Implementing clinical genomic sharing, security and governance

What is the patients' perspective?

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Melbourne Genomics Health Alliance
Melbourne Genomics Health Alliance

Alliance members

The Royal Melbourne Hospital
The Royal Children's Hospital Melbourne
The University of Melbourne
Walter + Eliza Hall Institute of Medical Research
Murdoch Childrens Research Institute
CSIRO
agrif
Peter Mac
Peter MacCallum Cancer Centre
Victoria Australia
Austin Health
Monash Health

Supported by

VICTORIA State Government
Approach

STREAM 1: WORKFORCE DEVELOPMENT
Build the literacy, skills and confidence of the clinical and diagnostic workforce in genomics, as relevant to each professional role.

STREAM 2: ASSESSING THE VALUE OF GENOMICS
Evaluate the place of genomics in health care practice, by:
(1) evaluating the process and outcomes of genomic tests in practice, and
(2) establishing and applying a platform for health service research, program evaluation, economic evaluation and translational research in the use of genomics in health care.

STREAM 3: INNOVATION AND RAPID ADOPTION
Develop and deploy systems to ensure patients have access to cutting-edge, high quality genomic testing that is cost-effective.

STREAM 4: ACCESS TO GENOMIC INFORMATION
Develop and implement a single set of standards, policies and procedures to support a common infrastructure for the management and use of genomic data by stakeholders in Victoria.

STREAM 5: NATIONAL AND INTERNATIONAL IMPACT
Establish active relationships and participation in national and international initiatives with the aim of disseminating, communicating and collaborating on the work of the Alliance and its implications.

DISEASE FLAGSHIPS
Flagships are the mechanism through which genomic sequencing is provided to patients with defined clinical conditions or indications. Flagships will also be the means by which the workforce is developed, innovation is adopted, outcomes are evaluated and information systems trialled, and underpin the five streams.
Technology to enable clinical genomics
**GenoVic** a clinical system for genomics providing end-to-end modular cloud services for multiple laboratories
Genomic data context
Modern genetics means you should say goodbye to privacy

KEVIN LORIA
NOV 4, 2015, 5:18 AM

In-Depth: Consumer genomics furthers healthcare foothold but privacy, resource concerns persist

Lauren Lovett | 11 Jul 2018

TO PROTECT GENETIC PRIVACY, ENCRYPT YOUR DNA
Modern genetics means you should say goodbye to privacy

KEVIN LORIA
NOV 4, 2015, 5:18 AM

The Golden State Killer case shows how swiftly we’re losing genetic privacy

By Norman A. Paradis | Updated May 5, 2018, 10:24am EDT

In-Depth: Consumer genomics furthers healthcare foothold but privacy, resource concerns persist

Laura Lovett | Jul 11, 2018

TO PROTECT GENETIC PRIVACY, ENCRYPT YOUR DNA
My Health Record can store genomic information but critics say it's not ready

The federal government's My Health Record system is capable of storing genomic information, such as a person's genetic risk of developing cancer, which could turbocharge medical research but has intensified privacy and security fears.

Fairfax Media can reveal Sydney-based whole genome sequencing company Genome.One developed “necessary infrastructure” in order to upload highly sensitive genomic information onto My Health Records.

• Genomic data can be uploaded to My Health Records, sparking new concerns.
• Critics question whether My Health Record is ready to hold such sensitive data.
• They say the lack of disclosure will foster further fear and distrust.
My Health Record can store genomic information but critics say it's not ready

By Esther Han
5 August 2018 – 9:28pm

The federal government’s My Health Record system is capable of storing genomic information, such as a person’s genetic risk of developing cancer, which could turbocharge medical research but has intensified privacy and security fears.

Your genome is the complete set of genetic instructions encoded in the two metres of DNA in most of your cells.

Photo: Alamy

• Critics question whether My Health Record is ready to hold such sensitive data.
• They say the lack of disclosure will foster further fear and distrust.
Grumpy Voter  1 MONTH AGO

Never has the saying “Big Brother is watching you” been more apt. It is a worrying trend that the Coalition is intruding more and more into our private, which flies completely in the face of their “smaller government” platitudes. I have opted out. It’s the only way I feel I can safeguard my medical records.
**Grumpy Voter**  1 MONTH AGO

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---

**mjcpaull**  1 MONTH AGO

So now we know, what was presented as centralised system to improve efficiency and access to services had a clandestine agenda - a national DNA database with unfettered police access.

