Australian Government
Department of Health

General practice data and electronic clinical decision support

Issues Paper

Request for feedback and comment

The Department of Health (the Department) is releasing this initial Issues Paper as part one of a two-stage consultation process to inform thinking around primary health care data and the use of electronic clinical decision support (eCDS) systems in primary health care. The two policy areas have been combined into a single Issues Paper given the overlap in stakeholders and links between primary health care data and eCDS in the broader health care ecosystem. The combined process will enable stakeholders to consider and share their views regarding one or both policy areas and provide insights that can improve patient outcomes, health care provider experience and health policy design.

This paper provides an overview of the current context and explores some of the high-level issues that are involved with both primary health care data and eCDS. The paper also seeks to elicit stakeholder views around the current system, potential issues with the current environment and highlights a range of potential responses that Government could, if appropriate, explore moving forward. The paper provides an opportunity for stakeholders to highlight issues as they see them. This initial consultation will provide information and insights that can then feed into the second stage of consultation.

The second stage of the process will include a formal Consultation Regulatory Impact Statement (CRIS) which will lay out potential regulatory options and seek stakeholder views as to whether there should be formal advice to Government that a regulatory option is justified. The CRIS is scheduled to be completed in the first half of 2022.

Submission process

You are invited to provide submissions to this Issues Paper. Submissions will be open from 1 November 2021 through to 18 February 2022. If you provide a preliminary submission this will not preclude you from uploading a revised submission before the end of the submission period.

Some stakeholder consultations are expected to occur during the submission period. If you are interested in an early engagement with the Department, please reach out to the contact below.

You may choose to provide feedback on the Issues Paper through the free text fields in this survey or through uploading a document at the end of the survey, or both. Uploaded documents should be in Word or PDF format.

Uploaded documents should include the name of your organisation (or your name if the submission is made as an individual) and contact details for the submission, including an email address and contact telephone number where available.

Submissions will be made available to the public via the Department of Health's Consultation Hub <https://consultations.health.gov.au/>. If you would like all or part of your submission to remain in confidence, including contact details, please indicate this, and the relevant parts of the submission will be redacted. Automatically generated confidentiality statements in emails do not suffice for this purpose. Any future request made under the *Freedom of Information Act 1982* for a submission marked 'confidential' to be made available will be determined in accordance with that Act.

Closing date for submissions: 18 February 2022, 5.00 pm.

Enquiries: May be initially directed to the PHN Policy and Performance Section via email at PHN.DWG@health.gov.au

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Introduction and context

The Importance of General Practice Data and eCDS for Improved Health and Wellbeing

A consultation with a general practitioner (GP) is usually a person's first and most frequent interaction with the Australian health care system. The data that results from this interaction is a by-product of its primary use to support the GP, and the general practices in which they work, in an individual's consultation by providing historical notes, supporting referrals and payments, and obtaining information such as imaging and pathology to inform treatment planning and delivery. However, there is also growing global recognition of the potential to leverage general practice data to provide wider benefits to public health. This includes the ability to effectively use general practice data to support quality improvement, clinical decision-making, evidence-based policy development, preventive health measures, consumer outcomes, and development of products and services.

New and ongoing challenges in the health sector and public health emergencies, such as the 2019-2020 bushfire season and the COVID-19 pandemic, have put additional pressure on the primary health care system and have reinforced the importance of primary health care, including general practice, at the centre of the Australian health care system. These challenges highlight the importance of making effective use of primary health care data, particularly general practice data, that could assist in the responses to these emergencies, for example knowing the proportions of the population who have health conditions which exacerbate risk factors when inhaling bushfire smoke or contracting COVID-19.

The development, improvement and use of digital health solutions to support care delivery has also been highlighted in recent times. As technological advancements continue at a rapid rate, new opportunities for software use in healthcare settings have arisen to meet emerging challenges. One example of this is the introduction of eCDS in general practice settings. This software has evolved over time to specifically support and enhance clinical decision making in a range of general (e.g., general practice) and specialist areas of health care (e.g., diagnostic imaging and pathology testing).

Some of the current and potential use cases and benefits of general practice data and clinical decision support are listed below:

- De-identified or aggregate data can be analysed and shared back with GPs and general practices to support benchmarking and quality improvement. This data can support a general practice to better understand their practice and evaluate their own performance to improve care provision and efficiency. Quality improvement activities also support practices to maintain their accredited status. In addition, access to data can also help general practices understand consumer behaviour and make effective operating decisions.
- Data provided to Primary Health Networks (PHNs) informs better service and system planning at the local or regional level and, by extension, enables better resource allocation and coordination. As part of this, PHNs use data and work with GPs, general practices and other primary health care providers to identify gaps in the provision of primary health care services and the health care needs of the local population. The PHNs can then focus delivery of services based on those needs to minimise gaps or duplication.
- Aggregate primary health care data, particularly general practice data, used at the national and regional levels can identify changing trends around health and morbidity; inform population health planning, policy and programs; support evidence-based funding; facilitate clinical and practice-based research; and improve support for priority populations.
- There are opportunities for general practice data to be linked with other health service data at the federal or state and territory level, providing new insights on the patient journey throughout the health system. This will assist with identification of opportunities to improve patient outcomes and support decision-makers to make value-based healthcare investment

decisions. Data linkage can also provide additional feedback to general practice to help them benchmark performance against other practices in their region and/or jurisdiction and better manage for example, population cohorts with chronic and complex health conditions. There is also significant opportunity for general practices to see the impact they are making in reducing premature morbidity and mortality and improving health system sustainability.

