despite its BT status, a high proportion of the reports were considered serious. All the reports, apart from one patient report, were submitted by healthcare professionals.

Warfarin was the 4th most frequently reported drug in Scotland with 20 reports, all of which were considered serious. Seventeen of these reports were related to a bleed. Warfarin was not listed in the top 10 UK reports.

Ticagrelor was the 7th most reported drug in Scotland with 15 reports, 12 of which were considered serious. It had been in 8th equal position the previous year. The majority of reports were related to either haemorrhage (9) or respiratory problems (4). All reports were submitted by healthcare professionals. Ticagrelor is not included in the top 10 reports for the UK **Apixaban** was in 10th equal position with 13 reports, 7 of which were serious. This was also the 6th most frequently reported BT drug. Five of the reports were related to bleeding.

Thus for the novel oral anticoagulant drugs (NOACs), apixaban and rivaroxaban, 53% of all reports involved bleeds and for warfarin 85% of reports were associated with a bleeding incident

Paediatric reports were mainly vaccines with the exception of fluorides.

Herbal reports

There were 5 herbal reports this year which was higher that the one report the previous year. The products involved were: Chinese oolong tea, phytoestrogens, brahmi compound, black cohosh and a pro-hormone and all 5 reports were considered serious. Four of these reports were submitted by healthcare professionals with the 5th being submitted by the patient.

3hSource of reports – detailed breakdownTable 15 below details the reports received by reporter origin over the last 3 years.Table 15 - Reports received by reporter origin

Poportor	201	2/13	2013/14		2014/15	
Reporter	Number	% of total	Number	% of total	Number	% of total
Carer	4	0.5%	6	0.5%	8	0.6%
Parent	8	0.9%	43	3.6%	66	5.3%
Patient	71	8.3%	122	10.4%	211	16.9%
Community Pharmacist	47	5.5%	54	4.6%	63	5.1%
Hospital Pharmacist	86	10%	119	10.1%	123	9.9%
Pharmacist	10	1.2%	4	0.3%	10	0/8%
Pharmacy Assistant	-	-	-	-	-	-
Pre-reg pharmacist	7	0.8%	20	1.7%	17	1.4%
Hospital Nurse	73	8.5%	81	6.9%	66	5.3%
Nurse	108	12.6%	106	9.9%	119	9.6%
GP	131	15.3%	231	19.7%	200	16.1%
Hospital Doctor	173	20.2%	253	21.6%	265	21.3%
Physician	7	0.8%	5	0.4%	5	0.4%
Coroner	-	-	-	-	-	-
Dentist	4	0.5%	13	1.1%	7	0.6%
Midwife	2	0.2%	3	0.3%	1	0.1%
Optometrist	3	0.3%	1	0.09%	2	0.2%
Chiropodist	2	0.2%	1	0.09%	-	-
Radiographer	2	0.2%	4	0.3%	9	0.7%
Hospital Healthcare Professional	25	3%	31	2.6%	33	2.7%
Healthcare Assistant	2	0.2%	2	0.2%	-	-
Other Healthcare Professional	89	10.4%	71	6%	37	3.0%
Medical Student	1	0.1%	3	0.3%	-	-
Unknown	-	-	-	-	-	-
Total	855		1173		1242	

4. Interpretation of reporting figures

A total of 1242 Yellow Card reports were submitted from Scotland, covering 394 different drugs.

Overall Yellow Card reporting in Scotland has increased by 6% in 2014/15 compared with 37% in 2013/14. This is still an encouraging upward trend although not as high as the UK increase of 11%. As a proportion of the UK average Scotland achieved 6.7% in 2013/14 and 6.4% in 2014/15. This year's ratio was still greater than that of 6.0% in 2012/13. This can partially attributed to the utilisation of electronic integrated Yellow Cards within GP systems in England that has not yet been achieved in Scotland.

Influenza vaccines were the most frequently reported products for the second year running and their reporting has increased from 89 reports in 2013/14 to 128 in 2014/15. Ninety nine influenza vaccine reports were for the Black Triangle (BT) Fluenz intranasal influenza vaccine which had been rolled out to include being offered to all children from 2 years upwards incorporating all primary school children compared with just 2 and 3 year-olds the previous year. A relatively high proportion of these (44, 44%) reports were from parents. 32 of the parent reports for the intranasal influenza vaccines were identified as serious by the parents (including reactions such as headache, pyrexia, upper abdominal pain, cough and malaise) whereas only 9 of the 54 reports from healthcare professionals identified the ADRs as serious.

