Evaluation of patient reporting to the Yellow Card System

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Background

- Patient reporting to the Yellow Card system began in October 2005
- Evaluation funded by NIHR HTA and involved universities of Nottingham, Aberdeen, Liverpool John Moores, and DSRU
- Further details available from: http://www.hta.ac.uk/project/1628.asp

Objectives

- To evaluate the pharmacovigilance impact of patient reporting to the yellow card system
- To report on patient experiences of the yellow card system
- To assess public awareness of being able to report to the yellow card system
- To offer recommendations for improvements to patient reporting

Studies undertaken

- Quantitative analysis of yellow card reports including signal generation analysis
- Qualitative analysis of yellow card reports
- Questionnaire survey of patient experiences of reporting
- Telephone interviews with patients who have reported
- National survey of public awareness
- Focus groups and usability testing with patients
- Further review of the world literature on patient reporting systems

Key points from quantitative analysis (1)

- 5180 patient reports and 20,949 from HCPs
- More reports on women than men for both patient reports and HCP reports
- Patients report more suspected reactions per report than HCPs (median 3 vs 2)
- A higher proportion of patient reports (16%) contained more than one suspect drug than HCPs (9%)

Key points from quantitative analysis (2)

- HCP and patient reports have similar proportions of “dictionary serious” suspected ADRs (58.8% vs 58.3%)
- HCP reports have a higher proportion of ADRs :
  - causing hospitalisation (19% versus 13%)
  - that were life-threatening (11% versus 6%)
  - causing death (2.6% versus 0.7%)
- Patient reporters took significantly longer to report their reactions (median 104 days versus 28 days for HCP), even in the 2nd year that patients were able to report (median 147 versus 34 days).

Key points from quantitative analysis (3)

- Word count in patient reports is greater than in HCP reports (median 45 vs 15 words)
- Patients report a different spectrum of reaction types compared with HCPs, although there is a reasonable amount of overlap
- Patients and HCPs differ in the types of drug most commonly reported

Signal generation analysis (1)

- Data analysis done on the 5180 patient, and 20,949 HCP reports
- There was a total of 41,001 drug-reaction pairs
- Only 10.6% of pairs were present in both patient and HCP reports
- Used Proportional Reporting Ratio method to generate SDRs

Signal generation analysis (2)

- HCPs generated a higher proportion of signals than patients for:
  - Dictionary serious reactions (48% versus 29%)
  - Black triangle drugs (31% vs 11%)
- Similar proportions of SDRs in both groups were not listed on SPCs

Signal generation analysis (3)

- In the pooled reports, the inclusion of patient reports meant that:
  - 508 additional signals were generated that had either not been present or had not reached the signal threshold in the HCP reports
  - 186 (9.6%) of HCP signals no longer reached the signal threshold in the pooled data

Qualitative analysis of yellow card reports

- This study explored the nature and richness of patients’ descriptions of their suspected ADRs compared with health professionals
- Reports on a wide range of drug-ADR pairings selected for 230 patients and 179 HCPs
- We undertook a content analysis of reports followed by and in-depth qualitative analysis

Content analysis findings

- Patients more likely than HCPs to report:
  - Symptoms (93% vs 78%)
  - Impact of the ADR (47% vs 12%)
  - Temporal relationship between drug and suspected ADR
  - Extreme nature of the suspected ADR (47% vs 17%)
- Patient reports tended to be more elaborate in description of suspected ADRs

In-depth qualitative analysis

- Reports from patients illustrate:
  - Detailed descriptions of symptoms and the social, emotional and occupational impact of these
  - Temporal relationship between drugs and suspected ADRs

Questionnaire survey of patients reporting to the yellow card system

- MHRA sent questionnaires to patients (soon after having made a report) between March 2008 and January 2009
- Questionnaires sent back to research team
- We obtained 1362 responses from 2008 questionnaires sent out (68% response rate)

Key findings from questionnaire survey

- Median age 57 years
- 67% female
- 49% of respondents learned about the Yellow Card Scheme from pharmacies
- 93% thought the report was fairly easy or very easy to complete, but 16% noted some difficulties they had experienced
- 33% expected feedback from MHRA
- 60% would have liked feedback

Telephone interviews of patients reporting to the yellow card system

- Semi-structured telephone interviews conducted with 27 patients
- Main reasons for reporting:
  - To highlight issues and stop someone going through the same symptoms
  - A duty to report back
  - To find other people with the same problem

National survey of public awareness of being able to report

- 2028 respondents, broadly representative of the UK population
- Only 8.5% aware of the yellow card scheme
- 24% had experience of a side-effect from a medicine
  - Of these, 85% said they reported it to a HCP
  - Of these, less than 1% reported their side-effect to the yellow card scheme

Focus groups and usability testing with patients

- We recruited 40 diverse members of the public in the Nottingham area
- Seven focus groups and usability testing sessions have taken place using facilities at the University of Nottingham
- We have obtained views on the different methods of reporting and ways in which the system could be improved

Key findings from focus group

- Scheme thought to be important but needs to be better advertised
- Suggested methods of further advertising include:
  - The media
  - Leaflets issued with dispensed medicines
  - Giving information about the scheme on patient information leaflets

Key findings from usability testing

- Paper forms
  - Not enough space to write in key information, particularly on drugs and side-effects
  - Report does not conveniently fit in the envelope
- On-line
  - Not very easy to navigate through the on-line form
  - Drop-down menus can be confusing

Literature review

- Based on the emerging findings from the studies, we have conducted a further literature review focusing on issues that may be of particular relevance to improving aspects of ADR reporting by patients
- Two major descriptive studies identified since Blenkinsopp review from 2006, and we have identified a number of additional countries where patient reporting takes place

Recommendations (1)

- To improve the timeliness and value of patient reporting; increase the numbers of reports from patients, and improve patient experiences of reporting, the following might be considered:
    - Increasing the publicity for patient reporting
    - Providing information on patient reporting within patient information leaflets, with particular emphasis on informing patients about relatively new “black triangle” drugs
    - Making improvements to the design of paper reports and the online reporting system and increasing the number of hours during which telephone reports can be made
    - Providing a greater level of general feedback to patients on what the MHRA do with reports, and specific feedback in relation the problems reported by patients

Recommendations (2)

- To increase the validity of future comparisons of patients and healthcare professionals it would be helpful to ensure that similar information is collected from both groups, particularly with respect to seriousness.

Ideas for further research

- Investigate further the extent to which the extra information from patient reporters contributes to pharmacovigilance in terms of signal generation and helping regulators to better recognise the impact of ADRs on patients' lives
- Investigate the advantages and disadvantages of pooling patient reports with healthcare professional reports for the purposes of signal generation
- Investigate whether increases in publicity and/or improvements to reporting systems increase the numbers and quality of reports from patients
- Explore the value of using patient reports of ADRs for educational purposes for health care professionals (to help better understand the impact of ADRs on patients' lives) and for education and self-help purposes for patients

Summary

- We have undertaken an ambitious series of studies on patient reporting to the Yellow Card Scheme
- Our findings are encouraging in terms of the contribution of patient reporting
- Important to retain the three different methods of reporting, to develop these further, and to increase publicity of patient reporting

Further information

- Executive summary and full report available:
  - http://www.hta.ac.uk/project/1628.asp

- International conference on patient reporting is being held next Friday, 24th June 2011, Friends Meeting House, Euston Road, London, book via:
  - http://www.primm.eu.com