

VOLUME 2 RESEARCH REPORTS

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**Research  
Report 6** **How should HealthConnect  
be governed?**



APRIL 2003

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HealthConnect is Australia's proposed network of electronic health records that aims to improve the flow of information across the health sector. The concept of HealthConnect is based on the recommendations of the National Electronic Health Records Taskforce in its July 2000 report to health ministers. In November 2000, ministers subsequently agreed to fund two years research and development work to test the value and feasibility of HealthConnect ahead of implementation on a national scale.

As a research project, the HealthConnect Project is shaped by a set of high-level research questions which are intended to gauge the potential of HealthConnect to be developed as a national system. They are:

- 1 Can HealthConnect prove its value?
- 2 Is HealthConnect technically feasible?
- 3 Is there a preferred implementation model?
- 4 What role should the private sector play?
- 5 What will be necessary to manage privacy?
- 6 How should HealthConnect be governed?
- 7 What will HealthConnect cost and is it sustainable?

The HealthConnect Project has also undertaken an assessment of the progress to date on national building blocks – that is, the design and development of health infostructure requirements which are necessary not only for HealthConnect but for the broader e-health agenda.

Each of the research questions and the assessment of building block development are the subject of a stand alone research report. This report addresses the issues underpinning Question 6. The findings should be considered as interim only. The findings will be reviewed at the end of the two-year research and development phase, following completion of the HealthConnect trials in June 2003.

# 1 INTRODUCTION

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The importance of governance relates to issues of trust and accountability. Trust is something that will be essential to *HealthConnect*, particularly because of its voluntary nature – unless consumers and providers are able to trust the integrity of *HealthConnect*, they won't participate. Accountability is important not only in terms of the likely significant investment of resources, particularly in terms of public sector funding, but also in the sense that *HealthConnect* has the potential to make a major difference to health care delivery in Australia. Developed in full, *HealthConnect* would be a significant undertaking and therefore should be properly managed.

There are three broad areas of governance that need to be considered in developing a governance model for *HealthConnect*: namely – the detailed operational policy, setting the business rules and managing the process; actual implementation of *HealthConnect*; and the way access to *HealthConnect* information should be managed.

The purpose of this paper is to define the elements of *HealthConnect* that need to be governed; consider the legislative/regulatory/social/political context and environment in which *HealthConnect* would operate; consider the options for how each such element could be governed; and discuss possible models of governance for *HealthConnect* if implemented on a national basis. As this is a background paper intended only to inform discussion, formal legal advice on the governance options has not been obtained.

## 2 WHAT IS GOVERNANCE?

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In essence, governance is about guiding. The Centre on Governance, based at the University of Ottawa describes governance as the processes by which human organisations (public or private) steer themselves. Thus, governance includes the distribution of rights, obligations and power underpinning an organisation; understanding the patterns of coordination that support an organisation's diverse activities and sustain its coherence; the organisational fit against the social environment, and whether or not that fit contributes to dysfunction and performance issues; and establishing benchmarks, building tools, and knowledge sharing capacities.<sup>1</sup>

Importantly governance pertains not only to the structural entity itself but also to, "the complex ways in which public, private and social organisations interact and learn from one another. The manner in which citizens contribute to the governance system, directly and indirectly, through their collective participation in civil, public and corporate institutions; and the instruments, regulations, and processes that define the 'rules of the game'".<sup>2</sup>

The World Bank has defined the key elements of good governance as (1) representative legitimacy; (2) accountability; (3) competency and appropriateness; and (4) respect for due process.<sup>3</sup>

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<sup>1</sup> Centre on Governance, *Overview: What is governance?*, viewed 10 January 2001 at <[http://www.gouvernance.uottawa.ca/english/overview/o\\_defi.htm](http://www.gouvernance.uottawa.ca/english/overview/o_defi.htm)>.

<sup>2</sup> *ibid.*

<sup>3</sup> World Bank, *Governance: The World Bank's experience*, World Bank, Washington DC, 1994.

## 3 GOVERNANCE REQUIREMENTS FOR HEALTHCONNECT

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In broad terms, the governance model for HealthConnect would need to define the detailed operational policy for the network, set the business rules, oversee the overall implementation and operation of the network and have an ongoing monitoring and regulatory role. The actual on the ground implementation and operation could potentially be undertaken by a number of players in both the public and private sectors.

Possible delivery options for HealthConnect range from a wholly public sector controlled and operated HealthConnect to an entirely private sector owned and operated network, with public/private sector mixed models in between. The extent to which the delivery of HealthConnect rests within the public sector or the private sector will, in turn, clearly influence the nature and type of governance arrangements. As the delivery end moves further away from government ownership and control, it is more likely the governance model would lean towards a core national body overseeing national policy direction setting with the operations side being subject to regulation rather than direct governance control.

Ahead of discussing how these various business models might influence the nature of the governance arrangements for HealthConnect (section 5 Potential governance models for HealthConnect), it is useful to map out what actually needs to be governed within HealthConnect — that is, the ‘functional requirements’ for its governance.

### 3.1 National direction setting

Regardless of the implementation model, HealthConnect is first and foremost a national network — and therefore, the capacity to provide national leadership, direction setting, high level policy making, coordination and oversight is fundamental to both its development and implementation.

As a national network requiring substantial public infrastructure, the governance structure will need to include Commonwealth, state and territory representation in some form to ensure that HealthConnect has the necessary government support to enable it to operate across all jurisdictions. In terms of accountability, given the level of investment required from the Commonwealth, states and territories, it is also expected that any national governance arrangements would include the requirement to report to Australian health ministers.

### 3.2 Clinical governance

Given the primary objectives of HealthConnect to collect, store and exchange personal health information for improved clinical decision making, key functions within HealthConnect, regardless of how it is implemented, will be that of: overseeing the development and agreement of both the nature and content of event summaries and views used within HealthConnect; setting standards for the capture and recording of clinical information; monitoring quality and accuracy of the clinical information held on

HealthConnect; and having responsibility for adjudicating and correcting, as appropriate, in cases where a consumer or provider participant believes there is an error contained within a record. Such functions can most usefully be described as ‘clinical governance’ functions.

Another important area that needs to be included in any proposed clinical governance arrangement is that of decision support. Clearly, any decision-support tools used as part of HealthConnect would need to meet standards acceptable to relevant professional organisations; and would need to be reviewed periodically to ensure their relevance and currency over time. As new decision-support tools emerge over time, HealthConnect needs to have the capacity and expertise to assess the usefulness and appropriateness of such tools in the context of HealthConnect practices. Additionally, review and accountability processes need to be built into HealthConnect governance arrangements to reduce the risk to the individual’s care and of any liability arising from practitioners relying on inappropriate decision-support tools in administering treatment or care.

The National Electronic Decision Support Taskforce has reviewed the issue of governance with respect to electronic decision-support activities in Australia in general.<sup>4</sup> As a short-term measure, it has recommended that an interim national implementation unit be established within the National Institute for Clinical Studies, subsequently reviewing the longer-term governance requirements necessary for insuring a nationally coordinated approach to the development of electronic decision-support systems by end 2003. Given the need for electronic decision-support systems to integrate seamlessly with electronic health records, the National Electronic Decision Support Taskforce saw opportunities for bringing both these functions together under one governance umbrella. This would create the opportunity to have nationally compatible systems that are used more effectively and efficiently by health care professionals. Thus, in the longer-term, consideration would need to be given to how decision-support issues might be incorporated into the overall governance structure for HealthConnect.

### 3.3 Access control

Given the sensitivity of personal health information, the governance of the access control functions for HealthConnect will be critical in establishing its credibility and engendering stakeholder trust. Indeed, the National Electronic Health Records Taskforce regarded this function as going ‘to the heart of what will be legitimate consumer and provider concerns about privacy and confidentiality’.<sup>5</sup>

From a functional requirements perspective, HealthConnect access control functions would need to encompass the rules about access; how consent will operate; the processes by which users of HealthConnect data can be authorised; monitoring of access arrangements, investigation of complaints; and taking action against individuals or organisations found to be in breach of access rules. Supporting legislation with penalties for access breaches is also likely to be necessary, based on stakeholder views to date. For the purposes of this discussion, the issues relating to governance of HealthConnect access control functions are dealt with separately under section 8 Access control functions.

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<sup>4</sup> National Electronic Decision Support Taskforce, *Electronic Decision Support for Australia’s Health Sector*, Department of Health and Aged Care, Canberra, 2002.

<sup>5</sup> National Electronic Health Records Taskforce, *A Health Information Network for Australia: Report to Health Ministers*, Department of Health and Aged Care, Canberra, 2000, p. 155.

