

Yellow Card Centre Northern & Yorkshire

ANNUAL REPORT 2010/2011

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

May 2011

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

Dr A Dyker	Consultant Physician Pharmacology, Regional Drug and Therapeutics Centre
Ms H Gates	Senior Medical Information Scientist, Regional Drug and Therapeutics Centre
Ms S Harvey	Secretary, Regional Drug and Therapeutics Centre
Ms N Kane	Medical Information Scientist, 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, Regional Drug and Therapeutics Centre
Dr L Yates	Head of Teratology, Regional Drug and Therapeutics Centre
Dr R Thanacoody	Consultant Physician/Clinical Toxicologist, Regional Drug and Therapeutics Centre
Prof SHL Thomas	Director RDTC, Reader in Therapeutics (YCCNY Director)
Mrs J Wood	Business Manager, Regional Drug and Therapeutics Centre

2. Summary

The Yellow Card Centre Northern and Yorkshire (YCCNY) encourages the appropriate reporting of adverse drug reactions (ADRs) from the North East of England, Yorkshire and Cumbria. During the 2010-11 financial year 1577 reports were received from these areas, a 13% decrease from 2009-10. The decrease in reports appears to be largely due to the absence this year of reports via the swine flu portal, which accounted for 16% of total reports in 2009-10. Reporting from GPs and hospital doctors increased by 27% and 11% respectively, and reporting from nurses increased a further 5% on figures for 2009/10..

As part of its promotional activities, the centre produced a short version of the 2009/10 annual report which summarised Yellow Card reporting in each PCT. This was sent to the Heads of Medicines Management of each PCT. It is difficult to compare this year's reporting to 2009-10, since reports from the swine flu portal last year were not attributed to PCTs. However PCTs that were priority areas for raising Yellow Card awareness this year all saw increased reporting, with numbers doubling in North Lincolnshire and tripling in Hull Teaching PCT and Redcar & Cleveland.

Patients have been able to report ADRs since November 2005. Encouragingly, this year there has been an increase in patient reporting of 2%. We continue to seek to raise awareness of patient reporting through our educational work directed at healthcare professionals, who are also 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. This year has also seen the introduction of The MINT (Medicines Information News Today) which discusses drug news relevant to primary care health professionals as well as promoting use of Yellow Card.

The YCC Northern and Yorkshire website has recently undergone an improvement and 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.

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.

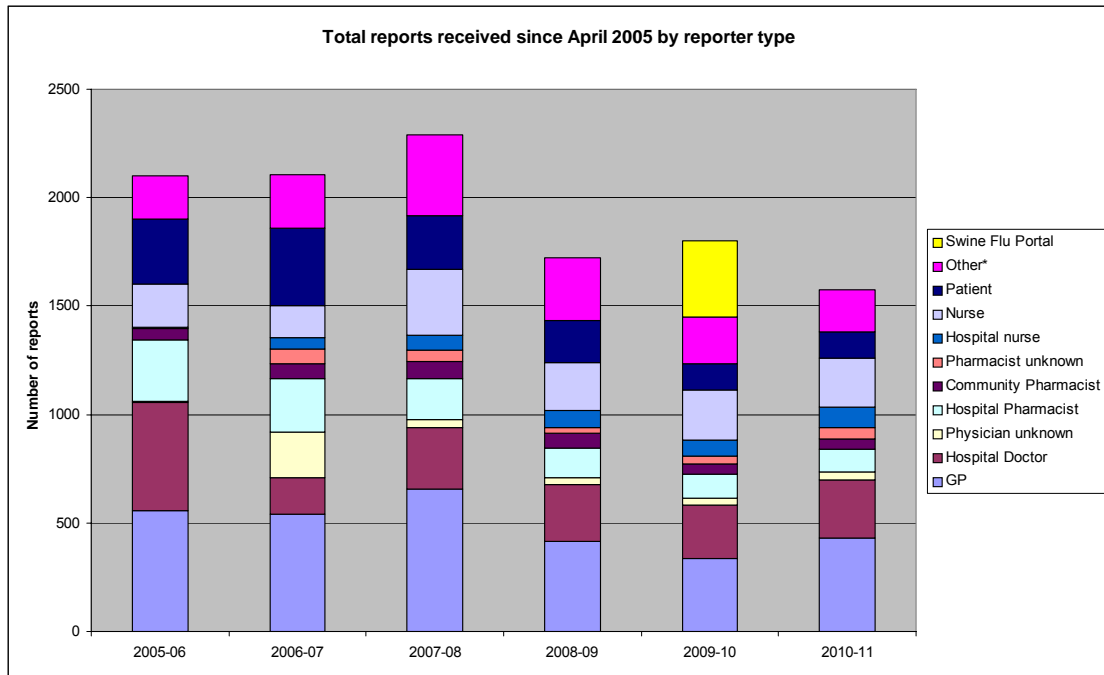
The YCC Northern and Yorkshire has continued to work closely with the MHRA and other YCCs to develop training materials for use nationally.

3. Yellow Card Data

3.1 Overview

A total of 1577 reports were received from Northern and Yorkshire during the 2010-11 financial year, a 13% decrease on 2009-10. This decrease is caused largely by the absence of reporting this year from the MHRA swine flu portal. When swine flu reports are discounted from the 2009-10 data, an increase 9% becomes evident, although figures remain lower than in previous years (Chart 1).

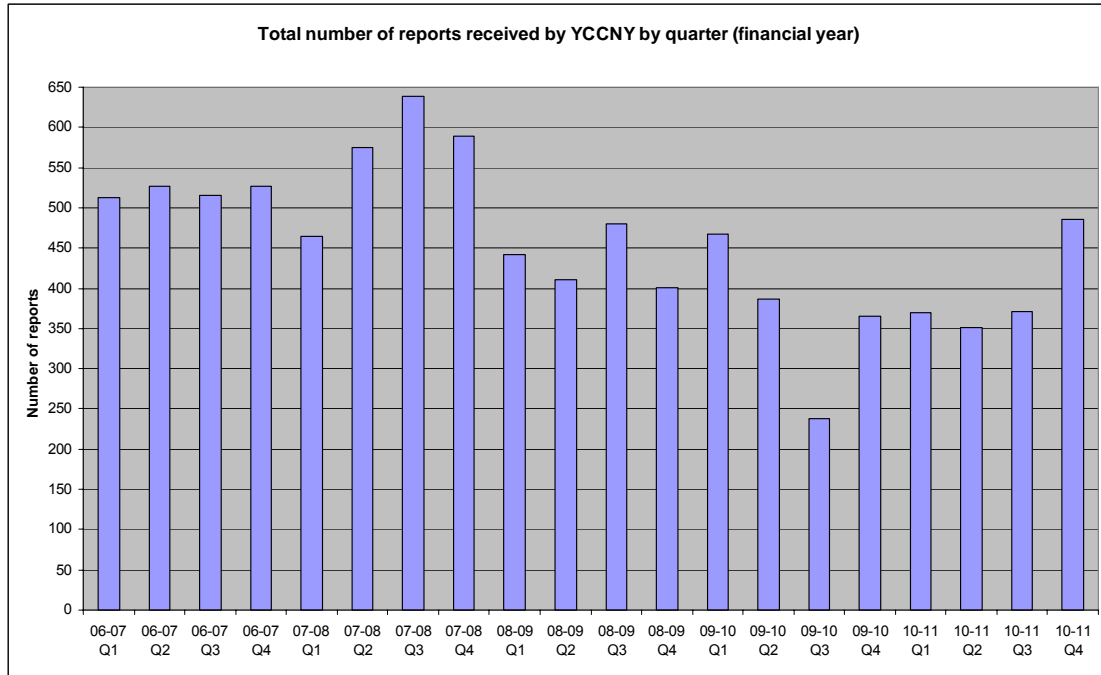
Chart 1



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

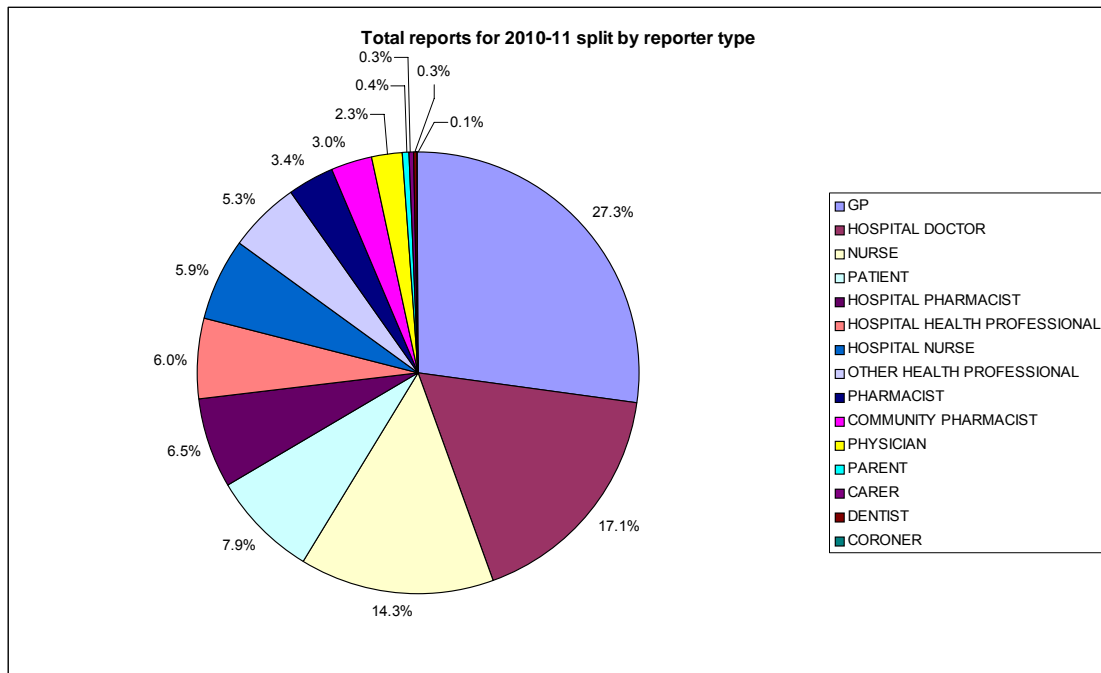
Reporting remained relatively constant in quarters 1 to 3 of 2010-11, but increased considerably in quarter four (chart 2). The centre aims to build on this momentum for the coming year.

