Yellow Card Centre Scotland

Annual Report
April 2020 to March 2021

Yellow Card Reports (Scotland)
excluding COVID-19 vaccine reports

-16% decrease

1,203 reports

22 reports per 100,000 population

Reports submitted to the Yellow Card Scheme are for suspected adverse reactions that have not been proven to be related to the drug, and should not be interpreted as known side-effects

COVID-19 Vaccine Yellow Card reports (Scotland)

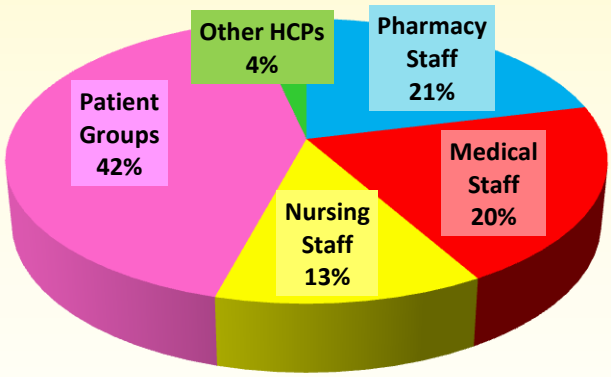
10,948 reports

200 reports per 100,000 population

COVID-19 Vaccine reports

Yellow Card reports in relation to the COVID-19 vaccines are handled and reported separately by the Medicines and Healthcare products Regulatory Agency (MHRA). A weekly summary of Yellow Card reporting is available on the MHRA website.

Source of Non-COVID-19 Reports



Top Reported Non-COVID-19 Medicines

- INFLUENZA VACCINE
- IVACAFTOR/TEZACAFTOR /ELEXACAFTOR
- =ROTAVIRUS VACCINE =SERTRALINE
- EDOXABAN

CONTENTS

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

2020–2021

1. Team

Professor Simon Maxwell	Consultant Clinical Pharmacologist/Medical Director YCC Scotland
Professor Angela Timoney	NHS Lothian Director of Pharmacy and Medicines
Dr James Dear	Consultant Clinical Pharmacologist/Deputy Medical Director YCC Scotland
Ms Tracy Duff	Lead Pharmacist Lothian Medicines Information Service/ YCC Scotland
Ms Louise Summers	Senior Pharmacist Lothian Medicines Information Service/ YCC Scotland
Mr Alexander Kiker	Information Officer Lothian Medicines Information Service/ YCC Scotland

2. Executive Summary

As is clear from the headline data, most Yellow card reports in Scotland in 2020/2021 have been for COVID-19 vaccines. Vaccines always generate significant reports and excluding COVID-19 vaccine they are still two of the top 5 reported medicines in this report. We have separately reported the Covid-vaccine data.

Due to the COVID-19 pandemic, 2020/2021 has been an extremely challenging year for everyone, affecting the way we all work, including the Yellow Card Centre Scotland (YCCS). Restrictions have in particular impacted our ability to deliver promotional activities, with all face-to-face teaching, meetings and conferences suspended. The team at YCCS rose to the challenge, learning new modes of delivery for remote teaching, in order to continue to raise the profile of adverse drug reactions (ADRs) as an important safety issue amongst healthcare professionals. Regular scheduled teaching continues to be delivered to non medical prescribers, and undergraduates in pharmacy, pharmacology, medicine and podiatry.

Throughout 2020/2021 YCCS has continued to engage with the public, albeit in different ways. Enquiries received via the YCCS helpline and our website in relation to suspected adverse drug reactions, and Yellow Card reporting, especially regarding the COVID-19 vaccines, have increased. The team have been busy assisting the public to report suspected reactions, and to seek appropriate clinical advice where indicated.

Due to the large volume of Yellow Card reports in relation to the COVID-19 vaccines, and the importance of timely and appropriate analysis and dissemination of safety information, this data is handled and reported separately by the Medicines and Healthcare products Regulatory Agency (MHRA). The MHRA's pharmacovigilance strategy has four main strands and the Yellow Card scheme underpins one of these strands. Whilst Yellow Cards in isolation are sufficient to allow signal detection, the MHRA will enhance the system by analysing reports in the context of near real-time information on the number of doses of administered at the relevant time point, stratified by age and gender, and the background rate of the event of interest in the absence of vaccination. This allows continuous evaluation of the 'observed' number of reports of a suspected serious side-effect in the context of the naturally-occurring rate in a given time period in the same sized cohort and in the absence of vaccination. A weekly report covering suspected adverse reactions to approved COVID-19 vaccines is available online via https://www.gov.uk/government/publications/coronavirus-covid-19-vaccine-adverse-reactions.

As stated, the COVID-19 vaccine reports are not detailed in the main body of this annual report. As this excludes the vast majority (90%) of Yellow Card reports submitted in Scotland this year, any trends highlighted in this report should be interpreted in this context. With this in mind, we have not provided the same level of analysis as in previous reports. The Yellow Card Centres are in discussion with the MHRA regarding how best to combine these reports in future. A brief summary of COVID-19 vaccine reports (Scotland) is included in Appendix 1.

Given the COVID-19 pandemic, and resulting pressures on healthcare professionals during 2020/2021, it is not surprising that non COVID-19 related Yellow Card reporting has declined. In the context of an overall 750% increase in reporting in Scotland (when COVID-19 vaccine reports are included), the tremendous effort in reporting suspected ADRs should

be recognised. A huge thank you from the team at Yellow Card Centre Scotland (YCCS) to all our healthcare professionals and patient groups across Scotland for their part in this. These reports have made a vital contribution to the ongoing safety monitoring of these new vaccines, providing valuable data to enhance patient safety.

The data have been widely cited, debated and also misused. However, these discussions have provided us with the opportunity to disseminate some very important messages relevant to pharmacovigilance:

- The safety profile of any new medicine (not just those approved under emergency authorisations) is never fully known at the point it is launched onto the market
- Although the scientists and manufacturers have primary responsibility for the safety of medicinal products, everyone (including members of the public) has a role to play in that process by reporting suspected ADRs
- It can be hard to distinguish adverse events occurring in association with medical treatment from spontaneous events that happen frequently in the population; a causal association only becomes clearer as more Yellow Cards reports are made ('signal generation')

Going forward it is important to ensure that awareness of and enthusiasm for reporting suspected ADRs is maintained for all medicines, and in particular for any new medicine. Healthcare professionals have a vital role in this.

Please discuss this report, and the importance of reporting suspected adverse drug reactions to the Yellow Card Scheme with your colleagues and peers. Do not hesitate to contact Yellow Card Scotland at yccscotland@nhslothian.scot.nhs.uk for information on how we can help to support any local initiatives to raise awareness in your area.

Message from the MHRA:

The Yellow Card Scheme is a vital tool in helping the MHRA monitor the safety of all healthcare products in the UK to ensure they are acceptably safe for patients and users. The contribution made by healthcare professionals, particularly during the COVID-19 pandemic, in promoting the Yellow Card Scheme as well as submitting reports themselves has proven an invaluable part of the MHRA's role in monitoring the safety of all medicines and vaccines.

The governance of the centre remains with the YCCS Management Board (Chair: Professor Maxwell) and the YCCS Advisory Group (Chair: Yvonne Semple). The former group meets four times each year to manage operational issues while the latter is a vehicle for Scottish stakeholders oversight, support and direction to our objectives. Details are available on our website http://www.yccscotland.scot.nhs.uk/.

3. Yellow Card Data

3a Total Scottish Reports

Yellow Card reports in relation to the COVID-19 vaccines are handled and reported separately by the Medicines and Healthcare products Regulatory Agency (MHRA).

Excluding these, a total of **1,203 reports** of suspected adverse drug reactions were submitted from Scotland in 2020/21, representing an overall 16% decrease compared to last year (2019/20). There were **10,948 additional reports** of suspected adverse drug reactions in relation to the COVID-19 vaccines during 2020/2021. Combined, a total of 12,151 reports were submitted from Scotland, representing an increase of 750% compared to last year.

