

Yellow Card Centre Northern & Yorkshire

ANNUAL REPORT 2007-8

Regional Drug and Therapeutics Centre
Wolfson Unit of Clinical Pharmacology
Claremont Road
Newcastle NE1 4LP

July 2008

1. Staff involved in the work of YCC Northern & Yorkshire

Ms S Brent	Director of Pharmacy, Regional Drug and Therapeutics Centre
Dr A Dyker	Consultant Physician Pharmacology, RDTC
Miss C Gilfillan	Medical Information Scientist
Dr S Hill	SpR Clinical Pharmacology, Royal Victoria Infirmary
Mrs A Makepeace	Secretary, Royal Victoria Infirmary
Mrs P Martindale	Secretary, Regional Drug and Therapeutics Centre
Dr PR McElhatton	Head of Teratology, Regional Drug and Therapeutics Centre
Mrs J Metcalf	Secretary, Regional Drug and Therapeutics Centre
Mrs RA Prior	Senior Pharmacist Pharmacovigilance
Dr SHL Thomas	Director RDTC, Reader in Therapeutics (YCCNY Director)
Mrs J Wood	Business manager, Regional Drug and Therapeutics Centre

2. Summary

During 2007-08 2,265 adverse drug reaction (ADR) reports were received from Northern and Yorkshire, a 9% increase in reporting compared with 2006-07, continuing an upward reporting trend since April 2004. There has been a further increase in the number of reports of serious reactions, while the number of reports relating to black triangle drugs (i.e. those under intensive surveillance) has decreased by 3%. Reports involving children have decreased by 25%. The most frequently reported suspect drug was varenicline; 583 reports were received from our region, echoing the national picture.

The number of reports from healthcare professionals has increased by 8% since 2006-07. This includes a 21% increase in reporting from GPs, reversing the previous downward trend. Reporting from community pharmacists has also increased, although numbers remain lower than for other healthcare professionals. The number of reports from nurses has increased by 46%, reversing the decline recorded over the previous 3 years. However, reporting from hospital doctors and hospital pharmacists has continued to decline.

Patients have been able to report adverse reactions since November 2005. During 2007-08 a total of 248 reports were received from patients, carers and parents, a reduction of 31% over the previous year. Of these reports, 71% involved a serious reaction, a proportion comparable to that seen with healthcare professional reporting in our region (66%). The level of patient reporting to black triangle drugs is low (6%), as would be expected. The patient reporting scheme was re-launched by the MHRA in February 2008, with a 6-week promotional campaign in community pharmacies nationwide and media coverage of the scheme. The centre supported this initiative by liaising with local PCTs and area managers of the major community pharmacy multiples, to promote the campaign, offering support and training for community pharmacists; unfortunately despite initial interest in training no sessions were delivered. Hospital Chief Pharmacists were also contacted and encouraged to display promotional materials during the duration of the campaign. In addition, a number of initiatives have been undertaken to raise awareness of patient reporting, alerting healthcare professionals about patient reporting and to ensure they continue to report themselves.

A primary function of the Northern & Yorkshire Yellow Card Centre (YCC) is to encourage ADR reporting from local health professionals, by providing support and education, targeted according to local reporting patterns. The centre has promoted the Yellow Card scheme at five local training events for healthcare professionals. Non-medical prescribers

have been identified as a significant group of reporters to whom support has been directed, as part of a regional programme to promote non-medical prescribing.

The centre has continued to produce the bulletin series *Safer Medication Use* to highlight emerging or significant drug safety problems. This provides guidance to ensure safe, appropriate prescribing and raise awareness of ADR detection and reporting. In collaboration with the Newcastle Regional Drug and Therapeutics Centre, two of their published *New Drug Evaluation* documents on varenicline and rimonabant, which are widely circulated to GPs, pharmacists and other healthcare professionals, were updated following the provision of new safety information by the MHRA.

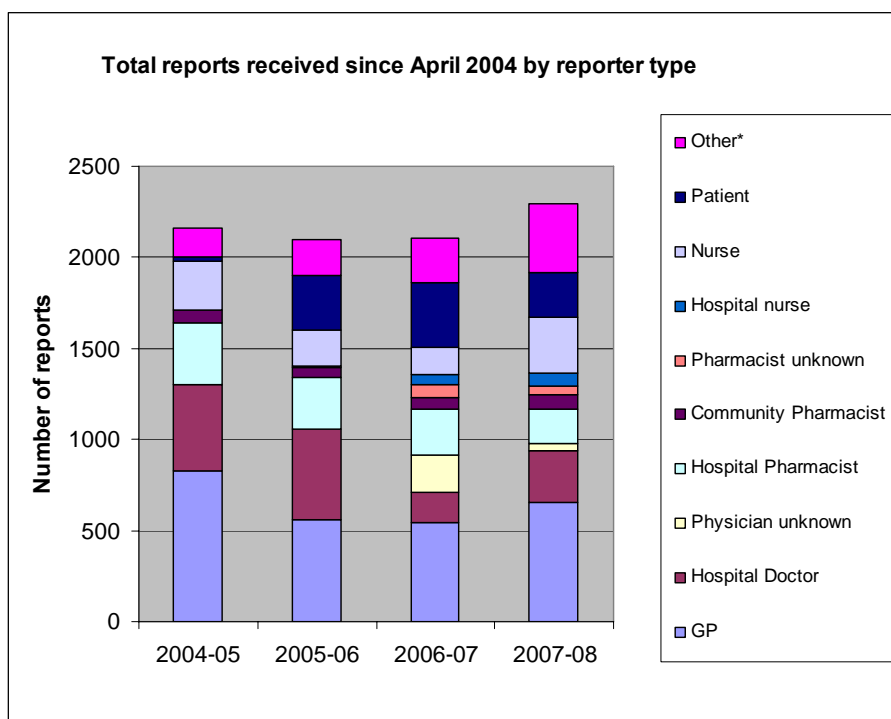
The YCC Northern and Yorkshire website has been maintained and developed, to provide guidance and support to healthcare professionals completing a Yellow card and continues to be well-used. The site contains educational material developed by the centre, information on adverse reactions, including emerging safety issues and recently published papers in the field of drug safety. In August 2007, when *Drug Safety Update* was launched, a link to this was created on the website, with a news item on the homepage and the first few issues were circulated by e-mail to all PCT Medicine Management leads, Clinical Governance leads, trust Chief Pharmacists and Medicines Information pharmacists in YCC Northern and Yorkshire. In addition all talks and awareness sessions include information about the bulletin.

3. Yellow Card Data

3.1 Overview

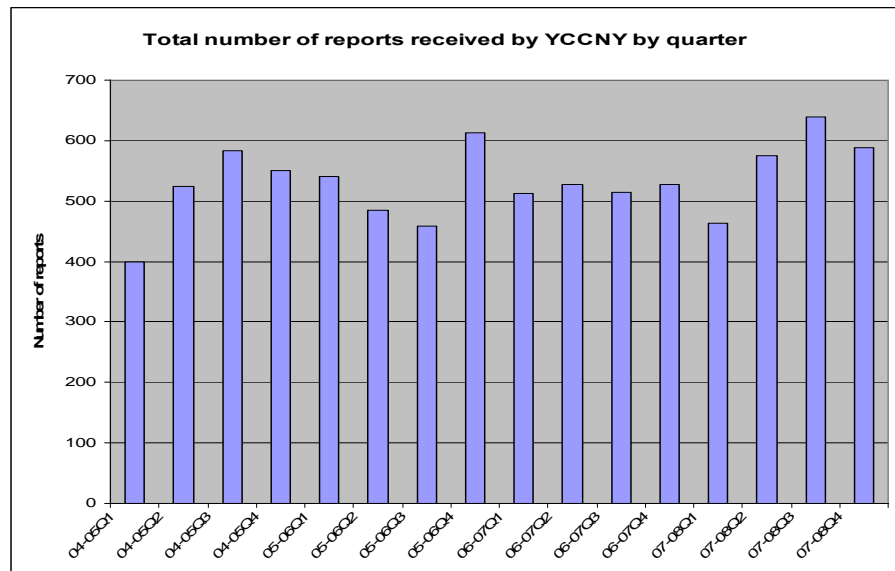
A total of 2,265 reports were received from Northern and Yorkshire during 2007-08, a 9% increase in reporting compared to 2006-07. This increase reverses a downward trend seen in previous years (chart 1). However, this year has seen a 31% reduction in the number of reports from patients.

Chart 1



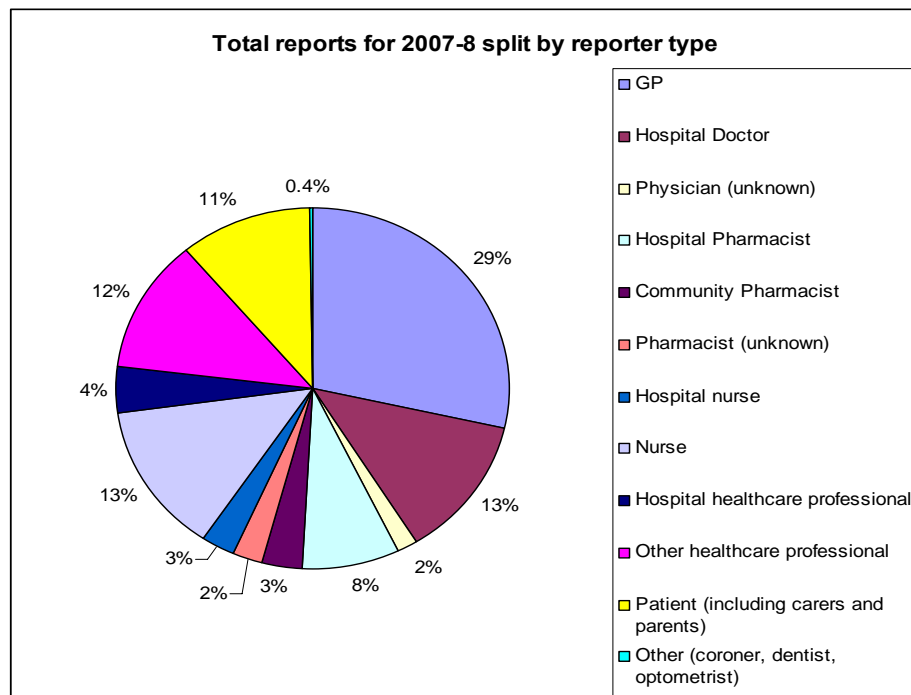
* coroner, dentist, hospital health professional, other health professional, optometrist

Chart 2



Despite a reduction in the reporting in the 1st quarter 2007-08, the overall trend in reporting from YCC Northern and Yorkshire this year is upwards (chart 2). The growth is due to a 14% increase in healthcare reporting (2044 reports) across all disciplines, with the exception of hospital pharmacists, who submitted 24% fewer reports. The breakdown of reports by reporter group shows that doctors reported most adverse reactions (44%), with nurses (16%) and pharmacists (13%) the next highest reporting groups (chart 3). More detailed discussion of reporting rates by each reporter group is provided in section 3.3 onwards.