Chart 2



The breakdown of reports by reporter type shows that doctors reported the most adverse reactions (44%), but nurses (20%), healthcare professionals (11%) and patients [including patients and carers] (9%) also made 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 Yorkshire and the Humber submitted the most reports (995) in the 2010-11 financial year in numerical terms (Chart 4) but after correction for population, rate of reporting was highest from the North East SHA (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. It should be noted that in the North West YCCNY receives yellow cards from Cumbria only, while YCC North West takes responsibility for Lancashire.

Chart 4

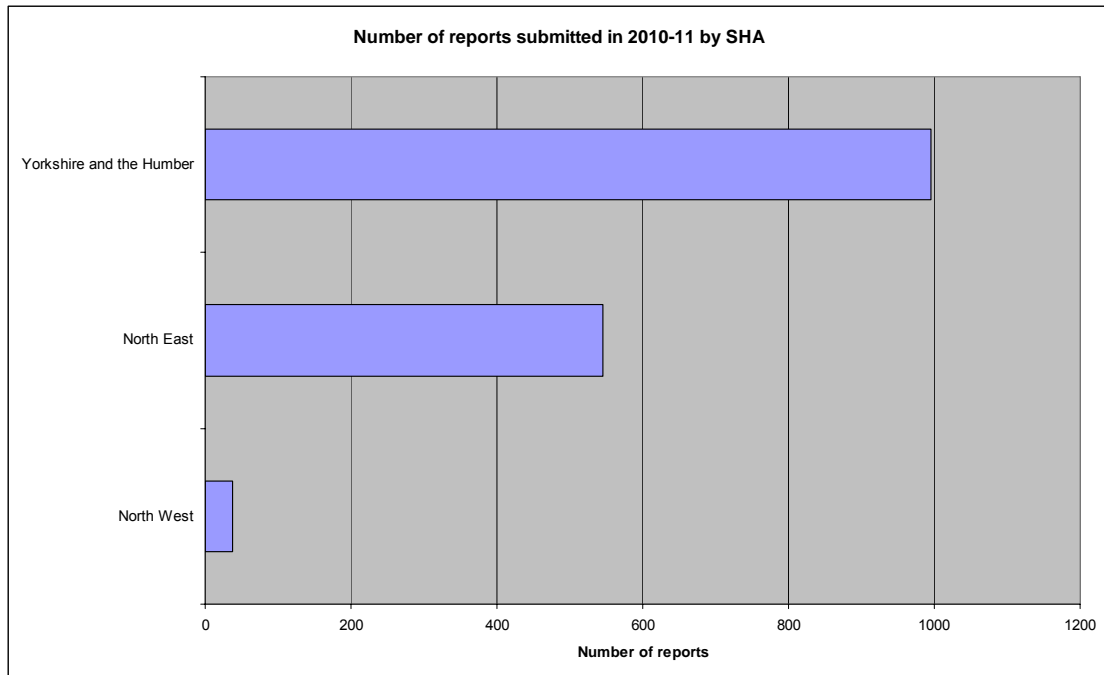
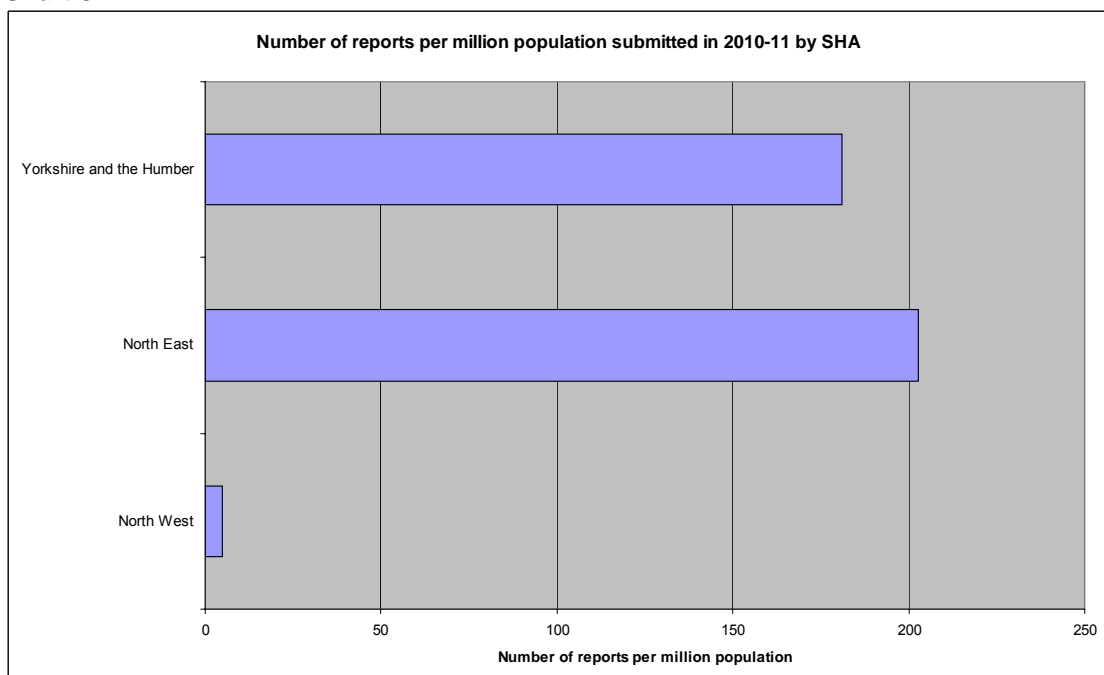


Chart 5



Yellow Card reporting varied widely by Primary Care Trust (PCT) (chart 6), with the highest number of reports submitted from North Yorkshire and York PCT (226) and the fewest from Hartlepool PCT. Hartlepool will be a priority area 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 Hartlepool remains the lowest reporting PCT (Chart 7).

Chart 6

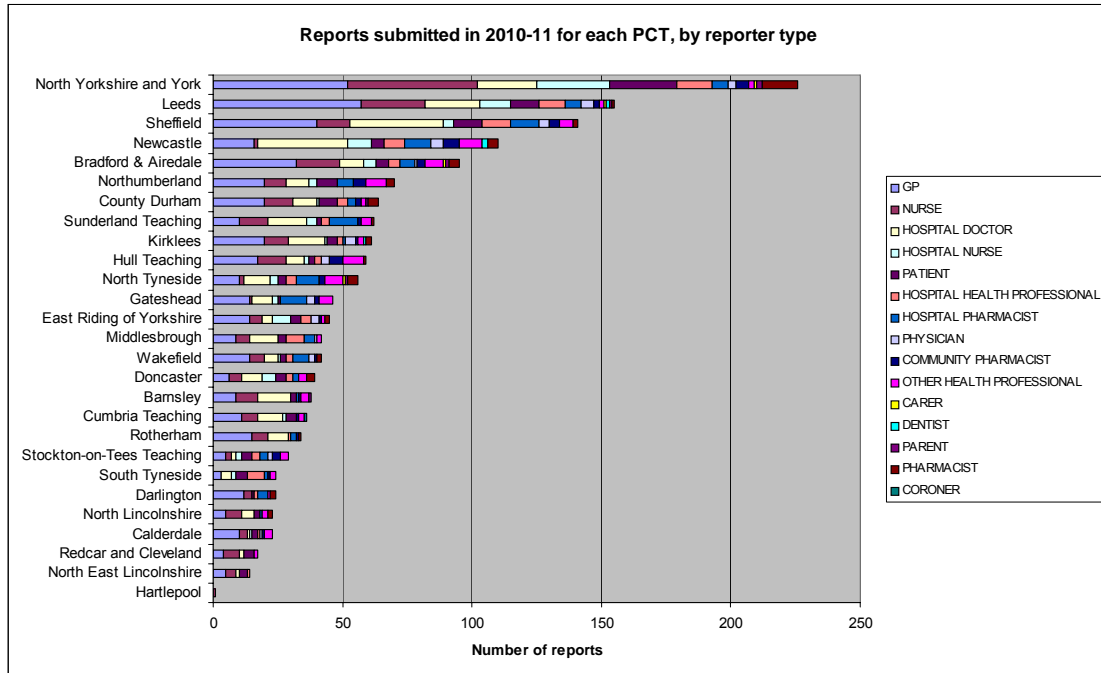
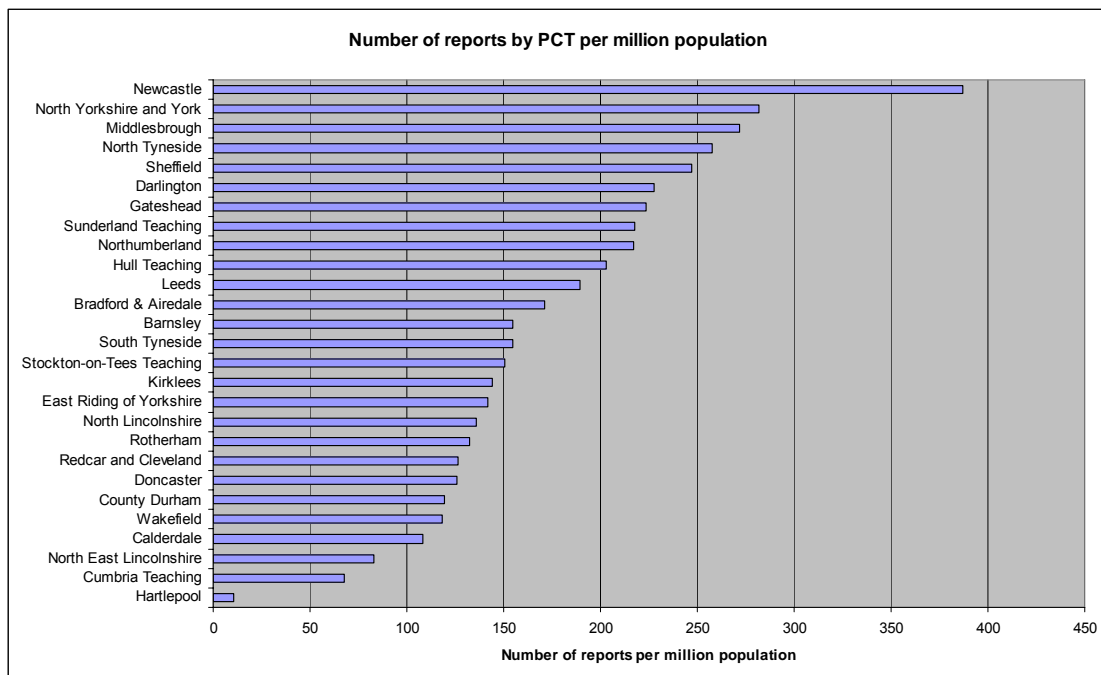


Chart 7



3.3 GP Reporting

There has been a 27% increase in GP reporting in the 2010-11 financial year compared with the previous year, with 430 reports submitted. This reverses the downward trend of the last two years, although reporting still remains lower than previously (Chart 8). GP reporting increased in 17 PCTs, with the largest rise seen in Hull. Darlington PCT submitted the highest number of reports per million population from GPs, while no reports were received from Hartlepool (chart 9).

