

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

Yvonne M Hopf^{1,2}, Christine Bond¹, John Haughney¹, Peter Helms²

¹Centre of Academic Primary Care, University of Aberdeen

²Department of Child Health, University of Aberdeen



yvonne.hopf@abdn.ac.uk



Introduction

- Off-label and unlicensed prescribing is common in children^{1,2}.
- 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).



Figure 1: Linkage is proposed between Primary Care data, Scottish Morbidity Records (SMR) and dispensed prescriptions, PCCIU=Primary Care Clinical Informatics Unit.

- 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):



Figure 2: Overview of study design. NB: Delphi study ongoing and included here only for completeness.

- 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.

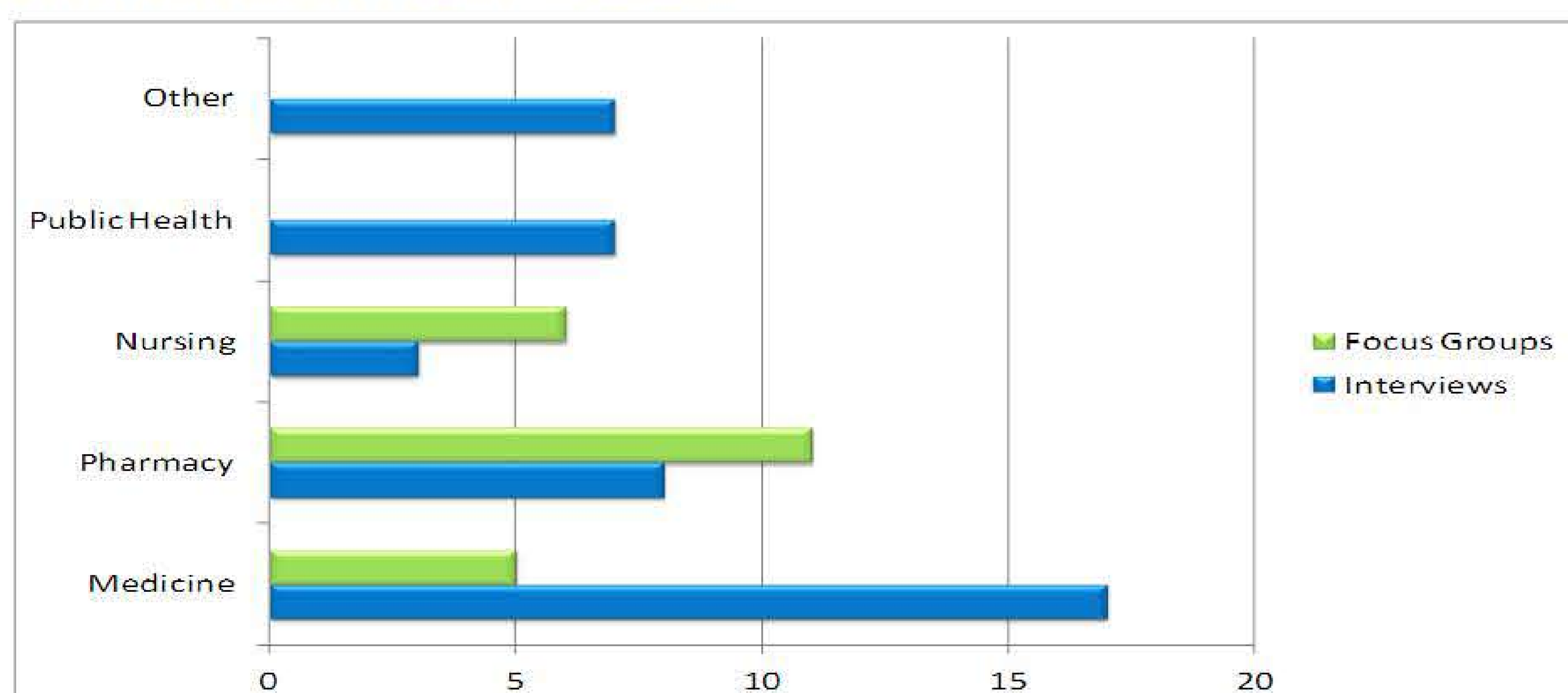


Figure 3: Clinical Background of interview and focus group participants.

Results continued

- This poster discusses 'Issues with Pharmacovigilance' (see Figure 4), one of the nine subthemes within the pharmacovigilance theme.

