



College Submission  
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# Consultation Regulation Impact Statement: General Practice Data and Electronic Clinical Decision Support

## About the Australian College of Rural and Remote Medicine (ACRRM)

ACRRM's vision is *the right doctors, in the right places, with the right skills, providing rural and remote people with excellent health care*. It provides a quality Fellowship program including training, professional development, and clinical practice standards; and support and advocacy services for rural doctors and the communities they serve.

ACRRM is accredited by the Australian Medical Council to set standards for the specialty of general practice. The College's programs are specifically designed to provide Fellows with the extended skills required to deliver the highest quality Rural Generalist model of care in rural and remote communities, which often experience a shortage of local specialist and allied health services.

ACRRM has more than 6000 rural doctor members including 1000 registrars, who live and work in rural, remote, and Aboriginal and Torres Strait Islander communities across Australia. Our members provide expert front line medical care in a diverse range of settings including general practices, hospitals, emergency departments, Aboriginal Medical Services, and other remote settings such as RFDS and Australian Antarctic Division.

## Initial Comments

ACRRM welcomes the opportunity to provide feedback on the Consultation Regulation Impact Statement (CRIS) relating to general practice data and electronic clinical decision support.

The primary purpose of recording data is to support GPs in their individual interactions with patients, however as general practice data links patient demographics with diagnosis and treatment, and includes consultation notes, diagnoses, treatment, medications, allergies, test results, sociodemographic information and more, it undoubtedly provides a valuable source of information which can be used to inform policy, program development and delivery, best practice health care, workforce initiatives and identification of service delivery gaps. Data collection also informs Continuous Quality Improvement within medical general practice.



Data collected from general practices and more broadly across primary care is important in providing detailed information on the diversity of practice occurring in primary healthcare practice models. This has particular relevance for our rural, remote, and Aboriginal and Torres Strait Islander communities where the Rural Generalist scope of practice extends beyond primary needs into secondary and tertiary care.

Whilst the College agrees that general practice data can assist in improving health outcomes for patients if that data is of good quality, appropriately deidentified and aggregated, and shared, this needs to be underpinned by a patient centred system which ensures the sharing of data supports improvements which benefit patients and communities. The need to assure both patients and GPs that health information is confidential and secure and to demonstrate and define prospectively how data will be used if and when it is shared, is increasingly important in the digital world. The guiding principles should include safety, quality, security, process transparency and fairness and individual privacy.

## General Comments

ACRRM supports the ethical sharing or linkage of data for the public good, limited to initiatives which aim to improve the health and health outcomes of patients and their communities. In addition, the proposed use must not harm to patients, healthcare providers or the health system as a whole.<sup>1</sup> Using general practice data in accordance with the Quintuple Aims would be a good starting point.<sup>2</sup>

It is widely accepted that the current processes for sharing and accessing data are complex, disjointed, and inconsistent, include multiple stakeholder groups with competing interests. The College agrees that the “public good purposes” role of aggregated health data and insights from analysis would benefit from a nationally consistent approach, however this must be supported by robust governance and the implementation of the necessary legislative, regulatory and ethical frameworks.

The CRIS identifies four broad reform options ranging from maintaining the status quo to the introduction of legislative mechanisms and mandatory requirements, and each option comprises both positive and negative components, and highlight several key risks for general practice in their scope and implementation which must be considered in the development of the final Regulation Impact Statement.

### Key Risks

Any proposed regulatory framework must consider potential negative impacts related generally to privacy issues.

It also needs to consider potential perverse consequences on rural and remote general practice, which is currently grossly underfunded and struggling to remain viable:

- Increased costs in implementing the necessary PMS to ensure compliance with regulatory frameworks could result in general practice only being a viable business option for large corporates.
- Mandating requirements both in terms of interoperability of systems and level of data recorded will lead to cost and time implications for rural general practices.
- Whilst expansion of the PIP QI is welcomed in principle, it will be important to ensure the expansion does not result in additional administrative burdens for GPs and their practices.

