



NUS
National University
of Singapore

Centre for Biomedical Ethics
Yong Loo Lin School of Medicine

Building Trustworthy Governance for Sharing Genome Data in Singapore

Tamra Lysaght PhD

Centre for Biomedical Ethics

Workshop on Genome Editing and Prenatal Testing

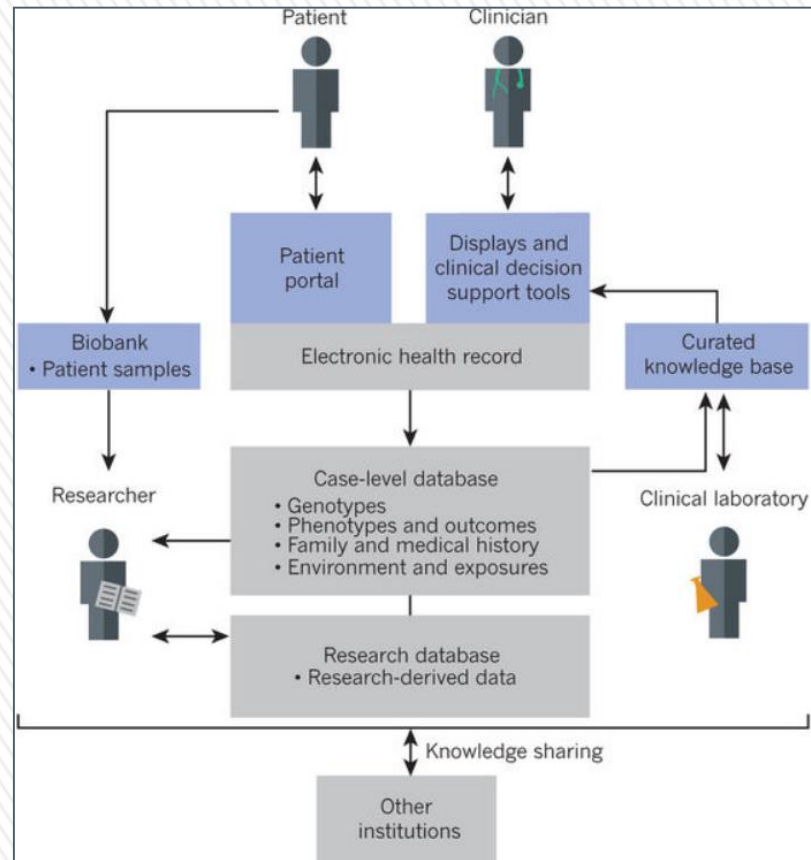
Centre for Bioethics, Chinese University of Hong Kong

Genome science initiatives

- **Genomics-driven precision medicine**
 - Tailoring health interventions based on underlying clinical, socio-demographic and genetic profiles
 - A*Star-funded programmes
 - SG10K Project
 - Platinum Asian Genomes
 - Big Data Analytics in Precision Medicine
 - POLARIS
 - NMRC-funded programmes
 - NUS Singapore Genome Variation Project
 - Duke-NUS Institute of Precision Medicine (PRISM)
 - NUHS Centre for Precision and Personalised Health (CPPH)

Precision medicine eco-system

- Data sharing-information flows



Soft infrastructure

- **Legislative framework**
 - **Personal Data & Protection Act (2013)**
 - Requires informed consent to collect, store & disclose personally identifiable data
 - Ex anonymised or de-identified data
 - Quasi-Privacy legislation
 - **Human Biomedical Research Act (2015)**
 - IRB review of all human subject and tissue research
 - Ex biological materials not individually-identifiable (eg. cell line)
 - **Private Hospitals and Medical Clinics Act (2007)**
 - Regulations for Electronic Medical Records

Non-discrimination laws

- **No legal protections against discrimination**
 - **Article 12 of the Constitution of Singapore**
 - Prohibits discrimination against Singapore citizens
 - "on the ground *only* of religion, race, descent or place of birth"
 - The law, appointment to public offices, and carrying on of any trade, business, profession, vocation & employment.
 - Discrimination may be permissible when one of these grounds in combined with another factor, such as age or state of health.
 - **Risks of harms from genetic discrimination**
 - Insurance
 - Disclosure of medical test results required
 - Disclosure of genetic tests results not required (yet)
 - Employers

Good Governance



Global Alliance
for Genomics & Health
Collaborate. Innovate. Accelerate.

- **Best practices for sharing genome data**
 - **Global Alliance for Genomics and Health (GA4GH)**
 - Framework for Responsible Sharing of Genomic and Health-Related Data (2014)
 - Principles for sharing genomic and health-related data
 - Respect Individuals, Families and Communities
 - Advance Research and Scientific Knowledge
 - Promote Health, Wellbeing and the Fair Distribution of Benefits
 - Foster Trust, Integrity and Reciprocity
 - **Policies & guidance on specific issues**
 - Intended to facilitate international norms
 - Interpreted in a manner that recognises local cultural practices and the different contexts for storing and sharing data.

