RACGP

Royal Australian College *of* General Practitioners

RACGP response:

Issues paper - General practice data and electronic clinical decision support

February 2022

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Introduction

The Royal Australian College of General Practitioners (RACGP) is pleased to provide a response to the *General practice data and electronic clinical decision support issues paper*.

Data governance is an important area of focus for general practice and the RACGP. The RACGP established a Data Governance Advisory Committee (DGAC) in June 2020. Its role is to:

- provide advice on the needs and interests of general practice related to the collection and analysis of healthcare, patient and workforce data
- promote a consistent approach to the management of general practice data, and
- advise on data quality improvement activities.

Data collected by general practice contributes to improving health in Australia by informing policy, public health initiatives, research, and service delivery.

To help practices evaluate requests for data, minimise risk, and comply with relevant legislation, the RACGP has developed guiding principles for the provision of de-identified general practice data for secondary use and a supporting checklist. This resources currently being updated to better reflect the current challenges when collecting and using de-identified data for secondary purposes.

Electronic clinical decision support (eCDS) is also an area of great interest to the RACGP. The RACGP developed a position statement on eCDS in general practice in 2021, which outlines the principles for high quality eCDS.

The RACGP has also been advocating for resourcing to establish an Australian authority for general practice eCDS to oversee the development and maintenance of technical and clinical standards.

About the RACGP

The RACGP is Australia's largest professional medical college. The RACGP sets and maintains the standards for high quality general practice in Australia and advocates on behalf of the general practice discipline. As a national peak body representing over 43,000 members working in or towards a career in general practice. This includes 9,500 GPs working in rural and remote Australia. Our core commitment is to support Australian general practitioners (GPs) address the primary healthcare needs of the Australian population.

As an independent member-based organisation, we lead the way in facilitating continuous improvement in general practice through clinical, educational and digital advances. The RACGP is responsible for defining the nature of the discipline including setting the standards, creating the curriculum, and providing ongoing education and training. We support GPs in their pursuit of excellence in health care and community service.

The RACGP response

The RACGP makes the following key recommendations:

- general practice ownership and clinical leadership of GP data needs to be clearly acknowledged
- the importance of a clear value proposition for general practice must be at the heart of developments
- where data is linked across multiple data sets this needs to be articulated and the intended outcomes of these linkages understood
- third parties must collect the minimum amount of data only and with clear reasoning
- primary care research must be supported by ensuring access to data
- GP advisors must be involved in data analysis and interpretation
- an extensive public engagement exercise is required to raise awareness and communicate the benefits of secondary use of deidentified and aggregated data
- consumers should be given the option to opt out of secondary use of their health data
- funding is required to develop trusted, independent standards for eCDS and for 'living guidelines' to underpin the clinical content that sits behind eCDS

Response to survey questions

Introduction and context

1. Do you agree with the policy objectives outlined?

The RACGP largely agrees with the policy objectives outlined and we suggest additional objectives under question 2. We also make the following comments and recommendations for inclusion.

The document should acknowledge more clearly that GP clinics own the data recorded and maintained by the practice.

Rather than "ensuring that GP data is available", the focus should be on enabling practices, and patients, to share data to help realise and share in the benefits sharing data can bring. This change in focus will also help more clearly articulate and demonstrate the value proposition for general practices and patients to get involved in data sharing initiatives. It needs o be acknowledged there are limitations on GPs when collecting data in software systems and qualitative data is not the only source of information which demonstrates good clinical practices

2. Are there other objectives Government should consider?

The Government should consider including an objective around patient awareness and/or consent. This is important to ensure the public are informed and included in discussions about the consumer health-benefits of appropriate use of primary care data.

While there is no specific legal requirement to notify patients or receive their consent for the secondary use of de-identified data, there is a social contract between general practice and patients about the use of health information that needs to be respected. GPs have long-term trusted relationships with their patients that must be maintained. For this reason, the RACGP recommends patients should be made aware and given the option to opt out of secondary use of their health data.

There is also an assumption in the Paper that all eCDS use de-identified data, which is not the case, as many eCDS systems are integrated with general practice clinical information systems (CIS).

The RACGP also recommends an objective to ensure that data held by PHNs, AIHW and other government agencies, should be available for academic research. Access to aggregated data should be made available to

approved organisations (such as the RACGP and universities in which GPs are a critical part of a research team) or individual practices to conduct their own analyses of the data and create more personalised and relevant reports.

