

**YCC North West**

**ANNUAL REPORT  
2017/18**

# YELLOW CARD CENTRE NORTH WEST ANNUAL REPORT TO THE MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY

2017/18

## 1. STAFF

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## 2. EXECUTIVE SUMMARY

In 2017/18, 3,936 Yellow Cards (YCs) were submitted by health professionals, patients and carers from the Yellow Card Centre North West (YCCNW) region. This is a 5.3% increase on 2016/17, reporting has increased by 112% over the last five years.

Hospital pharmacists reported more YCs than any other group, 1,608 reports (41% of the total). Reporting increased substantially by; pharmacists (mainly practice based pharmacists) 95 reports (up by 72%), GPs 382 reports (up by 60%), pharmacy technicians 114 reports (up by 32%), and healthcare assistants 28 reports (up by 360%), 25 of which were to the RIDR scheme. Reporting by nurses (primary and secondary care) and community pharmacists fell slightly this year.

Serious adverse drug reactions (ADRs) accounted for 59% of all reports (62 reports [2.7% of serious reports] had a fatal outcome).

The top reported suspect drug this year was apixaban with 134 reports; it had been the 3<sup>rd</sup> most reported suspect drug in 2016/17. Seven of the 2017/18 top ten also appeared in 2016/17; influenza vaccine, meningitis B vaccine, rivaroxaban, apixaban, sertraline, ibuprofen and aspirin. New to the top ten are phenoxymethylpenicillin, levothyroxine and ciprofloxacin.

Reporting of ADRs via YCs embedded in electronic healthcare systems now account for 23.1% of all our reports. Current systems in use in the North West are MiDatabank (pharmacy medicines information system) which contributed 592 reports (32% of hospital pharmacy reports), SystmOne (GP patient management system that is also used in prisons and some hospices) which contributed 308 reports, up from 152 reports in 2016/17 and Vision (GP patient management system which went live for Yellow Card reporting during the 2017/18). 57% of North West GP reports were made using either SystmOne or Vision. In 2017/18 13 of 32 North West CCGs had GP practices using SystmOne or Vision. 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.

The North West-wide network of Yellow Card Champions, set up in 2015 to share good practice, explore ideas and initiatives and lend support, met twice in 2017/18 and continues to expand. Secondary care and community or mental health trusts who send representatives to meetings (18) contributed 1,577 reports in 2017/18 (40% of all reports, 66% of secondary care reports and 35% of community/mental health trusts). Nine of 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 2017/18 over 20 training sessions were provided addressing over 650 individuals.

In 2017/18 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 e-learning programme on ADR reporting.
- by updating ADR information in the CPPE /NHS Medicines Safety App.

## 3. YELLOW CARD DATA

- **ADR reports received**

Overall 3,936 reports of suspected ADRs were made by healthcare professionals and patients/carers from the YCCNW region in 2017/18. 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 these data. Figure 2 shows the split by reporter type for Yellow Card reports originating in the YCCNW region in 2017/18 and Figure 3 compares the number of reports for each reporter type received in 2017/18 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
<b>2017/18</b>	<b>3,936</b>	<b>+ 5.3%</b>
2016/17	3,738	+5.1%
2015/16	3,554	+52.7%
2014/15	2,328	+25.1%
2013/14	1,861	+26.2%

