General practice data and electronic clinical decision support: Consultation Regulation Impact Statement (CRIS)

The RACGP response (February 2023)

RACGP

Introduction

The Royal Australian College of General Practitioners (RACGP) welcomes the opportunity to provide a response to the Department of Health and Aged Care's General practice data and electronic clinical decision support Consultation Regulation Impact Statement (CRIS).

Data governance is an important area of focus for general practice and the RACGP. To help practices evaluate requests for access to data, minimise risk and comply with relevant legislation, the RACGP has developed key principles for the provision of de-identified general practice data for secondary use.

Electronic clinical decision support (eCDS) is also an area of great interest to the RACGP. The RACGP published a position statement on eCDS in general practice in 2021, and continues to advocate for resourcing to establish an Australian authority for general practice eCDS to oversee the development and maintenance of technical and clinical standards.

The RACGP provided a submission to the Department's consultation on the Issues paper on General practice data and electronic clinical decision support in February 2022.

The RACGP thanks the Department for the opportunity to provide feedback on the CRIS.

About the RACGP

The RACGP is the voice of general practitioners (GPs) in our growing cities and throughout rural and remote Australia. For more than 60 years, we have supported the backbone of Australia's health system by setting the standards for education and practice and advocating for better health and wellbeing for all Australians.

As a national peak body representing over 46,000 members working in or towards a career in general practice, our core commitment is to support GPs from across the entirety of general practice address the primary healthcare needs of the Australian population.

We cultivate a stronger profession by helping the GPs of today and tomorrow continue their professional development throughout their careers, from medical students and GPs in training to experienced GPs. We develop resources and guidelines to support GPs in providing their patients with world-class healthcare and help with the unique issues that affect their practices. We are a point of connection for GPs serving communities in every corner of the country.

Australia's GPs see more than two million patients each week, and support Australians through every stage of life. The scope of general practice is unmatched among medical professionals.

Patient-centred care is at the heart of every Australian general practice, and at the heart of everything we do.

Summary

The RACGP makes the following key recommendations in its response to the CRIS:

- standards for interoperability between clinical information systems should be a priority for development and implementation,
- standards and regulatory schemes to improve data entry in general practice are not appropriate
- the best options for improving data inputs are well-designed incentive schemes, together with improvements to the design of clinical information systems to ensure they are interoperable and user friendly
- GPs must lead the analysis and interpretation of general practice data
- improving data quality is not merely the purview of the primary care sector: it requires a system-wide approach

- only the minimum amount of data should be collected, and the goals of data sharing should be clearly articulated
- governments should be prevented from using general practice data for the purposes of compliance and public benchmarking
- healthcare consumers should have visibility over the secondary uses of data and opting out should be an easy and painless process
- while useful, eCDS tools cannot provide accurate advice in all circumstances. GPs must have clinical autonomy in decision making
- GPs should not be penalised for failing to use eCDS tools
- Robust professional liability policies should indemnify clinicians when adverse events occur as a result of eCDS failures
- eCDS tools must be trustworthy (based on strong, current evidence), user-friendly, and align with clinical workflows
- the RACGP would welcome an opportunity to play a central role in the development of clinical and technical standards for eCDS and is well-placed to lead this work.

The RACGP response

General practice data: The problems to solve

1. Do you agree with the policy problems described above?

The RACGP broadly agrees with the policy problems as stated, though there are gaps which we address below.

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

There must be a broader value proposition for general practice in collecting and curating data for the purposes of sharing: that is, there must be clear benefits to patient care, patient experience, general practice workflow and/or other key metrics. Policy should demonstrate a clear vision of the goal of data sharing and examples of what can be achieved.

There is little discussion in the CRIS about the costs borne by general practice in curating data. Any policy changes must not increase the non-clinical requirements of GPs in documenting clinical care, unless these changes are appropriately remunerated. Time pressures continue to affect the entry of data, and there are few incentives for GPs to meaningfully improve data inputs.

Data is useful in policy and planning, but also in academic research. Chronic underfunding of general practice research is in itself a significant problem. With the cessation of major general practice data programs Bettering the Evaluation and Care of Health (BEACH) and NPS MedicineInsight, national data about general practice workflows and outcomes is lacking. Such data would bear out the exceptional worth and efficiency of general practice. Accessing general practice data for research should be as straight-forward as accessing hospital data in Australia.