Chart 8

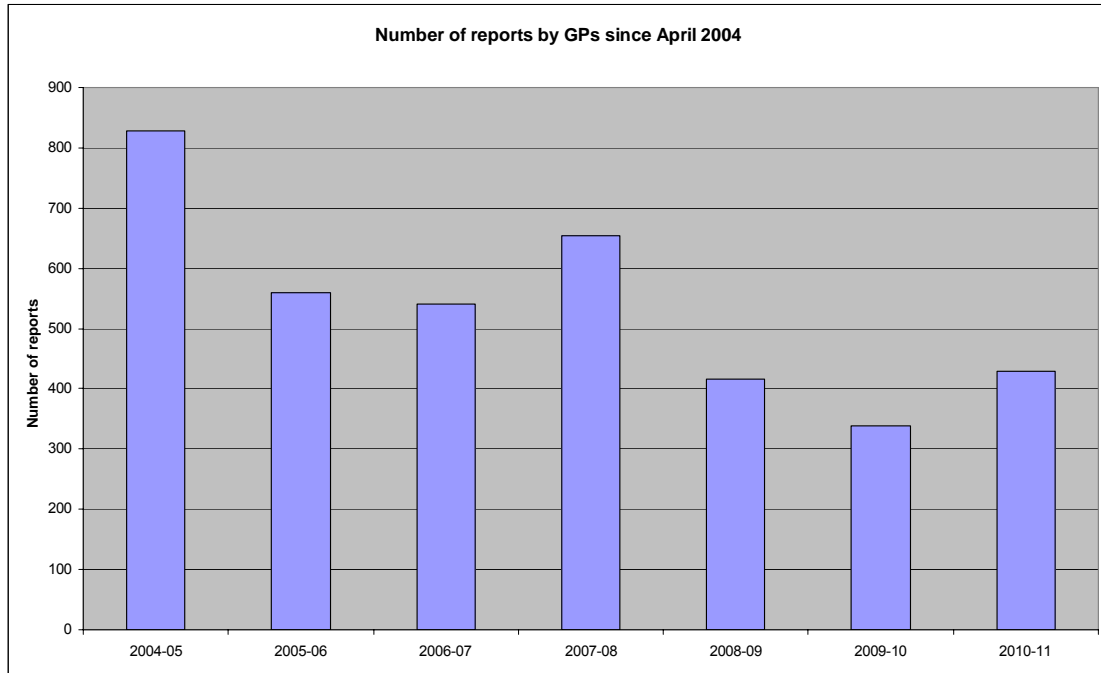
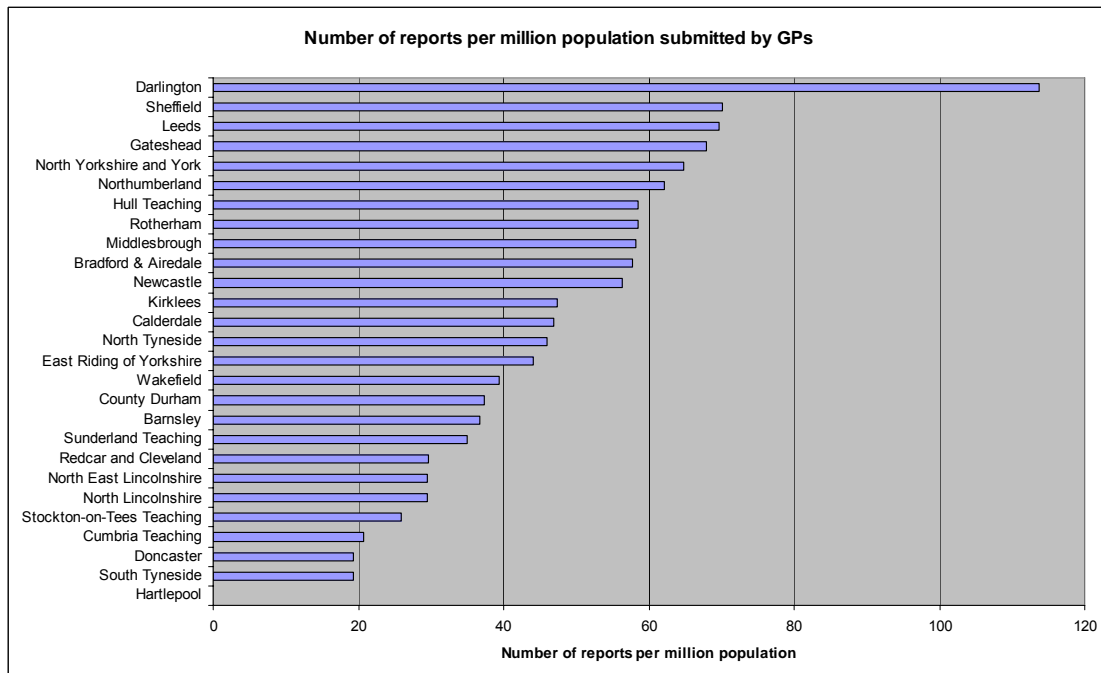


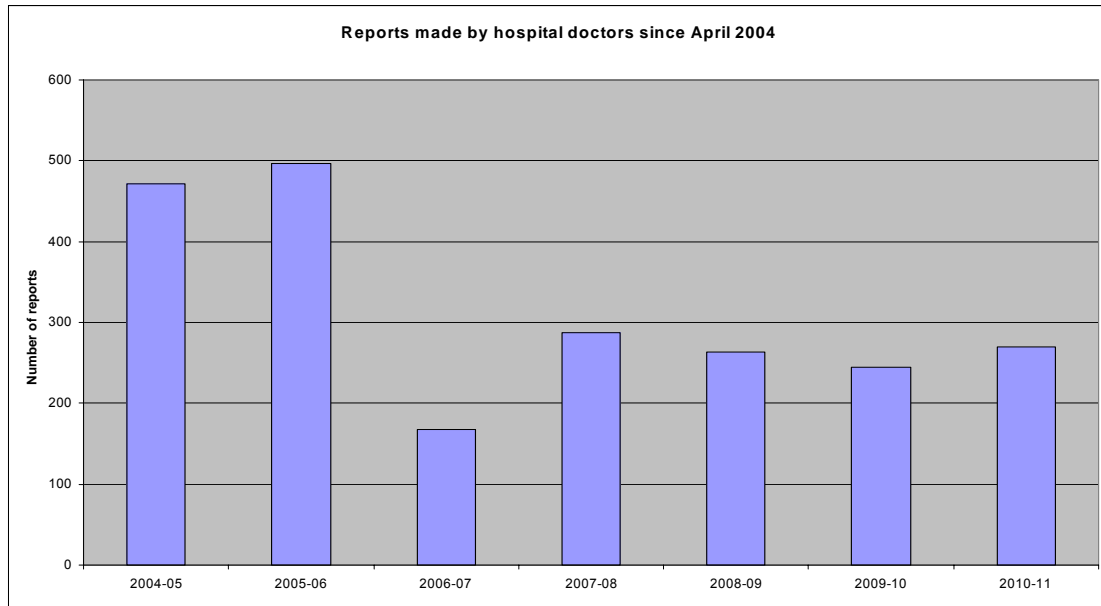
Chart 9



3.4 Hospital Doctor Reporting

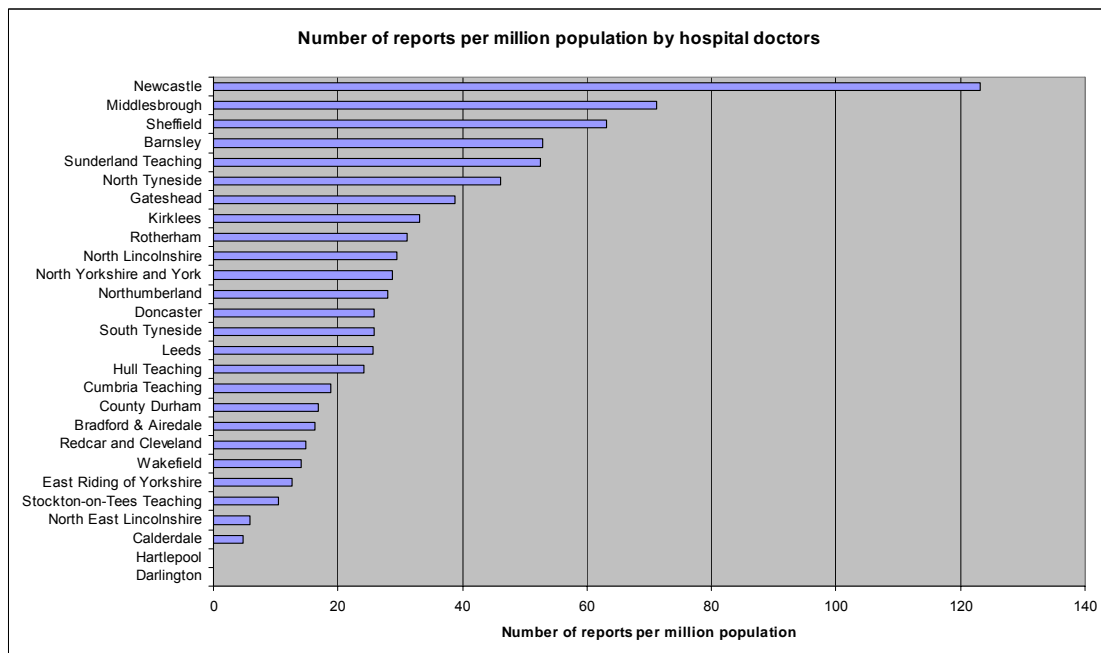
Hospital doctors in the Northern and Yorkshire region submitted 270 Yellow cards during 2010-11, an increase of 11% on the previous year. Figures have previously shown an underestimate of hospital doctor reporting as a significant portion of reports came from physicians (sector n/k) and the MHRA SENTINEL database is unable to classify by reporter type. This problem has continued over recent years, although to a lesser extent. If all unclassified reports are assumed to originate from hospital doctors, the increase in hospital doctor reporting remains at 11%.

