



# Yellow Card Centre North West

## ANNUAL REPORT

TO THE MEDICINES AND HEALTHCARE  
PRODUCTS REGULATORY AGENCY

# 2018/19

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**2018/19**

### 1. STAFF

Professor Sir Munir Pirmohamed – Director  
Christine Randall – Senior Medicines Information Pharmacist  
David Moloney – Medicines Information Technician  
Helen Edmondson – Medicines Information Technician  
Marian Madden – Administrative Assistant

### 2. EXECUTIVE SUMMARY

In 2018/19 a total of 4,148 Yellow Cards (YCs) were submitted by health professionals, patients and carers from the Yellow Card Centre North West (YCCNW) region. This is a 5.4% increase on 2017/18, reporting has increased by 78% over the last five years.

Hospital pharmacists reported more YCs than any other group, 1,636 reports (39% of the total). Reporting increased substantially this year by; pharmacy technicians/assistants 346 reports (up by 204%), 'pharmacists' (not further specified) 111 reports (up by 85%) and radiographers 37 reports (up by 54%). Reporting by GPs fell to 306 reports (down by 20%), nurses (primary and secondary care) and community pharmacists also fell slightly this year. RIDR reports fell to 12 this year (down by 48%). Patient/carer reporting continues to increase, up by 6.2% in 2018/19 and accounting for 18% of reporting.

Serious adverse drug reactions (ADRs) accounted for 60% of all reports (54 reports [2.2% of serious reports] had a fatal outcome).

For the second year the top reported suspect drug was apixaban with 179 reports. Eight of the 2018/19 top ten suspect drugs also appeared in the 2017/18 top ten; apixaban, influenza vaccine, phenoxymethylpenicillin, rivaroxaban, sertraline, meningitis B vaccine, aspirin and omeprazole. New to the 2018/19 top ten are ramipril and flucloxacillin. We received one Tobacco Product Directive (TPD) report via the e-cigarette portal this year.

Reporting of ADRs via YCs embedded in electronic healthcare systems now account for 27% of all our reports. Current systems in use in the North West are MiDatabank (pharmacy medicines information system) which contributed 832 reports (33% of hospital pharmacy reports), SystmOne (GP patient management system that is also used in prisons, custody centres and some hospices) which contributed 285 reports, down from 308 reports last year (7% decline) and Vision (GP patient management system which went live for Yellow Card reporting during 2017/18). 72% of North West GP reports were made using either SystmOne or Vision with 37% of those made by GPs working in the prison service. The majority of GP practices in the North West use EMIS who have yet to roll out a system upgrade to enable inclusion of an embedded Yellow Card, this development is due in 2019/20.

The North West-wide network of Yellow Card Champions was set up in 2015 to share good practice, explore ideas and initiatives and lend support. The Champions meet twice a year and the group continues to expand. Secondary care and community or mental health trusts who send representatives to meetings (20 of 28 acute plus 4 of 8 community /mental health) contributed 1,990 reports in 2018/19 (48% of all reports, 76% of secondary care reports and 64% of community/mental health trusts). The top ten reporting secondary care trusts actively participate in the Champions network.

YCCNW continues to accommodate many and varied requests to talk to and support local reporters, health professionals, students and patients. In 2018/19 over 20 training sessions were provided addressing over 600 individuals.

In 2018/19 YCCNW continued to support reporting to the Yellow Card Scheme:

- locally by providing quarterly feedback to NHS Trusts on their reporting.
- nationally by co-ordinating feedback of MiDatabank ADR reporting on behalf of the MHRA and UKMi via emails to the MiUK discussion group and posted on the Specialist Pharmacy Services website.
- nationally by contributing one review of medication safety alerts, communications and publications for the monthly MSO WebEx event facilitated by NHS England.
- by updating the CPPE ADR e-learning programme assessment.
- by updating ADR information in the CPPE /NHS Medicines Safety App.

### 3. YELLOW CARD DATA

- **ADR reports received**

Overall 4,148 reports of suspected ADRs were made by healthcare professionals and patients/carers from the YCCNW region in 2018/19. Table 1 highlights the total number of reports originating from the YCCNW region for the past five years and Figure 1 is a graphical representation of this data. Figure 2 shows the split by reporter type for Yellow Card reports originating in the YCCNW region in 2018/19 and Figure 3 compares the number of reports for each reporter type received in 2018/19 with those received in previous years.

