

Yellow Card Centre Northern & Yorkshire

ANNUAL REPORT 2009/2010

Regional Drug and Therapeutics Centre
Wolfson Unit of Clinical Pharmacology
Claremont Road
Newcastle upon Tyne
NE2 4HH

July 2010

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

Dr A Dyker	Consultant Physician Pharmacology, Regional Drug and Therapeutics Centre
Ms S Harvey	Secretary, Regional Drug and Therapeutics Centre
Mrs A Makepeace	Secretary, Royal Victoria Infirmary
Mrs J Metcalf	Secretary, Regional Drug and Therapeutics Centre
Ms B Reddy	Acting Director of Pharmacy, Regional Drug and Therapeutics Centre
Mrs S Smith	Senior Pharmacist Pharmacovigilance
Dr S Stephens	Assistant Head of Teratology, Regional Drug and Therapeutics Centre
Dr R Thanacoody	Consultant Physician/Clinical Toxicologist
Prof SHL Thomas	Director RDTC, Reader in Therapeutics (YCCNY Director)
Mrs J Wood	Business Manager, Regional Drug and Therapeutics Centre

*Please note the total number of reports includes those received via the Swine flu portal. However, data received via the portal was unable to be split into reporter group or geographical area and is therefore not included in those figures

**Data could not be split via black triangle drug as the MHRA did not supply this data.

2. Summary

The Yellow Card Centre Northern and Yorkshire (YCCNY) makes a significant contribution to patient safety by encouraging the reporting of adverse drug reactions (ADRs). During the 2009-2010 financial year 1812 reports were received from Northern and Yorkshire, a 5% increase over 2008/2009. This increase would have been larger had there not been the postal problems experienced by the Medicines and Healthcare Regulatory Agency (MHRA) resulting in yellow cards going astray.

This year saw the introduction of the Swine Flu Portal via which ADRs to antivirals and the pandemic flu vaccine could be reported. The Northern and Yorkshire region provided 356 reports via the portal (though the MHRA are unable to break reports down to geographical area or reporter type, we have included them in our data (Figure 1)). Reporting from nurses continues the upward trend with a 2% increase on last years figures. Reporting from hospital doctors has also increased. Of concern however, is the continued decline in reporting from GPs and hospital pharmacists.

The centre produced a summary version of the previous year's annual report which was sent to the Heads of Medicines Management, of each PCT in our region. This summarised Yellow Card reporting in each PCT. Reporting by PCT for the period April 2009-2010 is shown in figure 2. It is difficult to compare this years reporting with that of the previous recording period as the MHRA were unable to supply data from the swine flu portal other than the number of reports, though a 31% increase was seen in the number of reports received from Hull Teaching PCT.

Patients have been able to report ADRs since November 2005. Disappointingly, this year there has been a decrease in patient reporting despite the centre working to engage local patient groups and publishing an article in a patient magazine. We continue to seek to raise awareness of patient reporting through our educational work directed at healthcare professionals, who are encouraged to continue reporting themselves. The centre also delivered yellow card training as part of medicines information sessions to nurse assessors, health information advisors and dental nurse advisors at NHS Direct. The training focused on informing patients that they may fill in a Yellow Card should they contact NHS Direct regarding an adverse drug reaction

The centre has continued to publish the bulletin series *Safer Medication Use* which promotes safer prescribing, highlights emerging or significant drug safety problems, and raises awareness of adverse drug reaction detection and reporting. The bulletin is aimed at prescribers and other healthcare professionals who encounter patients with ADRs. However, it is also of value to Drug and Therapeutics Committees, Medicines Management Groups, clinical governance leads and non-medical prescribing leads to inform policy decisions and risk management strategies. During the 2009-10 financial year, bulletins have discussed proton pump inhibitors and osteoporotic fracture and the safety of tricyclic antidepressants in the elderly. Future editions are planned to discuss current and emerging drug safety issues.

The YCC Northern and Yorkshire website is regularly updated with information regarding safety problems and recently published papers in the field of Pharmacovigilance. The site also contains educational materials developed by the centre. All users accessing the site for information on the completion of a Yellow Card are encouraged to use the electronic form. The site also promoted the 'Swine Flu ADR Portal' on behalf of the MHRA in order to identify safety problems with antivirals and the H1N1 vaccine during the recent flu pandemic.

We continue to encourage ADR reporting by health professionals, providing support and education, targeted according to local reporting patterns. The centre has promoted the Yellow Card scheme at a number of local training events for healthcare professionals. We also continue to work closely with local universities offering educational resources and specialist speakers on ADRs and Yellow Card.

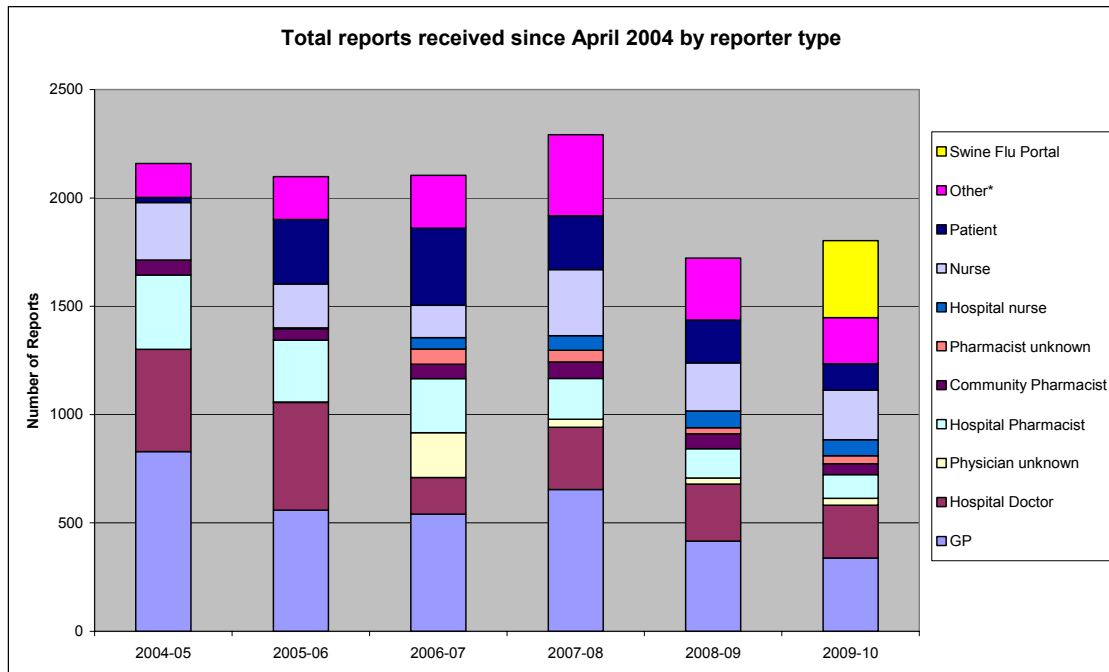
The YCC Northern and Yorkshire has continued to work closely with the MHRA and other YCCs to develop training materials for use nationally.

3. Yellow Card Data

3.1 Overview

A total of 1812 reports were received from Northern and Yorkshire during the 2009-2010 financial year, a 5% increase on 2008/2009. This increase reverses the downward trend seen last reporting period though figures remain lower than previous years (Chart 1). The MHRA estimates that 1000-2000 yellow cards may have been lost during postal problems and this may contribute to the lower figure seen. This year has seen a 2% increase in nurse reporting, but a 19% decrease in reporting from GPs.

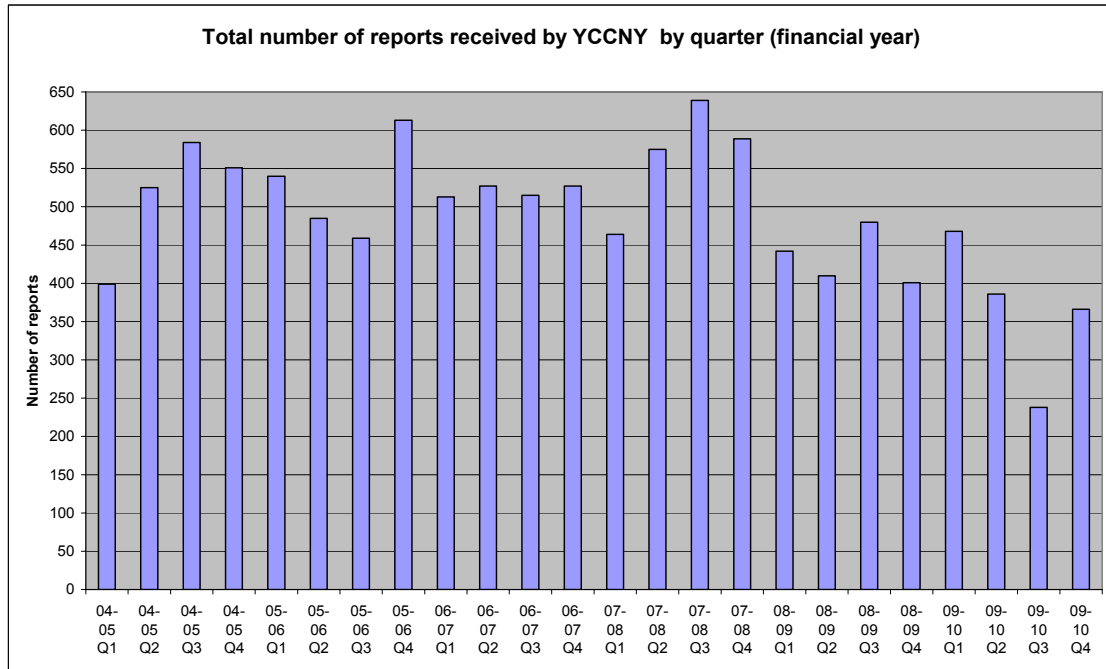
Chart 1



*coroner, dentist, hospital health professional, optometrist, other health professional, carer, consumer, parent

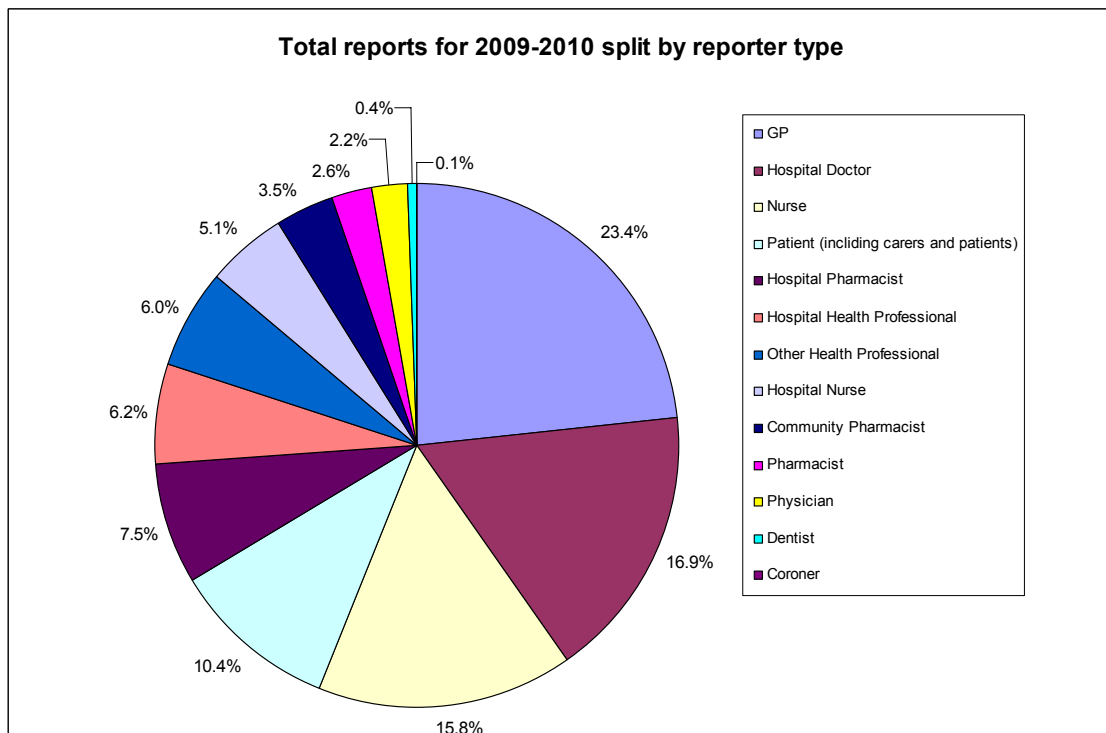
Despite a strong start to the 2009-2010 year the number of reports reduced in quarter 3 and 4. This is period in which the Royal Mail problems became apparent and may have resulted in yellow cards going astray. These data do not include that of reports from the swine flu portal (chart 2).

