

## Data for health

Fiona Stanley

### **Why can't we get action from science?**

AS A CHILD HEALTH RESEARCHER and advocate, there are many situations which make me anxious in Australia in 2014. Child abuse and neglect is apparently rising, as are substance abuse and mental health problems in both young people and their parents (probably linked) and the resulting irreversible fetal alcohol group of disorders. However, my overriding anxiety is one that is more likely to affect not only today's children but those of the next generations for generations to come. It is climate change and its associated over-consumption, pollution and depletion of our planet's resources and biodiversity. It is challenging our ability to survive successfully in our environment, and it is unlikely that we can reach a new equilibrium that will sustain us as it has in the past.

The science and the data are scary — there are data from such a rich variety of sources, all pointing to the overuse of fossil fuels, rising greenhouse gas emissions, and the excessive production of waste. The considerable impact on our health and wellbeing is already obvious, not just from more frequent severe weather events, but also from pollution, heatwaves and other extreme weather and changes in our environments.<sup>1</sup> The tragedy in this is that the data are as clear as such complicated science ever can be, and for a host of short-term and short-sighted greedy reasons, companies and individuals who deny that the science is accurate are influencing our politicians.

When such important issues are politicised, the data and the science actually go out the window. We are left with debates which are not real discussions of the issues and what needs to be done, but instead argue that we should just continue on a path to even more excess.

it's 3:23 in the morning  
and I'm awake  
because my great great grandchildren  
won't let me sleep  
my great great grandchildren  
ask me in dreams  
what did you do while the planet was plundered?  
what did you do when the earth was unraveling?  
surely you did something  
when the seasons started failing?  
as the mammals, reptiles, and birds were all dying?  
did you fill the streets with protest  
when democracy was stolen?  
what did you do  
once you knew?

Drew Dellinger

This poem is a part of Jaime Yallop's email signature; she is a young activist with whom I am working with at 350.org, an international group trying to get appropriate political, business and community responses to this issue.

At the recent University of Melbourne's Festival of Ideas (<http://www.ideas.unimelb.edu.au/>), we debated the issue of whether today's democracy and our political systems in Australia were truly serving our society, given the major challenges that we face. There were strong feelings that they were not and that we needed ways other than the political to address these complex issues to avoid them being politicised and inappropriately acted upon. Of particular interest was a presentation from Jane Smith of the Museum of Australian Democracy in Ballarat (see MADE.org). She had studied the very large number (nearly one million) of young people who

had not registered to vote in the last federal election; they were not disinterested in the issues as many were working for a range of non-government organisations and other groups such as GetUp and Crikey. They just no longer trusted the elected politicians to respond appropriately to their fears, hopes and dreams for Australia and the world.<sup>3</sup>

For me, this raises the issue of data and evidence and how we need to use them wisely to guide our practices and policies. While the climate change issues are foremost for us as a nation and a world, it is the data relating to our health about which I know most and hence the title of this chapter is ‘Data for health’. I am excited about what we could do in Australia if those in charge of policies and practices around data in the health system understood the power and capacity they are sitting on (literally!), but I am also concerned at the amount of time it is taking us to get proper systems for the more extensive and sensible use of the data we collect.

### **History of population data and record linkage in Australia**

Since I returned from training in epidemiology and public health in the United Kingdom and the United States in the 1970s, I have worked almost exclusively in population data focusing on maternal, child and youth health and wellbeing. Initially, we used birth records and midwives’ birth notifications linked to death certificates and then to total hospitalisation data to describe maternal and child health outcomes in Western Australia. I recall in the late 1970s feeling exhilarated about these data being brought together for the first time in Australia — never before had we been able to analyse infant and child death rates by birth weight or gestational age, by Aboriginal status or to look at geographic variations. Did it matter where you were born, what you weighed at birth, who your mother and father were, how old they were, what the outcomes of their previous pregnancies had been, how well off

or poor they were? It certainly did — the variations were almost as large as I had seen in the data in the UK in their wonderful Office of Population Censuses and Surveys (now Office of National Statistics). And, as in the UK and in the US, I could see just how important it was to identify mothers and infants at risk and how that could influence their care. It showed me that data were powerful; they are essential for advocacy, for improving outcomes and for evaluating services.<sup>2</sup>

My team and I then looked at the most common causes of death in very early life. There they were so very clearly: birth defects, unexplained stillbirths, conditions associated with being born too early (preterm) or too small (growth restricted). In infancy, the overwhelming cause was so-called ‘Sudden Infant Death Syndrome (SIDS)’ or ‘cot death’, as so many of these children were found dead in their cots. We showed that the most risky age was four months old and that of every 1,000 children born, almost 4 would die from SIDS. Moving into childhood, the differences for Aboriginal children were even more obvious, and deaths from preventable infections stood out. Many studies came from these initial data that would lead to prevention and reduced deaths and illnesses; but it was obvious that we needed to establish better data on birth defects and other conditions that were not fully recorded in these statutory collections.

