THE ETHICAL, LEGAL, AND SOCIAL ACCEPTABILITY OF HEALTH DATA LINKAGE IN THE AUSTRALIAN CONTEXT: AN INVESTIGATION OF CURRENT PRACTICES, PERCEPTIONS, AND PUBLIC ATTITUDES

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TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

ABSTRACT

Vast collections of electronic data are held by a variety of health organisations, including government and non-government agencies, hospitals and universities. Data linkage involves combining such data sets for secondary purposes such as population health research. Data linkage currently occurs in Australia and is rapidly developing into a key tool both for Government and researchers. There are considerable benefits to data linkage, including the ability to conduct high quality research which may lead to advances in clinical practice, the development of public health policy, the prevention of disease, the conduct of public health surveillance. However, the associated ethical and legal issues require analysis and consideration to determine the moral and legal ramifications of such uses of data and so that indeterminate ethical and legal issues do not restrict agencies' and researchers' ability to fully support a co-ordinated national approach to data linkage. Lagging substantially behind recent developments in Australia and internationally is knowledge and clarity about the public's acceptance of data linkage practices.

This thesis presents findings of a multi-phase project comprising a theoretical component and two empirical studies. The theoretical component examines the ethical, legal and social acceptability of data linkage (Phase 1), and two empirical components (Phases 2 and 3) present the views of community members about data linkage.

In Phase 1 I argue that the non-consensual use of data is morally acceptable under certain conditions. It is currently legally acceptable in Australia despite certain impediments arising from the strict interpretation and complexity of Australian privacy legislation, an issue which is currently being addressed through amendments to the Australian Commonwealth privacy legislation.

Phase 2 comprised in-depth face-to-face interviews to determine participant views in relation to privacy and their preferred consent options in four hypothetical data linkage scenarios. Phase 3 involved the administration of a questionnaire before and after a citizens' jury to gauge, amongst other issues, these citizens' attitudes to health data linkage and to determine whether the provision of detailed information about the data linkage process, as well as the ethical and legal issues it raises, had an impact on previously held views and perceptions.

Participants quickly acquired an understanding of data linkage. They generally supported the non-consensual use of data provided that there were protection mechanisms in place such as the removal of identifiable data. Most participants believed that consent should be sought for data linkage projects if the linkage were being conducted by researchers with fully identifiable data. Participants weighed up opposing values such as the need for privacy against the potential benefits arising from data linkage research using an informal moral reasoning framework. The wealth of justifications for their decisions highlighted the participants' values.

This research aims to contribute to the Australian and international literature at a time when this method of combining data is being considered by researchers world-wide. In addition, the findings will assist in discussions and activities in relation to the development of the national data linkage framework, a key Australian Government research target within the next five to ten years.

THESIS STATEMENT

This work contains no material which has been accepted for the award of any other degree or diploma in any university or other tertiary institution to Vicki Xafis and, to the best of my knowledge and belief, contains no material previously published or written by another person, except where due reference has been made in the text.

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* Xafis, V., C Thomson, AJ Braunack-Mayer, KM Duszynski, and MS Gold (2011). "Legal impediments to data linkage." Journal of Law and Medicine **19**(2): 300-315.

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PRESENTATIONS ARISING FROM THIS THESIS

Contributors, Date, Location	Conference	Title
V Xafis, AJ Braunack-Mayer, C Thomson, MS Gold **2012, 26-29th June (NETHERLANDS, Rotterdam)**	11th World Congress of Bioethics	*The lay person's view of privacy in data linkage - do theory and people's perceptions intersect?* (Poster)
Ms Vicki Xafis, Ms Katherine Duszynski, Professor Annette Braunack-Mayer, Dr Michael Gold **2011, 29th October (AUSTRALIA, Adelaide)**	Public Health Association of Australia (SA) Conference *'Population Health: Working across sectors, settings and ages'*	*Public understanding of data linkage - indications from a South Australian citizens' jury.*
V. Xafis, A. J Braunack-Mayer, C. Thomson, M.S. Gold, K. Duszynski **2010, 20-22nd September (UNITED KINGDOM, University of Oxford)**	International Data Sharing Conference	*Ethical, legal and social considerations in administrative health data linkage in Australia.*
Ms V Xafis, Prof C Thomson, Prof A Braunack-Mayer, Dr M Gold, Ms K Duszynski **2010, 17-19th August (AUSTRALIA, Adelaide)**	Public Health Association Australia 12th National Immunisation Conference	*Legal impediments to data linkage: Remoto impedimento, emergit actio*
Ms Vicki Xafis **2010, 1-4th July (AUSTRALIA, Adelaide)**	Australasian Bioethics and Health Law Conference	*Privacy considerations in data linkage.*
Ms V Xafis, A/Prof A Braunack-Mayer, Dr M Gold, Prof C Thomson **2009, 31st October (AUSTRALIA, Adelaide)**	2009 State Population Health Conference: Challenges and Successes in Population Health	*Health data linkage in Australia: analysing the ethical, legal and social issues and exploring public perceptions and values.*

AWARDS ARISING FROM THIS THESIS

I was awarded the Faculty of Health Sciences Postgraduate Travelling Fellowship to support my attendance at the International Data Sharing Conference, 20-22nd September 2010, University of Oxford, United Kingdom.

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Coming to the end of my thesis I look back and think about all the people who helped along the way and enabled me to reach the point of writing this section. While this is one of the most important pieces of research I will ever tackle on my own, it could not have been completed without the support and guidance of a number of people.

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Last but not least, I thank Jacqui Howard for her assistance with formatting the final draft of the thesis and her patience as I took it back to her several times for minor changes.

A thesis is by no means a piece of work completed with technical assistance alone. There is a very human dimension to it all.

On a number of occasions during my candidature, I was asked to present the student's perspective to new PhD candidates so that they would be prepared, encouraged, and informed as they entered this new phase of their lives. What I always stressed during these talks is the fact that this large body of research needs to be completed within a limited number of years, and try as we may, it is impossible to put the rest of our lives on hold. Amidst the inevitable dramas of the research itself, there would be great life events some of which included weddings, births, deaths, divorces, and health issues, to name but a few.

What had previously been a simple observation later became a constant reminder in my own life. The events that unfolded from the second year until the final year of my studies were the most significant I have ever experienced and came like an avalanche, one after the other, as if to test my ability to cope. I am truly blessed to be surrounded by extraordinary people. I would like to thank them all for their support and for the laughter and joy they have always brought into my life.

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My family have always believed in me and supported everything I have done in life and this journey was no exception. My brother, Michael, a truly remarkable man, supported and encouraged me every step of the way. I dedicate this work to my mother, who is a woman of great courage and who has shown us all what it means to love. I also dedicate this work in memory of my father whose passing in the last year of my studies was one of the saddest events of my life. He would have been so very proud.

This thesis, entitled: "The Ethical, Legal and Social Acceptability of Data Linkage in the Australian Context: An Investigation of Current Practices, Perceptions, and Public Attitudes", is one component of a four-part study entitled *Vaccine Assessment Using Linked Data* (VALiD) Safety Study.

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As this thesis was one component of VALiD Study, I feel that it appropriate to acknowledge the various **VALiD Advisory Committees** comprising the following members:

Overall Advisory Committee: A/Prof Michael S Gold, Chair (University of Adelaide, SA); Prof Annette J Braunack-Mayer (University of Adelaide, SA); Prof Philip Ryan (University of Adelaide, SA); Prof John McNeil (Monash University, Vic); Dr Lee Taylor (New South Wales Department of Health, NSW); Dr Jim Buttery (Royal Children's Hospital, Vic); Prof Elizabeth Elliot (The University of Sydney, NSW); Prof Colin Thomson (University of Wollongong, NSW); A/Prof Glenda Lawrence (University of New South Wales, NSW); A/Prof Jane Freemantle (University of Melbourne, Vic); A/Prof Elizabeth Roughead (University of South Australia, SA); Dr Gary Lacey (Therapeutic Goods Administration, ACT); A/Prof Peter Richmond (University of Western Australia, WA); Sean Tarrant (Medicare Australia, ACT); Tony Woollacott (SA Health, SA).

Data Linkage Consent Advisory Committee: Prof Annette J Braunack-Mayer, Chair (University of Adelaide, SA); Dr Julie Leask (University of Sydney, NSW); Bernadette Richards (University of Adelaide, SA); Heather Petty (SA Health, SA); Maureen Watson (SA Health, SA); Dr Rod Givney (John Hunter Hospital, NSW); Prof Colin Thomson (University of Wollongong, NSW); Rebecca Horgan (SA Health, SA).

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PREFACE

A journey of a thousand miles must begin with a single step.

Lao Tzu [The Way of Lao-Tzu, 64]

In retrospect, I did travel a thousand miles to reach the point of commencing my doctoral studies, and then another thousand to reach the point of writing this section. Not by design, my education and professional career have followed a somewhat unusual path. Each turn, however, has offered a new dimension thus helping to integrate my current views within a multidisciplinary base.

Having obtained my teaching qualification, I spent many years teaching English as a second language and then studied linguistics, this already appearing to be a backward process. I felt that I discovered myself when, coincidentally, I fell into research ethics as a researcher, and then obtained a Master of Bioethics while at the same time having moved on and working as a professional in the area of research ethics.

Initially, my views on research ethics and the application of the law to research activities were rigorous and unyielding, shaped in the culture of the institution where I first encountered the discipline of ethics. Over time, however, as I developed more experience in the area, and aided by both my studies in bioethics and later by teaching medical ethics, I developed a more flexible and balanced approach to the tensions that often exist between moral values and other important interests when trying to determine the most ethically acceptable course of action. In addition, I began to better recognise that the conduct of research within a legal framework is also often fraught with tensions.

Coincidentally, once again, doctoral research became available in the already defined research area of data linkage and vaccine safety surveillance. As much as I would like to say that I had pondered the ethical, legal and social acceptability of data linkage long

before realising my dream of conducting research in the area, I obviously cannot. What I have pondered for many years, however, are issues of privacy, consent, research and policy transparency, which includes uses of personal and health data, and the application of the law in research and policy development.

My teaching background offers me the confidence that people with no prior knowledge of an area can, and do, acquire an adequate understanding of the most complex areas of human activity provided that the presentation of information is digestible, and that they have some interest in understanding it. I dare speculate that we all have an interest in data linkage, even if we are members of the general public, given that it potentially involves the use of our very own personal and health data.

Before articulating the research problem, research questions, aims and objectives of this research and the theoretical framework within which it was conducted, I present in the introductory chapter a non-technical description[1] of what data linkage entails and does not entail, aided by a diagrammatic representation of the process considered best-practice due to its attention to privacy protections.

[1] Greater detail on the technical aspects and some benefits of data linkage are available in (1) presented in Chapter 4. Chapter 4 comprises a legal paper published as part of the thesis and necessarily contains a brief description of some key technical features of data linkage as well as benefits arising from such activities. Hence, I felt that a non-technical description of the process was appropriate in the Introduction.

INTRODUCTION

Good ethics starts with good facts, even if good facts are not sufficient to get us to good ethics

Swinton, C. H. and J. D. Lantos (2010)

The research problem

The Australian Government is currently contributing vast resources for the development of sophisticated information and communication technology aimed at making possible the sharing of information for a variety of purposes, including research (2-4). In 2008, the National Collaborative Research Infrastructure Strategy (NCRIS) revised the *Strategic Roadmap for Australian Research Infrastructure* (2), which outlines Australia's strategic research infrastructure requirements over the next five to ten years. One of the aims identified in this document is to create "...the largest health data linkage system in the world."(2 p.53). To achieve this end, the Population Health Research Network (PHRN) program, which is supported by the Australian Government and all Australian State and Territory Governments, has established data linkage infrastructure in recent years which is increasingly enabling the linkage of health data from a number of jurisdictions (5).

Given the Australian Government's ambitious target, consideration of the ethical, legal and social issues that arise from and pertain to data linkage is vital. This is especially so given the lack of public understanding regarding what data linkage entails, how it may benefit society, and, importantly, the general unease regarding ethical and lawful uses of health and personal information (6-8) in a society that places great value on individual privacy. The Australian Government has already committed itself to the development of data linkage infrastructure so it is crucial that the public become aware of and engaged in these developments.

The dearth of empirical data about people's views about the uses of their information for research and policy development, conceptions of privacy, and the importance they place on privacy protections versus activities which promote the common good needs to be addressed rapidly. Broadly speaking, this is the focus of the research presented in this thesis.

I take as a given that data linkage can yield enormous societal benefits in the area of health. This assertion is based on ever increasing literature (9-18) , and is exemplified in Chapter 4. However, I also take as a given that privacy and consent hold a historically significant place in Western society and a key position in all considerations of our societal conduct. In addition, I see the role of legislative regulation of human affairs as vitally important for a society that values adherence to the rule of law. The issue therefore is to determine the relative weight given to these different values by citizens as well as to examine their respective weights theoretically.

Defining Data Linkage

There is much confusion and misunderstanding about the meaning of the term 'data linkage'. This section aims to clarify what data linkage is, what it involves, and what it does not relate to.

What is not data linkage

Before elaborating on what data linkage entails, it is appropriate to clarify what is *not* included in its description. Data linkage does not aim to create more complete files of *identified* individuals, which might be useful for surveillance of individuals or other such purposes, nor does it relate to data mining[2], as used in the commercial world and the world wide web[3]. Data linkage has been equated with the much-discussed electronic health records which aim to improve the sharing of individually identifiable health records across services in order to improve the quality of health care provision for individuals. Data linkage does not relate to this process either.

[2] "Data mining is a set of automated techniques used to extract buried or previously unknown pieces of information from large databases. Successful data mining makes it possible to unearth patterns and relationships, and then use this "new" information to make proactive knowledge-driven business decisions."(19 p.4), e.g. one's online access to various sites can reveal one's interests, habits etc. and help direct commercially profitable approaches towards that individual.

[3] See for example (20, 21))

What data linkage entails

All interactions with the health care system generate individual files containing both personal and health data. For example, patients' interactions with GPs, oncologists, radiologists, and other specialists they have engaged with in the treatment of their cancers are all recorded in hospital records and also in cancer registries. Typically, collections of such data are used to facilitate the provision of health care and to enable the efficient and effective operation of health care systems. Beyond such uses of these data, however, combining these administrative electronic collections from a variety of sources, e.g. medical records and deaths data, into single de-identified data sets provides researchers and policy makers with rich data of potentially great medical, epidemiological, economic, and policy significance.

There are generally three groups of people involved in the linkage of data: *data custodians* entrusted with a complete data collection (e.g. a government organisation that holds vaccination records); *data linkage experts* who create a code so that data collections that share only a limited number of common data variables (e.g. name, date of birth, post code) can be combined with a level of confidence that the records linked do in fact relate to the same individual; and finally, *researchers* who are given access to de-identified health data sets, which they are able to combine with the code created by the data linkage experts, as well as some non-identifying personal data, such as post code and age, for the purposes of analysis. Although implicit in the above description, it is important to bear in mind, throughout any discussion of data linkage and the related ethical issues, that the keys created to enable linkages between separately held datasets cannot be created without the use of identifiable data. We currently lack a single unique identifier that is shared across all health records. If unique identifiers were available for the data collections currently being considered many of the issues I shall be discussing would not need to be raised[4], provided the linkages were ethically and legally permissible.

The key feature of best-practice data linkage processes involves the separation of the various tasks required to achieve the linkage. Therefore, no single third party entity ever

[4] In Australia, in the near future, the linkage of disparate health data sets will be facilitated by the newly introduced health identifiers adopted in the *Healthcare Identifiers Act 2010*. A novel aspect of this legislation is the recognition that these identifiers can be used for the purposes of research provided that the research has been approved by a Human Research Ethics Committee (Sect 24 1(iv)) (22).

has access to the fully identifiable data set which data custodians hold[5]. In addition to this key feature, there are also stringent processes such as technical and physical protections of data (e.g. no web access, restricted access areas, encryption, password protection, tracking of activities, etc). Finally, Memoranda of Understanding and Confidentiality Agreements are entered into by the respective parties to further enhance the secure handling of data. Figure 1 below shows the data each entity has access to and the process required for de-identified data to be made available to researchers.

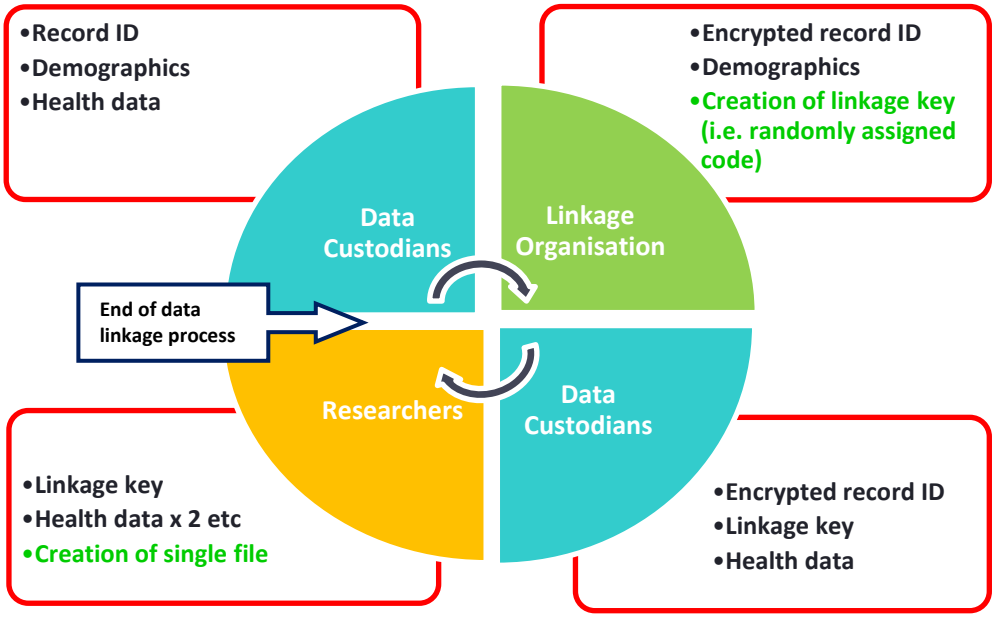


Figure 1. Data linkage process and entities involved

(adapted from (1))

Aims and objectives of this thesis

The aim of this research is to describe and analyse the ethical, legal and social issues which arise in data linkage in the Australian context.

Key Objectives:

a. To examine theoretically the key ethical issues and Australian privacy legislation as they relate to data linkage.

[5] As my friend, Jeff Chapman, pointed out when I described the process to him, the data custodian has possession of the whole puzzle (i.e. the whole data set they have been entrusted with) but others in the data linkage process only hold certain pieces of the puzzle (i.e. the linkage organisation only has the encrypted record ID and demographic data), which on their own are of little value.

b. To assess and interpret citizens' opinions and understanding of data linkage, and related ethical issues.
c. To gain an in-depth understanding of the citizens' underlying values and beliefs held in relation to data linkage and related ethical issues.
d. To explore the relationship between theory and empirical findings.
e. To inform the policy and practice of data linkage in the Australian context, having regard to key ethical, legal and social issues.

Research questions

Theoretical component (Phase 1)

1. What ethical issues arise and need to be considered in the context of data linkage?
2. What is the nature and the ethical and legal role of consent in data linkage research?
3. Is it acceptable to conduct data linkage research for the public good without obtaining consent, and if so, how can this be justified?
4. What legislative requirements apply to Australian data linkage research and how do they affect the conduct of research?
5. How is current health and privacy legislation interpreted and applied to data linkage research?
6. Is there a need for legislative reform?

Empirical component (Phase 2)

1. How do lay people conceptualise privacy in non-medical settings?
2. Do lay people place less value on privacy and established consent processes in relation to data linkage once they become familiar with the processes adopted in data linkage?
3. How do lay people resolve the tension that exists between opposing values such as privacy and the common good that arises from data linkage projects?
4. How do lay people justify the decisions they arrive at when making consent choices in the context of data linkage?

Empirical component (Phase 3)

1. How would a better understanding of core concepts and research-related facts affect the public's views on non-consensual[6] uses of data for data linkage?

Based on existing literature, a number of assumptions were proposed at the outset[7]:

- Participants will generally have a limited understanding of what data linkage is and what it involves
- Most participants will want to opt in and provide specific consent
- Participants will generally prefer to provide consent for both identifiable and de-identified data

Theoretical framework and methods

The research described in this thesis is multi-disciplinary, multi-phase, and adopts a mixed methods approach in the empirical components, as it endeavours to ascertain what perceptions exist and why such views are held by lay people.

The relationship between the normative and empirical components of this work is iterative; that is while normative views were formed as a result of theoretical enquiry, the empirical components necessarily informed the shape they ultimately took. In other words, instead of seeing a tension between the two elements of the research, these elements are viewed as complementary.

The three phases described below need to be viewed at two different levels: at the higher level, they form parts of a broader consideration of the research questions, and, as such, can be considered a multi-method approach. However, due to the diverse groups and methods adopted, each phase also needs to be considered as a distinct investigation with its own intricacies and considerations.

[6] *Non-consensual* uses of data refers to uses where individuals' consent has not explicitly been sought.
[7] A detailed explanation of how and why I included assumptions in the design of the study is presented in Chapter 5.

Project structure

This research is one component of a four-part study entitled *Vaccine Assessment of Linked Data* (VALiD)[8] (see Appendix 1). VALiD is funded by an Australian Research Council (ARC) Linkage Project Grant. In turn, this thesis presents research comprising three components, referred to as Phases 1-3. It should be noted that, while I designed all materials, the VALiD research team and the *Data Linkage Consent Advisory Committee*[9] were provided with the opportunity to comment on these, particularly where the citizens' jury pre and post questionnaire was concerned.

Phase 1 of the research is a theoretical examination of the ethical, legal and social issues pertinent to the consideration of linking administrative health data for research or public health purposes. Following an exposition of currently held views in ethics and the current legal environment in Australia in relation to data linkage projects, arguments are developed to support my normative views; that is, this component also discusses what I believe *ought* to be, following an explication of the key views and current practices.

Phases 2 and 3, aim to examine the same issues, as experienced by individuals in a real-world situation (i.e. mothers/fathers of new-born babies), and the general public in the context of a citizens' jury about vaccine safety surveillance. These empirical components provide an understanding of the ethical and social considerations as they are perceived and understood by lay people, and therefore provide insight into community views and why such perceptions are held.

Researchers engaging in a combination of theoretical and empirical research in ethics are working in a complex space. One view is that conclusions arrived at theoretically regarding the moral acceptability of data linkage can only be challenged with opposing theoretical arguments and that they cannot be influenced by the public's perceptions discovered through empirical research. On this view, the public's perceptions regarding the moral acceptability, or not, of data linkage can be said to align with or diverge from a theoretical determination of its moral acceptability. However, empirical data can also challenge a widely accepted norm and question its validity (23) thus bringing into

[8] More information is available at http://health.adelaide.edu.au/paediatrics/research/valid/

[9] The *Data Linkage Consent Advisory Committee* comprises individuals from a number of Australian jurisdictions with extensive relevant expertise.

sharper focus the true normative standards of a particular society. The relationship between theoretical and empirical research or, in more familiar philosophical terms, the relationship and tension between *is* and *ought* (24) is not straightforward but, as Zussman (25) notes, normative ethics can benefit greatly from insights gained through empirical research. Such empirical insights in the area of data linkage can be of immense importance, as they inform a process forward, either in implementing data linkage with the public's support, or evaluating the reasons for divergence of views followed by corrective measures to narrow the gap.

Significance of the research

While studies examining issues of consent in relation to research have been emerging in recent years (see (26)), there are still areas that require further in-depth exploration. For example, Noble and colleagues in the UK (27) have identified a need for further research into why individuals object to non-consensual access and use of their health information for research. In addition, they highlight the need for further research into whether such individuals would be willing 'to sacrifice their autonomy' (27, p. 81) for the public good after being made aware of the strict guidelines and measures in place for the conduct of research, such as Human Research Ethics Committee (HREC) reviews. The need for additional research into the views of patients and the public on access and use of health data for a variety of purposes such as public health surveillance and monitoring, research, and the provision of health care has also been identified by O'Brien and Chantler (28). Australian data on the public's views regarding the use of health data are all (with the exception of a few studies (29-31)) limited to reports on the public's attitudes to privacy laws in a number of social contexts (32), (33), (34) and therefore provide limited insight into the public's views regarding the use of health data in research.

This study adds to the literature in a novel way, as it considers an area not previously explored. It examines the issues that are most relevant when considering data linkage from a theoretical perspective and also involves empirical research which focuses on the same issues. The empirical research provides a better understanding of the public's views on data linkage practices. The studies elucidate participants' justifications for the views they hold, the values that underlie them, and how people balance conflicting

values when arriving at views regarding appropriate consent choices in the context of data linkage. The findings will contribute to current discussions for a co-ordinated national approach to data linkage and will also feed into the international literature, as data linkage is now also the focus of considerable international attention.

Thesis structure

Chapters 1-4 comprise Phase 1, the theoretical component of this thesis. They aim to provide a sound theoretical basis on which to assess the moral and legal acceptability of data linkage. In essence, these chapters raise what are often viewed as impediments to data linkage and provide a response to these. Privacy concerns, consent requirements for data linkage, an examination of the moral justification of non-consensual uses of personal data for data linkage and legal impediments that arise, either as a result of the current legal framework in Australia or its narrow interpretation, are all issues examined in these initial chapters. These chapters are critical for the subsequent analysis and discussion of the empirical studies.

Chapters 5-8 address Phase 2 of the project, the empirical study involving a total of 26 parents who participated in semi-structured face-to-face interviews and discussed their views on a number of data linkage scenarios. Phase 2 provides the richest data in terms of participant contributions. Chapter 5 provides an account of the methodology for the interviews, while Chapter 6 presents people's consent preferences in relation to four hypothetical data linkage scenarios. Chapter 7 follows on with further analysis of justifications of the consent choices discussed in the previous chapter and identifies the moral reasoning framework participants applied when making decisions. Chapter 8 presents participants' conceptions of privacy, its justification, as well as other features of privacy participants considered important.

Chapter 9, which forms Phase 3, presents findings from a pre and post questionnaire administered as part of a citizens' jury held in South Australia to consider the efficacy of data linkage as a vaccine safety surveillance mechanism. Consideration of this issue entailed considering the ethical and legal issues that arise in all data linkage projects. The aim of the questionnaire was to track changes to views following the 'educative' process jurors underwent as part of the expert presentations on various aspects of data linkage, including technical, ethical and legal considerations.

Finally, Chapter 10 discusses the findings of both the theoretical and empirical components and discusses implications of the findings in the empirical studies undertaken. This is done with reference to the theoretical analysis and enables a re-examination of my positions in light of the empirical data. Recommendations are made based on both the theoretical and empirical components. Finally, the limitations of this research are discussed, as are future areas of enquiry. This chapter also presents a brief conclusion.

CHAPTER 1

THEORIES OF PRIVACY

If we can never be sure whether or not we are being watched and listened to, all our actions will be altered and our very character will change.

Hubert H. Humphrey Jr.
American politician (1911-1978)

Introduction

Privacy has been central in considering the acceptability of data linkage in both legal and ethical terms. If any serious discussion regarding the wider implementation of data linkage projects and the impact this may have on society is to take place, it is necessary to have a good understanding of this concept. An exploration of the theoretical foundations of privacy provides a good starting point.

The philosophical literature does not provide a comprehensive theory of privacy. Most accounts of privacy have focussed only on certain aspects of this complex concept. Hence, the focus in this chapter will be on a broader sense of privacy rather than restricting discussions to informational privacy alone, as a narrow conception of privacy cannot provide a full account of the nature, scope, and value of privacy. Without such an understanding of privacy, it is difficult to adequately discuss the need and justification for protecting personal privacy.

Briefly explored in the following sections are a number of ways privacy has been conceived of in the philosophical literature, with regard to both the nature and value of privacy. The nature of privacy is explored via classic definitions of the concept in the literature which have been classified under *control of information*, *restricted access*, *seclusion or secrecy*, or privacy viewed as a *cluster concept.* The value of privacy is

discussed in relation to its role in the development of autonomy and a sense of self, interpersonal relationships, and its functioning in society. It is important to note at the outset that privacy is being considered in its positive sense, that is, as a concept which contributes to human flourishing, rather than in its negative sense, where it can provide an environment which fosters the concealment of facts, events and acts that harm individuals.

Following this, I briefly present an account of the *Restricted Access/Limited Control* (RALC) theory of privacy, as this conception of privacy aims to provide a more comprehensive account by incorporating a definition of privacy, a consideration of the value of privacy for human life, and the role control plays both in the justification and management of privacy. Because of its breadth, this theory of privacy cannot be applied to data linkage precisely, but it informs a fuller understanding of the role of control in privacy and, by explaining how individual and external controls operate, allows an examination of how privacy can be considered in the context of data linkage.

Background to ways of viewing privacy

For over a hundred years, philosophers and legislators have attempted to elucidate the elusive concept of privacy[10] but have, on each occasion, illuminated only some aspects of privacy while ignoring other key issues. For example, in his much discussed work *Why Privacy is Important*, Rachels (36) considers the value of privacy from the limited perspective of controlling access to and information about oneself, but stops short of providing a precise definition of the concept.

There are various forms of privacy for which we seek protection; *accessibility privacy*, which relates to access to our person in a physical sense, *decisional privacy*, which enables us to make decisions and take directions in life without coercion or threats, and *informational privacy*, which relates to our ability to control the flow of information about our person (37 p. 131) (38). These forms of privacy, however, are rarely treated as parts of a broader concept. Moreover, most theorists explore not only a certain form of privacy but also only certain aspects of that form, for example, either the nature of

[10] While considerations of public versus private domains date back as far Aristotle, privacy only attracted methodical treatment as a concept separate to property rights and liberty through considerations of requirements to amend and supplement American legislation in the 1800s (35).

privacy, or the value of privacy, or a combination of these while omitting other important considerations. The articulation of a privacy theory that adequately addresses all related philosophical considerations is extremely difficult, as evidenced by the literature. However, a theory of privacy that considers key issues such as what is meant by privacy, whether it is valuable and how it is achieved and protected is more comprehensive. In the next section, I will describe a range of conceptions of privacy before moving to Moor's conception of privacy (39, 40). His is a theory that takes account of a number of complexities involved in the discussion of the concept, which is especially useful in the context of data linkage.

Conceptions of privacy

The following sections aim to provide an account of the variety of ways in which privacy has been conceived of and treated in the literature with regard to its meaning (The concept of privacy) and the role privacy plays in our functioning as social beings (The value of privacy).

The concept of privacy

The purpose of this section is twofold; it presents some of the most widely discussed definitions of privacy as well as a classification of these definitions, as proposed in the literature, e.g.(8), (38).

Privacy viewed as control of information

A 'control theory' of privacy is prominent in the literature and a number of versions relating to the control of information about our persons exist. One of the most influential accounts has been that of Alan Westin (41) who suggests that universally, at an individual level, humans have an innate desire to learn more about their environment and their fellow citizens, expressed in the form of curiosity. At a societal level, surveillance mechanisms ensure that societal norms are observed and that people do not adopt behaviours which would harm their society (41). Against these invasive behaviours is people's desire for privacy, which Westin defines as: '... the claim of individuals, groups, or institutions to determine for themselves when, how, and to what extent information about them is communicated to others' (41 p.7).

In his treatment of the concept, Fried sees privacy as being '…control over knowledge about oneself' (42 p.483) rather than merely what people do not know about us. He clarifies that we cannot speak of privacy unless there is the possibility of granting or denying access to information. Therefore, if we were to remove ourselves from society, we could not speak of increased privacy, as privacy can only be experienced in the presence of others who may access or be given access to our person or information about our person. Fried alludes to the importance of the quantity and quality of information controlled but does not discuss this in great detail (42).

While Rachels only alludes to a definition of the concept (36 p.329), he also adopts the control theory of privacy, given that social relationships are based on degrees of knowledge of personal information about one another (which we control as required), and norms regarding appropriate behaviours for the relevant roles assigned to people in our lives.

A more recent construal of the control theory of privacy is offered by Shoemaker (43), who views it as control over personal information that relates to one's self-identity rather than *all* information relating to the same individual. Information that relates to one's self-identity is information about the self that evokes an emotional response (either positive or negative) or, as Shoemaker puts it, relating to "...properties that ground one's emotions of self-esteem" (43 p.11). According to this conception of privacy, unauthorised access to such personal information undermines one's autonomy, as it deprives the individual of the ability to "manage" their public image (43). In addition, such access diminishes an individual's ability for self-determination simply by virtue of the fact that someone is privy to the information and not necessarily as a result of the harmful ways to which the information could be put to use. This view of privacy arises from considerations of privacy in a public domain, e.g. in data mining (43).

Privacy viewed as restricted access

Gavison argues that privacy is distinct from other values and that the concept of privacy must be descriptive and be characterised by neutrality to enable an identification of losses of privacy without introducing issues of the value of the concept in such considerations (44). She views privacy as "...a limitation of others' access to an individual" (44 p. 428) and believes that both complete privacy and complete loss of

privacy do not exist in human society[11]. She does, however, suggest that theoretically 'perfect privacy' (44 p.428) could be achieved if no one had any kind of access to an individual (44).

Privacy viewed as seclusion or secrecy

Westin offers a second definition of privacy from the perspective of social engagement. In this context, privacy is the '...voluntary and temporary withdrawal of a person from the general society through physical or psychological means, either in a state of solitude or small group intimacy or, when among larger groups, in a condition of anonymity or reserve' (41 p.7). According to this view, people experience a natural tension between two opposing desires: that of seclusion from other individuals and that of involvement in social life, which reduces the privacy they can enjoy (41).

Similarly, Gavison believes that privacy is achieved via three elements: '*secrecy, anonymity and solitude*' (44 p.433), which are independent of each other yet intricately related to one another. In this context, *secrecy* relates to lack of information about the individual, *anonymity* refers to the fact that the individual is not the focus of people's attention, and *solitude* relates to the fact that the individual cannot be physically accessed by anyone (44). Individuals experience a loss of privacy as people gain informational, cognitive, or sensory access to an individual (44).

Even though Parent may oppose his conception of privacy coming under the banner of secrecy, if one closely examines his definition "Privacy is the condition of not having undocumented personal knowledge about one possessed by others" (46 p.269), it is not unreasonable to conclude that what he is in fact discussing is secrecy (47). In Parent's conception of privacy, *undocumented* is any information not on public record and *personal information* comprises both personal facts which the average person would withhold from most people as well as information about which the individual displays a particular sensitivity, e.g. one's shoe size (even though most people may not) (46 p.270). Parent clarifies that considerations of privacy in relation to personal information change over time, so while disclosure of some personal information may cause distress today, in the future the same information may be openly discussed without embarrassment (46).

[11] Total institutions could be said to deprive people of most forms of privacy but inmates still do retain control over their personal thoughts (see Goffman (45)).

Privacy viewed as a cluster concept

DeCew's conception of privacy could also be considered a variation of the control theory. However, unlike other theorists, she argues that privacy should be viewed as a multi-faceted concept comprising a number of interests, such as information, mental and physical access, and decisional freedom, over which we wish to have control (35).

Also in this category is the Restricted Access/Limited Control (RALC) theory of privacy initially developed by Moor (39, 40) and further elaborated on and refined by Moor and Tavani (38), (48). It is made up of three distinct parts which provide an account of the *concept of privacy*, *the justification of privacy*, and *the management of privacy* (38). Due to its theoretical structure and relevance to data linkage, however, it will be discussed separately in a subsequent section.

Reductionist conceptions of privacy

In most of the literature, privacy merits attention and consideration as a distinct and valuable concept which contributes to human flourishing. However, there is another account of privacy which, although not supported by most philosophers, nevertheless warrants mentioning. It is the reductionist account of privacy, the most prominent and greatly discussed of which is that offered by Thomson (49). According to this account, privacy is not a right in itself but can be simplified into other rights such as "...the right that his face shall not be looked at." (in the context of covert surveillance) (49 p.304) or the 'right not to be caused distress by the publication of personal information' (49 p.309) (in the context of the publication of private information). Thomson concludes that there are no *privacy* rights per se, as these can always be reduced to other rights, such as property rights.

Summary of the concept of privacy

The above sections have briefly illustrated the various ways in which privacy has been conceived and the classifications under which these concepts fall. When attempting to define privacy, theorists such as Westin, Fried, Rachels, and Shoemaker have proposed that it relates to the control people exercise over their information. In these accounts we observe variations in the nature of the information referred to as requiring control. Theorists, such as Gavison, have also attempted to relate privacy to restricted access to information while others see the concept of privacy as relating to secrecy or seclusion, for example, Westin and Gavison. DeCew, Moor, and Tavani view privacy as a more

intricate concept and their accounts therefore come under the classification of a 'cluster concept', even though the specific details of each account vary vastly. Finally, the reductionist account of privacy (Thomson) completely rejects the notion that privacy is a separate concept in itself. Rather, Thompson states that privacy can always be reduced to more fundamental rights. Having briefly examined the concept of privacy, we now move to considerations of the value of privacy.

The value of privacy

We value privacy for a range of reasons relating to its central role in the development of the self and one's autonomy, as well as one's ability to develop and maintain a range of relationships. In addition to this, its role in the functioning of society itself has been much discussed. Each of these will be presented below in more detail.

In examining the value of privacy, it is important to consider whether privacy is intrinsically or instrumentally valuable. In order for something to have intrinsic value, it must be deemed valuable because of its very nature and not because of any goods that arise from its existence (i.e. instrumental value). The discussion below points to the fact that privacy is so crucial to human existence (given its close connection to the self-concept, autonomy, social and intimate relationships) that it cannot be considered in isolation from humans. In this sense, it can be seen to have intrinsic value. Without privacy these states of existence and socialisation would simply not develop and this in turn would render us incapable of functioning as individuals able to interact with each other in the manner we are accustomed to at present.

In Westin's view, privacy functions to promote autonomy, provide emotional release from the stresses and strains of social co-existence, to provide an opportunity for self-evaluation and information processing, as well as to promote "limited and protected communication"[12] (41 p.38), which enables us to maintain our social relationships.

Fried defends the view that privacy is essential for the development and maintenance of intimacy upon which respect, love, friendship and trust are based (42) and eloquently expresses the value of privacy in human society in the following (42 pp.477-478):

[12] 'Limited communication', (41 p.38) refers to the space that we require in all relationships, ranging from formal to intimate, that allows us to retain some information for ourselves. Conversely, 'protected communication' (41 p.38) relates to communication that is kept in confidence and not shared with third parties.

> *To make clear the necessity of privacy as a context for respect, love, friendship and trust is to bring out also why a threat to privacy seems to threaten our very integrity as persons. To respect, love, trust, feel affection for others and to regard ourselves as the objects of love, trust and affection is at the heart of our notion of ourselves as persons among persons, and privacy is the necessary atmosphere for these attitudes and actions, as oxygen is for combustion.*

In his consideration of privacy, Fried (42), has come under intense criticism for the following observation in relation to the connection between privacy and intimacy (42 p.484):

> *To be friends or lovers persons must be intimate to some degree with each other. But intimacy is the sharing of information about one's actions, beliefs, or emotions which one does not share with all, and which one has the right not to share with anyone. By conferring this right, privacy creates the moral capital which we spend in friendship and love.*

Reiman (50) argues that, by connecting the granting and withholding of personal information with intimacy, Fried commodifies the notion of intimacy. Reiman rejects the link between privacy and intimacy and argues that it is the context of *caring* that enables people to develop intimate relationships, i.e. it does not matter who I have shared personal information with but rather who cares about the information I have imparted. However, it is hard to imagine that at the very beginning of a friendship there is *any* context of caring at all within which personal information is shared.

Rachels also views privacy as playing a crucially important and central role in the development of social and intimate relationships (36). We value privacy because it enables us to develop a wide range of social relationships and take on a multitude of social roles. Relationships, according to Rachels (36), can only develop if different aspects of the self are revealed to the variety of people with whom we interact and with whom we adopt the norms typical of the particular role we are playing at any given time. This is achieved by divulging varying degrees of personal information while withholding aspects of our personality that are not appropriate in a particular relationship (36). For example, the information willingly provided to a doctor could cause great embarrassment, or even harm, if disclosed to one's employer or friends. Similarly, intimate behaviour shared only with one's partner would be inappropriate and damaging in the workplace.

In accordance with DeCew (35, 51), the value we place on privacy relates to the control we need over areas of our life such as our person, our personal information, and our

ability to make decisions without interference from others. Control over these aspects of our life, according to DeCew, creates an environment conducive to developing individual expression, a variety of social relationships and the ability to lead a life without fear of embarrassment, judgement or scrutiny.

Gavison (44) argues that the value of privacy can be understood not by examining the neutral concept of privacy, required for the identification of losses of privacy, but rather by identifying the relationship between privacy and other values we consider important, i.e. by identifying the instrumental value that privacy holds. In her view, privacy promotes other values such as autonomy, liberty, personhood, human relations and a liberal society, which could not develop in an environment of constant scrutiny and interference from others (44).

The role that privacy plays in the development of an autonomous person has been widely discussed in the literature (41, 42, 44, 50-56). In order for an individual to develop and maintain autonomy, it is necessary for them to enjoy a degree of privacy, which enables the development of an autonomous self-concept, i.e. a concept of oneself as self-determining, and able to direct his/her plans in life (52). For an autonomous self-concept to develop, an individual must be able to relate the body that she occupies with the thoughts that she has, and the acts she performs and view them as forming an integral part of her identity over which she has some control (52). As Kupfer notes, *"...an individual is not in control of his life, is not self-determining, unless he conceives of himself as such*" (52 p.82).

A thought experiment that highlights the importance of privacy (52) involves a society which has deliberately been led to believe that they are under 24-hour surveillance via a number of dummy surveillance devices and measures. As a result of these measures people believe that they enjoy no privacy[13]. Despite the fact that the citizens in question actually do enjoy privacy, they conduct themselves as if constantly monitored, and therefore are not autonomous in the real sense of the notion. In other words, under these conditions, while individuals may seem to be directing their lives in accordance with their own wishes, the very fact that they believe they are being monitored may be

[13] We can envisage the usefulness of such an illusion in controlling violence and maintaining public order.

influencing the decisions and choices they are making, which might differ considerably from the decisions and choices made if they felt they were not being monitored.

Goffman offers an anthropologically-based theoretical treatment of privacy when he considers the '*mortification of the self"* (45 pp. 23-72), which occurs in total institutions, such as prisons and concentration camps. In environments where individuals are systematically stripped of privacy, the sense of self is eroded (45). For example, the requirement to share all aspects of personal information, including information that shames the inmate, not only with staff but also with other inmates in confession sessions, the lack of privacy when sleeping and going to the toilet, as well as the inability to avoid surveillance cause inmates to lose their sense of self and their capacity to determine their own existence in the most basic ways (45).

The role of privacy in the development of the self also has a social dimension, through which *"...an individual's moral title to his existence is conferred*" (50 p.39). In other words, an individual develops a sense of personhood not in isolation, but in an ongoing social context where people both recognise and communicate to the individual that his body, his views, and his existence belong to him (50).

In his work, Schwartz considers the function of privacy in the social organisation of human beings and comments on its "stabilizing effect upon two dimensions of social order" (56 p.744). If individuals were not afforded privacy, relationships could not be sustained, as we would find constant contact intolerable (56) (the "horizontal order" p.744). Furthermore, privacy enables us to maintain differing levels of status divisions within a community, e.g. the personal assistant to a manager acts as a shield against intrusions the manager would otherwise suffer (the "vertical order" p.744).

A value which most people readily recognise in privacy is the protection it affords from harm. The harms and losses that it protects against can relate to a number of areas in our life, e.g. financial, social and psychological, and have been much discussed in the literature (35, 36, 46, 53, 57).

Summary of the value of privacy

A broad range of values is attached to privacy, as the discussion above demonstrates. On an individual level, its role in the development of autonomous persons is widely recognised, as is the fundamental role privacy plays in the development and

maintenance of intimate and other social relationships. On a societal level, privacy enables us to maintain appropriate distances from each other and is instrumental in our ability to co-exist. Privacy provides a release from the pressures of human co-habitation and constant scrutiny from others and is therefore also key in contributing to good mental health. One of the most evident justifications for privacy is its role in protecting us from a variety of harms impacting on a number of areas of human existence.

I now turn to a theory of privacy, RALC, which takes into account a number of issues discussed in the previous sections.

The Restricted Access/Limited Control Theory of Privacy

The *Restricted Access/Limited Control* (RALC) theory of privacy draws on components of the most influential theories of privacy in an attempt to provide a comprehensive account of the concept and its value (38). It is for this reason that it is given some prominence in this chapter. Figure 2 below provides a visual representation of the elements that comprise the theory. These are **the concept of privacy**, which provides a definition of privacy and other important distinctions relating to the concept, **the justification of privacy** and its **management**, both of which are discussed within the context of controlling one's privacy.

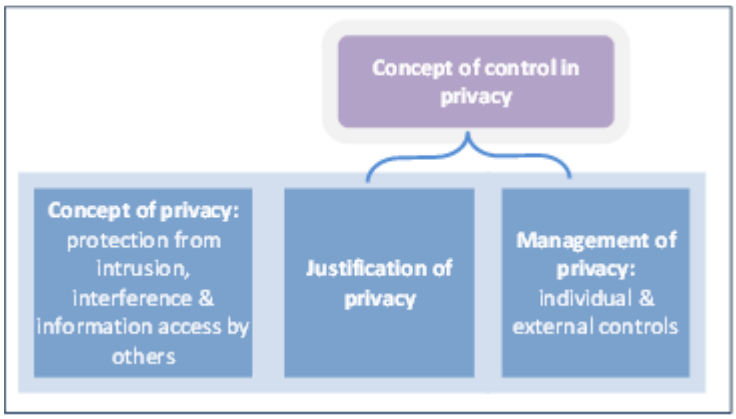


Figure 2. Components comprising the RALC theory of privacy

The following sections briefly describe this three-pronged theory of privacy as proposed by Moor and Tavani and will also relate their theory with discussions of a similar content by other theorists.

RALC concept of privacy

In accordance with this conception of privacy, a person or group of people possess privacy "*in a situation if and only if in that situation the individual or group or information related to the individual or group is protected from intrusion, observation, and surveillance by others*" (39 p.76). According to this definition of privacy, a *situation* can range across a number of contexts which warrant privacy protection, such as "*an activity in a location"*, "*a relationship*" or "*the storage and use of information...in a computer database*" (39 pp.76-77). Of equal importance in this theory is the distinction between *naturally private and normatively private* situations.

A *naturally private situation* is one in which people are protected from privacy intrusions due to external factors which provide natural protection (39) e.g. a built structure, a closed door, an isolated country trail etc. On the other hand, a *normatively private situation* is one which is protected from intrusions either legally or morally (39) and would include the privacy which we enjoy in our home (e.g. home intrusions are prohibited by law), on the telephone with friends and family (e.g. telephone tapping is illegal, except in certain limited and specified circumstances), in consultations with our doctor (e.g. legislation and codes of conduct require that doctors keep their patient's health information confidential) and information gathered about us for the provision of services (e.g. privacy legislation is designed to protect personal information disclosed to services). Some situations may be afforded both natural and normative privacy, as is the case with one's home; the structure affords natural protection from intrusions but the occupants are also legally protected from privacy intrusions (38, 39). The distinction between *naturally private and normatively private situations* is important, as it enables us to consider the *condition of privacy*[14] and the *right to privacy* as distinct (38) (39) and as a result also makes possible the distinction between a *loss* of privacy and a *violation* of one's privacy. A person can experience a loss of privacy in a naturally private situation but not a violation of privacy, as naturally private situations are not protected by law. On the other hand, in a normatively private situation, for example, e-mail communication with a friend both a loss and violation of privacy can be experienced if a third party accesses the e-mail communication. While not identical in nature, Scanlon also distinguishes between zones of privacy and considers there to be zones of privacy

[14] The *condition of privacy* refers to "*...what is necessary to have privacy in a descriptive sense"* (38 p.10).

protected by "*explicit social rules*" (58 p.316), such as laws or conventions, and zones of privacy which are merely social "*vague and informal understandings*" (58 p.316) regarding appropriate behaviour, for example, towards fellow citizens' private space in public places.

An additional point of great significance with regard to the concept of privacy is that normatively private situations are not uniform in all societies, as the conception of which situations should be afforded normative protection vary both culturally and over time (39, 41, 59). To generalise from Fried's view of informational privacy (42), the most important element is not *which situations* are normatively protected but rather the fact that in all societies *some situations* are normatively protected via legal or social conventions. It has been shown in a number of studies (41, 59) involving humans[15] in societies of varied advancement that privacy is a universal value without which societies and individuals could not function. Even in societies where privacy may appear not to exist, or not to hold any remarkable position in social interactions, for example, in Java where the bamboo huts have no doors and entry is not controlled during the day and early evening, privacy norms still exist. The Javanese employ psychological barriers to counter the lack of natural privacy; they are restrained, softly spoken and unlikely to express their feelings even to close family members (41)[16]. In addition, despite the lack of natural privacy in the home, the area where family members bathe and change offers a degree of privacy, as it conceals parts of the body between the knee and shoulder area (41).

One of the key features of the definition of privacy provided by Moor and Tavani is the fact that privacy relates not only to natural persons but also more generally to other spheres of life. This distinction enables the discussion of privacy protections warranted in relation to persons and, importantly, in an age of technology, data contained in databases, for example. In addition, the distinction made by Moor and Tavani between naturally private and normatively private situations enables the distinction between losses and violations of privacy. Following the explication of the concept of privacy

[15] There have also been animal studies indicating that privacy (in the form of separation from animals of the same species) is critical for their survival (41, 59).
[16] Information about the Javanese is found in Westin's *Privacy and Freedom* (41) but was originally provided by Clifford Geertz in an unpublished paper.

proposed by Moor and Tavani, I now move to the second component of their privacy theory, that is, the justification of privacy.

RALC justification of privacy

In order for a theory of privacy to be complete, it should address the reason or reasons why people should be afforded normative privacy protection and should consider the role of an individual's control in such a theory.

In the social life that nearly all people lead, it is not possible to have complete control over who has access to us, especially in the highly computerised age in which we live, but the need for us to have *some* control is crucial to a meaningful existence in a number of ways (48). Moor and Tavani view privacy as promoting the development of the self and of liberty (39), as well as self-determination, which enables us to control the manner with which we lead our lives and develop relations with people (48). They also recognise the protection from harm that privacy affords and the ability it offers us in deciding what projects to engage in and what level of risk we wish to assume in relation to these projects (48).

Arguably, the most tangible reason why a certain amount of control over our persons, personal information, and privacy is desired is protection from harms that we could suffer if privacy protection were not afforded (38, 39). For example, unauthorised disclosures of health information can result in financial, social, psychological harm (53) (more so in some societies than others). Furthermore, mere threats in relation to either unauthorised disclosures of information, or other aspects of our private lives such as our bodies and our ability to make autonomous decisions, can create a state of distress and feelings of loss of control (57). It is for this reason that privacy protections are so vital in providing a degree of freedom required to live autonomously.

RALC management of privacy

In accordance with the RALC framework, individual control is central to the management of privacy and is achieved via three elements: *choice*, *consent*, and *correction* (38, 48). These controls are made available through the promulgation of legislation and privacy policies (38).

People can manage privacy through *choice* in both naturally and normatively private situations (48). For example, if you do not wish to be seen eating cake in public, you can

choose to eat it at a location where you are sure you will not be observed by others. Similarly, you can choose to become involved in some internet interactions but reject others depending on the privacy provisions available. In order, however, for individuals to have *real* choice, the levels of security offered in a variety of exchanges need to be transparently disclosed (48). For example, it is necessary to know if the information you provide will be used solely for internal business purposes or whether it is to be shared with other entities.

A degree of control of privacy is also exercised through *consent* (38, 48). Consent gives the right to a third party to use someone's information or to access their body (or to make decisions on their behalf) thus legitimising an otherwise unlawful act (48). The provision of consent (or its refusal) enables us to make choices regarding our body, our information and the directions our lives take[17].

The third way with which privacy is managed through control by the person to whom information pertains is *correction*. The ability to ensure that information held about an individual is accurate via the correction of false or incorrect information reduces the likelihood that the individual will be misrepresented with information that never did or no longer pertains to that person (48).

In addition to the *individual* controls discussed above, *external* controls in the form of policies, codes, legislation (as well as sanctions for breaches) provide additional protections for normatively private situations (48). These external controls regulate access to our person or our information by declaring zones of privacy which have to be respected and thus further assist in the adequate management of privacy. In the last decade, changes to privacy legislation both in Australia and abroad were made in order to harmonise such protections at an international level and to facilitate the conduct of international business (60).

In an era where information is sought and shared at inconceivable speeds, the above elements cannot possibly provide complete control of all accesses to our information; nevertheless, they do provide limited controls regarding who has the right to access it.

[17] There is a number of forms of consent, modes of granting consent, and numerous conditions for consent to be considered valid and meaningful. While they are recognised as issues of great importance and interest, they are not central to the current discussion and will therefore be dealt with in the following Chapter.

Conclusion

This chapter has provided a brief view of the multiplicity of conceptions of privacy provided in the literature. The justification of privacy has also been discussed and it is evident from the rich literature that privacy plays a critical role in human development, human interactions, and wellbeing. The chapter has focused on the RALC theory of privacy, which although not directly applicable to data linkage, as data linkage entails no individual controls, is a very useful conception of privacy, as it clearly articulates the role of control in privacy. Accepting the RALC articulation of control in privacy, requires a discussion of whether one such control, that is, consent, can justifiably be dispensed with in the context of data linkage. A consideration of the role of control in privacy will assist in discussions to follow in subsequent chapters.

Having discussed privacy, I now turn to another issue of central importance in all research, including data linkage. Privacy considerations underlie discussions relating to consent, which is the area of focus in Chapter 2.

CHAPTER 2

CONSENT

Better a friendly refusal than an unwilling consent

Spanish proverb

Introduction

The role of consent in privacy was only briefly discussed in Chapter 1, in the context of the *Restricted Access/Limited Control* (RALC) theory of privacy. However, a number of other issues are relevant to consent; for example, the nature of consent, the forms that are viewed as acceptable and its function and value are currently issues of great interest in bioethics circles and biomedical literature and therefore warrant some discussion.

It is evident in the most recent update of the *Declaration of Helsinki Ethical Principles for Medical Research Involving Human Subjects* (Declaration) (61) that a paradigm shift has occurred in considerations of consent requirements. The Declaration, for the first time since its adoption by the World Medical Association in 1964, recognises that, under certain conditions, research using identifiable data or human material can justifiably be conducted without consent.

The emphasis on consent requirements is deeply rooted in Western history as a result of the atrocities of World War II which resulted in the widely accepted view that consent is a fundamental prerequisite and expression of respect for individual autonomy. The general consensus in the literature is that the provision of consent choices enables us to make rational unbiased choices regarding our body, our information, and the direction our lives take (62, 63). However, in recent years there have been renewed discussions surrounding consent with some novel approaches to this process offered (64, 65). More will be said on this in the following sections.