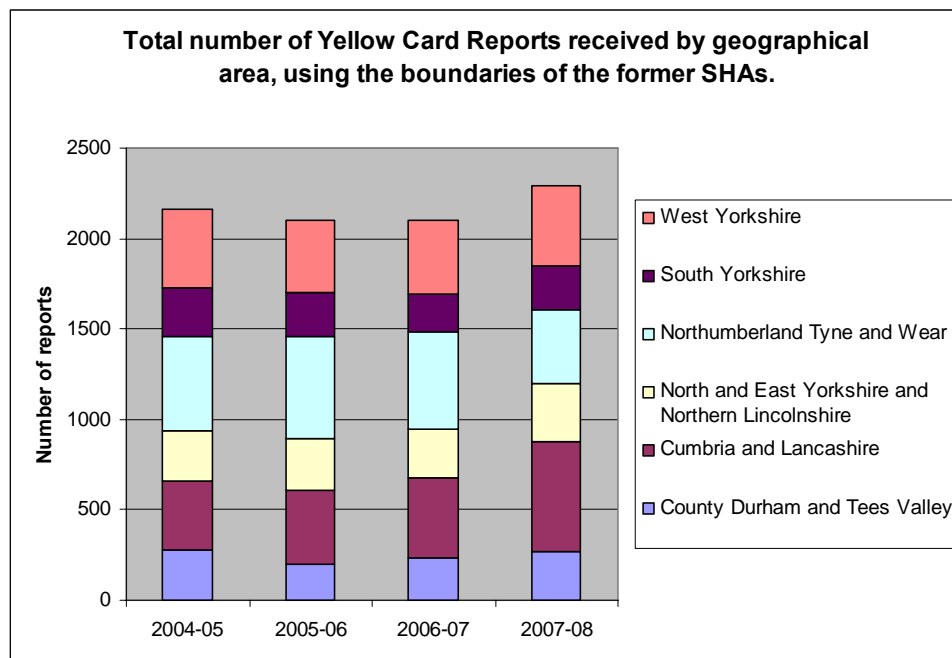
Chart 3



3.2 Reporting rates by geographical area

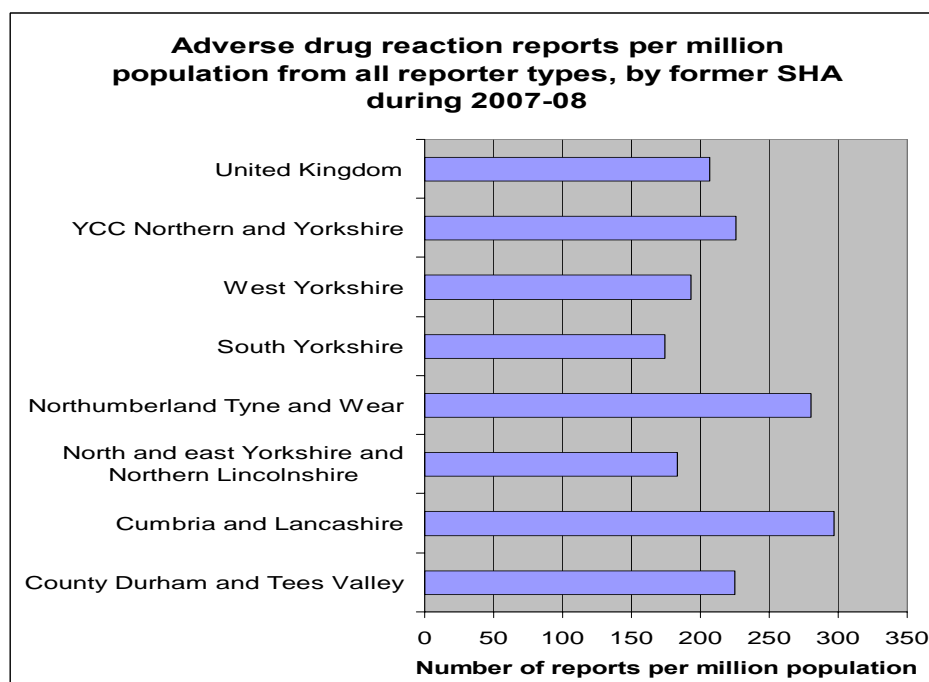
Reporting rates by geographical area, using the boundaries of the former Strategic Health Authorities (SHA) prior to re-organisation in 2006, have increased in all areas barring the former Northumberland Tyne and Wear SHA where reporting has decreased by 24% this year (chart 4). Reporting from the former Cumbria and Lancashire SHA has seen the largest increase (39%).

Chart 4



Regional variations in reporting are not accounted for by differences in population size (chart 5). Reporting rates are not currently available from the MHRA by PCT or hospital trust.

Chart 5

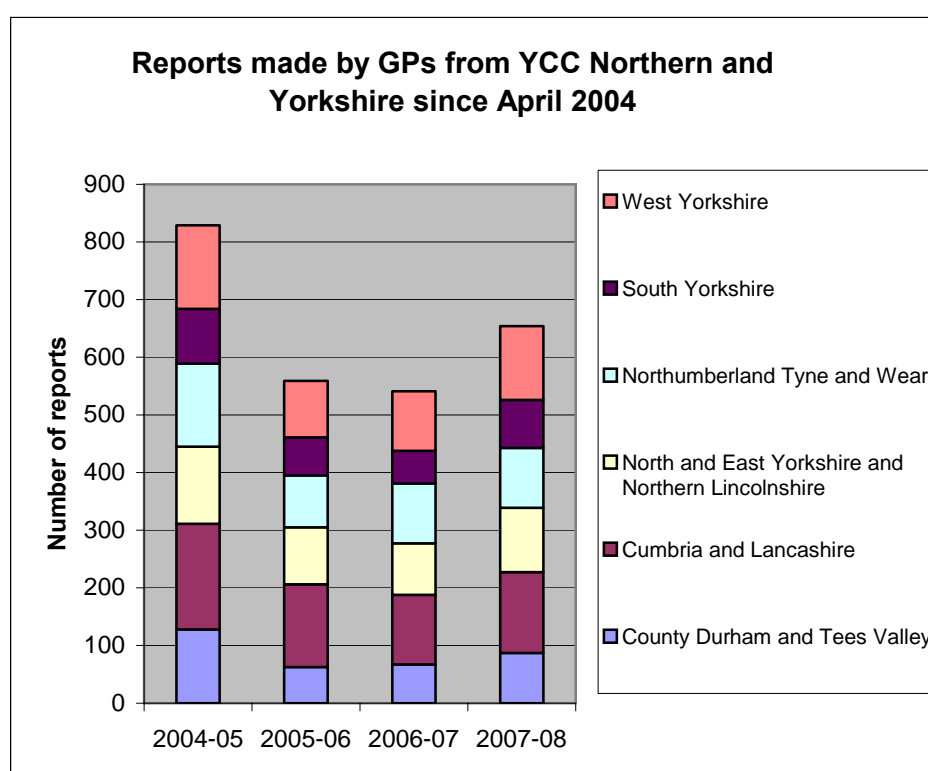


Data is presented by former SHA, not as a comparison of the reporting rates between the different geographical areas, but to facilitate the prioritisation of educational initiatives to those organisations with low or falling reporting rates. As such trusts in South Yorkshire (which has low reporting rates across all professions) and North East Yorkshire and North Lincolnshire, will be priority areas for raising awareness of the Yellow Card Scheme, in the coming year. See appendix 2 for further data at former SHA level.

3.3 GP Reporting

There has been a 21% increase in reporting from GPs in 2007-08 compared to 2006-07, with 654 reports submitted (chart 6). Reporting rates by GPs have increased in every former SHA, reversing the trend seen in the previous 2 years. However reporting rates remain substantially lower than 2 years ago.

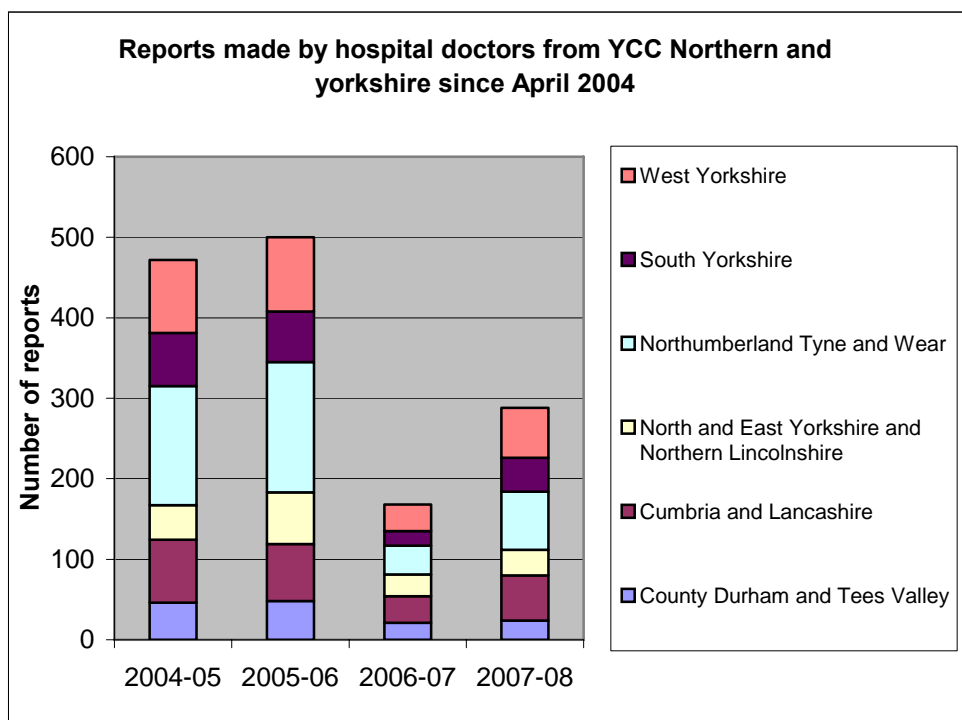
Chart 6



3.4 Hospital Doctor Reporting

Northern & Yorkshire hospital doctors submitted 325 ADR reports during 2007-08, an apparent 71% increase over the previous year (chart 7). However, these figures are potentially misleading since during 2006-07 a significant proportion of physician reports (208), could not be classified by their reporter type on the MHRA SENTINEL database. This will have resulted in an underestimate of hospital doctor activity. The same problem has continued into this year but to a lesser extent (37 physician reports). Nonetheless, even if all unclassified reports originate from hospital doctors, the levels of hospital doctor reporting is still considerably lower than that seen previously in 2005-06 and 2004-05 (chart 7). It is not known whether this trend is nationwide, (reporting rates in every former SHA in our area, barring one, are reduced this year); nor whether other hospital healthcare professionals are reporting instead.