- eCDS systems are intended to improve healthcare delivery by enhancing medical decisions at point of care with targeted clinical knowledge, patient information and other health information.[1] This support could be provided in the form of prompts, reminders and recommendations to assist primary health care practitioners, such as GPs, in their clinical decision making.[2]

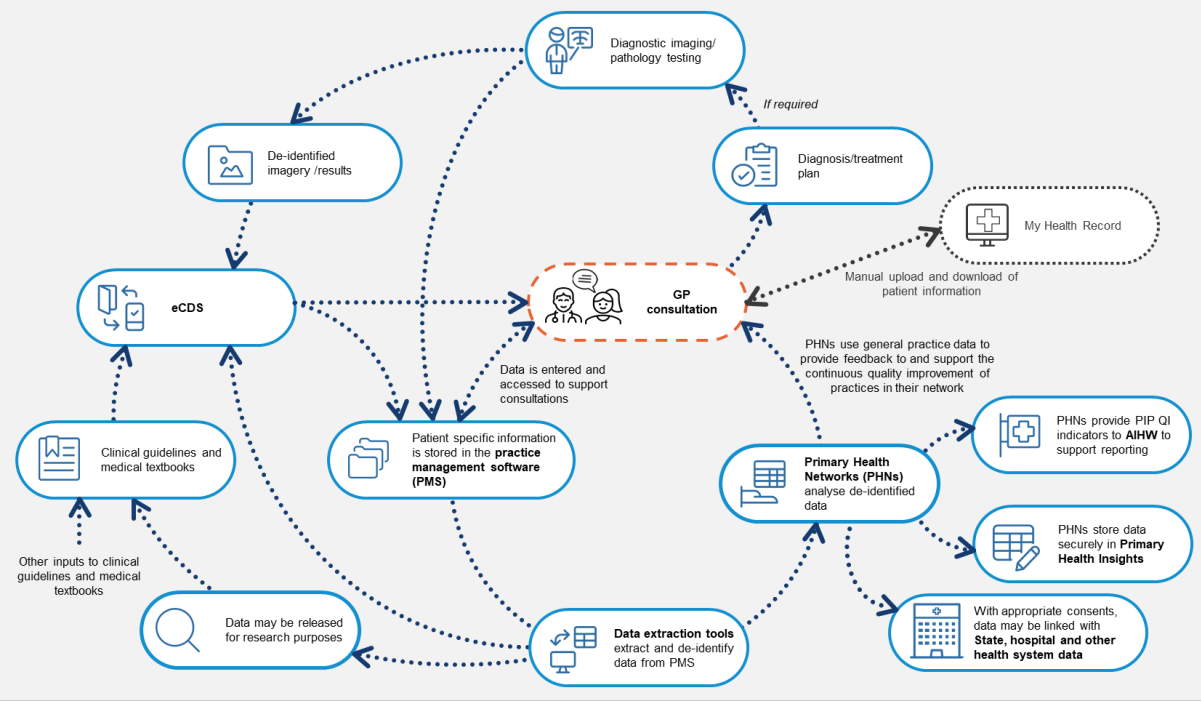
These uses of general practice data and the use of eCDS ultimately provide benefits to patients through more efficient, effective, appropriate and holistic care, health services and clinical planning for treatment and care.

Stakeholder interactions with general practice data and eCDS

There are a range of stakeholders involved in collecting, storing, analysing and sharing general practice data and other clinical information to support the central GP-patient interaction. These include general practices, software companies, PHNs and government agencies such as the Australian Institute of Health and Welfare (AIHW).

Figure 1 provides an overview of how general practice data is currently created by and informs the core GP-patient interaction, which is also supported through eCDS. It is important to note that while the My Health Record is an element of the current general practice data landscape, it is not the focus of this Issues Paper. The key terms used in this diagram are explained in Appendix B.

Figure 1 | Current linkages between general practice data and eCDS through the GP-patient relationship



1 Sutton, R.T. et al., 2020. An overview of clinical decision support systems: Benefits, risks, and strategies for success. npj Digital Medicine, 3(1).

2 2021. Implementing clinical decision support systems. Center for Disease Control and Prevention. Available at <https://www.cdc.gov/dhdsp/pubs/guides/best-practices/clinical-decision-support.htm>

Policy objectives

General practice data provides a range of benefits to primary health care stakeholders, including improved patient treatment and care, general practice quality and business improvement, better access by patients to their own information and improved service and system planning.

The Department is proposing the following objectives for the sharing of general practice data to allow these benefits to be realised:

- ensure general practice data is available into the future to support GPs, PHNs and other health system actors to carry out their respective roles and participate in continuous quality improvement at individual practice and regional, jurisdictional and national health system levels
- ensure any access to or sharing of general practice data is conducted safely and securely and that privacy continues to be protected, including through effective de-identification of personal information
- ensure that the safe, secure sharing of de-identified general practice data is not inhibited by systems or costs
- support continuous improvement in the quality and comparability of general practice data.

The Department also considers there are a range of significant potential benefits from eCDS use. Noting this, there are still a range of issues/challenges that are impacting the useability and widespread implementation of eCDS amongst general practices.

The Department is seeking to consult on these issues to gain a broader understanding of the current state of eCDS use and explore potential responses. The objective of this broad consultation process on eCDS is to:

- ensure the safety, efficacy and quality of primary and specialist care in Australia
- ensure technological advancements in digital health are supported
- ensure software use in GP settings is appropriately designed, implemented and oversighted
- achieve efficiencies across the broader health system.

Questions for consideration

1. Do you agree with the policy objectives outlined?
2. Are there other objectives Government should consider?
3. Are there other current or potential future benefits or uses of general practice data that should be considered?

Some issues with current general practice data arrangements

There are multiple stakeholders across the private and public sectors who are engaged in various aspects of the general practice data journey. The involvement of multiple players and standards complicates the flow of data and blurs transparency and accountability. This may be compounded by lack of trust and potential vendor lockout (e.g., restriction behind paywalls or movement to the cloud which may restrict access to data).