<sup>1</sup> AMA Position Statement, Data Governance and Patient Privacy in Healthcare, 3 Feb 2023

[file://acrrm.org.au/dfs/Home/g.jamieson/Downloads/Data%20Governance%20Position%20Statement%20-%20FINAL%20\(3\).pdf](file://acrrm.org.au/dfs/Home/g.jamieson/Downloads/Data%20Governance%20Position%20Statement%20-%20FINAL%20(3).pdf)

<sup>2</sup> The Evolution of the Quintuple Aim, Itchhaporia, et al. J Am Coll Cardiol. 2021 Nov, 78 (22) 2262-2264

<https://www.sciencedirect.com/science/article/pii/S0735109721078815?via%3Dihub>



There should be clear principles surrounding how and why PIPQI data will be used, who 'owns' that data, and the respective roles of PHNs and AIHW in the custodianship of aggregated data

- Regulatory solutions must be "rural-proofed" to guard against unintended consequences such as data harvesting, particularly as rural and remote practice does not generate sufficient numbers to allow for truly deidentified data processing

## Response to Consultation Questions

We have responded to the Consultation Questions pertinent to the work of the College.

### General practice data

#### **The problems to solve**

##### **Problem area 1 – Data sharing and consent**

*There is a lack of clear and agreed rules and standards around the collection and sharing of general practice data:*

- Data sharing depends on private companies allowing and enabling access to data.*
- The data required for public good purposes is not consistently being shared.*
- The lack of clarity regarding consent and privacy requirements.*
- Stakeholders have differing views on their rights to store, share and use general practice data.*

##### **Problem area 2 – Data quality, comparability, and linkage**

*The quality of data is inconsistent:*

- General practice data is inconsistently entered, stored, and shared.*
- The lack of consistency in general practice data reduces its potential to be used for public good purposes.*
- The absence of system and data interoperability limits continuity of care between GPs, other health professionals and across systems and jurisdictions*
- The lack of interoperability also results in high barriers to entry for new PMS providers.*

#### **The problems to solve:**

##### **Problem area 3 – Data governance, oversight, and coordination**

*There is insufficient oversight of coordination to drive work relating to general practice data or establish rules:*

- There is a risk that general practice data is used inappropriately in the absence of governance.*
- Lack of understanding of roles and data requirements has led to confusion and the risk of data being shared inappropriately.*
- Data linkage cannot occur without clear governance.*
- The lack of coordination and direction is limiting progress and resulting in inefficiencies.*



**Question 1: Do you agree with the policy problems described above?**

The College generally agrees with the policy issues outlined in problem areas one to three. General practice and the primary health care system face increasing challenges to the provision of care, including workforce issues, aging populations, the burden of chronic disease, the ongoing impacts of COVID-19, and these issues are acutely felt across rural, remote, and Aboriginal and Torres Strait Islander communities.

The potential for sharing quality general practice data to provide benchmarking and feedback to support continuous quality improvement, assess population health needs and inform service planning; and the appropriate linking of that data with hospital and other health system data, has clear benefits particularly in light of the Strengthening Medicare Taskforce Report<sup>3</sup> and its commitment to better use data and digital technology to inform value based care, and drive insights for planning, resourcing and continuous quality improvement.

Sound governance is crucial to the management of data, and a culture of data governance needs to be developed at the practice level. ACRRM's experience is that data governance at the jurisdictional level often poorly understands the specific settings of rural and remote Australia and the practice of rural generalists. Ensuring the necessary governance framework is in place is of paramount importance, particularly as the sector is currently operating in a commercial space without regulation. It is also crucial that any framework takes cognisance of the unique characteristics of, and challenges facing, rural and remote general practice.

A key issue that must be addressed in the governance of data sharing is an explicit commitment to transparently defining the intended use of the data and to ensure that going forward that it is only accessed and used within these agreed parameters. We would suggest that another tenet of the data-sharing governance should be that patients can opt-out of having their personal details shared particularly where they may have issues of personal protection.

The College supports in principle the sharing of general practice data where the sharing of data is patient centred, is governed by processes which can ensure that principles of rights to privacy and natural justice can be upheld and leads to improvements in safety and health outcomes for patients as well as facilitating whole of system benefits. A connected, interoperable healthcare system must be based on principles of data safety, data quality, data privacy and data portability.<sup>4</sup>

The approach to change principles on pages 40-42 of the CRIS provide a solid starting point for the shaping and development of regulatory options. The collaborative approach, cognisance of variations in health maturity, enhancements of patient safety, quality of care and health outcomes, consistent processes for obtaining consent, nationally consistent data standards, and interoperability are all welcomed. Recognition that eCDS should complement but not complicate GP clinical interaction and should evolve to meet emerging needs are similarly welcomed.