Chart 10



When data is 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 Hartlepool or Darlington (Chart 11). It is not possible to provide information by NHS trust, just by the PCT the trust is sited in.

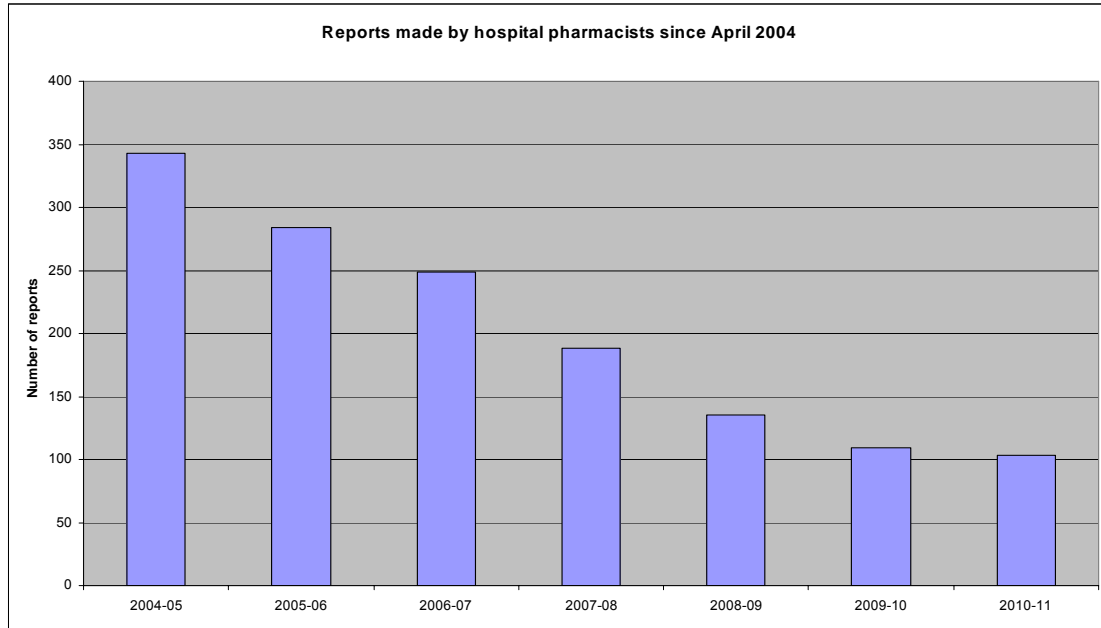
Chart 11



3.5 Hospital Pharmacist Reporting

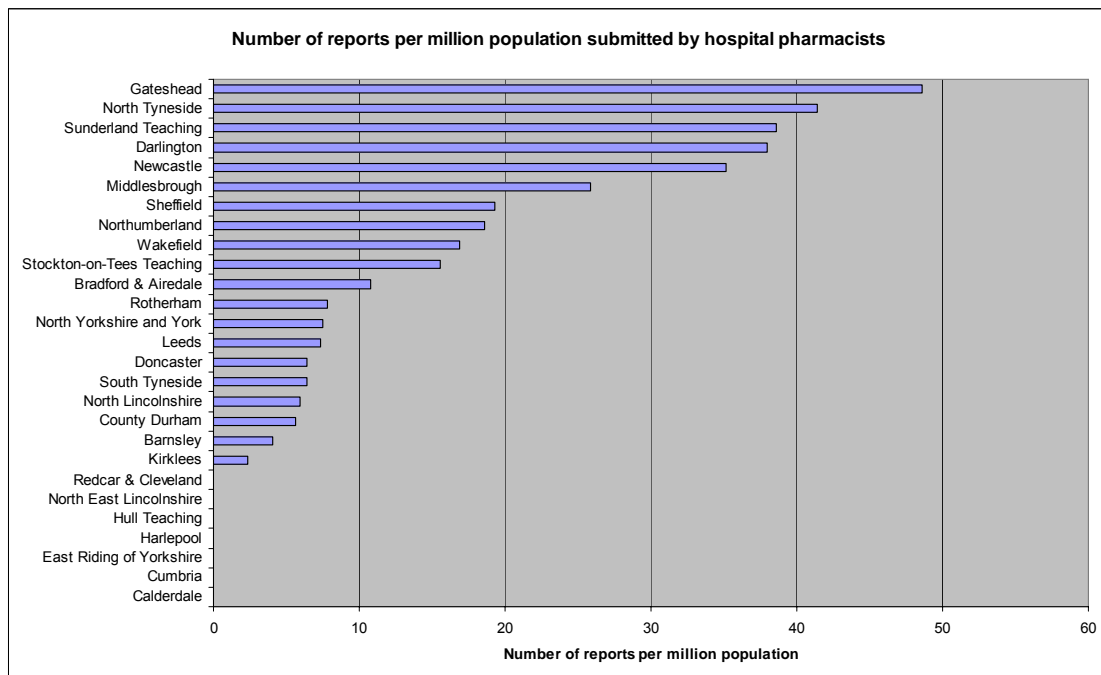
A total of 103 reports were received from hospital pharmacists in the Northern and Yorkshire region in 2010-11, a decrease of 6% on the previous year. This continues the downward trend seen since 2004-2005 (chart 12). These data do not include figures from the 'pharmacist unknown' category, which has increased by 43% this year. In the coming year, each hospital trust in the Northern and Yorkshire region will receive a summary annual report for their PCT in the hope of stimulating reporting.

Chart 12



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

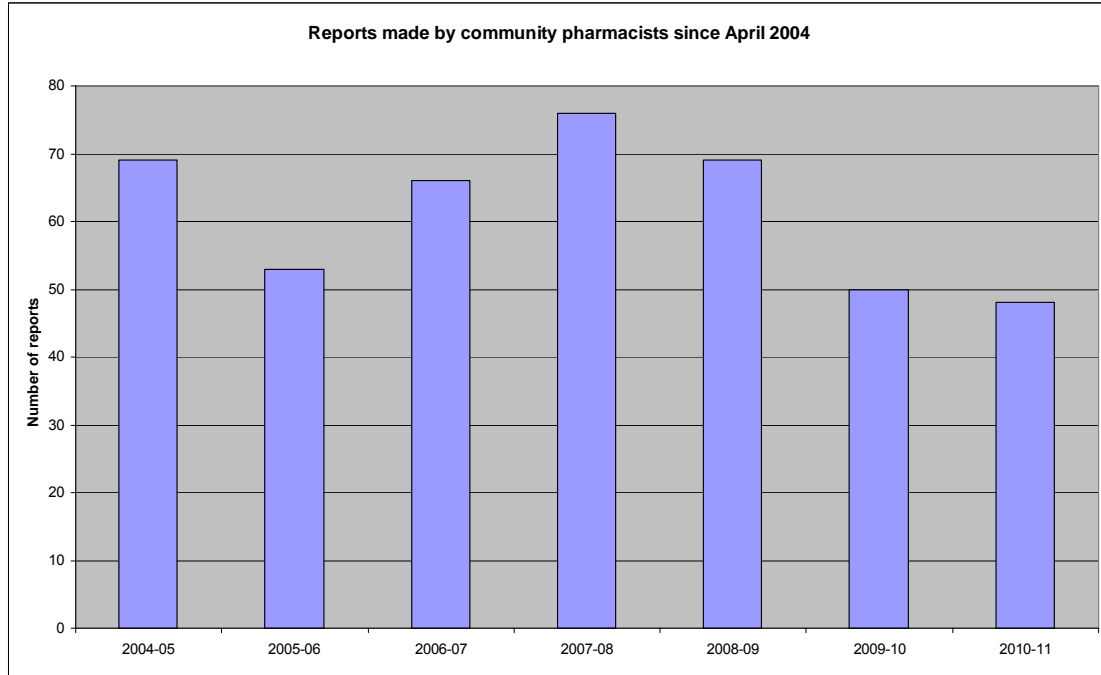
Chart 13



3.6 Community Pharmacist Reporting

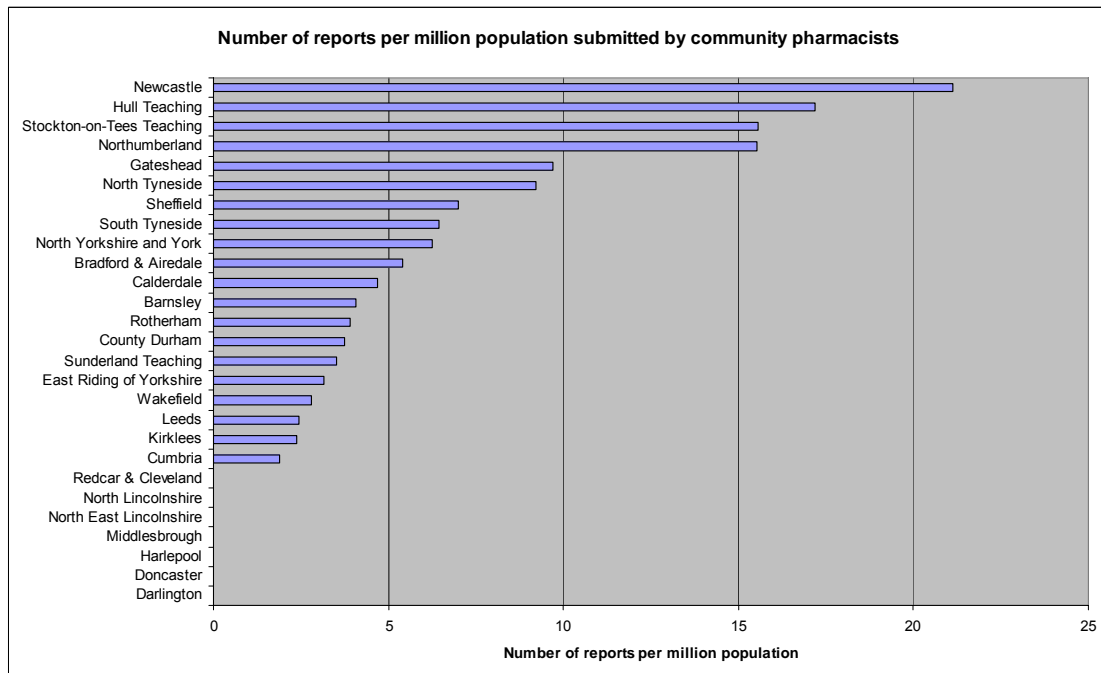
A total of 48 reports were received from community pharmacists in the 2010-11 financial year, a decrease of 4% on the previous reporting period (Chart 14). This continues the decline seen since 2008, when a nationwide campaign in community pharmacies occurred to highlight the Yellow Card to patients. Community pharmacists are a target area for promotion this coming year.

