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PAPER

Ethical questions must be considered for electronic health records

Merle Spriggs,¹ Michael V Arnold,² Christopher M Pearce,^{3,4} Craig Fry¹

¹Health Ethics & Policy, Murdoch Childrens Research Institute, Parkville, Victoria, Australia

²History and Philosophy of Science, University of Melbourne, Parkville, Victoria, Australia

³Melbourne East General Practice Network, Melbourne, Victoria, Australia

⁴Department of General Practice, Monash University, Clayton, Victoria, Australia

Correspondence to

Dr Merle Spriggs, Health Ethics & Policy, Murdoch Childrens Research Institute, Flemington Road, Parkville, Victoria 3052, Australia; merle.spriggs@mcri.edu.au

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ABSTRACT

National electronic health record initiatives are in progress in many countries around the world but the debate about the ethical issues and how they are to be addressed remains overshadowed by other issues. The discourse to which all others are answerable is a technical discourse, even where matters of privacy and consent are concerned. Yet a focus on technical issues and a failure to think about ethics are cited as factors in the failure of the UK health record system. In this paper, while the prime concern is the Australian Personally Controlled Electronic Health Record (PCEHR), the discussion is relevant to and informed by the international context. The authors draw attention to ethical and conceptual issues that have implications for the success or failure of electronic health records systems. Important ethical issues to consider as Australia moves towards a PCEHR system include: issues of equity that arise in the context of personal control, who benefits and who should pay, what are the legitimate uses of PCEHRs, and how we should implement privacy. The authors identify specific questions that need addressing.

INTRODUCTION

National electronic health record initiatives are in progress in many countries around the world but the debate about the ethical issues that are entailed and how they are to be addressed has thus far been overshadowed by technical issues and technical priorities such as functionality, system programming and design, interoperability, governance structures, proof of record ownership and data quality and security, even where matters of privacy and consent are concerned. Yet it is clear that confidence in the ethics of the system is 'mission critical'; indeed, a 'technical and managerial focus' and a failure to think about 'ethics and values' have been cited as a key factor in the failure of the UK health record system.^{1 2} This occurred despite there being clear guidelines available for health informatics professionals³ and existing standards to guide them (such as ISO TR 21089-2004: health informatics trusted end-to-end information flows). The ethical issues inherent in e-health are multi-faceted and range from technical issues to the complexity of funding and outsourcing.⁴

Personally Controlled Electronic Health Records (PCEHRs) represent a particular challenge as they change the traditional power structure in information control in favour of the patient.^{5 6} In this paper, we identify the important ethical issues with implications for the success or failure of electronic health records systems. These include questions of

equity and justice in a system of personalised control, and who benefits and who should pay for electronic health records. We also consider questions about the legitimate use of personal information for a public purpose or for purposes other than healthcare, how to implement privacy and the degree of control afforded to young people. While our focus is the government developed PCEHR to be launched in Australia, this paper is relevant to and informed by the international context.

Our focus would not seem to be reflected in the consultation process in Australia, which is currently paying little attention to important ethical issues. By its own admission, the focus of the National E-Health Transition Authority (NEHTA) in its *Concept of Operations* is on 'technical' and 'business' requirements for the PCEHR system although purportedly addressing issues from the public consultation process.⁷ Our paper seeks to draw the attention of opinion leaders and decision makers to specific ethical questions posed by electronic health records. We argue that these questions must be addressed and that value judgements must be transparent and we suggest a way forward in addressing some of these questions and judgements.

BACKGROUND: PCEHR

There are similarities and some differences between the PCEHR and the UK system. The PCEHR will contain a Shared Health Summary that is similar to the UK Summary Care Record. It includes information such as current medications, adverse reactions, allergies and immunisations. The PCEHR, however, is a 'distributed system of service providers working in concert' rather than a single centralised database, and it is opt-in rather than opt-out.⁷ After the initial roll out phase of the PCEHR there will also be provision for consumers to enter notes through a consumer portal.⁷ This 'personal health diary', which was to be one of the key parts of the PCEHR, has become merely 'a memory aid for individuals' visible only to individuals and their carers or representatives.⁷ Legislation will preclude it being exposed to clinicians.