This chapter addresses a range of issues relating to consent, beginning with a brief justification of consent, followed by an explanation of the different types of consent and mechanisms for consent. Following this, the consent types endorsed for Australian research, a critique of approved consent types in Australian research and the impact of strict consent requirements on research are explored. The manner which data linkage is dealt with in the *National Statement on Ethical Conduct in Human Research* (National Statement)(66) provides an understanding of the consent requirements that apply to this activity in Australia. Finally, I present a review of empirical literature focusing on people's consent preferences, as well as gaps in our knowledge about what people prefer. This chapter also provides an understanding and context for the empirical study conducted as part of this research to explore the consent options a group of lay people thought were appropriate for hypothetical data linkage research scenarios.

The issues raised in this chapter serve to highlight a conflict that arises in relation to consent and consent processes. On the one hand, we recognise the ideal of obtaining consent from all research participants in order to show them respect and not frustrate their wishes regarding participation or not in research. On the other hand, we are confronted with a number of issues which seem to directly conflict with this ideal: firstly, we accord more power to the protection from harm that consent can provide to research participants than is actually provided. I argue below that such broad conceptions of the protections that consent offers are in fact misguided. Secondly, there is a number of types of and mechanisms for consent (and the varied language and extensive set of labels used for these can be confusing) and, as would be expected, guidelines articulate what valid consent involves. I argue that there is a discrepancy between the general requirements for valid consent, as described in Australian guidelines, and particularly one of the types of consent acceptable in accordance with the same guidelines. Thirdly, there are practical issues in obtaining consent from very large cohorts, the impact of which in itself has ethical dimensions, as it renders some forms of important research either impossible to conduct or vitiates the scientific validity of such research due to the biases that arise. In examining consent, it is not possible to avoid considerations of the role that consent plays in a person's autonomous choices, an issue which I address briefly as a concern when discussing consent. I argue that consent requirements need to be considered from a different perspective where data linkage is concerned, as this method of research has only arisen in recent years and

entails methods of protection not previously available or widely used. It is also vitally important to take account of the views of individuals who take part in research and to conduct more extensive empirical research in this area. Such research, however, is of little value if we do not endeavour to incorporate the views in consent processes and requirements which accord with people's preferences.

Consent in research

Justifying consent

Consent needs to be sought only in cases where ethical, legal or other social norms would otherwise be violated by action taken by the individual(s) seeking consent (64). Its main functions are to promote autonomous decision-making but also to protect those seeking consent from sanctions which would otherwise apply. Research is an activity where the default position is that consent should be sought to observe ethical, legal and social norms. Given this, blanket consent requirements are generally not appropriate, as evidenced by the legally acceptable waiver of consent in data linkage research approved by Australian HRECs (and elsewhere). In other words, the very existence of mechanisms to provide waivers of consent indicates that consent can be absent only in certain specific circumstances (which need to be stated in great detail in applications to HRECs for waivers). Despite the ability to waive consent requirements, however, the acceptability of the criteria that apply to requests for waivers are sometimes brought into question[18], as discussed in greater detail in Chapter 4.

Consent is also thought of as a protection mechanism, particularly for invasive or higher-risk research such as clinical trials. Protections offered by consent processes arise from the ability to decline to participate as well as the conditions that consent imposes on the research. It is unclear, however, how the provision of consent, which is an 'informed'[19] decision to participate in research or other such activities, can itself truly provide any protection from certain harms. Clinical trials with participant consent, for example, have resulted in severe health outcomes in healthy participants. An example

[18] Similar difficulties were experienced in the US when Institutional Review Boards were required to provide consent waivers in accordance with Guidelines issued in relation to the Health Insurance Portability Accountability Act (HIPAA) Regulations (67).

[19] This is a conceptually ambiguous, even if widely used, term but I will not enter into this discussion at present. Suffice it to say that it is sometimes only possible to assume that a person's decision is *informed* if it either coincides with a decision we hold to be reasonable or through extensive discussions that help illuminate the decision pathway and reasoning adopted by the individual.

much discussed in the media in 2006 was the British drug trial involving the antibody TGN1412 (68) in which unforeseen harm to participants arose. The unfortunate participants had consented to taking part and had agreed to assume the risks, as described to them during the consent process, but it is counterintuitive to claim that their consent could, or did in fact, have the power to protect them against the adverse events they suffered. The consent process is intended to provide evidence to participants that research is rigorously designed, that appropriate high quality assessment of the scientific rigour of the proposed studies has been conducted, and that appropriate monitoring which can assist in minimizing risks inherent in research is available. Despite this, however, extreme adverse events continue to occur in some studies.

Types of consent and mechanisms for consent

The *National Statement* (66), in its revised version, has made amendments to the manner with which consent is treated. It now discusses different forms of consent (66, p.21) and the scope of such consent options:

> *specific* consent is given for a single project, and precludes the use of the data in future research
>
> *extended* consent enables the re-use of data or human tissue in research closely linked to the initially approved research or research in the same field
>
> *unspecified* consent enables the re-use of data or human tissue in any kind of research conducted in the future.

The mechanisms for obtaining consent can vary depending on the research under consideration; consent can be *explicit* in its expression, i.e. delivered orally or in writing, or *implied*. Implied consent is granted through action that a patient or research participant takes (69), e.g. completing a questionnaire or opening one's mouth for the dentist to examine the teeth.

The complexity of consent considerations is illustrated in the conflation of *types* of consent with *mechanisms* for obtaining consent, as seen in Hofmann (70), where all types and mechanisms are considered to be forms of consent. In opposition to Hofmann's treatment of consent, I contend that there are numerous combinations for consent which involve combinations of both the *type* of consent, i.e. specific, extended,

or unspecified, and *mechanisms* for obtaining consent, e.g. explicit and implied or opt-in and opt-out consent.

Opt-in consent can be provided for a single project or health care programme and requires active consent but it is not necessarily restricted to a single use of the data (71). Opt-out consent, on the other hand, enables the inclusion of all individuals considered unless they expressly request not to be included (71). Individuals may opt-out of a specific project but may also opt-out of a series of projects (if this option is provided). Currently, the opt-out consent option is generally not encouraged in research in Australia and this is also evidenced by the fact that the National Statement does not provide any information regarding this consent mechanism (66). Even though it is viewed as not providing enough scope for voluntary decision-making, opt-out consent should be considered as a potentially appropriate mechanism for some types of research, as it involves the provision of information but removes the burden from participants having to take positive action to be included in studies they wish to participate in.

Opt-out consent should not be confused with non-consensual uses of data, as the former informs individuals of the use to which their data will be put, while the latter does not allow any opportunity for participants to find out that they have even taken part in research or a health care programme. It should also be noted that *opt-out* consent is necessarily expressed explicitly and cannot be implied.

In addition to the types of consent discussed above, an additional option that must be considered is the option of *no consent*, as there are certain instances where informed consent cannot or should not be sought (72), (73). Most public health policies, for example, rely on the implementation of measures, rules and requirements for which individual consent cannot be sought, as any level of refusal to consent could contribute to the failure of the policy. In discussing the *no consent* option, we need to bear in mind the fact that our current research ethics guidelines (74) only consider the 'no consent' option indirectly, as permitted by privacy legislation. In other words, there has been no public policy discussion or debate on the ethical acceptability of the no consent option.

Critique of consent types approved in Australian research

The National Statement (66, p.19) specifies the following in relation to consent:

> *…consent should be a voluntary choice, and should be based on sufficient information and adequate understanding of both the proposed research and the implications of participation in it.*

and also the following:

> *2.2.2 Participation that is voluntary and based on sufficient information requires an adequate understanding of the purpose, methods, demands, risks and potential benefits of the research.*

Given the above requirements, it is unclear how adequate information provision can be achieved for future research, the nature of which may be impossible to even imagine at the time *unspecified* consent is sought[20]. The most researchers can provide is information about the *kind* of future research that may be conducted, and ethics committees can consider whether the proposed future research falls within the description that was initially provided. This, however, in most cases is a creative solution to a practical problem, i.e. a need to gain access to data for future uses while at the same time requiring ethics approval based on very specific consent requirements which cannot be satisfied due to the lack of knowledge of the true nature of the proposed research. It is important to bear in mind the frequent need to amend research that has already been approved as researchers discover that the approved research is not yielding the desired or expected results, e.g. recruitment numbers etc. If this is the case with research projects whose details have been considered carefully and discussed at length both by the researchers and the approving HREC, it is not difficult to imagine that a future proposed research project whose details can oftentimes not even be envisaged may turn out quite differently at the time of its conduct.

The claim in the *National Statement* is: *The necessarily limited information and understanding about research for which extended or unspecified consent is given can still be sufficient and adequate for the purpose of consent* (66, p.21). Both the information available and its comprehension, however, are by definition limited, particularly in the case of unspecified consent. It appears that what is of interest in this kind of consent is not that an individual provides an *informed decision* based on information provided, but rather, an individuals' *choice*. Manson and O'Neill rightly ask, 'Why should all choices – even those not based on an adequate grasp of others'

[20] It could be argued that the same concern applies to *extended consent*. Extended consent, however, is provided for future re-use of data which is **closely linked** to the original research and, while not all details may be available, this link necessarily provides a context and understanding accessible to participants providing their consent.

proposals – be protected at all costs?' (64 p. 70). A plausible explanation is so that those requesting consent will be protected. So it appears that much talk about autonomous decisions could in fact have little to do with promoting autonomy and more to do with providing protections for all involved in the conduct and approval of research. Another possible explanation is that those making the choices (i.e. future research participants) have a right to make them, whether or not it is beneficial to them to do so. However, if we recognised this as being a valid explanation, it is hard to imagine why protections should exist at all. Along this line of argumentation, it would seem that requiring protections is interference in people's autonomous decision-making capacity even if they were deciding to engage in something that was not beneficial to them. It is true that people may be more likely to exercise their rights when they know that there are some protections in place. However, here we are not considering the protections in place as part of the research; what we are considering is the protection of choices available to participants.

Whether unspecified consent can be regarded as true consent is contentious. On the one hand, some claim that autonomous individuals can provide such consent, especially in the context of research where there is oversight by HRECs. One of the arguments put forth to support the ethical acceptability of unspecified consent is the claim that such consent options actually promote autonomy: 'Acceptance of broad consent and future consent implies a greater concern for autonomy than if such consents are prohibited.' (75 p. 267). This view rests on an argument that what promotes autonomy is a requirement that one is not to be treated in a certain way without one's consent; broadening the range of ways of being treated to which one can legitimately consent therefore broadens the range of ways in which one can autonomously conduct one's life. The concern here, of course, is the legitimacy of the consent provided. A second view, and one which I support, is that unspecified consent lacks legitimacy because people do not truly know what they are consenting to apart from the fact that, for example, they are consenting to some research in a particular field of study with a limited set of clearly defined parameters. It is impossible to know how closely aligned such people's conceptions of the research are with those of the researchers'. Hence, such consent may not necessarily broaden autonomy, as it is based on too many unknown variables.

I claim that it may be more legitimate and morally acceptable to give consideration to only two types of the aforementioned consent options in the National Statement, i.e. *specific* and *extended*. The requirements for consent, as stated in the *National Statement*, do not support *unspecified consent*; simply providing a label and weak arguments for the acceptability of *unspecified* consent does not make it a morally acceptable form of consent. Given that a review of empirical consent studies has revealed that research participants' understanding of research information is very low (26) for projects where adequate information *has been* provided, an in-depth understanding of future research for which *no* specific information can be given would inevitably be even more difficult, if not impossible, to achieve.

The value of re-using data[21] without engaging in prohibitively expensive and time-consuming consent processes is not being challenged here; what *is* being challenged is the use of contradictory concepts. On the surface, such contradictions appear to raise issues of transparency and could be said to be disrespectful towards individuals, as such forms of consent cannot, by definition, focus on the requirements of participants, but rather, simply appear to attempt to address regulatory and institutional requirements.

Impact of strict consent requirements on research

Having considered the types and mechanisms for consent and the role and value of consent, I now turn to considerations of the negative impact stringent consent requirements can have on research and public health activities requiring the use of large data sets. In considering consent processes that are appropriate in large data linkage projects, I am not advocating that such research should not undergo ethics approval processes that most research is required to undergo before its conduct. This issue is discussed in detail in Chapter 4.

Discussions of losses of privacy (Chapter 1) would be redundant if consent were sought for the use of all information in data linkage projects. Where small data sets such as small registries are concerned and where it is feasible to obtain consent, especially where the formation of new databases is concerned, consent could be sought but considerations of future scientific validity of studies conducted with these data must be taken into account if large numbers do not wish to provide their consent. If data are collected for 'once-off' projects, there is no reason why consent should not be sought.

[21] Human tissue is not being considered in this argument.

Where large data linkage studies are concerned or where epidemiological research is envisaged (76) numerous challenges arise from strict requirements to obtain consent in cases. First and foremost, much research, such as epidemiological research, is significantly enhanced by the availability of large data sets. Serious difficulties faced when there are stringent requirements to obtain consent include the scarcity of funds and time to contact thousands/millions of potential participants, the possibility of refusals to participate, which compromises the quality of the research, and the difficulty in locating persons (76). It has also been shown that consenting participants share characteristics different to those of non-consenters, a fact which can bias research findings (67, 77, 78) and can therefore have consequences for evidence-based policies or processes that arise from the research.

An example of the detrimental effect arising from an inability to obtain consent, either due to patient preferences or death, is illustrated by Tu and his colleagues (79) in relation to the Canadian stroke registry. In Phase 1 of the study the recruitment rate was a mere 39.3% of a total of 4285 patients who were eligible to be included, while Phase 2 of the study attracted only 50.6% of the total number of eligible patients (n=2823), rates which resulted in selection biases (79).

The option of employing opt-out consent for data linkage projects may seem appealing at first glance, as it caters for the requirement to obtain consent but is not overly onerous for potential participants. However, the implications of using the opt-out consent process in large data linkage projects require serious consideration; the researchers' ability to reach all potential participants cannot be guaranteed and the scientific integrity of the research may still be compromised, as some may choose to opt-out. Scientific integrity aside, even if contacting all potential participants were feasible, there would be technical and practical difficulties relating to the development of appropriate systems to ensure that those who have opted-out amongst the thousands or millions, depending on the data sets involved, are not included.

Treatment of data linkage projects in the National Statement

The treatment of linkage projects in the *National Statement* (66, p.24) with regard to actually making attempts to obtain consent from participants is clear, as can be seen in

the following excerpt addressing conditions under which HRECs can waive standard consent requirements[22]:

> *(c) it is impracticable to obtain consent (for example, due to the quantity, age or accessibility of records);*
> *(d) there is no known or likely reason for thinking that participants would not have consented if they had been asked;*

Despite the ability to have data linkage research approved without the requirement for consent, at a theoretical level, in reality, many obstacles emerge when requests for datasets are made[23].

These difficulties arise perhaps not only due to legal matters and higher levels of protection deemed to be appropriate for certain datasets, as previously discussed, but also possibly as a result of the lack of rigorous discussions and consideration of the *ethical* issues associated with non-consensual uses of data, not so much in the literature, but more so in the Australian research community. In other words, issues of non-consensual uses of data are discussed, considered, and approved by data custodians[24] and HRECs purely in legal terms, as this is the only framework available to such bodies. Perhaps then the tension that appears is in relation to deeply held views in the minds of data custodians and those considering and approving data linkage research that there are *morally* challenging reasons why identifiable data should not be disclosed (even if legally permitted).

Summary of key aspects of consent in research

In the preceding sections I have highlighted tensions between the role attributed to consent and actual approved consent practices. I have suggested that consent needs to be obtained so as not to violate ethical, legal, or other social norms but that we ascribe a much greater capacity for consent to protect participants than consent can actually provide.

[22] There are additional conditions that need to be met before consent can be waived and these relate to low risk, the balancing of benefits and harms, protections for participants, confidentiality of data, dissemination of findings, entitlements arising from research, and the legal acceptability of the waiver (66). However, the above listed additional conditions do not specifically relate to the act of obtaining consent and are therefore not being discussed here.

[23] The VALiD Study experience alone can attest to this, as it has taken over three years to reach the final stages of obtaining approval for a vitally important data linkage project, the scientific merit and public benefit of which has never been in dispute.

[24] As I clarify in Chapter 4, approval for data linkage projects must be obtained both from data custodians and HRECs.

I provided the definition for valid consent in accordance with the *National Statement* and a description of the types of consent and mechanisms for obtaining consent. A contradiction was noted between the requirements for valid consent and *unspecified consent*. I argued that this contradiction arises from idealistic views held in relation to consent and the realities surrounding the conduct of research, much of which will require access to data for future research whose nature is yet unknown but whose need for conduct is foreseeable. I also argued that insisting on the acceptability of unspecified consent lacks transparency.

The critique of consent types considered acceptable in the *National Statement* does not imply that stringent consent requirements are appropriate in all kinds of research activity. The above sections highlighted a number of negative effects such strict requirements can have on potentially valuable research involving large data sets. In addition, I argued that, while there are mechanisms to assist in obtaining consent waivers where it is not possible to obtain consent, these are entrenched in a legal framework that does not truly consider the ethical issues involved. It is perhaps for this reason, despite approval mechanisms, that difficulties sometimes arise in approving research which requires consent waivers. Having considered the formal requirements for consent and the tensions that lie therein, I will now examine what people involved in research prefer in relation to consent through empirical research that aims to obtain such views.

What we know about people's consent preferences

This section presents an overview of recent empirical research seeking to determine people's preferences for consent in a health research context. Many of the studies focus on patients' perspectives but there are some which provide insights into non-patient views. The studies were sourced using conventional search strategies rather than processes adopted in systematic reviews. I present some of the most recent research spanning across the past decade[25] from the most recent to the oldest. What this section does not present is studies aiming to determine consent rates observed in a variety of data linkage or medical records studies (see for example (80)) as these do not shed light on participant preferences.

[25] The period covered is from 2003-2012.

Preferences regarding uses of health information for secondary purposes

A recent Australian study (31) focusing on attitudes towards privacy, medical research, and consent employed both focus groups and a survey. This study found that both respondent groups held similar views. The vast majority of participants (98% of survey participants) strongly supported the conduct of medical research, as did the focus group participants but both groups also valued the protection of their privacy with 37% showing concern or great concern about the use of their de-identified data if it was possible for it to be linked back to their identifying information. The question was asked in the context of electronic health records and it is revealing that 33% of survey respondents indicated that they were not at all concerned about their health data being used even if they knew that it could be linked back to their identifiable information. The study found that people's concerns about privacy are reduced when they are aware of security measures in place to protect privacy and that the strong preference that participants displayed for consent to be sought related more to people's desire to have some control over their information, a desire to be shown respect, and having the means to trace those accessing their information in cases where this access has a detrimental effect on them than to concerns about privacy. This study also found that privacy concerns are reduced at the extremes of the age continuum, that is, in younger (18-19 year-olds) and older (60+) people. Other social characteristics which appear to influence people's reduced concerns about privacy in medical research were higher levels of education and unemployment. There were certain medical conditions which prompted most concerns about the use of health data in research included, for example abortion, infertility, sexually transmitted diseases, mental illness etc. The fact that this study considered the use of health information in the context of electronic health records and the fact that participants were advised that 'de-identified' data is never truly de-identified, as clever programs can trace information back to patients' names, may have influenced the findings.

Preferences regarding release of GP de-identified versus identifiable data

An Irish study (81) found that, of the 1575 individuals who completed a postal survey, 83.7% (n=1318) were *willing* to allow their GPs to provide de-identified health data to researchers without consent, while 12.1% (n=190) were not. When asked if they would *prefer* to be asked for consent for the release of *de-identified* information, despite the impact that this might have on the ability to conduct research, 20.1% (n=317) indicated

that they would prefer consent to be sought, and 71.5% (n=1126) indicated that consent did not need to be sought. The remaining 6.3% (n=99) stated that they were uncertain about this. Conversely, when asked whether participants would be willing to allow their GP to release *identifiable* health data without their consent for research, 38.75% (n=609) stated that they would be willing for this to happen while 45.55% (n=716) stated that they would not (81). Despite their response in relation to their *willingness* to allow GPs to release *identifiable* information for research, however, when asked about their *preferences* for consent for the release of *identifiable* data, their responses did not match precisely, with 71.9% (n=1133) indicating that they would prefer to be asked for consent and only 22.3% (n=351) indicating that this would not be necessary. This discrepancy is an indication of the complexities of making such decisions, especially when there is no opportunity to qualify one's responses. While the findings of this study are illuminating of people's consent preferences, they do not enable us to understand how these same individuals would respond if asked about the release of identifiable data for data linkage purposes, given the specific methods used in data linkage.

Preferences regarding handling and use of de-identified electronic medical records

A Canadian randomised trial (82) also involved the completion of the Health Information Privacy Questionnaire (HIPQ) by 46 physicians (written questionnaire) and 490 patients (Computer Assisted Telephone Interviews) in relation to the handling and use of electronic medical records. This study found that the majority of patients were not concerned with the release of de-identified records for hospital-based research but, as the authors concede, the reluctance of even 20% of the patient cohort to allow access to their de-identified records without consent could result in selection bias, an issue that would affect the quality of research conducted, as previously noted. The authors also acknowledged that the source of people's reluctance to enable access to their de-identified data, e.g. lack of trust, lack of familiarity with harms and benefits arising from the sharing of electronic medical records, or simply a desire to have some control over their health information, could not be discovered through the administration of the HIPQ (82).

Lay views regarding process of de-identification of data and their use in data linkage

In a study (83) examining lay views[26] regarding the process of de-identifying data and making them available to researchers via the 'warehouse'[27] data linkage model adopted in Scotland, focus group participants (n=19) found that lack of trust in the robustness of processes aimed to de-identify data did not increase participants' demands to have greater consent requirements. These participants displayed a remarkable level of insight given that the provision of consent does not necessarily increase the protection of data, as previously discussed. Only a minority considered it essential for consent to be sought for the use of data even though the data have been de-identified, as they felt that people have a 'natural right to privacy' (83 p.1145). The majority, however, were supportive of the use of linked de-identified data for research purposes and showed a preference for research not to be hindered by administrative hurdles (83).

Consent preferences of people with potentially stigmatising health conditions and members of the general public

A Canadian study (84) involved participants with one (or more) of seven potentially stigmatising health conditions (hypertension, diabetes, chronic depression, alcoholism, HIV/AIDS, breast cancer, and lung cancer)(n=1137) as well as a reference group with no serious health issues. Participants were presented with five scenarios in a survey, of which one related to linkage of information (i.e. linking health information to work, education, or income data)[28]. Participants were also offered five consent choices, ranging from no consent required to no consent granted for this use. In the context of linking health information with work, education, and income information, participants showed a reluctance to allow the linkage to go ahead without consent, with only 11% of the reference group participants and 15% of participants with health conditions considering this option as appropriate. Conversely, 30% of participants with health conditions and 43% of the reference group participants believed that consent should be sought for the linkage to occur. In a follow-up focus group discussion reasons provided for these choices included beliefs that the different information sets can lead to an

[26] All participants were aged 60 years of age or older.

[27] The warehouse data linkage model entails the electronic transfer of whole databases to the warehouse via the National Health Service intranet. Data are linked by a programmer upon request from researchers with the aid of unique patient identifiers and are then de-identified. The researcher receives the de-identified linked data for analysis (83). This data linkage model differs significantly from the model discussed in this thesis.

[28] There were two additional linkage scenarios but these involved biological samples and this thesis does not focus on biological material.

understanding of who people are (as opposed to use of biological samples which only reveal our biological composition). In addition, participants cited the likelihood of identification of participants when such information is linked.

Consent preferences for uses of personal information in health research

A study involving 98 Canadians in 7-day long public dialogues around Canada (85) found that the majority supported what was called *broad opt-in consent*[29] for uses of personal information in health research. The two remaining consent choices were the standard *consent for each study* and what was termed *assumed consent*[30] (85). It was found that participants were in favour of certain features of each consent option and disliked other features. For example, seeking consent for each project was seen to be respectful towards people and enabled people not only to exercise greater control over their information but also to come to know of the purposes towards which their information was being proposed for use. They also acknowledged the practical implications arising from such consent, i.e. selection bias and additional burden for research teams and potential participants. In relation to the assumed consent option, participants recognised the benefits, i.e. reduced bias, and burdens, but were troubled with the effort for opting out, lack of control, lack of knowledge about the research and increased possibility for abuse. The option of broad opt-in consent was seen as the intermediate and most appropriate of the three.

Preferences for use of personal and health data

A study of 166 patients who completed a questionnaire about their consent preferences for use of personal and health data (86) revealed that only a minority (13%) insisted on being asked for consent for use of some or all of the information in their medical records. Of these individuals, 20% insisted on the provision of consent for use of their medical histories. Overall, this research found that participants did not distinguish between purposes towards which their information would be used, e.g. research, audits. Participants in this study indicated that they preferred to provide permission for use of data once while still in hospital. The study highlights the desire that some people have to be notified of future uses of their data but the provision of such permissions

[29] This form of consent involves a participant opting into a study but also authorizing the use of their data in future research (with the ability to exclude specific uses of their data they do not agree with and the ability to completely withdraw from having their data used if they wish).

[30] *Assumed consent* is not having consent sought for research projects but being notified of one's inclusion in research and having the ability to opt-out.

does not equate with the current consent model applied in most research practices, where great detail about the nature of each research project needs to be provided.

Willingness to allow researchers to access medical records

A mixed methods study involving a deliberative forum and pre and post forum questionnaires with veterans in relation to the use of Veterans Affairs (VA) medical records (87) revealed that the factor most influencing veterans' willingness to allow VA researchers to access medical records without consent was the trust they had in the VA; increased trust in the VA correlated with a willingness to accept less stringent consent processes (87). In the baseline survey prior to the deliberative process, although participants recognised the critical or very important role that conducting medical records research has (86%, n=513), a high proportion of participants also felt it was critically-very important to obtain consent separately for each study conducted (73%, n=513). The deliberative process yielded similar responses but offered insight into the consent types veterans preferred. Of the total 170 participants, 34% felt it was appropriate to continue to allow ethics committees to determine whether consent should be obtained, 17% believed opt-out consent was appropriate, 23% felt that blanket authorisation was appropriate, while 26% felt that consent should be obtained for each study.

It is important to recognise that this study, while providing insights into patient preferences, does focus on a very specific population and the results may therefore not be specific to general patient views or to the general population.

Justifications for non-participation in research

All too often it is difficult to capture those individuals who do not consent to participate in research to learn more about the reasons underlying their refusal. A study conducted by Williams et al. (88) with participants aged 65-84 years of age revealed that only 28% of the total of number of questionnaire respondents (n=256) who had previously declined an invitation to take part in a study which related to physical activity in older people cited not being interested in research as their reason for initial non-participation. One of the key findings was that a vast majority (88%) had refused to participate in the original study as a result of misunderstandings about the research. Other reasons cited for non-participation included privacy concerns and personal

reasons (88). This study highlights the importance of the provision of clear information that the lay person can utilize to make choices that reflect their true preferences.

British public's views on the use of identifiable health data in cancer research

A large scale national probability sample survey (89) involving 2872 members of the British public related specifically to people's views about whether privacy was invaded by the inclusion and use of certain identifiable pieces of information in the National Cancer Registry. While this study does not directly relate to data linkage per se, it is of note that the researchers conclude that these findings suggest strong support for the confidential use of such identifiable information for purposes other than treatment, including research.

Patient consent preferences for uses of electronic medical records data

A two-phase study conducted in Canada (90) employing a semi-structured interview and a structured survey arising from the interviews found that these patients generally preferred to have consent sought prior to the use of their information. The findings specific to the structured survey are more relevant to data linkage, as the scenario put to participants (n=106) involved the de-identification of records before researchers used the information, an end result which also applies in data linkage, and it is therefore these findings that I will present here briefly.

A larger proportion of participants (74%, n=78) showed a preference for consent (either verbal or written) before health information was used. The remaining 28 patients (26%) felt that being notified of the study and having the ability to opt out if they wished was satisfactory[31]. This research also examined the level of detail participants preferred when informed of research projects. Of the 106 survey participants, 57% expected to be provided with detailed information and more women (68%) than men (46%) indicated their preference for detailed information. It is important to note that these participants valued and took part in research indicating that they viewed both the conduct of research and privacy as being important.

Summary of findings

The above studies indicate that consent choices are not straightforward for those engaged in making them. Some of these studies highlight the value that people place

[31] The response options are not provided so it is difficult to determine which consent options were made available to respondents and how these were framed.

both on the conduct of research and the protection of privacy while at the same time acknowledging the constraints that consent places on research. Of note is that many participants discriminate between uses of identifiable and de-identified information.

Overall, these studies seem to support the non-consensual use of data more so than the requirement for consent. However, it must be acknowledged that such conclusions are by no means straightforward and clear-cut. For example, while participants may generally indicate support for the non-consensual use of information, this is either done under certain specific and unique circumstances as was the case with the Veterans Affairs data where trust in this organisation played an important role in the views expressed. In addition, in some cases a no consent option may be indicated but followed on with a preference of some form of notification or information provision. Interestingly, it appears that the no consent preference may not always in fact reflect a reluctance to participate but may result from other factors such as misunderstanding the research.

In some studies, there was much stronger support for the provision of consent in all research or related to the research described. This preference, once again, is not straightforward. For example, the kind of information being linked (even if it is de-identified) influenced participants' views with linkage of health information to information drawn from a variety of sources outside the health sector posing a concern. In two studies consent was the preferred option but both consent options incorporated future use of data without the need to re-consent participants. Such responses may relate to issues of trust, i.e. once participants have engaged with a group of researchers and trust them, they are willing for the information to be re-used by the same research team. It is interesting to note that a lack of trust in de-identification processes did not increase participants' desire to have greater control over their information via consent.

What does appear to emerge is that people generally prefer to have some knowledge of the use to which their information is put, with a desire for greater or lesser degrees of information provision and control over the process.

Few of the studies provide any insight into the reasons why people make the decisions that they arrive at; insights which are only discoverable through qualitative research and which also clarify whether their choices are in fact representative of what they intended. The discussion below identifies gaps in our knowledge in greater detail.

What we do not know about people's consent preferences

The literature described above does not explore in great detail people's consent preferences in relation to data linkage. When data linkage is referred to in limited studies, it appears as one of many scenarios presented in the general health research context. In addition, what the literature presents is people's final decisions, sometimes expressed without the ability to revise this decision and certainly without insight into the complex decision-making processes people engage in to arrive at that decision. A better knowledge and understanding of consent preferences in the context of data linkage would add to the very limited body of knowledge regarding people's attitudes to data linkage and the choices they feel should be made available to them in this kind of activity. No studies have been conducted in the area of data linkage in relation to the decision process people follow when considering consent options, the considerations that lead to changes in views, and the justifications and reasons people provide, which may shed light on their underlying values. Furthermore, there is little evidence of the influence an educative process relating to data linkage may have on lay people's views in relation to data linkage and consent requirements. Unless we gain an understanding of what motivates people and what characteristics help shape their views, it will be difficult to address adequately the issues that arise in data linkage considerations.

Conclusion

This chapter has considered the function of consent and justifications for its use in the research context. I sought to highlight the difference between consent types and mechanisms, both of which are often confused in the literature. I offered a critique of the consent mechanisms that are considered appropriate in Australia and briefly discussed the manner in which data linkage is dealt in Australian research ethics guidelines. I also reviewed the impact that stringent consent requirements have on the ability to conduct certain forms of research, and importantly, on research outcomes. The chapter concluded with a description of our current understanding of consent preferences followed by the current knowledge gap regarding consent preferences in data linkage. Having now considered privacy and consent issues, in the next chapter I discuss the moral concerns that the conduct of data linkage projects raises.

CHAPTER 3

MORAL JUSTIFICATION OF NON-CONSENSUAL USES OF IDENTIFIABLE DATA IN DATA LINKAGE

When we say that humans have a "right" not to be used for these purposes, this means simply that the interest of humans in not being used as non-consenting subjects in experiments will be protected even if the consequences of using them would be very beneficial for the rest of us.

Gary L Francione
American legal scholar (1954-)

Introduction

Discussions of privacy in Chapter 1 and consent in Chapter 2 enable us to turn to the consideration of ethical issues that emerge in relation to data linkage. These are varied and have previously been discussed in greater or lesser detail and rigour in the literature (12, 15, 53, 72, 73, 91-93).

This chapter considers the moral concerns that data linkage activities raise; issues which relate to privacy, consent, trust, respect for autonomy, as well as respect for persons. Through responding to these concerns, I aim to provide a rationale for the uptake of data linkage activities. In doing so, I also propose the inclusion of processes which I consider essential from an ethical and social[32] perspective.

The issues raised and discussed are not unlike those raised by utilitarians or those espousing contractarian views. However, they also closely align with issues viewed through a responsive communitarian's lens. This is a good starting point for such

[32] In this discussion the ethical issues are intricately related to the social context within which they are examined.

discussions because this school of thought offers a more balanced and unbiased approach compared to, for example, libertarian treatments of these issues which polarise such debates and cannot respond to questions of what corresponding social duties arise from individual rights.

Responsive communitarianism arose in the 1990s and should not be seen as the opposing end of the liberal - communitarian continuum (94), which would automatically and emphatically bias any discussions against privacy and autonomy and in favour of the common good[33]. It is, therefore, important to clarify the difference between *authoritarian communitarianism* where the common good overrides all individual values and *responsive communitarianism* where it is recognised that autonomy and the common good are in conflict, but where neither has primacy (94). The conflict between the two values, according to responsive communitarianism, cannot be removed but it can be resolved (94). This clarification points to the fact that the starting point of any discussion and general approach to conflicting values and issues regarding data linkage differs significantly from the treatment of the same issues in traditional communitarian approaches.

It is also important to clarify that responsive communitarianism views social influences such as "…informal social controls, persuasion, and education…" (94 p.364) (rather than the state through its legislative instruments and powers) as the key elements for ensuring that society complies with the norms arising from the values of autonomy and common goods (94).

The chapter commences with a clarification of privacy-related issues in the context of data linkage. Following this, I discuss a number of concerns in relation to the conduct of data linkage research. This is followed by a section that provides responses in support of the moral acceptability of using data non-consensually for data linkage purposes. My key argument is that the potential harms associated with data linkage activities are both minimal and improbable (provided that all the protective measures involved in data linkage are adequately enforced), while the benefits arising from data linkage research are potentially great. The section concludes with a consideration of requirements for

[33] Etzioni, one of the main proponents of this school of thought, defines 'the common good' as "…those goods that serve the shared assets of a given community: for example, preserving national monuments, supporting "basic" scientific research, advancing national security, protecting the environment, and promoting public health." (94 p.365)

public involvement in the determination and understanding of uses to which their information is put, and finally a summary of the key points addressed in the chapter.

Privacy and data linkage

When considering privacy in relation to data linkage, it is important to separate conceptually the legal from the ethical issues even though some legal aspects do affect the manner in which we speak about privacy. For example, we cannot properly speak of a *violation* of privacy in data linkage when identifiable data are accessed by the data linkage unit, as this access is legally permissible when a waiver for consent has been granted by the approving HREC; hence there is no violation in a legal sense. Similarly, we cannot speak of an *invasion* of privacy, as this also implies forced access to information for which one would expect legal ramifications in certain jurisdictions. To avoid these potentially confusing terms, when discussing privacy in data linkage from an ethical perspective, I refer to accesses of personal information for data linkage purposes as entailing a *temporary loss* of privacy[34]. Immediately, however, it becomes apparent that the distinctions made in the RALC theory of privacy are being abused, as *loss* of privacy in this theory only relates to cases where there are no legal or ethical norms requiring protections. Despite this, I shall adopt the term *loss*, qualified by *temporary,* to refer to such accesses to personal information in order to both differentiate data linkage accesses from illegitimate accesses and with the qualifier 'temporary' to also indicate that once the linkage key (code) is created, the identifiable data are no longer required, as they have fulfilled the purpose for which they were initially accessed and were hence only temporarily used to achieve this aim.

I also presume that losses of information privacy can exist only if the information in question is identifiable. In addition, assuming that we have a right to privacy, I suggest that privacy rights and violations of these rights cannot begin to be considered if the information is not connected to a specific individual, in the same way that accessibility and decisional privacy cannot be violated in the absence of the person whose rights are being considered. When we refer to a loss of privacy in data linkage, this relates to the

[34] Using this term has the benefit that it does not raise legal considerations to confuse the points being discussed. Loss of privacy occurs whether the person whose data are accessed is aware of the access to their data by a third party or not. In this case, it is a 'temporary' loss, as the data are accessed once only during the initial stage of the data linkage process by the data linkage unit, with no possibility of re-accessing the data.

very first stage of the linkage process where the personal information[35], such as name, post code, date of birth, are made available to linkage organisations so they can create a linkage key. The stage involving the analysis of data by researchers cannot be considered to lead to losses of information privacy, as no one can be identified in the resulting datasets, provided that standard protections apply regarding the size of dataset. Theoretically speaking, breaches of privacy might be possible but given the separation of tasks and the stringent security measures surrounding the use of de-identified datasets, as further clarified in Chapter 4, this would be highly unlikely.

Ethical concerns about data linkage

From an ethical and social perspective, what is really at stake if people's identifiable personal information is used without their knowledge? Below I examine a number of concerns, including those relating to harms, arising from a variety of theoretical perspectives.

The loss of privacy resulting from access to personal data potentially compromises the trust that exists between the public and research institutions or governments. If the public has generally been unaware of such uses of data, their trust in the security of data may diminish and they might question the extent to which other data are used, not to mention the extent to which they are safe from *harmful* uses of their data[36]. As all health data (including personal details belonging to such records) are made available to health services in confidence, a breach of confidentiality is also involved. This could have detrimental effects on the candid provision of health information to services (95), which, in turn, would affect both medical professionals' ability to appropriately treat patients and could contribute to an erosion of the trust required between the medical profession and society (96).

Such non-consensual uses of data could be viewed as undermining not only people's privacy but also people's autonomy in a society where we expect to have options regarding our participation or not in certain activities, such as research. Using data non-

[35] It is important to note that some health data are in fact also revealed at this level, not in detail, but by virtue of the fact that identifying personal data, such as one's name, is included in a specific health-related database, e.g. a cancer registry. Hence, *Maggie Yip*, for example, must have breast cancer given that her name is included in a breast cancer registry.

[36] Here I make the assumption that knowledge of the use of such data sets will eventually become available. If the public remained ignorant, their trust could not be eroded.

consensually precludes this choice and renders us pawns in a research/health policy game, as we lack decisional power to direct our lives in the manner we wish.

Seen from another perspective, if privacy is viewed as power (97), in data linkage practices we lose considerable power in our ability to control who accesses our information. This loss of power could be seen as crippling and links in with the issues of trust and autonomous decision-making mentioned above, leaving us feeling less in control of our lives.

Finally, respect for persons is considered a value liberal societies prize highly and strive towards and we have come to expect that we should be shown due respect in our interactions with both research institutions and governments. By not involving people in decisions regarding uses of their identifiable data, there is an element of disregard towards individuals, as we disregard certain rights they have over their informational privacy. According to Benn, if we are to respect someone as a person, this entails ascribing certain rights to them and behaving towards them in a way that shows recognition of their rights (98).

Ethical arguments in favour of data linkage

The above issues are important and cannot be dismissed lightly. In this section, I address them by focusing on our interactions in an organised society where certain rights also entail certain obligations which contribute to a more harmonious and flourishing society. Such obligations, for example, might include foregoing certain interests, provided that this does not undermine core values[37], in order to secure collective goods. The discussion, necessarily, involves broader issues than that of privacy alone.

Miller (93) argues that basing research using medical records on consent undermines the principle of fairness, as it is unfair for some to refuse to participate yet reap the benefits of such research. I believe this shifts the focus to a secondary issue; the

[37] For example, if we are asking people to forego their privacy for the purposes of data linkage but there are no guarantees that their private information will not be broadcast widely, such a request would be seen as undermining core interests and values relating to individual autonomy.

concern about non-participation (at least in data linkage research) relates to the impact non-participation has on the robustness of research outcomes rather than to fairness[38].

Limits to privacy

As noted above, the most common ethical concerns in relation to non-consensual uses of data relate to privacy. Three points need to be considered here in responding to these concerns. Firstly, there are different views about the weighing up of privacy against other goods. An important starting point in considering privacy in relation to data linkage, is to bear in mind that privacy, like all other values, is not absolute and must, on occasion, give way to other important values (51 p. 214), such as the benefits that can arise from data linkage projects. In medicine, for example, individual privacy and confidentiality are lost in varying degrees both in the treatment of individuals but also in cases where the protection of whole populations is deemed necessary. While we highly value individual privacy, we acknowledge that some losses are necessary for the protection of the public. In the same vein, the initial loss of privacy that occurs in developing the linkage key should be balanced against competing values and community expectations. For example, one such expectation is that quality research should be conducted when the means to solve medical and health care issues which impact on people's lives are available. This issue is further discussed below. Secondly, losses of privacy need to be viewed along a continuum[39], ranging from trivial to significant losses, as judged by the impact of these losses. Finally, the benefits arising from losses of privacy as well as the harms from not using available data can also be viewed along a continuum.

It is impossible to examine privacy and the harms that arise from its loss without considering the controls available to protect it. Using the RALC theory of privacy with a focus on individual and external controls over personal information, we can develop a better understanding of the relationship between such controls, harms that may arise from the use of identifiable data, and the social benefits that can arise from uses of information for purposes other than those for which the information was originally collected, such as data linkage. The following simplified schema (Figure 3) provides an

[38] Important ethical issues are, in turn, raised with the conduct of research which cannot produce robust findings due to the nature of the data collected.

[39] I am very grateful to A/Prof Dominic Wilkinson who briefly discussed privacy with me, which reminded me of an earlier analysis I had engaged in at the beginning of my candidature and have now incorporated in this section.

accessible manner for considering the interplay between the aforementioned elements in the context of data linkage where personal information is identifiable at the beginning of the process.

	Situation	Individual controls	External controls	Probability of harm to individuals	Social benefits
a	**Banned use of personal data**	×	√	×	×
b	**Banned use of personal data**	√	√	×	×
c	**Restricted use of personal data**	×	√	×	√
d	**Unlimited use of personal data**	×	×	√	√

The **x** denotes that there is an absence of the discussed feature while the **√** denotes that the feature exists in that scenario

Figure 3. Probability of harm to individuals and social benefits from the application of individual and external controls to uses of identifiable data

The schema represents varying degrees of controls imposed on uses of identifiable data for purposes other than those for which the data were originally collected. Situation *a* rests at the one extreme where such uses of data are banned by external controls (for example, laws) but where citizens are not granted any control over uses of information that pertains to them. Such controls may apply in totalitarian regimes. Resulting from the complete ban imposed is the very low probability of harm to individuals but also the lack of societal benefits as a result of not using the data for the other purposes which aim to enhance society.

Estonia provides a unique example of the effect of implementing strict external controls on the usage of personal and health data. The implementation of the Personal Data Protection Act 2003 has resulted in the crippling of health and epidemiological research, as reported by Rahu and McKee (99). This has come about not so much as a result of the Estonian Data Protection Inspectorate insisting on researchers obtaining individual consent but because of unyielding external controls, including apparently irrational prohibitions to collect and access data. For example, the linkage of cancer registry data and deaths data is prohibited thus rendering current cancer survival rates unreliable. In 2006 the Data Protection Inspectorate even refused to allow researchers to seek

consent for future use of identifiable data from individuals whose data were being collected as part of the Estonian Health Behaviour Survey. Whatever the motives for excessive privacy protection, the result is the same: the Estonian research community is now powerless to conduct quality health and epidemiological research, which ultimately serves the community within which it is conducted.

A scenario similar to *a* arises in *b*, where citizens have some control over their information and because of the individual and external controls in place they do not suffer any harms arising from uses of their information. Due to the ban on further uses of the data, however, there are no societal benefits arising from additional uses of previously collected data in such communities.

Scenario *c* represents uses of identifiable data over which individuals do not have any control but which are regulated by external controls, e.g. laws, regulations, codes etc. Provided that the external controls in place are adequate and appropriate for the uses to which the data are put, no harms arise for the individuals whose data are used. As a result of the uses to which the data are put, there may be societal goods from which people benefit. Data linkage falls into this category of uses of identifiable data where, despite the lack of control individuals have over their data, their privacy is protected by the adoption and implementation of strict and varied external controls.

Finally, at the other extreme, we can imagine a situation where a lack of individual and external controls for managing our information would lead to an absence of privacy and, as a result, an inability to exert any control over our information and, ultimately, the impact this may have on our autonomy. Arising from such a situation could also be harms associated with losses of privacy, such as discrimination, loss of income, or an impact on our physical and mental wellbeing. While an absence of any form of control over uses of personal and health data would make it easier to conduct good quality research, these goods would need to be balanced against the greater harms suffered by individuals. It is difficult to imagine a society in which great public goods could be deemed to be acceptable if, in the process of achieving them, individuals were severely harmed.

An adequate discussion of privacy in data linkage also needs reference to the protections in place that aim to preserve people's privacy. The mechanism of central

importance in preserving people's privacy in data linkage is the creation of the linkage key.

This mechanism, however, does not address the initial disclosure of identifiable *personal* information which is required to generate the linkage key. It is this stage of the data linkage process where a loss of privacy occurs[40]. Therefore, it is an issue which requires careful consideration.

It could be argued that people should expect to forego some privacy (as we in fact do in a number of contexts, most of which occur without our explicit agreement) in order for society to function in a manner which protects and enhances our most central interests. However, this view might be criticised because it can lead to the conclusion that *any* non-harmful use of people's information (or property more broadly) without consent to benefit others is morally justifiable. I contend that it is morally unacceptable to make use of people's information, despite the potential benefits, without tacit agreement regarding such uses of information both at an individual and at a societal level. The latter refers to governments and researchers being transparent about the uses to which personal and health information are put and this can only be achieved by starting to engage communities in such discussions. My position is that data linkage does involve a loss of privacy at the initial stage but that this loss of privacy is justifiable because of the process adopted to protect participants, because harm is improbable, and because of the potential benefits arising from such practices. However, uses of people's identifiable information in data linkage only becomes *morally* acceptable when citizens and governments share an understanding of the need for such uses of information and, importantly, when the conditions under which non-consensual uses of information occur are clearly articulated and highlighted.

Issues of trust

Citizens' concerns about the trustworthiness of governments are justified as, historically, governments in some parts of the world have exploited and abused their citizenry. In the research context we need not look far to find historically recent

[40] It is, once again, useful to highlight two facts: that personal information provided does not reveal full details about the individual and is therefore of little use and interest, and that the generation of the linkage key is achieved through sophisticated computer programs, with minimal manual checking by people engaged in the process.

examples of inhumane treatment of human beings for the advancement of science (see (100))[41].

Issues of trust between governments and their citizenry are crucial, as citizens entrust their wellbeing to government. This trust cannot be blind, however; in a democratic society we need to be in constant dialogue with governments to ensure that they are indeed governing in the manner the majority condone. Therefore, in the context of data linkage, if we are to ensure that research and other health related activities do not breach the public's trust, it is of crucial importance that governments be transparent and informative about data linkage initiatives and projects.

It is likely that the Australian public has little understanding of the conduct of data linkage, as there is little public discussion around this topic. There is currently information on Government websites regarding the development of data linkage infrastructure (2), but it is unlikely to be accessed by most citizens, as they would not be aware of the sites unless prompted or notified of their existence. The use of other more accessible media, as well as public discussions regarding, first and foremost, the conduct of *current* data linkage projects and how they function, as well as the benefits of such endeavours seem to be important for the dissemination of information relating to data linkage. Suspicion and distrust grow in environments where full disclosure of facts is not forthcoming. Conversely, where there is full knowledge and an awareness of the absence of harms, there should also be increased acceptance for the use of personal and health data in such projects. Knowledge of the systems in place, in conjunction with the benefits that potentially arise[42], would serve well in allaying concern that governments cannot be trusted in data linkage endeavours.

Issues of autonomy

The principle of respect for autonomy is central to western health care; it underpins a wide range of moral rules, including the obligation to respect privacy, to be truthful, to ensure that confidential information is protected, to obtain consent from people, and assist in decision-making when this is requested (63). Bearing these rules in mind, it

[41] Chilling accounts of the Tuskegee Syphilis Study (100) suffice as an example of the circumstances under which trust between governments and their citizenry can be eroded. Reverby (100) attempts to demystify and dispel fallacies surrounding the study; nevertheless, the facts remain horrifying and instructive.

[42] This gains even greater relevance for citizens when they themselves may be recipients of the resulting benefits.

appears that uses of data for data linkage projects where participants cannot choose whether their data will be included or not undermine autonomy.

There is a vast literature on autonomy. However, here I present briefly two important points in relation to the above concern. Firstly, respect for autonomy does not always take precedence over all other principles (63, 101). For example, there are limits on respect for autonomy when our choices threaten to endanger others (63, 101). Mill's *Harm Principle* identifies harm to others as the single condition under which governments in liberal societies have the right to override people's autonomy and place limits on their liberty (102)[43]. Secondly, while autonomy is highly valued in Western societies, it is important to acknowledge that *full* autonomy is antithetical to social functioning; it is illusory to think that full autonomy is achievable or desirable in social contexts, as we are all constrained by the wishes and desires of those we love (or simply need to peacefully co-exist with), issues which impact on our intentions[44], and we constantly make sacrifices to a greater or lesser extent taking others' wishes into account. We see great benefits in living in societies rather than in isolation; one of the advantages, amongst many others, is our ability to pool resources, which includes data, in order to collectively benefit. It is essential, however, that policies initiatives and programmes that appear to reduce people's autonomy be made known to the public. Here, I am by no means alluding to authoritarian societies in which "…personal autonomy is subordinated to 'objective' moral values as declared by the 'authorities'." (101 p.16). I am, however, signalling that governments can help shape our common values through communicating the benefits of certain programs, one of which is the development of data linkage infrastructure, rather than simply implementing these without any meaningful interaction with those affected. The latter is damaging in a number of ways; it raises suspicion about true motives and gains, shows a lack of respect towards people, and removes power from citizens.

[43] While this is a principle central to discussions on the limits imposed on autonomy, it is not central to my argument, as data linkage cannot be justified on the Harm Principle. I will therefore not elaborate on it further.

[44] If our concerns regarding impositions on our autonomy relate only to governments, we are then applying a double standard, i.e. it is acceptable for those whom we love or need in order to progress in life (but not necessarily love) to restrict our autonomy but not appropriate when governments do so, even if the impositions are small and aimed at ultimately benefiting society. I am certainly not condoning oppressive regimes, which strangle personal autonomy and stifle the concept of freedom. In democratic societies, however, it is unrealistic not to be expected to make some concessions in exchange for benefits we receive. For example, we all dislike paying taxes but recognize their function.

Issues of potential harm

Objections to uses of data often stem from concerns about real or perceived harms resulting from such uses. Such concerns are not unwarranted, as harms can and do come about when data are used in research, as described, for example, by Etzioni in the American context (103). Tavani and Moor (48) speak of individual and external controls which promote and aim to protect privacy. While the methods employed in data linkage do not enable us to exercise any individual controls over the data, that is, through *choice, consent*[45]*,* and *correction*, there are numerous external controls in place, which, for the purposes of harm minimization, decrease the need for individual controls. In addition to the external controls provided by the methods adopted in the data linkage process itself, there are further external controls imposed by privacy legislation both at a state and federal level in Australia, as well as legislation governing certain data sets, as discussed in greater detail in Chapter 4. Therefore, even though individual controls are not exercised in the case of data linkage, increased external controls are in place to ensure that harm, in the form of privacy infringement, is avoided. Such external controls are adopted precisely because the protection of individual privacy and minimization of harm to individuals are regarded as being critically important.

Practical constraints hindering research

As previously noted, the imposition that stringent consent requirements place on research can lead to an inability to conduct some research and to biases which compromise the integrity of the research outcomes. In addition, monetary and time constraints often make seeking consent impossible. Finally, the age of the records can pose insurmountable difficulties in locating the persons whose consent researchers may wish to seek. When health records relating to people who have died are considered for use, consent requirements would entail seeking consent from relatives, an option which in itself raises serious ethical issues. All but the last of the issues raised here are of a practical nature and it is often contended that they lack a moral dimension and can therefore not be used as valid moral justifications for the non-consensual use of data for research purposes (104) in cases such as data linkage.

What may appear reasons unrelated to moral concerns are in fact of great moral import. A clarification, however, is necessary; the conduct of such research is a great

[45] The role of consent in protecting privacy was discussed in the previous chapter.

common good not because it has intrinsic value, i.e. scientific research is not in and of itself valuable. In fact, if there were privacy losses solely for the purposes of advancing science, I would argue that this is morally reprehensible. However, when such research helps us to better understand disease, improve treatment options, more justly allocate scarce health care funds and conduct population level surveillance to protect whole populations, this justifies giving a moral dimension to pragmatic arguments in favour of data linkage.

The value that we place on research is evidenced by the public funds allocated to such endeavours. It is widely acknowledged in the research community that funds for individual research projects are scarce. To 'squander' a large proportion of these funds to satisfy consent requirements for data linkage projects whose harm to participants is improbable seems a poor use of public funds. In addition, to spend years attempting to contact potential participants is not just a matter of inconvenience to researchers; it also stifles research and delays advances in the health care sector.

It is important not to overlook the harms that arise from not using data already available, an example of which has already been provided in relation to Estonia where the cancer registry data has become so unreliable that it is impossible to provide reliable cancer statistics in this country (99). Of equal importance, however, is the need to gauge the magnitude and probability of harms arising from unrestricted access to identifiable information and the methods used to access such information.

Issues of consent

What does not always seem to weigh into arguments for uses of personal information to create the linkage key in data linkage projects is the *intention* underlying disclosures of and access to identifiable data. In research, including data linkage research, disclosures of and accesses to data are made purely 'for *impersonal* ends' (64 p.114). There is no interest in individuals in the dataset per se (64). In fact, as previously noted, the initial process is undertaken to protect individual interests. Given this intention, consent for data linkage as a research/public health activity, should perhaps be regarded differently from consent to other research activities. In addition, some consideration should also be given to the treatment of the personally identifying information that data linkage units handle. The thousands/millions of variables are coded by sophisticated computer programs and are not accessed and manipulated

individually by data linkage experts, except for the quality assurance checks which are conducted randomly.

The current treatment of consent also raises an additional issue given its relevance only to those who have the capacity to consent. If consent were required for access to data in data linkage projects, it would appear that the records of all those lacking capacity to consent would either need to be excluded or researchers would have to seek consent from their legal guardians. Even if all the other practical difficulties arising from stringent requirements were absent, this requirement alone would be gravely detrimental not only to the quality of the research but also, and importantly, potentially to persons approached for consent. On the other hand, exclusion of such data as a result of researchers' inability to obtain consent could in fact potentially have a detrimental effect on such individuals by virtue of their exclusion. The same considerations for consent would also extend to relatives of those who are deceased. Should consent also be sought from these individuals? Would the potential harms justify our insistence on consent?