Reports of suspected adverse drug reactions to COVID-19 vaccines are not included in the remainder of this report. A brief summary of COVID-19 vaccine reports (Scotland) can be seen in Appendix 1.

Table 1 and Figure 1 below illustrate the trend in reporting in Scotland, over the last 5 years.

Table 1 – Number of Yellow Card Reports from Scotland over the past 5 years

Year	Number of reports	Percentage change on previous year
2016/17	1463	+1%
2017/18	1427	-2%
2018/19	1429	+<1%
2019/20	1432	+<1%
2020/21	**1203**	**-16%**

Figure 1 - Number of Yellow Card Reports from Scotland over the past 5 years

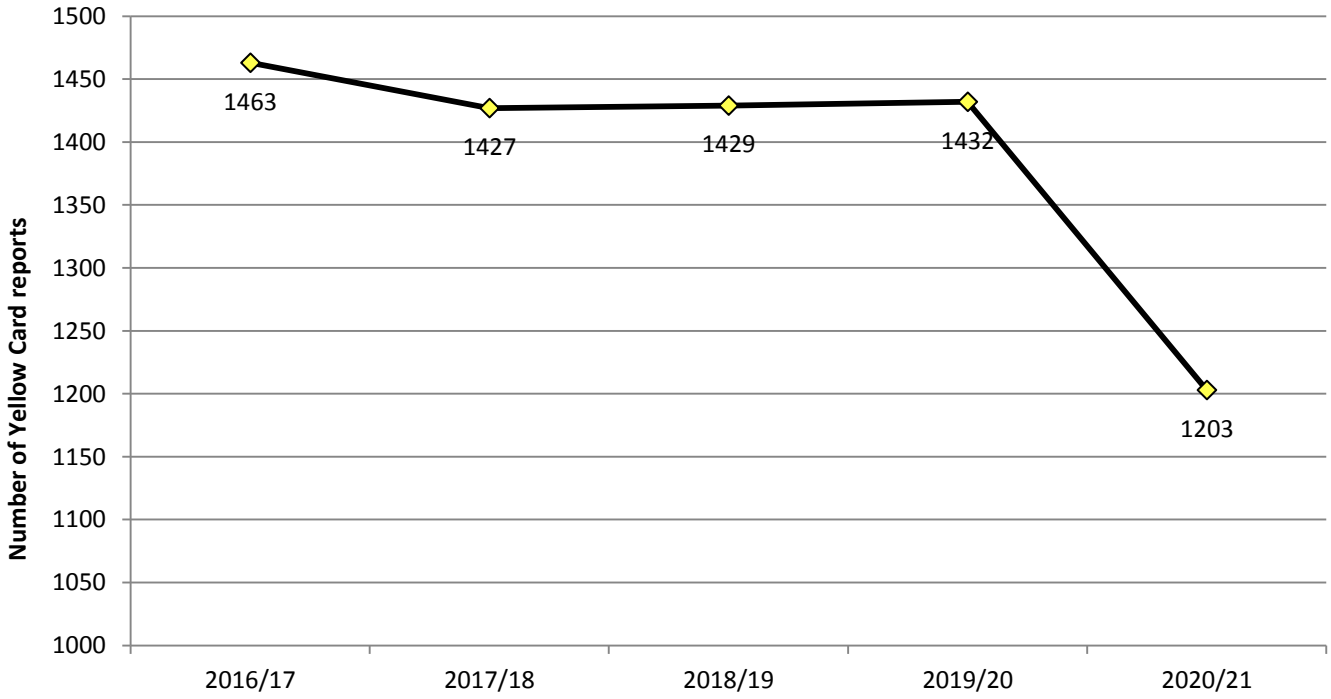
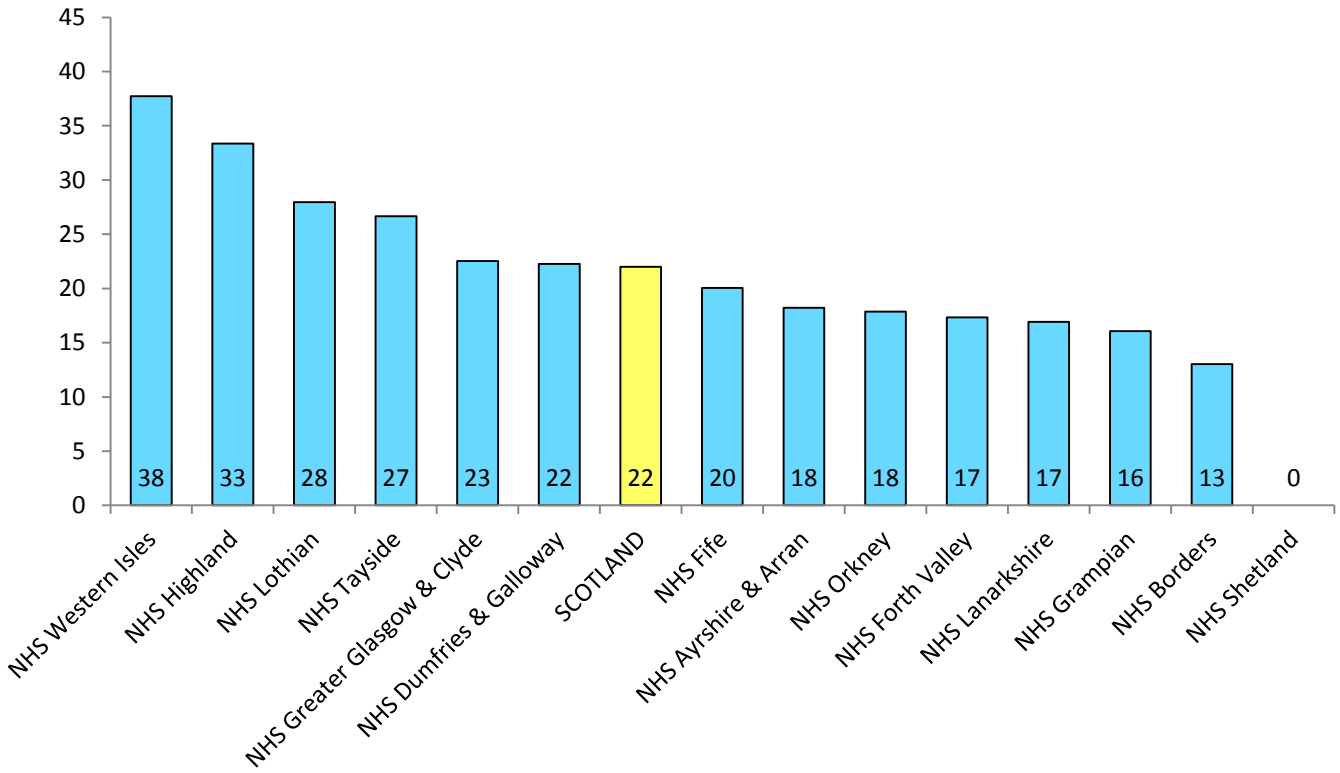


Figure 2 - Health Board Yellow Card Reporting per 100,000 population (Scotland 2020/21)



Statistics from National Registers of Scotland, Population estimates mid-2020* 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 shows how health boards in Scotland compare to the Scottish average (reports per 100,000 population). The average number of Yellow Card reports per 100,000 population in Scotland is 22, compared to the previous year where this was 26.

The top 3 reporting health boards per 100,000 population in 2020/21 were NHS Western Isles, NHS Highland and NHS Lothian. Caution is necessary in interpretation of these results due to the very low number of reports received, in particular in the Western Isles and Orkney.