## 3.4 Operational governance

HealthConnect is intended to operate anywhere in Australia, 24 hours a day. Achieving this will be no mean feat, particularly as the operations would not be vested with only one organisation. Rather, there is likely to be a number of service providers in both the public and private sectors including state and territory governments, the Commonwealth (for example, HIC (Health Insurance Commission) and private sector information technology and health services.

Ensuring that HealthConnect functions efficiently and effectively as a national network will require a uniform approach to ensure that, regardless of which organisation is responsible for operating specific functions of HealthConnect, it complies with the desired standards, operational policies and business rules set for HealthConnect. Depending on the extent to which HealthConnect operations are devolved to different public and private sector organisations, accreditation of providers is also an issue to be considered. Monitoring of the network's performance (such as the operation of storage node functionality, transaction speeds, data currency, access, backup and responsiveness) will be an integral function of operational governance. Overseeing of consumer and provider registration processes (for example, establishing proof of identity and certification processes) would also be an important governance function.

## 3.5 Corporate governance

The Department of Finance and Administration (Finance) defines corporate governance as:

a term used in the public and private sectors, nationally and internationally, to identify processes by which organisations are directed, controlled and held to account...corporate governance arrangements allocate responsibility for business functions and define the control and reporting mechanisms within entities...The essence of any system of good corporate governance is to allow managers to drive their organisation forward within a framework of effective accountability...<sup>6</sup>

In connection with this, Finance further states, 'In dynamic organisations, corporate governance, adaptability, flexibility, supported by an enabling regulatory framework, is a prerequisite for high performance.'

The Organisation for Economic Co-operation and Development (OECD) definition of corporate governance is similar to those above.<sup>7</sup> The Auditor-General of Australia in 2000 clarifies this definition by including, 'corporate governance is about how an organisation is managed, its corporate and other structures, its culture, its policies and the ways in which it deals with its various stakeholders...It is concerned with structures and processes for decision-making and with controls and behavior that support effective accountability for performance outcomes/results'.<sup>8</sup>

Good management and risk practices within a corporate governance framework result in the creation of credibility, without which HealthConnect will fail to achieve its objectives.

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<sup>6</sup> Department of Finance and Administration, 'Corporate Governance', <[http://www.dofa.gov.au/publications/resourceframework/pr.../corporate\\_governance.htm](http://www.dofa.gov.au/publications/resourceframework/pr.../corporate_governance.htm)>, 2000 (accessed 10 January 2001).

<sup>7</sup> Organisation for Economic Co-operation and Development, *OECD Principals of Corporate Governance*, OECD, Paris, 1999.

<sup>8</sup> PJ Barrett (AM), Auditor-General for Australia, *Corporate Governance in an Environment of Devolved Authority*, 2000, viewed at <<http://www.anao.gov.au/4A2568E90083.../D2EAACDA04129F604A25694B000349B>>.

The elements of good corporate governance include:

- 1 Accountability — that is, being held accountable for the performance of the organisation in providing particular services, particularly with respect to resource expenditure. Achieving optimal accountability requires an organisation to have: clear roles and responsibilities; clear performance expectations; balanced expectations and responsibilities; credible reporting; and reasonable review and adjustment.<sup>9</sup>
- 2 Transparency — underpinning good accountability, transparency ensures that decision-making processes and the reasons for making decisions are adequately documented and communicated to stakeholders.
- 3 Risk management — ensuring that appropriate processes and practices to manage all risks associated with an organisation's operations are in place. In the public sector, risk management involves making decisions in accord with statutory and other regulatory requirements consistent with public service values and ethics. Implicitly, this concept also deals with risk management not equating to risky management practices.
- 4 Control — control structures are important in achieving effective performance and ensuring that accountability obligations are discharged appropriately. Inherent in this is the need for appropriate record keeping, compliance with legislation, laws and regulations, and reduction of fraud risk. The Australian Auditor-General's view is that 'effective control structures within the corporate governance framework are a vital part of providing assurance to clients and Parliament that an agency is operating in the public interest, and that it has established clear lines of responsibility and accountability for its performance'.<sup>10</sup>
- 5 Performance management — this covers a wide range of issues, including devolution of decision-making, accountability for performance, measurement and benchmarking of performance, responsiveness through service quality initiatives, review of performance through program evaluation and performance auditing, the use of performance contracting mechanisms, the use of strategically oriented management and planning, and creation of autonomous agencies.<sup>11</sup>
- 6 Performance assessment information is critical for ongoing monitoring. At different levels of the organisation, performance information can give vital feedback on resource allocations, ensure that programs are running efficiently and smoothly, ensure stakeholder concerns are minimised, and maximise outputs for related outcomes. In this context, the tabling of annual reports in parliament is a useful tool, not only as an accountability mechanism but also as a means for the government to oversee how funds are utilised in the public interest.

The establishment of a performance culture supported by clear lines of accountability is an essential part of the government's approach to reform in the Australian Public Service.<sup>12</sup> Notwithstanding this, there still remains a broader range of social and political objectives that are often not easily assessable. For example, policy objectives, legislation requirements, community services and international obligations can all impact on public organisations complicating performance mechanisms.

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<sup>9</sup> J Mayne, 'Governance and accountability: ministerial or public servant...or neither? — Synopsis', *National Institute for Governance 2000 Twilight 200 Seminar Series*, 16 November 2000.

<sup>10</sup> 'Corporate Governance in an Environment of Devolved Authority', op cit.

<sup>11</sup> OECD *Principles of Corporate Governance*, op cit.

<sup>12</sup> 'Corporate Governance in an Environment of Devolved Authority', op cit.

- 7 Strategic planning — this refers to the ability to develop plans and objectives to fulfil an organisation’s purpose, including an assessment of:
- markets, products and customers; a review of company strengths and weaknesses along with opportunities and threats to marketplace position
  - success factors, including technological leadership
  - product attributes
  - elements for competitive advantage (or streamlined operations)
  - review of human resource management issues to project financial flexibility and needs for achieving strategic objectives.<sup>13</sup>

It is usual in the public sector that corporate plans include estimated data relating to a minimum three year forecast period. In the case of a government business enterprise (usually a statutory authority or public company) the corporate plan must also contain actual and estimated performance information for a minimum five year period.

## 3.6 Stakeholder representation

HealthConnect will have to encompass the interests of a diverse group of stakeholders, right through from funding, to operation, to end users — particularly consumers and health care providers. Funders will be seeking a governance structure that provides them with a degree of autonomy over expenditure of their respective funding and also is compatible with their respective sector/jurisdiction’s legislative requirements. Ensuring the appropriate mix of stakeholders is represented within the governance arrangements while maintaining the capacity to be responsive and able to move fast, will not be easy.

Given the high level of trust and credibility that a governance model for HealthConnect will have to uphold, it will also be critical to ensure that the arrangements meet stakeholder expectations from the outset. In relation to MediConnect, the electronic medication record system currently under development by the Commonwealth Department of Health and Ageing, stakeholders have identified a number of key issues for the governance arrangements for the body that oversees the operation of that scheme.<sup>14</sup> Chief among these key issues is the need for the body charged with overseeing the operation of the scheme to have independence in decision-making, and in particular, independence from commercial interests.

Stakeholders have emphasised that statutory powers under the scheme should not be exercised by the government, but rather, should be vested directly in the body that is charged with overseeing the operation of the scheme. This would include the power to appoint an operator. It is anticipated that the operator of the database would be bound by legal obligations of privacy and security and that the operator’s role would be subject to audit and investigation.

Stakeholders have stressed that whatever body is developed to oversee the role of the MediConnect operator, it will be necessary for it to have powers and functions that cover performance monitoring,

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<sup>13</sup> Teachers’ Insurance and Annuity Association-College Retirement Equities Fund 2000, *TIAA-CREF Policy Statement on Corporate Governance*, viewed 22 February 2001 at <<http://www.tiaa-cref.org/libra/governance/>>.

<sup>14</sup> MediConnect, formerly known as the Better Medication Management System, is a Commonwealth funded project aimed at developing a national system of electronic medication records. MediConnect will become the medication record component for HealthConnect in the longer term.

reporting, setting standards and protocols and exercising discretionary powers over the release and control of data within the legislative framework. It is likely that similar views will hold for HealthConnect governance arrangements, although these have yet to be formally tested beyond the very early thinking contained within Version 0.7 of the HealthConnect Business Architecture that was circulated for comment in April – June 2002.

### 3.7 Relationship with other national e-health initiatives

HealthConnect will need to establish close linkages with other key e-health initiatives at the national level to ensure that synergies and opportunities are maximised, duplication of effort minimised, and that new and emerging technologies are fully compatible with HealthConnect over time. The governance framework for the health information agenda more generally has recently been reviewed as part of the Australian Health Care Agreements process. In the context of the newly created overarching governance structures (Australian Health Information Council and the National Health Information Group) responsible for developing e-health policy and strategic directions, it will be important to ensure a close working relationship is established and maintained between the HealthConnect governance structure and these national structures.