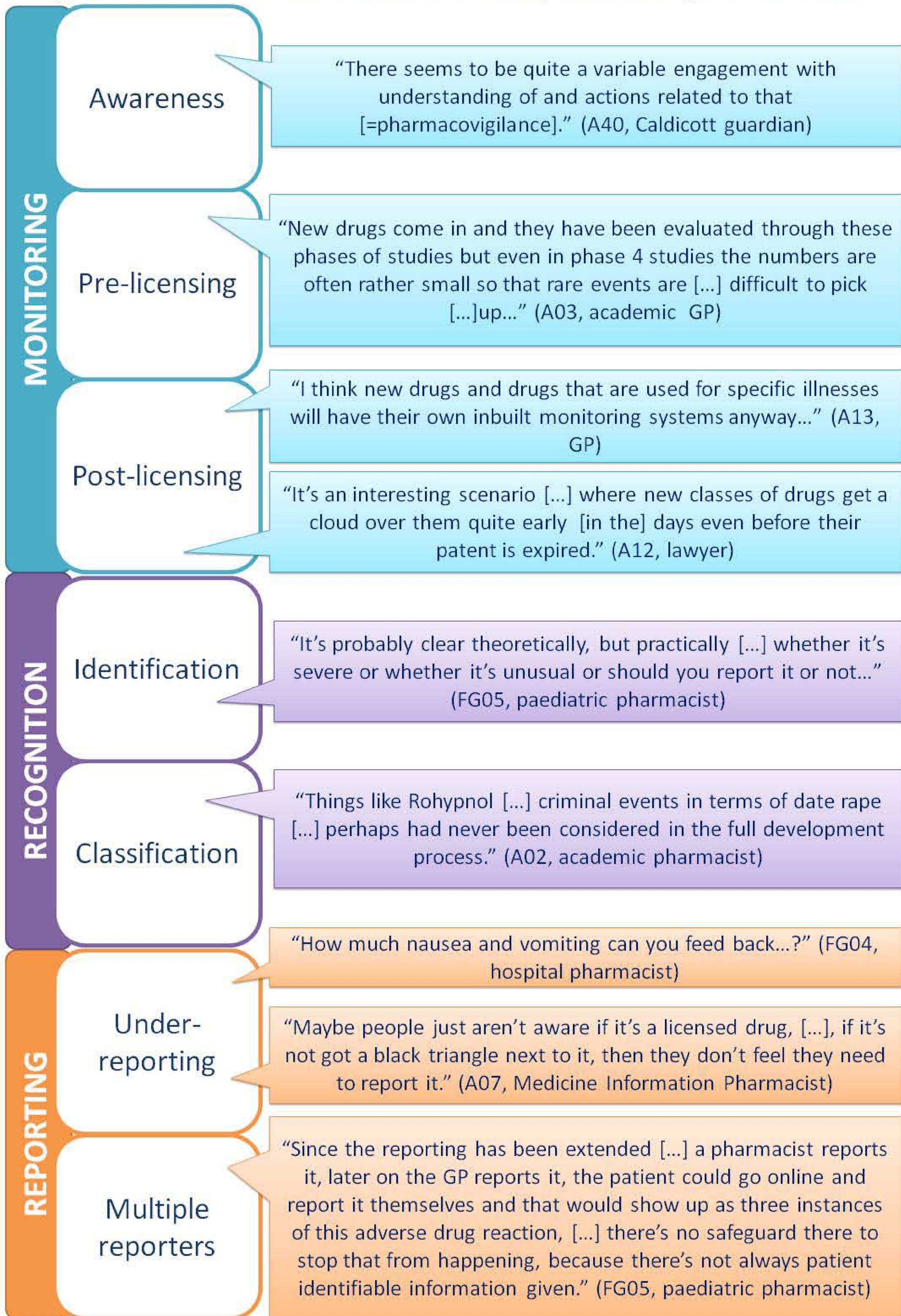


Figure 4: 'Issues with Pharmacovigilance' can be further divided; sub-themes are illustrated by quotes from interviews (A) and focus groups (FG).

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.

References

¹Ekins-Daukes S, Helms P, Simpson CR, Taylor MW, McLay J. Off-label prescribing to children in primary care: a retrospective observational study. *Eur J Clin Pharmacol* 2004; 60: 349-353

²McIntyre J, Conroy S, Avery A, Combs H, Choonara I. Unlicensed and off-label prescribing of drugs in general practice. *Arch Dis Child* 2000; 83 (1):498-501

³Ritchie J, Spencer L. 1994. Qualitative data analysis for applied policy research. In: A. Bryman and RG Burgess, eds., *Analyzing Qualitative Data*.

Acknowledgements



The CHIMES study is funded by the Chief Scientist Office as part of an NHS Applied Programme Grant. Yvonne Hopf is seconded by NHS Grampian to the University of Aberdeen. Conference attendance kindly funded by the Chief Scientist Office.

