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Safe and Responsible use of AI in Australia

Medical Software Industry Association's Submission to Department of Industry, Science & Resources

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Executive Summary

WHO - The Medical Software Industry Association ("MSIA") represents the interests of over 165 Australian companies to enable a vibrant more efficient effective health system for Australians. MSIA members provide health software to all sectors of Australia's healthcare[1] market to enable the collection, delivery, management, and storage of health information including administration and payment systems. Australia's healthcare depends on our members systems which are integral to healthcare delivery.

WHAT - Digital health software powers healthcare delivery, consumer access, and importantly, supports major reforms in our health and care sector.[2] In Australia, health software has genuinely replaced the stethoscope as the most important single tool for clinicians, and plays an increasingly important role in Australia's health equity[i3] productivity[4], economy[5], and export, with significant future potential.[6]

WHY we are responding - The use of AI[7] is well established in the health industry. Examples include General Practice clinical information systems which routinely include it for drug interaction checks,[8] suggestions for preventative health[9] and logic to improve Medicare compliance.[10] This early adoption in health, which is arguably one of the most high-risk areas, makes healthcare a useful area to focus on in an assessment of AI regulation. Virtually every interaction demands a balancing of risks and benefits to humans - and sometimes communities - by all participants. This calibration demands a regulatory framework which reflects the full scale of risks and benefits, and will avoid retrospective over-regulation of existing safe evidence-based applications of AI,

The MSIA advocates for risk-based regulation[11] together with:

Transparency – So that the provenance of AI outputs is appropriately managed in a risk-based framework. Where the risks are higher, the onus to be able to present information for an audit trail may be required, versus simple low-risk tasks[12] .For instance, in the simple examples of AI use

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[1] The MSIA members health software reflects the WHO definition of health is "a state of complete physical, mental and social well-being and not merely the absence of disease and infirmity." Our members help social determinants (e.g., InfoXchange), and addiction/ prevention (e.g., *Hello Sunday Morning*).

[2] National Digital Health Strategy, National Preventive Health Strategy 2021–2030 and the Primary Health Care 10 Year Plan Including processing of all MBS and PBS items digitally, ePrescribing, Australian Immunisation Register, National disease registries, the COVID-19 response including virtual care and telehealth.

➔ [3] The Department of Health's National Preventive Health Strategy 2021–2030 says: "Digital technology and capability are embraced by the prevention system, There is a focus on digital inclusion especially for priority populations, to ensure that technological advancements do not inadvertently deepen the equity divide in Australia."

[4] The Australian Institute of health and Welfare's report 'Australia's health 2022: data insights'

[5] *GS1 Healthcare. GS1 Healthcare Reference Book 2016-2017, Stories of successful implementations of GS1 standards. Brussels: GS1 Healthcare; 2017.*

[6] The Medical Journal of Australia made a case for investing in digital health technologies in its paper 'Show me the money: how do we justify spending health care dollars on digital health?' & https://techcouncil.com.au/wp-content/uploads/2023/07/230714-Australias-Gen-AI-Opportunity-Final-report-vF4.pdf

[7] The MSIA uses the term to describe the various types and levels of AI defined on p4-5 of the Discussion Paper.

[8] checks performed synchronously with new data entry clinical record. For example, a clinician prescribing a new medication is instantly notified of the presence of an ingredient that has been noted elsewhere in the clinical record as an allergen for the patient.

6. E.g., not related to a patient's presentation that may be of interest, for example identifying that a conversation about smoking cessation should be considered by the clinician where the patient has been noted to actively smoke.

7. examples include a warning notifying the user that the combination of MBS items applied to an invoice cannot be co-claimed, an automatic application of the multiple operation rule when co-claiming eligible procedures or observing that a chronic disease management item has been completed within a clinical consult and suggesting to the clinician that the corresponding item number may be eligible to be claimed for this visit.

[11] The so-called "Goldilocks" approach advocated by Corrs Chamber Westgarth

[12] E.g., the practice administration, and other examples provided above,

provided above, the provenance may be guidelines from the *Australian Commission for Safety and Quality in Health Care* ("ACSQHC"), in areas of serious risk, say surgery, an audit trail may be required.