Importantly, any proposed governance model for HealthConnect must ensure that it can take on the responsibility for governance of MediConnect. MediConnect is a wholly Commonwealth funded initiative, although states and territories will be involved on the hospital side further down the track. While the governance arrangements for MediConnect have not been finally determined, governance arrangements previously proposed were to establish a board under specific Commonwealth legislation covering the functions and operations of MediConnect.

### 3.8 Need for flexibility over time

From the evidence gathered to date in Research Reports 3 and 4 in this volume,<sup>15,16</sup> it is clear that, at least in the first stages of implementing HealthConnect on a national basis, funding, ownership, building and operationalising of HealthConnect is likely to be a largely public sector enterprise. However, the private sector role as a builder, operator, owner is expected to expand over time. The extent and timeframe within which the private sector might take on a substantial funding role is fairly speculative – not withstanding this, the governance arrangements for HealthConnect will need to accommodate the potential for the private and non-government sector to take on such roles over time. It also needs to be recognised that changing technologies will also impact on the network storage and messaging arrangements over time. Thus, the governance arrangements must be able to accommodate changing governance functions in the future.

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<sup>15</sup> Research Report 3, *Is there a preferred implementation model?*, vol. 2 of this publication.

<sup>16</sup> Research Report 4, *What role should the private sector play?*, vol. 2 of this publication.

## 3.9 Education and communications

As a national network, there would need to be some central production of communications, training and education materials for the general public and for health care providers. While these would clearly need to be tailored to specific community groups, and even local communities, a key function for the governance body would be to develop, implement and monitor national communications and stakeholder engagement activities.

## 3.10 Legislative/regulatory environment

Regardless of the governance model and existing legislation that may pertain to its entity type, maintaining stakeholder trust and credibility in HealthConnect would most likely need to be underpinned by specific legislation and regulations, be it stand alone legislation or incorporated into existing legislation.

A threshold issue that would need to be considered in this respect is the mechanism by which national, uniform legislation and regulations covering HealthConnect could be enacted by the Commonwealth, states and territories. Possible mechanisms that could be investigated in this context include: through existing Commonwealth Heads of Power (for example, para 51(v) ‘postal, telegraphic, telephonic, and other like services’); referral of powers by states and territories to the Commonwealth; or through states and territories enacting mirror, or complementary legislation to Commonwealth legislation. Mirror, or complementary, legislation could be a feasible route, given that HealthConnect will be a joint Commonwealth, state and territory initiative. This would require agreement through the Council of Australian Governments (COAG).

## 3.11 Regulation

Regulation specifies how a body will enact its corporate governance framework. For example, regulation may use laws or codes of conduct and ethical behavior to prescribe accountability criteria to an organisation, and in turn to individual action. Alternatively, regulation can specify the minimum standard of expected operational performance or coherence. In providing these mechanisms, regulation produces a control and transparency mechanism in provision of operational frameworks.

Regulation includes any laws or other government ‘rules’ that influence the way people behave. Regulation is necessary when a reasonable expectation by governments for compliance is needed. When properly designed, regulation offers an efficient means for achieving policy objectives.

Under Commonwealth Government policy, regulation must be both effective and efficient in achieving a particular policy goal. As a result, a cost-benefit approach to policy development is imperative. A Regulation Impact Statement (RIS) allows systematic objective and transparent assessment of any proposed regulation to be made against policy outputs. The Commonwealth has mandated the necessity of compliance to RIS development for all such policy formulation.

Regulatory options include:

- Self-regulation — industry formulated rules and codes of conduct with industry responsible for enforcement.

- Quasi-regulation — business compliance, without legislative backing.
- Co-regulation — where industry develops and administers its own arrangements and government supplies legislative backing to enforce the arrangements.
- Explicit regulation — based on the prescription of primary or subordinate legislation. This is the most commonly used form of regulation. This type of regulation is also known as black letter regulation.

Regardless of the agreed governance arrangements for HealthConnect, an initiative on the scale of HealthConnect is likely to be explicitly regulated in legislation (that is, black letter regulation) to ensure that the highest privacy and security standards are in place at all levels of the network.

## 3.12 Liability issues

Electronic health record systems raise issues about who is liable at different points along the system —for example:

- Who is ultimately responsible for the accuracy of the HealthConnect record given it potentially pulls together information from several sources?
- Who is liable if a provider is unable to access patient information at a critical time due to system failure?
- Where does liability lie in the case of adverse events arising from incorrect treatment being given based on incorrect information held on the record?

As stated in Research Report 4, *What will be the role of the private sector?*, the private sector will want to see an entity that can be sued in place, ahead of investing in any part of HealthConnect. Issues relating to the legal liability of providers in relation to HealthConnect are dealt with in greater detail under section 9 *Specific legal issues pertaining to HealthConnect*, noting that formal legal advice has not yet been sought on issues relating specifically to HealthConnect.

## 4 INTERNATIONAL/NATIONAL EXPERIENCES

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While there are a number of electronic health record initiatives being undertaken in both Australia and other countries — notably the UK, Canada, New Zealand and the US — there is no system currently operating that is comparable in scale to what is proposed under HealthConnect and thus, there are no clear examples in place to substantially inform the discussion about governance arrangements for HealthConnect.

New Zealand and the UK are examples of where governance over electronic health record systems rests with national authorities, reflecting both countries' centralised health service delivery models.

### 4.1 New Zealand

New Zealand has established a National Health Information Service (NZNHIS), which is located within the NZ Ministry of Health. The NZNHIS has responsibility for the collection and dissemination of health-related data, including the National Health Index (NHI) that provides a mechanism to uniquely identify health care users and the Medical Warning System, comprising medical warnings, event summaries and donor information.

A Health Intranet Governance Board has been established which provides standards and recommends infrastructure for secure messaging services and online services across the hospital and community sectors. The Health Intranet Governance Board has the overall responsibility for governance of e-health initiatives and reports to the Deputy Director General Finance and Information, a senior official in the Ministry of Health.

The Governance Board comprises representation from District Health Boards and primary care providers. Within the hospital sector, the Health Intranet is delivered by Telecom NZ (a private sector telecommunications company). In the community/primary care sector, the Intranet messaging between providers and services is delivered by HealthLink which is a private sector organisation. In the near future it is expected that Telecom and HealthLink will enter a connectivity agreement. The terms of reference of the Governance Board are currently undergoing review, including membership and reporting arrangements. It is expected that the Board will then report to a ministerial advisory committee on health information standards.

### 4.2 United Kingdom

The UK has been a world leader in embracing the potential of electronic health records in the delivery of health care. In 1999, the UK government established the National Health Service Information Authority (NHSIA). Established on a full statutory basis, the authority is charged with implementing the government's information for health strategy, that focuses on developing a lifelong electronic record for the population. In its early years, the focus of investment was on connecting general practitioners

to NHSNet, developing information services for primary care and assisting with funding for local implementation.<sup>17</sup> The NHSIA funds NHSNet to provide health care professionals with access to secure email, NHSweb and the internet. More recently, the overall governance of the NHS information technology has undergone review to increase the level of national direction for information technology with strategic outsourcing of major components of the NHS information technology program. The NHSIA will be responsible for delivery of the standards and infrastructure for the national health record service.

As part of this strategy, the NHS has developed a number of pilot projects through the Electronic Record Development and Implementation Programme (ERDIP) aimed at testing different electronic health record models. The Walsall ERDIP project, discussed in detail in the Electronic health information systems case studies at volume 3 of this publication, has been overseen by a Clinical Reference Group with privacy and access control functions managed through the Caldicott Guardian, a senior health official who is responsible for agreeing, monitoring and reviewing protocols governing access to personally identifiable information.

## 4.3 Canada

Canada is facing some of the issues that Australia faces in a federated system. A good many initiatives are being undertaken at the provincial and institutional level, while the national effort is focussing on development of the infostructure to ensure that such systems are ultimately interoperable. At the national level, Health Canada has established the Office of Health and the Information Highway (OHIH) to provide project leadership and funding for government projects. OHIH has funded electronic health record projects under the Canada Health Infostructure Partnership Program (CHIPP), supporting almost 30 projects that integrate telehealth services into everyday health care delivery.

A separate entity Canada Health Infoway Inc (a not for profit organisation) has been established as an arm's-length from government organisation to foster and accelerate the development of interoperable electronic health information systems across Canada. Infoway consists of the federal/provincial and territorial Deputy Ministers of Health of Canada's 12 provinces (excluding Quebec). Infoway's first priority is to have the major components of an interoperable electronic health record system in place across Canada within five to seven years. Infoway views its role as working with key stakeholders to lead, facilitate, promote and foster the accelerated development of the national health care infrastructure rather than developing and implementing solutions.