Figure 3 – Number of Yellow Card Reports submitted over the last 5 years (top 5 reporting health boards in 2020/21)

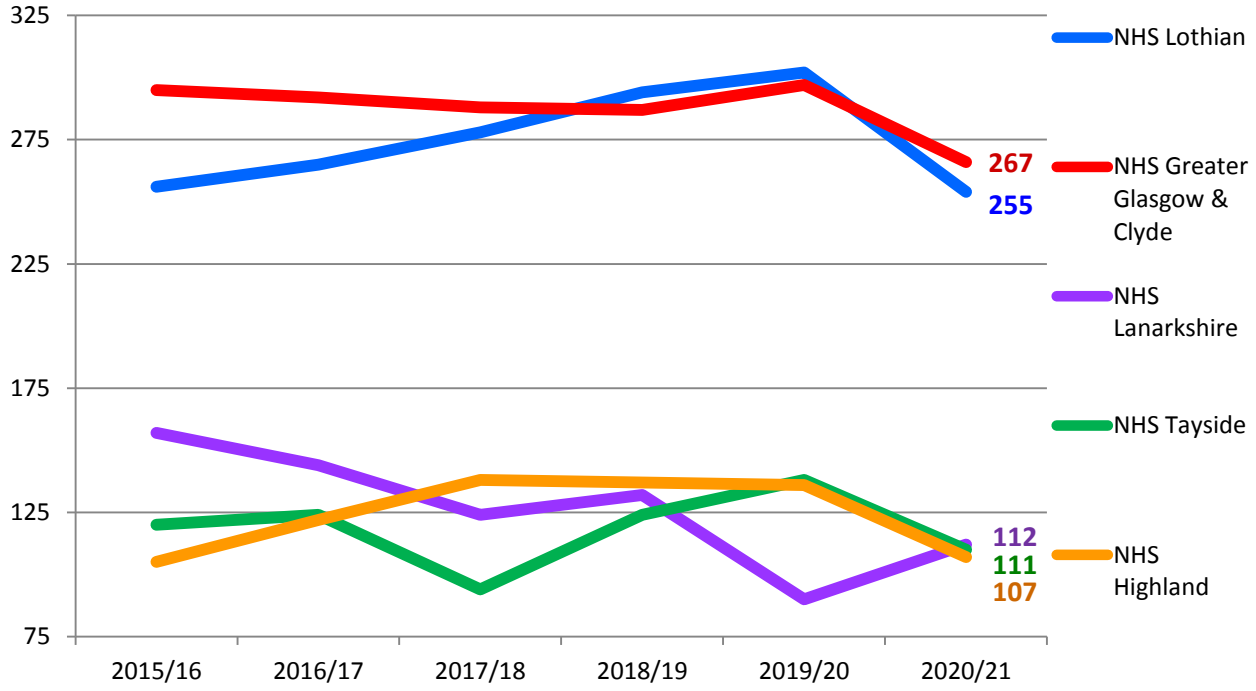


Figure 3 shows the 5 year trend in reporting for the five health boards that submitted the highest number of reports (total) in 2020/21.

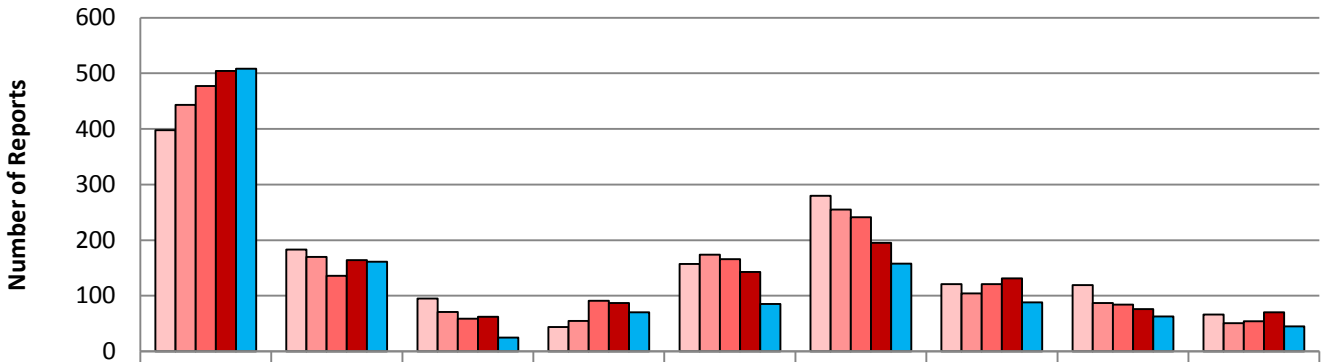
Overall reporting has declined in the majority of health boards compared to the previous year with NHS Borders, NHS Grampian, and NHS Forth Valley showing the largest declines.

For the NHS Western Isles, NHS Shetland and NHS Orkney, the number of reports is overall too low to allow trend analysis.

Further details can be provided to health boards on request.

3b Reporter Groups

Figure 4 - Scotland total Yellow Card reports by reporter groups 2016/17 to 2020/21



	Patient Groups	Pharmacy (Hospital)	Pharmacy (Community)	Pharmacy (Other)	Doctor (GP)	Doctor (Hospital)	Nursing (Hospital)	Nursing (Other)	Other Healthcare Professional
2016/17	398	183	95	44	157	280	121	119	66
2017/18	443	170	71	55	174	255	104	87	51
2018/19	477	136	59	91	166	241	121	84	54
2019/20	504	164	62	87	143	195	131	76	70
2020/21	508	161	25	70	85	158	88	63	45

Patient Groups: Patients; Parents; Parents; Consumers
Pharmacy Other: Not specified; Pharmacy Assistant/Technician; Pre-Reg Pharmacist
Nursing Other: Not specified; Community; Midwife
Other Healthcare Professional: Chiropodist; Optometrist; Healthcare Assistant; Radiographer; Paramedic; Dentist; Medical Student; Not specified; Not specified (hospital)

Healthcare Professionals (HCPs) accounted for 58% of the total reports in Scotland; with a decrease in the total number of reports from 928 in 2019/20 to 692 in 2020/21. This represents a decline in reports from all healthcare professionals across all sectors.

Reporting from patient groups remained stable during the COVID-19 pandemic. The patient group, consisting of patients, parents, and carers, remains the highest reporting group in Scotland and accounts for 42% of the total reports for 2020/21, compared to 35% in 2019/20.

Figure 4 shows the contribution of specific reporter groups to the total reports submitted in Scotland in 2020/21. These are grouped by profession, and subdivided into sector where the data allows.

A further breakdown of the “Other Healthcare Professional” reports is illustrated in Figure 5 – collectively these constitute 4% of all Scottish reports. These incorporate the lowest reporting groups (those who submitted 5 or fewer reports), and those not that did not specify their profession, but selected either hospital or other healthcare professional – hospital (NOS) and Other (NOS). For this year, this includes dentists, radiographers and optometrist.

