# SHARING LINKED DATA FOR HEALTH RESEARCH

Health research around the world relies on access to data, and much of the most valuable, reliable, and comprehensive data collections are held by governments. These collections, which contain data on whole populations, are a powerful tool in the hands of researchers, especially when they are linked and analysed, and can help to address 'wicked problems' in health and emerging global threats such as COVID-19. At the same time, these data collections contain sensitive information that must only be used in ways that respect the values, interests, and rights of individuals and their communities. *Sharing Linked Data for Health Research* provides a template for allowing research access to government data collections in a regulatory environment designed to build social license while supporting the research enterprise.

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## CAMBRIDGE BIOETHICS AND LAW

This series of books – formerly called Cambridge Law, Medicine and Ethics – was founded by Cambridge University Press with Alexander McCall Smith as its first editor in 2003. It focuses on the law's complex and troubled relationship with medicine across both the developed and the developing world. In the past twenty years, we have seen in many countries increasing resort to the courts by dissatisfied patients and a growing use of the courts to attempt to resolve intractable ethical dilemmas. At the same time, legislatures across the world have struggled to address the questions posed by both the successes and the failures of modern medicine, while international organisations such as the WHO and UNESCO now regularly address issues of medical law. It follows that we would expect ethical and policy questions to be integral to the analysis of the legal issues discussed in this series. The series responds to the high profile of medical law in universities, in legal and medical practice, as well as in public and political affairs. We seek to reflect the evidence that many major health-related policy and bioethics debates in the UK, Europe and the international community over the past two decades have involved a strong medical law dimension. With that in mind, we seek to address how legal analysis might have a trans-jurisdictional and international relevance. Organ retention, embryonic stem cell research, physician-assisted suicide and the allocation of resources to fund health care are but a few examples among many. The emphasis of this series is thus on matters of public concern and/or practical significance. We look for books that could make a difference to the development of medical law and enhance the role of medico-legal debate in policy circles. That is not to say that we lack interest in the important theoretical dimensions of the subject, but we aim to ensure that theoretical debate is grounded in the realities of how the law does and should interact with medicine and health care.

*Series Editors*

Professor Graeme Laurie, *University of Edinburgh*
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# Sharing Linked Data for Health Research

## TOWARD BETTER DECISION MAKING

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*'Would you tell me, please, which way I ought to go from here?'*
*'That depends a good deal on where you want to get to,' said the Cat.*
*'I don't much care where —' said Alice.*
*'Then it doesn't matter which way you go,' said the Cat.*
*'— so long as I get* somewhere, *' Alice added as an explanation.*
*'Oh, you're sure to do that,' said the Cat, 'if you only walk long enough.'*

Lewis Carroll, *Alice's Adventures in Wonderland*

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# Foreword

I have dedicated my working life as a doctor and an epidemiologist to improving the lives of children and their families. As an epidemiologist, I believe that the best way to identify the causal pathways to health and disease, to prevent disease, or to enhance health is through rigorous research. As we are unable to conduct randomised controlled trials (accepted as the gold standard for the evidence of care) on many of the most important things affecting children and their environments (including social and emotional as well as physical), we need to use the best alternative methods. This is why I have championed the use of population-level linked data. Linked data can tell us much about the social and environmental determinants of health and other outcomes, which guide our service agendas for prevention and improvement. They can evaluate whether and for whom the expensive services, policies and practices are working, are useless or are even causing harm, and, if we are clever, we can provide cost-effective evidence to guide decision making across governments.

Over the decades of establishing databases, such as registers of health data, and accessing agency data and linking them, we have many examples of research that has delivered huge benefits to the community. For example, my work with Professor Carol Bower on the link between folate deficiency and neural tube defects in babies required linked data to demonstrate that folate supplementation and fortification prevent neural tube defects. Our linked data clearly demonstrated the impact of this intervention, but it showed that poor and Indigenous women were not responding. This led to major mandatory folate fortification of flour nationally, and our data sets showed the dramatic falls in neural tube defects in babies of these disadvantaged women. Many countries have now implemented folate fortification and supplementation programmes. I have been privileged to witness the impact this knowledge can make in people’s lives.