As the sharing of general practice data is voluntary, issues and complications in its flow potentially put ongoing access to general practice data for public good purposes at risk. Without high quality and standardised data, the ability of the health system to meet patient needs and develop better patient interventions and treatment pathways could be compromised. For example, if PHNs are unable to access data they would be restricted in effectively providing services for their populations. Primary health care services and research would be adversely impacted. The substantial benefits to be gained in the future by linkage of data across care settings – especially general practice and hospital – might not be realised.

Some of the issues that are a cause for concern about the future of general practice data are outlined below:

Ongoing access to general practice data

Throughout the general practice data flow process, there are multiple players who have access to, share, analyse and store general practice data. Without a clear and agreed pathway for the data, together with documentation of the rights of access and use of the data by key players, there is a risk that access might be interrupted or denied along the pathway. The potential for use of general practice data at a regional, jurisdictional or national level in times of public health emergency will depend on specific understandings around access and accompanying documentation around usage.

Currently data flow is governed by a range of individual agreements between the various parties. The impacts of some of these agreements might not be fully understood by the multiple players involved. This raises the potential for general practice data to be monetised for commercial research or other purposes without the knowledge of patients and GPs.There are multiple companies involved in the provision of general practice software, with increasing concentration of ownership and expansion of data sharing activity.

With the move of data to the cloud, there is the potential for contracts and data access models to be revised which could restrict access to general practice data for one or more players. As software vendors move towards storage in the cloud there need to be clear requirements about how datasets can be shared, including considering opportunities for general practice systems to share data directly with trusted external parties, including PHNs.

Lack of transparency

Related to the issue of ongoing access to data, there is currently a limited transparency around general practice data flow and use. This includes uncertainty as to:

- what agreements and requirements, such as consent requirements, are in place (or should be in place) with each stakeholder,
- whether data is being used as intended and
- how each player is transforming the data.

There is a lack of clarity regarding **privacy and consent requirements** and the associated responsibilities of different groups. This includes concerns about obtaining consent and ensuring proper data lineage (i.e., clarity on the chain of consent to share data at each stage). While there

is no legal obligation for consent to use de-identified data, there are instances where data could potentially be re-identified. GP relationships with patients may be damaged if consent is not explicitly handled.[3] Moreover, as *Breen v Williams*[4] places ownership of medical records with general practices, they may be ultimately liable or at risk if patient data is misused by players to whom general practices have given access. This is an issue for general practices, as many may have signed up to provide their data without full comprehension of how it is used.

The expansion of data sharing activity through the sharing of de-identified patient data including prescriptions and diagnostic testing records, requires a clear understanding of who has rights to the data once it leaves the general practice's systems. While increased data sharing can have many benefits, including to enable GPs to compare their activity with other doctors, the implications for data flow must also be transparent and clearly understood.

Stemming from questions regarding consent, there is also a need for greater transparency regarding **data usage** expectations and authority. Amongst the many stakeholders involved (patients, GPs, general practices, software vendors, PHNs and government agencies), there may be different views regarding custodianship and how data can be used by different parties. Each of these parties may have modified or analysed the data in some way and stored the data in their own repositories. This understanding also varies based on the type of data (i.e., unit-level vs aggregated, identified vs de-identified, re-identifiable, PIP QI indicators vs full dataset).

Regarding **data transformation**, the model used to map data to standards is proprietary and therefore not shared with stakeholders. Therefore, it is unclear how extracted data is mapped to standards and how this mapping varies based on the practice management software (PMS) or extraction software that is involved.

This lack of transparency also feeds into questions regarding quality of general practice data as outlined below.

Data quality and standards

Stakeholders have concerns about the quality of the data given the lack of standardisation or regulation of either the software, data definitions or data entry requirements for general practice data.

Variations in data entry: Data quality due to variations in data entry will likely always be limited as research is not the primary purpose for which that data is collected. However, the lack of either technical or semantic interoperability standards remains a significant issue. Different practice management software collect data in different ways, with some using SNOMED CT and HL7 standards, and others not.

Variations in data extraction: Different data extraction tools work in different ways, with some providing real-time extraction and others monthly extraction. The data extraction tools extract, analyse and present data in different ways, with each vendor determining what discrete data they extract and the format of the data they provide, albeit in consultation with the general practices and PHNs. There is also variability in the model they use to map data producing variation in

3 The Privacy Act 1988 (the Privacy Act) covers health information and includes content on how this information should be treated by parties who have access to that information. According to the Office of the Australian Information Commissioner (OAIC), to the extent that information has undergone an appropriate and robust de-identification process, it is not personal information, and is therefore not subject to the Privacy Act 1988 (Cth).

4 The High Court Decision in Breen v Williams (1996) has the proposition that the GP, not the patient, owns the health record. However, the ownership of medical records will depend on the way in which the medical practice is conducted. For example, a practice can be conducted on the basis that the GPs are employed by the practice. In which case, the records are likely to be property of the employing practice rather than the treating GP.

results.The high level PIP QI indicators are the only element of the general practice dataset that is provided in a consistent format due to existing governance and reporting requirements.[5]

These variations can and do lead to a lack of comparability, high uncertainty when interpreting data, and the potential for misinterpretation and unreliable insights.

Data security

There are variabilities between stakeholders across the general practice data flow in how data is stored and transferred and its associated security.

Variations in the type of storage used: Many general practices currently store data in local servers which may impact data security with variability depending on the practice. The movement by software vendors towards storing data in the cloud may improve consistency and level of security, however it could require changes to data access and sharing protocols to support ongoing access to general practice data.

Range of storage locations and access points: The range of storage locations may increase the risk of data breaches, data loss or interruptions to access. A recent development related to this is providers considering the use of Application Programming Interfaces (APIs), which sit within practice management software and directly interact with APIs in the software of users of that data.

Balancing the benefits of enhanced data access and sharing with the risks is an important consideration for general practice data.

Data governance

While each of the above issues can be dealt with independently, they impact each other and would benefit from a holistic approach to future access to general practice data. Data governance can provide the scaffold in which the other issues can be addressed and can provide clarity on who uses general practice data, in what form, how it is used and how it is stored securely.