Figure 5 – Percentage of Total Reports in Scotland for each Reporter Group

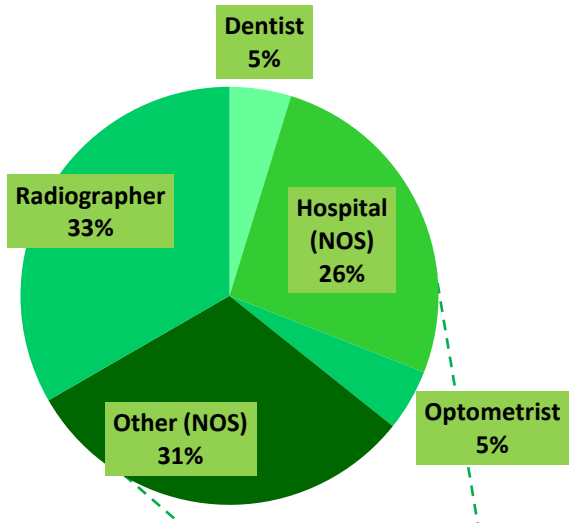


Figure 5c – Percentage of reports for reporter types categorised as 'other healthcare professionals'

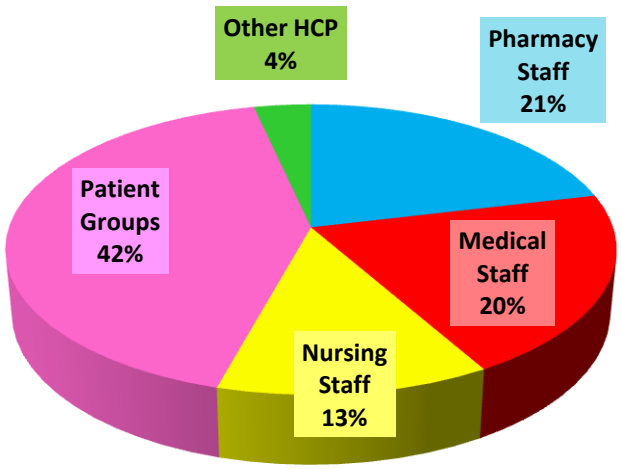


Figure 5a – Percentage of reports for the five primary reporter groups: patient; nursing; medical; pharmacy; and other

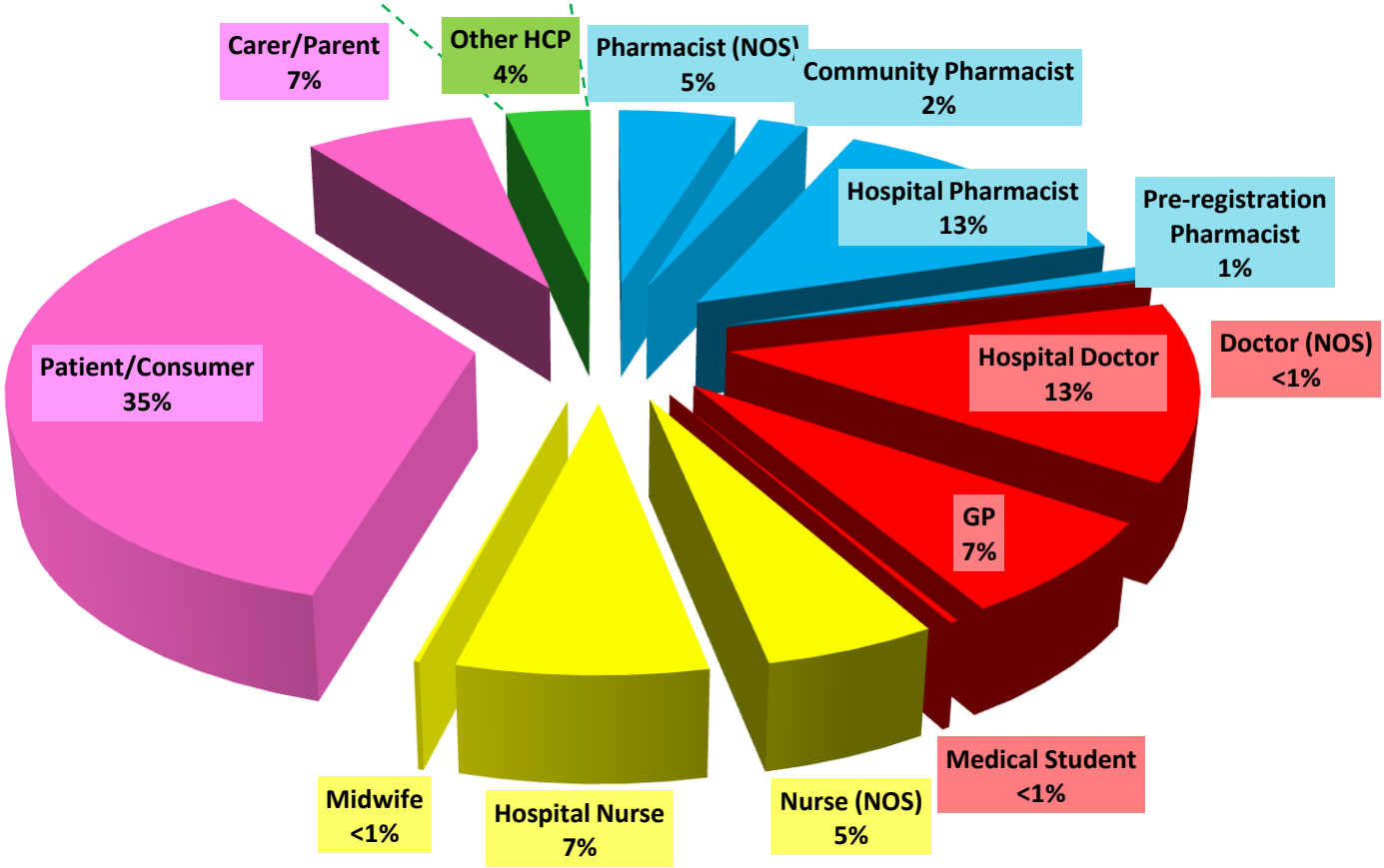


Figure 5b – Percentage of reports for individual reporter type, coloured to reflect the five primary reporter groups in Figure 5a

Table 2 - Reports from hospitals 2020/21 (Scotland)

Health Board Area	Total reports 2020/21	Hospital reports 2020/21	Hospital reports as a % of Board's total reports	
			2020/21	2019/20
NHS Ayrshire & Arran	67	20	30%	34%
NHS Borders	15	2	13%	36%
NHS Dumfries & Galloway	33	14	42%	36%
NHS Fife	75	18	24%	24%
NHS Forth Valley	53	14	26%	42%
NHS Grampian	94	32	34%	27%
NHS Greater Glasgow & Clyde	267	121	45%	42%
NHS Highland	107	26	24%	32%
NHS Lanarkshire	112	47	42%	24%
NHS Lothian	255	81	32%	36%
NHS Orkney	4	0	0%	20%
NHS Shetland	0	0	0%	0%
NHS Tayside	111	41	37%	49%
NHS Western Isles	10	4	40%	0%
Total (Scotland)	**1203**	**420**	**35%**	**36%**

Table 2 shows the number of reports submitted by each health board, and the number, and proportion, which originated from hospitals in each health board.

NHS hospitals this year accounted for 35% of all reports in Scotland. This figure is largely unchanged compared to the previous year.

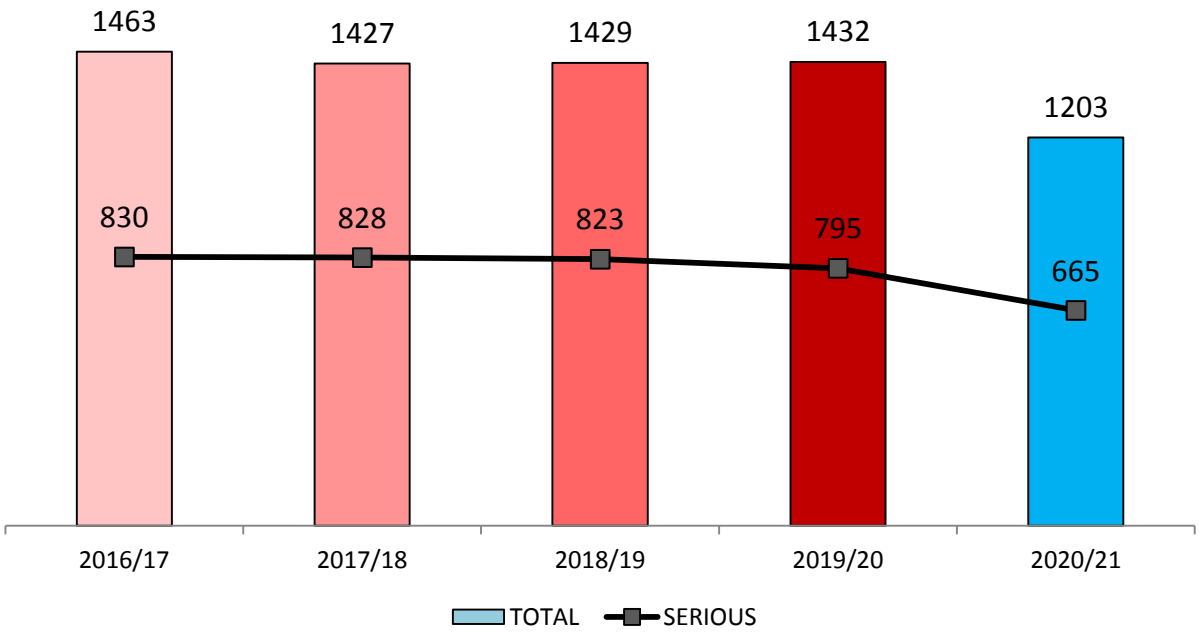
3c Serious Reports

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%
2017/18	828	58%	0%
2018/19	823	58%	-1%
2019/20	795	55%	-4%
2020/21	**665**	**55%**	**-16%**

