

Review of the Health Act 1958

This submission has been developed on behalf of the Monash University Department of Epidemiology and Preventive Medicine based at the Alfred Hospital in Melbourne.

We have a long history of involvement in the development and maintenance of disease and procedure registries and are currently partners in the Victorian State Trauma Registry, the Victorian Orthopaedic Trauma Outcomes Registry, ASCTS Cardiac Surgery Registry, Melbourne Interventional Cardiology Group, Melbourne Vascular Surgeons Association Registry, Australian NZ Heart Failure Registry, Australian Rheumatological Association Registry, Bosentan Patient Registry and the ANZ Dialysis and Transplant Registry.

We would like to comment on two of the issues raised in the Review of the Health Act 1958: A new legislative framework for public health in Victoria: A discussion paper:

22. Are the current powers of the Secretary under the Health Act with respect to the collection of health information adequate to ensure access to comprehensive and reliable data necessary to monitor and protect in the protection of public health, and

23. Should the new Act make more explicit the forms which such collection of comprehensive data may take? For example, should the new Act provide for the Secretary to establish registers, databases and other collections of public health information and to state some of the uses of that information?

Disease & Procedure Registries

Registries involve a collection of basic information about individuals undergoing specific procedures or developing a particular illness. This information is collected in an identical manner and transferred to a central location for analysis. It is usually followed by a systematic collection of follow-up data, typically by a phone call or by linkage to other databases such as the national death registry.

Registries have been most commonly established for high-cost high-volume procedures such as cardiac surgery and transplantation. However their value is increasing recognised for monitoring the safety of new drugs and devices and a much broader range of diseases.

The benefits of collecting and pooling such data is increasingly recognised as fundamental to:

- a. monitoring of access to and appropriateness of care
- b. providing the data needed to allow hospital boards and other relevant bodies to monitor the quality of care in their institutions
- c. providing the key information needed to assist in credentialing and awarding of privileges
- d. providing a basis to identify factors associated with poor outcomes and seek approaches to remedy them.
- e. identifying preventive opportunities and evaluating new strategies for prevention.

The role of registries in improving the safety and quality of care through the benchmarking of outcomes after surgery is a particularly important. The ANZDATA Registry for example, have shown the value of such information for the practice of nephrology and transplantation and numerous examples exist of the value of similar systems elsewhere.

The data provided by registries however, particularly those involving procedures, is fundamentally dependent on collecting all cases.

The adverse consequences of incomplete data collection have recently been highlighted in a number of local and international publications ⁽¹⁻⁶⁾.

Participation rates in the Hamburg and Nordrhein-Westfalen cancer registries fell to less than 70% following the introduction of legislation requiring informed consent. As the result of incomplete data capture, the registries failed to achieve their missions and after 50 years of contributions, no longer publish results in *Cancer Incidence in Five Continents*, an International Association for Research on Cancer Science publication ⁽³⁾.

In the USA, the Program to Improve Care in Acute Renal Disease, a multicentre registry established to determine practice outcomes associated with favourable and unfavourable outcomes among patients receiving treatment for acute renal failure in intensive care units, only achieved a 52% voluntary enrollment rate, limiting the usefulness of the gathered data ⁽⁴⁾.

In Canada, the overall voluntary participation rate in the Registry of the Canadian Stroke Network was less than 50%, resulting in important selection biases, such that registered patients were not representative of the typical stroke patients presenting to each of the collaborating stroke centres. Furthermore, it was estimated that approximately \$500000 (Canadian dollars) was spent on consent-related issues during the first two years of the registry ⁽⁵⁾.

The Western Australian Autism Register was only able to obtain written consent from 35% of parents of eligible children to collect identifying data. The consent rates were worst for the most marginalized children including those living in rural areas or from non-Australian born or non-English speaking families. The application of the register is limited without the inclusion of identifying information at a time when the research community and affected families are desperately seeking information and solutions for their children ⁽⁶⁾.

