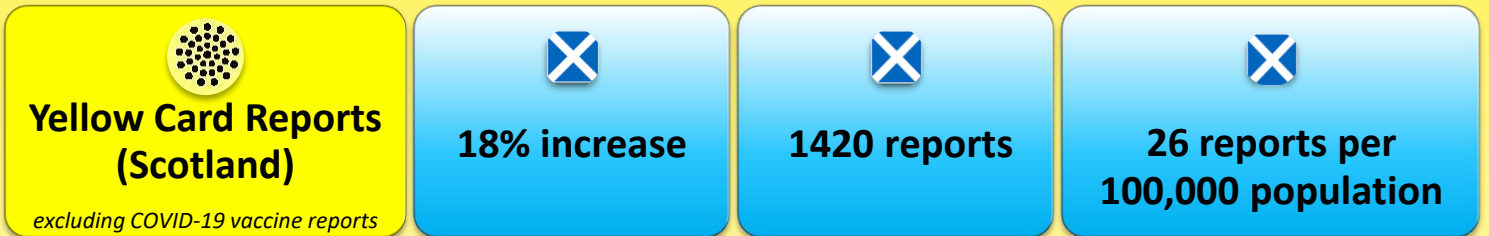


Annual Report April 2021 to March 2022



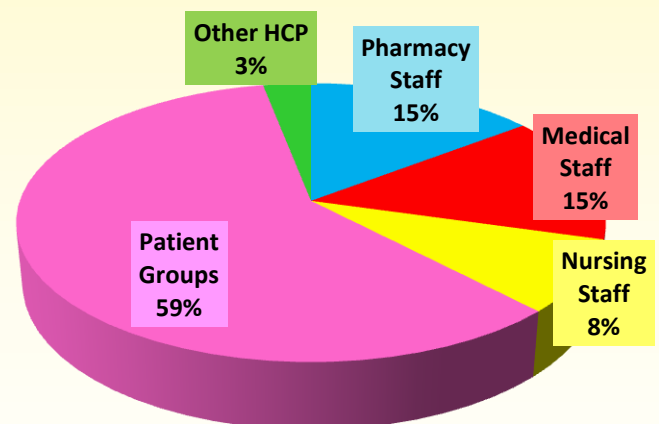
Reports submitted to the Yellow Card Scheme are for suspected adverse reactions that have not been proven to be related to the drug, and should not be interpreted as known side-effects



COVID-19 Vaccine 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 monthly summary of Yellow Card reporting is available on the MHRA website.

Source of Non-COVID-19 Reports



Top Reported Medicines (Excluding Covid-19 vaccines)

INFLUENZA VACCINE

NIRMATRELVIR/
RITONAVIR

IVACAFTOR containing medicines

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

2021–2022

1. Team

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

2. Executive Summary

The impact of the COVID-19 pandemic on Yellow Card reporting, and the activities of the Yellow Card Centre (YCC) for Scotland continued throughout 2021/2022. Similar to the previous year, the majority of Yellow card reports in Scotland during 2021/2022 were for COVID-19 vaccines (representing 94% of the total), the suspension of face-to-face activities continued, and teaching remained online. As we enter a new phase of the pandemic, adjusting to living with COVID-19, we look forward to resuming activities in the year ahead.

Excluding COVID-19 vaccine reports, a total of 1,420 Yellow Card reports were submitted in Scotland in 2021/22, representing an 18% increase in reporting compared to the previous year. This figure is comparable to pre-pandemic reporting levels, which is encouraging. In 2021/22 an additional 22,018 reports were submitted in Scotland for the COVID-19 vaccines, almost twice the number submitted in 2020/21 (10,948). This contributed to a further 92% increase in total reports compared to 2020/21 (which had already increased 750% from the previous pre-pandemic year). This remarkable response was largely attributable to patient reporting – reporting has declined across all healthcare professions.

Covid-19 vaccine data continues to be handled and reported separately by the Medicines and Healthcare products Regulatory Agency (MHRA). Consequently, the COVID-19 vaccine reports are not detailed in the main body of this annual report. As this excludes the vast majority (94%) of Yellow Card reports submitted in Scotland this year, any trends highlighted in this report should be interpreted in this context. A brief summary of COVID-19 vaccine reports (Scotland) is included in Appendix 1.

Notably, the end of 2022 will mark an important milestone for the Yellow Card Centre Scotland – 20 years since the Centre was established, largely through the efforts of Professor Nick Bateman, Professor Norman Lannigan and Dr Bill Scott (Chief Pharmaceutical Officer). The Yellow Card (YC) scheme has evolved since then, with expansion of the platform to include medical device incidents, suspected adverse reactions to defective or falsified (fake) medicines and e-cigarettes; patients report suspected side effects alongside healthcare professionals; and “Yellow Cards” (paper reports) have been largely replaced by electronic reports. Anyone can view “what is being reported” via the website (<https://yellowcard.mhra.gov.uk/idaps>), including suspected adverse reaction information on COVID-19 vaccines (<https://www.gov.uk/government/publications/coronavirus-covid-19-vaccine-adverse-reactions>).

Crucially, direct electronic Yellow Card (e-YC) reporting is now possible via a number of electronic clinical systems, however this is not currently widely available across systems in NHS Scotland (except *Vision*). The MHRA have since built an API (Application Programming Interface), and are in the process of transitioning from individual e-YC integration with third parties, to using APIs to perform this task. This will simplify integration with other electronic systems, e.g. HEPMA, and hopefully expedite progress in this very important area. In the meantime, we will continue to raise the profile of adverse drug reactions (ADRs) as an important safety and quality issue amongst both healthcare professionals in Scotland through the delivery of training and promotional activities, but we recognise these limitations.

We would like to take this opportunity to remind everyone in GP practices using *Vision*, that YC reports can be automatically populated with information from the *Allergy and Intolerance*

page, and submitted directly. Direct e-YC reporting is also available via Pharmacy Medicines Information systems (*MiDatabank*). Please reach out to us if you need any assistance with this – it really is quick and easy.

We also welcome Mr Scott Garden, NHS Lothian Director of Pharmacy and Medicine, to the team following the retiral of Professor Angela Timoney earlier this year.

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.

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 **1420 reports** of suspected adverse drug reactions were submitted from Scotland in 2021/22, representing an overall 18% increase compared to the previous year (2020/21).

