FARSITE for Healthcare e-Labs: Clinical Study Feasibility and Consent Architecture

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This Talk

• Healthcare need for e-Labs

• Efficiency & governance of clinical studies

• Mobilising clinical study communities
Problem: Ravines of Healthcare Communication & Organisation

Self Care

Primary Care

Hospital A

Clinical Care

Secondary Care

Hospital B
Disease Knowledge Bridges: Integrated Care Pathways

Self Care

Primary Care

Clinical Care

Secondary Care

Hospital A

Hospital B
**Missing:** Patient & Community
‘Big-picture’ Across Pathways

Self Care

Primary Care

Hospital A

Clinical Care

Secondary Care

Hospital B

\( \Pi = \text{Avatar} \)
Pulling evidence together into one, realistically-complex model: e.g. MRC IMPACT II

Outputs: Population-based incidence, prevalence; Deaths prevented; Life-Years; Life expectancy; Costs; Cost-effectiveness ratios
Unified Open Models

Current

Researchers
Modellers
Policy Makers
Practitioners

Separate Thinking

Future

CLAHRC Systems

Software Engineers
Statisticians
Health Economists
Healthcare Managers
Epidemiologists
Clinicians
Public Health Workers
Peer Reviewers

Expert Interfaces

Unified Open Model

Leading Methodology
Local Scenario Planning
Open to Scrutiny

Co-thinking
Sufficient input for unified models?

Natural Experiments of Healthcare

Healthcare Evidence Base
Digital Dust (data deposit > use)
Cloud of millions of care messages in the **local health economy**

Organise

**Structured Data**

Transform & Examine

**Structured Data & Metadata**
NHS e-Lab: Salford Pilot

- Real-time Data Repository in PCT
- Anonymised Data Repository in PCT

Outputs

- Optometrist
- Eye screening
- Community nurses
- Podiatry
- Deaths, Demographics etc.

- Sense-making software & support

- Person-identifiable and sensitive information removed

- Trusted person poses question(s)

- 24-hourly updates

- Biomics Data

- Link on NHS number

- Firewall
Anaemia at lower levels of kidney impairment than commonly thought

Clinical (audit) question leading to scientific finding:
required local metadata (assay change) not in national datasets
Unclear Public Good

Audit; Research; Intelligence

De-identify

Linked Health Records

Clear Public Good

Research & Decision Objects

e-Lab for a defined community

Local Ownership

Asset Enrichment

Linked Health Records
Research Objects: Currency of e-Labs

Workflows

Collections of Outputs

Services

Encapsulated → (DAG) discovery?
Typical Health Sciences Signal Path

Problem Space

Observation Space

Data Space

...like squinting at an image through a doyley and prism

e-Lab must harness observers & thinkers not just data & methods
Trust & Benefit in Research across Health Records

Now
Database-centred

Clinical

x Health Agencies

Clinical Information Governance

Research Governance

Ethical Oversight

Research

x Research Agencies

Future?

e-Lab: Community-centred

Anonymised e-Lab

Integrated Health

x Health Communities
Federation: More local use → better quality data

Federation of e-Labs → sharing tools, know-how and insights

Sum (Making sense of local healthcare) = quicker, more comprehensive insights
Major Issues with Clinical Studies

- Bias & generalisability
- >50% over-run
- >30% don’t hit recruitment targets
- Unrealistic feasibility assessment
- Consent-management confusion
openCDMS

An Open Source System for:

• multi-centre remote electronic data collection;
• highly configurable security system employing Role Based Access Control;
• fully customisable data set definition including data elements, validation rules and scheduling;
• fully configurable online randomisation with email and SMS text message notification;
• project management reporting including recruitment, completion and UKCRN accrual;
• on-line and off-line data collection;
• flexible query system for identifying eligible trial participants and nested case-control studies;
• designed for compliance with 21 CFR part 11; EMEA GCP; ISO 27001
openCDMS in use

• PsyGrid study – cohort of 700+ schizophrenics followed from first episode for 18 months

• Running numerous mental health trials

• ADDRESS – Type I+II diabetes 10y cohort study

• DARE – Diabetes cohort (phenotype and genotype)
Investigator-shaped data capture
Clean Data

Test Hypothesis

Explain Results

Publish

Fuse Data

± Link External Data

± Collect Observations

Recruit Participants

Test Feasibility

Seek Ethical Approval

Design Study

Generate Hypothesis

Governance

(Helsinki & local)
Managing clinical studies

Making sense of local healthcare

openCDMS clinical data management system

+ community

e-Lab
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.
FARSITE

Feasibility Assessment

and Recruitment System

for Improving

Trial Efficiency
Study Protocol (sponsor)

+/− Tweak

Recruitment Estimate (researcher)
[de-identified records]

Refined Search

Email to attending clinicians
“Click to identify your eligible patients”

[health e-record]

Study Management (identifiable)

Study Management (e-Lab: de-identified)

Rapid, Consistent Feasibility & Audit

F I R E W A L L
Realistic Recruitment Estimates

### Patient Search

**How to search:** (more...)

- **Match all conditions**
- **Match any condition**

<table>
<thead>
<tr>
<th>Condition</th>
<th>Comparison</th>
<th>Value</th>
<th>Add Remove</th>
</tr>
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<tbody>
<tr>
<td>Hba1c</td>
<td>less than</td>
<td>100</td>
<td></td>
</tr>
<tr>
<td>BMI</td>
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</tr>
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<td>is</td>
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<td>Year of Birth</td>
<td>greater than</td>
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</table>

[Search Clear]
Multi-site clinical studies management = e-Lab plug-in federation
Conclusions

• e-Labs of de-identified health records support rapid feasibility assessment for trials

• Rapid recruitment can be achieved without breaking consent-for-consent

• The care-research boundary is a federation of local communities – an open research frontier
If only they had an e-Lab...

Methods ↑

Contextual expertise ↔

Data ↑↑↑↑