In terms of major projects being undertaken at the provincial level there are different models of governance, including wholly government (for example, HealthNet BC) and the private sector (PharmaNet). Two examples of substantial Canadian electronic health record initiatives in place within provinces are:

- The British Columbia PharmaNet, developed by the British Columbia Government, College of Pharmacists, Pharmacy Association and College of Physicians and Surgeons.

Both the College of Pharmacists and the College of Physicians and Surgeons have access to the complete dataset for prescribing/dispensing pattern monitoring. Government has access only to those prescriptions for which benefits were paid. In addition, the College of Pharmacists takes responsibility for correcting errors and other data integrity tasks.

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<sup>17</sup> Cornwall, A, *Connecting health: a review of electronic health records projects in Australia, Europe and Canada*, Public Interest Advocacy Centre, Sydney, 2002.

The College is responsible for verifying all new drugs, maintaining data integrity and conducting regular audit checks. The dataset is also available in a de-identified form for researchers (approximately 20 requests per year). Applications are made to the College of Pharmacists and assessed by a committee that includes a civil liberties advocate. Other requests for access for legal purposes are only granted with a court order. The College of Pharmacists of British Columbia is the licensing and regulatory authority for the profession of pharmacy and its practice environment, obtaining authority from the Pharmacists, Pharmacy Operations and Drug Scheduling Act. The College is responsible for the administration of the Act and is accountable to the public.

- Toronto electronic Child Health Network (eCHN) project (Electronic health information systems case studies, volume 3 of this publication) that has eight member organisations and more than 80 member physicians. While eCHN is incorporated as a non-profit organisation, it currently remains closely affiliated and supported by the Hospital for Sick Children in Toronto. Staff of eCHN are therefore staff of this hospital. Ultimately, the plan is to establish a board with one representative from each eCHN member organisation.

## 4.4 Australia

Other than HealthConnect, there are three major electronic health record initiatives of relevance:

- *MediConnect* (formerly known as the Better Medication Management System). This is Commonwealth funded and operated. Previous investigation of governance arrangements demonstrated a preference for a statutory committee (or ‘board’) comprising stakeholder representatives to oversee the effective running of the system. The board’s functions and powers would be specified within specific *MediConnect* legislation, with membership drawn from medical practitioners, pharmacists and consumers (two representatives from each group) along with one Commonwealth and one state/territory representative. It has been proposed that the *MediConnect* Board, which would report to the Minister for Health and Ageing, would have a range of functions that include: establishment, maintenance of the *MediConnect* record (‘the record’); monitoring of the *MediConnect* system; authorising release of de-identified and identifiable data; and carrying out investigations and dealing with administrative sanctions for prescribed breaches.<sup>18</sup> It was proposed that the secretariat, located in the Department of Health and Ageing, would have responsibility for overseeing the operations of *MediConnect*.
- Oacis system. This system, funded by the South Australian health authority, is overseen by an enterprise wide steering committee which sets strategic directions and makes decisions, with a number of other committees/groups advising on particular issues (Electronic health information systems case studies, volume 3 of this publication). These governance arrangements are quite complex, involving a lot of different individuals. There have been some difficulties due to different, competing priorities for the public sector, supporting the need for governance arrangements to include clear lines of decision-making and the capacity to oversee prioritising of timelines and other issues.
- EHR\*Net. This project, which aims to develop a statewide system of electronic health records, is being undertaken by NSW Health. Governance arrangements remain within NSW Health with appropriate stakeholder representation in an advisory capacity.

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<sup>18</sup> Better Medication Management System Bill 2001—exposure draft, viewed at <<http://www.medicconnect.gov.au/pdf/exposedraftbill.pdf>>.

## 5 POTENTIAL GOVERNANCE MODELS FOR HEALTHCONNECT

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As stated earlier, governance arrangements for HealthConnect will be largely influenced by the business model by which HealthConnect is delivered. While there is potentially a range of possible public/private sector models, from the governance perspective the following scenarios are sufficiently broad to cover the various permutations:<sup>19, 20</sup>

- 1 public sector ownership
- 2 mixed economy model — public ownership, private sector ownership side by side
- 3 limited government ownership of central ‘root directory’ with much greater capacity for approved private sector organisations to build, own and operate node facilities.

### 5.1 Public sector ownership

In this model government (in this case, Commonwealth, states and territories) would fund, own and operate all or most of the HealthConnect infrastructure, solutions and services. Private sector involvement could be either as suppliers of goods and services under contractual arrangements, or as potential providers of loan capital/lease finance to HealthConnect.

As a ‘pure’ public sector model for funding and implementing, governance arrangements would logically likewise remain in the public sector domain, at the same time ensuring representative legitimacy for other key health sector stakeholders.

A possible governance model in this scenario could be to establish the one national entity that would be wholly responsible for setting the rules and for implementing each element of HealthConnect, from applications through to storage sites. The actual delivery of services could be contracted out as appropriate, albeit still under the control of the central governance body. However, given the scale of national implementation for HealthConnect within all jurisdictions and the public and private sectors, a centralist governance body of this dimension would be very unwieldy and lacking in sufficient responsiveness to meet local needs. On these grounds, this governance model was likewise dismissed by the National Electronic Health Records Taskforce in its deliberations.

It would seem more sensible to establish a governance body in this scenario that has responsibility for establishing and regulating the operational policy and rules, with the responsibility for implementation given over to others. In the case of the public sectors, responsibility for overseeing implementation would lie with the state and territory health authorities, as likewise would the day to day operations. Responsibility for implementation in the private sector could fall within either the public or private sector (in the case of MediConnect, for example, HIC could have initial responsibility for running the day to day operations of MediConnect in the private sector, as well as public hospital discharge information).

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<sup>19</sup> These approaches are derived from models contained in Research Report 4, What role should the private sector play?

<sup>20</sup> The ensuing discussion assumes that there is agreed national legislation for HealthConnect in place either through Commonwealth legislation alone or accompanied by mirror state/territory legislation.

Based on this latter approach, the following public sector models that could be considered are:

- a separate unit based in the Commonwealth Department of Health and Ageing
- a statutory authority or statutory agency
- other separate organisation accountable to health ministers.

The first of these options would see the governance body being ultimately accountable to the Commonwealth Minister for Health and Ageing. While state and territory and stakeholder representation could be incorporated into the overarching structure, as a Commonwealth body it is less likely to be perceived as representing all jurisdictions.

The second option of a statutory authority/statutory agency has a number of different sub-options. One such sub-option could see the establishment of a statutory authority, established by its own legislation but subject to the *Commonwealth Authorities and Companies Act 1997* (CAC Act).<sup>21,22</sup> Statutory authorities of this type are separate legal entities from the Commonwealth. Accordingly, such authorities are not subject to the rules and processes for dealing with Commonwealth money that are laid down in the *Financial Management and Accountability Act 1997* (FMA Act). In this regard, therefore, they are at arm's-length from the Commonwealth. They can sue and be sued in their own name. They can hold their own seal and bank accounts and hold and trade property. They are governed by a board of directors, appointed by the Governor-General or the Minister, with operational matters delegated by the legislation to a Chief Executive/Managing Director who is accountable to the board for the authority's performance. The Chief Executive/Managing Director could be appointed by the portfolio minister, the Governor-General or the board of the authority. An act of parliament is required to establish a statutory authority.

Staff can be employed under the *Public Service Act 1999*, in which case it is known as a Statutory Agency for purposes of the Public Service Act — for example, the Australian Institute of Health and Welfare. Staff of Commonwealth authorities (and companies) that are not agencies under the Public Service Act are subject to the Workplace Relations Act and internal rules established by the board and management (as is the case with private sector companies).

An authority subject to the CAC Act could be set up within the Commonwealth Health Portfolio, as is the case with HIC. However, this could run the risk of not being seen as sufficiently representative of other jurisdictions' interests.

Alternatively, a governance body could be established as a statutory authority established under the CAC Act but operating entirely independently of the Health Portfolio. The CAC Act provides specific rules and regulations to be followed against an accountability framework. Such a body could be set up along the lines of the National Road Transport Commission (NRTC)<sup>23</sup> a small independent body established under Commonwealth legislation and funded jointly by the Commonwealth (35 per cent), states and territories (65 per cent). The Commission is overseen by a board, which makes recommendations to a ministerial council of all nine transport and roads ministers. Each minister has one vote and if approved by a majority, all governments are expected to implement the proposal.