3. ***Are there other current or potential future benefits or uses of general practice data that should be considered?***

The issues paper should also note the potential for primary care data to:

- support primary care research
- automate post-marketing surveillance of medication and medical devices
- to provide automated audit and feedback to support CPD and GP training programs
- support disaster planning and primary care operations during disruption
- support testing for new service delivery innovations
- test and compare diagnosis and treatment options
- answer questions about high-value and lower-value management options
- support a growing primary care research capacity with lasting dividends
- to improve clinical and administrative software that GPs use particularly where there is inconsistent or incomplete recording of data. For example, if certain data elements are recorded poorly, in unstructured ways, inconsistently or not at all, these findings can be used to improve the design and function of the software that GPs use to facilitate and to improve the recording of necessary or desirable data.
- make secondary care more effective and affordable
- inform better targeted secondary/tertiary care and improved coordination of non-admitted care in hospital.

Some issues with current general practice data arrangements

4. What aspects of the current system in relation to general practice data work well?

The RACGP believes the following aspects are working well:

- general practices have choice of whom they want to share their data with, for example, universities, NPS, PHNs
- the richness of GP data is unquestioned - prescribing, diagnostic test requesting, physical and demographic information, incoming pathology information
- data aggregation and analysis researchers are advancing data dictionaries and translation of data originating from different practice management software
- the accuracy of more recent data analysis is positive, and
- the acceptance of sharing PIP QIMs has increased as more stakeholders understand the data is aggregated.

5. What aspects of the current process in relation to general practice data are of concern?

There are a number of areas relating to general practice data that are of concern and must be addressed − the lack of a national system, lack of interoperability, work pressure affecting coding and quality of data and limited consent and understanding from patients.

Not all organisations extracting data have a clear and transparent data governance process. Researchers, for example, are held to a higher standard as they need to seek ethics approvals to access and analyse data, whereas government bodies do not and their governance has often been less clear, including what data they are extracting.

There is a lack of overview on who is extracting GP data and for what purposes. Data sets extracted are often more extensive than required. GPs often have little or no access control over the data once extracted and are not always involved in data analysis and interpretation.

There is a lack of uniformity in data extraction tools as different tools extract data differently. This results in variation in the quality of data analysis depending on the data extraction tool and coding utilised.

There appears to be a move for PHNs and then AIHW to be the sole holders of general practice data, which would remove choice , introduce cost and undermine independent research. Primary care research in this area has been influential and innovative but it is chronically underfunded. Restricting access to data will make it less viable and this should be recognised and addressed.

Practice management system vendors have different approaches to API access and data extraction. The choice of general practices to contribute to different data sets and to access clinical decision support products needs to be assured and not impacted by transition to the cloud.

6. What general practice data should be shared, with whom and for what purposes?

Data collected by general practice has a role to play in improving health in Australia by informing policy, public health initiatives, research and service delivery.

The RACGP recognises there are many data elements that may be shared with many different parties for various purposes, with appropriate clearly defined permissions. The ‘problems to be solved’ should be defined before decisions on data sharing are made.

The RACGP's key principles for the use of general practice data by third parties, as outlined in question 1, provide guidance to ensure that personal data collected in general practice is adequately protected in terms of privacy, ethical management and use, while at the same time encouraging appropriate secondary use of data.

Government requires access to data (or data analysed by third parties) to facilitate planning and policy development. However, Data must not be used against GPs for punitive and regulatory measures.

Access needs to be broader than government and its agencies.. Data is important for quality improvement, research, training and so data needs to be more broadly available to answer questions that are important to the profession.

7. Under which conditions should governments have access to aggregate general practice data?

This as a critical question. Government access should not risk trusted relationships between GPs and their patients, GPs and software providers and, GPs and PHNs. Access accepted by patients and the profession as appropriate.

There should be a clear and transparent process where government access is subject to independent oversight with GP and consumer involvement. The purpose should be transparent, pre-defined and clearly stated. The emphasis should be on improving service delivery and healthcare outcomes and GP advisors should be involved in data analysis and interpretation.

