



21 October 2024

Via email: PHIconsultation@health.gov.au

**Catholic Health Australia Submission: Safe and Responsible Artificial Intelligence in Health Care —
Legislation and Regulation Review**

Catholic Health Australia (CHA) would like to thank you for the opportunity to provide feedback on the public consultation *Safe and Responsible Artificial Intelligence in Health Care — Legislation and Regulation Review*.

Artificial Intelligence (AI) in healthcare is revolutionising the way we approach medical treatment and patient care. The integration of AI technologies offers numerous benefits, including enhanced diagnostic accuracy, personalised treatment plans, and improved patient outcomes.

The adoption of AI in healthcare is not without its challenges. One of the primary concerns is data privacy and security. The sensitive nature of medical data necessitates stringent measures to protect patient information from breaches and unauthorised access. Additionally, there is the potential for algorithmic bias, which can arise from unrepresentative training data or flawed algorithm design. This bias can lead to disparities in healthcare outcomes, particularly for underrepresented groups.

The successful implementation of AI in healthcare requires robust regulatory frameworks to ensure patient safety and ethical use of these technologies. Regulatory bodies must establish clear guidelines and standards for the development and deployment of AI systems in medical settings. Another significant consideration is the need for substantial investment in technology and training. Healthcare professionals must be equipped with the necessary skills to effectively utilise AI tools, which involves ongoing education and training programs. Additionally, health services must invest in the infrastructure required to support AI technologies, such as advanced computing systems and secure data storage solutions.

If you wish to discuss anything further, please contact Dr Katharine Bassett, Director of Health Policy on 0420 727 709 or at katharineb@cha.org.au.

Yours sincerely,

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Catholic Health Australia

www.cha.org.au

Catholic Health Australia (CHA) is Australia's largest non-government grouping of health, community, and aged care services accounting for over 15 per cent of hospital-based healthcare in Australia. Our members operate hospitals in each Australian state and in the Australian Capital Territory, providing about 30 per cent of private hospital care and 5 per cent of public hospital care in addition to extensive community and residential aged care. CHA Members also provide approximately 12 per cent of all aged care facilities across Australia, in addition to around 20 per cent of home care provision.

CHA not-for-profit providers are a dedicated voice for the disadvantaged which advocates for an equitable, compassionate, best practice and secure health system that is person-centred in its delivery of care.

Overview

AI has the potential to revolutionise healthcare in Australia by enhancing diagnosis, monitoring, drug discovery, and research. AI algorithms can analyse vast amounts of medical data quickly, identifying patterns and predicting disease progression more effectively than traditional methods. However, several considerations must be addressed, including data privacy and security, the potential for algorithmic bias, and the need for robust regulatory frameworks to ensure patient safety and ethical use. Additionally, integrating AI into healthcare systems requires significant investment in technology and training for healthcare professionals to effectively utilise these advanced tools. Balancing these benefits and challenges is crucial for the successful implementation of AI in healthcare.

Response to recommendations

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

AI holds immense potential to revolutionise the health and care sector in Australia. The Productivity Commission's report on leveraging digital technology in healthcare highlights that the sector stands to gain significantly from AI adoption. The clinical opportunities for AI are vast, encompassing areas such as diagnosis, monitoring, drug discovery, and research.

Diagnostics

One of the primary benefits of AI in diagnostics is its ability to improve accuracy. Traditional diagnostic methods often rely on the subjective interpretation of healthcare professionals, which can lead to variability in outcomes. AI, on the other hand, provides consistent, data-driven insights, reducing the likelihood of human error. AI can identify patterns and anomalies that might be missed by the human eye across a range of diagnostic tests, facilitating early diagnosis and intervention, including:

- medical images such as X-rays, magnetic resonance imaging (MRI), and computed tomography (CT)
- pathology, in particular scanning and interpreting slides
- electrocardiograms and echocardiograms to detect heart conditions such as arrhythmias and heart failure, as well as predict the risk of future cardiac events
- the diagnosis of retinal diseases such as diabetic retinopathy and age-related macular degeneration
- analysing genetic data to diagnose hereditary diseases and conditions, as well as identifying genetic mutations associated with diseases

Monitoring

AI is increasingly being integrated into health and care monitoring, offering innovative solutions to enhance patient care and improve outcomes. This includes real-time tracking of vital signs and health metrics such as heart rate, blood pressure, and glucose levels, leveraging technologies such as wearable devices, monitoring equipment, and EHRs. This not only allows patients to be more attuned to their own health, but it can also enable healthcare professionals to monitor patients remotely. Examples include:

- monitoring patients with heart conditions to predict potential future cardiac events
- AI-powered continuous glucose monitors which track blood sugar levels in real-time and provide insights into how different foods, activities, and medications impact glucose levels
- detecting signs of depression, anxiety, and other mental health conditions by analysing patient data
- monitoring the health and wellbeing of older Australians, particularly those living alone or in residential aged care facilities, to detect falls, monitor daily activities, and alert caregivers of any unusual patterns or behaviours.

Predictive analytics and personalised care

AI's ability to process vast amounts of data quickly makes it an invaluable tool for predictive analytics in healthcare. By analysing historical health data including genetic information, lifestyle data, and medical history, AI can identify early signs of conditions like diabetes, cardiovascular diseases, and cancer, as well as manage chronic diseases and prevent hospital readmissions. Additionally, AI can analyse health data to provide tailored recommendations for treatment care to ensure patients receive the most effective interventions based on their unique health profiles. For example, AI can help in managing medication adherence by analysing a patient's behaviour and providing personalised reminders and support to ensure they take their medications as prescribed.

Drug discovery

AI is revolutionising the field of drug discovery, offering new methods to identify potential drug candidates more efficiently and accurately. Traditional drug discovery is a lengthy and costly process, often taking over a decade and billions of dollars to bring a new drug to market. AI has the potential to significantly shorten this timeline by automating and optimising various stages of the drug discovery pipeline:

- **Target identification:** AI can analyse vast amounts of biological data to identify potential drug targets. By examining genetic, proteomic, and clinical data, AI algorithms can uncover new targets that may not be apparent through traditional methods. For example, AI can identify proteins or genes associated with specific diseases, providing a starting point for drug development.
- **Compound screening:** one of the most time-consuming steps in drug discovery is screening millions of compounds to find those that interact with the target. AI can streamline this process by predicting which compounds are most likely to be effective. Machine learning models can analyse the chemical properties of compounds and their interactions with biological targets, significantly reducing the number of compounds that need to be tested in the lab.
- **Drug design:** AI can assist in designing new drug molecules with desired properties. Generative models, such as deep learning algorithms, can create novel compounds by learning from existing chemical structures. These models can generate compounds that are more likely to be effective and have fewer side effects, accelerating the drug design process.
- **Predicting drug efficacy and safety:** AI can predict the efficacy and safety of drug candidates by analysing preclinical and clinical data. Machine learning models can identify potential side effects and toxicities early in the development process, reducing the risk of failure in later stages. This predictive capability helps in selecting the most promising candidates for further development.

Not only does AI reduce the time required to identify and develop new drugs, but the efficiency can also lead to significant cost savings, the identification of more effective and safer drug candidates, and the development of drugs that are tailored to the specific needs of patients (personalised medicines).

Research

AI algorithms can analyse vast amounts of research data, identifying patterns and trends which can forecast disease outbreaks, patient outcomes, and treatment responses. For example, AI can optimise clinical trial design by identifying suitable participants, predicting outcomes, and monitoring patient responses in real-time. AI can also be used in adaptive trial designs, where protocols are modified based on interim results, improving the efficiency and effectiveness of trials.

