

The New Genetics:

Access and Integration Strategies for Australian Healthcare



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ALRC-AHEC Inquiry 2001-2003

- Australian Law Reform Commission
- Australian Health Ethics Committee (of the National Health & Medical Research Council)
- ‘The Protection of Human Genetic Information’ – terms of reference:

In relation to human genetic information and samples, how do we best:

- protect privacy
- protect against *unfair* discrimination
- ensure highest ethical standards

Application to *many* specific contexts

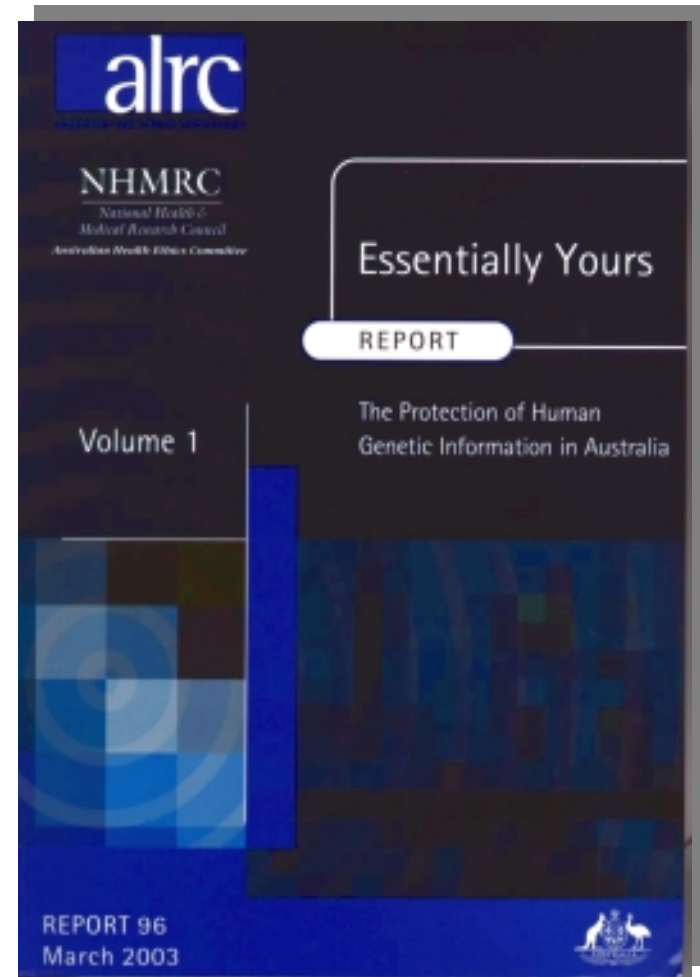
- Medical research
- Clinical practice
- **Systemic health care issues**
- Genetic databases, tissue banks & registers
- Employment
- Insurance
- Law enforcement
- Kinship and Identity (eg immigration; parentage testing; Aboriginality?)
- Other services, entitlements (eg education, sports,)