For the second year running the most notable increase in reporting has come from Patients, Parents and Carers, especially patients whose reporting has increased from 122 in 2013/14 to 211 in 2014/15. As the reports from a number of the areas where YCC Scotland provided patient group awareness sessions had more than doubled, it is possible that this intervention has helped to boost patient reporting.

GP reporting has diminished although hospital doctor reporting continues to rise and the overall number of healthcare professional reports has actually reduced from 1002 in 2013/14 to 957 in 2014/15. This is a trend which will require to be addressed by the YCC Scotland team over the next year. It is hoped that, with the introduction of the eYellow Card to the GP Vision Computer System we can promote the ADR eLearning packages to GPs and other surgery-based primary care professionals and improve reporting with these healthcare professionals.

The MHRA Yellow Card (YC) strategy and the subsequent Roadmap have been promoting patient Yellow Card reporting and reporting of ADRs associated with adverse events and medication errors. The MHRA also launched the new Yellow Card electronic interface in November 2015 incorporating reporting of faults with medical devices as well as defective and counterfeit medicines. These initiatives will all have helped in the promotion of Yellow Card reporting

At a local level in Scotland members of the YCC Scotland Management Board have also been actively involved in developing links between reporting of medication errors, defective medical devices and the Yellow Card Scheme The YCC Scotland team have also engaged with non-medical prescribers, GP and hospital doctors, the third sector and a range of patient, parent & carer groups to promote YC reporting. The patient engagement in particular may have influenced the increase in patient reporting in Scotland to some extent.

Although YCC Scotland has been proactive in the facilitation of integration of the eYellow Card into various GP computer systems including Vision, and Hospital Electronic Prescribing and Medicines Administration (HEPMA), this had not yet come to fruition in 2014/15.

5. Promotional activities

5a Training delivered to healthcare professionals and their respective groups

ADR e-learning modules

The 6 ADR eLearning modules were officially launched during June 2014. As well as being incorporated into pre-registration pharmacist and FY1 training, they have also been incorporated into blended learning for non-medical prescribers and other training schemes and have been added to the LearnPro platform as continual professional development for all healthcare professionals.

Table 16 details the face-to-face education and training sessions delivered to healthcare professionals and undergraduates by the staff of YCC Scotland in 2014/15. A total of 21 lectures and training session were delivered covering 37.5 hours of face-to-face training and 1544 participants.

Audience	Session	Duration (hours)	Number of	Total audience	Total hours
		· /	sessions	numbers	training
Healthcare Professionals					
Independent prescribers – University of Dundee	Lecture/ Workshop	3 hours	2	49	6
Independent & Supplementary Prescribers - Napier University	Lecture/Workshop/Bl ended Learning	1	1	60	1
Independent & Supplementary Prescribers - Napier University	Lecture/ Workshop	3 hours	1	50	3
Medical postgraduates	Module	2 hours	1	25	2
 University of Edinburgh, MSc Translational Medicine 	(Adverse Drug Reactions)				
Medical postgraduates – RCPE, MSc Internal Medicine	Lecture (Adverse Drug Reactions I, II)	1 hours	2	60	2
Medical postgraduates – University of Strathclyde	(Pharmacovigilance)	1 hour	1	120	1
Medical postgraduates – University of Strathclyde	Workshops (Pharmacovigilance)	1.5 hours	2	60	3
Undergraduates					
Nursing undergraduates – University of Edinburgh	Lecture/ Workshop	1.5 hours	1	25	1.5
Biomedical Sciences undergraduates – University of Edinburgh, Final year	Lecture/ Workshop	2.5 hours	1	40	2.5
Medical undergraduates	Lecture	1 hours	2	250	2
 University of Edinburgh, Year 1 MBChB 	(Adverse Drug Reactions)				
Medical undergraduates	Lecture	1.5 hours	1	250	1.5
 University of Edinburgh, Year 3 MBChB 	(Adverse Drug Reactions)				
Medical undergraduates	Lecture	1 hour	1	250	1
 University of Edinburgh, Year 4 MBChB 	(Prescribing to prescribe)				
Medical undergraduates	Workshops on	3 hours	2	150	6
 University of Edinburgh, Year 5 MBChB 	processing				
Nursing undergraduates – University of Edinburgh	Lecture/ Workshop	1.5 hours	1	25	1.5
Podiatry undergraduate	Lecture/	2 hours	1	40	2
students	Workshop				
Pharmacy Undergraduates – Robert Gordon University	Lecture	1.5 hours	1	90	1.5
Total			21	1544	37.5

