

Annual Report

April 2022 to March 2023



**Yellow Card
Reports
(Scotland)**



29% increase
*Excluding COVID-19 vaccine
reports from both years*

86% decrease
*Including COVID-19 vaccine
reports from both years*



3172 total reports
*(1345 of which are
COVID-19 vaccine
reports)*



**58 reports per
100,000
population**
*(including COVID-19
vaccine reports)*

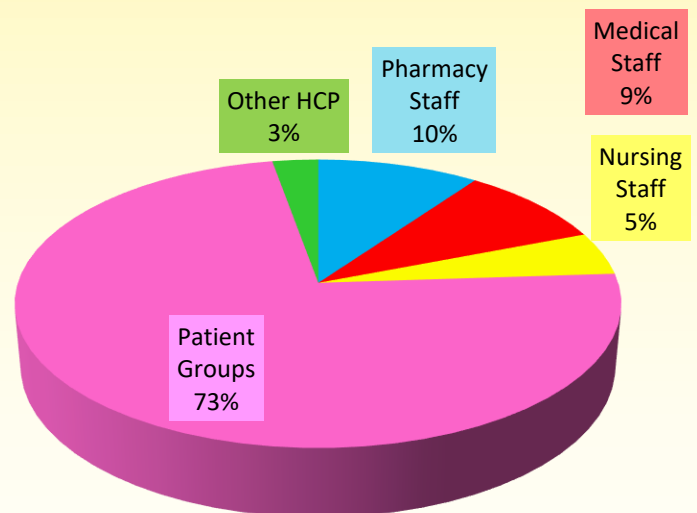


Reports submitted to the Yellow Card Scheme are for suspected adverse reactions that have not been proven to be related to the drug, and should not be interpreted as known side-effects

YCC Scotland Key Messages

From July 2022, the standard reporting data has been expanded to include reports for COVID-19 vaccines. This has led to a significantly increased number of reports for 2022/23 overall compared to the previous year, which did not include COVID-19 vaccine reports within the standard dataset.

Source of Reports



Top Reported Medicines

COVID-19 Vaccine

Influenza
Vaccine

Nirmatrelvir/
Ritonavir

Pneumococcal
Vaccine

Sertraline

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

2022–2023

1. Team

| | |
|--------------------------------|----------------------------------------------------------------------------|
| Professor Simon Maxwell | Consultant Clinical Pharmacologist/Medical Director YCC Scotland |
| Mr Scott Garden | NHS Lothian Director of Pharmacy and Medicines |
| Professor James Dear | Consultant Clinical Pharmacologist/Deputy Medical Director YCC Scotland |
| Ms Lesley Macher | Acting Lead Pharmacist Lothian Medicines Information Service/ YCC Scotland |
| Ms Louise Summers | Principal Pharmacist Lothian Medicines Information Service/YCC Scotland |
| Ms Louise Smith | Principal Pharmacist Lothian Medicines Information Service/YCC Scotland |
| Mr Alexander Kiker | Information Officer Lothian Medicines Information Service/ YCC Scotland |

2. Executive Summary

Like many services and organisations, the Yellow Card Centre for Scotland has continued to respond to the ongoing changes that have resulted from the pandemic. These include the reporting of adverse events involving vaccines and treatments specifically for COVID-19 while also responding to requests to use virtual methods for teaching and meeting purposes.

From April 2022 to March 2023, 3172 reports were submitted via the Yellow Card scheme from Scottish addresses.

The COVID-19 vaccines continued to be the highest reported items with 1345 reports being completed. This number is considerably lower than in 2021/22 when over 22,000 reports of suspected adverse drug reactions were received.

Excluding COVID-19 vaccine reports, a total of 1827 Yellow Card reports were submitted in Scotland in 2022/23, representing a 29% increase in reporting compared to the previous year. This figure now exceeds pre-pandemic reporting levels without considering COVID-19 vaccine reports. For the 5 years prior to the pandemic (April 2015 to March 2020 inclusive), reporting averaged around 1440 reports annually.

This year the Medicines and Healthcare products Regulatory Agency (MHRA) have included COVID-19 vaccine reports as part of the business-as-usual reporting so they will be included throughout this report. Any trends highlighted or comparisons in this report should be interpreted in this context.

Patient groups have continued to represent the greatest number of reporters; with many healthcare professional groups also contributing to the overall increase in reporting. Reporting by radiographers showed a 371% increase when compared with last year across ten different health board areas within Scotland. No specific intervention has been identified in association with this.

Reporting methods have remained relatively consistent, with the website remaining the preferred method and an increase in reporting via the app.

This report presents an opportunity to remind INPS Vision prescribing system users in general practices that Yellow Card reports can be automatically populated with information from the *Allergy and Intolerance* page and submitted directly. Reporting via this method was down 12% in 2022/23 compared with the previous year.

Direct e-YC reporting is also available via Pharmacy Medicines Information systems (*MiDatabank*). Reporting using this method had increased by 85% compared with the previous year.

As the MHRA continues to promote Yellow Card reporting for adverse incidents involving medical devices in England and Wales, YCC Scotland continue to work with the Incident Reporting and Investigation Centre (IRIC) within NHS National Services Scotland. Local authorities and health boards throughout Scotland are directed to IRIC for such reporting (<https://www.nss.nhs.scot/health-facilities/incidents-and-alerts/report-an-incident/>) while the public are asked to submit reports for medical devices via the Yellow Card scheme at

<https://www.gov.uk/report-problem-medicine-medical-device> scheme or by email to aic@mhra.gov.uk

In response to the increased dependence on digital solutions for promoting and teaching, YCC Scotland have been working closely with NHS Education for Scotland to review the current e-Learning modules on the TURAS platform and improve accessibility. The 6 e-Learning modules are used as part of blended learning with positive feedback.

In the coming months members of the YCC Scotland team are eager to return to interactive sessions where possible to ensure opportunities are taken to promote reporting by all patient and healthcare professional groups. The advisory group also recognised the importance of reviewing how the service will deliver teaching and promotion post-pandemic and has commissioned a communications strategy for review.

Recent engagement with Healthcare Improvement Scotland and their Medicines Safety Strategy Clinical Leadership Fellow has introduced an opportunity to be involved with their work in reducing medicines-related harm.

There have been significant changes to the YCC Scotland team this year with Tracy Duff (Lead Pharmacist Medicines Information / YCC Scotland) leaving officially in October 2022. Lesley Macher (Acting Lead Pharmacist) joined the team in January 2023 and Amy Halliwell (Senior Pharmacist) moved on from her temporary post late 2022. Louise Smith (Principal Pharmacist) has subsequently joined the team in July 2023.