**Table 1. The total number of reports and percentage change over the last five years from the YCCNW region.**

Year	Number of reports	Percentage change on previous year
2018/19	4,148	+5.4%
2017/18	3,936	+5.3%
2016/17	3,738	+5.1%
2015/16	3,554	+52.7%
2014/15	2,328	+25.1%

**Figure 1. Line graph summarising the total number of reports originating from the YCCNW region for the past five years.**

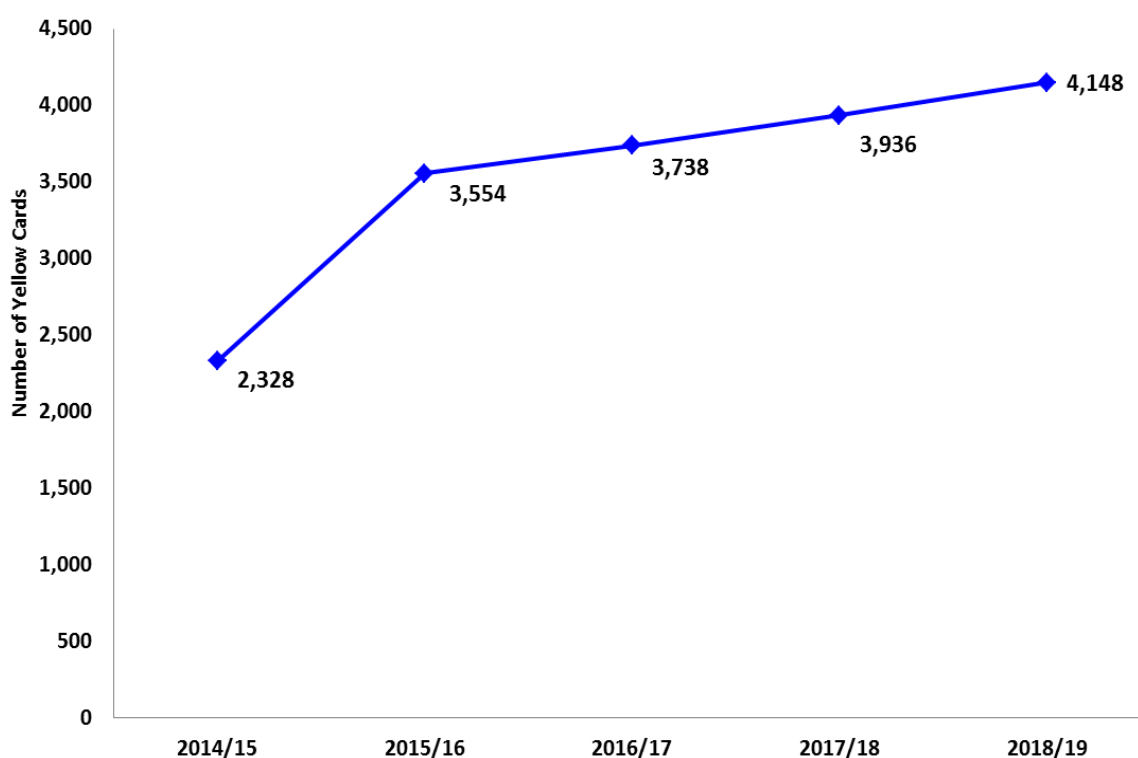


Figure 2. Percentage of Yellow Card reports that originated from the YCCNW region for each reporter group in 2018/19.

