"I don’t know how the yellow card works" - Issues with Pharmacovigilance

Yvonne M Hopf1,2, Christine Bond1, John Haughney1, Peter Helms2
1Centre of Academic Primary Care, University of Aberdeen
2Department of Child Health, University of Aberdeen

Introduction

- Off-label and unlicensed prescribing is common in children1,2,
- This practice is linked to a higher risk of adverse drug reactions.
- The current system of pharmacovigilance could be improved.
- The CHIMES (Child Medical Records For Safer Medicines) programme is investigating ways to improve the detection of adverse drug reactions in children through data linkage (see Figure 1).
- As part of CHIMES, this study explores the views of Scottish health professionals on data linkage for paediatric pharmacovigilance.

Methods

- This was a mixed methods study, conducted in Scotland (see Figure 2):
  - Interviews
    - National key stakeholders (health professionals)
    - Included experts in ethics, public health, data protection, pharmacovigilance, data linkage, paediatrics, prescribing
  - Focus groups
    - Health profession specific (medical doctors, nurses, pharmacists)
    - Borders, Forth Valley, Grampian, Greater Glasgow & Clyde, Lanarkshire, Lothian, Tayside
  - Survey
    - Delphi survey to random sample of health professionals (n=825)
    - 3 rounds completed between August 2011 and February 2012
- A mixture of purposive and convenience sampling was used.
- Interviews and focus groups were transcribed verbatim; transcriptions and field-notes informed the analysis.
- Themes were identified via a framework approach3.
- Data management was aided by the use of NVivo.
- Ethical approval was granted by the North of Scotland Research Ethics Service.

Results

- Six broad themes were identified, of which one was pharmacovigilance.
- Interviews (n=40) were conducted in twelve Scottish Health Boards.
- Focus groups were conducted (22 participants, see Figure 3) in seven Scottish Health Boards.

Conclusion

- Many issues with pharmacovigilance were identified, including under-reporting due to practical challenges, i.e. time required, multiple reporters, as well as recognition of ADRs and assessment of causality which was perceived as difficult due to poly-pharmacy, co-morbidities and unintended uses.
- Healthcare professionals would profit from clearer guidance regarding when, what, and how to report suspected ADRs.
- The identified issues will inform the development of an enhanced pharmacovigilance system.