I have also experienced the challenges, frustrations, and complexities of navigating access to government administrative data and have spent many years advocating for better access to these data for research. I was delighted when the authors, whose careers I have supported and encouraged, asked me to write the Foreword to this book.

It is critical, in my view, that government data collections of personal health information are seen as a public good, as a resource to be used for societal benefit. Although the information in these data collections relates to individuals, the collections themselves relate to communities and populations and can provide invaluable information about their health and well-being. Using and sharing these data collections for research has unlimited potential to improve the quality of healthcare and to save lives. And early interventions for families and children have been shown, using these data, to enhance their whole of life chances, not just in relation to health, but to education, disability, employment, and avoiding interactions with the justice system.

This book considers the ethical, human rights, and legal issues that arise when making decisions about how such data collections are used and shared. Decision-makers in this realm – law and policy makers, ethics committees, and data custodians – hold the keys to realising the benefits of the rich research resources held by governments at all levels in Australia and around the world. It is imperative that this decision-making power is exercised in a way that recognises the full range of stakeholders and the full range of interests at stake in the research enterprise. The authors' analysis of these issues is both thoughtful and thought-provoking. The book provides a detailed critique of the current decision-making processes in Australia, Canada, and the United Kingdom, including where they give rise to unjustified barriers to meritorious and ethically sound research.

This is not just an issue of national concern. The interdependence of people everywhere has been demonstrated in a stark fashion by the COVID-19 pandemic. Protecting and improving public health cannot be achieved within national borders. Cooperation between nations in understanding health challenges is vital. The rapid movement of people around the world makes sharing and linking reliable data across international borders crucial to this endeavour. Many countries are now engaged in linking data for health research in different ways. The cultural and historical contexts vary greatly, and the differences in process and principles for researcher access reflect this variation.

A common understanding of the appropriate ethical and legal parameters consistent with international human rights is essential to global cooperation in linking and sharing data. This book makes an important contribution to this endeavour. It examines the international research ethics guidelines and international human rights instruments and compares the ways in which these are applied in the domestic law and approval processes in Australia, Canada, and the United Kingdom. It illustrates the similarities between these jurisdictions and draws out the essential ingredients for good decision making by governments in using and linking data for health research. By comparing the experience gained in other countries, we can move towards shared principles and facilitate future international collaboration.

One of the most important achievements of this book is to draw attention to the importance of including the community in decision making about the use of government data for linkage and research. When I began my career, research was carried out in a paternalistic way. Research into the health of Aboriginal children in Australia, for example, was typically initiated by city-based researchers who determined the research questions and then went out into communities and gathered their data. There has now been a radical change, and research today is initiated by Aboriginal communities and Aboriginal health services and is conducted in collaboration with communities by Aboriginal researchers. This has had a profound effect on the quality and application of Indigenous research. Giving power to Aboriginal health professionals during the Australian COVID-19 pandemic resulted in them having the best outcomes in the world. This should now be the model of how research is conducted and how services are developed for the diverse community groups in our society. The vital need to give information to such groups about vaccination is another example, as is the need to collect and access data to evaluate that success (or not!).

At the Telethon Kids Institute, Perth, Western Australia, we have had a focus on community involvement for many years and fostered the establishment of the Consumer and Community Health Research Network which works with universities, health and medical research institutes, health service providers, and non-governmental organisations to bring together consumers and people with lived experience and connect them with health and medical researchers. This transformation is reflected in the expansion of community participation in the design and conduct of research in many areas of health research. It is equally important that the community is involved in making decisions about the use of health data collections for research. Increasingly, governments (federal, state and local) are requesting our input into their decision making for service provision and policies. This book argues that this is essential, both morally and pragmatically.

The three authors of this book are uniquely placed to traverse this multidisciplinary landscape, bringing to their research and writing decades of experience in the legal and ethical regulation of research using linked data. They are all scholars as well as practitioners and, as such, bring both theoretical and practical perspectives to bear on the complex issues under consideration. They provide a detailed and evidence-based analysis of existing decision-making processes and make many profound and practical suggestions for reform. It is a book for our time and essential reading for all those who do research and develop and implement policy, and for those professionals who need to know that what they are doing will be good and not harmful.