Table 3 and Figure 6 show the number, and proportion of reports classed as serious that originated from Scotland in 2020/21, and the trend over the last 5 years. A fatal outcome was reported in **33** Yellow Card reports in 2020/21.

Figure 6 - Serious reports as a proportion of total reports from Scotland 2016/17 to 2020/21



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	0%
2017/18	95	+34%
2018/19	78	-18%
2019/20	42	-46%
2020/21	**33**	**-21%**

• It is important to note that suspected adverse drug reactions do not necessarily have an established causal link between the suspect medicines and the fatal outcome.

3e Age Banding (Scotland)

Tables 5 to 7 and Figure 7 show the number of Yellow Cards reported in Scotland, stratified by the patient's age, for the past 3 years.

Table 5 - Age Banding Reports Scotland 2017/18 to 2019/20

Age Banding	Reports 2018/19	Reports 2019/20	Reports 2020/21
Unknown	53	47	38
Under 2 years	37	46	56
2–6 years	43	53	31
7–12 years	33	37	19
13–17 years	49	42	42
18–24 years	87	116	84
25–34 years	133	167	158
35–44 years	157	158	130
45–54 years	190	182	150
55–64 years	207	190	155
65–74 years	241	210	188
75+ years	199	184	152
TOTAL	**1429**	**1432**	**1203**

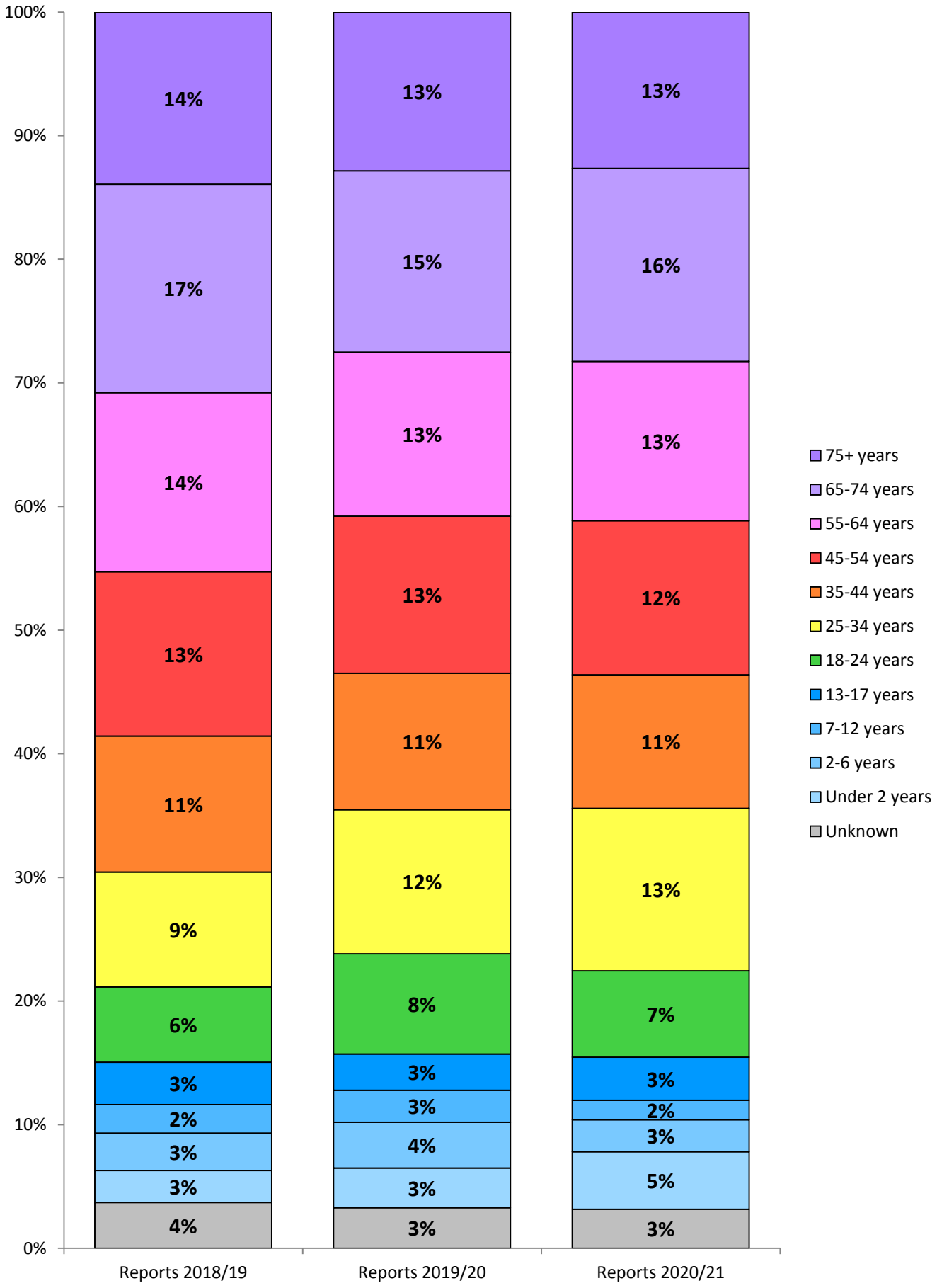
Table 6 - Age Banding Paediatric Reports Scotland 2020/21

Age Range	Number of Paediatric Yellow Card Reports	% of Paediatric Yellow Card Reports
Children (0–11 months)	40	27%
Children (12–23 months)	16	11%
Children (2–11 years)	45	30%
Adolescents (12–17 years)	47	32%
TOTAL	**148**	

Table 7 - Age Banding over 65 years Reports Scotland 2020/21

Age Range	Number of over 65 yrs Yellow Card Reports	% of over 65yrs Yellow Card Reports
65–74 years	188	56%
75–84 years	118	34%
85–94 years	30	9%
95+ years	4	1%
TOTAL	**340**	

Figure 7 - The percentage of Yellow Card reports from Scotland, stratified by age group (2018/19 to 2020/21)



3f Top 10 Suspected Medicines

Table 8 - Scottish top ten suspected medicines reported 2019/20 & 2020/21

	2019/20		2020/21	
Rank	**Drug Name**	**Reports**	**Drug Name**	**Reports**
1	Influenza Vaccine* (Inactivated ▼/Intranasal)	81	Influenza Vaccine	104
2	Glatiramer	32	Ivacaftor containing regimen Orkambi▼ (n=1) Symkevi▼ (n=8) Kaftrio▼ (n=37)	46
3	Edoxaban ▼	31	=Rotavirus Vaccine =Sertraline	27
4	Adalimumab ▼	26	—	
5	MMR Vaccine	25	Edoxaban	22
6	Doxycycline	21	Adalimumab Amgevita ▼ Imraldi ▼ Humira Adalimumab (brand unspecified)	21
7	=Empagliflozin ▼ =Sertraline	20	Flucloxacillin	18
8	—	-	MMR Vaccine	15
9	HPV Vaccine	17	=Amoxicillin =Doxycycline	13
10	=Trimethoprim =Clarithromycin =Pneumococcal Vaccine	16	—	