The RACGP remains concerned about the potential for government to use big data for the purposes of compliance and/or public benchmarking of GPs or general practices. These risks are not adequately described in the CRIS.

As it stands, there is no standard data format across the medical field. As a result, clinical data such as diagnostic images are often stored (sometimes insecurely) outside of clinical information systems, for example in email inboxes. All clinical data should be able to be stored appropriately, accessed easily by relevant parties, and incorporated into eCDS as applicable. To achieve the policy objectives as stated, particularly with regard to data linkage, the same standards of data collection and curation must apply to all other medical specialities in Australia. Data consistency is an issue for the healthcare system as a whole, not just the primary care sector, and it requires a system-wide approach.

eCDS: Background and context

3. Are there other components to consider when looking at the digital health ecosystem?

Non-government activities being undertaken in relation to eCDS include co-design, implementation and evaluation of eCDS tools by general practice researchers, funded by bodies including the RACGP Foundation, National Health and Medical Research Council (NHMRC), and Medical Research Future Fund (MRFF).

eCDS: The problem to solve

4. Do you agree with the problem statement for eCDS?

The RACGP provides qualified support for the problem statement, with the following caveats.

There is an assumption in the statement that provision of eCDS will always increase knowledge and consistency of patient care. eCDS tools cannot advise of best practice in all circumstances or with all patient populations. The limitations of guidelines and other eCDS inputs need to be more clearly stated.

GPs (and all doctors) need additional information at times, and this information can sometimes be difficult to access at the point of care. eCDS tools can be helpful in these circumstances. However, eCDS tools are not always helpful: for example, drug intervention checkers might be unable to distinguish between theoretically relevant interactions and clinically relevant interactions. Any effort to increase eCDS tool use must respect GPs autonomy in clinical decision making. eCDS systems must never override the ability for GPs to use their vast knowledge and expertise to guide clinical care. There should be no legislative or financial penalty for failure to use or adopt the advice of eCDS tools. Clinicians should be indemnified against liabilities that occur as a result of adverse events associated with eCDS use.

Further, if eCDS tools do not align with general practice workflows, they will inadvertently burden GPs with an increased administrative load, which takes time away from the provision of quality care. GPs must be involved in the design of eCDS, particularly those clinicians with expertise in health informatics.

eCDS tools should be incorporated within a learning health system, where their implementation is facilitated by quality improvement activities and the tools can be improved following feedback from end users.

While the problem statement articulates one area of focus (health outcomes), it neglects to consider several other key areas essential to the development of good health policy: patient experience, provider experience, value (cost-effectiveness), and sustainability (both of the environment and the healthcare system). In particular, the importance of both the experience of the patient and provider have been understated in the problem statement.

Options to address policy problems

Option 2: Facilitate stakeholder-led regulation

Component 2.1 | Develop general practice data sharing principles and contract guidelines

5. What are the three most important aspects to include in data sharing agreements?

1. All parties must act ethically with regard to data. That is, data sharing agreements should demonstrate a commitment by third parties to refrain from using general practice data for inappropriate purposes, such as for benchmarking, pay-for-performance systems or performance management, revalidation/credentialing of health professionals, purely commercial purposes not linked to the goal of improving patient care, on-selling, or low-quality/dubious (unethical) research.

2. General practices must retain access and control over what can be extracted from their systems. Data generated by a practice must remain available to that practice for all purposes for which it deems appropriate; that is, third parties must not restrict access. Data collected from a general practice should be made available to that practice for quality improvement purposes on request.
3. There must be a value proposition for general practice. Third parties must be able to explain how data sharing will provide benefit to general practice (by improving patient care and/or practice workflow). Data sharing agreements must also make clear the nature of the data the practice will receive in return (eg, geographical area-level data, practice-level data, or individual GP-level data) and how the data will be presented to the practice. Further to this point, data sharing agreements should reflect the fact that practices are entitled to compensation for the time and effort they take to prepare data for sharing, and might require training and other supports to engage in quality improvement activities.

6. Who would be best positioned to provide leadership over the establishment of principles to support data sharing?

GPs must be at the forefront of the design of data sharing principles by virtue of their roles as gatekeepers to other branches of the healthcare system, and as the primary recipients of healthcare data. As the peak organisation for general practice in Australia, the RACGP is in the best position to provide leadership in this arena, and already has a range of resources that can be used to this end, including Three key principles for the secondary use of general practice data.