Now you can debate the merits or otherwise of a national DNA database, in the same way as you can debate compulsory ID cards - supported by officials in black uniforms wearing mirrored sunglasses - but that is the point: it is a democracy and it should be a debate - the government should present this as a policy objective, argue the merits and build a consensus. Instead we have Greg Hunt trying to slide this through under the covers - this attracts one adjective only... deceit.
Grumpy Voter  1 MONTH AGO

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mjcpaul  1 MONTH AGO

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chet.mannly  1 MONTH AGO

What a massive invasion of privacy! Who on earth in Government thought people would be OK with this?

The Police will have a field day. When they combine it with the facial recognition data they already have it’s nothing short of a police state database on everyone. The Stasi would have been envious.
Never has the saying “Big Brother is watching you” been more apt. It is a worrying trend that the Coalition is intruding more and more into our private, which flies completely in the face of their “smaller government” platitudes. I have opted out. It’s the only way I feel I can safeguard my medical records.

I’m going to have my DNA surgically removed.

What a massive invasion of privacy! Who on earth in Government thought people would be OK with this?

The Police will have a field day. When they combine it with the facial recognition data they already have it’s nothing short of a police state database on everyone. The Stasi would have been envious.
Patient perspectives
Research by...

**Executive Director**
A/Prof Clara Gaff

**Evaluation Team**
Dr Melissa Martyn
Dr Emily Forbes
Anaita Kanga- Pariaba
Nessie Mupfeki

**Clinical team**
Elly Lynch
All the GCs who administered surveys
Sophie Beck

**Alliance members**
Penny Gleason
Dr Christine Walker

**GenoVic team**
Melbourne Genomics Health Alliance
Melbourne Genomics patients

Real World Patients

1198 patients to date have had clinical testing after pre-test genetic counselling

- Complex paediatric cases
- Genetic kidney disease
- Dilated cardiomyopathy
- Complex neurological and neurodegenerative diseases
- Congenital deafness
- Immune deficiency
- Perinatal autopsy

- Advanced solid cancers
- Advanced lymphoma (non-Hodgkins)
- Bone marrow failure
Cohort characteristics

<table>
<thead>
<tr>
<th></th>
<th>Our cohort</th>
<th>Victoria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median age</td>
<td>35</td>
<td>37</td>
</tr>
<tr>
<td>Gender</td>
<td>F: 48%</td>
<td>F: 51%</td>
</tr>
<tr>
<td>Indigenous</td>
<td>1%</td>
<td>1%</td>
</tr>
<tr>
<td>Born overseas</td>
<td>14%</td>
<td>28%</td>
</tr>
</tbody>
</table>
Clinical consent for data sharing

No choice: ‘Anonymised’ data is shared

Opt in: to share re-identifiable data

98% agree
Results: Patient perspectives
Recall is high

Majority accurately recall their data sharing decision

- 94% correct
- ~1% incorrect
- ~5% do not recall

Majority understand anonymised data may be shared

- 92% correct
- ~1% incorrect
- ~7% do not recall
Information about data sharing was satisfactory

Majority received enough information

Most had no remaining concerns about data sharing
Genomic Privacy

Ease of identification & Level of concern if identified

How difficult do you think it would be for someone to be identified from their stored genome sequence? & How concerned would you be if someone identified you from your stored data?
Patients with suspected hereditary conditions significantly more likely to be concerned about being identified.

Trend towards patients having panel testing to be less concerned.
**Who can have access to **identified** data**

<table>
<thead>
<tr>
<th>Identified Data</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Members of the Alliance</td>
<td>~80 High trust</td>
</tr>
<tr>
<td>The organisation managing the data</td>
<td></td>
</tr>
<tr>
<td>Australian not for profits</td>
<td></td>
</tr>
<tr>
<td>Overseas not for profit</td>
<td></td>
</tr>
<tr>
<td>Pharma</td>
<td></td>
</tr>
<tr>
<td>Government</td>
<td>~30</td>
</tr>
<tr>
<td>Other industries</td>
<td></td>
</tr>
</tbody>
</table>

