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The Regulation of Genetic Testing & Protection of Genetic and Medical Information

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Overview

- My background and the approach in this talk
- Some legal notes on genetic information
- Parents: consent, disclosure, counselling
- Parents: Impact of Risks
- Children: What May be Tested For?
- The Right Not To Know

Background & Approach

- The Singapore National Bioethics Advisory Committee (BAC) http://www.bioethics-singapore.org
- The Human Genetics Subcommittee (HGS)
- Consultations and Reports
- Embryonic Stem Cells, Therapeutic Cloning, Human Tissue Banking & Research, Institutional Ethical Governance Framework – but Genetic Testing and Medical Information turned out to be more difficult!
- Approach – insights into how another jurisdiction approached issues, a survey of issues?

On Genetic Information

- Whether 'genetic exceptionalism' and special rules should apply: but reality is that difficult to draw line between 'genetic information' and 'non-genetic' medical information (e.g. family history, non-DNA tests, non-inheritable mutations, epigenetics?) – US Genetic Information Nondiscrimination Act (GINA) of 2008 definition includes family history
- Arguments centre on qualities such as immutability (unlike clinical presentation snapshots), possibility / certainty of expression (Huntingdon's), and relational implications and inherently shared nature of genes and genetic information – so is wider consent required?

On Genetic Information

- Dust has settled somewhat: at least clear that it is– Personal Data (Privacy) Ordinance (PDPO) personal and medical information and subject to minimum protection as such applies – no special get-out provisions, also special provisions such as Register A under Human Reproductive Technology Ordinance secrecy obligations
- PDPO obligations not trivial – criminal sanctions for breach, and administration overheads for compliance may be costly
- Collections not risk-free assets: potentially continuing legal liabilities, especially for genome banks, biobanks, clinical WGS collections

Consent - Parents

- Paramount requirement – but bear in mind that genetic information *never* relates just to the individual alone – relational information – wider implications for confidentiality obligations
- Testing without consent – *cf* s.45 UK Human Tissue Act 2004 (non-consensual testing of DNA) – crime, jail & fine – 'waste' tissue is not waste
- *quare* also civil liability in tort? (trespass as in *Moore v UCLA* (1990) – big unknown
- Both parents must consent? – *Cf* s.2.12.4 HKMC Code of Professional Conduct (216) – 'major or controversial medical procedures' – CPC says to consult your lawyers!

Consent - Parents

- Consent needs to be informed: must be adequate disclosure of risks (implications for parents, child, siblings of child, and potentially extended family)
- Disclosure now governed by stricter patient-centric standard laid down in *Montgomery v Lanarkshire Health Board* [2015] UKSC 11
- Note changes to in HKMC CPC s.2.10.2 on consent: (https://www.mchk.org.hk/files/newsletter22.pdf)
- Counselling integral part of the duty of disclosure?
- "Risks" no longer simply a question of physical harm – if results cause emotional distress, or breakup of family?

Consent – Parents - Risks

- Risks are real, and have real world impact: discrimination in employment (hence US GINA 2008) – employers' fear of medical claims / insurance / downtime costs - my own experience!
- *Quare* whether genetic disease or vulnerability fits Hong Kong Disability Discrimination Ordinance fits Ordinance's definition of 'disability'*

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* 'Section 2: **disability** (殘疾), in relation to a person, means—

... (c) the presence in the body of organisms causing disease or illness;

(d) the presence in the body of organisms capable of causing disease or illness;

(e) the malfunction, malformation or disfigurement of a part of the person's body;

...and includes a disability that—

(i) presently exists;

(ii) previously existed but no longer exists;

(iii) may exist in the future; ...'