Streamlining administrative tasks

AI has the potential to significantly streamline administrative tasks, leading to improved efficiency, reduced costs, and enhanced patient care. For example, AI can automate the scheduling of patient appointments as well as optimise appointment slots. AI can also streamline billing and claims processing as well as optimise

the allocation of healthcare resources. Furthermore, AI can improve the management of patient data by automating data entry, extraction, and organisation, as well as assist healthcare organisation in maintaining regulatory compliance by automating the monitoring and reporting of compliance-related activities.

Supporting mental health

AI applications in mental health include chatbots and virtual therapists that provide support and counselling to individuals experiencing mental health issues. These AI tools can offer immediate assistance, monitor patient progress, and alert healthcare providers if intervention is needed. AI-powered mental health platforms are currently being used to support individuals with anxiety, depression, and other mental health conditions.

Measuring and delivering benefits of AI

To fully realise these benefits, it is crucial to measure and deliver the benefit of AI efficiently. Measuring the benefits of AI requires measurement of:

- key performance indicators such as accuracy, precision, efficiency, and cost-benefit
- user adoption and satisfaction
- productivity gains including time savings, output quality, and the reduction of errors

Delivering the benefits of AI requires the following:

- identifying and communicating the strategic objectives for AI in the health and care sectors, including key areas where AI can add value
- alignment of AI initiatives with the strategic objectives, and developing a clear roadmap for implementing AI initiatives
- engaging stakeholders involved in the planning and implementation
- investment in robust data management practices, including data collection, cleaning, and integration, to ensure AI models are trained on accurate and relevant data
- implementation of monitoring, evaluation, and continuous improvement activities, as AI initiatives require ongoing review and adjustment to adapt to changing needs
- outlining how ethical issues such as bias, transparency, and accountability will be addressed
- training and education on AI technologies and their applications to enhance adoption and utilisation.

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

As outlined in Question 1, AI has the potential to significantly improve access to care by enhancing healthcare delivery, reducing barriers to access, and optimising resource allocation. To fully realise these benefits, some regulations need to be amended and/or introduced. This includes:

- amending existing data privacy regulations to ensure patient data used by AI systems is protected
- introducing regulations that mandate regular audits and assessments of AI systems to ensure compliance with data privacy standards
- establishing interoperability standards to ensure AI systems can seamlessly integrate with existing healthcare infrastructure
- encouraging the adoption of interoperable systems through incentives and regulatory requirements
- developing guidelines for the ethical use of AI in healthcare, addressing issues such as bias, transparency, and accountability

- mandating the inclusion of diverse datasets in AI training to minimise bias and ensure AI systems are representative of the entire population
- streamlining the regulatory approval processes for AI-based healthcare solutions to accelerate their deployment
- introducing regulation that allows for the testing and validation of AI systems in real-world settings under regulatory oversight
- implementing regulations that require healthcare professionals to receive ongoing training and education, including understanding AI algorithms, interpreting AI-generated insights, and integrating AI into clinical workflows
- creating partnerships between public and private sectors to drive innovation and investment in AI and share learnings

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?

AI in healthcare offers numerous benefits, but it also poses certain risks to patients, consumers, and healthcare professionals. Understanding these risks and their magnitude is crucial for safe and effective AI implementation. Key risks include:

- **Diagnostic errors:** AI systems can sometimes produce incorrect or biased diagnoses due to limitations in the training data or algorithmic errors. This can lead to misdiagnosis or delayed treatment, potentially impacting patient outcomes.
- **Data privacy and security:** The use of AI involves processing large amounts of sensitive patient data. If not properly secured, this data can be vulnerable to breaches, leading to privacy violations and potential misuse of personal information.
- **Bias and discrimination:** AI algorithms can inadvertently perpetuate existing biases present in the training data, leading to discriminatory practices. This can result in unequal treatment and outcomes for different patient groups.
- **Over-reliance on AI:** Healthcare professionals might become overly reliant on AI systems, potentially diminishing their own diagnostic and decision-making skills. This over-reliance can be risky if the AI system fails or provides incorrect recommendations.
- **Job displacement:** The automation of administrative and some clinical tasks by AI could lead to job displacement for certain healthcare roles, creating economic and social challenges for affected workers.

