

Collaborating with Consumers: the Key to Achieving Statutory Notification for Birth Defects and Cerebral Palsy in Western Australia

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Abstract: **Introduction:** The Western Australian Birth Defects Registry and the Western Australian Cerebral Palsy Register used multiple sources of voluntary notification without consent and have a high level of case ascertainment, but there were concerns over privacy and a call for statutory notification. **Objective:** To seek consumer consensus on whether notification to the registers should be statutory or only with consent. **Methods:** Two facilitated workshops for consumer and community members of groups representing people with birth defects, cerebral palsy and disability, and the Western Australian Health Consumers' Council. **Results:** Parent groups and the Health Consumers' Council were unanimous in their support for statutory notification, with 3 conditions: that comprehensive and open information be provided to consumer groups and community; that consumers have input into the development of statutory notification; and that an opt-out clause be included. A Consumer Reference Group was established. They decided on a name for the new register (Western Australian Register of Developmental Anomalies), developed an opt-out clause and reviewed drafts of the regulations for statutory notification. The regulations came into effect in January 2011. **Conclusions:** Consumers were key to achieving statutory notification. We encourage others to engage with their consumers and community in equal partnership for mutual benefit.

Key words: consumers, birth defects, cerebral palsy, surveillance, register

Introduction

The Western Australian Cerebral Palsy Register was established in 1977 and the Western Australian Birth Defects Registry in 1980 to obtain high-quality, complete, and population-based information on cerebral palsy and birth defects respectively in Western Australia and to use this information to: establish how often these conditions occur; conduct research into their causes and prevention; investigate changes in their frequency; evaluate screening, treatment and prevention interventions; assist in planning health care facilities; provide information to health professionals; and increase knowledge generally about them.^{1,2}

Since their inception, notifications to the registers have come from several vital statistical sources (the Midwives' Notification of Birth forms, death registrations and the hospital morbidity system) and a large number of voluntary sources, including private practitioners, diagnostic, and treatment services. While some notifiers either informed parents or sought parental consent before notification, most cases were ascertained without consent. Validation studies have shown that case ascertainment by the registers is high³⁻⁵ and the data from both registers have been used extensively for monitoring, research, and health service evaluation (for example⁶⁻⁹).

While notification of birth defects to registers in Victoria and New South Wales^{10,11} and both birth defects and cerebral

palsy in South Australia¹² is covered by legislation, this was not the case in Western Australia (WA) until 2011.

Other valuable data collections in Western Australia are statutory (for example, cancer) and on several occasions since establishment of the WA cerebral palsy and birth defects registers, statutory notification had been considered but rejected by the Department of Health, mainly because the registers were working well with a system of non-statutory notification. However, with growing community and medical practitioner concern, changes in attitudes towards consent and national privacy legislation, this situation was no longer deemed to be tenable. The National Privacy Principles (1988) in relation to use and disclosure require an organization not to disclose personal information about an individual for a secondary purpose (such as a notification to a register) unless the individual has consented to disclosure or, if the information is health information for research or public health, it is approved by the Privacy Commissioner, or it is required by law (<http://www.privacy.gov.au/materials/types/infosheets/view/6583>). Several medical practitioners had indicated that they would not continue to notify to the registers in the absence of statute and nor were they able to obtain individual consent, in some instances because they had no direct contact with the parent (for example, laboratory pathologists).

Thus, in 2004, a further request was made to the

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Minister for Health for notification to become statutory in WA. The Minister was supportive of the request, but wanted consumer consultation before proceeding.

Written advice was sought from the Health Consumers' Council in WA and from several community support groups for parents and a presentation was made to the Board of the Health Consumers' Council. While the parent groups were in favor of statutory notification, the Health Consumers' Council (HCC), as a rights-based organization, believed the registers should require consent.¹³ When these findings were provided to the Minister, he replied that until consensus was reached, statutory notification would not proceed.

Methods and Results

In order to address this issue, we took 2 complementary approaches. A computer-assisted telephone (CATI) survey of a random sample of the adult population of WA was undertaken and has been reported separately.¹⁴

Secondly, we consulted with the Consumer Advocate (AM), who manages a joint consumer and community involvement program for researchers at the Telethon Institute for Child Health Research and the University of Western Australia School of Population Health.¹⁵ On her advice, we conducted 2 workshops with consumer representatives of families with birth defects and cerebral palsy and the Health Consumers' Council, to seek consumer consensus on the preferred model for notification. We report here the conduct and outcomes of the 2 workshops and the steps taken following the workshops to achieve statutory notification.