Chart 2



The breakdown of reports by reporter type shows that doctors reported the most adverse reactions (40%), but nurses (21%), healthcare professionals (12%) and patients [including patients and carers] (10%), also make important contributions (chart 3). More detailed discussion by reporter type is provided in section 3.3 onwards.

Chart 3



3.2 Reporting rates by geographical area

Reporting rate by geographical area, using boundaries of Strategic Health Authorities (SHA) show that the Yorkshire and Humber submitted the most reports (863) in the 2009-2010 financial year in numerical terms (Chart 4) but after correction for population, rate of reporting was highest from the North East SHA cards (chart 5).

Data is analysed in this way to facilitate the prioritisation of educational initiatives, targeting those with low or falling rates of reporting. Further data on reporting by SHA can be found in Appendix 1.

Chart 4

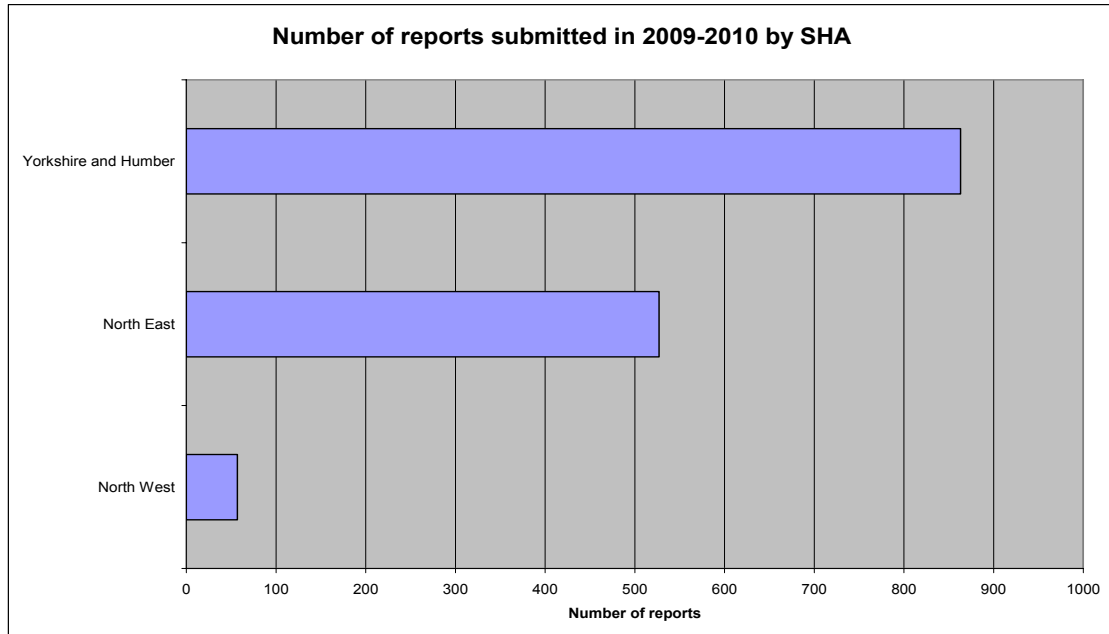
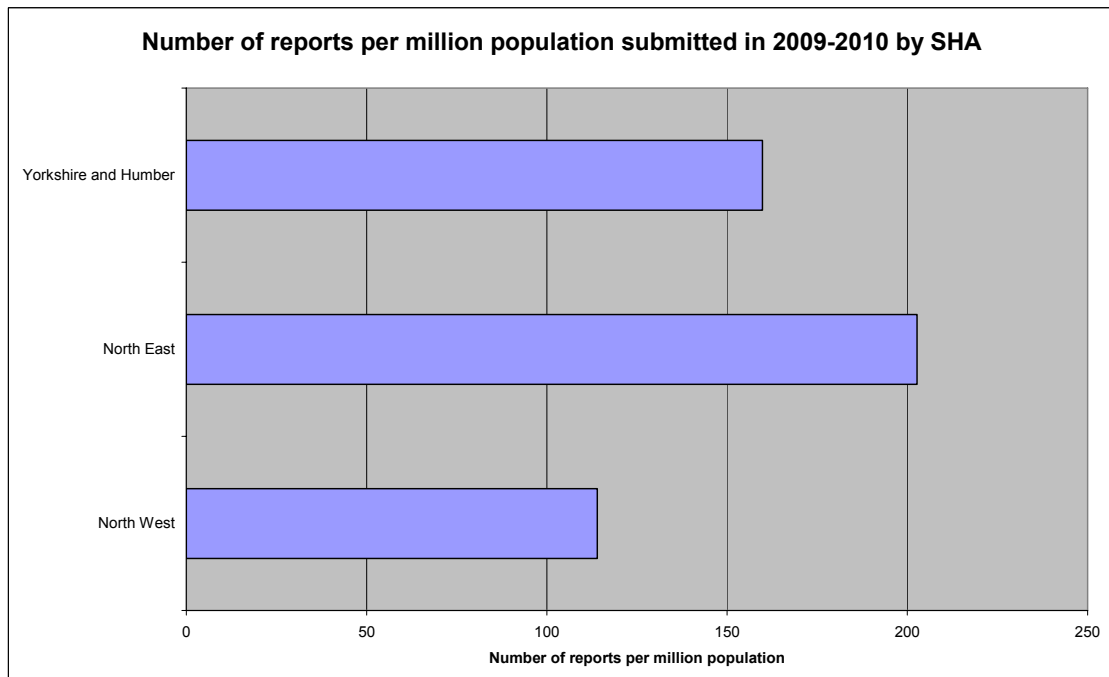


Chart 5



Yellow Card reporting varied widely by Primary Care Trust (PCT) (chart 6), with the highest number of reports submitted from Leeds PCT (165) and the fewest from Redcar and Cleveland, North Lincolnshire and Hull Teaching. These PCTs will be priority areas for raising awareness of the Yellow card scheme in the coming year.

When analysed by number of reports per million population Newcastle PCT submitted the most reports and Redcar and Cleveland and Hull Teaching remain the lowest reporting PCTs (Chart 7)

From this reporting year, the boundaries of Yellow Card Centres have changed. The YCCNY is now responsible for all of Cumbria and YCC North West takes responsibility for Lancashire.

Chart 6

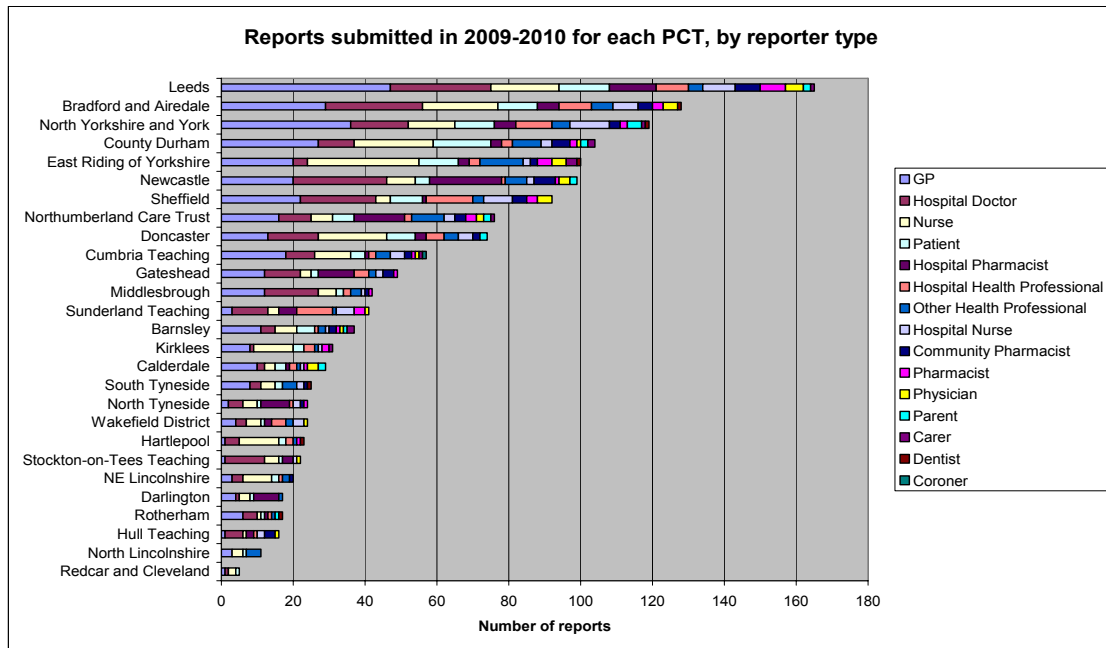
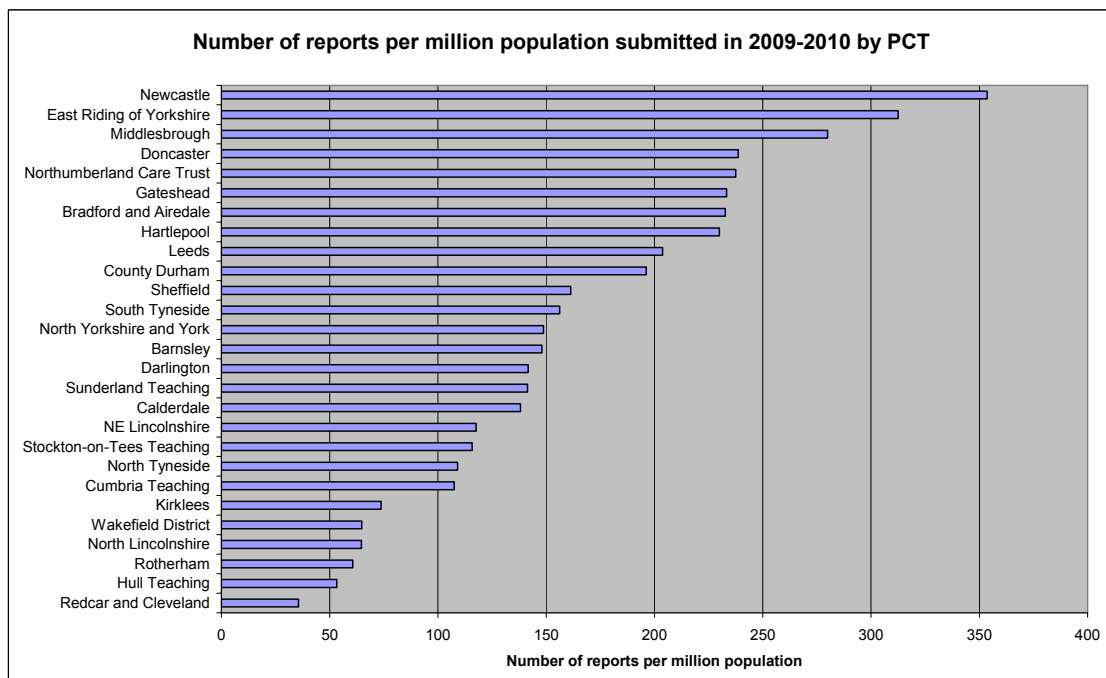