In the 1970s, the horror of thalidomide was very new and of huge concern to those of us in paediatrics and child health; if this drug, taken in pregnancy to prevent nausea, caused these horrendous defects then it was quite likely that other exposures in pregnancy might cause other defects. With the determination to detect early and prevent another thalidomide disaster, we set up the first birth defects registry in Australia in WA. The other major change happening in perinatology was the marked increase in survival of preterm infants. The big question that was on our minds was how these children would develop: Were

they likely to be brain damaged or have normal development? Hence, our next register was again the first (and for many years the only) cerebral palsy register in Australia. And, yes, we did show that the rates of brain damage in preterm and very preterm infants went up as they survived in increasing numbers. This drove research into how best to prevent brain damage in these immature and vulnerable children.<sup>3</sup> The cerebral palsy register also contributed to the international debate on the myth that most cases of cerebral palsy were due to asphyxia at birth, which drove the damaging litigation resulting in costly and defensive obstetric care and unnecessary increases in caesarean sections. We also started lobbying then for a national system of disability insurance to provide for any disabled person irrespective of the cause of their disability; it has only taken over 20 years to get this up!

These registers were vital to the study of folate to prevent spina bifida and related defects, fetal alcohol syndrome, and the multiple other causes of the cerebral palsies. As well, we linked all the WA data together to enable the evaluation of clinical and maternal and child health programs across the whole state, including 'Reducing the risks' campaign, which dramatically reduced cot deaths. We had a special interest in studying Aboriginal families and their children. We are now the envy of the world (including the UK and the US), who for various reasons have not got such rich data sets, nor the capacity to link them together to tell the important stories about causes, prevention, need, social injustices and other consequential aspects of our health and wellbeing. Having been world leaders in these methods around population data, concerns about privacy in Europe and America in the late 1990s had negatively impacted on their ability to collect, access, link and analyse their previously excellent data sets. Australia, Canada and the Scandinavian countries were unique in having such capacity.

I tell this story because this should be a good news story for Australia, not a frustrating one as has happened in UK. Such data and capacity should be across all of our states and territories, not just in WA. Australia spends \$140 billion on health services and all states and territories to collect lots of data on health and other outcomes and how services are utilised. In addition to statutory collections (births, deaths, hospitalisations, birth defects, cancer, and so on), we have lots of agency data collected on all of us who use health, mental health, drug and alcohol, vaccinations and lots of other services.

Most of the community would like to think that the services provided were fully evaluated by such data to ensure that the effectiveness and efficiency of the systems was clearly demonstrated, that any harms would be quickly identified and that evidence of the most effective ways of providing care was guiding policies and practices. I have given you just a few examples above of how our WA data on maternal and child health were so powerful in improving outcomes and preventing deaths and disease. However, there is a reluctance in Australia by those who hold these data — the so-called data custodians (usually those running the services) — to release data in a timely fashion to researchers.

This would be less of a problem if they ran the research and evaluation themselves, but these valuable data are grossly under-utilised by custodians themselves for any analyses except the most basic. There is certainly no linkage across agencies to look at ways that each service provides cross-jurisdictional outcomes. The major reason given for this is the desire to keep the information on individuals private and to ensure the confidentiality of sensitive information. While this is expressed by the custodians, they make the case that this is reflecting the desire of the community to keep their data private. However, the methods used by researchers have been developed over decades to ensure privacy, and there are strict guidelines for

health researchers, as developed by the National Health and Medical Research Council and overseen by a huge network of human ethics committees nationally.

The dialogue has now shifted from excessive concerns about privacy, and consumers are voicing their concerns that the data are not being used to improve services and prevent harm. It may also be that the capacity within the bureaucracies to understand and analyse the data that they have has diminished over the past 20 years; the so-called public service — using the best data and evidence to serve the public good — has changed considerably. No longer do they feel confident to give ‘frank and fearless’ advice to their ministers, and they appear to be timid rather than visionary in their actions.