Table 16 – Education and training sessions

The standard evaluation form was used for 6 of the face-to-face education sessions delivered (i.e. Biomedical Science students and Nursing Undergraduates at Edinburgh University; Independent & Supplementary Prescribers at Edinburgh Napier University; Independent Prescribers at the University of Dundee; and Pharmacy students at Robert Gordon University). In total 184 attendees completed the questionnaires. Figures 7 to 9 below show a high level of satisfaction with the programmes delivered and constructive feedback has been used to ensure future training continues to meet the needs of the student groups.

One of the questions asked on the back of the evaluation form was if the content of the presentation would change the participant's practice. Of those who completed this section, 128 (??%) indicated that it would change their practice (positively).



Figure 7 – Overall rating of the ADR education session



Figure 8 – Were learning needs met by the ADR education session

Figure 9 – Delivery of the ADR education session



5b Training delivered to patients

Engagement with patient groups

Throughout 2014-15 members of YCC Scotland have approached and arranged information sessions with patient groups across Scotland. The first 4 meetings were with different patient and carer support groups associated with Parkinson's Disease. These all involved a brief presentation followed by an informal discussion with the group members. The fifth session involved a short Powerpoint presentation at a national meeting of the Brittle Bone Society held in Dundee. We also had our new display stand at the Dundee meeting which drew a lot of interest and stimulated further discussion with the delegates who included patients, carers and healthcare professionals.

A third poster based Patient Reporting campaign through the Community Pharmacy Public Health Scheme had originally been scheduled for February 2015 however, due to circumstances outwith our control, this has been re-scheduled to April/May 2015. It was agreed with Community Pharmacy Scotland that a link to the NES/YCC Scotland e-Learning modules would accompany information about the campaign on their website to encourage all Scottish community pharmacists to increase their own knowledge and understanding of Yellow Card reporting. A Copy of the poster developed for the campaign can be found in appendix 2

Audience	Session	Duration (hours)	Number of sessions	Total audience numbers	Total hours training
Patient groups					
Airdrie Parkinsons Self-	Presentation/	2 hours	1	35	2
Help Group	discussion				
Glasgow Parkinsons	Presentation/	1	1	35	1
Support Group	discussion				
Stirlingshire Parkinsons	Presentation/	1	1	30	1
Support Group	discussion				
Perth Parkinsons Self	Presentation/	1	1	25	1
Help Group	discussion				
Brittle Bone Society	Presentation	0.5	1	60	0.5
Patient Workshop					
Total		5.5 hours	5	185	5.5

Table 17 Patient Group Engagement

5c – Achievement of engagement with patient groups, Healthcare professionals and undergraduates against objective

Figure 10 shows the achievement against the objectives set by the MHRA for YCC Scotland for engagement with patient groups and healthcare professionals. Both of these objectives were met in full in 2014/15 with 21 lectures and workshops for healthcare professionals and students and 5 presentation and workshop sessions with patient groups.

Figure 10 - Engagement with patient groups, healthcare professionals (HCPs) and students compared against agreed 1.2 and 2.2 objectives (Annex 1)



5d Lectures delivered (invited)

Invited lectures in 2014/15 included the following:

Presentations

McIver L, <u>Cuthbert M</u>, Mair A, <u>Maxwell S, Timoney A</u>. *Integrating Yellow Card into the healthcare and health education systems*. Presented at the Yellow Card 50th Anniversary Scientific Conference, Royal College of Physicians Edinburgh on 20th March 2015

<u>Cuthbert M</u>. Routes to reporting suspected side effects of medicines and herbal remedies; and the importance of feeding back and gathering information. Presented at the Alliance/ABPI Scotland Joint Seminar on Rare Conditions, ABPI Scotland, Edinburgh on 3rd December 2014

<u>Cuthbert M</u>. An update on ADR reporting. Presented at the Royal Infirmary of Edinburgh Pharmacy Education Session, Edinburgh on 8th October 2014

<u>Cuthbert M</u>. *Psychotropic side effects.* Presented at Scottish Mental Health Non-medical Prescribers Annual Conference, Ninewells Hospital, Dundee on 23rd May 2014

