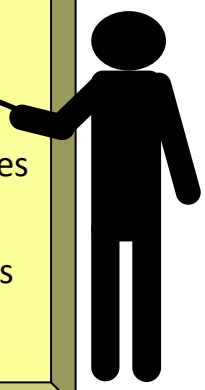
Yellow Card Centre Scotland

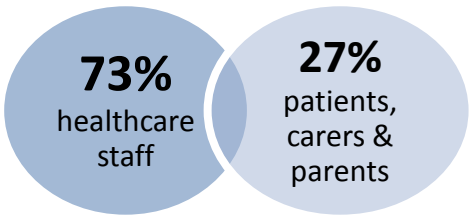
Yellow Card Reports (Scotland)	1% increase	1463 reports	27 reports per 100,000 population

YCC Scotland Training

29 teaching sessions/ events
>2500 Healthcare & Student attendees
7 Patient/ carer events attended
6 Conferences reaching 750 delegates
2169 online modules completed



Source of Reports



Top Reported Medicines

1. MENINGOCOCCAL B VACCINES
2. APIXABAN
3. WARFARIN
4. RIVAROXABAN
5. INFLUENZA VACCINES (INTRANASAL)

Annual Report
April 2016 to March 2017

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

2016-2017

1. STAFF

Professor Simon Maxwell	Consultant Clinical Pharmacologist, Medical Director YCC Scotland
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2. Executive Summary

Yellow Card Centre Scotland (YCCS) has continued to raise the profile of adverse drug reactions (ADRs) as an important safety and quality issue amongst both healthcare professionals and the public in Scotland. This has been achieved through collaboration with key stakeholders, provision of education on ADRs and promotion of the Yellow Card Scheme at conferences and events.

YCCS has strengthened communications with the Scottish Government, notably by the appointment of Professor Rosemarie Parr (Chief Pharmaceutical Officer, Scottish Government) to the YCCS Management Board. Her addition to the management team was intended to strengthen the links between the work of YCCS and Scottish Goverment, and ensure that our work is aligned to national policy making with regard to the safer use of medicines. We are also pleased to have appointed our first patient representative to the YCCS Advisory Group, which continues to meet twice yearly, providing oversight, support and direction to our objectives.

The growth in the total number of Scottish ‘direct’ reports has reached a plateau this year with only a slight (1%) increase from 1447 in 2015/16 to 1463 in 2016/17. Efforts to increase reporting amongst community pharmacists and patients appear to have been successful. However, increases in reporting by those groups has been offset by another

significant decline in GP reporting. Reversing the longterm decline in GP reporting remains a considerable challenge in Scotland. YCCS is hoping to harness the benefits of integrating YC reporting within GP electronic patient record systems (e.g. *Vision*, *SystmOne*), which appears to have stimulated reporting in England. We would also like to pursue the example of Wales where ADR reporting via the Yellow Card System has become a National prescribing Indicator. Investment in IT systems to enable direct reporting will be critical to future growth (direct reporting is now available via *Vision* but requires an update to the DLM 500 release). In the meantime, we will continue to encourage GP reporting by standard means (e.g. education, feedback). We will also be looking to learn from the example of NHS Highland, which is a notable exception to this trend towards declining GP reporting.

YCCS has been busy with a number of new initiatives. Some of these arose out of improvements that were suggested during a "you said, we did" consultation exercise run in association with 50th Anniversary roadshow events in November 2016. We are now issuing quarterly updates to all health boards on local YC reporting (as a summary with infographics), which have been well received. We have also developed a YCCS "toolkit", bringing all our resources together in a user-friendly format supported by a clinical knowledge publisher.

Early this year we issued a survey to all educational establishments in Scotland to scope out current coverage of pharmacovigilance (PV) in both undergraduate and postgraduate courses. The results of this exercise will be analysed shortly, and will help inform our training programme for 2017/18 and beyond. The YCCS/ NES ADR modules continue to be a huge success, and remain firmly embedded in our blended learning sessions which we deliver to healthcare professionals and undergraduates across Scotland. New technology is now available which will enable improvements in the functionality, including better tracking, and a refresh of these is planned for later in the year.

YCCS has engaged with the Community Pharmacy Champions network in Lothian, to test the feasibility of YC promotion through these existing contacts in Scotland (in the absence of any equivalent of the MSO network). This new initiative has been very successful and led to a significant increase in community pharmacist reporting. We hope to extend the process in 2017/18 with support from the National Steering Group for the Collaboration in Quality Improvement in Pharmacy (collaborating organisations include YCCS, NHS Education Scotland, Healthcare Improvement Scotland, Community Pharmacy Scotland, the Alliance and Royal Pharmaceutical Society).

Finally, we are excited to announce the launch of our new YCCS Twitter account (@YCCScotland). Since going live in January, YCCS have issued regular tweets and we have a growing number of followers, which we will work to expand in 2017/18.

