Gathering data for decisions: best practice use of primary care electronic records for research

Rachel Canaway1, Douglas IR Boyle2, Jo-Anne E Manski-Nankervis1, Jessica Bell1, Jane S Hocking9, Ken Clarke2, Malcolm Clark2, Jane M Gunn1, Jon D Emery1

Making more effective use of data is part of a global movement to improve health information exchange, decision making and policy development, consumer and business outcomes, and development of products and services. However, Australia is falling behind.1 Australia’s health sector reportedly “stands out among other developed countries as one where health information is poorly used”.1 Secondary use of electronic medical records (EMRs) for research purposes occurs throughout the world. It has the potential to provide significant public health gains by informing evidence-based health care education, policy, practice and service delivery.2-4 But such use of EMRs in Australia is ad hoc. Also, non-use of such data could have negative effects on the public, such as causing a financial burden on society.1,3,6

Combined data from primary care EMRs can be used to evaluate the outcomes of interventions, provide practitioners with evidence for clinical decision making, assess uptake of best practice principles, facilitate quality improvement, highlight inequities in access and outcomes, determine need for services, and potentially assist in earlier detection of disease.3,5,7 The scope of interdisciplinary research using primary care clinical datasets is enormous (Box 1). Further, the ability to link different data sources together (eg, primary care and hospital data) also has enormous value. It can increase the range of questions that research can answer, improve statistical properties of data, and improve use of resources.5,9-12 Despite these benefits, the full potential of such data-based research has not been realised. In this article, we examine issues relating to the use of EMRs for research in Australia, and discuss how data extraction software can enable fuller use of EMRs in research, auditing, and surveillance of population health and disease. We also provide a model that shows how harnessing the untapped potential of EMRs can support decision making by general practitioners and thereby improve patient care.

Australian context

Australian general practices were early adopters of clinical practice software tools and EMRs.13 First-generation general practice software assisted clinicians with drug prescribing, but over time evolved into many clinical patient management software packages. These packages were designed to help GPs manage patient care and referrals, and improve practice efficiency. However, each package has been developed with limited need to comply with clinical coding, interoperability, or national accreditation standards.13 Because of these limitations, little research and population health research, and quality assurance activities. However, little research has been conducted on the general public’s and practitioners’ concerns about secondary use of electronic health records in Australia.

In Australia, there is limited use of primary health care data for research and for data linkage between health care settings. This puts Australia behind many developed countries. In addition, without use of primary health care data for research, knowledge about patients’ journeys through the health care system is limited.

There is growing momentum to establish “big data” repositories of primary care clinical data to enable data linkage, primary care and population health research, and quality assurance activities. However, little research has been conducted on the general public’s and practitioners’ concerns about secondary use of electronic health records in Australia.

International studies have identified barriers to use of general practice patient records for research. These include legal, technical, ethical, social and resource-related issues. Examples include concerns about privacy protection, data security, data custodians and the motives for collecting data, as well as a lack of incentives for general practitioners to share data.

Addressing barriers may help define good practices for appropriate use of health data for research. Any model for general practice data sharing for research should be underpinned by transparency and a strong legal, ethical, governance and data security framework.

Mechanisms to collect electronic medical records in ethical, secure and privacy-controlled ways are available.

Before the potential benefits of health-related data research can be realised, Australians should be well informed of the risks and benefits so that the necessary social licence can be generated to support such endeavours.

In 2012, the Australian Government introduced its digital health record system: My Health Record. As a result of the move from opt-in to opt-out in 2019, most Australians will soon have a My Health Record containing online summaries of their health information, unless they opt out (https://www.myhealthrecord.gov.au/). As outlined in the Australian Government’s Framework to guide the secondary use of My Health Record system data, secondary use must be demonstrably consistent with “research and public health purposes” and “likely to generate public health benefits and/or be in the public interest.”14

