Data Linkage For Pharmacovigilance Using Routinely Acquired Electronic Health Records

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Background

- Adverse Drug Reactions (ADRs) are a Problem
- High cost to NHS
- Current Pharmacovigilance limitations
- Additional methods required
- Data linkage using routine data
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

<table>
<thead>
<tr>
<th>Work Package 1</th>
<th>Work Package 2</th>
<th>Work Package 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>User Communities</td>
<td>Evidence Synthesis</td>
<td>Pharmacovigilance</td>
</tr>
</tbody>
</table>
Child Medical Records for Safer Medicines (CHIMES)

- Accuracy and validity of routinely acquired linked NHS data to support a routine mechanism for post marketing surveillance of medicines in children

**Work Package 1**  
User Communities

**Work Package 2**  
Evidence Synthesis

**Work Package 3**  
Pharmacovigilance
Research Questions

- What routine NHS data are available for post market drug surveillance?
- What's the best way to link data to support Pharmacovigilance and Pharmacoepi?
- How accurate are the data?
What routine NHS data are available for post market surveillance?

<table>
<thead>
<tr>
<th>ADMINISTRATIVE</th>
<th>DIAGNOSIS</th>
<th>DRUGS</th>
</tr>
</thead>
<tbody>
<tr>
<td>HOSPITAL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Admissions (SMR 1) – 32m records</td>
<td></td>
<td>Ø Prescribing Information System (PIS) – 1bn records</td>
</tr>
<tr>
<td>Maternity (SMR 2) – 4m</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cancer Registrations (SMR 6) – 1m</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mental Health (SMR 4) – 1m</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Outpatients (SMR 0) – 51m</td>
<td></td>
<td></td>
</tr>
<tr>
<td>GENERAL PRACTICE</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HIC (Dundee)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PCCIU (Aberdeen)</td>
<td></td>
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<tr>
<td>GPRD (UK)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

SURVEY

Ø HIC (Dundee)
Ø PCCIU (Aberdeen)
Ø GPRD (UK)
# Measuring Error in Databases

<table>
<thead>
<tr>
<th>RELIABILITY</th>
<th>AGREEMENT</th>
<th>VALIDITY (ACCURACY)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Same source used more than once for the same individual</td>
<td>Different sources compared, without one being distinctly ‘superior’</td>
<td>Different sources compared, one being distinctly ‘superior’ (gold / ‘alloy’ gold standard)</td>
</tr>
<tr>
<td>-&gt; Comparison of these results</td>
<td>-&gt; Not validity or reliability!</td>
<td>-&gt; Sensitivity (aka completeness)</td>
</tr>
<tr>
<td>-&gt; Not validity!</td>
<td></td>
<td>-&gt; Specificity</td>
</tr>
</tbody>
</table>

Measuring Error in Databases

**SENSITIVITY**
Degree to which inferior data source correctly identifies individuals who, according to the superior data source, *have the characteristic of interest*

-> Completeness

**SPECIFICITY**
Degree to which the inferior data source correctly identifies individuals who, according to the superior data source, *don’t have the characteristic of interest*

One may be more important than the other, depending on the study.

Number of items dispensed in the community in Scotland

Number of Dispensed Items (millions)

No. of Dispensed Items
Percentage of dispensed items with a unique patient identifier

[Graph showing the percentage of dispensed items with a unique patient identifier from 1993 to 2011. The y-axis represents the number of dispensed items (millions) and the x-axis represents the years from 1993 to 2011. The graph includes a line indicating the percentage of valid CHI.]
Percentage of dispensed items with valid CHI
Reliability

-> Same source
Same shape occurs year on year. Typically, males receive less medication than females...
Number of drug classes dispensed in Scotland (Oct – Dec 2010)
Agreement

-> Different sources
Insulin prescribing can act as a proxy for type 1 diabetes in children

5m Total Subjects (2010)

56,848 Insulin* Patients

28,358 Insulin (no co-prescriptions)

1,171 first time insulin

425 first time insulin < 20 years old

28,490 patients on co-prescriptions (chronic steroids, anti-diabetics, pancreatin)