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

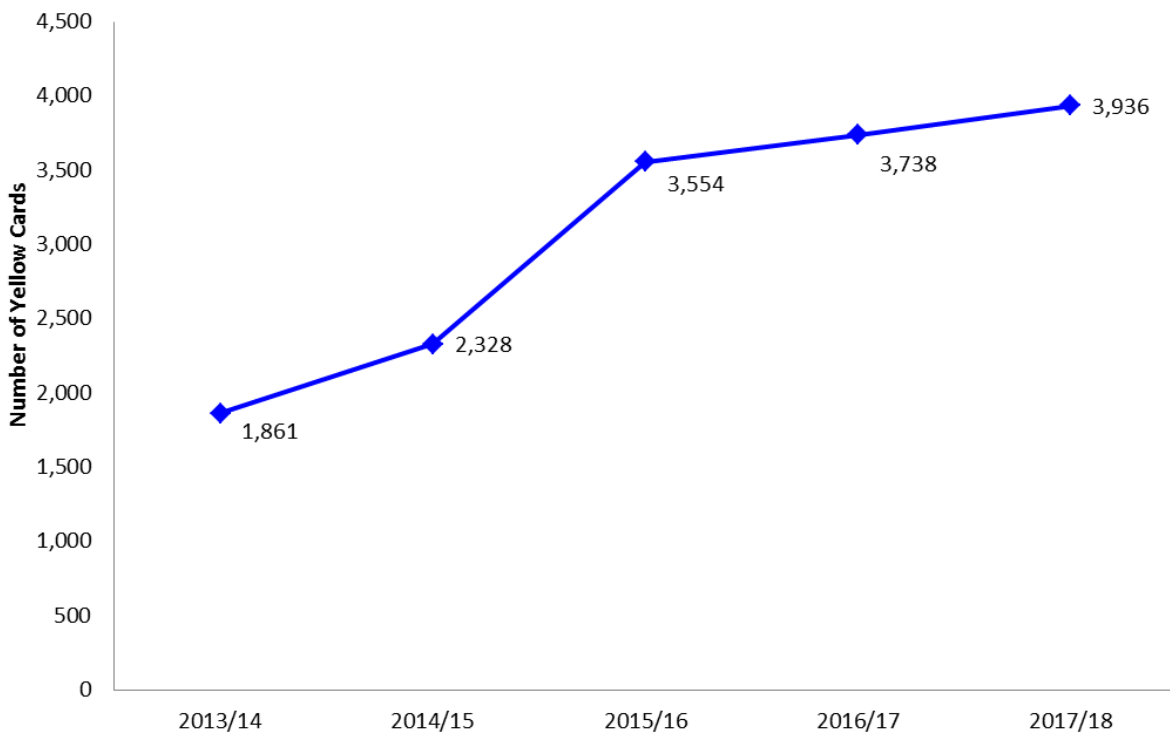


Figure 2. Percentage of Yellow Card reports that originated from the YCCNW region for each reporter group in 2017/18.