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

7. What is the key priority area for general practice data and eCDS that requires standardisation?

For general practice data, the key priority area for standardisation is interoperability between clinical information systems used within general practice, and between those used in general practice and secondary and tertiary healthcare providers. This would involve a standardisation of data structures, data element names and associated definitions, and systems of medical terminology and coding, as well as an ability to easily share data between systems. All patient parameters (including medications, pathology results, imaging results, and results of other investigations) should be presented and stored in a standard format.

Consumer consent and privacy is also of critical importance as this is a confusing and fraught area. Although there is no legal requirement for general practices to notify patients or receive their consent for the secondary use of general practice data, patients place their trust in GPs to safeguard their health information. As per the RACGP's response to the Issues paper, patients should be made aware of their general practice's policy on the secondary use of data, and given the opportunity to opt out of this process.

For eCDS, standardisation of inputs should be prioritised as gains in functionality are unlikely to be made without significant work to improve the quality and consistency of the source material. eCDS tools are only as valuable as the data used to inform their recommendations. Without high-quality, up-to-date clinical guidelines created by reputable organisations, the tools are not going to be of use to general practice. However, failure to integrate eCDS tools into the general practice clinical information systems will continue to disrupt clinical workflows, which is also a critical stumbling block to wider uptake.

8. What specific standards do you think should be explored in relation to general practice data?

Policymakers could look to international models to build interoperability standards (eg, New Zealand, Denmark, England and Wales). The RACGP has worked with key industry players to develop minimum requirements for clinical information systems.

No software vendor should be permitted to prevent or inhibit reasonable data extraction or seek ownership of GP data. As described in the CRIS, the RACGP is concerned about moves to cloud-based storage of general practice data and

what vendors will do with it. General practices should retain access to and control of their data for all purposes the practice deems appropriate. Third parties should be prevented from restricting access to or charging fees for access to a practice's own data.

In relation to consumer consent, dynamic systems are required so that patients can give, moderate and remove their consent at any point across their healthcare journey. General practices struggle to provide appropriate information to patients on secondary uses of data, and systems to opt-out of data provision lack transparency.

9. What specific standards do you think should be explored for eCDS inputs (e.g., guidelines must be published in smart forms to allow for easy integration into eCDS)?

Suggestions include:

- use of smart forms as discussed.
- guidelines should always include clear information on the authoring body, endorsement, the strength of the evidence informing recommendations, the relevance of the recommendations to primary care (ie, what setting the eCDS is to be applied in), the date guidelines were produced and/or updated, and other information important in clinical decision making. At present, the evidence underpinning recommendations within eCDS is often opaque to the user.
- guidelines must be endorsed/produced by a reputable organisation such as NHMRC, the RACGP, and/or other bodies.
- links to the source guidelines and authoring bodies should be embedded within the tools.
- commercial entities such as pharmaceutical or device companies should not be involved in creating or funding eCDS tools
- the RACGP should be involved in decision making about which guidelines are used to underpin eCDS.

10. What specific standards do you think should be explored in relation to eCDS functionality to ensure optimum eCDS use (e.g., eCDS must be integrable into PMS)?

- as noted, it is essential eCDS be integrated into general practice clinical information systems. Tools that sit outside of these systems impede GP workflows and will not be used as intended.
- eCDS tools must support, not impede, clinical workflows. They must be unobtrusive. For example, tools must not generate excessive or irrelevant pop-up boxes that waste time and actually detract from their clinical usefulness, creating 'notification/alert fatigue'.
- eCDS tools must also be integrated into other clinical information systems used by GPs, such as those used in residential aged care facilities (RACFs).
- GPs' use of eCDS tools must be optional
- ideally, guidelines must be able to be updated in real time (ie, serve as 'living guidelines').
- there must be a uniform approach to the presentation of advice.

11. Are there any established standards that are suitable for adoption either for eCDS, for data or for both?

Australia lacks a co-ordinated approach to clinical guideline development which would underpin work to improve eCDS inputs. Successful international models include the UK's National Institute for Health and Care Excellence (NICE) and the US' Centers for Disease Control and Prevention (CDC).

12. Which organisation or collection of organisations would be best positioned to provide leadership over the establishment of standards for eCDS, for data or for both?

