‘Not linking the data would be unethical’: Views of Healthcare Professionals

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Context

- Current systems of pharmacovigilance not effective enough
- Improving detection of adverse drug reactions through data linkage
- Off-label prescribing in children linked to higher rates of adverse drug reactions
Child Medical Records for Safer Medicines (CHIMES)

- Acceptability and validity of datasets derived from linked routinely acquired 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.
Research Questions

1) What is the range of available clinical databases within the UK as well as the extent of data linkage among them?

2) What is the understanding of professional stakeholders to pharmacovigilance in general and of current UK Pharmacovigilance systems?

3) What are the views of professional stakeholders towards linked NHS data across Scotland?

4) What essential system components would be required for professional stakeholders to accept the proposed linkage of health care data?
Methods

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

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

- Consensus Study
  - Delphi Survey (analysis ongoing)
  - Triangulation (to be started in April)

- Ethical approval granted by North of Scotland Research Ethics Service (NoSRES)
Research Questions

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Methods

**Interviews**

- Professional Stakeholders (n=25)
- Purposive sampling, heterogeneous sample
- Semi-structured

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

**Focus Groups**

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

- No insurmountable issues identified
  - Security, anonymisation and legal challenges have to be addressed

> “Whatever it is, the IT security has to be good so that people can’t be hacking in and all the rest of it.” (A09)

- Recommendations include
  - Information and involvement of public
  - Control of access to data
    - Vetting of people
    - Meaningful sanctions
Focus Group Results

- No insurmountable issues so far identified
  - Funding of project as potential concern
  - Expectation that ‘standard’ governance standards are imposed and met
  - Unintentional identification of patients considered an associated risk

“The health service is not exactly over-financed at this moment in time, so why use the extra money, [or] do we need to use it, do we put towards patient care and that, rather than developing systems that are not required.” (FG03, Nurse)
Summary Qualitative Work

- Proposed data linkage seen as beneficial
- General support of data linkage if identified issues are addressed

“The benefits are so enormous and the risks are so minimal that denying this activity [data linkage] is unethical.” (A04)

“As a professional I can see the huge advantages of linking the data [...], I think it would be fantastic if it works.” (FG05, Paediatric pharmacist)
Research Questions

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Delphi Survey: Seeking Consensus

- Developed by the RAND corporation for US military
- Characteristics include repetitive process, anonymity of participant, controlled feedback, and statistical group response
- In social research used to obtain a reliable group opinion
Theoretical Domain Framework (TDF)

- The TDF is used to investigate specific behaviours
- Use of TDF within the Delphi design:
  - Useful framework for survey design?
  - Is clinical problem addressed adequately?
  - Is Delphi method enhanced in general?
  - Can it identify relevant implementation techniques to overcome identified barriers?
The Theoretical Domain Framework (TDF)

- Knowledge
- Skills
- Social/professional role and identity
- Belief about capabilities
- Belief about consequences
- Motivation and Goals
- Memory, attention and decision process
- Environmental Context and resources
- Social Influences
- Emotion
- Behavioural Regulation
- Nature of behaviours
Target behaviour

**Facilitating the data linkage** means

- continuing to record data as usual
- requesting consent/explaining opt-out
- reassuring the patients/parents
  - i.e. explaining the purpose of the linkage to patients
Delphi Rounds

- Sampling
  - Purposive selection of HCP groups
  - Random selection within HCP groups
- Round 1: qualitative, open-ended questions
- Round 2: quantitative to gain consensus
- Round 3: quantitative feedback to review consensus
Item reduction across rounds

- **Round 1**: 1130 statements
- **Round 2**: 149 statements
- **Round 3**: 46 statements
Characteristics Participants across Rounds

Composition of rounds by clinical background of participants (%)

<table>
<thead>
<tr>
<th></th>
<th>Round 1 (n=61)</th>
<th>Round 2 (n=46)</th>
<th>Round 3 (n=50)</th>
<th>Round 2&amp;3 (n=27)</th>
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<td>Medics</td>
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<td>39.6</td>
<td>37</td>
</tr>
</tbody>
</table>

Legend:
- **Blue**: Medics
- **Green**: Pharmacists
- **Red**: Nurses
Characteristics Participants (2)

Round 1
Round 2 and 3
‘Delphi’ Group
Results Delphi

- n=27 answered Round 2 and 3
- ‘Top-10’ items score ≥92%
- Significant changes in agreement (p≤0.05) for 11 items
  - Regarding professional standards
  - Discussing requirements for linkage
  - Regarding potential feedback
Agreement: Top-10

When working as part of a multi-disciplinary team it is important to consider all views. 100%

Facilitating the linkage is not in conflict with my professional standards if the data is anonymised. 96.3%

The agencies that currently hold the different datasets need to agree to the sharing of the data. 96.3%

A good understanding amongst health professionals of the purpose and the benefits of the linkage is required. 96.3%

The appropriate IT resources would need to be in place before I can facilitate the linkage. 96.3%

Adverse events in secondary care need to be recorded electronically. 96.3%

Employers would have to support the facilitation. 96.3%

Ethical approval for the data linkage would be required. 92.6%

Prescribers would have to accurately record the indication for the treatment for the data linkage to be successful. 92.6%

My professional guidelines do not conflict with my facilitation the linkage. 92.5%
Facilitating the linkage is not in conflict with my professional standards if the data is anonymised:

- Round 2: median 7 [7-9]
- Round 3: median 9 [8-9]
- $p=0.005$
- No change 30%
- ↑agreement 56%
The agencies that currently hold the different datasets need to agree to the sharing of the data.

- **Round 2:** median 8 [7-9]
- **Round 3:** median 9 [9-9]
- $p=0.006$
- No change 48%
- ↑agreement 41%
Ethical approval for the data linkage would be required (%)

- Round 2: median 8 [7-9]
- Round 3: median 9 [8-9]
- [p = 0.056]
Patient consent would be required for facilitating the linkage (%)

- Round 2: median 8 [6-9]
- Round 3: median 9 [7-9]
- Agreement: 77.8%
- p=ns
Discussion Delphi Study

- Linkage is beneficial
  - Obtaining new information
- Appropriate project governance required
  - Ethical approval required
  - Patient consent required
  - Anonymisation as enabler
- Feedback as motivation
- No consensus achieved for the following:
  - Cost-efficient way of conducting research
  - Media mishandling information
  - Replication of work already done
Summary

- Development of linked database supported by health professionals in Scotland
- Issues, concerns and requirements identified at different levels
  - Governance of database important
  - Feedback as motivator and control mechanism
- Data will be supported by and cross-referenced to a parallel study investigating the views of the public
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