Is the use of linked routinely acquired NHS data for pharmacovigilance in children acceptable to parents and young people?

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Introduction

• Adverse drug reactions (ADRs) are an important cause of mortality and morbidity

• ADRs are under reported by the UK Yellow Card Scheme, especially with respect to children

• ‘Off label’ prescribing is common in children and increases the risk of ADRs

• Linking routinely collected NHS data sets could potentially be used to identify ADRs
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

Parents/guardians, young people and their representatives
Aims

• To describe the opinions and attitudes of parents/guardians/children to a national programme of linked information on medicine utilisation

Purpose

• To ensure that the construction and use of pharmacovigilance databases from routinely held NHS data satisfies the public’s expectations and concerns
Methods

Interviews with representatives of parents/guardians & young people n=17 purposive sample (Completed)

Content setting focus groups with parents/guardians & young people n= 4 recruited via libraries, secondary schools and snowballing (Completed)

Web based questionnaire; parents/guardians & young people invited via commercial research panel pilot n= 60, main sample n= 282

In-depth interviews with participants from initial interviews and focus groups n= 3 – 5
Analysis: Main Themes Identified
Combined data from Interviews and Focus Groups

Opinions Regarding Privacy and Confidentiality

Awareness and Opinions on Medicine Safety

Opinions Regarding Data Sharing and Linkage

Trust Relationships, and Promoting the Greater Good.

Communication/Public Consultation and Engagement with Proposed Database
Opinions Regarding Privacy and Confidentiality of Health Information

- Slight risk to confidentiality acceptable for benefit of greater good
- Opt-out as a method of consent acceptable
- Mechanism for consent should be transparent and accessible
- Young people should be involved in a consent process

I think a strong and realistic opt-out option makes people feel better about a new system and is actually relatively low risk, ‘cos people tend not to opt out, but I certainly think those feelings of having control make people more comfortable with a new data usage...Adult
Awareness and Opinions on Drug/ Medicine Safety

- The Yellow Card Scheme is not common knowledge
- An expectation that prescribed drugs are ‘safe’
- Medicine safety in children was a new concept for participants
- Monitoring medicine safety in children felt to be important

Yeah, well it’s important (monitoring adverse drug reactions in children). I suppose not just a specific group but the whole sort of one ‘cos you have to make sure that everything’s safe ‘cos if it’s not safe then you know you can’t prescribe it. You can’t sell it ‘cos you can’t cure one thing by making you ill with another. Young Person
Opinions Regarding Data Sharing and Linkage

• Data linkage is viewed as potentially beneficial

• Should be managed within a legal and ethical framework

• Data should be anonymised

• Access to data by commercial companies acceptable if data protection is in place

• Young people appear to be more comfortable with data sharing and linkage than adults

• Linkage of data regarding sensitive information raised most concerns

I would be comfortable with it (linking data), I’m not sure if parents might be less comfortable... Young Person
Trust Relationships and Promoting the Greater Good

- NHS seen as a trusted body in terms of managing health data in a confidential manner

- NHS is the preferred manager of proposed database

Because simply that trust (in the NHS) is there, that would be a good starting point I would think to perhaps reassure individuals who maybe already have some concerns about another database of information being set up, at least they know that the information that’s already there about their health care has been in safe hands for many years ...Adult

( I would be happy for data to be linked and shared if) it was benefitting improvements in health care... Adult
Communication/Public Consultation and Engagement with Proposed Database

The public want to be informed of:

• Why the database is being proposed
• Who may benefit from such a database
• Nature of data to be collected and linked
• Who may access data
• Mechanisms to protect confidentiality
• Mechanisms for consent to take place

I think it would have to be sold very, very, very well to parents... because the whole issue of digital information is scary for some people with their records being shared and not knowing about it...Adult
## Preliminary questionnaire data

### Recruitment and response rates

<table>
<thead>
<tr>
<th>Parents/Guardians</th>
<th>Number of email invitations sent</th>
<th>Number of completed questionnaires</th>
<th>Response rate %</th>
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<tbody>
<tr>
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<td>83</td>
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<table>
<thead>
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<th>Young People</th>
<th>Number of email invitations sent</th>
<th>Number of completed questionnaires</th>
<th>Response rate %</th>
</tr>
</thead>
<tbody>
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<td>65</td>
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<tr>
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<tr>
<td>Total</td>
<td>1441</td>
<td>132</td>
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</table>
I am aware that the NHS routinely combines (links) health care data to provide information about the health of people in general.
Routine monitoring of adverse drug reactions makes future use of children's medicines safe (for young people 'it is important to regularly check that children's medicines are safe')
Are you worried about identity theft when using online social networking sites?

- Extremely concerned
- Concerned
- Somewhat concerned
- Slightly concerned
- Not at all concerned

Young People

Parents Guardians
If, following a well publicised information campaign about the combining (linking) of anonymised health data to help make children's medicines safer, you were asked to give consent, which method of those outlined below would you prefer?
There is no need to ask parents/guardians or young people for consent to use their routinely collected anonymised health data to help monitor the safety of children's medicines.
It is acceptable for the NHS to be responsible for the anonymised health data, once it has been combined (linked)
A slight risk to my privacy when (linking) health data is OK if the results benefit the health of everyone in the community.
Summary

• There is an expectation that the NHS would already be employing anonymised nationally collected health data to improve population health

• Legal and bioethical issues raised are primarily concerned with maintaining confidentiality and privacy of the individual

• A consent mechanism of some kind appears to be integral to young people and parents/guardians support of data linkage

• People want to be informed about data linkage BEFORE it begins

• The preferred methods of being informed about data linkage for medicine safety are poster and leaflet campaigns and the web sites
Thank you.

Any questions?

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