Research Capability Programme

NHS-HE Forum, 22\textsuperscript{nd} April 2009

UPDATE

Alex Markham
Research Capability Programme - SRO
What is the Research Capability Programme?

It is a formal programme of work within NHS CFH looking at how information held in the National Programme for IT systems may be used for research purposes.

It will take forward the recommendations in the “Report of Research Simulations” produced by the UKCRC Advisory Group to NHS CFH.

It has a Senior Responsible Owner, who is a nominee of the DH Director-General of R&D. A programme board and external reference group provide strong governance.

The primary objective is to enable research to achieve its full potential as a “core” activity for healthcare, alongside other uses of NHS data that lead to improvements in the quality and safety of care.
Background

- Dec 2005 – Chancellor’s commitment
- Jan 2006 – DH strategy *Best Research for Best Health*
- July 2006 – R&D advisory group to NHS CFH established by UKCRC
- June 2007 – UKCRC R&D advisory group report
- August 2007 – CRDB SUS working group report
- August 2007 – Research Capability Programme initiated
- September 2007 – Health Select Committee Report
Guide to Acronyms

UKCRC – United Kingdom Clinical Research Collaboration
CRDB – Care Record Development Board
NIGB – National Information Governance Board
NHS CRS – NHS Care Records Service
SCR – Summary Care Record
DCR – Detailed Care Record
SUS – Secondary Uses Service
R&D – Research and Development
Recent Reports discussing access to Personal Information

- “Personal Data for Public Good: using Health Information in Medical Research” (2006), http://www.acmedsci.ac.uk/images/project/Personal.pdf;
- “Towards Consensus in the use of Electronic Patient Records for Research in General Practice” (2008), the Wellcome Trust;
- The “Health Informatics Review” (2008), http://www.dh.gov.uk/en/Publicationsandstatistics/Publications; and

Also, a variety of changes in relevant legislation…….
Research Capability Programme

High level overview:
- Enabling Phase, August 07-June 08
- Implementation Phase, July 08-March 09 and beyond
- Key Partnerships
- Key Deliverables
- Key Challenges
Enabling Phase

Has achieved:

• Appointment of Programme Chair (SRO) and Group Programme Director
• Establishment of a Programme Board
• An agreed phase 1 *Programme Initiation Document*
• Agreed terms of reference for an *External Reference Group* operating under the aegis of the Office for Strategic Co-ordination of Health Research (OSCHR)
• Engagement with *stakeholders* to create a common vision
• Substantial progress on the recommendations identified in the UKCRC report
• A defined scope of work for the Programme and for related initiatives
• Production of a high level requirements documentations *PD00 to PD20*
• An approved *Strategic Outline Case*
• An agreed *Programme Initiation Document* for the Full Programme
• Development of the genesis of an *Outline Business Case*
• Completed an Office of Government Commerce *Gateway 0* review
**We produced a total of 21 documents running to about 800 pages in the Enabling Phase via 6 work streams**

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<th>RCP work streams</th>
<th>Areas of focus</th>
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<td>Infrastructure</td>
<td>Honest broker(s) and business model, Safe havens</td>
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<td>Functional scope</td>
<td>Services to be provided centrally; business models</td>
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<td>Data quality and standards</td>
<td>Data standards, terminologies, options for linkage of datasets</td>
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<td>Technical architecture</td>
<td>How data will be stored and accessed</td>
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<td>Information Governance</td>
<td>Data security and measures to manage the threats, patient consent</td>
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<tr>
<td>Communications and stakeholder engagement</td>
<td>Initial consultation exercise; communications with public/physicians and with research community</td>
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RCP Data Sources?

- Assessing feasibility of:
  - Demographic Data (NHS patient index)
  - Vital events (births, deaths)
  - Primary care clinical records (GP system extracts, research collections)
  - Secondary care clinical records (Hospital system extracts, research collections)
  - NHS National Data Collections (HES/MHMDS)
  - NHS CRS National Systems (Summary Care Record, Choose and Book, Electronic Prescription Service)
  - Disease Registries (National and Regional)
  - Diagnostic data (Laboratory tests)
  - NHS Specialist Collections (Clinical Audit)
  - Other data collections (research datasets, education, social care, deprivation, socio-economic)
Functional scope: those research capabilities that the RCP aims to deliver

RCP will increase data available; provide services to support research; and provide services to reduce the need for identified data.