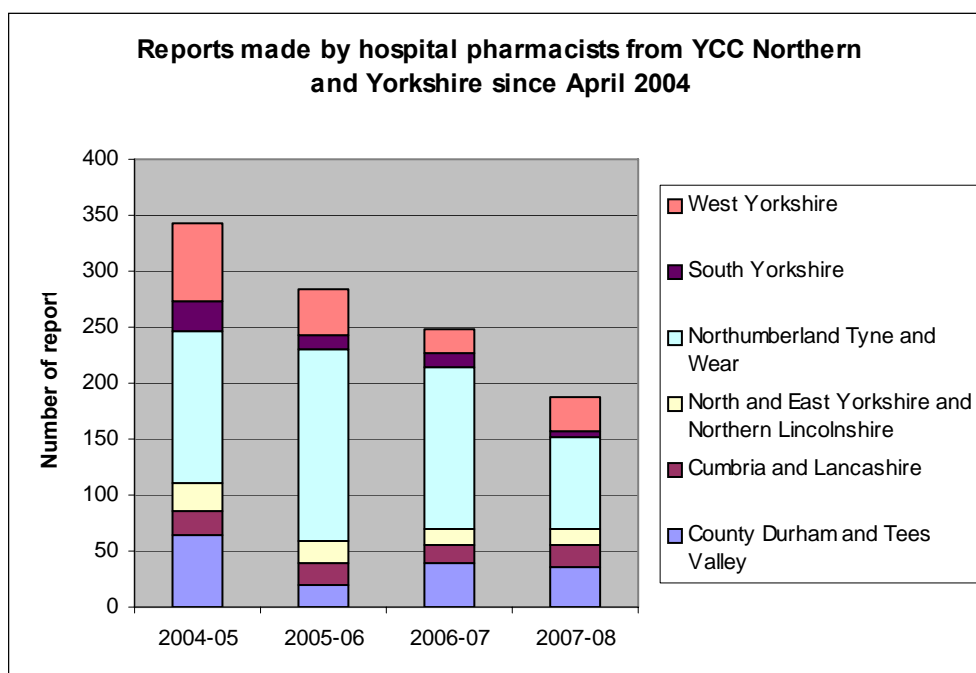
Chart 7



3.5 Hospital Pharmacist Reporting

A total of 188 reports were received from hospital pharmacists in Northern & Yorkshire during 2007-08, a decrease of 24% over the previous year (chart 8). There has been a reduction in reporting from most former SHAs, in line with the decrease in reporting nationally, which during was estimated to be 12% January to November 2007. The former Northumberland Tyne and Wear SHA has continued to report significantly more adverse drug reactions than other geographical areas.

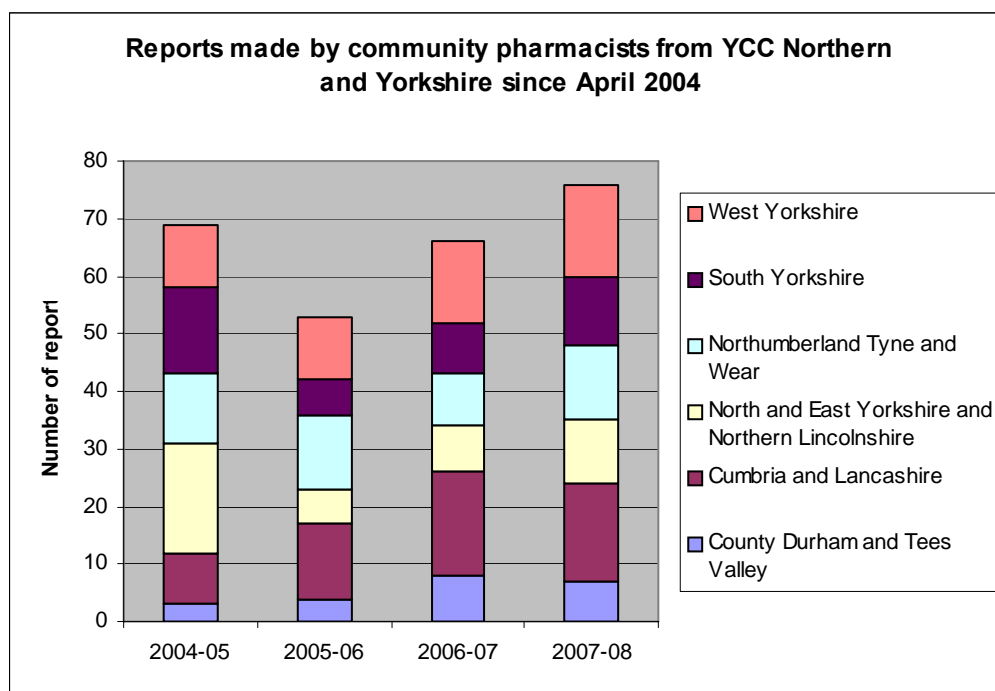
Chart 8



3.6 Community Pharmacist Reporting

Community pharmacists in Northern & Yorkshire submitted 76 reports during 2007-08, an increase of 15% from 2006-07, continuing the upward trend observed last year (chart 9). This increase in reporting does not follow the national picture, which saw a small decrease in reporting from community pharmacists during 2007. This may reflect the targeting of educational activity to community pharmacies by YCC Northern & Yorkshire. However, it should be noted that overall numbers remain small.

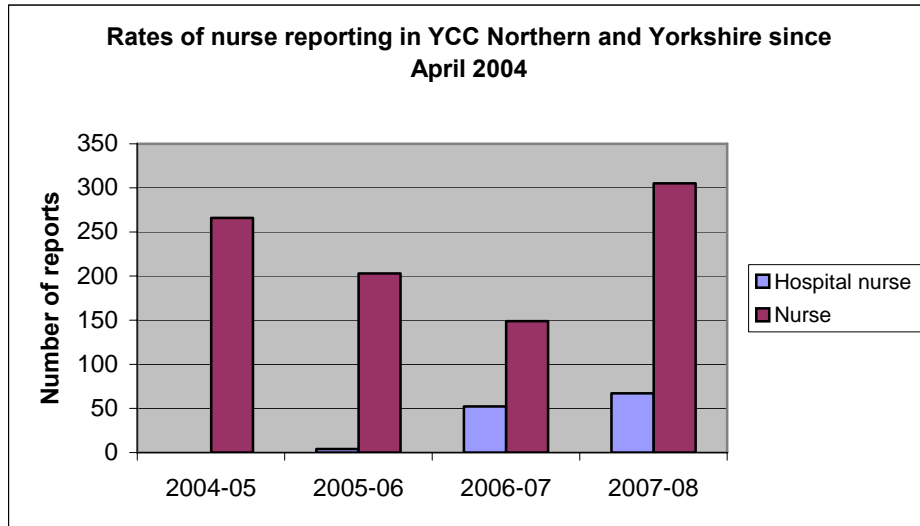
Chart 9



3.7 Nurse reporting

Nurses continue to make an important contribution to ADR reporting (chart 10). In Northern and Yorkshire, reporting increased by 46% this year, mirroring the national increase in nurse reporting. This increase is due to a rise in the number of reports submitted from those working in primary care. In previous years community nurses have usually made more reports than their hospital counterparts.

Chart 10

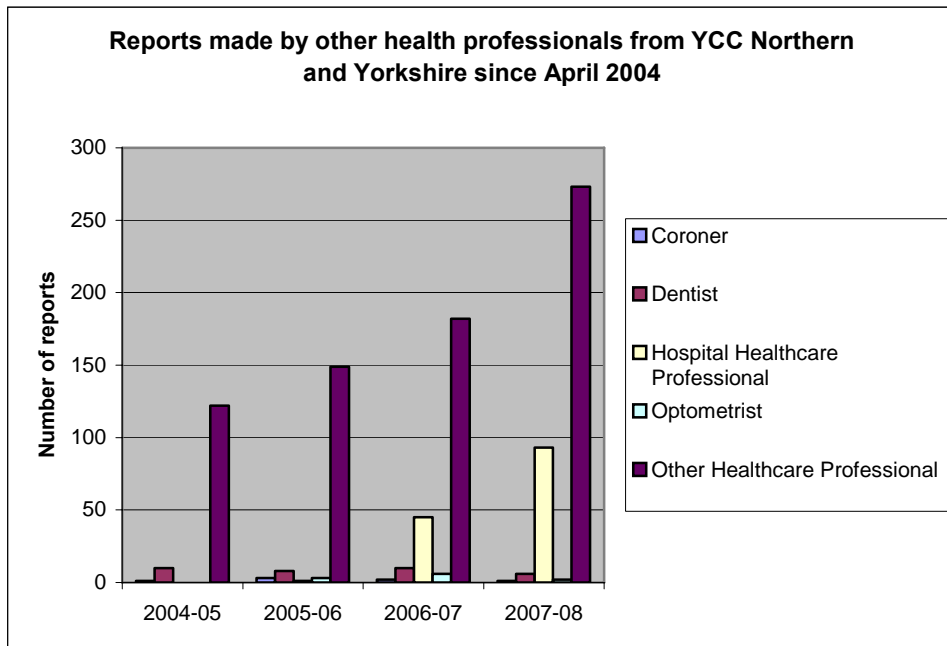


* Prior to May 2006 all reports from community and hospital nurses were classified on the MHRA ADROIT database as 'nurse'. Following the introduction of the SENTINEL database, reports from nurses are classified as 'Hospital nurse' and 'nurse' the latter covering those nurses based in primary care.

3.8 Other healthcare professionals

Reporting from other healthcare professionals has increased over the last four years, whilst the number of reports from coroners and dentists has remained static, and accounts for very few reports (chart 11). This year has seen a significant increase in the number of reports from healthcare professionals based in primary care. This may be explained in part by the increase in reporting adverse events related to varenicline from smoking cessation clinics (see top 10). Some of these reports may have been made by nurses and pharmacists, when their status has not been included in the report.