### **A fabulous example of public good that we could do right now — pharmacovigilance**

The example of thalidomide and other chemical exposures in pregnancy provides an example of a simple linkage that could provide the public and our health leaders with an excellent example of public good. In Australia, we are very lucky to have a Pharmaceutical Benefits Scheme data base which computerises all drug prescriptions that are filled at community and hospital pharmacies. We have done a feasibility study in WA to demonstrate that the PBS data can be linked successfully to the birth defects register and to birth and hospital records.<sup>4</sup> This is a near perfect system to detect the ‘next thalidomide’, as well as to monitor whether those drugs known to cause birth defects (for example, Roaccutane, used for acne) are being prescribed and used appropriately (that is, that women are advised to use contraception when on them). While this linkage has been done for the small number of WA births and has found some significant new results, the willingness to approve national linkage has fallen on deaf ears; and data has not been released to any WA researchers since 2009. We need to do better than this.<sup>5</sup>

## **Public good versus privacy protection — are we stopping great research by excessive privacy protectionism?**

I think that the best way for me to illustrate this is a hypothetical illustration, which we recently concocted for a paper on this issue.<sup>6</sup> While this is a fictional account, it is actually based on our frustrations at not being able to get such data for our investigations of drugs in pregnancy and their effects on the fetus.

### ***A hypothetical illustration***

This illustration is fictitious; however, it mirrors relevant real-life facts and the collective experiences of the authors. It illustrates that the dangers of privacy protectionism are not abstract, but can cause real harm to individuals.

‘Maleveril’ is a new and therapeutically valuable drug approved under the *Therapeutic Goods Act 1989* (Cth) for use in pregnancy. It has become a favoured drug in Australia because, unlike the more expensive alternative, it does not require a special authority script. There are now anecdotal reports that it increases the risk of certain birth defects (as happened with thalidomide in the 1970s), so there is an urgent need for post-marketing adverse event analysis in pregnant women and their babies. Australia is the ideal place for such research due to the high utilisation of the drug and because it has total population collections of birth defects in almost every state. These birth defect data collections were established in Australia (and many other countries) after the thalidomide disaster when inadequate records hampered investigative studies. One of the stated aims of establishing the population registers of birth defects was to detect another thalidomide disaster more rapidly.

An Australian research team from a child health research institute run by a charitable trust applies for anonymous linked data<sup>7</sup> from the Pharmaceutical Benefits Scheme and from statutory registers covering birth defects, obstetric care, hospital inpatient episodes and death data sets to evaluate the hypothesis that



Maleveril increases birth defects. They have approval from their local university human research ethics committee and the local health department's ethics committee. The research conforms to the strict guidelines for human research and has the strong support of the institute's consumer and community advisory group. The researchers obtain approval for the release of data from some of the data custodians; however, the researchers are frustrated because they are unable to obtain the approval of one of the data custodians. Barriers and delays are raised in the name of privacy. Eventually, after five years of delay, the funding for the project expires and the project is abandoned.

Meanwhile, researchers in Canada, with their own linked data, have demonstrated clearly that Maleveril causes a rare combination of cardiac and facial defects and they sound the alarm. The drug is withdrawn from use in pregnant women in Australia and elsewhere.

Angry Australian parents, who suspect that their children have been adversely affected by the drug, organise themselves into an action group to lobby the government to permit the Australian research to proceed. They want to use the results as potential local evidence that they have been victims of the drug, but they understand that anonymous data about them alone (for which they would willingly give consent) is useless. The researchers need the anonymous data on everyone exposed to the drug, regardless of whether they have an affected baby or not to accurately ascertain the risk. Eventually, the researchers are given 'special' access to the data as they originally proposed. The retrospective results confirm that the problems found with the drug in Canada apply equally in Australia.

Due to the delays, Maleveril has remained on the market for seven years longer than it would have if the research had gone ahead when it was first proposed. In that time, it is estimated that 210 severely malformed babies have been born in Australia as a result of the use of Maleveril.

One family has two severely disabled children following in utero exposure to the drug over the last three years and they believe that the government's policies have caused their children's disabilities. They ask why the anonymous data, which were available and could have been used legally, were not used to prevent this disaster and to avoid the severe malformations in their children. They want to know who is responsible and whether there is any redress for the harm suffered by their children.<sup>8</sup>

### **Summary and recommendations**

The main message from this piece is that the data we have at our disposal are enormously powerful and exciting resources for the health and wellbeing of our society. We live in challenging times for our health and other services: climate change, population changes, including ageing and increases in non-communicable diseases associated with sedentary lifestyles and poor diets, mental health problems and stress in the workplace, substance abuse, and social inequities are all of concern, and all demand the best data, research and evidence to guide the most effective policies.