**In scope**
- NPfIT data and systems
- Access to other healthcare data
- Catalogues
- Linkage mechanisms
- Functions to reduce need for identified data

**Out of scope**
- Access to non-English NHS data
- Research services
- Support for the detailed operation of research studies

Health Research Support Services (HRSS): the overall solution provided by the programme.
Examples of services that are within the scope of the RCP would include:

- Negotiating agreements with current data custodians for existing databases to be made available through the HRSS
- Developing new linkages between a GP database and a secondary care database such that the combined data can be used for research
- Providing access to data sources
- Providing regular reports from new datasets built on systems being established within the NPfIT
- Storing and archiving data
- Verifying data
- Providing cohort management services
- Anonymising or coding data
- Re-identifying individuals from coded data
…but these cannot be seen in isolation: they build upon what we have now and what is being developed

Examples

<table>
<thead>
<tr>
<th>Building on what we have now now:</th>
<th>Building on what is coming...</th>
<th>Building on what is coming...</th>
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<tr>
<td>Excellent primary care data</td>
<td>Honest broker</td>
<td>Information on prescriptions dispensed (ETP)</td>
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<tr>
<td>Some hospital data, eg HES</td>
<td>Infrastructure</td>
<td>Imaging data (PACS)</td>
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<td>Clinical Research Networks</td>
<td>Linkage and anonymisation services</td>
<td>Use of a unique patient identifier</td>
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<td>Governance on use of data</td>
<td>Access to data sets</td>
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<td>Catalogues and advice</td>
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<td>Standard costs for clinical trials</td>
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<td>Streamlined study approval processes</td>
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Data on cohort studies

Predefined processes for research approvals (including scope, ethics, funding and agreement to proceed)

Study management interface receives request for information required for the studies and validates the request to confirm the scope and nature of the data required

Cohort Management Function

Data sources (NCRS, SUS, GPRD etc)

Meta Data Services

Linkage Mechanism

Anonymisation / Pseudonymisation Services

Linkage Services

Study output stored as snapshot or raw data plus query

Final output to the researcher

Set of analytical tools for the researcher to use on the study output

Study finishes and output plus report is archived

LEGEND

- Denotes in place now
- Early Deliverables
- Organisational component
- Data sources
- Final deliverables
How were stakeholders engaged?

Representation on the External Reference Group:
The External Reference Group has been established and has common membership with the OSCHR E-Health Research Board, as well as the same chair, in order to ensure coordination of activities. It includes representation from a wide range of stakeholders (academia, ABPI, BIA, NHS etc) as well as Patients/Public Reps and UK Devolved Administrations.

A public consultation
To test the findings and recommendations of the CRDB SUS working group report with professionals and patients and to probe public attitudes towards the use of medical information for research purposes. Launched September 2008. Report completed March 2009. Currently with Ministers for approval.
I hope you were able to respond.

Series of Town Meetings, Spring and Autumn 2008
Regular presentations to a wide range of interested stakeholders
## Research Capability Programme

### External Reference Group Membership

<table>
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<tr>
<th>Name</th>
<th>Institution/Role</th>
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<tr>
<td>Professor Ian Diamond</td>
<td>ESRC</td>
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<tr>
<td>Dr Richard Barker</td>
<td>ABPI</td>
</tr>
<tr>
<td>Rob Thwaites</td>
<td>GSK</td>
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<tr>
<td>Dr Cathy Emmas</td>
<td>Astra Zeneca</td>
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<tr>
<td>Dr Charles Brigden</td>
<td>Amgen</td>
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<tr>
<td>Dr David Roblin</td>
<td>Pfizer Global R&amp;D</td>
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<tr>
<td>Dr Paul Cloud</td>
<td>GE Healthcare</td>
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<tr>
<td>Dr John Parkinson</td>
<td>GPRD, MHRA</td>
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<tr>
<td>Professor Ronan Lyons</td>
<td>HIRU</td>
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<tr>
<td>Professor Tony Avery</td>
<td>University of Nottingham</td>
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<tr>
<td>Professor Frank Sullivan</td>
<td>University of Dundee</td>
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<tr>
<td>Professor Rory Collins</td>
<td>UK Biobank University of Oxford</td>
</tr>
<tr>
<td>Professor Carol Dezateux</td>
<td>ICH, UCL</td>
</tr>
<tr>
<td>Professor Paul Elliot</td>
<td>Imperial College</td>
</tr>
<tr>
<td>Professor John Williams</td>
<td>University of Swansea</td>
</tr>
<tr>
<td>Dr Louise Wood</td>
<td>NIHR</td>
</tr>
<tr>
<td>Dr Tim Hubbard</td>
<td>Wellcome Trust Sanger Centre</td>
</tr>
<tr>
<td>Dr Janet Valentine</td>
<td>MRC</td>
</tr>
<tr>
<td>Christine Vial</td>
<td>Patient / Public Member</td>
</tr>
<tr>
<td>Tony Sargeant</td>
<td>Patient / Public Member</td>
</tr>
<tr>
<td>Nick Partridge</td>
<td>INVOLVE</td>
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Research Capability Programme
Board Membership