Trust: Co-Design and Education - Maintaining and growing the trust of health care organisations, providers and consumers in appropriate AI is critical both for market investment and uptake. Trust is hard won and easily lost in all facets of life,[13] but arguably most crucial in healthcare given that Australians trust health care professionals and services more highly than any other sector.[14] Codesign of regulation followed by community education will be key to success in this area, as reflected by the work of the TGA and MSIA co-design of "Software as a Medical Device "in 2021. Australia's *Digital Platform Regulators Forum* promotes the risks and benefits[15], which could be leveraged and supplemented with a campaign, like the successful road trauma campaign in Victoria[16]

Taxonomy - A more detailed taxonomy of AI to enable a precision-based approach to regulation of applications in existing and potential areas. This will enable greater understanding by the software developers, the deployers of the software, the implementers of software into clinical settings and the consumer as the ultimate subject and or beneficiary if the potential improvements to healthcare. This will assist the human element to co-pilot the mapping into the use of approaches to avoid fear, doubt, and uncertainty.

The MSIA welcomes this opportunity to contribute to the Safe and responsible AI in Australia discussion paper ("**the Discussion Paper**"), to which our membership has actively contributed. This is because of the unintended consequences of over-regulating existing safe software use,[17] and conversely not regulating inappropriate AI use which could undermine the confidence of health professionals, Government, and consumers in the safe and effective use of AI. AI can improve equity and access to healthcare through efficiencies, together with innovation and productivity.[18] AI should be viewed through economic, social and security lens rather than a regulatory hard-line approach. AI must be welcomed and resourced to ensure Australia retains its international top ranking for health outcomes and efficiencies[19]. Australia already has research underway[20] on the efficacy of using synthetic data sets. It could become an international magnet for investment and research in AI. This will depend on the regulatory framework adopted, The MSIA looks forward to working with the Government in the co-design of this vital regulation.

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[13] 49% of Australians won't use a service following a data breach https://australiancybersecuritymagazine.com.au/trust-online-is-hard-won-easily-lost-and-non-existent-for-14-of-australians/

[14] OAIC Consumer Attitudes to Privacy 2020 https://www.oaic.gov.au/__data/assets/pdf_file/0015/2373/australian-community-attitudes-to-privacy-survey-2020.pdf

[15] https://www.esafety.gov.au/newsroom/media-releases/digital-platform-regulators-forum-puts-generative-ai-on-agenda

[16] https://acrs.org.au/files/arsrpe/RS07067.pdf

[17] Note the Therapeutic Goods Administration currently regulates "software as a medical device."

[18] https://www.racgp.org.au/gp-news/media-releases/2023-media-releases/july-2023/ai-has-potential-to-revolutionise-healthcare-but-n & https://www.mckinsey.com/industries/healthcare/our-insights/tackling-healthcares-biggest-burdens-with-generative-ai https://techcouncil.com.au/wp-content/uploads/2023/07/230714-Australias-Gen-AI-Opportunity-Final-report-vF4.pdf

[19] Commonwealth Fund

[20] "University of Queensland - National Infrastructure for Federated Learning in Digital Health (NINA) recently received a grant from the MRFF and"… will prepare and harmonise the data to global standards which protect individual privacy and enable researchers to use machine learning to progress their research." Associate Professor Clair Sullivan

1. Do you agree with the definitions in this paper? If not, what definitions do you prefer and why? Related terms here (ISO/IEC 22989:2022).

- Yes. These appear to be useful and not contentious.
- It would also be useful to include types of governance frameworks not founded on hard definitions here, including examples as has been done clearly in Canadian regulations on "Software a s a medical device,"[21]usefully adapted in Australia by the Therapeutic Goods Administration.
- A full taxonomy would be useful. There is a risk of hybrids falling within/outside regulation e.g., low risk activities [22]being implicated into high-risk AI regulation retrospectively.
- For example, RippleDown is a good example of a self-organising decision tree approach that is not necessarily recognised as AI but can carry significant complexity in the decisions it makes. In theory is more transparent and allows the user to seek reasoning behind conclusions with which many ML approaches struggle.
- In addition, the various human actors in the AI process could be usefully defined including developers, producers, deployers, users, subjects, and consumers. All have a crucial role requiring specificity for appropriate regulation.

2. What potential risks from AI are not covered by Australia's existing regulatory approaches? Do you have suggestions for possible regulatory action to mitigate these risks?