Research on Australians’ opinions regarding appropriate secondary use of EMRs is very limited. Opinion polling of a nationally representative sample of 1011 Australians has indicated that there is strong support for the use of health records for research, with 93% of Australians either strongly or somewhat supporting it and only 7% opposed, and strong public trust in medical researchers (67% high or very high trust, 29% moderate

Summary

- In Australia, there is limited use of primary health care data for research and for data linkage between health care settings. This puts Australia behind many developed countries. In addition, without use of primary health care data for research, knowledge about patients’ journeys through the health care system is limited.
- There is growing momentum to establish “big data” repositories of primary care clinical data to enable data linkage, primary care and population health research, and quality assurance activities. However, little research has been conducted on the general public’s and practitioners’ concerns about secondary use of electronic health records in Australia.
- International studies have identified barriers to use of general practice patient records for research. These include legal, technical, ethical, social and resource-related issues. Examples include concerns about privacy protection, data security, data custodians and the motives for collecting data, as well as a lack of incentives for general practitioners to share data.
- Addressing barriers may help define good practices for appropriate use of health data for research. Any model for general practice data sharing for research should be underpinned by transparency and a strong legal, ethical, governance and data security framework.
- Mechanisms to collect electronic medical records in ethical, secure and privacy-controlled ways are available.
- Before the potential benefits of health-related data research can be realised, Australians should be well informed of the risks and benefits so that the necessary social licence can be generated to support such endeavours.

1 Department of General Practice, University of Melbourne, Melbourne, VIC.
2 Health and Biomedical Informatics Centre, University of Melbourne, Melbourne, VIC.
3 Melbourne Law School, University of Melbourne, Melbourne, VIC.
4 School of Population and Global Health, University of Melbourne, Melbourne, VIC.
5 Networked Society Institute, University of Melbourne, Melbourne, VIC.
6 dboyle@unimelb.edu.au • doi: 10.5694/mja2.50026
Despite these positive opinions, researchers sometimes wait years for approvals to access patient data for research. Funding to access datasets is also an area of concern, with a recent news item suggesting that general practice research in Australia is nearing crisis point, largely due to inadequate funding, and not because of lack of GP enthusiasm for research. So the barriers to using EMRs for research or other secondary purposes need to be addressed.

International experience

Internationally, public opinion on the appropriate use of EMRs for purposes other than providing direct clinical care is mixed. A systematic review of public opinion on the use of patient data for research in the UK and the Republic of Ireland was undertaken after the 2013 introduction, public backlash and 2016 closure of NHS England’s care.data program. The care.data program enabled extraction of identifiable patient data from general practice records to the Health and Social Care Information Centre (now NHS Digital), where it was linked to other data sources (eg, hospital records) with plans to make linked, pseudonymised data available to a range of data recipients. The public backlash voiced concerns about who can access the data, the amount of transparency regarding secondary use, security controls, and the ability to retain control over who can access data and for what purpose.

Data de-identification

In Australia, when data are de-identified, it is legally no longer considered personal information. Data are considered de-identified when the risk of a person being re-identified in the data is very low within its data access environment. This means that whether data are considered personal or de-identified can vary depending on the context in which the data are held. The process of de-identifying data involves removal or alteration of personal identifiers, and the application of additional controls or safeguards in the data access environment to appropriately manage the risk of re-identification. It is sometimes possible to re-identify some individuals by interrogating the data with the intention to find individuals by searching for multiple, specific, identifying characteristics of a person who might be represented in the dataset. Where there is a risk of re-identification, the data should not be made public. Re-identification of individuals within public, uncontrolled and purportedly de-identified datasets has been proven to be possible. This highlights the importance of the data environment controls and safeguards.

The term “de-identification” is not consistently defined or used. Other terms used to refer to similar concepts and processes include “anonymisation” and “confidentialisation.” In the European Union and the UK, “pseudonymisation”, rather than de-identification, is in common use.