Professor Sir Alex Markham (Chair) University of Leeds
Professor Ian Diamond                 Economic and Social Research Council
Professor Michael Thick               NHS Connecting for Health
Dr Louise Wood (Observer)            Department of Health
Jeremy Thorp                        NHS Connecting for Health
Marc Taylor                         Department of Health
Peter Knight                        NHS Connecting for Health
Marie von Hildebrand                Patient and Public Involvement
OSCHR

Strategic oversight of research-related activities

OSCHR e-Health Research Records Board

• Advisory group to OSCHR on e-Health Research Records
• External Reference Group for NHS CfH Research Capability Programme
• Forum for developing activities jointly funded with non-government stakeholders-UKCRC

NIHR Information Systems Programme

DH RDD

NHS National Programme for IT Programme Board

NHS Connecting for Health Research Capability Programme

• Manages infrastructure programme enabling research and analysis to improve quality and safety of care
• Ensures research input to SUS, SIP, NHS NP, ISB

Information Standards Board

NHS CIH Comms & Stakeholder Engagement

Chief Clinical Officer and National Clinical Leads

Service Implementation

Secondary Uses Service

NHS Number Programme

National Information Governance Board
**Full Programme Stages**

Implementation Programme

- Stage 1 – Procurement, Pilot and Proof of Concept
- Stage 2 – Mobilisation
- Stage 3 – Building the infrastructure
- Stage 4 – Federating data sources
- Stage 5 – Transfer to Business as usual
- Stage 6 – Programme closure and benefits realisation
RCP Implementation Phase

- Strategic Outline Case
- Outline Business Case
- Output Based Specification 1
- Output Based Specification 2
- Full Business Case
- Office of Government Commerce, Gateway Reviews
- Financial Approval Processes: NHS CFH, Department of Health, HM Treasury
- Pilot Studies
- Procurement
- Ongoing role for ERG/OSCHR E-Health Records Research Board
- Funders’ Forum
- Continuing engagement with the research community
RCP – Full Programme Stage 1

The Programme structure:

- Business Cases and Procurement Project
- Commissioning of the IG Services Programme
- Pilot Programme
- Public Consultation Project
- Programme Communication
- Programme Assurance
RCP Key Partnerships

**Established Players** (in no particular order):
- Other NHS CFH Programmes
- NIHR IT Programme
- UK Biobank
- Secondary Uses Service
- The Information Centre for Health and Social Care
- GP Research Database/MHRA
- QResearch and other primary care datasets
- GP Extraction Service (Information Centre for Health and Social Care)
- Office for National Statistics/Registrar General
- Public Health Observatories
- National Cancer Intelligence Network
- University Health and Medical Librarians Group
- NHS-HE, Janet/N3 Forum

........and many, many others.
RCP Key Partnerships

The Research Communities

• Public Health Researchers
• Observational Epidemiologists
• Clinical Trialists
• Health Services Researchers
• Pharmaco-”vigilantes”/ Post-marketing Surveillance
What challenges do we face?

• Ensuring the opportunities are maximised
• Developing better linkage between new and existing databases
• Data quality and standards
• Information Governance:
  – Patient confidentiality;
  – Access – who, when, where, what, how, why;
  – Pseudonymisation / anonymisation; and
  – Patient consent and “consent for consent”.
• Consolidating different stakeholder views e.g. professional vs patient groups or across different professional groups
RCP Key Challenges

Concepts that several colleagues in this area are addressing:

- Honest Brokers
- Safe Havens
- Trusted Third Parties

……..changing the terminology might help
RCP Key Challenges

INFORMATION GOVERNANCE

• National Information Governance Board (NIGB)/PIAG
• DH Chief Information Officer
• DH Information Policy Unit
• Information Commissioner
• General Medical Council
• British Medical Association
• Medical Royal Colleges
• Medical Insurers
• Caldicott Guardians
• SHA Chief Information Officers
• Public Health Observatories
• NHS CFH Information Governance Board
• Director, NPfIT
• Chief Statistician etc, etc, etc

...all set against a bewildering assortment of legislation..... and Parliamentary Statements as to what the laws are supposed to mean.....and conflicting views as to how the Parliamentary Statements are then to be interpreted
Research Capability Programme Key Challenges

• This is not going to be easy!!
• Essential to maintain stakeholder support and momentum
• Thank you for your invitation and in anticipation of your support in the future.