Standards for eCDS development should be developed by the profession and properly funded at the national level. The RACGP is well-placed to lead work on the establishment of clinical and technical standards for both general practice data and eCDS, as outlined in our position statement on eCDS.

Component 2.3 | Establish the conformance environment to empower standards

13. What method of conformance do you think would be most effective (e.g., code of conduct) for eCDS, for data or for both?

Under the framework outlined, a code of conduct for both general practice data and eCDS would be appropriate.

The CRIS discusses how the RACGP's Standards for general practices could be updated in a future edition to include more prescriptive directions for data entry. While this is possible, the benefit to enhancing direct patient care and safety must be clear and this would need to be supported by standardisation of clinical information system products (uniformity of data structures, coding etc) and improved useability. As before, any initiatives to improve the quality and uniformity of general practice data need to examine factors that impinge upon the ability of GPs to collect and collate clean data for secondary purposes, such as time pressures, lack of remuneration, and software products that are not as efficient and user friendly as they could be.

The RACGP also wishes to emphasise that eCDS should never provide a substitute for a clinician's judgement and there should be no legislative penalties for failure to use eCDS tools.

An accreditation/licensing scheme for eCDS is unlikely to be appropriate as standards might quickly become irrelevant. Artificial intelligence (AI) is developing at speed and regulators will continue to struggle to keep pace with technological advancements in this area.

14. What other options, new or existing, could help to establish a conformance environment for eCDS, for data or for both?

Establishing a conformance environment should be a profession-led process and should occur under an authority established to manage the requirements for eCDS.

15. Which stakeholder groups would be best placed to support the uptake of standards and create a conformance environment for eCDS, for data or for both?

The RACGP is well placed to oversee the development of standards on eCDS, with guidance from the Commonwealth Scientific and Industrial Research Organisation (CSIRO), medical software industry representatives/the Medical Software Industry Association (MSIA), general practice academic units, pathology and imaging bodies, and other areas of speciality outside the scope of general practice.

Component 2.4 | Establish governance arrangements to oversee self-regulation mechanisms

16. Who could be involved in a stakeholder reference group to oversee self-regulation mechanisms for data, for eCDS or for both?

The RACGP, CSIRO, primary care researchers, medical software industry representatives/the MSIA, PHNs, and consumer groups could be involved.

Option 3: Establish incentive-based compliance

Component 3.1 | Enhance incentives to share quality general practice data

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

The questions to be answered with the data must be defined before determining what data elements should be included in the data set. Data should not be extracted because it could be useful in the future. The intended purposes of data extraction must be clearly delineated in any data sharing agreement.

The RACGP's position is that third parties should aim to extract the minimum amount of data needed to achieve their purpose; that is, complete medical records should not be extracted.

Further, as discussed above, there must be a reciprocal benefit to general practice in collating and sharing data with others in the health system.

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

See question 17.

The RACGP reiterates its concern about the possibility of stakeholders misusing practice-level data for inappropriate purposes, including commercial gain (eg, establishing competing services) and compliance/pay-for-performance/public benchmarking.

There is also the potential for data to be misused when GPs are not involved in analysis and interpretation. For example, recent public discourse about GP use of the MBS item numbers for mental health care provision has seen GPs accused of a dereliction of duty to review patients with a mental health condition, an egregious accusation which neglects to consider the inadequacies, perverse incentives, and complexities of the MBS. It is imperative stakeholders have an intimate understanding of general practice, the context in which the data were collected, and the nature of the data. GPs can help explain the provenance and meaning of data.

19. What other financial incentives could facilitate improvements in this environment to support data only, eCDS only or both?

Suggestions include:

- funding for the development and evaluation of living guidelines by RACGP/relevant bodies/primary care researchers to support eCDS
- financial compensation for general practices to update technologies required to collate and maintain data and use eCDS (eg, computers, software, high-speed internet)
- funding equipment that automatically integrates with clinical information systems, such as measuring devices (eg, blood pressure machines, scales, blood glucose monitors, pulse oximeters)
- making high-quality eCDS available at no cost to general practices. General practices currently have to pay for clinical resources freely available to doctors in public hospitals (eg, Therapeutic Guidelines).
- funding for QI programs such as the Australian Primary Care Collaboratives (APCC) Program to 'buy back' time for GPs to engage with data and engage in meaningful improvements to clinical practice
- incentives for public and private hospitals, specialists, and allied health professionals to send machine-readable letters and specialist reports to general practice
- funding for staff training in quality data collation.