- The current regulatory approaches which respond to consumer law[23], therapeutic devices[24], corporate behaviour[25], privacy[26], security[27] and safety[28] provide a regulation for most activities but are not harmonised or easy to navigate. Where the regulation is principles based, such as in the Privacy Act 1988, there is sufficient flexibility for technological advances to be included. However, this technically agnostic approach spawns' uncertainty which is not good for industry or safety.
- The lack of consistency or information about AI products requires attention, particularly for the inclusion of overseas models into otherwise regulated products.
- A standardised "checklist" of essential conformance, for instance a privacy impact assessment, etc could address the inefficiency and grow confidence in the safe adoption of AI.[29]
- The risks of confusion usually result in a default setting where products are not adopted, or, in the case of privacy, information which should be shared is not resulting in the tragic circumstances which led to the Caldicott Review in the United Kingdom and then The Caldicott Principles which essentially brought clarity into what had become an area obfuscated by too many complex conflicting regulations.

[21] https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/application-information/guidance-documents/software-medical-device-guidance-document.html

[22] See footnote 5-7 for examples.
[23] Australian Consumer law as administered by ACCC.
[24] TGA
[25] ASIC.ASX
[26] Privacy Act 1988, as administered by the OAIC plus 8 Jurisdictional Laws and Guidelines and health specific regulations.
[27] ISM Essential 8 and ASD handbooks
[28] Australian Commission for Safety and Quality in healthcare
[29] At the risk of dumbing this down, having a" heart safe" type checklist nuanced to the specific users at any stage of the AI adoption would be useful.

- A programme of ongoing review by a panel such as the *Digital Platform Regulators Forum*, should be entertained to address the swift introduction and adoption of new AI, like the generative AI brought to consumers by ChatGPT.

- Careful use of synthetic data sets.[30]

3. Are there any further non-regulatory initiatives the Australian Government could implement to support responsible AI practices in Australia? Please describe these and their benefits or impacts.

- Specific education to health provider groups. For example, resource the RACGP to provide specific education and guidance to both allay the fear and encourage responsible use. This is essential for uptake by clinicians.[31]
- The CSIRO Everyday AI: A CSIRO Podcast is an excellent example of useful educational resources that are already available to consumers.
- AI-Impact Assessment tools would be an excellent initiative for all levels of users.
- Adapted governance frameworks for use for health and technology organisations.
- Harmonisation of the multi government agency approach so that there is clarity of how the various departments, Agencies and Regulators work together, which to follow when, hierarchy when there is conflicting regulation etc.

- Taiwan managed its technical response to COVID-19 through a clear policy of communication of purpose, how the technologies worked, the benefits and the risks 9for non-compliance). It embraced the principles of "Fast, Fair and Fun" with highly successful [32]results.

- The use of practical safeguards ought to be increased. For example, if the Department of health and Human Services (now Services Australia) had used the simple practice of a sandbox in testing, then the devastating effects of Robodebt could have been avoided.

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4. Do you have suggestions on coordination of AI governance across government? Please outline the goals that any coordination mechanisms could achieve and how they could influence the development and uptake of AI in Australia.

- A new entity comprised of representatives of existing entities with heightened expertise if required, together with specification of roles of existing regulators.[33]

- The UK Government's Policy paper *A pro-innovation approach to AI* and *AI Regulation Policy Paper* suggests this decentralised approach but suggests monitoring, multi-regulator sandbox[34]

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[30] See reference in footnote 20.

[31] A majority of clinicians believe AI isn't ready for medical use, according to a GE HealthCare survey of 7,500 clinicians in eight countries. Less than half of respondents – 26% in the US – are ready to trust AI.

[32] https://www.wired.com/story/how-taiwans-unlikely-digital-minister-hacked-the-pandemic/"Hacking the pandemic: how Taiwan's digital democracy holds COVID-19 at bay" — https://theconversation.com/hacking-the-pandemic-how-taiwans-digital-democracy-holds-covid-19-at-bay-145023

[33] E.g., Clarify boundaries between OAIC and ACCC to reduce the legal and regulatory burden on industry as it navigates issues.

[34] 20https://www.gov.uk/government/publications/ai-regulation-a-pro-innovation-approach/white-paper

21 https://www.gov.uk/government/publications/establishing-a-pro-innovation-approach-to-regulating-ai/establishing-a-pro-innovation-approach-to-regulating-ai-policy-statement

Responses suitable for Australia

5. Are there any governance measures being taken or considered by other countries (including any not discussed in this paper) that are relevant, adaptable, and desirable for Australia?

- Follow the *TGA* in their method of adopting where appropriate international approaches, but not slavishly following or being afraid to "Australianise" where appropriate.