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Trust levels:
- **High trust**: Members of the Alliance
- **Low trust**: Australian not for profits, Overseas not for profit, Pharma, Government, Other industries
Who can have access to **deidentified** data

<table>
<thead>
<tr>
<th>Members of the Alliance</th>
<th>Identified Data %</th>
<th>Deidentified Data %</th>
</tr>
</thead>
<tbody>
<tr>
<td>~80</td>
<td>~95</td>
<td></td>
</tr>
</tbody>
</table>

| Researchers              | ~30               | ~40                 |
| Australian not for profits |                  |                     |
| Overseas not for profit  |                  |                     |
| Pharma                   |                  |                     |
| Government               |                  |                     |
| Other industries         |                  |                     |

Would country influence decision?

>50% said **YES**

<30% said **NO**

I don't care about the country as long as it was being used in an ethical way and for research that would be beneficial ie not to discriminate against certain groups and not for eugenics etc
Melbourne Genomics Health Alliance

No clear preference for one model of consent

N=585

Control

Permissiveness

- No permission
- Opt in each time
- Opt out each time
- Ongoing use unless opt out
- Permanent reuse
Overall most are informed, accepting and permissive BUT

No concern with medical professionals. Greatly concerned if shared more widely e.g. insurers, employers
Cancer, agreed to share

I only want to help cancer research. I don’t want to …be shared for any other purposes
Cancer, agreed to share

I strongly believe it is an invasion of my privacy and sensitive information
Hereditary, agreed to share

CEOs/Leadership
Gareth Goodier (RMH)
Christine Kilpatrick (RCH)
Stephen Smith (University of Melbourne)
Doug Hilton (WEHI)
Kathryn North (MCRI)
Lynne Cobiac (CSIRO)
Sue Forrest (AGRF)

Steering Group
James Angus (Chair)
Julian Clark
Sue Forrest
Clara Galf (Exec Director)
Trevor Lockett / David Hansen
Andrew Sinclair
Mike South
Paul Waring / Jon Emery
Ingrid Winship

Advisory Groups

Information Management Advisory
David Hansen (Chair)
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Ken Doig
Rowan Gronlund
Andrew Lorie
Fernando Martin-Sanchez
Wayne Malher
Emeline Ramos
Brenda White

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Margaret Saffar
Janney Wale
Christine Walker
Liat Watson

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Damien Bruno
Paul Ekert
Monique Ryan
Charlotte Slade
Alison Trainer

Genomics & Bioinformatics Advisory
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Denis Bauer
Paul James
Andrew Lorie
Simon Sadedin
Kirby Siemering

Data Access Advisory
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Kurt Lackovic
Steven Manos
Candice McGregor
Owen O’Neill
Gayle Philip
Bernie Pope
Melissa Southey

Advanced Users Group

Flagships

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Ian Majewski
Seong Lin Khaw
Francoise Merchinad
Edward Chew

CMT
Monique Ryan
Paul James
Tim Day
Lynette Kiers
Adrienne Sexton

CRC
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Finlay Macrae
Alison Trainer
Ingrid Winship
Michael Bogweltz

CS
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Zornitza Stark
Tsong Tan
Paul Ekert
Christiane Theda
David Amor
Malcolm Walsh
Patrick Yap

Epilepsy
Patrick Kwan
Terry O’Brien
Ingrid Schiffler
Piero Pencicha
Paul James

Information Systems

CPipe / MG LOVD VLSCI
Andrew Lorie
Simon Sadedin
John Paul Plazzer
Charlotte Anderson
Anthony Marty
Peter Georgeson
Denis Bauer
Harriet Darnish
Guido Graziel
Richard Sinnott
Glenn Tesla
Clare Stroggel

Clinical Systems - MCRI & REDCAP
Jane Halliday
Susan Donath
Leanne Mills
Rosa Dunn
Luke Stephens
BIGGRID
Maureen Turner
Leon Heller
Alice Johnstone

Working Groups

Patient-entered data tool
Patient survey
Research access
Education symposium
Evaluation
Information requirements
Reporting
Database users
Pipeline platform

Project Team
Clara Galf (Exec Director)
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Ivan Macciocca (Clinical)
Karen Meehan (Comms)
Natalie Thorne (Bioinf)

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Rupendra Shrestha