Response to the Safe and Responsible Artificial Intelligence in Health Care – Legislation & Regulation Review

October 2024

Introduction

Formerly known as the Society of Hospital Pharmacists of Australia (SHPA), Advanced Pharmacy Australia (AdPha) is the progressive voice of Australian pharmacists and technicians, built on 80 years of hospital innovation that puts people and patients first. AdPha supports all practitioners across hospitals, transitions of care, aged care and general practice to realise their full potential. We are the peak body committed to forging stronger connections in health care by extending advanced pharmacy expertise from hospitals to everywhere medicines are used.

AdPha welcomes the opportunity to provide feedback to the Department of Health and Aged Care consultation titled – Safe and Responsible Artificial Intelligence (AI) in Health Care – Legislation and Regulation Review.

AdPha convenes various Specialty Practice Groups, including Pharmacy Informatics and Technology, of which members from this group have provided their expert insights to inform AdPha's response to this consultation.

If you have any queries or would like to discuss our submission further, please contact Jerry Yik, Head of Policy and Advocacy at jyik@adpha.au.

Benefits of AI

Question 1: How can AI benefit health and care in Australia and how can we measure and deliver these benefits?

AdPha acknowledges that digital transformation and the technological advancements will revolutionise the delivery of healthcare in the coming years. However, utilising Artificial Intelligence (AI) in healthcare settings is multifactorial and discussions regarding its benefits should not be confined to clinical settings and improvement of population health outcomes. AI has greater potential to assist in the automation of administratively repetitive and burdensome tasks as highlighted in AdPha's Pharmacy Forecast Australia 2024 report.[1] The concept of technostress is one that breeds burdensome when undertaking tasks utilising digital health systems. Therefore, utilisation of AI tools in health care settings can serve to improve health care provider capacity, whereby they can engage in expanding scope of practice innovations, leverage virtual care models and foster a sustainable healthcare workforce that can better meet the demands of the evolving complexities across the population.

To this end, in the short-term AI can be used to, but not limited to, collating dispensing records, summarising clinical documentation, and adopting proactive dispensing approaches. These benefits will improve efficiencies in workflow processes as a means of effective utilisation of health resources, which are already currently stretched.

As stated in Pharmacy Forecast Australia 2024, in the medium to long term, the most impactful AI-enabled tools will be seen in domains involving analysis of data streams from collated patient data (e.g. remote monitoring, decision support and alerts). Internet of things (IoT) devices will play an increasing role as remote monitoring in virtualised care models as they are adopted and mature.[2] Data science skillsets will become an expected part of the healthcare worker toolkit, which will require the workforce to adapt and learn these skills to enable its impact.

Evidently, the benefits from AI-enabled tools expands broadly from involvement in administrative tasks to improve efficiencies, improving population health outcomes, enhancing clinician experience and ensuring the sustainability of a quality healthcare system into the future. Focusing on AI driven innovation to drive clinical reasoning and be embedded in clinical decision-making tools requires long-term maturity in experience with AI models and systems. To ensure AI tools can improve population health outcomes, this requires patient sensitive information and large 'cleaned' datasets to be curated. This must be accepted as a longer-term vision, as it is essential to cement the foundations for using AI in healthcare by experiencing its application in low-risk practical settings which does not directly impact patient health outcomes.

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In the pharmacy profession, there are many activities that can be finetuned by utilising AI tools. An example of implementing AI and upholding digital innovation in pharmacy settings can be to manage supply logistics and medicine stock management. The current inadequacies in managing and coordinating medicine shortages owing to inaccessibility to timely data and information can be improved by incorporating AI models and systems. Enhancing current systems to identify potential upcoming shortages or changes in demand and usage through advanced tracking and identification processes, robust monitoring and analysis mechanisms is an ideal example of how pharmacy settings can entwine AI innovation into current practice by exploring its impact in a low-risk practical application setting.

AdPha foresees the benefits of AI in health care settings, especially in the pharmacy profession. However, foundational exploration in low-risk practice settings is crucial to discover potential risks prior to translating AI into clinical practice that can directly impact patient health outcomes. AI in healthcare can see significant improvements in health system capacities without limiting its use to improving population health outcomes.

Question 2: Can AI improve access to care, and what regulations could be amended or added to enable this?

AI innovation has the potential to improve access to care as there are current examples, in their infancy, that are being utilised to assist in triaging patient hospital presentations and the need for overnight stays in hospitals, along with diagnosis of cancer and cardiac health conditions. However, AdPha believes AI driven tools and systems that assist with streamlining diagnosis, triaging patient presentation that aim to improve access to care in a timely manner must be complemented by embedding continual support structures based on the output from AI-driven tools. There must be appropriate evidence-informed measures in place to ensure continuity of care in a timely manner is maintained when AI tools are utilised to improve access to care.

