



# Patient Reporting of Adverse Drug Reactions

## A Qualitative Study



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### BACKGROUND

- Spontaneous reports of suspected adverse drug reactions (ADRs) are submitted via the 'Yellow Card Scheme' (YCS).
  - ADRs represent a major clinical problem in the UK
    - Considerable morbidity and mortality<sup>1</sup>
    - Prolonged hospital stays<sup>2</sup>
    - Cost the NHS over £466m per year<sup>1</sup>
- 70% of ADRs are preventable<sup>3</sup>; pharmacovigilance schemes, like the YCS are therefore vital.
  - In February 2006, the YCS was extended to allow patient reporting of ADRs. There have been questions over the quality and value of these reports<sup>4,5</sup>. A MHRA pilot prior to the launch, however, showed that patients report similar numbers of serious reactions but give greater details on impact upon quality of life.
  - In 2006, the 'Yellow Card Centre Scotland' provided materials for a compulsory 6-week poster campaign in every community pharmacy in Scotland, to increase awareness of patient reporting. This was in addition to materials provided by the MHRA UK-wide.

### AIMS

**STUDY 1:** To measure the **success** of the Scottish community pharmacy campaign to increase patient reporting.

**STUDY 2:** To compare the **quality** of patient Yellow Card (YC) reports to those submitted by health professionals (HPs).

### METHODS

- Anonymous ADR data was supplied by the 'Medicine and Healthcare Products Regulatory Agency' (MHRA).
- All UK YCs submitted between 22/03/2007 – 06/03/2009 were analysed: **25,463 YCs**, recording **61,965 ADRs**.

#### STUDY 1: Analysis of Community Pharmacy Campaign

- Campaign success** was analysed by comparison of YC submission rates over pre-campaign, campaign and post-campaign periods.
  - Comparisons were made with data from the 'Northern and Yorkshire' regional monitoring centre (RMC) due to similar population demographics.
  - Results were standardised as YCs submitted/10000 population/week.
- Three reporter groups** were compared – Community Pharmacists (CPs), HPs, and patients.
  - The proportion of **serious ADRs** submitted was analysed by region, and for all groups in each of the periods.

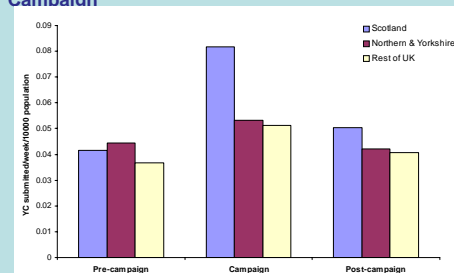
#### STUDY 2: Comparison of Patient and Health Professional Reporting

To compare patient and HP reporting, all YCs submitted during the 2 year period were analysed for the whole of the UK. CPs were included with HPs for this part.

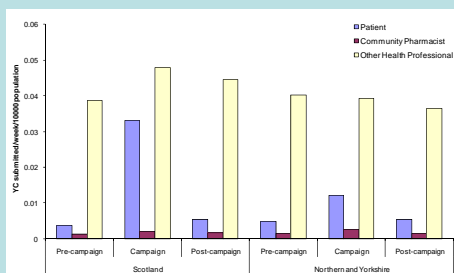
#### TOP 10 DRUGS and ADRs REPORTED

- Comparison of the most frequently recorded drugs and ADRs for each group
- SERIOUS REACTIONS**
  - Comparison of **proportion** of serious reports and recording of **non-recovery**.
- QUALITY ASSESSMENT**
  - The **level of non-recording** in each of the YC fields was assessed for each group

### RESULTS: STUDY 1 Analysis of Community Pharmacy Campaign

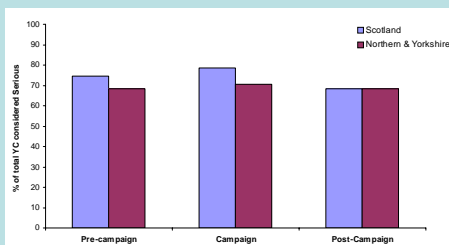


- YC submission in **Scotland doubled** during the campaign and fell post-campaign. Some improvement was sustained.
- A **similar trend** of rising and falling was seen in **N&Y** and the **UK**, but with a smaller increase and little post-campaign improvement (fig.1)