Data extraction tools and their role

Data extraction tools are software tools designed to extract data from a GP computer system and transmit the data elsewhere for audit, surveillance, data linkage and/or research. Several such tools are in use in Australia – for example, the Canning Tool, cdmNet, GRHANITE, Pen CAT and POLAR GP. Some of these tools have been used to collect primary care data for research for over 10 years, mostly on a resource-intensive, project-by-project basis. Such tools exhibit a variety of features:
3 A model for primary care data sharing for research

1. Preparing for data collection
   - Obtain ethics approval for data collection and undertake legal review.
   - Establish a robust and secure data housing environment with independent data governance oversight and proactive security review.
   - Establish a comprehensive standard operating procedure and policies for data curation and stewardship.

2. Recruiting a general practice
   - Establish a legal agreement with the practice and gain their informed consent. This ensures that both parties have a clear understanding of the terms under which data are shared.
   - Support any technical requirements for data extraction.
   - Inform patients that the practice is sharing de-identified data. Explicit patient consent is not required if the data extraction tool can provide de-identified data that satisfies the definition of de-identification as per the Privacy Act 1988 (Cth). NHMRC guidelines on waiving patient consent should also be met. A best practice approach would enable patients to easily withdraw consent.

3. De-identifying and transmitting patient and practitioner data
   - Data should be de-identified on the practice computer.
   - Data should be transmitted securely to a protected database in a secure, on-shore data storage facility.

4. Following due process
   - Maintain ongoing, proactive data security. This may include using accredited secure environments from which authorised researchers can access the data (depending on sensitivity of the data and the amount of data).
   - Ensure that researchers who are provided with data obtain ethics approval and sign a legal agreement stipulating the terms under which they manage, store, use and dispose of the data.
   - Use mechanisms to assess competence of researchers to safely and responsibly use the data for research.
   - Ensure that the research group includes (or consults with) someone who has experience practising in Australian general practice to ensure that results are interpreted appropriately.
   - Ensure that an independent data governance committee reviews all applications by researchers to access data.
   - Use principles of data minimisation to limit data sharing with researchers to the minimum necessary to complete their research.

5. Delivering research outputs
   - Research funders should not prevent researchers from publishing their findings.
   - Researchers should make publicly available plain language community reports of their research outcomes.
   - Researchers should contribute their data coding to repository-specific data user groups.

6. Using consumer, clinician and researcher panels
   - Consult health care consumers and providers — ask them for ideas on how data are used and suggestions regarding potential research projects and questions. Such input should be fed back to researchers to inform future research.
   - Engage researchers to contribute insights, data cleaning and analytic codes, so that other research can build on what has already been done.

Appropriate use of health data for research

The Australian Institute of Health and Welfare suggests that to undertake thorough data-based research of general practice, data should:

- be analysable at the individual patient level
- be linkable to actions (eg, prescription, clinical procedure, and pathology or imaging request)
- include diagnosis or symptom pattern
- allow tracking of presenting problems and their management over time
- enable examination of patient outcomes.

To use data at the individual level for such purposes, best practice principles must be adhered to (Box 2). We propose a model for using primary care health data for research (Box 3).

Privacy-protecting record linkage enables researchers to examine patients’ journeys through the health care system. It can be enabled by middleware, which generates a unique person-identifying signature or code. Some types of middleware do this through irreversible “cryptographic hashing” of person-identifying information while the data are confined still in the clinical setting, so no person-identifying information is transferred during data transmission. Others use statistical linkage key (SLK) algorithms (eg, SLK81) to generate signatures from person-identifying information, but these signatures contain personal data (which are often encrypted). Approaches like hashing, where no identifiable data are transmitted, are preferable. When data from hospital or administrative datasets are extracted using particular data extraction tools, the same SLKs or hashes may be generated, enabling data linkage. Data linkage has been described as leading to “joined-up thinking” which, as well as enabling services to better meet public needs, can provide greater perspectives towards finding solutions to intractable problems.

As new technologies allow, additional functions will likely be incorporated into health care-related data extraction tools, such as collection of consent preferences from patients via apps and smart devices (dynamic consent). Allowing patients to be personally involved could increase participation rates, trust levels, and the depth and strength of data available for research. 

