Ethical Issues in E-Science
The View From Clinical Genetics

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Starting a Project
The Mountain of Paperwork

- R+D approval
- MREC approval
- LREC locality approval
- Data protection
- Honorary contracts
- Caldicott
- PIAG

Wouldn't it be better if it all just blew away?

It is important to distinguish the beurocracy of ethical approval from ethical behaviour.

Typical E-Science Grant Proposal

We are going to collect a large amount of patient data, access it via the GRID and do something interesting with it.

Key words: Data Mining, GRIDS, Object Oriented Database

Inputs to a Medical Research Database

Clinical Information
High Quality
Many Patients

Death Certificates
Birth and Marriage Certificates
Hospital Discharge
Laboratory Investigations

Cancer Registry

Large Database Projects

- Open Ended Research Question
  - Cannot specify nature of study at point of consent
- Indefinite storage of data
- Open access to data
- Complete anonymisation of data impossible
  - Family structure
  - Genotypes
  - MRI scans
  - History
- Can infer important clinical information from data available
Example Data: The Family Tree

Jean 45  Helen 60  Fred 62  Anne 55

Jean 35  Angela 38

The Family Tree
What The Patient Sees

Jean 51
Cancer

Helen 60
Fred 62
Anne 55
Breast CA 40

Jean 35  Angela 38

The Family Tree
Clarified by a Geneticist

Jean 45
Ovarian Cancer 42

Helen 60
Fred 62
Anne 55
Breast CA 40

Jean 35  Angela 38

The Family Tree
What The Geneticist Sees...

Lifetime Breast Cancer Risk

Jean 45
Ovarian Cancer 42
30%

Helen 60
Fred 62
Anne 55
Breast CA 40
40% 40%

Problems Surrounding Family History

• Storage of information on individuals without their consent
• Not easy to preserve family structure and important details when anonymising data
• Important clinical observations are made from data derived on individuals who do not know they are being observed
• It does not take much data to reach worrying conclusions

Other data
E-Diamond Specific Issues

• Mammograms available on GRID
  - Security and access
• Matched with some clinical data
  - Effective anonymisation
• Type of analysis not pre-determined
  - Is informed consent possible?
• Possible Risks of Participation
  - Previously unidentified cancer
  - New risk factors derived from mammogram
EGC Package - Proposed flow of information

Anonymisation + Security

National research tools

Regional Database
- Clinical data
- Family tree data
- Screening data
- Multimedia Data (e.g., Mammograms)
- Pathology
- Microarray data

Request

Tabulated Data

Local research tools

Clinical Domain

Conclusion

- E-Science has a lot to offer medical research
- The ethical challenges are not trivial
- The paperwork is the least of the problems

Conclusion

Ethical design has to be inherent in the database

- System design has to take into account
  - Patient consent
  - Who accesses data (and who decides)
  - How the data is accessed
  - How the data is exported
  - How system use is policed