Chart 11



3.9 Patient reporting

Since November 2005 patients or their carers in the UK have been encouraged to report suspected adverse drug reactions to the MHRA, using a patient Yellow Card. The scheme was re-launched to the public in February 2008, with a 6-week promotional campaign in community pharmacies nationwide and media coverage of the scheme. In 2007-08, 248 reports were received from patients, a 31% decrease compared with the previous year and a reversal of the previous upward trend (chart 12). Patients themselves continue to submit the vast majority of reports (chart 13). 71% of reactions reported were serious, an increased proportion compared to the previous year. As patients are encouraged to report all adverse reactions, the levels of reporting to black triangle drugs remains low (6% of patient reports), as expected. The contribution from patients to the Yellow Card Scheme is increasingly important and should continue to be encouraged.

Chart 12

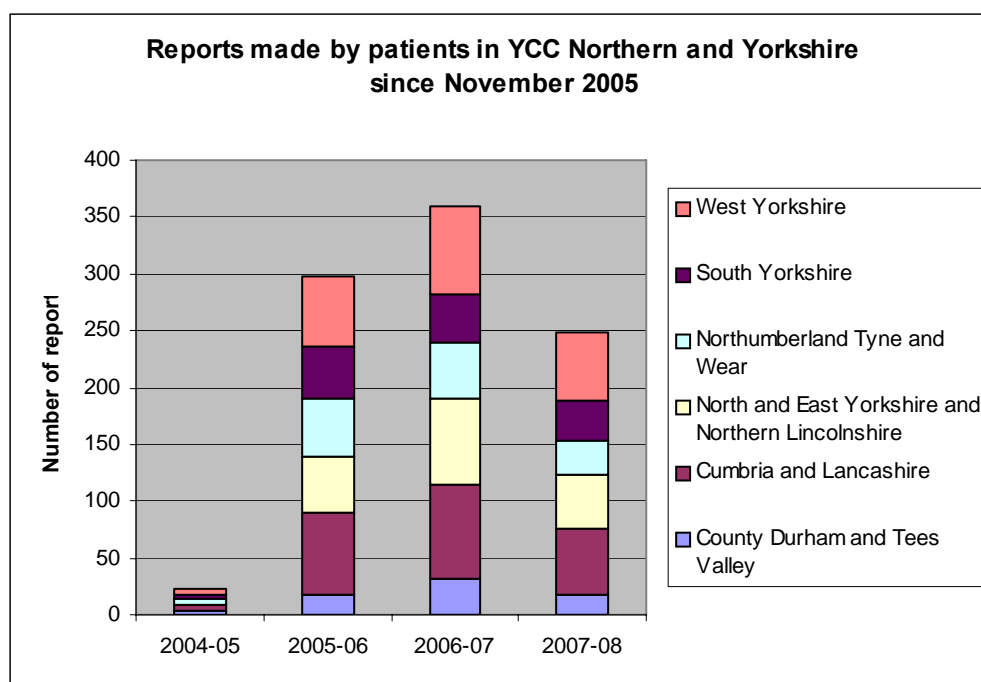
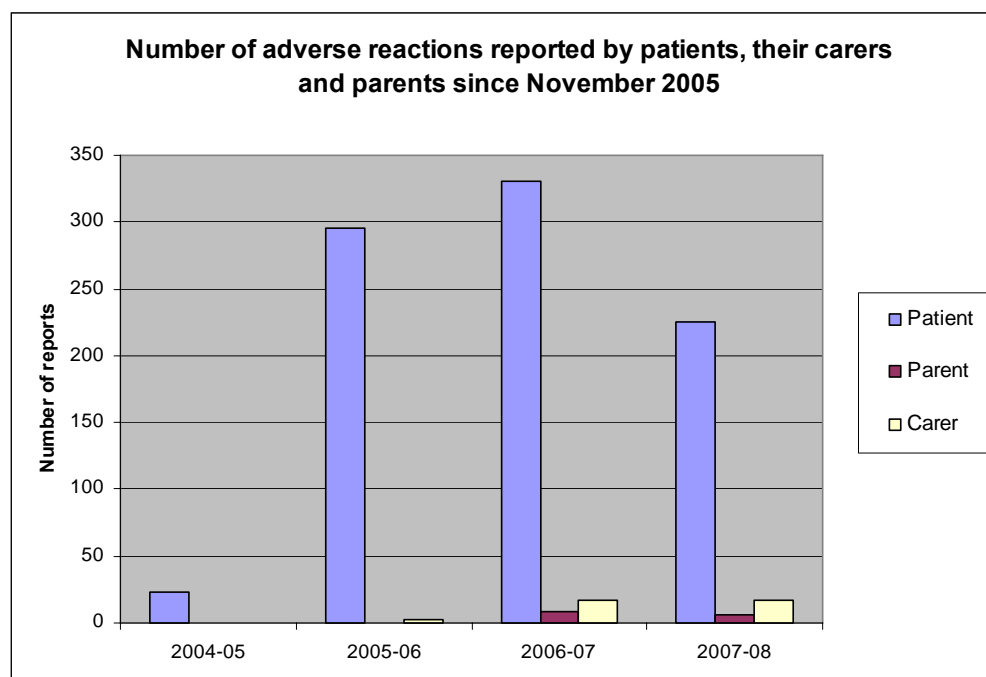


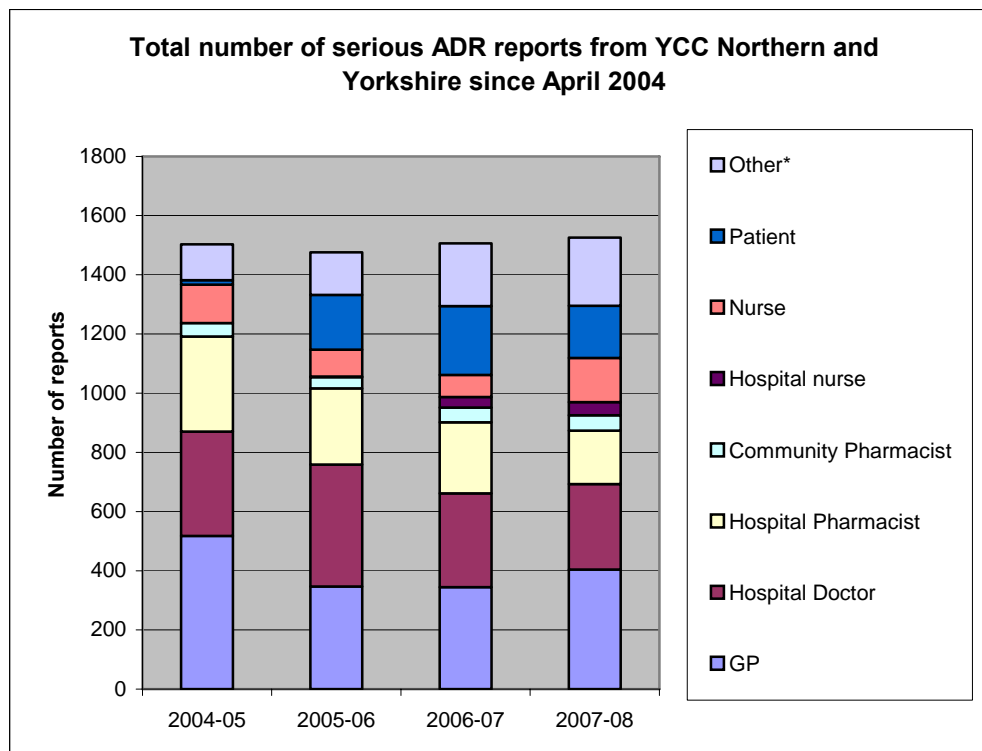
Chart 13



4.0 Serious reactions

A total of 1525 reports of serious reactions were received in 2007-08, a 1% increase over the previous year (chart 14). The level of reporting of serious reactions has not changed appreciably over the last 4 years. However, the proportion of serious reports relative to the total number of reports has reduced to 66% from 71% in the previous year. The proportion of serious reactions reported in YCC Northern and Yorkshire is lower than the national figure, which between January and November 2007 ranged from 80 to 85%.

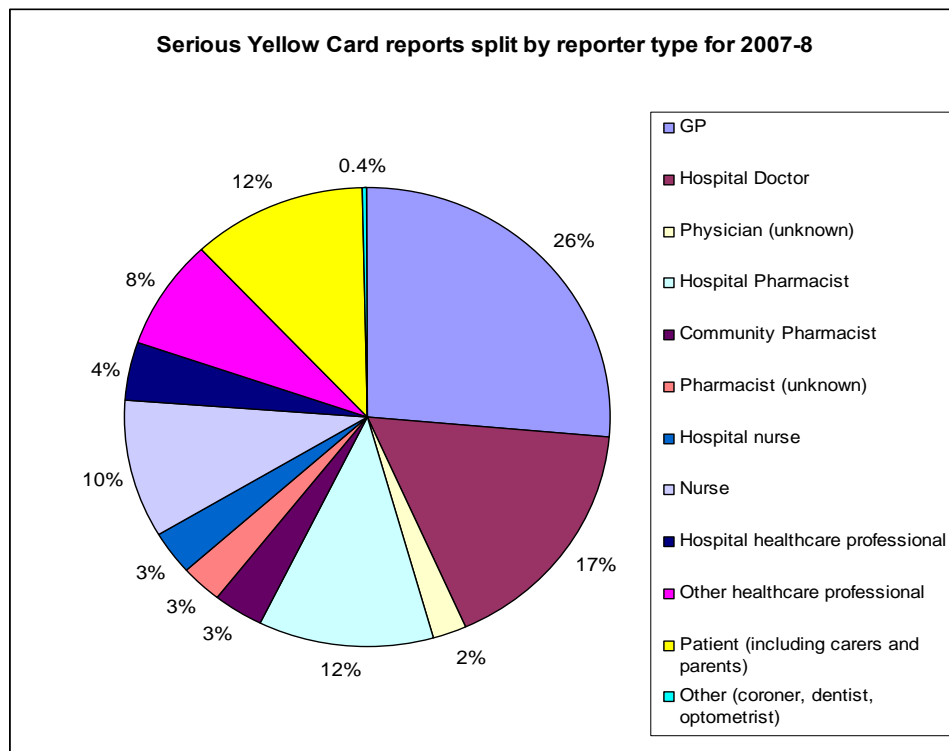
Chart 14



* coroner, dentist, other healthcare professional, pharmacist (unknown), physician, optometrist

The breakdown of serious reports by reporter group shows that 45% of these were received from doctors, with an increase from both GPs and hospital doctors since last year (chart 15). Pharmacists reported 18% of the serious adverse events, a reduction compared to last year, whilst the number from community pharmacists has not changed. 13% of reports were from primary or secondary care nurses. The number from hospital nurses has not changed, whilst the number from nurses based in primary care has increased to 10% this year. Patients reported 12% of serious reactions, a reduction compared to the previous year.