Workshop 1

Support groups representing people with birth defects, cerebral palsy and disability, the WA Health Consumers' Council, the Genetic Support Council of WA, the Ministerial Advisory Council on Disability, the advisory committees of the 2 registers, register staff and Department of Health staff were invited to send representatives to participate in the workshop. Nineteen people attended. One of us (AM) facilitated the workshop and another (CB) presented information about the nature, functions and sources of notification of the registers and experience of other consent-based registers.¹⁶⁻²⁰ The results of the CATI survey¹⁴ were also presented, which indicated limited knowledge of birth defects and the Western Australian Birth Defects Registry but general acceptance of statutory notification. Three possible models were described: the current model (non-statutory notification); the consent model (notification only with consent); and the statutory model (statutory notification without consent).

Following a question and answer session, the register and Department of Health staff left the room while the consumers discussed the options further. The consumers decided that they needed more information, wider consultation, and another workshop. They concluded that the current model should continue in the meantime and that, whatever the final model, parents and community must be better informed about the registers.

Workshop 2

For the second workshop, we engaged an external facilitator. The aim was to explore the issues further and reach a consensus for either statutory notification or notification with consent, using a method aligned with "dynamic facilitation" (<http://www.iaf-methods.org/methods>). Dynamic Facilitation is a form of facilitating where people address difficult issues creatively and collaboratively, through a process of talking and thinking that builds mutual respect, trust, and the sense of community. The dynamic facilitator helps foster shifts of heart and mind by following the natural flow of conversation and supporting group spontaneity, with the aim of reaching consensus.

Invitations to attend were extended to all support groups invited to the first workshop and to others nominated by them. There were 10 attendees, and several potential participants who were unable to attend provided out-of-session input. No register or Department of Health staff attended, apart from the medical officer of the Birth Defects Registry (CB). Neither the medical officer nor the consumer advocate contributed to any of the discussions except to clarify matters of fact. It was made clear to the participants that, should they reach a consensus decision, that consensus decision would be the model under which the registers would function in the future.

The facilitator asked participants to list the issues they wanted to cover in the workshop. These included: access to the data collected; how to do the best for parents of children with birth defects or cerebral palsy; how to inform parents and the community that the registers exist; the best model to maximize research outcomes; how to ensure the community embraces the need for a register; how much information is retained and how individuals can opt out; how to reach everyone to obtain accurate information; the vulnerability of new mothers when gathering information; who is responsible for notification; and issues of consent.

Following this, 2 presentations were made. The first, by the Birth Defects Registry medical officer, was a repeat of that given at the first workshop. The second, by the executive director of the Health Consumers' Council was about the council's role as an independent community-based organization, representing the consumers' "voice" in health policy, planning, research and service delivery. Community members with whom the council had spoken were surprised that the Department of Health holds such a large amount of health data without their knowledge or consent. The council was of the view that consent should be sought and given before inclusion of data on individuals on the registers.

Participants then considered the best and worst aspects of the current register model. The best was thought to be the high quality of the data collected and its availability for planning and improving facilities, public health, research and prevention, and the worst was the low community awareness of the registers.

In their final consideration, participants reached a unanimous decision in favor of statutory notification, with 3 conditions: that comprehensive and open information

Figure 1. Timeline from commencement of WA Cerebral Palsy and Birth Defects Registers to Enactment of Statutory Notification



be provided to consumer groups and community; that consumers have input into the development of statutory notification; and that an opt-out clause be included. All groups involved expressed appreciation of being able to contribute. The executive director of the Health Consumers' Council noted that the consultation process was an example of good practice and was the first time that the community had been invited to give input into the reporting process of a register in Western Australia.

Next Steps

The Minister for Health was informed of the consumer and community consensus for statutory notification,

following which he consented to statutory notification proceeding and the Legal and Legislative Services in the Department of Health began drafting regulations to combine cerebral palsy and birth defects notification in 1 statutory register.

Several attendees at the workshops volunteered to be members of a consumer reference group (CRG) for the new register, to ensure that the conditions under which statutory notification had been agreed to by the consumers were met.

The CRG devised an opt-out clause for the regulations, allowing parents/guardians (or affected adult individuals) to have identifying information (names, address) removed from the register 6 years or more after first notification,

while retaining the diagnostic information. The CRG also requested that the new register be called the Western Australian Register of Developmental Anomalies (WARDA), to better reflect the 2 groups of conditions to be included (birth defects and cerebral palsy). Both the name change and the opt-out clause were included in the regulations. The consumer reference group reviewed and revised the draft regulations on several occasions and the regulations were made law in January 2011.