Please discuss this report, and the importance of reporting suspected adverse drug reactions to the Yellow Card Scheme with your colleagues and peers. For information on how we can help to support any local initiatives to raise awareness in your area please contact yccscotland@nhslothian.scot.nhs.uk

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

A total of **3172 reports** of suspected adverse drug reactions were submitted from Scotland in 2022/23 via standard Yellow Card reporting, representing an overall 124% increase compared to the previous year (2021/22). This increase can be partly attributed to reports for COVID-19 vaccines (n=1345) which are included in the standard dataset as of July 2022, whereas in previous years they were listed separately. Excluding the reports for COVID-19 vaccines leaves a total of 1827 reports, which still represents an increase of 29% from the previous year's standard reporting data.

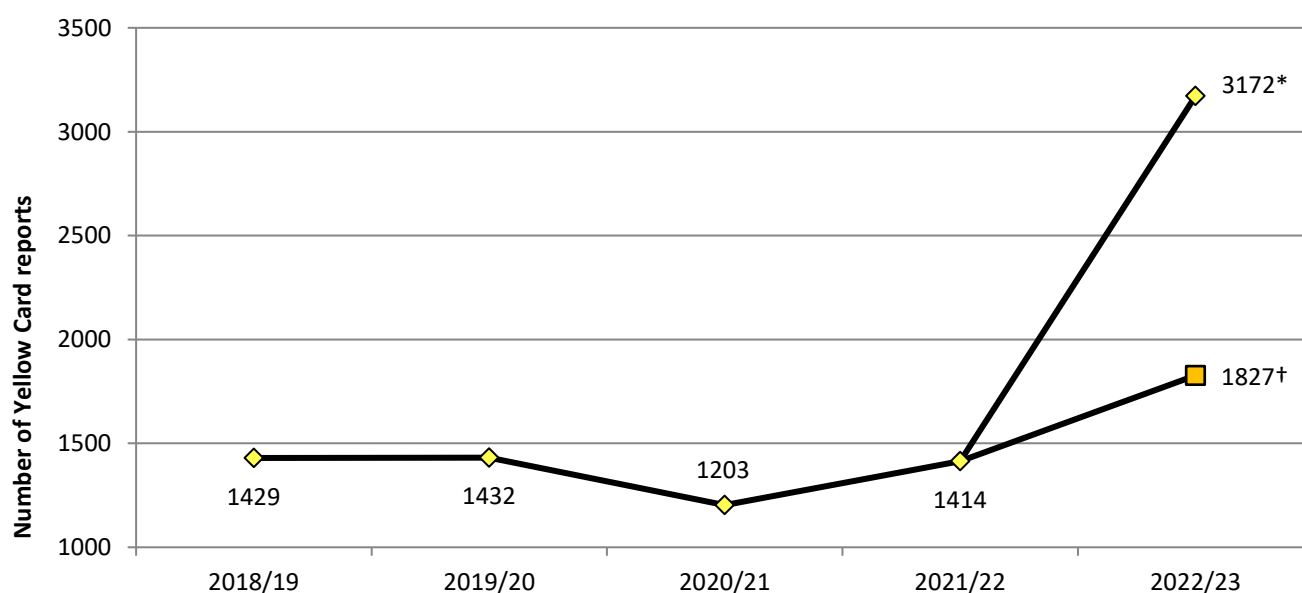
Within the remainder of this report, the data for 2022/23 will largely include reports for COVID-19 vaccines but will be compared to data for 2021/22 which excluded COVID-19 vaccines. This is because of a change in the way adverse reactions to COVID-19 vaccines are reported, as these reports are processed via the standard Yellow Card reporting pathway rather than via a dedicated COVID-19 workstream.

Table 1 and **Figure 1a** below illustrate the trend in standard reporting in Scotland over the last 5 years. **Figure 1b** shows the trend in reporting for all products, including reports for COVID-19 vaccines, over the last 3 years.

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

| Year | Number of reports | Percentage change on previous year |
|----------------|-------------------|------------------------------------|
| 2018/19 | 1429 | 0% |
| 2019/20 | 1432 | 0% |
| 2020/21 | 1203 | -16% |
| 2021/22 | 1414 | +18% |
| 2022/23 | 3172 | +124% |

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



*all standard data, including COVID-19 vaccine reports from July 2022 onwards

†excluding 2022/23 COVID-19 vaccine reports

Figure 1b - Number of Yellow Card Reports from Scotland over the past 3 years (including COVID-19 vaccine reports)

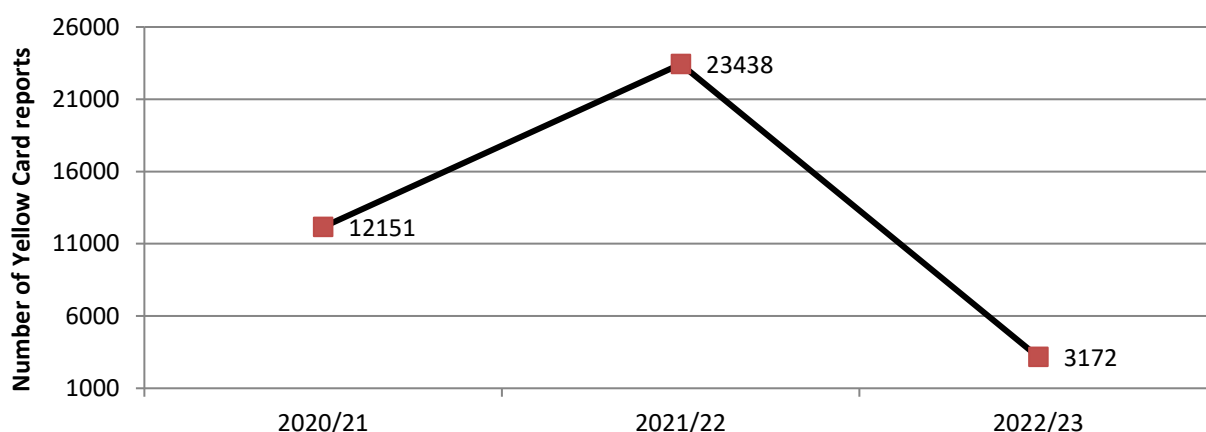
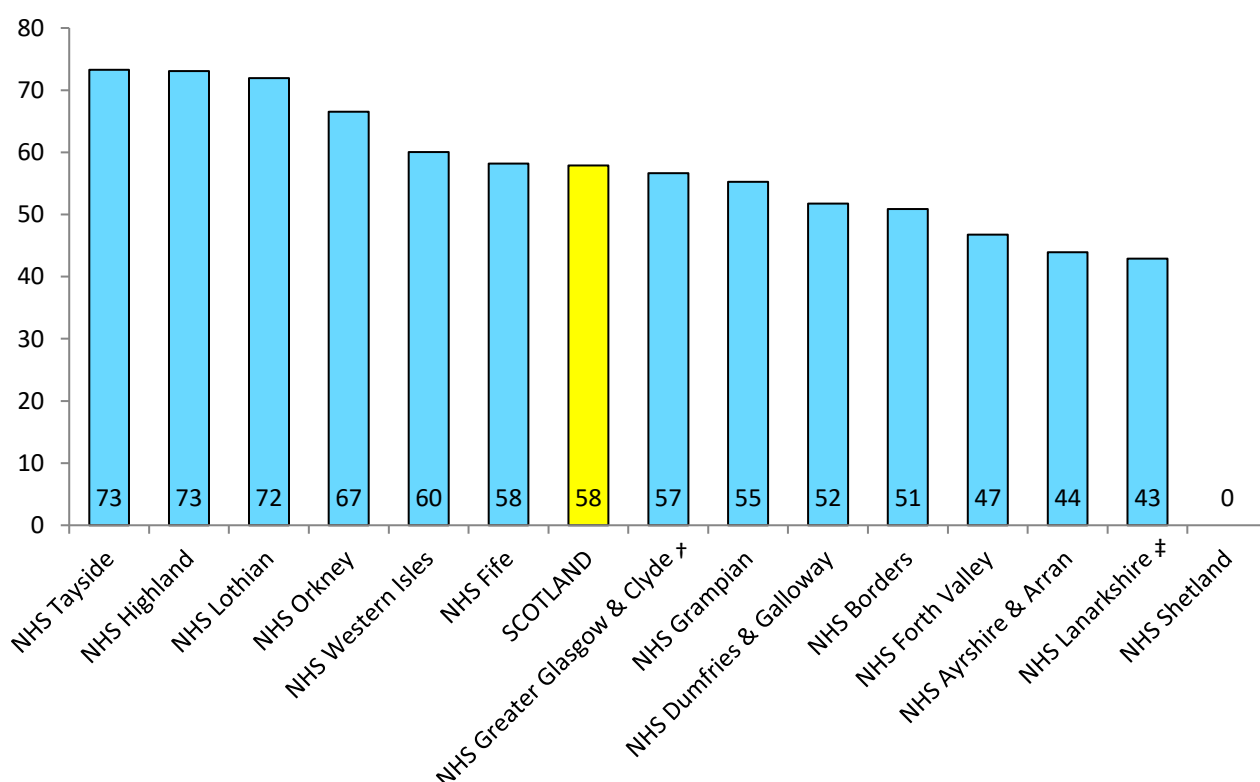