There were **22,018 additional reports** of suspected adverse drug reactions in relation to the COVID-19 vaccines during 2021/2022. Combined, a **total of 23,438 reports** were submitted from Scotland, representing a doubling of reports compared to the previous 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
2017/18	1427	-2%
2018/19	1429	0%
2019/20	1432	0%
2020/21	1203	-16%
2021/22	1420	+18%

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

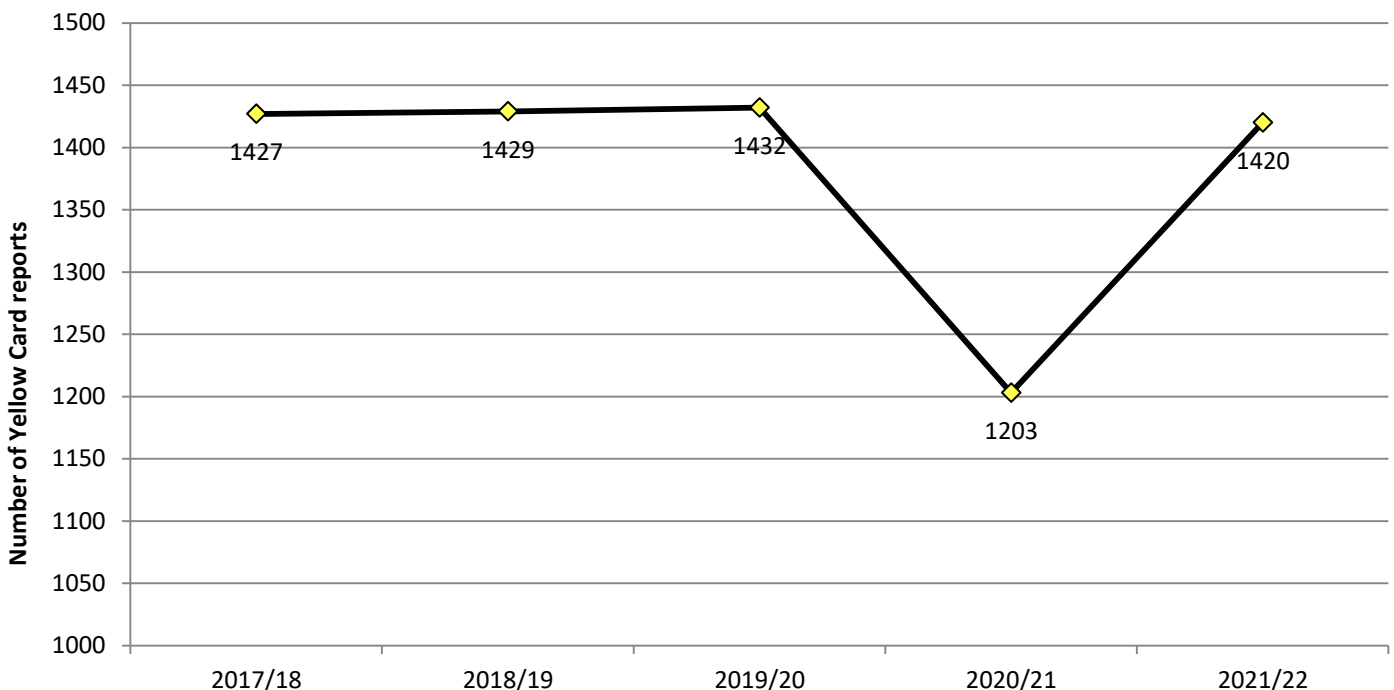
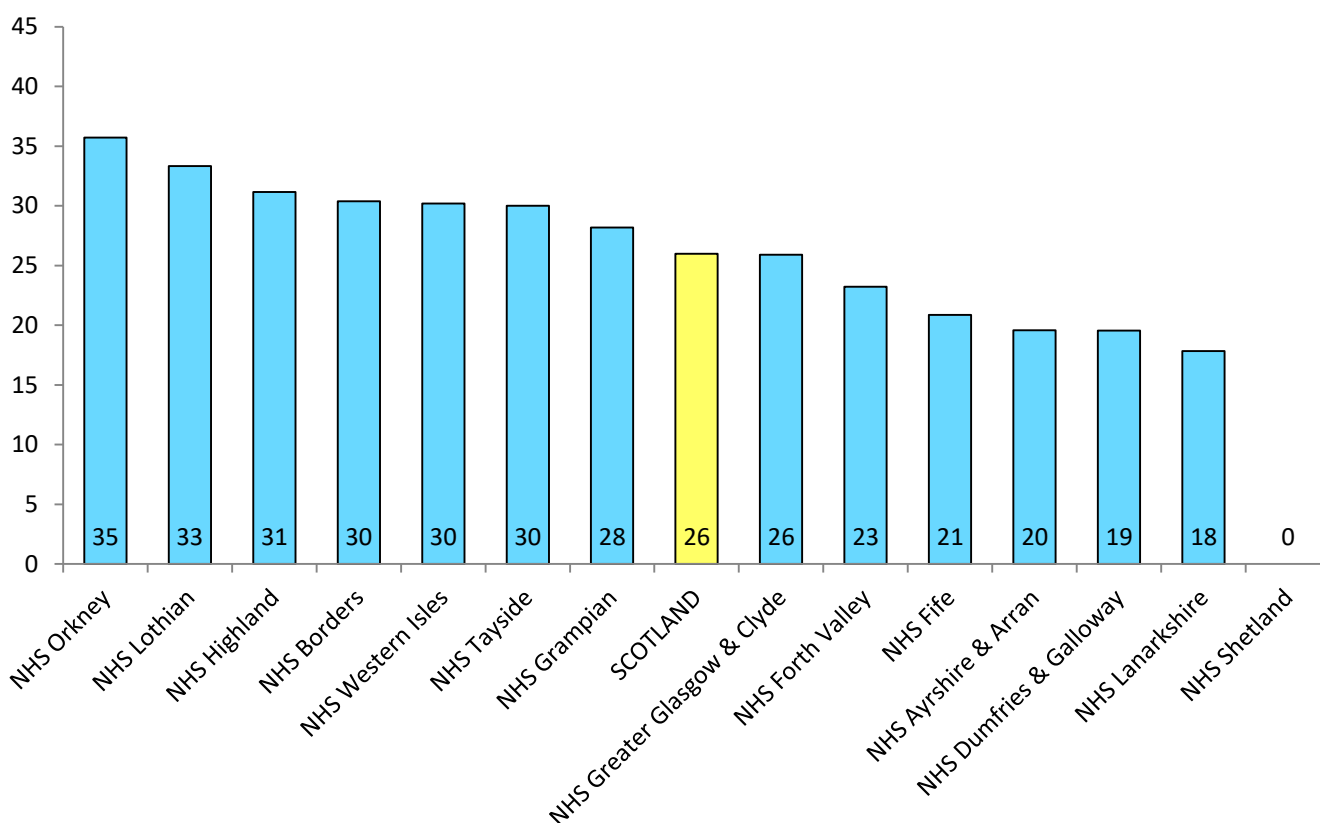


Figure 2 - Health Board Yellow Card Reporting per 100,000 population (Scotland 2021/22)



Statistics from National Registers of Scotland, Population estimates mid-2021* 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 26, compared to the previous year where this was 22.

The top 3 reporting health boards per 100,000 population in 2021/22 were NHS Orkney, NHS Lothian, and NHS Highland. Caution is necessary when interpreting these results due to the very low number of reports received from some of the NHS Scotland Health Boards, in particular for NHS Shetland, NHS Western Isles, and NHS Orkney.