Ethical issues in using de-identified data

To this point, I have focused on the personal data used at the initial phase of the data linkage process. However, it could be argued that, despite the separation of identifiable data from the individual's health data, and the numerous rigorous controls employed in data linkage, there is still a loss of privacy by virtue of the fact that *de-identified* data about individuals are utilised without their consent. Privacy is so intricately related to the person to whom the information relates that it is hard to imagine how an individual's privacy might be lost when personal and health information is no longer connected to the identity of that individual. Provided that it is not possible to identify someone, a detailed list of their medical conditions, treatments provided, and clinical outcomes separated from the person to whom they pertain is simply a medical history. In addition, no harms can come to this particular individual. Instead of considering that there is a *loss of privacy* when de-identified data are used without consent, it is more appropriate that we consider the fact that our failure to obtain consent could be construed as a lack of respect for the individual involved[46]. My claim that information no longer connected to an individual does not constitute a loss of privacy for that

[46] I propose a solution which affords respectful treatment of people in the following section.

individual will also be scrutinised in the empirical research, the reporting of which follows in Chapters 6-8.

It could further be argued that while individuals may not be directly harmed in relation to privacy in data linkage projects, the use of their de-identified data for purposes to which they are personally vehemently opposed could be considered harmful to them in a broader sense. For example, the development of a public policy resulting from a data linkage project may be viewed as disadvantageous to such individuals, who unwittingly participated in the project from which it arose. It is important, however, to highlight the fact that it is impossible to provide public policy that satisfies all members of a given community.

Informing the public of future uses of their data

On the basis of my arguments so far in this chapter, it would seem that some knowledge of the use to which people's personal and health data will be put is necessary both because this approach is respectful and helpful in the long term, as more people are likely to support such uses of data when they are informed. I argue that we need to consider the acceptability of accessing and using of data, in the context of data linkage for example, based on *notification of future use*, a process that could be adopted at the initial point of data collection. This would entail the provision of information regarding data linkage uses (among other potential uses) with explanations of the protections in place to ensure that individual privacy is protected. This process of informing the public would be relatively straightforward but has not been widely implemented in Australia. The acceptability of such a process is based on communitarian values; it is justified by the fact that the public would be advised, and by the fact that the use of identifiable data is a temporary, yet essential, measure to enable the linkage (28).

In addition, even if consent cannot be sought on an individual basis for some types of research or public policy development, it should not be assumed that other avenues for obtaining public support or taking into account the public's concerns cannot be pursued. Public discussion mechanisms are both necessary and useful. It is only through dissemination of information about new technologies via multiple communication avenues that new information can enter the public's consciousness and begin to be considered in relation to its acceptability or not.

As with previous claims made after consideration of the current state of affairs and the literature, the above proposal for notification of future uses of health and personal data at the initial point of collection of such data also needs to be explored in the qualitative research.

Conclusion

This chapter outlined a number of privacy related issues in relation to the implementation of data linkage. I suggested that a balance between competing values needs to be struck. This cannot be achieved with data linkage, however, unless there is transparency regarding its conduct, its benefits, and the protections it offers. My position is that there are *some* situations in which non-harmful uses of people's data without their consent are *justifiable*. These situations will hold when there are clear and substantial benefits from the non-consensual use of data, improbable risk of harm, and no practicable alternatives to achieve the ends desired. Central to my position is the need to show respect to persons, both at an individual level by providing information about future uses of data at the initial point of contact with services but also at a broader community level by transparently discussing uses to which personal and health information should be put. When people have the requisite knowledge and understanding, objections to some sacrifices of personal privacy are viewed as acceptable, both morally and socially. Often overlooked when considering data linkage are the harms arising from *not* using valuable data already collected for other purposes as a result of privacy-related objections. The empirical research will clarify whether these assumptions and conclusions are socially acceptable and seen to hold the same moral import.

CHAPTER 4

AUSTRALIAN PRIVACY LEGISLATION

Laws and institutions, like clocks, must occasionally be cleaned, wound up, and set to true time.

Henry Ward Beecher
American politician (1813-1887)

The following published paper examines the use of personal and health data and the legislation that aims to provide protections when such uses occur.

Statement of Authorship

Xafis, V, C Thomson, AJ Braunack-Mayer, KM Duszynski, and MS Gold (2011). "Legal impediments to data linkage." Journal of Law and Medicine **19**(2): 300-315.

Vicki Xafis (Candidate)

Conceived the idea, conducted the searches, structured the arguments, designed the paper, interpreted the legislation and its implications, drafted the manuscript and acted as corresponding author.

Signed: ..... Date: 31/1/13

Colin Thomson

Contributed to the structure of the arguments, provided expert legal commentary, assisted with the interpretation of the legislation and its implications, and reviewed the manuscript. I give consent for Vicki Xafis to present this paper towards examination for the Doctor of Philosophy.

Signed:. ..... Date: 31.1.2013.....

Annette Braunack-Mayer

Contributed to the structure of the arguments and reviewed the manuscript. I give consent for Vicki Xafis to present this paper towards examination for the Doctor of Philosophy.

Signed ..... Date: 31.01.2013

Katherine Duszynski

Contributed to the structure of the arguments and reviewed the manuscript. I give consent for Vicki Xafis to present this paper towards examination for the Doctor of Philosophy.

Signed: ..... Date: 04/02/2013

Michael Gold

Contributed to the structure of the arguments, contributed to the design of paper, and reviewed the manuscript. I give consent for Vicki Xafis to present this paper towards examination for the Doctor of Philosophy.

Signed: .... Date: 04/02/2013.

Xafis, V., Thomson, C., Braunack-Mayer, A.J., Duszynski, K.M. & Gold, M.S. (2011) Legal impediments to data linkage.
Journal of Law and Medicine, v. 19(2), pp. 300-315

NOTE:
This publication is included on pages 64-79 in the print copy
of the thesis held in the University of Adelaide Library.

CHAPTER 5

PHASE 2 – QUALITATIVE STUDY METHODOLOGY

He who loves practice without theory is like the sailor who boards ship without a rudder and compass and never knows where he may cast.

Leonardo Da Vinci
Italian architect, musician, anatomist, inventor, engineer, sculptor, geometer, and painter (1452 – 1519)

Introduction

Much has been written about consent and privacy but, in the context of data linkage, little is known about people's conceptions and perceptions of these issues. A qualitative component was vital to the thesis, as this component would enable a better understanding of what people know, think, and have as underlying values, and why they hold these views, primarily in relation to issues of consent and privacy in data linkage contexts.

This chapter describes the conduct of the first empirical study (Phase 2), focusing first on the small pilot study conducted and followed by detailed information regarding the main study. The chapter also includes reflections regarding my role in and influence on the research, set out in boxed sections throughout the chapter. Reflexivity in qualitative research has been defined variously (105) and has been aligned closely with a variety of different qualitative approaches including feminist research (106) and action research (107). In this work, I define reflexivity as the awareness a researcher has in relation to her position in the research context taking into account the views and influences which shape her thinking and through which she perceives the world (105). It is also a self-critique of influences on research, sometimes only recognized after the event but raised nevertheless both as an important step to more transparent research but also with the

view to continually developing as a researcher. The reflections primarily relate to the design of the research and conduct of the interviews and while the analysis is not commented on in the same depth perhaps, it is important to note that the very method of analysis adopted is a direct result of how I structure meaning and perceive constructs. I take this claim to apply to the analysis and interpretation of findings, to a smaller or larger extent, in all research, qualitative and quantitative alike, despite the imposed methodological rigour required of the latter. The reflections follow on sequentially and are intended to be read as part of the main text.

Nature of study

Phase 2 was a qualitative study comprising a small pilot study and the main study entitled: *The ethics of linking health data for research and health surveillance purposes: views held by parents of children eligible for vaccination*. The study received ethics approval from the Children, Youth & Women's Health Service (CYWHS) Human Research Ethics Committee (HREC)[47]. The aforementioned Human Research Ethics Committee was approached as the participants were drawn from a pool of mothers and fathers whose babies had been born at the above hospital and who had participated in the VALiD Randomised Controlled Trial (RCT)[48] regarding data linkage. The University of Adelaide HREC was advised of the approval, as there is a reciprocal approval arrangement between these institutions.

This qualitative study aimed to gain an in-depth understanding, via face-to-face interviews, of participants' underlying values and beliefs in relation to data linkage and related ethical issues. Further details regarding all aspects of the study are provided in the following sections.

Pilot Study

The pilot study aimed to determine whether materials to be used in the main study required amendment and whether recruitment procedures were appropriate. The total number of participants intended to be included in the pilot study was six. However, inclusion of male participants proved difficult and time-consuming so the pilot was concluded on 1 June 2010 after successful recruitment of four female participants,

[47] The *Children, Youth & Women's Health Service* (CYWHS) has recently been rebadged to *Youth & Women's Health Service*.
[48] As previously mentioned, this research is one of four components of the VALiD Study.

drawn from the six categories listed below. These were also the categories from which participants were drawn in the main study:

Table 1. RCT categories from which study participants were drawn

Group	RCT arm	Consent status	Participation in pilot study
FEMALE <30 - Agreed to data linkage	Opt-out[49]	Passive consent[50]	Yes
FEMALE <30 - Did not agree to data linkage	Opt-in[51]	Passive decline[52]	Yes
FEMALE ≥30 - Agreed to data linkage	Opt-out	Passive consent	Yes
FEMALE ≥30 - Did not agree to data linkage	Opt-in	Passive decline	Yes
MALE* (all ages) - Agreed to data linkage	Opt-out	Passive consent	No
MALE* (all ages) - Did not agreed to data linkage	Opt-in	Passive decline	No

*Not included in pilot

Potential participants were contacted to determine their interest in participating in the pilot study. Information sheets and Consent Forms (see Appendix 2) were sent to potential participants and their written consent was sought on the day of the interview following their verbal agreement over the telephone, at which time the interviews were also arranged.

The pilot phase proved useful, as it helped refine the research rules pertaining to recruitment methods (see Appendix 3) to be used in the main study. The interview schedule (see Appendix 4) itself was not amended based on feedback received from participants. Participants were asked to respond to a number of issues relating to their participation in the pilot study via a short questionnaire offering a number of choices

[49] 'Opt-out' refers to the opt-out consent group to which individuals in the RCT were randomly allocated. Opt-out consent requires a written request not to be involved in a study. If this is not submitted, participants are included in the study.
[50] 'Passive consent' refers to the participants' agreement to participate, as they have not indicated that they wish to be excluded.
[51] 'Opt-in' refers to the opt-in consent group to which individuals in the RCT were randomly allocated. Opt-in consent requires a written request to be involved in a study. If this is not submitted, participants are not included in the study.
[52] 'Passive decline' refers to participants' unwillingness to participate, as indicated by their not returning a signed consent form indicating that they wish to take part.

and an opportunity for additional comments. Aspects of the study for which feedback was sought included: length of interview, repetition of various items during the interview, scenarios presented, usefulness of handouts provided, suggestions on improvements that could be made, interviewer skills, recruitment letter and Participant Information Sheets.

Pilot Study Participant feedback

All participants thought the interview length was appropriate. In addition, they felt that the introductory questions relating to the RCT assisted them in focusing on the scenarios and issues further investigated in the current study. The majority felt that these questions helped them remember the RCT but one participant thought that there were too many questions and indicated that she found them difficult to respond to as she had little recollection of the details of the RCT in which she had participated.

All participants found the scenarios easy to understand and half the participants stated that they were all relevant. One individual felt that the bolded writing in the scenarios did not enhance her comprehension of them.

Participants acknowledged the need for repetition of interview items (e.g. *should consent be sought?*, a question asked about all scenarios) recognising that the scenarios they were presented with were all slightly different from each other. One individual further indicated that the repetition helped her keep her train of thought.

Three handouts were supplied to participants at appropriate stages of the interview and were left with participants: (*data linkage sheet* - explaining how data linkage works (see Appendix 5), *scenarios* (see Appendix 6), *legislation & guidelines sheet* - illustrating the various pieces of privacy legislation and research ethics guidelines that apply to research (see Appendix 7). The majority of participants found these handouts helpful and believed that they clarified things for them but one participant stated that, while they were nice to have, they were unnecessary. Another individual indicated that it would have been helpful to spend more time looking at the *How Data Linkage Works* handout. Pilot study participants were given the handouts to keep as were participants in the main study.

When asked if any improvements should be made to the interview schedule, participants felt that this was not necessary. As the interview schedule had been

carefully considered and designed prior to the pilot study, I felt that no alterations were required given the feedback from pilot study participants.

With regard to the researcher's interviewing skills, participants indicated that I made them feel at ease, displayed confidence, had good interviewing skills and did not influence them in their responses. One participant indicated that I did influence her but clarified that she was influenced to the extent that the interview '*…challenged my own thinking and helped me realize my own inconsistencies*.'

When asked, participants did not offer any comments regarding the letter and information sheets provided for recruitment purposes.

I determined that the time allotted to explaining and studying the handout on *How does data linkage work*[53] (see Appendix 5), which was presented near the beginning of the interview, would depend on the needs of the individual being interviewed and on the queries they had in relation to the mechanics of data linkage.

Main Project Design

Aims and objectives

Knowledge gained from previous research, the aims of the research, the research questions and my own epistemological perspective have all been used to inform the design of this study.

I hold the view that the natural world exists independently of humans and their consciousness, and that '*...all* meaningful reality...is socially constructed' (108, p. 55). Social constructionism asserts that social reality is constructed and maintained through human interaction with the world and objects around them (108) so the view that each individual creates their own reality is rejected. Rather, we interpret and give meaning to the world with the knowledge we inherit from the society in which we live and we may further interact with this knowledge to create modified views of the world.

The aim of this research was to determine and analyse what participants regarded as the ethical and social issues arising in data linkage in the Australian context, examined in the context of vaccine safety surveillance and other health-related fields. Specifically, the key questions to be answered were:

[53] The diagram was designed by the VALiD Project Manager, Katherine Duszynski.

1. How do lay people conceptualise privacy in non-medical settings?
2. Do lay people place less value on privacy and established consent processes in relation to data linkage once they become familiar with the processes adopted in data linkage?
3. How do lay people resolve the tension that exists between opposing values such as privacy and the common good that arises from data linkage projects?
4. How do lay people justify the decisions they arrive at when making consent choices in the context of data linkage?

Key Objectives:

1. To assess and interpret participants' opinions and understanding of data linkage, and related ethical issues.
2. To gain an in-depth understanding of participants' underlying values and beliefs held in relation to ethical issues relating to data linkage.
3. To inform policy and practice regarding key ethical and social issues pertaining to data linkage in the Australian context, as described by the participants of this study.

The aims and objectives of the current study coincide with the aims and objectives of the entire project, as shown in its subsequent components.

Presuppositions

Having been exposed to the literature on data linkage and related ethical and legal aspects, I could not ignore the influence this understanding had exerted on me and I felt it to be pretentious to even articulate the desire to investigate these issues qualitatively without specifying presuppositions that arose in my thinking when designing the research. When designing the research I made the following assumptions:

Assumption 1 - Participants will generally have a limited understanding of what data linkage is and what it involves

Assumption 2 - Most participants will want to opt in and provide specific consent

Assumption 3 - Participants will generally prefer to provide consent for both identifiable and de-identified data

The original assumptions articulated also included the following two assumptions:

Assumption 4 - Participants will not be aware of the security measures or research guidelines

Assumption 5 - Participants may have developed concerns about data linkage and/or research based on media reports of privacy breaches.

The interview data collected was rich and therefore it was necessary to make decisions during its analysis regarding my ability to analyse formerly all material that related to the assumptions. I chose not to analyse some aspects, including assumptions 4 and 5, in order to give greater attention to more central parts of the enquiry. The assumptions are discussed in greater detail in Chapter 6.

Reflections

The articulation of what a researcher thinks they will discover in an enquiry may be viewed by some as biasing in qualitative research. It may be considered that the researcher, influenced by their thinking and beliefs, is unable to resist shaping both the data and their interpretation in ways that align with their preconceived notions of what is. However, given my own theoretical orientation (see, for example (109)), I found that I could not function honestly as a researcher if I did not take the literature and my understanding of it into account. Indeed, these assumptions 'whetted my appetite' for what I would in fact discover as a result of the interviews. I was cognizant of the fact that the assumptions arose as a result of the constructs influencing my understanding and saw any discrepancy between assumptions and findings as an important finding in itself, which should be shaping our understanding of the world around us by revising the shared and personal constructs through which we filter our experiences and explain phenomena.

Participants

This study involved participants (see Table 2) recruited from a pool of individuals who had taken part in an RCT, another component of the VALiD study. In the RCT from which they were recruited, eligible parents[54] of every consecutive child born at the Women's and Children's Hospital[55] over a 13-week period, who agreed to participate in the trial, were randomised to one of two groups. The RCT groups differed in the requirement to consent to data linkage for vaccine safety surveillance (opt-in vs. opt-out). During their telephone interview, all RCT participants were asked about their views on data linkage, vaccine safety surveillance, and consent options for this kind of activity. They had also been asked if they were willing to be contacted and invited to participate in a face-to-face interview to further elaborate on their views about data linkage.

Table 2. Participant characteristics

[54] For further details on the RCT inclusion and exclusion criteria, see (110).
[55] At the time of the interview their babies were only a few months old.

Pseudonym	Age	Allocation to group	Level of education	Continent Born
Margaret	27	1. F-30Y-OO-PC-1[56]	University degree (Dip, B, Hons)	Australia
Mary	28	1. F-30Y-OO-PC-2	Dip/Cert at TAFE (incl. trades)	Australia
Molly	28	1. F-30Y-OO-PC-3	Dip/Cert at TAFE (incl. trades)	Australia
Mel	29	1. F-30Y-OO-PC-4	University degree (Dip, B, Hons)	S Asia
Mandy	29.6[57]	1. F30+Y-OO-PC-5	University degree (Dip, B, Hons)	S Asia
Helen	26	2. F-30N-OI-PD-1[58]	Yr 11 or equivalent	Australia
Holly	24	2. F-30N-OI-PD-2	Yr 12 or equivalent	Australia
Haley	29	2. F-30N-OI-PD-3	Dip/Cert at TAFE (incl. trades)	Australia
Henrietta	24	2. F-30N-OI-PD-4	University degree (Dip, B, Hons)	N America
Harmony	27	2. F-30N-OI-PD-5	University degree (Dip, B, Hons)	Australia
Teresa	41	3. F30+Y-OO-PC-1	University degree (Dip, B, Hons)	Australia
Tina	39	3. F30+Y-OO-PC-2	Dip/Cert at TAFE (incl. trades)	Australia
Tracey	30	3. F30+Y-OO-PC-3	University degree (Dip, B, Hons)	S Asia
Tegan	31	3. F30+Y-OO-PC-4	University degree (Dip, B, Hons)	Australia
Trixie	39	3. F30+Y-OO-PC-5	University degree (Dip, B, Hons)	Europe
Vanessa	35	4. F30+N-OI-PD-1	University degree (Dip, B, Hons)	Australia
Vallery	30	4. F30+N-OI-PD-2	Dip/Cert at TAFE (incl. trades)	Australia
Victoria	32	4. F30+N-OI-PD-3	Post graduate degree	Australia
Verity	33	4. F30+N-OI-PD-4	University degree (Dip, B, Hons)	Australia
Virginia	34	4. F30+N-OI-PD-5	University degree (Dip, B, Hons)	Australia
John	36	5. M-Y-OO-PC-1	Dip/Cert at TAFE (incl. trades)	Africa
Jack	30	5. M-Y-OO-PC-2	University degree (Dip, B, Hons)	Australia
Jacob	31	5. M-Y-OO-PC-3	University degree (Dip, B, Hons)	S E Asia
Darren	25	6. M-N-OI-PD-1	Yr 10 or equivalent	Greater Middle East
Danny	31	6. M-N-OI-PD-3	University degree (Dip, B, Hons)	Asia
Don	31	6. M-N-OI-PD-2	University degree (Dip, B, Hons)	Greater Middle East

Suitability of sample

This pool of individuals was considered appropriate for inclusion in this qualitative study, as these individuals had had the complex process of data linkage explained to them as part of the RCT. Despite this, it was expected that participants would have a limited understanding of the intricacies of data linkage for several reasons: the complexity of the process, the fact that it had only been explained verbally over the

[56] 1. F-30Y-OO-PC-1 means:1.= Group 1, F= Female, -30= under 30 years of age, Y= Consent option facilitated RCT data linkage, OO=Opt-out arm of RCT, PC=Passive consent,-1=first recruited in this group.

[57] There was an error in the original data, which was only identified after the analysis of the data. As a result, this participant was 29 and 7months but was included in the 30+ group.

[58] 2. F-30N-OI-PD-1 means: 2= Group 2, F=Female, -30=under 30 years of age, N=Consent option did not facilitate RCT data linkage, OI=Opt-in, PD=Passive decline, 1=first recruited in this group. For further details see Figure 4. Purposive sampling method for identification of 6

telephone, the fact that they had most likely not considered data linkage since their involvement in the RCT, and, finally, as a result of the effects of the intervening time and involvement in important life activities far removed from considerations of data linkage. Nevertheless, in examining issues such as privacy and consent in relation to data linkage, I considered it important that there be at least some prior contact with the concept and process of data linkage, the understanding of which was explored at the beginning of the interview and then further explained with the aid of a visual representation of the process (see Appendix 5).

In addition to having been exposed to the concept of data linkage, these parents had also previously provided an indication of their views on some ethical issues that arise in relation to data linkage in the context of vaccine safety surveillance in a scripted telephone interview (conducted as part of the RCT). My study provided the opportunity to investigate in-depth a number of ethical and social issues on which these participants were asked to justify their views.

Eligibility criteria

All mothers and/or fathers who had taken part in the VALiD RCT were eligible to participate in the study but only those who had already agreed to be contacted for this research at the time I commenced recruitment were approached. No exclusion criteria applied, other than not having been involved in the RCT.

Sampling method

A stratified purposive sample comprising a total of 26 participants who consented to participate in the study was employed. I decided that, if data saturation was not achieved with this sample size, the sample would be increased until data saturation was achieved.

The sample was stratified by gender and age[59] (for the mothers). I surmised that age and gender may be features that will provide variation, as young mothers, for example, are known to share different characteristics from those of older mothers (111). The sample was also stratified in terms of implied agreement or not to have the child's vaccination data linked to his/her hospital data – as determined by return/non-return of the RCT study form. Once stratification groups were derived from the total number of

[59] Jesia Berry assisted with the stratification of the sample.

parents who had agreed to participate, the participants from each group were randomly selected as numbers within each group were large enough to enable this process. The sample was stratified not because there was an intention to produce generalizable findings but in order to capture a variety of views. The following figure demonstrates the sampling method adopted.

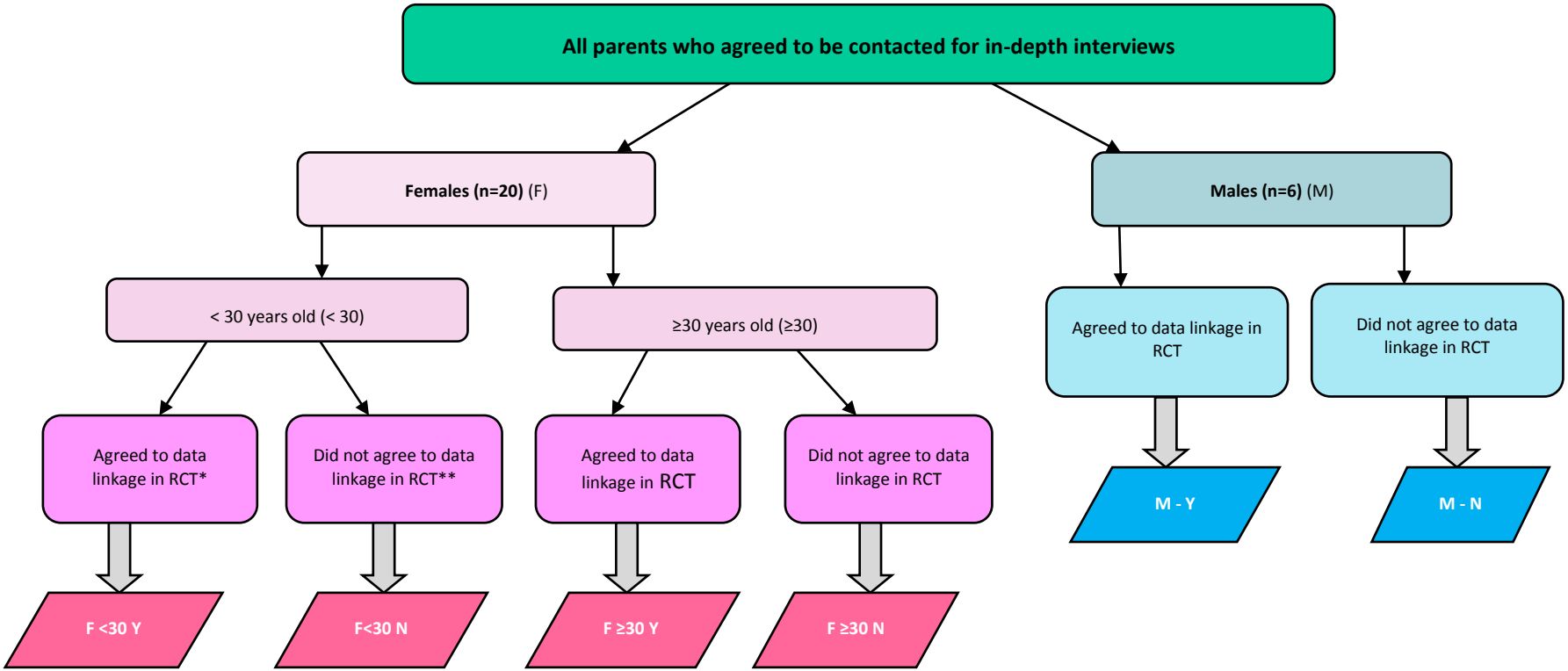


Figure 4. Purposive sampling method for identification of 6 pertinent groups

* "Agreed" means the parent returned a study form in the opt-in arm OR did not return a study form in the opt-out arm, thereby facilitating the data linkage of the child's vaccination data to his/her hospital data Coded as **Y** ** "Did not agree" means the parent returned a study form in the opt-out arm OR did not return a study form in the opt-in arm, thereby precluding the data linkage of the child's vaccination data to his/her hospital data Coded as **N**

Participants were randomly selected from the resulting 6 groups: **F<30Y (Group 1), F<30N (Group 2), F≥30Y (Group 3), F≥30N (Group 4), M–Y (Group 5), M–N (Group 6).** As shown in Figure 4 above, there were two groups of five mothers aged up to and including 29 years[60] and two groups of five mothers aged 30 years or older. One group in each of the age groups comprised mothers who agreed to having their baby's data linked by returning a study form in the opt-in arm or not returning a study form in the opt-out arm of the RCT, and the other group comprised mothers who returned a study form in the opt-out arm or did not return a study form in the opt-in arm of the RCT, thus precluding the data linkage of the child's vaccination data to his/her hospital data.

In addition, six fathers in total were recruited to explore tentatively the role that gender might play within the sample. Three had agreed and three had not agreed to have their baby's health data linked. The number of fathers included was guided by the fact that the total number of males agreeing to be contacted was significantly smaller than that of females, as fewer males had taken part in the RCT[61]. It was for this reason that fewer males were included and the reason why males were not stratified by age.

The total number of participants was dictated by practical considerations arising from the nature of the data collected. In qualitative research, in-depth interviews are known to yield large amounts of data which can become unmanageable if very large sample sizes are used (112).

Selection bias

I recognised early on that the participants who agreed to take part in this study would share features different from those of the general population by virtue of their willingness to be involved in the research. The implications of this are that the data collected may not represent the views of a wider segment of the population, as the individuals recruited may have slightly different views regarding research in general, and more specifically, in relation to data linkage and the use of their data in such activities.

[60] The median age for maternal childbirth in Australia in 2006 was 30.0 (111).

[61] At the time of recruitment, 922 parents in the RCT had completed the telephone interview in full (839 females and 83 males). Of the 763 (80%) who had agreed to be contacted, 704 are females and 59 were males.

Recruitment

Contact details of potential participants were made available to me, in accordance with permission granted by the potential participants and ethics approval for this method of initial contact. I contacted potential participants by phone so I could advise them of the study and ask whether they would like to receive additional information in order to decide whether to participate or not (see Appendix 8). Those who agreed to receive information were sent written information about the study (see Figure 5).

The 763 individuals who agreed to be contacted became potential participants for the current study (see Figure 5). The 26 randomly selected resulted from contact attempts made with a total of 161 different individuals. Multiple contact attempts were made in each case, as a result of people being unavailable the first time contacted or requesting that I call back. Thus 476 calls were made in total.

The same letter, Information Sheet, and Consent Form amended to refer to the main study rather than the pilot were used in the main study (see Appendix 9). A few days after the letter and project information were sent out, I made telephone contact again to discuss the project, ascertain whether the individual wished to participate and to arrange an interview time with those interested. The telephone call also provided an opportunity to actively invite potential participants to ask questions and have any queries discussed prior to their consent being sought. I collected the signed consent form on the day of the interview and a copy of both the Information Sheet and Consent Form was left with the research participant.

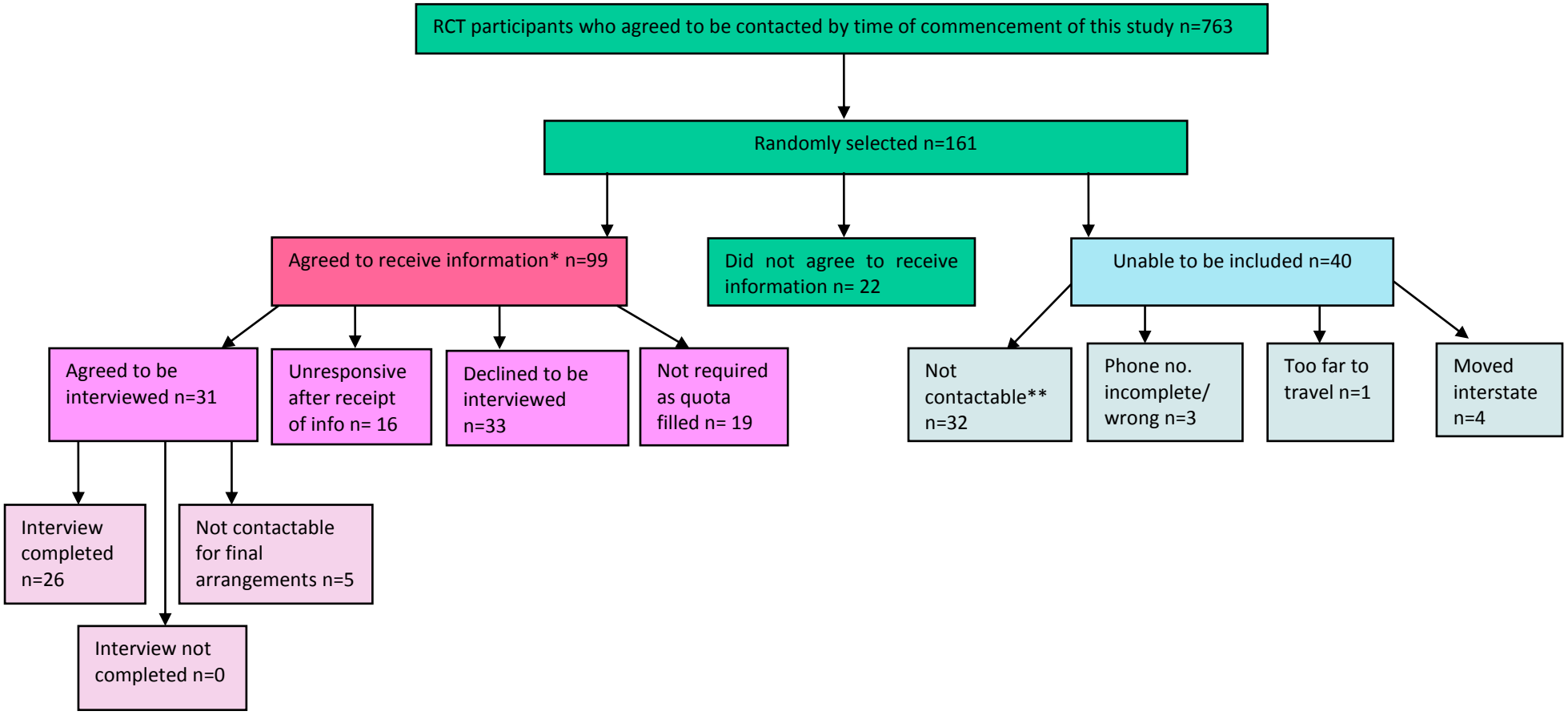


Figure 5. Interview selection method

*Information packs were sent by the Project Manager of the VALiD study, Katherine Duszynski
***Not contactable* refers to calls not being answered, phones being disconnected, or unresponsiveness to messages left

As I am also a qualified teacher of English as a Second Language (ESL), I used my professional expertise to gauge potential participants' ability to take part in the interviews. If, despite limited comprehension skills, the potential participant wished to take part, they were not denied this opportunity, as I felt that every person interested must be afforded the respect they deserve for their efforts to contribute to the research. I also felt that it would be disrespectful and unethical to collect the information and not make use of it. There was only one such interview and, as expected, it did not always yield the depth of information envisaged with fluent or near-fluent speakers. However, this individual offered a unique insight into the manner with which he viewed privacy as a result of his vastly different life experiences.

Data collection method

I conducted in-depth semi structured face-to-face interviews of approximately 45-90 minutes in participants' homes[62] with the length of the interview depending entirely on how much the participant wished to contribute. These interviews took place from June 2010-September 2010.

Face-to-face interviews were deemed more appropriate than any other data collection method for a number of reasons; first, the cognitive load for participants involved in face-to-face interviews compared to, for example, telephone interviews is low (113). It was important to take this into account given the complexity of the issues discussed and the fact that a number of participants were speakers of English as an additional language. Second, face-to-face interviews have the advantage of providing visual cues which assist the interviewer in gauging the interviewee's understanding of concepts or questions[63]. Third, compared to telephone interviews, face-to-face interviews have a higher item and completion rate and are people's preferred mode of administration of questionnaires[64] (113).

[62] Given the fact that interviews were conducted in private homes, I developed safety measures which involved informing the VALiD Project Manager, Katherine Duszynski, of my arrival at the interview venue and immediate notification upon conclusion of the interview (both communications were unknown to the participants). Only one participant came to the university, as he was also employed there and it was therefore more convenient for him.

[63] My teaching experience was useful in providing me with an in-depth understanding of the subtleties of communication cues, such as visual cues referred to here.

[64] In this case, it was a semi-structured interview.

Most participants were confident in expressing their views. Some, however, were less confident and verbalised their initial uncertainty regarding the subject matter and concepts involved. To put participants at ease, I agreed that the concepts were indeed hard to grasp at times, that these were issues we do not usually devote our attention to unless provoked by circumstances, and that many other participants had struggled equally in verbalising their views[65].

There are, however, also drawbacks related to face-to-face interviews. Like telephone interviews, face-to-face interviews are generally also subject to high social desirability, agreement, and interviewer biases (113). However, in this study, participants were robust and did not appear to be concerned about 'pleasing' me when responding. On the contrary, it appears that a better understanding of the facts surrounding data linkage methods, as explained diagrammatically to participants, was the influencing factor for shifts in views. Evidence of their confidence was the fact that, in several interviews, points I had rephrased to ensure that my understanding was accurate were confidently rejected and a correction or clarification was offered in their place. In some interviews participants were slightly concerned that their views did not present them in the best light but in response I reiterated that there were no right or wrong answers to any of the questions and that each participant's views were of great interest.

Reflections

I believe that this approach was successful and encouraged participants to express their views more confidently without further concerns about the appropriateness or not of their positions.

Reflections

I made great efforts to reduce interviewer bias to the minimum. However, a constructionist approach acknowledges that a researcher will always shape the data collected and is always co-constructing meaning in the space between the participant and herself. For example, in the interviews with the least fluent participant, it was hard to gauge whether he truly had intended to verbalise what I offered in an attempt to understand what he had said, or whether he seized on the opportunity to adopt what approximated his view.

Reflections

The bi-directional influence of the context within which the interviews took place and social interactions between the interviewee and me became very apparent to me from the start of the interviews. As I was influenced by crying babies, husbands, wives, or friends interrupting the interview, I am sure that such external factors also influenced my interviewees. On occasion, I did feel a sense of urgency as I was

[65] Another method I adopted to put participants at ease was to dress very casually so that they would not regard me as an academic elitist, a characterisation I have heard levelled at academics.

> *sensitive to the 'pause' I had created in some of my interviewees' busy lives and did not wish to impose on them any longer than was necessary. This was particularly the case when the 5-year-old son of one of my interviewees came into the kitchen where we were sitting and asked his mother, "When is she leaving?" Conversely, in other interviews, I felt as if it was more a friendly chat than an interview. Conscious of the difference my behaviour might have on my interviewees, I tried very hard to be 'constant' during all interviews and adopted a calm and thoughtful approach to all participants (no matter how disruptive the environment). It is, once again, extremely difficult to state with utter certainty that I achieved this despite my efforts.*

The interviews were audio taped and transcribed verbatim by a professional transcribing agency. The interviewees were given unique identifiers[66] and pseudonyms[67] in case clarification was required during or following transcription.

Interviews were mainly held in or around Adelaide but there were occasions which required travel, the furthest location being 564km from the University of Adelaide.

Interview schedule and conduct of interview

I commenced the interview with questions about the participants' involvement in the RCT in order to ease them into the interview with something known to them. It proved, however, that some did not have much recollection of their involvement in the RCT.

Following this discussion (see Appendix 4 for the full interview schedule), four scenarios, which formed the main component of the interview, were discussed. Each scenario related to a hypothetical data linkage research project. The scenarios were designed to display incremental complexity, i.e. Scenarios 1 and 2 involved only health data linked by experts, Scenario 3 involved health and criminal records data linked by experts (and consent was not given as an option), Scenario 4 involved health, WorkCover records, and employment data to be linked by researchers (hence researchers would have access to identifiable data). As a result of the content and order of presentation, the scenarios also performed an educational function: Scenario 1 provided the ***training***, Scenarios 2 and 3 enabled ***application*** of the data linkage and ethical concepts and Scenario 4 functioned as ***testing*** of participants' understanding of concepts.

Inclusion of data sets unrelated to health was deemed important, as it provided a contrasting effect. In other words it brought to the fore the issues people consider

[66] The coding for individual participants followed the stratification group formats, e.g. F < 30 Y-1, F < 30 Y-2, F< 30 Y-3 etc ; F < 30 N-1, F < 30 N-2, F < 30 N-3 etc.

[67] Pseudonyms for individuals belonging to the same group all commenced with the same letter to simplify identification of same-group participants.

pertinent when considering linkage of health data alone, compared to health and other data. This contrast proved extremely useful as will be shown in subsequent chapters.

The responses provided by participants arose from questions regarding requirements for consent. If participants indicated that consent was required, I put a series of considerations, such as time and monetary constraints in the research context, security of information etc., to participants to see if their view regarding the need for consent would be affected. In most cases, before presenting these considerations I announced what I was intending to do so that participants would understand why I continued to ask whether they still thought consent needed to be sought and would therefore not become impatient at being asked the same question repeatedly. Following the scenarios I asked questions about privacy, privacy protection measures and a question about foregoing consent for benefits arising from data linkage projects.

Participants sometimes struggled to verbalise their views as they had not ever given detailed or in-depth consideration to some of the issues prior to our discussion. In addition, participants wavered between opposing considerations but ultimately all came to a final decision about which consent requirement they believed was most suitable in the context of the hypothetical scenario under consideration.

Reflections

> *I made an effort to remain neutral during the interviews but retrospectively noted some language which could have been deemed as affecting the participant's view, for example, 'obviously' implies that the researcher's view corresponds with the question being asked, and repetition of words may have influenced a respondent's answer. An example of less than optimal interviewing techniques is provided below.*

Interview excerpt:

> *So obviously, in this case, in this scenario, the type of information made a really, really big difference for you because it was sensitive mental health information and police records. So that actually made a really big difference to the way you thought about it.*
>
> Oh, okay.
>
> *Didn't it?*
>
> I guess so.
>
> *Because you said that without consent, the study shouldn't go ahead. Is that accurate?*
>
> Yes.
>
> *What I'm saying is that this information was different to the cancer information. You found it a lot more sensitive. Is that right?*

> I can't really understand why you can't get consent for it. My view would be the same for the others. If you couldn't get consent, it probably shouldn't go ahead.

There were differing views in relation to what the participant claimed was their position and what they believed others felt was appropriate. In these cases, I scrutinised the data to determine whether participants were in fact voicing their own view through the prism of others' supposed views.

This research presents participants' consent preferences, including the oftentimes multiple shifts in views, before settling on their final choice. Therefore, it enables the tracking of participant views both within and across the scenarios presented thus highlighting the complexity of such consent decisions. In this research participants had concrete scenarios relating exclusively to data linkage. This necessarily emphasised the processes involved, the potential real or perceived risks of harm, and the potential benefits arising from such pursuits. It also necessarily brought into focus the very real constraints that stringent consent requirements impose of the conduct of data linkage projects. Directing participants' focus towards these issues throughout the interview enabled a better processing of the issues that require consideration, rather than having participants disperse their attention on numerous contextually different uses of personal and health data, which may involve a slightly different set of ethical and social considerations.

Data analysis

The data analysed related to people's conceptions of privacy and their views and justifications for consent based on the four scenarios presented to them. I focused on these data because they addressed the research questions in my thesis and corresponded with the theoretical components of the thesis.

Reflections

> *As with much qualitative research, it was regrettably not possible to analyse all the data collected for the purposes of this thesis. The wealth of data collected was great and I intend to explore the remaining data in the near future, in order that the generous contributions made by these participants not be wasted but be used to assist in our greater understanding of people's perceptions of issues relating to data linkage.*

The *framework approach* (112, 114, 115) was employed for the analysis of the data. This approach was developed within the National Centre for Social Research (UK), an independent social research centre (see http://www.natcen.ac.uk/). The framework approach was initially primarily used for qualitative research in the area of applied policy research, which is characterised by pre-defined objectives and questions for which answers need to be sought within short periods of time (114). The framework approach illuminates the research process and enables easy access to findings by individuals who do not always have an in-depth understanding of (or, I would suggest, an appreciation for) qualitative research (114). Unlike other qualitative research methods, the framework approach better tracks the processes adopted from raw data analyses to the interpretation of data and therefore displays greater transparency in the analysis of the data and the researcher's interpretation of the data (115).

In recent years, the framework approach has become an increasingly popular analytical method in healthcare research due to the systematic approach it requires for the analysis of the data (116). A wide range of studies has adopted the framework approach in the analysis of their data some recent examples of which include studies as diverse in subject matter as childhood obesity treatment (117), substance misuse management (118), venous thromboembolism and cancer diagnosis and management (119) and the role and practice of epilepsy specialist nurses (120).

The framework approach entails the following stages (112):

Familiarisation - thorough consideration of the raw data

I printed out entire copies of the interviews and read through them to gain a general sense of the content of all interviews and to begin to identify similarities and differences between interviews.

Identification of a thematic framework - identification of the main themes/issues which are informed by the aims and objectives of the research.

I had a good understanding of the nature of the main themes, as the interview questions were based on the areas of greatest interest to me. However, as was expected, new themes I had not anticipated also emerged. Themes were identified and demarcated on the paper copies of the interviews.

Indexing – systematic application of the thematic framework to the text with suitable annotations.

The thematic framework was rigorously applied to interviews and extensive Word documents were created under each theme. These were examined and re-examined with sections and themes shifting slightly as a result.

Charting – drawing out the data that belong to specific thematic categories and developing charts with summarised views/experiences.

I created numerous charts to track not only interviewees' responses and justifications for their responses but also shifts in their views during the interviews, as a result of further consideration of pertinent issues, in the order in which these occurred. Each Scenario is represented in at least one chart but if the subject matter required so, more than one chart was created. There is no published method for the creation of charts so I devised these in the manner I understood them to be of greatest assistance and convenience, both mine and the readers'. There are also charts which combine findings from all scenarios in order to provide a clear understanding of the general findings. Some charts are contained within the body of the work while other larger charts can be found in Appendices 10-15.

Mapping and interpretation – definition of concepts and creation of associations between the various themes, as well as a provision of how the themes can be interpreted with respect to research objectives and unanticipated themes which emerged.

The final process of mapping and interpreting the data was achieved after careful and close consideration of the trends observed as well as consideration of theories of privacy and consent.

Though the analytical process adopted in this study is highly structured, the interpretation of the data nevertheless demands '…the creative and conceptual ability of the analyst to determine meaning, salience and connections' (114:177).

I found this approach appealing, as it is a transparent and systematic method of analysing such data. The charts, for example, not only provide a clear and concise descriptive analysis of the data but also, importantly, better enable the reader to ascertain how and why the data have been interpreted in a particular manner. In other

words, there are fewer leaps (not to mention leaps of faith) between the raw/semi-raw data and the interpretation of the data, an issue which has often troubled me in qualitative research. In the following section some further details regarding the charts are given to assist with their interpretation and understanding.

The first and second level codes were primarily predetermined as a result of the approach adopted. In other words, they arose directly from the questions posed to research participants as certain key concepts such as privacy and consent were the primary focus of the interviews. For example, a first level code was *privacy*, which had as second level sub codes *definition* and *justification*. An additional second level code for privacy arose directly from participants' contributions and this was *contextualizing features of privacy.* So in this case, the second level code found its title and identity via the contributions rather than the contributions being slotted under the sub code, as was mostly the case throughout the coding. All third level sub codes arose in abstraction directly from participants' expressed views. Some participant comments, however, belonged to more than one third level sub code. In some cases, the same comment also came under a third level code of a different second level code. For example, the same comment may have included content belonging under *Privacy-Definition-Anonymity* but also *Privacy-Justification-Minimizes Harm.*

Reflections

> *Assigning participants' contributions to the correct third level sub codes was sometimes tricky. The connections were not immediately obvious because a number of concepts were intermixed within a single utterance. Verbal communication is not always as orderly as written communication, the latter of which allows reflection and correction. Such cases were examined closely to ensure that I was not imposing meaning unintended by the participant. Discerning the various categories under which complex statements came was occasionally conceptually demanding as meaning and concepts appeared to blur and I had to make sure I was not 'forcing' comments into categories in which they did not in fact belong.*

To ensure that I was avoiding such impositions on the data, codes were checked by an experienced qualitative researcher, Dr Victoria Wade. There were very few discrepancies in the coding but when these arose, they were discussed and codes were changed to reflect the consensus arrived at as a result of the discussion. In addition, on a few occasions I judged after discussion that a third level sub code was better placed under a different and more appropriate second level sub code. QSR International's NVivo 8 software (121) was used to assist with the management of the data.

Charts

The following section provides additional information about the charts created by studying the raw data. These charts provide a summary of the issues pertinent to the chart descriptor. The categories identified in each chart (including justifications for choices made by participants) arise from the data and reveal the issues which participants thought worthy of mention in relation to the topic of discussion. Some of these issues are stated explicitly by participants and some are inferred by their responses.

The charts provide key information relating, not only to individual views, but also to shifts in participants' views, as well as the direction of such shifts. Tracking participants' shifts in views provides an understanding of the manner in which these individuals arrived at their final views and the complexity of the process. In addition, participants' justifications for their view(s) are also summarised in the charts. The justifications, which are further analysed in Chapters 6 and 7, provide valuable insight into the issues these individuals perceived as being intricately related to the notion of consent and also revealed the manner with which people balanced apparently conflicting requirements. This method of analysis not only provides a useful overview of an individual participant's course through the decision-making process, but also provides an accessible overview of the whole group's position on consent issues in each scenario, as well as privacy issues, which are examined in Chapter 8.

Each respondent group was colour-coded in the charts and randomly chosen pseudonyms starting with the same letter were assigned to members of the same group to function as a practical means of identifying which individuals belonged to the groups created using the selection criteria mentioned above. All charts include participants' pseudonyms to aid in tracking responses at an individual level.

The charts pertaining to the scenarios are intended to be read from left to right, starting with the requirement for consent as the default option. If, however, opinions shifted in the opposite direction, i.e. from right to left, capital letters were used to denote this. Supporting the views expressed regarding consent are participants' justifications[68], which are listed on the right of the charts. The justifications vary from chart to chart, as

[68] The justifications are summary themes and not actual participant comments. This method enables the grouping of several participant views under the same summary justification theme.

they depend entirely on what participants voiced during the interviews. Conversely, the charts created in relation to privacy do not contain tracking of changes, as this did not arise in the discussion regarding privacy.

An example of how charts should be read is provided in Chapter 6 immediately prior to the analysis, the proximity of which was felt to be of greater convenience to the reader.

Higher level analysis

The justifications provided by participants for consent choices made for the hypothetical data linkage scenarios were analysed at two levels. In Chapter 6, my analysis remains closer to the source data and is descriptive in nature. However, in order to make sense of the general framework that participants were applying, if indeed one existed, it was necessary to abstract to a higher level. This was achieved by identifying themes that the initial justifications presented in Chapter 6 came under. It was immediately noted that patterns emerged across scenarios and that the themes appeared to somewhat resemble Beauchamp and Childress' moral reasoning framework (63). I therefore, re-analysed the data applying their framework to the data but found that although there was a degree of agreement, the categories were not perfectly harmonious[69]. I then reverted to the initial analysis but have included a partial analysis applying the Beauchamp and Childress framework in Chapter 7 in order to demonstrate the similarities and differences as well as discrepancies.

Reflections

> *This exercise initially appeared to be a time-consuming pursuit and necessarily threw me back into extensive reading and endless hours of contemplation and, to an extent, frustration at not being able to immediately grasp the solution. I engaged a colleague in a discussion regarding the matter and things appeared brighter and more accessible for a day or two, but when attempting to write about the issue, I noted that I reverted to an earlier stage of uncertainty and frustration. The analysis of the justifications and the resulting chapter were by far the most demanding, but also possibly the most rewarding.*

Analysis of justifications

In the analysis of justifications in Chapter 7, I adopted an inductive approach involving the assignment of themes to each of the justifications provided by participants. The justifications were not treated on an individual basis, as were the consent preferences discussed in Chapter 6, but rather in accordance with the options of *consent, no consent*

[69] Additional detailed information is provided in Chapter 6.

and *notification*. While I made reference to the number of individuals providing the same justification, the emphasis in my analysis (see Chapter 7) was on the themes that arose from the justifications, as this analysis attempts to clarify the kinds of principles, norms and other practical considerations lay people brought to bear in moral reasoning about the specific case of consent requirements in data linkage.

I considered all justifications on an equal basis, i.e. all justifications were included whether they related to initial or final decisions. The initial identification of justification themes arose from Scenario 1 and when I identified themes that had not emerged in the first scenario, I added them to the existing inventory from which I removed themes not relevant to the specific scenario under consideration. The emerging themes for all scenarios and all choices included: *rights/preferences, trust, respect, harm minimization, assumed social/legal/ethical norms, pragmatic considerations, protection mechanisms, benefits, and harms*. Once I had considered the justifications for each scenario in accordance with the above themes per scenario, I considered the themes across scenarios to determine similarities and differences between the kinds of justifications provided for participants' consent choices.

I classified justifications in accordance with the themes that arose from the content of these justifications. In some cases, the content was explicitly stated, e.g. *People have right to choose* was placed under the theme *rights/preferences*, while in others it was inferred, e.g. *People want to control their information* was also placed under *rights/preferences* because any claim to a certain state of affairs involves one's perception of a right one has to it.

In order to discuss the justification themes arising in each scenario, I need to clarify the meaning and content of some of the less obvious theme titles, such as *Pragmatic considerations, Harm minimization, Protection mechanisms, and Assumed social/legal/ethical norm.*

- *Pragmatic considerations* include justifications relating to, for example, time and monetary constraints recognised as applying to research, or justifications such as *There are ways to achieve contact to request consent despite difficulties* (in support of the consent option).
- *Harm minimization* was considered to relate to justifications referring to a reduction in the risk of people incurring real or perceived injurious effects

(including feelings of being exploited, not being valued, or respected) arising from disclosures of identifiable information.

- Conversely, the theme *Protection mechanisms* refers to measures which intend to reduce or eliminate risks, such as identification, and includes justifications such as *Acceptable if security and safety measures* [are] *in place* or *Provided that the linkage organisation was involved so that tasks are separated*. This theme relates specifically to either features of data linkage or legislation and other measures that are intended to assist in the protection of information.
- The theme *Assumed social/legal/ethical norms* includes norms that participants took for granted as applying in our society. These norms varied substantially in nature and included justifications such as *Consent is required for everything*, *Seeking consent for use of private information is an ethical requirement*, or *collecting this kind of information without consent may not be legal*. The accuracy, or not, of the statements did not affect the classification of the justifications. For example, the justification *Acceptable to do mental health research without consent* was classified under *norms* irrespective of the fact that it is false and contrary to established research ethics and legal requirements. This is a view shared by some but certainly not all members of our society. Nevertheless, the justification was included in the theme of *norms* because, according to the individual(s) who uttered it, this was quite acceptable in their thinking and they, no doubt, believed it to be acceptable to others as well[70].

Similarities with Beauchamp and Childress' moral reasoning framework

The initial themes identified in the analysis of justifications, i.e. *rights/preferences, trust, respect, harm minimization, assumed social/legal/ethical norms, pragmatic considerations, protection mechanisms, benefits,* and *harms*, displayed congruence with Beauchamp and Childress' framework of moral principles (63)[71]. The rationale for abstracting to this higher level was that principlism is now a widely accepted framework for moral decision-making in bioethics and functions within coherence theory. Hence, in

[70] It is fair to say that in recent years much work in the area of mental health has focused on removing the stigma associated with mental illness. My view is that our society is beginning to both understand mental health issues and embrace equal treatment of members of our community who suffer such conditions. Time is required, however, for a complete transition to revised views and beliefs on this delicate issue.

[71] Much thought was given to the usefulness of attempting to apply the framework directly to the data, omitting the first level of abstraction presented in the analysis of the data.

addition to the four principles respect for autonomy, non-maleficence, beneficence and justice, comprising the framework, this model also takes into account other factors, such as rules and other moral considerations, all of which are appealed to in the process of moral decision-making. The danger, however, of applying the framework directly to the data of my study was that a number of participant justifications appeared to require further justification thus regressing to principles used in the framework that might not actually have been intended by the participants[72].

Reflections

> *Had I had any notion that the justifications provided by participants were to align in the least with Beauchamp and Childress' moral reasoning framework, I could have guided participants to supply their end justification through appropriate prompting. However, this part of the inquiry was exploratory given the dearth of published literature in the area.*

The correspondence of the themes in the first level of analysis with the principles considered in Beauchamp and Childress' moral reasoning framework is provided in Table 20, Chapter 7. As can be seen in Table 20, the only principle participants did not consider when reasoning through the options was that of justice.