Among these tools, some address data privacy concerns through data being de-identified or aggregated before they leave the GP clinic. Use of such tools can contribute to research being conducted according to best practice principles (Box 2). However, it is important that other principles — such as independent data governance and ethical, not-for-profit use of collected data — are also observed to avoid public backlash against use of de-identified data. Provisions that manage patients’ consent preferences at the practice, and multiple layers of security to protect data during transmission, are other best practice principles.

For GPs and the public to trust any model of data sharing, and consent to data sharing, transparency should be maintained at every stage. Also, the model must adhere to national and international laws, and best practice principles relating to data governance, security, privacy protection and ethical use of data.

In addition to governance issues, capture of poor quality patient data (eg, due to shortcomings in system use such as free text data entry instead of coded data entry) is a limitation of research based on passive capture of EMRs. So improving the quality of data entered in EMRs by GPs is an ongoing aim. Nonetheless, research methods can often adjust for poor quality data capture, so long as the data limitations are clearly understood. Data custodians can help to increase awareness among all clinical and non-clinical general practice staff of the value of accurate and comprehensive data capture. Having clinician researchers...
involved in data analysis is one way to ensure correct interpretation of the data. Clinician involvement through research discussion panels can also drive data quality improvements when GPs discover firsthand the implications of poor quality data capture.

Some data extraction tools and primary care data repositories already facilitate timely access to data to generate new knowledge to inform evidence-based policies, practices and reforms that may translate into cost savings, improved care and better outcomes for patients. Examples of data repositories that do this include NPS MedicineWise’s MedicineInsight (www.nps.org.au/medicine-insight) and the University of Melbourne’s Data for Decisions research initiative (www.gp.unimelb.edu.au/datafor-decisions). In the coming years, use of My Health Record data for research is also likely to increase and should contribute towards these goals.3 Policy makers and decision makers need to further support data sharing by providing greater incentives to GPs to contribute data for research, and by addressing jurisdictional barriers and disciplinary silos to enable linkage of datasets.

Conclusion

Despite most Australians having most of their health-related interactions in the primary care sector, primary care-based research is disproportionately low. Access to quality EMR data, lack of resources to remunerate GPs, and a lack of understanding among some GPs of the value and importance of secondary use of EMR data are barriers to data sharing. Data extraction tools that enable ethical, secure and privacy-protected access to routinely collected datasets nationally have been developed. The task now is to build trustworthy primary care data repositories for research that will provide researchers with timely access to quality-assured general practice data. Linkage with other datasets could enable significant scale-up of primary care-based research in Australia, contributing new knowledge in public health, health promotion, economics and evidence-based clinical care. Technologies that allow consumers to have greater control over how their data are used can provide better options to policy makers, hence investment in this area is essential. Educating clinicians and the public about the need for, and existence of, research based on de-identified patient medical records has the potential to generate greater social licence and acceptance of this emerging area of study. This has the potential to generate significant gains in terms of service delivery, economics and patient health. We can “do the right thing” now, but we must never become complacent.

Acknowledgements: Jane Hocking is supported by an NHMRC Senior Research Fellowship (1136117).

Competing interests: All authors except Ken Clarke are associated with the Data for Decisions research initiative at the University of Melbourne. Douglas Boyle created the GRHANITE data extraction tool. Douglas Boyle, Joe-Anne Manski-Nankervis, Jane Hocking, Jane Gunn and Jon Emery have been investigators on GRHANITE-related research projects, including NPS MedicineWise projects and a joint project in conjunction with the Australian Digital Health Agency. Douglas Boyle is a member of the Australian Digital Health Agency My Health Record Benefits Measurement Steering Committee. Jon Emery is a member of the NPS MedicineWise MedicineInsight Data Governance Committee.

Provenance: Commissioned; externally peer reviewed.

© 2019 The Authors. Medical Journal of Australia published by AMPco Pty Ltd

This is an open access article under the terms of the Creative Commons Attribution License, which permits use, distribution and reproduction in any medium, provided the original work is properly cited.