Conference stands

Yellow Card Centre Scotland Exhibition Stand at the Scottish Non-medical Prescribers Annual Conference, Beardmore Hotel, Glasgow on 10th November 2014

Yellow Card Centre Scotland Exhibition Stand at the Brittle Bone Society Patient Day Workshop, West Park Conference Centre, Dundee on 28th February 2015

50th Anniversary Scientific Conference

The MHRA 50th Anniversary Scientific Conference was held on the 20th March 2015 at the Royal College of Physicians in Edinburgh and members of YCC Scotland Management Board were actively involved in its planning and content. The first Dunlop Award for the first report of a major new drug association was presented in honour of Professor Derek Dunlop, the Edinburgh physician who introduced the Yellow Card Scheme in 1964. The joint recipients were Dr Oliver Flossman and Dr David Hunt of Edinburgh who identified a link between recombinant interferon-beta and a potentially fatal disease of small blood vessels (i.e. thrombotic microangiopathy) in a patient who presented with deteriorating renal function and new-onset hypertension. The identification of this serious adverse drug reaction led to the world-wide implementation of measures to reduce risk to patients.

Engagement with Scottish Government Bodies

Melinda Cuthbert has been working in collaboration with the Scottish Government, Health Improvement Scotland (HIS) and Health Facilities Scotland Incident Reporting and Investigation Centre (IRIC) to develop an integrated platform to support pharmacovigilance in Scotland.

5e Materials developed for YCS promotion

A display stand was designed and purchased by the YCC Scotland team and used to excellent effect at 2 events encouraging discussion and dissemination of Yellow Card Scotland promotional materials. A new batch of promotional pens and Post-it notes have also been purchased to encourage Yellow Card awareness and reporting

5f Internal communications

Ongoing quarterly teleconferences have been held between the YCCs and the MHRA and these are proving very useful for information sharing and planning.

6. Publications & posters

Ryan C, Ross S, Davey P, Duncan EM, Francis JJ, Fielding S, Johnston M, Ker J, Lee AJ, MacLeod MJ, **Maxwell S**, McKay GA, McLay JS, Webb DJ, Bond C.Prevalence and causes of prescribing errors: the PRescribing Outcomes for Trainee Doctors Engaged in Clinical Training (PROTECT) study. PLoS One. 2014 Jan 3;9(1):e79802. doi: 10.1371/journal.pone.0079802. eCollection 2014.

Ryan C, Ross S, Davey P, Duncan EM, Fielding S, Francis JJ, Johnston M, Ker J, Lee AJ, Macleod MJ, **Maxwell S**, McKay G, McLay J, Webb DJ, Bond C. Junior doctors' perceptions of their selfefficacy in prescribing, their prescribing errors and the possible causes of errors. *Br J Clin Pharmacol.* 2013;**76**:980-7

Gibson KR, Qureshi ZU, Ross MT, **Maxwell SR**. Junior doctor-led 'near-peer' prescribing education for medical students. *Br J Clin Pharmacol*. 2014;**77**:122–129.

Haffey F, Brady RR, **Maxwell S**. Smartphone apps to support hospital prescribing and pharmacology education: a review of current provision. *Br J Clin Pharmacol.* 2014;**77**:31–38.

Maxwell S, Cameron IT, Webb DJ. Prescribing Safety Assessment. Lancet. 2015;385:579-581

Therapeutics and good prescribing. In *Davidson's Principles and Practice of Medicine*, 22nd Edition. Eds. Walker BR, Colledge NR, Ralston SH, Penman I. Elsevier, 2014. Chapter 2, pp 17–40.

The Unofficial Guide to Prescribing. Eds Qureshi ZU, Maxwell SRJ. Elsevier, 2014. 380 pages.

Introduction to prescribing. In *The Unofficial Guide to Prescribing*. Eds Qureshi ZU, **Maxwell SRJ**. Elsevier, 2014. Chapter 1, pp 1–32.

Therapeutics and good prescribing. In *Davidson's Essentials of Medicine*, 2nd Edition. Ed. Innes IA. Elsevier, 2015. Chapter 18, pp 731–794.

Qureshi ZU, Rodrigues MA, Lattey K, Tang C-M, Gimzewska M, Gee C, Ross M, Byrne P, Hotton E, Hunt T, Andrew J, Wood M, **Maxwell S**. A long-term, sustainable, inclusive, international model for facilitating junior doctor and medical student–led publishing. *Res Medica* 2014;**22**:149–158.

