

Confidentiality of Medical Records and Medical Research

Terms of Reference

In 1987 the Commission was asked to review the law relating to the use of patients' medical records for the purpose of medical research.

The reference was directed towards a specific area of privacy, under the general privacy reference,¹ which was agreed between the Commission and the Attorney-General in 1986.

Background of Reference

The Health Department had become increasingly concerned that the developing law of confidentiality would unduly restrict or obstruct medical research in Western Australia. Unlike the legislation of the Commonwealth² and some other Australian states,³ there is no specific statutory provision in Western Australia regulating the use of medical records for research purposes.

Given the absence of statutory authority, it was feared that a hospital's disclosure of medical records to a researcher, in a form that identified individual patients, was a breach of a legal duty of confidence. The breach would only be avoided if the patients had consented to the disclosure. Researchers claimed that in many cases it was impracticable to obtain such patient consent.

The Commission issued a discussion paper in March 1989 for the purpose of obtaining public comment. The Commission's report⁴ was delivered in August 1990.

Nature and Extent of Consultation

The Commission received 32 comments upon the discussion paper from a variety of sources including research organisations, hospitals, doctors and private individuals.

Recommendations

The Commission made the following recommendations:

1. The law should be clarified to ensure that the disclosure to researchers of patient-identifiable information without patient consent does not involve a breach of the legal duty of confidence, provided the research has been approved by a prescribed Institute Ethics Committee (IEC) in accordance with specified criteria.
2. Prescribed IEC's should be those of the teaching hospitals, WA universities and the state Health Department and of any other body prescribed by the Minister for Health which have consented to being prescribed.
3. In giving its approval the IEC should be satisfied that:
 - (a) The research project has as its purpose the advancement of medical knowledge or the improvement of health services in Western Australia;
 - (b) Access to patient-identifiable information is necessary for the scientific validity of the project;
 - (c) Access to that information without patient consent is justified having regard to specified factors; and that
 - (d) The public interest in undertaking the project outweighs the public interest in maintaining confidentiality.

1 Law Reform Commission of Western Australia, *Privacy*, Project No 65(I) (referred 1976, withdrawn 1993).

2 *Privacy Act 1988* (Cth); *Epidemiological Studies (Confidentiality) Act 1981* (Cth).

3 *Health Administration Act 1982* (NSW); *Privacy and Personal Information Act 1998* (NSW); *Health Act 1937* (Qld); *Health Commission Act 1976* (SA); *Health Services Act 1988* (Vic).

4 Law Reform Commission of Western Australia, *Confidentiality of Medical Records and Medical Research*, Project No 65(II) (1990).

4. As a further condition of the project being granted approval, the researcher should be required to comply with a prescribed code of conduct for the safeguarding of the information in his or her hands.
5. Record-keepers of patient-identifiable information should be entitled to act on a certificate of a prescribed IEC that the project conforms to the statutory criteria.
6. The researcher, and any other person who acquires patient-identifiable information directly or indirectly from the researcher, should be placed under an express duty of confidence towards the subject of the information.
7. It should be an offence for a researcher or third party, without lawful excuse, to communicate patient-identifiable information to any other person.
8. Patient-identifiable information in researchers' hands should be immune from disclosure in judicial proceedings.
9. Legislation should be enacted so as expressly to authorise disclosure of Health Department records for research purposes, subject to specified safeguards.
10. Departments and agencies should be required to impose restrictions on access to any patient-identifiable information in their records when transferring those records to the state archives.

Legislative or Other Action Taken

The Attorney-General withdrew the general privacy reference in 1993, influenced by the fact that proposals for a Privacy Bill were being developed by the Ministry of Justice. In February 1996, an information and options paper prepared by the Ministry of Justice, was forwarded to the Attorney-General and the Ministry of Premier and Cabinet.

The development of a Privacy Bill has stalled, primarily due to the perceived need for uniformity between Australian state jurisdictions. This issue has been considered at various times by the Standing Committee of Attorneys-General, which established its own working party on privacy.

Currency of Recommendations

On 21 December 2001 the *Privacy Amendment (Private Sector) Act 2000* (Cth) ("the Act") came into effect, extending the operation of the *Privacy Act 1988* (Cth) to cover the private health sector throughout Australia. The Act establishes a national scheme providing, through codes of practice adopted by private sector organisations and the National Privacy Principles ("the Principles"),⁵ for the appropriate collection, holding, use, correction, disclosure and transfer of personal information by private sector organisations. The Act provides greater protection of sensitive personal information and medical records by placing stricter limits on how this information is collected and handled by private sector organisations.