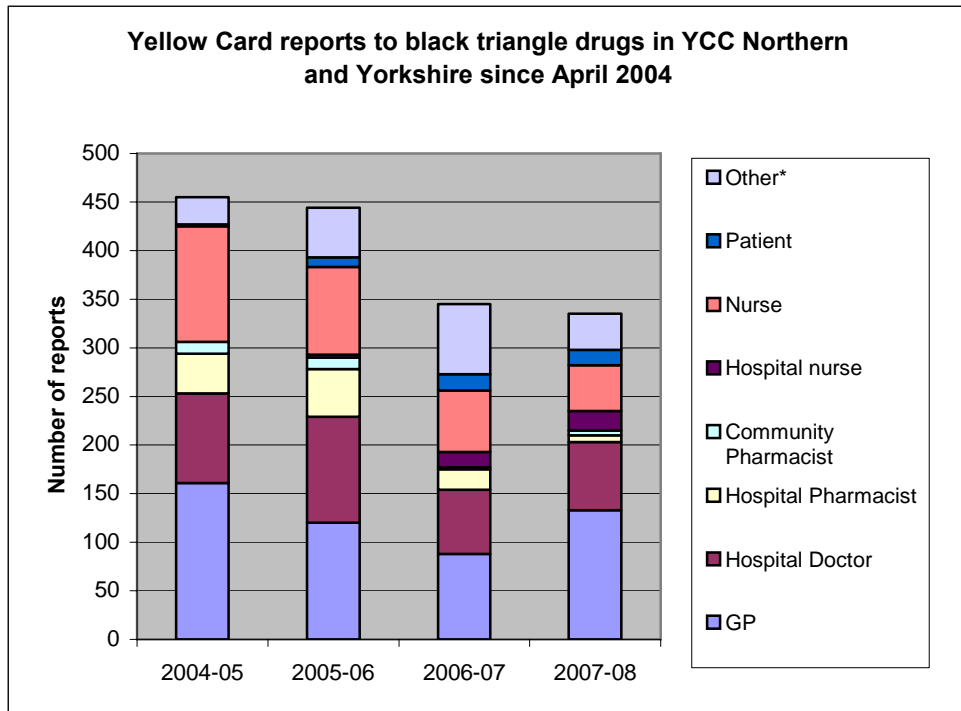
Chart 15



5.0 Reactions to black triangle drugs

There has been a 3% reduction in reports from Northern & Yorkshire involving drugs under intensive surveillance (chart 16). This year 15% of reports were to black triangle drugs as compared to 16% last year. The low levels of reporting about drugs under intensive surveillance, is of concern as these reports are vital in the safety monitoring of new drugs. Such information contributes to the ongoing safety assessments and can lead to the issue of safety warnings, as occurred this year with varenicline and rimonabant. However, changes may reflect changes in the overall prescribing and patterns of use of newer drugs, data on this is not currently available.

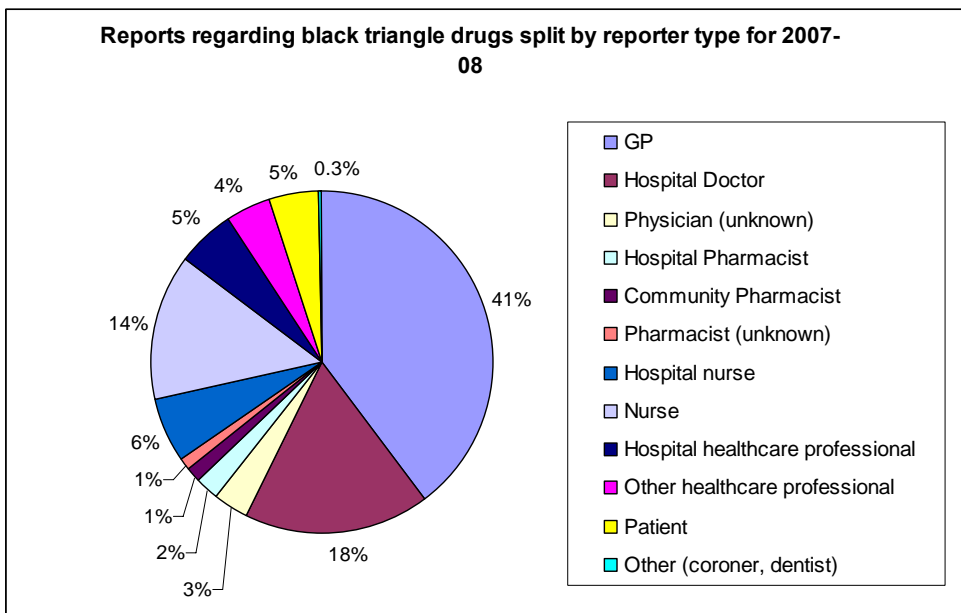
Chart 16



* coroner, dentist, other healthcare professional, pharmacist (unknown), physician, optometrist

GPs continue to submit the greatest number of reports to black triangle drugs (41%) with nearly two-thirds of all reports to new drugs originating from doctors (chart 17). There was also significant reporting from nurses (14%), principally as a result of their involvement in administering vaccines, many of which are black triangle products. Patients made 5% of reports relating to black triangle drugs, which is similar to last year.

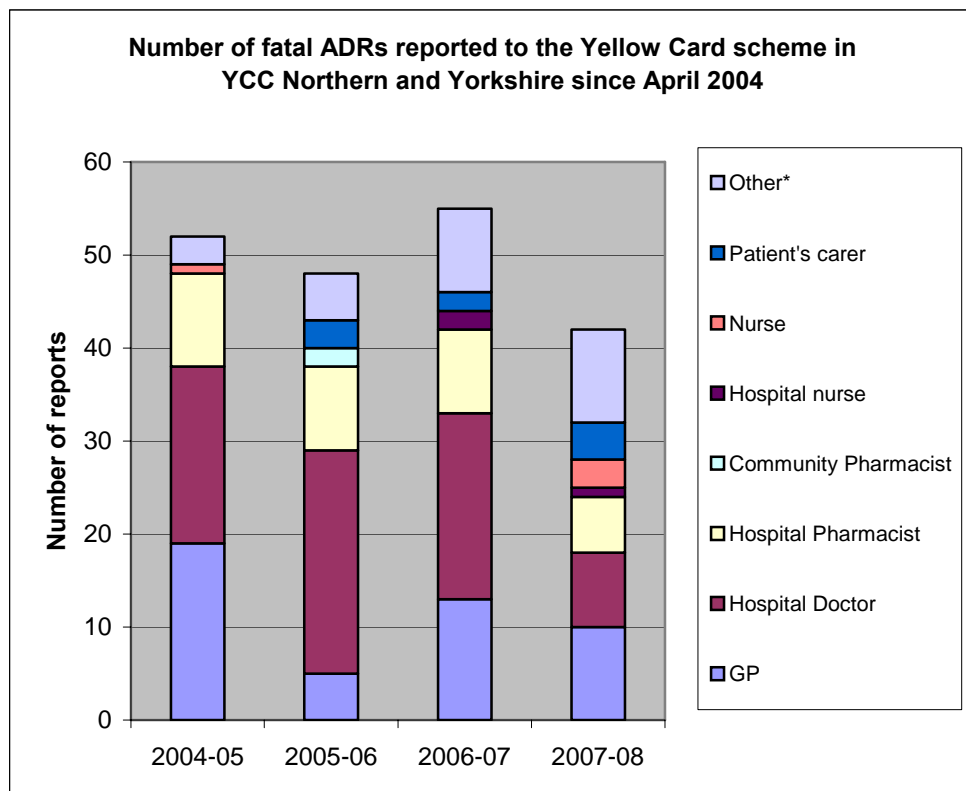
Chart 17



6. Fatal reports

The number Yellow Cards submitted regarding fatalities suspected to be related to drug treatment this year have reduced by 24% compared to the previous year (chart 18). GPs continue write the most fatal reports. Hospital doctors are the next most frequent reporters, but are now submitting significantly fewer fatal reports.

Chart 18



* coroner, dentist, other healthcare professional, pharmacist (unknown), physician, optometrist

7. Reporting by age

Reports to adverse reactions in children (<18 years) are now reported separately due to the importance of reporting in this age group. In 2007-08 there were 175 reports in children (8% of the total number of reports) a 25% decrease on the previous year (chart 19). The age range of patients in whom suspected adverse reactions have been reported is shown in chart, with most reports in the 55-64 year age range (chart 20).