The value of the benchmarking information provided by registries comprised solely of those volunteering to participate is virtually nil.

The opportunity for the results to be biased by incomplete data collection is so great that they would not hold credibility amongst either clinicians or researchers. Decisions based on such data would have as little value as those derived from a hospital admission register based solely on those volunteering to have their names recorded.

The registration of all eligible participants and the complete collection of all relevant data is vital both to ensure the scientific integrity of registry findings and thereby to maximise the benefit of the registries to the participants and their communities.

Constraints on the establishment of registries

At present the capacity to establish and maintain new registries in Victoria is limited by legal constraints.

Most importantly, under current legislation, decisions about whether or not to participate in a register are left to individual hospital ethics committees. These bodies are charged with making the decision about whether the 'public good' likely to be achieved by the register is sufficient to outweigh the infringement on individual privacy.

In order to establish the Victorian State Trauma Registry, the purpose of which is to monitor the state wide system of trauma management in order to reduce preventable deaths and permanent disability from major trauma, it was necessary to seek approval from over 130 human research ethics committees (HRECs), each of which separately weighed this decision ⁽⁷⁾.

Many HRECs have a limited capacity to weight up all of the factors relevant to this decision, either because they lack of the necessary scientific expertise) or the legal expertise to determine whether or not the collection of identifiable patient level data either contravenes or is exempt from the provisions of state and federal privacy legislation.

This resulted in a broad mix of opinions with several HRECS refusing to participate and several posing significant riders and constraints that have made the establishment of the register a difficult and dispiriting process. Failure to achieve 100 percent participation has diminished the value of the data provided.

Although the National Health and Medical Research Council statement on multicentre research encourages individual HRECs to adopt the reasons for ethical approval or disapproval of another HREC in reaching its own decision, this is not enforceable ⁽⁸⁾.

In the United Kingdom, the Central Office for Research Ethics Committees manages regional Multi-centre Research Ethics Committees (MRECs) on behalf of the Department of Health. Research carried out at five or more sites is reviewed by the MRECs with respect to all but locality issues such as local research facilities and specific issues relating to local communities and a favourable opinion then covers the whole of the United Kingdom ⁽⁹⁾.

If the consent and privacy issues involved in the registry establishment and management are not addressed by reform of the Health Act and other relevant legislation, the State's ability to develop new registries and take advantage of this most effective tool for improving the quality of medical care will be seriously impaired.

Recommendations

1. The Health Act should recognise the developing importance of disease registries and incorporate a mechanism to allow those registries of high public health significance to be established.

2. When considering 'candidate' data collections the committee should take into account

- the public health importance of the data collection
- whether personal identifying information (or an identifying number) will be required (this may be necessary to prevent double counting, allow outcomes to be measured and to track individuals through the healthcare system)
- the nature and personal sensitivity of the data to be collected
- the nature of the institution where the data will be accumulated, including its capacity & reputation for high level epidemiological research
- the security and governance arrangements applying to the data

3. Priority public health data collections recommended by this committee should be passed for consideration by the Health minister who should have the power to approve centralised collection of key medical information from the individuals concerned without specific consent and subsequent linkage of this data to other key health-related databases if this is believed to be strongly in the public interest and if privacy concerns have been adequately addressed.

4. The capacity to undertake high-level analysis of major data sets exists largely in a few major academic departments and research institutes. At present privacy legislation provides no recognition of any special status for such departments and institutions. Consideration should be given to incorporating into the Health Act a special recognition for a few key academic departments that are able to ensure the privacy of identified healthcare information. This recognition would be based on strict requirements and regular audit in a fashion similar to the approval given to specific laboratories that to handle hazardous biomaterials.

5. A method for allowing a single statewide ethics approval process should be developed and its authority recognised in the legislation.

We would be pleased to discuss this important matter with members of the review committee.

Yours sincerely



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