Figure 2 - Health Board Yellow Card Reporting per 100,000 population* (Scotland 2022/23)



*Statistics from National Registers of Scotland, Population estimates mid-2022 as mid 2023 data was unavailable

†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 in 2022/23 was 58 reports per 100,000 population in Scotland, compared to the previous year of 26 reports per 100,000 population.

The top 3 reporting health boards per 100,000 population in 2022/23 were NHS Tayside, NHS Highland, and NHS Lothian. 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.

Figure 3 – Number of Yellow Card Reports submitted over the last 5 years (top 5 reporting health boards in 2022/23)

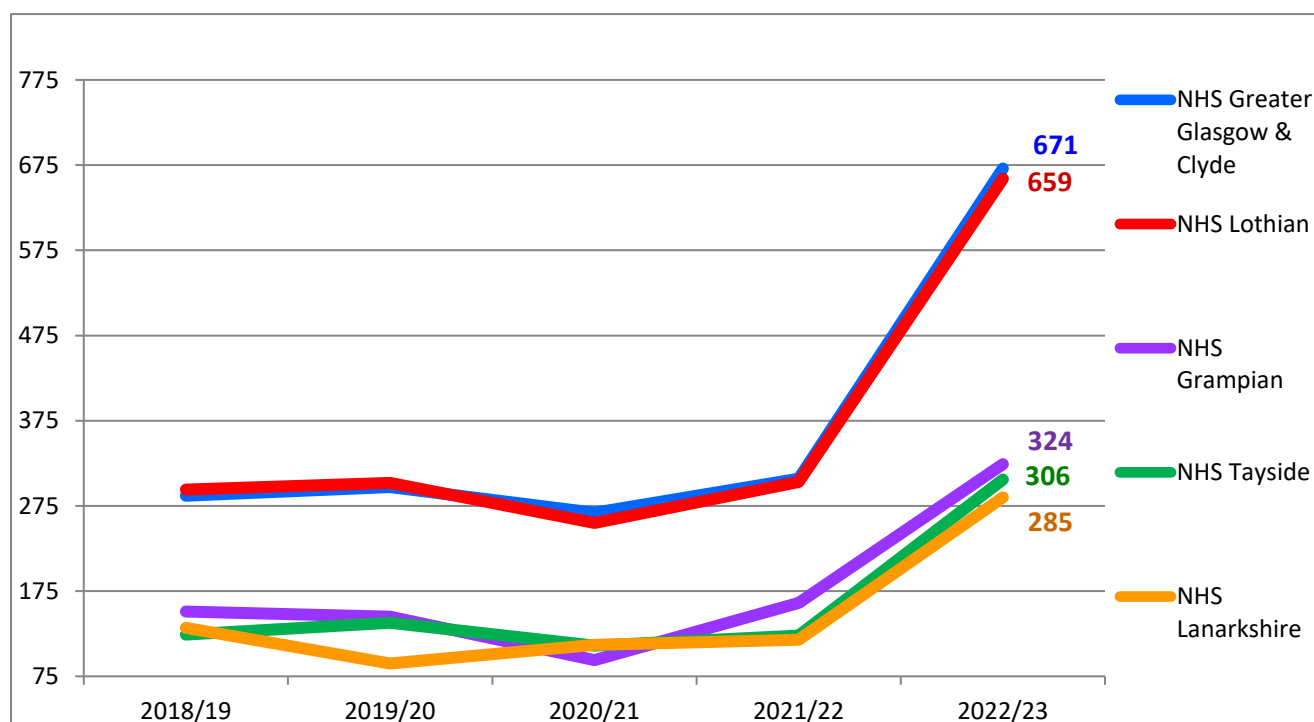


Figure 3 shows the 5-year trend in reporting for the five health boards that submitted the highest number of reports (total) in 2022/23.

Reporting has improved across all health board areas in 2022/23 compared to the previous year, with NHS Fife showing the largest proportional change with an increase of +176% (from 2021/22 - 79 reports to 2022/23 – 218 reports).

