On the Importance of Intellectual Property Rights for eScience and the Integrated Health Record

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Introduction

• Use of data from primary health care
• eScience – new kinds of research
  – Use of medical data raising broader issues
• Integrated Health Record
• Legal frameworks that underpin these initiatives
  – Intellectual Property (IP)
  – How does IP relate to databases in IHR or eScience?
A Vision for Data

- **eScience**
  - New kinds of computational resources
  - New kinds of research collaborations
  - Building virtual organisations at a national or international level.

- **Integrated Health Record**
  - National accessibility

- **Making access seamless**

- **Making data mobile**
The Realities of Current Practice

- Data is shared for research
  - In mutually beneficial collaborations
- Trust & long term relationships
  - eg. with University depts, or specific researchers
- Commercial collaborations are also critical
  - Benefits for the participating clinic
- Data is a resource used to ensure maximum benefit for the health service
- *Ad hoc* local arrangements
- Current practice vs. eScience vision
Technology raises issues

• If data becomes accessible at a national level:
  – Who should be entitled to make deals with external researchers and organisations?
  – Who should benefit from such deals, and how?
  – What interest do external organisations acquire in shared data and do the rights of data custodians change?

• A lack of clarity on these issues could lead to:
  – An unwillingness to share data for research, or
  – costly litigation when conflicting claims arise
An eSocial Science Project

• IMaGE
  – Intellectual Property Rights in
  – Medical Data in
  – a
  – Grid
  – Environment

• Law, social science & computer science

• How future law should operate

• eDiaMoND
eDiaMoND Case Study

• Large interdisciplinary eScience project
  – £4.25m; 5 Universities; 4 NHS Trusts; 2 Commercial partners

• Focus on the UK National Breast Screening Programme

• Aim: “develop a next generation Grid enabled prototype to demonstrate the potential benefits of a national infrastructure to support digital mammography”
  – Expected shift from analogue to digital radiography
  – Manage digital images using eScience technology
The eDiaMoND Database

• Need significant quantity of patient data
  – 4 participating clinics; 4 participating universities; 1600 cases total
  – Data straight from patients and existing training archives
  – Digital and film-based equipment
    • scanning films, entering patient records; a significant task
  – Ethical clearance
Licensing of Data

• Most clinics contributed data freely to the project
• However, one requested formal IP terms & conditions
• Resulting 3-way negotiation took over a year to settle
  – Resulting in a complex pair of back-to-back collaboration agreements.
  – This uncertainty was highly problematic for the data collection effort.
Legal Issues: Introduction

- The basics: IP and photography
  - Owning a photographic print
  - Owning the copyright in the image

- Digital data and IP
  - Computers copy data in order to function
    - Ownership without copyright = stultification

- IP ownership is controlled by:
  - Custom and practice
  - Shaped by contractual licenses (formal or implied)
IP: Copyright

• Copyright Designs and Patents act 1988
  – Grants various exploitation rights to 'author' who 'creates' a work.
  – Originality, skill, judgement & effort are all important
  – Copyright usually granted to original author
    • True for independent contractors
    • But not for full employees
  – CPDA also governs copyright transfer and licensing
    • Licence form: written, oral, or implied by conduct
    • Licence type: exclusive or non-exclusive; full or partial.
eDiaMoND Contractual Structure
eDiaMoND Copyright Analysis

- Copyright in: mammograms, annotations, patient records.
  - Skill & judgement by clinical staff required in each
- Less clear if second layer of copyright exists in the scanned images & typed patient data
  - some skill required for reclassification of data.
- NHS Trusts (broadly) retain copyright
  - Explicit licence in one case (for specific purpose)
  - Implied licences elsewhere
    - But scope & duration of licence is hence unclear.
    - Ambiguity remains wrt independent contractors
IP: Database Law

• UK Copyright and Rights in Databases Regulations 1997:
  – Database: a collection of independent works, that are arranged in a methodical way, while remaining individually accessible.

• 3 tiers of legal protection for databases:
  – Copyright in their contents (described previously)
  – Copyright in the database design
    • Requires high standard of originality
  – Investment in gathering the data guarded by separate 'database right'
    • In recognition of risk & initiative therein
eDiaMoND Databases Analysis

- Overall eDiaMoND database
  - Claim to copyright in database
  - Claim to database right
    - However, in this mixed public / private partnership, it is less clear is who actually holds this right (likely shared).
- Existing training databases contributed by NHS Trusts
  - Could also claim copyright in database
  - And a database right
- Data taken 'straight from waiting room'
  - copyright & database right: seem weak or unlikely
The Current Situation

- eDiaMoND has finished
  - Ethical clearance has ended
  - Data has been archived
- What if ethical clearance was granted for further research?
  - Who has authority to control eDiaMoND data?
    - Implied licences are ambiguous.
    - Prudent to request permission again from every Trust?
  - Would this approach scale to a national level?
  - eScience vision of seamless sharing
Alternative Models for IP Ownership

- Vest ownership with NHS Trusts (*status quo*)
  - Tighten honorary contracts for ind. contractors
  - 'Grid Contract,' to achieve uniform policy?
  - Short term solution for eScience
- Vest ownership with Patients
  - Contrary to current law, and to current NHS policy on the exploitation of IP
- Vest ownership in a national organisation
  - Single body for the control & exploitation of data
    - But how to balance against local control and benefits?
  - Long term implementation through legislation
Conclusions

- Confusion over 'who owned the data' resulted in:
  - Time consuming negotiations
  - Disagreement over who controls future use of data

- Our aim: to develop models of ownership that maximise the benefits to all parties involved whilst protecting patient's rights.

- In sum, we believe a clear IP framework is vital to eScience and IHR.
And finally...

- If you, or people you know, are affected by the issues raised in this programme, or even if you'd just like to find out more...

- ...please do attend our symposium!

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