Empirical research



- **Exploratory qualitative study**
 - **Inform ethical framework for consent**
 - Storing & sharing data from clinical tumour profile panel test with institutions in Singapore and abroad
 - Panel of 93 gene variants
 - 37 semi-structured interviews with patients and oncology clinicians at the National Cancer Centre (NCCS)
 - 11 clinicians within Singhealth
 - 26 cancer patients at the NCCS

Bylstra, Lysaght et al. Ethical Frameworks for Obtaining Informed Consent in Tumor Profiling: An Evidence-Based Case for Singapore. *Human Genomics*. Accepted Nov 2017.

Empirical research



- **Key findings**
 - **General support for broad consent**
 - Donors consent once to store data
 - Delegating decision-making authority for sharing data on specific projects to ethics committee/IRB
 - Only de-identified data should be shared
 - No sharing of personal information
 - **Concerns over misuses of data**
 - Potential for discrimination
 - *“I am assuming that nothing [personal] will be released to a third party without my consent. If my tumour profile indicates something and that is then used to discriminate against me in a job or something then that can be horrible.” (Patient 7);*

Empirical research



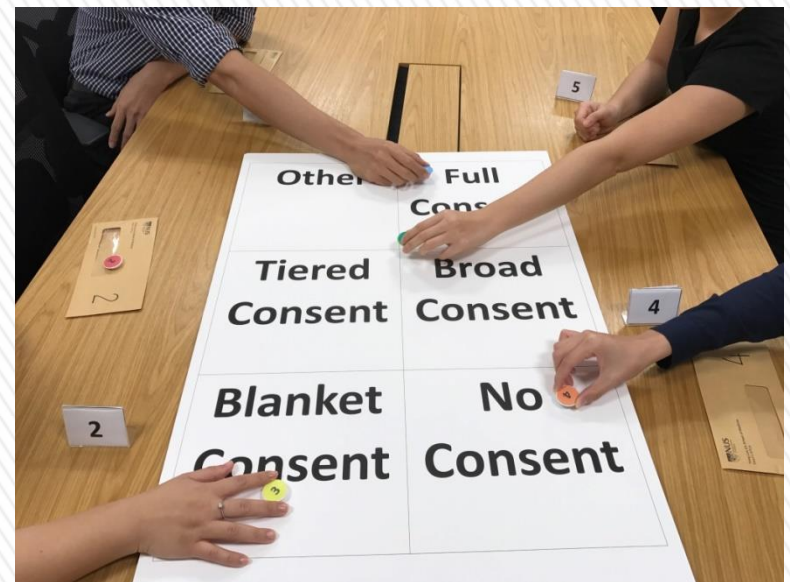
- **Key findings**
 - **Willingness to trust in local regulatory systems and public institutions**
 - Privacy breaches generally not a major concern
 - *“I think we are just not so paranoid [laughs]. We are used to living under a totalitarian [government].. Joking aside, most patients do not really care about privacy issues. All they can see if that their extra tissue is left aside is not my major personal data. They don’t really care”. (Clinician 3)*
 - **Socio-political context of Singapore**
 - Cultural norms accept public institutions accessing and storing their personal and health information
 - State interference in public/private spheres of life with paternalistic forms of governance
 - Comfortable in deferring decision-making to trustworthy sources, e.g. families, doctors, health care providers etc

Empirical research

- **Qualitative study**
 - **Integrating Ethics Policy in Precision Genomics**
 - Centre for Precision & Personalised Health (NUHS)
 - Humanities & Social Sciences Seed Fund (NUS)
 - PI – A/Prof Jacqueline Chin
 - Co-I – Dr Owen Schaefer
 - **Multi-institutional study with focus groups, interviews & stakeholder workshops**
 - National University of Singapore
 - National University Hospital
 - Singapore General Hospital
 - KK Women's and Children's Hospital
 - National Cancer Centre Singapore

Empirical research

- **Game board method**
 - **Eight focus groups & six interviews**
 - 56 participants
 - 29 Experts (genetics, oncologists, clinicians)
 - 27 lay persons (patients/carers)



Empirical research

- **Key findings**
 - **General support for broad consent**
 - Sharing non-identifiable data
 - More stringent (tiered) consent for sharing identifiable data
 - Donors can opt-out of sharing identifiable data
 - Concerns over discrimination harms
 - *“DNA is unique that information can ultimately point back to me, and it might affect my insurance policies for example, in the future, because insurance policies may be used published information to calculate the risk and increase my premiums..”*
(Expert)

Empirical research

- **Key findings**
 - **Trustworthiness & accountability**
 - Greater trust in publicly funding institutions
 - Less trust in for-profit companies
 - Perceived conflicts of interests
 - Perceived lack of control/accountability
 - More trust in public-private entities
 - Government has greater control over public institutions
 - “[We] should also take into consideration that there are proper controls in place... So for example, if you, let's say there's no way out of modern technology, you can de-identify these subjects, then there could be laws and regulations in place which makes it an offence to do so. So there could be some controls.” (Expert)

Discussion

- **Real or perceived risks of discrimination?**
 - **Law protects sharing personal data (PDPA 2013)**
 - Non-disclosure of information, not the same as privacy
 - Harms arising from privacy breaches
 - Technical challenges with anonymisation
 - Limited value of completely severing health links to data
 - Few variables needed to re-identify patients in Singapore
 - **Insurance usage of genetic information**
 - Singapore Life Insurance Association (LIA)
 - Position paper for BAC genetic testing report (2015)
 - *“Insurers have no intention to seek genetic tests as a part of the screening process for life or health insurance applications”.*

myDNA

- **Complementary gene panel test**
 - **Purchase of eligible insurance plans**

myDNA brought to you by PRUDENTIAL

About Important Notes myDNA Wellness Passport FAQ

Unlock the Secrets to Your DNA

myDNA

Love. Life. Health.

powered by Prenetics

Everyone is unique.
Even twins.