8. Are there any issues not covered above that impact on ongoing access to general practice data?

The RACGP views the following issues as possibly impacting on ongoing access to general practice data:

- costs associated with increased government regulation
- support for training to general practice on data use
- consumer involvement in research and policy development - consumer involvement in data governance processes, such as representation in data governance committees, should be encouraged to ensure that consumers' views are captured
- general practice and the RACGP needs to be recognised as an essential stakeholder in this setting and must be involved in any data interpretation by PHNs and government
- the value to general practice in participating in data sharing initiatives

9. What is the single, most pressing issue facing ongoing access to general practice data?

There are a number of pressing issues facing ongoing access to general practice data that must be addressed, including:

- the lack of national leadership governing the use of general practice data which could result in organisations using data for financial gain rather than to benefit patient health outcomes.
- the failure of governments to devote appropriate resources towards supporting practices improve data quality
- the lack of interoperability and common terminology between existing systems, which has secondary impacts causing major problems for access to data
- the lack of transparency and public uncertainty around the use of health data – the public needs to be educated about the benefits of data use as there is the potential for widespread mistrust of secondary use of health data
- the transition of practice management systems to the cloud

10. What upcoming developments may impact the flow of general practice data?

The RACGP believes the transition of practice management systems to the cloud could impact the flow of general practice data, but also considers that cloud storage could also facilitate access to data. The method of storage may not be the issue, rather the policies and practices of the organisation who 'owns' and controls the stored data.

Examples of systems and solutions implemented overseas

11. Are these examples relevant to Australia?

The RACGP believes these examples do have some relevance and are useful to inform future policy decisions, however, they need to be viewed in context of the health systems in which they have been implemented and their future vision for general practice. In some instances, these examples could create an environment where practices cannot choose and move between providers easily and should be viewed cautiously.

ProCare has selected a PMS that is most suitable for its needs, but the needs of individual general practices should also be taken into consideration. The purpose of a PMS is to facilitate clinical care, not to make data collection for health services easier. Practices often use other tools, eg. online booking systems such as HotDoc, which would need to be compatible with new systems. Paying the costs of transition of practices would also be important. The ability to integrate third party applications and the impact on innovation also must be considered.

Choosing from a panel of approved PMS would seem to be more appropriate as innovation is still possible and new products could be added to the panel if they fulfil requirements.

The NHS Digital approach does make sense, however there are concerns about increasing bureaucracy, costs and difficulties accessing data in a timely manner. It is also worth noting that UK tax-payers have been investing in primary care computing systems for over two decades.

There are also concerns about how NHS Digital integrates with other commonly-used datasets, which are not accessed through NHS Digital. Other healthcare datasets have continued to be key outside this system and would likely be the case in Australia. Many hospitals provide data to the government but also retain their own data which they can use in research without seeking government permission. This needs to be retained for general practice.

12. What other examples might inform the secure future for general practice data in Australia?

One of the suggestions is to look outside governments and government-funded bodies. There have been some successful partnership models with universities and the private sector, for example, DARTNet Institute, FaMe-net, RCGP Research and Surveillance Centre and NPS MedicineWise Medicine Insight.

Electronic clinical decision support for GPs at the point of care

13. What aspects of the current system in relation to eCDS work well?

Real-time eCDS for quality use of medication and to prompt for preventative care in high-risk patients has been working well but with limited scope. There are many drug interaction alerts, drug-disease alerts and drug-pregnancy alerts used by all the major software companies which work well. There are also demonstrated innovations to apply CDS for pathology and radiology recording that have the potential to improve adherence to best-practice guidelines and improve communication across the health system.

A balance needs to be found between 'prompting' and creating 'pop-up fatigue', a lot of GPs will not turn these real time decision support prompts off because they can be too invasive.

14. What aspects of the current process in relation to eCDS are of concern?

Electronic clinical decision support (eCDS) is well established in general practice but there are some clear areas of concern that must be addressed to improve its role in supporting the delivery of high-quality, evidence-based care.

GPs must be able to trust the information and advice provided by eCDS. The current unregulated environment creates significant risks for practitioners due to the varying quality and currency of information, as well as the lack of consistency across different software. It is important that there is confidence in the development processes that underpin eCDS and in the way that information is delivered.

There have been instances of inappropriate sources of information being incorporated into some PMS (at no additional cost) when access to quality evidence-based resources produced by Therapeutic Guidelines and RACGP are not. The potential of commercially driven advice is of great concern. Not all currently available CDS tools refer to Australian guidelines and there is no process or agreement as to which guidelines should be used to develop eCDS. For example, there is no requirement to utilise endorsed guidelines (e.g. National Health and Medical Research Council or RACGP endorsed). To facilitate integration, guidelines need to be available in a standard format that supports integration into eCDS systems.

The current medication eCDS systems are proprietary and the algorithms are opaque. There is no clear understanding of the evidence base behind these systems.