Where a statutory authority's enabling legislation does not provide for it to be a body corporate (that is, it is not a separate legal entity) it will be part of 'the Commonwealth' and therefore not able to hold money or property on its own account — that is, the money and property it deals with will belong to

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<sup>21</sup> A statutory authority is an authority established under legislation.

<sup>22</sup> The CAC Act 1997 regulates certain aspects of the financial affairs of a Commonwealth authority. In particular, it has detailed rules about reporting and accountability. The Act also deals with other matters relating to a Commonwealth authority such as banking and investment and the conduct of officers.

<sup>23</sup> This is actually a CAC Act related body — that is, it is only subject to certain aspects of the CAC Act.

the Commonwealth. Such an authority is then subject to the Financial Management and Accountability Act (FMA Act) and it may be prescribed as a separate agency under the FMA Act. An FMA agency is headed by an individual or Chief Executive for the purposes of the FMA Act. Additionally, its enabling legislation could provide that it constitutes a statutory agency under the *Public Service Act 1999*, such as the National Blood Authority.

The National Blood Authority, recently established as a statutory body under the *National Blood Authority Act 2003*, is an example of a statutory agency subject to the Public Service Act. Commonwealth, state and territory governance arrangements are specified via a separate inter-governmental agreement (the National Blood Agreement). The Act establishes the National Blood Authority Board and a general manager as a statutory office, together with appointment conditions for board members and the general manager. The Authority is jointly funded by the Commonwealth and each of the states and territories on a 63:37 cost-share basis. Financial accountability for the NBA is subject to the FMA Act. The authority will also be subject to the *Public Service Act 1999* and the *Auditor-General Act 1997*, amongst other legislation.

Statutory authorities can be made more independent than companies as their enabling Act will set out the tenure of directors and the powers of ministerial directions. Companies, on the other hand, are reasonably susceptible to direction in that members have a relatively unfettered power to appoint and dismiss the board. The enabling legislation of a statutory authority can be tailored to the particular circumstances and requirements of the entity concerned. The level of operational independence from Government, especially the Commonwealth, available to agencies/authorities subject to the FMA Act is generally to a lesser degree than that subscribed to statutory authorities/agencies under the CAC Act. For this reason, a statutory authority/agency subject to the CAC Act could be preferable, being more likely to be perceived as being at arm's-length from the Commonwealth and therefore able to act with relative autonomy.<sup>24</sup> Any changes to legislation would require passage through both Houses of Parliament. Jurisdictions and stakeholder representatives could have authority via the board of directors overseeing the authority, with reporting lines to Australian health ministers. For these reasons, a statutory authority subject to the CAC Act could be an appropriate structure for both the public sector and the mixed economy scenarios for HealthConnect.

The third option includes three possible sub-models for establishing the governance body:

- a committee/council established by, and reporting to health ministers
- an independent, for-profit company limited by shares, with shares being held by stakeholders — in this case Commonwealth, state and territory governments and other stakeholders
- a company limited by guarantee in which the Commonwealth, states and territories and other stakeholders would be represented in proportion to their amounts guaranteed.

The first of these sub-models would build on existing structures — hence the newly established Australian Health Information Council or the National Health Information Group, could take on a role in overseeing the development of HealthConnect. The work (policy, planning, overall management, service level agreements with delivery agencies, monitoring progress and so forth) would be undertaken in an existing agency, possibly the Commonwealth Department of Health and Ageing (as is currently the case). While this model has worked well with the current HealthConnect Program Office which is located within the Department of Health and Ageing, this model would lack the necessary legal capacity needed for an undertaking of the size of HealthConnect beyond the current level of research and development

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<sup>24</sup> The degree to which a statutory authority is operationally independent of the Commonwealth will be dependent on the provisions of its enabling Act.

activities. Nor is it likely to meet the prerequisite of ensuring the Commonwealth and states and territories have sufficient control over the building and implementation of the various components.

A variation on the above model would be to establish a board that is not a body corporate but rather a statutory committee – for example, the proposed *MediConnect* Board which would be established under its own enabling act, be appointed by the Commonwealth Minister for Health and Ageing and would report to the minister. However, the board would not have the capacity to enter into contracts, and would not have any financial powers.<sup>25</sup> The rationale behind selecting this model for *MediConnect*, was that the funding for *MediConnect* is solely Commonwealth, with money being appropriated to the Department of Health and Ageing. This model was previously chosen as the most flexible model, given that it would need to be accommodated within *HealthConnect* governance arrangements in the longer-term – as opposed to setting up a separate statutory authority under Commonwealth legislation.

The second of the sub-models could be formed as a limited company trading for profit, established under the *Corporations Act 2001*. Although special legislation is not required, supporting legislation can be employed – for example, to establish transitional arrangements and/or exemptions from Commonwealth or state laws (such as state and local government taxes). The liability of shareholders is also limited to the amount of unpaid shares held by them. Such companies can be either proprietary or public companies. Public companies can raise capital from the public at large, whereas a proprietary company can only raise through private means by attracting a limited investor base.

Companies can also be established under the CAC Act, but this only applies to companies for which the Commonwealth has a controlling interest or is wholly owned by the Commonwealth. Such companies have reporting and accountability rules additional to those that apply under the *Corporations Act*. The National Institute for Clinical Studies (NICS) is an example of a Commonwealth company established subject to this Act. The Commonwealth is both funder and sole shareholder of NICS, with a board of directors appointed by the Minister for Health and Ageing. However, given the need to balance Commonwealth, state and territory control, a company whose main control rests with the Commonwealth is not likely to be a feasible option for *HealthConnect*.

Given that *HealthConnect* is being developed as a public good, a for-profit company would be less attractive as a model as it could be distrusted by many stakeholders who might perceive a profit motive as being incompatible with the provision of an equitable service to a wide range of users. Profit would be generated by selling information and this may exclude or burden some users, particularly consumers who would be the source of information in the first place.

The third of the sub-models, the model of a company limited by guarantee, is best exercised for non-profit or charitable enterprises as companies limited by guarantee have no actual share capital. The National Prescribing Service, set up with the aim of improving prescribing practices, is an example of such a body. Often companies limited by guarantee do not have great demand for capital outside that which can be raised from its membership/fees. The liability of members in a company limited by guarantee is limited to the amounts members guarantee to contribute in the event of company wind up. Generally, the company's constitution states the guarantee limit of each member. Members cannot receive dividends or profits from the company's business as there is no share capital.

Such a model would provide the independence from any one jurisdiction, allow representation from all sectors and could have a sufficiently robust constitution to allow it to function with a reasonable level of autonomy. At the same time, stakeholder participation through guarantor arrangements would

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<sup>25</sup> This model of governance for *MediConnect* was proposed early in its development. However, these proposed governance arrangements will be reviewed in the context of *HealthConnect*, ahead of proceeding with national implementation.

allow stakeholder groups to have ownership and actual buy-in to the whole developmental process. Guarantors would then be able to nominate the board of directors, which would be accountable to all of the guarantors. The Department of Health and Ageing and HIC, along with state and territory health agencies, would have a powerful influence in the management of the company but their influence would, presumably, be balanced by provider and consumer interests. In terms of corporate governance functions and reporting, this model would come under the *Corporations Act 2001*. Additional requirements could be added in legislation specific to *HealthConnect*, setting out the guarantor arrangements and so forth. Guarantor arrangements could be according to funding share or population size or some other agreed formula (for example, based on the current AHMAC cost share arrangements the Commonwealth could retain fifty per cent of the total shares).

The major risk in this model is the potential for the guarantors/members to change the corporation's charter by vote, which could potentially allow commercial interests to prevail. Thus, a critical safeguard would be to choose the composition of the members/guarantors to ensure adequate control.

Another option, in theory, could be to establish the *HealthConnect* governance body as an incorporated association, similar to a company limited by guarantee, but established under state law. While an incorporated association is in many ways similar to a company limited by guarantee, it is generally a more appropriate structure for situations where legal capacity and autonomy are needed, but the complexity, scale and non-commercial nature of the association's activities do not justify imposing the safeguards and level of accountability appropriate to commercial organisations. In doing so, the 'association' may use a common seal and may sue or be sued,<sup>26</sup> hold property in its own name and employ staff or enter contracts under its own terms and conditions (similar to a statutory authority in this regard).

Given the complexity and scale of *HealthConnect*, this model would not provide sufficient accountability requirements to meet stakeholder expectations and is therefore an unlikely option.

## 5.2 Mixed economy model

In this model, the government (that is, Commonwealth, states and territories) would build, own and operate the *HealthConnect* 'root directory' and provide the overarching management and overseeing of the *HealthConnect* environment. A limited number of *HealthConnect* storage repositories would be built, owned and operated by state/territory governments (hospital and community health), the major private sector health groups (private sector) and HIC (*MediConnect*).