Central to the concept of PCEHRs is the idea of 'personal control'. Individuals can exercise personal control by (a) deciding whether or not to have an active PCEHR, (b) setting access controls giving general or limited access to healthcare organisations, (c) authorising others such as family members to access their PCEHR and (d) choosing which information is stored by and is accessible through their PCEHR. Personal control is further enhanced by enabling users to make queries and



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complaints about the way information is managed in their PCEHR and to 'view an activity history' setting out who has accessed what on their PCEHR.⁷ Note that in each of these instances, personal control is read as a technical affordance—as a property inherent in the options provided by the system. Personal control thus becomes a technical issue, and the personal attributes and social conditions needed to exercise personal control have thus far not been the subject of discussion in the Australian electronic health records context.

The proposed nationally networked PCEHR system where up-to-date information is readily accessible by patients and by healthcare providers has potential benefits for patients, healthcare providers and healthcare sector. These include improvements in patient care, health outcomes, safety and efficiency.⁸ The realisation of the benefits depends on participation by consumers and by health providers and on the continuation of public support and funding. Ethical questions are central to these matters.

Personal control, equity, health literacy and cognitive capacity

It is expected that the PCEHR system will provide records that are more current and reliable than existing systems, and that personal control may promote greater patient engagement with their health record, translating into better health outcomes.⁷ However, the international experience of the benefits of personal control suggests that such assumptions should be scrutinised. For example, Google is retiring the 'Google Health' product because of poor uptake,⁹ suggesting that personal ownership of one's medical record is not as attractive as might be thought. Some argue that if personal control includes the ability to lock off or change record content, the record will not be regarded as 'trustworthy' by healthcare professionals,^{10 11} suggesting a new record that is of less use than the old. And, some experts suggest that PCEHRs require cognitive and health literacy skills that not all consumers have.^{12 13}

The technical implementation of personal control takes the form of an opt-in process, where there are options to control data and professional access to that data. We know that many people will not take up these options and will not engage with PCEHRs or in their own healthcare more generally, often due to higher priority factors like social instability, poverty, major family stress or serious disabilities.¹ A medical record is an important resource in the healthcare platform, and to shift its status from a professionally controlled infrastructure to a personally controlled option raises important ethical questions such as: 'to what degree is it appropriate to accept a person's choice to be relatively disengaged with regard to their own healthcare?' and to 'what extent should less engaged individuals be punished' for their 'ignorance' or 'unhealthy lifestyle choices'¹² ?

With regard to personal control, some commentators question the implicit assumption that the 'patients should know as much as possible about their own care' and that they should 'take more responsibility for healthcare decisions'.¹² It is recognised that patients may legitimately have 'other concerns' that 'override their interest in maximizing their physician's access to all possibly relevant information'.¹⁴ A case study of the UK HealthSpace personal electronic health record shows that consumer motivation, the alignment of personal electronic records with consumer attitudes and self-management practices are key factors determining uptake.¹ So a number of variables are at work in determining the shape of the PCEHR and its position in future healthcare—the take-up of the PCEHR, the data it contains, the access professionals have to the record, the

patient's engagement with the record and the professionals' trust in it. The exercise of personal control creates a system of medical records that varies according to the options exercised by the individual, and in so far as healthcare relies on the PCEHR, the medical record ceases to be standardised infrastructure. The individuation of the medical record through its personal control will advantage some and not others, exacerbating the inequity associated with the exercise of other forms of choice, individuation and privatisation in conditions where some are better resourced to make choices than others.

Who should pay for PCEHRs?

An influential report, referred to at the NEHTA 2010 e-health conference in Melbourne and at stakeholder roundtables, advocates an investment model for e-health in Australia.¹⁵ The issue of who pays for the PCEHR in the long term is a question that requires deliberation on the costs, benefits and success of PCEHRs. Although matters of ethics are receiving relatively little attention in the implementation and operation of electronic health records, internationally there is a large and rapidly expanding literature of an empirical nature measuring the impact of electronic health records in terms of costs, benefits and success. However, extensive though this literature is, international experts undertaking systematic reviews are critical of the lack of agreed definitions. Of central concern is the lack of agreement on what counts as success or failure.^{1 16 17} Some of these experts argue that science and economics are not going to resolve the 'contested nature of these most fundamental definitions'. Instead, these are matters that 'require citizens and policy makers to deliberate about ethics and values'.² With this we concur.