Overarching governance and oversight of general practice data across all the aspects of the data flow could improve many aspects of the arrangements. The current state has resulted in multiple parties developing individualised governance arrangements or agreements for data sharing.

The PIP QI Data Governance Framework supports governance of the PIP QI indicators.[6]

The PHN Cooperative's National Data Governance Committee has developed a National Data Governance Framework which all PHNs have agreed to deliver against. This framework covers all primary health care data and it applies to the PHNs' secure data storage arrangement, Primary Health Insights. The Committee has written a manual which is more detailed to sit under the framework. As part of establishing consistent data governance, the Committee audited every PHN against the framework and provided each PHN a set of recommendations to support their improvement. The Committee is currently working on a comprehensive data governance policy.

Overarching governance can also impact quality and transparency. For example, the inconsistent application of data entry, analysis and outputs can impact data quality. Data is also more easily available to some stakeholders than others, and there is a lack of clarity on approved uses for

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5 The Department has developed the Practice Incentives Program Eligible Data Set Data Governance Framework which outlines the data in the dataset, who the local, regional and national data custodians are, privacy information, how the data is managed, collected and used, and its security requirements. The Department has also developed PIP QI guidelines, fact sheets and FAQs to support stakeholders in understanding and taking part in PIP QI.

6 The Department engaged Doll Martin Associates to conduct a review into the privacy and security controls in place for data collected through the PIP QI incentive. The review found that while there were variations in the method of collection, there were appropriate controls in place to protect privacy and security. The review made 14 recommendations to further strengthen the PIP QI incentive.

general practice data. There is also a lack of shared understanding on how all the data flow services fit together which may lead to duplication and confusion. Each of these issues can cause inefficiencies and negatively impact decision making, ultimately resulting in a loss of trust.

Questions for consideration

4. What aspects of the current system in relation to general practice data work well?
5. What aspects of the current process in relation to general practice data are of concern?
6. What general practice data should be shared, with whom and for what purposes?
7. Under which conditions should governments have access to aggregate general practice data?
8. Are there any issues not covered above that impact on ongoing access to general practice data?
9. What is the single, most pressing issue facing ongoing access to general practice data?
10. What upcoming developments may impact the flow of general practice data?

Examples of systems and solutions implemented overseas

While each country has unique features in how the primary health care system operates, it is useful to look at how other countries have approached the issues of ensuring ongoing access to quality general practice data. Some examples of interest are outlined here.

New Zealand's largest Primary Health Organisation (PHO) has a preferred PMS provider

In 2019, ProCare (Auckland's PHO) conducted a year-long review of several different PMS options and selected one called Indici as the most suitable system for its needs. A number of other PHOs have also nominated Indici as their preferred system.[7] ProCare signed a contract directly with Indici's parent company[8], and has since been transitioning its member practices towards Indici, providing technical and training support directly to individual practices as they learn the new system.[9]

In the UK, GPs must choose from a panel of approved PMS

The GP IT Futures program sets technology, data standards and capabilities that all practice management software systems must meet. It also established a 'digital marketplace', the Digital Buying Catalogue, an online platform that allows practices to search and compare approved suppliers' solutions on the framework and procure clinical IT system capabilities. There is also a financial incentive for GPs and software companies to participate, as "costs for selected services are covered via a central call off agreement with each participating supplier."[10]

The UK has centralised agencies tasked with managing healthcare data and research

NHS Digital was established in 2013 and is "responsible for collecting, analysing and disseminating England's health and social welfare data". The Health Research Authority is a single entity that streamlines and regulates health and medical research, as well as protecting the interests of patients. These centralised agencies simplify and rationalise the collection, storage, access to and use of primary health care data in order to make sure it is treated and used as securely and efficiently as possible.[11]

Questions for consideration

11. Are these examples relevant to Australia?
12. What other examples might inform the secure future for general practice data in Australia?

7 McBeth, R, 2019. New Zealand's largest PHO ProCare selects Indici in PMS review. Healthcare IT News. Available at <https://www.healthcareitnews.com/news/asia/new-zealand-s-largest-pho-procare-selects-indici-pms-review>

8 Reid, M, 2018. ProCare signs contract with Valentia Technologies to pilot indici practice management system. New Zealand Health IT. Available at <https://www.healthit.org.nz/news/procare-signs-contract-with-valentia-technologies-to-pilot-indici-practice-management-system>

9 ProCare, 2020. ProCare Annual Report 2020. Available at <https://www.procare.co.nz/media/2388/procare-annual-report-2020.pdf>

10 NHS Digital, 2021. GP IT Futures systems and services. Available at <https://digital.nhs.uk/services/gp-it-futures-systems>

11 Srinivasan, U. et al., 2018 Flying Blind: Australian Researchers and Digital Health. Digital Health Cooperative Research Centre, Australian Health Data Series 2. Available at <https://flyingblind.cmcrc.com/files/cmcrc_flying_blind_vol_2_web4.pdf>

Electronic clinical decision support for GPs at the point of care

Types of eCDS

While there are a range of categories for decision support systems, including communication-driven, model-driven and data-driven; eCDS are frequently categorised as either knowledge-based or non-knowledge based. Knowledge-based eCDS typically contain a mechanism to communicate, an inference engine and a knowledge base consisting of rules and compiled data (such as clinical guidelines). The inference engine uses the patient's data (entered into the PMS by the GP), in conjunction with the rules from the knowledge base, to produce prompts, reminders and recommendations.

Non-knowledge based eCDS do not rely on data drawn from an established knowledge base, rather they use a form of artificial intelligence (AI) called machine learning to generate new data. Machine learning allows computer software to learn from past experiences and/or find patterns in clinical data. A key difference between knowledge-based eCDS and non-knowledge based eCDS is that with the former, it is usually possible to trace the output back to the parent body of knowledge (e.g., a specific clinical guideline). Conversely, non-knowledge based eCDS are algorithm-based (the algorithm itself may be commercial-in-confidence) and therefore do not provide this 'line of site' from the output back to the parent body of knowledge.