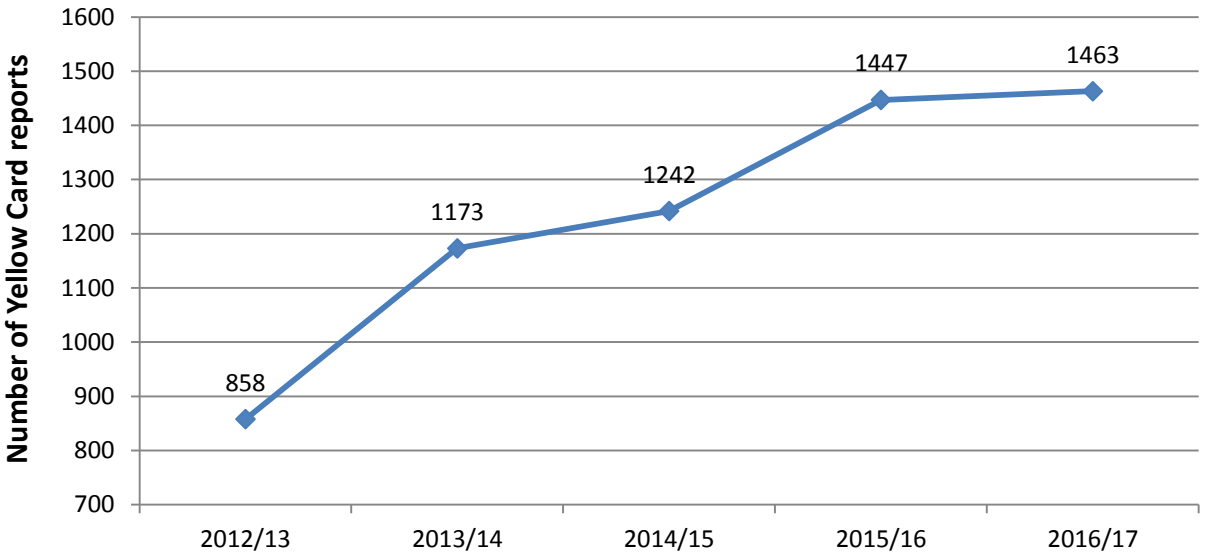
3. Yellow Card Data

3a Total Scottish Reports

Table 1 – Yellow Card reporting for Scotland 2012/13 to 2016/17

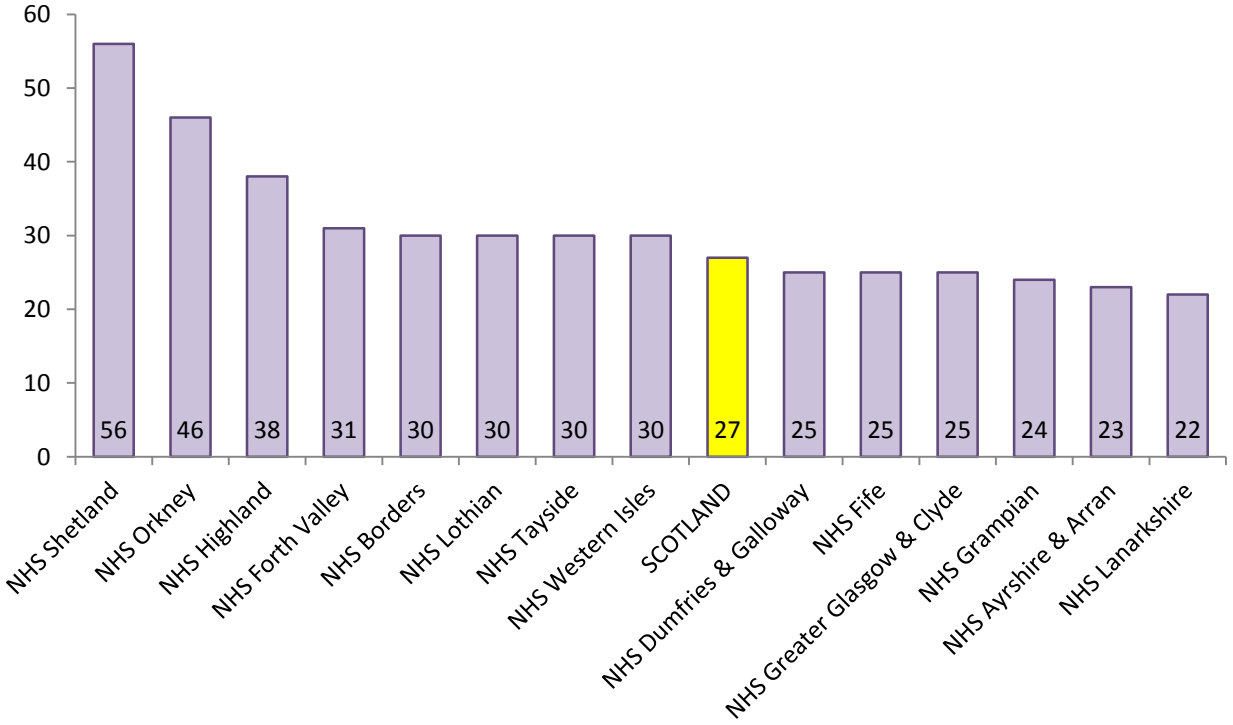
Year	Number of reports	Percentage change on previous year
2016/17	1463	+1%
2015/16	1447	+17%
2014/15	1242	+6%
2013/14	1173	+37%
2012/13	858	-6%

Figure 1- Total number of Yellow Card Reports in Scotland 2012/13- 2016/17



The growth in the total number of Scottish direct reports has reached a plateau this year with only a slight (1%) increase from 1447 in 2015/16 to 1463 in 2016/17. These data should be seen in the context of the particular challenges posed by the reduction in reporting by GPs, the former largest reporter group. Efforts to increase reporting amongst community pharmacists' and patients' appear to have paid off, however this is offset by another significant decline in GP reporting. Thus future growth in reporting by prescribers will be dependent on investment in IT systems in Scotland to enable direct reporting, notably from within GP electronic systems. Direct reporting is now available via *Vision* but requires update to the DLM 500 release.

Figure 2 - Health board Yellow Card Reporting per 100,000 population (Scotland 2016/17)



Statistics from National Registers of Scotland, Population estimates mid-2016* reports for Golden Jubilee Hospital are included in NHS Greater Glasgow and Clyde. Reports for the State Hospital are included in NHS Lanarkshire.

Figure 2 demonstrates that the average number of YC reports per 100,000 population in Scotland is 27; no change from the previous year. Compared to 2015/16, increases in reporting are evident in the Highlands (16%), Western Isles (33%), Shetland (18%) and Orkney (25%). In the Highlands the most notable increase is in reporting by doctors (GPs and hospital). Note that for the Western Isles, Shetland and Orkney the overall number of reports are small, and individual reports can therefore significantly influence the average number/ population.

Although still comparatively low, reporting has also increased since last year in Grampian (14%) and Ayrshire & Arran (21%). In Ayrshire & Arran this increase is mainly from an increase in patient, hospital doctor and hospital nurse reporting. In Grampian the increase is largely from the hospital sector (pharmacists, nurses and doctors).

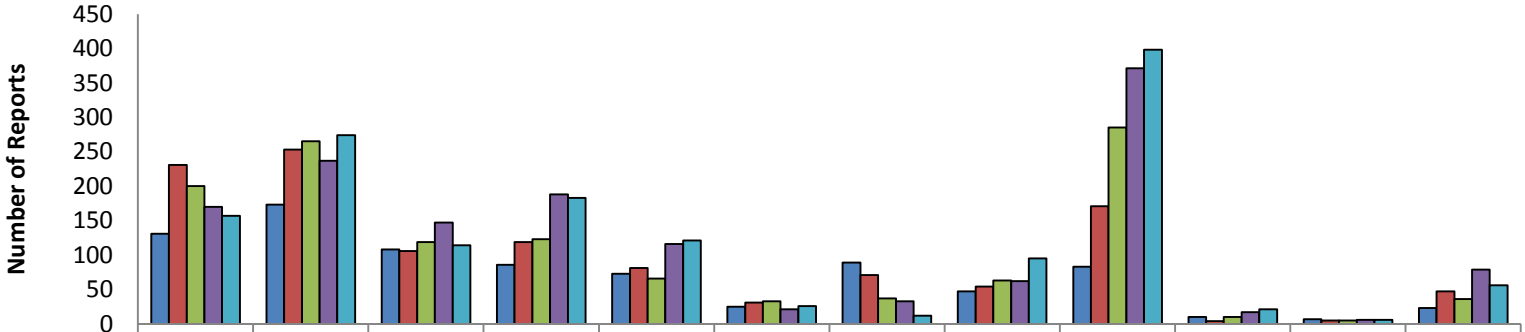
Slight increases are evident also in NHS Lothian (4%), Forth Valley (1%) and Tayside (3%). In Tayside there are notable increases in patient and community pharmacist reporting, with a decrease in reporting by hospital nurses and pharmacists. No obvious changes in patterns of reporting are evident in Lothian or Forth Valley.

A decrease in reporting from the previous year is noted for Dumfries & Galloway (-32%), Fife (-11%), Borders (-17%), Greater Glasgow & Clyde (GGC,-2%) and Lanarkshire (-10%). Overall numbers are small for the Borders and Dumfries & Galloway, so small changes in the number of reports influence the average, however this reduction is mainly due to reduced GP reporting.

In Fife, there has been an increase in patient and community pharmacists reporting, but this is offset by decreased reporting in other groups most notably GPs. In GGC hospital and community pharmacist reporting has significantly increased, but this is offset by a fall in GP and nurse reporting. In Lanarkshire an increase in reporting by hospital doctors is offset by a decrease in reporting by hospital nurses and pharmacists. The numbers of reports received from GPs and community pharmacists is low, but a slight increase is evident compared to the previous year.

3b Reporter Qualifications

Figure 3 – Scotland total Yellow Card reports by reporter qualification 2012/13 to 2016/17



	GP	Hospital Doctor	Nurse	Hospital Pharm't	Hospital Nurse	Hospital HCP	Other HCP	Comm' Pharm't	Patient Groups	Pharm't	Physician	Other*
2012-13	131	173	108	86	73	25	89	47	83	10	7	23
2013-14	231	253	106	119	81	31	71	54	171	4	5	47
2014-15	200	265	119	123	66	33	37	63	285	10	5	36
2015-16	170	237	147	188	116	21	33	62	371	17	6	79
2016-17	157	274	114	183	121	26	12	95	398	21	6	56

*Other = dentist, healthcare assistant, optometrist, medical student, radiographer, chiropodist, midwife, pre-registration pharmacist, pharmacy assistant

Healthcare Professionals (HCPs) accounted for 73% of the total reports; with a decrease in the total number of reports from 1076 in 2015/16 to 1065 in 2016/17 (1% decrease). Overall this is proportionally similar to 2015/16 (HCPs accounted for 74% of total reports).