The question therefore of whether an 'investment model' is appropriate to measure the success of the proposed PCEHR system involves questions of justice and equity in addition to economics. It prompts consideration of the idea that there is something ethically different about healthcare as opposed to other social goods¹⁸ and it demands careful consideration about what counts as success and what counts as a cost or a benefit—and to whom. For example, the responsibility and the cost associated with the management of paper records currently falls to healthcare providers, and on this basis the benefits flowing from the efficiencies of electronic records will also flow to providers. Providers might thus be expected to meet the bulk of the costs—but this position is undermined by an insinuation that PCEHRs belongs to patients and the argument that the patient is the primary beneficiary of the PCEHR.

In addition to questions about who benefits and who bears the costs of electronic health records are questions about resource allocation. In the USA, healthcare providers and hospitals are receiving financial incentives totalling nearly \$30 billion to adopt and use electronic health records.¹⁹ Even if this does not raise healthcare costs for individuals, it raises ethical questions about priorities and the rationing of health funding. Within finite health budgets, what else could that money provide? Ethical considerations are paramount in resolving questions about resource allocation and we would like to see transparency around the value judgements informing evaluations of costs and benefits and the allocation of funding.

What are the legitimate uses of PCEHRs?

The UK experience shows that it is difficult for consumers to develop an understanding of how their personal information could be shared or distributed, and that there is no 'best practice' in this area: '...it is not straightforward for users to find out how

their data will be used, stored, passed on or sold to third parties, or what would happen in the case of the company involved going into administration.²⁰

While PCEHR data will be primarily used in patient health-care, other potentially beneficial uses exist in the domains of policy, research, audit and public health. These uses will be facilitated by paper becoming electronic but they also magnify the question of the ethics of using personal information for a public purpose.

There is little research on patient views about secondary uses of their health information.^{16 17} The small amount of literature that exists on patient's views (leaving security, privacy and consent issues aside) suggests that patients consider research and public health legitimate reasons to use their information.^{21 22} They consider it legitimate because it is for the benefit of patients generally, even though it may not benefit individual patients directly.^{21 22}

Illegitimate uses include the exploitation of health data by those who seek to profit from illness. The position of pharmaceutical companies in the public mind—as either private-profiters or public interest health product providers—will be important to public acceptance of their use of PCEHRs. Patients also perceive as problematic the potential for those 'beyond the clinical circle of care',²¹ such as insurance companies, employers, police or the government, to use information in a way which may result in unjust discrimination or disadvantage.^{21 22}

During the NEHTA consultation process in Australia, stakeholders were told that information in the PCEHR would not be used for secondary purposes. Topics such as research and the secondary use of data did not feature in the *Draft Concept of Operations* that went out for public consultation.²³ Some groups commented on this omission in their submissions. Most notably, the Consumers Health Forum made a recommendation that arguments for and against the 'contentious issue' of secondary use be canvassed.²⁴ Nevertheless, the next version of the *Concept of Operations* declared that the secondary use of information will be allowed: 'particular secondary uses and disclosures of personal information permitted under the Privacy Act will continue to be allowed in the PCEHR System'.⁷

In the case of research, however, what is going to be allowed goes beyond existing law. It includes unknowns such as 'forthcoming PCEHR legislation, governance and any policies and procedures of the PCEHR Operator'.⁷ Given the lack of debate that has taken place on the important question of when it is ethically acceptable to use private health information for public purposes, the assertion that there will be a 'strong emphasis' on '[s]upporting research with a proper ethical basis and public benefit' sounds hollow.

Furthermore, accompanying this sole concession to matters of ethics in the *Concept of Operations* is the promise to not use information that identifies a person—'where possible'.⁷ This is not a good start or a good basis to the public trust essential to the research enterprise. We believe the question of what is the legitimate use of personal information for public purposes deserves more serious consideration. Relevant debates about private interests and public interests in the context of genetic and electronic health record databases are occurring in the ethics literature and should be informing public debate.²⁵

If PCEHR information is to be used in research, clear guidelines for researchers and Human Research Ethics Committees will be needed to ensure ethical practices. For example, protocols and consent procedures must clarify the limits of anonymisation processes. If online consent processes are employed, important issues to consider include consent withdrawal and the specificity

of the consent (ie, for all future research, or case by case), and how consent is negotiated and recorded in virtual space. Some of these things can be addressed with processes and technical solutions but we argue in what follows that the ethical underpinnings of informed consent are something that should not be ignored.