Chart 19

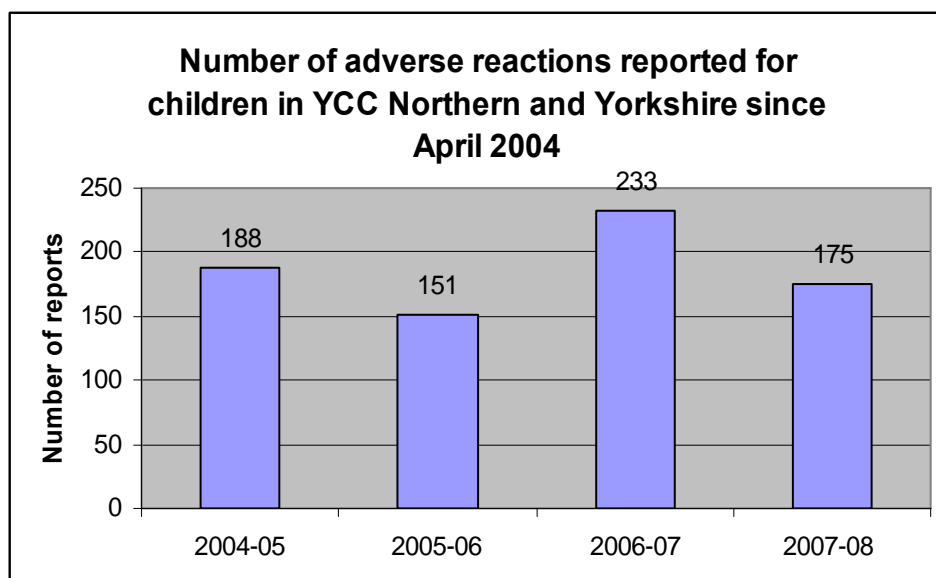
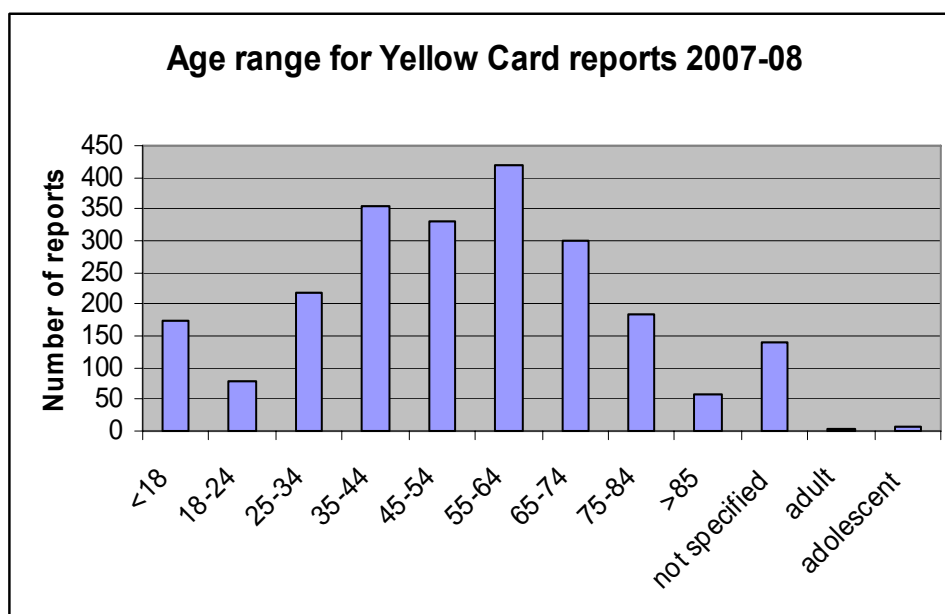


Chart 20



8. Source of yellow cards

The source of yellow cards received from YCC Northern and Yorkshire during 2007-08 is shown in table 1 below:

Table 1: Source of Yellow Card reports

Source	Number of reports	(%)
Paper	1789	79%
Electronic	464	20%
Telephone	12	1%
Total	2265	

9. 'Top 10' suspect drugs

The ten most frequently reported suspect drugs during 2007-8 are shown in table 2. During this time period varenicline was the most reported drug in Northern and Yorkshire, contributing 8% of reporting. This finding is similar to the national picture.

Table 2 : Top 10 drugs

	Drug	Number of reports	Rank order 2006-07	National rank 2007-08
1	Varenicline ▼	583	-	1
2	Aspirin	228	1	2
3	Simvastatin	205	2	3
4	Paracetamol	122	3	5
5	Lansoprazole	114	7	9
6	Bendroflumethiazide	101	4	7
7	Salbutamol	92	10	10
8 =	Atenolol	90	5	13
8 =	Furosemide	90	6	11
10	Ramipril	88	12	6

10. Follow up of reports

Between April 2007 and March 2008 further information was requested by the centre, at the direction of the MHRA, for 84 reports (3.7% of the total), an increase on the previous year. To date follow-up information has been received in 61% of cases, also increased compared with the previous year. The implementation of a revised follow up procedure in October 2007 will have contributed to the improved number of reports followed up successfully. The MHRA has followed up directly 38 cases originating from our region but the number of cases where follow up was successful is not known.

Table 3: Yellow Card follow up

Year	Followed up by	Number of reports followed up	Number of reports successfully followed up
2006-07	YCCNY	59 (2.8%)	19 (32%)
	MHRA	62	Data not supplied
2007-08	YCCNY	84 (3.7%)	51 (61%)
	MHRA	38	Data not supplied

11. Promotional Activities

The main activities of the YCC Northern and Yorkshire this year have been to promote the Yellow Card scheme to healthcare professionals and raise awareness of the centre

within the region, building on initiatives started during 2006-07, and against the objectives agreed with the MHRA (see appendix 3).

The centre has continued to publish the bulletin series *Safer Medication Use* which promotes safer prescribing; highlighting emerging or significant drug safety problems, providing guidance to ensure safe, appropriate prescribing and to raise awareness of adverse drug reaction detection and reporting. The bulletin is aimed at prescribers and healthcare professionals who can report ADRs, but is also of value at an organisational level such as Drug and Therapeutics Committees and Medicines Management Groups, plus clinical governance and non-medical prescribing leads to inform policy decisions and risk management strategies. Bulletins published this year have discussed bisphosphonates and inhaled corticosteroids; future editions are planned to discuss current and emerging drug safety issues.

The YCC Northern and Yorkshire has also worked collaboratively with the Newcastle Regional Drug and Therapeutic Centre (RDTC), to update two of their published *New Drug Evaluation* documents, which are widely circulated to GPs, pharmacists and other healthcare professionals within Northern and Yorkshire. These revised publications on rimonabant and varenicline included the updated safety information regarding psychiatric disorders, quoted Yellow Card data, provided guidance for prescribers and reminded healthcare professionals to complete a Yellow Card for all suspected adverse reactions to these drugs. In July 2007, YCC Northern and Yorkshire sought agreement from the RDTC that all New Drug Evaluations would include information regarding reporting of suspected reactions to black triangle drugs.

The YCC Northern and Yorkshire website, which was launched in February 2007, is updated regularly with information regarding emerging safety issues and recently published papers in the field of pharmacovigilance. The site also contains educational materials developed by the centre; two new documents were added this year, which provide general guidance about adverse drug reaction reporting, in the format of an academic detailing aid and a quick reference guide to completing a Yellow Card. All users accessing the site for information on the completion of a Yellow Card are encouraged to use the electronic form. In addition the website address of the electronic Yellow Card appears on all YCCNY publications and correspondence. The centre collects statistics regarding the use of the website. During 2007-8 the site received 38,040 visitors, the *Safer Medication Use* page was the most visited (see chart 21). The Yellow Card was the most frequently downloaded image from the website (see chart 22).

Staff at the centre continue to contribute to local educational programs, provided to all reporter types within the region, with the aim of alerting health professionals to the Yellow Card scheme, including patient reporting; five such sessions have been provided this year. Non-medical prescribers have been identified as a significant group of reporters to whom support has been directed, as part of a regional programme to promote non-medical prescribing. The centre has been unable to provide data on reporting rates at trust level since 2005, consequently there has been limited contact with Medical Directors, Trust Chief Pharmacists, Trust Clinical Governance leads and Primary Care Medicines Management Leads to promote the Yellow Card scheme, but it is anticipated that this will resume once data becomes available. We continued to work closely with Newcastle University this year, supporting undergraduate and postgraduate teaching. Contact with other healthcare professional education providers in the region is being established, with a view to extending our support to other establishments.

Chart 21: Most Popular Pages visited on the YCCNY website during 2007-08

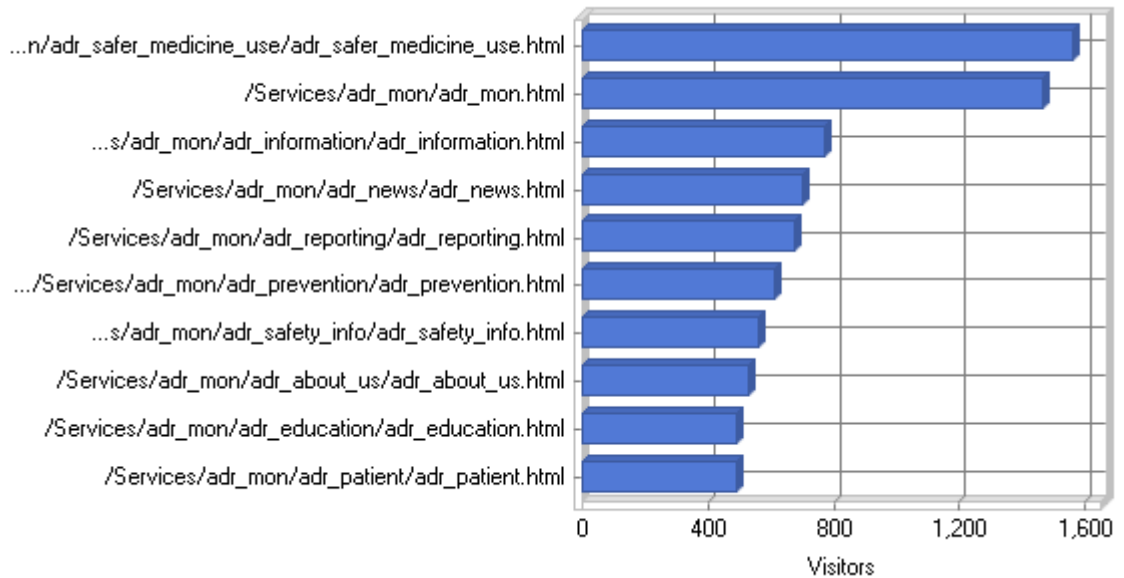
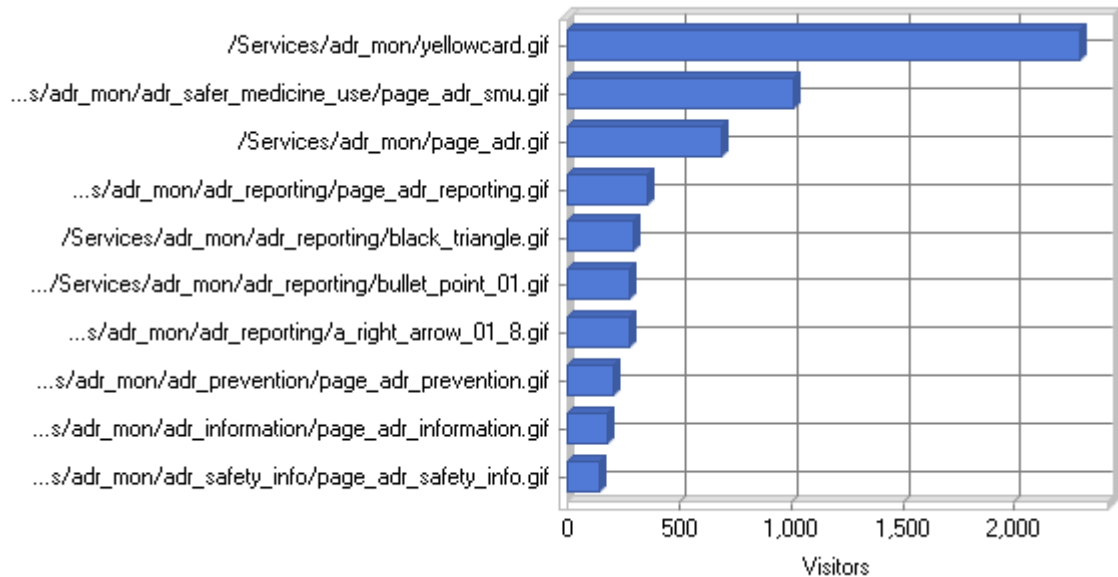


Chart 22: Most Requested Images on the YCCNY website during 2007-08



During 2007-08 the centre answered 184 enquiries about adverse reactions to specific drug(s). It is policy with such enquiries that the callers (including patients contacting us via NHS direct) are encouraged to complete a Yellow Card report where appropriate.