The copyright line for this article was changed on 3 April 2019 after original online publication.

1 Productivity Commission. Data availability and use, inquiry report. Canberra, Productivity Commission, 2017. https://www.pc.gov.au/inquiries/completed/data-access/report (viewed Nov 2018).

2 Royal Australian College of General Practitioners. Secondary use of general practice data. Melbourne: RACGP, 2017. https://www.racgp.org.au/download/Documents/e-health/Secondary-use-of-general-practice-data.pdf (viewed July 2018).

3 Raghupathi W, Raghupathi V. Big data analytics in healthcare: promise and potential. Health Inf Sci Syst 2014; 2: 3.

4 Menzies Foundation. Public support for data-based research to improve health: a discussion paper based on the proceedings of a Menzies Foundation Workshop 16th August, 2013. https://www.lowitja.org.au/sites/default/files/docs/10-Menzies-Foundation-Public-support-data-based-research.pdf (viewed July 2018).

5 Public Health Research Data Forum. Enabling data linkage to maximise the value of public health research data: final report to the Wellcome Trust. https://wellcome.ac.uk/sites/default/files/enabling-data-linkage-to-maximise-value-of-public-health-research-data-phrdf-mar15.pdf (viewed July 2018).

6 Jones KH, Laurie G, Stevens L, et al. The other side of the coin: harm due to the non-use of health-related data. Int J Med Inform 2017; 97: 43–51.

7 Australian Institute of Health and Welfare. Review and evaluation of Australian information about primary health care: a focus on general practice (AIHW Cat. No. HWI 103). https://www.aihw.gov.au/reports/primary-health-care-review-evaluation-australian-primary-health-care-contents/table-of-contents (viewed July 2018).

8 Australian Government Department of Health. Framework to guide the secondary use of My Health Record system data. Canberra: Department of Health, 2018. http://www.health.gov.au/internet/main/publishing.nsf/Content/eHealth-framework (viewed July 2018).

9 Einarsdóttir K, Preen D, Sanfilippo F, et al. Mortality in Western Australian seniors with chronic respiratory diseases: a cohort study. BMC Public Health 2010; 10: 385.

10 Einarsdóttir K, Preen D, Emery J, et al. Regular primary care decreases the likelihood of mortality in older people with epilepsy. Med Care 2010; 48: 472–476.

11 Brown A, Kirichek O, Balkwill A, et al. Comparison of dementia recorded in routinely collected hospital admission data in England with dementia recorded in primary care. Emerg Themes Epidemiol 2016; 13: 11.

12 Herrett E, Shah AD, Boggon R, et al. Completeness and diagnostic validity of recording acute myocardial infarction events in primary care, hospital care, disease registry, and national mortality records: cohort study. BMJ 2013; 346:F2350.

13 McInnes DK, Saltman DC, Kidd MR. General practitioners’ use of computers for prescribing and electronic health records: results from a national survey. Med J Aust 2006; 185: 88–91. https://www.mja.com.au/journal/2006/185/2/general-practitioners-use-computers-prescribing-and-electronic-health-records

14 Gordon J, Miller G, Britt H. Reality check – reliable national data from general practice electronic health records. Deebie Institute Brief No. 18. 14 July 2016. http://ahha.asn.org.au/system/files/docs/publications/deebie_institue_issues_brief_no_18.pdf (viewed July 2018).

15 Research Australia. Australia Speaks! Research Australia Opinion Polling 2017. https://researchaustralia.org/wp-content/uploads/2017/08/2017-Opinion-Poll-Digital.pdf (viewed Mar 2018).

16 Sturgiss L. Australian general practice research is nearing crisis point. newsGP 2018; 17 May. https://www.racgp.org.au/newsGP/Professional/Australian-general-practice-research-is-nearing-cr (viewed Mar 2018).