The magnitude of these risks can vary:

- **High risk:** Diagnostic errors and data privacy breaches are considered high-risk due to their potential to cause significant harm to patients and undermine trust in healthcare systems.
- **Moderate risk:** Bias and discrimination are moderate risks, as they can lead to systemic issues and unequal care but may be mitigated through careful algorithm design and monitoring.
- **Low risk:** Over-reliance on AI and job displacement are generally lower risks but still require attention to ensure balanced integration of AI and human expertise.

To characterise the risk posed by AI in healthcare, the following criteria can be used:

- **Severity of impact:** Assess the potential harm that could result from an AI error or failure. This includes physical harm to patients, data breaches, and ethical implications.

- **Likelihood of occurrence:** Evaluate the probability of the risk occurring based on historical data, system reliability, and the robustness of the AI algorithms.
- **Detectability:** Determine how easily the risk can be detected and mitigated. High-risk scenarios are often those where errors are not easily identifiable or correctable.
- **Vulnerability:** Consider the vulnerability of the affected population. Risks that disproportionately affect vulnerable groups are of higher concern.
- **Regulatory and ethical compliance:** Ensure that AI systems comply with existing regulations and ethical standards. Non-compliance can elevate the risk level.

Consumers should be informed when AI is used, even in low-risk ways. Transparency is key to building trust and ensuring informed consent. Patients have the right to know how their data is being used and the role of AI in their care. This allows them to make informed decisions about their treatment. Additionally, transparency about AI use fosters trust between patients and healthcare providers. It reassures patients that their care is being managed responsibly and ethically. It also ensures patients understand who is responsible for their care and how decisions are being made. Ultimately, educating patients about AI can help demystify the technology and reduce apprehension. It also empowers patients to engage more actively in their healthcare.

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

Assessing the benefits, risks, and safety of AI in rural and regional Australia requires careful consideration of factors such as access to technology, workforce training, cultural sensitivity, and data privacy. Other communities, including Aboriginal and Torres Strait Islander peoples, older Australians, and low-socioeconomic populations, also face specific risks when implementing AI-driven healthcare. To ensure all Australians have access to the benefits of AI, it is essential to focus on:

- **Equitable distribution of resources:** ensure AI technologies are distributed equitably across urban, rural, and remote areas. This includes investing in infrastructure and providing financial support to underserved regions.
- **Inclusive policy development:** Develop policies that consider the unique needs of different communities. This involves engaging with these communities to understand their specific challenges and requirements.
- **Education and awareness:** Raise awareness about the benefits and risks of AI in healthcare through public education campaigns. Providing information in multiple languages and formats can help reach diverse populations.
- **Collaboration and partnerships:** Foster collaboration between government, healthcare providers, technology companies, and community organisations to ensure that AI solutions are designed and implemented in a way that meets the needs of all Australians.
- **Monitoring and evaluation:** Implement robust monitoring and evaluation frameworks to assess the impact of AI on different communities. This includes collecting data on health outcomes, access to care, and patient satisfaction to identify areas for improvement.

By addressing these considerations, AI can be effectively integrated into healthcare to improve access and outcomes for all Australians.

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

Healthcare professionals should have a choice about whether they use AI as part of their work. Respecting their autonomy and professional judgment is essential for maintaining their confidence and satisfaction. Providing adequate training and support, ensuring patient-centred care, managing risks, and developing flexible organisational policies and regulatory frameworks are crucial for the responsible integration of AI in healthcare. By addressing these considerations, AI can be effectively integrated into healthcare in a way that enhances patient care and supports healthcare professionals.