Knowledge-based and non-knowledge based eCDS can offer a range of information and tools to strengthen clinical decision making in primary health care. In practice, eCDS can provide GPs with clinical information, guidance and workflow functionality, such as prescribing support, requests for pathology testing and diagnostic imaging services, and referrals for other specialist advice. This functionality strengthens connections across the health system by enabling efficient communication and information sharing between primary health practitioners and specialist health care providers.

eCDS inputs

eCDS utilise several information and data inputs that form the evidence-base for decision support. As shown in Figure 1, the three key inputs for eCDS are:

- **Clinical practice guidelines.** Clinical practice guidelines are evidence or consensus-based statements that include recommendations intended to optimise patient care and assist health care practitioners to make decisions about appropriate health care for specific clinical circumstances.[12] These guidelines are used to assist clinicians and patients in shared decision making. These guidelines are often based on the analysis of published medical research and population health data.
- **De-identified imagery/results.** Personal information is de-identified if the information is no longer about an identifiable individual or an individual who is reasonably identifiable.[13] Common reasons for de-identifying data, particularly in the health space, is to retain an individual's privacy and ensure no sensitive or personal information is shared. De-identified imagery or results inputted into eCDS can draw upon the outputs from diagnostic imaging and pathology testing.
- **De-identified primary care data.** De-identified primary health care data draws upon the information collected through GP/patient interactions. This data is collected by a GP at the point of care and entered into a PMS. This information is then extracted from the PMS and is

12 National Health and Medical Research Council, 2014. Clinical practice guidelines portal. Australian Clinical Practice Guidelines. Available at <https://www.clinicalguidelines.gov.au/portal>

13 Privacy Act 1988, section 6 'Interpretation', Available at < https://www.legislation.gov.au/Details/C2021C00379>

used to support GP feedback loops, medical research, clinical guideline development and input into eCDS (predominantly non-knowledge based eCDS).

How eCDS can be used

As noted above, eCDS is primarily used to support clinical decision making at the point of care. eCDS are used by primary health care practitioners, bringing together a range of information and data to generate recommendations and supporting clinical information. Using eCDS can enhance care quality and patient safety, as the software provides on-the-spot access to clinical data/guidelines during the often high-pressure, fast-paced patient consultations.

The level of eCDS use by GPs currently reflects GP preference, access and useability of software. While some GPs may choose not to use eCDS, others can use it to support their needs as a GP, at various stages of their career. eCDS is a useful tool to support those who are in the early stages of practice, to increase confidence and support decision making. For those who have significant practice experience, it can provide support to ensure advice being provided at the point of care draws on up-to-date clinical information and guidelines.

In terms of functionality, eCDS can be used as a stand-alone software or can be integrated into other elements of the clinical workflow. The software commonly incorporates widely-used non-proprietary standards and agreed clinical terminologies to maximise interoperability and future integration into other medical software. There is increased focus from software developers on achieving seamless integration of eCDS into clinical workflow.

Questions for consideration

13. What aspects of the current system in relation to eCDS work well?
14. What aspects of the current process in relation to eCDS are of concern?
15. What upcoming developments may impact eCDS functionality and integration into clinical workflows?

The current regulatory framework for eCDS

Regulatory approach by the Therapeutic Goods Administration

The Therapeutic Goods Administration (TGA) regulates the safety and performance of medical devices, and has been reviewing the regulation of software-based medical devices, including undertaking extensive consultation and industry engagement in 2019 and 2020 to clarify both the existing regulatory requirements and scope of regulation.

The digital health environment is rapidly evolving and includes many new medical device software products, and many health-based products which are crossing and/or blending traditional boundaries of therapeutic product definitions. This has caused therapeutic goods regulators around the world, including the TGA, to implement changes to their frameworks to address uncertainties as to what meets the definition of a medical device and to allow for innovation while still ensuring safety and performance, and patient/user confidence in such devices.

Following a decision by the Government, the TGA has implemented reforms to the regulation of software-based medical devices. These changes took effect from 25 February 2021, and additional guidance for software-based medical devices has been published on the TGA website. This includes guidance specifically for CDSS as well as a broader package of materials.

Under theregulatory framework for medical devices, CDSS[14] that meets the definition of a medical device must be included in the Australian Register of Therapeutic Goods (ARTG), unless otherwise exempt.[15]

Therefore, eCDS is currently regulated by the TGA if:

- it is manufactured or supplied in Australia; and
- it is a medical device;[16] and
- it is not excluded from TGA regulation.

An eCDS medical device is exempt if it meets all three of the following criteria:

- it is not intended to directly process or analyse a medical image or a signal from another medical device (including an in vitro diagnostic device); and
- it is intended only for the purpose of providing or supporting a recommendation to a health professional about prevention, diagnosis, curing or alleviating a disease, ailment, defect or injury; and
- it is not intended to replace the clinical judgement of a health professional in relation to making a clinical diagnosis or decision about the treatment of patients.

If any of these criteria are not met, the eCDS is not exempt and requires inclusion in the ARTG.

Alternatively, if all three of the above are met, sponsors *must notify the TGA*, ensure the device meets the relevant essential principles for safety and performance of a medical device, *and comply with other requirements but do not need to apply* to include it on the ARTG. “

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[14] eCDS is referred to as Clinical Decision Support (CDSS) in TGA documentation.

[15] Australian Government Department of Health. Therapeutic Goods Administration, 2021. Clinical decision support software. Available at <https://www.tga.gov.au/resource/clinical-decision-support-software>

16 Australian Government Department of Health. Therapeutic Goods Administration, overview of medical devices and IVD reguatlion <https://www.tga.gov.au/sme-assist/medical-devices-regulation-introduction>

Other forms of oversight

There are currently no endorsed guidelines or standards specifically developed for eCDS design, manufacture or use within Australia. While other medical software, data standards and/or clinical terminology[17] may be applied to eCDS, they do not specifically relate to the functionality of eCDS and their use within general practice settings.