Quotes

Participants' quotes in all subsequent sections aim to provide detail in relation to the summarised data. The quotes have been chosen with a view to ensuring that quotes from all participants were included. Some participants contributed more and their quotes may therefore appear more frequently than others'. The quotes sometimes also include my question or response, which are in italics to differentiate my contributions from those of the respondents.

Summary

In this chapter I have outlined the steps I undertook in recruiting, collecting and analysing the data for Phase 2 of the research which involved face-to-face interviews with lay members of the community.

I have reflected on methodological aspects adopted in the research as well as the influence the environment, my views, and interactions with participants may have had

[72] I am grateful to my colleague, Dr Drew Carter, with whom I discussed my quandary; a discussion which helped both identify the problem and clarify my thinking.

on the data both when it was being collected and also during its analysis and interpretation.

The design of the study was guided by the aims and objectives but also by presuppositions arising from examining the literature in the theoretical component. In the following chapters (Chapters 6-8), I address a number of the aims and objectives of the research as a whole and provide responses in relation to the assumptions made at the outset.

CHAPTER 6

PEOPLE'S CONSENT PREFERENCES

...information acquires ethical and normative significance not because it is about certain special aspects of the world, but because it can or may be used in certain inferences and actions.

(122 pp. 107-108)
Manson N.C. & O'Neill, O.
Philosophers

Introduction

In Chapter 2, I outlined research that has been conducted in relation to the public's views on the use of health data for secondary purposes. While the research presented explores participant consent preferences, it does not explore in depth the complex considerations people take into account when expressing views about consent or, importantly, their underlying values in such decisions. In addition, unlike the research examined in Chapter 2, the research reported in this chapter and the ones which follow focuses exclusively on data linkage.

The findings in relation to people's consent preferences are reported in two separate chapters. In this chapter I present participants' consent preferences and changes in their views as they emerged during the interviews, as well as a description of the justifications provided for their choices. I also include findings to the assumptions about respondents' views and understanding posited at the outset of the study. In Chapter 7, I further analyse the justifications for participants' decisions and outline a theoretical framework which participants employ when justifying their choices. A series of charts which form an integral part of the analyses and which pertain to both chapters can be found in Appendices 10-15. They have been included as Appendices

for ease of reference given that reference to them will be required in both the current and following chapters.

Before delving into the detailed data relating to participants' consent preferences, I provide an overview of the key finding. I then briefly describe how the charts should be read and provide an example using one of the respondents' answers.

Key findings

Despite previous contact with the concept, participants displayed limited understanding of what data linkage is at the start of the interviews. However, through the analysis presented in this chapter I will show that in a very limited space of time it was possible for lay people to gain a good understanding (as judged by the responses provided) of the basic workings of the complex data linkage process. Most participants supported the use of data for data linkage purposes without the need to seek consent from those whose information would be used. Participants understood the constraints that stringent consent requirements impose on research but made a distinction between consent requirements for identifiable and de-identified data. They showed concern about the linkage of certain kinds of information, especially where there was no separation of tasks. In this case, they strongly supported the consent option. Participants provided an impressive number and variety of justifications for their responses, and these will be further explored in Chapter 7. Many participants made a number of shifts between consent choices, indicating not indecisiveness but, rather, a struggle to resolve conflicting needs and values of which they were very much aware. A striking feature in many cases was the debate participants had with themselves when trying to settle on a final view. The incremental difficulty of each scenario proved to be useful in ascertaining whether participants had truly grasped the concepts rather than simply providing any response without due consideration of the issues being discussed.

Consent choices in the context of hypothetical data linkage scenarios

This section commences with a clarification of what 'consent preferences' refers to in this study. I then briefly revisit the role of the charts, as these will need to be accessed throughout the analysis, which commences with findings relating to Scenario 1. Before the detail of each section of the analysis is provided, I provide a

brief contextualising description of each scenario, as well as the exact wording, as presented to participants. Each section also features participant quotes to exemplify the issues described and discussed.

Participants' consent preferences were sought in relation to four hypothetical data linkage research scenarios. The term 'consent preferences' refers to a number of consent options, which include *consent*, *no consent*, or *notification* of use of data but no full consent process.

Information on participants' views regarding the requirement, or not, for consent in each scenario is summarised in the charts provided in Appendices 10-15. As previously stated, the charts provide not only detailed information on the choices and the decision pathways but also summarise the whole group's responses and justifications.

At the outset, I assumed that the participants in this study would know very little, if anything at all, about data linkage. Given the methods adopted in data linkage and the complexity of the best practice process discussed with these participants, I was uncertain if they would understand the process sufficiently well to respond to questions regarding consent. However, despite some protestations from participants regarding the complexity of the concepts, participants demonstrated that they were able to consider these carefully and they articulated their views in varied and interesting ways.

How the charts should be read

A brief explanation of the manner with which a participant's responses should be read on the chart is provided below. I use Margaret's responses, extracted from the larger Table, as she made several shifts in relation to her preferences for consent, or not, in Scenario 1.

Table 3. Scenario 1-Example of how charts should be read

Respondent	Consent should be sought	Justification for consent	Consent need not be sought	Justification for no consent	No consent but dissemination of findings
Margaret	xAC	(A-16,18) (C-18)	xB	j,k,d	

Justifications for consent provided by Margaret:
16. People need to be aware of what is happening
18. Consent should be sought at initial point of data collection

Justifications for no consent provided by Margaret:
j. Knowledge of data linkage process allays concerns so no consent is acceptable
k. Participants are not directly involved
d. Acceptable practice because of the benefits

Margaret followed the decision-making process with corresponding justifications which is outlined below:

i. Consent should be sought because people need to be aware of what is happening and because consent should be sought at the initial point of data collection [**A** (indicates 1st choice) - **16, 18** (indicate which justifications in a whole list of justifications Margaret provided)]
ii. Consent need not be sought because knowledge of the data linkage process allays concerns so *no consent* is acceptable, participants are not directly involved, and it is an acceptable practice because of the benefits [**B** (indicates 2nd choice) -**j,k,d** (indicate which justifications in a whole list of justifications Margaret provided)]
iii. Consent should be sought at the initial point of data collection so in this case consent should be sought [**C** (indicates 3rd and final choice) - **18** (indicates which justification in a whole list of justifications Margaret provided)]

We see that Margaret initially expressed the view that consent should be sought. This view was often expressed spontaneously and participants indicated that it was out of habit, as they were used to consent being sought for everything. It is evident that Margaret understood why, in data linkage, consent need not be sought, as expressed via her considered justifications. However, in the first scenario, she was not able to escape her deeply held conviction that consent should always be sought

for future use of data when information is initially collected from individuals accessing the health care system.

Looking at Margaret's journey through all scenarios (see Table 3) we note that she started with a preference for consent in Scenario 1 but then preferred the no consent option in Scenarios 2 and 3. She reverted to the consent option for scenario 4, which indicates that she was guided by her beliefs regarding the protections that consent is considered to provide.

Scenario 1

Scenario 1 involved the linkage of three sets of health data. A data linkage unit would create the linkage key and the de-identified health data would be analysed by university researchers. The content of Scenario 1, as presented to participants, is provided below for the reader's convenience.

A study is being conducted by university researchers and they want hospital information (which includes the medical history, name, age, ethnicity, and postcode), a cancer register, and a deaths register to be linked with each other. The researchers want to find out if there is a link between lung cancer and living next to busy main roads. The findings will contribute to better town planning. In order for the study to be successful and so that it provides accurate findings to ultimately help with the management of some forms of cancer, it's very important for everyone on the cancer register (several thousand people) to be included in the study. The researchers will never have any identifying information because they will not do the linkage themselves and all information that identifies people will be removed before they get the linked data.

An analysis of the responses given in relation to Scenario 1(see Appendix 10) is provided in the following section.

Constant responses

Of the 26 participants, a total of nine remained constant in their response throughout the discussion. Of these nine, four participants expressed outright that consent does not need to be sought while five maintained throughout that consent should be sought, even after considering the practical considerations attached to seeking consent. Although these participants recognised the difficulties that arise when attempting to seek consent from thousands of potential participants, they did not waver in their view that consent is of prime importance. An example is provided below:

Harmony

> *Does it make a difference if there are thousands of people on the cancer register? So it might actually be difficult to contact them all from a practical point of view.*
>
> I think that would depend on what country it was in or what the circumstances are.
>
> *Let's assume it's here.*
>
> I think if you really want to contact someone here you can.
>
> *What do you mean? That it's easy to find their contact details or - is that what you mean?*
>
> Yes. Compared to say a third world country.
>
> So, you still think that consent is required. Now if you were to consider all these issues together, do you still think that consent is required?
>
> Yes.
>
> *What if we were also to add another issue that if some people didn't agree to take part in the research, then the validity of the project may be compromised in some way? Does that make a difference to your consideration?*
>
> Not necessarily. I mean you would have to have a fair few not giving consent for it to reduce the validity that much. I think still you could some pretty good results. I guess it would depend on the levels of response. Maybe if it was trying to do the study for several years and everyone was just saying no, then you might reassess it.

The views of the majority of participants (n=17), however, did shift during the discussion, with some eventually shifting back to their original position after exploring other options. Views mainly changed from a position in favour of consent to one of no consent.

Consent →No consent

Eleven participants shifted from the view that consent was required to the view that consent was not required. The justifications provided originally for the consent option focused primarily on participants' understanding that consent is a legal and ethical requirement, that it is sought for everything, including all research, and that not seeking consent leads to difficulties for the researchers. Conversely, when switching views and supporting the no consent option, over half of these participants cited the fact that de-identified data does not require consent as their justification for their choice. The next most prominent justification (n=5) related to strict protections of the data, while some (n=2) indicated that protections are provided by the sheer size of the data sets under consideration. Some participants (n=3) felt the

no consent option was acceptable because data linkage does not involve contact with participants.

No consent →Consent

Interestingly, one participant's views (Molly) moved in the opposite direction, i.e. 'no consent required' to 'consent required'. It was evident that this participant was struggling with the two opposing positions. She held the view that de-identified information does not require consent for use, that not obtaining consent is acceptable because of the benefits yielded, and that increased participation yields more robust research. Ultimately, however, she rejected her well justified view that consent is not required and settled on the view that consent should be an option, indicating that opt-out consent might be most appropriate.

Multiple shifts

Three participants moved from consent to no consent and back to consent in final comments. This highlights the difficulties that these individuals were faced with when pressed to make a choice. They clearly understood the difficulties involved in trying to obtain consent from very large cohorts but one suggested that consent for the use of de-identified data could be sought at the initial point of data collection while another participant progressed through arguments for and against but finally settled on the concept on opt-out consent, which she felt would still enable large numbers to be included in the research, as many would simply fail to take action, i.e. not send in the form. The third participant seemed to have settled on notification without consent (which came further on in the discussion) but then, almost as an afterthought, indicated that when notifying people, a choice to consent should be provided:

Haley

> *Do you think that it would be appropriate, instead of asking for consent maybe, is it appropriate to just tell them about the research, but not ask for their consent?*
>
> Actually, yeah that would be another way of getting around it. If they were aware of the research and the benefits that it's going to achieve by maybe stopping someone else from going through what maybe they're going through - what they've been through. Then yeah I think that's another way around it, of you doing it. But then you also should give them the option, whether they consent or not.

Okay. So it's not appropriate to just give people information but not give them the option?

No, that's right. I always think that you need to give people the option to say yes or no.

Another participant (Danny) moved from his original view that consent is required to a view that it is not and finally settled on the view that it is appropriate to simply inform people of the research findings but not obtain consent.

Finally, another participant (Victoria) initially indicated that consent does not need to be sought. Eventually, however, she indicated that not only should findings be disseminated but that ultimately it is more appropriate to notify potential participants of the research as they would 'feel valued' and know that they had contributed to the improvement of someone else's life. Her final decision did not entail obtaining consent, but rather, simply notifying participants of the research and the research findings.

Scenario 1 - Justification of choices

Most participants provided a number of justifications when supporting their views in favour of consent or supporting the absence of the requirement for consent. Only six participants in both categories provided a single justification. Below are some excerpts which illustrate the rich and varied kinds of justifications provided by participants.

Danny

Do you think the researchers need to get consent from the people with cancer?

Yes.

Can you explain why you think that's necessary?

It depends on the individual preference of the person. I guess it's their right to see whether they want to be linked to something like this or not. I mean, personally, I would say because this is for the good of the community, it should be just straight forward and you don't need a consent for it.

But you've got to take into account I guess everyone's individual ideas and beliefs and interests. Some people may not want to know that. It's unfair to force something onto them like that without their consent.

[…]

Do you think that if this process were explained to people that they would still hold fears that the health information may actually still have identifiable information?

If it was explained properly and then if there was an emphasis on the security of it, I don't think it would be an issue. I think people will give out the information, but again I would rather the individual give the consent rather than having a broad law or general thing where people give consent regardless.

Don't give consent and their information is used?

Yeah, is taken.

Are you speaking about what you think people generally prefer or are you saying what you prefer?

I'm saying what people I know generally prefer. I guess this is a matter of culture as well because I'm not from an English speaking background. So, with what I know from my parents and from my relatives, they probably wouldn't understand things like this. They're not into giving out information when it doesn't look like it's benefiting them at all. Where there's a risk of them losing something. With myself particularly, it's different because I'm in a culture where this is the norm. So to me consent is fine. I guess you've just got to give people that choice.

You said for you, consent is fine. Did you mean consent or not getting consent? You meant asked…

To me, not getting consent is fine. For myself personally. But, like I said, because of my family background, I understand that there will be people out there that won't understand that process. And it's unfair for them.

Verity

So do you think that the researchers need to get consent from the people with cancer?

Yes.

Can you just elaborate on that a bit?

I just feel any information to do with yourself you should have to give consent to.

Notification without consent

As part of the discussion regarding consent, participants were asked if they thought it would be appropriate to simply notify people of the study but not request their consent. It is important to note that this question came after discussing consent options so that participants had available to them the full range of options and had given each some consideration already rather than being presented with the notification only option and no others to compare it with. The question was specific to Scenario 1 but some participants responded more generally about what they thought was appropriate for all data linkage projects and referred to what should happen at the initial point of data collection, for example, when one is first admitted to hospital. In order to understand Chart 4 (see Appendix 11), it is necessary to bear

in mind that the question was about *notification without requesting consent*. Therefore, an affirmative answer indicates that the participant is *in favour of notification without consent* whereas a negative response may indicate either that they thought that *consent should be sought* or that they thought that *neither notification nor consent is required* and that de-identified health data should simply be used in data linkage projects without any contact with participants. To provide some clarity to this response I have included the justification for their negative response. The language in the justifications varies slightly to reflect the tone of the participants' responses, e.g. *consent needs to be sought*, *option to consent should be given, consent could be sought* etc.

Five participants held the view that consent for future use of data needs to or could be obtained at the initial point of data collection. Some had already mentioned this view in earlier parts of the conversation and simply repeated it when asked the question. Others, however, came to this view when asked, as they had not previously considered the option of notification without obtaining consent. One participant (Vallery) made the distinction between what she preferred and what she thought others preferred. One participant (Tina) was not asked the question, as she had expressed strong views about the requirement to obtain consent. It was therefore assumed that notification alone would not be seen as appropriate for this respondent. Finally, there are missing data in regard to one participant (John).

Three participants were undecided about the appropriateness of notification without consent; one (Danny) went through all the options available, i.e. consent→ no consent →dissemination of findings only→ notification without consent →undecided. These changes did not reflect his inability to express his own view but rather the intricacies of balancing opposing considerations. For example, Danny thought that notifying people would be taken as a sign of respect towards them but when asked whether the researcher-community relationship might be affected negatively if researchers simply notified about research without giving the opportunity to consent, he acknowledged that this issue was difficult. Hence, his indecision arose as a result of both not having considered the issues in-depth previously but also as a result of the complexity of the matter. Another participant (Molly) wrestled with apparently conflicting considerations throughout the

discussion about scenario 1 and was also unsure of her final position regarding notification. Finally, a third participant (Tegan), who was opposed to obtaining consent from the start, was uncertain about the value of notifying people and did not settle on a preference.

When considering these responses in conjunction with responses regarding consent requirements (see Appendix 10), all were consistent with each other. It might appear, at first blush, that those who consistently supported the concept of no consent, would also consider notification unnecessary, or indeed, inappropriate. However, many participants had not previously considered the option of notification without consent and given that the two concepts are not conceptually incompatible, it is not surprising that some viewed notification without consent positively. Only one participant raised the issue that notifying people may unnecessarily raise concerns in the minds of those not conversant with the intricacies of data linkage.

Summary of Scenario 1 findings

Participants demonstrated an in-depth understanding of the practical difficulties posed when seeking consent from large cohorts and the impact that this can have on the quality of the research. All participants weighed up the options and of the 26 participants, four participants did not change their original view that consent in this data linkage project was not required. At the opposing end, five participants remained firm in their view that consent should be sought despite recognizing the difficulties this would entail. The remaining participants (n=17) shifted views during the discussion. While most of these participants shifted from the view that consent was required to consent was not required, three went through all the options and settled on their original view that consent was required. One participant only shifted from the view that consent was not required to the view that it was required.

Scenario 2

Scenario 2 also involved health data, some from sources mentioned in Scenario 1 (e.g. hospital data, deaths register) and some different (i.e. ambulance data). Once again, participants were asked about difficulties that arise when attempting to obtain consent from extremely large cohorts to determine whether their views would shift following such considerations.

Researchers in collaboration with the ambulance service are conducting research into cardiac arrests and resuscitation to see if call-out response times affect survival rates. They will need to have data about approximately 300,000 people on the ambulance databases, hospital admissions, and death registers linked. The researchers will never have any identifying information because they will not do the linkage themselves and all information that identifies people will be removed before they get the linked data.

A summary of a number of consent-related issues is provided in Chart 5 (see Appendix 12). This Chart presents participants' views on whether consent should be sought or not but also specifically presents their views on information pertaining to deceased individuals. Therefore, the categories that arose from participants' responses included: *consent should be sought, consent should be sought for deceased people, consent need not be sought, consent need not be sought from deceased people*, and *no consent but notification*. All categories are also accompanied by the justifications participants provided for their choice. Shifts in views are represented from left to right of the chart with capital letters used to indicate shifts that did not follow the left to right pattern.

Consent required

Only four participants remained constant in their view that consent should be sought for the use of the information in question. Two of these felt that this requirement also applied to people who are deceased citing reasons such as seeking consent shows respect towards the deceased and the fact that consent should have already been sought at the initial point of contact with the patient when they were alive. The remaining, however, treated the issue of consent differently depending on the status (i.e. alive or dead) of the individuals involved, i.e. they expressed the view that consent from deceased people's relatives is not required.

The justifications for consent in this group of individuals varied and did not greatly overlap with each other. Two thought that obtaining consent protects people against becoming upset, one thought that achieving contact is possible and should therefore be attempted, another did not provide a justification for this scenario but stated that consent should be sought at the initial point of data collection and had cited respect as the justification when this was first discussed in Scenario 1. This justification was deemed to hold in the second scenario as well. Finally, one participant provided a number of reasons for obtaining consent, i.e. people have a right to choose, not

obtaining consent is an infringement of one's privacy, people want to control their information, and the fact that consent is an expression of respect towards people.

Harmony

> *Should researchers get consent from all these people?*
>
> Three hundred thousand?
>
> *Three hundred thousand people, yes.*
>
> They should try.
>
> *Why?*
>
> I guess they're not thinking about it at the moment. It might be hard to actually - no, I think they should probably get consent.
>
> *But why do you think it's important?*
>
> Same reason as before because some people might have objections.
>
> *You noted that it's 300,000 people right. Does that make any difference to your opinion about whether consent should be sought?*
>
> A little bit, just because I'm thinking how hard it would be, but not in principle. Not on the principle. The only thing that is making me think it's less - with the cancer register it would be more information about you. That was just my impression that it could be type of cancer, other factors like that. It seems like if it's just admissions, then it's less information. It's sort of more yes, no or this happened, rather than a lot of detail about you.
>
> *So less level… A smaller level of information.*
>
> Yes, but I still think…
>
> *That consent should be sought.*
>
> Yes.

Consent →No consent

A further three participants initially decided that consent was required, citing justifications such as: information belongs to people, non-consensual use of information leads to difficulties for researchers, consent is a requirement for all research activities, and consent should be sought at the initial point of data collection. Two of these participants thought that consent for the use of deceased people's information was required and justified this view by stating that seeking consent from families is appropriate because the family is comforted by the fact that their relative is making a contribution posthumously or that deceased people continue to have rights. Another participant held the view that deceased people's information does not require consent from relatives, as de-identified data does not require consent.

Jack

I want to start with a similar question, should researchers get consent from all these people?

[Laughter]

It's the same principle all the time for me. Um, yes.

For the same reasons, you don't need to go…

All I'm saying is, aim of the study doesn't change it,…

The number…

…who's doing it, the number,…

The strict guidelines…

…I believe the aim is ridiculously good, the aim of the first one's really good. I agree I wouldn't care because I want people to be helped in the future. But, I still reckon there will be people out there that would argue that you do need to get permission. I understand that you're talking 300,000 people, perhaps it's not possible in that situation. Maybe I would agree to the tough call of - yeah, use the data but make sure your legals are well documented, you've crossed your Ts and dotted your Is and - we are not going to get any repercussions from the libertarians.

What kind of repercussions could you envisage?

Look, people create issues over the smallest things and if someone feels that they're human rights or their private information has been violated, I don't - I'm not familiar with the law but, I'm assuming they could challenge the way in which their information is being used in some kind of legal way. I'm also assuming that there would be a lawyer out there who would be willing to take it on for them, in perhaps a very big class action, if there were more than one.

The above exchange may appear to support the consent option but Jack is clearly stating a revised view in his tentative statement:

> I understand that you're talking 300,000 people, perhaps it's not possible in that situation. Maybe I would agree to the tough call of - yeah, use the data but make sure your legals are well documented, you've crossed your Ts and dotted your Is and - we are not going to get any repercussions from the libertarians.

Don

Okay, so do you think the researchers need to get consent from the people with cancer?

Yes, yeah.

Okay, why do you think that that's important?

Sorry, what exactly the meaning of consent?

Oh, consent - permission, permission to use their information.

Oh, yes, yes. Because every people has a different idea on different lives. For some people, the personal information is very important. They feel

> very private about that. So I think it is very necessary to get permission, yeah.
>
> Do you think it's a good idea for the researchers to tell the people on the cancer register there that they're going to do the research but they don't ask for their permission, they just tell them about the research? I think when it is necessary to access to their personal information like date of birth or address or name, I think it is necessary to get permission. If they don't access to the personal information, just they access to the data or other health information, it is not necessary to get…yeah.

No consent

A total of 17 participants indicated that consent was not required for Scenario 2 and they did not change views throughout the discussion. This view was held for both the participants in the scenario who were alive and for those deceased. The justification provided most often (n=12) for Scenario 2 participants who were alive was that de-identified data does not require consent; this was followed by the justification that non-consensual use of de-identified data is acceptable because of the benefits yielded (n=7). There were several other justifications of interest some of which included: the recognition of difficulties arising from attempts to obtain consent from thousands (n=4), the view that consent is not required for audit-type activities (n=3), the fact that consent is not required because participants are not directly involved (n=1) or that requesting consent could create difficulties, as people's confidence in the fact that research uses de-identified data might be reduced (n=1).

Victoria

> *Should researchers get consent from all these people?*
>
> No, there's just far too many, 300,000 people. I think that if you should if the information about identifying people is removed then I think it should just be fine to be able to go ahead.
>
> *Okay. Does that also apply to the Death's Register where people aren't alive anymore? Should it be treated in the same way as other places where people are alive?*
>
> I think so, yes definitely.
>
> *Okay.*
>
> As long as their names are removed and all that is removed, I think it should be okay, yes.
>
> *Okay. Any particular reason why, the same as before?*
>
> Yes, the same that I don't think that it's necessary and it's just going to be a waste of resources and time and money to get consent. I think that should, - and also bothering people, you know people are time poor. I think that yeah you should just go ahead.

The most widely expressed justification for the non-consensual use of deceased people's data was again the fact that that de-identified data does not require consent (n=7) followed by considerations of the trauma that requesting consent from relatives might cause (n=4).

Tegan

> *So should we be dealing with consent issues slightly differently for these people? Like should we be seeking consent from their relatives for instance?*
>
> Unless they were identified I really don't think so.
>
> *So they should be treated the same as anyone who's alive on the database?*
>
> Uh huh.

Margaret

> *Now some of the people on this database that we're considering now will have died. Do you think it's reasonable to include these people in the research without getting consent from their families?*
>
> Yeah.
>
> *For the same reasons?*
>
> I'm a bit - yeah - for the same reasons yeah. I don't think it's a - if anything it might be upsetting for the family to be - all those emotions to be brought back up. Whereas that information should just be able to be used I think yeah.

Multiple shifts

One participant (Mel) started with the view that consent is required and should be sought at the initial point of data collection but then proceeded through all the other options only to settle on the consent requirement option in the end. Despite this and with no justification provided, this participant did not think consent for deceased people's information was required.

Mel

> *We are talking about 300,000 people, do you think consent should be sought from 300,000 people?*
>
> No. Because this is 300,000 people, it may be one million or two million or whatever. But I think it's very time consuming and something as fatal as a cardiac arrest, I mean, whatever your research is about and obviously if the results are good and they can do something about it, so that the fatalities go down, so it should be as quick as possible. Because by the time you're supposing they're contacting some 300,000 people and it takes them two or three years for that. Even if you have some 10 fatalities due to this, it's not good.

[section omitted due to length]

As far as consent is concerned though, because you said that it's important not to get consent for this study and I'm assuming that that also includes the people who have died. You wouldn't want to get consent from their family, would you?

I'm not talking about consent. It's like you talked earlier that at least you should inform them that we may use this for…

So they should be informed? Do you think that generally, in all healthcare contexts, wherever we come in contact with the healthcare system, do you think that they should tell us then, that our information might be used?

Yeah.

Like if I break my arm and I go to hospital, emergency, should they tell me then that, by the way, your information that we're collecting today may be used in research. Do you think that's a good idea?

It is, because whatever operations or whatever we do, we always have a consent form in there. If you just add a line in there that, whatever information you're giving us here can be used in further studies and definitely assuring them of not revealing their identity. It's just a line, and the person can go through it and you can always keep an option. It's not that their consent won't be considered if they say no to that. But definitely you can have an option there, yes or no. It would be a much bigger time saver than anything else.

Another participant (Henrietta) started with the view that consent is not required, shifted to the view that consent is required and then finally fell back to her initial view. These multiple shifts back and forth, once again, demonstrate the complexity of the issue and illustrate that participants were trying to balance conflicting values.

The shift back to the original position in both these cases indicates that, through the discussion, the participants' views became crystallized and they were more confident with their original spontaneous response. The following excerpts are placed sequentially to illustrate the shifts observed.

Henrietta

Should researchers get consent from all these people?

No.

Why not?

They're still going to have to write up what's happened anyway.

They do for medical reasons yes, for medical purposes.

Just use that information.

Do you think it's generally okay when we go to hospital all the information that they write up for us to be able to use it for research without asking for consent?

No. It's really hard isn't it?

[section omitted due to length]

> *Would you be happy for researchers to use the information to do this research without getting your consent after you'd survived, of course? Or would you expect them to get your consent before the information can be used?*
>
> Yes, probably they'd need to get my consent. Like when you leave maybe say can we use your information.

[section omitted due to length]

> Why can't you access it and do you need to ask them for consent [unclear]. If it's already stored away and they're not going to know, then I think you should have access to it.
>
> *When you say they're not going to know who are you talking about?*
>
> The people that have had the heart attack. Because it's not going to be prejudiced against them it's for information.

Summary of Scenario 2 findings

Scenario 2 introduced the added consideration of information pertaining to deceased persons. The vast majority of participants felt that consent was not required for the conduct of the data linkage project in Scenario 2. For these participants the same view applied irrespective of whether the individuals whose data are used were alive or deceased. The main justification for their position related to the non-identifiability of the data; the second most quoted justification related to the benefits such research could yield. A small minority (n=4) of participants were constant in their view that consent should be obtained but for two of these participants this view did not hold for the use of deceased persons' data. Three participants initially supported the consent option but settled on the no consent option eventually for information relating to both people who are alive and deceased. Finally, a very small minority (n=2) considered all the options available but reverted to their original position of consent eventually. In total, therefore, the final decision for no consent was assumed by the vast majority of participants. The justifications provided for all choices were insightful and demonstrated that these individuals had a very good understanding of both barriers to obtaining consent but also reasons why consent is important to obtain despite the difficulties in doing so.

Scenario 3

Scenario 3 differed from Scenarios 1 and 2 in the kind of information participants were required to consider, as it involved the linkage of health and non-health related information. In addition, this scenario required that participants also consider the

retention of the linkage key to enable the conduct of future research without researchers, and all others involved, having to re-engage with the linkage process anew. A key difference in relation to consent issues in this scenario was that the option of consent was not given. In other words, I informed participants that this time consent was not going to be sought both because of the large number of participants and because some of the research participants would not be able to provide consent themselves. The question posed to participants was whether they thought the research should proceed nevertheless. The scenario is provided below:

> University researchers and researchers from a mental health organisation want to study violent behaviour in people experiencing mental health issues. They need to link about 50,000 mental health hospital records Australia-wide (including admissions and discharge information) with police incident information, such as calls for domestic violence. The researchers will never have any identifying information because they will not do the linkage themselves and all information that identifies people will be removed before they get the linked data. The Police will not have access to the mental health hospital records.
>
> Now still talking about the same research, the process of linking such a lot of information from a number of States/Territories is very complex, expensive and very time-consuming. So in this research, once linked, the identifying information will be removed but a key will be held separately. The key connects the identifying information of all the people on the databases and the codes they were given. The key will make it possible for researchers from various States/Territories to ask for de-identified information about their State/Territory so that they can do further research without having to have all the information linked from the start.

In this section, the focus continues to be on views surrounding consent and, once again, justifications for choices voiced by participants are provided. This scenario related to behaviours which have an impact on others, an issue raised by some participants as a justification for their choice of consent option. Again, changes in views are taken into account and these move left to right unless otherwise indicated by the use of capital letters. Chart 6 can be found in Appendix 13.

Consent

Only three participants remained constant in their view that consent was required for participants in Scenario 3. Of the three participants, two provided justifications of a general nature (for example, *people have a right to choose*) and also at least one relating specifically to the nature of the research in question (for example, s*ensitivity of data requires that consent be obtained*). The third participant (Tracey), however, mainly provided justifications relating to the specific hypothetical project (for example, *research involving 'vulnerable' people requires consent*). Overall, the

justifications generally varied but one which was given by two of the three participants was that the requirement for consent should not be dismissed simply because participants are experiencing mental health issues. These participants thought that consent can and should be obtained either from the participant directly or their authorised representative, in cases where they cannot provide consent themselves. Two of these participants (Harmony and Tracey) felt that the sensitivity of the data necessitated seeking consent. Finally, two of these participants (Harmony and Tina) were ones who were firm in their views about consent but one participant (Tracey) revised her consent preference in this scenario as a result of the target population and the need she felt they have for additional protection.

Tina

> I think that if they have a nominee, if they have like a carer who can - who basically decides things on their behalf - I think that that is adequate. If they can do that, well then the study could take place.
>
> *But what if they weren't planning to get consent? They simply weren't planning to consider getting consent? Do you think then that the study should go ahead?*
>
> Well with - no, because even though they might have problems being mental health patients and they might have good patches and bad patches I still think that they understand what is going on and they still do have the choice to allow a study to take place or for the information to be given or released.
>
> *Now just to clarify, the reason why the researchers aren't planning to get consent in this scenario is not because the people have got mental health problems. It's primarily because of the large number of people.*
>
> Oh, I do understand that but still I just have a thing that they should have the consent of people. It's their choice whether their information goes out there, whether it's linked to who they are and what they are or whether it's like situational things like violence towards people and stuff. I still do think that they do require consent to do so. I know it's a large number of people and such, but I still do think that consent should be given.

Shifts in views

Only one participant initially felt that consent should be obtained in this hypothetical but then decided that consent was not required. The fact that the hypothetical research involved individuals who experience mental health issues appears to have significantly influenced this participant's views. When talking about the need for consent, the participant did not in fact provide a 'reason' for this but simply stated that consent should probably be sought if a legal guardian was able to provide it. Conversely, the reasons cited for the research to proceed without consent mainly

centred on issues relating to the specific group of individuals in question (for example, *given the difficulties in obtaining consent, it is best to conduct research as benefits would be great* – N.B. the 'difficulties' referred to here relate to accessing legal guardians- *some participants cannot consent*).

Interestingly, one participant (Mary) shifted from the view that consent is not required because of the use of de-identified data and because of the benefits arising to the view that consent should be sought. The latter view was voiced when the participant was asked whether the type of data to be linked influenced her view about whether the research should proceed without consent. Her justification for the need to obtain consent related to the sensitivity of the data.

Mary

> *Now does the type of information that's going to be linked without consent, for example the mental health data of police records etcetera, does that make a difference to whether this research should be conducted or not?*
>
> I guess it does make a bit more of a difference because it is about police stuff. So I guess that's a soft spot in everyone's lives that I guess that is - yes it's almost like you should probably ask for consent.
>
> *Even if it's done in this way? [Researcher points to diagram depicting data linkage process] Does the way that it's done make a difference, the fact that researchers actually don't know whose information it is, it's just a number?*
>
> That's right. Well to me it doesn't matter but I'm sure to lots of people it does.
>
> *Even if it's de-identified.*
>
> That's right. Lots of people wouldn't want their information at all out.

No consent

The majority of participants (n=21) expressed the view that consent need not be sought. The most common justifications related to the benefits arising from the research (n=15) and the use of de-identified data (n=12) followed by considerations of the difficulties of obtaining consent (n=5). The participants seemed to think that the same standards did not apply to this research group because of their mental health issues; for example, two expressed the view that consent is not required in mental health research. Four participants indicated that they were aware that there are alternative methods of obtaining consent when an individual is unable to consent for themselves but this did not influence their decision, as other justifications

appeared to provide greater support for the choice of no consent, for example, *de-identified data does not require consent* (n=3).

A number of participants raised the issue that this scenario differed as harm to third parties was involved. The nature of the research therefore provided a justification for many supporting the no consent option, for example, *research focusing on issues such as violence, which affects others/the whole community, justifies not obtaining consent; consent not very important where safety issues are concerned*.

Don

So it's not possible for the researchers to get consent from such a large number of people, and some of the people can't give consent themselves. So should the research go ahead without permission?

I think yes.

Why?

Because, again, there is not any personal information and also it is impossible to get permission from every people.

Because of the large number?

Because of the large number of people, yeah.

Haley

Should this research go ahead without consent?

Yes.

Why?

Obviously it is a mental health issue.

Yeah.

You want to know whether or not it's going to affect people with violent behaviour, obviously. I mean, once again, you can ask for consent but then you'd have to go to your next of kin to ask for consent. I think in the long run, I mean, you're better off getting that information and getting some sort of benefit from it, than asking for consent, in that aspect.

Okay.

I think when it's something to do with someone's safety, I think your consent goes out the window.

Public notification of research

Participants were asked whether the public should be informed about the hypothetical research being conducted in Scenario 3. In response to this question there were, once again, shifts in views and these are represented in the yes/no responses provided in Chart 7 (see Appendix 14) and should be read from left to right

to indicate order of shifts. The justifications for affirmative responses are provided with numbers, while justifications for negative responses are in letters.

Public notification supported

The vast majority of participants (n=17) expressed the view that the public should be informed of the conduct of such research. While the reasons given varied, they included: *public notification leads to better understanding of benefits of research*; *more involvement in community*; *confidence that research in this area is indeed being conducted*; *knowledge of research being conducted encourages people to take part in future research projects* etc. Another set of justifications focused on the public's right to know either what information was being used or what research was being conducted (with some indicating that this is so because research is publically funded), the ability that notification provides for the public to make further enquiries, or to express dissent. One participant (Tracey) thought that information should be disseminated carefully so as not to create an adverse public reaction and hinder the progress of the research. She felt that public comments by those who do not understand research can encourage the general public to oppose research. Overall, however, it appears that participants viewed the dissemination of information about this research positively, with many generalising their comments to include other research projects as well.

Danny

> *Do you think that the public should be informed that such research is going to be done?*
>
> Yes.
>
> *Can you just elaborate on that?*
>
> With I guess public knowledge, it helps people to understand why we're doing this and whether the researchers are using it to the community's advantage. That's when people see the benefit of something like that.

No public notification

A total of six participants believed that no public notification is required. The majority of justifications for this position related to the participants' views that people simply do not want/need to receive information about all research being conducted. Other justifications related to concerns about the cost of notification, or the lack of impact such notifications would have (unless researchers needed to recruit directly, as one

person indicated). Only one of the six participants (Virginia) supporting no public notification gave a research-specific justification by indicating that public knowledge about mental health research might serve to reinforce entrenched misconceptions about people with mental health issues.

Virginia

> *Okay and should the public be informed that it's going to be going ahead?*
>
> Actually I think this time, no.
>
> *Why is that?*
>
> Because it would reinforce in people's minds the idea that all people with mental health issues are violent and it's not the case.
>
> *Yes, okay.*
>
> So I think it would be - you're weighing up the thing of the good etiquette that people are told against the risks of increasing an entrenched misconception already there.

As can been seen from Chart 7 (see Appendix 14), four of the participants who felt that public notification of the conduct of the research was not required did mention that the research findings should be made available to the public. These participants were therefore aware of the need to be informed of progress made in research but not necessarily the step-by-step process of the conduct of research.

Shifts in views

Two participants shifted views in relation to public notification. One (Helen) moved from a negative response which was justified in relation to the cost to a view that the public should be informed because such knowledge gives the public a better understanding of the benefits of research. Another (Vallery) shifted from a negative to affirmative and then back to a negative response. It appears that she was responding both on what she felt other people might want and also how she personally felt about public notification of research. Her justifications initially related to her perception of the public's adverse reaction to the knowledge of the conduct of such research. She then acknowledged that it is good for the public to know what research is being conducted and that they have a right to know. Finally, she indicated that she would not feel aggrieved if she did not find out what research was being conducted. Finally, a third participant (Teresa) qualified her affirmative response rather than shifting completely from an affirmative to negative response. Initially, she stated that public notification was beneficial because it is important for the

public to know about publically-funded research being conducted. However, when asked what she preferred, she indicated that she did not like receiving information that she did not want and pointed out that public notification in the form of individual letters is too costly. This participant settled for notification via websites such as those of Health Departments.

Helen

> *Do you think that the public should be informed that such research is going to be done and if so, how could they be informed, in what way?*
>
> I don't know how they would be informed, if to be informed. I think it would probably be easier just to do the research. There's such a big amount of people, it'd be so costly for a start.
>
> […]
>
> *But, I mean what if your information wasn't going to be used, just to know that this kind of mental health research is going on?*
>
> Yeah, well I think it's a good idea to let people know because with people with mental illness they're like oh good, somebody's doing something about it so that's another aspect to look at.

Summary of Scenario 3 findings

Scenario 3 differed from the previous two in two ways; it related to the use of information pertaining to individuals with mental health issues, and participants were not given the option of consent but simply asked whether the research should be conducted if consent were not an option provided by the researchers. Despite posing the question in this manner some individuals (n=3) were adamant that consent should be sought. Another participant moved from a no consent preference to a consent preference, making the distinction between what she thought was appropriate and what others generally think is appropriate. Only one participant shifted from a consent preference to a no consent preference while the majority (n=21) remained stable in the no consent preference. The majority of justifications for the no consent option did not differ from those given in other types of research, i.e. they related to the non identifiability of data or the benefits yielded. A minority of justifications, however, illustrated an underlying view that people with mental health issues can be treated differently to the rest of the population or that areas of research aiming to enhance people's safety should be treated differently.

Overall, the majority of participants supported public notification of research, with a number of justifications relating to the positive impact such notifications have in

relation to the public's understanding and support of research endeavours. Other justifications focused on the public's right to be advised of research funded via the public purse. Only a small minority (n=6) indicated that public notification of research is not necessary mainly because the public are simply not interested or because of the costs involved in disseminating such information.

Scenario 4

Scenario 4 was the last of the scenarios discussed with participants and differed from the previous three significantly, given that the researchers in this hypothetical scenario would be doing the data linkage themselves. It was explained to participants who raised this issue, that Human Research Ethics Committees would require the researchers to remove identifying information at the earliest possible stage after the linkage. Once again this scenario involved the linkage of health data with data unrelated to health. In this discussion all consent options available were explicitly discussed, i.e. opt-in consent, opt-out consent, no consent, notification but no consent. Participants did not appear to have difficulties dealing with such a large number of consent choices, possibly because consent and alternatives to consent, i.e. no consent, notification without consent, had previously been discussed in detail. The scenario is provided below:

University researchers are conducting research on work-related stress on behalf of Work Cover to discover whether there is a link between increased levels of stress and work insecurity, for example caused by casual employment. They need to link 100,000 work stress claims[73] containing identifiable general and mental health information with employment data including employment history, leave information, seniority level etc. for the same individuals who are employed at the Government organisations involved in the research. In this instance, the linkage will not be done by an independent team of data linkage experts. Instead, the researchers will do the linkage themselves. A report with de-identified findings will be made available to Work Cover.

Consent requirements

This scenario evoked a strong response in participants, evidence that participants understood the concept of 'separation of tasks' which is achieved via the use of a data linkage unit to develop the linkage key. While the intricacies of the process could not be explained in the time available[74], it is clear from participants' responses

[73] In discussions with participants, it was made clear that such claims would be accessed from WorkCover.

[74] Apart from the time restraints, it would have been unhelpful to provide the intricate technical details of how data linkage is achieved.

to the issue of consent in this scenario that they were aware of the fact that the data linkage unit receives only personal information to create the linkage key and is thus not privy to the medical details associated with a particular individual. There was a concentration of final responses in the consent option, with some participants exploring other options before ultimately arriving at this view. It is important to note that some of the justifications give the initial impression that they could have been collapsed into a single category, e.g. *consent required when researchers do the linkage*, a*ccess to identifiable data by researchers requires consent*. However, they were kept separate to preserve the finer nuances between each statement.

Consent

Even though a larger number of participants (n=18) ultimately chose the consent option for this scenario, there were only 13 who did not shift from their original view that consent was required, despite being reminded of the constraints that can make seeking consent from large cohorts difficult. Included in this category is a participant (Jack) who had a strong preference for consent even though he did agree that notification might be a viable option. Also included in this category is a participant (Vanessa) who expressed her preferences in relation to there being a data linkage organisation involved. Given that the scenario precluded this her original choice of consent was taken to be her preference. Not included in this group is Trixie, as her strong preference was the no consent option and consent (opt-out) was only mentioned as a second preference. Her second preference has been recorded on the chart in the order in which it came in the discussion with an explanatory note attached. Chart 8 (Appendix 15) shows that participants who felt that consent should be sought were much more vocal in their justifications compared to most of the remaining participants. The justification for consent most frequently provided (n=8) in this group related to the perception that consent provides protection from harm. One of the harms identified in this scenario related to the potential future impact the hypothetical research might have on its participants. Closely following this justification (n=7) was the view that when researchers access identifiable data, they must obtain consent to do so. A justification specific to this scenario provided by a number of individuals in this group (n=6) related to the fact that a number of spheres of the hypothetical participants' lives would be focused on in the research, an issue

of concern, as it would enable researchers to piece together a more comprehensive picture of the person whose information was being handled. This fact seemed to alarm a number of interviewees and, when asked about it, they indicated that they felt most uncomfortable about the employment data being provided to researchers, especially given the identifiability of the data. In this scenario, it became apparent that a number of participants understood the notion of separating tasks in data linkage, which was referred to in a variety of ways all relating to the fact that researchers would have direct access to identifiable data. Four participants supporting the consent option in fact used the expression 'lack of separation of tasks' as their justification for this option.

Danny

> *Do the researchers need to get individual consent?*
>
> Yes.
>
> *Can you explain why?*
>
> Because they're actually going through a lot of personal information with something like this which may potentially affect that person in the long term.
>
> *In what way?*
>
> For example, if someone was to go through my information and see that I am the type of person that is easily stressed and I've got some mental issues is that going to affect my employment in the future with other departments? I know it's meant to be strict with the guidelines, but for someone to probe into my - because this is affecting my whole life really. It's a little bit over the top.
>
> *What's over the top exactly? Doing the research or not getting consent?*
>
> Not getting consent. Doing the research that involves not just one particular aspect of my life, but the whole general aspect of my life which is a bigger issue than just having one part of me.

Preferences for opt-in and opt-out consent in those who remained constant in their preference for consent were almost evenly divided between participants in this group (n=7 opt-in; n=5 opt-out). It is unclear which consent option was preferred by one of the participants (Victoria), hence the discrepancy in the figures. When examining all participants who preferred that consent be sought, including those who ultimately settled on consent, the preference for opt-in consent (n=8) and opt-out consent (n=8) was evenly divided[75]. Not everyone provided a justification for

[75] Margaret was excluded from the opt-out group, as she referred to an opt-out model which differs slightly from conventional opt-out consent processes (please see section on Consent →Notification).

their choice of consent mode but it was evident that the differences between the two types of consent were well-understood by participants, which is important both because the terms are often used in research and other contexts but also because of the implications of not understanding the difference on people's ability to preserve some control over their data.

The main justification for opt-in consent was the sensitivity of the data and the perception that harm could arise from participation in the research. Four participants stated that opt-out consent would increase the number of participants involved, as they recognised that fewer people would take action to participate than people actively sending in a form to avoid participation. Some of the reasons cited for this included lack of time to read mail and lack of time to attend to mail. Some of these participants felt that opting out was the best option, as it addressed the needs of both the participants and the researchers; this consent option would enable a larger number of people to be included in the research but would also address participant needs to have some control over their information.

Verity

> Yeah, I would go opt out.
>
> *Okay, so why do you think that that's the most appropriate?*
>
> Going back to what we discussed previously, I think that opt out means that you are going to get a bigger number of people, going back to the people who are too lazy to send in the opt out. So it's only going to be the people that I definitely do not want you accessing my information and I care enough to sign this form and send it back in. So you know that you are not going to be able to use those people, but everyone else you are still going to get, so you are going to get a bigger percentage of people than option one.

No consent →Consent

Three participants initially supported the option of no consent but eventually settled on consent as being the most appropriate option for this scenario. Included in this group is Jacob even though it is unclear if he in fact intended to support the option of no consent despite voicing this. It was not possible to determine from his justification if this was indeed his intention. Two of the three participants justified their choice of no consent by stating that eventually (i.e. after the linkage) researchers would be working with de-identified data so it would be acceptable not to obtain consent. Justifications for consent from these three participants related to issues of rights,

lack of separation of tasks, consent to protect against intrusion and consent to prevent people from becoming upset.

Molly

> I don't have a problem with it but I think you should probably give people the opportunity to say no.
>
> *Okay. So why is it important to give people the opportunity to say no?*
>
> I don't know, it makes them feel like they have some sort of control over what people are - like, how people use their information.

Multiple shifts

The general pattern in the multiple shifts was from no consent → consent → notification. Four participants made such shifts. The nature of the justifications for no consent very much reflected practical considerations, such as the difficulty in obtaining consent from large cohorts, its effect on participation rates, the fact that researchers would ultimately be using de-identified data etc. However, the justifications for the no consent option from one participant were based on erroneous assumptions, which become evident when examining her justifications:

- *information given to WorkCover can be shared with researchers, as it was given confidentially* (in fact, privacy legislation mandates that this information **not** be shared);
- *researchers will not use information obtained without consent in ways that could harm participants* (while not incorrect, it is a broad assumption and is ambiguous in nature).

When considering their shift to the consent option, interestingly, these participants did not appear to be truly committed to the consent option as seen from their justifications, that is, *having the option to consent is good*; *it is very good to obtain consent if it is simple to do so*. The participants who ultimately settled on the consent option did not justify this shift in terms of the fact that researchers would themselves be handling the data. All but one of the participants finally settled on the view that notification is appropriate. Most, however, did not provide a justification for this. One participant believed that notification is appropriate because transparency in the conduct of research is reassuring to the public and allays fears of harm. Don, who had not been very committed to the idea of obtaining consent, reverted to the no

consent option finally, citing the difficulties in obtaining consent from large cohorts as his reason for doing so.

On the surface, a fifth participant (Vanessa) appears to have made several shifts in her thinking (consent → no consent → notification) but, when examined more closely, it becomes apparent that she in fact supported the option of consent. Vanessa was very clear in her insistence that the no consent option was appropriate provided that a linkage unit was involved. Given, however, that Scenario 4 revolved around researchers conducting the linkage, her response clearly rejects this practice. Vanessa's justifications for consent were rich and varied and included reference to participants having the right to choose, the protection that consent provides against harms, the need for consent when a number of aspects of a person's life are accessed, the need for consent when researchers access identifiable data and do the linkage themselves, and finally, the need for consent when there is no separation of tasks. These justifications were again an example of the sophistication of thought on this topic, the intricacies of which most were only introduced to approximately half an hour before these statements were made.

No consent

Only one participant (Trixie) supported the no consent option but did declare that the opt-out consent option would be her second preference. Trixie's justification for no consent included views such as the findings being reported in a de-identified manner, the fact that people have an inflated view of how interesting their information is to others and that researchers are not interested in specific cases. She also felt that the no consent option was appropriate because the information is already available and because of the benefits that arise from such a practice. It is important to note that this participant was well-educated when it came to the health system, as her family circumstances have necessitated constant close contact with certain medical services. She was clearly an advocate of sharing information for the betterment of medical services and enrichment of medical knowledge.

Trixie

> *Do the researchers need to get individual consent here [i.e. 4th scenario]?*
>
> No, again it's the de-identified findings. It's about your records that are already kept.

> *So the fact that the researchers actually go through this process, it doesn't make a difference?*
>
> I don't think so. I'd be very surprised if any of the researchers were particularly interested in individual cases. I think we have an exploded view of how interesting we are for each other. My WorkCover and state government work history are probably pretty tame reading for most people. I don't have a problem with it.

No consent →Notification

Three participants moved from the no consent option to notification. The justifications for no consent varied, were generally detailed for most participants, and related to the complexities of obtaining consent from thousands as well as the protections provided by guidelines and laws. In this group, I have included one participant who, on the surface, may not appear to belong. John indicated quite clearly that practical constraints would not permit the consent option and his quote below is telling of the value he placed on consent and the constraints he perceived on conducting research both 'ethically' and methodologically correctly.

John

> If you want to do it ethically, you want to follow all the ethical procedures, so you need money, you need time, you need everything - all the resources you can to get to the 100,000 people. If you can't get it, then it means that some of the population will not be reached. You can't do it. If you can't reach a lot of the population, it means that there will be some kind of a bias in your report.

All of these participants viewed notification positively but one felt that even notifying people of research would be very costly. One participant (Tracey) settled on notification as her ultimate choice but did not justify it.

Consent →Notification

A transition from consent to notification may, at first, appear an unusual leap, especially when the multiple justifications provided by the sole participant who expressed this view (Margaret) are considered. Like others, Margaret felt that consent was required when researchers access identifiable data and do the linkage themselves. She also believed that consent provides protections against potential harms and that people have a right to choose if they wish to participate or not in research. When discussing consent options, she felt that opt-out consent was more appropriate because it results in more people being involved. Perhaps her preference for the kind of notification she was considering naturally addresses both these

apparently conflicting needs, i.e. to ensure that participants and their rights are protected but also ensure that research is not hampered by low participation rates. Margaret proposed that people be notified but also be provided with the opportunity to be excluded from the research if they did not wish to be included[76]. They would not be provided with forms to send in to indicate this choice as in the usual opt-out model but rather would have to initiate contact themselves and ask to be excluded. Hence, despite its resemblance with the opt-out model employed by Australian researchers, the focus of this model differs slightly[77]. Margaret indicated that each participant would receive a letter but dissemination of the information could also be more general, e.g. radio/tv etc., the latter of which is an additional point of difference with currently practiced opt-out models.

Margaret

> *That's another option. So you send out information, you tell people it's happening, you don't ask for their consent and you tell them that there are no risks involved.*
>
> Yeah, well that's a good way to do it as well because if someone is still really passionate about them not wanting to be involved, they'll get in contact with whoever needs to be in contact. So maybe that's even a better way than asking them to send something back if they want to be involved, just let them know it's happening. Then if they don't want to be involved, make sure there's a contact, there's contact information on there. So if people have more questions or...
>
> *But what if they [the researchers] don't want to accept refusals to participate? What if the intention is just to inform people but not to have people contact them?*
>
> Yeah, well I think there needs to be - if I got that letter and I was really passionate, I did not want my information to be used and I called up and said I don't want - there needs to be some way that then that person can be taken off that research. I think that's important - it's not like the person on the other end of the phone will say well sorry you have to. You have to be involved in this. I think people still need that choice. But I think the letter just telling them about it with a phone number if they want any more information - because 99 per cent of people go alright yeah that's good, just chuck that in the recycling [laughs] if they're anything like me. Yeah I'm happy for that - that's good. Whereas you might get - I don't know what the statistics would be but the occasional person that puts their foot down and says no, my information isn't being used for that.

[76] It is for this reason that she has been ultimately been considered to prefer the consent option.

[77] The difference lies both in the dissemination of the information and in the manner with which the choice made by potential participants would be communicated to researchers. This consent type resembles *assumed consent* as discussed by Willison and colleagues (123).

Summary of Scenario 4 findings

Scenario 4 differed significantly from the rest of the scenarios in that no data linkage organisation was to be involved and the type of data being linked also included employment data. The scenario also served to test whether participants were being agreeable or whether they had 'become conditioned' and so used to choosing the no consent option after being alerted to the practical difficulties of obtaining consent from large cohorts. The scenario clearly raised alarm in the majority of participants, most of whom had previously seen the no consent option in data linkage as appropriate. Despite the variously expressed justifications, the key concern was access to identifiable data. A number of participants (n=8) started from the position of no consent and moved to a preference for consent but not because researchers would have access to identifiable data. A minority ultimately settled on the notification option but did not provide clear justifications for this shift. This scenario also provided the opportunity for participants to indicate their preferred consent option type. It was evident that participants understood the difference between the types of consent and also the impact each type of consent has, for example, opt-in consent is more likely to attract those who have consciously chosen to take part, whereas the opt-out option may also include people who simply did not read the material or failed to send in their form.

Description of consent preferences across scenarios

To this point, I have presented individual changes to views *within* each scenario. This section considers the changes made by participants across the four scenarios. Chart 10 has been retained in the body of the Chapter, as it summarises data from all scenarios. It has been colour-coded to help the reader determine at a glance the number of changes participants made across the four scenarios.

