The Academy of Medical Sciences

Response to the House of Lords' Artificial Intelligence Committee call for evidence
September 2017

Summary

- The impact of artificial intelligence (AI) on biomedical research and the healthcare system is likely to be profound. Key benefits include improved efficiency of research and development processes, new methods of healthcare delivery, more informed clinical decision-making and empowerment of patients in managing their health. AI is already being used in these areas and this is certain to increase in the future.
- The ever-increasing volume of data being generated by the NHS, and through technology such as health apps and wearables, is further driving the development and use of AI.
- The key strength of AI is in rapidly analysing complex datasets. These data could be uninterpretable by a human or AI could automate existing human analyses, making interpretation faster and more accurate. It is expected that AI-based algorithms in healthcare will be used to complement the work of healthcare professionals but not fully replace them.
- The performance of AI is dependent on the quality of the data it uses. Therefore datasets should be high-quality and comprehensive to maximise the effectiveness of an AI algorithm and minimise the introduction of inaccuracies or bias.
- AI algorithms should be thoroughly tested and it should be shown that the system offers clinical benefit, accuracy and reliability over the alternative before implementation.
- Acceptability of AI and data sharing processes in healthcare should be informed by engagement with key stakeholders including patients and the public. Transparency around how and where AI is used is important to allow effective evaluation and validation of the system, and to enhance its trustworthiness amongst the public and key stakeholders.
- It is important to establish proportionate regulation of AI that balances appropriate safeguards against stimulation of innovation in this field.

Introduction

1. The Academy of Medical Sciences promotes advances in medical science and supports efforts to ensure that these are translated into healthcare benefits for society. Our elected Fellowship comprises some of the UK's foremost experts in medical science, drawn from a diverse range of research areas, from basic research through clinical application to commercialisation and healthcare delivery.
2. We welcome the opportunity to respond to this call for evidence on the implications of advances in AI. The Academy is monitoring the developments in, and applications of, AI in medical science and healthcare through various workstreams: improving the health of the public in 2040; enhancing the use of scientific evidence; health apps; real world evidence; multi-morbidity; and regulation and governance of health research.[1,2,3,4,5] This work has informed our input to relevant consultations such as the House of Commons' Science and

[1] Academy of Medical Sciences (2016). *Improving the health of the public by 2040*. https://acmedsci.ac.uk/file-download/41399-5807581429f81.pdf
[2] Academy of Medical Sciences (2016). *Real world evidence.* https://acmedsci.ac.uk/file-download/38667-573d8796ceb99.pdf
[3] Academy of Medical Sciences (2015). *Health apps: regulation and quality control.* https://acmedsci.ac.uk/file-download/37073-552cc937dcfb4.pdf
[4] Academy of Medical Sciences (2015). *Multiple morbidities as a global health challenge.* https://acmedsci.ac.uk/file-download/38330-567965102e84a.pdf
[5] Academy of Medical Sciences (2016). *Regulation and governance of health research: five years on.* https://acmedsci.ac.uk/more/events/regulation-and-governance-of-health-research-five-years-on

Technology Committee's inquiry on algorithms in decision-making.[6]

3. This response outlines some of the opportunities and challenges that use of AI may have for medical research and healthcare. The response is based on our recent policy work and the views of the Academy's Fellows and other experts with whom we collaborate.
4. AI refers to systems used to simulate human intelligence, and is a growing field due to increases in computational power that allow processing and analysis of large and complex datasets. Much of AI today exists in the form of machine learning, where algorithms use a set of training data to learn how to spot patterns in datasets that would otherwise be too complex for human analysis. It is expected that future developments will lead towards systems which interact with humans more directly, particularly when paired with robotics.

Implications for biomedical science and research and development

5. AI is being increasingly applied to further our understanding of basic science by detecting patterns or features that have been previously missed by researchers or are too complex for humans to identify. It is also used for a variety of functions across research and development (R&D) including computer-assisted drug design, clinical trial data interpretation and clinical trial simulations such as pharmacological modelling.
6. Randomised clinical trials (RCTs) are often used to generate information on the safety, efficacy and effectiveness of medicines. However, interventions are tested on a sub-section of a population group that meets eligibility criteria, for example age or number of conditions, which means that it can be challenging to generalise results to the wider 'real' patient population. Our Fellows have suggested that AI-simulated trials can make RCT results more applicable to real world usage, and could also be used for license expansions (for example beyond the original population in which a drug was approved, such as in the elderly) or drug repurposing without the need for expensive and lengthy Phase III trials.
7. AI has the potential to utilise the increasingly large and complex pool of data collected through multiple sources such as wearable devices, health monitors and genome sequencing, with implications for both research and clinical care. As such datasets become more accessible, this opens up the possibility for greater patient and public involvement in (PPI) research, and the commercial sector is likely to be a major driver in this area with initiatives such as Google DeepMind Health and IBM Watson Health in development. In addition, the NHS offers a unique source of health data, presenting the opportunity for academic and commercial research to partner with the NHS in developing new AI tools. In such cases, it would be desirable for the research outputs to be developed and made available in collaboration with the NHS. Alongside research, smart-phone apps and wearable devices that monitor health measures such as heart rate or distance walked can be linked to GP surgeries to send data for use in clinical care.