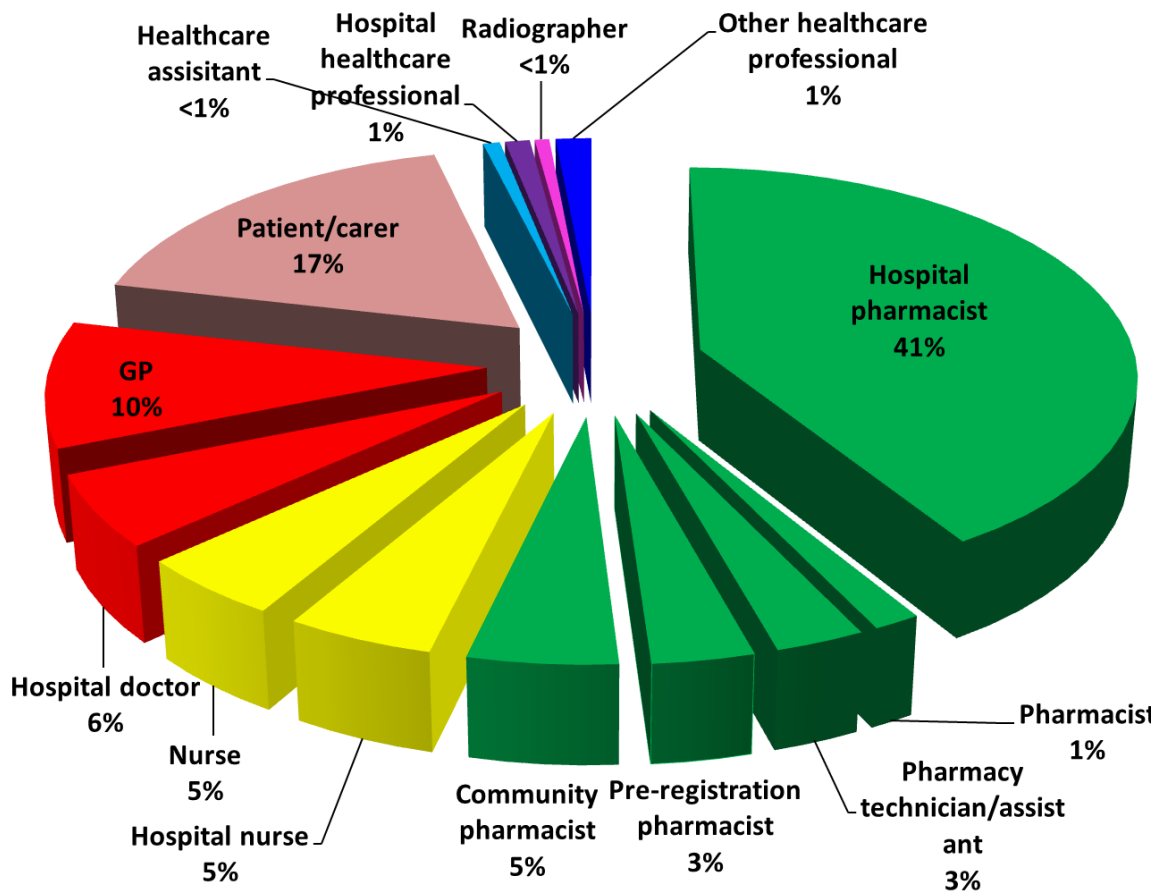
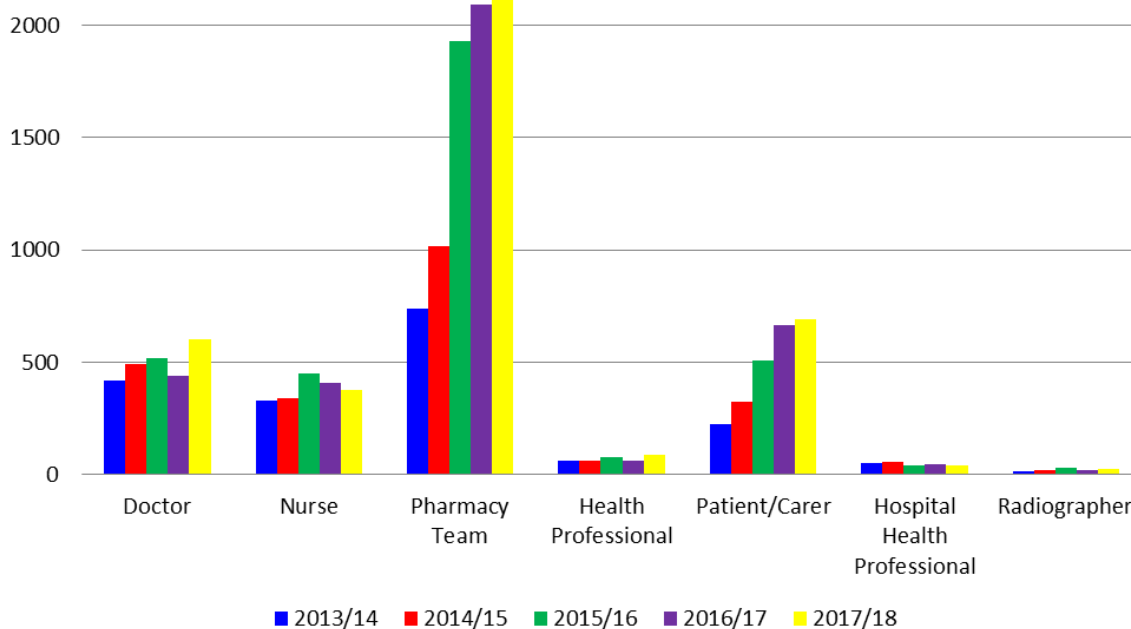


Figure 3. Number of Yellow Card reports received from each reporter group in 2017/18 compared with the previous four years.