Table 4. Chart 10-Final consent choices per scenario

Respondent	Scenario 1			Scenario 2			Scenario 3			Scenario 4		
	Consent should be sought	Consent need not be sought	Notification of findings	Consent should be sought	Consent need not be sought	Notification only	Consent should be sought	Consent need not be sought	Notification only	Consent should be sought	Consent need not be sought	Notification only
Danny			x		x			x		x		
Darren	x			x				x			x[c]	
Don		x			x			x			x	
Haley	x				x			x		x		
Harmony	x			x			x			x		
Helen		x			x			x				x
Henrietta		x			x			x		x		
Holly		x			x			x				x
Jack	x				x			x		x		
Jacob	x			x				x		x		
John		x			x			x				x
Mandy		x			x			x				x
Margaret	x				x			x		x		
Mary		x			x		x			x		
Mel		x		x				x		x		
Molly	x				x			x		x		
Tegan		x			x			x[a]		x		
Teresa		x			x			x		x		
Tina	x			x			x			x		
Tracey		x			x		x[b]					x
Trixie		x			x			x			x	
Vallery		x				x		x		x		
Vanessa		x			x			x		x[d]		
Verity	x				x			x		x		
Victoria			x		x			x		x		
Virginia		x				x		x		x		
Total	**9**	**15**	**2**	**5**	**19**	**2**	**4**	**22**	**0**	**18**	**3**	**5**

[a] Struggled with response, as it conflicted with people's general expectations regarding consent requirements (as stated by participant); [b] Consent preferable but acknowledges impact of monetary constraints on ability to obtain consent from thousands of participants; [c] It is possible that the participant was experiencing comprehension difficulties, as English was not his first language; [d] Consent required if there's no linkage organisation involved. If there is a linkage organisation involved, no consent required

Colour coding for no. of changes		Total no. of changes
	No change in consent preferences	**4**
	One change in consent preferences	**9**
	Two changes in consent preferences	**8**
	Three changes in consent preferences	**5**

No change in consent preferences across scenarios

Only four of the 26 participants remained constant in their consent choice throughout the discussion of scenarios. Two (Harmony, Tina) thought that consent should be sought for all four scenarios. Their justifications throughout were consistent and while there was not much overlap between participants' justifications, they all centred around issues relating to such things as people's rights, protections provided by consent, people's negative reaction to not being asked to consent, people's need to control their information, and consent functioning as a mark of respect towards people.

Conversely, two participants (Don, Trixie) maintained throughout that consent need not be sought. Of the two, Trixie was not only well-informed about health issues with professional experience in the area but, more importantly perhaps, has an ongoing engagement with the health care sector, as a result of a family member's health care needs. She consistently held the view that information must be shared to enable us to share in the benefits that arise. Trixie has a vested interest in quick developments in health care sector, which she obviously associated with data linkage activities. Don, on the other hand, immediately changed to the 'no consent' option after the initial clarification regarding de-identified data being used by researchers. This participant wavered in Scenario 4, which involved the researchers doing the linkage themselves, but eventually opted for the 'no consent' option justified by the pragmatic view that monetary and time constraints render seeking consent from thousands of participants impossible.

One change in consent preferences across scenarios

Nine participants made a single change in their otherwise steady consent choice of 'no consent' (n=8) or 'consent' (n=1). Eight of these individuals changed consent preferences in Scenario 4, by far the most controversial scenario given that the data related to a number of areas of life (health, employment) and the fact that the researchers would be linking the data themselves. Four of the eight (Henrietta, Tegan, Teresa, Vanessa) moved from a constant 'no consent' option to a 'consent' option supporting this choice with overlapping justifications primarily around lack of separation of tasks (i.e. researchers doing the linkage and the research), protections provided by consent, and the view that consent is required when data from other spheres of life are accessed and linked with health data. The latter may appear to contradict these same

individuals' consent preference of 'no consent' for Scenario 3, which also involved sensitive data from a non-health related area of life, i.e. police reports. However, it should be noted that these individuals seemed to understand the significance of the separation of tasks observed when data linkage units are involved, as was the case in Scenario 3 but not in Scenario 4. This, therefore, might be the factor that justifies their seemingly dissonant choices.

The remaining four (Helen, Holly, John and Mandy) moved from a constant 'no consent' preference in Scenarios 1-3 to a 'notification only' option in Scenario 4. One did not provide a justification for this but the remaining three supported their preference by stating that notification is reassuring for the public, it is acceptable because of the benefits, and that it is a good option if feasible. The reason for this shift cannot be determined with certainty but one can speculate that perhaps these individuals saw the notification option as a good alternative to the 'no consent' option they had consistently chosen for the other scenarios given the nature of the data and the conditions of its linkage.

Finally, one participant (Jacob) shifted his consent choice of 'consent' to 'no consent' in Scenario 3 and supported this shift by stating that a 'no consent' option is acceptable in cases where others' safety was at risk.

Two changes in consent preferences across scenarios

A total of eight participants alternated between two consent choices throughout the discussion. Five of these expressed evenly divided preferences between 'consent' and 'no consent' with the Scenarios 1 and 4 receiving the 'consent' option and Scenarios 2 and 3 the 'no consent' option. A re-examination of the shifts in Scenario 1 makes evident the fact that only one of the five (Jack) had a steady preference for the 'consent' option in scenario 1 while the remaining four (Haley, Margaret, Molly and Verity) shifted between options and finally settled on the 'consent' option. Their justifications for consent in Scenario 1 were varied and centred around rights, control, people's reaction to not being asked, and trust. When considering these individuals' justifications for consent in Scenario 4, identifiability of the data was a key concern for a number of participants. Other justifications related to rights, protections, and control.

On the other hand, justifications provided for the 'no consent' option in Scenario 2 related to non-identifiability of the data in most cases for these individuals. While non-

identifiability of data supported the 'no consent' option for some in Scenario 3, the benefits arising from the research were what most people had as a common justification. Interestingly, for these individuals consent did not appear to be considered as important an issue in Scenario 3, possibly due to that fact that it related to mental health research.

Considering all the shifts made by these individuals enabled me to identify the issue that primarily concerned them: identifiability of data.

Three changes in consent preferences across consent scenarios

Four participants in total made three different consent choices across the four scenarios. Of note is the fact that in three scenarios (Scenarios 2, 3, 4), three participants had the same consent preferences. These preferences are discussed in greater detail subsequently. In Scenario 1 two participants (Tracey, Virginia) considered that consent need not be sought and justified their choices differently, but nevertheless pragmatically. The first (Tracey) did not consider it necessary for consent to be sought for retrospective uses of data, especially given the protections in place to preserve privacy while the second (Virginia) referred to the non-identifiability of the data and the fact that attempts to seek consent can lower participation rates. Two participants (Danny, Victoria) indicated that the notification of findings would suffice for Scenario 1. Justifications were not sought for this option but it is important to mention that both these participants had originally made different consent choices before settling on notification for Scenario 1.

Three of the four participants (Danny, Tracey and Victoria) opted for the no consent option in Scenario 2 and justified their choice but their justifications were dissimilar; the first justified it in terms of benefits, the second in terms of the non-involvement of individuals in the analysis, while the third was pragmatic and felt that cost and time constraints as well as the burden on participants if asked to consent coupled with the view that de-identified data does not require consent adequately justified her no consent choice. The fourth of this group of participants believed that notification of the conduct of the research might be nice after being provided with this option following her initial 'no consent' preference.

Similarly, in Scenario 3, three participants (Danny, Victoria, and Virginia) preferred the 'no consent' option for which justifications primarily related to public benefits. Victoria,

however, remained constant in her justification that de-identified data do not require consent. The opportunity to consent was considered most appropriate by the fourth in this group (Tracey), who did, however, acknowledge that monetary constraints can impact on researchers' ability to obtain consent from thousands. Tracey provided a series of justifications centering chiefly around the sensitivity of data and the vulnerability of participants.

These same individuals (Danny, Victoria, and Virginia) switched their consent preference to one of consent in the case of Scenario 4. This was mainly because Scenario 4 entailed researcher access to identifiable data and involved the collection of data from a number of areas of the hypothetical participants' lives. Oddly, in this scenario, Tracey settled on the option of 'notification only' without justification after considering other options in the order one might not necessarily have expected (i.e. 'no consent' to 'consent').

Summary of consent choices across scenarios

So far in this chapter I have presented lay people's consent preferences and justifications for these for four hypothetical scenarios of increasing complexity. I now present the consent preferences in summary and highlight the key findings in relation to participants' preferences (see Table 5).

Table 5. Percentage of consent preferences across scenarios

	Consent should be sought	Consent need not be sought	Notification only
Scenario 1	35% (n=9)	58% (n=15)	8% (n=2)
Scenario 2	19% (n=5)	73% (n=19)	8% (n=2)
Scenario 3	15% (n=4)	85% (n=22)	0% (n=0)
Scenario 4	69% (n=18)	12% (n=3)	19% (n=5)

Key finding 1

The preferred majority consent option throughout scenarios 1-3 was 'no consent', as shown in Table 5.

An explanation of the variations throughout the scenarios could be that, in Scenario 1, participants had just had the concepts (i.e. data linkage) explained to them, and by admission from a number of participants, their spontaneous consent preference had arisen from previously strongly-held views, which did not necessarily apply to the case of data linkage given the protective measures in place to preserve privacy. Scenarios 2

and 3, by far, show the greatest support for the 'no consent' option. The point of note in relation to Scenario 3 is that, although it evoked a number of strongly-held views about why these hypothetical participants experiencing mental health issues should be given the choice to consent, a number of participants appeared to view their circumstances as a reason not to seek consent. This consent option was further supported by the fact that the public benefits of this research were seen to be of considerable import given the potential risk of harm to members of the community from the hypothetical participants of Scenario 3.

The no consent preference consistently increased from Scenario 1 through to Scenario 3. This may indicate that participants were becoming more accepting of the notion of no consent in the context of data linkage and were relinquishing previously held automated responses supporting the consent option, which may have resulted from the very high value our society places on individual rights.

Key finding 2

Unlike Scenarios 1-3, Scenario 4 attracted a majority view that consent should be sought. Scenario 4 also differed from the other scenarios in that it yielded the highest percentage of preferences for 'notification'.

The reverse order of preferences in Scenario 4 was a function of the multiple disparate data sets which were to be accessed and the fact that there was no separation of tasks, i.e. the researchers would be accessing identifiable data to create the linkage key and also doing the analysis. This scenario served to identify what participants truly understood about data linkage methods and associated issues after the explanations provided. By this stage some had even adopted the language used by experts, e.g. *separation of tasks*, even though this expression was not used throughout the discussion but only arose in the explanation provided at the start of the scenarios. The increased support for the 'notification only' option may have arisen as a compromise by those who would have preferred the 'no consent' option but were also conscious of the sensitivity of the data being used for the research. Participants had concerns that linkage of such (identifiable) data enables the creation of a much more comprehensive picture of the individual.

Summary of participants' justifications

The justifications provided both in support of consent and no consent, as well as notification, where discussed, were exceptionally rich and diverse. Those who supported the consent option throughout did not seem to provide justifications of a different nature compared to those who changed views depending on the specifics of the scenario, as the latter also raised issues of rights, protections provided by consent, the need to control information, and consent being a mark of respect towards people.

The most notable finding with regard to justifications for their consent options was that participants seemed to have a wealth of understanding and knowledge which they themselves were unaware of and which several of them underestimated, as made apparent by their the view that they had never thought about these issues before and were therefore not knowledgeable enough to comment. A detailed discussion of these justifications is provided in the next chapter.

Non-consensual use of health data

Following the discussion on the four hypothetical scenarios, participants were asked if it was ever acceptable to use health data without obtaining consent (see Appendix 16). The majority (n=18) indicated that it was acceptable and the main justification themes that arose related to anonymity and safety measures (n=17), benefits that arise from data linkage research (n=14), and the reduction of harm to participants offered via data linkage processes (n=6). A large number of additional justifications was provided but these were expressed by few participants. Some examples include: wastage of resources required to obtain consent from large numbers (n=2), an understanding of data linkage process promotes agreement for research to be conducted without consent (n=2), and that the ability to conduct research is 'more important than one individual's right to give consent or not' (n=1).

Fewer participants (n=7) indicated that non-consensual use of health data was never acceptable, with three of these participants changing their view in favour of non-consensual use of such data to supporting the consent option. The main justification related to the need for people to be able to make the choice regarding participation themselves (n=4) followed by the belief that secondary uses of data require consent (n=2).

Discussion

In this section I draw together the findings in this chapter by relating them to three of the assumptions I had made before the conduct of the research. I then discuss the key findings in relation to participants' support for research, support for data linkage, their attempts to balance conflicting interest, the practical implications of consent requirements in data linkage, and, finally, the participants' views on information provision in relation to data linkage.

Assumption 1: Participants will generally have a limited understanding of what data linkage is and what it involves

Participants generally did not remember the information provided as part of their involvement in the randomised control trial. Their understanding of data linkage in many cases related to the misconception that data linkage equates with the sharing of personal and health information within the health care system. An understanding of the real nature of data linkage and its processes developed out of the explanation given during the face-to-face interviews with the assistance of the diagram used and referred to in the interview where appropriate. This demonstrates that lay people with little or no recollection of the complex processes data linkage involves are indeed able to quickly grasp the basic concepts involved in order to discuss the ethical, social and legal (to some extent) issues that are relevant.

Assumption 2: Most participants will want to opt in and provide specific consent

The initial assumption proved to be far removed from what these lay people considered appropriate. Most participants considered it appropriate to conduct data linkage projects without consent provided that there is separation of tasks so that researchers do not obtain identifiable data. Participant quotes below highlight this point.

> But at the end of the day researchers aren't going to have your personal information so it shouldn't really matter. (Vallery)
>
> So I just think that once the information is in there and it's all numbers and letters, then it's not an issue, I don't think, no (Teresa)
>
> If it's no information as in names and phone numbers and addresses of people is going to be let out then it should take place. It's probably not that important to get the okay because it is just information (Mary)

The responses provided in relation to the non-consensual use of health information matched the responses in relation to the scenarios, as the majority of participants

indicated that consent was not required in data linkage projects because of the protections provided and the fact that data are de-identified.

This preference is also reflected in findings from a recent Irish study where the vast majority of participants were comfortable with GPs releasing de-identified data for research purposes (81).

It was somewhat surprising, and against my expectations, that most participants preferred the no consent option rather than notification of the intent to use data, which at least alerts people to their inclusion in future research, both for specific projects and more generally for unspecified future uses. This may indicate, as some participants stated, that there is a high level of trust towards services which handle personal and health data. A minority of participants, however, thought that the provision of information indicating future use of data should be accompanied with the option for consent.

Assumption 3: Most participants will prefer to provide consent for both identifiable and de-identified data

On balance, most participants believed that consent was not required for data linkage. Many participants were clear that de-identified data should not be treated in the same way as identifiable data because they thought that the fact that data could not be traced back to specific persons was morally significant. Many of the participants with this view also expressed the view that once the identifiers were removed, the information became completely detached from individuals and was just 'information' which could be used to benefit others in society. The quotes below illustrate this point.

> They're just getting information. It's not anybody. It's A or B or a number, it's not actually a person…. There is a separation from the person. So it's just information, it's not a person; it's not a name or a phone number or an age. It's just information. (Mary)

> Yeah, because obviously the identity is not revealed. Supposing I'm number 24, even I won't know that I'm number 24. So it really doesn't raise a question about me not giving consent because you'll just have in your chart that number 24 is whatever, whatever the health information that she's got, there's that, that, that. But you don't have my name, you don't have my address, you don't have my phone number. Even if that goes to somebody else, all he knows is that number. He doesn't know that it's me. Even if my husband is conducting a research, he won't still know that it's his wife. So it doesn't really matter. (Mel)

> As long as information is being separated and it is not name orientated or where somebody lives. …. But, if there is no linkage to the data, then there's

> no personal - it's not really personal then, is it, if it's not getting linked? If it's just a statistic or a number it's not really… (Holly)
>
> I think the fact that there is no identifying the people involved. They could be somebody sitting next to them and they just don't know. To them it's just information to use for research; so no, not at all. I don't think it's an issue. (Teresa)

This finding conflicts with views expressed by Australians in the recent nation-wide study conducted by King and colleagues (31). In this study, 92% of survey participants expressed the view that consent should be sought for the use of their health information when used for purposes other than treatment. The disparity between the findings may be explained by the fact that participants in the King et al study (31) were considering research conducted with electronic health records and were advised that de-identified data can be linked back to identifying information. In my study, however, participants were informed that the data linkage process considered and the strict regulations surrounding such uses of data did not permit de-identified data to be linked to identifying data.

Participants in my study who expressed the view that de-identified data is just 'information' did not support the no consent option indiscriminately. Rather, they sometimes chose the consent option, potentially indicating in this way that they were still in the process of assimilating new understandings with previously held views about consent.

Participants who supported the 'no consent' option did not view the initial disclosure of personally identifying information for the purpose of creating the linkage key as a concern but some did indicate that the data linkage organisation would need to be trustworthy. This finding may point to one of two things: that views regarding privacy are changing, or that the restrictions placed on health and personal data have not reflected community views but rather reflected concerns by legislators and administrators. The focal point for participants was very much the analysis of the linked data rather than the handling of personal information in the initial data linkage stages. Concerns about identifiability arose prominently in Scenario 4 where the linkage was to be done by researchers, even though participants were assured that researchers would be required to de-identify data as soon as was practicable. It was not so much a lack of trust in researchers that raised concerns, but, for some, the fear that a person known to them might access the data and discover things about them that they did not wish to

reveal. In another Australian study, 37% of respondents (n=700) would be concerned or very concerned if the use of the de-identified health information could lead to them being identified, 29% were slightly concerned while 33% indicated that they would not be concerned about the use of their de-identified health information even if it could be traced back to their identity (31).

All participants supported the use of data in any form of research that would benefit society. Benefits arising from data linkage were also a major focus in responses regarding the non-consensual use of health data. During the discussions about the scenarios, participants indicated that they were positively disposed to participating in research. Their willingness to take part in research is a limitation of the study but is not uncommon as research, unsurprisingly, attracts those interested in research or a specific topic. Despite their support for research, the participants recognised that people do have a right to refrain from contributing but that they should be able to enjoy the benefits arising from research. My findings are consistent with those of other studies that show that people generally support research in both Australian (31) and international research (87) (90). However, in contrast to the findings of my study, in these studies people's general support of research did not align with a preference for no consent. People in these studies still wished to be informed of the use to which their data will be put.

Support for data linkage

Overall, participants were very supportive of data linkage research but did hold concerns regarding the linkage of certain kinds of data, especially data related to occupation. It was not clear whether their concerns were about the use of employment data or the fact that in the scenario I presented the linkage was to be done by researchers. Participants in a Canadian study were also more reluctant to have information about income, occupation and education linked to health data, with 30-40% of individuals both from the general public and with a specific health condition expressing the need for consent in such a scenario (84). Conversely, the same participants were more accepting of the linkage of health data and biological samples (with no commercial profit) (84). Participants in this study were most comfortable with the linkage of health data but were willing for other kinds of data to be linked if the public benefits arising from the research were deemed to be great. This especially

applied to research which directed its focus to an understanding of violence against others (Scenario 3), which they assumed would ultimately translate into a reduction of such behaviours. Participants' support for data linkage was further confirmed when the non-consensual use of health data was discussed more broadly and not specifically relating to the scenarios.

Balancing conflicting values

Participants demonstrated an understanding of the need to balance public benefits with the protection of privacy. A noteworthy feature was the struggle that participants experienced when trying to settle on their final position. This was due to conflicting values, notably between privacy protection and public benefits, which participants had to consider throughout the scenarios. Many participants made numerous switches within each scenario with the thought process, when vocalised, resembling that of a debate. Some participants were concerned that they would seem inconsistent if they made different choices for different scenarios. This may indicate that we are relatively inflexible with regard to issues such as consent and not readily accustomed to weighing up opposing values. In fact, the spontaneous response regarding the need for consent, especially during the first scenario, was confessed by some to have been offered out of habit, as they perceived that most things require consent: "*I know that you need to get consent for everything*" (Henrietta) or "*I mean instantly I thought yes they should be asked* [for consent] *but really there's no impact on them"* (Margaret). This may be indicative of a culture which places greater value of the individual rather than the community as a whole.

The shifting of views and justifying and re-justifying also alerts us to the fact that, when asked about these complex issues in research involving questionnaires, or modes where limited time is available (e.g. telephone interviews), the responses may not truly reflect what participants think ought to hold in that particular case. In addition, of course, written responses do not allow for clarifications to be made.

Practical implications of consent requirements in data linkage

A number of participants were cognizant of the practical implications of seeking consent from large cohorts, as were the majority of participants in a study examining a Scottish data linkage system (83). However, many participants in my study only considered this aspect as well as the implications for selection bias when I raised the issue. A lack of

understanding of such details may be commonplace given that research is not widely discussed in the media or in public discourse. As previously stated, this is an issue which impacts on the public's ability to arrive at informed views about data linkage.

Information provision

Participants indicated that excessive information provision about any kind of research or research practices was unhelpful, as people did not always need or want to know about everything. Some indicated that a lot of information that came in the post was relegated to the rubbish bin unopened due to time constraints and a decision that the issue was not relevant or of great priority in their lives. These views, although not elaborated on in my research, may relate to explanations regarding the reasons Michael offers for people remaining ignorant towards science (1996 in (124)); either science does not feature prominently in their lives, or people mistrust the authority of science (124). Such considerations should be borne in mind when devising methods of information dissemination regarding data linkage. Some participants indicated that the provision of information should be handled carefully, as misunderstandings regarding the use of data can have detrimental effects on the relationship between the public and the research community and can cause delays or hinder certain types of important research.

What may be appropriate when 'educating' the public is the provision of clear succinct and balanced explanations that provide a context within which issues can be considered and decisions can be made[78], especially in relation to technically complex systems. In the case of data linkage, once a general public understanding of data linkage is achieved, issues and discussions regarding the most appropriate consent option, including the *no consent* option, can begin to be considered.

Conclusion

This group of South Australians showed a good understanding of issues surrounding consent and its application and relevance to data linkage. The views expressed indicate that lay people have the ability to discern issues of philosophical, cultural and political relevance and gain an understanding of pertinent issues within a relatively short exchange and limited exposure to the complex nature of data linkage.

[78] I will not enter into discussions about the impact that the nature of the information *provided* or *not provided* has on participants (64) but do acknowledge the importance of this issue.

Overall, the majority supported the no consent option, when protections were deemed to be adequate, especially, for example, if researchers did not access identifiable data. Many participants thought that health information not linked to specific individuals no longer held the same value and could be used for research purposes without consent. The majority of these participants did not appear to think that notification of future use of data was necessary. This finding does not require the abandonment of this method of involving the public but does certainly enrich our understanding of the views held by some members of the public.

The multiple shifts between consent preferences was evidence that lay people can and do consider the conflicting values and interests that arise when considerations central to the protection of people's information, societal benefits, and the nature and constraints of research need to be balanced.

While such findings are not generalizable, there is an indication that the public can quite readily understand enough about data linkage to discern between uses of data that might cause harm and uses that include adequate protections.

CHAPTER 7

THE JUSTIFICATION OF CONSENT PREFERENCES

...most people in society lack the time, inclination, and perhaps the intellectual aptitude to engage in rigorous philosophical theorizing.

(125)
Arras J.
Bioethicist/philosopher

Introduction

Chapter 6 presented the findings from Phase 2 in relation to people's consent preferences in four hypothetical data linkage research scenarios. In addition to the consent choices, Chapter 6 also presented a descriptive account of the justifications offered for each of the participant's choices but did not further analyse these justifications. In this chapter I extend the analysis of consent with an account of the justifications for consent that participants provided. I also provide an account of the theoretical issues underpinning these justifications.

I use coherence theory to frame this analysis (63). This mid-level theorising originates from Rawls' political philosophy and enables the inclusion and consideration of intuitive justifications rooted in our moral traditions and understanding which are explained and organised by an appeal to moral principles and moral, political, and social theories but also specific cases (125)[79].

The chapter is organised in relation to the consent options available: *Consent justifications for scenarios 1-4, No consent justifications for scenarios 1-4, Justifications*

[79] High moral theory does not always provide a good backdrop for moral reasoning at an applied level, as these theories tend to stand on a limited number of philosophical principles and are not able to account for all aspects and intricacies of real-life cases (125), which typically involve a tension between one or more principles that must be resolved.

for public notification in Scenarios 3 and 4, Justifications for no public notification in scenario 3. Following these sections, I examine all scenarios to highlight emerging patterns across the justifications provided for each of the scenarios. This analysis is the first level abstraction applied to the data in which the justifications derived remain close to the original data. The justifications are then also briefly discussed at a second level drawing on moral principles. The moral principles appealed to in this second analysis are those widely employed in biomedical ethics as part of a moral reasoning framework developed by Beauchamp and Childress (63).

My analysis indicates that, in determining which consent option was most appropriate in each scenario, participants were guided by a set of moral values such as rights, trust, and respect, as well as concerns such as benefits, harms, protections. The practical difficulties that arise in research were also deciding factors in participants' reasoning.

Participants recognised the importance of privacy protection as well as the value of consent and the protections it can afford while also recognising the need for research to be conducted so that society can benefit. The shifts in views observed throughout the interviews were evidence of the balancing of these values and ends. The participants attached great importance to the security measures offered in the data linkage process and, when participants felt assured that measures would protect their privacy, they generally supported the non-consensual use of data in data linkage.

I also show in this chapter the similarities between justifications relied upon by these participants and the moral reasoning framework developed by Beauchamp and Childress (63). I conclude that lay people's intuitive moral reasoning shares similarities with more theoretical constructs in academia and clinical practice.

Consent justification themes in Scenarios 1-4

In this section I present the consent justification themes that emerged from the consent justifications offered by participants in each scenario. Details of the rationale adopted in this analysis have been provided in Chapter 5 under the heading Higher Level Analysis.

Scenario 1

In total, 55 justifications were provided by participants in relation to the requirement for consent in scenario 1. Out of these emerged six consent justification themes; these were: *rights/preferences, trust, respect, harm minimization, assumed*

social/legal/ethical norms, and *pragmatic considerations* (see Table 6). The theme with the most justifications was *harm minimization*, closely followed by *rights/preferences* and *assumed social/legal/ethical norms*. While reference to most justifications within each consent justification theme was relatively evenly distributed, some justifications were referred to with greater frequency, i.e. *People have a right to choose* and *People need to be aware of what is happening* were most prominent in the theme *rights/preferences*, while *To ensure people are not upset/do not object* was most prominent in the theme *Harm minimization* and *Consent should be sought at initial point of data collection* in the theme *Assumed social/legal/ethical norms*.

Table 6. Consent justification themes and justifications-Chart 3 Scenario 1

Consent justification themes	Consent justifications
Rights/preferences	**People have right to choose (6)*** Unfair to force participation (1) Information belongs to people (4) People prefer to be given the choice (3) People want to control their information (1) **People need to be aware of what is happening (6)**
Trust	Some don't trust that information stays anonymous (1)
Respect	Seeking consent is courteous (1) Seeking consent is a sign of respect (2)
Harm minimization	Consent provides protection (2) Consent required because of cultural differences; some people don't like their information used if they derive no benefits, or if there are perceived risks (1) Consent ensures that privacy is protected (3) **To ensure people are not upset/do not object (6)** Use of information without consent leads to trouble for researchers (2) Consent is required when researchers access identifiable information (1) Consent is required when other spheres of life (apart from health) are involved (1)
Assumed social/legal/ethical norms	Consent is required for everything (2) Seeking consent for use of private information is an ethical requirement (1) Consent should be sought for all research (2) **Consent should be sought at initial point of data collection (5)** Disclosure of information to a third party requires consent (2) Consent is a legal requirement (1)
Pragmatic considerations	To cater for future uses of the same data (1)

*Bracketed numbers indicate how many participants offered the justification

Scenario 2

Similar themes to those arising in Scenario 1 were identified in relation to Scenario 2 (see Table 7). These were: *rights/preferences, respect, benefits, harm minimization, assumed social/legal/ethical norms,* and *pragmatic considerations.* However, there were fewer justifications within each category (n=18) and these were so evenly spread that none dominated over other justifications offered. The themes *Rights/preferences* and *Assumed social/legal/ethical norms* contained the largest number of justifications used, with some of these referring to deceased individuals. There were a number of justifications relating to deceased individuals' information, with at least some participants indicating that rights extend to this group and that this group is owed respect which is demonstrated through consent processes involving the deceased persons' relatives.

Table 7. Consent justification themes and justifications-Chart 5-Scenario 2

Consent justification themes	Consent justifications
Rights/preferences	People have right to choose (1)* Information belongs to people (1) People want to control their information (1) Consent for deceased person's information should be sought because they still have rights (D1)
Respect	Seeking consent is a sign of respect (1/D1)**
Benefits	Seeking consent for deceased people's information is appropriate because knowledge that they are contributing to society would bring comfort to families (D1)
Harm minimization	To ensure people are not upset/do not object (2) Use of information without consent leads to trouble for researchers (1)
Assumed social/legal/ethical norms	Not seeking consent infringes privacy (1) Consent should be sought for all research (1) **Consent should be sought at initial point of data collection (4)** Consent for use of data should be sought whenever health services are accessed. Therefore, a deceased person's consent would have already been obtained (D1)
Pragmatic considerations	There are ways to achieve contact to request consent despite difficulties (1)

*Bracketed numbers indicate how many participants offered the justification. **D denotes justifications provided in relation to deceased individuals' information

Scenario 3

Compared to Scenarios 1 and 2, the consent justification themes were considerably fewer in number in Scenario 3 (see Table 8) with only three themes emerging: r*ights/preferences, harm minimization, assumed social/legal/ethical norms*. The total number of justifications was also smaller (n=11) compared to the previous two scenarios. The theme with the most justifications was *Assumed social/legal/ethical norms* but no one justification was more prominent. The decline in both the number of themes and the justifications within the themes for the consent option resulted from the greater shift to the no consent option (see Table 8).

Table 8. Consent justification themes and justifications-Chart 6-Scenario 3

Consent justification themes	Consent justifications
Rights/preferences	People have right to choose (1)*
Harm minimization	The more sensitive the data, the greater the need to obtain consent (2) Sensitivity of data requires that consent be obtained (2)
Assumed social/legal/ethical norms	Not seeking consent infringes privacy (1) Consent should be sought for all research (1) Mental health issues do not warrant not obtaining consent from participant or authorised carer (1) The need for large number of participants is no excuse for not considering obtaining consent (1) Research involving 'vulnerable' people requires consent (1) If there is a legal guardian, consent should probably be sought (1)

*Bracketed numbers indicate how many participants offered the justification

Scenario 4

Five consent justification themes arose in Scenario 4 (see Table 9): *rights/ preferences*, *respect*, *harm minimization*, *assumed social/legal/ethical norms*, and *pragmatic considerations* with a total of 65 justifications across all themes. Scenario 4 clearly raised concerns in participants and this is evidenced by the prominence of the *harm minimization* justifications, not only in the number of different justifications but also in the number of participants offering these justifications. In the context of data linkage research, the justifications *Consent required when researchers do the linkage* (n=7) *and Access to identifiable data by researchers requires consent* (n=9) could in fact be collapsed into a single category. This further highlights participants' concerns about the lack of separation of tasks in this scenario and was evidence that participants had grasped the protective nature of best practice data linkage methods. While the themes

were similar to those found in Scenarios 1, 2 and 3, there was a marked shift in the emphasis given to certain justifications which singles out Scenario 4 from the rest.

Table 9. Consent justification themes and justifications-Chart 8-Scenario 4

Consent justification themes	Consent justifications
Rights/preferences	People have right to choose (4)* Information belongs to people (1) People want to control their information (1) Researchers using identifiable information without consent is intrusive (1)
Respect	Consent required when participants are experiencing mental health issues, as they may not welcome people delving into their affairs at that point in their lives (1)
Harm minimization	**Consent provides protection against potential impact of research (10)** Researchers may disclose information to third party (2) Someone on the research team may know the research participants (2) Consent required because of lack of separation of tasks (4) To ensure people are not upset/do not object (2) **Consent required when researchers do the linkage (7)** **Access to identifiable data by researchers requires consent (9)** **Consent is required when other spheres of life (apart from health) are involved (7)**
Assumed social/legal/ethical norms	Consent should be sought for all research (1) Consent should be sought at initial point of data collection (1) Having the option to consent is good (2) Collecting this kind of information without consent may not be legal (1)
Pragmatic considerations	**Opt-out consent would result in more participants being involved (6)** Opt-in consent captures the people who really want to participate (2) It is very good to obtain consent if it is simple to do so (1)

*Bracketed numbers indicate how many participants offered the justification

No consent justifications in Scenarios 1-4

Scenario 1

Forty nine justifications were offered in support of the *no consent* option for Scenario 1 (see Table 10). The no consent justification themes that emerged from the data differed slightly from the themes encountered in the justifications for consent but did nevertheless have some overlap in themes but not justifications within each theme, as might be expected. The themes included *benefits, trust, protection mechanisms, assumed social/legal/ethical norms,* and *pragmatic considerations*. The theme with the largest number of justifications was *protection mechanisms* but also including a larger number of justifications were *assumed social/legal/ethical norms,* and *pragmatic considerations*. Close to half the participants cited a norm (*Use of de-identified data does not require consent*) as their justification for not requiring consent while the second most cited justification (n=9) came under the category *benefits* (*Acceptable*

practice because of the benefits). Participants showed an understanding of the protection mechanisms in place in data linkage projects as well as some of the practical constraints to which research is subject when consent is considered for large numbers of participants.

Table 10. No consent justification themes and justifications - Chart 3-Scenario 1

No consent justification themes	No consent justifications
Benefits	**Acceptable practice because of the benefits (9)** The more participants involved the better the quality of the study (1)
Trust	No need for consent if data linkage organisation is trustworthy (1) Knowledge of data linkage process allays concerns so no consent is acceptable (2)
Protection mechanisms	Large data sets serve as protection against identification (3) Acceptable if security and safety measures in place (2) Medical information will not be provided to other parties (1) Strict measures/guidelines provide protection (3) Participants are not directly involved (3)
Assumed social/legal/ethical norms	**Use of de-identified data does not require consent (12)** Use of de-identified information does not breach privacy (1) Privacy legislation binds researchers and protects participants (2) Retrospective use of data does not require consent (1)
Pragmatic considerations	Acceptable depending on study (1) Practical considerations of obtaining consent from thousands (3) Acceptable due to cost and time constraints involved when obtaining consent (1) Consent lowers research participation rates (3)

*Bracketed numbers indicate how many participants offered the justification

Scenario 2

The justification themes for no consent were very similar to those arising in Scenario 1 but included the theme *Harms* in place of *Trust* (see Table 11). In total, 38 justifications were offered in relation to information about people who are alive while 26 justifications for the no consent option related to the use of deceased individuals' information. The justification most often cited for both participants who are alive (n=13) and those deceased (n=9) was that the *Use of de-identified data does not require consent,* which falls within the *norms* theme and followed the pattern observed in Scenario 1. The next most prominent theme (for information pertaining to those who are alive) was *benefits* with participants indicating that data linkage in this scenario was acceptable without consent because of the benefits that arise from the research. One of the harms mentioned by a number of participants in relation to the use of deceased persons' information was *Requesting consent for deceased people's information could*

traumatise family. The themes *Protection mechanisms* and *Pragmatic considerations* included a larger number of justifications but the number of participants providing these justifications was relatively evenly spread.

Table 11. No consent justification themes and justifications–Chart 5–Scenario 2

No consent justification themes	Justifications for no consent
Benefits	**Acceptable practice because of the benefits (8/D1)*** Data regarding deceased people is invaluable and should be included (D2)
Harms	Requesting consent for deceased people's information could traumatise family (D5) Requesting consent could create difficulties, as people's confidence in the fact that research uses de-identified data might be reduced (1)
Protection mechanisms	Acceptable if security and safety measures in place (1) Use of information will not prejudice participants (1) Acceptable not to seek consent from those who cannot be contacted if strict guidelines adhered to (1) Not dealing with people directly (1)
Assumed social/legal/ethical norms	**Use of de-identified data does not require consent (13/D9)** Retrospective use of medical data acceptable (1) Audit type activities do not require consent (3/D1)
Pragmatic considerations	Practical considerations of obtaining consent from thousands (4/D2) Acceptable due to cost and time constraints involved when obtaining consent (3/D2) Relatives will be unaware of use of data relating to deceased relative (D2) Requesting consent for use of de-identified data is burdensome, as people are time-poor (1/D1) Use of deceased people's information does not impact on deceased person or their family (D2)

*Bracketed numbers indicate how many participants offered the justification. *D* is used to distinguish justifications relating to deceased individuals.

Scenario 3

Four no consent justification themes arose in Scenario 3 (see Table 12), compared to 5 in the previous two scenarios. These were *benefits, protection mechanisms, assumed social/legal/ethical norms,* and *pragmatic considerations*. However, the justifications were similar in number (n=47). The theme with the greatest number of justifications was *Pragmatic considerations* but the category with the greatest number of participants supplying the same justification was *benefits*, with *Acceptable practice because of the benefits* cited by 15 participants, a considerable increase from Scenarios 1 (n=9) and 2 (n=8). As discussed earlier (see Chapter 6), this scenario related to violent behaviour; hence, research in this area was deemed important by many participants. Consistent with previous scenarios, the justification *Use of de-identified data does not require*

consent in the theme *Assumed social/legal/ethical norms* was cited by the same number of participants (n=12).

Table 12. No consent justification themes and justifications–Chart 6–Scenario 3

No consent justification themes	Justifications for no consent
Benefits	**Acceptable practice because of the benefits (15)*** Research focusing on issues such as violence, which affects others/the whole community, justifies not obtaining consent (3) When you weigh up individual vs. community benefits, community benefits here are greater (1)
Protection mechanisms	Strict measures/guidelines provide protection (2) No harm to individuals because they will not be named (or 'outed') (1)
Assumed social/legal/ethical norms	**Use of de-identified data does not require consent (12)** Acceptable to do mental health research without consent (2) Consent not very important where safety issues are concerned (2)
Pragmatic considerations	Practical considerations of obtaining consent from thousands (5) Given the difficulties in obtaining consent, it is best to conduct research as benefits would be great (4) No impact on participants, who will be unaware that their data were used (1) Some participants cannot consent (1) Trying to get consent (including from relatives) could delay research, which should be done promptly because if its nature (1) Some participants may not have guardians (1)

*Bracketed numbers indicate how many participants offered the justification

Scenario 4

Scenario 4 displayed the largest number of themes (see Table 13) compared to the other scenarios and these included: *benefits, harms, trust, protection mechanisms, assumed social/legal/ethical norms,* and *pragmatic considerations*. Despite the larger number of themes, however, this scenario had the lowest number of justifications for the no consent option (n=32). The justifications were fairly evenly distributed across all the themes except for the themes *benefits* and *harms*, which each included a single justification. The theme *Pragmatic considerations* included the largest variety of justifications (n=6).

Table 13. No consent justification themes and justifications–Chart 8–Scenario 4

No consent justification themes	Justifications for no consent
Benefits	**Acceptable practice because of the benefits (5)***
Harms	Getting consent could have detrimental effect on participants (1)
Trust	No need for consent if data linkage organisation is trustworthy (1) Researchers will not use information obtained without consent to harm participants (1) Researchers are not interested in specific cases (2)
Protection mechanisms	Strict measures/guidelines provide protection (2) Provided that the linkage organisation was involved so that tasks are separated (1) Researchers will be dealing with de-identified data eventually (1) The findings are presented in de-identified form (3)
Assumed social/legal/ethical norms	Acceptable depending on study (1) Consent would have been given at data collection point (1) Information given to WorkCover can be shared with researchers, as it was given confidentially (1) Retrospective use of data does not require consent (1)
Pragmatic considerations	Practical considerations of obtaining consent from thousands (3) Acceptable due to cost and time constraints involved when obtaining consent (2) Consent lowers research participation rates (2) Low participation rates impact on quality of research (2) The information is already there so it should just be used without consent (2) People have inflated view of how interesting they are to others (1)

*Bracketed numbers indicate how many participants offered the justification

Justifications for public notification in Scenarios 3 and 4

Scenario 3

The justification themes supporting public notification of data linkage projects included r*ights/preferences, benefits, assumed social/legal/ethical norms, and pragmatic considerations* (see Table 14). In total, 24 justifications for public notification were offered and the theme with the most justifications was *benefits* (n=8) followed by *rights/preferences* (n=6). One of the benefits cited by a single participant was that public notification *Gives public opportunity to express dissent*. This participant considered that, if information is to be made available to the public, an opportunity to consent should also be offered. In this regard, therefore, their preference was in fact for the consent option rather than for public notification. Despite this, it was retained in this category, as it illustrates the struggle between a desire to embrace what seems a practical and

acceptable practice with the conventional view that consent should be sought for all uses of data, even if de-identified.

Table 14. Notification justification themes and justifications–Chart 7–Scenario 3

Notification justification themes	Notification justifications
Rights/preferences	Public has the right to know how their information is being used (1)* Public would want to know about research relating to violent behaviour (1) Public can choose to read about it or not read about it in public media (2) Public likes to be informed of research going on (2) Important for public to know what research is going on if it is publicly funded (2) Public has a right to know what research is being conducted (1)
Benefits	Gives public understanding of benefits of research (3) Instils confidence in public that such issues are being dealt with (1) Gives public confidence that government is focusing on mental health (1) Knowledge of research positively predisposes future participation (2) Sometimes it is good to know what research is going on (1) Knowing about research enables people to be more involved in the community (1) Gives public opportunity to express dissent (1) Gives public opportunity to make enquiries if they think they may be included in participant group (1)
Assumed social/legal/ethical norms	Researchers have to notify public about research (1) Public should be aware that mental health research is being conducted (1) Public interested in research if it relates to them in some way (1)
Pragmatic considerations	Careful dissemination required so as not to hinder research due to adverse public reaction (1)

*Bracketed numbers indicate how many participants offered the justification

Scenario 4

The justification themes for public notification in Scenario 4 (see Table 15) were similar to those in Scenario 3, with the only difference being that *rights/preferences* (cited in Scenario 3) was replaced with *trust* in Scenario 4. The justifications were less varied in this scenario than in Scenario 3, and there were fewer in number (n=8). This is to be expected given the strong preference for the consent option in this scenario. Of interest, again, is the confusion regarding notification and consent in the justification in the theme relating to norms. The justification was retained here for the reasons articulated in relation to the previous scenario.

Table 15. Notification justification themes and justifications–Chart 8–Scenario 4

Notification justification themes	Notification justifications
Benefits	Would be happy to simply know that some research is being conducted in the area. Acceptable because of the benefits (1) Sensible to have a register of all research being conducted so people with vested interest in certain types of research or those simply interested can become informed (1)
Trust	Having the information in public domain reassures people that nothing is being hidden from them and that no harm will come to them (2)
Assumed social/legal/ethical norms	Notification better than opt-out consent if there is opportunity for participant to withdraw from research (but they must be given the choice to do so) (1)
Pragmatic considerations	It may be appropriate in this case with only a few dissenters who you could 'deal with' individually (2) If it is possible to notify so many people, it is a good idea, but there are many practical constraints such as money, time, resources (1)

Justifications for no public notification in Scenario 3

Fewer participants supported the view that public notification of research is not required (see Table 16) and their justifications, the total of which was 24 in number, gave rise to four themes: *preferences, harms, assumed social/legal/ethical norms, and pragmatic considerations.* The theme with the largest number of justifications was *pragmatic considerations.* In addition, some saw harms arising from public notification of research, one of which related to research in general, while the other related to the negative impact on the participant group that knowledge about the specific hypothetical research may have.

Table 16. No notification justification themes and justifications–Chart 7–Scenario 3

No notification justification themes	No notification justifications
Preferences	Personally not bothered if they are not informed of research being conducted (1)*
Harms	Notification can hinder research due to adverse public reaction (1) Public knowledge about mental health research might serve to reinforce entrenched misconceptions about people with mental health issues (1)
Assumed social/legal/ethical norms	Most people do not have interest in research being conducted unless it relates to them (1)
Pragmatic considerations	Notification of research costs a lot (2) Notification does not make difference (1) Public does not need to know about every research project being conducted (2) No need to give public information they do not want (3) No need for researchers to announce research unless they need public to know for volunteering purposes (1)

*Bracketed numbers indicate how many participants offered the justification

Comparison of themes across scenarios

Consent justification themes

While the justifications offered in each theme did vary slightly depending on the scenario, there was great consistency of justification themes across all scenarios (see Table 17). Values relating to *trust* and *respect* were the themes which varied the most across scenarios. Scenario 1 generated the greatest diversity of rationales, which then reduced as subsequent scenarios were discussed. Considerations related to *benefits* were only raised in relation to Scenario 2 in the context of consent for use of deceased persons' data. However, considerations related to *rights (/preferences)* were consistent across all scenarios. *Harm minimization, assumed social/legal/ethical norms,* and *pragmatic considerations* also arose in all four scenarios. While the justifications offered did vary slightly depending on each scenario, there was great consistency in the content.

Table 17. Consent justification themes across scenarios

Consent justification themes	Scenario 1	Scenario 2	Scenario 3	Scenario 4
	Rights/ preferences	Rights/ preferences	Rights/ preferences	Preferences
	Trust			
	Respect	Respect		Respect
		Benefits		
	Harm minimization	Harm minimization	Harm minimization	Harm minimization
	Assumed social/legal/ ethical norms	Assumed social/legal/ ethical norms	Assumed social/legal/ ethical norms	Assumed social/legal/ ethical norms
	Pragmatic considerations	Pragmatic considerations	Pragmatic considerations	Pragmatic considerations

The use of *harm minimization* as a rationale referred to real or perceived risks which, in this context, could be averted via the consent process. Although participants clearly perceived that providing a consent option did minimize the risk of harm, this does not necessarily hold true in the conduct of research. For example, the provision of consent does not, in itself, reduce the risk of harm to participants if other protective measures are not in place and observed; in ideal situations, it simply serves as a mechanism to inform participants of the potential risks involved in the research and enables them to make a choice as to the level of risk to which they are prepared to expose themselves in research. Participants could be forgiven for this, however, as the same concept is often used by those professionally involved with considerations of consent.

No consent justification themes

The *No consent* justification themes across all four scenarios (see Table 18) also yielded a pattern of consistency, particularly in relation to *benefits, protection mechanisms, assumed social/legal/ethical norms,* and *pragmatic considerations.*

Table 18. No consent justification themes across scenarios

No consent justification themes	Scenario 1	Scenario 2	Scenario 3	Scenario 4
	Benefits	Benefits	Benefits	Benefits
	Trust			Trust
		Harms		Harms
	Protection mechanisms	Protection mechanisms	Protection mechanisms	Protection mechanisms
	Assumed social/legal/ ethical norms	Assumed social/legal/ ethical norms	Assumed social/legal/ ethical norms	Assumed social/legal/ ethical norms
	Pragmatic considerations	Pragmatic considerations	Pragmatic considerations	Pragmatic considerations

The justification raised in relation to the *benefits* arising from the research across all categories was that not obtaining consent is acceptable when the benefits of the research are considered. Justifications regarding the mechanisms employed in data linkage to protect privacy and justifications related to practical considerations, such as monetary constraints and time were also present across all four scenarios. Issues relating to trust were not as prominent but were, nevertheless, raised in relation to two scenarios.

Notification justification themes

The same pattern of consistency emerged in the justification themes for notification across scenarios 3 and 4 (see Table 19). The theme *rights* emerged in Scenario 3 while in Scenario 4 the theme of *trust* emerged. Despite having the same type of justification themes, the content in each differed considerably. The greater contribution of justifications in Scenario 3 compared to Scenario 4 can, once again, be assumed to relate to the very different response that participants provided for Scenario 4, where most felt that data linkage should not be conducted without consent or with only public notification of the research being conducted.

Table 19. Notification justification themes across scenarios

	Scenario 3	Scenario 4
Notification justification themes	Rights	
		Trust
	Benefits	Benefits
	Assumed social/legal/ethical norms	Assumed social/legal/ethical norms
	Pragmatic considerations	Pragmatic considerations

Higher level analysis – Beauchamp and Childress moral reasoning framework

This section considers a partial analysis of the data and demonstrates the correspondence between the analysis I adopted and the well-established moral reasoning framework developed by Beauchamp and Childress, which is widely used in academia and clinical decision-making. This higher-level analysis was exploratory in its approach and, while the Beauchamp and Childress framework (BC framework) did not correspond perfectly, the similarities were striking enough to warrant consideration. The significance of this higher level analysis lies in the fact that lay people's moral decision-making process aligns so closely with that of specialists in the field of moral decision-making.

As can be seen in Table 20, the only principle which participants did not consider when reasoning through the options was that of justice[80].

Table 20. Correspondence between themes by level of abstraction

	1st Level abstraction	2nd Level abstraction: principlism
themes /principles	rights/preferences	respect for autonomy
	trust	respect for autonomy
	respect	respect for autonomy
	harm minimization	nonmaleficence
	protection mechanisms	nonmaleficenece- data linkage specific
	harms	nonmaleficence
	benefits	beneficence
	social/legal /ethical norms	guiding rules
	pragmatic considerations	

[80] Justice relates to a 'group of norms for distributing benefits, risks, and costs fairly' (63p.12).

This information, however, does not prove immensely helpful without the provision of the justifications, which clarify how the justifications themselves fit under the principles and guiding rules of the framework. For this reason, Table 21 (relating to Scenario 1 consent justifications) and Table 22 (relating to Scenario 1 no consent justifications) are presented below with both levels of abstraction to enable a comparison between themes at the two different levels of abstraction and clarify the distribution of justifications under the principles of the BC framework.

Table 21. Correspondence of 1st level abstraction with 2nd level abstraction themes – Scenario 1 consent option

1st level Consent justification themes	Consent justifications	2nd level Consent justification themes	Consent justifications
Rights/ preferences	**People have right to choose (6)*** Unfair to force participation (1) Information belongs to people (4) People prefer to be given the choice (3) People want to control their information (1) **People need to be aware of what is happening (6)**	**Respect for autonomy**	**People have right to choose (6)*** Unfair to force participation (1) Information belongs to people (4) People prefer to be given the choice (3) People want to control their information (1) **People need to be aware of what is happening (6)** Seeking consent is courteous (1) Seeking consent is a sign of respect (2)
Trust	Some don't trust that information stays anonymous (1)		
Respect	Seeking consent is courteous (1) Seeking consent is a sign of respect (2)		
Harm minimization	Consent provides protection (2) Consent required because of cultural differences; some people don't like their information used if they derive no benefits, or if there are perceived risks (1) Consent ensures that privacy is protected (3) **To ensure people are not upset/do not object (6)** Use of information without consent leads to trouble for researchers (2) Consent is required when researchers access identifiable information (1) Consent is required when other spheres of life (apart from health) are involved (1)	**Non-maleficence**	Consent provides protection (2) Consent required because of cultural differences; some people don't like their information used if they derive no benefits, or if there are perceived risks (1) Consent ensures that privacy is protected (3) **To ensure people are not upset/do not object (6)** Use of information without consent leads to trouble for researchers (2) Consent is required when researchers access identifiable information (1) Consent is required when other spheres of life (apart from health) are involved (1) Some don't trust that information stays anonymous (1)
Social/legal/ ethical norms	Consent is required for everything (2) Seeking consent for use of private information is an ethical requirement (1) Consent should be sought for all research (2) **Consent should be sought at initial point of data collection (5)** Disclosure of information to a third party requires consent (2) Consent is a legal requirement (1)	**Guiding rules**	Consent is required for everything (2) Seeking consent for use of private information is an ethical requirement (1) Consent should be sought for all research (2) **Consent should be sought at initial point of data collection (5)** Disclosure of information to a third party requires consent (2) Consent is a legal requirement (1)
Pragmatic considerations	To cater for future uses of the same data (1)	**Pragmatic considerations**	To cater for future uses of the same data (1)

As can be seen in Table 21, the justifications in the *rights/preferences* theme fit neatly under the *respect for autonomy*[81] principle with the justifications that came under *respect* also subsumed under the *respect for autonomy* principle. Similarly, the theme *harm minimization* and the corresponding justifications seem to correspond well with the principle of *non-maleficence.* Also included in the theme of *non-maleficence* was the justification that originally came under the category *trust.* The theme *assumed social/legal/ethical norms* simply received a different title, i.e. *guiding rules,* to better cohere with the BC framework. Finally, the category of *pragmatic considerations* appeared to stand on its own and was not subsumed under any of the other 2nd level analysis principles.

An example of the uncertainty of the end justification intended by participants can be seen in the justification *To ensure people are not upset/do not object,* which has been placed under *non-maleficence,* as people becoming upset or distressed in any way can be viewed as a harm to these individuals. However, the very same justification might be considered as a candidate for the *principle respect for autonomy* if we extended the justification by adding content such as *to ensure people are not upset/do not object [because they perceive that their right to make choices about their information and how it will be utilized are not respected].* It immediately becomes apparent that further probing during the interview could have indeed clarified the participants' intentions and end justification. Alternatively, the same justification could have been placed under both principles. However, doing so repeatedly through the framework would have produced a messy and unhelpful outcome and would not guarantee that it truly represented what participants had intended.

Table 22 below, which relates to the no consent justifications for Scenario 1, provides a slightly different arrangement of the principles in the BC framework. Present in this instance are the principles *beneficence* and *non-maleficence.* However, the latter is qualified as relating specifically to data linkage given the content of the justifications thus introducing a nuanced variation to this established framework. As was the case in the consent justifications, the *assumed social/legal/ethical norms* theme was simply renamed *guiding rules* retaining all the same justifications. The justifications originally under the category *trust* were subsumed under the principle of *beneficence*. Once

[81] Respect for autonomy is 'a norm of respecting the decision-making capacities of autonomous persons' (63 p. 12)

again, *pragmatic considerations* lay outside the BC framework but could be considered case-specific issues, which also need to be considered when engaging in moral reasoning in relation to consent in data linkage, as they are pertinent issues, even if they have no moral flavour themselves. Once again, however, we could extend the concepts, which in this case were likely to have been intended, and consider the moral nature arising from such justifications. For example, the enormous number of participants whose consent would need to be sought would stifle research, which brings many benefits to society. In such a case, we would be justified in shifting the justification *practical considerations of obtaining consent from thousands* under the *beneficence* principle. While this latest example appears to reflect participants' views, it is nevertheless evident that applying the BC framework to my data would entail endless hypothesizing and speculation, rendering this second level of abstraction too risky to adopt.