Qureshi ZU, Rodrigues MA, Lattey K, Tang C-M, Gimzewska M, Gee C, **Maxwell S**. Flipped publishing: a new paradigm for medical textbooks. *Advances in Healthcare Sciences* 2015; *Submitted for publication*

Bradley A, Mason K, Rodrigues MA, Tang C-M, Ross M, **Maxwell S**, Qureshi ZU. 12 Tips for junior doctors and medical students writing and publishing undergraduate textbooks. *Medical Teacher* 2015; *Submitted for publication*

Rajasekaran S, Ramanan R, Durning S, Kripalani S, Schlepper JL, Karpa K, **Maxwell S**, Nierenberg D. Survey of US medical students views on education in medication safety. *Teaching and Learning in Medicine* 2015;*Submitted for publication*

NHS Scotland Polypharmacy Guidance March 2015. **M Cuthbert** was on the Model of Care Group that contributed to the content of the updated guidance.

NHS Education for Scotland Vocational Training 3 Infection and antimicrobial stewardship training module- **S Noble** project managed the development and production of this module

NHS Education for Scotland Antimicrobial Stewardship Education Workbook for nurses – **S Noble** assisted in the development and production of this module.

Sabbisetti VS, Waikar SS, Antoine DJ, Smiles A. Wang C, Ravisankar A, Ito K, Sharma S, Ramadesikan S, Lee M, Briskin R, De Jager PL, Ngo TT, Radlinski M, **Dear JW**, Park BK, Betensky R, Krolewski AS, Bonventre JV. (2014). Plasma Kidney Injury Molecule-1 is a biomarker of acute and chronic kidney injury and predicts progression to ESRD. *J. Am. Soc. Nephrol.* Published online.

Vliegenthart, ADB, Tucker, CS, Del Pozo, J, Rider, S, **Dear, JW.** (2014). Retro-orbital blood acquisition facilitates circulating microRNA measurement in zebrafish with paracetamol hepatotoxicity. *Zebrafish.* 2014;11(3):219-26

Dear, J.W., Antoine, D.J., Starkey Lewis, P.J., Goldring, C.E., Park, B.K. (2013) Early detection of paracetamol toxicity using circulating liver microRNA and markers of cell necrosis. *Br J Clin Pharmacol* 2014;77(5):904-5

Hornby RJ, Starkey Lewis P, **Dear J**, Goldring C, Park K. (2014). MicroRNAs as potential circulating biomarkers of drug-induced liver injury: key current and future issues for translation to humans. *Expert Review of Clinical Pharmacology*. 2014;7(3):349-62.

Dear, J.W. (2014) Urinary exosomes join the fight against infection. J. Am. Soc. Nephrol. Published online

Vliegenthart, ADB, Tucker, CS, Del Pozo, J, **Dear, JW.** (2014). Zebrafish as model organisms for studying drug induced liver injury. *Br J Clin Pharmacol.* In press.

Bateman DN, Carroll R, Pettie J, Yamamoto T, Elamin ME, Peart L, Dow M, Coyle J, Cranfield KR, Hook C, Sandilands EA, Veiriaiah A, Webb DJ, Gray A, Dargan PI, Wood DM, Thomas SH, **Dear JW**,

Eddleston M. (2014). Effect of the UK's Revised Paracetamol Poisoning Management Guidelines on Admissions, Adverse Reactions, and Costs of Treatment.

<<u>http://www.ncbi.nlm.nih.gov/pubmed/24666324</u>> Br J Clin Pharmacol. Published online.

7. Documents uploaded to Citrix Share File

There was a total of 6 items uploaded in 2014-15 to the Citrix Shared Space. These included the following:

-Education and training materials for patient groups

-Powerpoint Lecture for Biomedical Students

-Presentation and workshop for GPs

-Presentation on ADRs associated with biopharmaceuticals

-Presentation and workshop for podiatrists

-Presentation on ADRs associated with drugs for rare diseases

8. YCC Website

8a Website update The YCC Scotland Website is maintained and updated regularly including the newsfeed. <u>http://www.yccscotland.scot.nhs.uk</u>. Links to it have been added to various external sites including the NES website and the NES ADR training modules so it is anticipated that these figures should improve over time.

8b Number of website hits

The YCC Scotland website has received a total of 228 views between 1/4/14 and 31/3/15 with 58 unique visitors. This is quite disappointing and we plan to promote the website in a number of different ways over the next year.