In most cases, private organisations will not be able to collect sensitive information without consent. Where the information is relevant to public health, public safety, or the management, funding or monitoring of a health service, health information may be used for research. This is subject to the proviso that there was no reasonable way of obtaining a patient's consent, that the organisation has shown that the information is necessary for research and that all identifying features have been removed prior to publication. The Act also allows Australians to access their own medical records in accordance with guidelines set by the Privacy Commissioner⁶ and allows for the disclosure of confidential patient information in certain circumstances to family members and health professionals.⁷

⁵ National Privacy Principles are legislative benchmarks for handling personal information. Private organizations may develop privacy codes in accordance with the Principles that, once approved by the Privacy Commissioner, operate in place of the legislative standards.

⁶ The Office of the Privacy Commissioner was created as a separate Commonwealth statutory authority by the *Privacy Amendment (Office of the Privacy Commissioner) Act 2000* (Cth).

⁷ Office of the Federal Privacy Commissioner, 'Guidelines on Privacy in the Private Health Sector', 8 November 2001, <http://www.privacy.gov.au/publications/hg_01.doc>. See also <<http://www.law.gov.au/privacy>>.

◀ Confidentiality of Medical Records and Medical Research

There is still, however, a need for legislative uniformity as existing state privacy provisions vary widely.⁸ For instance:

- In New South Wales, a state Privacy Commissioner with jurisdiction generally limited to the public sector has been established.⁹
- Victoria passed the *Information Privacy Act 2000 (Vic)* adapting the Principles to the state public sector. Additionally, on 1 July 2002 the *Health Records Act 2001 (Vic)* will come into effect to protect all personal information held by health service providers in the public and private sectors.¹⁰
- In December 2000 an administrative regime was approved for the Queensland public sector involving guidelines based on the Principles that apply to the Commonwealth Government public sector.
- South Australia has issued an administrative instruction requiring its government agencies to generally comply with the Principles and at this stage does not intend to develop privacy legislation for either the public or private sectors.¹¹
- Tasmania issued its own Information Privacy Principles in 1997 based on the federal legislation and recommended them to Tasmanian government agencies.¹²
- The Act applies to Australian Capital Territory government agencies and is currently administered by the federal Privacy Commissioner.
- The Northern Territory intends to introduce legislation to cover the Northern Territory public sector to “complement the Commonwealth legislation and create a seamless framework of privacy protection”.¹³

Western Australia does not currently have a privacy regime. However, various confidentiality provisions cover government agencies and some of the Principles are reflected in Freedom of Information legislation.¹⁴ With the establishment of a comprehensive national scheme, the Commission's recommendations may be implemented to complement the federal legislation.

Action Required

A new legislative enactment is required to implement the Commission's recommendations. However, rather than being a discrete piece of legislation dealing specifically with confidentiality of medical records and medical research it is desirable that these be encapsulated within more general privacy legislation which reflects the existing Commonwealth legislation.

Priority – High

There is an increasing need for Western Australia to adopt laws that safeguard the use of confidential information. However, this need is tempered by the desirability of uniformity in Australian jurisdictions, particularly in light of advances in information technology which allow instantaneous data exchange across jurisdictional boundaries. With the expanded operation of the Commonwealth legislation, Western Australia has the opportunity to enact comprehensive state legislation to complement the federal scheme and enhance national uniformity in the protection of an individual's acknowledged right to privacy.

8 Office of the Federal Privacy Commissioner, 'Good Privacy, Good Business: Privacy in Australia', October 2001, <<http://www.privacy.gov.au/publications/pia.doc>>.

9 *Privacy and Personal Information Protection Act 1998 (NSW)*.

10 See <<http://www.dhs.vic.gov.au/privacy/index.htm>>.

11 Above n 8.

12 See <<http://www.justice.tas.gov.au/legpol/privacy/index.htm>> for the full text of the Tasmanian Information Privacy Principles.

13 On 22 April 1999 the Northern Territory Chief Minister issued a Ministerial Statement to the Northern Territory Legislative Assembly on Access to Information and Privacy, above n 8.

14 'The Privacy Situation in Western Australia', 29 October 2001, <<http://www.ecc.online.wa.gov.au/matrix/priv-wa.htm>>.