Senate Inquiry of Healthcare Identifiers Bill 2010

Submission by Susan Smith,

Thank-you for the opportunity to comment on the exposure draft of the proposed Healthcare Identifiers Bill 2010.
Please note that the views submitted herewith are my personal views gained through practical experience from managing a register of clinical outcomes information, stored electronically, over 15 years in an acute tertiary level hospital. They are not intended to represent the views of my employers, although others in the area of Quality and Safety indicate support for these views.

The contribution of clinical registries and the secondary use of clinical information to monitoring the quality of clinical care and Quality Improvement is a well recognised concept and the need to collect such information at times without specific opt-in consent is understood[1].

Quality Improvement processes can be defined as "systematic data-guided activities designed to bring about immediate improvements in healthcare delivery in particular settings". [2] It should be considered an ethical integral part of normal medical practice[3]. The Quality Improvement process usually follows a cyclical pattern of steps leading to improvements in patient care: 1. Plan (develop a strategy to address an issue, including objectives, process and measures); 2. Do (implement the plan, documenting progress); 3. Study (analyse the results); 4. Act (decide on the next action eg adapt plan for further improvement or disseminate improvement strategy to wider community). It is not 'experimental' and is intended to implement best practice standards in medicine. Morris and Dracup[4] state

- QI is designed to bring about immediate improvements in healthcare delivery.
- QI is designed to have its findings applicable only to the local institution.
- QI is designed to sustain the improvements.
- QI does not require rigid, fixed protocols; within QI activities it is acceptable to adapt the project over time.

Quality Assurance processes described as "a system for evaluating performance, as in the delivery of services or the quality of products provided to consumers, customers, or patients"[5], may be allowed to use Healthcare Identifiers since monitoring and evaluation are specified in the proposed Bill.

However the proposed Bill stops short of authorising use of Healthcare Identifiers for implementing Quality Improvement, which may benefit from the use of Healthcare Identifiers in the non-evaluative aspects of planning or implementation, particularly in non-acute settings where a hospital identifier is not useful.

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[1] For example: McNeil J, S Evans, N Johnson and P Cameron. *Clinical-quality registries: their role in quality improvement.* 2010 MJA 192: 244-5. and
Einbinder, JS and DW Bates. *Leveraging Information Technology to Improve Quality and Safety*. IMIA Yearbook of Medical Informatics 2007, p22-9

[2] Lynn, J., et al., *The ethics of using quality improvement methods in health care.* Ann Intern Med, 2007. 146(9): p. 666-73.

[3] Davidoff, F. and P. Batalden, *Toward stronger evidence on quality improvement. Draft publication guidelines: the beginning of a consensus project.* Qual Saf Health Care, 2005. 14(5): p. 319-25

[4] Morris, P.E. and K. Dracup, *Quality improvement or research? The ethics of hospital project oversight.* Am J Crit Care, 2007. **16**(5): p. 424-6.

[5] The American Heritage® Medical Dictionary Copyright © 2007, 2004 by Houghton Mifflin Company. Published by Houghton Mifflin Company.

It is not clear that Quality Improvement processes could be considered an aspect of any of the listed authorised other purposes. Previously the Office of the Privacy Commissioner has stated "'management, funding or monitoring of a health service' may include some quality assurance and audit activities", which does not include Quality Improvement. Therefore the only option to legally access the Identifiers for this purpose may be to treat the project as research and apply for authorisation via a Human Research Ethics Committee.

There is considerable published literature demonstrating the harm resulting from the limitations of Privacy legislation causing Quality Improvement projects to be treated as research requiring ethics committee review overseas.[6] For example there are significant issues regarding the availability and capacity of Ethics committees especially in regional districts. This can be avoided in Australia. I believe the term 'improvement' should be specifically referred to in the proposed Bill. The useful phrase 'funding, management, planning, monitoring, improvement or evaluation of a health service' was introduced in the document *'Healthcare identifiers and privacy: Discussion paper on proposals for legislative support*' issued by the Australian Health Ministers' Advisory Council, July 2009, and it is unsatisfactory that this phrase has been replaced with a less instructive, less clear phrase. An emphasis on how to protect against misuse of information without impeding Quality Improvement activities would be more beneficial, eg by promoting Quality Improvement activities as integral to clinical practice and as such ensure they be subject to calibrated clinical oversight by eg clinical program directors [7].

Addition of the phrase 'or quality improvement' as indicated below will help prevent the issues described above. Although State legislation may apply to support current activities, this is important because:
1.There is a continuing call for harmonisation of health privacy legislation which implies an eventual progression towards a Federal standard.
2. There is a progression towards a more unified health system demanding greater interoperability across states again diminishing dependence on State legislative structures;
3. It is unclear whether State legislation will include the Health Identifier itself as 'health information' per se and therefore allow it's use under the legislation concerning health information disclosure.

A second important issue is that the authorisation only appears to apply to a healthcare provider, whereas others who are not *healthcare providers* of the patients involved (such as Quality Registry staff or Quality and Safety staff) may need to disclose the healthcare identifier to support secondary use in management, monitoring or evaluation activities, but are not authorised under the wording of this Bill.

Suggestion for change in the Relevant section in the Bill:

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[6] For example Candib, L.M., *How turning a QI project into "research" almost sank a great program. .* Hastings Center Report., 2007 **37(1)**: p. 26-30 and
Birnbaum, D. and R. Ratcliffe, *Overzealous oversight of healthcare quality improvement projects.* Clinical Governance: An International Journal, 2008. **13**(4): p. 290-294.

[7] Lynn, J., *When does quality improvement count as research? Human subject protection and theories of knowledge.* Qual Saf Health Care, 2004. **13**(1): p. 67-70. and
Morris, P.E. and K. Dracup, *Quality improvement or research? The ethics of hospital project oversight.* Am J Crit Care, 2007. **16**(5): p. 424-6.

15 Disclosure and use for other purposes

(1) A healthcare provider or approved entity is authorised to use a healthcare identifier, or to disclose a healthcare identifier to an entity, for the purposes of communicating or managing information, as part of:

(a) the provision of healthcare to a healthcare recipient; or
(b) the management, funding, monitoring, evaluation or quality improvement of healthcare; or
(c) the conduct of health or medical research that has been approved by a Human Research Ethics Committee.