9. Research

During the summer of 2014 a student for Strathclyde University, Dr Mamoon Al Deyab, undertook an analysis of the impact of the 2011 Patient Reporting Campaign as part of his MSc submission under the supervision and mentorship of Sheila Noble. The results demonstrated that, due in part to the poor weather at the time of the intervention, the poster campaign did not have a significant impact upon patient reporting however a number of pointers to make the next campaign more effective were identified. The study also showed that the introduction of pre-populated electronic Yellow Cards via GP SystmOne computer systems in the comparator Yellow Card Centre in Northern & Yorkshire did have a significant positive impact on GP reporting.

10. Conclusion

Yellow Card reporting in Scotland has continued to increase for the second year in succession during 2014/15 with a 6% increase compared with the previous year. A number of factors may have contributed to this increase:

- YCC Scotland continues to provide a constantly updated training and education programme for both undergraduate and postgraduate healthcare professionals highlighting the importance ADRs, how they can be identified and reported and who can report them.
- The launch of the NES/YCC Scotland eLearning modules in the early summer of 2014 will have stimulated understanding and awareness of Yellow Card reporting to healthcare professionals
- YCC Scotland has been actively engaging with key stakeholders within Scotland to promote Yellow Card reporting and ensure that there is easy access to the electronic Yellow Card
- YCC Scotland was proactive in approaching a number of patient groups to whom they provided presentations and discussion sessions

• The expansion of the Black Triangle intranasal influenza vaccine to cover all primary school children stimulated Yellow Card reporting both from healthcare professionals working in primary care and from parents and patients.

ANNEX 1 – Progress	report summary	against obje	ectives
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General Objectives	Performance measures and targets	Progress at end of year 2013/14
1. <u>Education</u> – To educate and inform stakeholders including healthcare professionals	1.1. To develop and update on-going training programmes for students, including undergraduates and postgraduates, and all healthcare professional stakeholders, including GPs, community pharmacists, hospital pharmacists, hospital doctors and hospital nurses	Achieved and ongoing
and patients about the Yellow Card Scheme	1.2. To provide at least 15 lectures, workshops or other events per year, to educate students and healthcare professionals about ADRs, medications errors, pharmacovigilance and the Yellow Card Scheme	Achieved
	1.3. To maintain and expand current network of stakeholders	Achieved
2. <u>Patient Reporting</u> – To increase patient awareness of Yellow Card reporting and help drive an increase in patient reporting	2.1. To engage with community pharmacists to increase patient awareness of Yellow Card reporting	5 week Scottish Yellow Card reporting promotional campaign via Community Pharmacy organised for April –May 2015 Promotional information on e- ADR materials was sent to all community pharmacies in Scotland in Q3 2014/15 prior to the campaign and a link to the eLearning modules was added to the Communnity Pharmacy Scotland website. Posters delivered March 2015 for this campaign.
	2.2. To engage or make contact with five local patient groups per financial year, including giving presentations and talks	Achieved and exceeded.
	2.3. To develop and maintain strategy programmes which can include talks, for sharing information such as Yellow Card data, case studies and reporting trends with stakeholders including local patient groups, hospital pharmacists and GPs to promote patient awareness of patient Yellow Card reporting	Ongoing.
3. External/Stakeholder	3.1. To develop and maintain the YCC website, ensuring that they contain easily accessible information on the reporting of ADRs	Achieved and ongoing
communications – To communicate	3.2. To ensure that the YCC websites contain accessible links to agreed Yellow Card partners	Achieved

information about the Yellow Card Scheme to stakeholders	3.3. YCCs that wish to communicate information to stakeholders through educational material on their websites are to develop and update these training and resource materials accordingly on their websites, including promoting e-learning modules where e-learning modules are available	 Achieved and ongoing. Some examples of engagement meetings with stakeholders include: YCC Scotland Advisory Group meeting ((September 2014) Meeting between MHRA, Healthcare Improvement Scotland, IRIC, YCC Scotland, Scottish Government Pharmaceutical Division and other devolved adminsitrations regarding expanded Yellow Card Platform and implications for medical device reporting (Jan 2015), Healthcare Improvement Scotland compact work between YCC Scotland Lead Pharmacist and Chief Pharmacist HIS on the adverse events workstream requires ongoing liaison and progress discussions. In addition the following meetings attended in this capacity: Adverse Event Infrastructure and Measurement Group (2 meetings) Adverse Event Board (4 meetings) Adverse Event Framework Event (October 2014) NHS Education Scotland and Aurion-ongoing communications to deliver the launch of 6 e-learning modules on ADRs in June 2014.
		 Association of Scottish MI Pharmacists (quarterly meetings)

