

# Case study: Evaluation of patient reporting of adverse drug reactions

## Importance to NHS

The monitoring of Adverse Drug Reactions through drug monitoring is vital to patient safety as rare, serious and/or unexpected reactions often appear only when drugs are used in everyday practice by many people. Spontaneous reporting of ADRs is one method of drug monitoring, and in the UK this is undertaken through the Yellow Card Scheme (YCS). Since 1964, healthcare professionals have been able to report ADRs and from October 2005 the scheme was opened up to patients or their representatives.

**An adverse drug reaction (ADR) is a reaction to a drug and/or combination of drugs which is harmful and unintended and which occurs at a dose normally used for prophylaxis, diagnosis or treatment.**

Relatively little is known about the drug monitoring impact of patient reports. There have also been few studies on the views and experiences of patients/consumers on the reporting of suspected ADRs.

## Evaluation of patient reporting of adverse drug reactions to the UK 'Yellow Card Scheme'

Researchers led by Professor Avery, Professor of Primary Care at the University of Nottingham, were commissioned by the National Institute for Health Research Health Technology Assessment (NIHR HTA) programme to conduct a trial to evaluate the patient's views and experiences of using the YCS. They have recently published their findings in *Health Technol Assess* 2011, Vol.15:20.

## The study sought to establish:

- What are the views and experiences of patients reporting to the YCS?
- What are the views of members of the public on the YCS including user-friendliness and usability of different mechanisms of patient reporting?
- What is the level of awareness of the YCS among members of the general public in Great Britain and what are their views on the convenience of three different ways of reporting (online, telephone, completing and mailing a paper form)?
- How might the reporting system be improved?

## The research

The research team used a number of methods to gain an overall picture of the value of patient reporting:

- Over a two year period the team evaluated the drug monitoring impact of patient reporting through analysing the reports of suspected ADRs from the YCS. Over 26,000 Yellow card reports were received, with over 5000 of these being from patients
- Questionnaires were conducted to gain understanding of the views and experiences of patients and members of the public with regards to patient reporting
- Telephone interviews were conducted with patient-reporters
- Focus groups were conducted, which identified ways in which publicity and reporting methods might be improved
- Eight questions were added to the National omnibus survey to identify if any of the participants had heard of the YCS.





## Importance for clinical decision-making and quality of patient outcomes

*“Our study has shown that patient reports of adverse drug reactions add value by highlighting problems that are not commonly reported by healthcare professionals, and by providing detailed information about adverse reactions, including the impact on patients. Also, patient reports are just as likely as those from healthcare professionals to concern reactions that are considered serious,” said Professor Avery.*

The research team made a number of suggestions to improve the awareness of, and the value of patient reporting to the YCS:

- Increase publicity for patient reporting
- Provide further guidance to reporters on what information to report
- Increase patient awareness of medicines for which the MHRA is undertaking intensive monitoring
- Change the design of paper reports and the online reporting system
- Provide general feedback to patient reporters on what the MHRA does with reports
- Explore possibilities for providing specific feedback to patients in relation to the medicines and suspected ADRs that they report.

*“To aid future comparisons of reports submitted by patients and healthcare professionals it is important that similar information is collected from both groups, particularly with respect to categories of seriousness,” says Professor Avery. “According to patient accounts, some healthcare professionals seem to be unaware that patients can submit their own ADR reports, and some appear to be dismissive of patients who report suspected ADRs. Education at undergraduate and postgraduate level might help address these issues.”*

‘Evaluation of patient reporting of adverse drug reactions to the UK ‘Yellow Card Scheme’: literature review, descriptive and qualitative analyses, and questionnaire surveys’ published in *Health Technol Assess* 2011; Vol. 15:20. The full text is available for download at [www.hta.ac.uk/project/1628](http://www.hta.ac.uk/project/1628)

## Adding to the evidence base

Yellow Card reports were received from the Medicines and Healthcare products Regulatory Agency (MHRA), 19.8 per cent were patient reports and 80.2 per cent healthcare professional reports. The patient reports contained a significantly higher number of suspected ADRs per report than healthcare professionals.

The research team found that patient reporting of ADRs is richer in detail and better at describing the impact of suspected side effects on their daily lives than information provided by healthcare professionals.

*“The content analysis of text describing suspected reactions showed that patient reports were more likely than those from healthcare professionals to include information about symptoms and to stress the extreme nature of these,” says Professor Avery. “They were also more likely to highlight the impact of the reaction on the patient, particularly the emotional impact or social impact.”*

The telephone interviews with patient-reporters revealed that most became aware of the YCS by chance and many suggested that greater publicity was needed for patient reporting. Motivations for reporting included altruism and a desire to find out if others had experienced similar problems. Although patient voice is vital for drug monitoring the telephone interviews found that of over 2,000 members of the public only one in 12 had heard of the YCS.

