FARSITE

Evaluation of an Automated Trial Feasibility Assessment and Recruitment Tool

Presented by Gary Leeming

Authors: Sarah Thew, Gary Leeming, John Ainsworth, Martin Gibson, Iain Buchan
Feasibility And Recruitment System for Improving Trial Efficiency

Software to assist in identification and recruitment of participants for clinical trials.
OBJECTIVES

Improve efficiency and accuracy of study recruitment

Preserve Consent-For-Consent for recruitment of GP patients

Protect patient privacy; researchers only access anonymised and aggregated data

Share knowledge about the way medical data is recorded
Context

• Currently used for feasibility in Salford
• Developed with users in NW Diabetes Research Network and GM CLRN
• Datasets
  – Salford Integrated Record;
  – Secondary care and Primary care data;
  – Population of 242,000
Improving recruitment while preserving “consent for consent” and patient privacy

GP retains local control

NHS N3

Anon

Trial Protocol Design

Research Nurse

Patient Records

Trial Recruit

PCT

GP

Patient
Consent for Consent

is the consent to search an individual’s health record to determine whether or not they should be invited to take part in a clinical study

See MRC guidance: http://www.dt-toolkit.ac.uk/_db/_documents/Consent_for_Consent_DRAFT.pdf
Creating Feasibility Report

1. Protocol Arrives
2. Identify Code-able Items
3. Add criteria
4. Refine Codes
Instead of this…

...intelligible...
...and helpful...
...query creation
...with supported options
...and quick results

<table>
<thead>
<tr>
<th>Population Total</th>
<th>242,055 people</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Inclusion Criteria (Match All Include Groups)</strong></td>
<td></td>
</tr>
<tr>
<td>Include: Asthma Diagnosis</td>
<td>(Running Total) 31,247 people</td>
</tr>
<tr>
<td>Include: Short-acting beta2s</td>
<td>(Running Total) 14,425 people</td>
</tr>
<tr>
<td>Include: Recent exacerbation of asthma</td>
<td>(Running Total) 6,151 people</td>
</tr>
<tr>
<td><strong>Running Total (with duplicate matches removed)</strong></td>
<td>6,151 people</td>
</tr>
<tr>
<td><strong>Exclusion Criteria</strong></td>
<td></td>
</tr>
<tr>
<td>Exclude: Salmeterol</td>
<td>(Running Total) 2,481 people</td>
</tr>
<tr>
<td>Exclude: Other respiratory disease</td>
<td>(Running Total) 1,645 people</td>
</tr>
<tr>
<td><strong>Running Total (with duplicate matches removed)</strong></td>
<td>1,645 people</td>
</tr>
<tr>
<td><strong>Demographics</strong></td>
<td></td>
</tr>
<tr>
<td>Age is between 6 and 14</td>
<td>(Running Total) 451 people</td>
</tr>
<tr>
<td>Gender is Any</td>
<td>451 people</td>
</tr>
<tr>
<td>Ethnicity is Any</td>
<td>451 people</td>
</tr>
<tr>
<td>Smoker types: Any</td>
<td>451 people</td>
</tr>
<tr>
<td><strong>Recruitment Estimate</strong></td>
<td>451 people</td>
</tr>
</tbody>
</table>
# Exploring the detail

## Include: Asthma Diagnosis

<table>
<thead>
<tr>
<th>Condition</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Asthma (disorder) (with exceptions)</td>
<td>32,518 people</td>
</tr>
<tr>
<td>AND NOT Asthma resolved (finding)</td>
<td>31,247 people</td>
</tr>
</tbody>
</table>

## Include: Short-acting beta2s

<table>
<thead>
<tr>
<th>Condition</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>beta-2 agonists prescribed less than 1 Years ago</td>
<td>14,425 people</td>
</tr>
</tbody>
</table>

## Include: Recent exacerbation of asthma

<table>
<thead>
<tr>
<th>Condition</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Corticosteroids used in the treatment of asthma prescribed less than 6 Months ago</td>
<td>4,507 people</td>
</tr>
<tr>
<td>AND/OR CLENIL MODULITE 100micrograms CFC-free inhaler prescribed less than 6 Months ago</td>
<td>5,040 people</td>
</tr>
<tr>
<td>AND/OR CLENIL MODULITE 200micrograms CFC-free inhaler prescribed less than 6 Months ago</td>
<td>5,125 people</td>
</tr>
<tr>
<td>AND/OR CLENIL MODULITE 250micrograms CFC-free inhaler prescribed less than 6 Months ago</td>
<td>5,145 people</td>
</tr>
<tr>
<td>AND/OR CLENIL MODULITE 50micrograms CFC-free inhaler prescribed less than 6 Months ago</td>
<td>5,618 people</td>
</tr>
<tr>
<td>AND/OR Asthma attack performed less than 6 Months ago</td>
<td>5,621 people</td>
</tr>
<tr>
<td>AND/OR Asthma Accident and Emergency attendance since last visit performed less than 6 Months ago</td>
<td>5,631 people</td>
</tr>
<tr>
<td>AND/OR Prednisolone 5mg e/c tablet - product prescribed less than 6 Months ago</td>
<td>5,844 people</td>
</tr>
<tr>
<td>AND/OR Prednisolone 5mg tablet - product prescribed less than 6 Months ago</td>
<td>6,151 people</td>
</tr>
</tbody>
</table>