Figure 3 – Number of Yellow Card Reports submitted over the last 5 years (top 5 reporting health boards in 2021/22)

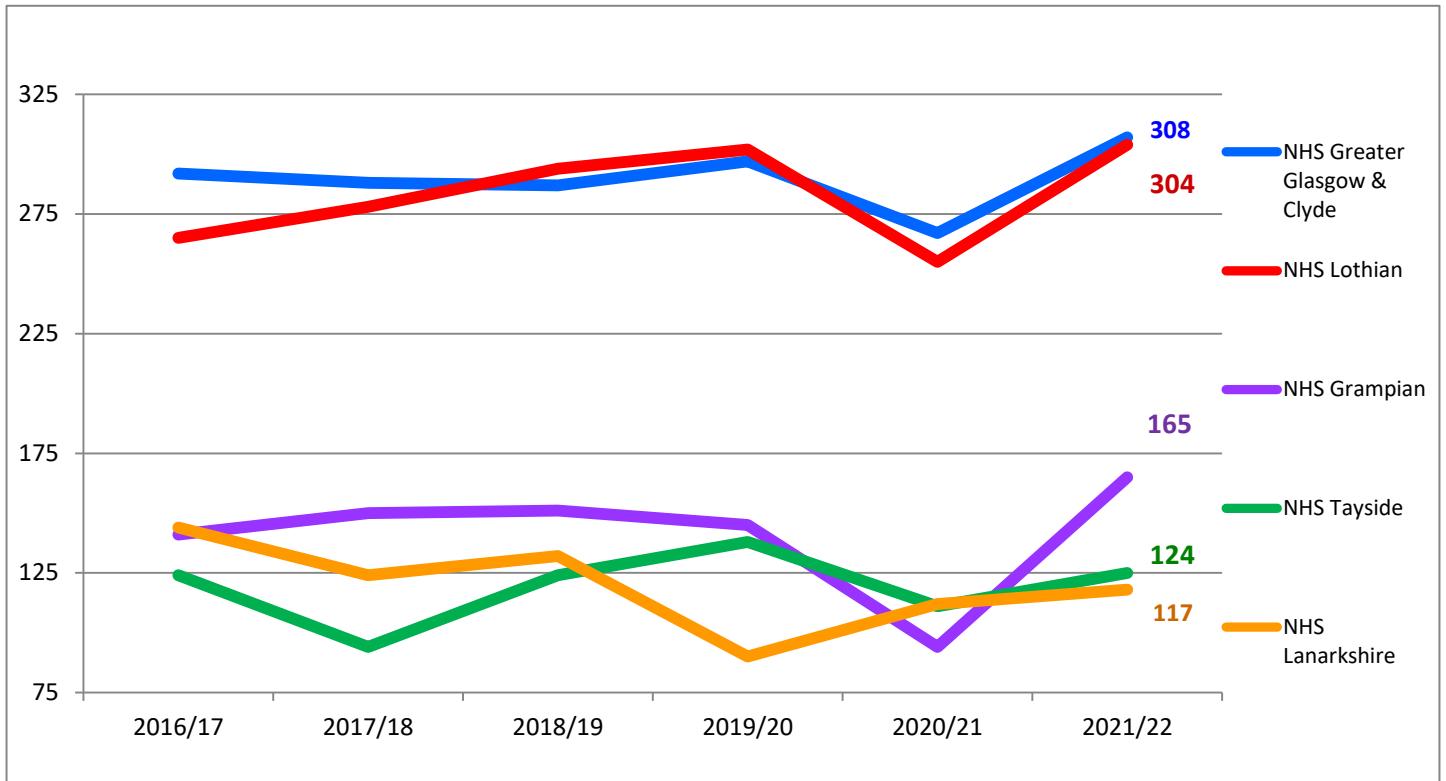


Figure 3 shows the 5 year trend in reporting for the five health boards that submitted the highest number of reports (total) in 2021/22. NHS Grampian have replaced NHS Highlands in the top 5, with NHS Lothian and NHS Greater Glasgow & Clyde remaining in the top 2 reporting health boards.

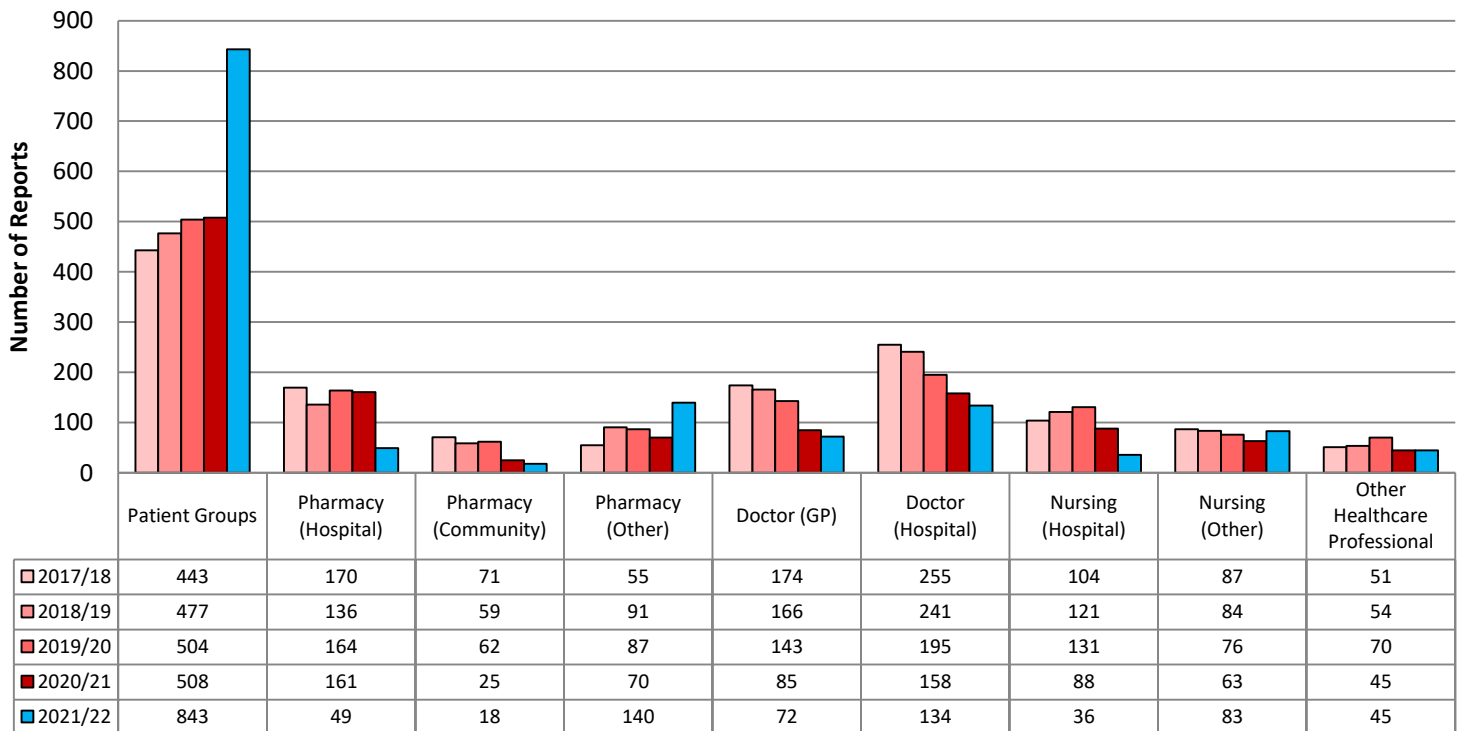
Overall reporting has improved in the majority of health boards in 2021/22 compared to the previous year, with NHS Borders showing the largest increase proportionally with an increase of +133% (this follows a decrease in the previous year, restoring reporting to previous levels). Substantial increases are evident in NHS Grampian (76%), NHS Forth Valley (34%) and NHS Lothian (19%).