Table 22. Correspondence of 1st level abstraction with 2nd level abstraction themes – Scenario 1 no consent option

No consent justification themes	No consent justifications	No consent justification themes	No consent justifications
Benefits	**Acceptable practice because of the benefits (9)** The more participants involved the better the quality of the study (1)	**Beneficence**	**Acceptable practice because of the benefits (9)** The more participants involved the better the quality of the study (1) No need for consent if data linkage organisation is trustworthy (1) Knowledge of data linkage process allays concerns so no consent is acceptable (2)
Trust	No need for consent if data linkage organisation is trustworthy (1) Knowledge of data linkage process allays concerns so no consent is acceptable (2)		
Protection mechanisms	Large data sets serve as protection against identification (3) Acceptable if security and safety measures in place (2) Medical information will not be provided to other parties (1) Strict measures/guidelines provide protection (3) Participants are not directly involved (3)	**Non-maleficence (data linkage-specific)**	Large data sets serve as protection against identification (3) Acceptable if security and safety measures in place (2) Medical information will not be provided to other parties (1) Strict measures/guidelines provide protection (3) Participants are not directly involved (3)
Assumed social/legal/ethical norms	**Use of de-identified data does not require consent (12)** Use of de-identified information does not breach privacy (1) Privacy legislation binds researchers and protects participants (2) Retrospective use of data does not require consent (1)	**Guiding rules**	**Use of de-identified data does not require consent (12)** Use of de-identified information does not breach privacy (1) Privacy legislation binds researchers and protects participants (2) Retrospective use of data does not require consent (1)
Pragmatic considerations	Acceptable depending on study (1) Practical considerations of obtaining consent from thousands (3) Acceptable due to cost and time constraints involved when obtaining consent (1) Consent lowers research participation rates (3)	**Pragmatic considerations**	Acceptable depending on study (1) Practical considerations of obtaining consent from thousands (3) Acceptable due to cost and time constraints involved when obtaining consent (1) Consent lowers research participation rates (3)

Discussion

This section discusses the justification patterns observed and elucidates the moral reasoning participants applied when arriving at a *consent, no consent,* or *notification* option. In addition, briefly commented on were similarities that appear to exist between this analysis and that of the moral reasoning framework proposed by Beauchamp and Childress (63).

Participants' moral reasoning

Participants offered a large and varied number of justifications as they weighed up conflicting interests for each consent option they were presented with. They appeared to apply a framework within which they deliberated drawing on a number of socially/legally/ethically acceptable norms, ethical principles and practical considerations that apply to the conduct of research, as well as case-specific considerations such as privacy protection mechanisms used in data linkage.

As seen in the previous chapter, few participants consistently supported the no consent option throughout all four scenarios. Rather, the majority started out supporting the consent option but then, recognising the benefits of data linkage research began to negotiate the difficult balancing of competing values, and, in particular, control over information and privacy vs. the common good.

It is unsurprising that a number of participants confessed that they automatically responded in the affirmative when asked whether consent should be sought in the first scenario given the prominence that consent has been given particularly in recent years in Australia. When asked to justify this initial response many cited reasons such as *Consent is required for everything.* There is no doubt that participants thought that they had a right to control their identifiable information through the provision of consent, which ultimately protects decisional privacy. *Harm minimization* justifications related to the positive outcomes participants saw arising from the provision of consent and the protection this is seen to provide, both in relation to other values and in relation to a safer environment in which people manage their affairs.

Participants also saw consent as protecting privacy and offered a number of justifications in this regard. They felt that people's privacy was most threatened when

information about areas of one's life was accessed, especially if it was to be identifiable. In presenting their justifications, participants were clearly identifying values that warrant protection.

In conflict with the above, participants clearly viewed the benefits of research as an important contribution to the improvement of life in a society in which we collectively stand to benefit from new research findings. Two categories of justifications appear to have guided participants through the reasoning process; *pragmatic considerations* relating to the ability (or not) to conduct such research depending on the level of privacy protection applied via consent processes, and, importantly, *protection mechanisms* available in best practice data linkages, such as the separation of tasks so that researchers only ever access de-identified data. These two sets of considerations weighed heavily in participants' struggle to determine the most appropriate consent choice. Overall, protection mechanisms in data linkage played the most decisive role in final decisions arrived at by participants. This was particularly evident in the swing back to the consent option (see Chapter 6) in Scenario 4, precisely because there was no separation of tasks. Hence, participants felt that the protection mechanisms were substantially lacking in that scenario.

Overall, participants considered that public notification offered a number of benefits including satisfying the public's need or right[82] to be informed of the research being conducted. Participants appealed to a number of values in justifying their choice but, as mentioned previously, the concept of public notification without the option of choice was confused in some participants' minds. This is evidence that consent still holds a central position in some people's thinking.

Given participants' dominant view that consent was generally not required in best practice data linkage, it might have been expected that, when offered the option of public notification without the option of consent, participants would have adopted this as their overriding choice of preference. This was not evidenced, however. In fact, even if they were a minority, some participants saw potential dangers associated with public notification, warning, for example, that dissemination of any research-specific

[82] Some participants viewed public notification as a need while others viewed it as a right.

information had to be handled carefully so as not to create obstructions for the research to proceed.

Similarities with BC moral reasoning framework

It is evident that a number of principles and guiding rules (to use the language of Beauchamp and Childress) were considered by participants, perhaps in a less sophisticated manner than would be considered by experts in biomedical ethics. Despite this, the similarities drawn between the analysis I adopted and the analysis that would have emerged had I chosen to apply the framework directly to the data perhaps provides some support that this framework can be extended beyond the confines of academia and clinical practice. The similarities, as identified in this partial analysis, indicate that there may be a correlation between philosophers' identification of ethical principles central to medical ethics and the justifications that lay people intuitively use, as a result of the influences exerted upon them in a society that values such moral principles.

Conclusion

Participants negotiated the difficult consent terrain assisted by their convictions regarding what is acceptable or not in our society, convictions shaped and modified as part of their membership in this society. Moral values such as rights, trust, and respect, as well as considerations such as benefits, harms, protections, and the realities imposed upon the conduct of research also weighed heavily in their reasoning process. It appears that these lay participants, most of whom confessed at the outset that they had never considered such issues, do not resemble those individuals John Arras had in mind when stating …*most people in society lack the time, inclination, and perhaps the intellectual aptitude to engage in rigorous philosophical theorizing*. (125).

CHAPTER 8

CONCEPTIONS OF PRIVACY

That which seems the height of absurdity in one generation often becomes the height of wisdom in the next.

John Stuart Mill
English economist & philosopher (1806 - 1873)

Introduction

The theoretical literature on privacy was examined briefly in Chapter 1 with the most striking feature being the multiplicity of conceptions of privacy, and its features and justifications. While many theorists link privacy to control of information, others view it as restricted access to persons, seclusion from others or absence of information about persons. Still others view privacy as multi-dimensional with interconnected facets. Finally, fewer theorists believe privacy is reducible to other more basic rights. The value of privacy has been much discussed in the literature with theorists linking it to the most fundamental aspects of human existence as well as to the foundation upon which human co-existence rests.

In the health context, we have gained an understanding of how *patients* conceive of privacy when undergoing treatment in medical settings (126-132). In medical settings it has been shown that, when considering privacy, patients focus primarily on the physical environment (for example, privacy of consultation rooms), communication of their health data, and the handling of their medical records. These findings relate particularly to primary uses of data but we have limited understanding of people's conceptions of privacy regarding secondary uses of their health data (83, 133).

In Chapter 6, I analysed the consent options participants in phase 2 of this study regarded as appropriate for data linkage and provided the justifications for their choices, which were further analysed in Chapter 7. Some participants regarded consent as being intricately linked with privacy and saw it as providing privacy protections. In this chapter, I extend the analysis to participants' understanding of conceptions of privacy and examine whether the lay people in this study shared similar conceptions to those espoused by philosophers and legal experts in the literature. This is an area which has not been explored previously.

The chapter starts with a discussion of participants' definitions. Some of the definitions are closely related conceptually, as might be expected, and my justifications for retaining the distinctions are provided in the relevant sections. The next section of the chapter deals with participants' justifications for privacy. As in the previous chapter, it was evident that these lay people have varied and sophisticated conceptions of the role that privacy plays in human interactions and society. I then discuss the complex and nuanced qualifiers participants gave for their definitions to demonstrate how participants contextualised privacy. These contributions, once again, align well with the literature and demonstrate that these lay people have a deep, varied, and sophisticated understanding of privacy.

The focus of the discussion with participants was data linkage. Nevertheless, participants were able to move beyond considerations of privacy in an informational context alone and meander through the dense jungle of other facets of privacy. To retain a link to the analyses in Chapters 6 and 7 in the Discussion, I return to the data linkage context and comment on the position that participants held in relation to privacy specifically in the context of data linkage.

The findings of this component of the study show that participants' views approximate to considerations of privacy in the literature. These lay people have the capacity to consider complex privacy issues. Their definitions of privacy related it to facets of our lives we choose not to share with everyone, the protection and control of information, anonymity, and not sharing confidential information. The justifications for privacy also matched well with those discussed in the literature. Participants justified privacy in terms of harm minimization, autonomy, respect for persons, its contribution to mental health, its ability to enable us to reveal or hide different aspects of our person, and the

sense of control it provides over our lives. Furthermore, they viewed privacy as having multiple levels and indicated that they communicate varying degrees of information to people depending on their relationship. They also recognised that there are different types of privacy relating to information, decision-making, and access to their person or their space and that privacy is interpreted differently by different people. Finally, many did not hold concerns about uses of their information if it did not contain identifying features. This has implications for data linkage, as is discussed subsequently.

Exploring people's conceptions of privacy

This section reports on the definitions participants offered for privacy. I then move on to examine the justifications for privacy participants offered and, finally, present features which contextualise privacy, as described by participants.

Privacy definitions

Participants defined privacy in five ways, with some participants offering more than one definition. These definitions were: *Aspects of one's life not shared, Protection of identifying information, Control over identifying information, Anonymity, and Not sharing information imparted in confidence* (see Figure 6). Woven into their responses regarding what privacy means to them, respondents often also provided a justification for privacy. The justifications are presented separately so that greater detail can be provided.

Figure 6. Privacy definitions

Just over half of the respondents (n=15) saw privacy as having multiple facets, with most identifying that it relates to aspects of our lives that we do not wish or think are appropriate to share with others (see Table 23 below).

Table 23. Chart 1a – Privacy definitions

Respondent	Aspects of one's life not shared	Protection of identifying information	Control over identifying information	Anonymity	Not sharing information imparted in confidence
Danny	x		x		
Darren	x				
Don	x				
Haley		x			
Harmony				x	
Helen	x		x		
Henrietta				x	
Holly		x			
Jack	x	x			
Jacob	x				
John	x	x			
Mandy		x			
Margaret		x		x	
Mary	x		x		
Mel	x	x		x	
Molly		x			
Tegan	x	x		x	
Teresa	x		x		
Tina	x		x	x	
Tracey	x		x	x	
Trixie	x	x	x		
Vallery	x				x
Vanessa		x			
Verity		x	x		x
Victoria		x			
Virginia			x		

Aspects of one's life not shared

When referring to aspects of their lives they do not wish to share, respondents made reference to either smaller or larger private 'units'; that is, some mentioned that there

is information about their person that they do not wish anyone else to have access to, including those with whom they have the most intimate relationships, while others seemed to consider the family as the smallest unit for which privacy needs to be considered.

Darren

> Privacy just means something that for myself, not even for my wife. It's my own thing that I don't need anyone to know.

Jack

> Protection of my patch, I guess.
>
> *What do you mean by that?*
>
> Well, my family, my home, my - we're not overly private people but there are certain elements in our life that we keep private and that's - like anyone I guess.

Protection of identifying information

Half of the respondents saw privacy as relating to the protection of identifying information with many providing concrete examples of information that would reveal identity. In offering this definition, a number of participants made reference to health information while others simply referred to personal information such as name and address. While a large number of participants, at different stages of their interviews, indicated that privacy concerns only arise when information is identifying, only one participant explicitly stated this when defining privacy. For some, privacy was seen to extend posthumously and as a result information regarding deceased persons, according to these participants, also needs to be protected, as can be seen in John's explanation below.

Margaret

> I think it comes back to a name, your name being linked to your information. I think that's where privacy becomes an issue.

John

> For me, what I consider as privacy is that my information that I provide to anybody should be protected. That's my privacy. Anything regarding me as a person, as a human being existing, still alive or dead, should be protected by all means possible, and everything that you do with information regarding me and my personal details should be protected every way possible.

Control over identifying information

A number of interviewees (n=9) saw privacy as relating to control over identifying information. The language used to discuss control was not always explicit; however, control was clearly being discussed with the use of phrases such as 'me choosing; unless I have signed or said yes, that's ok; that's my right to give that; without my permission/consent…' etc.

Helen

> If I want to give the information up then that's fine but it comes down to me choosing; if I want to choose to give information then that's up to me.

Teresa

> I have a right to give my address, my date of birth, my whatever it might be, that can link me, as an individual, to somebody else. That's my right to give that to them. If you're on Facebook and you've published it to the world you've forfeited that right; but it is my right, in a sense, to give that to you.

For the participants who saw privacy as relating to control, the issue of control over personally identifying information was on a continuum. At one end of the spectrum there was a milder expression of control with phrases such 'I am not willing to share' while at the other extreme, control over information was expressed as being a 'right'. At the latter end of the spectrum, participants appeared to express degrees of formality in relation to disclosing identifiable information, and were possibly alluding to the kinds of controls in place to protect identifiable information from unauthorised disclosures, e.g. '*give* someone your information; without my *permission*; without my *consent*; determine what *information is released*'.

Anonymity

Anonymity was considered by a number of interviewees (n=7) to be linked to the core meaning of privacy. The majority of participants made reference to personal information being kept apart from other information, but one participant referred to maintaining anonymity in a physical sense (see Tegan below) while another spoke about it in terms of the actions we can take to preserve our privacy, for example, through not listing our telephone numbers in the directory, which, to an extent, shields us from intrusive calls which we do not wish to receive.

Harmony

> *You talked about privacy, when you say privacy, what exactly do you mean by it? People have different conceptions of what it is.*

> I guess people knowing your address and your name and things like that. Linking different areas of your life and putting together a picture of you that you might not want other people to have.
>
> *Why wouldn't you want them to have it?*
>
> I guess identity issues and just privacy in and of itself.
>
> *What do you mean by that, 'privacy in and of itself'?*
>
> Just the idea of people knowing about you.

Tegan

> I guess privacy is not being seen - it's like in the evenings we'll draw the blinds because we want the privacy from the neighbours. We don't want them seeing us in our house eating dinner or any person on the street walking past.

Tegan's contribution might be considered to relate to the concept of invisibility rather than anonymity. While a degree of invisibility may be involved, nevertheless, the people who would be seen in the house if the curtains were not drawn do also remain anonymous when curtains are drawn; a passer-by knows that someone lives in that particular house but does not have access to their name. If the individual residing in the house were a public figure whose name was known, anonymity provided by drawing the curtain becomes even clearer. The definitions of *anonymity* and *protection of identifying information* appear to be closely linked. However, the difference I perceive between them is that a desire for anonymity is not necessarily related to considerations of harm but can simply relate to someone not wanting their identity revealed because they want to be left alone or because they consider it appropriate in particular circumstances, e.g. an anonymous benefactor. Conversely, *protection* always implies that 'someone or something [is kept] safe from injury, damage, loss, or other unpleasant effects or events' (134 p.1154).

Not sharing information imparted in confidence

Few participants (n=2) considered privacy as relating to the protection of information which was made available in confidence and only one interviewee made a distinction between the concepts of *privacy* and *confidentiality*.

Vallery

> It means if I, for instance, give you some information or tell you some information and you say this is private and confidential, that you don't tell or show that to anybody else. It's for you and you only, for that company and that company only.

Verity

> *What's associated with like, for instance, you've got a circle of friends and some friends you tell some information to, but other friends you don't. So what is it there, is it still harm?*
>
> Well, you tell some people because you trust them.
>
> *When you say trust, what exactly do you mean?*
>
> You know that that information is not going to go any further or I guess be used against you in some form of harm, I suppose depending on what the information is as to what level of harm it is actually going to be.

Summary of privacy definitions

Privacy was discussed within the context of data linkage and was therefore being considered in the informational context. Despite this, participants also provided definitions unrelated to informational privacy. A number of participants viewed privacy as being multi-faceted and provided more than one definition with most participants indicating that privacy relates to aspects of our lives we do not wish to share with others. Half the respondents linked privacy to the protection of identifying information while many viewed it as control over identifying information. Privacy was also defined as anonymity both in an informational context but also in a physical sense. Two participants related privacy to not sharing information which has been imparted in confidence, hence blurring the boundaries of privacy and confidentiality.

Privacy justifications

Participants offered an array of justifications for privacy with the majority (n=17) offering more than one justification. There were six types of justifications: [Privacy] *Minimizes harm to individuals, Allows autonomous living/non-interference, Displays respect for people's views/wishes, Contributes to mental health, Allows different facets of individual to be revealed/hidden,* and *Gives sense that you are in control of your life* (see Figure 7).

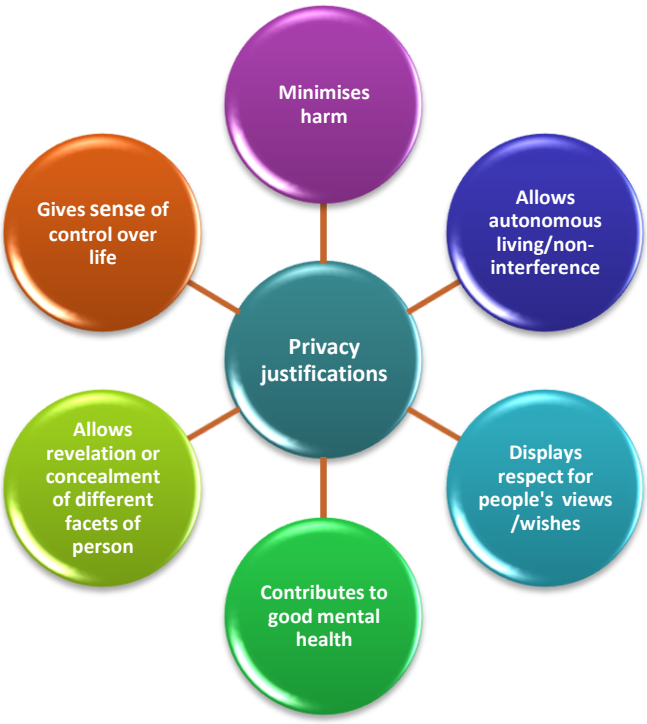


Figure 7. Privacy justifications

Bearing in mind that some participants used more than one definition, just over half of the interviewees expressed the view that privacy minimizes harm to individuals, half that privacy promotes autonomous living and non-interference from others and half, again, that privacy permits different facets of the individual to either be revealed through disclosure of information or hidden through non-disclosure (see Table 24 below).

Table 24. Chart 1b – Privacy justifications

Respondent	Minimizes harm to individuals	Allows autonomous living/non-interference	Displays respect for people's views/ wishes	Contributes to mental health	Allows different facets of individual to be revealed/ hidden	Gives sense that you are in control of your life
Danny					x	
Darren					x	
Don					x	
Haley	x				x	
Harmony			x		x	
Helen		x			x	
Henrietta	x					
Holly						
Jack	x				x	
Jacob					x	
John	x	x	x			
Mandy		x	x	x		
Margaret			x			
Mary		x				
Mel	x	x		x	x	
Molly	x	x				
Tegan	x	x				
Teresa	x	x	x		x	x
Tina		x	x			x
Tracey			x	x		
Trixie	x	x			x	x
Vallery	x	x	x		x	
Vanessa	x					
Verity	x		x	x	x	
Victoria	x	x				
Virginia	x	x				

Privacy minimizes harm to individuals

Even if unstated in this part of the interviews, constant throughout the discussion about protection was the underlying assumption that it was *identifiable* information that was being considered. This becomes clearer when considering the justifications that were provided in relation to consent which were necessarily intricately related to privacy and where non-identifiability of data was used as a justification by many participants.

Of the participants who believed that privacy is justified as it minimizes harms to individuals (n=14), a number did not clarify what kind of harm they were considering but simply mentioned that information can be used against people if it 'falls into the wrong hands'. Identity theft was discussed by many as being a key concern and the unauthorised disclosure of information through social networks such as Facebook were

cited as sources of potential harm, with one individual mentioning that there are 'predators' on the net from whom she kept family photos, especially images of her children. One participant raised the issue of researchers being able to commit identity fraud with the wealth of information they collect about individuals. Her view was that consent is a mechanism that assists in keeping information safe, as researchers are then obliged to use the information only in the manner that they stated they would. Other harms referred to were discrimination or marginalisation, both as a result of the disclosure of certain aspects of one's personal life and as a result of medical information becoming known; the specific example given related to HIV and the devastating effect that marginalisation might have on the individual experiencing this health issue. Physical harms and harms (of a non-specified nature) to the family were also mentioned as resulting from privacy breaches. Mentioned only by a single participant each were other harms such as emotional harm, social harm, harm to one's identity, harassment, and harm to one's dignity/respect. One participant (John) identified a breach of one's privacy as a harm in itself even if no other harm resulted from unauthorised access to someone's information.

Jack

> But, for security purposes it's also important that some of your information is private because it's quite easy these days for people to take advantage of any information in the public domain.

John

> … it's being used differently or for different other purpose.
>
> *Do you think that any harm could come to a person from that?*
>
> Well yes, in terms of if the person - in terms of their identity, in terms of their privacy might be breached. Breach of privacy is a harm to someone's dignity, rights.

Allows autonomous living/non-interference

In discussing the issue of autonomous living, half the participants referred to impositions on their autonomy resulting from uninvited intrusions by others into their personal affairs or space. Such actions, for example, included interference in a family's decision-making process, observing or spying on somebody, the knowledge that people are gossiping about you and impositions on people's time and access to them. Others provided insight into what they perceived autonomous living to be, ranging from references to the ability to think and live freely, doing things the way you want to,

having control over your life, to mundane activities such as 'being able to go and hang out my knickers in the backyard'.

Helen

> *When you talk about your privacy what do you think about?*
>
> I don't know, just being given the option to keep things to myself or not have people annoy me or not having everybody know my business. That's basically all I think of.

Mandy

> Generally, like if, for instance, some guests come into our house and they interfere in your daily matters of life, that's a privacy attack. Like every human being is free to think and free to live. So if you burden somebody with your ideas and stress them that you have to do it this way, that way.

Allows different facets of individual to be revealed/hidden

A number of participants (n=13) indicated that privacy enables the revelation or concealment of certain facets of their personality and lives. Participants' justifications of privacy related to either smaller spheres pertaining to the individual alone and to the concealment of certain aspects of their identity or lives even from family members or friends or to larger spheres, such as the family unit, i.e. concealing family matters from others. Some interviewees indicated that they do not wish to share certain aspects of their lives with others but did not specify exactly who 'others' referred to. As noted above, one participant indicated that privacy is important as it enables people to avoid having certain bits of identifiable information about them linked to allow a composite picture of the person to emerge. The elements of one's life one might want to keep private were not always explicitly discussed but some participants mentioned health issues or personal information such as name and address and property. It was evident in participants' responses that they viewed privacy as being intricately linked to personal identity. In other words, privacy enables us to reveal aspects of our person we wish to portray in certain contexts so that we are perceived in a certain light but also hide aspects that we do not think appropriate, useful, or safe to reveal. Participants' references to information that they are not willing to share with others may also have been related to assumptions made and conclusions arrived at about our person when third parties are privy to some information about our lives for which they often lack contextualising details. Such third-party assumptions and conclusions can be taken to be

far removed from the identity we think we portray to the outer world in a specific context.

Jacob

> Privacy means like that only you know that what you have, what you own so you don't need to someone else know that what's yours - you know what you have. That's my - in my opinion about privacy.

Danny

> Privacy is basically my personal information about the aspects of my life that I'm not willing to share with other people.

Harmony

> Linking different areas of your life and putting together a picture of you that you might not want other people to have.

Only four of the 26 participants had justifications in all three aforementioned categories.

Respect for people's views/wishes

Fewer than half (n=9) felt that privacy is important because it is an expression of respect for people. Respect was referred to in two main senses: respect for people's privacy by protecting information about them that they do not wish to have disseminated further and respecting people's wishes to preserve their own privacy via choices expressed through consent. The former in fact relates to preserving confidentiality while the latter demonstrates the close link people perceive between privacy and consent. A third view mentioned by a single participant related to respecting people's wishes to hold certain views.

Tina

> I think it's a bit of a respect thing, as well, that if people are obtaining your information without your knowledge, then you do - I think it's disrespectful as previously said. I don't know, I just feel that it's one person's choice to allow information to be given out to, you know, other parties whether it's for surveys or anything else. You have that choice of whether to give that information away or not.

Vallery

> *When you say privacy, what do you mean?*
>
> It means if I, for instance, give you some information or tell you some information and you say this is private and confidential, that you don't tell or show that to anybody else. It's for you and you only, for that company and that company only.

Contributes to mental health

A small number of participants (n=4) saw privacy as contributing to people's mental health and they referred to the issue using terms such as *mental health*, being affected *psychologically* and *emotionally*. They were all in agreement that privacy has an important function in maintaining and preserving good mental health.

Mandy

I don't think anybody can live peacefully without getting a private life.

So having privacy allows you to live the life that you want peacefully.

Yes, peacefully. That's important for your mental state, I think, with mental health.

Oh right, okay. Can you just explain that a bit more?

Like I give you an example that if somebody hinders with your ideas and you will be mentally upset that things are - not that things are not going - because everybody thinks in a different way. It's not necessarily that what one is thinking, one person is thinking is exactly right. So that hinders your mental state and you get upset and angry. That keeps - that shows in your atmosphere also.

Mel

But how does it affect you as a human being if this person knows about it?

I don't know, I won't feel very comfortable. If there is a particular thing that I want to hide about myself and I don't want the society to know it, then I don't want anybody to know it. It's something like that. It is possible that it's very common that people just go on spreading things and maybe she may not be very faithful to me and she may tell somebody else, then somebody else and it may be the whole world knowing about it.

But how does that affect you as a person?

Definitely it will affect me emotionally. Because if I have a particular condition, I don't want people to be talking about it or maybe sometimes it happens if a particular person is identified with some problem then people start keeping away. You may take an HIV patient for something, like if you come to know that that person is HIV, you won't have any contact with him. You won't let any other people come in contact with him, so that's not right.

Gives sense that you are in control of your life

Only three participants felt that privacy is important because it provides people with the sense that they have some control over their lives hence enabling them to take decisions about the direction their lives go in. Nine participants had *defined* privacy as being in part (or wholly) about control over identifying information but did not refer to privacy as offering greater control of their *lives*.

Trixie

How important is privacy for you personally?

It is important to me. I think it would be important to most people. I don't have a sense of being concerned about my personal medical information being used inappropriately because I am quite comfortable with the way it's managed. I'm very keen on my banking information remaining private. My son's health information being controlled by me in terms of what I tell the school, rather than the school being told by anybody else.

So to me I'm the gatekeeper there for the privacy for my son, although I don't actually withhold anything from them because it's in his best interest to actually have everybody knowing what's going on with him. But then the teacher and I will decide do we tell his classmates about his condition. And we have or do we then tell the whole student body; well no, we don't, because he needs to then be seen as [X] rather than the kid with the heart disease. So, that's different levels of privacy there as well.

Summary of privacy justifications

Five justifications were offered in relation to the value of privacy. Many participants spoke about the protection privacy offers in minimizing a range of harms from identity theft to marginalisation, physical, emotional, and social harms as well as harms to one's dignity. Privacy was considered to enable autonomous living and prevent intrusions of varying kinds into our personal and physical space. Half the participants highlighted the role that privacy plays in shaping the image we portray in a number of social contexts either as individuals or as units, for example a family unit. Some participants viewed privacy as demonstrating respect for persons while smaller numbers saw its value in preserving good mental health and providing us with a sense of control over what happens in our lives.

Contextualising privacy

Some features of privacy were not focused on specifically in the interviews but arose spontaneously in the discussions about privacy (see Table 25). Not all participants identified or referred to features that relate to privacy but those who did considered that privacy is perceived differently by different people, that there are different degrees of privacy and that there are different types of privacy.

Table 25. Chart 2 – Contextualising privacy

Respondent	Privacy is different for different people	There are degrees of privacy	There are different types of privacy
Danny			
Darren		x	
Don		x	
Haley		x	
Harmony			
Helen			
Henrietta		x	
Holly	x		
Jack			
Jacob		x	
John	x		
Mandy		x	x
Margaret			
Mary			
Mel		x	
Molly	x		x
Tegan			x
Teresa		x	
Tina		x	
Tracey		x	
Trixie		x	x
Vallery			x
Vanessa	x		
Verity	x	x	
Victoria		x	
Virginia	x		x

Privacy is different for different people

Six participants expressed the view that privacy is experienced differently by different people. The subjectivity attached to the concept of privacy was expressed most commonly through indicating that another member of the family held different views in relation to privacy as a result of their different personalities.

Vanessa

> As I said, my idea of privacy is very different to my partner's idea of privacy.

John

> Privacy, well - I can say privacy might be contested somehow. What I might consider private, somebody might say, no, it's not private to them. So that's why I say it might be contested.

There are degrees of privacy

Half the participants (n=13) indicated that privacy is graduated depending on our relationship with others. This provides a broader contextualising feature relating to the value of privacy in enabling the various facets of our personalities to be hidden or revealed. Participants also offered reasons for the degrees of privacy we experience in

relation to others; some mentioned harms that might arise if personal information were made available to the wrong people, while others indicated that the level of disclosure of information relates to trust and knowing that people will keep the information confidential. Some indicated that there are bits of information that they do not disclose even to the people with whom they have the most intimate of relationships. Other participants referred to degrees of privacy in a less direct manner by contrasting groups of people such as *everyone, the whole world* with *me* and levels of intimacy shared in different relationships, such as *friend* and *wife* These references demonstrate that respondents considered that there are different levels of privacy, as a result of which they monitor the amount of information they provide depending on the recipient of the information.

Tracey

> So if we are discussing something directly I would really want it to be private if it is identifying me in any way.
>
> *Why is it important to you? Why is that important?*
>
> I don't want everyone - the whole world to know what things are going on with me and what is personal.

Jacob

> Yeah, I think there is a relative kind of privacy. I mean that, for example, when you['re] with someone who you don't know maybe you have a higher level of privacy. When you['re] around someone like your friend maybe moderate privacy and when you have family, for example your wife, how you will get your privacy because you have to share with your wife what will you do. But still there is privacy.

On the surface, the content of this section may appear similar to that under the heading of *control of personal information* and *not sharing information received in confidence* and *aspects of one's life not shared*, all provided as definitions of privacy. While there is a connection, undoubtedly, the focus is quite different. What is at issue here is that people recognise that it is socially appropriate and even necessary to distinguish between the detail in information they provide depending on the social context, the intimacy of one's relationship with others, as well as the level to which they can trust someone. In this sense then the degrees of privacy we display towards others plays a central role in establishing and maintaining our relationships with others.

There are different types of privacy

A number of participants indicated that there are different types of privacy (n=6). Some participants initially referred only to informational privacy, an expected outcome given the discussion about data linkage. However, many of the participants volunteered the distinction between the different types of privacy while others offered this insight only when prompted by questions to the effect of, "So does privacy only relate to information?" or "Does privacy relate to other areas of life [other than information]?". Collectively, participants mentioned privacy in relation to information, decision-making, and access to their person or their space.

Trixie

> There's privacy around my banking details, my being able to go and hang out my knickers in the backyard. Those sorts of - I see it as different areas of privacy. Or at my son's school he has special needs and health issues and not everybody in the school knows that because that's his personal information. What it comes down to for me is I have a right to determine what information is released, that I have control of. I'm happy for all of our medical records to be used so that we can actually have effective health care. To me there are different areas of privacy in my life.

Molly

> *Okay. So for you does privacy only have to do with information that's stored in databases or is it more general?*
>
> I don't know, I guess it's more general.
>
> *In what way? ….*
>
> Yes, I don't want people just looking at us and spying on us like Big Brother but, apart from that, I want to be able to walk down the street when I want to walk down the street and not have someone staring at me. I don't know.
>
> *Okay. Does it relate to your home as well?*
>
> Yeah, I guess so.
>
> *Right.*
>
> I don't know, I guess I want to do it my way, I don't want anyone else to tell me what to do.

Summary of contextualising features of privacy

Participants contextualised privacy in a number of ways. Some participants recognised that privacy is viewed differently by people and that its value cannot be stated objectively. Participants also referred to the degrees of privacy we experience depending on the relationships considered. They indicated that in close relationships we have greater levels of disclosure (but not necessarily absolute disclosure) whereas in

more distant relationships, or in ones where the level of trust is low, we seek greater levels of privacy. Arising from this is that the degree of privacy we observe in relationships defines the kind of relationship we establish. Finally, despite the discussion taking place primarily in relation to informational privacy, a number of participants recognised that there are different types of privacy.

Discussion

Defining privacy

This section considers the implications of the definitions provided by participants for data linkage and discusses them in the context of the literature about privacy. Providing a definition for privacy was seen as a great challenge by some participants. Despite their uncertainty, however, all participants provided very insightful explanations and additional clarifications, either spontaneously or when further prompted.

Although the focus of the study was on data linkage, which primarily relates to informational privacy, participants offered more general definitions of privacy; many participants saw privacy as a multi-faceted concept. This reflects the treatment privacy has received in the literature. The definitions bore a resemblance to definitions in the scholarly literature although, as expected, they were not as sophisticated.

A common thread in many of the responses was that privacy relates to aspects of our person that we do not wish to share with others. This is significant when considering research that requires access to data pertaining to a number of aspects of our lives, including health information. With the anonymisation of data achieved in data linkage, access to data that may either embarrass or be perceived as harmful in a more material sense is very small. In other words, what some participants most fear in relation to the disclosure of information about them would be very unlikely to occur because of the way in which data are anonymised and handled. Therefore, knowledge of the protection mechanisms available would considerably assist in reducing people's privacy concerns about such linkages. Evidence of the reduced concerns that these participants expressed about anonymised data was ample, as many participants noted in the interviews that information not attached to their identifying information ceases to hold the same value as identifiable information. This accords with findings in a recent Australian study in which participants showed a lower degree of concern regarding the

need for consent when assured that health information intended for secondary uses was de-identified (31). In earlier research (90), however, most participants perceived no such difference between identifiable and de-identified data. In my study we see from participants' definitions of privacy and related qualifying remarks that they perceived *identifiable* information as relating to the core essence of privacy. This is further highlighted when taking into account participants' responses to the use of de-identified information.

Participants sometimes related the disclosure of information to aspects of their family unit rather than more narrowly to their person. The importance of the latter is discussed by Westin (41) in his examination of the conditions under which people can lose their sense of self in total institutions. Participants' reference to the family unit was not further probed in the interviews but could be the result of their newly arrived child and a more cemented view of their function as a single unit rather than distinct individuals comprising a family.

Participants' views that privacy relates to the protection and control of identifying information is consistent with theories of control in the privacy literature (36, 41, 42). Some participants also considered the protection of information posthumously important but it was unclear if they believed that this aided in the preservation of the deceased person's integrity or whether this was felt to be important because of the effect that release of data might have on the family. This echoes the requirements imposed in privacy legislation in some Australian States, as can be seen by the prohibition to disclose identifiable health information for a period of 30 years after one's death in the Victorian Health Records Act 2001 (s 95)(135).

Defining privacy as anonymity is well-established in the literature (44) and these participants did view anonymity both in a physical sense and in relation to identifiable information being known by others.

Justifying privacy

The justifications for privacy that participants provided matched well with accounts in the literature. Minimization of harm was key among the justifications and touched on many areas of human existence and interaction, from identity theft to marginalisation as a result of disclosure of certain facts about people. These participants were very aware of the need to preserve one's privacy on the internet, which is congruent with

findings from a review of the literature that revealed that adults have a greater awareness of the dangers that can arise from online social networking than teenagers (136). The diverse personal circumstances these participants had experienced shaped how they considered harm resulting from privacy breaches. For example, at least one participant had experienced persecution and his sense of the harms that could arise from privacy breaches was of a graver nature.

The role that privacy plays in promoting autonomous living was central for many of these participants and related very closely to its treatment in the literature (42, 44). Participants made reference to decisional privacy without which autonomous living cannot be achieved (38), and accessibility privacy; for example, pertaining to unwarranted intrusions in one's home environment (51). In this sense, although not explicitly stated by participants, the underlying justification in these contributions relates to the promotion of a sense of self. As Gostin notes (53) people cannot develop or maintain a sense of self without some degree of privacy being afforded to them.

Although only a minority, some participants provided justifications for privacy that related to the promotion of good mental health. Goffman's (45) analysis of the harm that the deprivation of privacy can cause to mental health was discussed in Chapter 1 and, while his analysis relates to extreme conditions, it nevertheless presents a chilling account of the effects that can result if no privacy is granted. This aspect is closely related to the harms participants identified as a result of intrusions into people's private matters, including the disclosure of certain health conditions which people may not wish to become public knowledge.

Participants both defined and justified privacy in relation to aspects of their lives they did not wish to share with others. While this is not a standard definition of privacy in the literature, it is certainly a justification for privacy as expounded in detail by Rachels (36). The value of presenting certain aspects of oneself to certain people in one's circle was clearly articulated by participants. A major concern for some participants appeared to be the ability to create a composite picture of an individual based on access to numerous identifiable sources of data. The suggestion here was that their image is of great significance to them and that it is important to be able to 'manage' this, as Shoemaker also suggests (43). It was for this reason that the separation of tasks employed in data linkage was such a reassuring feature for majority number of

participants, some of whom voiced the view in exactly these terms. The participants' frequent reference to the non-identifiability of data as a protection mechanism when discussing the scenarios in conjunction with their great concern at researchers handling identifiable data in Scenario 4 provide strong evidence for this. The significance of greater public knowledge and understanding of such privacy protection features in the linkage of data sets therefore becomes apparent.

Two perceptions of control were advanced in participants' contributions, the first of which has been discussed in relation to the definition of privacy and related to control over information. When contextualizing privacy, some participants considered that privacy is important as is provides a sense of control in people's lives. Respect for people's privacy allows people to engage, or not, in certain activities and not be included without their knowledge. Controlling the information others have about you can be one way in which people maintain control over their lives. However, it is not the only way and most of the participants who spoke of controlling access to information about them did not extend this to privacy as a vehicle for exerting control over their whole lives.

The features of privacy identified by some participants relate closely to those identified in the literature. For example, congruent with views expressed by Westin (41), privacy can be construed differently by different people, there are different levels of privacy depending on the person or group with whom we are interacting (36), and there are different kinds of privacy, one of which is informational privacy (35).

Similarities with the RALC theory of privacy

The contributions made by participants in relation to the definition of privacy, its justification, and the management of privacy via certain controls such as consent, or external controls such as mechanisms and legislation that aim to protect privacy bears similarity to the RALC theory of privacy, which was presented in Chapter 1, even if participants' contributions may not always have been expressed in exactly the manner the theory is conceptualised. Participants' definitions of privacy related to the *naturally private and normatively private situations* referred to in the RALC theory which are "…*protected from intrusion, observation, and surveillance by others*" (39 p.76); that is, participants referred to privacy offered in our homes by physical means but also the

protection from intrusions into our lives in relation to information we provide to others in a variety of contexts.

The justifications for privacy also aligned closely with views expressed by Moor and Tavani in the RALC theory of privacy; through their contributions, participants demonstrated that they saw privacy as being related to promoting the development of the self (39), as offering us the ability to manage our lives and experience different relations with people (48), and providing some protection from harms thus enabling us to control to an extent the level of risk we wish to assume in our dealings with others (48) (for example, not posting photos of her children on Facebook enabled one participant to control the level of exposure her children have to others).

Participants appreciated the contribution individual and external controls play in promoting the protection of privacy. They also recognised the value of external controls where no individual controls were available. In other words, they felt that external controls available in data linkage in the form of the separation of tasks and legislation aiming to protect privacy provided adequate protection and that individual controls such as consent were not required where adequate external controls were in place.

Conclusion

The participants' conception and understanding of privacy showed concordance with key issues described in the literature. The definitions participants provided included key concepts such as control of information, protection of identifying information, and anonymity. Similarly, issues such as harm minimization, autonomy, respect, and the facets of our person we reveal or conceal through privacy are justifications for privacy which are also developed in the scholarly literature. Participants also recognised that privacy is evident in varying degrees depending on our relationships, that there are different forms of privacy, and that it is variously interpreted by people, all of which are features of privacy analysed in philosophical works on privacy. It is therefore evident that lay people such as the participants in this study did have a solid understanding of a number of key concepts in relation to privacy. They held concerns regarding the inappropriate use of their identifiable information and had a refined understanding of the important role that privacy plays in all facets of human activity.

These findings provide insight into some lay people's understanding of a concept which is key in all our dealings with individuals and organisations alike in Western societies. The findings also clarify views held in relation to the non-identifiability of health and personal data as used in data linkage.

CHAPTER 9

DATA LINKAGE AND COMMUNITY ENGAGEMENT

Somewhere, something incredible is waiting to be known.

Carl Sagan
American astronomer, writer and scientist (1934-1996)

Introduction

The findings of the three previous chapters make clear that lay people are able to engage in discussion about the ethical acceptability of data linkage. With only minimal input regarding the data linkage process, participants demonstrated their ability to understand key features of the process and take these into account when considering both privacy and consent requirements. In addition, these lay people also had the ability to grasp key ethical concerns ranging from what privacy is and its importance in human interactions to how and when health and personal information can and should be used in the context of data linkage.

The interviews I conducted were a form of public consultation and shed light on individuals' perceptions and understandings. Their views were shaped, to an extent, during the interview, as a result of minimal intervention in the form of, firstly, information about data linkage and, secondly, probing questions designed to invite participants to consider other aspects of the topic under discussion. With extended knowledge and in-depth consideration and discussion of any topic of public interest come more informed and settled views. In a short interview, there are limits to the depth of knowledge and understanding a lay person can gain in relation to such processes and the related ethical issues.

This chapter uses a different approach to public consultation, a citizens' jury[83], to present insights on similar topics to those discussed by the participants in Phase 2. The main focus of this chapter is on one component of a citizens' jury held in South Australia; a questionnaire administered before and after the jury proceedings. The data considered in this chapter provide insight into participants' views on a number of issues relating to data linkage, such as use of identifiable and de-identified health data, jurors' understanding of data linkage, confidence in legislation/guidelines aiming to protect privacy, views on sacrificing personal privacy to achieve common goods, and views on notification of future use of health data at the point of initial collection. Also considered in this chapter are changes to these views which resulted from exposure to information surrounding data linkage itself as well as legal and ethical considerations pertaining to this activity in the context of vaccine safety surveillance. The findings indicate that the citizens' jury was educative and that exposure to expert information and the ensuing discussions resulted in shifts in some views. Before describing the design of this study and presenting the findings, I briefly describe the rationale for using a citizens' jury as part of my overall research and clarify which aspects of the citizens' jury data I am focusing on.

Rationale for use of a citizens' jury

The use of citizens' juries in this component of the overall research project was important, as it helped to determine public views regarding the acceptability of a public health intervention such as data linkage. It provided an opportunity for a fuller discussion surrounding privacy and consent, which can be very confusing and can often become blurred in the public mind. This deliberative forum was held in the context of the larger VALiD project of which my study is one component. As such, the focus of the forum was on the use of data linkage in the context of vaccine safety surveillance. Therefore, the key question the citizens' jury considered was: *Under what circumstances is it acceptable to link data for the purposes of vaccine safety*

[83] A citizen's Jury is one of many models of public consultation. The underlying understanding is that Citizen's Juries which comprise a small representative sample of the population can deliberate with conscience and arrive at a decision which is informed and which is also reflective of community values if they are provided with balanced expert information on important aspects of the topic in question. The deliberative process is such that during the course of the forum participants have full access to experts with knowledge in a variety of areas under consideration. The cornerstone of the approach is that jurors arrive at an *informed* position, rather than merely providing their initial intuitive and variously informed responses to an issue, which can often be the case with simple opinion polls or focus group discussions (137).

surveillance? In considering this question, the jury also examined more general issues of privacy, consent and legal and technical protections available for health data in Australia.

I do not report on the jury's deliberations in this chapter. Rather, I focus on the pre and post questionnaire which I administered as part of the deliberative process. The benefit of obtaining views and participants' understanding of data linkage before and after the jury proceedings is that it enabled me to check to what extent the proceedings affected their understanding of data linkage and their views on the use of health and personal information in data linkage.

Design

While this chapter focuses specifically on the pre and post jury questionnaire administered as part of the *Vaccine Safety Data Linkage Community Forum* (also referred to a citizens' jury), a brief description of the citizens' jury is provided in order to provide a context within which the questionnaire was administered.

Scope of citizens' jury

The *Vaccine Safety Data Linkage Community Forum* was convened in Adelaide, South Australia over the weekend of 25th and 26th March 2011 after receiving ethics approval from the University of Adelaide Human Research Ethics Committee.

The aim of the citizens' jury was to review the acceptability of data linkage as a vaccine safety surveillance mechanism, comparing it with existing passive surveillance mechanisms[84]. The jury reviewed the legal and ethical arguments and technical feasibility of obtaining consent for data linkage and deliberated on whether informed consent was ethically and technically required. It was these integrally related issues concerning privacy, consent and public goods that were of primary interest to me.

Participants

Selection criteria

The demographic variables used to stratify the selection of the jury were: gender, age (age categories 18-34, 35-54, 55+), paid work and non-work, and income (approximately

[84] *Passive surveillance* relies on voluntary reporting of adverse events following immunisation from health care professionals.

half with median household income >AUD$887 per week at the time according to the Australian Bureau of Statistics ((138)) and half with median household income ≤ AUD $887 per week).

Identification and selection process

The identification and screening of potential participants was undertaken by the Adelaide office of *Harrison Research*, a privately owned social and health research agency. Individuals previously involved in the Health Omnibus[85] and Health Monitor[86] Surveys are given the opportunity to express interest in participating in future research via Harrison Research, which maintains a register of such individuals. Once individuals expressed interest in becoming involved in the community forum, *Harrison Research* provided them with the study material on the research team's behalf in order for potential participants to decide whether they did indeed wish to take part. Consent forms were made available well in advance of the citizens' jury (along with information regarding the project) and these were signed and collected on the first day of the proceedings.

Demographics

A total of 18 individuals had agreed to participate. However, two individuals decided not to take part, reducing the total number of participants and respondents to 16, a size well within the norms of citizens' juries (137). Participants ranged in age (24-68 years of age) and education (year 11 or equivalent to postgraduate degree level) and included an almost equal number of female (n=9) and male participants (n=7). Table 26 below provides the respondents' demographic details collected via the pre jury questionnaire, administered on the first day of the forum.

[85] The Health Omnibus Survey (139), run by the SA Department of Health, is an annual health-related face-to-face survey involving approximately 400 South Australian households. It commenced in 1991 and operates out of the University of Adelaide on a user-pays basis with organisations in the health sector and includes questions which relate to the needs of specific projects or to their organisation.

[86] The Health Monitor Survey (140), also run by the SA Department of Health, serves as a supplement to the Health Omnibus Survey. It is conducted three times per annum via telephone interviews with around 2000 South Australian households and focuses on health and wellbeing.

Table 26. Citizen's jury demographic details

Age group	Sex	Highest level of education
18-34 (n=4)	M (n=1) F (n=3)	Year 11 or equivalent (n=1) Senior secondary school (n=1) Bachelor degree (n=1) Graduate diploma/certificate (n=1)
35-54 (n=6)	M (n=3) F (n=3)	Year 11 or equivalent (n=1) Trade qualification/apprenticeship (n=1) Senior secondary school (n=1) Bachelor degree (n=1) Graduate diploma (n=1) Advanced diploma (n=1)
55+ (n=6)	M (n=3) F (n=3)	Trade qualification/apprenticeship (n=1) Senior secondary school (n=2) Bachelor degree (n=2) Post graduate qualification (n=1)

Participants were invited to a dinner on the evening before the commencement of the proceedings to become acquainted with the research team and each other so as to promote a relaxed atmosphere on the first day of the proceedings.

Jury materials

Information leaflets were made available to participants after each expert presentation. Information leaflets made available related to the following areas: vaccines, vaccine safety, data linkage, ethical issues arising in data linkage, consent options in data linkage, and legal issues arising in data linkage.

The deliberative forum research team were aware of the need to ensure that the materials, the mode of presentation, as well as the overall process were transparent, fair and unbiased. To this end, numerous discussions were held and the materials were reviewed extensively. In the feedback survey participants were asked to complete over the phone, they were asked whether they believed that the proceedings had been conducted in an unbiased and neutral manner. The majority of respondents indicated that they were either *satisfied* or *very satisfied* with this aspect of the proceedings.

Pre and post jury questionnaire

Each juror completed a brief questionnaire prior to and after the deliberative process. The aim of the questionnaire was two-fold: firstly, it aimed to ascertain views and knowledge about data linkage, privacy, consent, laws and regulations intended to protect

privacy etc. pre jury and post jury. Secondly, it aimed to determine whether the jury had an educative and/or transformative effect on participants.

The pre and post questionnaires were identical in all respects except for three questions in the pre jury questionnaire relating to age, sex, and level of education (see Appendix 17). A total of 12 questions, predominantly drawn from themes explored in Phase 2, were included in order to enable a comparison between responses in the separate studies. The response options for all questions, except the demographic questions included in the pre questionnaire, were: *Yes, No, Not sure, Under certain circumstances* (with the option for brief commentary). In order for participants to be able to respond appropriately, certain terms had to be defined (definitions were included in both pre and post questionnaires). The terms defined were: *data linkage, identifiable* health information*, de-identified* health information.

Analysis

I analysed the questionnaire data descriptively and statistically. The descriptive analysis aimed to track numerical and directional changes in participant views. In order to achieve this, I recorded a number of variables for each question: the number of changes per question from pre to post jury; the nature of the changes, e.g. from a negative response to a positive response; and the number and nature of constant responses from pre and post jury. I also kept a record of de-identified individuals' responses and changes to ascertain if any patterns emerged in relation to specific respondents.

While exploring the statistical significance between the two time periods (pre intervention and post intervention[87]) was not the primary focus of the analysis, changes in the distribution of responses between the two time periods were also examined statistically. The null hypothesis was that no changes in responses would occur between time 1 (pre intervention) and time 2 (post intervention). Attempts were made to apply a number of additional statistical analyses in relation to the participants' demographic information and inconsistencies between responses. However, due to the limited number of participants (n=16) this was not possible.

[87] 'Intervention' refers to the citizens' jury in this context.

Jury details

Deliberative process

'Educating' lay members of the public on a specific topic is central to the concept of deliberative forums, as this is the process which arms participants with the knowledge required to arrive at a considered view. The initial phase of the deliberative process allows both experts to impart key facts about the issues in question and participants to request further clarification on complex aspects of the topic.

The proceedings were moderated by an independent moderator and transcribed by a professional transcriber for subsequent analysis. In addition, the small group proceedings were audio-taped and transcribed by a professional transcription service post jury.

On Day 2, all research staff, except for the moderator, left the room for several hours while participants engaged in discussions in order to arrive at their final deliberations. The research team's absence from proceedings at this stage was deemed appropriate, as it aimed to enable participants to freely discuss any issues they thought were relevant to the jury charge.

Results

The analysis of the pre and post questionnaire responses aimed to both shed light on the participants' views on the issues examined and to track changes to initial potentially 'uninformed' views as opposed to considered views following the educative process of the citizens' jury. Table 27 provides an overview of the themes I explored and the majority pre and post jury positions.

Table 27. Citizen's jury questionnaire themes and majority pre and post positions

Question themes	Pre jury majority position	Post jury majority position
It is acceptable for the safety of vaccines to be monitored by data linkage?	✓	✓
Permission for use of identifiable health data in research should be sought	✓	✓
Permission for use of de-identified health data in research should be sought	✓✗	✗
De-identified health information belongs to the person it is about	✓✗?	✗
When you first give your health information, they should get your permission for future de-identified uses	✓	✓✗
People sacrifice of some personal privacy for benefits to society	✓?	✓
The jury was confident in laws, rules, guidelines & measures aiming to protect health information	?	✓
The public should be better informed about research in Australia	✓	✓
The jury had knowledge of use of health information in research without consent	?	✓
The jury understood what data linkage is	?✓	✓

The tick denotes an affirmative response, the cross denotes a negative response, and the question mark uncertainty.

Table 27 provides a sense of the areas where most marked changes to views were observed. However, it does not indicate the strength of the views within the group pre and post jury. Therefore, in cases where the same view was held pre and post jury even though it may appear that there were no changes over the course of the jury, in fact, for most questions there were shifts which affected the final number of persons supporting the predominant view. I present such shifts in Table 28.

Multiple symbols indicate an almost even spread of views. A shift occurred in relation to permission required for the use of de-identified data: pre jury, there was a divide between the views that permission is required and that permission is not required for the use of identifiable data. This shifted to a majority negative response post jury. Multiple responses in relation to ownership of de-identified data were expressed pre jury. However, post jury the majority view was that de-identified data does not belong to the person to whom it relates. Pre jury, the majority view in relation to whether people should be notified about future uses of their de-identified data was affirmative but post

jury some revised their response to a negative response. In relation to sacrifices of privacy for the public benefit, pre jury some were uncertain as to whether such sacrifices of personal privacy should be made. Post jury, however, views were revised to a majority affirmative view. There was great uncertainty about the protections legislation provides for health information pre jury but post jury participants were more confident that legislation and regulations do provide protections for health data. Pre jury the majority of jurors was unaware that health data are used for research purposes without consent from the individuals whose data it is. Similarly, many jury members did not know what data linkage was. Post jury, however, all participants indicated that they understood what data linkage is.

Descriptive analysis

The pre and post questionnaire data were initially analysed descriptively. As previously stated, this analysis aimed to capture participants' understanding of key concepts and their views and to determine if any shifts in perceptions emerged post jury.

Table 28 below provides an overview of the findings from the pre and post jury questionnaires detailing the number and nature of changes in response to the questions asked as well as the number and nature of responses that remained constant despite the 'educative' process experience by participants[88].

[88] It is perhaps important to note that when participants were contacted after the deliberative forum and asked to provide feedback, no participants had changed the position they had arrived at during the jury process. Furthermore, all participants found the experience educative and indicated that the information imparted was both useful in their deliberations and interesting.