Under this scenario, the governance model would be smaller in terms of the control it has over the day to day operations of the various storage sites. As with the first scenario, the governance arrangements must cater for joint Commonwealth, state and territory investment, ownership and control — in this case the shared investment in the national 'root directory' and associated storage in the case of data store backup.

State and territory governments would be solely responsible for the operations of the storage repositories they own, but this would need to be in accordance with legislation, rules and standards agreed by the overarching governance arrangements. Likewise, ownership by the private sector groups or HIC would need to be bound under contractual arrangements to abide by these. In this case, requirements to have approved complaints processes, reporting requirements, performance measures and risk

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<sup>26</sup> In this case, the usual Commonwealth freedom of indemnity would need to be waived.

management strategies in place would need to be built into such contractual arrangements. Thus, contract management would be an integral role of the overarching governance body. In terms of reporting and accountability, the overarching governance body (that is, Commonwealth, state and territory, key stakeholder representatives) would ideally report to health ministers.

In this scenario, the private sector could own and operate the HealthConnect storage sites under licence to HealthConnect, with such licensing arrangements spelling out owner and operator obligations.

As the ownership moves away from a centralist, government model, so the governance arrangements would need to respond to issues arising from mixed ownership of storage sites. The private sector will have different expectations of how governance should operate — including such key attributes as:

- having the capacity to make decisions within a reasonable timeframe
- having the capacity to bind key stakeholders, including contractually
- being able to be sued.

Under this scenario, potential governance models move away from Commonwealth/state/territory dominated bodies to those of a statutory authority/statutory agency under the CAC Act or a corporation under the Corporations Act. Statutory authorities which are prescribed as agencies under the CAC Act employ staff under the Public Service Act which may not be viewed as favourably as the other two options by the private sector on the grounds that it may not be as responsive as desired. A statutory authority would provide an appropriate structure, given the potentially greater degree of autonomy and removal from government. However, private sector organisations wanting to invest in building, owning or operating storage facilities may have some concerns regarding the capacity of an authority to respond quickly to changing needs.

A possible governance model could be one of a company limited by shares, established under the Corporations Act which would also be subject to specific legislative requirements under the HealthConnect enabling legislation, particularly with respect to access control requirements, and assuming that an independent agency has authority to monitor and audit its operations. This would ensure that the necessary checks and balances are in place — that is, it would ensure accountability to government as well as being subject to independent scrutiny. The company could be operated through a board of directors, the composition of which could be stipulated in the company's constitution. Staff would not be employed under the *Public Service Act 1999*. Control of the company through membership on the board could be allocated according to shareholdings — for example, the Commonwealth, states and territories could be shareholders.

## 5.3 Private sector predominance

This scenario would see the private sector potentially playing a much greater role in building, owning and operating the electronic record repositories/nodes, including, potentially, direct revenue raising from health care providers.

In such an environment, the role of a national governance body would be likely to become much more of a regulator — that is, a body that sets the rules and standards for compliance and oversees the implementation of these rules. Notwithstanding the increased emphasis on regulation, there will still always be a need for a national governance body to set national policy, have the ability to manage and account for public funds, oversee the operations of HealthConnect as a national network, be accountable

to the public and so forth. As discussed in the following section on access control, there will always be a need for an independent ‘watchdog’ over HealthConnect. A possible model for governance in this instance then could be for functions such as overarching policy setting to be the role of a smaller, not for profit company, with an accompanying shift of regulatory functions to a statutory agency, or ‘HealthConnect Commissioner’, who could take on the role of accrediting, monitoring and regulating HealthConnect operators.

## 6 CLINICAL GOVERNANCE FUNCTIONS

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As a key function of HealthConnect, clinical governance needs to be incorporated into the overarching governance model. Given the level of professional and technical expertise required to oversee the selection and review of decision-support tools used in HealthConnect, provide expert clinical advice, and develop and review event summaries and views, an appropriate way to meet these needs could be through the establishment of a standing HealthConnect Clinical Review Committee, with secretariat support provided from within the HealthConnect governance body. This would comprise a panel of appropriately qualified experts who would meet on a quarterly basis, with out-of-session duties as needed. Appropriate levels of remuneration would need to be costed into the HealthConnect governance allocation.

By ensuring these functions are dealt with by a separate committee of independent professionals, it is intended that the credibility of the clinical information collected by HealthConnect and its accompanying decision-support tools will be maintained among health care providers. A committee structure would also stand the test of time with respect to any changes made to the governance body or to the level of private sector engagement over time.

## 7 RELATIONSHIP TO MEDICONNECT GOVERNANCE ARRANGEMENTS

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As mentioned earlier, the intention has been to establish the *MediConnect* Board to oversee *MediConnect*, which will become the medication record for *HealthConnect*. The expectation is that the functions and role of the *MediConnect* Board would be reviewed in the context of establishing the *HealthConnect* governance arrangements. This in turn would depend to some extent on what inter-government agreements are reached concerning the level of authority the *HealthConnect* governance body has over functions which are fully funded by a jurisdiction. As the Commonwealth is the sole funder of *MediConnect*, control is still likely to rest with the Commonwealth, with reporting to the Commonwealth minister. However, the governance arrangements for *HealthConnect*, including enabling legislation would need to ensure that there are clear lines of reporting against *MediConnect* by the Commonwealth, along with obligations for the Commonwealth in delivering the *MediConnect* component.

## 8 ACCESS CONTROL FUNCTIONS

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As stated earlier, the concept of access control in the context of *HealthConnect* covers a gamut of issues relating to privacy and confidentiality. Given the sensitivity of personal health information, the governance of the access control functions for *HealthConnect* will be critical in establishing its credibility and engendering stakeholder trust.

In the context of *HealthConnect* the scope of such access control functions encompasses the following:

- establishing rules around consent for both consumers and providers
- setting the rules relating to who can access what information held on *HealthConnect* and under what circumstances — this includes both primary use and secondary uses of data
- establishing and subsequently authenticating the identity of providers, consumers and others requesting access to data held on *HealthConnect*
- setting and monitoring security and privacy standards, including the capacity to audit and investigate, across the network
- ensuring clear, accessible and accountable complaints mechanisms are in place
- setting appropriate sanctions/penalties to both deter and punish privacy breaches
- ensuring that all *HealthConnect* operations are subject to independent scrutiny and monitoring.

In terms of legislation, research to date about *HealthConnect* among consumers and providers indicates the need for robust legislation to underpin the *HealthConnect* access control functions — as has likewise been the case with *MediConnect*. Consumers want, and expect, substantial penalties for privacy breaches to be in place, primarily, it would seem, as a deterrent to potential misuses of the data. Given the reluctance among consumers and providers for such data to be used for commercial purposes, there also needs to be legislation setting out limitations on use and disclosure.

Legislative safeguards will need to be consistent and compatible within the broader privacy environment, but it is likely that specific legislatively based access control measures would include:

- rules about release of *HealthConnect* data, including authorisation processes according to data type (for example, identifiable and de-identified data)
- consent arrangements for individuals participating in *HealthConnect* (including withdrawal of consent)
- obligations for participating health care providers
- complaints mechanisms, investigatory powers, procedures for dealing with investigations
- offences, sanctions, review processes
- the capacity for the legislation and regulations to be reviewed over time.

While the overarching governance model discussed earlier would assume responsibility for ensuring that the operations of *HealthConnect* are in accordance with relevant legislation, regulation and policies, it would be of critical importance that there is capacity for additional, rigorous scrutiny of the access controls within the system. While this can be built into expected accountability and reporting arrangements for the governance body, given stakeholder views to date, it is likely that they would want to see additional processes built into *HealthConnect* that enable some level of independent scrutiny over the access control functions.

The National Electronic Health Records Taskforce stated its preference for a separate access control body, established along the lines of the Office of the Federal Privacy Commissioner. This access control body would monitor access arrangements, investigate complaints and take action against individuals or organisations found to be in breach of access rules.

However, as the taskforce pointed out, it would be important not to replicate the existing functions of the Federal Privacy Commissioner in administering the *Federal Privacy Act 1988*.

In developing the *MediConnect* governance arrangements, a similar model to that above was initially proposed. However, following further deliberations by the *MediConnect* Development Group, it was agreed that a more workable and sustainable model would be to hand over some of the responsibility for investigating complaints made about *MediConnect* to the *MediConnect* Board as the governance body, while at the same time building on existing processes to investigate complaints about privacy breaches. In this way, independence from the Board would be maintained while at the same time, processes already in place are not replicated.

What has been proposed is that a person would be able to complain to the *MediConnect* Board about any matter relating to the *MediConnect*. However, the Board would be precluded from investigating complaints where the subject matter is not related to its functions or that matter would be better handled by another person, body or organisation.