Examples of AI used in research and development

- An example of AI used in research is a Stanford-developed algorithm that, using histological images, uncovered new morphological features of breast cancer that hadn't previously been identified by clinicians using the same images.[7]
- DIYgenomics is a non-profit organisation that allows members of the public to contribute their health and genetic data for use in AI driven studies.[8]

[6] Academy of Medical Sciences (2017). *Response to the House of Commons Science and Technology Committee inquiry into algorithms in decision-making.* https://acmedsci.ac.uk/file-download/79291192

Implications for the healthcare system and health outcomes

8. AI is becoming increasingly commonplace in healthcare, where it is routinely applied to calculate risk, aid diagnosis and generate medical images. These tools can guide the clinician, and others, through the diagnosis and decision-making process and support early intervention alongside prediction and prevention of future health problems.
9. Algorithms such as decision-support tools are key for supporting clinicians in making informed decisions about disease management, and can enable patients to take a more active role in decision-making. This is particularly important in choosing the best route of care in complex cases, such as circumstances where a number of medical conditions may need to be considered within the limited time available in a GP consultation. In addition, AI can enable automatic flagging of 'next steps' to a clinician when certain patient data is inputted, such as identifying the need to carry out specific diagnostic tests. However, the clinician-patient relationship should remain an integral part of care.[7] There will remain situations where a clinician is best placed to optimise care based on clinical experience and context, and so AI should be used to complement clinical care but not replace the need for healthcare professionals.[8]
10. Clinical decision-support tools should be the subject of research evaluation and supported by funders. NICE, in discussion with NHS Choices, should coordinate the development of these tools based on the evidence generated by them.[9]
11. Increased use of AI will lead to changes in the skillset required for professionals, and training programmes should reflect this to allow staff to maximise on the opportunities afforded by AI. As such, there is a need to identify and address any gaps in capability to ensure the necessary training for the integration, manipulation and analysis of the data within appropriate ethical and regulatory frameworks.[10]
12. As with all innovations, there is a risk of inequity of access to the applications developed from AI and this should be a consideration for commissioners, particularly if the application has been developed using publically-generated data sets.

Example of AI in health and social care
An example of an emerging diagnosis aid is a University of Washington School of Medicine study that used 100,000 optical coherence tomography images to train an algorithm to detect age-related macular degeneration. The algorithm achieved sensitivities and specificities of over 90% and could therefore be used for automated screening of patients.[13]

Regulation and governance of AI

13. The MHRA has guidelines for the requirements of digital medical devices such as apps and implants and the laws that cover their use.[12] However, these guidelines do not specify the process for the validation of algorithms, AI and devices and it is currently unclear how these devices fit with the regulatory framework or local infrastructure for implementation and

[7] Chewning B, *et al.* (2012). *Patient preferences for shared decisions: A systematic review*. Patient Educ Couns **86**, 9–18.
[8] Academy of Medical Sciences (2017). *Enhancing the use of scientific evidence to judge the potential benefits and harms of medicines*. https://acmedsci.ac.uk/file-download/44970096
[9] *Ibid.*
[10] Academy of Medical Sciences (2016). *Improving the health of the public by 2040*. https://acmedsci.ac.uk/file-download/41399-5807581429f81.pdf
[11] Lee CS, *et al.* (2017). *Deep learning is effective for the classification of OCT images of normal versus Age-related Macular Degeneration.* Ophthalmology Retina **124**, 1090-1095.
[12] MHRA (2014). *Medical device stand-alone software including apps.* www.gov.uk/government/uploads/system/uploads/attachment_data/file/564745/Software_flow_chart_Ed_1-02.pdf

evaluation of digital devices such as the Paperless 2020 initiative, or through Academic Health Science Networks (AHSNs), as proposed by the Accelerated Access Review.[13,14]

14. It is important to establish further proportionate regulatory processes around AI that maintain appropriate safeguards whilst also fostering a facilitative environment for innovation in this field. In addition, regulation should not impact the ability for companies to develop in-house AI systems that may be used for R&D but that do not directly affect health.