Moreover, similar to robust quality assurance and regulatory processes in place for registering a medicine in Australia, a comparable process must be adopted prior to utilising advancing digital health practices including AI incorporated health care models and systems.

Medicines undergo thorough, rigorous, assessment and clinical trial phases which lead to discovering inconsistencies between success in research conditions and when used in phase 2 of a clinical trial involving human participants. AdPha believes regulations and robust processes must be embedded when health technology advancements, including the use of AI, especially when they are being developed and trialled to ensure it delivers its intended purpose. If the intended purpose of the AI driven tool fails to be achieved in active healthcare environments, this must be detected prior to implementation and use of AI in health care settings, similar to medicines. There must be an equilibrium between fostering digital health innovation and ensuring robust, research and development

processes are strictly followed to implement evidence-informed advancements that are credible and justifiable to improve access to care and patient safety overall.

AdPha believes that to effectively utilise digital and technological advancements, robust governance and collaboration between health care providers, technology developers and regulatory bodies is crucial. This will foster establishment of equitable and safe AI tools, which are interoperable and encompass digital health strategies that meet the demands and needs across dynamic health environments.

Risks of using AI

Question 3: What risk does AI pose to patients/consumers or healthcare professionals? Are the risks high or low? What criteria could be used to characterise risk? Should consumers be informed when AI is used in these low-risk ways?

One of the main concerns discussed with respect to the use of AI is not related to the technology itself but the disinformation provided from AI tools that are not intended to deliver health care. This is due to the lack of guardrails on providing health advice from AI tools as there is no strict governance or regulations in place. Concerningly, tools such as large language models (LLM) are easily and readily accessible and provide misinformed advice and recommendations related to managing disease conditions and ailments that have no oversight related to its output.

AdPha believes that additional provisions and robust governance beyond local contexts are required to ensure consumers are protected from accessing misinformed health advice. Clear standards for health advice platforms and benchmarking must be in place by governments to lay the foundational requirements for providing health advice to consumers from readily accessible AI tools.

Additionally, a critical aspect of ensuring there is good clinical governance and risk management strategies when considering AI in healthcare is to develop robust disaster recovery plans and business continuity plans.[1] In pharmacy settings, owing to the use of multiple software solutions a complex disaster recovery plan is required. As AI tools and digitisation of healthcare settings become prevalent, the healthcare sector must consider the solutions embedded across other sectors and adopt similar business continuity strategies whilst acknowledging the higher level of risks associated with healthcare.

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Consideration for use in rural, regional and remote areas as specific communities

Question 4: What factors are important for rural, regional or remote Australia when assessing the benefits, risks, and safety of AI? Are there other communities that face specific risks when implementing AI in health care? What considerations should be made to ensure all Australians have access to the benefits of AI?

One of the main factors to consider when implementing AI in rural, regional and remote areas is to gain an understanding of the level of expertise that is required and available to implement AI models and systems within these health organisations. As outlined in Pharmacy Forecast Australia 2024, as digital health innovation emerges, clinical expertise and upskilling pharmacists and healthcare providers to be well-versed with appropriately and safely utilising AI tools is crucial for its success. Inadequate training and understanding of digital systems, specifically AI models and systems could pose safety risks to patients. Investment into continual education and training to support the upskilling of the healthcare workforce in utilising digital health systems must underpin advancing practice. Owing to current workforce shortages, ensuring there is a skilled workforce who have the expertise in the field of utilising AI in healthcare will be a challenge and is something that must be considered prior to implementing AI tools in rural, regional and remote areas.

Another consideration is imbuing entrustment of AI tools across the heath care sector, such that AI models and systems will be equitably adopted in metropolitan and rural health care settings. Health care providers should be provided with confidence in using these tools to aid delivery of care. AdPha recommends implementing a strategy similar to the Therapeutic Goods Administration (TGA) system of listing medicines with AUST R (Registered) and AUST L (Listed) numbers in Australia. This provides healthcare providers and consumers' confidence that the AI tool has been approved for its use. Assigning unique identifiers or registration numbers to AI systems and models can:

- **Ensure Traceability:** Unique identifiers allow for tracking of specific AI models and systems, facilitating monitoring and management throughout the AI tools' lifecycle.
- **Enhance Accountability**: Manufacturers would be required to maintain up-to-date information associated with each AI model and system, ensuring any changes or updates are appropriately documented and communicated.
- **Promote Transparency**: Clear labelling with standardised identifiers helps healthcare professionals and consumers easily recognise the involvement of AI in models and systems, understand its role, and access detailed information about its function and governance.
- **Facilitate Regulatory Oversight:** Potential regulators can more effectively oversee AI

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technologies ensuring compliance.