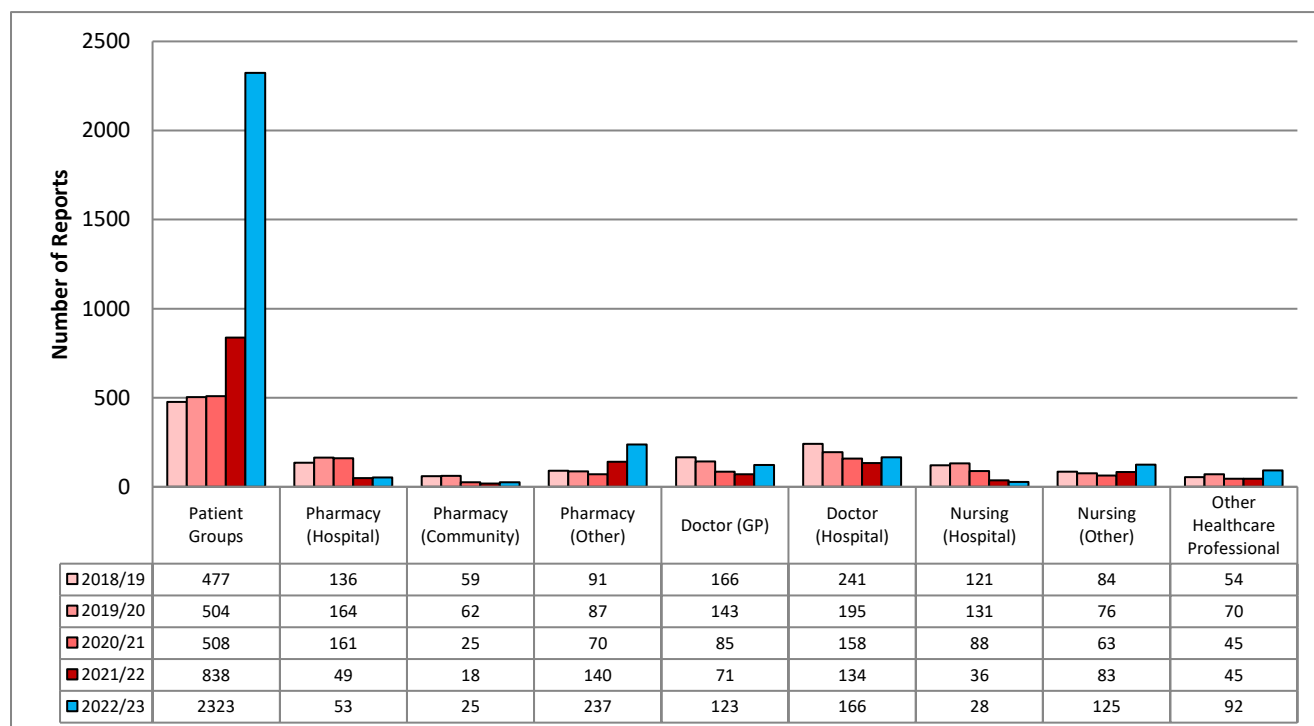
Substantial increases are evident across the whole of Scotland, and even the smallest change compared to the previous year (for NHS Borders) still represents an increase of +69% (from 2021/22 - 35 reports to 2022/23 – 59 reports).

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

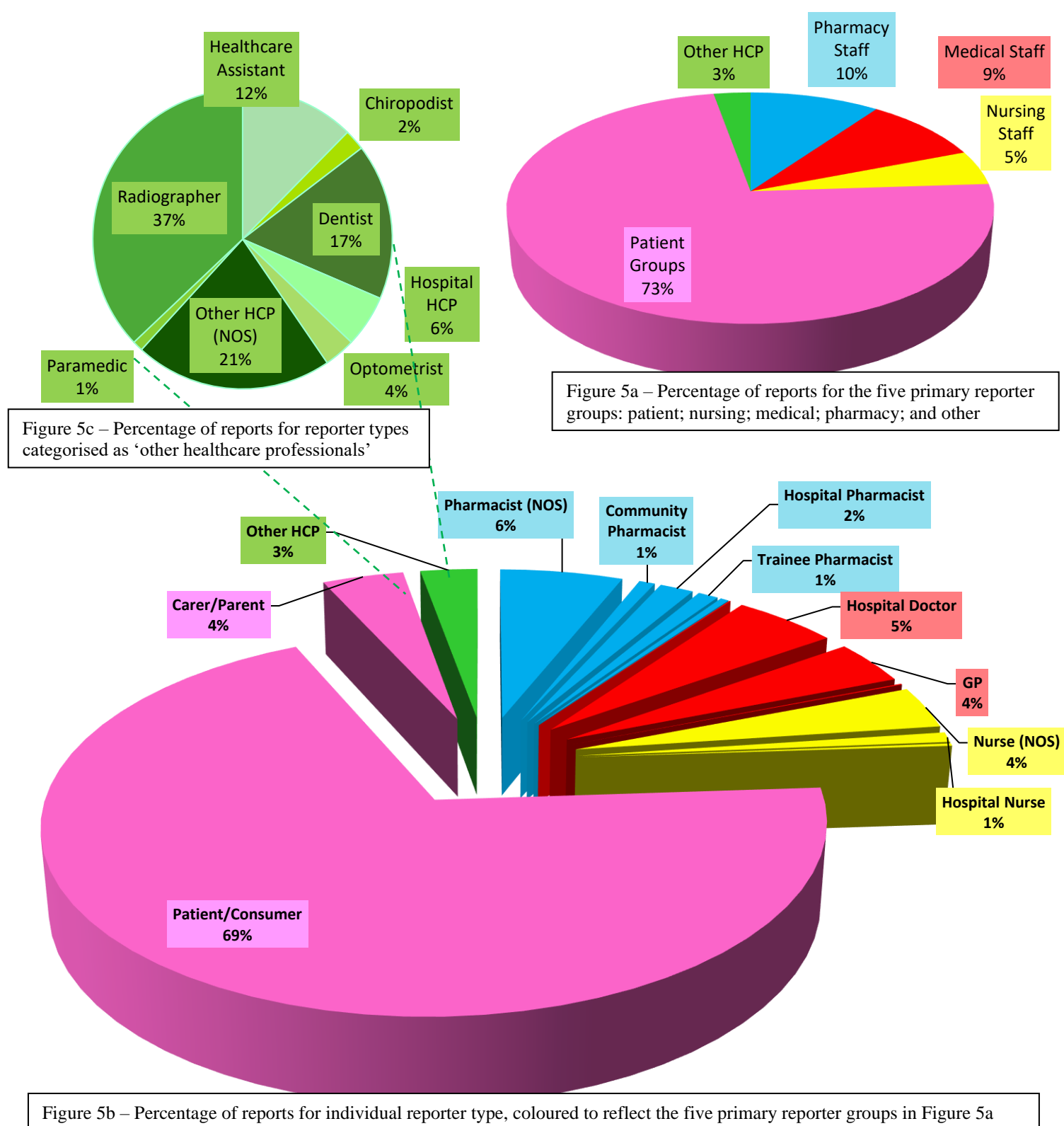
Figure 4 shows the contribution of specific reporter groups to the total reports submitted in Scotland over the last five years. These are grouped by profession, and subdivided into sector where the data allows.

Healthcare Professionals (HCPs) accounted for only 27% of the total reports in Scotland in 2022/23. Despite a +47% increase in the total number of reports submitted (from 577 in 2021/22 to 849 in 2022/23) the proportion of reports from HCPs is notably much lower than in 2021/22, when it was 41% of all reports. Almost all groups noticed an increase in reporting and specific mention is made to the 371% increase from last year by radiographers across ten different health board areas (captured under 'other healthcare professionals' for the purposes of this report).

Patient groups, including reports from patients, parents, and carers, accounted for 73% of the total reports in Scotland, representing yet another considerable increase in the total number of reports, from 843 in 2021/22 to 2323 in 2022/23 (177% increase).