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 over the last 5 years



Patient Groups: Patients; Parents; Parents; Consumers

Pharmacy Other: Not specified; Pharmacy Assistant/Technician; Trainee Pharmacist

Nursing Other: Not specified; Community; Midwife

Other Healthcare Professional: Chiroprapist; Optometrist; Healthcare Assistant; Radiographer; Paramedic; Dentist; Medical Student; Not specified; Not specified (hospital); Unknown

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

Healthcare Professionals (HCPs) accounted for 41% of the total reports in Scotland, representing a further significant decrease in the total number of reports, from 695 in 2020/21 to 577 in 2021/22. This represents a decline in reports from all healthcare professionals across all sectors, and in particular from hospital pharmacy. However, in the majority of reports by pharmacists, further details are unspecified by the reporter, so “other” will include pharmacists across all branches of pharmacy. Of note, trainee pharmacists accounted for 11% of all pharmacists reports. Similarly, this applies to nurse reports where the majority are further unspecified by the reporter, and so are included in “other”.

Patient groups, including reports from patients, parents, and carers, accounted for 59% of the total reports in Scotland, representing another considerable increase in the total number of reports, from 508 in 2020/21 to 843 in 2021/22 (66% increase).

A further breakdown of the “Other Healthcare Professional” reports is illustrated in Figure 5 – collectively these constitute 3% of all Scottish reports. These incorporate the professions which do not sit directly under the other primary categories of Medical, Nursing, Pharmacy, or Patient reports. Examples include dentists, radiographers and optometrists.

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

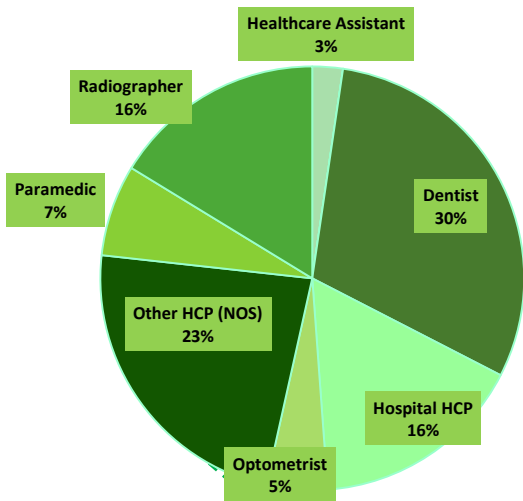


Figure 5c – Percentage of reports for reporter types categorised as ‘other healthcare professionals’

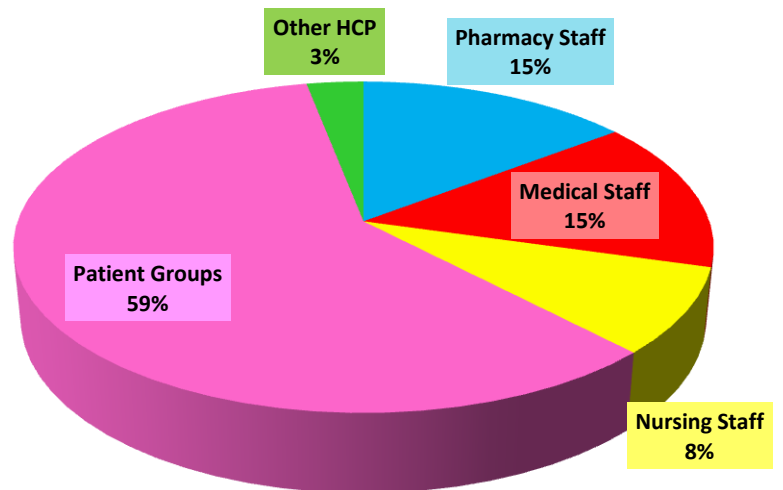


Figure 5a – Percentage of reports for the five primary reporter groups: patient; nursing; medical; pharmacy; and other

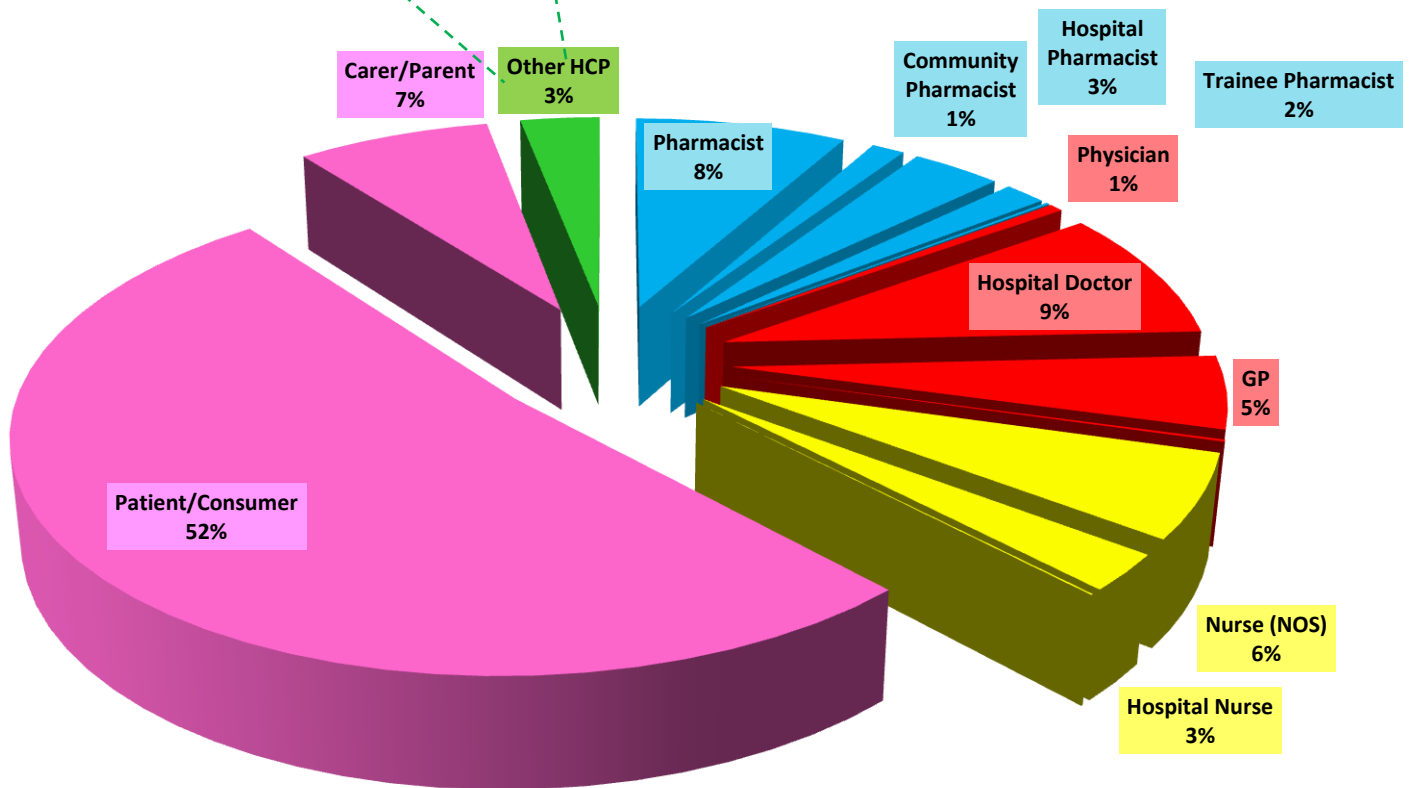


Figure 5b – Percentage of reports for individual reporter type, coloured to reflect the five primary reporter groups in Figure 5a

Figure 5b also includes reports of <1% total from Pharmacy Technicians/Assistants, Medical Students, and Midwives

Table 2 - Reports from hospital staff 2020/21 (Scotland)

Health Board Area	Total reports 2021/22	Hospital reports 2021/22	Hospital reports as a % of Board's total reports	
			2021/22	2020/21
NHS Ayrshire & Arran	72	11	15%	30%
NHS Borders	35	6	17%	13%
NHS Dumfries & Galloway	29	2	7%	42%
NHS Fife	79	12	15%	24%
NHS Forth Valley	71	6	8%	26%
NHS Grampian	165	12	7%	34%
NHS Greater Glasgow & Clyde	308	63	21%	45%
NHS Highland	100	22	22%	24%
NHS Lanarkshire	117	21	18%	42%
NHS Lothian	304	51	17%	32%
NHS Orkney	8	0	0%	0%
NHS Shetland	0	0	0%	0%
NHS Tayside	124	12	10%	35%
NHS Western Isles	8	1	13%	30%
Total (Scotland)	1420	219	15%	35%

Table 2 shows the number of reports submitted by each health board, and the number, and proportion, which originated from reporters who identified as hospital staff in each health board.