Choice for health care professionals to use AI

Question 5: Should health care professionals have a choice about whether they use AI as part of their work?

As AI-based technologies become increasingly ingrained across sectors, it would not be feasible for healthcare professionals to refuse using tools that incorporate AI in healthcare settings completely. While healthcare professionals may choose not to use certain aspects of technology that incorporate AI in some settings, many AI applications will be embedded in medical devices, software, or workflows that cannot be easily separated from the tool to allow for a choice prior to its use.

However, the key is not whether healthcare professionals should have choice, but rather ensuring that all AI models and systems that are utilised in healthcare settings are governed by strict regulatory oversight to build trust and confidence among health professionals. This approach is similar to current systems like Electronic Medical Records (EMR), where clinicians do not elect whether to use the system but rely on the governance bodies that regulate and ensure the safety, security, and efficacy of these technologies.

To this end, in cases where AI tools have demonstrated superior outcomes when undergoing rigorous testing and quality assurance compared to human processes, clinicians, from a safety and quality perspective, should not be permitted to have a choice to utilising these practices. Just as healthcare professionals are required to stay current with contemporary standards of practice that are evidence-informed, the inclusion of AI as a support tool in healthcare settings should be viewed no differently, if it is proven to lead to safer, optimal patient care. However, AI systems must be designed to integrate human factors into workflows, ensuring that while AI may aid clinical decision-making, the final decision remains with the healthcare professional, allowing for essential human oversight. This balance ensures that patient care benefits from technological advancements without compromising the clinician's professional judgment and experience.

Possible regulatory changes

Question 6: What unique considerations are specific to AI in health care, and why? Should the government address them through regulatory change?

A possible consideration is the concept of obtaining consent to utilise deidentified health data for AI models that are still undergoing trial phases. This is an area that requires further exploration and strict privacy measures governed by regulatory changes. Utilising health data for AI models requires a different lens, that identifies the potential risks and concerns that may emerge.

As digitisation across health care settings emerge and AI tools are commonly seen, cybersecurity concerns must be acknowledged and addressed by implementing appropriate safeguards to mitigate the threat of cyber-attacks

Question 7: How does the use of AI differ in healthcare settings compared to general or other sectors such as finance, education, etc.?

Utilising AI tools in healthcare settings carries significant risks to patients as it can directly impact the patient and lead to harm. The level of risk varies markedly compared to other sectors such are finance and education, as the harm that may occur to people is more likely to be irreversible and potentially life threatening. This heightens the importance of requiring robust, strict governance and regulatory oversight of the AI tools utilised in healthcare settings prior to rapidly implementing AI models and systems to parallel other sectors.

Additionally, the level of privacy that is associated with heath data and information is notably greater than that related to other sectors, which is a unique consideration specific to AI in healthcare

Question 8: Should there be an Australian body specifically dedicated to overseeing AI in health care?

Yes. As mentioned above, to ensure there is robust, strict, expert governance and oversight of the use of AI in healthcare it is crucial to have a dedicated Australian body that manages this process. A streamlined and well-coordinated body that oversees and regulates the use of AI is essential to imbue entrustment amongst healthcare professionals and consumers when utilise AI models and systems to deliver safe, quality patient care.

Members from AdPha's Pharmacy Informatics and Technology Leadership Committee provided further insights into considering a national AI taskforce to be established, similar to the New South Wales Health AI Taskforce.[3] This can standardise utilisation of AI

utilisation beyond local contexts and will create awareness of the possible implementation of AI in health care settings. This will prevent duplication of projects and transparency of nationwide AI incorporated strategies in health care.

Therefore, by having an Australian body that oversees the use of AI in healthcare will also enable transparency of AI tools that do not meet regulatory requirements, or have an exemption, to be easily identifiable by health care providers and end-users. There must be equally greater oversight and governance of the AI tools that do not meet the regulatory requirements to ensure they are not being utilised in practice and potentially causing patient harm. Transparency is paramount in the regulation of AI incorporated tools to ensure patient safety and uphold public trust. This visibility allows stakeholders to monitor for when an AI tool functionality may expand beyond its original intended purpose without appropriate oversight. By keeping a detailed log of exempted and unregulated AI tools, developers and regulators can ensure that any changes or new applications for the same AI tool are met with corresponding clinical rigor and regulatory review. If issues or complaints arise, transparent records enable a clear understanding of the exemption's basis and facilitate timely re-evaluation and action. Establishing systematic processes and maintaining transparency around exemptions and unregulated AI tools not only enhance accountability but also reinforce the increasing responsibility to oversee these evolving AI-incorporated technologies effectively in a timely manner.