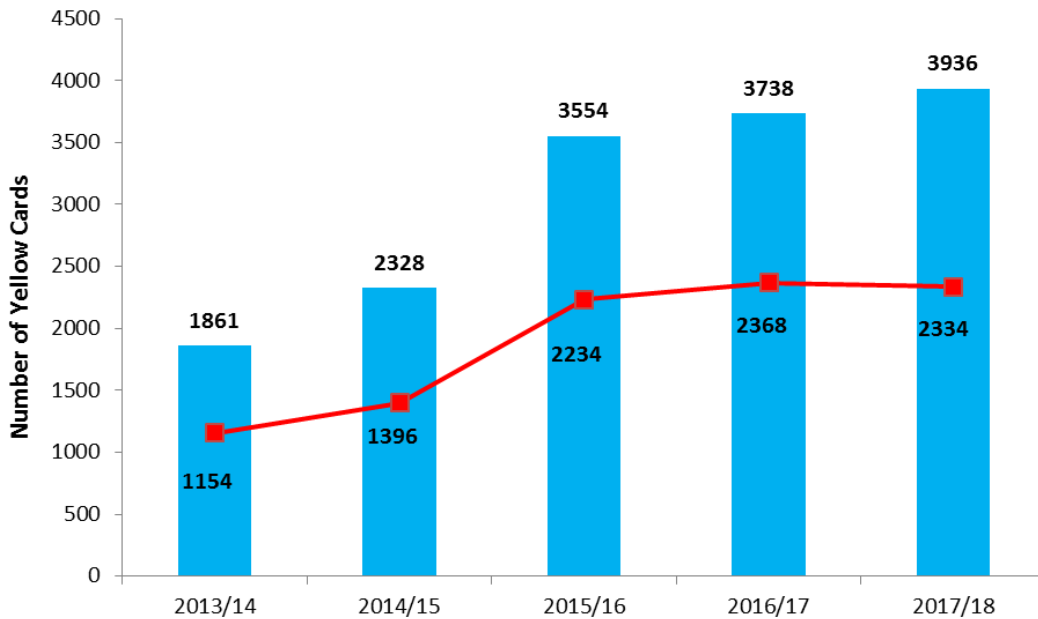
- Serious reactions**

Total number of reports classified as serious that originated from the YCCNW region in 2017/18 and comparative data for previous years are shown in Table 2 and displayed graphically in Figure 4. A fatal outcome was reported on 37 Yellow Cards in 2017/18.

**Table 2.**

Year	Number of serious reports	Percentage of total reports	Percentage change on previous year
<b>2017/18</b>	<b>2,334</b>	<b>59%</b>	<b>-1.4%</b>
2016/17	2,368	63%	+6%
2015/16	2,234	63%	+60.0%
2014/15	1,396	60%	+20.1%
2013/14	1,154	62%	+36.7%

**Figure 4. Serious Yellow Card reports as a proportion of total reports from 2013/14 to 2017/18 for the YCCNW region.**



- Fatal reports**

Total number of fatalities that were reported from within the YCCNW region in 2017/18 and comparative data from previous years are shown in Table 3.

Year	Number of fatal reports	Percentage change on previous year
<b>2017/18</b>	<b>62</b>	<b>+67%</b>
2016/17	37	-13.9%
2015/16	43	+7.5%
2014/15	40	+8%
2013/14	37	+42%

