“It’s about recognising how many people you’ve poisoned by giving them medication”: thoughts of healthcare professionals on pharmacovigilance

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Context

- Off-label prescribing in children linked to higher rates of adverse drug reactions
- Current systems of pharmacovigilance not effective enough
- Improving detection of adverse drug reactions through data linkage

Child Medical Records for Safer Medicines (CHIMES)

- Acceptability and validity of datasets derived from linked routinely acquired Scottish NHS data for post marketing surveillance of medicines in children

Work Package 1
User Communities

Work Package 2
Evidence Synthesis

Work Package 3
Pharmacovigilance

Health Care Professionals
Aim of my overall work

To explore the acceptability of linking routinely collected healthcare data to inform the design of a new system for pharmacovigilance in children.

Study Design

- **Literature review**
  - Data linkage (completed)
  - Attitude of healthcare professionals (ongoing)

- **Qualitative Study**
  - Interviews (completed)
  - Focus Groups (completed)

- **Consensus Study**
  - Delphi Survey (analysis ongoing)

➢ Ethical approval granted by North of Scotland Research Ethics Service.
Methods

Interviews
- Professional Stakeholders (n=40)
- Purposive sampling, heterogeneous sample
- Semi-structured

Focus Groups
- Frontline healthcare professionals
- n=6 (22 participants)
- Convenience sampling, heterogeneous sample

- Audio-taped, transcribed verbatim
- Transcripts and field-notes informed analysis
- Data management via NVivo

Identified Themes

Pharmaco-vigilance (PV)  Data  Data Linkage (DL)
Usage of linked data  Dissemination of Findings  Disclosure of personal data*

* Interviews only
Pharmacovigilance (PV)

- Definition of PV
- Importance of PV
- Current systems
- (Dis-) advantages of systems
- Issues with PV
- ADR reporting
- Purpose of PV*
- Recognition of ADRs*
- Paediatric Prescribing*

* Focus Groups only; Interviews only

WHO definitions

- Pharmacovigilance¹:
  Pharmacovigilance is the pharmacological science relating to the detection, assessment, understanding and prevention of adverse effects, particularly long term and short term side effects of medicines.

- Adverse Drug Reactions (ADRs)²:
  An adverse drug reaction is a noxious and unintended response to a drug which occurs at doses normally used in man.

¹ WHO, 2002. The Importance of Pharmacovigilance
² WHO, 2002. Safety of Medicines
Understanding of Pharmacovigilance

Monitoring

Surveillance

Adverse drug reactions

Yellow Cards

Safety

Monitoring & Surveillance

Not just medication (FG04, pharmacists)

Appropriateness of prescriptions (FG03, nurses)

“I could be quite flippant and say it’s probably about recognising how many people you’ve poisoned by giving them medication.” (A22, GP)

“…[a] record of what was done [clinically]…” (FG02, GP)
Yellow Cards & ADRs

“At least we’ve got a system…” (A24, pharmacist)

“Opportunity to report adverse reactions” (A34, Caldicott Guardian)

“Who is actually tasked [with] filling out a yellow card?” (FG04, pharmacist)

“I do not think that there is a lot of people that do know about the yellow card scheme…” (FG06, paediatric nurse)

“It [=YCS] should be easy to use but nobody does” (FG07, paediatrician)

Safety

• Main outcome of pharmacovigilance

“Safety and effectiveness {of medication} is the main thing.” (FG03, primary care nurse)

• Patient safety

“…even though I’m doing that every day, I’m not thinking ‘I’m doing this because of pharmacovigilance’, I’m doing it because I’m trying to keep the patient safe.” (FG06, paediatric nurse)

• Drug safety

“… enhancing the information […] about that particular drug and if there are any safety concerns, [ensure that] they are addressed […]so it’s really a safety measure…” (A36, pharmacist)
Discussion

• Varied understanding of pharmacovigilance
  – Yellow Cards as tool
  – Patient safety as outcome
  – Individual vs population based approach
  – Seen wider than original definition

• Inconsistent understanding as potential limitation for new initiatives

Next...

• Triangulation of three studies
  ➢ Identification of barriers and facilitators will inform the new system design
The CHIMES programme is funded by the Chief Scientist Office and supported by NHS Research Scotland (NRS) through NHS Grampian.
I would like to thank all participants throughout my study for their time and contributions.

THANK YOU

UNIVERSITY OF ABERDEEN
Centre of Academic Primary Care

We maybe should not disturb the medical community with such a ridiculous reaction after all
### Composition Focus Groups (1)

<table>
<thead>
<tr>
<th>Focus Group</th>
<th>Number of Participants</th>
<th>Total</th>
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<tbody>
<tr>
<td><strong>Doctors</strong></td>
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<tr>
<td>GPs (FG02)</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Paediatricians (FG07)</td>
<td>3</td>
<td>5</td>
</tr>
<tr>
<td><strong>Nurses</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Primary Care (FG03)</td>
<td>2</td>
<td></td>
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<tr>
<td>Secondary Care (FG06)</td>
<td>4</td>
<td>6</td>
</tr>
<tr>
<td><strong>Pharmacists</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Secondary Care (FG04)</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Paediatric Pharmacists (FG05)</td>
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<td>11</td>
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<tr>
<td><strong>Total Number of focus group participants</strong></td>
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<td>22</td>
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Composition Focus Groups (2)

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<th>Medicine</th>
<th>Nursing</th>
<th>Pharmacy</th>
<th>Total</th>
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</thead>
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<tr>
<td>Male</td>
<td>4</td>
<td>1</td>
<td>4</td>
<td>9 (41%)</td>
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<tr>
<td>Female</td>
<td>1</td>
<td>5</td>
<td>7</td>
<td>13 (59%)</td>
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<tr>
<td>Total</td>
<td>5 (23%)</td>
<td>6 (27%)</td>
<td>11 (50%)</td>
<td>22 (100%)</td>
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Clinical Background and gender breakdown of focus group participants

(Qualitative) Framework

- Developed during 1980s
- Widely used by qualitative researchers
- Allows to organise "raw" data into categories
- Different stages of analysis
  1) Familiarisation
  2) Identifying a thematic framework
  3) Indexing
  4) Charting
  5) Mapping and Interpretation
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