NHS hospital staff this year accounted for 15% of all reports in Scotland. This figure is quite significantly decreased compared to the previous year, and likely reflects known pressures across the NHS and the proportional increase in reporting from patient groups.

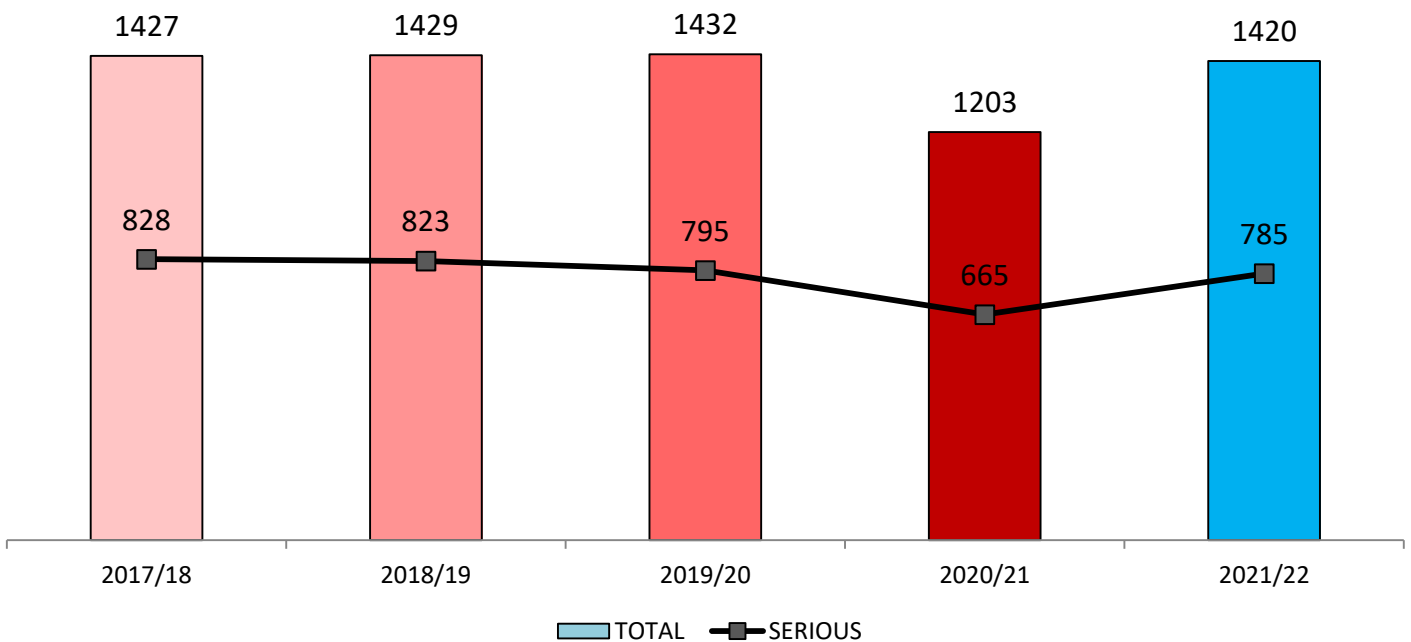
3c Serious Reports

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

Year	Number of serious reports	Percentage of total reports	Percentage change on previous year
2017/18	828	58%	+0%
2018/19	823	58%	-1%
2019/20	795	56%	-3%
2020/21	665	55%	-16%
2021/22	786	55%	+18%

Table 3 and Figure 6 show the number and proportion of reports classed as serious that originated from Scotland in 2021/22, and the trend over the last 5 years. A fatal outcome was reported in 29 Yellow Card reports in 2021/22.

Figure 6 - Serious reports as a proportion of total reports from Scotland over the last 5 years



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
2017/18	95	+34%
2018/19	78	-18%
2019/20	42	-46%
2020/21	33	-21%
2021/22	29	-12%

• 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 over the last 3 years

Age Banding	Reports 2021/22	Reports 2020/21	Reports 2019/20
Unknown	114	38	47
Under 2 years	35	56	46
2–6 years	28	31	53
7–12 years	30	19	37
13–17 years	51	42	42
18–24 years	113	84	116
25–34 years	192	158	167
35–44 years	160	130	158
45–54 years	194	150	182
55–64 years	207	155	190
65–74 years	173	188	210
75+ years	123	152	184
TOTAL	1420	1203	1432