27,187 on insulin < 2010

746 patients > 19 years old

* Short acting; intermediate and long acting insulins
Insulin prescribing compared to T1 diabetes in Scotland

Insulin prescribing compared to T1 diabetes outside Scotland

Pundziute-Lycka. Diabetologia 2002;45(6):783
Validity

-> Different sources (using a gold standard)
# Validity – Data Linkage

<table>
<thead>
<tr>
<th></th>
<th></th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Y</td>
</tr>
<tr>
<td>Prescribed insulin &lt; 20 years old (2007-11)</td>
<td>Y A) 1,020</td>
</tr>
<tr>
<td></td>
<td>N C) 38</td>
</tr>
</tbody>
</table>

Sensitivity \((A/(A+C)) = 96\%\)

Specificity \((D/(B+D)) = X\%\)
SUMMARY

• Reliable – consistent & expected patterns year on year
• Agreement – patterns of insulin prescribing & T1 diabetes
• Valid – 96% hospitalised diabetics can be identified via their prescription records
• Routine prescribing data useful for post market surveillance of medicines in children
Future Work

• Repeat measures using different disease sample (e.g. Asthma)
• Assess generalizability of results
• Publish validity of routinely collected national prescribing data in Scotland
• Continue working with ISD to build a platform for national Pharmacoepidemiology
CHIMES acknowledges the financial support of the Chief Scientist Office

Brad Kirby – Child Medical Records for Safer Medicines
Index based pharmaco-epi in Scotland (whole pop)
Data flow into the Prescribing Information System:

- **Doctor prescribing**
- **Pharmacy**
  - Dispensed & Collected Prescriptions

**National Services Scotland (NSS)**
- Practitioner Services – Payment Processing
  - DCVP
  - Validation on 5% Random Sample

**Information Services Division (ISD)**
- ETL
- Prescribing Information System (PIS)

- ~1200 Community Pharmacies
- ~8 million prescriptions per month
Data flow into the Prescribing Information System (Detailed):
Doctor Prescribing

- To patient

Patient Collects
- From community pharmacy (CP)

CP Claims
- From Practitioner Services Division (PSD)

PSD Prices & Validates
- Using the Data Capture Validation and Pricing (DCVP) system

ISD Extract, Transform & Load
- Into Prescribing Information System (PIS)
# Routine Datasets (Fields for linkage)

<table>
<thead>
<tr>
<th></th>
<th>EVENTS</th>
<th>MEDICINES</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Hospital discharges</td>
<td>Cancer Reg</td>
</tr>
<tr>
<td>Seeded Chi Number</td>
<td>✓</td>
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</tr>
<tr>
<td>CHI Number</td>
<td>✓</td>
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<tr>
<td>Surname</td>
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<tr>
<td>Forename</td>
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<tr>
<td>Date of Birth</td>
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<tr>
<td>Sex</td>
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<tr>
<td>Marital status</td>
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<tr>
<td>Postcode</td>
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</table>
## Routine Datasets (Fields for analysis)

<table>
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</thead>
<tbody>
<tr>
<td>Hospital discharges</td>
<td>Prescr.</td>
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<tr>
<td>Cancer Reg</td>
<td>E-Pharm</td>
</tr>
<tr>
<td>Deaths</td>
<td></td>
</tr>
<tr>
<td>Mental Health</td>
<td></td>
</tr>
<tr>
<td>OP</td>
<td></td>
</tr>
<tr>
<td>Maternity</td>
<td></td>
</tr>
<tr>
<td>A&amp;E</td>
<td></td>
</tr>
<tr>
<td>Condition</td>
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<tr>
<td>Procedure</td>
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</tr>
<tr>
<td>Drug</td>
<td>✓</td>
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<tr>
<td>Demographics</td>
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</tr>
</tbody>
</table>

- ✓ indicates that the field is included.
Percentage of dispensed items and hospital episodes with valid CHI
Typically, males receive less medicines than females...
Insulin prescribing compared to T1 diabetes outside Scotland