Introducing myDNA - Singapore's first health & wellness programme based on your unique DNA, to help you make better lifestyle choices.

Sign up for selected plans to receive a complimentary myDNA kit.

Learn how you can get myDNA »
Please read the disclaimers carefully »

Get in touch

myDNA is an innovative and market leading tool which is only available to Prudential customers in Singapore. With a simple saliva sample, myDNA will analyze over 40 of your DNA markers related to how your body responds to the food you eat and the exercise you perform. Having this information allows you to eat and exercise based on your genes.

myDNA

- **Disclaimers**

- myDNA is a non-diagnostic test. It should not replace health screenings and cannot be used to predict if one has or will develop certain health conditions. You should not change your health and lifestyle behaviors solely based on information from the myDNA report.
- myDNA is administered independently by Prenetics Limited. Prenetics will not share any of your personal data or test results with Prudential. Your test results will not affect your Prudential insurance application and/or coverage and will not be used by Prudential for any underwriting nor claims assessment purpose. You are not required to declare any of your test information and results in your insurance application with Prudential. However, once you are in receipt of the information, you may have to declare it to other parties if the other parties should so request for it e.g. other insurance companies.
- myDNA kit is not an accredited molecular test under Hong Kong Laboratory Accreditation Scheme (HOKLAS)
- Genetic information cannot provide you with conclusive information about the interaction between certain genes and environmental factors, which can significantly change a particular outcome.
- The genetic information provided by Prenetics is for informational and educational use only. Many of the genetic discoveries that we report have not been clinically validated, and the technology we use, which is the same technology used by the research community, to date has not been widely used for clinical testing.
- You should not change your health behaviours solely on the basis of information from Prenetics. You should always consult with a physician or other healthcare provider before you make any changes to your diet and lifestyle. Genes are only a small fraction of an individual's health. There may be unknown genes, environmental factors, or lifestyle choices that are far more important factors.
- You should always seek the advice of your physician or other healthcare provider with any questions you may have regarding diagnosis, cure, treatment, mitigation, or prevention of any disease or other medical condition or impairment or the status of your health.

myDNA



- **Disclaimers**

- myDNA is administered independently by Prenetics Limited (Hong Kong) and is not an accredited molecular test under Hong Kong Laboratory Accreditation Scheme (HOKLAS)
- Prenetics will not share any of your personal data or test results with Prudential. **Your test results will not affect your Prudential insurance application and/or coverage and will not be used by Prudential for any underwriting nor claims assessment purpose.** You are not required to declare any of your test information and results in your insurance application with Prudential. **However, once you are in receipt of the information, you may have to declare it to other parties if the other parties should so request for it e.g. other insurance companies.**

Insurance gene profiling

- **No need to access EMR or genome databanks**
 - **Industry will have its own databanks**
 - Risk profiling communities
 - Potential for group harms of discrimination
 - Vulnerable ethnic minorities socio-economic status predisposes higher risks of health morbidity
 - Off-shore sequencing companies
 - Fall outside of Singapore legal framework
 - **Potential to undermine public trust**
 - Efforts to facilitate responsible sharing of data for precision medicine

Trustworthy Governance?

- **Governance structures that promote trust**
 - **Not only ensure that personal data is protected**
 - Sharing data within morally-acceptable and socially-responsible parameters
 - Benefit individuals and populations
 - Minimizes harms from discrimination
 - Avoids further stigmatizing vulnerable racial/ethnic groups
 - Need for non-discrimination legislation

Trustworthy Governance?

- **Governance structures that promote trust**
 - **Inserting community values into governance**
 - Empirical research needed to identify values & moral parameters for sharing genomic and health-related data
 - Social Science Research Council, Singapore
 - **Normative questions of trustworthiness**
 - Consequentialist approach
 - *Building* public trust as an outcome
 - iCare.com?
 - Deontological approach
 - *Being* trustworthy (Onora O'Neill)
 - Transparency, honesty & competency within systems

Acknowledgements

POLARIS study

- Dr Patrick Tan – Genome Institute of Singapore
- Yasmin Blystra - SingHealth
- Jyothi Thrivikraman
- Sangeetha Watson - CBmE

CPPH study

- Prof E Shyong Tan – NUHS
- A/Prof Jacqueline Chin – CBmE
- Dr Owen Schaffer - CBmE
- Sangeetha Watson - CBmE

CBmE Funding Initiative

- Position papers on Big Data and Genome Editing
 - Funding for Working Groups and research symposia