Need to change existing health care laws and consideration of international approached

Question 9: Are there any specific changes to existing health care laws that would address AI-related harms or help AI to be used safely?

Yes.

- Governance and regulatory oversight

AI tools must be strictly regulated. Ensuring there is robust, strict, expert governance and oversight of the use of AI in healthcare is crucial to ensure AI can be used effectively and safely. Streamlined and well-coordinated processes overseen by a government body is essential, as they would regulate the use of AI to imbue entrustment amongst healthcare professionals and consumers when AI models and systems are utilised to deliver safe, quality patient care.

- Privacy and confidentiality

Privacy and ethical considerations require further exploration to protect patient health data in a systematic and appropriate manner. As digital health advances and AI technologies prolific, vast and complex datasets can be generated and collated owing

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to digitisation of health information.[1] A key priority area that requires close consideration is the concept of obtaining consent to utilise deidentified health data for AI models that are still undergoing trial phases. Owing to large, complex datasets that are utilised, this requires further exploration and strict privacy measures governed by laws and regulatory changes. Despite using complex, large-scale datasets which are deidentified, the possibility of exposing an identity can occur which would breach patient privacy.

Question 10: Which international approaches should we consider, if any, that are specific to health care?

Currently the National Health Service (NHS), England are undergoing a national pathology network transformation programme that aims to utilise AI tools such that 50% of whole slide images (WSI) used for reporting histopathology cases will be analysed using computerised analysis by the end of 2024/25.[4] Complementing this, real-time access to pathology results by patients is increasing across many countries, giving patients greater empowerment over their health and transparency of their conditions, if any. This is stemming concerns regarding ownership of health data and the lack of human oversight of interpreting the histopathology result in the example above.

As the future tracks towards utilising similar models, a paradigmatic shift in approach to diagnosis and communication is essential. Patients should be informed of the potential diagnosis that may be seen via accessing their own real-time pathology results and appropriately communicate the need to complete certain tests to aid differential diagnosis. This will see greater empowerment amongst patients as they will develop health literacy and take greater ownership for their health. As digital health cements across healthcare systems, a shift in processes will emerge and healthcare professionals must acknowledge this change but also be well equipped and trained to shift processes to seamlessly align with the rapidly advancing scope of practice.

These types of international approaches should be considered in Australia as it allows for timely access to health care and health information accessible by patients. Patient engagement increases yet this is coupled with certain risks and important considerations that must be addressed prior to implementation. As patients will have greater access and oversight of their own health data and information, interpretation of results and timely follow up with a healthcare professional may be hindered.

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Is AI always right?

Question 11: Should humans be able to overrule a finding or decision made by AI?

This highlights the importance of ensuring the foundations to implementing and utilising AI in healthcare is well governed, quality assured and tested to provide safe, quality care from its time of emergence. Appropriate governance in place will ensure AI tools will deliver their intended purpose and is embedded into practice as it is evidence-informed and has been regulated to meet strict quality assurance to align contemporary practice.

Question 12: Should there always be a person or "human in the loop" to make decisions or deliver a healthcare service? Are there any circumstances in which it would be acceptable to have fully automated health or care decisions made by an AI product?

Yes. As mentioned above, where AI tools have demonstrated superior outcomes when undergoing rigorous testing and quality assurance compared to human processes, clinicians, from a safety and quality perspective, should not be permitted to have a choice to utilising these practices. AI systems must be designed to integrate human factors into workflows, ensuring that while AI may aid clinical decision-making, the final decision remains with the healthcare professional, allowing for essential human oversight. This balance ensures that patient care benefits from technological advancements without compromising the clinician's professional judgment and experience.

Question 13: Should errors made by AI be reported? If yes, how should they be reported?