Component 3.2 | Establish data sharing partnerships

20. Would you support a data sharing partnership as an option?

If, as outlined in the CRIS, there are genuine benefits to general practice in terms of providing meaningful data and insights, and it would allow GPs to be involved in what happens to their data after it leaves their practices (including provision to access their own data for quality improvement purposes), the RACGP would support this option.

21. Which organisations or types of organisations should be supported to participate in a data sharing partnership?

This should be assessed on a case-by-case basis but should be broader than government and its agencies, as outlined in the RACGP's response to the Issues paper. Primary care researchers and health informaticists with experience in general practice data should be involved in the development of any partnership model.

As the College responsible for quality and safety in the general practice sector, the RACGP should have access to de-identified data.

22. What requirements should be in place as part of the agreements to address any risks or concerns?

A number of important requirements are listed in Three key principles for the secondary use of general practice data by third parties, under 'Checklist for third parties'.

23. What incentives could facilitate improvements in this environment?

Data sharing agreements must be mutually beneficial.

Component 3.3 | Incentivise quality performance for eCDS

24. What are the key clinical areas that could benefit from a centralised library (single source of truth) in support of eCDS?

In addition to common conditions, some areas include:

- multimorbidity
- shared care (particularly maternity care and endocrine care)
- medicines monitoring
- chronic disease monitoring
- stepped care for mental illness
- preventive care
- antimicrobial use
- fracture management.

The RACGP's clinical guidelines would be a valuable addition to such a library. A full range of titles is available on the RACGP website.

25. What would be the key challenges in establishing a centralised library for clinical guidelines in support of eCDS?

There are a range of challenges as touched upon in the CRIS, including:

- lack of consistency in the evidence base required for recommendations (eg, the circumstances in which consensus-based recommendations are appropriate)
- the speed with which science moves and the need for real-time updates to recommendations (living guidelines)

- the need to ensure clinical guidelines are appropriate to the Australian general practice context, not merely adapted for this purpose from another setting
- overlap/conflict between existing recommendations for the same patient groups, leading to confusion and variation in care
- risk of clinical guidelines overvaluing health economics above clinical care
- clinical guidelines not currently optimised for integration with clinical information systems as they are still published in PDF format: guideline developers would need funding to develop or reformat guidelines to support integration
- the importance of end-user (GP) testing throughout the development process in ensuring eCDS tools are fit-for-purpose
- lack of financial incentives for software vendors to integrate clinical guidelines into their products
- lack of consistency in medical terminology across digital systems
- expense and other issues associated with housing servers to handle the computer processing power to manage complex risk algorithms.

26. Who would be the most appropriate lead for establishing and maintaining the library (e.g., government or peak body)?

This should be conducted by an appropriately resourced and independent body, with input from bodies currently involved in guideline development. In addition to the RACGP, this includes (but is not limited to) Health Pathways, Therapeutic Guidelines, the Australian Medicines Handbook, and peak bodies such as the Heart and Lung Foundations and the Cancer Council).

27. What are the risks of implementing a centralised clinical library?

- clinical guidelines quickly become out-of-date with potential risks to the provision of safe clinical care
- risk of overreliance on guidelines in delivery of care to the detriment of the treatment of the individual patient
- potential to lose focus on more intangible principles, such as consumers' experiences of care and providers' experiences of delivery of care
- expensive to create and maintain
- disagreements likely to occur about methodology for guideline development
- potential to become a single point of failure
- problems in determining liability when adverse events occur.

Component 3.4 | Incentivise GPs to use eCDS

28. Do you think GP incentives would be effective in increasing uptake of eCDS?

Potentially. However, eCDS must be trustworthy (evidence-based), well-designed (user-friendly), optional and align with general practice workflows (not create additional work). Incentives will not work if the eCDS tools do not meet these criteria.

GPs must be involved in designing any incentives to ensure they are suitable to the setting in which they will be used.

Policymakers would do well to avoid the perverse outcomes sometimes associated with incentive schemes. Use of eCDS must represent true value to GPs.

As mentioned in answer to question 19, other ways to drive uptake of eCDS could include making these tools available at no cost to general practices, and/or funding general practices to purchase equipment associated with data collation and management.