For example, privacy complaints would be referred to the Federal Privacy Commissioner for investigation. To this end, consequential amendments would be made to the *Federal Privacy Act 1988* to empower the Commissioner to investigate and deal with all complaints that constitute a breach of *MediConnect* privacy and to inform the *MediConnect* Board of findings made in relation to breaches of *MediConnect* privacy. It was also proposed that the Board would have the power to impose administrative sanctions under the *MediConnect* legislation. These sanctions would not affect remedies available to an individual under the *Privacy Act 1988*. Additionally, it was also proposed that the *MediConnect* legislation would contain a number of prescribed offences to which criminal penalties could apply. These included offences related to privacy breaches or specific actions taken in contrary to a consumer's expressed consent.

Overall, then the draft *MediConnect* legislation handled the access control functions in the following ways:

- setting out the conditions under which the *MediConnect* record can be accessed and by whom, including consent rules, identification system and authentication mechanisms
- setting out the rules for use and disclosure of *MediConnect* data
- maintaining independence from the Board in investigating complaints re privacy breaches by handing this power to the Federal Privacy Commissioner
- allowing proven privacy breaches to be dealt with in a number of ways — either through administrative sanctions applied by the *MediConnect* Board, specified criminal offences and/or redress under the Federal Privacy Act.

Similarly, it would be expected that the legislation for *HealthConnect* would address each of these issues in some form or other.

However, while the *MediConnect* access control arrangements provide a useful starting point, such arrangements for *HealthConnect* would need to go beyond Commonwealth jurisdiction, given that *HealthConnect* would be a joint Commonwealth, state and territory initiative, straddling both the private and public health sectors.

This is particularly so with respect to complaints made about *HealthConnect*. From *HealthConnect* participants' viewpoints, complaints mechanisms need to be straightforward, unambiguous and accessible. While complaints mechanisms re privacy breaches are dealt with under Research Report 5 of this volume, it is important to recognise that complaints about *HealthConnect* (regardless of whether they are about privacy or non-privacy issues) will be made about, and to, a variety of different providers/ organisations. Thus, complaints could be made to general practitioners, hospitals, *HealthConnect* governance body, health ministers, state health authorities etc about any part of the *HealthConnect* system.

To deal with this effectively there needs to be an agreed, staged process in place for the lodging, recording, investigating, resolving and monitoring of all complaints. It would be important in the first instance, to direct individuals with complaints to the person/organisation about whom they have a complaint. However, if the complaint cannot be resolved adequately at that level, then there would need to be a clearly identified process to which the complainant could then refer his/her complaint. In the case of privacy complaints, these could be handled as outlined in Research Report 5, ensuring that the designated bodies are able to report back to the *HealthConnect* governance body.

However, it is likely that all other complaints would best be referred to a central body that has the power to investigate and deal with the complaint or can elect to refer the complaint to the appropriate body with subsequent follow up of action taken. The advantages of establishing a separate central body to oversee the management of *HealthConnect* complaints is that it would provide a clear mechanism by which complaints could be channeled; could provide the necessary independence from both the *HealthConnect* governance body and operators to maintain participant and public trust; have the power to investigate complaints where appropriate; and take necessary action or refer as necessary. It would be essential to ensure that the role of such a body did not overlap with existing federal or state/territory bodies dealing with health care or privacy complaints. This would require clear delineation of roles and responsibilities, possibly underpinned by formal memoranda of understanding with federal and state privacy commissioners, and health care complaints commissioners.

Additionally, such a central, independent body could take on responsibility for other access control functions – namely: overseeing the implementation and review of the *HealthConnect* legislation relating to access control functions; directing audits be undertaken with subsequent review; review of random audits, or specific purpose audits such as in the case of emergency overrides to access a record; investigating possible breaches of privacy; advising on appropriate privacy and security standards (technical and non-technical) and monitoring and reviewing such standards over time; and authorising applications to use *HealthConnect* data, including ensuring that appropriate ethics committee clearance has been obtained.

While there would be issues to be resolved in relation to the size, accountability and authority of such a body, stakeholders are likely to want such 'watchdog' processes to be in place for *HealthConnect*, given its size and scope.

One possibility could be to add *HealthConnect* access control functions to an existing body – such as the Commonwealth Ombudsman, the Federal Privacy Commissioner, or health care complaints commissioners. This would require a change to their powers as well as widening of functions beyond their current ones.

A more direct approach could be to appoint a *HealthConnect* Commissioner as a statutory agency with specific responsibility to administer prescribed access control functions contained within the *HealthConnect* legislation and be accountable to government. In this way, the Commissioner could be independent from both Government and the *HealthConnect* governance body.

Establishing the Commissioner as an independent entity from the start would not only assist in establishing trust in the initial implementation of HealthConnect, but it could also provide the capacity to take on greater regulatory oversight in the longer term in the event that the private sector takes on a more prominent role in owning and operating HealthConnect storage sites — that is, such an entity could take on the monitoring of licensing arrangements and requirements.

## 9 SPECIFIC LEGAL ISSUES PERTAINING TO HEALTHCONNECT

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The changing paradigm of information sharing through the use of electronic health record systems raises some new and unique legal challenges including the issues of:

- data ownership in relation to records held on HealthConnect
- legal liability arising from harm arising from reliance on incorrect, incomplete or inaccessible information in the context of HealthConnect.

### 9.1 Data ownership

The issue of data ownership is a threshold issue for HealthConnect and one that has had very little stakeholder input to date. In the landmark case for medical record ownership (*Breen v Williams*) the High Court held that medical records were ‘the sole property of the doctor who held all rights associated with ownership and that the records remained the intellectual property of the medical practitioner who had written them’.<sup>27</sup>

The only exception to this general rule recognised in *Breen v Williams* is investigative reports such as pathology and radiology reports. The High Court stated that the physical reports are owned by the patient or the organisation paying for the investigation to be conducted.

In relation to records created in a health care facility where treatment is provided, records created by employees are owned by the employer. Whether records created by independent contractors are owned by the facility will depend on the nature of the contract between the contractor and the facility employer.

In any case, the present law in Australia is that patients do not own the health records that pertain to them.

Applying the *Breen v Williams* principles to the electronic health record is difficult as the decision was limited to medical records only. In the USA, the issue of who owns the data in computer-based patient records has not been resolved.<sup>28</sup>

The electronic health record will include entries authored by numerous individuals. Applying *Breen v Williams* principles literally, each of the individuals and facilities where recorded treatment is provided would have an ownership claim over their respective entries. These principles would lead to an unworkable situation where the consent of each author and facility could be needed before information can be accessed or used by any other party.

NSW Health has recognised a view that ‘ownership of data is an outdated concept’.<sup>29</sup> Noting the existence of concepts more relevant to the electronic age it stated:<sup>30</sup>

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<sup>27</sup> (1996) 138 ALR 259

<sup>28</sup> PC Tang, and WE Hammond, ‘A progress report on computer-based patient records in the United States’, *The Computer-based patient record: an essential technology for health care*, rev edn, National Academy Press, Washington DC, 1997, p. 11.

<sup>29</sup> NSW Health, *Ethical Management of Health Information—Discussion Paper*, 1999, p. 13, viewed at <<http://www.health.nsw.gov.au/iasd/hi/ethics/ethical.pdf>>.

<sup>30</sup> *ibid.*

With the development of electronic records and more widespread use and sharing of data, perhaps a more useful concept is that of custodianship.

It is suggested that the focus should not be on 'ownership' of health records, that being a concept which is more closely aligned to a traditional 'document'. Rather, what is relevant to both health consumers and providers is the ability to exercise control over the content and the use of health record data. NSW Health put forward the suggestion that it may be desirable to develop principles which recognise the rights of the 'data collector, the intellectual rights of the provider and the rights of the community at large and individuals to whom the information relates'.<sup>31</sup>

Following on from the National Electronic Health Records Taskforce report, it is fair to say that the issue of ownership is yet to be debated beyond the HealthConnect trials. Within the context of MediConnect, the issue of ownership has not been explicitly defined. The prescribing data captured on the MediConnect record is data that is currently available through existing processes, so HIC is actually collecting no 'new' data.

In the context of other systems operating in public systems (such as the Oacis system operating in South Australia) the prevailing view appears to be that the system is the custodian of the data with the data being 'owned' by the public health system. Where systems cross public–private sector boundaries, the concept of custodianship seems to be accepted. Given the increasing trend in the US for individuals to either administer their own electronic health record or to engage a third-party in this capacity, the concept of custodianship resting with the organisation responsible for storing the data, with control over who has access to what information held on the record resting with the individual is compatible with the HealthConnect concept.