**Running Total (with duplicate matches removed)**

6,151 people
Investigating site feasibility
Making recruitment easier

Add patient consent form
Add patient information sheet (if separate)
Add ethics approval letter
Add protocol document

Patient invitation letter template

Dear [[PatientTitle]] [[PatientFirstName]] [[PatientLastName]]

-- Paste the invitation letter here --

Patient:

<table>
<thead>
<tr>
<th>Address Line 1</th>
<th>Address Line 2</th>
<th>Address Line 3</th>
<th>Address Line 4</th>
<th>Postcode</th>
</tr>
</thead>
<tbody>
<tr>
<td>Title</td>
<td>Firstname</td>
<td>Lastname</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

GP:

<table>
<thead>
<tr>
<th>Practice Name</th>
<th>Address Line 1</th>
<th>Address Line 2</th>
<th>Address Line 3</th>
<th>Town</th>
</tr>
</thead>
<tbody>
<tr>
<td>County</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Date

GP Name

<table>
<thead>
<tr>
<th>Address Line 1</th>
<th>Address Line 2</th>
<th>Address Line 3</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Choose File: ExampleDocument.txt
No file chosen
Choose File: ExampleDocument.txt
No file chosen
What the GP sees
Data is pseudonymised

• No identifiable patient information is stored in FARSITE
• Medical data about patients is pseudonymised
  – Name removed
  – NHS number removed
  – Date of Birth translated to Year and Quarter
  – Postcode translated to Super Output Area
• Only aggregated results are displayed
  – Values <6 are not returned
• Identification service returns patient information only when needed and only for valid users (GPs)
Design: Picking the right codes is hard

Protocol Criteria

- Asthma (disorder) (H33..)
  - Exercise-induced asthma (disorder) (173A.)
  - Asthma without status asthmaticus (disorder) (XUGPV)
  - Chemical-induced asthma (disorder) (XUNpV)
  - Mixed asthma (disorder) (H332.)
  - Asthma unspecified (disorder) (H33z.)
  - Asthma NOS (disorder) (XE0YX)
  - Pneumopathy due to inhalation of other dust (disorder) (H44..)
  - Brittle asthma (disorder) (Ua1AX)
  - Childhood asthma (disorder) (X101t)
  - Late onset asthma (disorder) (X101u)
  - Hay fever with asthma (disorder) (X1020)
  - Non-allergic asthma (disorder) (XE0YT)
  - Asthma attack (disorder) (XE0YW)
Need to be able to define and share understanding

### Asthma (QoF Register) (Common Criteria)

<table>
<thead>
<tr>
<th>Name</th>
<th>Asthma (QoF Register)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Creator</td>
<td>lucy</td>
</tr>
<tr>
<td>Created</td>
<td>04/11/2010</td>
</tr>
</tbody>
</table>

#### Protocol Criteria

- Asthma (disorder)
- AND NOT Asthma resolved (finding)

#### Sharing Options

Other users are allowed to see this common criteria
Feasibility Results

- Tested against studies currently in recruitment
- Results show poor recruitment where FARSITE shows low results
- Results also verified for individual practices by comparing local query results with FARSITE results
- GM CLRN working with a pharmaceutical company protocol to assist in designing where recruitment expectations can be shown to be realistic and quantifiable
Study 1

• Ongoing study recruited <10 patients in 12 months
• FARSITE identified max of 60 patients in area
Study 2

- Ongoing study with poor recruitment
- FARSITE identified ~1500 patients in area
- FARSITE confirmed local clinical practice not as required for study (as expected by local clinicians)
- Study redesigned...
Next Steps

- Test and prove recruitment with DRN and GM CLRN
- Develop use of system with national data by working with national DRN on Pathfinder project
- Work with other CLRNs to develop additional feasibility and recruitment databases
- Investigate other uses, e.g. re-use to provide GPs with same tools for own populations
Further details...

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