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

AI in healthcare presents unique considerations that stem from the sensitive nature of medical data, the critical importance of patient safety, and the ethical implications of automated decision-making. Addressing these considerations through regulatory change is essential to ensure the safe, effective, and equitable use of AI in healthcare. These considerations include:

- **Data privacy and security:** Healthcare data is highly sensitive and personal. Ensuring the privacy and security of patient data is paramount to prevent breaches and misuse. Additionally, AI systems often require large datasets to function effectively. Balancing the need for data sharing with stringent privacy protections is a critical challenge.
- **Accuracy and reliability:** AI systems must be highly accurate, as errors can lead to misdiagnoses and inappropriate treatments, potentially harming patients. Continuous validation and testing of AI algorithms are necessary to ensure their reliability and effectiveness in diverse clinical settings.
- **Bias and fairness:** AI systems can inherit biases present in the training data, leading to unequal treatment of different patient groups. Addressing and mitigating these biases is crucial for fair and equitable healthcare. Ensuring that AI systems are trained on diverse datasets that represent all population groups is essential to avoid disparities in care.
- **Transparency and explainability:** Many AI systems operate as “black boxes,” making it difficult to understand how decisions are made. Ensuring transparency and explainability is important for building trust among healthcare professionals and patients. This may include visibility over datasets used in building AI models and how this has informed choices around the adoption of selected AI models in the healthcare context. Patients should also be informed about the use of AI in their care and understand how AI contributes to decision-making processes.
- **Ethical and legal implications:** Determining accountability for AI-driven decisions is complex, especially when errors occur. Clear guidelines on responsibility and liability are needed. Additionally, ensuring that AI is used ethically, with respect for patient autonomy and consent, is fundamental to maintaining trust in healthcare systems.
- **Integration with clinical workflows:** AI systems must be integrated seamlessly into existing clinical workflows to enhance, rather than disrupt, healthcare delivery. Healthcare professionals need adequate training and support to effectively use AI tools, ensuring that they complement clinical expertise.

The government should address these unique considerations through regulatory change to ensure the safe, effective, and ethical use of AI in healthcare. This includes:

- **Strengthening data privacy laws** to protect patient information and ensure secure data handling practices. Regulations should mandate robust encryption, access controls, and regular audits.

- Establishing standards for the validation and testing of AI algorithms to ensure their accuracy and reliability. Regulatory bodies should require continuous monitoring and reporting of AI performance in clinical settings.
- Implementing guidelines to identify and mitigate biases in AI systems. Regulations should promote the use of diverse and representative datasets and require transparency in algorithm development.
- Mandating AI systems used in healthcare are transparent and explainable. Regulations should require that AI developers provide clear documentation on how decisions are made and ensure that patients are informed about AI use.
- Developing ethical guidelines and legal frameworks to address accountability and liability issues related to AI in healthcare. Regulations should clarify the responsibilities of AI developers, healthcare providers, and institutions.
- Providing support for the integration of AI into clinical workflows, including funding for infrastructure and training programs. Regulations should encourage the adoption of AI while ensuring that healthcare professionals are adequately prepared.

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

While AI applications in healthcare, finance, and education share some commonalities, the differences are pronounced due to the unique demands and ethical considerations of each sector. As outlined in Question 6, in healthcare, the focus on patient safety, data privacy, and ethical use is paramount, necessitating stringent regulations and careful integration with human expertise. Understanding these distinctions is crucial for developing and implementing AI solutions that are safe, effective, and equitable across different fields.

Question 8: Should there be an Australian body specifically dedicated to overseeing AI in health care? If so, how would this body differ from a broader organisation like the National AI Centre?