Chart 7



3.3 GP Reporting

There has been an 18.8% decrease in GP reporting in the 2009-2010 financial year compared with the previous year, with 338 reports submitted (Chart 8). Reductions have occurred in every PCT, reflecting the national trend in GP reporting (Chart 9). Newcastle and Middlesbrough PCTs submitted the highest number of reports per million population from GPs, whilst Hull Teaching PCT submitted the fewest for the second recording period running.

Chart 8

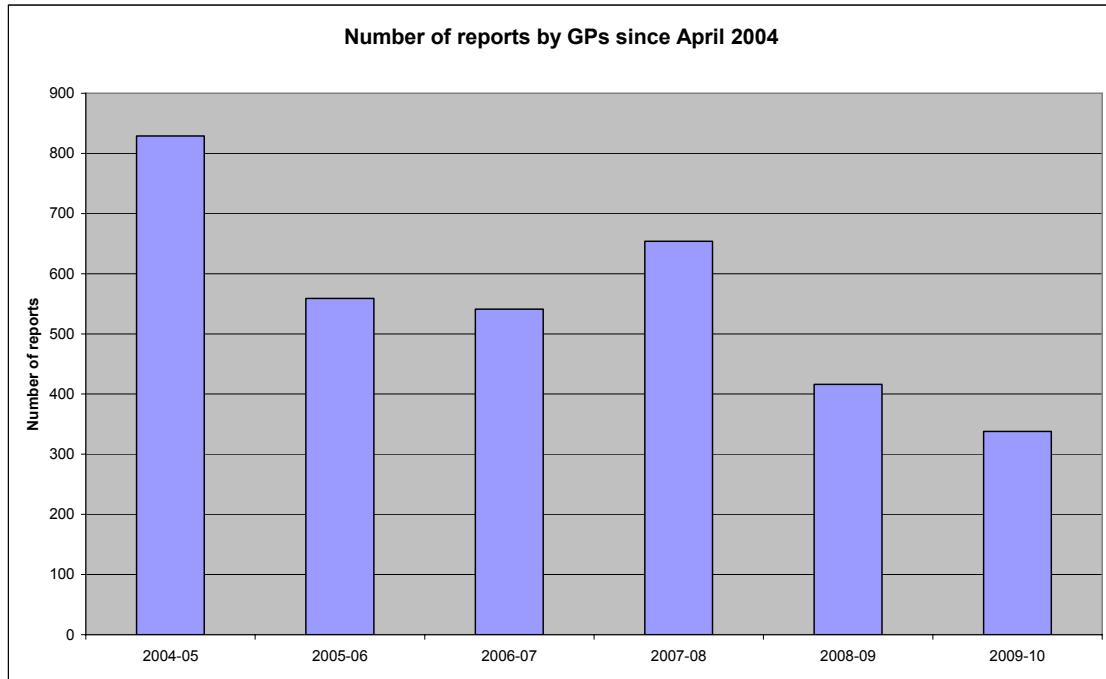
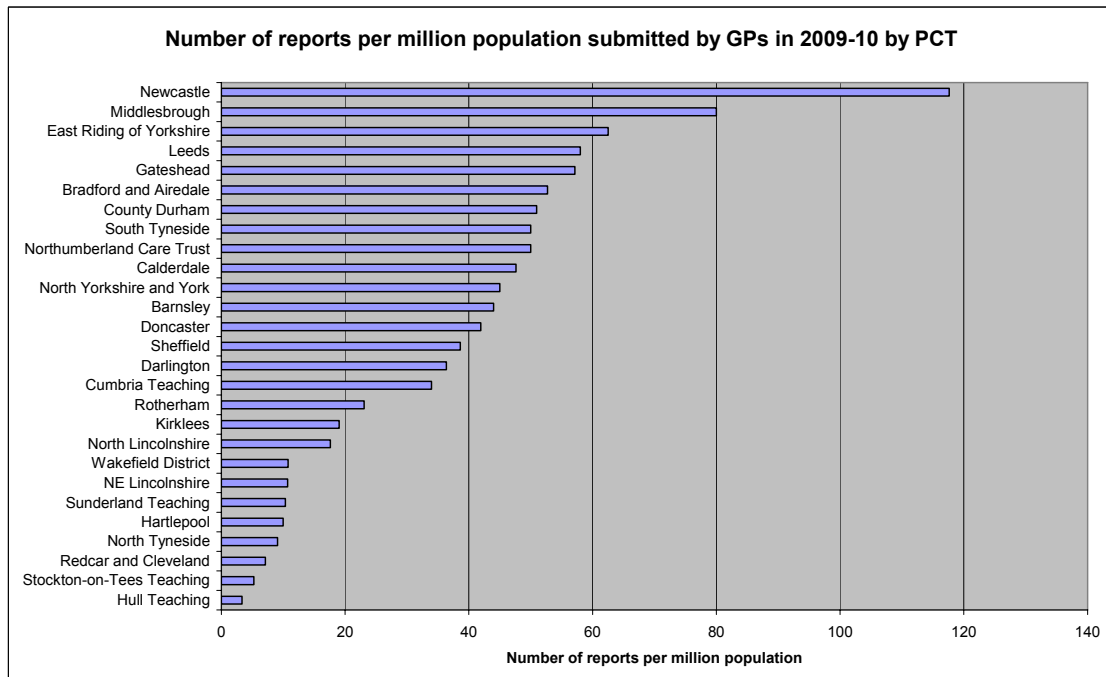


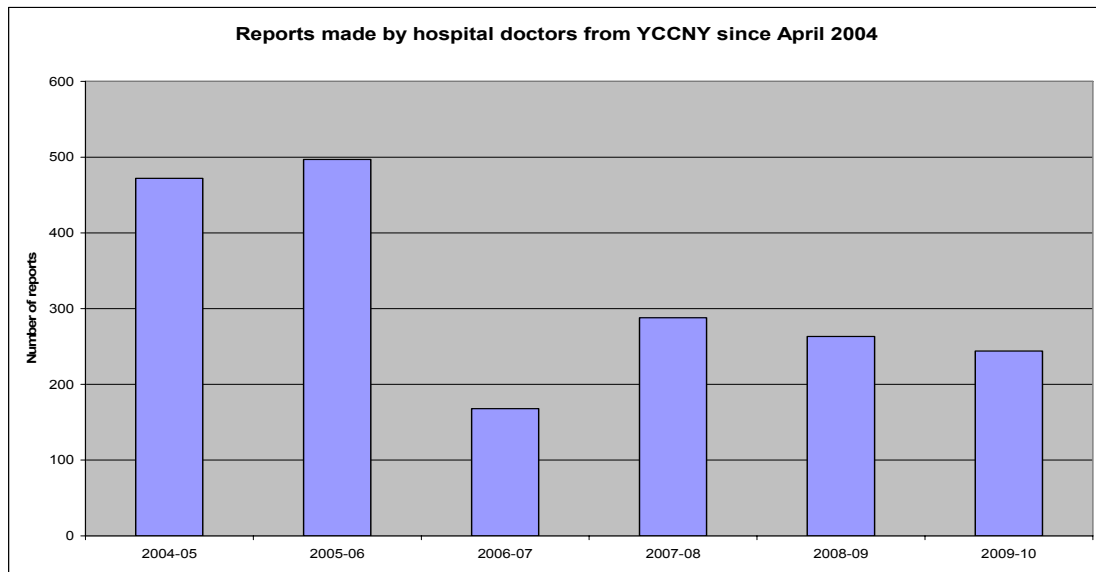
Chart 9



3.4 Hospital Doctor Reporting

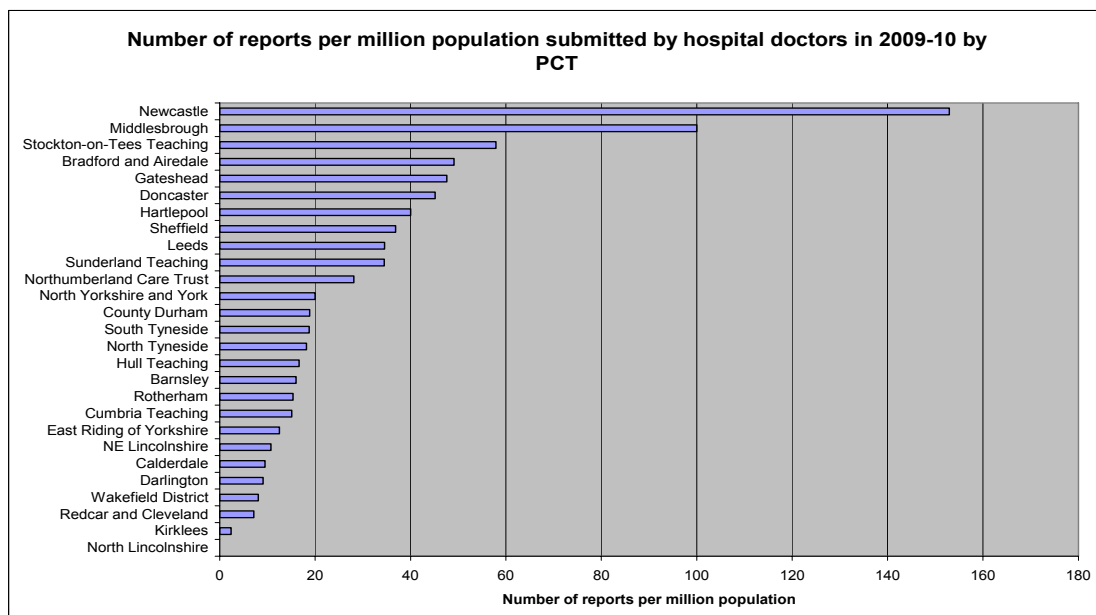
Hospital doctors in the Northern and Yorkshire region submitted 244 Yellow cards during 2009-2010. Figures have previously shown an underestimate of hospital doctor reporting as a significant portion of reports came from physicians (sector n/k) and the MHRA SENTINEL database is unable to classify by reporter type. This problem has continued over the last 2 years but to a lesser extent (29 and 32 'physician unknown' in 2008-2009 and 2009-2010 respectively). However, even if the unclassified reports originated from hospital doctors, the levels of hospital doctor reporting continue to decline. It is not known if this is a nationwide trend, nor whether other hospital healthcare professionals are reporting instead. The fact we are unable to break down data from the Swine Flu Portal also means a lower figure may be seen than actually occurred.