Table 9 - Top Five Medicines reported for paediatrics and aged 65+ in 2020/21 (Scotland)

Top reported medicines for paediatrics and over 65yrs 2019/20		
	Paediatrics	**Over 65 yrs**
1	Rotavirus Vaccine	Influenza Vaccine
2	Influenza Vaccine	Edoxaban
3	MMR Vaccine	Nitrofurantoin
4	Meningococcal B Vaccines	Flucloxacillin
5	Diphtheria/Tetanus/Pertussis/Hepatitis B/Poliomyelitis/Haemophilus Influenzae Vaccine	Apixaban

Notes
▼ Black triangle status (medicines subject to additional monitoring) at time of report – in some case this is brand specific

3g Sources of Reports

Table 10 – Detail for Scottish reports stratified by reporter over last 3 years

Reporter	2018/19		2019/20		2020/21	
	Number	% of total	Number	% of total	Number	% of total
Carer	16	1%	22	2%	20	2%
Consumer	2	<1%	3	<1%	1	<1%
Parent	81	6%	73	5%	64	5%
Patient	378	27%	406	28%	423	35%
Community Pharmacist	59	4%	62	4%	25	2%
Hospital Pharmacist	136	10%	164	12%	161	13%
Pharmacist	65	5%	66	5%	57	5%
Pharmacy Assistant	20	1%	8	<1%	-	-
Pre-reg pharmacist	6	<1%	13	1%	12	1%
Hospital Nurse	121	9%	131	9%	88	7%
Nurse	81	6%	73	5%	62	5%
GP	166	12%	143	10%	85	7%
Hospital Doctor	234	16%	195	14%	157	13%
Physician	7	1%	0	0%	1	<1%
Coroner	-	-	-	-	-	-
Paramedic	-	-	1	<1%	-	-
Dentist	3	<1%	5	<1%	2	<1%
Midwife	3	<1%	3	<1%	2	<1%
Optometrist	3	<1%	5	<1%	2	<1%
Chiropodist	-	-	4	<1%	-	-
Radiographer	14	1%	8	<1%	14	1%
Hospital Healthcare Professional	16	1%	20	1%	11	1%
Healthcare Assistant	3	<1%	1	<1%	-	-
Other Healthcare Professional	13	1%	23	2%	13	1%
Medical Student	2	<1%	3	<1%	3	<1%
Unknown	-	-	-	-	-	-
Total	**1429**		**1432**		**1203**	

3h Types of reports (Scotland)

Table 11 - Report submission routes

Report Type	2019/20		2020/21	
	Number	% of total	Number	% of total
App	11	1%	59	5%
Electronic Yellow Card	1184	83%	992	82%
MiDatabank (Pharmacy Medicines Information)	53	4%	41	3%
Paper	123	9%	56	5%
Vision (GP system)	58	4%	55	5%

Table 11 shows the ways in which our reporters submitted Yellow Cards in 2020/21.

4. Discussion of Yellow Card Data

Excluding COVID-19 vaccine reports, a total of 1,203 Yellow Card reports were submitted in Scotland in 2020/21, representing a 16% decline in reporting compared to the previous year. As this excludes the vast majority (90%) of Yellow Card reports submitted in Scotland this year, any trends highlighted in this report should be interpreted in this context. Taking into account the additional 10,948 COVID-19 vaccine reports, overall reporting in Scotland has increased 750%, compared to the previous year. Refer to Appendix 1: COVID-19 Yellow Card Reports Scotland 2020/21, for information on the COVID-19 vaccine reports. Unless otherwise indicated, trends highlighted below relate only to non COVID-19 reports.

Reporter Groups trends:

- **Patient groups:** Reporting by patient groups has increased again, representing 42% of all (non COVID-19 related) reports in Scotland, and 75% of all COVID-19 vaccine reports, highlighting an increase in public awareness of the scheme.
- **Healthcare professionals:** Reporting by healthcare professionals (HCPs) has declined across all reporter groups (excluding COVID-19 vaccine reports). Taking into account the additional 2,798 reports from HCPs in relation to the COVID-19 vaccines, reporting from health care professionals has dramatically increased overall. A notable trend in relation to the COVID-19 vaccine reports, is the relatively high proportion of reports from nursing staff and other HCPs (presumably from vaccinators/ vaccination teams).

Health board trends:

- **Top 3 reporting health boards (per 100,000 population):** NHS Western Isles, NHS Highland and NHS Lothian.
- **Notable increase:** NHS Lanarkshire

Suspect Medicines;

- **Top 10:** Notable changes include the appearance of the new cystic fibrosis drugs including Kaftrio (ivacaftor/tezacaftor/elexacaftor), Orkambi (ivacaftor/lumacaftor) and Symkevi (ivacaftor/tezacaftor) in combination with Kalydeco (ivacaftor). Collectively these are the highest reported suspect medicines excluding vaccines.
- **Kaftrio (ivacaftor/tezacaftor/elexacaftor):** this medicine is a newly marketed medicine which is subject to additional monitoring under the Black Triangle scheme. 97% of reports came from pharmacists, with 94% stating that they were hospital pharmacists. The reactions reported were varied and most were not considered to be serious.
- **Adalimumab:** Reports for adalimumab were mostly from hospital doctors or nurses. Similar to last year, a number of reports included multiple reactions – these were diverse, although skin reactions and injection site reactions were common themes.
- **Paediatrics:** vaccines are still the most commonly reported suspect medicines, as in previous years.
- **Over 65 years:** Excluding vaccines, edoxaban was the most commonly reported suspect medicine. No notable trends were highlighted.

Serious ADRS:

- 665 reports were classed as serious (55% of total), a similar proportion of the total as to previous years.

- **Fatal:** a fatal outcome was reported in 33 reports*. Due to the small number of reports and diversity

• It is important to note that suspected adverse drug reactions do not necessarily have an established causal link between the suspect medicines and the fatal outcome.

5. Promotional activities

5a Training delivered to healthcare professionals and their respective groups

NES/YCCS ADR e-learning modules

The NES/YCCS ADR modules were transferred to a new platform on *Turas Learn* and statistics for the year 2020/21 were not available as a result of this transfer.

Table 12 - Training delivered to healthcare professionals and their respective groups

Audience	Session	Duration (hours)	No of sessions	Total attendees	Total hours Training
Non-Medical Prescriber Students (2xQMU, 1x Aberdeen)	Virtual training session on ADRs and YCCS	2	3	~250	6
Non-Medical Prescriber Students (Napier)	Recorded training session on ADRs and YCCS	0.75	1	N/K	0.75
Ad hoc requests for help reporting	Advice provided for Yellow Card reporting	0.5	2	3+	1
MSc Internal Medicines Students*	Pre-recorded lectures provided*	1*	2*	100*	2*
MSc Internal Medicines Students	Tutorials on ADRs	1	2	70	2
MSc Internal Medicines Students	Toxicology teaching	1	1	100	1
Healthcare Professionals*	YCCS virtual waiting room for conference *	4*	3*	N/K*	1.5*
Healthcare Workers*	NHS Scotland health board areas contacted to promote Yellow Card Scheme*	0.25*	12*	N/K*	3*
Nurse Prescribers	ADR Teaching Session	1	2	90	2
Totals					

*Indirect through provision of slides and/or other training material

5b Training delivered to patients and their respective groups

Table 13 - Patient Group Engagement

Audience	Session type	Duration (hours)	Number of sessions	Audience numbers	Total staff hours
Patient	Telephone query about ADR	0.25	4	4	1
Patient	Telephone query about ADR, where further action required	0.5	8	8	4
Patient	Email query about ADR	0.5	3	3	1.5
GP Patients	Email correspondence with NHS Near Me	0.25	4	N/K	1

Although direct engagement with patients has not been possible during 2020/21 due to the restrictions imposed by the COVID-19 pandemic, YCCS has seen an increase in the number of direct queries from patients, which have been answered and actioned appropriately by YCCS staff members.