A further breakdown of the "Other Healthcare Professional" reports is illustrated in **Figure 5**. These figures include 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, and collectively these constitute 3% of all Scottish reports in 2022/23.

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



NB: Figure 5b also includes reports of <1% total from Pharmacy Technicians/Assistants, Medical Students, and Midwives
 NOS – not otherwise specified; HCP – healthcare professional

Table 2 - Reports from hospital staff 2022/23 (Scotland)

| Health Board Area | Total reports 2022/23 | Hospital reports 2022/23 | Hospital reports as a % of Board's total reports | |
|-----------------------------|-----------------------|--------------------------|--------------------------------------------------|------------|
| | | | 2022/23 | 2021/22 |
| NHS Ayrshire & Arran | 162 | 3 | 2% | 15% |
| NHS Borders | 59 | 5 | 8% | 17% |
| NHS Dumfries & Galloway | 77 | 5 | 6% | 7% |
| NHS Fife | 218 | 9 | 4% | 15% |
| NHS Forth Valley | 143 | 10 | 7% | 8% |
| NHS Grampian | 324 | 23 | 7% | 7% |
| NHS Greater Glasgow & Clyde | 671 | 73 | 11% | 21% |
| NHS Highland | 237 | 18 | 8% | 22% |
| NHS Lanarkshire | 285 | 10 | 4% | 18% |
| NHS Lothian | 659 | 56 | 8% | 17% |
| NHS Orkney | 15 | 0 | 0% | 0% |
| NHS Shetland | 0 | 0 | 0% | 0% |
| NHS Tayside | 306 | 34 | 11% | 10% |
| NHS Western Isles | 16 | 4 | 25% | 13% |
| Total (Scotland) | 3172 | 250 | 8% | 15% |

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 reports accounted for 8% of all reports in Scotland in 2022/23, which represents a proportional decrease of 3% compared to 2021/22 (15%). However, the number of reports had increased from 219 reports in 2021/22 to 250 reports in 2022/23 for this group.

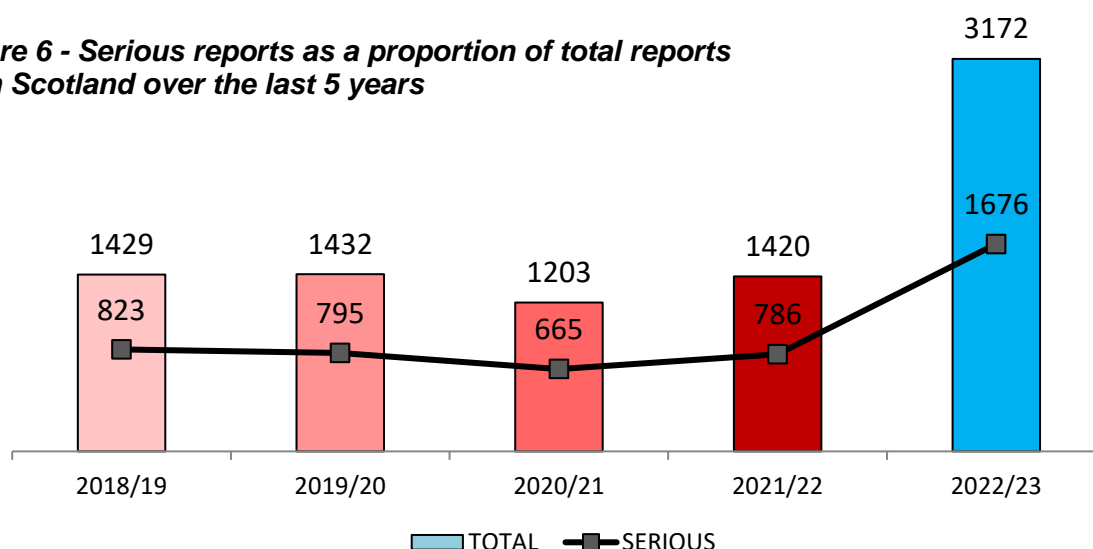
3c Serious Reports

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

| Year | Number of serious reports | Percentage of total reports | Percentage change on previous year |
|----------------|---------------------------|-----------------------------|------------------------------------|
| 2018/19 | 823 | 58% | -1% |
| 2019/20 | 795 | 56% | -3% |
| 2020/21 | 665 | 55% | -16% |
| 2021/22 | 786 | 55% | +18% |
| 2022/23 | 1676 | 53% | +113% |

Table 3 and **Figure 6** show the number and proportion of reports classed as serious that originated from Scotland in 2022/23, and the trend over the last 5 years. Despite the increase in total number of serious reports, the overall proportion of reports classed as serious remains at around half of all reports. Further review of reports by patient groups categorising events as serious align with many known side effects. A fatal outcome was reported in **56** Yellow Card reports in 2022/23 as shown in **Table 4**.

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 |
|----------------|-------------------------|---------------------------|
| 2018/19 | 78 | -18% |
| 2019/20 | 42 | -46% |
| 2020/21 | 33 | -21% |
| 2021/22 | 29 | -12% |
| 2022/23 | 56 | +93% |

*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 2022/23 | Reports 2021/22 | Reports 2020/21 |
|---------------|-----------------|-----------------|-----------------|
| Unknown | 618 | 114 | 38 |
| Under 2 years | 32 | 35 | 56 |
| 2–6 years | 39 | 28 | 31 |
| 7–12 years | 34 | 30 | 19 |
| 13–17 years | 45 | 51 | 42 |
| 18–24 years | 131 | 113 | 84 |
| 25–34 years | 264 | 192 | 158 |
| 35–44 years | 330 | 160 | 130 |
| 45–54 years | 423 | 194 | 150 |
| 55–64 years | 482 | 207 | 155 |
| 65–74 years | 497 | 173 | 188 |
| 75+ years | 277 | 123 | 152 |
| TOTAL | 3172 | 1420 | 1203 |