Consent – Parents - Risks

- Risks are real, and have real world impact: discrimination in insurance – this impacts not only on the individual, but also for family members
- Places doctors (and potentially researchers) between a rock and a hard place when asked to give information with 'consent' of proposer – like you do for family history already!
- Battle for information just only beginning: insurers obviously want information relating to risks, but actuarial impact is still unknown

Consent – Parents - Risks

- Since 2001, the Association of British Insurers and UK Govt has agreed on a truce – renewable Concordat and Moratorium on Genetics and Insurance – updated in October 2018 for 'permanent' Code on Genetic Testing and Insurance
- Basic agreement not to ask for information, except scheduled genetic risks (presently only Huntingdon's) for large policies (>£500,000)
- Obligation of insurers to explain loading and actuarial assumptions?
- Followed in Singapore. Hong Kong?
- Real risk of discouraging research participation

Consent – Parents - Risks

- Counselling should extend to risks *and* management of incidental findings?
- What do we do, and what do you want us to do if incidental findings having direct implications for either health or objectives of test are discovered?
- Parents may need to be counselled separately and consent taken separately – *e.g.* 'paternity discrepancy' 'misattributed paternity', 'paternity fraud' will compromise basis of testing the child – cannot be ignored!
- Not an insignificant risk – 0.8% to 30% in some studies (Bellis *et al*, *J Epidemiol Comm Health 2005*, 59: 749-754), lower estimates probably more realistic

Consent – Parents - Risks

- Plenty of debate as to when disclosure warranted: Christenhusz *et al*, *Eur J Human Genetics* (2013) 21, 248-255; Hecher & Jamal, *Applied & Trans. Genomics* 8 (2016) 36-39
- Much better to sort this out in advance with parents?
- Incidental findings having implications for others in family? Where treatment or preventive measures possible?
- *ABC v St George's Healthcare* [2017] EWCA Civ 336 – pregnant woman allowed to proceed with claim against hospital for not telling her that her father had Huntingdon's (case yet to be heard).
- Obligation to tell others at risk? Stay tuned.

Consent – Children

- Nominal age of consent 18, BUT children *do* have a legal right to consent or refuse if legally competent to make the decision
- ***See HKMC s.2.12 (s.2.12.1-2.12.6) on consent relating to '*Child patients*' *** - breach takes you outside of the protection of the *Bolam* Rule
- 2.12.1: 'Consent given by a child under the age of 18 years is not valid, unless the child is capable of understanding the nature and implications of the proposed treatment' – paraphrases the well-established common law '*Gillick* competence' principle established in *Gillick v West Norfolk AHA* [1986] AC 112

Consent – Children

- See 2.12.2 – 2.12.4 for details: a vexingly complex judgment to make, fraught with ethical and legal minefields – here definitely be dragons
- The child's consent is especially relevant in relation to the right *not* to know (see later discussion)
- Perhaps should be especially cautious in cases of minors near the age of 18, and where delaying testing until majority is unlikely to present significant risks?
- Note that testing *must* be for the benefit of the child being tested: if testing for purposes of PTT, 'saviour sibling', PGD etc where info is for benefit of parents – check with your EC and your lawyers

Children – What May Be Tested For?

- Different answers in different countries - wide disparity between communities as to sensitivity of genetic information (*e.g.* Singapore vs Japan)
- Ethical considerations require that social, cultural, religious perspectives and sensitivities be respected
- Notable absence of hard law in most jurisdictions, general approach of professional guidance – better approach: although higher responsibility burden for doctors, allows greater flexibility and discretion
- Will not deal with confirmatory diagnosis, or populational genetic screening (*e.g.* G6PD)

What May Be Tested For? Some Approaches

- Carrier testing (no implications for the future in adulthood, but possible implications for reproductive fitness): argument is simply respect for the future adult dictates that no testing be carried out, on footing that disclosure can be made by parents of their own status on the child reaching age of majority – child can then make own decision whether or not to test
- Carrier testing where results have implications for parents (*e.g.* decision to have further children, or technologies like PGD) more difficult, but arguably right of child not to know trumps this