Table 28. Overview of citizen's jury findings from pre and post questionnaires

	Questions asked	No. of changes per question pre to post jury	No. and nature* of changes	No. of affirmative responses pre and post by same participants	No. of negative responses pre and post by same participants	No. and nature of other same responses pre and post jury
1	Is it acceptable to link data to monitor the safety of vaccines?	3	2 (not sure→yes) 1 (ucc** →yes)	13	Nil	Nil
2	My permission should always be asked for before my identifiable health information is used for research purposes	6	3 (yes→ucc) 1 (yes→no) 1 (not sure→yes) 1 (not sure→no)	9	1	Nil
3	My permission should always be asked for before de-identified health information about me is used for research purposes	8	5 (yes→no) 1 (ucc→yes) 1 (yes→ucc)	Nil	8	1 (ucc)
4	De-identified health information about me belongs to me	11	4 (yes→no) 4 (not sure→no) 1 (ucc→yes) 1 (yes→not sure) 1 (no→ucc)	1	4	Nil
5	People have an obligation to sacrifice some privacy in research if the outcomes of the research will benefit society as a whole	7	3 (not sure→yes) 1 (no→ucc) 1 (ucc→yes) 1 (not sure→ucc) 1 (no→yes)	8	Nil	1 (not sure)
6	If the handling of people's information is protected by strict laws, rules and guidelines that do not let researchers analyse identifiable information, I am happy for my identifiable information to be used in data linkage projects	4	2 (yes→no) 1 (not sure→yes) 1 (no→yes)	11	Nil	1 (not sure)
7	Permission to use de-identified health information in research should be requested at the time the information is first collected (e.g. hospital admission)	7	5 (yes→no) 1 (yes→ucc) 1 (not sure→yes)	7	2	Nil
8	The public should be better informed about the kinds of health research we do in Australia	1	1 (not sure→yes)	14	1	Nil
9	I have confidence in the legislation and measures that aim to protect health information that's used in research	11	8 (not sure→yes) 2 (no→yes) 1 (yes→ucc)	4	Nil	1 (not sure)
10	If I had a better understanding of the measures that help protect health information, I would be more likely to agree to the use of my identifiable health data in data linkage	4	3 (yes→no) 1 (yes→not sure)	12	Nil	Nil
11	People's health information is currently sometimes used in research without their permission	10	9 (not sure→yes) 1 (not sure→no)	2	1	3
12	I completely understand what data linkage is	10	7 (not sure→yes) 3 (no→yes)	6	Nil	Nil
	*possible choices included *yes, no, not sure, under certain circumstances*			**ucc=under certain circumstances		

As the citizens' jury focused on the area of vaccine safety surveillance, the initial question asked in the pre and post questionnaires related to the acceptability of data linkage for

the purpose of vaccine safety surveillance (Q1). In response to whether it is acceptable to link data to monitor the safety of vaccines, all but three of the 16 participants responded affirmatively. In the pre jury questionnaire, two participants had indicated that they were not sure whether data linkage for this purpose was acceptable, while one participant indicated that this was acceptable under certain circumstances. In the post jury questionnaire all three indicated that data linkage for this purpose was acceptable.

The prevailing view both pre and post jury regarding whether permission should be obtained for the use of *identifiable* health information for research purposes was that it should (Q2). Post jury only two participants revised their view and responded in the negative, while three indicated that permission should only be sought under certain circumstances. Put simply, these participants shifted from a more 'conservative' view to a less 'conservative' view during the jury process.

Conversely, the jury process appears to have resulted in most participants thinking that de-identified data could be used for research purposes without consent. When asked if permission should be sought for the use of *de-identified* health information for research purposes, participants predominantly responded in the negative, both pre and post jury, or revised their response from an affirmative response pre jury to a negative one post jury (Q3). When asked whether consent for the use of de-identified health information should be sought at the point of initial data collection (e.g. when admitted to hospital), the vast majority responded in the affirmative pre jury while only half the respondents responded in the affirmative post jury (Q7). Five participants revised their response from the affirmative pre jury to the negative post jury thus providing an overall almost even split between the two opposing views. When examining Q 3 and Q 7 together to look for inconsistencies across responses (e.g. jurors who had indicated that it was not necessary to obtain consent for the use of de-identified data and also indicated that consent should be sought at point of initial data collection), it was found that six individuals held consistent views post jury and six held inconsistent views. Of the six who held inconsistent views, three participants' responses remained inconsistent in both pre and post jury responses. The remaining individuals' views cannot be classed as inconsistent because they went from a response of 'under certain circumstances' to an affirmative response or, in one case, vice versa.

When asked whether *de-identified* health data belongs to the person to whom it pertains, over half either thought it did or were uncertain pre jury (Q4). However, post jury there was a distinct revision of views with half the participants revising their view and stating that de-identified health data did not belong to the individual to whom it referred. These revisions resulted in the vast majority supporting this view post jury.

The vast majority of participants confidently held the view (i.e. both pre and post jury) that their identifiable health information may be used without consent in data linkage projects if there are strict laws, rules, and guidelines in place to prevent access to identifiable information by researchers (Q6).

All but two participants held the view both pre and post jury that the public should be better informed about the kinds of health research conducted in Australia. Of the two who did not provide an affirmative response pre jury, one revised her response to the affirmative post jury, while the other remained firm in his negative response (Q8).

Four questions related to the participants' level of knowledge or understanding of current states of affair or processes relating to the areas under consideration (i.e. Qs 9-12). Three of these questions (Qs 9, 11, 12) yielded the greatest variation in responses pre and post jury but one of the questions (Q 10) did not, possibly because it was expressed as a hypothetical. Participants felt more confident post jury in the protections provided by legislation and other measures in relation to the use of health information in research than they did pre jury (Q9). Similarly, the majority were more aware post jury that people's health information is currently sometimes used in research without their permission (Q11). The lack of understanding regarding the nature and purpose of data linkage indicated in the pre jury questionnaire was removed post jury with the vast majority of participants indicating that they now understood what data linkage is (Q12). Much less variation between pre and post jury responses was noted in relation to the hypothetical relating to whether a better understanding of the measures that help protect health information would be more likely to prompt participants to agree to the use of their identifiable health data in data linkage (Q10). The vast majority of respondents responded affirmatively in both questionnaires and there were three respondents who revised their answer to a negative response, while one revised their response to 'not sure'.

Statistical analysis

All analyses (see Table 29) were performed using Stata version 11(141) and changes in the distribution of responses between the two time periods were assessed formally using the Stuart-Maxwell test.

Table 29. Statistical analysis of citizen's jury pre and post responses

Questions	Chi2	df	Prob>chi2
1 Is it acceptable to link data to monitor the safety of vaccines?	3.00	2	0.223
2 My permission should always be asked for before my identifiable health information is used for research purposes	5.67	3	0.129
3 My permission should always be asked for before de-identified health information about me is used for research purposes	5.00	2	0.082
4 De-identified health information about me belongs to me	5.79	3	0.122
5 People have an obligation to sacrifice some privacy in research if the outcomes of the research will benefit society as a whole	6.44	3	0.091
6 If the handling of people's information is protected by strict laws, rules and guidelines that do not let researchers analyse identifiable information, I am happy for my identifiable information to be used in data linkage projects	2.00	2	0.367
7 Permission to use de-identified health information in research should be requested at the time the information is first collected (e.g. hospital admission)	7.00	3	0.071
8 The public should be better informed about the kinds of health research we do in Australia	1.00	2	0.606
9 I have confidence in the legislation and measures that aim to protect health information that's used in research	11.00	3	**0.011**
10 If I had a better understanding of the measures that help protect health information, I would be more likely to agree to the use of my identifiable health data in data linkage	4.00	2	0.135
11 People's health information is currently sometimes used in research without their permission	10.00	2	**0.006**
12 I completely understand what data linkage is	10.00	2	**0.006**

There was a statistically significant difference in responses between pre intervention and post intervention in relation to three questions: Q9 (p = 0.011), Q11 (p=0.006) and Q12 (p=0.006). While differences in relation to other questions were not statistically significant, three questions showed great shifts between the pre and post intervention

time periods (Q3 (p=0.08), Q 5 (p=0.09) and Q7 (p=0.07) - see Table 3 for details regarding direction of shifts)[89].

Analysis per respondent

There were no patterns of note with regard to age, gender or level of education. A statistical analysis of these data was not feasible due to the small sample of participants[90].

Summary of findings

The findings indicate that the jury process assisted in the clarification of concepts and the revision of views based on new information and consideration of technical, ethical, and legal issues. The post jury views expressed by participants indicate that these individuals believe that consent should be sought for the use of identifiable health data in research but not for the use of de-identified health data, which they viewed as not belonging to the individuals to whom it relates. Participants felt it acceptable for identifiable personal information to be accessed for the purposes of data linkage provided that strict measures and protections were in place. Post jury participants were almost evenly divided in relation to their preference for notification of future use of health data. Finally, post jury there was strong support for the view that people should sacrifice some personal privacy for the benefit of society.

Discussion

Two sets of insights were obtained by administering the pre and post jury questionnaires. The first relates to what using the questionnaire actually showed; it demonstrated that the citizens' jury had educative value, as it contributed significantly to participants' understanding of factual information. In addition, it showed that the deliberative process contributed to shifts in views. The second set of insights relates to what the questionnaire data themselves revealed. The range of responses and the final views held by respondents provided insight into the views and values held by a group of South Australians ranging in age, education levels and socio-economic status. In

[89] This analysis was conducted by Thomas Sullivan (Statistician, Data Management & Analysis Centre Discipline of Public Health University of Adelaide).

[90] Michelle Lorimer (Statistician, Data Management & Analysis Centre Discipline of Public Health University of Adelaide) assisted with this aspect of the study

addition, the findings are an indication that such views may be held by a large portion of the population but such a determination cannot be made conclusively based on these data given the small sample.

Before discussing in greater depth the specific insights gained in relation to the participants' understanding, views, and values, it is important to make a general observation about the participants. Depending on the method of participant selection, citizens' juries do not always attract individuals who are positively disposed towards the topic of interest, as such forums also provide an opportunity for those opposed to particular topics to voice their oftentimes strongly-held views. In the case of this jury, however, the almost unanimous response to the initial question regarding the acceptability of data linkage for the purpose of vaccine safety surveillance may indicate that this group was mostly in favour of the administration of vaccines. A close examination of the rest of the responses, however, does not appear to indicate a bias towards data linkage as a result of their favourable disposition towards vaccines.

Complex issues involving consent for the use of identifiable data cannot always be answered in a uniform and consistent manner, as there are numerous facets and factors which influence an individual's final response. This is particularly so in responses to written questions where respondents do not have the ability to provide qualifications to their responses. The complexity of the issue was evident in respondents' views regarding the requirement to provide consent for the use of identifiable data (Q2). While they responded largely in the affirmative to this question, they also almost unanimously agreed that the use of their identifiable data may be permitted without consent for data linkage purposes provided that researchers are not privy to their identifiable data (in accordance with current laws, regulations and guidelines)(Q6). The consistency of their responses pre and post jury points to the fact that respondents were not confused by an initial lack of understanding of the ethical and technical issues requiring consideration. If they had been, it is assumed that there would have been greater shifts in the responses post jury. A plausible explanation for the inconsistency between the two responses is that generally speaking, these people want or prefer to be informed about the use of their identifiable information. However, when they are aware that protective measures are in place, they have no, in principle, objection to its use for research purposes, especially when they understand what data linkage entails.

In contrast, according to half the group prior to the jury and in an even more pronounced manner post jury, the use of de-identified data did not require consent. The shifts may in part be a result of both ethical issues discussed (e.g. communitarian views regarding common goods) and the limited legal requirements for uses of *de-identified* data in research. When comparing responses to Q3 and Q4 pre jury, there was a mismatch between responses, i.e. one might expect that the view that permission is required for the use of *de-identified* health information should be accompanied with the view that de-identified health data *belongs* to the person to whom it refers. This however, was not always neatly matched. The jury proceedings must have provided some clarity regarding ownership of de-identified health data given the great swing in views which, post jury, were very consistent with participants' much stronger view that permission does not have to be sought for the use of de-identified data. This is interesting to note, as ownership of data was not overtly and specifically focused on in any of the expert presentations or clarifications to the group despite the issue being alluded to in discussions surrounding the implications of rights for consent.

Even though participants indicated that de-identified health data did not require permission for use, the majority pre jury indicated that permission for future uses of their de-identified data should be sought when data are first collected, for example, at the hospital where a patient is being admitted. Post jury, however, there was a shift resulting in only half the participants expressing the view that permission should be sought at the initial data collection point. It may be that participants who supported notification had in mind the ideal situation of always being notified of future uses of de-identified health data at the initial point of data collection even though, in principle, they do not have objections to such data being used without consent, as indicated in their previous responses. Clarification of this issue could only be achieved by further probing post jury, a method not within the scope of this particular activity.

Participants' views were influenced by the jury proceedings in relation to sacrificing some privacy for the common good. During the jury, participants were given a balanced account of the ethical arguments for and against strict privacy controls. Post jury there was a distinct shift in views with the prevailing view being that we all have an obligation to sacrifice some privacy in research in order to yield the benefits that research provides.

The fact that this group consistently held the view (pre and post jury) that the public should be better informed regarding the research being conducted in Australia may relate to the fact that these people are known to be willing to participate in research projects and are therefore possibly positively disposed to research. This is recognized as a limitation of the study, as it potentially introduces a selection bias.

There is clear evidence from the shifts in participants' responses to questions requiring knowledge or understanding of related issues (Qs 9, 11 & 12), i.e. factual information, that the deliberative process provided an enhanced level of understanding in relation to legal issues, current research practices and the nature of data linkage. The phrasing of Question 10 (*If I had a better understanding of the measures that help protect health information, I would be more likely to agree to the use of my identifiable health data in data linkage*) may have proved to be unfortunate, as the shift to a negative response by three participants or to uncertainty by a fourth respondent is difficult to interpret. A negative response to this statement following a previously held affirmative response makes it difficult to ascertain the true meaning behind this shift.

Overall, the views expressed in the questionnaire may demonstrate more broadly that people have firmly held positions in relation to privacy and its protection via mechanisms such as consent. It is apparent that people were able to distinguish between requirements for uses of identifiable versus de-identified data, even before any educative process or discussion took place. It is also evident that complex issues of great public interest and relevance can be explained and clarified to a degree that the average member of the public seems to able to understand. A better understanding of issues that affect the public may lead to a greater acceptance of new approaches to problems which have plagued our society for years through the introduction of data linkage. It was evident from participants' responses that an understanding of the protections in place instils in them greater confidence regarding the uses to which their identifiable data are put (e.g. for the purposes of data linkage).

Limitations

While interesting findings arose from the pre and post questionnaire analyses, the very small number of participants limits my ability to claim that the findings are generalizable. Future research in this area might consider holding a number of citizens'

juries around Australia, the geographic spread of which may add further benefits to its conduct.

Conclusion

This chapter has presented two key sets of findings from the pre and post questionnaire administered as part of the *Vaccine Safety Data Linkage Community Forum.* Firstly, the findings suggest that such forums have educative value and, as a result, play a role in transforming views. Secondly, despite the brevity of the questionnaire, a number of conclusions can be drawn from the responses. The responses indicated that participants:

- distinguished between identifiable and de-identified data
- believe consent should be sought for uses of identifiable health data
- believe that the initial access to identifiable data for data linkage purposes does not require consent provided there are measures in place to protect people's privacy
- believe that consent is not required for uses of de-identified data, which they view as not belonging to the individuals to whom it relates
- came to the belief that people should sacrifice some privacy for the common good
- are divided in their view regarding notification of future use of data at the initial point of data collection
- gained a good understanding of what data linkage is, confidence in the legislative and protective measures in research, and knowledge that health data are currently used in research without consent.

In the chapter that follows, the citizens' jury pre and post questionnaire findings and those of the interviews conducted will be compared.

CHAPTER 10

DISCUSSION AND CONCLUSION

Dispositions of the mind, like limbs of the body, acquire strength by exercise. [letter to Robert Skipwith, Aug. 3, 1771]

Thomas Jefferson

American Founding Father and politician (1743-1826)

Introduction

This thesis examined the ethical, legal, and social issues which arise when considering the wider implementation of data linkage infrastructure and data linkage projects. In the following sections I discuss findings in relation to the key objectives and research questions I set out to examine and address. This chapter has been structured around the research questions relating to both the theoretical component and the empirical components. In responding to the questions pertaining to the empirical components, I also compare the findings of Phases 2 and 3 and discuss these with reference to the theoretical component. I conclude the chapter with recommendations arising both from the theoretical and empirical components and discuss the limitations of this study as well as future directions of enquiry.

The thesis began with the proposition that both the protection of privacy and obtaining consent, on the one hand, and societal goods arising from data linkage projects, on the other, are valuable. However, arrangements designed to maximise the protection of privacy are likely to result in the reduction of social goods arising from data linkage. Consideration of pertinent issues, on a theoretical level, therefore entailed balancing these values and determining whether information privacy losses in data linkage projects could be so harmful to participants that non-consensual engagement in such projects should not be permitted. I showed that a number of privacy and privacy related

issues had to be considered in conjunction with the methods used in data linkage, legislation that aims to protect privacy, and the benefits that are yielded. Following my consideration of these issues, I conclude that it is possible to morally justify the necessary and temporary use of personally identifying data, as the privacy losses are small and no harm comes to participants while potentially great public benefits arise. However, two additional conditions must obtain: individuals should be notified of the future uses of their data and the government should engage the public, educate the public, and involve the public in discussions around these issues. Not doing so is disrespectful and potentially obstructive to future plans for the wider implementation of such methods.

I further argued that what initially appear to be arguments with no moral substance are, in fact, issues that do have a moral dimension; several practical issues relating to strict requirements to obtain consent can hamper efforts to conduct research urgently needed and potentially expected by the public. These practical issues include:

1. monetary and time constraints rendering obtaining consent prohibitive,
2. the impact of non-involvement in data linkage projects on scientific outcomes (as well as the consequences of developing policies and treatments on such outcomes),
3. the difficulties in accessing potential participants for the purpose of obtaining consent, or the inability to do so where health records relating to people who have died are concerned and
4. the difficulty in developing systems to ascertain which of the thousands or millions of potential participants do not consent to inclusion of their information if opt-out consent were to be employed, as well as the potential impact of their exclusion on the scientific integrity of the research.

These constraints, when considered in relation to the improbable harms that might arise for participants in data linkage projects, make evident the fact that insistence on consent requirements prejudicially favours privacy and privacy related interests. As previously noted in Chapters 2 and 4, the above considerations did not assume or infer that HREC approval for data linkage research is not required. The focus here was solely

on the constraints that strict consent requirements impose on potentially valuable research.

Theoretical component (Phase 1)

The theoretical component comprised Chapters 1-4 and examined ethical and legal issues relating to privacy and consent.

What ethical issues arise and need to be considered in the context of data linkage?

The key ethical issues that arise in relation to data linkage relate to privacy and consent requirements. In order to discuss these issues I first briefly examined the philosophical literature on privacy. I showed in Chapter 1 that there is no single definition of privacy in the philosophical literature and that privacy is conceived of in a number of ways, none of which provide a comprehensive theory of privacy. The justification of privacy holds a prominent position in the literature and plays a profound role in both the development and wellbeing of individuals but also in societies, as it provides the basis on which co-existence becomes possible. The RALC theory was given some prominence in Chapter 1, as it articulates the role that controls, in the form of consent and legislation or guidelines, play in maintaining privacy.

Chapter 2 focused on consent and examined a number of pertinent issues that enable a better consideration of consent in the context of data linkage. I provided a brief description of consent types and consent mechanisms and argued that there is a discrepancy between requirements for consent, as set out in the National Statement (66), and one of the consent types (unspecified consent) endorsed in the same document. This discrepancy highlights the tensions that exist between classic conceptions of consent requirements arising from historical events and the current awareness of research needs and capabilities. Chapter 2 also highlighted the impact of strict consent requirements on certain kinds of research including data linkage.

I then examined recent empirical research aiming to elucidate people's consent preferences in relation to the use of their health data. Findings from some of these studies highlight the fact that people have conflicting values as they recognise and support the conduct of research and recognise the constraints that consent places on research while at the same time wishing to have their privacy protected via consent

processes. Participants in these studies generally preferred to be informed, to a greater of lesser degree, of the uses to which their information would be put but, overall, the non-consensual use of data was favoured. People make distinctions between the kinds of data being used and show greater concern about the use of data that helps create a more comprehensive picture of their identity. Few of these studies focussed on data linkage and few provided insight into the reasons for participants' choices. None of the studies elucidated the decision making process participants adopted when asked their views.

What is the nature and the ethical and legal role of consent in data linkage research?

In Chapter 2 I stated that consent for participation in research[91] is sought for two main reasons: to promote autonomous decision-making and to protect researchers from sanctions which would apply if consent were not sought. The first of the reasons addresses the use of people's information from an ethical perspective while the second from a legal perspective. In addition, historically, consent has been viewed as the mechanism via which research participants are afforded protection against harms which might arise in research. Given the historically prominent position of consent in the West, the default position both from an ethical and legal perspective is for consent to be obtained for all uses of personally identifying information. However, I argued that we place an inordinate amount of trust in a mechanism which cannot provide protection once participants are included in the research. Consent can only enable potential participants to avoid assuming potential risks of harm arising from the research by not becoming involved.

An important aspect of the use of identifying information in data linkage, which is not always in focus, is that the requirement to obtain consent only applies to the initial stage of data linkage, i.e. for the provision of limited personally identifying information to the linkage organisation to create the linkage key. This very process is designed to protect the privacy of those involved and, morally, the intention is of considerable importance because it highlights the value we place on the protection of individuals' information privacy and provides a mechanism which in effect compensates for participants' inability to provide consent. However, in law, irrespective of intentions, the

[91] Use of people's information renders these people research participants even if they had no direct contact with researchers (66).

release and access to personally identifying information for some purposes other than those for which the information was originally collected is a breach of privacy (and often other) legislation. Where consent cannot be obtained, before research can proceed, a waiver of consent is required. I have argued in this thesis that consent needs to be considered more broadly, both at an individual and societal level, due to the nature of data linkage and the protections afforded by data linkage processes.

Participants attached importance to security measures offered in the data linkage process, i.e. the separation of tasks, and when participants felt assured that measures would protect their privacy, they generally supported the non-consensual use of data in data linkage. This aligns well with Etzioni's (94) contention that technological advances and protections imposed on data are more appropriate than attempts to obtain consent from large populations. The following section discusses this issue in greater detail.

Is it acceptable to conduct data linkage research for the public good without obtaining consent, and if so, how can this be justified?

In considering the opposing values involved, I adopted a responsive communitarian approach, as this approach does not give primacy to either privacy or the common good but rather recognises both as important values which are weighed up against each other differently depending on the society and the historical period (94).

The issue of consent is intricately related to a number of other values such as privacy, autonomy, trust, respect for persons, and protection from harm, all of which were considered in examining the acceptability of non-consensual uses of data in data linkage.

In Chapter 3 I started by acknowledging the importance of respecting and protecting privacy and confidentiality not only for their role in promoting autonomy but also because of the trust we have that our information is only used for the purposes for which it is collected. I acknowledged the role that privacy plays in providing a measure of control over what happens to us in life and recognised the importance of respecting persons, the rights that arise from such respect, as well as our obligation to recognise such rights.

I then argued that in organised society, as we know it, it is not possible to enjoy full privacy or full autonomy. Through a simple schema I illustrated that some losses of

privacy, which on a continuum are regarded as trivial in the case of data linkage, may provide great benefits with a low probability of harm to individuals involved. Such losses of privacy have no impact on individuals but contribute to potentially significant benefits for whole communities. In fact, I showed that the non-use of available health data for other purposes can result in harm to communities, as is the case with Estonia (99). However, unless there is transparency about how people's personal and health information is used in research, we fail to show respect to persons and risk compromising the trust that must exist between governments, the research community, and the public.

I take the position that it is morally justifiable to conduct data linkage research without consent. However, there are several conditions which must be met.

- Privacy must be sufficiently protected and participants must be exposed to negligible risks of harm; the best practice data linkage method described in this research promotes the protection of privacy and aims to minimize the risk of harm to participants by separating the various tasks and delivering de-identified data to researchers for analysis.
- There are no better alternatives to using personally identifying information to create the linkage key.
- There are clear and substantial benefits arising from the data linkage project[92].
- Respect to persons must be shown via two processes:
    - At an individual level, people should be notified of the future uses to which their information may be put at the initial point of collection of the information. Explanations regarding the data linkage process could be given at this point[93];
    - At a community level, there should be transparent discussions about the use of personal and health information in research, including in data linkage, so that such knowledge enters the public domain and

[92] Participants were aware that they themselves may not necessarily be the beneficiaries of goods arising from data linkage activities.

[93] Techincally, opt-out consent could be sought at this stage but the technical and practical difficulties that would arise as a result, as outlined in Chapter 2, render seeking opt-out consent impractical in large data linkage projects.

discussions can commence in relation to related issues such as consent.

The two processes above are essential as they engender trust between governments, researchers, and the community. Raising awareness of the potential future use of people's personal and health information in research via notification at an individual and discussions at the community level will develop an understanding in the community that such information is customarily used in research following HREC approval provided that harms to do arise for individual participants. The empirical research findings lent support for the conduct of data linkage research without consent. Participants attached great importance to security measures offered in the data linkage process, i.e. the separation of tasks, and when they felt assured that measures would protect their privacy, they generally supported the non-consensual use of data in data linkage. This finding aligns well with Etzioni's (94) contention that technological advances and protections imposed on data are more appropriate means of protection than attempts to obtain consent from large populations.

What legislative requirements apply to Australian data linkage research and how do they affect the conduct of research?

In more recent years, it has been recognised that consent cannot always be obtained in all research (61) (66). Because of the significance attached to obtaining people's consent, in order for such research to proceed, consent waivers must be granted by approving Human Research Ethics Committees (HRECs). In Chapter 4 I clarified that in Australia, HRECs providing consent waivers are in fact ensuring that no privacy (or other) legislation is being breached through a number of considerations not least of which is the weighing up of the public's interest in the protection of privacy and the public's interest in the benefits arising from the research.

The very nature of data linkage often entails the linkage of data across jurisdictions. In Australia there are several complexities involved in the conduct of cross jurisdictional research; these arise from the application of numerous pieces of legislation to various data sets and the lack of consistency and uniformity across legislation applying in different jurisdictions. In addition, the privacy and health privacy legislation both at a Federal and State/Territory level are similar in a number of ways as they are all based on

the same principles. Nevertheless, they do differ in small ways which creates great confusion for all parties involved. The interpretation of the privacy principles is also currently complicated by the existence of two similar sets of guidelines, which also differ in a number of ways. The complexity is such that researchers need to have a substantial understanding of the law before they are able to apply for a waiver of consent from the approving HRECs. It should be noted that since the publication of Chapter 4, the Commonwealth amending legislation has been passed and will commence in March 2014. There is therefore hope that these differences will diminish.

In addition to privacy and health privacy legislation, certain collections of data such as registers have been established and are governed by specific legislation in relation to the collection, use, and disclosure of the information in these collections. Difficulties arise with such legislation as it was often promulgated at a time when the use of the collections in research had not been envisaged and when modern techniques, such as data linkage, were not widely implemented. This difficulty will remain as privacy legislation is reformed to reflect emerging needs while other legislation remains archaic and out of touch with current practices and understandings.

How is current health and privacy legislation interpreted and applied to data linkage research?

In Chapter 4 I explained that data linkage is always considered to be research which requires a waiver of consent to proceed. However, I contend that in many cases data linkage could and should be viewed as an activity linked to the primary purpose for which the personal and health information were originally collected, for example in the case of vaccine safety surveillance. If data custodians were able to view such data linkage activities in this manner, ethics approval for the purposes of providing a consent waiver would not be required, as there would be no breach of privacy legislation. I did not support the conduct of data linkage activities with no oversight. However, I raised this point to illustrate that our conceptions of this activity are narrow both in law and in our general treatment of the activity. In addition, the current treatment of data linkage by HRECs focuses more on legal requirements and very little on the ethical implications of the research. Under the proposed amendments to privacy legislation, data linkage projects would still require review by local HRECs.

It is envisaged that data linkage research will increase dramatically in the coming years and will be facilitated to an extent via reforms to privacy legislation. It is for this reason that I proposed that a single HREC or similar review body be established with in-depth knowledge of the area, the intricate technical issues and the impact that such research may have on whole populations. Such treatment of data linkage projects would be in line with other similar government initiatives in Australia (e.g. Harmonisation of Multi-centre Ethical Review – HOMER) to streamline the review process of multi-centre research projects.

Is there a need for legislative reform?

Finally, in Chapter 4 I explained that the complexity of the Australian privacy landscape has been recognised by the Australian Law Reform Commission and the Australian Government. Recent reforms to privacy legislation were proposed by the Australian Law Reform Commission and are now well on the way to being implemented in the coming years.

A significant first is that data linkage as an activity will be written into Australian privacy legislation for the first time. In addition, it has been agreed that there should be a single set of privacy principles (Unified Privacy Principles[94]) and guidelines (Research Rules). However, there remain potential conflicts with State and Territory privacy and health privacy legislation, which may need to also be revised or indeed be dispensed with in place of the Federal legislation.

Summary

Privacy and consent are closely linked and discussions about one often raise issues about the other. Privacy is a complex concept and has received a number of different treatments in the literature. Consent is a mechanism which is viewed as providing for and protecting a number of important concerns, such as respect for autonomous choices, protection of researchers from sanctions, and protection from harm. Much importance has been attached to consent both in ethics and law. However, there is currently recognition that not all research activities can or need to be conducted with consent. In law, provided that the benefits substantially outweigh the public's interest

[94] Since the publication of Chapter 4, these principles have been renamed and are now referred to as Australian Privacy Principles (APPs).

in the protection of privacy and there is no alternative method of conducting the research[95], data linkage research can be approved by an HREC after being granted a waiver of consent. To determine, however, whether the non-consensual use of data is morally justifiable, it is necessary to consider a number of issues which do not relate to law. I conclude in my research that information can and should be used non-consensually when four conditions apply: the privacy of participants is sufficiently protected and participants are potentially exposed to only negligible levels of harms, the use of identifiable information is the only means with which the research can be conducted, the general future use of data and data linkage practices be explained at the initial point of collection of the information, and finally, that the use of personal and health data as well as data linkage practices enter public discussions so that the public has both knowledge of such practices but also agreement regarding the use of their data for the benefit of society.

Empirical components

The empirical research in this thesis was conducted to determine how a segment of the South Australian population views the issues under discussion and to determine whether they perceived data linkage to be an ethically, legally and socially acceptable practice. The empirical findings give us insight into the values these people hold and the way they go about balancing conflicting values. For this reason, the empirical components add to our understanding of the circumstances under which data linkage can be supported.

Phase 2 – face-to-face interviews

Phase 2 (Chapters 5-8) investigated how a group of lay participants conceived of privacy, what consent choices they thought were appropriate in relation to four hypothetical scenarios, and how they justified their decisions. The aim was to discover the underlying values that inform their decisions.

[95] As noted in Chapter 4, there are many additional considerations before a waiver can be granted. However, the two conditions I mention above are key in determining the suitability of granting a waiver.

How do lay people conceptualise privacy in non-medical settings?

Participants in this study showed that their conceptions of privacy were very similar to and as varied as those in the literature even if expressed in simpler terms. For some participants providing a definition for privacy was challenging but all of them were able to describe what they considered privacy to be; they related privacy to aspects of our lives we wish to share with only a limited number of people in our lives such as family and friends (or indeed with no one at all), to the protection and control of information, to anonymity, and for a smaller number, to not sharing confidential information.

Participants' justifications for privacy were equally insightful and rich in nature. Although privacy was focused on in the narrow context of data linkage both participants' definitions and, particularly, their justifications indicated that they were able to consider privacy more broadly than simply informational privacy.

The justifications participants provided related to the minimization of harm, some examples of which were identity theft, harm to children, marginalisation, and distress. They also saw privacy as playing an important role in enabling us to live autonomously, and make choices without interference from others, as well as its role in showing respect for persons either by accepting the choices they make or adhering to their wishes regarding the protection of their information. Some justified privacy in relation to the role it plays in maintaining good mental health, which might be linked to how non-autonomous living may impact on us as persons. Others saw privacy as playing a role in allowing us to reveal or hide different aspects of our person for a variety of reasons. Finally, for some participants privacy was important as it provides a sense of control over our lives. A number of participants expressed the view that they held no concerns about the use of their information when it was not connected to their identifying information.

Participants further contextualised privacy by expressing the view that privacy is experienced and conceived of differently by different people with some being more concerned about it than others. Some participants also indicated that there are varying degrees of privacy depending on the person or persons we are relating to. It was evident in their expression of this view that participants had in mind the degrees of privacy which enable the formation of closer or more distant social connections, an

important aspect of the manner with which we develop and maintain a multiplicity of social roles, as described by Rachels (36). Finally, as might be expected given their justifications and definitions of privacy, some participants recognised that there are different types of privacy and viewed it as a cluster concept in much the same way as DeCew (51).

Participants showed concerns about the linkage of data relating to numerous areas of their life, especially where researchers had access to identifiable information as such linkages enabled the formulation of a more comprehensive picture of the individual. Similar sentiments were expressed by Canadian participants when linkages of similar data were put to them (84).

Do lay people place less value on privacy and established consent processes in relation to data linkage once they become familiar with the processes adopted in data linkage?

When presented with hypothetical data linkage scenarios, these participants demonstrated that they had grasped the workings of data linkage in a very short amount of time. The participants' initial response was generally to opt for consent. However, upon considering issues such as the processes involved as well as other practical constraints consent places on data linkage research, many participants reviewed their choices and their justifications for their choices. The findings demonstrate that while consent was considered a mechanism via which privacy was protected, when data were not identifiable, participants did not consider the data to relate to the individual to whom they pertained in the same way as they would if identifiable. In short, such data were viewed as 'information' not as part of what makes up their person. Where de-identified information was concerned, many viewed consent as a hindrance to beneficial data linkage research and did not believe that it was necessary.

Conversely, when identifiable information was to be handled by researchers, and when the data related to a number of areas of their lives, including employment data, most participants believed that obtaining consent was necessary despite any impact this may have on the research. Participants' swing back to the consent option in Scenario 4 also indicated that their responses were based specifically on considerations relating to each scenario and were not a product of participants settling into a 'pattern' of responses

after exposure to the initial scenarios or a desire to produce responses that participants may have felt I favoured given the topic of investigation and their potential assumption that I supported the conduct of data linkage.

The separation of tasks was one of the issues referred to by a number of participants, as was the non-identifiability of data, both of which offer protections. Overall, participants saw the value in data linkage research and expressed support for such research provided that they were not identified.

It could be speculated that the fact that these lay people understood the workings of data linkage in such a short time was due in part to their previous exposure to the concept of data linkage as they had participated in a related RCT. However, very few remembered *any* of the content relating to their involvement in the RCT. The diagram that I used to describe the process and the clarifications that I provided were key in enabling participants to understand the basic working of data linkage. It may often be assumed that describing such a complex process to lay people would be problematic. However, the knowledge gained in this research makes clear that this complex process can in fact be described in sufficient detail and in brief so that the public can gain an understanding of what it involves.

How do lay people resolve the tension that exists between opposing values such as privacy and the common good that arises from data linkage projects?

Participants applied an informal moral reasoning framework to balance a number of conflicting values. This has not previously been considered in the literature and assists in understanding both what lay people take into account when considering data linkage but also how they weigh up opposing values to arrive at a final decision regarding the need for consent or not. Some decisions were not arrived at easily and participants seemed to engage in a struggle to ascertain which choice was best by providing a number of justifications and moving between choices before settling on their final view.

The kinds of justifications that these participants drew on when supporting the consent option related to: rights/preferences, trust, respect, harm minimization, assumed social/legal/ethical norms, and pragmatic considerations. Similar kinds of broad justification themes were referred to when supporting the no consent option: benefits,

harms, trust, protection mechanisms, assumed social/legal/ethical norms, and pragmatic considerations.

The framework that participants applied was similar in many ways to that of Beauchamp and Childress (63). This finding was unexpected, as such frameworks are usually considered only in the context of facilitating the decision-making process of professionals in biomedicine and are oftentimes taught as components of ethics courses to enable young medical practitioners to consider and weigh up competing values. In this instance, however, lay people spontaneously employed an approximation of this widely used moral decision-making framework. The finding is of great value, as it clarifies the manner with which ethical issues pertaining to data linkage can be discussed and presented to the general public, who may also share the discernment of these participants.

How do lay people justify the decisions they arrive at when making consent choices in the context of data linkage?

The shifts from one choice to another upon further consideration resulted in a large number of justifications which gave rise to justification themes. Below, I will discuss the most prominent justifications for the consent option, the no consent option, the consent for notification, and no consent for notification of future use of data.

Participants offering justifications for the consent option across scenarios, focused principally on people's rights and preferences stating in a number of different ways that people have a right to choose if they wish to be involved in research. Very prominent in their justifications were justifications relating to harm minimization. This set of justifications related to harm resulting from the research because the researchers had access to identifiable data (Scenario 4). These concerns remained prominent despite an explanation I gave regarding the requirement for researchers to remove identifiable information once the datasets were linked. Another harm participants cited as a justification for consent was the variety of datasets relating to different spheres of people's lives, an issue which they believed increased the need for consent. Participants also cited as a harm the fact that people would object or be upset if consent were not sought and also indicated that researchers would face sanctions. Finally, also prominent

in their justifications was the widely held view that consent is required in all research either by law, because it is an ethical requirement, or because it is the norm.

When justifying the no consent choices participants made across scenarios, the justifications that were most often cited related to three areas: benefits; social/legal/ethical norms; and protection mechanisms. Participants primarily acknowledged the benefits arising from the data linkage research. Another prominent justification for the no consent choice was that de-identified data do not require consent. Finally, the protection mechanisms including the actual process of data linkage with the separation of tasks as well as the protections provided by laws and guidelines to which everyone must adhere were also cited as a reason for the no consent requirement for data linkage.

Although not as widely supported as I had expected, justifications for the notification of use of data were varied and mainly centred around the benefits of providing some notification. Participants considered that such notification would provide the public with a better understanding of research, would instil confidence that beneficial research is being conducted, would positively dispose more to take part in research, and would enhance community involvement. Justifications concerning the benefits of notification were followed by those relating to people's rights or preferences to know what kind of research was being conducted with some mentioning the importance of this given that research is publically funded.

Other participants, however, felt that notification of research was not required or that it was not a good policy. The reasons that these participants provided related to pragmatic considerations, such as the fact that people are simply not interested in finding out or that notification of research requires considerable funds. A few participants felt that there are harms associated with notification, as it may result in negative reactions about research from the public.

The variety of justifications provided for their choices was not only surprising in number but also in depth and insight. Participants displayed an ability to quickly consider issues they admitted to not having ever considered with astounding clarity of thought and insight. This is encouraging because it gives us an understanding of the values of members of the community and the issues they believe are important when deciding on

consent choices in relation to data linkage. These findings also give us insight into the manner with which other lay people may tackle the same issues were they to be discussed more widely in the community.

Contextualizing participants' justifications in social philosophical theory

Considering the participants' justifications in the context of a social philosophical theory such as 'responsive communitarianism' (103 p. 198) is useful, as their journey through the consent options and their respective justifications appear to readily cohere with this theory. As previously noted, responsive communitarianism does not give primacy to community values over values that promote individual rights, as earlier forms of communitarianism did, but rather recognises the need to promote individuality within the communal setting, that is, it seeks '…to balance individual rights with social responsibilities, and individuality with community' (103 p. 198). There is, therefore, recognition that the values at opposing ends of this continuum must be protected and that excessive protection of one threatens to undermine the other thus upsetting the equilibrium that is seen as necessary to promote the social harmony (103) that a good life entails.

In the context of data linkage, exceptionally high standards of data protection, in the form of individual controls, such as consent, and external controls such as legislation limiting access to data, can reduce collective societal benefits that can arise from uses of identifiable data in research. I showed in Chapter 3 that the extreme tipping of the scales in favour of privacy can not only stall progress but can also harm society.

The participants in this study recognized not only the two extremes, i.e. privacy and common goods, both of which were vocally defended, but also the tension that arises between the two when making choices about the most appropriate consent option for data linkage projects. Etzioni's view is that we can promote common goods while at the same time not violating privacy by 'shift[ing] from relying on individualistic doctrines-gaining the "informed" consent of millions of people for all uses of information about them-to relying much more on new technologies and institutional safeguards.' (103 p. 140). This is precisely the consideration that influenced most participants in settling on a no consent option for data linkage (when it involved a separation of tasks). So it appears that the concept is not simply a theoretical articulation of a solution to protecting and

promoting both values but that it is also compatible with ordinary lay people's conception of what is socially and morally acceptable.

Phase 3 – citizens' jury pre and post questionnaires

In Chapter 9 I presented Phase 3 of the thesis which concerned findings related to 16 lay members of the South Australian public who took part in a citizens' jury. The component of the citizens' jury presented in this thesis was the pre and post jury questionnaire. The administration of the questionnaire aimed to gather participants' views on a number of issues requiring consideration in data linkage projects. It also aimed to gauge the effect of the intense educative process to which participants were exposed.

How would a better understanding of core concepts and research-related facts affect the public's views on non-consensual uses of data for data linkage?

As with Phase 2 participants, these participants appeared to have firm views on the role that consent plays in the protection of privacy. The educative process was beneficial where factual information was concerned, a finding which is unsurprising yet important for the dissemination of data linkage information, as it indicates that misconceptions can be corrected with adequate information. These participants appeared to discriminate between uses of identifiable and de-identified data even prior to the educative effects of the jury presentations. This finding combined with similar findings from Phase 2 need to be considered, as they point to the fact that this could be the prevailing view, at least in this community. The citizens' jury contributed to the participants' understanding of data linkage but also raised their awareness of the protective mechanisms in place which included the process itself but also the laws and guidelines that aim to protect participants. This finding also aligns with the findings from the interviews where participants became informed in a very short time when provided with information about the process.

A key understanding that arises from both empirical components is the lay view that de-identified information no longer relates to the person to whom it pertains and that de-identified data can be used without obtaining consent. This does not point to the moral acceptability of such a practice. However, their views do indicate that these lay people, in general, were less concerned about the use of their data if they were de-identified.

This view should be respected and taken into account in formulating policy. In addition, as stated previously, the public is owed respect via information provision, discussions and a tacit agreement that the use of de-identified date is acceptable for research that aims to benefit society.

Recommendations and future actions

The findings of this research clearly indicate that lay people do have the capacity to understand complex processes and mechanisms and to consider complex concepts such as privacy and consent in depth. This is encouraging and points to the fact that engaging with the public to inform them of current technologies and plans to extend these may not be as daunting as it appears initially.

Public engagement should take various forms so that the language of data linkage and the related ethical considerations become familiar incrementally. Low-cost options, using a range of media, should be employed to disseminate information and raise awareness. The effective use of various forms of mass media can reach out to a wider audience and help disseminate research related issues in a manner which is accessible to a broad range of people. There is an opportunity to engage more creatively with the media and commence the discussions that should take place before data linkage infrastructure becomes a commonplace, yet unknown to most, means of combining data.

This research adds a level of confidence that Australians would support extensive data linkage projects provided that protections remained at the high levels currently employed. Those involved in the development of the data linkage infrastructure may benefit from this knowledge and make greater concerted efforts to progress public engagement.

Limitations of the study

Phases 2 and 3 presented what may appear to be constraints typical of qualitative research; that of numbers and generalizability to larger populations. It must be borne in mind, however, that the purpose of qualitative research is not to be able to generalize to populations but to be able to make generalizations regarding the phenomenon under

consideration (142), which in this thesis related to lay views on privacy, consent, the acceptability of the use of health data in data linkage, as well as a consideration of uses of such data for the greater benefit of society.

While not a limitation of the study itself, it should be acknowledged that not all Phase 2 could be analysed due to the great wealth of data collected. I intend to analyse the remaining data in the near future.

Future directions

An understanding of the broader conceptions of privacy and its value as seen by lay people and lay views on the need or not for consent for the use of their health information enables us to better consider how to appropriately address issues central to data linkage.

The qualitative research has shown that much can still be learned in relation to lay people's conceptions and perceptions in relation to ethical issues highly valued in our society. This research has contributed to our understanding of the decision framework employed in lay people's moral decision making. However, as this research is novel, further research would add to the body of knowledge and clarify aspects not covered in this work. Furthermore, additional research would assist in determining the extent to which the moral decision-making framework aligns with frameworks familiar to clinical practice, so that experience with those could be drawn on. Further research will also help determine whether these findings can be supported more widely.

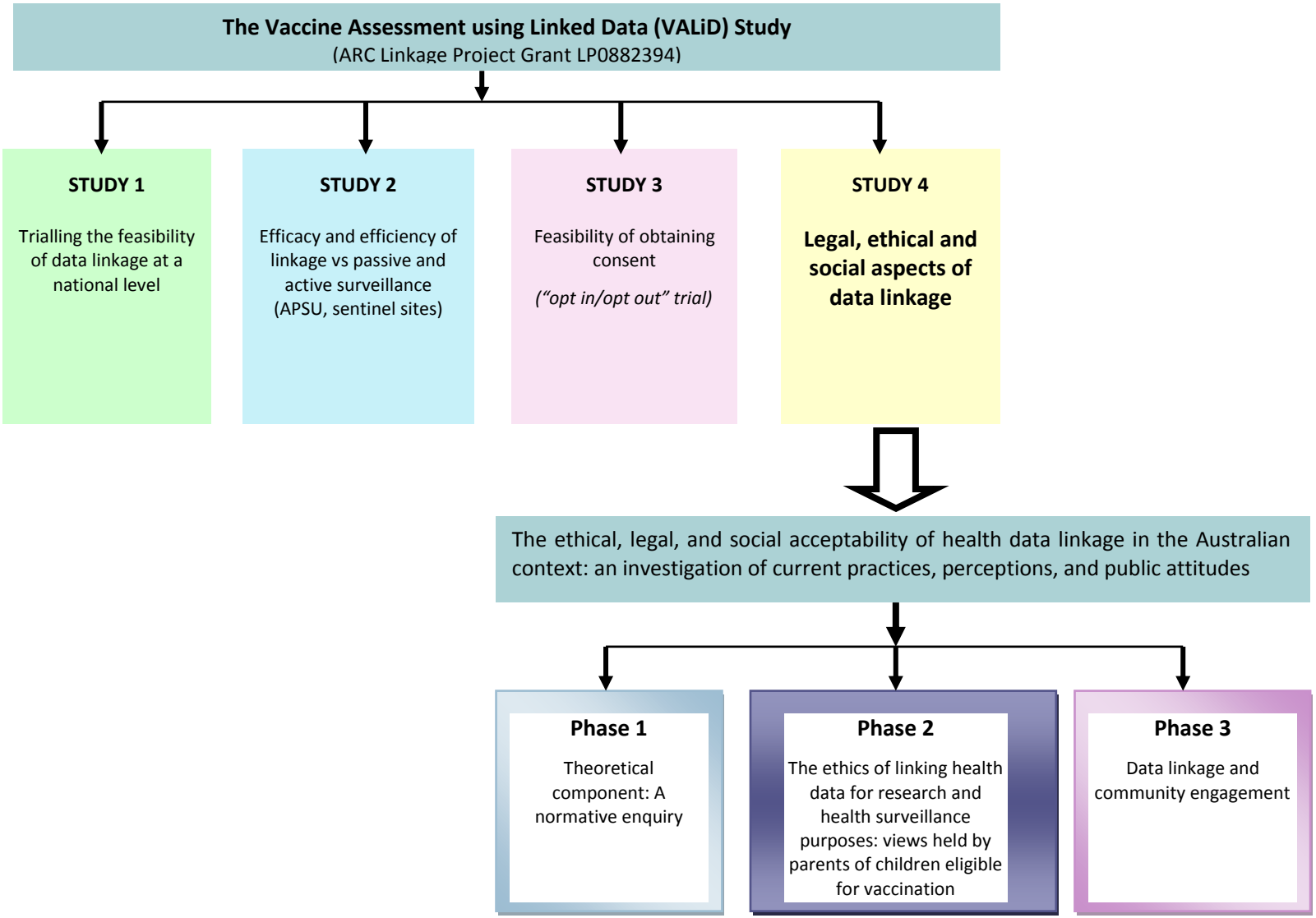
The in-depth interviews revealed that participants did not engage with the concept of notification of future use of data at the initial point of collection of information, e.g. hospital, to the extent that I had expected they would. This issue warrants further investigation, as this process appears to provide both a respectful and informative solution to individuals whose data may be used in data linkage projects.

The findings of this thesis provide a springboard from which to examine lay perceptions regarding consent in a variety of related research contexts, including research related to areas not investigated in this thesis such as the use of genetic material.

What this thesis has shown very clearly is that lay people are capable of engaging in some depth with issues often considered too complex to explain to a non-technical population. It is perhaps time to acknowledge that such perceptions hinder a transparent approach to public engagement in discussions regarding the implementation of new infrastructure and research capabilities. Informing and involving the public not only promotes a broader understanding of how people's health information can be used in data linkage and the benefits that might be derived but also instils confidence in safe uses of health information while at the same time showing respect towards the very people who make such research possible.

APPENDICES

Appendix 1 - Chapter 1: Structure of larger project and current research component



Appendix 2. – Chapter 5 - Pilot study participant information and consent form

<DATE>

<*Participant's Name*>

<*Street Address*>
<*SUBURB*> <*SA*> <*POSTCODE*>

Dear <*Participant's Name*>,

We were pleased that you recently expressed interest in taking part in a research project conducted by Women's and Children's Hospital and Adelaide University researchers. Before the study known as ***The ethics of linking health data for research and health surveillance purposes: views held by parents of children eligible for vaccination*** begins, we would like to pilot the questions we have chosen for the interviews. This process is explained more fully in the enclosed Information Sheet. This project is linked to the *Data Linkage Vaccine Safety Study* that you participated in during 2009 or early 2010.

The study aims to find out what parents think about linking health data for research or surveillance purposes. It will focus on whether it is acceptable to link people's health information from two or more databases. There are no right or wrong views. We simply want to gain an in-depth understanding of how people feel about the issues.

We would like your views on the questions asked during the interview, on what you thought of the way the interview was done and what you think would improve it.

The pilot study does not require you to visit the hospital or go out of your way. The PhD Candidate conducting this project would like to meet you at home, or at another convenient location, for a face-to-face interview at a time convenient for you.

Participation in the pilot study is voluntary and if you decide not to take part or to withdraw after agreeing to participate, this will not affect your relationship or future services provided to you by the Women's and Children's Hospital or Adelaide University.

We would be happy to answer any questions you might have. You can call Vicki Xafis (PhD candidate) on 8303 0191 during business hours.

Sincerely,
Dr Mike Gold
Discipline of Paediatrics Women's and Children's Hospital &
University of Adelaide

CHILDREN, YOUTH & WOMEN'S HEALTH SERVICE (CYWHS)

INFORMATION SHEET

Title: The ethics of linking health data for research and health surveillance purposes: views held by parents of children eligible for vaccination – PILOT STUDY

(Component of ***Vaccine Assessment using Linked Data Safety Study- VALiD***)

Researchers: Dr Michael Gold, Professor Annette Braunack-Mayer, Professor Colin Thomson, Professor Philip Ryan, Ms Katherine Duszynski, Ms Vicki Xafis, Ms Jesia Berry.

Why have you been sent this information?[96]

You are invited to take part in a pilot study examining the ethics of linking health information, which is being conducted by researchers at the Women's and Children's Hospital and the University of Adelaide. In 2009 or early 2010, you had agreed to be contacted about this study when talking to researchers involved in the Data Linkage Vaccine Safety Study.

What is this study about?

This research is part of a larger study called *The Ethical, Legal and Social Acceptability of Data Linkage in the Australian Context: an investigation of current practices, perceptions, and public attitudes*. It is being conducted as part of a PhD study undertaken by Vicki Xafis.

In this component we want to interview parents to see what their views are regarding whether it is acceptable to link people's health information to do research or monitor things such as vaccine safety.

What does the pilot study involve?

If you agree to participate in the pilot study, you will be asked to take part in a face-to-face interview and provide feedback on what you thought of the questions and the general process adopted by the researcher. The interview will be arranged for a time which is convenient for you and your baby and will take approximately 1 to 1.5 hours, depending on how much you would like to contribute. Interviews will be held at your house so that you are not inconvenienced (or at another convenient location of your choice) and they will be recorded so that the conversation can be transcribed accurately.

If something arises at the time of the interview or feedback session, e.g. your baby is upset and needs your attention, the interview can be stopped and the researcher can come back at a more convenient time for you.

What information is being collected?

We are interested in discussing your views on the use of health information in data linkage for research and other projects aimed at improving health. More importantly, however, we would greatly appreciate your feedback on the way the interview was done, the questions asked and anything else you think would improve the interview.

At the beginning of the interview, we will talk about your involvement in the telephone interview you may have taken part in last year in the Data Linkage Vaccine Safety Study. After that the researcher will give you a number of scenarios relating to the use of health information in research or public health surveillance. **It is important to remember that your answers will not be used in the main research, as we are interested in trying out the questions with you so that we can improve them. Please also remember that there are no right or wrong views.** This pilot study does not seek to collect any information about your baby.

How is my privacy protected?

The interviews will be coded, which means that your name will only appear on a list stored in a locked filing cabinet in a lockable office at the University of Adelaide. No other personal or health information will be collected.

Access to all research data, including the interview recordings and transcripts will be limited to members of the research team. The data will be stored in a lockable office on a password protected computer. In very rare cases, the approving Human Research Ethics Committee (Women's and Children's Hospital Research Ethics Committee) may request to see the data as part of an audit.

Your information will remain confidential except in the case of a legal requirement to pass on personal information to authorised third parties. It is highly unlikely that there will be any such legal requirements in relation to this study but we are required to inform you of this possibility.

What if I change my mind after I have agreed to take part?

Research (including the conduct of pilot studies) is voluntary and you are not obliged to take part if you do not want to. If you change your mind, even after you have agreed to participate, you can contact Vicki Xafis and let her know. If you decide to withdraw, your data will also be withdrawn.

[96] The font in information provided to participants was larger. It has been reduced for inclusion in the Appendices for practical purposes.

What if I don't want to take part?

Participation in this pilot study is voluntary and if you decide not to take part or to withdraw after agreeing to participate, this will not affect your relationship with or future services provided to you by the Women's and Children's Hospital or Adelaide University.

How do I find out about the results of the research?

Because this is simply a pilot study, there will be no results made available to you.

If you would like more information about the larger project of which this study is a component, the findings will be available in early 2012 and a summary can be made available to you.

What do I need to do now?

If you have any queries which you would like to discuss before deciding whether to take part or not, please do not hesitate to contact Vicki Xafis on (08) 8303 0191.

If you want to participate in the pilot study, simply sign and date the yellow Consent Form and have it available for the researcher when she comes to interview you. You should keep the white copy for future reference.

If you lose any of the study information and would like us to send you a replacement, please contact Vicki Xafis.

What will the researchers do now?

The researcher, Vicki Xafis, will call you in about 7 to 10 days from the day you received this information to answer any questions you may have, to see if you are happy to take part and to set an interview time that suits you (if you want to take part).

The researcher will collect the signed Consent Form on the day of the interview (yellow form). A copy of the signed Consent Form (white form) is for you to keep with this information sheet as part of your records.

Additional information

Both the study and the small pilot study you are invited to take part in have received ethics approval from the Women's and Children's Human Research Ethics Committee. If at any time, you wish to discuss the ethical approval process or have a concern or complaint please contact the Secretary of the Committee (Ms Brenda Penny) on (08) 8161 6521.