Patients have been able to report adverse reactions since November 2005, however the scheme was re-launched by the MHRA in February 2008, with a 6-week promotional campaign in community pharmacies nationwide and media coverage of the scheme. The centre supported this initiative by liaising with local PCTs and area managers of major community pharmacy multiples, to promote the campaign, offering support and training for community pharmacists; unfortunately despite initial interest in training no sessions were requested. It is too early to see the impact of the campaign on patient and community pharmacist reporting. Hospital Chief Pharmacists were also contacted and encouraged to display promotional materials during the duration of the campaign. In addition the patient reporting scheme is mentioned in all the centres educational sessions, to ensure that healthcare professionals are aware that patients can report and

that they continue to report themselves. It is reassuring that reporting rates from healthcare professionals have been maintained following the extension of the scheme.

A number of initiatives have been undertaken to support the national work of the MHRA in promoting drug safety. In August 2007 when *Drug Safety Update* was launched, a link to this was created on the YCCNY website, with a news item on the homepage. The 1st few issues were circulated by e-mail to all PCT Medicine Management and Clinical Governance leads, Trust Chief Pharmacists and Medicines information pharmacists in YCC Northern and Yorkshire, encouraging them to register for the e-mail alerts. In addition all the centres presentations and awareness sessions now include information about the bulletin.

Educational sessions

Hill S. Drugs of abuse – Update. NPIS National CPD Day, Newcastle, 24th April 2007

Prior R. Adverse Drug Reaction Reporting. Poster presentation at the NHS Northwest Non-medical Prescribing Leads Event, Bolton, 17 April 2007

Duration: poster presentation during lunchtime

Audience: 100 non-medical prescribing leads

Feedback: not available

Prior R. Adverse drug reactions and the A+E department. National Poisons Service (Newcastle) Drug Overdose and Poisoning study day, York, 19 April 2007

Duration: 30 minute presentation and case study

Audience: 70 doctors, nurses, pharmacists and other healthcare professionals working in A+E

Feedback: Extremely Useful 21% of respondents, Useful 34%, Fairly Useful 43%, Not Useful 0%, Not directly relevant 2%. Comments *“Will feedback presentation on ADR to other pharmacists in my department.”*

Prior R. Adverse Reactions and the Yellow Card Scheme. Northern Region Pre-registration Pharmacist Training Scheme, Morpeth, 18 May 2007

Duration: 30 minute presentation and case studies

Audience: 30 pre-registration pharmacists

Feedback: Generally positive, however the following comment *“Less ADR stuff as covered in university”*

Prior R. Adverse Drug Reactions. Diploma in Therapeutics. Newcastle University, 15 October 2007

Duration: 90 minute presentation and case studies

Audience: 12 GP, hospital doctors, community pharmacists and practice pharmacists.

Feedback: Content and presentation 87%, Practical value 90%, Intellectual stimulation 77%.

Prior R. Adverse drug reactions and the A+E department. National Poisons Service (Newcastle) Drug Overdose and Poisoning study day, Newcastle, 31 October 2007

Duration: 30 minute presentation and case study

Audience: 63 doctors, nurses, pharmacists and other healthcare professionals working in A+E

Feedback: Extremely Useful 11% of respondents, Useful 54%, Fairly Useful 26%, Not Useful 0%, Incomplete form 9%. Comments: "ADR session very relevant to staff working in A+E." "Now aware of agency to report adverse reactions."

Thomas SHL. 21st Century and the Drugs that Our Children Take. Paediatric A&E Conference, London, 7th July 2007.

Thomas SHL. Medical mysteries – 2 cases of aplastic anaemia. European Association of Poisons Centres and Clinical Toxicologists, Athens, 4th May 2007

Thomas SHL. Public Perception of Toxicologic Diseases: Is there a Bias? IUTOX meeting, Montreal Canada, 17th July 2007

Materials developed to promote the Yellow Card Scheme and published on the YCCNY website

Adverse Drug Reaction Reporting. Completing a Yellow Card. April 2007

Adverse Drug Reaction Reporting. Academic detailing aid. December 2007

Safer Medication Use published on the YCCNY website

Bisphosphonates. Safer Medication Use No. 2 January 2008

Inhaled corticosteroids. Safer Medication Use No. 3 March 2008

Bulletins published by YCCNY in collaboration with the Regional Drug and Therapeutics Centre

Rimonabant. New Drug Evaluation No.78 (update) August 2007

Varenicline. New Drug Evaluation No.81 (update) January 2008

Non MHRA meetings attended in YCC capacity

County Durham PCT and Darlington PCT Drug and Therapeutics Committee. 15th January 2008 to promote the patient Yellow Card Community Pharmacist campaign.

Gateshead Prescribing and Medicines Management Committee. 30th January 2008 to promote the patient Yellow Card Community Pharmacist campaign.

12. Publications

Book Chapters

Garbis H, McElhatton P. Psychotropic drugs. In: Drugs During Pregnancy and Lactation. Ed. Schaefer C, Peters P, Miller RK. 2nd edition Elsevier 2007 pp 288-320.

Miller RK, Peters P, McElhatton P. Occupational, industrial and environmental agents. In: Drugs During Pregnancy and Lactation. Ed. Schaefer C, Peters P, Miller RK. 2nd edition Elsevier 2007 pp 561-608.

Other publications

Beer C, Pakravan K, Hudson M, Smith LT, Simpson K, Bateman DN, Thomas SHL. Frequency of liver unit admission following paracetamol overdose when paracetamol concentrations are below current United Kingdom treatment thresholds. *Quarterly Journal of Medicine* 2007, 100: 93-96

Salih ISM, Thanacoody RHK, McKay GA, Thomas SHL. Comparison of the effects of thioridazine and mesoridazine on the QT interval in healthy adults after single oral doses. *Clinical Pharmacology and Therapeutics* 2007; 82: 548-554

Thanacoody RHK, Daly AK, Reilly JG, Ferrier IN, Thomas SHL. Factors affecting drug concentrations and QT interval during thioridazine therapy. *Clinical Pharmacology and Therapeutics* 2007; 82: 555-65

Thomas SHL. Low toxicity ingestions. *Medicine International* 2007; 35: p547

Thomas SHL. Is the cause toxicological? *Medicine International* 2007. 35: 540-541

Thomas SHL. Antihistamine poisoning. *Medicine International* 2007; 2007; 35: 592-3

Thomas SHL. Hot topics in toxicology – current approaches to the poisoned patient. *Ann Clin Biochem* 2007; 44: 11-12

Lawler JM, Thomas SHL. 'Off gassing' following fatal aluminium phosphide poisoning. *Clinical Toxicol* 2007; 45: p362

James DA, Lawler JM, Thomas SHL. Cardiac conduction defects following mirtazepine overdose. *Clinical Toxicol* 2007; 45: p365

Lawler JM, Thomas SHL. Poisons centre enquiries from prisons. *Clinical Toxicol* 2007; 45: 367-8

Newham JJ, Thomas SHL, MacRitchie K, McElhatton P, McAllister-Williams RH. Birth weight of infants after maternal exposure to typical and atypical antipsychotics: prospective comparison study. *Brit J Psychiatry* 2008; 192: 333-337

Hill S, Thomas SHL. Recreational drug toxicity. *Clinical Medicine* 2008: 8: 99-103

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13. Research

Because of its close ties with the UK National Teratology information Service, staff of the YCC Northern & Yorkshire continue to be active in pharmacovigilance relating to medicines use in pregnancy. During the year data has been published or presented on the adverse fetal effects of azole antifungals, statins, ACE inhibitors, lithium and mebendazole. Research has also been published on the effects of maternal antipsychotic exposure, both typical and atypical, on birth weight.

The centre has continued its collaboration with the European Medicines Agency as part of the ENCePP group. It is involved, as are the MHRA, as a partner in the EMEA 'PROTECT' consortium bidding for funding from the Innovative Medicines Initiative. The role of the centre will be in the development of aggregated data sets from European teratology services and the development and evaluation of a website designed to allow the on-line reporting by patients of medicines use in pregnancy and subsequent prospective follow up of fetal outcome.

The centre is also interested in the mechanisms of adverse drug reactions. During the year papers were published describing the lack of effect of CYP2D6 genotype on the extent of QTc prolongation produced by thioridazine. Although thioridazine concentrations are increased in slow hydroxylators, concentrations of the major metabolite mesoridazine are reduced in proportion and this metabolite has similar QTc prolonging effects to thioridazine in healthy volunteers.

14. Conclusions

This year YCC Northern and Yorkshire has continued to support the Yellow Card scheme by following up reports as necessary and providing education to healthcare professionals, in line with the objectives set by the MHRA. It is gratifying that the total number of reports has increased from the Northern and Yorkshire region by 9%, as a result of increased healthcare professional reporting, whilst the quality of reporting has been maintained. However, a reduction in reporting from hospital healthcare professionals, notably doctors and pharmacists, is a concern. Work in the coming year will build on the momentum gained and the initiatives started in previous years, in particular continuing to raise awareness of patient reporting for both healthcare professionals and patients, and to support local NHS organisations where the rates of Yellow Card reporting are not as high as we would hope.

Appendix 1: YCC Northern and Yorkshire data for the year 2007-08 from Sentinel

Total number of yellow card reports (including MAH holders) = 22355

Total number of yellow card reports (excluding MAH holders) = 12618

Total number of yellow card reports from Northern and Yorkshire region = 2265

Number of yellow card reports from each SHA by reporter qualification

*reports may have multiple reporters so the total will not necessarily equal the total number of reports received from the region.