A dedicated Australian body overseeing AI in healthcare is essential to address the unique challenges and requirements of AI applications in the medical field. This specialised body would differ from a broader organisation like the National AI Centre by focusing exclusively on healthcare, ensuring patient safety, ethical use, and seamless integration of AI into clinical workflows. By providing specialised expertise, regulatory oversight, and support for research and development, this body would play a crucial role in ensuring that AI technologies enhance healthcare delivery and improve patient outcomes in Australia.

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

There are several specific changes to existing healthcare laws that could address AI-related harms and help ensure the safe use of AI in healthcare. These changes would focus on enhancing data privacy, ensuring algorithmic transparency, mitigating bias, and establishing clear accountability frameworks, including:

- Strengthening existing data privacy laws to ensure robust protection of patient data used by AI systems. This includes implementing stricter data encryption standards, access controls, and regular audits to prevent data breaches.
- Amending laws to require explicit patient consent for the use of their data in AI applications, ensuring transparency about how data will be used and shared.
- Introducing regulations that mandate AI developers to provide clear documentation on how their algorithms work, including the data sources used, the decision-making process, and potential limitations.

- Requiring AI systems to be explainable, meaning that healthcare professionals and patients should be able to understand how AI-driven decisions are made. This can help build trust and ensure informed consent.
- Amending laws to require regular testing and validation of AI algorithms to detect and mitigate biases. This includes using diverse and representative datasets to train AI systems and conducting impact assessments to identify potential disparities in care.
- Establishing guidelines for the ethical use of AI, ensuring that algorithms do not perpetuate existing biases or create new forms of discrimination.
- Developing legal frameworks that clearly define the accountability and liability of AI developers, healthcare providers, and institutions when AI systems are used. This includes establishing protocols for reporting and addressing AI-related errors or adverse events.
- Amending existing malpractice laws to include provisions for AI-related incidents, ensuring that patients have recourse in case of harm caused by AI systems.
- Establishing a dedicated regulatory body to oversee the use of AI in healthcare, as outlined in Question 8. This body would be responsible for setting standards, conducting evaluations, and ensuring compliance with healthcare-specific regulations.
- Requiring AI systems to undergo rigorous testing and certification before they can be deployed in clinical settings, similar to the approval process for medical devices and pharmaceuticals.
- Amending laws to require continuous monitoring and evaluation of AI systems after they are deployed. This includes collecting data on their performance, identifying any issues, and making necessary adjustments to ensure ongoing safety and effectiveness.
- Implementing mandatory reporting of AI-related incidents and adverse events to a central database, allowing for transparency and continuous improvement.
- Introducing regulations that require healthcare professionals to undergo training on the use of AI tools. This includes understanding AI algorithms, interpreting AI-generated insights, and integrating AI into clinical workflows.
- Providing funding and resources for ongoing education and support to ensure that healthcare professionals stay updated on advancements in AI technology.

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

When considering international approaches to AI in healthcare, several countries have developed frameworks and guidelines that can serve as valuable references for Australia. These approaches focus on ensuring the safe, ethical, and effective use of AI in healthcare:

- **European Union:** The General Data Protection Regulation (GDPR) provides a robust framework for data privacy and protection, which is crucial for AI applications in healthcare. It emphasises patient consent, data minimisation, and the right to access and rectify personal data. Australia could adopt similar stringent data protection measures to ensure patient privacy and build trust in AI systems. The European Union has also developed guidelines that outline key requirements for trustworthy AI, including transparency, accountability, and fairness. These guidelines emphasise the importance of human oversight and the need to avoid bias in AI systems.
- **United States:** The Food and Drug Administration (FDA) has established a regulatory framework for AI and machine learning-based medical devices. This framework includes pre-market review, post-market surveillance, and continuous learning and adaptation of AI systems. Australia could consider a similar regulatory approach to ensure that AI-driven medical devices are safe and effective before they are deployed in clinical settings. Additionally, The FDA's approach to regulating AI/ML-Based Software as a Medical Device (SaMD) focuses on the total product lifecycle,

ensuring that these technologies are continuously monitored and updated to maintain their safety and effectiveness. Implementing a lifecycle approach to AI regulation can help address the dynamic nature of AI technologies in healthcare.