Chart 14



When 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 seven PCTs (Chart 15).

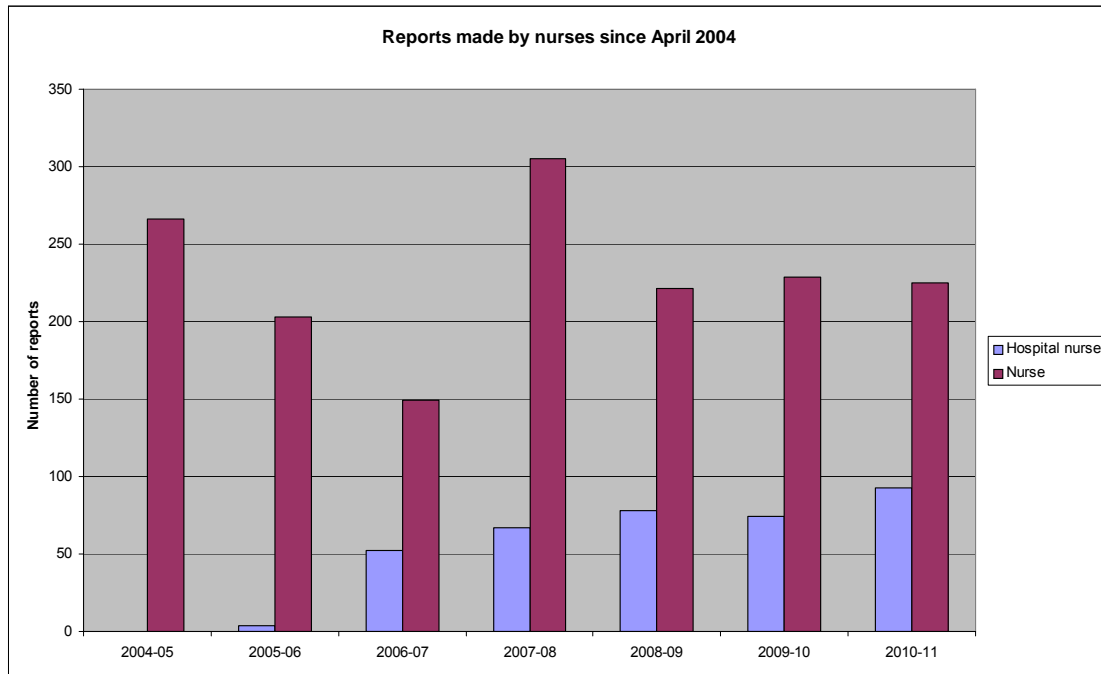
Chart 15



3.7 Nurse Reporting

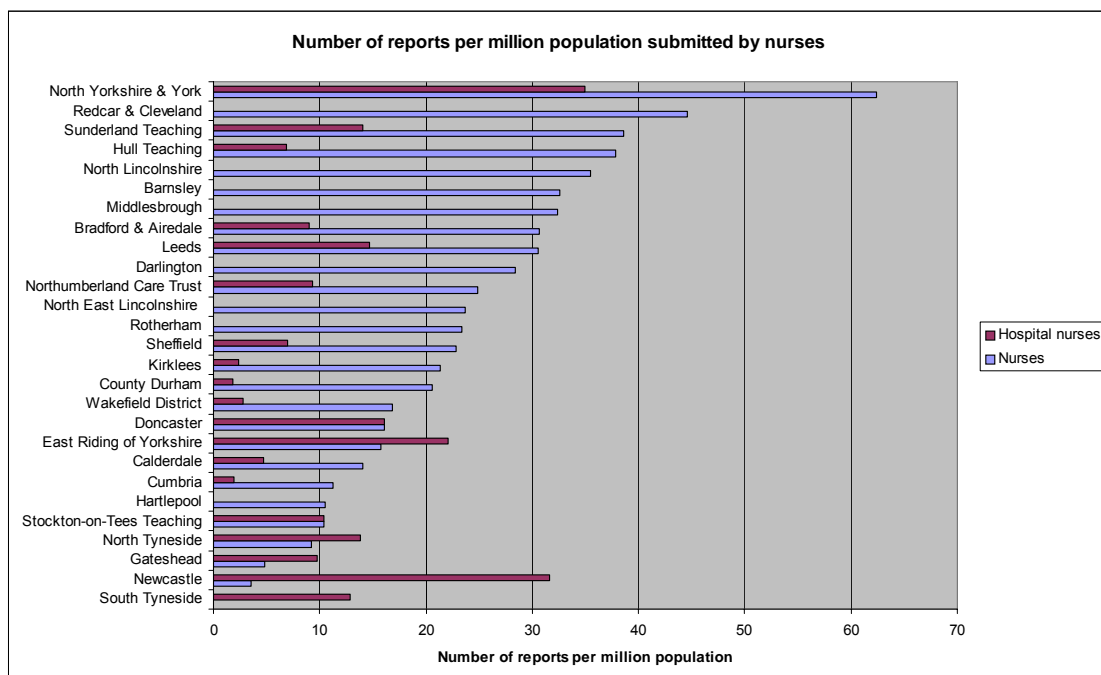
This year saw a 5% increase in total nurse reporting on the previous year (chart 16). This increase is due to an increase in the number of reports submitted by hospital nurses (26%), while reporting by other nurses has dropped slightly (2%). Nurses in primary care continue to make significantly more reports than those working in hospitals.

Chart 16



When data is analysed by PCT, nurses in North Yorkshire and York submitted the most Yellow Cards per million population. Hartlepool PCT submitted the least (Chart 17).

Chart 17

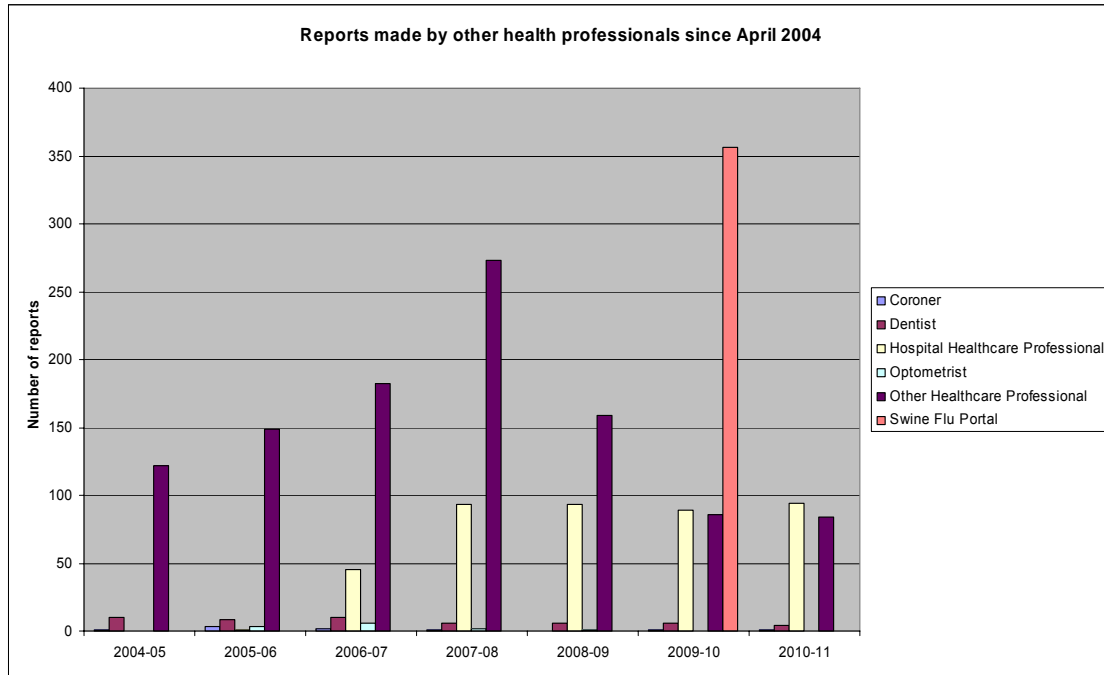


* Prior to May 2006 all reports from community and hospital nurses were classified on the MHRA ADROIT database as 'nurse'. Following the introduction of the SENTINEL database, reports from nurses are classified as 'Hospital nurse' and 'nurse' the latter covering those nurses in primary care

3.8 Other Healthcare Professionals

Reporting by hospital healthcare professionals increased by 11% in 2010-11, while reports from other categories remained static. Some of these reports may have been made by pharmacists or nurses, when their status has not been included in the report. Reporting from coroners and dentists remain very low. (chart 18). Reports from the swine flu portal from 2009-10 are included here since in most cases it is not possible to determine who made these reports.

Chart 18

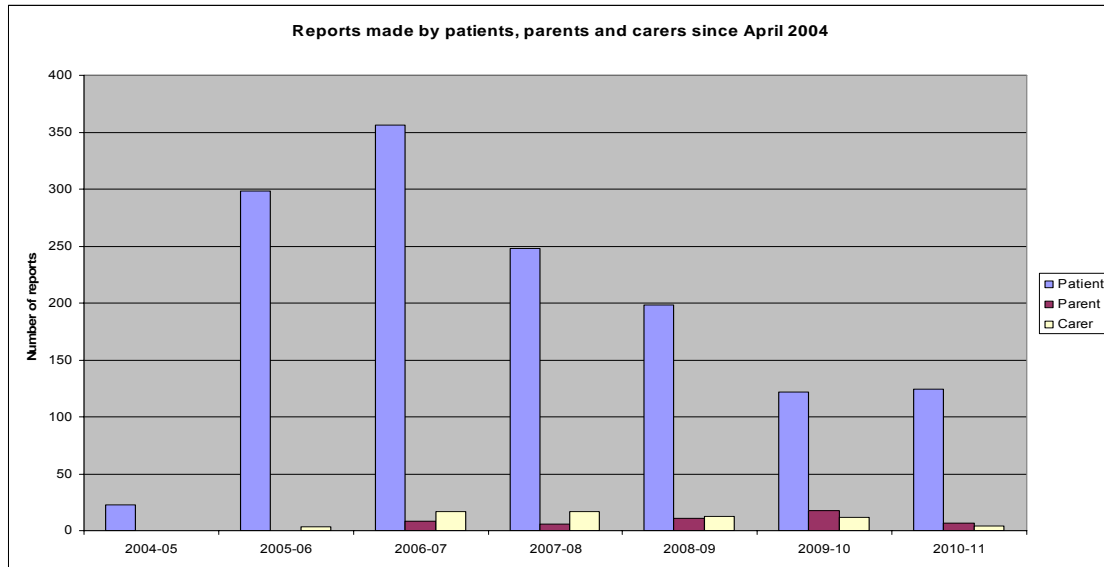


3.9 Patient Reporting

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. Reporting from patients has increased by 2% over 2009-10, but still remains lower than in previous years (Chart 19).