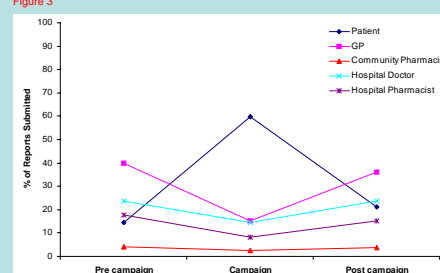


- The **Scottish** campaign produced a much larger increase in patient reporting than the comparative campaign in **N&Y**, with greater improvement in the post-campaign period (fig.2).

- There was very little variation in the percentage of YCs considered **serious** throughout the three periods, for both Scotland and N&Y (fig.3).



- In Scotland, whilst the proportion of **serious reactions** submitted during the campaign remained constant, there was significant variation in the **group responsible** for the submission of these reports (fig.4).



### RESULTS: STUDY 2 Comparison of Patient and HP Reporting

- During the two year study period, **patients** submitted an average of **3.90 ADRs per YC** (3864 YCs, 15,069 ADRs) and **HPs** submitted an average of **2.13 ADRs per YC**.

#### TOP 10 DRUGS and ADRs REPORTED

Top 10 Patient Drugs			Top 10 Health Professional Drugs		
Drug	No. of Reports	% of total reports	Drug	No. of Reports	% of total reports
1 Simvastatin	234	6.06	1 Venenline	3503	15.94
2 Venenline	133	3.44	2 Cervarix	1425	6.48
3 Paroxetine	120	3.11	3 Rimnabant	538	2.45
4 Citalopram	115	2.98	4 Simvastatin	428	1.95
5 Atorvastatin	85	2.20	5 Etanercept	327	1.49
6 Amlodipine	81	2.10	6 Prevenar	281	1.28
7 Ramipril	81	2.10	7 Pediacel	266	1.21
8 Venlafaxine	61	1.58	8 Adalimumab	258	1.17
9 Omeprazole	59	1.53	9 Citalopram	238	1.08
10 Fluoxetine	56	1.45	10 Infliximab	209	0.95

- ADRs reported by both groups were very similar (table 2).

Top 10 Patient ADRs			Top 10 Health Professional ADRs		
ADR	No. of Reports	% of total reports	ADR	No. of Reports	% of total reports
1 Nausea	407	10.53	1 Nausea	1751	7.97
2 Dizziness	367	9.50	2 Headache	1229	5.59
3 Headache	357	9.24	3 Dizziness	1046	4.76
4 Depression	306	7.92	4 Rash	886	4.03
5 Fatigue	301	7.79	5 Vomiting	859	3.91
6 Malaise	261	6.75	6 Depression	727	3.31
7 Diarrhoea	217	5.62	7 Dyspnoea	706	3.21
8 Insomnia	207	5.36	8 Malaise	686	3.12
9 Dyspnoea	201	5.20	9 Erythema	585	2.66
10 Vomiting	198	5.12	10 Pruritis	581	2.64

- 44.41%** of patient reports were considered **serious** by the reporter, and **94.40%** (including the same 41.41%) were considered **serious** by the **MHRA** and **upgraded**.
- 50.01%** of HP reports were considered **serious** by reporter, **66.34%** were considered **serious** by the **MHRA**.
- 31.87%** of patients reported **non-recovery**, compared with **21.44%** of HPs.

#### QUALITY ASSESSMENT

- Patients were **least likely** to record drug indication and route of administration.
- Doctors were **least likely** to record patient height and weight.

### CONCLUSIONS

- The compulsory Scottish community pharmacy campaign was **successful** in increasing patient reporting of ADRs
- Patients reported serious ADRs**; this supports the MHRA pilot data and refutes previous claims that patients only report trivial reactions.
- Patients** provide information on a **different spectrum of drugs** to HPs. Providing information that can be combined with HP data, to **improve detection of ADRs**.

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