- Both Cananda and the UK appear to have taken a more middle market approach where the risks are recognised but in the context of the benefits so that the burden of regulation does not deter appropriate innovation and investment in the AI industry, which could eventuate from the more hardline risk orientated regulation in the EU.

Target areas

6. Should different approaches apply to public and private sector use of AI technologies? If so, how should the approaches differ?

- The Government should be the gold standard to encourage confidence and investment in the value of AI.

- There seems no reason why there should be any lesser burden on either public or private sectors which interact and affect Australians.

7. How can the Australian Government further support responsible AI practices in its own agencies?

Avoid proliferation or regulators and regulatory requirements which lead to paralysis.

8. In what circumstances are generic solutions to the risks of AI most valuable? And in what circumstances are technology-specific solutions better? Please provide some examples.

- Leverage existing use and conformance profiles where feasible.
- Recognise and use the existing privacy and confidentiality laws.

- Audit tools are a clear example of a technological tool which can rapidly process risk profiles for human review. Even the most apparently innocuous aggregation of data can evoke invaluable human response, for instance the office worker in *"Saving Private Ryan"*, which are invaluable[35] and regrettably lost in the *Robodebt* scenario.

- Interoperability demands disclosure of security etc. Good software hygiene in future may require AI disclosures from 3rd parties to enable conformance and accreditation. Accordingly, a generic regulatory framework for this would be efficient.

[35] Unless of course, one dislikes the actor, Matt Damon.

- Lower the risk, the more appropriate and applicable technology focused solutions with less human oversight.

- Context and governance will determine the appropriate response.

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9. Given the importance of transparency across the AI lifecycle, please share your thoughts on:

a. where and when transparency will be most critical and valuable to mitigate potential AI risks and to improve public trust and confidence in AI?

- The higher the risk the greater the transparency at all stages of AI development and use. E.g., audit trails when low risk AI use.

- Existing successful use of AI can be exemplified for public trust given the justifiable conservatism of Doctors in adopting technology. Australians trust their health providers more than anyone else[36]

    - It should be noted that there will be an evolving ecosystem response to the transparency requirements of AI software as it becomes modularised or integrated with existing systems. The IP issues alone will demand a robust legal response.

    - Interoperability demands disclosure of security etc. Good software hygiene in future may require AI disclosures from 3rd parties to enable conformance and accreditation. Accordingly, a regulatory framework for this would be productive.

b. mandating transparency requirements across the private and public sectors, including how these requirements could be implemented.

- A useful example of how humans can be used to co-pilot this process can be seen in the Beamtree decision tree.

- A one size fits all response is to be avoided in public and private sectors in favour of a more risk based nuanced approach.

- Consideration of the "consent notice' fatigue is also relevant here in that excessive transparency and reporting will lead to impractically large reporting sets which then become unlikely to be read.

- Cost benefit analysis is also recommended.

10. Do you have suggestions for:

[36] OAIC Consumer Attitudes to Privacy 2020 https://www.oaic.gov.au/__data/assets/pdf_file/0015/2373/australian-community-attitudes-to-privacy-survey-2020.pdf

a. Whether any high-risk AI applications or technologies should be banned completely.

- Once the approach is determined, then it should be applied uniformly and at the extreme end where the risks are high and the value low, the product could be banned.

b. Criteria or requirements to identify AI applications or technologies that should be banned, and in which contexts?

- Reference to the recent decision by the Medical Board of Australia to re-issue Telehealth Guidelines which claim the use of asynchronous telehealth consultations are dangerous, has the net effect of banning these technologies as medical Indemnity insurers will not insure practice outside the AHPRA Guidelines.

- In this instance, there was no apparent technical demonstration, explanation, or evidence-based decision. Accordingly, having a checklist of what must be considered before an AI application is banned, could be extremely useful to avoid sporadic regulation by stealth which can be to the detriment of access by the most vulnerable Australians[37].

11. What initiatives or government action can increase public trust in AI deployment to encourage more people to use AI

- Note responses in introduction and Question 3.

- The TGA has adopted 2 Essential principles which have elicited trust from Australians during an unprecedented take up of virtual care and digital solutions during the Pandemic. These were exemptions when:
  7There was clinical oversight, and
  a. Where there was other regulation which mitigated the risk and did not need to be duplicated. This appears to be in line with the increasingly harmonised approach in respect of Software as a medical device[38]

Implications and infrastructure

12. How would banning high-risk activities (like social scoring or facial recognition technology in certain circumstances) impact Australia's tech sector and our trade and exports with other countries?