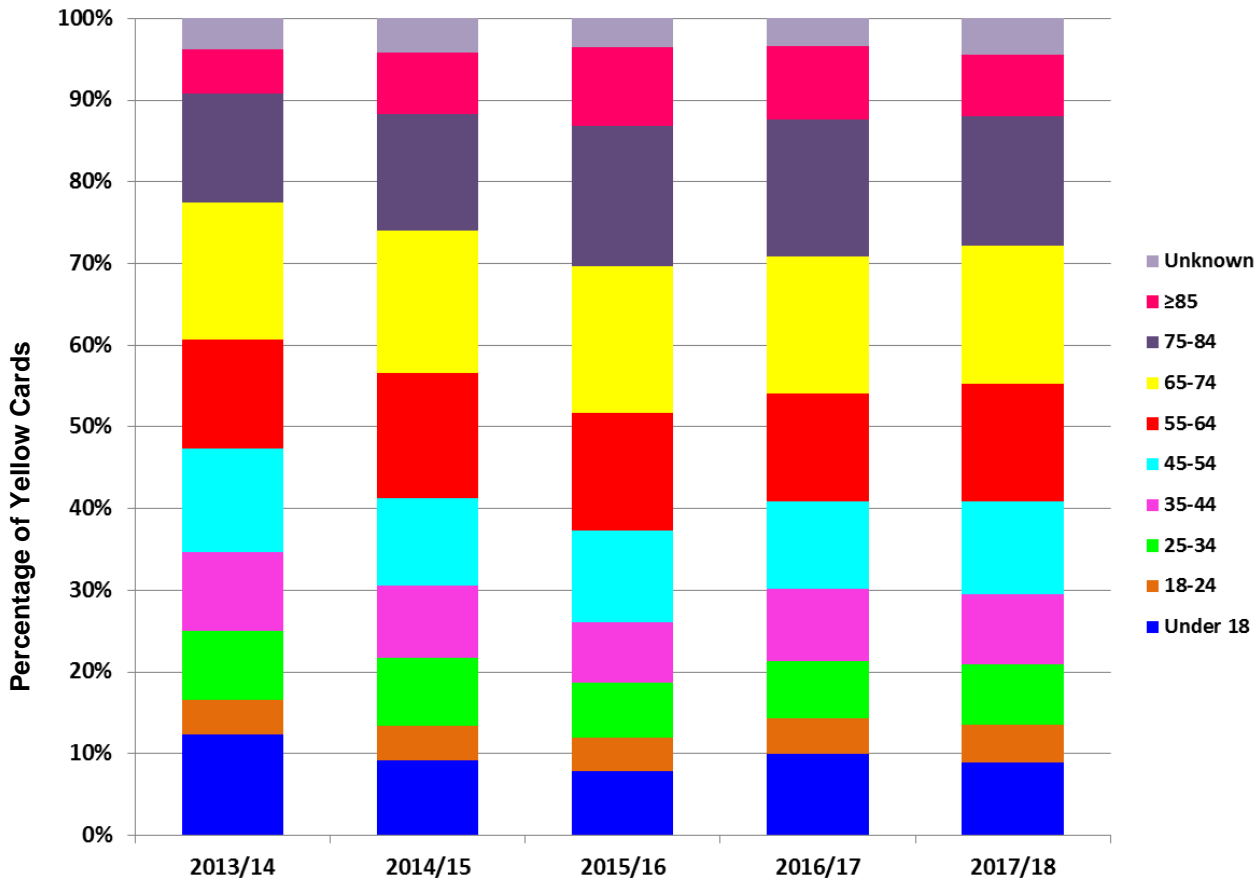
- Age breakdown

Table 4 shows the number of Yellow Cards originating from within the YCCNW region stratified by patient age at time of reaction, 2013/14 to 2017/18. Figure 5 is a graphical representation of these data.

Table 4

Age band (years)	2013/14	2014/15	2015/16	2016/17	2017/18
Under 2	62	46	93	91	95
2-6	51	46	38	101	77
7-12	53	52	44	67	68
13-17	64	70	102	111	110
18-24	78	99	146	166	183
25-34	157	192	240	262	293
35-44	179	207	263	332	338
45-54	237	248	400	397	445
55-64	248	356	513	493	569
65-74	312	408	636	631	661
75-84	249	331	612	625	627
≥85	100	177	340	338	296
Unknown	71	96	127	124	174
<b>Total</b>	<b>1,861</b>	<b>2,328</b>	<b>3,554</b>	<b>3,738</b>	<b>3,936</b>

Figure 5. Percentage of Yellow Card reports that originated from the YCCNW region, stratified by age group from 2013/14 through to 2017/18.



- **Top ten drugs**

Table 5 lists the top ten reported suspect drugs originating from within the YCCNW region for 2017/18. Overall there were 4,150 suspect drugs reported on 3,936 Yellow Cards (some Yellow Card reports had more than one suspect drug). The top ten suspect drugs accounted for 19% 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 2016/17; these drugs accounted for 16.6% of total suspect drugs reported on a Yellow Card in 2016/17.

**Table 5. 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	47
Clarithromycin	47
<b>Total</b>	<b>789 (10)</b>

**Table 6. The top ten reported suspect drugs for Yellow Cards that originated from the YCCNW region in 2016/17.**

Drug name	Number of times reported as a suspect drug (2016/17)
Meningococcal group B vaccine ▼	122
Rivaroxaban ▼	105
Apixaban	92
Sertraline	79
Influenza Vaccine (some ▼)	74
Warfarin	69
Omeprazole	62
Aspirin	60
Ibuprofen	60
Naproxen	60
<b>Total</b>	<b>783</b>

- Source of reports

Table 7 shows the Number of Yellow Cards originating from within the YCCNW region stratified by reporter type from 2015/16 to 2017/18.