17 Stockdale J, Cassell J, Ford E. “Giving something back”: a systematic review and ethical enquiry of public opinions on the use of patient data for research in the United Kingdom and the Republic of Ireland. Wellcome Open Res 2018; 3: 6. https://wellcomeopenresearch.org/articles/3-6/v1 (viewed July 2018).

18 Solon O. A simple guide to Care.data. Wired 2014; 7 Feb. www.wired.co.uk/article/a-simple-guide-to-care-data (viewed Mar 2018).

19 Boiten E. NHS Care.data still leaks like a sinking ship, but ministers set sail regardless. The Conversation 2015; 30 June. https://theconversation.com/nhs-care-data-still-leaks-like-a-sinking-ship-but-ministers-set-sail-regardless-63977 (viewed July 2018).
20 Mitchell C, Moraia LB, Kaye J. Restore public trust in Care.data project. *Nature* 2014; 508: 458.
21 Carter P, Laurie GT, Dixon-Woods M. The social licence for research: why Care.data ran into trouble. *J Med Ethics* 2015; 41: 404–409.
22 Parkin L, Paul C. Public good, personal privacy: a citizens’ deliberation about using medical information for pharmacoepidemiological research. *J Epidemiol Community Health* 2011; 65: 150–156.
23 Kim KK, Joseph JG, Ohno-Machado L. Comparison of consumers’ views on electronic data sharing for healthcare and research. *J Am Med Inform Assoc* 2015; 22: 821–830.
24 Spencer K, Sanders C, Whitley AE, et al. Patient perspectives on sharing anonymized personal health data using a digital system for dynamic consent and research feedback: A qualitative study. *J Med Internet Res* 2016; 18: e66.
25 Williams H, Spencer K, Sanders C, et al. Dynamic consent: a possible solution to improve patient confidence and trust in how electronic patient records are used in medical research. *JMIR Med Inform* 2015; 3: e3.
26 Consumers Health Forum of Australia. Engaging consumers in their health data journey. https://chf.org.au/publications/engaging-consumers-their-health-data-journey (viewed Nov 2018).
27 Australian Government. *Privacy Act 1988*. No. 119, 1988 as amended. https://www.legislation.gov.au/Details/C2014C00076 (viewed July 2018).
28 Office of the Australian Information Commissioner. De-identification and the Privacy Act. March 2018. https://www.oaic.gov.au/agencies-and-organisations/guides/de-identification-and-the-privacy-act (viewed July 2018).
29 Office of the Victorian Information Commissioner. Protecting unit-record level personal information: the limitations of de-identification and the implications for the Privacy and Data Protection Act 2014. May 2018. https://ovic.vic.gov.au/resource/protecting-unit-record-level-personal-information (viewed Nov 2018).
30 Teague V, Culnane C, Rubinstein B. The simple process of re-identifying patients in public health records. *Pursuit* 2017; 18 Dec. https://pursuit.unimelb.edu.au/articles/the-simple-process-of-re-identifying-patients-in-public-health-records (viewed May 2018).
31 Boyle D. Generic Health Network Information Technology for the Enterprise (GRHANITE): GRHANITE data, messaging and security provisions, July 2016. http://www.semphn.org.au/images/downloads/GRHANITE%20Data%20Security.pdf (viewed Apr 2018).
32 Australian Institute of Health and Welfare. Statistical linkage key 581 cluster. http://meteor.aihw.gov.au/content/index.phtml/itemId/349510 (viewed May 2018).
33 Stanley F, Glauert R, McKenzie A, et al. Can joined-up data lead to joined-up thinking? The Western Australian Developmental Pathways Project. *Healthc Policy* 2011; 6: 63–73.
34 National Health and Medical Research Council, Australian Research Council, Universities Australia. National statement on ethical conduct in human research 2007 (updated 2018). Canberra: NHMRC, 2018. https://www.nhmrc.gov.au/guidelines-publications/e72 (viewed July 2018).
35 Ghosh A, McCarthy S, Halcomb E. Perceptions of primary care staff on a regional data quality intervention in Australian general practice: a qualitative study. *BMC Fam Pract* 2016; 17: 50.