Chart 10



When the data I examined at a PCT level, the highest number of reports per million population from hospital doctors came from Newcastle PCT. There were no reports submitted from hospital doctors in North Lincolnshire PCT (Chart 11). It is not possible to provide information by individual NHS trust, but just by the PCT the trust is sited in.

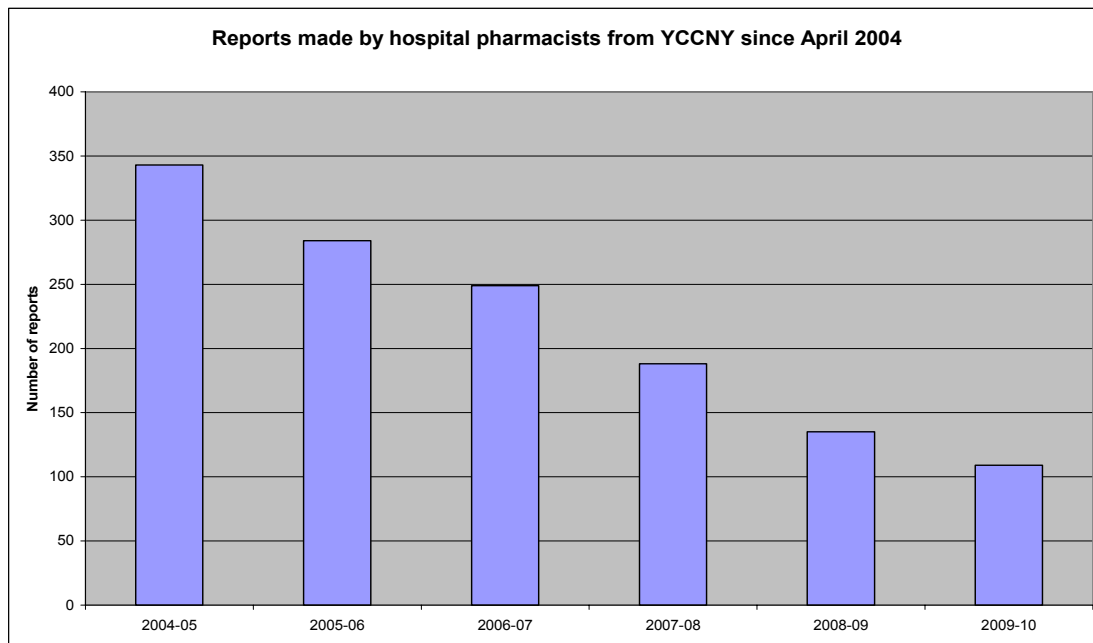
Chart 11



3.5 Hospital Pharmacist Reporting

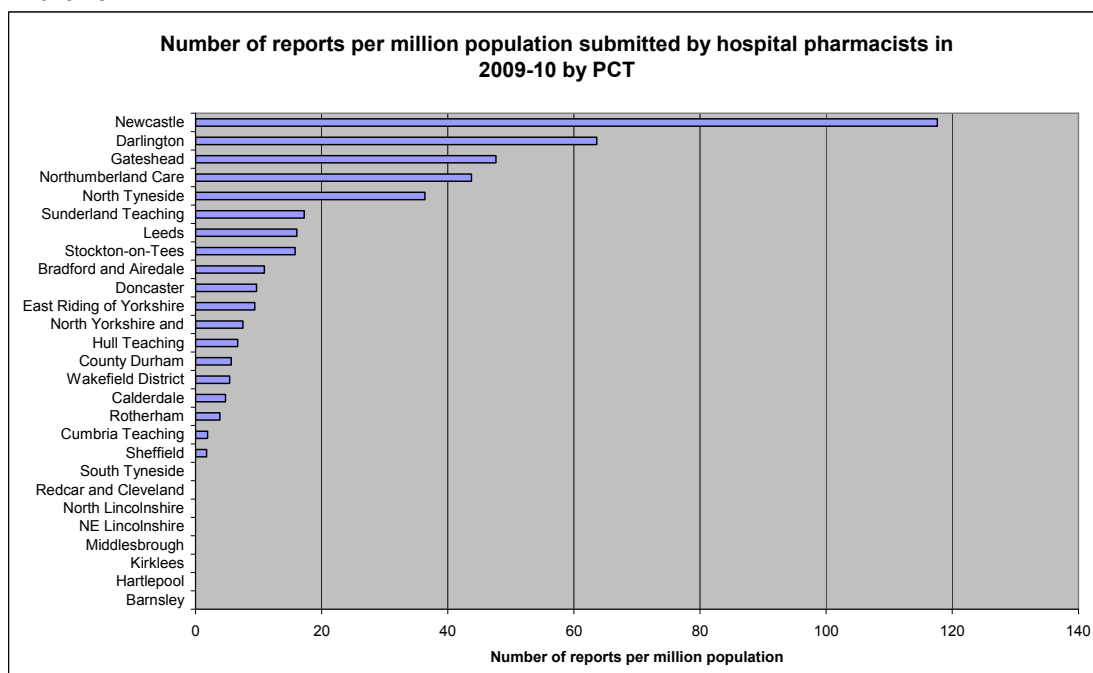
A total of 109 reports were received from hospital pharmacists in the Northern and Yorkshire region in 2009-2010. This is a 19% decrease on the previous reporting period and continues the downward trend since 2004-2005 (chart 12). However, this data does not include the data from the swine flu portal which may add to the figures. In the coming year, each hospital trust in the Northern and Yorkshire region will receive a summary annual report for their trust in the hope of stimulating reporting.

Chart 12



When the data is split by PCT, Newcastle PCT has the highest level of reporting per million population by hospital pharmacists. No reports from hospital pharmacists were received from hospitals within 8 PCTs (chart 13). It is not possible to provide information by individual NHS trust, but just by the PCT the trust is sited in.

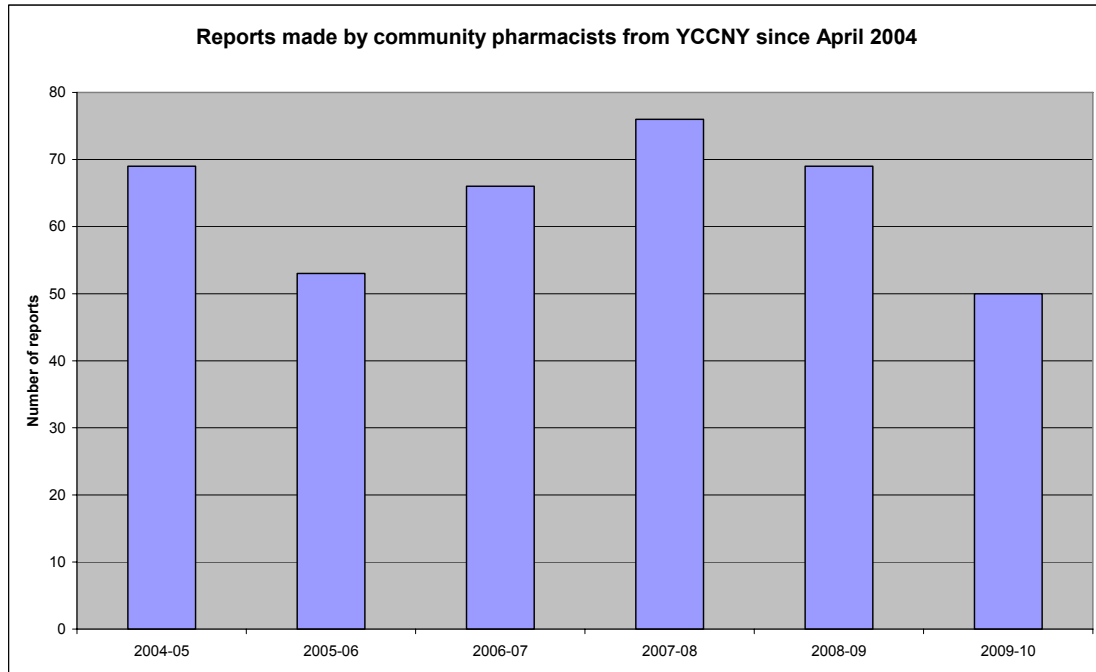
Chart 13



3.6 Community Pharmacist Reporting

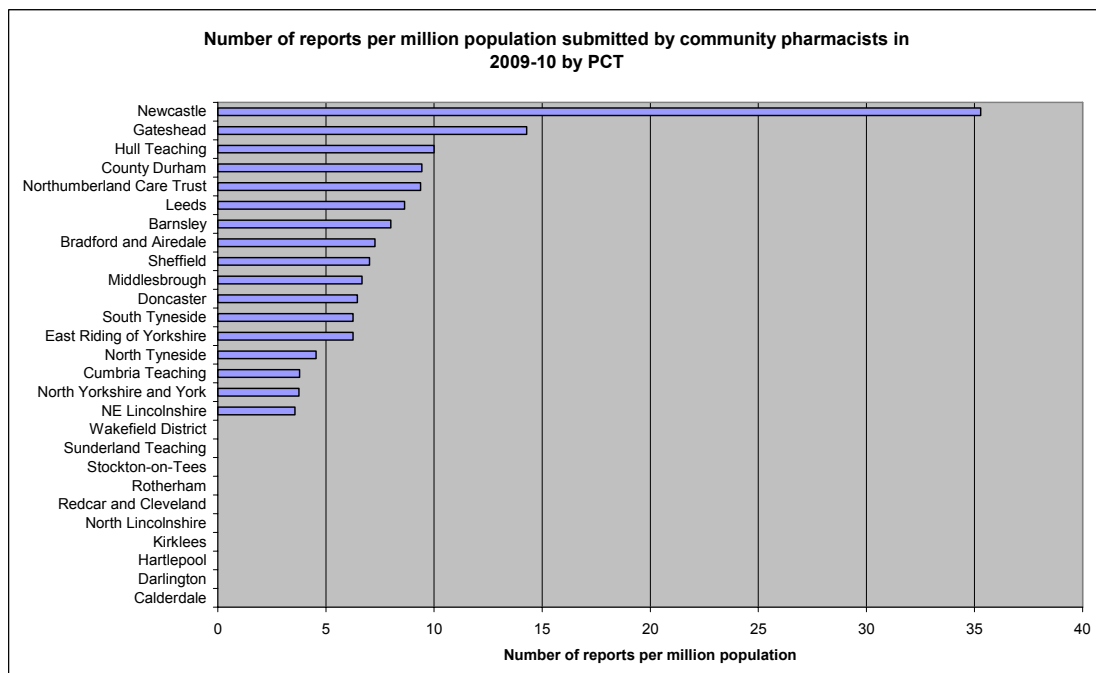
A total of 50 reports were received from community pharmacists in the 2009-2010 financial year, a decrease of 27% on the previous reporting period (Chart 14). This continues the decline seen since 2008, when a nationwide campaign in community pharmacies occurred to highlight the Yellow Card to patients. Community pharmacists are a target area for promotion this coming year.