**Question 2 - Are there any other key policy problems that should be considered as part of the RIS process?**

The CRIS makes certain assumptions about the "ownership" of data which require further scrutiny. It makes the following statement:

*"GPs are the owners of general practice data once they record a consumer's data."<sup>5</sup>*

The instinct towards propertising health information and asserting ownership is understandable in certain contexts. The assumption that general practice data is "owned" by the GP, naturally leads to

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<sup>3</sup> <https://www.health.gov.au/committees-and-groups/strengthening-medicare-taskforce>

<sup>4</sup> Ibid, Section 1.2

<sup>5</sup> CRIS, General Practice Data and eCDS, page 33



justifying decisions about what the owner can then do with the data they hold. For example, a GP may assume ownership of patient data in order to utilise that data in making a referral to a specialist.

However, assumptions pertaining to ownership can lead to opportunities to monetise or capture value<sup>6</sup>, and further discussion is required around this issue, particularly as data is currently being used to increase the profits of privately owned entities, without a regulatory framework in place.

Practice Management Software (PMS) companies are paid for the data they share, but there is no flow on benefit to the GPs whose patient data the PMS is sharing. PMSs hold the power in the relationship between them and the GP/practice.

A broader national discussion is required around the ownership of data. A starting point for the discussion might be to consider patients as the owners of their data, and to consider GPs, practices, PHNs, and PMSs as merely custodians of that data, as recommended by the AMA<sup>7</sup>, and to build a data governance framework around that principle.

The College agrees that the expansion of the sharing of de-identified general practice data requires a clear understanding of who has rights to the data once it leaves the general practice's systems and the scope of those rights, and government action is needed to ensure the underlying principle of value/improvement to the healthcare system is demonstrated in all data use and requests for data sharing.

### **Question 3 - Are there other components to consider when looking at the digital health ecosystem?**

ACRRM members would see specific value in shared access to data, and often are in situations where appropriate data sharing can be critical to addressing patient needs. They often work across jurisdictions including general practice and/or state hospital settings, and data sharing is crucial for patient care. They also have the problem of local patients who must travel significant distances for tertiary care (with little communication 'back to base') as well as dealing with large numbers of itinerant patients, with limited data. Treating general practice data in isolation may not allow a truly patient centred view to be explored.

## Electronic Clinical Decision Support (eCDS)

### **The problems to solve:**

#### **Problem area 4 – Greater use of eCDS by GPs will enable knowledge-gaining opportunities and lead to increased consistency of clinical interactions.**

*Challenges relating to oversight, integration and standardisation:*

- a. There is a lack of oversight of the implementation, integration and use of eCDS systems (either Government or third-party).*
- b. There is a lack of transparency of the evidence base for some eCDS recommendations.*
- c. Challenges arise from integrating eCDS functionality into clinical workflow.*
- d. There is no central repository or authority for clinical guidelines.*
- e. Clinical guidelines are not optimised for integration with eCDS functionality.*

<sup>6</sup> Patient data ownership: who owns your health? Lidekll, Simon, and Lucassen, Journal of the Law and Biosciences Vol 8, Usse 2, July to December 2021, Isab023 GPs <https://academic.oup.com/jlb/article/8/2/Isab023/6380070>

<sup>7</sup> Australian Medical Association Position Statement, Data Governance and Patient Privacy in Healthcare, 2022, <file://acrrm.org.au/dfs/Home/g.jamieson/Downloads/Data%20Governance%20Position%20Statement%20-%20FINAL.pdf>





#### **Question 4 - Do you agree with the problem statement for eCDS?**

Yes. Rural Generalists and doctors in training in rural and remote communities often work across several different work settings, including general practice, hospital and emergency departments, and are exposed to a range of different systems, each with their own operating requirements. This lack of consistency in the user interface and functionality poses a potential safety risk, as the margin for human error is increased.

Conversely, rural and remote clinical contexts are diverse and best practice healthcare needs to consider a range of germane factors related to the nuances of patient and practitioner access to facilities, resources and expertise which would be taken for granted in urban decision support models. It should be recognised that the eCDS is a useful tool but unlikely to be able to incorporate and thus always reflect the best possible approach in every rural and remote clinical context.