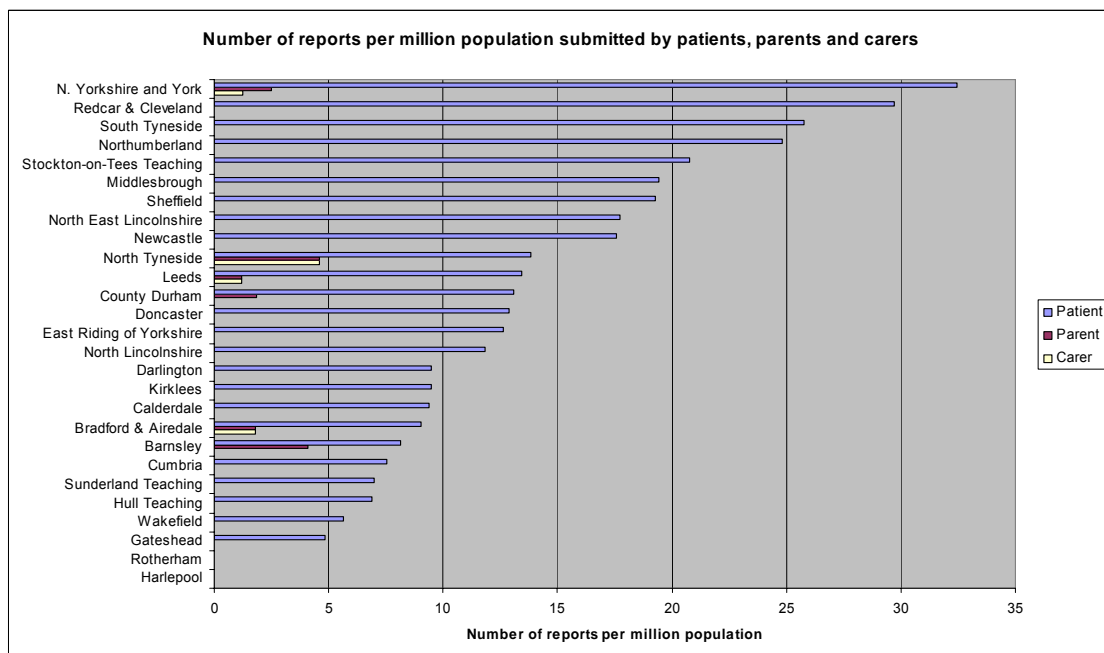
The YCCNY considers patient reporting increasingly important and continues to work with local patient support groups to raise the profile of the Yellow Card scheme to reverse this disappointing trend.

Chart 19



When the data is examined by PCT, patients, parent and carers in North Yorkshire and York PCT submitted the most Yellow cards per million population, while patients in 2 PCTs submitted no Yellow Cards (Chart 20).

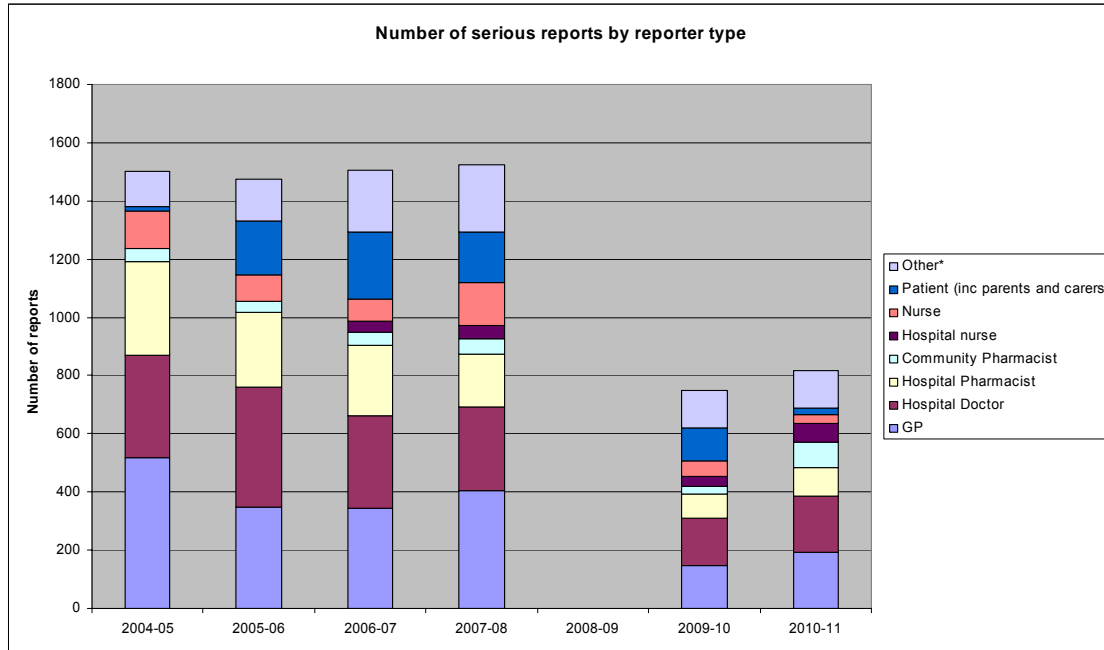
Chart 20



4. Serious Reactions

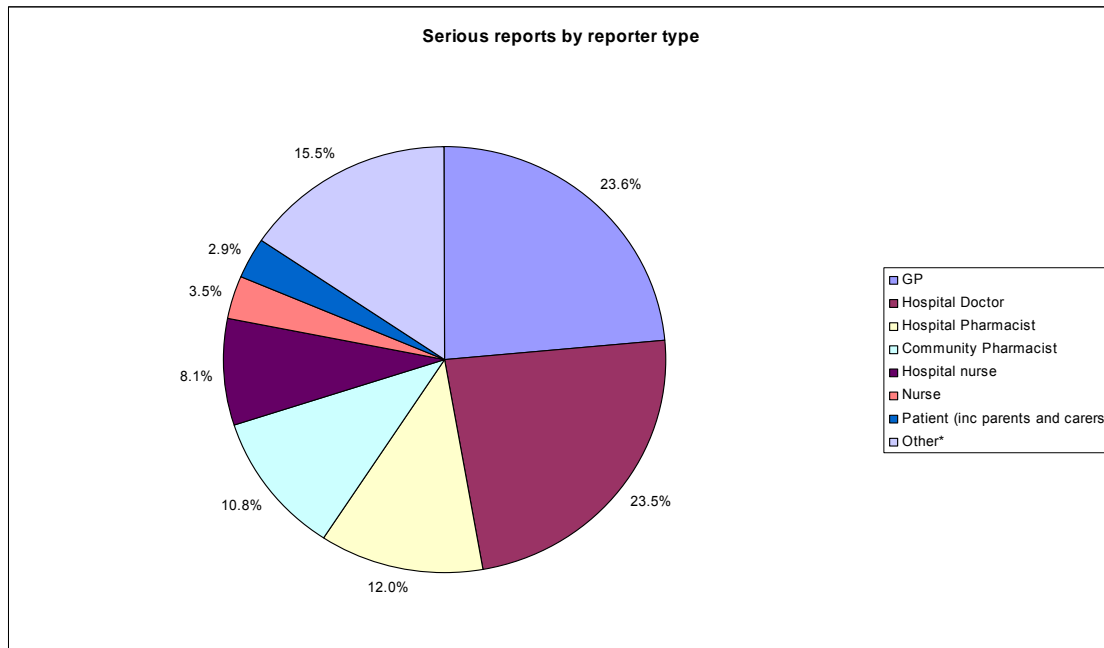
A total of 817 reports of serious reactions were received in 2010-11, comprising 52% of the total. The number of serious reports increased over 2009-10, but the overall proportion remains the same. Data was not supplied by the MHRA for 2008-09.

Chart 21



The breakdown of serious reports by reporter group shows that 47% were from doctors, an increase of 4% over the previous year (chart 22). Serious reports from community pharmacists increased by 7% over the period, while reports from patients, parents and carers dropped by 12%.

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 2010-11 are shown in table 1. During this period varenicline was the most reported drug in Northern and Yorkshire, contributing 7% of all reports.

Table 1. Drugs most commonly involved in ADR reports during 2010-11 financial year

	Drug	No. of reports
1	Varenicline (Champix®▼)	111
2	HPV vaccine (Cervarix®▼ & Gardasil®▼)	97
3	Simvastatin	29
4	Implanon®	24
5	Citalopram	23
6	Adalimumab (Humira®▼)	22
7	Rivaroxaban (Xarelto®▼)	21
8	Exenatide (Byetta®▼)	19
9	Sitagliptin (Januvia®▼)	19
10=	Ramipril	18
10=	Co-amoxiclav	18

6. Follow up of reports

Between April 2010 and April 2011 further information was requested by the centre, at the request of the MHRA, for 2 reports (0.1% of the total), a decrease on the previous reporting period of 2009-10. 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 50% of cases; a decrease on previous reporting periods, however the request for one follow up is still active and therefore the information may yet be received before the deadline in the new financial year.