It is difficult for GPs to access guidelines at the point of care, as there is no central repository of appropriate guidelines for general practice. Accessing these individual specialty-based guidelines does not always fit well into the clinical workflow and also relies on the GP identifying that they need to access the guideline, or that new knowledge or guidance may be in place.

The quality of the interface is a critical component, as it has the has the potential to waste time, create alert fatigue, or drive GPs away from patient-centred care. Information must be presented in a way that supports current clinical workflow, allowing the user to select eCDS if they need assistance, quickly make an informed decision and take action. Integration with clinical information systems is essential. Accessing external resources outside of a GP's primary software program is time consuming and creates a barrier to the use. Any eCDS should have built-in user feedback loops and robust governance structures.

The recent ACCC authorisation for PHNs to develop and jointly scale up their own data extraction software, which also has clinical decision support capability, is likely to have an impact on choice and innovation implications.. as general practices are likely to rely on government provided resources,

15. What upcoming developments may impact eCDS functionality and integration into clinical workflows?

The introduction of APIs and the shift in healthcare towards using FHIR as a standard has the potential to create consistency and compatibility in the way information is shared and displayed in eCDS. These technologies also create a further need for standardisation for eCDS to ensure are used effectively, safely and to improve the quality of healthcare. Standards for eCDS will ensure evidence and expertise is used to develop these systems as technology continues to evolve.

eCDS supporting quality use of medicines (choice, dose, monitoring, safety) has the potential to provide a layer of safety that exceeds that provided by community pharmacist dispensing, thus freeing up alternative more efficient methods of delivering medicines.

In the future, machine learning applied to data sets from general practice may be able to find patterns of outcomes related to certain aspects of care that had previously not been observed, and point these out when GPs are seeing patients with similar clinical situations. For example, "93% of patients who also had X, Y and Z were admitted to hospital within 7 days".

The current regulatory framework for eCDS

16. What do you think is the appropriate level of Australian Government involvement in the governance/oversight of eCDS?

The RACGP's position statement on eCDS in general practice recommends that an overarching body should be created to encourage the advancement of eCDS and oversee the development and maintenance of technical and clinical standards.[1]

In May 2021, the RACGP sent a letter to the Department of Health seeking support to establish an Australian Authority for General Practice eCDS to provide guidance on the development of eCDS in general practice and help determine which evidence based guidelines and resources should be used in their algorithms. In the letter, we proposed the RACGP to oversee the suggested authority, with representatives from various expert groups within the RACGP and external stakeholders as appropriately identified (medical software industry representatives, pathology and imaging experts and other experts in specialised areas not covered by RACGP expertise).

The TGA has updated its guidance regarding software as medical device, which includes eCDS. This will need to continue to evolve with time, particularly as eCDS will become sophisticated enough to alter clinician decision-making. The TGA or an equivalent body should specifically assess eCDS for bias to prevent eCDS being used to direct end-users for commercial or regulatory rather than quality care reasons. Current TGA documentation is tailored more to devices, eg. pacemakers and glucose monitors, and government could facilitate revision of these standards so that they are more appropriate for eCDS and reflect required standards.

The RACGP strongly recommends that any oversight other than, or in addition to the TGA, should include extensive input from GPs suitably experienced in health informatics.

Potential benefits of eCDS use across the health care ecosystem

17. What do you see as the benefits of eCDS use for shared decision making at point of care?

There are many benefits of eCDS use to support shared decision making, including:

- enhancing health outcomes with suggestions for possible investigations and diagnoses that match a patient's symptoms
- increasing quality of care through treatment guidelines and recommendations for ongoing care
- rapid access to new information and the latest evidence and guidelines
- the ability to access guidelines and consumer resources at the point of care
- reduced medical errors and an increase in health outcomes through facilitation of earlier diagnosis
- more appropriate use of medications and investigations, and
- personalised risk and benefit information by combining EMR information with risk calculators.

18. What do you see as the issues/challenges of eCDS design and use and what are the associated impacts?

There is an understanding that eCDS design and use in general practice is complex and there are a number of challenges that need to be considered.

Extensive work is needed for integration with different PMS systems to address structure and terminology differences. To facilitate integration, guidelines need to be available in a standard format that supports integration into eCDS systems, as clinical guidelines are often written in a way that can't be easily translated into a technical solution. Guideline writers or other bodies need to be funded to develop or reformat guidelines in a format that supports integration.