There must not be penalties for GPs (or general practices) who choose not to use eCDS or to act in accordance with their recommendations.

There must also be careful consideration of how incentives would be applied; that is, whether these would be allocated to the individual practitioner or to the general practice.

Option 4: Introduce legislation and establish a new regulatory scheme

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

29. Should meeting a standard for data entry and data sharing quality be mandated?

Mandating standards for data entry and quality is not appropriate.

The primary and most important use of general practice data is the provision of clinical care. Standards for data entry would need to ensure improvements in clinical care over and above the goal of improving data for others' use. Adding further bureaucracy to GP workloads will mean that they spend more time on paperwork and less time helping patients. Mandating standards for data entry may also have unintended consequences for the provision of care, including patient experience, an element of care provision that has been neglected in the CRIS.

Attempts to standardise data entry should focus on attempts to regulate the various data structures, data element names and associated definitions, systems of medical terminology/coding used in different clinical information systems.

As discussed, there is also a need to consider whole-of-system reforms, not merely in general practice. GPs should not be solely responsible for improving data.

Incentivising improvements to data entry is a more palatable solution given GPs are not adequately remunerated for data collation and management under current funding structures. This is an historically underfunded area, with successive governments failing to devote the resources required to address this.

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

30. Should interoperability standards, data standards and data sharing standards be mandated for PMSs?

Yes. The RACGP has long advocated for some standardisation across clinical information systems, culminating in the 2018 report for the Australian Digital Health Agency, Minimum requirements for general practice clinical information systems to improve useability. Many countries have already moved to regulate PMS products with standards. Of course, the proprietary information of medical software vendors and their need to innovate in a commercial environment must be respected.

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

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

Yes. As per the above, the RACGP does not support wholesale extraction of general practice data. General practice data must only be used for the express purposes outlined in a data sharing agreement. Data extraction companies should clearly outline the processes by which data is extracted, what is being extracted, and how it will be stored/secured (eg, what measures are taken to prevent malicious access and use of the data). There must be provisions for consumers, and where relevant, general practices, to easily opt-out of data sharing. General practices must retain control over what data can be extracted from their systems by third parties.

However, it should be noted that extraction of data is merely one component in the chain of secondary use and regulating data extraction companies would not assure the quality and trustworthiness of the data.

Component 4.4: Regulate security requirements for holders of row level general practice data

32. Should minimum security requirements to hold row level general practice data be mandated?

Yes. These data have potential to re-identify individuals. It is imperative trust between GP and patient is maintained through robust security and regulatory frameworks.

33. Should minimum security requirements for other types of general practice data be mandated?

Yes. As suggested in the CRIS, PHNs and others should have to comply with minimum standards in order to extract general practice data, and this could be supported with a licensing/accreditation scheme.

34. What best practice data security requirements should inform security legislation for data sharing only, for eCDS only, or for both?

Existing requirements for data security are well established in both the Australian and international contexts. The RACGP has a range of relevant resources, including:

- Information security in general practice
- Privacy and managing health information in general practice
- Three key principles for the secondary use of general practice data by third parties
- Standards for general practices (5th ed.).

Component 4.5 | Require entities to report to the federal government on how they store and use general practice data

35. Should the reporting of the sharing, receipt and use of general practice data be mandated?

Yes. This is an opaque process at the current time and the RACGP supports a system in which PHNs and others are required to report to government as described in the CRIS. However, not all general practice datasets are funded by government, so the mechanism for reporting is unclear. In the interests of transparency, all general practice data custodians should be required to report the recipients of the data, their projects, and the outcomes of those projects.

36. Which part of government would be suitable to receive reports on general practice data use?

Federal and/or State health departments and potentially AIHW. It would not be appropriate for Medicare Australia to receive these data.

37. What criteria could inform who should have access to reports about general practice data use, including publication?

A human research ethics committee or similar could be established for this purpose. As per the RACGP's response to the Issues paper, there should be a transparent process where government access is subject to independent oversight with GP and consumer involvement. The emphasis should be on improving service delivery and healthcare outcomes. GP advisors (including the RACGP) should play a central role in data analysis and interpretation.

Component 4.6 | Government led eCDS licencing system

38. What are some example requirements that could be included in the licencing system for eCDS?

The RACGP has no comment to make for this question.