		 National Services Scotland/ ASMIP/ Scottish Medicines Consortium and HIS meeting to discuss medicines safety assessments on contracts (1 core meeting with 3 follow up meetings for agreed work outputs from the meeting). Engagement with HIS Safer Medicines Network (Dec 2014)
	3.4. YCCs to promote and disseminate safety messages from MHRA to YCC stakeholders as required, such as drug safety updates, pharmacovigilance issue, and e-learning modules	Achieved and ongoing. Monthly dissemination of Dear Healthcare Professional letters summary from the MHRA to key contacts within each health board for onward cascade until December 2014 when transitioned to Drug Safety Update. The YCC Scotland Annual report and individual annual reports for each health board across
	3.5. To monitor the number of hits on YCC websites	Scotland on reporting via the Yellow Card Scheme were disseminated to each health board. Meetings commenced between SG/HIS/IRIC/YCC Scotland in February 2015 to review cascade of all safety alerts in Scotland. Achieved and ongoing.
4. <u>Facilitation</u> – To raise awareness and encourage facilitation of direct ADR reporting from healthcare systems	4.1. Raise awareness of electronic reporting methods in primary and secondary care such as MiDatabank and SystmOne	The continued promotion of reporting of suspected ADRs via MiDatabank is ongoing with Association of Scottish Medicines Information Pharmacists group to foster awareness and uptake of reporting via this platform. SOP recirculated to services for information and request to ensure suspected ADRs are reported.

5. <u>Internal</u> <u>communications</u> – To communicate with the MHRA on a regular basis regarding Yellow Card Strategy and ADR reporting from the YCC regions		SystmOne is not available in Scotland. Electronic yellow card reporting via e-systems is on the HEPMA agenda within Scotland.
	4.2. To identify potential local contacts for further development in this area	Ongoing compact work with Healthcare Improvement Scotland and liaisons with the Scottish government on medicines safety continue to foster ongoing developments within this area in Scotland.
		Discussion with chair of the Scottish e-health SMWG and Directors of Pharmacy representatives regarding the positioning of electronic yellow card reporting within the operational requirements of HEPMA specification for Scotland.
	4.3. To provide input to the MHRA on strategy and development of the Yellow Card Information Standard for the GP System of Choice	Ongoing.
	5.1. Annual report - YCCs to produce an annual report describing their activities over the past year. The report should be produced and sent to the MHRA within three months of receipt of annual Yellow Card data from the MHRA	Achieved.
	5.2. Quarterly Teleconference - To participate in a quarterly teleconference between the YCCs and MHRA to discuss progress and share information	Achieved. Representatives from YCC Scotland in attendance for all meetings.
	5.3. Yellow Card Strategy – To provide views and input into the Yellow Card Strategy	Achieved via input at YCC/MHRA quarterly teleconference ; and feedback on new roadmap provided.
	5.4. YCCs to provide further information and updates on research and education strategies	Ongoing via YCC/MHRA quarterly teleconference and Annual General Meeting.
6. <u>Analysis</u> – To analyse quarterly supply	6.1. To identify local geographical areas of low Yellow Card reporting by analysing Yellow Card quarterly data	Achieved. Enagagement with lowest reporting health board by head of population and educational

of Yellow Card data and identify targets for improvement		lectures/materials provided along with promotional sheet on e-ADR modules for cascade.
	6.2. To promote the Yellow Card Scheme with the intent of increasing reporting in these areas of low Yellow Card reporting	Ongoing.
	6.3. To identify low reporting groups and engage with them to promote the Yellow Card Scheme with the intent of increasing reporting	Ongoing, Community pharmacists targeted in this year. Engagement with community pharmacy Scotland to promote Yellow Card reporting and e- ADR modules via Community Pharmacy Scotland website and contacts prior to public health campaign.
	6.4. To provide MHRA with updates on any other actions taken with the quarterly statistics	YCC/MHRA quarterly teleconference allows for opportunity for this discussion but can be improved so will be a priority in 2015/16.

Appendix 1 Poster for Community Pharmacy Public Health Campaign prepared in Spring 2015