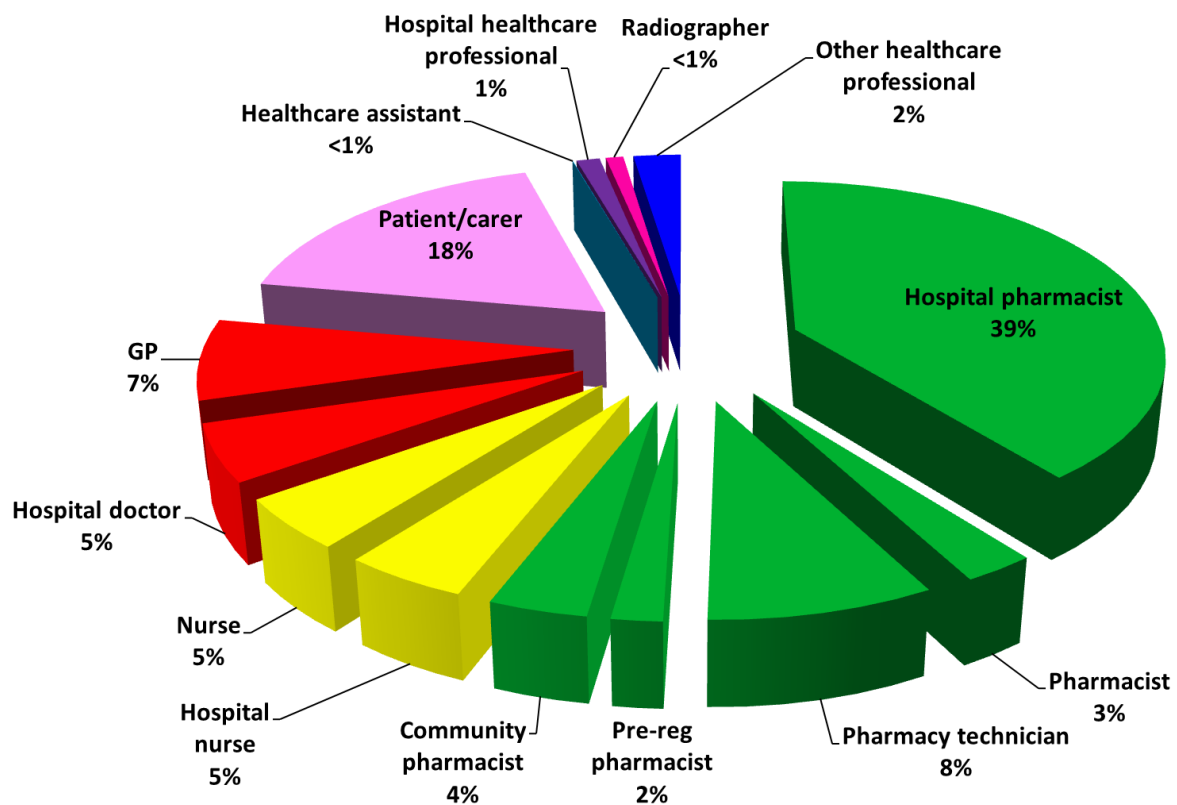
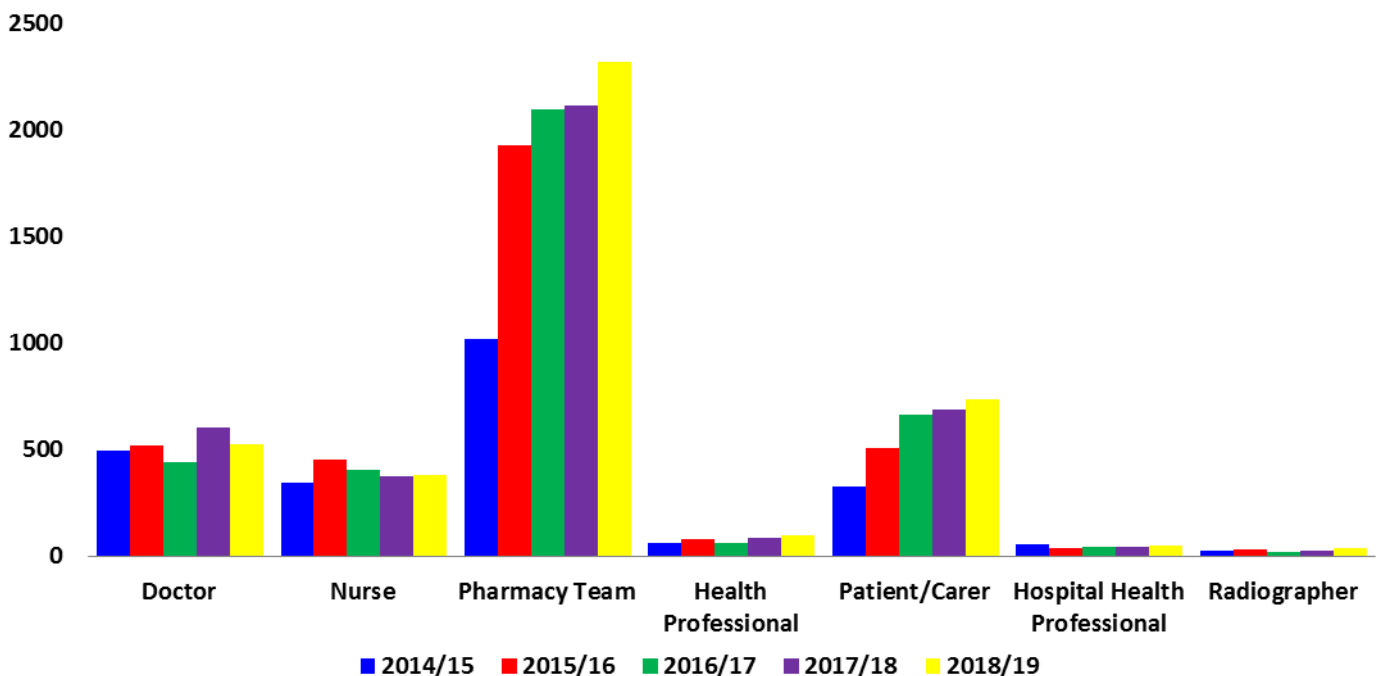


Figure 3. Number of Yellow Card reports received from each reporter group in 2018/19 compared with the previous four years.