To increase the visibility of the WARDA, the CRG assisted with the development of a Web site²¹ and a brochure for the new register. The CRG constructed a list of 59 consumer groups to whom the information about the WARDA and a supply of brochures were sent. A copy of the regulations is available on the Web site.²¹

The CRG continues to support the WARDA, with updates for the Web site and presenting at community forums about the WARDA. They also meet with prospective WARDA researchers to advise on matters such as approaches to parents, questions important to parents and how to ask them. The CRG requests that all researchers using WARDA data provide a lay summary of their proposal, which will be made publicly available on the WARDA Web site.

The staff of the WARDA attended a workshop on involving consumers in research, through the Consumer Participation Program at the Telethon Institute for Child Health Research¹⁵ and the process undertaken by the register has been included as a good practice example of consumer and community involvement in a resource manual for researchers.²²

Discussion

Through a process of consultation and discussion, consumer and community participants reached consensus for statutory notification of cerebral palsy and birth defects in Western Australia.

This conclusion is in agreement with the results of the CATI survey of a sample of 600 randomly selected WA adults conducted in WA during 2006. Respondents were asked their views about the statutory collection of identifiable data by the WA Birth Defects Registry and the extent to which the use of the data was perceived to be an invasion of privacy.¹⁴ In that survey, 96% felt the data collected was useful information for Western Australia and 79% supported a new law for mandatory notification.

Since their inception, both the birth defects and cerebral palsy registers have had links with support groups through presentations, collaboration in research²³ and health promotion (eg, promoting folic acid supplements for the prevention of neural tube defects), by providing register data to lay support groups to assist them in seeking services for children with birth defects and cerebral palsy and, like many registers, including consumer representatives on the registers' advisory committees. However, there had not previously been such an engagement of several groups simultaneously, as reported here, to consider how the registers operate.

How to involve consumers and the effects of such involvement in developing healthcare policy and research,

remain largely unevaluated and, in the absence of evaluated strategies, Nilsen et al suggest relying on advice based on practical experience and common sense.²⁴ This is what we did, seeking the advice of the consumer advocate, the experience of the Health Consumers' Council and through the engagement of a professional facilitator.

There is now a considerable body of evidence documenting problems with consent-based registers or surveillance systems, the major ones being incomplete and biased registration.¹⁶⁻²⁰ Incomplete registration for birth defects registers is clearly illustrated in a survey of European congenital anomaly registers.²⁰ Of 35 EUROCAT registries surveyed, 29 responded, 8 of them requiring opt-in informed consent. The experience of these 8 registers showed that informed consent is a serious threat to a high level of case ascertainment, largely because of logistical problems for busy clinicians to seek consent and multiple approaches to parents. Participants in our workshop also raised concerns about the appropriate time to seek consent. They felt that a parent who is emotionally distressed (as many will be when their child is first diagnosed) could be spared having to make a decision about consent if it was not a requirement.

We made it clear to the consumers and community members that, given the registers were for the benefit of Western Australian families, the decision about how the registers are run should be made by the people most concerned about children with birth defects and cerebral palsy—their parents. Ultimately, we believe this is what convinced the Health Consumers' Council and others to reach consensus in favor of a statutory register.

Although consumers in our workshops acknowledged the high case ascertainment, accuracy and independence of the registers in their current state and their value as a public health tool, they placed a high priority on the community in general and parents in particular needing to be better informed about the registers. Supporting this call from consumers are the results of earlier studies in Western Australia that have shown that the majority of participants in 2 community surveys thought birth defects only affected 1 in 200 births or less.^{25,26} Furthermore, in the CATI survey, only 6% of respondents were aware that there was a birth defects register in Western Australia.¹⁴

Of course, consumer involvement is not limited to registers—it is also important in health service delivery and research. Furthermore, the growth of genomic analysis that will likely affect not just individuals but families and communities, makes such involvement essential to ensure that the consumer and community voice is heard and heeded.

Conclusion

The consumer and community members were key to achieving statutory notification for the WARDA. They understood clearly that they were empowered to make the decision between a consent-based and a statutory register. We trusted that they would make the right decision for Western Australia and they trusted that we would honor that decision. Consumers understand research and its

benefits, and researchers need to understand the value of involving consumers in their research. We encourage others to engage with their consumers and community in equal partnership for mutual benefit.

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