Given that the data collected under HealthConnect will be in summary format and not the complete record, this may assist to some extent in diluting the arguments about ownership. Notwithstanding this, it will be essential that, whatever forms event summaries and views ultimately take, those groups of providers who contribute data to the record on behalf of their clients are engaged at all stages to ensure that there is support for final data elements and formats chosen.

## 9.2 Liability issues

Health care providers have expressed concerns about whether systems such as HealthConnect will add additional burdens of liability, particularly given the current medico–legal environment in which there is a rapidly rising incidence of litigation. The General Practice Computing Group (GPGC) has lead the way in considering the legal issues with the provision of an excellent guide.<sup>32</sup> The following section draws from this guide, noting that formal legal advice is yet to be obtained in the context of HealthConnect.

Essentially, providers using electronic health records for their own record keeping operate in, and are subject to, the same laws as those using paper-based records systems. Thus, in the electronic environment the fundamentals of good care and good medico–legal practice still prevail—just as they do in current paper-based systems. To the extent that information management/information technology simply provides additional tools for the health care provider's disposal, no new legal problems will arise.

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<sup>31</sup> *ibid.*

<sup>32</sup> B Milstein and J Togno, *Legal issues in general practice computerisation*, prepared for the Department of Health and Ageing and the General Practice Computing Group, Canberra, 2001, online version available at <<http://www.gpgc.org/publications.html>>.

Hence in the electronic environment, the fundamentals of good care and good medico–legal practice still apply. Good communication and clinical skills, common sense and adequate history taking will remain of critical importance. Additionally, common law requires health care providers only to exercise ‘reasonable’ rather than perfect care. It is likely that Australian courts will recognise that reasonable care can be delivered in different ways and that the courts will accept a ‘spectrum of information management/information technology proficiency’.

However, it is expected that, as electronic health record systems such as *HealthConnect* become increasingly the norm, expectations will change to the detriment of those providers unwilling to take up such technologies. Thus, as it is increasingly demonstrated in time that electronic health records do benefit the quality and safety of care, it is likely that it will become increasingly difficult to defend failure to adopt such technologies from a medico–legal perspective.

Undoubtedly, however, *HealthConnect* would introduce a raft of new players into the health care provider’s traditional practice, including technical support personnel, personnel/bodies responsible for creating and maintaining decision-support tools, other health care professionals contributing information to shared records, organisations operating storage sites, and messaging services.

This raises a number of legal questions including:

- Who is responsible if things go wrong?
- What things can go wrong?
- How much does a provider have to tell their patient about the system and what could go wrong?
- Can the provider’s rights and obligations be modified by contract or statute?

The issue of who is to blame if harm arises from incorrect information held on *HealthConnect*, is not new as health care providers currently rely on information provided by others. However, it does raise the challenges in respect to what extent the *HealthConnect* record can be relied on by a provider without needing to seek external verification by either taking a full history from the individual or by contacting the other provider(s) directly.

There are clearly going to be some legal issues arising from *HealthConnect* operational failures — for example, if the system is unavailable at a critical time, data is lost, incorrect data is supplied (such as in the case of the wrong record being supplied). Providers of information management/information technology goods and services with respect to *HealthConnect* would be required to comply with various statutory obligations under Trade Practices and Fair Trading legislation. In the case of the *HealthConnect* governance body, it would be important to define the extent to which it is liable for which parts of the network, particularly with respect to limiting its liability in relation to incorrect clinical information supplied by a participating provider.

The issue of individuals electing to withhold information from *HealthConnect* or in the case of *MediConnect*, suppressing information from other than nominated viewers, raises concerns by providers concerning their liability when acting on incomplete records.

However, the issue here is whether suppressing information is different from what consumers currently do — that is, it is not uncommon for consumers to actively choose to withhold information from a provider, either directly or indirectly, by seeing several different providers in different locations.

Moreover, consumers likewise have a duty to exercise reasonable care both to their providers and themselves. As such, they have an obligation to give a history to the doctor and to cooperate with the

doctor's attempts to elicit a proper history.<sup>33</sup> This clearly has ramifications if individuals withhold information from HealthConnect, or as in the case of MediConnect, suppress parts of the record from other health care providers without letting them know of such suppression.

## Benefits of electronic health records from a medico-legal perspective

Notwithstanding the issues outlined above, many of the benefits offered by electronic health records systems coupled with decision-support tools — such as envisaged in HealthConnect— can potentially have positive legal ramifications in the sense that they can potentially:

- improve the quality and safety of health care, thereby reducing the frequency of adverse events
- increase the consumer's informed participation in the decision-making process, thereby creating a satisfied, and therefore less litigious, patient
- focus increasingly on pro-active approaches to wellness rather than reactive treatment of illness
- improve the quality of care by delivering data to the doctor's desktop that embrace a best practice, evidence-based approach to care
- ensure that data is accurately and promptly disseminated to other carers, thereby avoiding the risk of obtaining incorrect or inaccurate information or of requiring a patient to undergo further testing with the risk of morbidity that it entails
- potentially enhance the protection of privacy, security and confidentiality by using technology to overcome long-established threats inherent in the system of paper-based record keeping
- provide better evidence to resolve factual disputes that often lie at the heart of medical liability claims — the 'who said what to who' fight
- improve the quality of one aspect of medical care that so often is the cause of litigation — that is, communication.<sup>34</sup>

## Liability issues for those providers not participating in HealthConnect

The issue of legal liability of those practitioners who elect not to participate in HealthConnect, (or those who may be excluded from HealthConnect due to previous breaches) — that is, in instances where death or injury or loss occur due to the information held on HealthConnect not being accessed by non-participating providers — has not yet been formally explored. However, the issue has been raised in relation to MediConnect, which provides some useful insights.

Basic professional duty requires the provider take reasonable care in relation to a patient. What is regarded as reasonable care at one point in time may vary according to developments in scientific knowledge and other relevant professional developments. In effect, therefore, the liability may change according to HealthConnect's developmental stage. Over time it could be postulated that HealthConnect has reached a stage of development and acceptance such that a provider's duty of care would require providers to participate in HealthConnect in order to ensure that they are in a position to obtain all

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<sup>33</sup> B Milstein and J Togno, *Legal issues in general practice computerisation*, prepared for the Department of Health and Ageing and the General Practice Computing Group, Canberra, 2001, online version available at <<http://www.gpgc.org/publications.html>>.

<sup>34</sup> *ibid.*

reasonably accessible information about their patients. What this point in time might be cannot be predicted at this stage. However, relevant factors in ascertaining the degree of acceptability would be the extent to which the relevant provider groups regard the information on HealthConnect as reliable and useful; the extent to which HealthConnect is being used in every day practice; and the extent of other means available to a provider promptly to obtain relevant information on a patient's condition.

Participation could only be part of what was necessary for a provider in order to meet that duty of care, that is, the provider's duty would still extend to, and might even be discharged by, the taking of other measures for the care of a patient — for example, seeking information from another source.

In short, therefore, the liability of providers in such circumstances would depend, among other matters, on the stage and development of HealthConnect. Taking the normal professional duty of care of the provider into account, there is a potential for HealthConnect to reach a stage of development and acceptance at some time, giving rise to such liability.

Notwithstanding the above, even in the event that the failure of a provider to access HealthConnect constituted a breach of the provider's normal professional duties, no liability would result unless that failure caused the patient to suffer reasonably foreseeable injury, loss or disease.

## 10 KEY FINDINGS

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Given that the model for delivering HealthConnect may change over time, the long term governance arrangements need to have the capacity to change — while, at the same time, ensuring that the HealthConnect functions and operations remain accountable to Commonwealth, state and territory governments and the public. To meet these long term requirements, a centralised governance body could be established, (either a statutory authority or a wholly government-owned corporation), with enabling legislation setting out its functions and obligations. Any changes to such functions and operations would be subject to parliamentary processes. These functions would be expected to cover, at least in the first stages, overseeing the implementation and operation of HealthConnect, providing clinical governance, overseeing registration processes for both consumers and providers, setting standards, undertaking contractual and licensing arrangements, and monitoring of compliance throughout the network.

To ensure that HealthConnect access control functions are maintained and open to independent scrutiny, a separate access control body could be established as a statutory agency under Commonwealth legislation, along the lines of the Office of the Federal Privacy Commissioner. Such a body could be charged with administering the HealthConnect legislation, complaints processes and monitoring HealthConnect access control functions. It could be located within the Commonwealth Health Portfolio, reporting directly to the Commonwealth Minister for Health and Ageing. Over time, this body could take on more of a regulatory/compliance role to meet the requirements of a changing business model for delivering HealthConnect.

An important area of future work needed in respect of HealthConnect governance is to obtain specialised legal advice on issues pertaining to data ownership and legal liability for providers participating in HealthConnect.

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