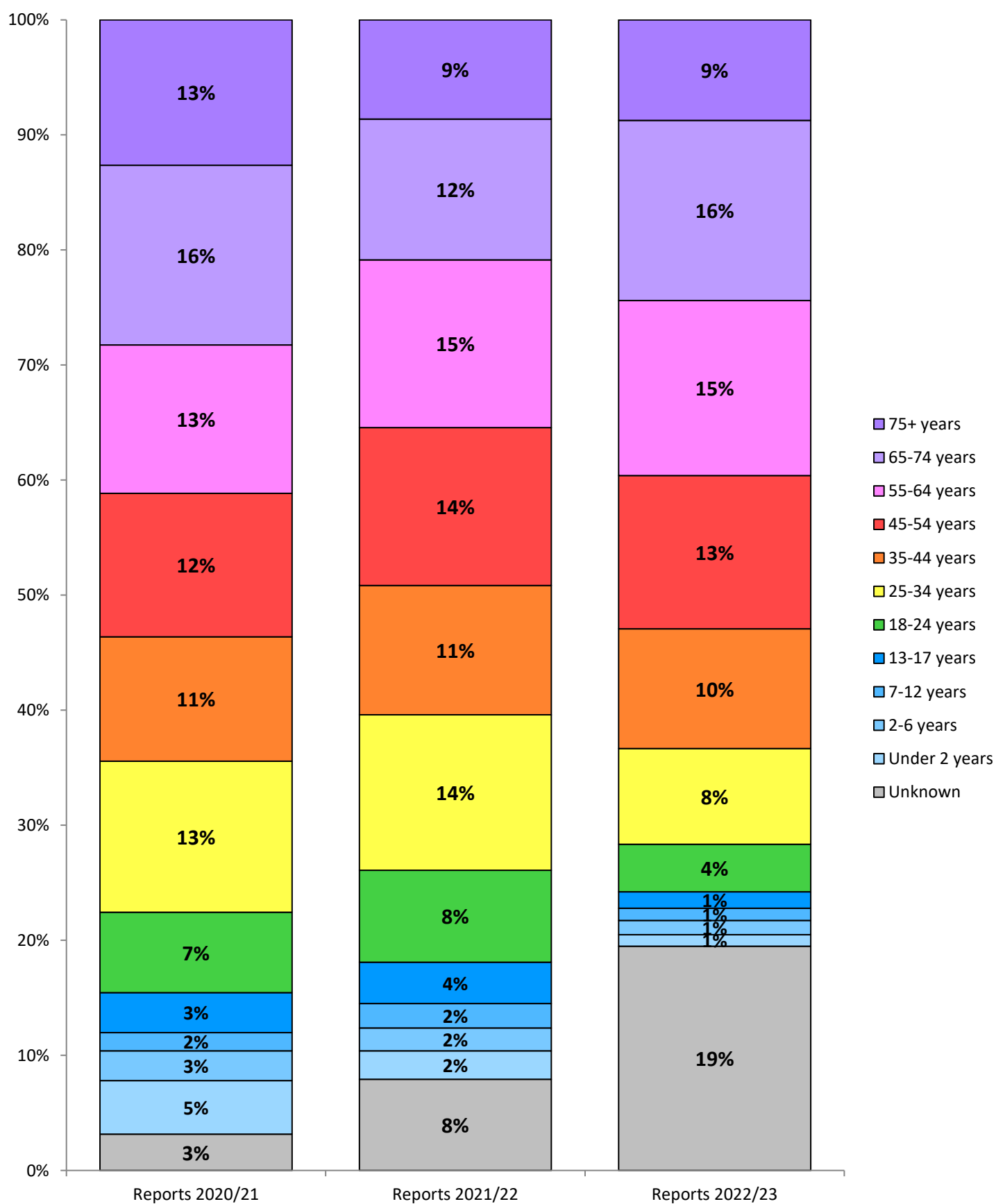
Table 6 - Age Banding Paediatric Reports Scotland 2022/23

| Age Range | Number of Paediatric Yellow Card Reports | % of Paediatric Yellow Card Reports |
|---------------------------|------------------------------------------|-------------------------------------|
| Children (0–11 months) | 10 | 7% |
| Children (12–23 months) | 22 | 15% |
| Children (2–11 years) | 64 | 43% |
| Adolescents (12–17 years) | 54 | 36% |
| TOTAL | 150 | |

Table 7 - Age Banding over 65 years Reports Scotland 2022/23

| Age Range | Number of over 65 yrs Yellow Card Reports | % of over 65yrs Yellow Card Reports |
|--------------|-------------------------------------------|-------------------------------------|
| 65–74 years | 497 | 64% |
| 75–84 years | 228 | 29% |
| 85–94 years | 47 | 6% |
| 95+ years | 2 | 0.3% |
| TOTAL | 774 | |

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 2022/23 & 2021/22

| Rank | 2022/23 | | 2021/22 | |
|------|-------------------------------------|---------|------------------------------------------------------------------------------------|---------|
| | Drug Name | Reports | Drug Name | Reports |
| 1 | COVID-19 Vaccine ▼ | 1345 | Influenza Vaccine | 136 |
| 2 | Influenza Vaccine | 178 | Nirmatrelvir/Ritonavir (Paxlovid) ▼ | 35 |
| 3 | Nirmatrelvir/Ritonavir (Paxlovid) ▼ | 134 | Ivacaftor containing regimen Kalydeco (n=5) Symkevi ▼ (n=2) Kaftrio ▼ (n=24) | 31 |
| 4 | Pneumococcal Vaccine | 89 | Sertraline | 24 |
| 5 | Sertraline | 43 | Estradiol | 20 |
| 6 | Varicella Zoster Vaccine | 41 | HPV Vaccine | 19 |
| 7 | Flucloxacillin | 29 | Vedolizumab | 18 |
| 8 | Doxycycline | 28 | =Doxycycline =Ciprofloxacin | 17 |
| 9 | =Atorvastatin =MMR Vaccine | 25 | — | |
| 10 | — | | =Metronidazole =MMR Vaccine | 16 |

Table 9 - Top Five Medicines reported for paediatrics and aged 65+ in 2022/23 (Scotland)

| | Paediatrics | 65 Years Plus |
|---|-------------------------------------------------------|--------------------------------------------|
| 1 | COVID-19 Vaccine ▼ (n=29) | COVID-19 Vaccine ▼ (n=403) |
| 2 | Influenza Vaccine (n=26) | Pneumococcal Vaccine (n=55) |
| 3 | MMR Vaccine (n=20) | Influenza Vaccine (N=51) |
| 4 | =HPV Vaccine (n=7) =Varicella Zoster Vaccine (n=7) | Nirmatrelvir/Ritonavir (Paxlovid) ▼ (n=38) |
| 5 | — | Varicella Zoster Vaccine (n=27) |