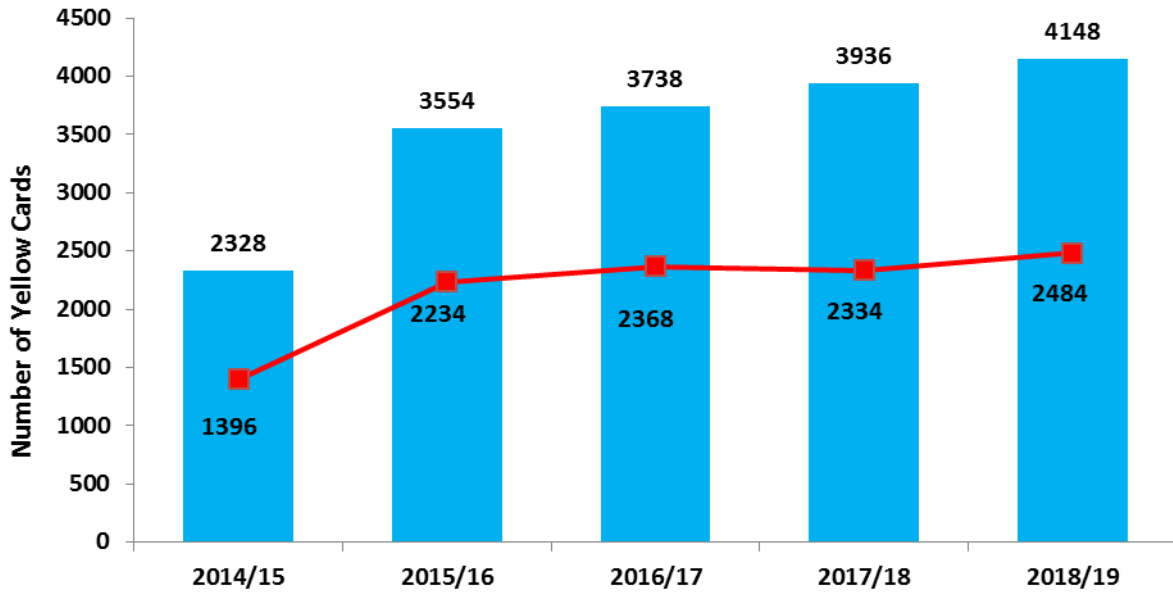
- **Serious reactions**

Total number of reports classified as serious that originated from the YCCNW region in 2018/19 and comparative data for previous years are shown in Table 2 and displayed graphically in Figure 4. A fatal outcome was reported on 54 Yellow Cards in 2018/19.

**Table 2**

Year	Number of serious reports	Percentage of total reports	Percentage change on previous year
2018/19	2,484	60%	6.4%
2017/18	2,334	59%	-1.4%
2016/17	2,368	63%	+6%
2015/16	2,234	63%	+60.0%
2014/15	1,396	60%	+20.1%

**Figure 4. Serious Yellow Card reports as a proportion of total reports from 2014/15 to 2018/19 for the YCCNW region.**



- **Fatal reports**

Total number of fatalities that were reported from within the YCCNW region in 2018/19 and comparative data from previous years are shown in Table 3.

**Table 3**

Year	Number of fatal reports	Percentage change on previous year
2018/19	54	-12.9%
2017/18	62	+67%
2016/17	37	-13.9%
2015/16	43	+7.5%
2014/15	40	+8%