Reporter	2015/16		2016/17		2017/18	
	Number	% of total	Number	% of total		
Carer	25	0.7%	40	1.1%	42	1.1%
Parent	54	1.5%	80	2.1%	95	2.4%
Patient	427	12.0%	546	14.6%	553	14%
Community Pharmacist	107	3.0%	163	4.4%	169	4.3%
Hospital Pharmacist	1,618	45.5%	1,669	44.6%	1,608	40.9%
Pharmacist	58	1.6%	55	1.5%	95	2.4%
Pharmacy Technician/assistant	22	0.6%	86	2.3%	114	2.9%
Pre-reg pharmacist	122	3.4%	121	3.2%	129	3.3%
Hospital Nurse	200	5.6%	183	4.9%	185	4.7%
Nurse	253	7.1%	224	6.0%	188	4.8%
GP	261	7.3%	238	6.4%	382	9.7%
Hospital Doctor	249	7.0%	199	5.3%	208	5.3%
Physician	7	0.2%	4	0.1%	10	0.3%
Coroner	1	0.0%	1	0.03%	1	0.02%
Dentist	14	0.4%	9	0.2%	5	0.1%
Midwife	4	0.1%	1	0.03%	3	0.1%
Optometrist	3	0.1%	2	0.1%	2	0.05%
Paramedic	1	0.0%	0	0.0%	4	0.1%
Radiographer	33	0.9%	20	0.5%	24	0.6%
Hospital Healthcare Professional	39	1.1%	45	1.2%	41	1%
Healthcare Assistant	4	0.1%	6	0.2%	28	0.7%
Other Healthcare Professional	51	1.4%	42	1.1%	48	1.2%
Medical Student	1	0.0%	2	0.1%	1	0.02%
Other	0	0.0%	2	0.1%	1	0.02%
<b>Total</b>	<b>3,554</b>	<b>100%</b>	<b>3,738</b>	<b>100%</b>	<b>3,936</b>	<b>100%</b>

Green – increasing figures  
 Red – decreasing figures



- **Type of report**

Table 8 shows the method used to report an ADR to the Yellow Card Scheme in 2017/18. Reporting via the Yellow Card app was introduced in July 2015.

**Table 8. Number of Yellow Card reports from each reporting method originating from the YCCNW region in 2017/18.**

	<b>Number of reports</b>	<b>Percentage of total reports</b>
Electronic Yellow Card	2670	67.8%
MiDatabank (Pharmacy medicines information)	592	15%
SystmOne (Patient management system)	308	7.8%
Paper	299	7.6%
RIDR (Report Illicit Drug Reactions scheme)	39	1%
APP	16	0.4%
Vision (Patient management system)	12	0.3%

#### 4. INTERPRETATION OF REPORTING FIGURES

Yellow Card reports originating from the YCCNW region increased by 5.3% in 2017/18 compared with 2016/17. Although the rate of reporting has slowed it is up by 112% compared to five years ago. In 2017/18 the biggest increase in reporting was by GPs; reporting rose by 60% (from 238 reports in 2016/17 to 382 reports in 2017/18). Other groups with substantially increased reporting include; pharmacists (mainly practice based pharmacists), 95 reports (up by 72%), pharmacy technicians 114 reports (up by 32%), and healthcare assistants 28 reports (up by 360%), 25 of which were to the RIDR scheme. Reporting by nurses (primary and secondary care) and community pharmacists fell slightly this year.

Reporting via electronic healthcare systems with embedded YCs continues to contribute substantially to total reporting with 912 reports (23% of all YCCNW reports) coming from MiDatabank (pharmacy medicines information system), SystmOne and Vision (both GP patient management system, also used in some hospices and prisons). Reporting via SystmOne has doubled in the last year from 152 reports in 2016/17 to 308 reports in 2017/18. Many of these reports originate either from one minor injuries unit or from prisons across the North West. Reporting via the APP remains low with only 16 reports in 2017/18.

The top reported suspect drug this year was apixaban with 134 reports; it had been the 3<sup>rd</sup> most reported suspect drug in 2016/17. Seven of the 2017/18 top ten also appeared in 2016/17; influenza vaccine, meningitis B vaccine, rivaroxaban, apixaban, sertraline, ibuprofen and aspirin. New to the top ten are phenoxymethylpenicillin, levothyroxine and ciprofloxacin. The high numbers of reports to phenoxymethyl penicillin come mainly from one minor injuries unit which reported

Serious adverse drug reactions (ADRs) accounted for 59% of all reports (62 reports [2.7% 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.

294 reports related to children under the age of 18 years, 42% of these reports related to vaccines and 16% related to antimicrobials.

The North West-wide network of Yellow Card Champions, set up in 2015 to share good practice, explore ideas and initiatives and lend support, met twice in 2017/18 and continues to expand. Secondary care and community or mental health trusts who send representatives to meetings (18) contributed 1,577 reports in 2017/18 (40% of all reports, 66% of secondary care reports and 35% of community/mental health trusts). Nine of the top ten reporting secondary care trusts actively participate in the Champions network.