Transparency and limitations of AI

15. AI systems should be open to scrutiny to allow validation of effectiveness, evaluation of their potential risks and biases and to promote trust amongst users, recognising the need to consider IP protection for commercial developers.
16. It is essential that AI-based algorithms that impact health are thoroughly tested and found to be robust prior to use. This can be tested by establishing that the system offers advantage, accuracy and reliability over the alternative before being implemented. As AI systems often improve over time as new data becomes available, new versions or updates must also be tested to ensure that they are as robust as the previous system, as this robustness cannot be assumed. Manufacturers should inform regulators of the changes to software, and regulation should be able to accommodate such iterative changes. In addition, dialogue between software developers and regulators should occur early on and throughout the design process to ensure that the software fulfils regulatory requirements and to allow thorough and timely appraisal.
17. The limitations of AI should be recognised as it is dependent on the data used to develop it and so may incorporate any biases present in the data. Socio-economic differences in access to digital technologies can accentuate such biases by limiting the availability of data that is fully representative of the population. An example of bias arising from incomplete datasets is a study that compared care given to women with breast cancer across affluent and deprived areas. A lack of data from women in deprived areas missed the observation that they presented more advanced tumours than women from affluent areas.[15]
18. Therefore testing and regulation should also include the propensity for algorithms to make errors and impart bias. These can be measured using test data and should be included in risk assessments. It is widely agreed that any algorithm used in clinical practice should undergo the same scrutiny as any new guideline or tool, including efficacy and risk analysis. Therefore there is a need for clear guidelines to assess acceptable risk and determine culpability in case an error is made or the performance of the algorithm falls below certain standards. This may require scrutiny of the methods employed by the algorithm.

Data sharing and privacy

19. The accuracy and robustness of algorithms is dependent on the quality of, and access to, both the data used to build and test the algorithm and the data inputted into the model. Therefore enabling access to comprehensive, high-quality data sources is key. Further to this, it is vital to note the importance of data quality, as well as quantity, to ensure high-quality data collection.
20. Communication and engagement with patients, clinicians and other key stakeholders is essential to help them to understand the value of health data and how it is used by AI in research and healthcare. This can help them to make informed decisions about contributing and sharing data. Initiatives to increase public dialogue and understanding around this should

[13] National Information Board and Department of Health (2014). *Personalised Health and Care 2020* https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/384650/NIB_Report.pdf
[14] Accelerated Access Review: Final Report (2016). https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/565072/AAR_final.pdf
[15] Macleod U & Watt GCM. (2008). *The impact of consent on observational research: a comparison of outcomes from consenters and non consenters to an observational study.* BMC Medical Research Methodology **8**, 1-6.

be promoted and the Academy is pleased to be working with Understanding Patient Data on a piece of public dialogue to inform this area.[16] Sharing of data, particularly with commercial bodies, can be contentious and there needs to be clarity and transparency around where, how and why data is shared for this purpose, with public acceptability being an important consideration.

21. In circumstances where publically generated data is shared for commercial use, it should be done so for the potential benefit to the health system or the public. Shared ownership of data between the NHS and commercial partners, or the IP generated from this data, could help to ensure that the exchange of data is of such benefit.
22. It is important to acknowledge that no mechanism of data anonymisation – particularly pseudo-anonymisation – will be entirely risk-free, but steps can be taken to minimise these risks. Appropriate safeguards which promote accountability and best practice in use of data, and appropriate sanctions for breaching data privacy, will help to reduce risks. In addition, good data governance practices are essential and these are supported by various guidance and legislation including the Information Commissioner's Office, the Government's response to the National Data Guardian's Review of data security, consent and opt-outs, and the new EU General Data Protection Regulation 2016, which comes into UK law in May 2018.[17] The risk of manipulation of data or an algorithm by outside interference needs to be considered and appropriate safeguards and sanctions put in place to minimise the risk of such an event.
23. Historically, patients give their consent for any aspect of their health data to be shared for a specific use. If the terms of use change, re-consent is usually required to ensure the patient remains informed about the use of their data. The Government's response to the recommendations of the National Data Guardian's recent Review accepts the proposed changes to this model in favour of a system more centred on 'opt-outs'.[18] Consent models across the health system should be homogeneous and standardised to ensure that patients are informed and developers understand what data is available to them.

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[16] https://understandingpatientdata.org.uk/
[17] Department of Health (2017). *Your Data: Better Security, Better Choice, Better Care.* www.gov.uk/government/uploads/system/uploads/attachment_data/file/627493/Your_data_better_security_better_choice_better_care_government_response.pdf
[18] *Ibid.*