Chart 14



When the data is examined by PCT, Newcastle PCT shows the highest level of reporting per million population by community pharmacists, however, no reports were received from 10 PCTs (Chart 15).

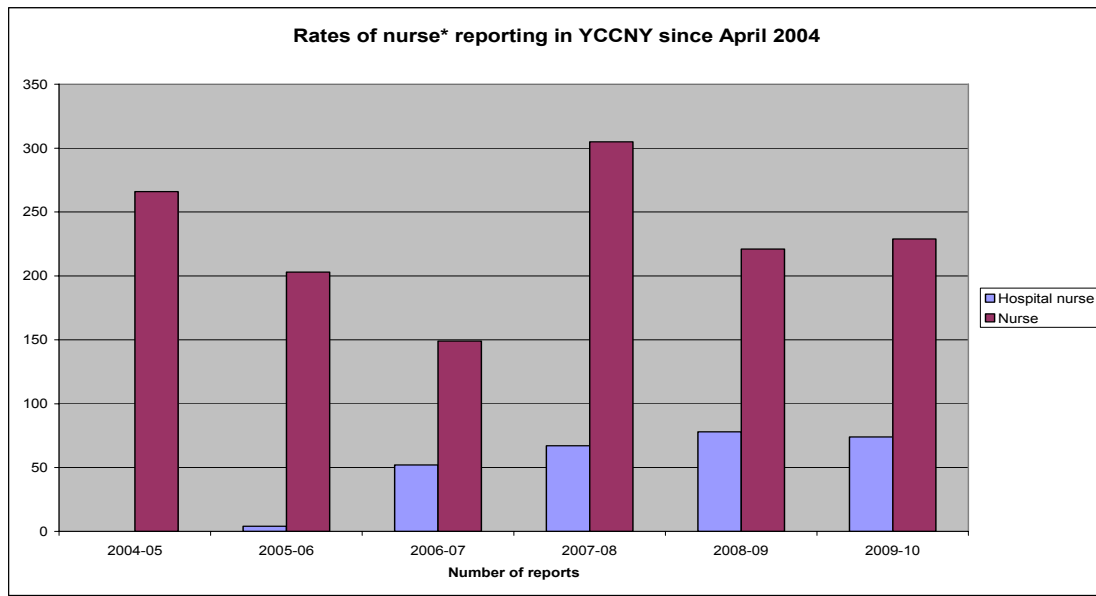
Chart 15



3.7 Nurse Reporting

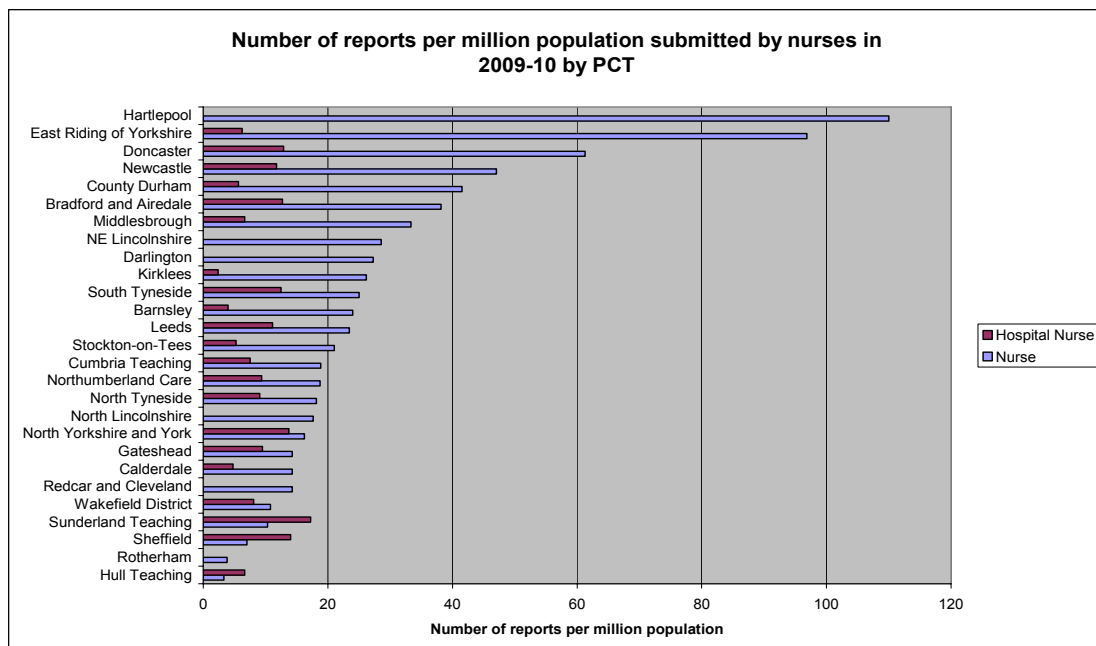
Nurses are now the second highest reporters behind GPs in the Northern and Yorkshire region. This year saw a 2% increase on the previous reporting year (chart 16). This increase is mainly due to an increase in the number of reports submitted by community nurses (4%). This increase may be explained by the increased adverse reactions reported relating human papilloma virus (HPV) vaccine, which is generally administered in a community setting. Nurses in primary care continue to make significantly more reports than those working in hospitals.

Chart 16



When the data is analysed by PCT, the Hartlepool submitted the most Yellow Cards per million population, all of which came from community nurses. Hull Teaching and Rotherham PCTs submitted the least (Chart 17).

Chart 17

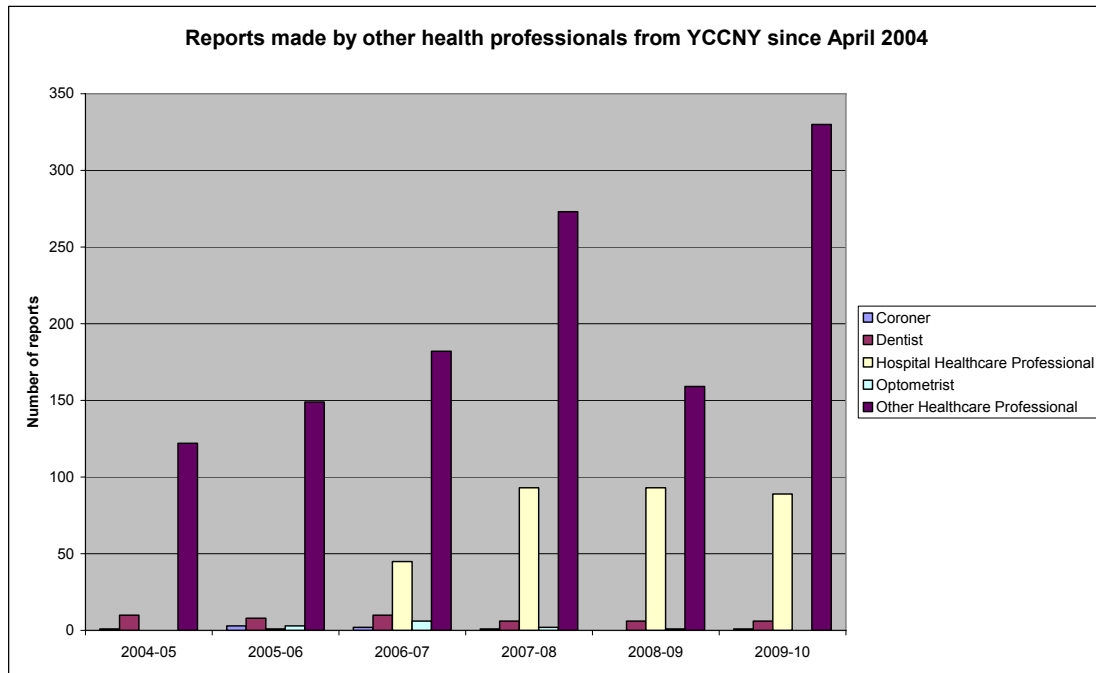


* Prior to May 2006 all reports from community and hospital nurses were classified on the MHRA ADROIT database as 'nurse'. Following the introduction of the SENTINEL database, reports from nurses are classified as 'Hospital nurse' and 'nurse' the latter covering those nurses in primary care

3.8 Other Healthcare Professionals

Reporting via the swine flu portal has been recorded as 'other health professional' when the data cannot be split by reporter group by the MHRA. The inclusion of these data has led to a 40% increase in reports for this reporting year. Reporting from coroners and dentists remain minimal. Hospital healthcare professional reporting also remains static; some of these reports may have been made by pharmacists or nurses, when their status has not been included in the report (chart 18).

Chart 18

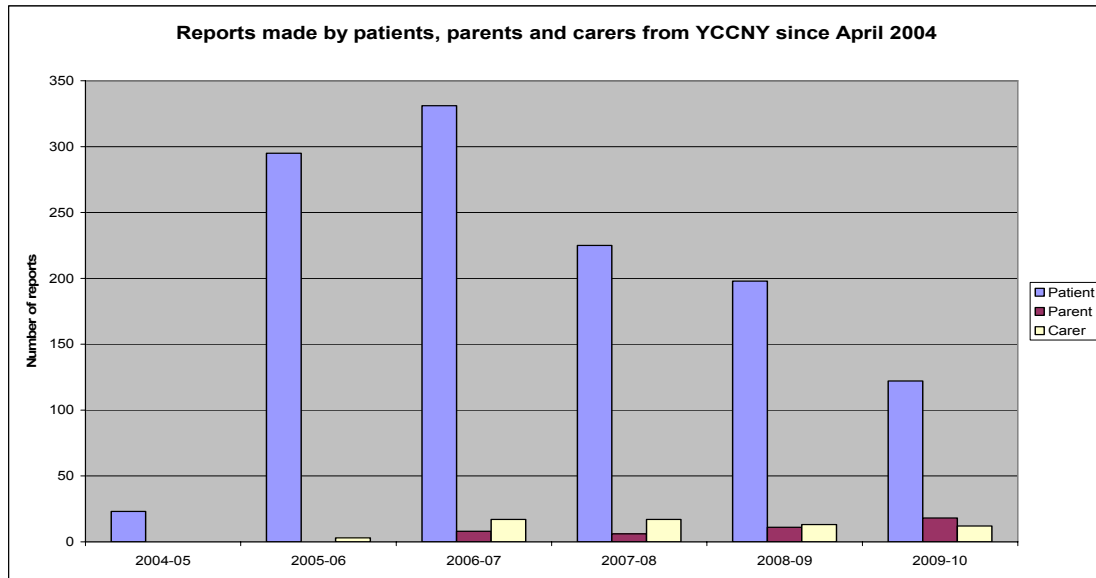


3.9 Patient Reporting

Since November 2005 patients, parents and carers in the UK have been encouraged to report suspected adverse drug reactions to the MHRA, using a patient Yellow Card. The scheme was relaunched in February 2008, with a 6 week promotional campaign in community pharmacies nationwide, however the figures since 2008 have continued to decline with a 32% decrease on the 2008-2009 figures (chart 19).