What May Be Tested For? Some Approaches

- [A] Testing for genetic conditions for which useful and effective interventions or management protocols are available in childhood: general agreement on allowing this, as being premised on the welfare of the child, particularly if early treatment can ward off catastrophic or greater disabilities:
  - Singapore BAC, *Genetic Testing & Genetic Research* (November 2005) http://www.bioethics-singapore.org/images/uploadfile/55211%20PMGT%20Research.pdf ('Singapore Genetics Report')
  - American Academy of Pediatrics, *Ethical and Policy Issues in Genetic Testing and Screening of Children* (2013 / 2018) https://pediatrics.aappublications.org/content/pediatrics/131/3/620.full.pdf ('AAP Policy')

What May Be Tested For? Some Approaches

- However, room for debate as to what constitutes 'useful' and / or 'effective'
- At what cost to the child – quality of life
- The degree of certainty of the benefit – is there a sufficiently strong association between the mutation and the disease
- The likely penetrance – few genetic disorders are as certain as Huntingdon's – most fall somewhere on the long, long tail of the bell curve …

What May Be Tested For? Some Approaches

- [B] Testing for adult-onset genetic conditions for which useful and effective interventions / management strategies are NOT available in childhood: general agreement that this should be discouraged, will not advance the welfare of the child, and will compromise her or his right not to know in adulthood (Singapore Genetics Report, AAP Policy)
- Wriggle room in AAP Policy for exception for 'families for whom diagnostic uncertainty poses a significant psychosocial burden, particularly when an adolescent and his or her parents concur in their interest in predictive testing' (at para 9). A Pandora's Box ...

What May Be Tested For? Some Approaches

- [C] Testing for genetic conditions for which no useful and effective interventions are available at all either in childhood or adulthood – *i.e.* nothing is available except symptomatic treatment when disease finally expresses itself: following from [B] and for carrier testing, same advice that testing should be discouraged?
- But parents may have other views: Shkedi-Rafid *et al*, 'Genetic testing of children for adult-onset conditions: opinions of the British adult population and implications for clinical practice', *European Journal of Human Genetics* (2015) 23, 1281–1285

What May Be Tested For? Some Approaches

- [C] Shkedi-Rafid *et al*:
  - 'Nearly half of the sample (47%) agreed that parents should be able to test their child for adult-onset conditions, even if there is no treatment or prevention at time of testing. This runs contrary to professional guidance about genetic testing in children. Testing for carrier status was supported by a larger proportion (60%). A child's future ability to decide for her/himself if and when to be tested was the least supported argument in favour of deferring testing.'
- A self-selected / biased sample? Should have asked children / adolescents / adults who faced such testing in childhood ...

The Right Not To Know

- Widely accepted principle applied to competent adults
- World Medical Association *Declaration of Lisbon on the Rights of Patients*:
  - Art. 7 'Right to information' – 'The patient has the right not to be informed on his/her explicit request, unless required for the protection of another person's life.'
- Similar expression in UNESCO *Universal Declaration of the Human Genome and Human Rights*

The Right Not To Know

- Consistent with current common law understanding of patients' right not to know and right to autonomy and self-determination *cf* R. Andorno, 'The right not to know: an autonomy-based approach' *J Med Ethics* 2004;30:435-440
- Clearly, a significant proportion of people at risk choose *not* to know (*cf* Andorno, above) – 'up to 80% for Huntingdon's'
- But recent push-back e.g. Berkman & Hull, *Am. J Bioeth* 2014 March: 14(3):28-31, where principle criticised as 'anachronistic' – but offer no compelling case, and verges on medical paternalism ('Who wouldn't want to know lifesaving information?')

The Right Not To Know

- Eagerness to use new genetic tools (particularly genomic databases) for research? Again, here be dragons …
- To summarize:
  - You need to consider who has the best right to the information;
  - Whether that person consents,
  - What it is to be used for;
  - For whose benefit;
  - Both law and the body of ethics are agreed on the right not to know on the principle of the right of autonomy and self-determination

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