## Options to address the policy problem

### Option 1 – maintain the status quo

The College agrees that in the absence of coordinated progress, the policy problems described in the CRIS are unlikely to be addressed and this would represent a negative outcome for our sector. Change is necessary in order that the potential benefits arising from improved data quality, governance and sharing or increased eCDS uptake can be realised.

### Option 2 – facilitate stakeholder-led regulation

We note this option involves “light touch” regulation predominantly led by stakeholders outside of government, where those involved voluntarily sign up to comply with rules or codes of practice.

The College agrees that self-regulation can be a useful tool in changing or emerging markets, however it does rely on stakeholders having an incentive to comply for viability, and this may not be the case for PMS providers. Due to the number of conflicting interests identified by the CRIS, co-regulation underpinned by legislation is more likely to align with the policy objectives<sup>8</sup> underpinning general practice data sharing outlined in the CRIS, which we would recommend are amending as follows (ACRRM recommended additions in *red text* below), to ensure all five components are included:

1. *Enable general practices to share general practice data to realise and share benefits, including enhanced consumer safety, quality of care and health outcomes, and*
2. *Ensure general practice data is available into the future to support GPs, PHNs, health professionals, researchers and other health system actors to efficiently and effectively carry out their respective roles and participate in continuous quality improvement at individual practice, regional, jurisdictional and national health system levels., and*
3. *Develop a consistent approach to access, collection and management of general practice data in Australia in line with whole-of-government approaches, including consumer consent practices and privacy preserving practices such as de-identification and aggregation of personal information, which is consistent with the principles of privacy and natural justice and supported by a governance framework which can ensure ongoing compliance with these principles, and*

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<sup>8</sup> CRIS, General Practice Data and eCDS, page 17



4. *Ensure that the sharing of general practice data is safe, secure, timely and not inhibited by incompatibility of systems, access costs or variations across jurisdictions and health settings.*
5. *Drive continuous improvement and standardisation of the quality of general practice data to ensure comparability with other health data at the point of care and robustness for secondary use.*

## Component 2.1- develop general practice data sharing principles and contract guidelines

### **Question 5 - What are the three most important aspects to include in data sharing agreements?**

A self-regulatory approach would require sector stakeholders to work together to:

- Clearly define data sharing principles
- Develop contractual clauses based on those principles
- Develop model agreements for data sharing

Working from this starting point, all data sharing agreements would be subject to the same principles and standardised contractual clauses. Whether the data sent to the requestor, the requester is granted access to the data, or the requestor is provided with outputs or insights would be a matter to be agreed between the contracting parties. A degree of adaptability to allow application to different use cases and scenarios would be necessary, on the proviso that the defined principles were always adhered to.

### **Question 6 - Who would be best positioned to provide leadership over the establishment of principles to support data sharing?**

Currently, health data governance is appropriately based on the Privacy Act and Australian Privacy Principles. Consistent with these principles, the College would see value in developing clear governance underpinned by legislation that could better facilitate coordination and progress. This could be best achieved by government in consultation with peak bodies.

## Component 2.2 – Establish and/or adopt agreed standards in relation to general practice data and eCDS

### **Question 7 - What is the key priority area for general practice data and eCDS that requires standardisation?**

Current systems would benefit from improvements in the design of the user interface so the presentation of health information, and associated alerts and warnings are delivered in a consistent manner. This would remove the need for learning across multiple platforms.

Setting Australian design standards for eCDS could potentially eliminate current challenges around eCDS use. For example, through our recent involvement with CSIRO's Primary Care Data Quality Foundations Program to develop a minimum data-set for the transfer of care, it is clear that more PMS vendors and eCDS vendors are willing to enhance their software to create a stable environment of standards and compliance/conformance. Recent enhancements to the production of electronic prescriptions and the introduction of active ingredient prescribing highlights the need for national



terminology to deliver an integrated solution across both prescribing, repository and dispensing vendors.

## Option 3 – Establish incentive-based compliance

The College notes that incentive-based regulation would involve coordination between government and industry, and encourage and induce compliance with agreed standards and processes.

The general practice sector in Australia, and particularly the rural general practice sector is currently grossly underfunded, and therefore although this option is likely to address the majority of problem areas identified by the CRIS, the increased costs to comply with new requirements would primarily impact GPs and general practices.