There has been an excessive, and in my opinion, misguided fear of invasion of privacy from those who believe that researchers are not capable of caring about how best to protect individuals' information. We have been accessing, linking and analysing population health and other data in WA for nearly 35 years and we have not had ONE breach of information. Individual privacy has been totally protected. And the public good has been enormous. The consumers in WA are demanding more from the data custodians — they say: 'We know that you collect data on us. We want it to be put to good use to avoid harm and to improve services. If you have data that will prevent deaths and complications and do not use it we feel that we have the grounds to sue you.'

Australia needs to wake up and get this sorted quickly, as other countries such as the UK, Scandinavia, Canada and the US are now leaping ahead of us in terms of capacity, sharing and use of data. The case is even being made for us to share data across the world to address the issues that are facing us in health. Our citizens deserve no less.

As well, we need to increase the capacity both within agencies and in academic centres to link and analyse population data. As Australia is the only OECD country that does not have a National Institute of Population Health as in European countries, or a Centre for Disease Control and Prevention as in the US, my strong recommendation is that we establish such a national initiative. This could be done (as has happened in Canada) by setting up a virtual capacity that links centres of research and population data capacity across all the states and territories with central coordination. The various data sets and the methods to link and analyse them, and how the information is then utilised to guide policy, practice and evaluation, could be the central infrastructure of such a national venture. The data would be made available in protected ways to those designated and ethically approved scientists who would work closely with the bureaucracies to ensure translation. Federation could actually work to help here as we could compare outcomes between states and territories that do things differently.

If we can implement the best data sets and use them intelligently, we will be able to avoid the next thalidomide disaster, reassure our citizens that their services are safe and effective, and provide our populations with the best advice on how to have healthy and productive lives. Surely there is no better investment than this?

In the late 20th century, scholars and politicians posed a key question: ‘What desires and needs do you have as an autonomous rights bearing person to privacy, liberty and free enterprise?’ Now it is impor-

tant to ask another kind of question: ‘What kind of community do you want and deserve to live in, and what personal interests are you willing to forgo to achieve a good and healthy society?’<sup>9</sup>

Larry Gostin, who is an internationally renowned lawyer in public and global health and was also a speaker at our Festival of Ideas, expressed here the importance of making decisions based on the best data.

## Endnotes

- 1 IPCC Report, retrieved from [http://www.ipcc.ch/publications\\_and\\_data/publications\\_and\\_data.shtml](http://www.ipcc.ch/publications_and_data/publications_and_data.shtml)
- 2 FJ Stanley et al., ‘A population database for maternal and child health research in Western Australia using record linkage’, *Paediatric and Perinatal Epidemiology*, vol. 8, no. 4, 1994, pp. 433-447.
- 3 FJ Stanley et al., ‘Cerebral palsies: epidemiology and causal pathways’, *Clinics in Developmental Medicine No. 151*, Mac Keith Press, London, 2000.
- 4 L Colvin et al., ‘Linking a pharmaceutical claims database with a birth defects registry to investigate birth defect rates of suspected teratogens’, *Pharmacoepidemiol Drug Safety*, vol. 19, no. 11, 2010, pp. 1137–1150.
- 5 FJ Stanley & EM Meslin, ‘Australia needs a better system for health care evaluation’, *Medical Journal of Australia*, vol. 186, no. 5, 2007, pp. 220–221.
- 6 J Allen et al., ‘Privacy protectionism and health information: Is there any redress for harms to health?’ *Journal of Law and Medicine*, vol. 21, 2013, pp. 473–485.
- 7 The protocol used for linkage of administrative health data in Australia enables data custodians to provide researchers with data which have had names, addresses and other identifiers removed. The data for a project from different sources are merged using an alphanumeric key created for that particular research project only.
- 8 Allen et al., *ibid.*
- 9 LO Gostin, ‘Law and ethics in population health’, *Australian and New Zealand Journal of Public Health*, vol. 208, no. 1, 2004, pp. 7–12.

## Suggested reading

- CW Kelman et al., ‘Research use of linked health data — a best practice protocol’, *Australian and New Zealand Journal of Public Health*, vol. 26, no. 3, 2002, pp. 251–255.
- D Hetzel, ‘Data linkage research — can we reap benefits for society without compromising public confidence?’ *The Australian Health Consumer*, no. 2, 2005, pp. 27–28. <https://www.chf.org.au/pdfs/ahc/ahc-2005-2-data-linkage-research.pdf>
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