- Where possible harmonisation with like Jurisdictions is best for the market.

13. What changes (if any) to Australian conformity infrastructure might be required to support assurance processes to mitigate against potential AI risks?

- Additional governance frameworks
- Transparency- but this follows existing ethical standards.
- Additional consideration of upstream AI in interoperability models to avoid unintended consequences, together with assurance.

[37] Asynchronous telehealth is frequently used by people with stigmatised conditions such as mental or sexual health issues, but also in cases of domestic violence, in smaller indigenous communities and it is not subsidised by MBS.

[38] See - *International Medical Device Reform Forum*

Risk-based approaches

14. Do you support a risk-based approach for addressing potential AI risks? If not, is there a better approach?

- Yes.
- A risk-based approach mirrors well established health practice, and consequently the use of AI, as described above,[39] is of necessity, very human focussed unlike financial institutions.
- Calibration of assessment and management will be required depending on context.

- Transparency of 3rd parties
- recognise tech risk, company risk and human risk

15. What do you see as the main benefits or limitations of a risk-based approach? How can any limitations be overcome?

- See above.

16. Is a risk-based approach better suited to some sectors, AI applications or organisations than others based on organisation size, AI maturity and resources?

- The MSIA supports a risk-based approach for health where there is a broad range of applications including administration through to microsurgery. The nature of health militates against a one-size fits all regulatory response. Finally, there are decades of experience with the use of AI in health software which should be used as exemplars, and not "dumbed down' or retrospectively banned on account of their nuanced application or hybrid nature, where human application has enabled safe responsible and useful implementation in Australia.

- There are a number of codes of conduct and assurance which could be usefully leveraged to provide the so-called 'guard-rails".
  We recommend investigating existing frameworks for scalability like, for example, the NSW AI Assurance Framework.[40] This is based on benefit to humans, society and environment, fairness, privacy positive, transparency, contestability, accountability, and reliability - all of which the MSIA endorse.

17. What elements should be in a risk-based approach for addressing potential AI risks? Do you support the elements presented in Attachment C?

- Yes.
- Impact Assessments, notices, keeping the human in the loop, explanation, training, and ongoing monitoring all make sense.

18. How can an AI risk-based approach be incorporated into existing assessment frameworks (like privacy) or risk management processes to streamline and reduce potential duplication?

- As additional modules in technology assessment, conformance profiles and assurance.

- 3rd party warranties/indemnities.

[39] Footnotes 5-7.

[40] https://www.digital.nsw.gov.au/policy/artificial-intelligence/nsw-artificial-intelligence-assurance-framework

19.How might a risk-based approach apply to general purpose AI systems, such as large language models (LLMs) or multimodal foundation models (MFMs)?

- In October 2021, the FDA, Health Canada, and the UK Medicines and Healthcare products Regulatory Agency (MHRA) jointly identified 10 guiding principles that can inform the development of "Good Machine Learning Practice" for medical devices and how they can help promote safe, effective, and high-quality use of AI/ML. Adopting and adapting such international principles is useful.

- The regulation should reflect the upstream and downstream risk. As noted above, with the right settings, developers and industry generally will be incentivised to provide appropriate transparency [41]to attract investment and uptake.

20. Should a risk-based approach for responsible AI be a voluntary or self-regulation tool or be mandated through regulation? And should it apply to:
a. public or private organisations or both?
b. developers or deployers or both?

- Developers, users, organisations and public and private will all have different requirements, risks, and abilities.

- Provided that there is transparency, mandatory *and* voluntary regulation and assessment can be based on the risk. Where there is an established high risk on the rating metrics, then regulation ought to be mandatory and where the risk is low and the benefit high, it should be voluntary.

  For instance, what is the point of mandatory regulation in instances of administration in healthcare?

  " The best use for generative AI in healthcare, doctors say, is to ease the heavy burden of documentation that takes them hours a day and contributes to burnout."[42]

- Similar to the TGA a schedule of carve-outs could be co-designed to ensure certainty and safety.

- Existing health regulators like the TGA and ACSQHC are best placed to co-design appropriate regulation with industry.

- Generative AI has shown the unexpectedly rapid adoption by the public, consequently any technology specific regulation is likely to be outpaced, particularly if it is mandated as opposed to being based on principles of transparency which will create a public expectation.

[41] Together with adherence to agreed principles.

[42] https://erictopol.substack.com/p/medical-ai-is-on-a-tear?utm_campaign=post&utm_medium=email