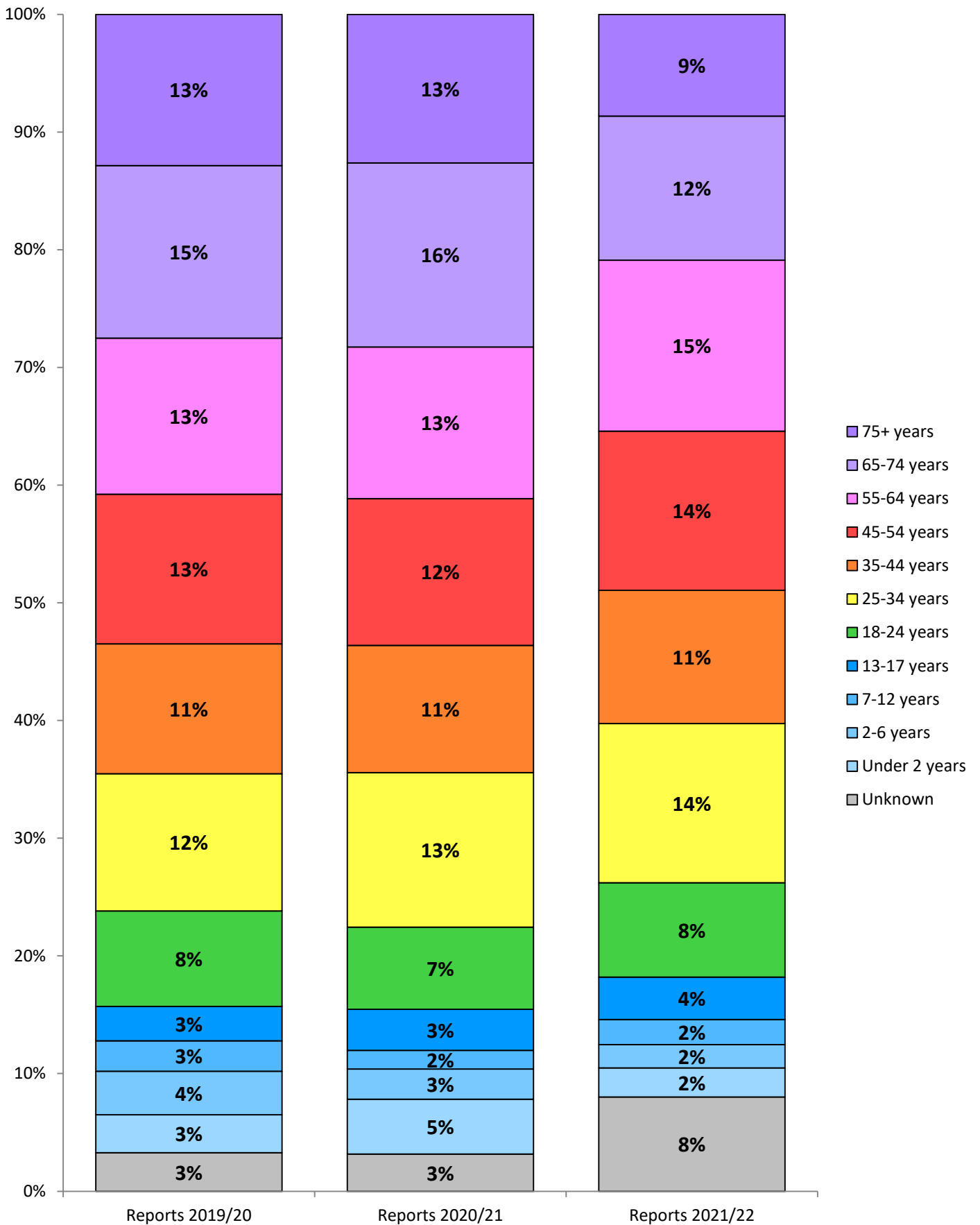
Table 6 - Age Banding Paediatric Reports Scotland 2021/22

Age Range	Number of Paediatric Yellow Card Reports	% of Paediatric Yellow Card Reports
Children (0–11 months)	20	14%
Children (12–23 months)	15	10%
Children (2–11 years)	49	34%
Adolescents (12–17 years)	60	42%
TOTAL	144	

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	173	58%
75–84 years	92	31%
85–94 years	31	10%
95+ years	0	0%
TOTAL	296	

Figure 7 - The percentage of Yellow Card reports from Scotland, stratified by age group over the last 3 years



3f Top 10 Suspected Medicines

Table 8 - Scottish top ten suspected medicines reported 2021/22 & 2020/21

Rank	2021/22		2020/21	
	Drug Name	Reports	Drug Name	Reports
1	Influenza Vaccine	136	Influenza Vaccine	104
2	Nirmatrelvir/Ritonavir (Paxlovid) ▼	35	Ivacaftor containing regimen Orkambi ▼ (n=1) Symkevi ▼ (n=8) Kaftrio ▼ (n=37)	46
3	Ivacaftor containing regimen Kalydeco (n=5) Symkevi ▼ (n=2) Kaftrio ▼ (n=24)	31	=Rotavirus Vaccine =Sertraline	27
4	Sertraline	24	—	
5	Estradiol	20	Edoxaban	22
6	HPV Vaccine	19	Adalimumab Amgevita ▼ Imraldi ▼ Humira Adalimumab (brand unspecified)	21
7	Vedolizumab	18	Flucloxacillin	18
8	=Doxycycline =Ciprofloxacin	17	MMR Vaccine	15
9	—		=Amoxicillin =Doxycycline	13
10	=Metronidazole =MMR Vaccine	16	—	

Table 9 - Top Five Medicines reported for paediatrics and aged 65+ in 2021/22 (Scotland)

	Paediatrics	Over 65 yrs
1	Influenza Vaccine (n=29)	Influenza Vaccine (n=23)
2	HPV Vaccine (n=17)	=Varicella Zoster Vaccine (n=7) =Nirmatrelvir/Ritonavir (n=7) =Amlodipine (n=7)
3	MMR Vaccine (n=14)	—
4	Rotavirus Vaccine (n=7)	—
5	DPT Vaccine (n=6)	=Pneumococcal Vaccine (n=6) =Flucloxacillin (n=6) =Ciprofloxacin (n=6) =Atorvastatin (n=6) =Nitrofurantoin (n=6)

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	2021/22		2020/21		2019/20	
	Number	% of total	Number	% of total	Number	% of total
Carer	19	1%	20	2%	22	2%
Consumer	4	<1%	1	<1%	3	<1%
Parent	86	6%	64	5%	73	5%
Patient	734	51%	423	35%	406	28%
Community Pharmacist	18	1%	25	2%	62	4%
Hospital Pharmacist	49	4%	161	13%	164	12%
Pharmacist	115	8%	57	5%	66	5%
Pharmacy Assistant	2	<1%	-	-	8	<1%
Pre-reg pharmacist	23	2%	12	1%	13	1%
Hospital Nurse	36	3%	88	7%	131	9%
Nurse	82	6%	62	5%	73	5%
GP	72	5%	85	7%	143	10%
Hospital Doctor	127	9%	157	13%	195	14%
Physician	7	1%	1	<1%	0	0%
Coroner	-	-	-	-	-	-
Paramedic	3	<1%	-	-	1	<1%
Dentist	13	1%	2	<1%	5	<1%
Midwife	1	<1%	2	<1%	3	<1%
Optometrist	2	<1%	2	<1%	5	<1%
Chiropodist	-	-	-	-	4	<1%
Radiographer	7	1%	14	1%	8	<1%
Hospital Healthcare Professional	7	1%	11	1%	20	1%
Healthcare Assistant	1	<1%	-	-	1	<1%
Other Healthcare Professional	10	1%	13	1%	23	2%
Medical Student	2	<1%	3	<1%	3	<1%
Unknown	-	-	-	-	-	-
Total	1420		1203		1432	

3h Types of reports (Scotland)

Table 11 - Report submission routes

Report Type	2021/22		2020/21	
	Number	% of total	Number	% of total
App	110	7%	59	5%
Electronic Yellow Card	1208	83%	992	82%
MiDatabank (Pharmacy Medicines Information)	21	1%	41	3%
Paper	31	2%	56	5%
Vision (GP system)	50	4%	55	5%

Table 11 shows the ways in which reporters in Scotland submitted Yellow Cards in 2021/22 compared with 2020/21.

4. Discussion of Yellow Card Data

Excluding COVID-19 vaccine reports, a total of 1,420 Yellow Card reports were submitted in Scotland in 2021/22, representing an 18% increase in reporting compared to the previous year. This figure is comparable to pre-pandemic reporting levels, which is encouraging.

Similar to the previous year, this excludes the vast majority (94%) of Yellow Card reports submitted in Scotland this year, therefore any trends highlighted in this report should be interpreted in this context. In 2021/22 an additional 22,018 reports were submitted in Scotland for the COVID-19 vaccine, which is double the number submitted in 2020/21(10,948). Overall, this represents a 92% further increase in reporting compared to 2020/21.

Refer to *Appendix 1: COVID-19 Yellow Card Reports Scotland 2021/22*, for information on the COVID-19 vaccine reports. Unless otherwise indicated, trends highlighted below are excluding COVID-19 vaccine reports.