Guidelines written by trusted professional bodies should be a priority for integration

There are multiple Australian guidelines created by different bodies that have different recommendations for the same patient groups, which leads to confusion and variation in care. This is particularly an issue in general practice due to multimorbidity. Guidelines often focus on one organ or disease, when many patients have multiple health issues.

There is also the concern that prompt/alarm fatigue and overly simplistic systems will impair uptake. eCDS design should be unobtrusive and information presented in a way that supports current clinical workflow, allowing the user to quickly make an informed decision and take action.

Some general practices require support to update their digital infrastructure. Some have no space left on servers and are using old operating systems.

Government support in the development of eCDS needs to be done in an open and transparent manner to support innovation and competition in this space and not be restricted only to PHNs.

19. Do you have any suggestions as to potential next steps to address any identified issues and challenges?

Funding is required to facilitate eCDS development in partnership with industry and professional groups, and there are examples of this being done internationally.

As a first step, it would be useful to start with a focused area to get it right before making broad changes. We would recommend asking GPs what kind of help they need, the issues they commonly face and what they would find useful and start from there.

The RACGP recommends in its eCDS position statement that an overarching body should be created to encourage the advancement of eCDS and oversee the development and maintenance of technical and clinical standards. An overarching body could help to address the issues of integration, selection and access to appropriate guidelines.

While the RACGP would like to see consistency of functionality across products, there is an appreciation that developers need to be able to continue to innovate and compete on the basis of differentiation. Developers' intellectual property (IP), technical design capacity and ongoing innovation must continue to be recognised and considered.

GPs and clinical software developers want high-functioning and usable eCDS to support patient care. A collaborative approach to minimum standards presents an opportunity for the GP and the developer community to prioritise eCDS requirements to meet current and future healthcare needs.

Some opportunities

20. Are there other levers the Government should consider introducing?

Government funding support for awareness raising is helpful

21. What impact might different levers have?

The sharing of full datasets is not supported by the RACGP and will be of concern to GPs, and patients.. Progress notes detailing confidential and very personal information should not be shared. The RACGP recommends "Comprehensive clinical measurements and data" may be a better expression.

Data linkage should not be used for compliance, pay for performance or public benchmarking purposes. These are unacceptable uses. Government messaging to GPs needs to be very clear about the purpose and limits of data sharing.

The generation and maintenance of comprehensiveness and local appropriateness of clinical guidelines is very resource-intensive. The rate of change of medical knowledge now makes "living guidelines" the only reasonable way to provide best-practice advice. Guideline production cannot be sustained by the membership fees of Colleges and other peak bodies. There is a need for clear economic evaluation of the value of guidelines to lift the value of care and reduce unacceptable variations in care. This economic evaluation should be translated into a commitment for taxpayer funded clinical guideline production by trusted organisations such as RACGP.

Funding is required for eCDS as it would be unreasonable to expect general practices to pay for eCDS without additional funding within the PIP.

Technical standards for eCDS would help to facilitate integration of approved eCDS products with PMS and alleviate the current limitations. However, there is a risk of stifling innovation. Aspirational and transparently comparable sets of standards for eCDS and PMS with incentives will work best in such a rapidly changing environment. The exception should be TGA (or equivalent) monitoring for bias and poor clinical content.

22. Which of these levers of change should be further explored and why?

All levers of change are worth exploring in conjunction with clinicians and peak bodies. As a starting point, the RACGP believes the following levers should be explored:

- acceptance of government being the messenger of advice
- mechanisms to streamline patient knowledge and normalise data sharing, and
- PMS standards to facilitate third party integration.

23. What specific options might be considered?

eCDS is in its early stages in Australia, providing opportunities for innovation and collaboration. This should be supported with open, transparent opportunities through tenders, Medical Research Future Fund, collaboration with professional colleges, practice based research and implementation networks.

Conclusion

The RACGP is a critical stakeholder in the areas of primary health care data and eCDS and urges government to partner with us during further consultation stages to ensure the interests of GPs, practices and patients are adequately represented to ensure the highest quality of care is delivered to the Australian population.

We look forward to working collaboratively with the Department of Health and other stakeholders.

Should you have any questions or comments regarding the RACGP's submission, please contact Ms Joanne Hereward, Program Manager Practice Technology and Management at joanne.hereward@racgp.org.au.

References.

1. RACGP Position - Electronic clinical decision support in general practice. https://www.racgp.org.au/advocacy/position-statements/clinical-and-practice-management/electronic-clinical-decision-support