- United Kingdom: The National Health Service (NHS) AI Lab is dedicated to accelerating the safe, ethical, and effective deployment of AI in healthcare. It focuses on developing standards, supporting innovation, and ensuring that AI technologies meet clinical needs. Establishing a similar dedicated body in Australia can help coordinate AI initiatives, support research and development, and ensure that AI solutions are aligned with healthcare priorities. The United Kingdom has also developed a code of conduct that outlines principles for the development and deployment of data-driven health technologies. This includes ensuring transparency, accountability, and patient involvement in the development process. Adopting a code of conduct can provide clear guidelines for AI developers and healthcare providers, promoting ethical and responsible use of AI.
- Canada: Canada's AI strategy includes a focus on ethical AI development, public engagement, and collaboration between government, academia, and industry. It emphasises the importance of addressing societal impacts and ensuring that AI benefits all citizens. A national strategy that includes public engagement and collaboration can help ensure that AI in healthcare is developed and implemented in a way that meets the needs of all Australians.
- Japan: Japan's AI Hospital Project aims to integrate AI into hospital operations to improve efficiency and patient care. This includes developing AI systems for diagnostics, treatment planning, and administrative tasks. Learning from Japan's experience with integrating AI into hospital workflows can help Australia develop practical solutions that enhance healthcare delivery.

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

Human oversight is essential in healthcare to ensure patient safety, uphold ethical and legal standards, address biases, build trust, and enhance collaboration. Allowing healthcare professionals to overrule AI decisions ensures that AI serves as a supportive tool, augmenting human expertise rather than replacing it. This approach helps create a balanced and effective healthcare system where AI and human professionals work together to provide the best possible care for patients.

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

While having a human in the loop is generally crucial for ensuring patient safety, ethical standards, and trust in healthcare, there are specific circumstances where fully automated AI decisions might be acceptable. Routine and low-risk tasks, remote monitoring, and resource-limited settings are examples where AI can operate with minimal human oversight. However, even in these cases, mechanisms should be in place for human review and intervention to ensure the highest standards of care. Balancing AI automation with human oversight can help harness the benefits of AI while maintaining the quality and safety of healthcare services.

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

Reporting AI errors is essential for ensuring patient safety, promoting accountability, and fostering continuous improvement in AI systems. Establishing a robust reporting system with mandatory requirements, anonymous reporting options, regular audits, and feedback mechanisms can help address AI errors effectively. By prioritising transparency and learning from errors, the healthcare industry can enhance the reliability and trustworthiness of AI technologies, ultimately improving patient care.

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

Transparency about AI involvement in healthcare and obtaining consent from both patients and healthcare professionals are essential for building trust, ensuring informed decision-making, and upholding ethical and legal standards. Clear communication, robust informed consent processes, thorough documentation, and effective feedback mechanisms are key to implementing these principles. By prioritising transparency and consent, the healthcare industry can foster a more trustworthy and effective integration of AI technologies, ultimately enhancing patient care and professional practice.

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

Generative AI developed for general use but applied in healthcare requires special treatment to ensure patient safety, uphold ethical standards, and protect data privacy. Implementing robust regulatory frameworks, ethical guidelines, data protection measures, training programs, and interdisciplinary collaboration can help achieve these goals. By addressing the unique challenges of using generative AI in healthcare, we can harness its potential to improve patient care while minimising risks.