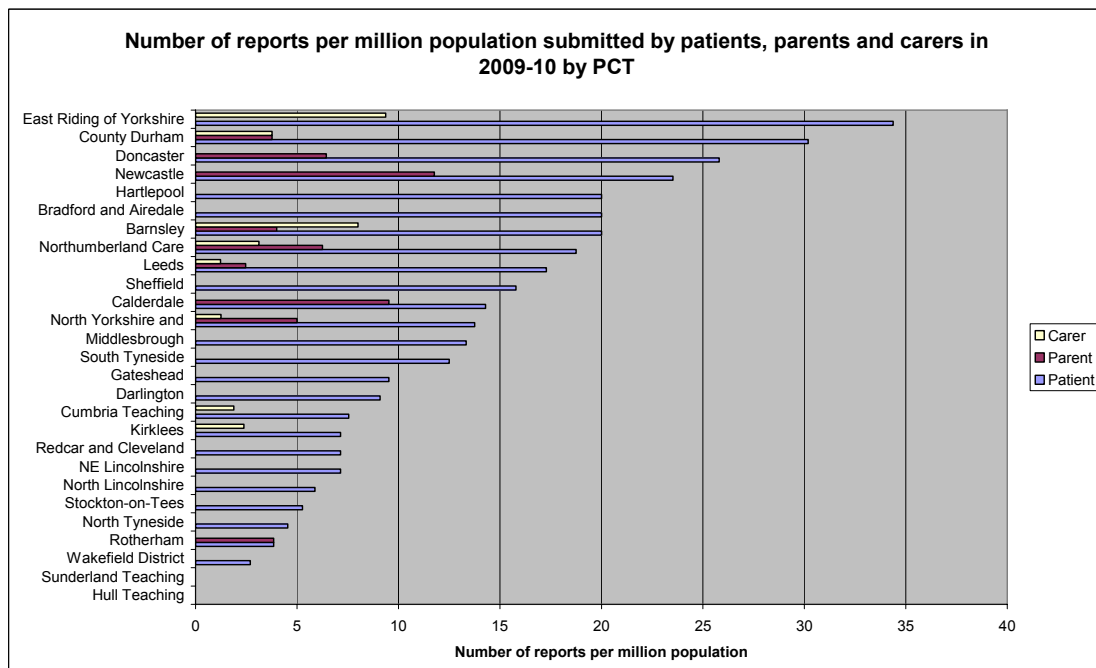
The YCCNY considers patient reporting increasingly important and continues to work with local patient support groups to raise the profile of the Yellow Card scheme to reverse this disappointing trend.

Chart 19



When the data is examined by PCT, patients, parent and carers in East Riding of Yorkshire PCT submitted the most Yellow cards per million population, whilst 2 PCTs received no Yellow Cards from patients (Chart 20).

Chart 20

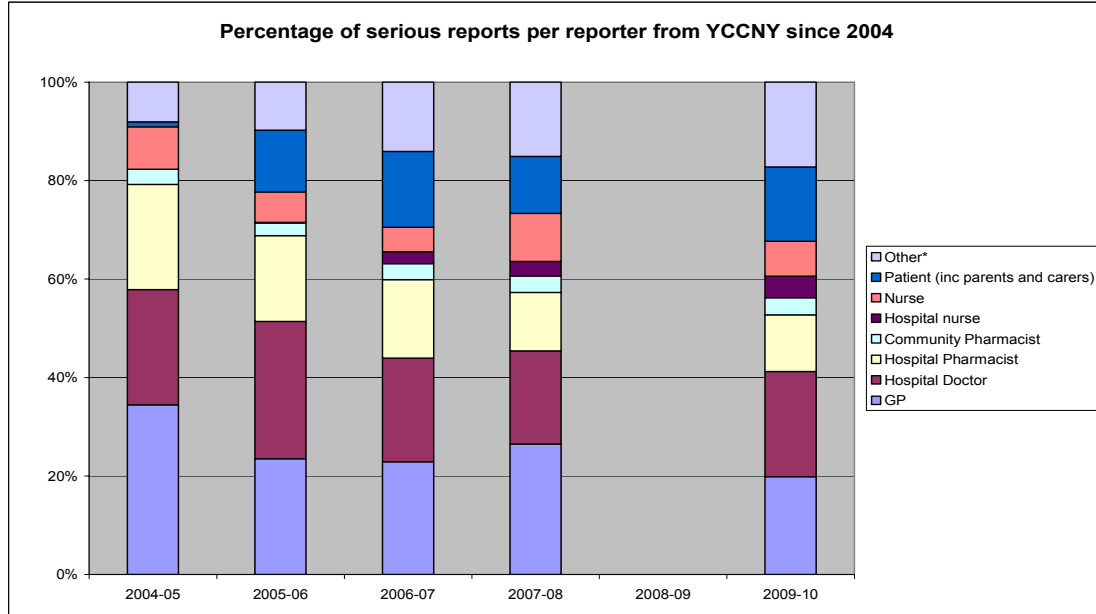


4. Serious Reactions

A total of 749 reports of serious reactions were received in 2009-10. The proportion of serious reports relative to the total number of reports has reduced to 52% from 66% in the previous reported year of 2007-08 (data was not supplied by the MHRA for 2008-09).

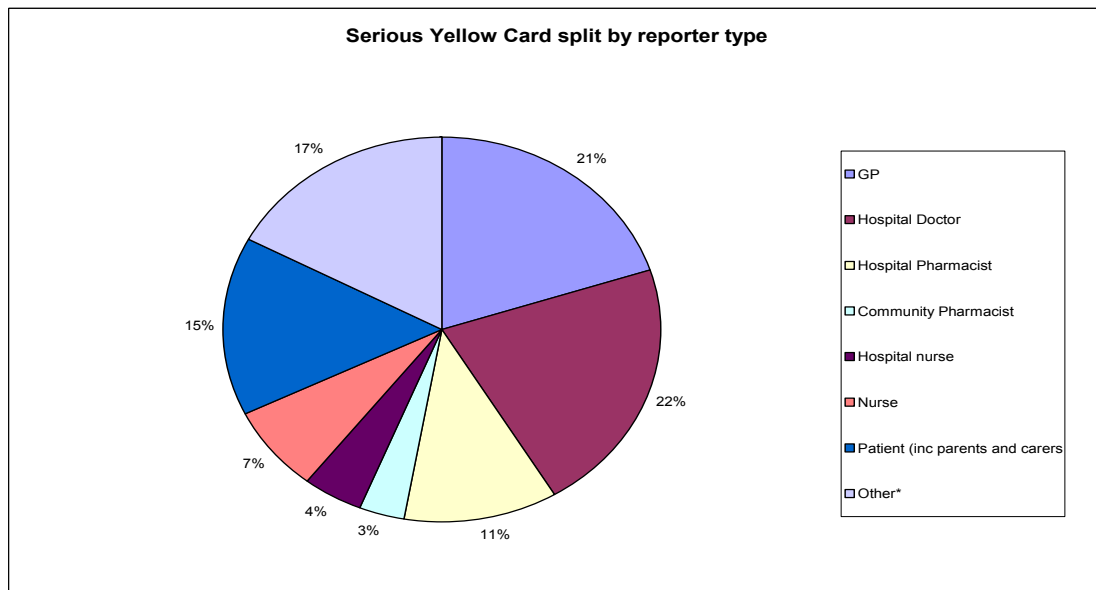
The Swine Flu portal did not supply data as to whether the reaction was graded serious and these data are therefore not included in the results.

Chart 21



The breakdown of serious reports by reporter group shows that 43% of these were received from doctors. Whilst there was a 2.5% increase in serious reports received from hospital doctors, a decrease in percentage of reports was seen from GPs (chart 22). Patients, parents and carers displayed a 4% increase in serious reports on the previous reported period of 2007-08. Other reporter groups remained unchanged on previous year.

Chart 22



* coroner, dentist, hospital health professional, optometrist, other health professional, consumer, pharmacist, physician

5. Top 10 Suspect Drugs

The ten most frequently reported suspect drugs during 2009-2010 are shown in table 1. During this time period the HPV vaccine was the most reported drug in Northern and Yorkshire, contributing 11% of all reports. Nationally clozapine was the most frequently reported drug, followed by the HPV vaccine and varenicline.

Table 1. Drugs most commonly involved in ADR reports during 2009/2010 financial year

	Drug	No. of reports
1	HPV vaccine (Cervarix®▼ & Gardasil®▼)	161
2	Varenicline (Champix®▼)	148
3	Simvastatin	39
4	Exenatide (Byetta®▼)	22
5	Etonogestrel (Implanon®)	20
6=	Adalimumab (Humira®▼)	17
6=	Citalopram	17
6=	Lansoprazole	17
9	Rivaroxaban (Xarelto®▼)	15
10	Sitagliptin (Januvia®▼)	15

6. Follow up of reports

Between April 2009 and April 2010 further information was requested by the centre, at the request of the MHRA, for 83 reports (6% of the total), a decrease on the previous reporting period of 2008-2009. This decrease is due to the decision by the MHRA to handle follow-up requests internally.

To date, follow-up information has been received in 75% of cases; an increase on previous reporting periods.

Table 2. 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
2008-09	YCCNY	149 (8.6%)	97 (65%)
	MHRA	Data not supplied	Data not supplied
2009-10	YCCNY	83 (5.7%)	62 (75%)
	MHRA	Data not supplied	Data not supplied

7. Pandemic flu data

A total of 356 reports were received via the swine flu portal in 2009-10 financial year, 31% of which were due to oseltamivir. Unfortunately, the pandemic data was extracted from a separate portal and as such data extraction was more limited. Reports can only be broken down by old SHAs and not by postcode, therefore for Northern and Yorkshire the data extraction has been based on Northumberland, Tyne & Wear, County Durham & Tees Valley, North & East Yorkshire & Northern Lincolnshire, West Yorkshire and South Yorkshire SHAs. Data from Cumbria has not been included in the report.