PCEHRs, personal control, privacy and consent

Recent Australian surveys show that privacy and security of health information are important concerns for Australians. Although support for electronic health records is strong, people want control over who can see their records and they want to be able to see who has accessed their records.^{26 27} Where PCEHRs and privacy are concerned, consent is an important matter. In the international ethics literature, there is debate about whether we should rely on consent to protect privacy no matter how burdensome or whether we should rely instead on strong privacy and security protections to protect the privacy concerns of consumers.²⁸ Whatever the choice, it must be unambiguous.

Consent sits at the intersection of legislation, technical design and consumer involvement. Consent is widely seen to be the panacea to privacy concerns and personal control can be taken to assume that privacy is protected. But this may not be the case. The PCEHR allows clinicians to assume consent by participation in the system, which makes for a simple technical solution and workflow issue for clinicians, but might not meet the needs of the consumer. 'Consent' is sometimes used to refer to mere permission or agreement—but that misses altogether key things about the ethical concept of informed consent—things such as the provision of relevant information and understanding of that information. This 'shallow' notion of consent does little to provide protection for privacy,^{28 29} and is therefore often poorly represented in legislation. There is a danger that without the ethical underpinnings of what gives consent its moral authority, a PCEHR system may reduce consent to a mouse-click.

Shallow consent and its associated risks might be avoided through the inclusion of mandatory questions on terms and conditions at the point of PCEHR registration for consumers. This might involve consideration of technical issues, a range of ethical matters and devising terms and conditions that are fair. The ethical matters include questions about what constitutes informed consent and what is relevant information for consumers regarding the advantages and disadvantages in their particular circumstances of having a PCEHR.

Unique consent and confidentiality challenges involving children and adolescents are a key area for consideration in PCEHRs.³⁰ Key ethical questions include:

- ▶ How can the challenges of privacy and trust in an electronic health records system be addressed to avoid deterring young people from seeking necessary healthcare?
- ▶ Can parents lock off information *for* or even *from* their children?
- ▶ What will be the status of information about or from third parties in the PCEHR?
- ▶ What policies or procedures are needed for cohort studies that collect biological samples and other data from children linked to continuously updated electronic health records?

Findings from UK public attitudes research on electronic health records reveal that growing up in an era of social networking sites such as Facebook 'does not mean that young people do not care about privacy or what happens to their personal information'.³¹ Young people have a 'strong need to be in control of their own records'³¹ and a significant concern is that parents 'should not automatically have access to their records'.³¹

Box 1 Ethical questions which must be considered in an Australian Personally Controlled Electronic Health Record (PCEHR) system

Equity, health literacy, cognitive capacity

- ▶ Will consumers/patients who choose not to engage in the PCEHR system be disadvantaged?
- ▶ What measures will govern the management and use of PCEHRs in cases where personal control of the record is problematic (eg, individuals with mental health or health literacy issues).

Who should pay for PCEHRs?

- ▶ What counts as success in the new PCEHR system?
- ▶ How will PCEHR costs and benefits be defined, and by whom?
- ▶ What is the potential for increased costs for individuals and families?

What are the legitimate uses of PCEHRs?

- ▶ How will acceptable secondary uses of PCEHR information be defined in the domains of policy, research, audit and public health?
- ▶ How will data be used, stored, passed on or sold to third parties?
- ▶ What happens if a company involved goes into administration?
- ▶ What guidelines will be developed for researchers and Human Research Ethics Committees to ensure ethical practices in using information from PCEHRs?

PCEHRs, personal control, privacy and consent

- ▶ What constitutes informed consent, and what is relevant information for consumers regarding the advantages and disadvantages in their particular circumstances of having a PCEHR?
- ▶ How will consent be negotiated and recorded in virtual space (eg, how will consent withdrawal and the specificity of consent for future research be managed)?
- ▶ Can parents lock off information *for* or *from* their children?
- ▶ How can the challenges of privacy and trust in a PCEHR system be addressed to avoid deterring young people from seeking necessary healthcare?
- ▶ In light of the special ethical problems and concerns with children and consent, what policies are needed for cohort studies that collect biological samples and other data from children linked to continuously updated electronic health records?

CONCLUSION

There are enough similarities between the UK model and the Australian system to suggest that a failure to adequately consider ethics and values in the implementation and planning process could limit the success of the intended Australian PCEHR system. We highlight some important ethical issues that must receive more consideration as Australia moves towards a PCEHR system—questions about equity and justice, who pays, what are the legitimate uses of PCEHRs and how privacy is implemented (See box 1). These issues are not merely technical matters to be left to system architects.

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