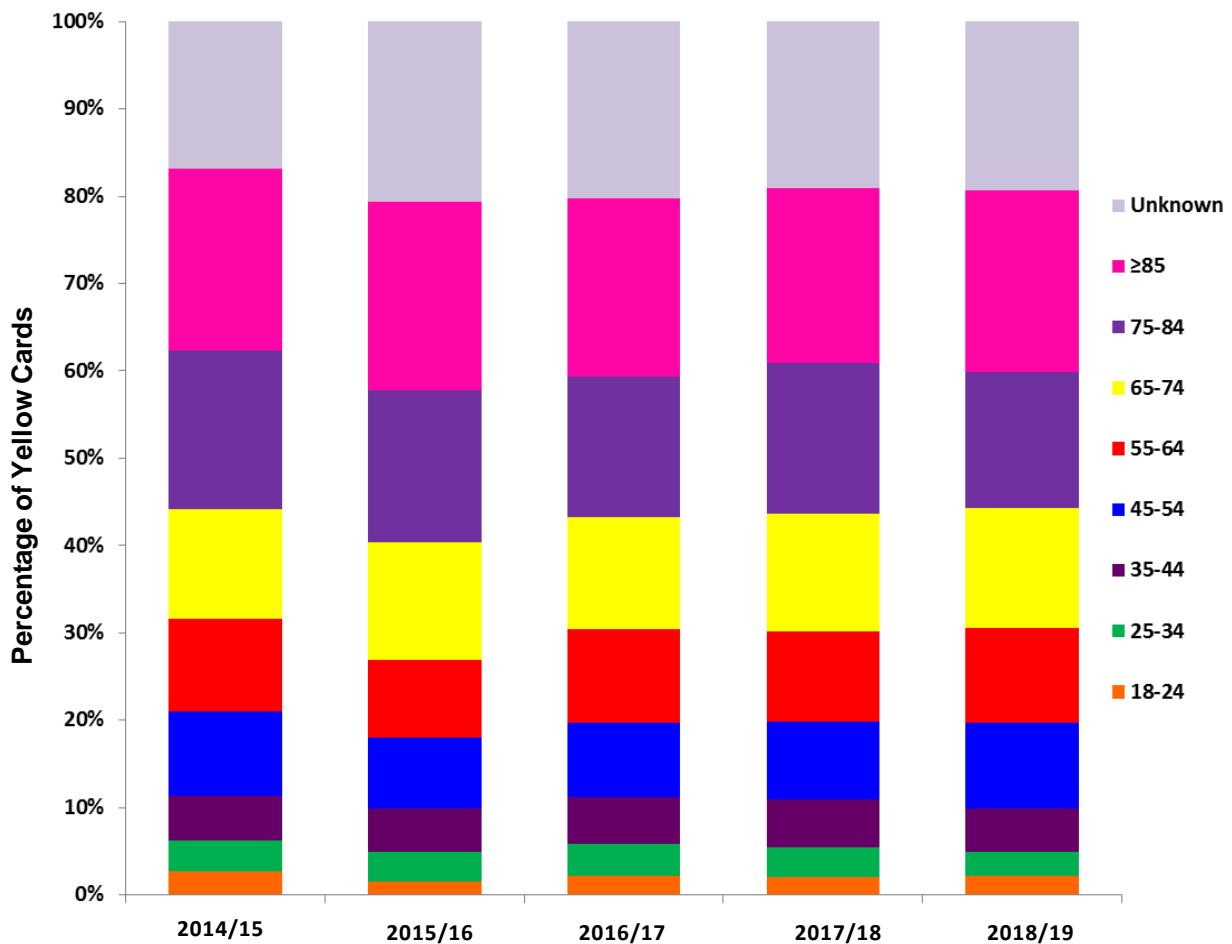
- **Age breakdown**

Table 4 shows the number of Yellow Cards originating from within the YCCNW region stratified by patient age at time of reaction, 2014/15 to 2018/19. Figure 5 is a graphical representation of this data.

**Table 4**

Age band (years)	2014/15	2015/16	2016/17	2017/18	2018/19
Under 2	46	93	91	95	98
2-6	46	38	101	77	89
7-12	52	44	67	68	71
13-17	70	102	111	110	97
18-24	99	146	166	183	165
25-34	192	240	262	293	334
35-44	207	263	332	338	367
45-54	248	400	397	445	464
55-64	356	513	493	569	525
65-74	408	636	631	661	704
75-84	331	612	625	627	653
≥85	177	340	338	296	371
Unknown	96	127	124	174	210
<b>Total</b>	<b>2,328</b>	<b>3,554</b>	<b>3,738</b>	<b>3,936</b>	<b>4,148</b>

**Figure 5. Percentage of Yellow Card reports that originated from the YCCNW region, stratified by age group from 2014/15 through to 2018/19.**



- **Top ten drugs**

Table 5 lists the top ten reported suspect drugs originating from within the YCCNW region for 2018/19. Overall there were 5,013 suspect drugs reported on 4,148 Yellow Cards (some Yellow Card reports had more than one suspect drug). The top ten suspect drugs accounted for 18% of total suspect drugs reported on a Yellow Card. Table 6 contains the top ten reported suspect drugs originating from within the YCCNW region for 2017/18; these drugs accounted for 19% of total suspect drugs reported on a Yellow Card in 2017/18.

**Table 5. The top ten reported suspect drugs for Yellow Cards that originated from the YCCNW region in 2018/19.**

Drug name	Number of times reported as a suspect drug (2018/19)
Apixaban	179
Influenza virus (some ▼)	113
Phenoxymethylpenicillin	101
Rivaroxaban ▼	91
Sertraline	86
Omeprazole	74
Aspirin	73
Meningococcal group B vaccine ▼	73
Ramipril	66
Flucloxacillin	60
Total	916

**Table 6. The top ten reported suspect drugs for Yellow Cards that originated from the YCCNW region in 2017/18.**

Drug name	Number of times reported as a suspect drug (2017/18)
Apixaban	134
Influenza Vaccine (some ▼)	121
Phenoxymethylpenicillin	116
Rivaroxaban ▼	99
Meningococcal group B vaccine ▼	67
Sertraline	56
Levothyroxine	51
Ibuprofen	50
Ciprofloxacin	48
Aspirin Clarithromycin	47
Total	789

- Source of reports

Table 7 Number of Yellow Cards originating from within the YCCNW region stratified by reporter type from 2016/17 to 2018/19.