GP reporting continues to decline for the fourth consecutive year; with a further 8% decrease since 2015/16. GP reporting was highest in NHS Highlands (increased since 2015/16) followed by Lothian and Grampian (both decreased since 2015/16).

Hospital doctors remain the highest reporting HCP group, accounting for 26% of all HCP reports (and 19% of the total reports). Reporting increased by 16% compared to 2015/16; with the highest number of reports in the last 5 years. NHS Lanarkshire and Highlands in particular have contributed to this increase. This is the fifth consecutive year where hospital doctors have greatly exceeded GPs in reporting (respectively 19% and 11% of total reports).

Nurse (incorporating all community) reporting has declined by 22%, and hospital nurse reporting has slightly increased by 4% compared to 2015/16; an overall decline in nurse reporting of 11%. 111/235 (47%) were neither serious nor black triangle (BT) reports. Vaccines were the most commonly reported, with meningococcal B vaccine (BT) being top. The other most frequently reported suspect drugs by nurses were fluticasone/ vilanterol (BT), umeclidinium bromide (BT) and varenicline (not BT status since May 2016).

Hospital pharmacist reporting is overall slightly lower compared to 2015/16, however this follows a 53% increase in 2015/16 (compared to 2014/15). An increase in reporting via Medicines Information is noted, with a substantially higher proportion of the total reports submitted electronically via MiDatabank (Medicines Information Enquiry Answering database) than the previous year (33% versus 24%). Lothian accounted for 47% of the reports submitted via MiDatabank (with a similar number of reports to the previous year). Lanarkshire and Tayside accounted for a further 22% (almost double the previous year) and 20% of MiDatabank reports respectively. Only 7% of these were submitted by GGC (an increase on previous year), and none were submitted by Grampian. It is noted that NHS Highlands have started reporting via MiDatabank this year. The Association of Scottish Medicines Information Practitioners (ASMIP), in collaboration with YCCS continue to promote electronic reporting via MiDatabank across Scotland, therefore it is hoped this upward trend will continue.

Community pharmacist reporting has increased substantially by 53% compared to 2015/16. It is very encouraging to see this following the efforts to improve reporting in this group in 2015/16. As part of the wider patient safety programme, contractors were offered financial incentives to ensure all pharmacy staff completed the YCCS/ NES ADR modules by March 2016. However 57% of these reports were neither serious nor black triangle (BT), although this is a slight improvement on the 61% reported (that were neither serious nor BT) in the previous year. GGC had the highest number of reports from community pharmacists, followed by Grampian and Tayside.

Patient group reports have increased by a further 7% this year, accounting for 27% of the total reports, remaining the highest reporting group (compared to 26% in 2015/16). Of these 312/ 398 (78%) were from patients; 75/ 398 (19%) from parents and 13/ 398 (3%) from carers which is similar to last year's pattern. The majority of parent reports were for HPV and influenza vaccines; patient and carer reporting was diverse.

Other reports came mainly from pre-registration pharmacists and radiographers; but included reports from dentists, medical students, midwives and pharmacy assistants.

Table 2 - Reports from hospitals 2016/ 17 (Scotland)

Health board Area	Total Reports 2016/17	Hospital Reports 2016/17	Hospital Reports as a % of Board's Total Reports	
			2016/17	2015/16
NHS Ayrshire & Arran	85	40	47%	36%
NHS Borders	34	22	62%	46%
NHS Dumfries & Galloway	38	18	45%	50%
NHS Fife	94	32	35%	35%
NHS Forth Valley	93	45	48%	54%
NHS Grampian	141	49	38%	24%
NHS Greater Glasgow & Clyde	288	140	49%	41%
NHS Highland	122	57	51%	49%
NHS Lanarkshire	142	75	53%	54%
NHS Lothian	265	120	45%	50%
NHS Orkney	10	3	40%	25%
NHS Shetland	13	4	31%	73%
NHS Tayside	124	49	44%	37%
NHS Western Isles	8	0	0%	33%
Golden Jubilee	4	4	N/A	N/A
The State Hospital	2	2	N/A	N/A
Total (Scotland)	**1463**	**660**	**45%**	**43%**

Table 2 shows that overall the number of reports received from NHS hospitals this year accounts for nearly half of the total reports (subject to geographical variation), with another modest increase compared to last year (continuing the trend).

3c Serious Reports

Table 3 - Serious reports over last five years (Scotland)

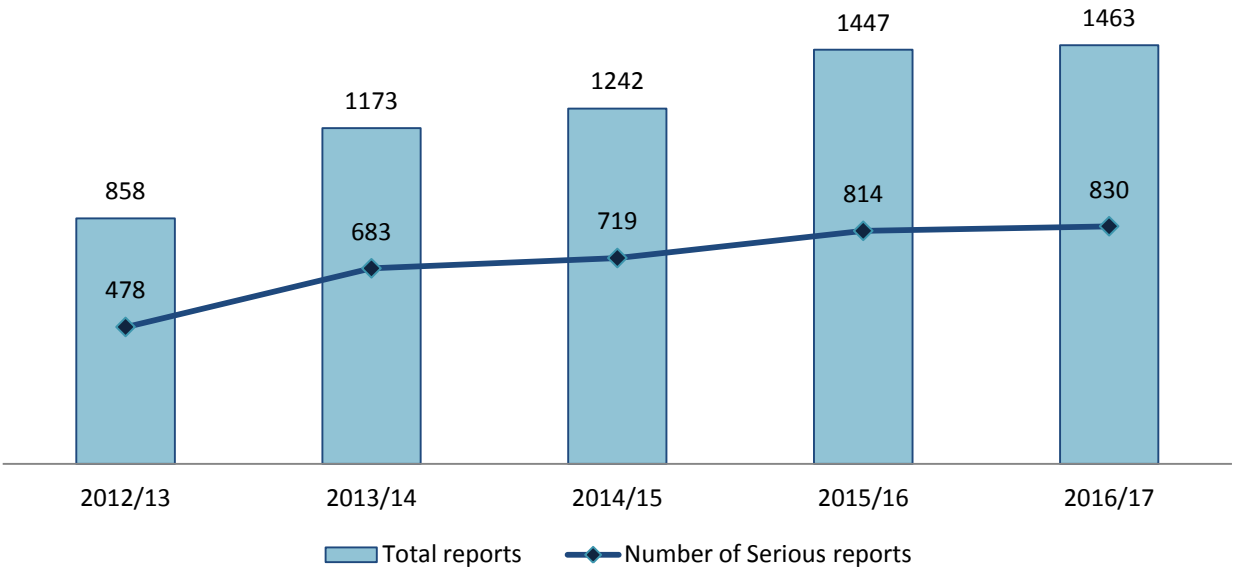
Year	Number of serious reports	Percentage of total reports	Percentage change on previous year
2016/17	830	57%	+2%
2015/16	814	56%	+13%
2014/15	719	58%	+5%
2013/14	683	58%	+43%
2012/13	478	58%	-1%

Table 3 and Figure 4 show the proportion of serious reports has remained constant. Note that 72% of reports from patient groups were considered serious (exactly the same proportion as in the previous year). Vaccines were the most commonly implicated drugs reported by parents, whereas patient reporting this year was much more diverse.

Warfarin, rivaroxaban (BT) and apixaban were still the most frequently reported suspect drugs associated with serious reactions. Of note, the number of serious reports for rivaroxaban was less than last year (25/ 830 versus 43/ 814). It is important to note that no

definite causal link is established between the medicines, and associated suspect adverse drug reactions reported via the YC scheme.