Table 3. Reports from the swine flu portal

	Number of Reports	Fatal Reports
Oseltamivir (Tamiflu®▼)	109	1
Zanamivir (Relenza®)	3	0
Swine Flu vaccines ▼	44	2
Total	356	3

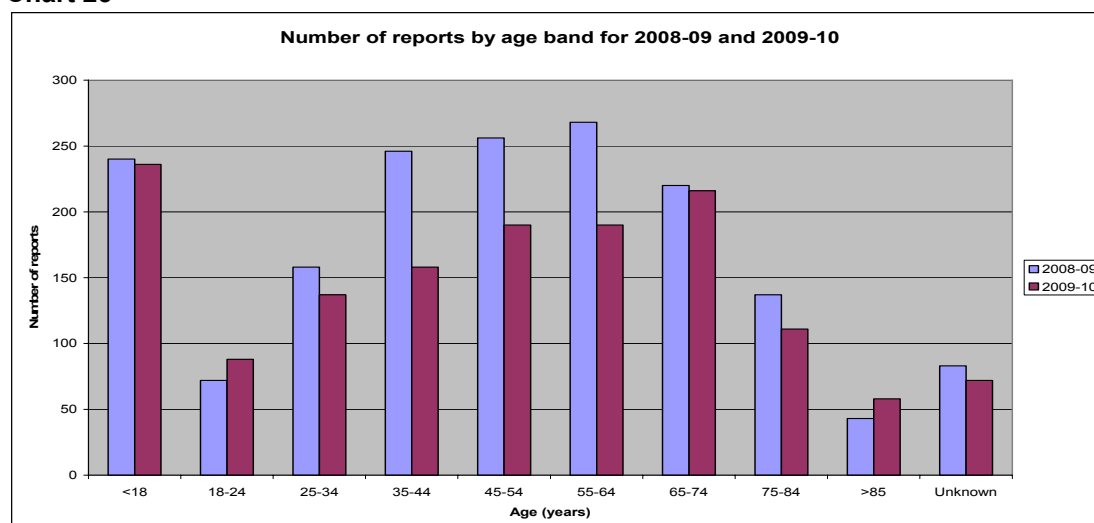
8. Age banding

Table 4 highlights the number of reports per age band in 2009/10. A 18% increase in number of reports was seen in the 18-24 year group (Chart 23). This may represent suspected ADRs in association with the HPV vaccine or the smoking cessation treatment varenicline. Data from the swine flu portal is not included in these figures.

Table 4. Number of reports per age range in 2009-10

Age Band (years)	Number of Reports
<18	236
18-24	88
25-34	137
35-44	158
45-54	190
55-64	190
65-74	216
75-84	111
>85	58
Unknown	72
Sum:	1456

Chart 23



9. 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 patients and raise awareness of the centre within the region, building on initiatives started during 2008-09, and against the objectives agreed with the MHRA (see appendix 2).

Staff at the centre have contributed to educational programs provided to all reporter types within the region, with the aim of alerting health professionals and patients to the Yellow Card scheme. Ten such sessions have been provided this year, including yellow card training as part of medicines information sessions to nurse assessors, health information advisors and dental nurse advisors at NHS Direct. The training focused on informing patients that they may fill in a Yellow Card should they contact NHS Direct regarding an adverse drug reaction. To further engage patients, work has also been undertaken with local expert patient support groups to promote the Yellow Card scheme directly to patients and their carers. The Blood Pressure Association produce a quarterly newsletter which has a circulation of 4000 copies nationally; the centre produced an article on patient reporting for the winter 2009 issue of this newsletter. In addition, an educational session was delivered to the Newcastle branch of the National Rheumatoid Arthritis Association (NRAS). We are currently awaiting a date to speak at the Epilepsy Action patient conference. Several other patient groups were also contacted with many agreeing to put internet links to our ADR webpage and the MHRA Yellow Card reporting website.

We continued to work closely with Newcastle University this year, supporting undergraduate and postgraduate teaching. In addition, all universities in our region providing undergraduate and postgraduate studies for healthcare professionals were contacted to offer our services to teach on courses, provide professional support or educational materials, or review their ADR teaching material. Subsequently, the pharmacy faculty of Huddersfield University requested a lecture for their Year 2 pharmacy students. Hull York Medical School requested resources in order to deliver the lectures themselves.

The centre produced a summary version of the previous year's annual report which was sent to the Heads of Medicines Management, of each PCT in our region, displaying Yellow Card reporting performance of each PCT. This resulted in presentations to three PCTs at their prescribing leads meetings on how to increase levels of reporting in their area.

The centre has continued to publish the bulletin series *Safer Medication Use* which promotes safer prescribing, highlights emerging or significant drug safety problems, and raises awareness of adverse drug reaction detection and reporting. The bulletin is aimed at prescribers and healthcare professionals who can report ADRs. However, it is also of value to Drug and Therapeutics Committees, Medicines Management Groups, clinical governance leads and non-medical prescribing leads to inform policy decisions and risk management strategies. During the 2009-10 financial year, bulletins have been published discussing whether proton pump inhibitors increase the risk of osteoporotic fracture and another discussing the safety of tricyclic antidepressants in the elderly. Future editions are planned to discuss current and emerging drug safety issues.

In an effort to improve poor levels of reporting from community pharmacists, the regional managers and training departments of the large community pharmacy multiples were contacted. This resulted in an educational session being delivered at the area meeting for Whitworths Chemist community pharmacists, with a view to provide sessions to pre-registration pharmacy graduates employed by Whitworths in the new academic year. Lloyds Pharmacy have also expressed an interest in educational sessions for their pre-registration pharmacists in the new academic year and now distribute our publication *Safer Medicines Use* around each branch.

The YCC Northern and Yorkshire has also worked collaboratively with the Newcastle Regional Drug and Therapeutic Centre (RDTC). Information from *Drug Safety Update* is included in the RDTC monthly horizon scanning document which is available to pharmacists and doctors in primary and secondary care, particularly those involved with commissioning

and providing services to patients. Indeed all YCC Northern and Yorkshire training materials include reference to this publication. The RDTC publication reviewing the evidence for newly marketed drugs *New Drug Evaluation*, continue to include information regarding reporting of suspected reactions to black triangle drugs.

The YCC Northern and Yorkshire website continues to be 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. 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 the 2009-2010 financial year the site received 3,465 visitors; the Adverse Drug Reactions Monitoring – main page was the most visited (Chart 24). The Yellow Card logo was the most frequently downloaded image from the website (Chart 25).

The screenshot shows the RDTC website interface. At the top left is the RDTC NHS logo. The page title is "Regional Drug & Therapeutics Centre". A search bar is located in the top right. A blue navigation bar contains the text "Page: Services - Adverse Drug Reaction Monitoring". On the left, a vertical menu lists: Home, About us, Management, Publications, Education, Services (highlighted), Links, Contact us, and Search. The main content area is titled "Adverse Drug Reaction Monitoring" and "Yellow Card Centre Northern and Yorkshire". It features a message about Adobe Reader: "You will need Adobe Reader to view any pdf file accessed from this website." Below this is a list of services with blue arrow icons: About us, Reporting suspected adverse drug reactions, Patient self reporting of adverse drug reactions, MHRA / CHM Safety information, Safer Medication Use, Prevention of adverse reactions, ADR education, and ADR links. On the right, under the "YellowCard" logo (with the tagline "Helping to make medicines safer"), there is a section for "Other RDTC services:" listing: Critical appraisal & drug evaluation, Education & training, Medicines information service, Poisons information services, Prescribing analysis & support, and Teratology information services. A "Back" button is at the bottom center, and the footer text reads "Page last updated 25/06/2010".

Chart 24

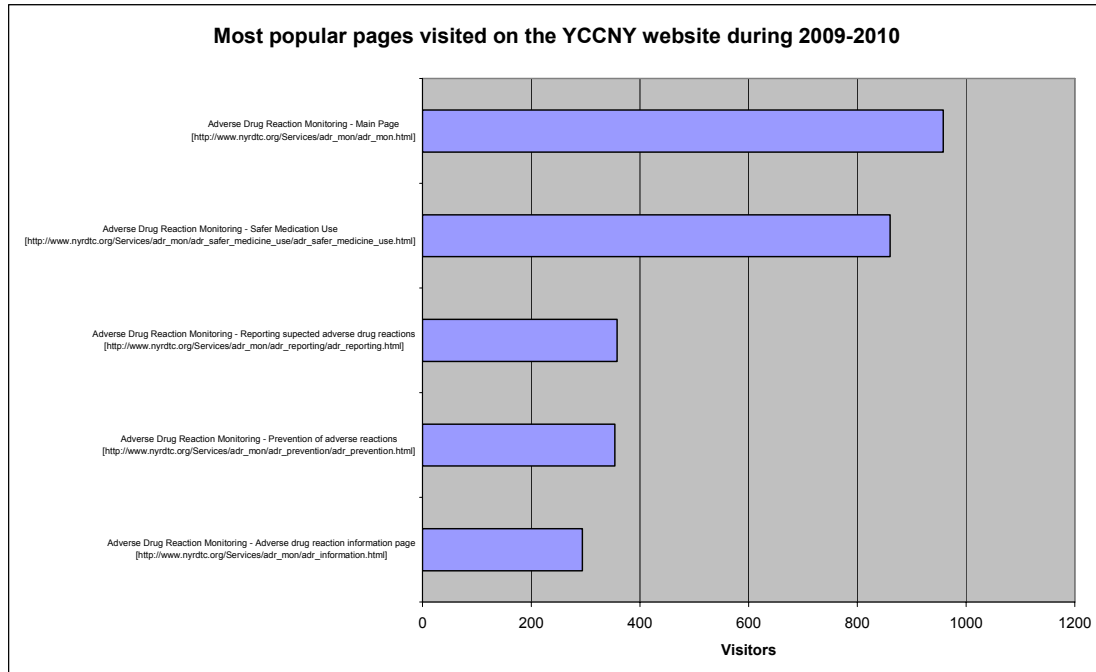
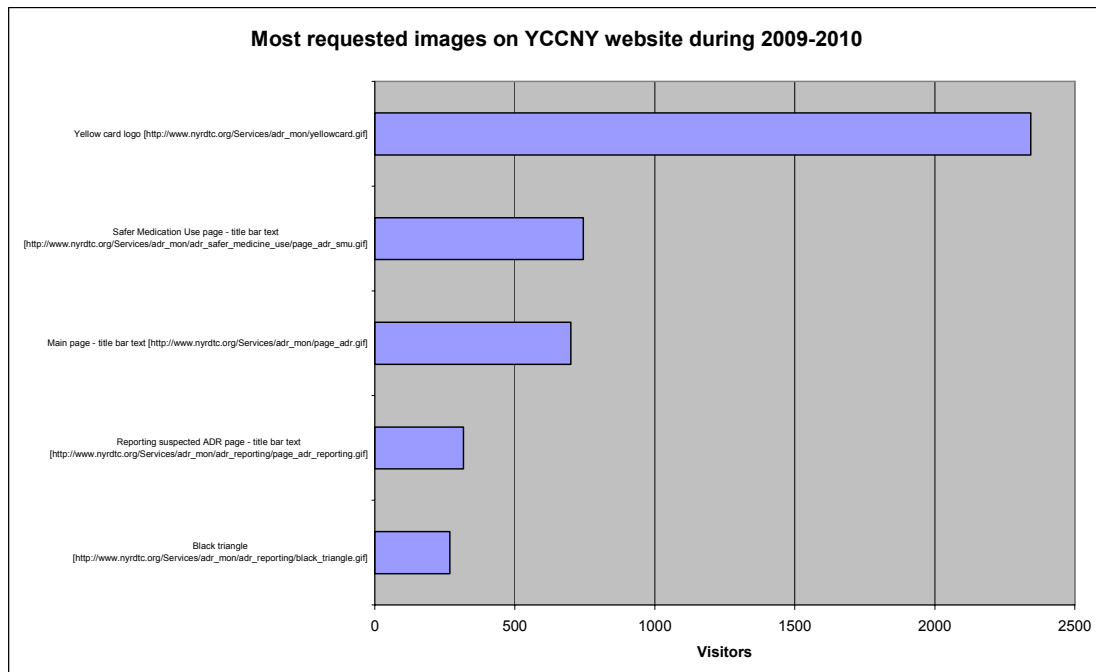


Chart 25



During the 2009/2010 financial year the centre answered 190 enquiries about adverse drug reaction to specific drug(s). It is a policy with such enquiries that the callers (including patient contacting us via NHS Direct) are encouraged to complete a Yellow Card report where appropriate.