5c Training delivered to undergraduates

Table 14 - Training delivered to Undergraduates

Audience	Session	Duration (hours)	No of sessions	Total attendees	Total hours
Medical Students	Virtual ADR training session	1	1	260	1
Pharmacy Students (RGU)	Recorded pharmacovigilance training session	1	1	100	1
Pharmacy Students (RGU)	Brief discussion of YCCS as part of virtual placements	0.25	1	180	0.25
Podiatry Students	Virtual training session on ADRs and YCCS	1.5	1	34	1.5
Total					

5d Materials developed for YCS promotion

Throughout the COVID-19 pandemic YCCS has provided a number of promotional and informational materials for the Yellow Card Scheme to healthcare professionals and students across Scotland. Materials were provided to universities and primary care sites, and communications teams for all health board areas across Scotland were contacted to promote the Yellow Card Scheme and the Yellow Card Biobank.

6. Publications

- Azithromycin in patients admitted to hospital with COVID-19 (RECOVERY): a randomised, controlled, open-label, platform trial.
  RECOVERY Collaborative Group. Lancet. 2021 Feb 13;397(10274):605-612.

- Activated neutrophil fluorescent imaging technique for human lungs.
  Craven TH, Walton T, Akram AR, Scholefield E, McDonald N, Marshall ADL, Humphries DC, Mills B, Campbell TA, Bruce A, Mair J, Dear JW, Newby DE, Hill AT, Walsh TS, Haslett C, Dhaliwal K. Sci Rep. 2021 Jan 13;11(1):976.

- Circulating argonaute-bound microRNA-126 reports vascular dysfunction and treatment response in acute and chronic kidney disease.
  Scullion KM, Vliegenthart ADB, Rivoli L, Oosthuyzen W, Farrah TE, Czopek A, Webb DJ, Hunter RW, Bailey MA, Dhaun N, Dear JW. iScience. 2020 Dec 13;24(1):101937.

- MicroRNA-122 and cytokeratin-18 have potential as a biomarkers of drug-induced liver injury in European and African patients on treatment for mycobacterial infection.
  Rupprechter SAE, Sloan DJ, Oosthuyzen W, Bachmann TT, Hill AT, Dhaliwal K, Templeton K, Matovu J, Sekaggya-Wiltshire C, Dear JW. Br J Clin Pharmacol. 2021 Aug;87(8):3206-3217.

- Transfer of hepatocellular microRNA regulates cytochrome P450 2E1 in renal tubular cells.
  Matthews O, Morrison EE, Tranter JD, Starkey Lewis P, Toor IS, Srivastava A, Sargeant R, Rollison H, Matchett KP, Kendall TJ, Gray GA, Goldring C, Park K, Denby L, Dhaun N, Bailey MA, Henderson NC, Williams D, Dear JW. EBioMedicine. 2020 Dec;62:103092.

- Long-term cardiovascular safety of febuxostat compared with allopurinol in patients with gout (FAST): a multicentre, prospective, randomised, open-label, non-inferiority trial.
  Mackenzie IS, Ford I, Nuki G, Hallas J, Hawkey CJ, Webster J, Ralston SH, Walters M, Robertson M, De Caterina R, Findlay E, Perez-Ruiz F, McMurray JJV, MacDonald TM; FAST Study Group. Lancet. 2020 Nov 28;396(10264):1745-1757.

- A case of ingestion of two vape cartridges.
  Osinski K, Ross H, Clarke L, Dear J, Veiraiah A. Clin Toxicol (Phila). 2021 Jul;59(7):674-675

- Effect of Hydroxychloroquine in Hospitalized Patients with COVID-19.
  RECOVERY Collaborative Group, Horby P, Mafham M, Linsell L, Bell JL, Staplin N, Emberson JR, Wiselka M, Ustianowski A, Elmahi E, Prudon B, Whitehouse T, Felton T, Williams J, Faccenda J, Underwood J, Baillie JK, Chappell LC, Faust SN, Jaki T, Jeffery K, Lim WS, Montgomery A, Rowan K, Tarning J, Watson JA, White NJ, Juszczak E, Haynes R, Landray MJ. N Engl J Med. 2020 Nov 19;383(21):2030-2040.

- Amplification-free profiling of microRNA-122 biomarker in DILI patient serums, using the luminex MAGPIX system.
  Marín-Romero A, Tabraue-Chávez M, Dear JW, Sánchez-Martín RM, Ilyine H, Guardia-Monteagudo JJ, Fara MA, López-Delgado FJ, Díaz-Mochón JJ, Pernagallo S. Talanta. 2020 Nov 1;219:121265.

- Dexamethasone in Hospitalized Patients with COVID-19.
  RECOVERY Collaborative Group, Horby P, Lim WS, Emberson JR, Mafham M, Bell JL, Linsell L, Staplin N, Brightling C, Ustianowski A, Elmahi E, Prudon B, Green C, Felton T, Chadwick D, Rege K, Fegan C, Chappell LC, Faust SN, Jaki T, Jeffery K, Montgomery A, Rowan K, Juszczak E, Baillie JK, Haynes R, Landray MJ. N Engl J Med. 2021 Feb 25;384(8):693-704.

- Comment on Fomepizole as an adjunctive treatment in severe acetaminophen ingestions.
  Bateman DN, Dear JW, Eddleston M, Vale JA. Clin Toxicol (Phila). 2021 Jan;59(1):81-82.

- Absolute measurement of the tissue origins of cell-free DNA in the healthy state and following paracetamol overdose.
  Laurent D, Semple F, Starkey Lewis PJ, Rose E, Black HA, Coe J, Forbes SJ, Arends MJ, Dear JW, Aitman TJ. BMC Med Genomics. 2020 Apr 6;13(1):60.

- Endothelin-1 Mediates the Systemic and Renal Hemodynamic Effects of GPR81 Activation.
  Jones NK, Stewart K, Czopek A, Menzies RI, Thomson A, Moran CM, Cairns C, Conway BR, Denby L, Livingstone DEW, Wiseman J, Hadoke PW, Webb DJ, Dhaun N, Dear JW, Mullins JJ, Bailey MA. Hypertension. 2020 May;75(5):1213-1222.

- Functionality of primary hepatic non-parenchymal cells in a 3D spheroid model and contribution to acetaminophen hepatotoxicity.
  Bell CC, Chouhan B, Andersson LC, Andersson H, Dear JW, Williams DP, Söderberg M. Arch Toxicol. 2020 Apr;94(4):1251-1263.

7. YCC Website/Social Media

7a Website updates

The previous Sharepoint host platform for our YCCS Website was discontinued in late 2020 and the website was fully migrated to a new platform hosted by Scottish Health on the Web (SHOW) in June 2020. This migration prompted a refresh of the website, which we performed using the content management software WordPress.

7b Website/Social Media Statistics

Website

Table 15 - Comparison of website hits 2019/20 to 2020/21

	2019/20	2020/21	% change 2019/20 to 2020/21
Total Number of Daily Unique Visitors	108	UNKNOWN	UNKNOWN
Total Number of Page Views	1,122	UNKNOWN	UNKNOWN

Due to the transfer of the website to the new SHOW platform, we have been unable to obtain analytic data for the year 2020/21. A plugin has been installed on the website that will generate this data for future years.

