Clinical e-Science Framework

Security and Confidentiality Approach

All Hands Meeting - 4th September 2003
Dr Dipak Kalra, UCL
on behalf of the CLEF Consortium
A Convergence of Need

Need for more and better clinical information

Evidence based health care

Clinical Practice, Audit & Governance

Post genomic research

Clinical trials recruitment
CLEF’s Goals

- Collect clinical information from multiple sites
- Analyse, structure and integrate it
- Make it available using GRID tools (e.g. myGrid)
- To authorised clinicians and e-Health scientists
- In a secure and ethical collaborative framework

Ethical oversight committee
The CLEF repository has to be:

• scalable to populate
  – capable of incorporating large numbers of fine grained personal health records
  – from many different clinical systems in primary, secondary and tertiary care
  – each longitudinally linked so that the CLEF record can grow as each actual patient's care progresses

• widely accessible to distributed research teams across the UK and ultimately internationally

• conformant to ethical and legal requirements
The CLEF ethics approach

1) de-identify the data
2) depersonalise the parts of the record which are most vulnerable to revealing who the patient is
3) still treat the data as having some small potential risk of re-identification
   regulate, restrict and monitor access
Reidentify
By Hospital

Depersonalise

Extract Information

Integrate & Aggregate

Significant clinical information identified in text
(e.g. diagnoses, drugs, clinical findings etc...)

Less obvious identifiers removed from text
(e.g. occupation)

Obvious patient names & identifiers masked by source hospital

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Pseudonymise in Hospital

Construct 'Chronicle'

References reconstructed between information
(e.g. Problem X was discovered during Investigation Y)...

Individual Summaries & Queries

Summarise & Formulate Queries

Knowledge enrichment

Hazard monitoring

Privacy Enhancement Technologies

Researchers invited to notify possible reidentification risks

...and also contribute additional information
(e.g. adding never stated diagnosis of anaemia if blood results suggest it)

Ethical oversight committee

Hospital exports its electronic records of regular clinical practice

Information extraction informed by data already in repository

Clinicians from original hospital can view summaries and query the repository...

...and reidentify specific patients, only with permission

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Ethical oversight committee

Clinical e-Scientists connected by Grid...query the repository for e.g. numbers of patients with specific diseases.

All interactions between e-Scientists and repository approved and monitored by ethical oversight committee.

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ROYAL MARSDEN NHS TRUST - PATIENT CASE NOTE
324A621F:MRS Dorothy Smith
DOB: 12/05/44
21, Park Crescent
Basingstoke B12 Q13

16 Dec 1992   Seen in General Surgical

This lady who has had a mastectomy and left open capsulotomy and removal of her prosthesis was seen by me in the clinic today on behalf of Mr Peterson. She has extensive bony lymphoedema in her left arm which does not seem to be getting any better although she is more or less reconciled to the problem. The original problem was that she complained of shooting pain in the direction of ulna nerve and although there does not seem to be any evidence of local, regional or distant recurrence the pain itself warrants management in a pain clinic. Mrs Smith could be seen in the pain clinic at the Marsden but as this would involve a lot of travelling would like to be treated nearer her home. I wonder whether it would be possible for you to investigate if there is a pain clinic available at Basingstoke as I am sure Dotty could be treated and benefit from its management. I have otherwise arranged for her to be seen in the clinic again in a year's time. There are no signs of recurrence at this time.

Mr Thomas Partridge
This lady who has had a mastectomy and left open capsulotomy and removal of her prosthesis was seen by me in the clinic today on behalf of Mr Peterson. She has extensive bony lymphoedema in her left arm which does not seem to be getting any better although she is more or less reconciled to the problem. The original problem was that she complained of shooting pain in the direction of ulna nerve and although there does not seem to be any evidence of local, regional or distant recurrence the pain itself warrants management in a pain clinic. XXXXXXXX could be seen in the pain clinic at the XXXXXXXX but as this would involve a lot of travelling would like to be treated nearer her home. I wonder whether it would be possible for you to investigate if there is a pain clinic available at XXXXXXXXXXX as I am sure Dotty could be treated and benefit from its management. I have otherwise arranged for her to be seen in the clinic again in a year's time. There are no signs of recurrence at this time.
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AB 1992  

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Extraction of key information into record structure

Radiology, pathology and other narrative reports

Information from laboratory and pharmacy systems

Interventions
- left open capsulotomy
- management
- management
- mastectomy
- removal of her prosthesis
- no signs of recurrence
- bony lymphoedema
- pain
- recurrence
- shooting pain in the direction of ulna nerve
- local, regional or distant
- left arm
- pain clinic
- General Surgical pain clinic
- pain clinic
- pain clinic
- clinic
- today
- a year’s time
- at this time

Problems

Problem Site

Locations

Time

Extracted information collected... across multiple documents
Access for e-Scientists

Cumulative repository is made accessible for remote querying by e-Scientists… …under control of oversight committee.

Once user is authenticated, level of access authority is retrieved from oversight committee.

Digital certificates issued per session.

Users of this site are bound by:
CLEF Privacy Policy
CLEF Security Policy
Data Protection Act
Medical Records Act

Use is monitored by the CLEF Ethics oversight board.
Male patients with adenocarcinoma of the breast were found. After 5 years, 20% (n=158) of patients who had a daily treatment were alive. After 5 years, 10% (n=49) who had alternate day treatment were alive. After 5 years, 5% (n=27) of the patients who had no treatment were alive.

Queries on small patient groups are blocked or the figures blurred. Further subanalysis on small groups increases the risk that a patient may be identifiable.

Queries logged, threats to confidentiality monitored.

With special authorisation researchers may examine individual records in anonymised form.

Graphical ‘time line’ view of CLEF Chronicle

Textual summary of CLEF Chronicle for patient #17
Female patients with adenocarcinoma of the breast with age at diagnosis less than 30.

Percentage of patients alive after 1 year and after 2 years and after 5 years.

Patients who received radiotherapy daily, compared with patients who received radiotherapy every other day and those who received no radiotherapy.

1792 patients diagnosed with adenocarcinoma of the breast were found. 788 had radiotherapy daily, 513 had it on alternate days and 491 had no radiotherapy.

After 5 years, 20% (n=158) of patients who had a daily treatment were alive. After 5 years, 10% (n=49) who had alternate day treatment were alive. After 5 years, 5% (n=27) of the patients who had no treatment were alive.
Intended final security results

• A validated approach
  – accepted by MREC, PIAG, and other stakeholder groups (BMA, GMS, NHS, etc.)

• Exemplar policies and procedures
  – Ethical Oversight Committee
  – employee/researcher contracts
  – safe data extraction
  – access controls

• Open source tools
  – mechanisms to support security
  – active monitoring of use, limiting risk of inferential attack