Reporter	2016/17		2017/18		2018/19	
	Number	% of total	Number	% of total	Number	% of total
Carer	40	1.1%	42	1.1%	35	0.8%
Parent	80	2.1%	95	2.4%	96	2.3%
Patient	546	14.6%	553	14%	603	14.5%
Community Pharmacist	163	4.4%	169	4.3%	151	3.6%
Hospital Pharmacist	1,669	44.6%	1,608	40.9%	1,636	39.4%
Pharmacist	55	1.5%	95	2.4%	111	2.7%
Pharmacy Technician/assistant	86	2.3%	114	2.9%	346	8.4%
Pre-reg pharmacist	121	3.2%	129	3.3%	78	1.9%
Hospital Nurse	183	4.9%	185	4.7%	191	4.6%
Nurse	224	6.0%	188	4.8%	193	4.7%
GP	238	6.4%	382	9.7%	306	7.4%
Hospital Doctor	199	5.3%	208	5.3%	216	5.2%
Physician	4	0.1%	10	0.3%	3	0.07%
Coroner	1	0.03%	1	0.02%	1	0.02%
Dentist	9	0.2%	5	0.1%	2	0.05%
Midwife	1	0.03%	3	0.1%	5	0.1%
Optometrist	2	0.1%	2	0.05%	1	0.02%
Paramedic	0	0.0%	4	0.1%	1	0.02%
Radiographer	20	0.5%	24	0.6%	37	0.9%
Hospital Healthcare Professional	45	1.2%	41	1%	49	1.2%
Healthcare Assistant	6	0.2%	28	0.7%	1	0.002%
Other Healthcare Professional	42	1.1%	48	1.2%	82	2%
Medical Student	2	0.1%	1	0.02%	6	1%
Other	2	0.1%	1	0.02%	0	0%
<b>Total</b>	<b>3,738</b>	<b>100%</b>	<b>3,936</b>	<b>100%</b>	<b>4,148</b>	<b>100%</b>

Green – increasing figures  
 Red – decreasing figures  
 Black – no changes



- **Type of report**

Table 8 shows the method used to report an ADR to the Yellow Card Scheme in 2018/19.

**Table 8. Number of Yellow Card reports from each reporting method originating from the YCCNW region in 2018/19.**

	Number of reports	Percentage of total reports
Electronic Yellow Card	2826	68%
MiDatabank (Pharmacy medicines information)	832	20%
SystemOne (Patient management system)	285	6.9%
Paper	188	4.5%
RIDR (Report Illicit Drug Reactions scheme)	12	0.3%
APP	12	0.3%
Vision (Patient management system)	4	0.1%
TPD (Tobacco Product Directive)	1	<0.1%

#### 4. INTERPRETATION OF REPORTING FIGURES

Yellow Card reports originating from the YCCNW region increased by 5.4% in 2018/19 compared with 2017/18. Although the rate of reporting has slowed it is up by 78% compared to five years ago. Reporting increased substantially this year by; pharmacy technicians/assistants 346 reports (up by 204%), 'pharmacists' (not further specified) 111 reports (up by 85%) and radiographers 37 reports (up by 54%). Patient/carer reporting continues to increase, up by 6.2% in 2018/19 and accounting for 18% of reporting. Hospital pharmacists continue to report more than any other professional group - 1,636 reports (39% of the total), approximately half were made using MiDatabank.

Reporting by GPs fell to 306 reports (down by 20%), nurses (primary and secondary care) and community pharmacists also fell slightly this year. RIDR reports fell to 12 this year (down by 48%).

Reporting via electronic healthcare systems with embedded YCs continues to increase and they now contribute 27% of all YCCNW reports (1,121 YC reports), contributions from each are:

- 832, MiDatabank (pharmacy medicines information system),
- 285 SystemOne (GP patient management system). Also used in prisons, custody suites, minor injuries units and hospices.
- 4 Vision (GP patient management system)

Reporting via the APP remains low with only 12 reports in 2018/19, four less than last year.

We received one Tobacco Product Directive (TPD) report via the e-cigarette portal this year plus 4 reports concerning e-cigarettes via electronic Yellow Cards.

The top reported suspect drug this year was apixaban with 179 reports. Eight of the 2018/19 top ten also appeared in 2017/18; apixaban, influenza vaccine, phenoxymethylpenicillin, rivaroxaban, sertraline, meningitis B vaccine, aspirin, and omeprazole. New to the top ten are, ramipril and flucloxacillin. Two thirds of reports for phenoxymethylpenicillin come from prisons, all these reports were made via SystemOne. Over a quarter of flucloxacillin reports came from one intravenous therapy centre.

Serious adverse drug reactions (ADRs) accounted for 60% of all reports (54 reports [2.2% of serious reports] had a fatal outcome). Black triangle drugs in the top ten include the oral anticoagulant rivaroxaban, meningococcal group B vaccine, and some influenza vaccines.

355 reports related to children under the age of 18 years, 70% of these reports related to vaccines and 13% related to antimicrobials.