In order to maintain quality care, risks and incidents must be recorded and reviewed in a timely manner, as per current healthcare models such as the National Safety and Quality Health Service (NSQHS) Standards Risk management approach.[5] AI can serve to function a range of applications in the clinical setting including, dispensing and procurement, patient interface, and even in providing feedback and assessment in health professionals' education Therefore, it is essential a similar approach is adopted when AI makes an error to identify the root cause and implement mitigation strategies to prevent future harm. AI and digital transformation of health systems improves efficiency and fosters timely care. However, it must parallel with robust monitoring and surveillance systems that can detect the quality of services provided by AI to ensure patient care is not compromised.

AdPha believes a national reporting database must be implemented to record, monitor and assess the errors or concerns raised by AI powered health care systems and models. A risk register is essential such that it will capture error reports in a centralised platform. These risk registers must be monitored routinely and, based on the level of risk of the error, needs to have quality improvement and mitigation strategies in place to prevent future occurrences. A national reporting database will provide greater oversight, from a national

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level, and prevent decentralised data collection. Similar to requiring regulatory oversight, the same professional body should manage the risk register to ensure a streamlined and central body has expert governance.

Healthcare settings and organisations that utilise AI within clinical settings must embed safeguards and strict policies highlighting the importance of recording all incidents and errors related to AI malfunctions. This requires a shift in organisational culture, that understands the importance of reporting incidents to protect patients and prevent future harm. Without routine collection and analysis of this data, as a nation it will be impossible to detect and evaluate the impact and effectiveness of AI powered advancements in practice.

Transparency of healthcare data

Question 14: Should there be transparency about when AI is involved in health or care, and should consent be requested from the consumer or healthcare professional?

Consumers should be made aware that decisions made about their care could be informed by data and information derived from AI models and systems. Following this, consumers must be equipped to entrust the provision of information provided by AI tools that aid patient care and this requires transparent, continual communication and collaboration with the consumers of healthcare. Partnering with consumers is a priority area and key standard set by the Australian Commission on Safety and Quality in Health Care (ACSQHC).[6] The standard highlights the importance of including consumers in all aspects of clinical decision making, thereby, emphasising the quality of care that can be provided through strong collaboration, transparency and communication. By identifying the use of AI tools in healthcare and providing comprehensive information, consumers can better understand the implications of AI in their care and most importantly be aware of the benefits and risks that follow AI tools. Evidence suggests partnering with consumers delivers better clinical outcomes, safety and quality and the patient experience is improved, and community perceptions of healthcare delivery and organisations are shifted.

Seeking consent from the consumer is not always feasible and applicable to many healthcare settings. Not all patients are in positions to cognitively make these decisions, especially during acute events. This further cements the need for requiring robust, strict governance and regulatory oversight of the AI tools utilised in healthcare settings such that healthcare professionals are applying evidence-informed practice whether that means utilising AI tools in healthcare or not.

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Regulatory need for generative AI

Question 15: Generative AI may be developed for general use, yet used in health care. Should generative AI have any special treatment, regulatory or otherwise?

No comment.

Management of privacy and consent

Question 16: What protections are needed for patient data used or generated by AI that are different for health care?

Patient data used or generated by AI requires strict protections and laws to maintain privacy and confidentiality for patients. AI in healthcare requires robust regulatory compliance specific to privacy requirements and this needs to be clearly communicated to developers of AI tools to be used in healthcare settings. Currently health data and information collected through EMR do not require patient consent given robust foundational requirements and regulation has taken place prior to implementation that ensures its safety in use within healthcare settings. Similar approaches are required and this continually cycles back to the importance of requiring strict governance when implementing and developing AI tools in healthcare.

Question 17: Is it acceptable for developers of AI products to use patient data to develop their products or to sell patient data collected from use of AI?

No. Strict privacy and confidentiality laws and regulations must be embedded such that developers of AI products, especially for healthcare, are required to closely adhere to these privacy laws and regulations. Using de-identified data from AI tools or for developing AI tools is not sufficient, and firm measures must be embedded to prevent misuse of patient data and breach of privacy and confidentiality. Utilising AI tools is innovative, but the risks that can arise must be appropriately managed prior to implementation. Patient privacy must be protected during the rapid emergence of AI tools.

Question 18: Should your healthcare information be kept in Australia? If yes, would your view change if this reduced ability to access advances in AI made overseas?

No. Healthcare information and useful datasets that can be sourced from and provided internationally may assist with developing robust, purposeful, and efficient AI tools to be utilised in healthcare. Confining healthcare information in Australia does not allow for opportunities for collaboration and greater innovation. However, as emphasised throughout this response, privacy and ethical considerations must be closely considered,

and strict laws and measures must be in place to allow for share-ability of useful de-identified healthcare information.

Question 19: Are there any specific safety considerations that have not been raised elsewhere?

No comment.

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