Government incentives

The Australian Government provides general practices access to a range of incentives under the PIP. This program provides funding for general practices to help them continuously provide quality care, enhance capacity and improve access and health outcomes for patients.[18]

The eHealth incentive (also referred to as Practice Incentives Program eHealth Incentive (ePIP) aims to encourage general practices to keep up-to-date with the latest developments in digital health and adopt new digital health technology as it becomes available. To be eligible for the ePIP incentive, practices must meet the following requirements:

- integrate healthcare identifiers into Electronic Practice Records
- have secure messaging capability to electronically transmit and receive clinical messages to and from other healthcare providers
- ensure that they are working towards recording majority of diagnoses for active patients electronically
- ensure that the majority of their prescriptions are sent electronically to a Prescription Exchange Service
- use compliant software for accessing the My Health Record system and creating and posting shared health summaries and event summaries.

Questions for consideration

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

17 An example of one such clinical technology is SNOMED CT-AU, which is a large 'dictionary' of clinical terms with a unique code that are machine-readable, and which is managed and distributed in Australia by the Australian Digital Health Agency (ADHA).

18 Australian Government, 2021. Funding for general practices to improve their service – Practice incentives Program (PIP). Available at < https://business.gov.au/grants-and-programs/Practice-Incentives-Program>

Potential benefits of eCDS use across the health care ecosystem

eCDS use in primary health care settings has the potential to support clinical decision making and enhance patient care as well as achieving additional benefits across the broader health care ecosystem. Some potential benefits to eCDS use include:

- **Enhancing patient safety and quality of care.** eCDS provides access to information at the point of care which informs shared decision making about patient diagnosis and treatment, using the information provided to suggest/recommend possible investigations and diagnoses that match a patient's symptoms. eCDS provides streamlined access to treatment guidelines and recommendations for ongoing care. Through this, eCDS can reduce medication errors and furthermore adverse events by providing drug dosage recommendations, alerts for drug interactions and drug disease adverse outcomes.[19]
- **Supporting primary health care practitioners through the provision of information**. eCDS allows GPs to remain up-to-date with the latest clinical guidelines, medical research and other clinical information as well as exposing them to a range of alternative treatment options. It can provide information and recommendations on evidence-based interventions as an alternative for prescribing, thereby decreasing potential adverse reactions from pharmaceutical use. eCDS empowers GPs by giving them increased confidence to make point of care diagnosis and treatment decisions without the need for specialist referrals by drawing upon the accumulated clinical knowledge contained within the eCDS knowledge base.
- **Improving efficiency and decreasing operational costs for GPs and the broader health care ecosystem.** eCDS identifies the most appropriate treatment and ongoing care from a patient safety perspective. It also helps to achieve cost benefits through improved use of the Medicare Benefits Schedule (MBS) and other health system financing, by reducing 'unnecessary' and/or 'low value' testing, diagnostic imaging and prescribing. This is currently imposing additional time and cost burdens on both patients (in relation to 'out of pocket' expenses) and the broader Australian health care system.[20] eCDS also enhance communication and data exchange by populating clinical details in diagnostic imaging and pathology requests, allowing more targeted reporting from the receiving specialist and therefore improving efficiency across the broader health care ecosystem.

19 Noting that many PMS may already have a drug-drug screening functionality, outside an eCDS, to alert GPs to drug-drug interactions that may result in treatment failure and/or adverse events.

20 The 2018 report from the diagnostic medical clinical committee, as part of the medical schedule benefits review taskforce, regarded eCDS, "as a superior intervention to improved requesting of diagnostic imaging and pathology services, noting the system would give clinicians access to up-to-date clinical advice at the point of care and information on specific texts for consumer education". Furthermore, the committee noted "the importance of providing requesting of diagnostic tests with the necessary support and enablers to facilitate better use of MBS items. The committee agreed that there were clinical areas where the use of MBS funded diagnostic services could be approved". Australian Government, Medicare Benefits Schedule Review Taskforce: report from the diagnostic medical committee 2018 <https://www.health.gov.au/sites/default/files/documents/2020/12/taskforce-final-report-diagnostic-medicine-clinical-committee-report-from-the-diagnostic-medicine-clinical-committee.pdf>

Some issues and challenges with eCDS design and use

While there are a range of potential benefits for eCDS use in primary health care settings, there are currently a number of issues/challenges. These include:

- **Factors impacting uptake of eCDS by GPs.** Practitioners are concerned about the varying quality and currency of information contained within the eCDS knowledge base as well as a lack of consistency of outputs across different software platforms and this could generate a lack of trust in eCDS and the information provided. Additionally, a lack of integration of eCDS into clinical workflows increases the time impost on primary health care practitioners and can create additional barriers for use. Furthermore, a high volume of alerts/warnings can interrupt GP interactions with patients and can potentially result in certain critical alerts being missed due to clinicians playing less attention to warnings (due to notification fatigue).
- **Challenges with the integration of clinical guidelines into eCDS.** Currently there is no regulatory requirement for endorsed guidelines (such as National Health and Medical Research Council guidelines) to be integrated into eCDS. This may create some doubt amongst practitioners that best-practice Australian guidelines are being drawn upon to inform clinical decision recommendations provided by eCDS. Another complicating factor is that many existing clinical guidelines are not optimised for electronic utilisation so that they can be interrogated by eCDS, therefore potentially impacting upon the completeness of any eCDS knowledge base.
- **Considerations for the integration of eCDS into the broader health care ecosystem**. Inconsistent clinical terminology entered in PMS and used for the inference engine in eCDS can impact the accuracy of clinical recommendations provided by the eCDS (noting that advances in translation software are reducing the impact of this issue). Overall, there is ambiguity in relation to who is responsible for eCDS oversight/regulation with potential roles for government agencies, clinicians peak bodies and the medical software industry.