Reporter Groups trends:

- **Patient groups:** Reporting by patients, parents, and carers accounted for 59% of the total reports in Scotland (and 90% of the Covid-19 vaccine reports). This represents another substantial increase and reflects a better awareness of the Yellow Card Scheme.
- **Healthcare professionals:** Reporting by healthcare professionals has further declined across all reporter groups, from 695 in 2020/21 to 577 in 2021/22. Healthcare reporting has also declined for the Covid-19 vaccines, compared to the previous year from 2,798 reports in 2020/21 to 2,167 reports in 2021/22. However, overall this reporting is higher than pre-pandemic levels, with a high proportion from nursing staff and other healthcare professionals (presumably vaccinators/ vaccination teams).

Submission routes:

- **MiDatabank (Pharmacy Medicines Information system):** Reporting via MiDatabank has further declined in 2021/22, representing a 49% decrease compared to the previous year. Of these, 71% were reported from NHS Lothian and 24% from NHS Tayside. Research is currently underway in NHS Lothian to further explore the barriers to medicines information (MI) pharmacists reporting e-YC via *MiDatabank*.

Health board trends:

- **Top 3 reporting health boards (per 100,000 population):** NHS Orkney, NHS Lothian, NHS Highland
- **Notable increase:** NHS Borders and NHS Grampian both displayed a notable increase in reports, with reports from NHS Borders increasing by +133% and reports from NHS Grampian increasing by +76% in 2021/22 compared to 2020/21.

Suspect Medicines:

- **Range of medicines:** It should be noted that, excluding vaccines, the range of suspect medicines reported is very diverse. In 2021/22 there were 460 different suspect medicines reported (for 1420 reports), in other words there are a third as many suspected medicines as there are reports (note that some reports include multiple suspect medicines).

This coincides with an increase in patient reporting and a decrease in reporting by healthcare professionals. A consequence of this shift in reporting is that (excluding vaccines) trends in suspect medicines are less evident, as the number of reports for individual medicines is relatively low. Only 2% of the total reports were for the top suspect medicine (0.1% including the COVID-19 vaccines).

- **Top 10:** Notably in 2021/22, the top reported suspect medicine was Paxlovid (nirmatrelvir/ritonavir), with the ivacaftor-containing cystic fibrosis medicines remaining prominent as the second top reported suspect medicine (excluding vaccines). Vedolizumab also featured in the top 10 suspect medicines.
- **Kaftrio (Ivacaftor/tezacaftor/elexacaftor) ▼:** The February 2022 MHRA Drug Safety Update (DSU) highlighted the risk of serious liver injury with Kaftrio- Kalydeco (ivacaftor). A number of reports of serious liver injury and abnormal liver function tests were reported via the Yellow Card Scheme. Following a European review of safety data, existing warnings on hepatotoxicity were strengthened. Yellow Card reports from Scotland contributed to this safety data, which included serious and non-serious suspected hepatic reactions. 16% of the total reports were serious, of which 80% were reported by healthcare professionals. Healthcare professionals also accounted for the majority of non serious reports.
- **Paxlovid (nirmatrelvir and ritonavir) ▼:** Paxlovid was granted a Conditional Marketing Authorisation (CMA) for the treatment of mild to moderate COVID-19 in adults who do not require supplemental oxygen, and are at increased risk for progression to severe COVID-19. Paxlovid was introduced in the last quarter of 2021/22, and as a new drug under additional monitoring (black triangle) it is not surprising to see these reports. Of the total, 89% were non-serious, of which 87% were patient reported. The most commonly reported reactions were consistent with the most common side effects reported in clinical trials (diarrhoea, vomiting and altered sense of taste).
- **Estradiol:** 95% of reports were from patients, with a spread across health boards (no particular cluster evident). These were generally consistent with the established side effect profile, and menopausal symptoms. Gastrointestinal, nervous system, reproductive system, mood and skin reactions were most commonly reported.
- **Vedolizumab:** A new formulation (pre-filled syringes/ pen for subcutaneous injection) was approved for use in NHS Scotland in 2020, which has been associated with injection site reactions in clinical trials. Consistent with this, injection site reactions were the most commonly reported suspected reaction in these reports including amongst patients who switched from IV. 67% of reports were from healthcare professionals (nurses and pharmacists) and 56% of the total reports were classed as non serious.
- **Paediatrics:** Vaccines remain the most commonly reported suspect medicines, as in previous years

Serious ADRS:

- 785 reports were classed as serious (55% of total), a similar proportion of the total as in previous years. Healthcare professionals are more likely to report serious reactions (i.e. those that are life-threatening, cause or prolong hospitalisation or are debilitating). Patients frequently report non-serious reactions (not life-threatening or resulting in hospitalisation) as serious. This limits interpretation of trends.
- **Fatal:** a fatal outcome was reported in 29 reports*

*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 are hosted in NES *Turas Learn* for all users. From August 2021 to April 2022 users accessed the ADR e-learning modules as below:

- Module 1: 955 users (880 completed)
- Module 2: 913 users (850 completed)
- Module 3: 860 users (834 completed)
- Module 4: 845 users (824 completed)
- Module 5: 856 users (833 completed)
- Module 6: 885 users (849 completed)

As this data is from August 2021 to April 2022, users who accessed the modules between April 2021 and July 2021 are not captured here, and so the actual total number of users for each module is likely to be higher. Unfortunately this data is no longer available, so an accurate estimate of this additional use cannot be made.

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 Prescribers	ADR & Yellow Card Training Session	2.5	7	93	17.5
Non-Medical Prescribers	Non-Medical Prescribers Leads Group Update	1	1	20	1
Podiatrists	Yellow Card Update	1	1	100	1
Senior Healthcare Professionals	ADTC Collaborative Update	0.5	1	30	0.5
Trainee Pharmacist	Telephone Conversation	0.25	1	1	0.25
Healthcare Professionals & Stakeholders*	Pharmacy Management Celtic Conference*	6*	1*	N/K*	0.5*
Totals					20.75

*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
Member of the Public	Telephone Conversation	0.25	8	8	2
Member of the Public	Email Conversation	0.25	6	6	1.5
Members of the Public	Article for Newsletter & Magazine	N/A	2	N/K	2

Face to face activities remained suspended throughout 2021/22, however YCCS continued to receive queries from the public via the YCCS website, Twitter account, and phoneline. YCCS supported members of the public to report suspected reactions to their medications and to seek appropriate medical advice where appropriate.

5c Training delivered to undergraduates

Table 14 - Training delivered to Undergraduates

Audience	Session	Duration (hours)	No of sessions	Total attendees	Total hours
Medical Students	ADR Training Session	1	1	N/K	1
Pharmacy Students	Pharmacovigilance Session	1	2	200	2
Podiatry Students	Pharmacovigilance Session	1	1	30	1
Total					

5d Materials developed for YCS promotion

- Recorded presentations developed for online teaching (aimed at healthcare professionals and students) have been uploaded to the YCCS website training page – “Yellow Card Scheme & YCCS” and “Adverse Drug Reactions”
- Introduction of a new blog site on the Yellow Card Centre Website, with first BLOG article uploaded in October 2021 “Pharmacovigilance during the Covid-19 pandemic and beyond”, available <https://www.yccscotland.scot.nhs.uk/>
- Updated article published in NHS Lothian Prescribing Bulletin (March 2022) <https://formulary.nhs.scot/media/mb4pegwq/lpb-issue-112-final.pdf>
- Articles written for Perth & Kinross Newsletter and National Rheumatoid Arthritis Society Magazine

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7. YCC Website/Social Media

7a Website updates

The YCCS website on SHOW has been maintained and updated to reflect the most current information. A new blog space for the website has been created, with an introductory blog entry written by Simon Maxwell, discussing pharmacovigilance during COVID-19.