Twitter

Table 16 - Twitter analytics Apr-March 2018/19 to 2020/21

	2018/19	2019/20	2020/21	% change 2019/20 to 2020/21
Number of Followers	1032	1236	1366	+10%
Tweets sent	244	238	98	-59%
Total number of Engagements*	2,612	1,880	713	-62%
Impressions**	270,200	225,600	77110	-66%

*Engagements are when a follower interacted with a tweet

**Impressions are the number of tweets delivered to twitter feeds

In 2020/21, our Twitter account @YCCScotland continued to gain new followers, reaching over 1,350 by the end of March 2021. Our activity on social media declined in 2020/21 due to more urgent pressures surrounding the COVID-19 pandemic, though YCC Scotland still made efforts to engage with social media posts from the MHRA and other healthcare organisations, especially around the COVID-19 vaccination program.

8. Research and ongoing initiatives

Research and new initiatives have been largely on hold during the pandemic. A few things to note for the year 2020/2021;

- Remote teaching and promotion: Due to the COVID-19 situation, face-to-face teaching sessions have mostly moved to a virtual platform. Online training resources and recorded presentations were developed and provided to higher education institutions across Scotland for virtual learning around the Yellow Card Scheme and adverse drug reactions throughout 2020/21.

- NES/YCCS ADR Modules: The ADR eLearning modules produced by YCCS in collaboration with NHS Educaiton for Scotland (NES) have been transferred to a new location on the NES digital Turas platform. This new platform will provide improved functionality and accessibility of the modules, and will allow for an easier and quicker update process of the modules going forward.

- Hospital radio: Scheduled interviews were postponed due to the COVID-19 pandemic, but it is hoped that we will be able to pick these up again moving forward.

- Advisory Group; We had a restructure of our Advisory Group, with new Chair Yvonne Semple (Director of Pharmacy, Golden Jubilee Hospital) joining in January 2021. Meetings were postponed during 2020, but resumed in January 2021.

9. Conclusion

Given the COVID-19 pandemic and resulting pressures on healthcare professionals during 2020/2021, it is not surprising that non-coronavirus related Yellow Card reporting has declined. A decline in reporting is evident across all health care professional reporting groups. However, this was offset by a surge in reports in relation to the new COVID-19 vacines – collectively, reporting increased by 750% compared to the previous year.

The patient group, consisting of patients, parents, and carers, remains the highest reporting group in Scotland and accounts for 42% of the total reports for 2020/21, compared to 35% in 2019/20. As a result of the UK COVID-19 vaccination program, YCC Scotland saw an increased number of calls to our advice line, mostly from patients asking about side-effects to the COVID-19 vaccine, as well as increased engagement from members of the public on our social media account.

The challenge going forward will be in maintaining reporting of suspected adverse drug reactions in relation to other medicines and vaccines, however a raised awareness of the MHRA and Yellow Card Scheme in general should hopefully provide opportunity for this.

10. Acknowledgements

YCC Scotland would like to acknowledge the following individuals for their help and support throughout 2020/21:

Scottish Government Chief Pharmaceutical Officer (CPO)

- Rose Marie Parr (CPO up to 1st October 2020)
- Alison Strath (Interim CPO from 1st October 2020)

Yellow Card Centre Scotland Advisory Group

- Yvonne Semple, Director of Pharmacy, Golden Jubiulee National Hosptial (**Chair**)
- Karen Harkness, Principal Medicines Information Pharmacist, NHS Tayside
- Scott Hill, Area Drug and Therapeutics Committee Collaborative National Clinical Lead
- Susan McGilp, Incident Reporting & Investigation Centre (IRIC) Co-ordinator
- Professor Tom MacDonald, Professor of Clinical Pharmacology & Pharmacoepidemiology, University of Dundee
- Professor James McLay, Senior Lecturer in Clinical Pharmacology and Therapeutics, University of Aberdeen
- Jane Harris, Programme Director for Nursing and Midwifery, NHS Education for Scotland
- Leon Zlotos, Principal Lead for Professional Development, NHS Education for Scotland
- Sue Cole, Patient Representative

Abbreviations

YCCS	Yellow Card Centre Scotland
YC	Yellow Card
ADR	Adverse Drug Reaction
HCP	Healthcare Professional
ADTC	Area Drug & Therapeutics Committee
NES	NHS Education for Scotland
eKSF	Electronic Knowledge for Skills Framework
UG/PG	Undergraduate/Postgraduate
MHRA	Medicines and Healthcare Products Regulatory Agency

Yellow Card Centre Scotland

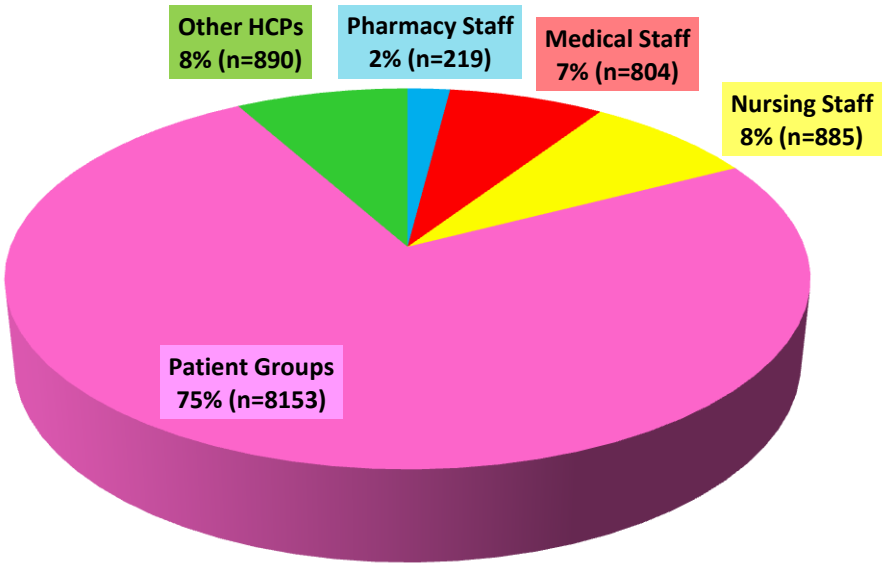
Appendix 1: COVID-19 Yellow Card Reports Scotland 2020/21

COVID-19 Vaccine Yellow Card Reports in Scotland (December 2020 to March 2021)

10948 COVID-19 vaccine reports =90% of all Yellow Card reports in Scotland for 2020/21

Reports submitted to the Yellow Card Scheme are for suspected adverse reactions that have not been proven to be related to the drug, and should not be interpreted as known side-effects

COVID-19 Vaccine Reporting by Reporter Group



Reporter Group	Reports
DOCTOR (GP)	568
DOCTOR (HOSPITAL)	186
DOCTOR (PHYSICIAN)	7
MEDICAL STUDENT	43
HCP (CHIROPODIST)	2
HCP (DENTIST)	41
HCP (HEALTHCARE ASSISTANT)	242
HCP (HOSPITAL)	83
HCP (OPTOMETRIST)	18
HCP (OTHER)	426
HCP (PARAMEDIC)	55
HCP (RADIOGRAPHER)	23
NURSE	625
NURSE (HOSPITAL)	228
NURSE (MIDWIFE)	32
PATIENT	6957
PATIENT (CARER)	175
PATIENT (CONSUMER)	635
PATIENT (PARENT)	386
PHARMACIST	105
PHARMACIST (COMMUNITY)	34
PHARMACIST (HOSPITAL)	18
PHARMACIST (PRE-REG)	6
PHARMACY ASSISTANT	56
UNKNOWN	0
Total	**10951***

*__NOTE__: the total for reporter groups ≠ 10948 because some reports have more than one reporter

Top Suspected Reactions Reported in COVID-19 Vaccines Yellow Cards

The most frequently reported reactions were all reactogenic type events, such as **headache** (n=2950), **pyrexia** (n=2451), **fatigue** (n=1956), **chills** (n=1748), and **nausea** (n=1434). This is generally consistent with the most frequent adverse reactions reported in clinical trials. A weekly report covering adverse reactions to approved COVID-19 vaccines is available via https://www.gov.uk/government/publications/coronavirus-covid-19-vaccine-adverse-reactions/coronavirus-vaccine-summary-of-yellow-card-reporting