Inquiry Processes

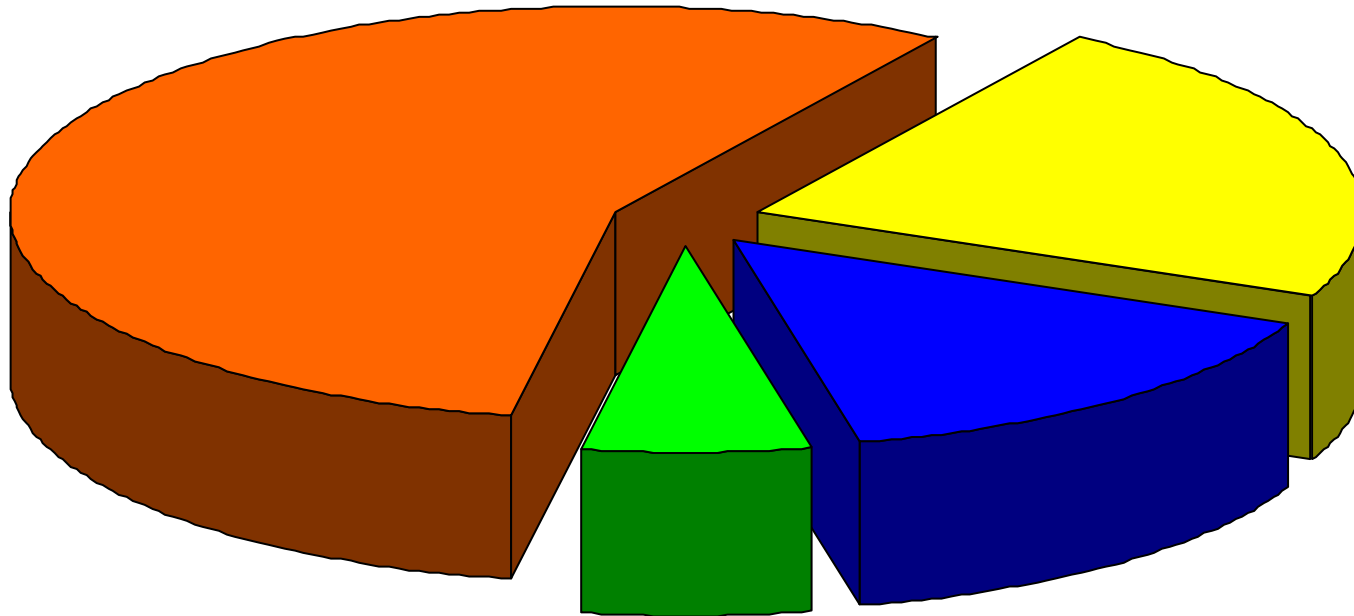
- Advisory Committee (genetic clinicians, researchers, bio-ethicists, consumers, public health administrators, insurers, actuaries, privacy and discrimination commissioners, lawyers, forensic scientists)
- Extensive research – national, international
- Consultation documents (IP 26, DP 66)
- 15 public forums held around Australia
- >200 targeted meetings, consultations
- >300 written submissions

Final Report – ‘ALRC 96’

- Launched by the two Ministers on 29 May 2003
- 144 recommendations
- Directed at **31 bodies**: federal/state/territory governments; AND also regulators; educators; health professionals; insurers; employers ...
- Dr Francis Collins: ‘a truly phenomenal job ... placing Australia ahead of what the rest of the world is doing’.



Implementation rates



- Substantial Implementation
- Partial Implementation
- Nil Implementation
- Proposals under consideration

Genetics and social ambivalence

Optimism about medical breakthroughs

- in diagnosis, treatment, prevention (eg, gene therapy, ‘smart drugs’) – affected families especially positive, and passionate

Anxiety about loss of control

- ‘mad science’ unrestrained by law, ethics or morality; ‘genetic essentialism’; eugenics
- commercialisation (‘Big Pharma’ = the new ‘Evil Empire’?)
- unlike Europe, Australians have **not** lost faith in the possibility of effective regulation of biotechnology in the public interest

Is genetic information *exceptional*?

- Powerful
- Ubiquitous
- Stable – from dinosaurs to disasters
- Uniquely individual ...
 - But humans 99.9% Ξ
 - But strong familial dimension
- Predictive value – but interactive, complex, contingent
- Sensitive – but so is HIV, depression &c
- **So** – need to recognise the special features and challenges of genetic information, but not embrace ‘genetic exceptionalism’

PHASE TWO: INTERPRETATION



A national advisory body?

Central recommendation: establish a new Human Genetics Commission of Australia.

- Recognising rapid change and social reach → need for continuing, independent, authoritative advice to government, industry and commerce, and the general public
- Need for broad-based membership (sci/med experts as well as ELSI/community)
- Need to provide a national forum, coordination
- Specific responsibilities for genetic testing:
 - in insurance, employment contexts
 - classification of genetic tests (below)

Regulating access to testing

- HGCA to identify 'sensitive' genetic tests requiring restricted access, counselling etc, and advise the regulator (Therapeutic Goods Administration) accordingly – analogy with approach to HIV-AIDS testing
- Request pathways for doctors, clinical genetic services (enforceable through Medicare); automatic triggers (test → counselling)
- DNA testing [reporting results] only to be done by fully accredited laboratories (with standards covering QA, *and* ethics/consent, counselling)

Regulating illicit testing?

- Decreased cost, increased availability, direct marketing, \$ incentives → encourage:
 - non-court, non-consensual paternity testing
 - surveillance testing of partners, children (for drugs, sexual activity)
 - illicit testing by employers, insurers, private investigators, journalists etc
- Recommend creating a new *criminal* offence:
Knowingly/recklessly submitting another person's genetic material for testing without consent or other lawful authority (eg court order, statutory authority)

Regulating curiosity?

