



Precision Medicine: Legal and Ethical Challenges

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Genetic Information and the Family: The Future of the Duty of Disclosure & The Limits of Confidentiality

Terry Kaan

Associate Professor, Faculty of Law
& Co-Director, The Centre for Medical Ethics & Law

A Joint Centre of the Faculty of Law & the Li Ka Shing Faculty of Medicine

The University of Hong Kong

kaan@hku.hk

<http://www.cmel.hku.hk>

Overview

- ✱ Work in progress on several disparate themes
- ✱ But in common - whether future technology will force a change of current paradigms in first-party relationships between physician-patient, and researcher-subject:
 - ✱ Disclosure in the physician-patient relationship
 - ✱ The limits of the duty of care of physicians in relation to holdings of genetic data
 - ✱ Any different for researchers?
- ✱ And in third-party relationships:
 - ✱ Is there a duty to warn 3rd parties?
- ✱ Implications for the future development of medical confidentiality

The Liability of Physicians

- ☀ The Agreement

- ☀ Easy to sequence
- ☀ But hard to interpret ...
- ☀ ... and expensive.
- ☀ So prudence dictates contractual limitation
- ☀ Unknowns and current technological limits favour the physician - causation
- ☀ But can contract override tort? Especially where physical harm / injury / death in issue?

The Liability of Physicians

☀ Disclosure

- ☀ Used to be simple.
- ☀ But not after *Montgomery Lanarkshire Health Board* [2015] UKSC 11
- ☀ *Bolam* shaken and restricted – duty of disclosure brought in line with Australian, NZ, Canadian approaches – logical refresh necessitated by rise of autonomy principle
- ☀ But other substantive changes under the hood may have greater impact down the road? – *Montgomery*: ‘doctor’s advisory role involves dialogue’ [90]

The Liability of Physicians

☀ Disclosure

- ☀ Continuing dialogue: if duty no longer liminal, what are its limits?
- ☀ A glass very darkly for now: but 10 years down the road, technology makes possible and commonplace analyses not possible now
- ☀ And give rise to new professional standards of prudence / good practice / SoPs
- ☀ Will it be a defence in 10 years time, if automated periodic screening of electronic medical and genetic records become routine – like screening for computer viruses is now?

The Liability of Physicians

☀ Dialogue

- ☀ But this is just the ground floor? With advent of cheap sequencing, inevitable that WGS becomes universal first / basic procedure (like asking for family history is now)
- ☀ Problem: Genomic data is qualitatively different from other clinical data, which are essentially snapshots of physiological function at particular point in time, may be predictively unreliable, subject to false negatives / positives, open to interpretation. But your book of life is definitive.
- ☀ What is not possible / reliable / known now will in the future be otherwise

And of Researchers & Data Holders

- ✴ And data holders?
- ✴ And researchers? Current refuge in arguments will fail in the future because of the certain and immutable nature of WGS data – it will be the same book read by clinicians
- ✴ Beyond WGS: epigenetics and human microbiomics
- ✴ Cautionary tale for data holders: in future, access and control of genetic data may come with legal responsibilities that blur the liability lines between physicians, researchers and data holders
- ✴ *Montgomery* still stuck on paradigm of a one-to-one physician-patient relationship in the law, but completely unreal in the context of HMOs, insurers, employers paying health benefits, the NHS?

And of Researchers & Data Holders

- ✦ As in medical negligence in England (and followers of *Bolam*), the liability battleground may shift to a reconsideration of the principles of causation and remoteness – where English common law has showed no reluctance in reworking liability in cases where physical harm or disease is in issue (*e.g. Fairchild v Glenhaven, Chester v Afshar*)
- ✦ But the law would also have to review its fundamental approach to the duty of care in negligence of parties other than physicians having a hand in the care of patients – and of their genetic data. Coming up ...

Third Parties

- ☀ Do third parties have a right to be warned of genetic vulnerabilities?
- ☀ Current English law on medical confidentiality premised on *AG v Guardian No 2*, *W v Egdell*, *X v Bedfordshire CC* etc – confidentiality *not* a legal privilege, a bare presumption in the public interest (not private interest) aimed at fostering full disclosure by patient to benefit of patient
- ☀ American developments such as *Tarasoff v UCLA* studiously ignored – liability for not disclosing threat of harm to 3P

Third Parties

- ✱ But main difference: genetic threats are *not* external threats – they are inherent threats in every sense of the word
- ✱ They are also shared
- ✱ But first shot across bow: *ABC v St George's Healthcare Trust* [2015] EWHC 1394 (QB)
- ✱ No doubt first of many. Huntington's - incremental approach to duty of care in *Caparo v Dickman* [1990] 2 AC 605 insisted on
- ✱ Claimant in *ABC* had to demonstrate that her claim could fit into an existing category of duty of care – or that her case was of that kind that merited an incremental expansion of an existing category – unlike previous *Anns v Merton* approach

Third Parties

- ✱ Current approach therefore denies possibility of entirely new categories – at odds with reality?
- ✱ But *Caparo* and its ilk deal with claims for pure economic loss – product of judicial concern for commercial certainty? – underlying policy considerations for the ‘closed categories’ approach in *Caparo* does not fit reality well
- ✱ Ethical codes around the world (GMC, HKMA etc) recognize that exceptions to confidentiality duty may be made on grounds of public safety , prevention of crime etc
- ✱ Is an inherent genetic risk to health or life any different?
- ✱ One difficulty: the right not to know

Third Parties

- ✱ Relational information: as healthcare IT systems move towards large-scale integration, what kind of liabilities may emerge from mere fact of possession or holding of information of many related persons?
- ✱ Working backwards: good to warn if we spot patterns in segment of general population, but as both segment and general population size decreases? What point does demands of privacy come into play?
- ✱ Shared information: Essential problem with genetic information is that is is by definition shared information – it is not wholly your own
- ✱ What common rights have groups of related individuals to this shared inheritance (which may be of commercial value)?

Third Parties

- ✱ What restrictions on individual rights if common shared rights of group is accepted?
- ✱ Return of benefits? Echoes of HUGO Ethics Committee - Statement on Benefit Sharing
- ✱ Consider: X., one of two identical twins, 'donates' his entire genome to science. What rights has Y. his identical twin?
- ✱ *Ragnhildur Guðmundsdóttir v Iceland* (2003) Supreme Court of Iceland (No 151/2003) – Health Sector Database Act successfully challenged
- ✱ Do current legal privacy paradigms premised on individual rights fit well with biological reality?

The Point of Privacy

- ✱ Nosy relatives and over-eager clinicians and researchers may be the least of your problems in the future: privacy laws have never deterred rogue states (and state entities), terrorists, criminals – and most of all commercial interests – from acquiring desirable or useful personal information
- ✱ The law is going to find it hard to catch up with future technology that allows sequencing from the tiniest traces of yourself
- ✱ The danger is that privacy paradigms for the future is driven by such concerns rather than the ultimate *raison d'être* for the concept of privacy: dignity and *welfare* of the individual.



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