Figure 4 – Serious reports as a proportion of total reports from Scotland 2012/13- 2016/17



3d Fatal reports

Table 4 - 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	% change on previous year
2016/17	71	No change
2015/16	71	22% increase
2014/15	58	8% decrease
2013/14	63	66% increase
2012/13	38	41% increase

There has been no change in the number of fatal reports compared to the previous year.

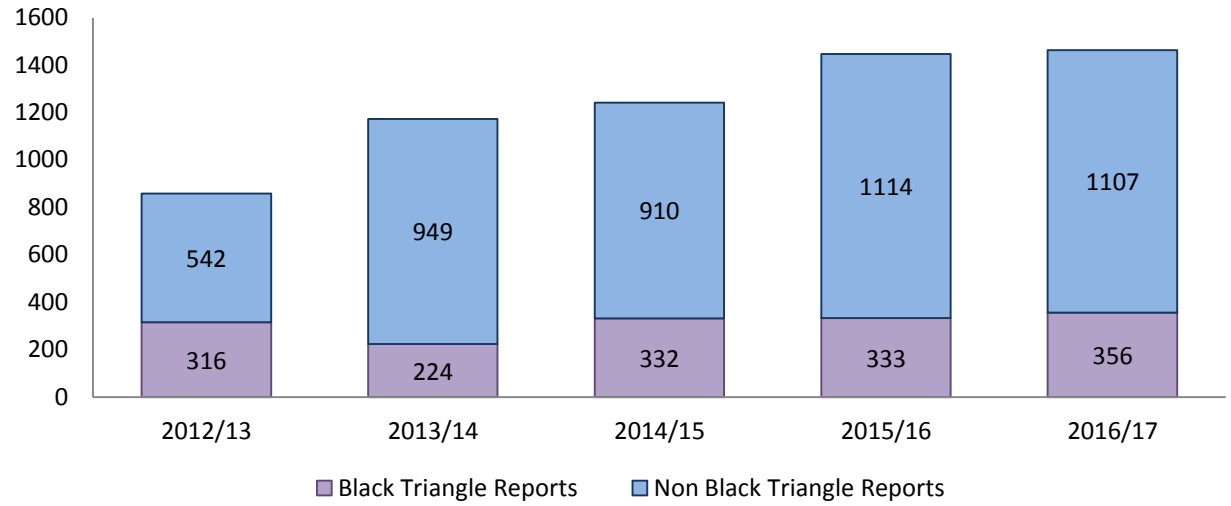
3d.1 Black Triangle (BT) Reports

Table 5 - Black Triangle reports over last five years (Scotland)

Year	Number of Black Triangle reports	Percentage of total reports	Percentage change on previous year
2016/17	356	24%	+7%
2015/16	333	27%	0%
2014/15	332	27%	+48%
2013/14	224	19%	-29%

2012/13	316	37%	+9%

Figure 5 – Black Triangle reports (Scotland) as a proportion of total reports (2012/13 -2016/17)



The number of BT reports has increased by 7% compared to the previous year. This is largely due to reports for fluticasone/vilanterol and umeclidinium bromide.

3e Age Banding (Scotland)

Table 6 - Age Banding Reports Scotland 2014/15- 2016/17

Age Banding	Reports 2014/15	Reports 2015/16	Reports 2016/17
Unknown	49	32	49
Under 2 years	31	70	44
2-6 years	68	70	54
7- 12 years	87	53	51
13- 17 years	28	83	52
18-24 years	61	89	77
25-34 years	97	112	122
35-44 years	113	135	140
45-54 years	167	147	176
55-64 years	164	206	233
65-74 years	200	212	236
75+ years	175	238	229
TOTAL	**1240**	**1447**	**1463**

Table 7 - Age Banding Paediatric Reports Scotland 2016/17

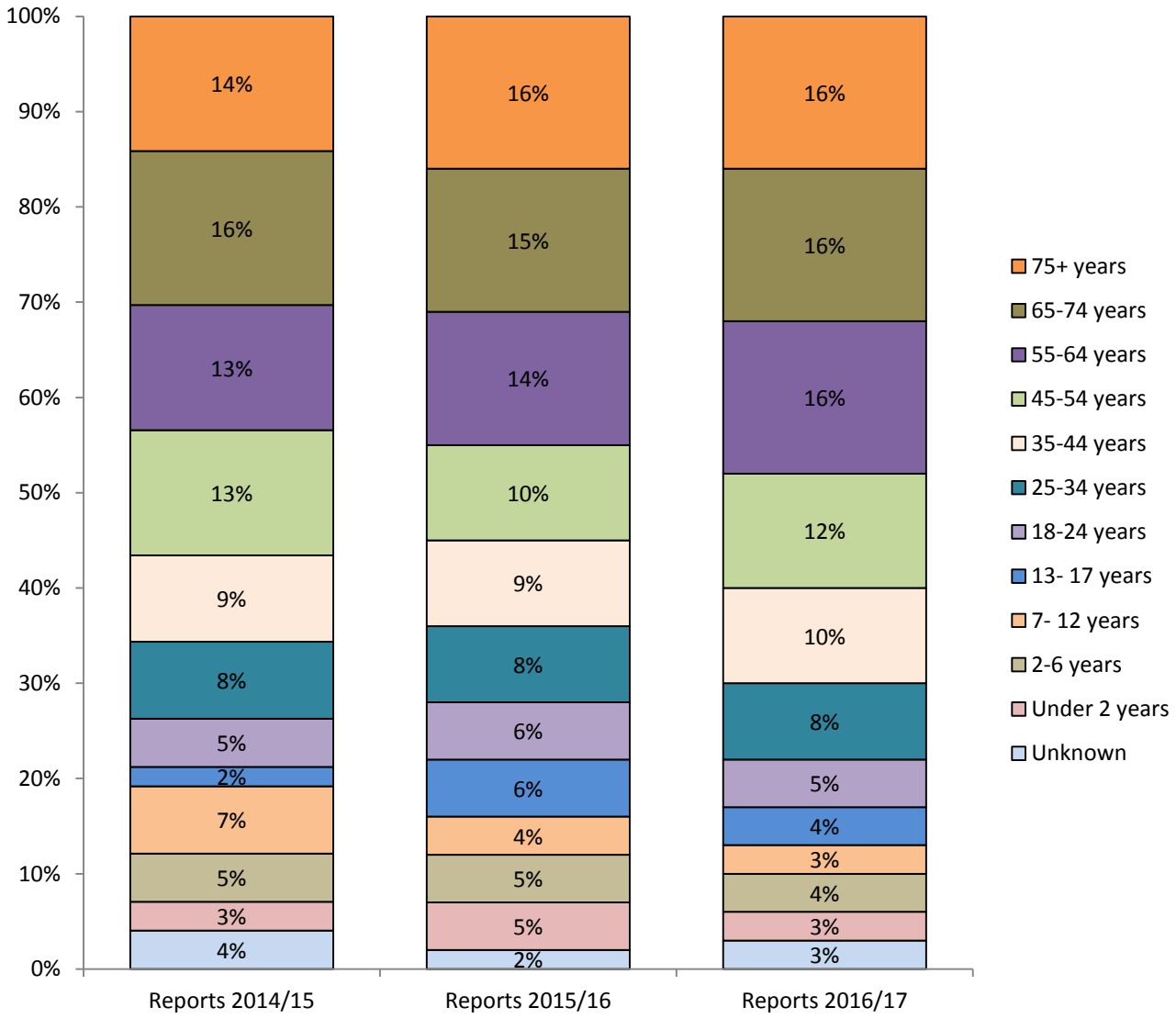
Age Range	Number of Paediatric Yellow Card Reports	% of Paediatric Yellow Card Reports
Children under (0-11 mths)	27	13%
Children (12- 23 mths)	17	8%
Children (2-11 yrs)	96	48%
Adolescents (12-17 yrs)	61	30%

TOTAL	**201**	

Table 8 - Age Banding over 65 years Reports Scotland 2016/17

Age Range	Number of over 65 yrs Yellow Card Reports	% of over 65yrs Yellow Card Reports
65yrs – 74yrs	236	51%
75yrs – 84yrs	171	37%
85yrs – 94yrs	55	12%
95+	3	0.5%
TOTAL	**465**	

Figure 6 – The percentage of Yellow Card reports from Scotland, stratified by age group (2013/14- 2016/17)



Tables 6-8 and Figure 6 show that there have been no major changes in any of the age bands with respect to the number of reports received, although there has been an overall

drop in the number of paediatric reports received (from 276 to 201; a 27% decrease). This reflects a reduction in reports for intranasal influenza vaccine and MMR vaccine in paediatrics, compared to the previous year.