- We are likely to see a rush of directly-marketed 'genetic health' test kits
 - Eg, Sciona's 'You and Your Genes', sold in the UK for £120 through the web, pharmacies, Body Shop.
- The need? Sciona's CEO:

'There is already a lot of information out there recommending, for instance, a diet high in fruit, broccoli and grains and low in char-grilled red meat, smoked and preserved foods and alcohol. Consumers find this advice daunting, as they are not sure to what extent it pertains to them as individuals.'

Mix of regulatory strategies

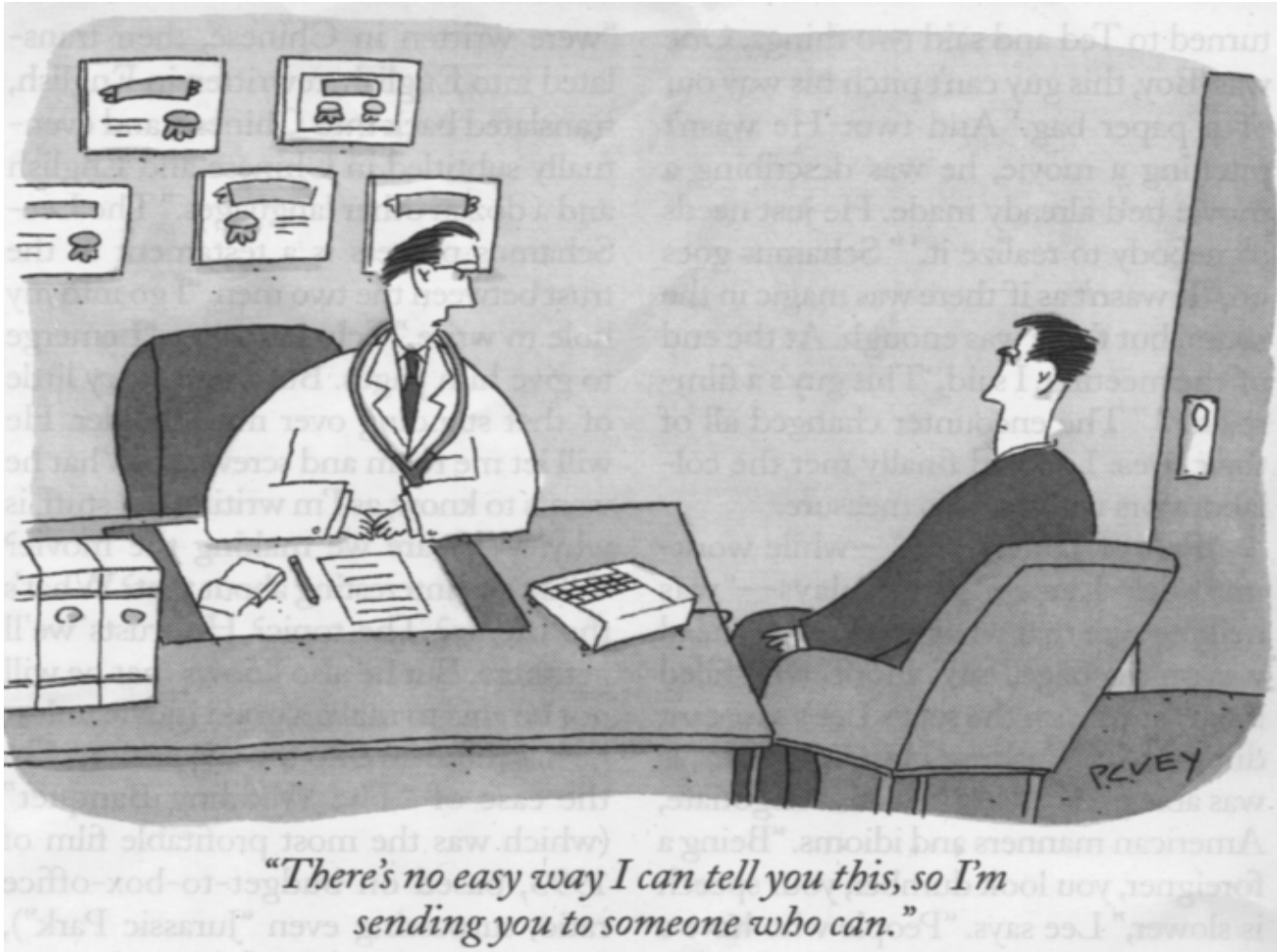
- What are the best responses?
 - consumer education?
 - financial dis/incentives?
 - formal regulation (of access, advertising)?
 - can we effectively regulate sales via the internet, or DIY kits with processing offshore?
 - criminal law?
 - buyer beware (for the genetic equivalent of the ‘Mood Ring’)?