Observations and associations in 2017/18:

- 134 reports listed apixaban as the suspect drug, 70% of these reports were made by hospital pharmacists.
- 30% of 169 community pharmacist reports were to vaccinations, almost half of these were to meningitis B vaccine.

- GP reporting increased by 60% in 2017/18; 43% of 382 reports were for antibiotics, in 90 reports phenoxymethylpenicillin was the suspect drug.
- Twelve cases of definite or suspected Steven's Johnson Syndrome were reported, the suspect drugs were; allopurinol, tolvaptan, amoxicillin (2), flucloxacillin, co-codamol, erythromycin, naproxen, sertraline, meropenem, sodium valproate, trimethoprim, vancomycin, carbamazepine, ibuprofen.
- Patients made over 75% of the reports associated with levothyroxine and of these 40% of reactions were suspected to have been caused by changes in the tablet manufacturer.
- Over half of the phenoxymethylpenicillin reports originated from either minor injury units or prisons where rash/hypersensitivity were the most commonly reported suspected reactions.
- Of the 208 reports made by hospital doctors 20 described anaphylactic reaction; four associated with atracurium, four with rocuronium, three with chlorhexidine and two with co-amoxiclav
- 39 reports to the pilot Report Illicit Drug Reactions (RIDR) scheme were made in the North West in 2017/18. Of these 29 were made by prisons. Ten RIDR reports listed the suspect drug as Spice and 24 were for a 'new psychoactive substance unspecified'.

## 5. PROMOTIONAL ACTIVITIES

### • Training delivered

Training carried out during 2017/18 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 2017/18**

Audience type	Session type	Duration (hours)	Number of sessions	Total audience numbers	Total hours training
Dentists	Lecture	0.33 hours*	6	160	2
Dentists – foundation trainees	Lecture	0.5 hours*	4	50	2
Diploma pharmacists	Lecture	1.75 hours	1	22	1.75
MRC fellows	Lecture	0.75 hours	1	12	0.75
MSc HCPs	Lecture	1.0 hours	1	30	1
Non-medical prescribers	Lecture	1.25 hour	2	40	2.5
Nurses - community	Lecture	2.0	2	50	3
Pre-registration pharmacists	One to one	0.5 hour	4	6	2
Pre-registration pharmacists	Lecture	1 hour	1	25	1
YCCNW Yellow Card Champions	Presentation	1.5 hours	2	40	3
<b>Totals</b>			<b>24</b>	<b>435</b>	<b>19</b>

\* ADR training delivered as part of medicines/prescribing-related training

**Table 10. Training provided to undergraduates in 2017/18**

Audience type	Session type	Duration	Number of sessions	Total audience numbers	Total hours training
Dental undergraduates	Lecture	0.5 hours	1	80	0.5
Dental undergraduates	Lecture (paediatric prescribing))	1 hour	1	80	1
Nurse undergraduates (final year)	Lecture	1.5 hours	2	30	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>2550</b>	<b>35.5</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 2017/18**

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	12	1.5

- **Lectures delivered (invited)**

Prof. Pirmohamed spoke at 16 national and 11 international meetings and conferences throughout 2017/18.

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- **Materials developed to promote YCS**

CPPE e-learning programme ADRs (Christine Randall author – on-going six-monthly review)

Part 1 – ADRs and Medicines Safety

Part 2 – Reporting ADRs

Part 3 – Patients and ADRs

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 (2017/18)

1. Alfirevic, A., & **Pirmohamed, M.** (2017). Genomics of Adverse Drug Reactions. *Trends Pharmacol Sci*, 38, 100-109.
2. Al-Naher, A., Wright, D., Devonald, M. a. J., & **Pirmohamed, M.** (2018). Renal function monitoring in heart failure - what is the optimal frequency? A narrative review. *Br J Clin Pharmacol*, 84, 5-17.
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4. Barton, C. D., Pizer, B., Jones, C., Oni, L., **Pirmohamed, M.**, & Hawcutt, D. B. (2017). Identifying cisplatin-induced kidney damage in paediatric oncology patients. *Pediatr Nephrol*.
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10. Carr, D. F., & **Pirmohamed, M.** (2018). Biomarkers of adverse drug reactions. *Exp Biol Med (Maywood)*, 243, 291-299.
11. Cliff, J., Jorgensen, A. L., Lord, R., Azam, F., Cossar, L., Carr, D. F., & **Pirmohamed, M.** (2017). The molecular genetics of chemotherapy-induced peripheral neuropathy: A systematic review and meta-analysis. *Crit Rev Oncol Hematol*, 120, 127-140.
12. Dear, J. W., Clarke, J. I., Francis, B., Allen, L., Wraight, J., Shen, J., Dargan, P. I., Wood, D., Cooper, J., Thomas, S. H. L., Jorgensen, A. L., **Pirmohamed, M.**, Park, B. K., & Antoine, D. J. (2018). Risk stratification after paracetamol overdose using mechanistic biomarkers: results from two prospective cohort studies. *Lancet Gastroenterol Hepatol*, 3, 104-113.
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## 7. YCC WEBSITE