3f Top 10 Suspected Medicines

Table 9 - Scottish top ten suspected medicines reported 2015/16– 2016/17 (including vaccines)

	2015/16		2016/17	
Rank	**Drug Name**	**Reports**	**Drug Name**	**Reports**
1	Meningococcal vaccines	89	Meningococcal B Vaccines	43
2	Influenza vaccines	73	Apixaban	37
3	Rivaroxaban	60	Warfarin	33
4	Varenicline	55	Rivaroxaban	32
5	Apixaban	39	Influenza Vaccines (Intranasal)	31
6	Fluorides	34	=HPV Vaccines = Influenza Vaccines (Exc Intranasal) = Fluticasone/ Vilanterol	24 24 24
7	Diphtheria containing vaccines	31	Varenicline	23
8	Measles Mumps and Rubella (MMR) vaccines	27	Pneumococcal vaccines	20
9	Pneumococcal vaccines	26	Measles Mumps and Rubella (MMR) vaccines	19
10	Warfarin	23	Omeprazole	18

Note that there is a change in the way that we have grouped some of the vaccines this year, which influences where they are positioned (table 9); influenza vaccines have been split into intranasal and other formulations (excluding intranasal). Likewise meningococcal vaccines have been further broken down. This is to capture adverse event reporting patterns which may be specific to newer formulations.

Table 10 - Top ten suspected medicines reported in Scotland compared to UK (2016/17)

Rank	Drug Name (Scotland)	Drug Name (UK)
1	Meningococcal B Vaccines	Neisseria Meningitidis
2	Apixaban	Rivaroxaban
3	Warfarin	Phenoxymethylpenicillin
4	Rivaroxaban	Meningococcal A,C,W135,Y Vaccine
5	Influenza Vaccines (Intranasal)	Apixaban
6	=HPV Vaccines = Influenza Vaccines (Exc Intranasal) = Fluticasone/ Vilanterol	Influenza Virus
7	Varenicline	Amoxicillin
8	Pneumococcal vaccines	Ibuprofen
9	Measles Mumps and Rubella (MMR) vaccines	DT IPV Vaccine

10	Omeprazole	Flucloxacillin

Table 11 - Top Five Medicines reported for paediatrics and aged 65+ in 2016/17 (Scotland)

Top reported medicines for paediatrics and over 65yrs 2016/17		
	Paediatrics	**Over 65 yrs**
1	= Influenza Vaccines (Intranasal) = Meningococcal B Vaccines	= Apixaban = Rivaroxaban
2	Methylphenidate Hydrochloride	Warfarin
3	Fluorides HPV Vaccines	Fluticasone/ Vilanterol
4	Measles Mumps & Rubella (MMR) vaccines	Umeclidinium Bromide
5	= Guanfacine Hydrochloride = Meningococcal A/C/W135/Y Vaccine = Poliomyelitis / Diphtheria/ Tetanus/ Pertussis Vaccine	Varicella-Zoster Vaccines

Table 12 - Top Ten Black Triangle Medicines 2015/16- 2016/17 (Scotland)

2015/16		**2016/17**	
Generic Drug Name	**Reports**	**Generic Drug Name**	**Reports**
Rivaroxaban	60	Meningococcal B Vaccines	43
Meningococcal vaccines	58	Rivaroxaban	32
Varenicline	55	Influenza Vaccines (Intranasal)	30
Influenza vaccines (intranasal)	48	Fluticasone/Vilanterol	24
Apixaban	23	Umeclidinium Bromide	17
Dapagliflozin	15	Dasabuvir Sodium Monohydrate	14
Mirabegron	10	Dapagliflozin	12
Infliximab	7	= Infliximab = Empagliflozin	11
Iron Isomaltoside 1000	7	Apremilast	8
Ledipasvir/Sofosbuvir	7	= Aflibercept = Nivolumab	7

Vaccines still dominate the top 10 suspect medicines reported, specifically meningococcal B. The meningococcal B vaccines are BT (introduced into the routine childhood immunisation programme in September 2015). Unlike the UK, MenACWY is no longer in Scotland's' top 10 (an increase in reports was evident in Scotland last year following changes to the recommendations widening the use), however it remains in the top 5 for paediatrics. Of note Nimenrix (Men ACWY) was removed from BT status in February 2017. Influenza vaccines are still amongst the top reported medicines (if grouped together these would be the second most commonly reported, the same as last year); 56% of reports are for the intranasal vaccine (BT).

The anticoagulants rivaroxaban, apixaban and warfarin remain in the top 10 suspected medicines reported in Scotland. Varenicline reporting has declined (58% reduction), consistent with the removal of its BT status (November 2015). Fluticasone/ vilanterol (BT) is now in the top 10, and the 4th most frequently reported suspect drug when vaccines are excluded.

3g Sources of Reports *Table 13 - reports received by reporter origin (Scotland)*

Reporter	2014/15		2015/16		2016/17	
	Number	% of total	Number	% of total	Number	% of total
Carer	8	0.6%	7	0.5%	13	1%
Parent	66	5.3%	87	6%	73	5%
Patient	211	16.9%	277	19.1%	312	21%
Community Pharmacist	63	5.1%	62	4.3%	95	6%
Hospital Pharmacist	123	9.9%	188	13%	183	13%
Pharmacist	10	0/8%	17	1.2%	21	1%
Pharmacy Assistant	-	-	6	0.4%	6	<1%
Pre-reg pharmacist	17	1.4%	17	1.2%	17	1%
Hospital Nurse	66	5.3%	116	8%	121	8%
Nurse	119	9.6%	147	10.2%	114	8%
GP	200	16.1%	170	11.7%	157	11%
Hospital Doctor	265	21.3%	237	16.4%	274	19%
Physician	5	0.4%	6	0.4%	6	<1%
Coroner	-	-	-	-	-	-
Dentist	7	0.6%	22	1.5%	6	<1%
Midwife	1	0.1%	2	0.1%	5	<1%
Optometrist	2	0.2%	3	0.2%	-	-
Chiropodist	-	-	1	0.1%	-	-
Radiographer	9	0.7%	26	1.8%	19	1%
Hospital Healthcare Professional	33	2.7%	21	1.5%	26	2%
Healthcare Assistant	-	-	1	0.1%	-	-
Other Healthcare Professional	37	3.0%	33	2.3%	12	1%
Medical Student	-	-	1	0.1%	3	<1%

Unknown	-	-	-	-	-	-
Total	**1242**		**1447**		**1463**	

3h Types of reports (Scotland)

Table 14 Report submission routes

Report Type	Number 2016/17	% of total reports
App	3	<1%
Electronic YC	1211	83%
MiDB	60	4%
Paper	189	13%

Table 14 shows an increase in the number of electronic reports in Scotland from 83% in 2015/16 to 87%, however this reflects an increase in reporting via the website and MiDB rather than via the App. Reporting via the App has declined from a modest 3% last year to <1%, despite YCCS continuing to promote the App.