Members of the research team you can contact if you have queries or want to know about your rights as a research participant are:

Principal investigator: Dr Michael Gold on (08) 8161 7266
Project manager: Katherine Duszynski on (08) 8161 7244
PhD candidate: Vicki Xafis on (08) 8303 0191
Or email us: vicki.xafis@adelaide.edu.au

We thank you for your assistance.

Dr Mike Gold
Discipline of Paediatrics
Women's and Children's Hospital & the University of Adelaide

Appendix 3. – Chapter 5 - Research Rules derived from pilot study

If able to leave message, leave contact details but do not indicate what call is about

If messages left, abandon contact after three attempts

Ring 2-3 days after receipt of information to enquire about willingness to participate

Exclude individuals who do not the language skills required to participate in interview (assessment to be made during initial call)

Ask participants if there is anything else they think is important/relevant which was not mentioned

Appendix 4. – Chapter 5 – Interview schedule

The ethics of linking health data for research and health surveillance purposes: views held by parents of children eligible for vaccination

Semi-structured interview

Vaccines and data linkage

1. You recently took part in a telephone interview for a study about vaccine safety and your baby. Can you tell me a bit about what the study involved?

Prompts:

What activities did the researchers ask you to consent to when you received the letter?

Do you remember if any information was going to be linked with any other information about your baby?

Do you remember which bits of information were going to be linked?

2. How did the researchers ask you to consent?
3. Do you think that this was a good way to get your consent?
4. In the study that you took part in, you were informed that linking information about babies' vaccinations and hospital and other health information is a fast and effective way of confirming that vaccines are safe. Do you think that health information should be linked to check the safety of vaccines? Why? Why not?
5. There were two parts to the study; the telephone interview and the linkage of your child's health information. Were you happy to take part in the telephone interview? Why? Why not?
6. And what about the linkage of your child's data? Were you happy to give permission for that to happen? Why? Why not?
7. Now, my next questions are about benefits and risks. Are there any benefits involved in linking vaccine data with hospital information? Can you please give some more details?
8. What about risks? Do you think that there are any risks involved?

Researcher: The Australian Government has invested, and will continue to invest, millions of dollars in the development of the nation's data linkage capability. That's why in this research, I am very interested in your views about linking information from different databases. But before we start, I'd just like to make sure that you understand that this research doesn't have anything to do with actually linking any of your information or your baby's information.

Scenarios

Now I'm going to give you some scenarios regarding linking people's information from a variety of sources. The scenarios don't have anything to do with vaccination but they do relate to other health information as well as other kinds of information found on various records. After each scenario, I'm going to ask you questions and I'd like you to tell me what you think and why.

a. A study is being conducted by **university researchers** and they want **hospital information** (which includes the medical history, name, age, ethnicity, and postcode), a **cancer register,** and a **deaths register** to be linked with each other. The researchers want to find out if there is a link between lung cancer and living next to busy main roads. The findings will contribute to better town planning. In order for the study to be successful and so that it provides accurate findings to ultimately help with the management of some forms of cancer, it's very important for **everyone on the cancer register** (several thousand people) to be included in the study. The **researchers will never have any identifying information** because they will not do the linkage themselves and **all information that identifies people will be removed before they get the linked data.**
    i. Do you think the researchers need to get consent from the people with cancer? Why? Why not?
    ii. (IF "YES") (SKIP IF NEGATIVE RESPONSE TO PREVIOUS QUESTION)
        1. Does it make a difference if people's identifying information will not be known to researchers?
        2. Does it make a difference if there are many strict procedures in place to protect people's information?
        3. Does it make a difference that there are thousands of people on the cancer register and so it's difficult to contact them from a practical point of view?
    iii. What if you consider all the things we've just talked about together- in other words, researchers won't have access to identifying information, the strict measures to protect data and the need to contact thousands of people? Do you still think that the researchers need to get consent from all participants? Why? Why not?
    iv. What about those on the register who are no longer alive? Should consent be sought from their family? Why? Why not?
    v. (IF "NO") (SKIP IF AFFIRMATIVE RESPONSE TO PREVIOUS QUESTION) Should all people on the register simply be informed that this study is taking place but not be asked to consent? Why? Why not?
    vi. Do you think that the de-identified linked database resulting from the above study should be kept so that researchers can use it for future

research without needing to get permission from everyone on the database, and so that the process of linking this information doesn't have to be repeated? Why? Why not?

vii. What if the same study was being done in the same way by Department of Health officials so they can plan better public health programs for cancer prevention? Would your opinions regarding consent be any different?

viii. Would it make any difference if the research was being done by relevant cancer organisations?

ix. How about doctors working in hospitals?

x. If the aim of this research is to guide policy development that will benefit society as a whole, is it necessary and practical to seek consent from people whose information needs to be used in the research? Why? Why not?

b. **Researchers in collaboration with the ambulance service** are conducting research into **cardiac arrests and resuscitation** to see if call-out response times affect survival rates. They will need to have data about approximately **300,000 people** on the **ambulance databases, hospital admissions, and death registers linked**. The **researchers will never have any identifying information** because they will not do the linkage themselves and **all information that identifies people will be removed** before they get the linked data.

i. Should researchers get consent from all these people? Why? Why not?

ii. (IF 'YES') (SKIP IF NEGATIVE RESPONSE TO PREVIOUS QUESTION) Does it make any difference that there are many thousands that would need to be contacted? Why? Why not?

iii. Some of the people on the databases will have died. Is it reasonable to include these people in the research without getting consent from their families? Why? Why not?

iv. This research will not benefit those patients whose information was used but it will benefit future patients. Do you think it's ok to use people's health information to benefit others? Why? Why not?

v. Do you think it's fair for people who weren't willing to take part in research or health programs to enjoy the benefits of such research/health programs? Why? Why not?

c. **University researchers and researchers from a mental health organisation** want to study violent behaviour in people experiencing mental health issues. They need to link about 50,000 **mental health hospital records** Australia-wide (including admissions and discharge information) with **police incident information**, such as calls for domestic violence. The **researchers will never have any identifying information** because they will not do the linkage themselves and **all information that identifies people will be removed before they get the linked data.** The Police will not have access to the mental health hospital records.

i. It's not possible for the researchers to get consent from such a large number of people, some of whom can't give consent because

of their illness. Should such research go ahead without consent? Why? Why not?

ii. Should the public be informed that such research is going to be done? Why and how could this be done? Why not?

Now still talking about the same research, the process of linking such a lot of information from a number of States/Territories is very complex, expensive and very time-consuming. So in this research, once linked, the **identifying information will be removed** but a **key will be held separately**. The key connects the identifying information of all the people on the databases and the codes they were given. The key will make it possible for researchers from various States/Territories to ask for de-identified information about their State/Territory so that they can do further research without having to have all the information linked from the start.

iii. What do you think of the identifying information being kept separately so that other researchers can later ask for some bits of the linked information to do more research? Is this a good/bad thing and if so, why or why not?

iv. Does the type of information that will be linked without consent (i.e. mental health data, police records etc.) make a difference to whether this research should be conducted or not? Why? Why not?

d. **University researchers** are conducting research on work-related stress **on behalf of Work Cover** to discover whether there is a link between increased levels of stress and work insecurity, for example caused by casual employment. They need to link **100,000 work stress claims** containing **identifiable general and mental health information** with **employment data** including employment history, leave information, seniority level etc. for the same individuals who are employed at the Government organisations involved in the research. In this instance, the linkage will not be done by an independent team of data linkage experts. Instead, the researchers will do the linkage themselves. A report with **de-identified findings** will be made available to Work Cover.

i. Do the researchers need to get individual consent? Why? Why not?

ii. (IF 'YES') (SKIP IF NEGATIVE RESPONSE TO PREVIOUS QUESTION) Does it make a difference that there are 100,000 people, none of whom would be identified in the final report?

iii. Should the researchers provide an opportunity for the potential participants to decline being involved in this research? Why? Why not?

iv. (IF "YES") (SKIP IF NEGATIVE RESPONSE TO PREVIOUS QUESTION) Should this apply to general health research as well?

v. Is it appropriate for the research team to send out a notification regarding the research to inform the participants of the research and assure them that there are no risks but **not** to ask for their consent? Why? Why not?

Data security

e. What do you know about security measures in research/government organisations for the protection of people's information?
f. What do you know about the way research and other uses of information are protected by guidelines and legislation?

Privacy and breaches of privacy

g. What's your understanding of 'privacy' and what does it mean to you? How important is it for you?
h. Has the use of your information in research or health care ever created any difficulties for you? Can you please elaborate?
i. If 'YES' (SKIP IF NEGATIVE RESPONSE TO PREVIOUS QUESTION) How did this experience affect your current views regarding data linkage, if at all?

Public benefits

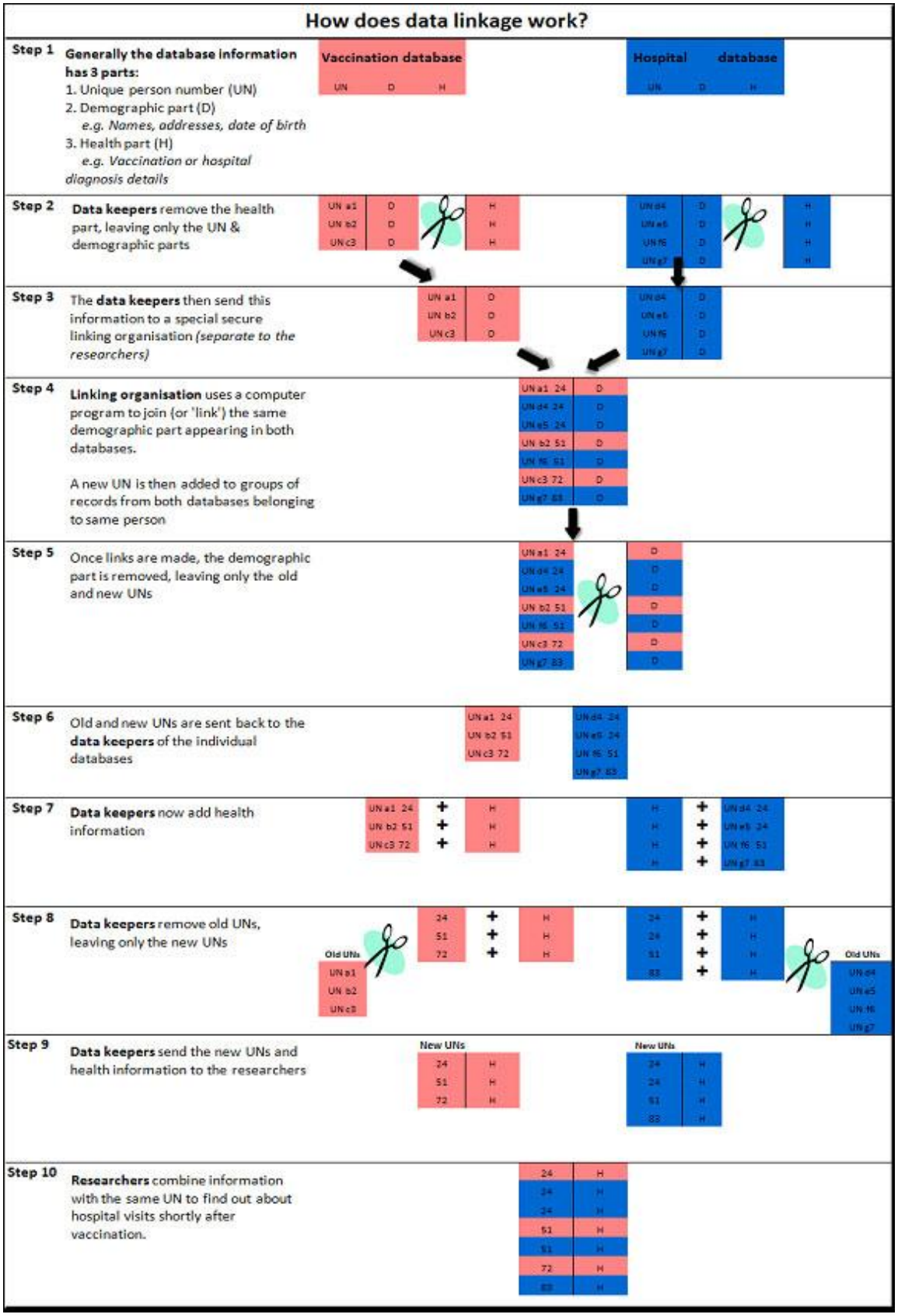
j. Is it ever acceptable for your information to be used without your knowledge for the benefit of society generally? If so, in what circumstances and why?
k. Does an understanding of the benefits arising from data linkage projects affect your views on the need for individual consent? In what way?

Impact of interview and provision of information

l. Has the information we have discussed today changed the way you see things in relation to the use of your health data? If so, how?
m. Should more information be given to people about how their health information is used? If so, what kinds of things should people be told?

Appendix 5. – Chapter 5 – How does data linkage work? – Participant handout

The diagram was designed by the VALiD Project Manager, Katherine Duszynski.



Appendix 6. – Chapter 5 – Scenarios – Participant handout

a. A study is being conducted by **university researchers** and they want **hospital information** (which includes the medical history, name, age, ethnicity, and postcode), a **cancer register,** and a **deaths register** to be linked with each other. The researchers want to find out if there is a link between lung cancer and living next to busy main roads. The findings will contribute to better town planning. In order for the study to be successful and so that it provides accurate findings to ultimately help with the management of some forms of cancer, it's very important for **everyone on the cancer register** (several thousand people) to be included in the study. The **researchers will never have any identifying information** because they will not do the linkage themselves and **all information that identifies people will be removed before they get the linked data.**

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The font on the copies provided to participants was slightly larger for ease of reading.

Appendix 7. – Chapter 5 – Guidelines and legislation that apply to research/certain programs

Guidelines/Legislation	State	Scope
National Statement on Ethical Conduct in Human Research	Australia-wide	All research conducted by Australian institutions
Australian Code for the Responsible Conduct of Research	Australia-wide	All research conducted by Australian institutions
Research-specific guidelines, e.g. for clinical trials, indigenous people etc	Australia-wide	Certain research types
Privacy Act 1988	Australia-wide	General private sector in all States/Territories & health private sector in some States
Guidelines Under Section 95 of the Privacy Act 1988	Australia-wide	Enables use of identifiable personal data held by Commonwealth agencies for medical research under strict conditions (without consent)
Guidelines Under Section 95A of the Privacy Act 1988	Australia-wide	Enables use of identifiable health information held by organisations in the private sector for a variety of purposes including research under strict conditions (without consent)
Privacy legislation	State-specific	All research & agencies collecting data (public sector)
Human Research Ethics Committees	Australia-wide	All research must be approved by before it can be conducted
Publication requirements	Australia & internationally	Many journals will not publish research results unless proof of ethics approval is provided.

Produced for the study: *The ethics of linking health data for research and health surveillance purposes: views held by parents of children eligible for vaccination*

Appendix 8. – Chapter 5 – Initial telephone contact with participants

Hello. My name's Vicki Xafis and I'm a researcher from the University of Adelaide.

Could I please speak to NAME?

Last year you told researchers involved in the **Data Linkage Vaccine Safety Study** that you would be happy to be contacted by the research team about related research we would do in the future.

Now we are doing some research into whether people think it's acceptable to link individuals' health information which is held in different databases.

I was wondering if you would like to receive more information about this new study to see whether you would be interested in being involved.

(affirmative response)

Thank you

Can I just confirm that the address we have on record from last year is still current? (check address)

You should receive the information within the next few days. The envelope will have the Women & Children's Hospital logo on it. I will call you again in about 7 to 10 days to discuss the project with you and see if you want to take part. What time is best to contact you?

Thank you very much for your time.

(negative response)

That's fine.

Would it be possible to use some basic information about you, without identifying you, to compare which groups wanted to take part in the research and which didn't?

(affirmative response)

Thank you.

Would you like to write down my number in case you have any queries later? The number is 08 8303 0191.

(negative response)

That's fine.

Thank you for your time anyway.

Good bye.

Appendix 9. – Chapter 5 – Main study participant information and consent form

Women's & Children's Hospital

Government of South Australia
SA Health

THE UNIVERSITY OF ADELAIDE
AUSTRALIA

DISCIPLINE OF PAEDIATRICS
SCHOOL OF PAEDIATRICS &
REPRODUCTIVE HEALTH
FACULTY OF HEALTH SCIENCES
THE UNIVERSITY OF ADELAIDE
SA 5005 Australia
Postal address:
University Department of Paediatrics
WOMEN'S AND CHILDREN'S HOSPITAL
72 King William Road
NORTH ADELAIDE SA 5006

Telephone: +61 8 8161 7266
Facsimile: +61 8 8161 7031

Date

Dear ,

We were pleased that you recently expressed interest in receiving information about a research project conducted by Women's and Children's Hospital and Adelaide University researchers. The study, known as ***The ethics of linking health data for research and health surveillance purposes: views held by parents of children eligible for vaccination***, is explained more fully in the enclosed Information Sheet. This project is linked to the *Data Linkage Vaccine Safety Study* that you participated in during 2009 or early 2010.

The study aims to find out what you and other parents think about linking health data for research or surveillance purposes. It will focus on whether it is acceptable to link people's health information from two or more databases. It is very important to remember that there are no right or wrong views. We simply want to gain an in-depth understanding of how people feel about the issues.

The study does not require you to visit the hospital or go out of your way. The PhD Candidate conducting this project would like to meet you at home, or at another convenient location, for a face-to-face interview at a time convenient for you.

Participation in the research is voluntary and if you decide not to take part or to withdraw after agreeing to participate, this will not affect your relationship or future services provided to you by the Women's and Children's Hospital or Adelaide University.

We would be happy to answer any questions you might have. You can call Vicki Xafis (PhD candidate) on 8303 0191 during business hours.

Sincerely,

Dr Mike Gold
Discipline of Paediatrics
Women's and Children's Hospital &University of Adelaide

CHILDREN, YOUTH & WOMEN'S HEALTH SERVICE (CYWHS)

INFORMATION SHEET

Title: The ethics of linking health data for research and health surveillance purposes: views held by parents of children eligible for vaccination

(Component of ***Vaccine Assessment using Linked Data Safety Study- VALiD***)

Researchers: Dr Michael Gold, Professor Annette Braunack-Mayer, Professor Colin Thomson, Professor Philip Ryan, Ms Katherine Duszynski, Ms Vicki Xafis, Ms Jesia Berry.

Why have you been sent this information?

You are invited to take part in a study examining the ethics of linking health information, which is being conducted by researchers at the Women's and Children's Hospital and the University of Adelaide. In 2009 (or at the beginning of 2010), you had agreed to be contacted about this study when talking to researchers involved in the Data Linkage Vaccine Safety Study.

What is this study about?

This research is part of a larger study called *The Ethical, Legal and Social Acceptability of Data Linkage in the Australian Context: an investigation of current practices, perceptions, and public attitudes*. It is being conducted as part of a PhD study undertaken by Vicki Xafis.

In this component we want to interview parents to see what their views are regarding whether it is acceptable to link people's health information to do research or monitor things such as vaccine safety.

What does the research involve?

If you agree to participate, you will be asked to take part in a face-to-face interview. The interview will be arranged for a time which is convenient for you and your baby and will take approximately 1 to 1.5 hours, depending on how much you would like to contribute. Interviews will be held at your house so that you are not inconvenienced (or at another convenient location of your choice) and they will be recorded so that the conversation can be transcribed accurately.

If something arises at the time of the interview, e.g. your baby is upset and needs your attention, the interview can be stopped and the researcher can come back at a more convenient time for you.

Please note that there is no payment for participation.

What information is being collected?

We are interested in discussing your views on the use of health information in data linkage for research and other projects aimed at improving health.

At the beginning of the interview, we will talk about your involvement in the telephone interview you took part in last year in the Data Linkage Vaccine Safety Study. After that, the researcher will give you a number of scenarios relating to the use of health information in research or public health surveillance. Your views on questions regarding these scenarios would be extremely useful to our research. **It is important to remember that there are no right or wrong views. We are simply interested in your views.** This research does not seek to collect any information about your baby.

How is my privacy protected?

The interviews will be coded, which means that your name will only appear on a list stored in a locked filing cabinet in a lockable office at the University of Adelaide. No other personal or health information will be collected.

Access to all research data, including the interview recordings and transcripts will be limited to members of the research team. The data will be stored in a lockable office on a password protected computer. In very rare cases, the approving Human Research Ethics Committee (Women's and Children's Hospital Research Ethics Committee) may request to see the data as part of an audit. Your information will remain confidential except in the case of a legal requirement to pass on personal information to authorised third parties. It is unlikely that

there will be any such legal requirements in relation to this study but we are required to inform you of this possibility.

What if I change my mind after I have agreed to take part?

Research is voluntary and you are not obliged to take part in this study if you do not want to. If you change your mind, even after you have agreed to participate, you can contact Vicki Xafis and let her know. Please be aware that your data can only be withdrawn up to the point where they have not been analysed. Once the analysis begins, it will not be possible to withdraw any of the data. It is expected that the analysis will be completed 2-3 months after the interview was conducted.

What if I don't want to take part?

Participation in this research is voluntary and if you decide not to take part or to withdraw after agreeing to participate, this will not affect your relationship with or future services provided to you by the Women's and Children's Hospital or Adelaide University.

How do I find out about the results of the research?

This study is expected to be completed by the end of 2010. If you would like to obtain the research findings, your name and contact details will be collected separately at the time of the interview and the results will either be posted or e-mailed to you.

If you would like more information about the larger project of which this study is a component, the findings will be available in early 2012 and a summary can be made available to you.

What do I need to do now?

If you have any queries which you would like to discuss before deciding whether to take part or not, please do not hesitate to contact Vicki Xafis on (08) 8303 0191.

If you want to participate in the research, simply sign and date the yellow Consent Form and have it available for the researcher when she comes to interview you. You should keep the white copy for future reference.

If you lose any of the study information and would like us to send you a replacement, please contact Vicki Xafis.

What will the researchers do now?

The researcher, Vicki Xafis, will call you in about 7-10 days from the day you received this information to answer any questions you may have, to see if you are happy to take part and to set an interview time that suits you (if you want to take part).

The researcher will collect the signed Consent Form on the day of the interview (yellow form). A copy of the signed Consent Form (white form) is for you to keep with this information sheet as part of your records.

Additional information

The study has received ethics approval from the Women's and Children's Human Research Ethics Committee. If at any time, you wish to discuss the ethical approval process or have a concern or complaint please contact the Secretary of the Committee (Ms Brenda Penny) on (08) 8161 6521.

Members of the research team you can contact if you have queries or want to know about your rights as a research participant are:
Principal investigator: Dr Michael Gold on (08) 8161 7266
Project manager: Katherine Duszynski on (08) 8161 7244
PhD candidate: Vicki Xafis on (08) 8303 0191
Or email us: vicki.xafis@adelaide.edu.au

We thank you for your assistance.
Dr Mike Gold
Discipline of Paediatrics
Women's and Children's Hospital & the University of Adelaide

CHILDREN, YOUTH & WOMEN'S HEALTH SERVICE (CYWHS)

HUMAN RESEARCH ETHICS COMMITTEE (HREC)

CONSENT FORM

STUDY TITLE

The ethics of linking health data for research and health surveillance purposes: views held by parents of children eligible for vaccination

I _____hereby consent to my involvement in the research project entitled:

The ethics of linking health data for research and health surveillance purposes: views held by parents of children eligible for vaccination

1. The nature and purpose of the research project described on the attached Information Sheet has been explained to me. I understand it and agree to take part.
2. I understand that I may not directly benefit by taking part in this study.
3. I acknowledge that the possible discomforts and inconveniences, as outlined in the Information Sheet, have been explained to me.
4. I understand that I can withdraw from the study only before the data are analysed. I also understand that my withdrawal will not affect my relationship or future services provided to me by the Women's and Children's Hospital or Adelaide University.
5. I understand that there will be no payment to me for taking part in this study.
6. I have had the opportunity to discuss taking part in this research project with a family member or friend.
7. I am aware that I will be provided with a copy of the Consent Form, when completed, and that I should retain this and the Information Sheet for my records.
8. a) I consent to taking part in a 60-90 minute face-to-face interview at a time that is convenient for me. I agree to the researcher contacting me by phone to negotiate a convenient time.

   b) I **do / I do not** (**please circle only one option**) consent to having the interview audio taped

c) I **do / do not** consent (**please circle only one option**) to the interview data being used in another research project. I understand that if the interview data are used in other research projects, the researchers must first seek approval from the Women & Children's Hospital Human Research Ethics Committee.

9. I understand that my information will be kept confidential as explained in the information sheet except where there is a requirement by law for it to be divulged.

10. I have been provided with the contact details of the:

    Researcher conducting the interviews;

    The Women & Children's Hospital Human Research Ethics Committee Secretariat.

Full name of participant: .....

Signed: .....

Dated: .....

Appendix 10. – Chart 3 – Scenario 1 - Consent requirements

Respondent	Consent should be sought	Justification for consent	Consent need not be sought	Justification for no consent	No consent but dissemination of findings
Danny	x	1,2,22	x	a	x
Darren	**x**	**3,4,8,16**			
Don	x	5,23	x	b	
Haley	xAC	6,1,4	xB	c,d	
Harmony	**x**	**6,4,16,9**			
Helen	x	1	x	d	
Henrietta	x	7,4,8	x	e,f	
Holly	x	1,5	x	f,b	
Jack	**x**	**9,10,11,12,18**			
Jacob	**x**	**13,5,18**			
John	x	14,15,16	x	g,n,h	
Mandy	x	16,21,13	x	d,i,k	
Margaret	xAC	(A-16,18) (C-18)	xB	j,k,d	
Mary	x	9,4,7	x	b	
Mel			**x**	**b**	
Molly	xB[b]	1	xA[c]	b,d,p	
Tegan			**x**	**l,b,m,a**	
Teresa	x	18	x	b	
Tina	**x**	**15,6,19**			
Tracey	x	17	x	k,n,q	
Trixie	x	20	x	b,n,a	
Vallery	x	17	x	b,d,h	
Vanessa			**x**	**g,o,d**	
Verity	xAC	19,4,6,1,16	xB	b,g,l,d	
Victoria			x	d,j,b	x
Virginia			**x**	**b,l**	

Justification for consent

1. People have right to choose
2. Unfair to force participation
3. To cater for future uses of the same data
4. To ensure people are not upset/do not object
5. Consent ensures that privacy is protected
6. Information belongs to people
7. Use of information without consent leads to trouble for researchers
8. Consent is required for everything
9. People prefer to be given the choice
10. Some don't trust that information stays anonymous
11. People want to control their information
12. Seeking consent is courteous
13. Seeking consent is a sign of respect
14. Seeking consent for use of private information is an ethical requirement
15. Consent should be sought for all research
16. People need to be aware of what is happening
17. Consent provides protection
18. Consent should be sought at initial point of data collection
19. Disclosure of information to a third party requires consent
20. Consent is required when other spheres of life (apart from health) are involved
21. Consent is a legal requirement
22. Consent required because of cultural differences; some people don't like their information used if they derive no benefits, or if there are perceived risks
23. Consent is required when researchers access identifiable information

Justification for no consent

a. Large data sets serve as protection against identification
b. Use of de-identified data does not require consent
c. Use of de-identified information does not breach privacy
d. Acceptable practice because of the benefits
e. Acceptable depending on study
f. Acceptable if security and safety measures in place
g. Practical considerations of obtaining consent from thousands
h. Privacy legislation binds researchers and protects participants
i. Acceptable due to cost and time constraints involved when obtaining consent
j. Knowledge of data linkage process allays concerns so no consent is acceptable
k. Participants are not directly involved
l. Consent lowers research participation rates
m. Medical information will not be provided to other parties
n. Strict measures/guidelines provide protection
o. No need for consent if data linkage organisation is trustworthy
p. The more participants involved the better the quality of the study
q. Retrospective use of data does not require consent

Appendix 11. – Chart 4 – Scenario 1 – Notification without consent

Respondent	Notification without consent[1]									
	At point of data collection for all research					Project-specific notification				
	Yes	No	Justification for negative response	Undecided	Not stated	Yes	No	Justification for negative response	Undecided[2]	Not stated
Danny					x	x			x	
Darren					x		x	consent needs to be sought		
Don					x	x	x	consent required for use of identifiable data		
Haley					x		x	option to consent should be given		
Harmony					x		x	opt-out consent appropriate		
Helen					x	x				
Henrietta					x	x				
Holly					x	x				
Jack		x	consent at data collection point appropriate							
Jacob		x	data custodians should seek consent							
John					x					x
Mandy					x	x				
Margaret		x	consent at data collection point appropriate							
Mary					x	x[3]				
Mel					x	x				
Molly					x				x	
Tegan					x				x	
Teresa		x	consent required				x	consent required		
Tina					x[4]					x
Tracey					x		x	option to consent should be given		
Trixie					x	x				
Vallery	x[5]					x[6]				
Vanessa					x	x				
Verity					x		x	need to be given choice		
Victoria					x	x				
Virginia					x	x				

[1]The question about notification was asked specifically about scenario 1 but some respondents generalised and suggested that notification was/was not appropriate at the point of data collection. Where the response is in the affirmative, it means that consent is not required; where it is in the negative, it means either that the respondent had a preference for consent to be sought or that both consent and notification are not required/appropriate.

[2] Undecided refers to both indecision but also instances where the respondent has contradicted him/herself and not arrived at a definitive view one way or the other.

[3] Only on the condition that the researchers are not legally obliged to obtain consent

[4] Participant indicated that she does not view the use of information as a problem as it would be de-identified if used. However, she is not opposed to consent being sought at the initial point of contact with the service.

[5]Not asked about this as very strong preference for consent expressed

[6]Others may prefer opportunity to consent

[7]Interviewee's preference

[8]Participant indicated that neither notification nor consent are practicable due to numbers but also that identifiability is protected. Consent would be required only if the sample was small and identifiability therefore became an issue.

[9]Participant thinks that general information might be appropriate, as it motivates people to participate in research

Appendix 12. – Chart 5 – Scenario 2 - Consent requirements

Respondent[a]	Consent should be sought	Justification for consent	Consent should be sought-deceased people	Justification for consent-deceased people	Consent need not be sought	Justification for no consent	Consent need not be sought – deceased people	Justification for no consent-deceased people	No consent but notification
Danny					x	b	x	b	
Darren	x[b]	10					x	i	
Don					x	e,a	x	h	
Haley	x[b]	4			x	a	x	i	
Harmony	x[b]	2	x	7					
Helen					x	b,a	x	j,k	
Henrietta	xB	9			xAC	b,f,g	x	h	
Holly					x	d,b	x	i,a,j	
Jack	x[b]	5	x[e]	11	x[d]	d	x	d	
Jacob	x	9	x[f]	12					
John	x[bc]	8,9	x	13	x	o,a	x	o,a	
Mandy					x	e,d	x	e	
Margaret					x	a	x	a,i	
Mary					x	a	x	a	
Mel	xAD	9			xB	d,b	x	h	xC
Molly					x	b,a	x	i,a	
Tegan					x	a,c,b	x	a	
Teresa					x	b,a,q	x	a	
Tina	x[b]	2,3,6,7,1					x	l	
Tracey					x	p	x	h	
Trixie					x	a,m	x	h	
Vallery					x	m,a	x	a	x[g]
Vanessa					x	i	x	d	
Verity					x	m	x	m	
Victoria					x	a,e,n	x	a,e,n,k	
Virginia					x	a	x	l*	x[g]

Justification for consent

1. People have right to choose
2. To ensure people are not upset/do not object
3. Not seeking consent infringes privacy
4. Information belongs to people
5. Use of information without consent leads to trouble for researchers
6. People want to control their information
7. Seeking consent is a sign of respect
8. Consent should be sought for all research
9. Consent should be sought at initial point of data collection
10. There are ways to achieving contact to request consent despite difficulties
11. Seeking consent for deceased people's information is appropriate because knowledge that they are contributing to society would bring comfort to families
12. Consent for use of data should be sought whenever health services are accessed. Therefore, a deceased person's consent would have already been obtained
13. Consent for deceased person's information should be sought because they still have rights

Justification for no consent

a. De-identified data does not require consent
b. Acceptable practice because of the benefits
c. Acceptable if security and safety measures in place
d. Practical considerations of obtaining consent from thousands
e. Acceptable due to cost and time constraints involved when obtaining consent
f. Use of information will not prejudice participants
g. Retrospective use of medical data acceptable
h. No justification provided
i. Requesting consent for deceased people's information could traumatise family
j. Relatives will be unaware of use of data relating to deceased relative
k. Data regarding deceased people is invaluable and should be included
l. Use of deceased people's information does not impact on deceased person or their family
m. Audit type activities do not require consent
n. Requesting consent for use of de-identified data is burdensome, as people are time-poor
o. Acceptable not to seek consent from those who cannot be contacted if strict guidelines adhered to
p. Not dealing with people directly
q. Requesting consent could create difficulties, as people's confidence in the fact that research uses de-identified data might be reduced

[a] Unless otherwise stated with the use of capital letters, opinions shifted from left to right of the Chart
[b] Acknowledges difficulties in seeking consent
[c] Obtain consent from those from whom it is feasible but also use information pertaining to those from whom it was not possible to obtain consent following strict guidelines
[d] Participant makes concession when he considers large number of participants but warns that researchers had better ensure that they have done everything appropriately; otherwise, there could be legal repercussions.
[e] This response came up earlier in the conversation but when asked again, participant was unsure of the need to get consent from relatives
[f] The participant expressed this view when discussing scenario 1 but it is evident that he intended it generally. Therefore, he was not asked this question again
[g] Participant indicated that it might be nice to be notified of research
*family not mentioned

Appendix 13. - Chart 6 – Scenario 3 – Consent requirements

Respondent[a]	Consent should be sought	Justification for consent	Consent need not be sought	Justification
Danny			x	b,e,k,l
Darren			x	f,a,g
Don			x	a,c
Haley			x[e]	g,h,f,b,a
Harmony	x	3,8		
Helen			x	a,m,b
Henrietta			x	b[f]
Holly			x[e]	b,a
Jack	x	4	x	g,c,j
Jacob			x	e
John			x[e]	a,g,c,n
Mandy			x	e,c,d
Margaret			x	b,a
Mary	x[b]B	5	xA	b,a
Mel			x	b,h,a
Molly			x	b
Tegan			x[c]	b,i
Teresa			x	a
Tina	x	6,1,2		
Tracey	x[d]	5,6,7,9,8		
Trixie			x	a,b
Vallery			x[e]	b
Vanessa			x	b,c,d
Verity			x	b
Victoria			x	a
Virginia			x	b

Justification for consent

1. People have right to choose
2. Not getting consent is an infringement of people's privacy
3. Consent should be sought for all research
4. If there is a legal guardian, consent should probably be sought
5. The more sensitive the data, the greater the need to obtain consent
6. Mental health issues do not warrant not obtaining consent from participant or authorised carer
7. The need for large number of participants is no excuse for not considering obtaining consent
8. Sensitivity of data requires that consent be obtained
9. Research involving 'vulnerable' people requires consent

Justification for no consent

a. De-identified data does not require consent
b. Acceptable practice because of the benefits
c. Practical considerations of obtaining consent from thousands
d. Strict measures/guidelines provide protection
e. Research focusing on issues such as violence, which affects others/the whole community, justifies not obtaining consent
f. Acceptable to do mental health research without consent
g. Given the difficulties in obtaining consent, it is best to conduct research as benefits would be great
h. Consent not very important where safety issues are concerned
i. No impact on participants, who will be unaware that their data were used
j. Some participants cannot consent
k. Trying to get consent (including from relatives) could delay research, which should be done promptly because if its nature
l. When you weigh up individual vs community benefits, community benefits here are greater
m. No harm to individuals because they will not be named (or 'outed')
n. Some participants may not have guardians

[a] Unless otherwise stated with the use of capital letters, opinions shifted from left to right of the Chart.
[b] Makes distinction between what she prefers (no consent necessarily) to what others prefer (consent)
[c] Struggled with response, as it conflicted with people's general expectations regarding consent requirements (as stated by participant)
[d] Consent preferable but acknowledges impact of monetary constraints on ability to obtain consent from thousands of participants
[e] Aware that consent can be sought from authorised carers where individual cannot consent

Appendix 14. – Chart 7 – Scenario 3 – Public notification

Respondent[a]	Public notification	Justification	Dissemination of findings
Danny	Yes	1	
Darren	Yes	2	
Don	Yes	3	
Haley	Yes	4,1	
Harmony	Yes	5	
Helen	No/Yes	a,1	
Henrietta	No	b	x
Holly	Yes	6	
Jack	Yes	7,8	
Jacob	Yes	9	
John	Yes	10	
Mandy	Yes	11	
Margaret	No	c	
Mary	Yes	12	
Mel	Yes	13,14	
Molly	Yes	8	
Tegan	No	d,e	x
Teresa	Yes/No	9,d,a[b]	
Tina	Yes	14	
Tracey	Yes	15	
Trixie	No	c,d,a	x
Vallery	No/Yes/No	f,16,17,g	
Vanessa	Yes	5,6,18	
Verity	No	h	
Victoria	Yes	19	
Virginia	No	i	x

Justification for public notification

1. Gives public understanding of benefits of research
2. Researchers have to notify public about research
3. Public has the right to know how their information is being used
4. Public would want to know about research relating to violent behaviour
5. Gives public opportunity to express dissent
6. Public can choose to read about it or not read about it in public media
7. Gives public opportunity to make enquiries if they think they may be included in participant group
8. Public likes to be informed of research going on
9. Important for public to know what research is going on if it is publicly funded
10. Instils confidence in public that such issues are being dealt with
11. Justification not offered
12. Public should be aware that mental health research is being conducted
13. Gives public confidence that government is focusing on mental health
14. Knowledge of research positively predisposes future participation
15. Careful dissemination required so as not to hinder research due to adverse public reaction
16. Public has a right to know what research is being conducted
17. Sometimes it is good to know what research is going on
18. Knowing about research enables people to be more involved in the community
19. Public interested in research if it relates to them in some way

Justification for no public notification

a. Notification of research costs a lot
b. Notification does not make difference
c. Public does not need to know about every research project being conducted
d. No need to give public information they do not want
e. No need for researchers to announce research unless they need public to know for volunteering purposes
f. Notification can hinder research due to adverse public reaction
g. Personally not bothered if they are not informed of research being conducted
h. Most people do not have interest in research being conducted unless it relates to them
i. Public knowledge about mental health research might serve to reinforce entrenched misconceptions about people with mental health issues

[a] Where more than one response is offered, the participant expressed opposing views in the order in which the responses are given

[b] Teresa specifies that information in the form of letters/leaflets need not be distributed, for the reasons stated, but that there should be information available on websites.

Appendix 15. – Chart 8 – Scenario 4 – Consent requirements

Respondent[a]	Consent should be sought	Justification for consent	Opt-in consent	Opt-out consent	Consent need not be sought	Justification for no consent	Notification (Justification)
Danny	x	6,8,1	x				
Darren					x[e]	i	x(A)
Don	xB[b]	21			xAD	c,d	xC(B)
Haley	x	10,11,19,3	x				
Harmony	x	5,6	x				
Helen	xB[c]	12	x		xA	a,e,f,b	xC(C)
Henrietta	x	8,6,18		x			
Holly	xB	9,18		x	xA	t	xC (A)
Jack	x	2,8,13		x			x[o](C)
Jacob	xB	7[d]	x		xA	j,**a**	
John	x[p]	21			x	c,**a**,d,e,**k,t**,f,k	x(D)
Mandy					x	c,a,l,p	x(E)
Margaret	x	10,11,6,18,1		x			x(F)
Mary	x	6,10,11,14,15,16		x			
Mel	x	10,11,8,6,19	x				
Molly	xB	4,1		x	xA[f]	s	
Tegan	x	15,16,18		x			
Teresa	x	16,17,6,8		x[n]			
Tina	x	11	x[k]	x[k]			
Tracey	xB[h]	12		x	xA	m,n,o,g	xC(B)
Trixie	xB[i]	9		x[j]	xA	t,p,**k**,q,a	
Vallery	x	11,14,6,18	x	x			
Vanessa	x[l]	1,6,8,10,11,16	x		x[l]	r,h	x(G)
Verity	x	11,10,8,6,18		x			
Victoria	x	10,16,11	x[m]				
Virginia	xB	16,20,2		x	xA	**g**,s	

Justification for consent

1. People have right to choose
2. To ensure people are not upset/do not object
3. Information belongs to people
4. People want to control their information
5. Consent should be sought for all research
6. Consent provides protection against potential impact of research
7. Consent should be sought at initial point of data collection
8. Consent is required when other spheres of life (apart from health) are involved
9. No reason given
10. Consent required when researchers do the linkage
11. Access to identifiable data by researchers requires consent
12. Having the option to consent is good
13. Collecting this kind of information without consent may not be legal
14. Researchers may disclose information to third party
15. Someone on the research team may know the research participants
16. Consent required because of lack of separation of tasks
17. Researchers using identifiable information without consent is intrusive
18. Opt-out consent would result in more participants being involved
19. Opt-in consent captures the people who really want to participate
20. Consent required when participants are experiencing mental health issues, as they may not welcome people delving into their affairs at that point in their lives
21. It is very good to obtain consent if it is simple to do so

Justification for no consent

a. Acceptable practice because of the benefits
b. Acceptable depending on study
c. Practical considerations of obtaining consent from thousands
d. Acceptable due to cost and time constraints involved when obtaining consent
e. Consent lowers research participation rates
f. Low participation rates impact on quality of research
g. Strict measures/guidelines provide protection
h. No need for consent if data linkage organisation is trustworthy
i. Getting consent could have detrimental effect on participants
j. Unclear reason
k. The information is already there so it should just be used without consent
l. Consent would have been given at data collection point
m. Information given to WorkCover can be shared with researchers, as it was given confidentially[g]
n. Researchers will not use information obtained without consent to harm participants
o. Retrospective use of data does not require consent
p. Researchers are not interested in specific cases
q. People have inflated view of how interesting they are to others
r. Provided that the linkage organisation was involved so that tasks are separated
s. Researchers will be dealing with de-identified data eventually
t. The findings are presented in de-identified form

Justification for notification

(A) Having the information in public domain reassures people that nothing is being hidden from them and that no harm will come to them
(B) No reason given
(C) It may be appropriate in this case with only a few dissenters who you could 'deal with' individually
(D) If it is possible to notify so many people, it is a good idea, but there are many practical constraints such as money, time, resources
(E) Would be happy to simply know that some research is being conducted in the area. Acceptable because of the benefits.
(F) Notification better than opt-out consent if there is opportunity for participant to withdraw from research (but they must be given the choice to do so)
(G) Sensible to have a register of all research being conducted so people with vested interest in certain types of research or those simply interested can become informed

[a] Unless otherwise stated with the use of unbracketed capital letters, opinions shifted from left to right of the Chart.
[b] It is good to obtain consent if we can but if cost and other practical issues such as accessing thousands etc. complicate the issue of obtaining consent then it is not necessary to pursue it
[c] Participant stressed that need for consent depends on a number of factors. Having the option to consent is good but it depends on the study and who is doing it and how they intend to use the data. If it is for commercial purposes (i.e. pharmaceutical companies) consent must be sought. Additional value in seeking consent is getting data on those who declined to take part so you can talk to them separately.
[d] In reference to WorkCover data
[e] It is possible that the participant was experiencing comprehension difficulties, as English is not his first language
[f] Indicated she could not understand scenario. Scenario explained again and she then changed her response
[g] Misunderstanding of the handling of confidential data
[h] Did not revert to this view entirely but when option was presented said that opt-out would be a good idea
[i] Listed as second preference to 'no consent'
[j] Opt-out preferred because it takes a 'fair bit of effort for people to opt out'
[k] First preference is opt-in and second preference is opt-out consent
[l] Consent required if there is no linkage organisation involved. If there is a linkage organisation involved, no consent required
[m] Preference for consent over the phone (opt-out consent: not evident that they have even read the information, written opt-in consent results in fewer participants because people do not send consent forms in)
[n] Not entirely clear if participant supports opt-out or opt-in consent
[o] Obtaining consent would be preferable
[p] Consent should always be sought where numbers are small (e.g. 50-100 participants)

Appendix 16. - Chart 9 – Non-consensual use of health data

Respondent	Acceptable	Justification/Conditions	Unacceptable	Justification
Danny	x	1,2		
Darren[a]				
Don	x	3		
Haley	x[b]	1	x	b
Harmony			x[c]	c
Helen			x	d
Henrietta	x	3		
Holly	x	1,4,5,13,10	x	e
Jack	x	1,4		
Jacob			x	f,g,h
John	x	1,17		
Mandy	x	5,1,15,12		
Margaret	x	6,1		
Mary	x	4,7,1,19		
Mel	xB	4,8,1,20	xA	d
Molly	x	4		
Tegan	x	1,4,8		
Teresa	x	4		
Tina	x[d]	4	x	d,b
Tracey	x	9,1		
Trixie	x	10,1,11,12		
Vallery	x	15,7		
Vanessa	x	13,14		
Verity			x	a,d
Victoria	x	10,15		
Virginia	x	6,16,18,1		

Justification for acceptability of non-consensual use of health data

1. Because of the benefits to community/advancement of society
2. Use of information leads to harm minimization for whole community
3. No reason provided
4. Provided information is anonymous
5. Understanding of data linkage process promotes agreement
6. If consent were always sought, no progress would be made as a result of wasting resources including time, effort to get consent
7. Provided security and safety measures are in place
8. Provided no harm comes to participants
9. Retrospective use of data is acceptable
10. De-identified data does not require consent
11. Strict measures/guidelines provide protection
12. Large data sets serve as protection against identification
13. Unreasonable to expect to get consent from thousands especially when benefits flow back to participants
14. People who stand to benefit should have their information included
15. Data linkage process appropriately protects individuals
16. Giving option for consent 'opens up a can of worms'. The more people know, the more control they want
17. Anonymised data reduces harm to participants
18. The ability to conduct research is 'more important than one individual's right to give consent or not'
19. Information without identifying features is just 'information'; it could be anyone
20. Provided people are informed that a study is being conducted

Justification for unacceptability of non-consensual use of health data

a. People prefer transparency and wish to be notified of what is going on
b. Use of people's information for other purposes requires consent
c. Linkage of information helps build up a bigger picture of individuals and so consent is required even if the information is anonymous
d. It is important to give people the choice to participate or not
e. Research which relates to traumatic personal experiences (e.g. rape, torture etc.) requires consent even if data are de-identified eventually
f. Consent should be sought at initial point of data collection
g. Obtaining consent shows respect for people
h. Not obtaining consent is deceptive and equates to something similar to a 'crime'

[a]Missing data
[b]Haley was not at all committed to the no consent option but did indicate that she was not completely opposed to it even though ultimately she had a strong preference for the consent option when personal/health data are used
[c]Harmony elaborated at length why she thought consent needs to be sought but ended with 'For me, I wouldn't care. Given her detailed justification, I took the consent option to be her view for the use of her information as well
[d]Tina indicated that people probably expect anonymised health data to be used but that use of demographic data would probably annoy people

Appendix 17. - Citizen's jury pre and post questionnaires

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Vaccine Safety Data Linkage *Community Forum*

Participant questionnaire

Please answer the questions below with the answer that best describes your views.
All information will remain confidential.
Participant answers will be analysed and detailed in a report.
No individual answers will be presented.

Before you answer these questions let us explain what data linkage is. Data linkage is the merging of data that are held separately but that relate to the same people. In order to merge separate databases, a computer program matches the information using unique identifiers such as name, date of birth, sex, and postcode, to make sure that the information being linked relates to the same individuals. An independent data linkage unit performs the linking of unique identifiers, but does not have access to the health information. Researchers never get to see who the data are about because they only receive health data without identifying information.

1. **Is it acceptable to link data to monitor the safety of vaccines?**

   Yes ☐
   No ☐
   Not sure ☐
   Under certain circumstances ☐

   Please briefly explain the circumstances:

   _____
   _____

2. ***Please tell me what your view is regarding the following statement:*** **My permission should always be asked for before my identifiable* health information is used for research purposes.** **Identifiable health information* is health information which has been collected from you and has personal information like your name, age, postcode etc. so people can tell that it is about you.*

   Yes ☐
   No ☐
   Not sure ☐
   Under certain circumstances ☐

   Please briefly explain the circumstances:

   _____

3. **My permission should always be asked for before non-identifiable* health information about me is used for research purposes.**
   **Non-identifiable health information is health information which has been collected from you that doesn't have your name, age, postcode etc. attached to it anymore so no one can tell that the information is about you.*

   Yes ☐
   No ☐
   Not sure ☐
   Under certain circumstances ☐

   Please briefly explain the circumstances:

   _____
   _____

4. **Non-identifiable health information about me belongs to me.**

   Yes ☐
   No ☐
   Not sure ☐
   Under certain circumstances ☐

   Please briefly explain the circumstances:

   _____
   _____

5. **People have an obligation to sacrifice some privacy in research if the outcomes of the research will benefit society as a whole.**

   Yes ☐
   No ☐
   Not sure ☐
   Under certain circumstances ☐

   Please briefly explain the circumstances:

   _____
   _____

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6. If the handling of people's information is protected by strict laws, rules and guidelines that do not let researchers analyse identifiable information, I am happy for my identifiable information to be used in data linkage projects.

- Yes ☐
- No ☐
- Not sure ☐
- Under certain circumstances ☐

Please briefly explain the circumstances:

_____

_____

7. Permission to use *non-identifiable health information* in research should be requested at the time the information is first collected (e.g. hospital admission).

- Yes ☐
- No ☐
- Not sure ☐
- Under certain circumstances ☐

Please briefly explain the circumstances:

_____

_____

8. The public should be better informed about the kinds of health research we do in Australia.

- Yes ☐
- No ☐
- Not sure ☐
- Under certain circumstances ☐

Please briefly explain the circumstances:

_____

_____

9. I have confidence in the legislation and measures that aim to protect health information that's used in research.

- Yes ☐
- No ☐
- Not sure ☐
- Under certain circumstances ☐

Please briefly explain the circumstances:

_____

_____

10. If I had a better understanding of the measures that help protect health information, I would be more likely to agree to the use of my identifiable health data in data linkage.

- Yes ☐
- No ☐
- Not sure ☐
- Under certain circumstances ☐

Please briefly explain the circumstances:

_____

_____

11. People's health information is currently sometimes used in research without their permission.

- Yes ☐
- No ☐
- Not sure ☐
- Under certain circumstances ☐

Please briefly explain the circumstances:

_____

_____

12. I completely understand what data linkage is.

- Yes ☐
- No ☐
- Not sure ☐

Any comments?

_____

_____

Before finishing, please provide some general information about yourself.

13. How old are you? _____ years old

14. And are you

- Male ☐
- Female ☐

15. What is the highest level of education you have obtained?

- Postgraduate Degree level ☐
- Grad. Diploma/Grad. Certificate level ☐
- Bachelor Degree level ☐
- Advanced Diploma/Diploma level ☐
- Certificate level ☐
- Trade qualification/apprenticeship ☐
- Senior secondary education ☐

(e.g. Year 12, Senior Secondary Certificate of Education or equivalent)

- Year 11 or equivalent ☐
- Junior secondary education ☐

(e.g. Year 10 or equivalent)

- Primary education ☐
- Pre-primary education ☐
- Other education ☐

(Please specify): _____

- No education ☐
- Don't know ☐

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Vaccine Safety Data Linkage *Community Forum*

Completion questionnaire

Please answer the questions below with the answer that best describes your views.
All information will remain confidential.
Participant answers will be analysed and detailed in a report.
No individual answers will be presented.

Before you answer these questions let us explain what data linkage is. Data linkage is the merging of data that are held separately but that relate to the same people. In order to merge separate databases, a computer program matches the information using unique identifiers such as name, date of birth, sex, and postcode, to make sure that the information being linked relates to the same individuals. An independent data linkage unit performs the linking of unique identifiers, but does not have access to the health information. Researchers never get to see who the data are about because they only receive health data without identifying information.

1. **Is it acceptable to link data to monitor the safety of vaccines?**

   Yes ☐
   No ☐
   Not sure ☐
   Under certain circumstances ☐

   Please briefly explain the circumstances:

   _____
   _____

2. ***Please tell me what your view is regarding the following statement:*** **My permission should always be asked for before my identifiable* health information is used for research purposes.** **Identifiable health information* is health information which has been collected from you and has personal information like your name, age, postcode etc. so people can tell that it is about you.*

   Yes ☐
   No ☐
   Not sure ☐
   Under certain circumstances ☐

   Please briefly explain the circumstances:

   _____
   _____

3. **My permission should always be asked for before non-identifiable* health information about me is used for research purposes.**
   **Non-identifiable health information is health information which has been collected from you but that doesn't have your name, age, postcode etc. attached to it anymore so no one can tell that the information is about you.*

   Yes ☐
   No ☐
   Not sure ☐
   Under certain circumstances ☐

   Please briefly explain the circumstances:

   _____
   _____

4. **Non-identifiable health information about me belongs to me.**

   Yes ☐
   No ☐
   Not sure ☐
   Under certain circumstances ☐

   Please briefly explain the circumstances:

   _____
   _____

5. **People have an obligation to sacrifice some privacy in research if the outcomes of the research will benefit society as a whole.**

   Yes ☐
   No ☐
   Not sure ☐
   Under certain circumstances ☐

   Please briefly explain the circumstances:

   _____
   _____

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6. If the handling of people's information is protected by strict laws, rules and guidelines that do not let researchers analyse identifiable information, I am happy for my identifiable information to be used in data linkage projects.

Yes ☐
No ☐
Not sure ☐
Under certain circumstances ☐

Please briefly explain the circumstances:

_____
_____

7. Permission to use *non-identifiable health information* in research should be requested at the time the information is first collected (e.g. hospital admission).

Yes ☐
No ☐
Not sure ☐
Under certain circumstances ☐

Please briefly explain the circumstances:

_____
_____

8. The public should be better informed about the kinds of health research we do in Australia.

Yes ☐
No ☐
Not sure ☐
Under certain circumstances ☐

Please briefly explain the circumstances:

_____
_____

9. I have confidence in the legislation and measures that aim to protect health information that's used in research.

Yes ☐
No ☐
Not sure ☐
Under certain circumstances ☐

Please briefly explain the circumstances:

_____
_____

10 If I had a better understanding of the measures that help protect health information, I would be more likely to agree to the use of my identifiable health data in data linkage.

Yes ☐
No ☐
Not sure ☐
Under certain circumstances ☐

Please briefly explain the circumstances:

_____
_____

11. People's health information is currently sometimes used in research without their permission.

Yes ☐
No ☐
Not sure ☐
Under certain circumstances ☐

Please briefly explain the circumstances:

_____
_____

12. I completely understand what data linkage is.

Yes ☐
No ☐
Not sure ☐

Any comments?

_____
_____

Thank you very much for completing both questionnaires

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. . .to new beginnings. . .

Every new beginning comes from some other beginning's end.

Seneca
Roman philosopher (ca. 4BC – AD65)