Systemic healthcare issues

1. Start preparing the system **now** for the time when 'all medicine will be genetic medicine'
 - strategic planning, costs, training needs etc
2. Prepare family doctors to be the key 'gatekeepers' for genetic testing
 - Lots of criticism from patients and support groups about lack of knowledge, communication skills
 - Develop integrated education: med schools, Royal (specialist) Colleges, continuing ed programs
3. More resources, back-up for genetic support groups (peer support) – are very effective

Genetic counselling

4. Need for more and better genetic counselling (human resources/facilities)
 - ‘The heroes of the inquiry’ – cf Google!
 - Communicating risk/probability: difficult for patients to understand, weigh complex information
 - Ongoing psycho-social counselling for patients and genetic relatives (eg HD, BRCA)
 - Recommend recognition as a distinct allied health profession (despite → ‘provider numbers’ → implications for Medicare costs)
 - Improve the articulation between/among GPs, clinical geneticists and genetic counsellors



Health professionals handling shared genetic information

5. Confronting the tension between patient confidentiality and shared genetic information
 - conflict between patient privacy/confidentiality and the health/well-being of genetic relatives
 - dysfunctional families / real dilemmas
 - the right **not** to know
 - dangers in encouraging a duty of care to warn
- On balance: recommend NHMRC consider whether/how to allow health professionals to disclose information where a patient's genetic relative would be at serious risk of harm



Managing genetic databases

6. No Australian equivalent of Iceland's DeCODE or UK's BioBank, but there are numerous 'inchoate'/unorganised genetic databases:

- Guthrie cards (national 'collection');
- pathology labs, blood banks;
- tissue banks, familial cancer registers;
- 000s of research projects (unis, biotechs &c)

This requires better management through:

- more effective oversight by Ethics Committees
- better consent, disclosure protocols
- de-identification, 'gene trustees' &c
- extending Privacy Act beyond data to cover **samples**
- maybe a licensing/registration scheme?

Population genetics, screening

7. Better consideration of the costs/benefits and ethics of population screening
 - targeting ‘at risk’ populations
 - neonatal (‘Guthrie cards’)
 - school-based (eg Tay-Sachs in Jewish schools)
 - in the workplace – ‘HaemScreen’ initiative
8. Balancing effective patient care, personal privacy and epidemiology:
 - linkage of electronic health records
 - use of population databases (eg Guthries) to predict/plan public health needs and allocate resources accordingly?

ALRC's new inquiry

- On 'Intellectual property aspects of genetic materials and technologies'
- Issues Paper 27 on 'Gene Patenting and Human Health' now out; final report is due by 30 June 2004
- The key is to balance:
 - encouraging innovation and investment;
 - without harming *further* research or reasonable access to clinical genetic services; and
 - complying with international obligations (TRIPS)

Gene patenting and human health

9. Implications of gene patents for the running costs and quality of the public health system:

- effects of monopoly control over testing?
- effects on further improvement and innovation?
- effects on cost and access to clinical genetic testing?
 - NSW Health *still* negotiating royalties with Roche for PCR

Some important differences from the US situation:

- comprehensive public healthcare provision, with subsidised, community-rated, private health insurance
- most genetic testing occurs within the public system (for now; private market emerging)
- less active/aggressive enforcement of patent rights?

Current work program

- Established Expert Advisory Committee (researchers, biotechs, health consumers, IP lawyers and patent attorneys, clinical geneticists)
- Holding extensive consultations, considering submissions and collecting empirical material about the extent of any real problem in Australia with clinical access, research use
 - Nicol and Nielsen (UTas) study similar in design to Cho et al (Stanford);
 - the Myriad/GTG controversies (and the aftermath)

Possible approaches to reform

- Looking at the potential for more effective use of existing law and procedural mechanisms –
 - compulsory licensing and Crown use;
 - competition (anti-trust) law;
 - Government purchasing power (PBS, MBS and monopsony)
- Any other reform options – eg, statutory medical treatment exception and/or research exception?
- Altered criteria for patentability (but very limited scope in light of TRIPS)?

For further information

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www.alrc.gov.au

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