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 in healthcare requires specific protections due to the sensitive nature of medical information and the potential impact on patient privacy and safety. These protections include:

- Implementing robust access controls to ensure that only authorised personnel can access patient data. This includes multi-factor authentication and role-based access permissions.
- Encrypting patient data both in transit and at rest to protect it from unauthorised access and breaches. Advanced encryption standards should be used to ensure data security.
- Using techniques to anonymise or de-identify patient data before it is used by AI systems. This helps protect patient privacy while allowing data to be used for analysis and training.
- Obtaining explicit informed consent from patients before using their data for AI purposes. Patients should be fully informed about how their data will be used, the benefits and risks, and their rights.
- Clearly communicating to patients how their data will be used by AI systems. This includes explaining the purpose of data collection, how it will be processed, and any potential sharing with third parties.
- Collecting only the minimum amount of data necessary for the AI application. Avoid collecting excessive or irrelevant data to reduce the risk of misuse.
- Using patient data only for the specific purposes for which it was collected. Ensure that data is not repurposed for unrelated activities without additional consent.
- Implementing continuous monitoring of AI systems to detect and address any data privacy or security issues. This includes real-time monitoring for unauthorised access or anomalies.
- Conducting regular audits of AI systems and data handling practices to ensure compliance with data protection regulations and identify areas for improvement.
- Appointing data protection officers (DPOs) to oversee data privacy and security practices. DPOs should ensure that AI systems comply with relevant regulations and standards.
- Establishing clear accountability frameworks to define who is responsible for data protection at each stage of the AI lifecycle. This includes data collection, processing, storage, and sharing.
- Implementing measures to detect and mitigate biases in AI systems. This includes using diverse and representative datasets and regularly auditing AI outputs for fairness.

- Ensuring data used by AI systems is collected and processed in a way that promotes fairness and avoids discrimination. This helps protect vulnerable populations and ensures equitable care.
- Providing patients with the right to access their data and obtain copies in a portable format. This empowers patients to control their data and share it with other healthcare providers if needed.
- Allowing patients to request the deletion of their data from AI systems. This right to erasure helps protect patient privacy and ensures that data is not retained longer than necessary.

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?

Using patient data to develop AI products can be acceptable if done ethically, with informed consent, and in compliance with data protection regulations. However, selling patient data collected from the use of AI is generally unacceptable without explicit patient consent and is often illegal. Developers must prioritise patient privacy, adhere to ethical standards, and comply with legal requirements to ensure the responsible use of patient data. By doing so, they can build trust and ensure that AI technologies are developed and used in a way that benefits patients and respects their rights.

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?

While keeping healthcare information in Australia ensures robust data privacy and security, it is important to consider the potential benefits of accessing advanced AI technologies developed overseas. Balancing these priorities requires careful consideration of data-sharing agreements, regulatory harmonisation, and ethical standards. By establishing secure and compliant frameworks for international data collaboration, Australia can protect patient privacy while leveraging global AI advancements to improve healthcare outcomes.

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

Other safety considerations include:

- Ensuring that AI systems have user-friendly interfaces is crucial. Poorly designed interfaces can lead to user errors, especially in high-stress healthcare environments.
- Implementing redundancy in AI systems can help prevent failures. This includes having backup systems and fail-safes to ensure continuous operation.
- Developing protocols for managing AI system downtime is essential to maintain patient care quality. This includes having manual processes in place as a backup.
- Ensuring AI systems are compatible with existing healthcare IT infrastructure is crucial. Poor integration can lead to data silos, miscommunication, and errors.
- Adopting standardised protocols for data exchange can enhance interoperability and reduce the risk of errors due to incompatible systems.
- AI systems must provide timely responses, especially in critical care situations. Delays in AI decision-making can have serious consequences for patient outcomes.
- Continuous real-time monitoring of AI systems can help detect and address issues promptly, ensuring that decisions are made based on the most current data.
- Appropriate controls are in place to accommodate the various concerns around the use of AI systems in specific contexts.
- Regular maintenance and updates of AI systems are necessary to ensure their long-term reliability and effectiveness. This includes updating algorithms based on new medical knowledge and technological advancements.

- Ensuring there are sufficient resources, including financial and human, to support the ongoing operation and improvement of AI systems is crucial for sustainability.