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	142 (7.8%)	47 (33%)
2010-2011	YCCNY	2	1 (50%)
	MHRA	Data not supplied	Data not supplied

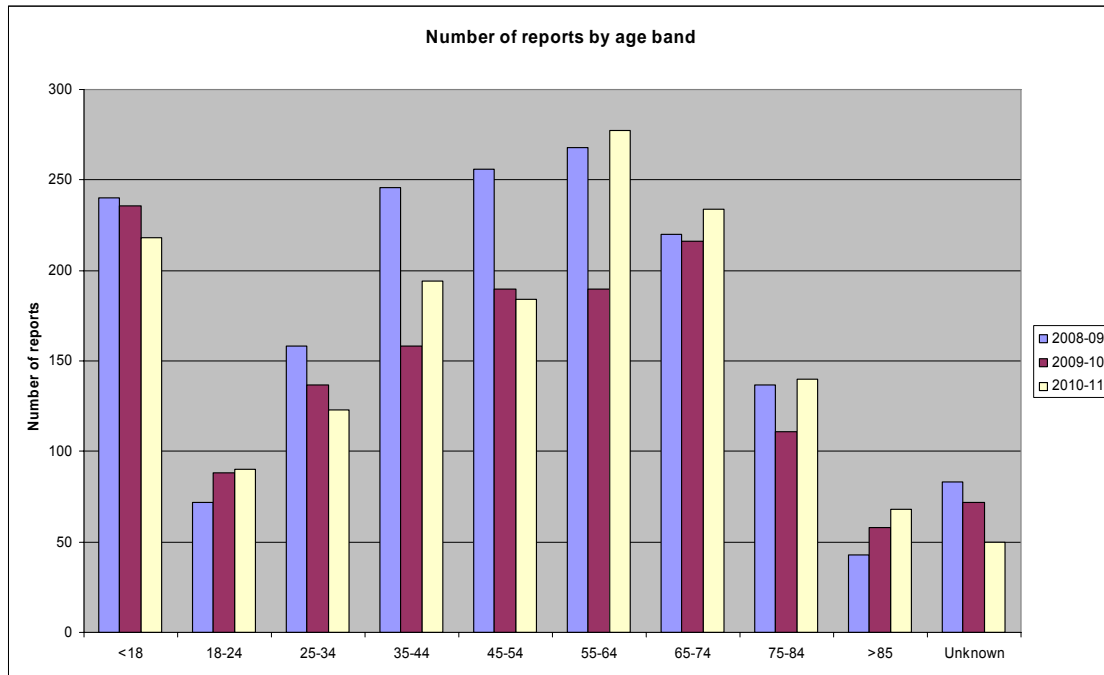
7. Age banding

Table 3 highlights the number of reports per age band in 2009/10. An increase of 46% was seen in the 55-64 age group, while reporting also remains high in the under 18 and 65-74 age groups.

Table 3. Number of reports per age range in 2010-11

Age Band (years)	Number of Reports
<18	218
18-24	90
25-34	123
35-44	194
45-54	184
55-64	277
65-74	234
75-84	140
>85	68
Unknown	50
Total:	1578

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 2009-10, 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. Fourteen such sessions have been provided this year, including yellow card training as part of medicines information sessions to health information 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. An educational session was delivered to the Gateshead branch of the Polymyalgia Rheumatica and Giant Cell Arteritis North East support group, with plans to also speak to other branches within the area in the new year. 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 and Leeds University requested a session for their non-medical prescribers course. 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 Primary Care Trust (PCT) in our region, displaying Yellow Card reporting performance of each PCT. Hull PCT and Sheffield PCT then asked for training regarding Yellow Card reporting to be delivered to non-medical prescribers within the trust.

Following the release of the Care Homes Use of Medicines Study (CHUMS report) which concluded that there was an unacceptable level of medication errors in care homes, all PCTs in our region were contacted to offer support to care home staff regarding adverse drug reactions. This resulted in three educational sessions in the Sheffield PCT to approximately 100 care home staff regarding adverse drug reactions and reporting via the yellow card scheme being delivered.

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 2010-11 financial year, bulletins have been published discussing the safe use of opioids and antipsychotic use in elderly dementia patients. Future editions are planned to discuss current and emerging drug safety issues.

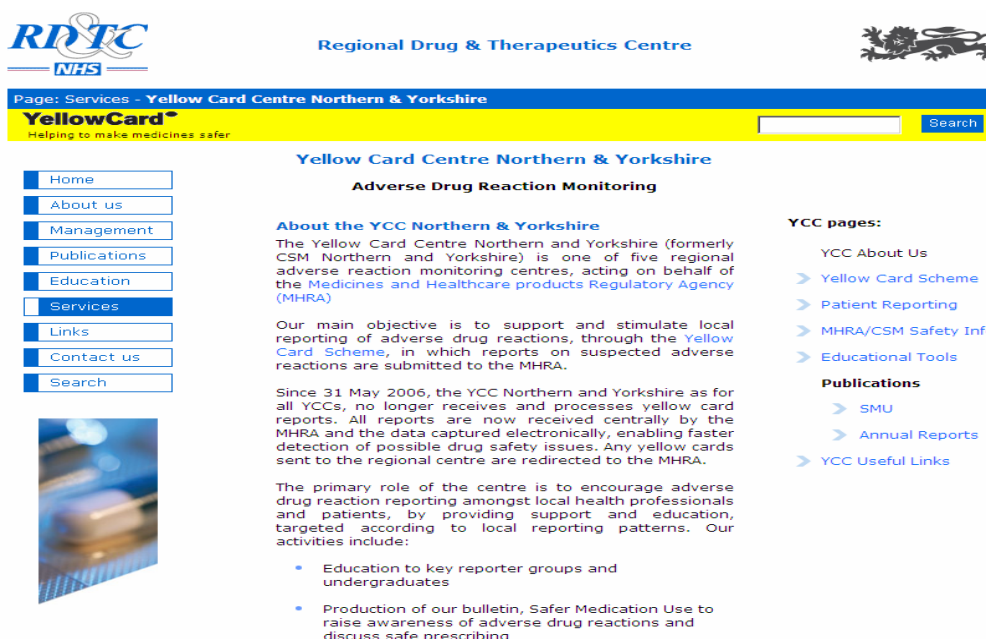
This year has also seen the addition of The MINT (Medicines Information News Today) to the centres publications. The MINT is a newsletter produced quarterly by the Medicines Information department of the centre which is circulated to PCT advisors and health professionals working in primary care such as practice pharmacists, community pharmacists, nurses and GPs. Each newsletter contains a section to promote Yellow Card reporting.

A Q&A article was produced for the National Electronic Library of Medicines (NeLM) describing how to complete a Yellow Card. NeLM is aimed at health professionals with in the NHS and aims to promote the safe, efficient and effective use of medicines.

A research project was conducted in collaboration with the Medicines Information department of the Newcastle Regional Drug and Therapeutics Centre (RDTC) to investigate the correlation between adverse effect enquiries to the RDTC and Yellow Cards submitted in the Northern and Yorkshire region. It found the GPs not only submit the largest proportion of Yellow Cards but also the most adverse reaction enquiries. Community pharmacists, a group that has historically had poor Yellow Card reporting rates were the 2nd largest group of enquirers suggesting they encounter ADRs in practice but do not report. Information from this project will provide direction for promotional activities for the 2011-12 year. The abstract and poster was displayed at the UK Medicines Information (UKMI) Practice development seminar in Warwick to an audience of MI pharmacists and technicians.

The YCC Northern and Yorkshire has also worked collaboratively with the Newcastle 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 under went a complete overhaul and now features information not only of use to health professionals but also patients. The site was rebranded with yellow colours to differentiate from the rest the RDTC website. It 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, included lay presentations as well as those aimed at health professionals, patient and universities. 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 2010-11 financial year the site received 2,508 visitors, and the Safer Medication Use bulletin page was the most visited (chart 24).



RDTC
NHS

Regional Drug & Therapeutics Centre

Page: Services - Yellow Card Centre Northern & Yorkshire

YellowCard
Helping to make medicines safer

Yellow Card Centre Northern & Yorkshire
Adverse Drug Reaction Monitoring

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About the YCC Northern & Yorkshire
The Yellow Card Centre Northern and Yorkshire (formerly CSM Northern and Yorkshire) is one of five regional adverse reaction monitoring centres, acting on behalf of the Medicines and Healthcare products Regulatory Agency (MHRA)

Our main objective is to support and stimulate local reporting of adverse drug reactions, through the Yellow Card Scheme, in which reports on suspected adverse reactions are submitted to the MHRA.

Since 31 May 2006, the YCC Northern and Yorkshire as for all YCCs, no longer receives and processes yellow card reports. All reports are now received centrally by the MHRA and the data captured electronically, enabling faster detection of possible drug safety issues. Any yellow cards sent to the regional centre are redirected to the MHRA.

The primary role of the centre is to encourage adverse drug reaction reporting amongst local health professionals and patients, by providing support and education, targeted according to local reporting patterns. Our activities include:

- Education to key reporter groups and undergraduates
- Production of our bulletin, Safer Medication Use to raise awareness of adverse drug reactions and discuss safe prescribing

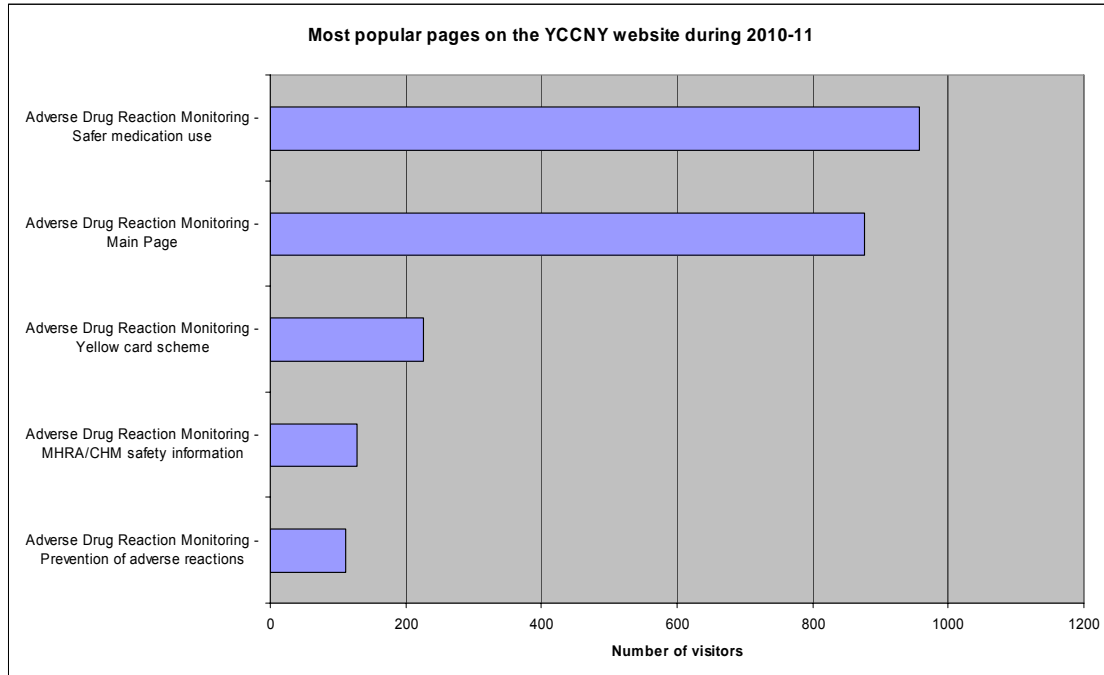
YCC pages:

- > YCC About Us
- > Yellow Card Scheme
- > Patient Reporting
- > MHRA/CSM Safety Info
- > Educational Tools

Publications

- > SMU
- > Annual Reports
- > YCC Useful Links

Chart 24



During the 2010-11 financial year the centre answered 134 enquiries regarding adverse drug reactions to a specific drug or drugs. 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

Russell P. Adverse Drug Reactions. Role Preparation for Health Information Advisors; Handling Medicines Calls. NHS Direct, Newcastle. 6th September 2010

North East Public Health Observatory Conference. Equity and Excellence – what can the Public Health Observatory do to support GP Commissioning. Wolfson Research Institute. University of Durham. 20th September 2010

McDonald H. Adverse Reactions and the Yellow Card Scheme. Pre-registration Hospital Pharmacist Training Scheme, Boldon, 22nd September 2010

Smith S. Side effect reporting by patients. Polymyalgia Rheumatica and Giant Cell Arteritis North East Support Group. Gateshead, 27th September 2010

Smith S. Adverse Drug Reactions. Diploma in Therapeutics. Newcastle University, 7th October 2010

Russell P. Adverse Drug Reactions. Role Preparation for Health Information Advisors; Handling Medicines Calls. NHS Direct, Newcastle. 4th October 2010

Smith S. Adverse Drug Reactions and the Yellow Card Scheme. Care Home Staff. Sheffield Primary Care Trust. Sheffield, 1st November 2010

Smith S. Adverse Drug Reactions and the Yellow Card Scheme. Non-medical prescribing course. Leeds University, 6th December 2010

McDonald H, Russell P. Yellow Card Reporting. Leeds Primary Care Trust. Leeds, 9th December 2010

Smith S. The Yellow Card Scheme: Reporting Adverse Drug Reactions. Information scientists. Regional Drug and Therapeutics Centre. Newcastle, 17th January 2011

Smith S. Adverse Drug Reactions and the Yellow Card Scheme. Year 2 Pharmacy Students. Huddersfield University. 18th January 2011

Smith S. Adverse Drug Reactions and the Yellow Card Scheme. Care Home Staff. Sheffield Primary Care Trust. Sheffield, 1st February 2011

Smith S. Adverse Drug Reactions and the Yellow Card Scheme. Non-medical Prescribers. Sheffield Primary Care Trust. Sheffield, 1st February 2011

Smith S. Adverse Drug Reactions and the Yellow Card Scheme. Non-Medical Prescribers. Hull Primary Care Trust. Hull, 7th February 2011

Smith S. Adverse Drug Reactions and the Yellow Card Scheme. Non-Medical Prescribers. Hull Primary Care Trust. Hull, 1st March 2011

Safer Medication Use published on the YCCNY website

Oral Antiplatelet drugs. *Safer Medication Use*, No. 7 May 2010

Using Strong Opioids Safely. *Safer Medicines Use*, No. 8 May 2010

Antipsychotic Use in the Elderly with Dementia. *Safer Medicines Use*, No. 9 September 2010

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

Smith S. Summary Annual Report 2010-11. Distributed to Medicines Managers of each PCT in Northern and Yorkshire region. November 2010

Smith S, McDonald H, Cassidy V. The MINT (Medicines Information News Today). August 2010

Smith S, McDonald H, Cassidy V. The MINT (Medicines Information News Today). November 2010

Smith S, McDonald H, Cassidy V. The MINT (Medicines Information News Today). March 2011

Non MHRA meetings attended in YCC capacity

New Drugs Meeting, Regional Drug and Therapeutics Centre. Monthly 2010-11

UKMi Clinical Governance Working Group. London, 13th May 2010

UKMi Clinical Governance Working Group. Teleconference, 30th September 2010

Regional Medicines Information Meeting, Regional drug and Therapeutics Centre. Newcastle, 19th October 2010

UKMi Clinical Governance Working Group. Birmingham, 30th November 2010

UKMi Clinical Governance Working Group. Teleconference, 15th February 2011

10. Research

Staff of the Yellow Card Centre Northern and Yorkshire participate in research projects relating to adverse drug reactions and clinical toxicology, usually in collaboration with Newcastle University (Institute of Cellular Medicine), the National Poisons Information Service and the UK Teratology Information Service. Recent research has concentrated on drug induced arrhythmias and on adverse maternal and fetal effects of use of medications and vaccines during pregnancy.

10.1 Drug-induced arrhythmias

During the year the results of the SCOP Study have been published. This was a large scale open randomised controlled clinical trial that demonstrated an increased cardiovascular mortality associated with sertindole, a drug known to prolong the QT interval, compared with risperidone, a drug with little if any ECG effects.. These differences are offset by small reductions in rates of suicide and suicide attempts in recipients of sertindole and overall mortality was not significantly different between the two drugs.

Drug overdose offers a useful model for studying drug-induced ECG effects which may only be seen uncommonly after therapeutic use. To illustrate this, studies have been done examining the ECG effects of methylphenidate when taken in overdose. This research did not demonstrate longer QT intervals after methylphenidate overdose compared with other non cardiotoxic drugs taken in overdose such as paracetamol.

Staff of the YCC are closely involved in the EU FP7 funded ARITMO (Arrhythmogenic potential of drugs) Study, which is a European collaboration examining drug-induced QT

prolongation and torsade de pointes concentrating on antipsychotic and antimicrobial agents.. Specific work packages include a systematic review of drug induced QT prolongation in randomised controlled clinical trials and observational studies and a field study set up locally to obtain further ECG evidence from psychiatric patients receiving currently prescribed antipsychotic drugs.

Recently a project was completed looking at cross sectional data from ECGs of psychiatric patients undergoing routine physical health checks in the last 5 years. This as yet unpublished research has demonstrated a substantially lower prevalence of QT prolongation compared with a cohort studied in the mid 1990's who were largely receiving typical antipsychotic drugs including thioridazine and droperidol.

10.2 Medication exposure in pregnancy

A study funded by the National Institute for Health Research has examined the maternal effects of H1N1v influenza during pregnancy and established risk factors for admission to hospital. Further follow up is taking place to establish pregnancy outcomes and the impact on these of H1N1v infection and the use of antiviral medications or vaccines. Additional unconditional grants from vaccine manufacturers have enabled the collection of data from a substantial cohort of women accepting vaccination to compare with equivalent data from women who declined vaccination during pregnancy. Preliminary data has been analysed but the final data set is anticipated at the end of 2011.

Using routine surveillance statistics collected by the UK teratology Information service, research has also been presented examining the adverse fetal effects of overdose of ibuprofen or diazepam and of exposure to mifepristone during pregnancy.

11. Publications

Papers

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Perera N, Eddleston M, Hill SL, Alldridge G, Thomas SH. Characteristics and management of poisoning with ethylene glycol and methanol in the United Kingdom. *Clinical Toxicology* 2010; 48: p290

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Stephens S, Yates L, Chincholkar V, Thomas SHL. Outcome of pregnancy after maternal exposure to mifepristone. *Birth Defects Research Part A: Clinical and Molecular Teratology*. 2010; 88 (5): 433.

Thomas SHL, Good AM, Spears R, Cooper G, Weatherall I. UK trends in toxicity relating to drugs of misuse from National Poisons Information Service data. *Clinical Toxicology* 2010; 48: p304

Thomas SHL. Risk factors for paracetamol (acetaminophen) hepatotoxicity. *Clinical Toxicology* 2010; 48: p266

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Posters

Smith S. Comparison of adverse effect enquiries received by the RDTC with Yellow Cards submitted in the Northern and Yorkshire region. UKMi Practice Development Seminar. September 2010.

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 disappointing that the total number of reports has decreased in the Northern and Yorkshire region by 13%, however the large volume of reports last year from the swine flu portal largely accounts for the drop. Increased reporting from doctors, nurses, pharmacists and patients is encouraging. 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 2010-2011

Number of Yellow Card reports from each SHA by reporter qualification in 2010-2011 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	296	155	42	25	34	57	66	168	38	78	5	3	2	26	0	995
North East	123	105	61	22	18	37	26	51	44	42	2	1	2	11	0	545
North West	11	10	0	1	1	0	1	6	2	4	0	0	0	0	1	37
Total	430	270	103	48	53	94	93	225	84	124	7	4	4	37	1	1577

Total number of yellow card reports from Northern and Yorkshire region in 2010/11 = 1577

Reports per quarter (calendar year)

Number of reports per quarter in 2010-2011

April – June 10	(Q1)	369
July – September 10	(Q2)	351
October – December 10	(Q3)	371
January – March 11	(Q4)	486
TOTAL		1577

Follow-ups

Follow-ups by YCCNY in 2010-2011	2
Number of successful follow-ups	1

Appendix 2: YCC Northern and Yorkshire objectives for 2007-11

General Objectives	Performance measures and targets	Progress at 31st March 2011
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	Overhaul of website complete. Teaching resources available for health professionals, patients and universities
	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 July 2010 to offer general support regarding ADR reporting and education. Whitworths asked for educational session and Lloyds Pharmacy interested for new 2010 pre-reg pharmacy graduates – so far no further correspondence
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	Thirteen universities contacted who provide undergraduate and postgraduate courses for healthcare professionals. Lecture delivered at Huddersfield university to pharmacy students and Leeds non-medical prescribers as well as students completing Diploma in Therapeutics at Newcastle university. 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.	2010-11 Nine 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 July 2010 to offer general support regarding ADR reporting and education. Whitworths asked for educational session and Lloyds Pharmacy interested for new 2010 pre-reg pharmacy graduates – so far no further correspondence. Yellow Card leaflets and posters supplied to community pharmacies. MINT newsletter forwarded to community pharmacies registered with our centre.
	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.	Correspondence with Royal Victoria Infirmary pharmacy departments regarding Yellow Card reporting rates. Also in discussion for research project regarding under reporting of ADRs in secondary care. Educational session delivered to all hospital pre-reg pharmacists in region.
	3.3 Engage with local expert patient groups to promote the Yellow Card Scheme	Local offices of national support groups contacted. Asked to put links to RDTC ADR page and MHRA Yellow Card website on sites. Polymyalgia Rheumatica and Giant Cell Arteritis North East Support group – 2 educational meetings 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