	Carer	Community Pharmacist	Coroner	Dentist	GP	Hospital Doctor	Hospital Health Professional	Hospital Nurse	Hospital Pharmacist	Nurse	Optometrist	Other Health Professional	Parent	Patient	Pharmacist	Physician	Sum:
County Durham and Tees Valley		7		3	87	24	10	15	36	43		17	2	15	10	4	273
Cumbria and Lancashire	3	17		3	140	56	17	8	20	99		171	1	55	11	6	607
North and East Yorkshire and Northern Lincolnshire	7	11			112	32	14	11	13	32	1	38	1	40	2	4	318
Northumberland, Tyne & Wear	3	13	1		104	72	19	7	82	36		21		27	14	9	408
South Yorkshire	1	12			83	42	8	7	7	23		11	2	31	5	7	239
West Yorkshire	3	16			128	62	25	19	30	72	1	15		57	12	7	447
Sum:	17	76	1	6	654	288	93	67	188	305	2	273	6	225	54	37	2292

Number of serious YC reports from each SHA by reporter qualification

	County Durham and Tees Valley	Cumbria and Lancashire	North and East Yorkshire and Northern Lincolnshire	Northumberland, Tyne & Wear	South Yorkshire	West Yorkshire	Sum:
Carer		2	5	2	1	3	13
Community Pharmacist	4	10	7	8	11	11	51
Coroner				1			1
Dentist	1	3					4
GP	47	89	69	65	60	74	404
Hospital Doctor	21	52	29	66	37	53	258
Hospital Health Professional	5	10	10	15	5	18	63
Hospital Nurse	8	5	9	5	5	13	45
Hospital Pharmacist	34	18	12	82	7	28	181
Nurse	28	53	11	14	4	39	149
Optometrist						1	1
Other Health Professional	9	57	23	12	7	11	119
Parent		1	1		1		3
Patient	12	39	31	24	21	33	160
Pharmacist	7	9	2	11	4	9	42
Physician	4	5	3	7	6	6	31
Sum:	180	353	212	312	169	299	1525

Number of black triangle YC reports from each SHA by reporter qualification

	County Durham and Tees Valley	Cumbria and Lancashire	North and East Yorkshire and Northern Lincolnshire	Northumberland, Tyne & Wear	South Yorkshire	West Yorkshire	Sum:
Community Pharmacist	1	2		2			5
Coroner				1			1
GP	20	26	20	21	23	23	133
Hospital Doctor	2	7	12	13	13	12	59
Hospital Professional Health	1	5	2	2		8	18
Hospital Nurse	6	2	3	4	1	4	20
Hospital Pharmacist		2	1	1	2	1	7
Nurse	7	10	5	6	1	18	47
Other Health Professional	1	7	1	3		2	14
Parent	1		1				2
Patient	1	2	1	1	2	7	14
Pharmacist		1		1	1	1	4
Physician	3	1	1	4	1	1	11
Sum:	43	65	47	59	44	77	335

Age banding

All reports:

Age range	number of reports
<18	175
18-24	79
25-34	218
35-44	356
45-54	329
55-64	419
65-74	300
75-84	183
>85	57
not specified	140
adult	2
adolescent	7
Total	2265

Child reports split by SHA

*where age is <18

Reporter region	number of reports
Cumbria and Lancashire	33
North and East Yorkshire and Northern Lincolnshire	19
Northumberland, Tyne & Wear	36
South Yorkshire	34
West Yorkshire	42
County Durham and Tees Valley	18
Total	182

Source	number of reports
Paper	1789
Electronic	464
Telephone	12
Total	2265

Fatal reports

Total fatal reports from Northern and Yorkshire = 38

*reports may have multiple reporters so the total will not necessarily equal the total number of fatal reports received from the region.

	County Durham and Tees Valley	Cumbria and Lancashire	North and East Yorkshire and Northern Lincolnshire	Northumberland, Tyne & Wear	South Yorkshire	West Yorkshire	Sum:
Carer			2	1			3
Coroner				1			1
GP		4	1	2	1	2	10
Hospital Doctor			2	1	2	2	7
Hospital Professional		1	1	1	1	1	5
Hospital Nurse						1	1
Hospital Pharmacist			1	4	1		6
Nurse		1				2	3
Other Health Professional		1		1			2
Patient			1				1
Pharmacist	1					1	2
Physician				1			1
Sum:	1	7	8	12	5	9	42

Number of reports per quarter

	number of reports
April - June	464
July- September	575
October - December	639
January - March	589
Total	2267

Follow ups

Followed up by:	number of reports
YCC	52
MHRA	70
Total	122

Appendix 2: Number of Yellow Card reports by reporter type for each former SHA since April 2004

Total reports by reporter type for County Durham and Tees Valley

	GP	Hospital Doctor	Hospital Pharmacist	Community Pharmacist	Hospital nurse	Nurse	Patient	Other (coroner, dentist, other HCP, pharmacist [sector N/K])	Total
2004-05	128	46	65	3	n/a	26	3	10	281
2005-06	63	48	19	4	0	27	18	18	197
2006-07	67	42	40	8	8	16	32	24	237
2007-08	87	28	36	7	15	43	17	40	273

Total reports by reporter type for Cumbria and Lancashire

	GP	Hospital Doctor	Hospital Pharmacist	Community Pharmacist	Hospital nurse	Nurse	Patient	Other (coroner, dentist, other HCP, pharmacist [sector N/K])	Total
2004-05	183	78	20	9	n/a	65	5	23	383
2005-06	143	71	21	13	2	45	72	42	409
2006-07	121	76	16	18	10	43	83	69	436
2007-08	140	62	20	17	8	99	59	202	607

Total reports by reporter type for North and East Yorkshire and Northern Lincolnshire

	GP	Hospital Doctor	Hospital Pharmacist	Community Pharmacist	Hospital nurse	Nurse	Patient	Other (coroner, dentist, other HCP, pharmacist [sector N/K])	Total
2004-05	134	43	26	19	n/a	32	1	21	276
2005-06	99	64	19	6	0	21	50	27	286
2006-07	89	46	13	8	5	13	75	31	280
2007-08	112	36	13	11	11	32	48	55	318

**Total reports by reporter type for Northumberland,
Tyne and Wear**

	GP	Hospital Doctor	Hospital Pharmacist	Community Pharmacist	Hospital nurse	Nurse	Patient	Other (coroner, dentist, other HCP, pharmacist [sector N/K])	Total
2004-05	144	148	135	12	n/a	36	5	36	516
2005-06	90	162	172	13	1	33	51	48	570
2006-07	104	103	146	9	11	24	50	90	537
2007-08	104	81	82	13	7	36	30	55	408

Total reports by reporter type for South Yorkshire

	GP	Hospital Doctor	Hospital Pharmacist	Community Pharmacist	Hospital nurse	Nurse	Patient	Other (coroner, dentist, other HCP, pharmacist [sector N/K])	Total
2004-05	95	66	28	15	n/a	24	3	38	269
2005-06	66	63	11	6	0	19	45	30	240
2006-07	57	38	11	9	6	16	42	28	207
2007-08	83	49	7	12	7	23	34	24	239

Total reports by reporter type for West Yorkshire

	GP	Hospital Doctor	Hospital Pharmacist	Community Pharmacist	Hospital nurse	Nurse	Patient	Other (coroner, dentist, other HCP, pharmacist [sector N/K])	Total
2004-05	145	91	69	11	n/a	83	6	29	434
2005-06	98	92	42	11	1	58	62	33	397
2006-07	103	71	23	14	12	37	77	74	411
2007-08	128	69	30	16	19	72	60	53	447

Appendix 3: YCC Northern and Yorkshire objectives for 2007-09

<u>General Objectives</u>	<u>Performance measures and targets</u>	<u>Progress at 31st March 2008</u>
<p><u>1. Communications</u></p> <p>Communicate information about the Yellow Card Scheme with a view to improving and increasing ADR reporting.</p>	<p>1.1 To develop and maintain the YCC website and to update the existing yellow-card teaching resource pack and make it available via the Website</p>	<p>Maintenance ongoing. 2 pieces of training material available on YCCNY website</p>
	<p>1.2 Develop the YCC, with a lay guide to reporting adverse drug reactions</p>	<p>Agreement for YCCs to collaborate on the production of the lay guide. Meeting to be arranged.</p>
	<p>1.3 Ensure Website has appropriate links to agreed YC partners</p>	<p>Updated according to links provided by MHRA.</p>
	<p>1.4 To make contact with the area managers for the major community pharmacy multiples within YCC area.</p>	<p>Area managers contacted (Feb 08) to coincide with the promotion of patient YC in community pharmacies. General support and regarding ADR reporting and education offered. Quick electronic questionnaire included, 1 response out of 11 letters sent.</p>
<p><u>2. Education</u></p> <p>Act as a point of information to inform stakeholders about Yellow Card reporting initiatives and provide education to reporters on what and how</p>	<p>2.1 To contact all providers of undergraduate and postgraduate education for healthcare professionals involved with medicines prescribing in Northern and Yorkshire by April 2008, to establish the current level of teaching regarding ADR and the Yellow card Scheme, and offer support in the form of education materials and sessions</p>	<p>Deferred to after April 2008, as target 1.4 and 3.1 undertaken in preference. To be completed by end 2008</p>

to report	2.2 Deliver 4 training sessions per year to relevant healthcare professional groups to raise awareness of the Yellow card scheme and stimulate reporting.	4 training sessions delivered to healthcare professionals and one poster presentation at non-medical prescribing conference.
3. Patient Reporting Engage in the Yellow Card Strategy to increase Yellow Card reporting from patients	3.1 To work with community pharmacists as part of a national campaign to engage patients in the Yellow Card Scheme	Liaison with local PCTs and hospital trusts to promote the scheme. Training materials adapted. No sessions delivered due to lack of user engagement. Press release written in collaboration with MHRA for those PCTs requesting it.
	3.2 To increase patient awareness of adverse drug reaction reporting in secondary care by contacting all hospital pharmacies in Northern and Yorkshire to seek their views on how written information about the scheme can be passed on to patients. To establish a mechanism in at least 1 hospital trust, to provide written information to patients about the Yellow Card scheme by April 2008	All Chief Pharmacists contacted prior to patient YC promotional campaign in Feb 2007, including electronic poster and Yellow cards. Written agreement from one trust who used all promotional materials in outpatient pharmacies during the campaign. Contacted Northern Chief Pharmacists group to discuss patient YC reporting.
	3.3 Engage with local expert patient groups to promote the Yellow Card Scheme	No progress. To complete prior to end 2008
4. ADR Follow-up Request follow up information from reporters in the region and supply to MHRA	4.1 Request follow up information in accordance with MHRA agreed procedures	Ongoing as per operational procedures