Educational sessions

Mcdermott D. Adverse Reactions and the Yellow Card Scheme. Pre-registration Hospital Pharmacist Training Scheme, Morpeth, 18th September 2009

Smith S. Adverse Drug Reactions and Reporting them using the Yellow card Scheme. Whitworths Chemist Ltd area meeting. Durham, 28th October 2009

Smith S. Adverse Drug Reactions and Reporting to the Yellow Card Scheme. Medicines Managers. NHS Cumbria, Kendal, 9th December 2009

Smith S. Adverse Drug Reactions and the Yellow Card Scheme. Year 2 Pharmacy Students. Huddersfield University. 12th January 2010

Smith S. The Yellow Card Scheme: Reporting Adverse Drug Reactions. Information scientists and pharmacist staff. Regional Drug and Therapeutics Centre. Newcastle, 10th February 2010

Smith S. The Yellow Card Scheme: Reporting Adverse Drug Reactions. Junior Doctors (F1). Newcastle Upon Tyne Hospitals NHS Trust. 8th March 2010

Smith S. Side Effect Reporting by Patients. National Rheumatoid Arthritis Society patient forum. Newcastle. 11th March 2010

Russell P. Role Preparation for Dental Nurse Advisors; Handling Medicines Calls. NHS Direct, Newcastle. 16th March 2010

Safer Medication Use published on the YCCNY website

Can Proton Pump Inhibitors Increase risk of Osteoporotic Fracture? *Safer Medication Use*, No. 5 December 2009

Tricyclic Antidepressants and the Elderly. *Safer Medicines Use*, No. 6 March 2010

Articles written by YCCNY for externally published bulletins / newsletters in collaboration with the Regional Drug and Therapeutics Centre

Smith S. Summary Annual Report 2008. Distributed to Medicines Managers of each PCT in Northern and Yorkshire region. December 2009

Smith S. Give side-effects the Yellow Card. *Positive Pressure*. Blood Pressure Association magazine. Issue 26. Winter 2009/10

Non MHRA meetings attended in YCC capacity

New Drugs Meeting, Regional Drug and Therapeutics Centre. Agreement for details of the latest Drug Safety Update to be included in the monthly horizon scanning document sent out to General Practitioners, PCT advisors and Hospital Chief Pharmacists.

UKMi Clinical Governance Working Group. Teleconference, 23rd September 2009

Yorkshire and Humber Medicines Management Leeds, 20th October 2009. Local Yellow Card reporting rates by GPs and community pharmacists – discussion of initiatives to increase reporting rates.

UKMi Clinical Governance Working Group. Birmingham, 10th November 2009

County Durham PCT and Darlington PCT Drug and Therapeutics Committee. Durham 17th November 2009 to promote Yellow Card reporting to PCT leads

10. Research

The YCC Northern and Yorkshire works closely with the UK Teratology Information Service (UKTIS) and the Institute of Cellular Medicine (ICM), Newcastle University, both of which have research interests relating to adverse drug reactions.

UKTIS receives enquiries from health professionals about medicines exposure during pregnancy and, where feasible, attempts to collect information on fetal outcome once the pregnancy is completed. Over many years a substantial database of fetal outcomes has been obtained and UKTIS seeks to publish pregnancy outcome data on individual drugs when sufficient information is available. During 2009/10 UKTIS has published information on fetal outcomes relating to maternal aspirin overdose and hepatitis A and B vaccination during pregnancy.

The emergence of the pandemic of H1N1v influenza in the summer of 2009 has focussed research efforts at establishing maternal and fetal effects of the infection and of the antiviral drugs and vaccines used during the pandemic, with funding was from the Health Technology Assessment Programme. Details of more than 2000 women with influenza infection, receiving antiviral drugs or accepting or declining H1N1v vaccination have been provided to UKTIS and several hundred women have consented to detailed follow up of pregnancy outcomes. These details will be provided to MHRA when available as well as being submitted for publication in the peer reviewed literature.

Staff of the centre and ICM continue to be interested in ADRs related to drug induced arrhythmias. During 2009/10 research has been published demonstrating an absence of effect of methylphenidate on cardiac repolarisation after overdose. The lack of effect in overdose makes important affects on repolarisation during therapeutic doses less likely as a cause for sudden death during methylphenidate use in normal doses. Staff of the centre have also been involved in a large randomised clinical trial comparing the safety of two atypical antipsychotic drugs. Although total mortality, the primary end point, was not different comparing the two drugs, increased cardiovascular mortality was demonstrated with sertindole, a drug with a high propensity to cause QT interval prolongation on the ECG. Research has also been conducted comparing adverse electrocardiographic and clinical outcomes with antipsychotic drugs and antidepressants after overdose and in therapeutic doses. These data are expected to be published during 2010/11.

YCC staff are also interested in adverse reactions related to medicines used to treat poisoning. One of the most commonly used is acetylcysteine. Funding and ethical approval has been obtained to perform a randomised control trial examining different regimes of acetylcysteine administration with the aim of reducing the frequency of adverse effects experienced by patients.

11. Publications

Reviews

Hill S, Thomas SHL. What's new in... Toxicity of drugs of abuse? *Medicine* 2009; 37: 621-626

Papers

Thomas SHL, Drici MD, Hall G, *et al.* Safety of sertindole versus risperidone in schizophrenia: principal results of the sertindole cohort prospective study (SCoP). *Acta Psychiatrica Scandinavica* 2010; in press (DOI 10.1111/j.1600-0447.2010.01563)

Hill SL, El-Khayat R, Sandilands E, Thomas SHL. Electrocardiographic effects of methylphenidate overdose. *Clinical Toxicology* 2010, in press

Reports

Stephens S, Yates L, Knight M, Wilson G, Jones D, Thomas SHL. AH1N1v Influenza 2009 in Pregnancy: A systematic review of published and unpublished data. Submitted to the HTA as part of a NIHR funded study

Yates L, Pierce M, Stephens S, Mill AC, Spark P, Kurinczuk JJ, Brocklehurst P, Thomas SHL, Knight M. Influenza A/H1N1v in pregnancy: An investigation of the characteristics and management of affected women and the relationship to pregnancy outcomes for mother and infant. Submitted to the HTA as part of a NIHR funded study

Abstracts

Stephens S, Jones D, Wilson G, Gilfillan C, McElhatton P, Thomas S. The fetal effects of aspirin overdose during pregnancy *Clinical Toxicology* 2009; 47: 453-4

Hodson K, Hill S, Thomas SHL. Effect of lamotrigine overdose on the QT interval. *Clinical Toxicology* 2009; 47: p454

Wilson G, Jones D, Stephens S, Bradley S, McElhatton P, Thomas SHL. Preliminary data on exposure to trichloroethylene during pregnancy. *Clinical Toxicology* 2009; 47: p459

Galal HKA, Hill S, Gray J, Thomas SHL. Differential effects of tricyclic antidepressants in overdose on the QRS interval. *Clinical Toxicology* 2009; 47: p474-5

Thomas SHL. Adverse drug reactions and their relevance to Poison Centres. *Clinical Toxicology* 2009; 47: p488-9

Galal HKA, Hill S, Hodson K, Gray J, Thomas SHL. Differential clinical toxicity of tricyclic antidepressants in overdose following acute hospital admission. *Clinical Toxicology* 2009; 47: p495-6

Stephens S, Glen Wilson, Dacia Jones, Thomas SHL. Preliminary data on the use of cannabis in pregnancy. *Reproductive Toxicology* 2009; 28; 117-284

Wilson G, Stephens S, Jones D, Thomas SHL. Preliminary data on the use of hepatitis A and B vaccines during pregnancy. *Reproductive Toxicology* 2009; 28; 117-284

Book chapters

Thomas SHL, White J. Poisoning. In 'Davidson's Principles and Practice of Medicine,' Colledge, Walker, Ralston (Eds). 21st Edition (2010).

12. 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 5%. However, a reduction in reporting from GPs and hospital 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 2009-2010

Number of Yellow Card reports from each SHA by reporter qualification in 2009-2010 financial year

SHA	GP	Hospital Doctor	Hospital Pharmacist	Community Pharmacist	Pharmacist	Hospital Health Professional	Hospital Nurse	Nurse	Other Health Professional	Patient	Parent	Carer	Dentist	Physician	Coroner	Total
Yorkshire and Humber	213	132	38	28	23	62	49	144	47	80	12	8	4	23	0	863
North East	107	104	70	20	13	25	21	75	35	38	6	3	2	8	0	527
North West	18	8	1	2	1	2	4	10	4	4	0	1	0	1	1	57
Total	338	244	109	50	37	89	74	229	86	122	18	12	6	32	1	1447

Total number of yellow card reports from Northern and Yorkshire region in 2009/10 = 1447
(1812 when reports from Swine Flu Portal included)

Reports per quarter (calendar year)

Number of reports per quarter in 2008

April – June 09	(Q1)	468
July – September 09	(Q2)	386
October – December 09	(Q3)	238
January – March 10	(Q4)	366
TOTAL		1447

Follow-ups

Follow-ups by YCCNY in 2009-2010	83
Number of successful follow-ups	62

Appendix 2: YCC Northern and Yorkshire objectives for 2007-10

General Objectives	Performance measures and targets	Progress at 31st March 2009
1. Communications Communicate information about the Yellow Card Scheme with a view to improving and increasing ADR reporting.	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	Maintenance ongoing. 2 pieces of training material available on YCCNY website.
	1.2 Develop the YCC, with a lay guide to reporting adverse drug reactions	On website
	1.3 Ensure Website has appropriate links to agreed YC partners	Updated according to links provided by MHRA.
	1.4 To make contact with the area managers for the major community pharmacy multiples within YCC area.	Area managers contacted in September 2009 to offer general support and regarding ADR reporting and education offered. Whitworths asked for educational session and Lloyds Pharmacy interested for new 2010 pre-reg pharmacy graduates
2. Education Act as a point of information to inform stakeholders about Yellow Card reporting initiatives and provide education to reporters on what and how to report	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	Six universities contacted who provide undergraduate and postgraduate courses for healthcare professionals. Lecture delivered at Huddersfield university to pharmacy students, whilst Hull York Medical School took up an offer to use our resources.
	2.2 Deliver 4 training sessions per year to relevant healthcare professional groups to raise awareness of the Yellow card scheme and stimulate reporting.	2009-10 Eight training sessions delivered to healthcare professionals.
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	Area managers contacted in September 2009 to offer general support and regarding ADR reporting and education offered. Whitworths asked for educational session and Lloyds Pharmacy interested for new 2010 pre-reg pharmacy graduates. Yellow Card leaflets and posters supplied to community pharmacies.
	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.	This financial year we intend to produce summary annual reports for each hospital in order to engage hospital pharmacists
	3.3 Engage with local expert patient groups to promote the Yellow Card Scheme	24 local offices of national support groups contacted. Information about YC scheme included in Blood Pressure Association 'Positive Pressure' magazine. Circulation 4000 copies. National Rheumatoid Arthritis Society – educational meeting with local branches arranged with regional director.
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