Notes

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

3g Sources of Reports

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

| Reporter | 2022/23 | | 2021/22 | | 2020/21 | |
|----------------------------------|-------------|------------|-------------|------------|-------------|------------|
| | Number | % of total | Number | % of total | Number | % of total |
| Carer | 6 | <1% | 19 | 1% | 20 | 2% |
| Consumer | 75 | 2% | 4 | <1% | 1 | <1% |
| Parent | 121 | 4% | 86 | 6% | 64 | 5% |
| Patient | 2121 | 67% | 734 | 51% | 423 | 35% |
| Community Pharmacist | 25 | 1% | 18 | 1% | 25 | 2% |
| Hospital Pharmacist | 53 | 2% | 49 | 4% | 161 | 13% |
| Pharmacist | 192 | 6% | 115 | 8% | 57 | 5% |
| Pharmacy Assistant | 13 | <1% | 2 | <1% | - | - |
| Trainee Pharmacist | 32 | 1% | 23 | 2% | 12 | 1% |
| Hospital Nurse | 28 | 1% | 36 | 3% | 88 | 7% |
| Nurse | 118 | 4% | 82 | 6% | 62 | 5% |
| GP | 123 | 4% | 72 | 5% | 85 | 7% |
| Hospital Doctor | 164 | 5% | 127 | 9% | 157 | 13% |
| Physician | 2 | <1% | 7 | 1% | 1 | <1% |
| Paramedic | 1 | <1% | 3 | <1% | - | - |
| Dentist | 15 | <1% | 13 | 1% | 2 | <1% |
| Midwife | 7 | <1% | 1 | <1% | 2 | <1% |
| Optometrist | 3 | <1% | 2 | <1% | 2 | <1% |
| Chiropodist | 2 | <1% | - | - | - | - |
| Radiographer | 33 | 1% | 7 | 1% | 14 | 1% |
| Hospital Healthcare Professional | 5 | <1% | 7 | 1% | 11 | 1% |
| Healthcare Assistant | 11 | <1% | 1 | <1% | - | - |
| Other Healthcare Professional | 19 | 1% | 10 | 1% | 13 | 1% |
| Medical Student | 3 | <1% | 2 | <1% | 3 | <1% |
| Unknown | 0 | 0 | - | - | - | - |
| Total | 3172 | | 1420 | | 1203 | |

3h Types of reports (Scotland)

Table 11 - Report submission routes

| Report Type | 2022/23 | | 2021/22 | |
|---------------------------------------------|---------|------------|---------|------------|
| | Number | % of total | Number | % of total |
| App | 968 | 31% | 110 | 8% |
| Electronic Yellow Card via website | 2076 | 65% | 1208 | 85% |
| MiDatabank (Pharmacy Medicines Information) | 39 | 1% | 21 | 1% |
| Paper | 45 | 1% | 31 | 2% |
| Vision (GP system) | 44 | 1% | 50 | 4% |

Table 11 shows the ways in which reporters in Scotland submitted Yellow Cards in 2022/23 compared with 2021/22.

4. Discussion of Yellow Card Data

Including COVID-19 vaccine reports, a total of 3172 Yellow Card reports were submitted in Scotland in 2022/23.

Comparisons with the previous year's data are complicated by a change from the MHRA using a dedicated COVID-19 platform to using the standard Yellow Card reporting pathway for reports involving COVID-19 vaccines.

In 2021/22, 23,438 reports were submitted (1420 Yellow Card reports and 22,018 COVID-19 vaccine reports).

In 2022/23, 3172 reports were submitted (1827 non-COVID-19 vaccine reports and 1345 COVID-19 vaccine reports).

Comparing 2022/23 total number of Yellow Card reports (3172) with 2021/22 (1420) represents an overall increase of 124% in Yellow Card reporting. This increase can be partly attributed to reports for COVID-19 vaccines (n=1345) which are included in the standard dataset as of July 2022, whereas in previous years they were listed separately.

Excluding the reports for COVID-19 vaccines leaves a total of 1827 reports, which still represents an increase of 29% from the previous year's standard reporting data. This figure now exceeds pre-pandemic reporting levels without considering COVID-19 vaccine reports. Prior to the pandemic, reporting averaged around 1440 reports annually from the 5 years prior to the pandemic (April 2015 to March 2020 inclusive).

Reporter Groups trends:

- **Patient groups:** Reporting by patients, parents, and carers accounted for 73% of the total reports in Scotland (and 85% of the Covid-19 vaccine reports). This represents another substantial increase and possibly reflects a better awareness of the Yellow Card Scheme.
- **Healthcare professionals:** Reporting by healthcare professionals increased in number but decreased in proportion accounting for only 27% of the total reports. Despite a +47% increase in the total number of reports submitted (from 577 in 2021/22 to 849 in 2022/23) the proportion of reports from HCPs is notably much lower than in 2021/22, when it was 41% of all reports. Almost all groups noticed an increase in reporting and specific mention is made to the 371% increase from last year by radiographers across ten different health board areas with suspect substances ranging from COVID-19 vaccines to typically used medicines in a radiology department.

Submission routes:

- **MiDatabank (Pharmacy Medicines Information system):** Reporting via MiDatabank has improved in 2022/23, representing a 86% increased compared to the previous year. Of these, 48% were reported from NHS Lothian and 28% from NHS Tayside. Research is almost complete 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 Tayside, NHS Highland and NHS Lothian.
- **Notable increase:** NHS Fife displayed a notable increase in reports, increasing by +176% in 2022/23 compared to 2021/22.

Suspect Medicines:

- **Range of medicines:** It should be noted that, excluding vaccines, the range of suspect medicines reported is very diverse. In 2022/23 there were 444 different suspect medicines reported (for 3172 reports). Excluding the COVID-19 vaccine, 443 different suspect medicines were included within 1827 report. It is noted that some reports include multiple suspect medicines. This is a reduction on last year where 460 different suspect substances were included in reports. 42% of reports were for COVID-19 vaccines and 6% of the total reports were for the second top suspect medicine, the influenza vaccine.
- **Top 10:** Notably in 2022/23, the third top reported suspect medicine was Paxlovid (nirmatrelvir/ritonavir), with pneumococcal vaccine remaining prominent while generic medicines sertraline, flucloxacillin, doxycycline and atorvastatin feature.
- **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. It was adopted into national guidance for non-hospitalised patients and as health boards prepared patient pathways for assessment and prescription of this medicine, there has unsurprisingly been an increase in the number of reported adverse reactions by 283%.
Of the total, 76% were non-serious. The most commonly reported reactions were consistent with the most common side effects reported in clinical trials (diarrhoea, nausea and altered sense of taste). Advanced age was included in the eligibility criteria and will have influenced the presence of reports for patients who are 65 years and over.
- **Sertraline:** 63% of reports were from patients, with a spread across Scotland. The reported reactions were in keeping with the known side effect profile including gastrointestinal, nervous system, sex hormone dysfunction, mood and skin reactions were reported.
- **Flucloxacillin, doxycycline and atorvastatin:** The reported reactions were in keeping with the known side effect profiles.
- **Paediatrics:** Vaccines remain the most commonly reported suspect medicines, as in previous years.

Serious ADRS:

- 1676 reports were classed as serious (53% 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 56 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.

Drug safety updates 2022/23 – observations and associations:

- **Fluoroquinolone antibiotics:** We have continued to receive reports of serious reactions with fluoroquinolone antibiotics (ciprofloxacin, delafloxacin, levofloxacin, moxifloxacin, ofloxacin) including tendinopathy and tendon rupture. Healthcare professionals are reminded to be alert to the risk of disabling and potentially long-lasting or irreversible side effects - see August 2023 Drug Safety Update for details.
- **Janus kinase (JAK) inhibitors:** Users of JAK inhibitors, e.g., tofacitinib (Xeljanz), abrocitinib (Cibinqo ▼), baricitinib (Olumiant), upadacitinib (Rinvoq ▼), and filgotinib (Jyseleca ▼) are reminded of measures to reduce risks of major cardiovascular events, malignancy, venous thromboembolism, serious infections and increased mortality when used for chronic inflammatory disorders. We have received reports of some of these ADRs in patients on JAK inhibitors in 2022/2023. More information is available in the April 2023 Drug Safety Update.
- **Nitrofurantoin:** we have received reports of pulmonary adverse drug reactions with nitrofurantoin, the risks of which were highlighted in the April 2023 Drug Safety Update (along with hepatic ADRs). Healthcare professionals prescribing nitrofurantoin should be alert to the risks of pulmonary and hepatic adverse drug reactions and advise patients to watch out for signs and symptoms that indicate a need for further investigation.