Observations and associations in 2018/19:

- 179 reports listed apixaban as the suspect drug, 63% of these reports were made by hospital pharmacists and 16% made by pharmacy technicians, the pharmacy team accounted for 86% of apixaban reports. The apixaban reports included 78 of haemorrhage/bleeding reactions and 24 associated with a thromboembolic event.
- 35% of 151 community pharmacist reports were to vaccines, including 27 for meningitis B vaccine and 24 for influenza vaccines. This probably reflect the increasing role of community pharmacists in delivering vaccinations.
- Of 306 reports made by GPs 126 (41%) were to antimicrobials with 68 of these for phenoxymethylpenicillin which all came via SystmOne. GPs also made 17 reports associated with NSAIDs, 14 to opiate analgesics and 12 involving antidepressants.
- Eleven cases of serious skin reactions were reported; three of definite or suspected Steven's Johnson Syndrome (carbamazepine, ertapenem, fluconazole), four of toxic epidermal necrolysis (trimethoprim [2], apixaban, carbamazepine) and four of erythema multiforme (sertraline, amoxicillin, terbinafine, ivacaftor).
- 28 reports were for ECG QT interval prolongation suspected to be associated with medication, these included; 4 amitriptyline, 3 fluoxetine, 3 sertraline, 2 citalopram, 2 clarithromycin and 2 fluconazole.
- Patient reports included eight with ciprofloxacin as the suspect drug and which described adverse effects which had affected the musculoskeletal and/or nervous systems, some were disabling, long-lasting, all similar to those detailed in Drug Safety Update (March 2019).
- Of the 219 reports made by hospital doctors 20 described anaphylactic reaction; eight involved neuromuscular blocking agents and eight involve antibiotics.
- Following the Drug Safety Update article *Hydrochlorothiazide: risk of non-melanoma skin cancer, particularly in long-term use* in November 2018 we received 2 reports of basal cell carcinoma and two for squamous cell carcinoma suspected to be associated with hydrochlorothiazide.
- Wrightington, Wigan and Leigh NHS Foundation Trust accounted for 68% of all technician reporting in the north west.

## 5. PROMOTIONAL ACTIVITIES

### • Training delivered

Training carried out during 2018/19 in relation to ADRs and reporting to the Yellow Card Scheme is documented in Tables 9, 10 and 11. Table 9 contains data relating to training of healthcare professionals, table 10 contains data relating to training undergraduates and table 11 relates to presentations given to patients.

**Table 9. Training provided to healthcare professionals in 2018/19**

Audience type	Session type	Duration (hours)	Number of sessions	Total audience numbers	Total hours training
Dentists	Lecture	0.33 hours	4	190	2
Dentists – foundation trainees	Lecture	0.5 hours	4	50	2
MRC fellows	Lecture	0.75 hours	4	50	3
MSc HCPs	Lecture	1.0 hours	1	30	1
Non-medical prescribers	Lecture	1.25 hour	4	180	2.5
Pre-registration pharmacists	Lecture	1 hour	1	25	1
YCCNW Yellow Card Champions	Presentation	1.5 hours	2	45	3
<b>Totals</b>			<b>20</b>	<b>570</b>	<b>14.5</b>

**Table 10. Training provided to undergraduates in 2018/19**

Audience type	Session type	Duration	Number of sessions	Total audience numbers	Total hours training
Dental undergraduates	Lecture	0.5 hours	1	80	0.5
Nurse undergraduates	Lecture	1.5 hours	2	60	3.0
Medical students*	Lecture (introduction to personalised medicine)	1 hour	1	360	1
Medical students*	Lecture (prescribing in renal impairment)	1 hour	1	360	1
Medical students*	Lecture (ADRs and interactions)	1 hour	1	360	1
Medical students*	Lecture (drug overdose)	1 hour	1	360	1
Medical students*	Lecture	1 hour	14	360	14
Medical students*	Tutorial ( safe prescribing and harms of medicines)	1.5 hours	8	360	12
Medical students	Lecture (YYC NW/ ADRs)	1.0	1	200	1
<b>Totals</b>			<b>31</b>	<b>2500</b>	<b>34.5</b>

\*These lectures are delivered by clinical pharmacologists who are affiliated with YCCNW through links with The University of Liverpool's department of Clinical Pharmacology and Therapeutics. Lecture topics include: Introduction to analgesic drugs; How do drugs cause harm?; Introduction to interindividual variation; Prescribing safety in pregnancy; Pharmacology and movement disorders; Antidepressants; Therapeutic drug monitoring; Immunosuppressants; Ten ways to kill a patient; Drugs for diabetes; Biologics and biosimilars; Paediatric pharmacology; Cancer chemotherapeutics and Management of epilepsy. All of these lectures have adverse drug reactions as a learning outcome.

**Table 11. Training provided to patients in 2018/19**

Audience type	Session type	Duration	Number of sessions	Total audience numbers	Total hours training
Patient group (Polymyalgia rheumatic/Giant cell arteritis support group)	Lecture	1.5 hours	1	15	1.5

- Lectures delivered (invited)**

Prof. Pirmohamed spoke at 9 national and 16 international meetings and conferences throughout 2018/19.