4. Discussion of Yellow Card Data

A total of 1463 Yellow Card reports were submitted in Scotland in 2016/17, a slight overall increase of 1% compared to 1447 in 2015/16. The average number of YC reports per 100,000 population in Scotland remains the same as last year at 27. This is an achievement given the current limitations in Scotland with regard to direct YC reporting via GP systems.

Healthcare Professionals (HCPs) accounted for 73% of the total reports; while patient groups accounted for 27% of the total reports. This reflects a further 7% increase in patient reporting from last year; thus remaining the highest reporting group.

Overall the number of reports received from NHS hospitals accounts for nearly half of the total reports (subject to geographical variation), continuing the trend. Hospital doctors remain the highest reporting HCP group, accounting for 26% of all HCP reports (and 19% of the total reports). Reporting increased by 16% compared to 2015/16. This is the 5th consecutive year where hospital doctors have greatly exceeded GPs in reporting (respectively 19% and 11% of total reports).

GP reporting continues to decline for the 4th consecutive year; with a further 8% decrease since 2015/16. Influencing reporting in this group is YCCS's biggest challenge, as compared to the rest of the UK where electronic YC reporting is embedded within clinical systems (such as SystmOne and Vision). The reversal of this trend in Scotland is dependent on investment in IT systems, to enable direct YC reporting from GP systems. Direct reporting is now available via VISION but requires update to the DLM 500 release.

Overall nurse reporting has declined by 11% despite a slight increase in reporting by hospital nurses. Vaccines were the most commonly reported, with meningococcal B vaccine (BT) being top.

A shift in pharmacist reporting is evident, with an overall slight decrease in hospital pharmacist reporting, and a substantial increase in reporting by community pharmacists.
It is very encouraging to see this increase in community pharmacist reporting following efforts to improve reporting in this group in 2015/16. As part of the wider patient safety programme, contractors were offered financial incentives to ensure all pharmacy staff completed the YCCS/ NES ADR modules by March 2016.
Efforts targeting community pharmacists have continued in 2016/17, with engagement with community pharmacist champions and the follow up roadshow event in May 2017.

The number of electronic reports in Scotland has further increased from 83% in 2015/16 to 87%, however this reflects an increase in reporting via the website and MiDatabank rather than via the App. Reporting via the App has declined from a modest 3% last year to <1%, despite YCCS continuing to promote the App. With the Association of Scottish Medicines Information Practitioners (ASMIP), in collaboration with YCCS continuing to promote electronic reporting via MiDatabank across Scotland, it is encouraging to see this further increase. It is hoped that with more centres reporting via MiDB this trend will continue.

There has been no change in the proportion of fatal or serious reports compared to last year. The number of BT reports has increased, largely due to fluticasone/vilanterol and umeclidinium bromide.There have been no major changes in any of the age bands with respect to the number of reports received, although there has been an overall drop in the number of paediatric reports received. This reflects a reduction in reports for intranasal influenza vaccine and MMR vaccine.

Vaccines still dominate the top 10 suspect medicines reported, with meningococcal vaccines remaining number one in Scotland, specifically meningococcal B. This follows the introduction of meningococcal B vaccines (BT) into the routine childhood immunisation programme in September 2015. The anticoagulants rivaroxaban, apixaban and warfarin remain in the top 10 suspected medicines reported in Scotland, however a shift in the pattern of reporting is evident. Compared to last year there has been a 47% decrease in reports for rivaroxaban, and a 43% increase in warfarin reports. The overall number of reports for apixaban is similar to last year despite the change in BT status in 2015/16. The main changes to the suspect drugs are the decline in varenicline reporting (58% reduction following removal of its BT status); and the appearance of fluticasone/ vilanterol (BT) in the top 10 (the majority were non-serious; with nurses accounting for 61% of reports).

5. Promotional activities

5a Training delivered to healthcare professionals and their respective groups

ADR e-learning modules

Table 15- Online ADR modules data

Module activity 01/04/2015- 31/03/2016	
NES Portal MCQ completed	246 completed (covering all modules)
NES ADR Reporting pages- unique users	532
Learnpro (all 6 modules completed)	209
Learnpro Module 1(completions)	448
Learnpro Module 2 (completions)	342
Learnpro Module 3 (completions)	294

Learnpro Module 4 (completions)	289
Learnpro Module 5 (completions)	276
Learnpro Module 6 (completions)	274

Table 15 shows that the NES/ YCCS ADR modules continue to be a well used resource in Scotland; they are the 3rd most popular NES online resource. These modules are embedded in blended learning teaching sessions in Scotland, and are mandatory in some health boards for staff administering medicines under Patient Group Directives (PGDs).

Table 16- Training delivered to healthcare professionals and their respective groups

Audience	Session	Duration (hours)	No of sessions	Total attendees	Total hours Training
Postgraduate (MSc Internal Medicine)	Lecture- Adverse Drug Reactions	1	1	60	1
Non Medical Prescribers (Dundee)	Lecture- Adverse Drug Reactions	1.5/ 1	2	57	2.5
Non Medical Prescribers (Napier)	Blended Learning- ADRs & YC Reporting	1.25/ 1	2	110	2.25
NHS Fife Specialist Epilepsy Nurses	Teaching (invited)- Yellow Card and ADR reporting	1	1	20	1
MOD Pharmacy Technicians	Teaching (invited)- Yellow Card and ADR reporting	1.5	1	10	1.5
Pharmacists	Yellow Card Roadshow Follow-up	1.5	1	25	1.5
Pharmacists	Unconference Session- 'All for One' study Day Stirling	1	1	5	1
European Association of Poisons Centres and Clinical Toxicologists (EAPCCT)	Lecture- 'Safer acetylcysteine regimens for paracetamol poisoning'	1	1	200	1
National Poisons Information Service – Cardiff :	Lecture- 'Safer acetylcysteine regimens for paracetamol poisoning'	1	1	50	1
Marie Curie Hospice. Glasgow	Lecture- 'Yellow Card Reporting'	1	1	10	1
Toxtalks 2017	Lecture- 'How to report an ADR'	1	1	40	1
Wellcome Trust	Lecture- 'ADRs	1	1	30	1

Translational Pharmacology	and how to report them'				
British Pharmacological Society (Training for independent prescribers)	Lecture-'Adverse drug reactions and Monitoring medicines'	1	1	30	1
Royal College of Physicians NES training day (Core Medical Trainees)	Lecture- ADRs	0.75	1	40	0.75
Diabetes MKN conference (Health Care Professionals)	Stand	1.5	1	90	3
Cradle to Grave NES Study Day at Golden Jubilee in Clydebank (GPs, Pharmacists)	Stand	5	1	80	10
NMPs Conference Queen Margaret University (multidisciplinary HCP)	Stand	4	1	100	8
NMPs Conference Royal Infirmary of Edinburgh (multidisciplinary HCP)	Stand	0.5	1	80	1
ADTC Conference "Will my medicines make me better?" (multidisciplinary HCP/ patients)	Stand	7	1	200	14
Totals			**21**	**1237**	**53.5**

YCCS almost doubled the MHRA targets for delivering teaching to healthcare professionals in 2016/17 through a mixture of lectures, workshops, blended learning (with ADR modules) and attendance at events with the YCCS stand. These targeted non-medical prescribers, pharmacists, pharmacy technicians, nurses and doctors (including GP's). The YCCS stand continues to be popular amongst HCP and patient groups alike.