Questions for consideration

17. What do you see as the benefits of eCDS use for shared decision making at point of care?
18. What do you see as the issues/challenges of eCDS design and use and what are the associated impacts?
19. Do you have any suggestions as to potential next steps to address any identified issues and challenges?

Some opportunities

Government has a number of levers that are potentially available to meet the Department's policy objectives. The following tables provide an overview of some of these levers and provide examples of potential options under each.

Awareness, education and training
Communications and educational material/programs to build stakeholders' understanding of the policy objectives and actions which can support those objectives
Options include: • Communications to stakeholders (patients, GPs, general practices, PHNs, etc.) on the benefits of sharing general practice data, importance of standardisation and consent, and the use and benefits of eCDS in primary health care settings. • Educational/informative materials on the benefits of better access to general practice data, how it is used, privacy and consent requirements, etc. • Training to support end-users increase digital literacy and support seamless and efficient use of eCDS. • Co-designed value propositions for the sharing of general practice data with all stakeholders.

Guidance
Practical tools and support that allow stakeholders to undertake practices that enable the policy objectives
Options include: • Co-designed guidance and resources for stakeholders (GPs, general practices, software companies, PHNs, etc.) to support general practice data-related activities such as a checklist when entering a contract with other stakeholders or guidance on how to enter data and how to better share data back to general practices.[21] • Additional guidance regarding the 'full dataset' shared with PHNs. • A touchpoint or organisation to answer questions and provide guidance on relevant activities, such as how a general practice can make use of quality improvement and benchmarking data. • Introduction of better practice guidance for use of eCDS. This could support providers implement new ways of working, ensure compliance and provide guidance on how to best utilise eCDS in practice.

21 The Royal Australian College of General Practitioners (RACGP) provides guidance to its members through the Guiding principles for managing requests for the secondary use of de-identified general practice data. The guidance includes a checklist to help practices evaluate requests for data, minimise risk and comply with relevant legislation. RACGP has also published the Minimum requirements for general practice clinical information systems report, to provide recommendations to improve usability in data collection, management, use and sharing.

Incentives

Financial and non-financial rewards which encourage stakeholders to support policy objectives, such as funding, subsidies, information or recognition

Options include:

- Incentives for:
  - compliance with guidance or best available practice;
  - sharing full dataset with PHNs;
  - new products/players to simplify the current flow of general practice data or provide alternatives to enable more competition; and/or
  - general practices who use compliant software.
- Preferred provider status for companies who voluntarily sign on to adhere to co-designed standards.
- Potential inclusion of eCDS in the ePIP to increase uptake of eCDS.
- Introduce new incentives for software manufacturers to co-design eCDS products with health care practitioners. This could include options to incentivise integration with PMS.

Voluntary standards and guidelines

Requirements which are set out and voluntarily agreed to by stakeholders which help them to improve their practices, systems and processes and align them to the policy objectives

Options include:

- Co-design of voluntary code of practice or standards for software and for data sharing (potentially through industry or peak bodies).[22]
- Development and maintenance of technical standards for eCDS. These standards would relate to the device design and inputs, such as standardisation of clinical terminology, impact of human factors, and the currency and range of clinical guidelines.

22 For example, the CSIRO Primary Care Data Quality Foundations Programme brought together stakeholders from the clinical profession, software industry, AIHW and the Australian Digital Health Agency (ADHA) to co-design the foundations of data standards in primary health care. Phase 1 of the project, completed in 2019, led to the development of an agreed core clinical primary care data dictionary and the adoption of a common clinical language in primary care systems through the development of the Primary Care SNOMED CT value sets.

Regulatory actions

Requirements which are mandated and must be met by stakeholders in order for them to be involved in activities in the policy areas

Options include:

- Transparent and objective software accreditation required for a solution to be used by stakeholders.
- Government to undertake a tender/panel process to select compliant software vendors which stakeholders must select from.
- Establish regulation that provides a framework for how data should be used and shared.
- Establish an independent governing body to govern general practice data, provide guidance and oversee compliance regarding the sharing and use of general practice data.
- Mandatory adoption of SNOMED CT and HL7 standards.
- Leverage Medicare rebate requirements to require the sharing of general practice data and adherence to standards.
- Leverage general practice accreditation requirements through the Australian Medical Council to require the use of compliant software.
- Increase the current scope of eCDS regulation to provide additional scrutiny and assessment of individual eCDS design, evidence-base and quality of device.

It is important to note that these levers do not need to be used independently and selecting one lever does not preclude the use of other levers. In fact, using multiple levers for change can strengthen and reinforce the shift towards the policy objectives.

Questions for consideration

20. Are there other levers the Government should consider introducing?
21. What impact might different levers have?
22. Which of these levers of change should be further explored and why?
23. What specific options might be considered?

Appendix A: Consolidated questions for consideration

Introduction and context

1. Do you agree with the policy objectives outlined?
2. Are there other objectives Government should consider?
3. Are there other current or potential future benefits or uses of general practice data that should be considered?

Some issues with current general practice data arrangements

4. What aspects of the current system in relation to general practice data work well?
5. What aspects of the current process in relation to general practice data are of concern?
6. What general practice data should be shared, with whom and for what purposes?
7. Under which conditions should governments have access to aggregate general practice data?
8. Are there any issues not covered above that impact on ongoing access to general practice data?
9. What is the single, most pressing issue facing ongoing access to general practice data?
10. What upcoming developments may impact the flow of general practice data?

Examples of systems and solutions implemented overseas

11. Are these examples relevant to Australia?
12. What other examples might inform the secure future for general practice data in Australia?

Electronic clinical decision support for GPs at the point of care

13. What aspects of the current system in relation to eCDS work well?
14. What aspects of the current process in relation to eCDS are of concern?
15. What upcoming developments may impact eCDS functionality and integration into clinical workflows?