- Materials developed to promote YCS**

CPPE e-learning programme ADRs – review and updating of assessment questions

Christine Randall contributes to updating the NHS Medicines Safety App. The app is a quick way for healthcare professionals to test their knowledge on high risk areas for medicines safety incidents. It provides a quiz with a series of ten multiple choice questions chosen randomly from a bank of questions for each topic or mixed up in a 'lucky dip'.

Training materials used to deliver educational sessions on ADRs and the Yellow Card scheme continue to be updated, with PowerPoint presentations tailored to the audience type.

## 6. PUBLICATIONS (2018/19)

1. Nicoletti P, Aithal GP, Chamberlain TC, Coulthard S, Alshabeeb M, Grove JI, Andrade RJ, Bjornsson E, Dillon JF, Hallberg P, Lucena MI, Maitland-van der Zee AH, Martin JH, Molokhia M, **Pirmohamed M**, Wadelius M, Shen Y, Nelson MR, Daly AK; International Drug-Induced Liver Injury Consortium (iDILIC). Drug-Induced Liver Injury due to Flucloxacillin: Relevance of Multiple Human Leukocyte Antigen Alleles. *Clin Pharmacol Ther*. 2019 Jul; 106(1):245-253.
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3. Floyd JS, Bloch KM, Brody JA, Maroteau C, Siddiqui MK, Gregory R, Carr DF, Molokhia M, Liu X, Bis JC, Ahmed A, Liu X, Hallberg P, Yue QY, Magnusson PKE, Brisson D, Wiggins KL, Morrison AC, Houry E, McKeigue P, Stricker BH, Lapeyre-Mestre M, Heckbert SR, Gallagher AM, Chinoy H, Gibbs RA, Bondon-Guitton E, Tracy R, Boerwinkle E, Gaudet D, Conforti A, van Staa T, Sitlani CM, Rice KM, Maitland-van der Zee AH, Wadelius M, Morris AP, **Pirmohamed M**, Palmer CAN, Psaty BM, Alfirevic A; PREDICTION-ADR Consortium and EUDRAGENE. Pharmacogenomics of statin-related myopathy: Meta-analysis of rare variants from whole-exome sequencing. *PLoS One*. 2019 Jun 26;14(6):e0218115.
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## 7. YCC WEBSITE

### Website updates

Due to IT issues the website has had limited updates, hosting issues are being investigated at the moment with a planned move to a new server. The move will also involve access to new software that will allow the website to be updated and maintained more frequently.

### Number of website hits

We are unable to obtain this information, however this should become available once the hosting issues are resolved.

### Twitter presence

In October 2018 we created a twitter account, @yellowcardnw, we have 82 followers with a moderate engagement on average of 4.4k. It is currently used to raise local and national awareness around safety in health and medicines, reporting ADRs as well as promoting our learning days and champions meetings.

## 8. RESEARCH AND ONGOING INITIATIVES

### North West Coast CLAHRC

The North West Coast Collaboration for Leadership in Applied Health Research and Care (CLAHRC) are developing four projects related to adverse drug reactions as part of their Delivering Personalised Health and Care theme.

The aims of the projects are:

Project 1 - Evaluate implementation of the Liverpool ADR Causality Assessment Tool in clinical practice. The Royal Liverpool (adult) and Alder Hey (paediatric) are selected sites for this evaluation.

Project 2 - Establish a biobank to investigate factors (genetic and non-genetic) underlying the onset of new ADRs.

Project 3 - Evaluate effectiveness of an educational programme in improving awareness of junior doctors to adverse drug reactions, and methods of reporting.

### YCCNW Champions network

The North West-wide network of Yellow Card Champions was set up in 2015 to share good practice, explore ideas and initiatives and lend support. The Champions meet twice a year and the group continues to expand. Secondary care and community or mental health trusts who send representatives to meetings (20 of 28 acute plus 4 of 8 community /mental health) contributed 1,990 reports in 2018/19 (48% of all reports, 76% of secondary care reports and 64% of community/mental health trusts). The top ten reporting secondary care trusts actively participate in the Champions network.

Presentations at Champions meetings:

- Yellow Card reporting at Alder Hey - Dr Dan Hawcutt, Paediatric Clinical Pharmacologist, Alder Hey Children's Hospital.
- Strategies to improve the detection and reporting of adverse drug reactions (how can the Liverpool ADR Causality Assessment Tool be implemented into clinical practice) - Anita Hanson, Lead research nurse at the Wolfson Centre, University of Liverpool.

## 9. CONCLUSION

In 2018/19 4,148 Yellow Cards were submitted by health professionals, patients and carers from the YCCNW region. This is a 5.4% increase compared to 2017/18. Hospital pharmacists continued to be the highest reporting group (1,636 reports (39% of the total)). This continuing high level of hospital pharmacy reporting correlates well with attendance at North West-wide Champion network meetings. The highest increase in reporting in 2018/19 came from pharmacy technicians (up by 204% 2017/18) again confirming that attendance at North West-wide Champion network meetings is impacting on reporting behaviours.