Component 4.7 | Mandatory standards for eCDS inputs and functionality

39. What specific standards should be mandatory for eCDS?

- data must be based on an Australian population sample
- details of authorship must be easily accessible when using the eCDS (ie, provide in-tool links to source organisation)
- source organisation/author must indicate date of currency of guidelines and maintain currency of content
- must be integrated into the PMS
- must use a reputable framework for grading of evidence to inform recommendations.

Component 4.8 | Implementation of an independent statutory body

40. What are the most appropriate functions for a regulatory body to adopt to support data sharing only, eCDS only or both?

The RACGP is in favour of light-touch regulation. It is sensible to streamline the many agencies currently involved in providing advice. Efforts to regulate and support PHNs and software vendors are welcomed.

The RACGP would not support on-site monitoring to include spot-checks of general practice data to ensure GPs comply with relevant data quality standards. The RACGP would also oppose the implementation of a burdensome and punitive complaints mechanism, which could undermine the clinical autonomy of the GP. The primary use of general practice data is the provision of clinical care. The primary mechanism for improving the quality of practice data is through the practice's clinical governance processes.

41. What functions could be absorbed by an existing agency or regulatory body to support data sharing only, eCDS only or both?

The RACGP has nothing to add here.

42. What is the most appropriate governance model for a regulatory body to adopt to support data sharing only, eCDS only or both?

Of the options proposed, the establishment of a statutory office within the Department of Health and Aged Care appears to be the best governance model. Any regulatory body must have GP representation to guide decision making.

43. What existing governance models for regulatory bodies could inform a new regulatory body for general practice data and eCDS?

The need for a new regulatory body specifically for general practice data and eCDS is not clear. Establishing such a body would come at great cost to a chronically underfunded section of the health system.

Impacts of reform options

Impacts of Option 1: Retain the status quo

44. Would the impact of maintaining the status quo represent a positive, negative or neutral outcome for your business, sector or community?

Maintaining the status quo represents a negative outcome for general practice.

Done well, centralisation and standardisation have the potential to improve the consistency and quality of data, and in turn, the provision of clinical care in all tiers of the healthcare system. It could greatly aid general practice research following the departure of BEACH and NPS MedicineInsight from this landscape. It could help reduce pointless and burdensome administration for GPs.

45. Please outline any additional impacts of this option that have not been identified in the current impact analysis.

Without adequate data about the provision of primary care, general practice will continue to be undervalued and under-resourced. GPs are subject to significant data demands but are not adequately remunerated for this work.

High-quality, easy-to-use, and non-intrusive eCDS will empower GPs to work to the top of their scope of practice.

46. Please provide further information, including quantitative data, on the costs and benefits to your organisation associated with this option.

The indirect costs to general practice of maintaining the status quo are well documented in the CRIS. However, the RACGP does not have faith in the idea that this option will result in an 'organic collaboration' between general practice and the software industry as this is yet to occur despite the good faith of relevant parties. Investment and infrastructure are required.

Impacts of Option 2: Facilitate stakeholder-led regulation

47. Would the impact of pursuing self-regulation represent a positive, negative or neutral outcome for your business, sector or community?

Stakeholder-led regulation is not the RACGP's preferred option as it is unlikely to effect change.

The RACGP would support the establishment of data sharing principles as described in component 2.1 and can contribute to this process, but also believes adoption of data standards should be a task for the entire healthcare sector, with strong GP representation in development and implementation.

The implementation of data entry standards as described under component 2.2 might represent a negative outcome for general practice as it places a significant burden on GPs who already operate under extremely time-poor conditions.

Interoperability and statistical standards for software vendors and data extraction companies have the potential to have a positive impact (provided software vendors do not pass on costs to their GP users). The RACGP has advocated for such standards in its responses to the National Healthcare Interoperability Plan (2021) and National Data Security Action Plan (2022).

48. Please outline any additional impacts of this option that have not been identified in the current impact analysis.

General practices would need significant support (both financial and practical) to meet data entry standards. This would burden an already overstretched and under-resourced sector. The risk that smaller general practices will struggle to meet compliance requirements has been understated in the CRIS.

Funding would be required to facilitate co-design of accreditation and licensing systems and conformance schemes. This would have a negative impact on (or limited participation by) general practices, given current workforce issues. General practice participation in design and implementation would need to be funded.