Professor Fiona Stanley AC

# Acknowledgements

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# Abbreviations

| | |
|---|---|
| ACT | Australian Capital Territory |
| AIDS | acquired immune deficiency syndrome |
| AIHW | Australian Institute of Health and Welfare |
| ALRC | Australian Law Reform Commission |
| APPs | Australian Privacy Principles |
| CAG | Confidentiality Advisory Group (UK) |
| CEO | chief executive officer |
| CHI | Community Health Index |
| CIHI | Canadian Institute for Health Information |
| CIHR | Canadian Institutes of Health Research |
| CIOMS | Council for International Organizations of Medical Sciences |
| COE | Council of Europe |
| CT | computed tomography |
| Cth | Commonwealth of Australia |
| DASH | Data Access Support Hub (Canada) |
| DHHS | Department of Health and Human Services (Tasmania) |
| DHSC | Department of Health and Social Care (UK and Scotland) |
| DNA | deoxyribonucleic acid |
| DPA | Data Protection Act |
| ECHR | European Convention on Human Rights |
| eDRIS | Electronic Data Research and Innovation Service (Scotland) |
| ERB | Ethics Review Board |
| ESC | Economic, Social and Cultural Rights |
| EU | European Union |
| EU | GDPR European Union General Data Protection Regulation |
| FAQs | frequently asked questions |
| GAfREC | Governance Arrangements for Research Ethics Committees (UK) |
| GDPR | General Data Protection Regulation (EU) |
| HDRN | Health Data Research Network Canada |

| | |
|---|---|
| HIV | human immunodeficiency virus |
| HPV | human papillomavirus |
| HRA | Health Research Authority (UK) |
| HREC | Human Research Ethics Committee |
| HUGO | Human Genome Organisation |
| ICD | International Classification of Diseases |
| IC/ES | Institute for Clinical Evaluative Sciences (Ontario, Canada) |
| ID | identifier |
| IDI | Integrated Data Infrastructure (New Zealand) |
| IRB | Institutional Review Board |
| IT | information technology |
| LGBTIQA | lesbian, gay, bisexual, transgender, intersex, queer/questioning, asexual |
| MCHP | Manitoba Centre for Health Policy |
| NHMRC | National Health and Medical Research Council (Australia) |
| NHS | National Health Service (UK) |
| NHSCR | National Health Service Central Register (UK) |
| NSS | National Services Scotland |
| NSW | New South Wales |
| NZ | New Zealand |
| OAIC | Office of the Australian Information Commissioner |
| OAS | Organization of American States |
| OECD | Organisation for Economic Co-operation and Development |
| OPCC | Office of the Privacy Commissioner of Canada |
| PBPP | Public Benefit and Privacy Panel for Health and Social Care (Scotland) |
| PHRN | Population Health Research Network (Australia) |
| PIPEDA | Personal Information Protection and Electronic Documents Act (Canada) |
| REB | Research Ethics Board |
| REC | Research Ethics Committee |
| SAIL | Secure Anonymised Information Linkage (Wales) |
| SeRP | Secure eResearch Platform |
| SPIRE | Scottish Primary Care Information Resource |
| SURE | Secure Unified Research Environment (Australia) |
| TDLU | Tasmanian Data Linkage Unit |
| UDHR | Universal Declaration of Human Rights |
| UK | United Kingdom |
| UK | GDPR United Kingdom General Data Protection Regulation |
| UN | United Nations |
| UN | ICCPR International Covenant on Civil and Political Rights |

| | |
|---|---|
| UN | ICESCR International Covenant on Economic, Social and Cultural Rights |
| UNESCO | United Nations Educational, Scientific and Cultural Organization |
| USA | United States of America |
| Vic | Victoria |
| WA | Western Australia |
| WHO | World Health Organization |
| WMA | World Medical Association |
| WWII | World War II |