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?

Some benefits, issues and challenges with eCDS design and use

17. What do you see as the benefits of eCDs use for shared decision making at point of care?
18. What do you see as the issues/challenges of eCDs design and use and what are the associated impacts?
19. Do you have any suggestions as to potential next steps to address any identified issues and challenges?

Some opportunities

20. Are there other levers the Government should consider introducing?
21. What impact might different levers have?
22. Which of these levers of change should be further explored and why?

23. What specific options might be considered?

Appendix B: Key Definitions

Australian Institute of Health and Welfare (AIHW): The role of the AIHW is to collect, manage and analyse health data from state, territory and federal government agencies to provide insights that inform policy and service delivery decisions. The AIHW is considered the national data custodian for general practice data. It receives and analyses aggregated PIP QI data and develops an annual report[23]. This report analyses data across the 10 Quality Improvement Measures, collated from general practices across the country, to improve patient care and planning at the national level.

De-identification: Personal information is de-identified if the information is no longer about an identifiable individual or an individual who is reasonably identifiable. Generally, de-identification of information involves two steps:

- removing personal identifiers, such as an individual's name, address, date of birth or other identifying information; and
- removing or altering other information that may allow an individual to be identified, for example, because of a rare characteristic of the individual, or a combination of unique or remarkable characteristics that enable identification.

Electronic Clinical Decision Support (eCDS): This software supports clinical decision making within the health care system. Within primary health care, eCDS software can be used as an input into GP/patient interactions, providing notifications and recommendations at the point of care. eCDS can be used as a stand-alone software or as a built in/add on component within PMS. The key inputs into eCDS used in primary health care are clinical guidelines, de-identified images/results and de-identified primary health care data.

Extraction tools are used to collect general practice data from practice management software to support data sharing, such as the sharing of PIP QI indicators and full datasets with PHNs. There are a number of extraction tools in the market and each extracts and processes information in different ways. Data extraction software companies also offer tools that provide feedback to general practices at the practitioner, practice and individual patient levels to support comparison and patient management.

General practices and practitioners (GPs): The main purpose of collecting and entering data is to provide quality care for their patient. GPs use PMS and eCDS systems to enhance interactions with patients and support broader patient care activities (e.g., specialist referrals).

My Health Record: A secure online summary of an individual's health information which can be accessed and added to by authorised healthcare providers. It does not replace existing clinical records and is instead intended to supplement these records with a shared source of patient information to improve care planning and decision making. GPs can upload information such as shared health summaries, event summaries and ePrescriptions. The information which is uploaded to the My Health Record is manually selected by GPs during the upload process. My Health Record can be accessed through some PMSs which are My Health Record-ready or over the web.

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23 Australian Institute of Health and Welfare, 2021. Practice Incentives Program Quality Improvement Measures: National Report on the first year of data 2020-21. Cat. No. PHC 5. Canberra: AIHW. Available at <https://www.aihw.gov.au/reports/primary-health-care/pipqi-measures-national-report-2020-21/contents/about>

Practice management software (PMS)[24]: These provide computer programs that assist GPs to manage their data for multiple purposes. GPs use PMS systems for business and administrative purposes, such as billing and scheduling, as well as multiple other clinical activities within the practice. They may also integrate eCDS tools within the system. There are many different PMS options for GPs to choose from.

Primary Health Insights (PHI): This is a health data storage and analytics platform initiated and built by PHNs with Commonwealth funding. PHNs can currently store de-identified primary health care data in the secure PHI database. Each PHN has a secure individual storage space, and they are also able to compare data with other PHNs when collaboration is necessary. PHI holds general practice data securely for PHNs, acting as an 'office building' where PHNs have 'shared tenancy'. Each PHN has its own 'floor' or lockbox, with multiple layers of security installed. Only people from within the PHN who have the 'key' can access the floor and there is a second layer of security to access individual 'rooms' or datasets on the floor. Additionally, PHI offers a 'conference room' where PHNs can collaborate in a secure environment. The Western Australia Primary Health Alliance (WAPHA) which manages PHI does not have access to other PHNs' data, except in a 'break the glass' situation which would be transparent. While only 27 out of 33 PHNs currently store their data on PHI, it is owned by all 33 PHNs and they each have their own lockbox even if it is not currently in use. Some of the remaining PHNs have plans to move data to PHI in the near future. Although many PHNs store their data in PHI, they are at varying stages of progress in transferring all the data previously held within their own servers. Most have moved general practice data in, however, not all the primary health care data they hold.

Primary Health Networks (PHNs): These are independent public entities funded by the Commonwealth. PHNs receive de-identified data, including PIP QI indicators, from general practices (using PMS and data extraction software) in accordance with agreements with general practices in their region. PHNs use this data to provide feedback to GPs and general practices and inform the PHN's own work. PHNs have agreements with general practices to receive data, including PIP QI indicators and full datasets, through the use of data extraction software.These agreements provide for licences for extraction software to be made available to the general practices in the region. Some PHNs also share data with states and territories to support data linkage that can provide a more holistic picture on health service usage. PHNs receive de-identified data from general practices and only share de-identified data against PIP QI indicators with the Commonwealth via the AIHW, not the full dataset. PHNs also share information back to general practices to support quality improvement and benchmarking.

Practice Incentives Program Quality Improvement (PIP QI) incentive: The PIP QI incentive was introduced in 2018. It incentivises quality improvement and the data sharing activities that support it, by encouraging general practices to share data regarding the ten PIP QI indicators with PHNs, and further-aggregated data with the AIHW. The aim of PIP QI is to improve patient outcomes through better methods of practice, standards and information.

24 In this paper, we understand practice management software to include clinical information as well as broader practice information such as appointments, billing, etc. The use of practice management software in this paper encompasses clinical information/management systems (CIS/CMS) and may also include electronic clinical decision support.

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All information in this publication is correct as at October 2021