49. Please provide further information, including quantitative data, on the costs and benefits to your organisation associated with this option.

The RACGP agrees with the costs and benefits to general practice as outlined in the CRIS.

Impacts of Option 3: Establish incentive-based regulation

50. Would the impact of establishing incentive-based compliance represent a positive, negative or neutral outcome for your business, sector or community?

With regard to component 3.1, attempts to expand of the Practice Incentive Payment (PIP) scheme must support clinical care delivery and proportionally reward time and complexity. If data entry demands increase without a proportionate increase in the financial incentive, there is a real risk general practice will turn away from the PIP. Without GP input into the development of new criteria for incentives, there is also the risk of developing a flawed scheme that supports perverse incentives. For example, poor-quality Shared Health Summaries (SHSs) can be uploaded to My Health Record purely to meet PIP criteria, instead of SHSs containing meaningful and well-curated data to improve patient outcomes. Although expanding the PIP might result in better data to achieve policy aims, it will be more difficult to use this as a tool to encourage GP behaviour change.

The RACGP could support incentives for the establishment of data sharing partnerships (component 3.2), providing general practices (including both general practice owners and other GPs) can have meaningful input into the terms to ensure mutual benefit.

The establishment of a centralised clinical guideline library (component 3.3) might benefit general practice, provided the challenges itemised in response to question 27 could be overcome.

Incentives for GP use of eCDS (component 3.4) has the potential to drive uptake, though perverse outcomes would need to be considered. Most importantly, GPs will not support eCDS if the products are not easy to use, trustworthy, and provide useful clinical information. They must not increase the workloads of GPs, practice nurses, administrative staff or practice owners. These fundamentals must be established before designing incentive schemes.

51. Please outline any additional impacts of this option that have not been identified in the current impact analysis.

Regarding component 3.1, appropriate support would need to be provided to software vendors to adopt changes to compliance regulations to ensure they do not pass costs on to their end users. General practices cannot be expected to carry the administrative and financial burdens of changing software providers if their current system does not meet requirements, even if as described the cost might be partially offset by future incentive payments. This is a hugely disruptive and expensive process that carries the risk of data being lost in the process.

As previously mentioned, there is also a need for careful consideration about who should be the beneficiary of incentives; that is, whether they should be paid to the GP or the general practice. Service Incentive Payments (SIPs) paid to the practitioner could be designed to incentivise eCDS use, perhaps in combination with PIPs.

Funding for new incentive schemes should not be drawn from the existing pool of funds for general practice.

Where there is a minimum level for receiving incentives (or a minimum requirement for meeting mandated standards), there is a risk of stifling development or preventing improvements beyond this level.

52. Please provide further information, including quantitative data, on the costs and benefits to your organisation associated with this option.

The RACGP has no further information to add.

Impacts of Option 4: Introduce legislation and establish a regulatory scheme

53. Would the impact of introducing legislation and establishing a regulatory scheme represent a positive, negative or neutral outcome for your business, sector or community?

The RACGP is opposed to a regulatory scheme for data entry. This is a blunt instrument that would place an enormous burden on a sector already struggling.

However, some forms of regulation might be necessary to drive investment by key players, such as those described under components 4.2-4.8. In particular, regulation of clinical information system and data extraction software would be welcomed. This would lead to more user-friendly and interoperable systems and standardisation of data. Software vendors must be compensated for this to recognise the significant work required to meet standards, and to avoid passing the costs on to general practice users.

The RACGP also provides in-principle support for legislation that requires third parties to report on how they use general practice data to ensure transparency in this domain.

Any regulatory scheme would need to be developed via a co-design approach with general practice input. There would need to be appropriate remuneration for GPs and general practices to meet any costs associated with those standards (eg, investment in staff training, reimbursement for software/hardware costs).

54. Please outline any additional impacts of this option that have not been identified in the current impact analysis.

As already described, improving data quality is not merely the responsibility of general practice or any one sector. It must be a collaboration between everyone involved, including other medical professionals, software developers, and policymakers.

The costs of complying with new standards will likely be challenging for general practice academic units, given the paucity of research funding for this sector. Further investment would be required to assist these units to meet additional standards.

55. Please provide further information, including quantitative data, on the costs and benefits to your organisation associated with this option.

The RACGP has no further information to add.