### Website updates

Due to IT issues there have been no updates to the YCC NW website in 2017/18 (New appointment due to start October 2018)

### Number of website hits

We are unable to obtain this information.

## 8. RESEARCH AND ONGOING INITIATIVES

### North West Coast CLAHRC

YCCNW is working with the North West Coast Collaboration for Leadership in Applied Health Research and Care (CLAHRC) who 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.

### **ISoP conference 2017**

Professor Pirmohamed chaired the Local Organising Committee for the 2017 International Society of Pharmacovigilance (ISoP) conference which took place in Liverpool in October 2017. The theme of the conference was '*Pharmacovigilance in the 21<sup>st</sup> Century – Innovation for Patient Benefit*'.

The programme began with two pre-conference courses:

- Pharmacovigilance and social media
- Paediatric pharmacovigilance

The three day conference programme included ([full programme](#)):

### **Monday**

Keynote: On the importance of quantifying and propagating uncertainty in healthcare (Mark Girolami, Imperial College London)

Lectures:

- Big data approaches in pharmacovigilance (Jeremy Rassen, Aetion, USA)
- Social media and pharmacovigilance: an industry perspective (David Lewis, Novartis)

Round Table Discussion: Regulation in the 21st Century

(Chair: Mick Foy, MHRA, Panelists: Sabine Brosch, EMA, UK; Judith Zander, FDA, USA; Shanthi, Pal, WHO, Switzerland; Alex Dodoo, WHO, Ghana; Michael Dougan, University of Liverpool, UK)

PARALLEL SESSIONS

- A. Training in Pharmacovigilance
- B. Pharmacogenomics and Pharmacovigilance

### **Tuesday**

Lectures

- CIOMS Lecture: The new CIOMS (Lembit Rägo, Council for International Organizations of Medical Sciences (CIOMS))
- Pharmacovigilance for herbal and traditional medicines: towards solutions and innovations (Phil Routledge, University of Cardiff)

Lectures - Phenotypic approaches to risk management

- Clinical assessment for risk management: a general overview (Kin-Wei Chan, University of Harvard)
- Serious cutaneous adverse drug reactions (Maja Mockenhaupt, Freiburg)
- Drug-induced liver injury (Guru Aithal, University of Nottingham)

PARALLEL SESSIONS

- C. Medicines for women
- D. Implications of WEB-RADR for pharmacovigilance

### **Wednesday**

Bengt Erik Wiholm Lecture / ISoP Lecture

- The language of pharmacovigilance (Jeff Aronson, University of Oxford)

Lectures

- Adverse effects of advanced cell therapies (Brigitte Keller-Stanislawski, Paul-Ehrlich Institute)
- Pharmacovigilance of biologics and biosimilars (Gianluca Trifirò, University of Messina)
- Pharmacovigilance of anti-cancer medicines: opportunities and challenges (Anna Olsson-Brown, University of Liverpool)

### **YCCNW Champions network**

The North West-wide network of Yellow Card Champions, set up in 2015 to share good practice, explore ideas and initiatives and lend support, met twice in 2017/18 and continues to expand. Secondary care and community or mental health trusts who send representatives to meetings (18) contributed 1,577 reports in 2017/18 (40% of all reports, 66% of secondary care reports and 35% of community/mental health trusts). Nine of the top ten reporting secondary care trusts actively participate in the Champions network.



## 9. CONCLUSION

In 2017/18 3,936 Yellow Cards were submitted by health professionals, patients and carers from the YCCNW region. This is a 5.3% increase compared to 2016/17. Hospital pharmacists continued to be the highest reporting group (1,608 reports (41% 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 2017/18 came from GPs (up 60% compared to 2016/17) and reflects an increase in reporting via the patient management system SystemOne which has an integral Yellow Card enabling direct reporting of ADRs at the point of care.