Arguably these increased costs could be offset over time, however if it is to be effective the impact on general practice, particularly rural and remote general practice must be addressed. In rural and remote areas, with Medicare funding at levels insufficient to sustain general practice, the rural Practice Incentive Program (PIP) is generally viewed as critical to practice viability.

## Component 3.1 - Enhance Incentives to share quality general practice data

***Question 17 - What data elements and level of data should be included in an agreed general practice dataset that is shared with health system actors?***

Currently, data against ten indicators is shared with PHNs and AIHW to receive the PIP QI incentive payment. The College agrees with the suggestion of expanding the incentive to include all the data elements required, and the introduction of a new service incentive payment (SIP) for data entry where GPs would receive a payment for clinically coding all data elements required to receive the expanded PIP QI incentive or another agreed dataset.

In all cases, mechanisms for patients and GPs to opt out of data sharing for secondary use must be incorporated.

***18. What data should various stakeholders (including government, PHNs and researchers) receive?***

The relevant data elements should be determined through consultation with GPs, PHNs, peak bodies and Colleges to ensure the data supports improved planning and design of the health care system, as well as providing insights back to general practice to improve health outcomes for patients and communities.

## Component 3.2 - Establish data sharing partnerships

***Question 20 - Would you support a data sharing partnership as an option?***

The College would broadly support data sharing partnerships as an option, however agrees that combining this approach with a standards or accreditation approach where only those holding accreditation would be able to enter partnership agreements. This would ensure high security standards are met and maintained.





## Component 3.4 Incentivise GPs to utilise eCDS

### **Question 28 - Do you think GP incentives would be effective in increasing uptake of eCDS?**

Yes. Our members report that greater use of eCDS by GPs will enable knowledge- gaining opportunities and lead to increased consistency of clinical interactions. However it is important that in all cases eCDS should complement but not complicate GP clinical interaction and should evolve to meet emerging needs.

## Option 4 – introduce/review legislative mechanisms

Whilst the introduction of new legislation and establishment of a regulatory scheme has the potential to realise the benefits of general practice data and eCDS adoption and address the policy problems identified in the CRIS, it is imperative that further consideration is given to the the potential impact on GPs and general practice of mandating standards. Particularly in light of the current issues of viability facing general practice.

General practice in rural and remote Australia faces an uncertain future and will continue to do so until progress has been made on the recommendations of the Strengthening Medicare Taskforce.

Sustainability issues aside, the benefits of national coordination and a single statutory body to provide oversight and coordination of activities relating to general practice data and eCDS adoption in general practice are clear, and could achieve the policy objectives and principles discussed in the CRIS, as well as enforcing regulation and providing a governance framework.

## Component 4.1 – Regulate to ensure consistency in data capture at the practice level

### **Question 29 - Should meeting a standard for data entry and data sharing quality be mandated?**

Requirements to clinically code items in order to receive MBS payments and to use compliant software will impact practices which are time and resource poor, and this is likely to place considerable strain on rural and remote practices in particular which are already facing challenges to sustainability

## Component 4.2 - Regulate that PMSs must meet standards to facilitate better data recording, interoperability and sharing

### **Question 30 - Should interoperability standards, data standards and data sharing standards be mandated for PMSs?**

The current use of different coding and termsets between PMS vendors is a barrier to effective comparison of information and the effective analysis of general practice data, however mandating interoperability standards is likely to have an impact on the cost of these systems to general practice, as vendors may have to increase operating costs to cover the cost of mandated compliance with particular standards.

Whilst the benefits of interoperability and data sharing are not in doubt, the issue is that general practice may be left meeting the cost burden of the imposition of mandatory standards.



## Component 4.3 – Regulate that data extracted from PMSs must meet quality standards

### **Question 31 - Should data extraction companies be regulated in how they extract and share general practice data to ensure quality, trusted data?**

The College agrees that ensuring that data is mapped to a standardised terminology will improve the consistency of outputs received by PHNs, allowing them to maximise benefits of general practice data and produce valuable insights for general practice. Legislation which specifies the format, granularity and content of the data would be welcomed however further consultation with GPs, PHNs, and peak bodies will be necessary to determine the data elements and level of detail required.

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*ACRRM acknowledges Australian Aboriginal People and Torres Strait Islander People as the first inhabitants of the nation. We respect the Traditional Owners of lands across Australia in which our members and staff work and live, and pay respect to their Elders past present and future.*