5b Training delivered to patients and their respective groups

Table 17 Patient Group Engagement

Audience	Session type	Duration (hours)	Number of sessions	Audience numbers	Total staff hours
General public	Health in Focus Article on Yellow Card Reporting and the Yellow Card App on NHS Inform website				
NHS 24 Patient Information Manager	Meeting (phone)	1	1	N/A	1
Tayside Public and Patient meeting	Presentation	0.5	1	20	0.5
Edinburgh Council Carer Manager	Meeting	1	1	N/A	1
Edinburgh Council Carers event	Stand	2	1	N/A	5
Tayside MS Therapy Support	Presentation	0.5	1	25	0.5
Parkinson's UK-SE Region	Email contact				
Vocal Carers Event	Awareness Raising	2	1	3	2
Vocal Carers Event	Awareness Raising	2	1	6	2
ADTC Conference "Will my medicines make me better?" (multidisciplinary HCP/ patients)*	Stand*	7*	1*	200*	14*
Totals			**10**	**254* (54 exclusive)**	**26* (12 exclusive)**

*Also included under HCP training (not possible to separate audience into patients/ HCPs so the total has been included under both)

YCCS were proactive in engaging with patient groups in 2016/17, with a change in approach from targeting specific specialist patient groups to the broader general public. MHRA targets were met for the year and reporting from patient groups has continued to rise in Scotland.

5c Training delivered to undergraduates

Table 1 Training delivered to Undergraduates

Audience	Session	Duration (hours)	No of sessions	Total attendees	Total hours
Undergraduates (Medical- Edinburgh)	Lecture- Adverse Drug Reactions	1	3	750	3
Undergraduate (Pharmacy- Strathclyde)	Lecture- Pharmacovigilance	1	1	230	1
Undergraduate (Pharmacy- Strathclyde)	Workshop Pharmacovigilance	2	2	230	4
Undergraduate (Pharmacy- RGU)	Lecture- Pharmacovigilance	1	1	93	1
Undergraduate (Podiatry- QMU)	Blended Learning- ADRs & YC Reporting	1.5	1	13	1.5
Total			**8**	**1266**	**10.5**

YCCS issued a survey on ADR teaching in undergraduate and postgraduate programmes in educational establishments across Scotland in January 2017, seeking to identify any gaps in core content which may benefit from YCCS input. The initial response rate was poor, so the survey was re-issued and will shortly be closed for evaluation. The results will be used to inform future training.

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

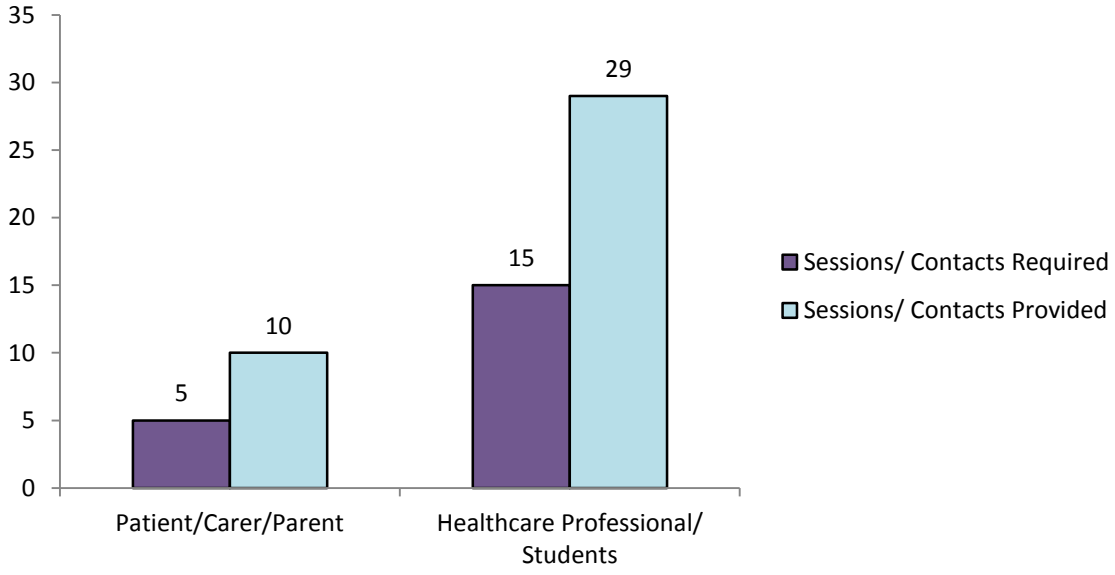
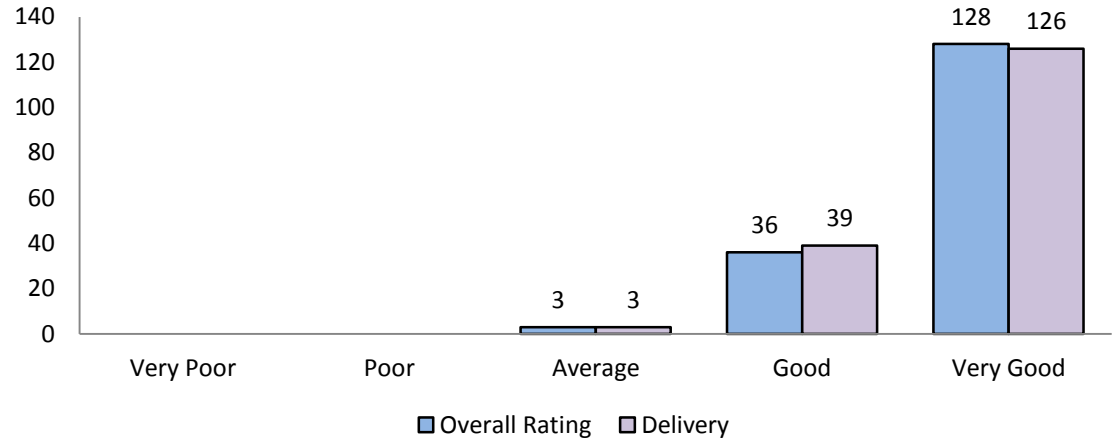


Figure 11 – Overall rating and the delivery of the ADR education sessions



The standard evaluation form was used for a cross section of teaching sessions. In total 168 forms were completed, and figure 11 shows an overall high level of satisfaction with the programme and delivery.

5d Materials developed for YCS promotion

A number of new materials were developed/ professionally printed in 2016/17;

- New lanyards with a more striking yellow ribbon.
- *Printed MHRA patient information/ Healthcare Professional cards- these are for inclusion in carer packs.*
- YCCS 1/3 A4 flyers
- YCCS outreach and training flyer
- Updated HCP Crib sheets
- Slides for display in GP surgeries
- YCC Scotland “Toolkit” for online use (still in draft format).

The previously designed carrier bags, pens, and flyers also remain popular at events. The laminated crib sheets are also very popular amongst HCPs, and are displayed in treatment rooms and community pharmacy dispensaries.

6. Publications

1. Melinda Cuthbert*, James Dear, Simon Maxwell. & Sheila Noble*, Yellow Card Centre Scotland (*and Lothian Medicines Information Service) Poster abstract for UKMI Practice Development Seminar 2016. YCC Scotland/NES ADR eLearning Modules
2. Melinda Cuthbert, James Dear, Tracy Duff*, Simon Maxwell, Sheila Noble*, Angela Timoney & Donna Watson*, Yellow Card Centre Scotland (*and Lothian Medicines Information Service). Poster abstract for UKMI Practice Development Seminar 2016. Developments following the Yellow Card 50th Anniversary Road Shows in Scotland
3. Aldeyab, M. A., Noble, S. C., Cuthbert, M., **Maxwell, S**., Dear, J. & Boyter, A. (2016) Assessment of the impact of the Scottish public health campaign on patient reporting of adverse drug reactions. Drugs and Therapy Perspectives, 32(5); 209-218 10