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, but data on number of users is not yet available on this new platform.

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 | 176 | 17.5 |
| Non-Medical Prescribers | Non-Medical Prescribers Leads Group Update | 1 | 2 | 27 | 2 |
| Pharmacists | Yellow Card Teaching & Promotion | 0.75 | 2 | 44 | 1.5 |
| Senior Healthcare Professionals | ADTC Collaborative Update | 0.5 | 1 | 30 | 0.5 |
| Healthcare Professionals | Grand Rounds ADR Teaching & Promotion | 1 | 1 | 85 | 1 |
| Toxicologist | Individual Training Session | 1 | 3 | 3 | 3 |
| Totals | | | 16 | 365 | 25.5 |

Additional activity included contacting the Communications departments for all geographic Scottish health board areas with digital banners to promote adverse drug reactions and pharmacovigilance on their websites and intranet pages, and providing digital banners and informational slides to be displayed during virtual conferences for Scottish healthcare professionals.

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* | 6 | 6 | 1.5 |
| Member of the Public | Email Conversation | 0.3* | 4 | 4 | 1.2 |
| *Average number of hours across all instances; actual time spent for each instance ranged from 0.1 hours to 0.5 hours | | | | | |

Although face-to-face activities began operating again throughout 2022/23, YCCS did not attend any events in person and primarily maintained an online presence. YCCS continued to receive queries from the public via email, Twitter and telephone. 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 |
|-----------------------------------------|----------------------|------------------|----------------|-----------------|-------------|
| Undergraduate Medical Students | ADR Teaching Session | 2 | 1 | ~200 | 2 |
| Postgraduate Internal Medicine Students | ADR Teaching Session | 2 | 1 | ~50 | 2 |
| Total | | | 2 | ~250 | 4 |

6. Publications

1. Haslam E, Wilson K, Bollington L, **Maxwell S**. The prescribing safety assessment: Looking to the future. *Pharmacol Res Perspect*. 2023 Apr;11(2):e01073. doi: 10.1002/prp2.1073.
2. Power A, Stewart D, Craig G, Boyter A, Reid F, Stewart F, Cunningham S, **Maxwell S**. Student and pre-registration pharmacist performance in a UK Prescribing Assessment. *Int J Clin Pharm*. 2022 Feb;44(1):100-109. doi: 10.1007/s11096-021-01317-z.

7. YCCS Website/Social Media

7a Website Updates

The YCCS website on SHOW has been maintained and updated to reflect the most current information. Simon Maxwell has written a second article for the YCCS website blog, discussing adverse drug reaction monitoring in a post-pandemic world.

In order to comply with GDPR regulations, a consent banner would need to be implemented to obtain usage data for the website. After investigation into the feasibility of this, it was decided that this information will no longer be gathered to keep the website as user-friendly and uncomplicated as possible.

7b Social Media Statistics

Twitter

Table 16 - Twitter analytics over the last 3 years

| | 2022/23 | 2021/22 | 2020/21 | % change 2021/22 to 2022/23 |
|------------------------------|---------|---------|---------|-----------------------------|
| Number of Followers | 1470 | 1462 | 1366 | 0% |
| Tweets sent | 40 | 75 | 98 | -47% |
| Total number of Engagements* | 492 | 951 | 713 | -48% |
| Impressions** | 20,372 | 40,220 | 77,110 | -49% |

* Engagements are when a follower interacted with a tweet

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

The number of followers for the YCCS Twitter account has not changed significantly over the last year, though it is difficult to say what effects the changes to the management of Twitter will have had. The number of posts from YCCS was considerably lower in 2022/23 compared to 2021/22, and the number of engagements and impressions are similarly lower. Efforts will be made to prevent any further decline in the use of the social media platform, and posts will be scheduled on a more regular basis going forward in 2023/24.

The top Twitter posts for 2022/23 were all posts relating to Medicines Safety week, with a combined total of 11348 impressions and 248 engagements across six separate posts.

8. Research and ongoing initiatives

- MiDatabank e-YC reporting. Research is currently underway in NHS Lothian to explore the barriers to Medicines Information (MI) staff reporting e-YC via *MiDatabank* (MSc Advanced Pharmacy; Louise Smith NHS Lothian).
- Identifying barriers to reporting for professional groups – in 2023 the focus will be with primary care pharmacy colleagues with scope to expand to other professional groups across the territorial boards (Quality Improvement; East Region Trainee Pharmacists, Education Research and Development and Louise Smith NHS Lothian).

9. Conclusion

The known pressures within the health service and society in general have continued to influence Yellow Card reporting and the activities of the Yellow Card Centre for Scotland throughout 2022/23. It is encouraging to note a further increase in reporting by patient groups and that numbers of reports (excluding COVID-19 vaccines) now exceed pre-pandemic levels.

During the 2022/23 period the service had a change in leadership. During this time of transition, the team continued to deliver training and promotion using similar methods used during pandemic times.

As a centre for a devolved nation, YCC Scotland recognises that the messaging from the MHRA on the promotion of the Yellow Card scheme for medical devices in England and Wales may have an impact on reporting in Scotland. The impact of mixed models for reporting will be closely monitored and discussed with colleagues from IRIC who are represented within the Yellow Card advisory group.

From 2023/24 onwards, YCC Scotland will seek to have a renewed outlook on education and promotion in response to the many changes that have occurred post-pandemic. A detailed communications strategy and a plan to seek feedback from stakeholders will allow for a better understanding of the drivers and challenges behind the reporting trends by certain groups and geographical areas.

Finally, there is a continued focus nationally on digital innovations around the integration of prescribing and medicines administration systems with electronic Yellow Card reporting to facilitate efficient reporting.

10. Acknowledgements

YCC Scotland would like to acknowledge the following individuals for their help and support throughout 2022/23:

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- 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
- Peter Hamilton, Principal Lead for Professional Development, NHS Education for Scotland
- Catriona Sinclair, Community Pharmacy Scotland (CPS) Representative
- Sue Cole, Patient Representative

*YCC Scotland was sad to learn of the passing of Professor McLay during this reporting year after many years of association with pharmacovigilance in Scotland

Abbreviations and descriptions

| | |
|-------|-------------------------------------------------------|
| 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 |
| TURAS | NHS Education for Scotland's single, unified platform |
| UG/PG | Undergraduate/Postgraduate |
| MHRA | Medicines and Healthcare Products Regulatory Agency |