7b Website/Social Media Statistics

Website

Table 15 - Comparison of website hits 2020/21 to 2021/22

	2021/22	2020/21	% change 2020/21 to 2021/22
Total Number of Daily Unique Visitors	UNKNOWN	UNKNOWN	N/A
Total Number of Page Views	UNKNOWN	UNKNOWN	N/A

Due to the transfer of the website to the new Scottish Health on the Web (SHOW) platform, analytic data for the year 2020/21 was not available. Solutions are currently being investigated with SHOW. GDPR compliance rules out the use of plugins to generate this data.

Twitter

Table 16 - Twitter analytics over the last 3 years

	2021/22	2020/21	2019/20	% change 2020/21 to 2021/22
Number of Followers	1462	1366	1236	+7%
Tweets sent	75	98	238	-23%
Total number of Engagements*	951	713	1,880	+33%
Impressions**	40,220	77,110	225,600	-48%

* Engagements are when a follower interacted with a tweet

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

The YCCS Twitter account has seen a modest increase in the number of followers over the last year, despite a reduction in activity. YCCS engaged with the Medicines Safety Week campaign in November 2021, and reached a wide audience through this engagement.

The top tweet for 2021/22, which reached over 1700 people and generated significant engagement, focused on the importance of pharmacovigilance and the Yellow Card Scheme, and made use of the #drugs and #pharmacovigilance hashtags.

8. Research and ongoing initiatives

- MiDatabank e-YC reporting. Research is currently underway in NHS Lothian to explore the barriers to medicines information (MI) pharmacists reporting e-YC via *MiDatabank* (MSc Advanced Pharmacy; Louise Davies NHS Lothian).
- MHRA – Pregnancy and Breastfeeding Assessment. Professor Maxwell has been collaborating with the MHRA, Royal College of Physicians and British Pharmacological Society to develop self-assessment learning materials to support safer medicines use in pregnancy and breastfeeding amongst healthcare professionals. This new online resource is delivered as a 1-hour formative assessment, containing 12 practical case studies about the drug management of common conditions in pregnancy and breastfeeding. Each case is presented in an easy to follow, question-and-answer format, with access to immediate question-by-question feedback and links to further reading and relevant guidelines. The material has been written and reviewed by content specialists and includes key topics, such as those highlighted by the MHRA in recent patient safety alerts. It is aimed at healthcare professionals wishing to improve their knowledge of safe prescribing in this important area. The content is freely available and those wishing to access it can do so at <https://portal.bpsassessment.com/product/mhra-pregnancy-breastfeeding-assessment/>

9. Conclusion

The COVID-19 pandemic and resulting pressures have continued to influence Yellow Card reporting, and to impact on the activities of the Yellow Card Centre for Scotland throughout 2021/2022. It is encouraging to note the return to pre-pandemic levels of reporting for medicines and non-COVID-19 vaccines, yet it is unsurprising that overall reporting is still dominated by reports for the COVID-19 vaccines.

All things considered, 2021/2022 has been a successful year for the Yellow Card Scheme, highlighting a greater awareness amongst the general public. Patient reporting is at its highest ever with patient groups (including parents and carers) accounting for 59% of reports (excluding COVID-19 vaccines) and 90% of reports for COVID-19 vaccines. We will continue to engage with patient groups, and will investigate further how to reach the broader general public.

Excluding the COVID-19 vaccines, reporting across all healthcare professions has further declined. However, when considering the contribution to reporting for the COVID-19 vaccines, overall reporting by healthcare professionals is higher than pre-pandemic levels. It is important to acknowledge this, especially given the current pressures on healthcare services. Moving forward, it is essential that reporting is as efficient as possible, and that new technology is harnessed to ensure e-YC integration with electronic clinical systems in NHS Scotland.

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)

- Alison Strath

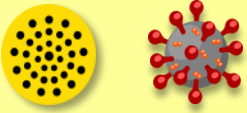
Yellow Card Centre Scotland Advisory Group

- Yvonne Semple, Director of Pharmacy, Golden Jubilee National Hospital (**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

Appendix 1: COVID-19 Yellow Card Reports Scotland 2021/22



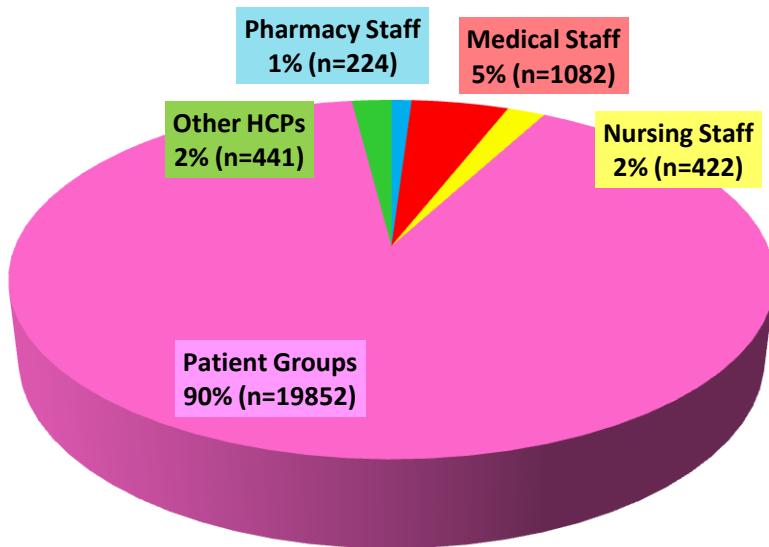
COVID-19 Vaccine Yellow Card Reports in Scotland (April 2021 to March 2022)

22018 COVID-19 vaccine reports =94% of all Yellow Card reports in Scotland for 2021/22

! 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)	670
DOCTOR (HOSPITAL)	375
DOCTOR (PHYSICIAN)	13
MEDICAL STUDENT	24
HCP (CHIROPODIST)	4
HCP (DENTIST)	45
HCP (HEALTHCARE ASSISTANT)	121
HCP (HOSPITAL)	19
HCP (OPTOMETRIST)	9
HCP (OTHER)	215
HCP (PARAMEDIC)	16
HCP (RADIOGRAPHER)	12
NURSE	327
NURSE (HOSPITAL)	84
NURSE (MIDWIFE)	11
PATIENT	17790
PATIENT (CARER)	93
PATIENT (CONSUMER)	801
PATIENT (PARENT)	1168
PHARMACIST	120
PHARMACIST (COMMUNITY)	28
PHARMACIST (HOSPITAL)	32
PHARMACIST (PRE-REG)	17
PHARMACY ASSISTANT	27
UNKNOWN	1
Total	22022*

Top Suspected Reactions Reported in COVID-19 Vaccines Yellow Cards

The most frequently reported reactions were all reactogenic type events, such as **headache** (n=4843), **fatigue** (n=4077), **pyrexia** (n=3101) and **nausea** (n=2287). This is generally consistent with the most frequent adverse reactions reported in clinical trials. A monthly 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>

*NOTE: the total for reporter groups ≠ 22018 because some reports have more than one reporter