4. Antoine, D. J. & **Dear, J. W.** (2017) Transformative biomarkers for drug-induced liver injury: are we there yet? Biomarkers in medicine, 11(2):103-106. doi: 10.2217/bmm-2016-0338
5. Brinkman DJ, Tichelaar J, Okorie M, Bissell L, Christiaens T, Likic R, Mačiulaitis R, Costa J, Sanz EJ, Tamba BI, **Maxwell SR**, Richir MC, van Agtmael MA; Education Working Group of the European Association for Clinical Pharmacology and Therapeutics (EACPT). (2017) Pharmacology and therapeutics education in EU needs harmonisation and modernisation: A cross-sectional survey among 185 medical schools in 27 countries. Clin Pharmacol Ther, Mar 15. doi: 10.1002/cpt.682. [Epub ahead of print]
6. Clarke, J. I., **Dear, J. W**. & Antoine, D. J. (2016) Recent advances in biomarkers and therapeutic interventions for hepatic drug safety - false dawn or new horizon? Expert opinion on drug safety, 15(5):625-34. doi: 10.1517/14740338.2016.1160057
7. **Maxwell SR.** (2016) Rational prescribing: the principles of drug selection. Clin Med (Lond), 16(5):459-464
8. **Maxwell S.** (2016) Safe Introduction of New Medicines into Clinical Practice. Clin Ther. 6;38(10S):e8. doi: 10.1016/j.clinthera.2016.07.102
9. **Maxwell SRJ**, Coleman JJ, Bollington L, Taylor C, Webb DJ. (2017) Prescribing Safety Assessment 2016: Delivery of a national prescribing assessment to 7,343 UK final-year medical students. Br J Clin Pharmacol. Apr 27, doi: 10.1111/bcp.13319. [Epub ahead of print]
10. Rajasekaran SK, Schnipper J, Kripalani S, Ramanan R, **Maxwell S**, Karpa K, Durning S, Nierenberg D, Kenison K, Englander R. (2017) Medication Safety Curricula in US Medical Schools—A Call for Action. Med.Sci.Educ, doi 10.1007/s40670-017-0388-2
11. Reid F, Power A, Stewart D, Watson A, Zlotos L, Campbell D, McIntosh T, **Maxwell S**. (2017) Piloting the United Kingdom 'Prescribing Safety Assessment' with pharmacist prescribers in Scotland. Res Social Adm Pharm. Jan 6, pii: S1551-7411(16)30209-1. doi: 10.1016/j.sapharm.2016.12.009. [Epub ahead of print]
12. Vliegenthart, B., Kimmitt, R. A., Seymour, J. H., Homer, N., Clarke, J. I., Eddleston, M., Gray, A., Wood, D. M., Dargan, P. I., Cooper, J. G., Antoine, D. J., Webb, D., Lewis, S., Bateman, D. N. & **Dear, J**. (2017) Circulating acetaminophen metabolites are toxicokinetic biomarkers of acute liver injury. Clinical pharmacology and therapeutics, 101(4):531-540. doi: 10.1002/cpt.54

7. YCC Website/ *Social Media*

7a Website updates

The website has been refreshed and expanded, and is now linked to our Twitter account. Activity includes;

- Maintenance of all pages to ensure materials and links are up to date, including publications.
- Maintained Links to the MHRA Drug Safety Updates, and Dear Healthcare Professional letters.
- Updated the Advisory Group pages including members profiles and ToR.
- Maintained news pages- average 20 articles uploaded/ month.
- Twitter has been added to the homepage- with Tweets visible.

- Updated and added links to new documents and resources e.g. Health Improvement Scotland Medicines leaflet and MHRA "Contributions of YCs to identifying safety issues".

7b Website/*Social Media*

Website

Table 19- Comparison of website hits 2014/15- 2016/17

	2014/15	2015/16	2016/17	% change 2015/16- 2016/17
Total number of Unique Visitors	58	209	143	-31%
Total number of Page Views	228	2,498	1,235	-50%

The website remains popular, although the number of unique visitors and page views has declined compared to last year. This is partly due to the launch of our Twitter account in January, which is now our main method of communication for our events. It should be noted that last year's surge in visitors to our website, was largely from registration for our roadshow events.

Twitter

Table 20- Twitter analytics Jan- April 2017

First tweet	20/01/17
Followers (30/03/17)	51
Total number of engagements (when a follower interacted with a tweet)	148
Tweets sent	40
Impressions (number of tweets delivered to twitter feeds)	7944

YCC Scotland is now live on Twitter @YCCScotland. Between its launch in January and the end of March we issued 40 tweets promoting the Yellow Card Scheme, YCC Scotland and our events. Our follower numbers were modest at this point having only been live for 3 months, but have seen a substantial increase since then. We continue to Tweet regularly items of interest to both the general public and healthcare professionals, in relation to medicines safety. We have a suite of standard tweets that are set up on Hootsuite for release at regular intervals. Unfortunately we launched after the MHRA social media campaign, but intend to re-run this (or similar) in 2017/18.

8. Research and ongoing initiates

ADR Modules: The YCCS/ NES ADR modules continue to be a huge success, and remain firmly embedded in our blended learning sessions which we deliver to healthcare professionals and undergraduates across Scotland. New technology is now available which will enable improvements in the functionality, including better tracking, and a refresh of these is planned for later in the year. These are complimentary to the MHRA modules, providing healthcare professionals with in-depth training on ADR recognition, management and avoidance. This will be a significant undertaking, but is an agreed priority for YCCS in 2017/18.

Survey of Educational Establishments: Early this year we issued a survey to all educational establishments in Scotland to scope out current coverage of pharmacovigilance (PV) in both

undergraduate and postgraduate courses. The results of this will be analysed shortly, and will help inform our training programme for 2017/18 and beyond.

Collaboration with Community Pharmacy Champions: YCCS have engaged with the Community Pharmacy Champions network in Lothian, to test the feasibility of YC promotion through these existing streams in Scotland, in the absence of an established MSO network. This has been very successful with the Champions taking our promotional material and tools (CRIB sheets) out to community pharmacies, helping to promote YC reporting. YC reporting has also been added to their meeting agenda in September for further discussion, with the offer of training from the YCCS team. It is notable that community pharmacist reporting has dramatically increased, so we hope to roll this out further in 2017/18. We will also investigate taking this forward through the National Steering Group for the Collaboration in Quality Improvement in Pharmacy, which YCCS remains part of (with NES, HIS, Community Pharmacy Scotland and the Alliance in collaboration with the Royal Pharmaceutical Society).

Screening for adverse events project: YCCS were asked to support this research project which aims to develop and test a standardized tool for assessment of ADRs in clinical practice. YCCS provided feedback on the proposed patient questionnaire, and supported the notion of a joint proposal to test this in Scotland.

9. Conclusion

Overall, it has been a successful year for YCC Scotland with the activities of 2015/16 seeing a further increase in patient reporting, and a huge increase in community pharmacist reporting.

Our strategy for 2017/18 is to expand collaboration with Community Pharmacist Champions in Scotland, with consideration to linking YC reporting into the existing QI framework. We will continue to promote electronic reporting via MiDatabank across Scotland by engaging with MI networks, and working together to overcome barriers in health boards that have not embedded this into practice. We will continue to engage with patient groups, and will investigate further how to reach the broader general public. We are optimistic that having a patient representative on the Advisory Group will help inform our strategy for this. Twitter has proven a successful communication tool so far, and we will seek to increase our social media presence in 2017/18.

Of obvious note is the further decline in GP reporting, which must be addressed as a priority going into 2017/18. Influencing GP reporting is a considerable challenge in Scotland, in contrast to England where GP reporting has risen with the integration of electronic YC reporting with GP systems (Vision, SystmOne), and Wales following the adoption of a National prescribing Indicator for Yellow Cards. Investment in IT systems to enable direct reporting will be critical to future growth (direct reporting is now available via Vision but requires update to the DLM 500 release). However delays in progress mean that other strategies will need to be considered to encourage reporting by GPs in Scotland in the interim. NHS Highlands is a notable exception to this trend, and further exploration of this geographical variation is warranted in 2017/18. Hopefully, our newly appointed GP representative on the YCCS Advisory Group, can offer advice on how to tackle this challenge going forward.