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Artificial Intelligence (AI) technologies offer new opportunities to improve surgery but there is a growing recognition that the development of these technologies can unintentionally create or exacerbate inequalities. In the context of surgery, AI can be used in several ways, including detecting and characterising signs of disease, providing guidance to surgeons during procedures (for example through improving endoscopic navigation or providing augmented reality overlays) and in surgical robots. The future success of these emerging technologies in surgery will depend on ensuring they are designed with, and for the public and patients.

technologies. They also asked if there are effective strategies in place to deal with specific local health contexts and ensure support for those who need to travel to benefit from these technologies.

The pressure to develop complex infrastructures and inter-linkages (which need shared skills as well as shared standards) has sometimes been addressed by turning to the tools big tech firms have available, which may not be sustainable both from a reputational and practical point of view.

Transparency and clear messaging on how the data is going to be used is important. Often the value of data and who will benefit from it is not clear. Participants noted that patients may have concerns that NHS data will be exploited for monetary gain, where private firms are involved in handling patient data.

Potential **solutions** in the design and development of medical devices (specifically focusing on Artificial Intelligence and Surgery)

Based on the issues highlighted above, participants suggested actions that might help to improve research practices and deliver more equitable health outcomes. Below we present ideas for further investigation based on the insights and experience of all participants involved, rather than fully worked up recommendations.

1) RESEARCH AND INNOVATION PRECEDING DEVELOPMENT AND MANUFACTURING;

In general, there was agreement that the research and in7ata c9ING; btcEtℝE-1.llr moropeign aninclocuvees. mea (nin f publicon)⟁J0 -1.3 Tdengnkaeemenl witt patientn ant thpublic,tn antont itenfyd,

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It is also important to develop consensus on what a good dataset looks like. This will make the argument for data sharing easier[3]. Furthermore, the platforms where this data is shared and accessed can also be improved with data stewardship or cooperative initiatives, which may make it easier for researchers to comply with regulations. Once the above are in place, we will have the key ingredients to develop a secure system where data sharing between institutions is the default and patients are able to make informed choices about their data. This will also allow a public record of decision making to make healthcare more democratic and allow scrutiny from the wider public.

Specific ideas for further exploration:

- Promote and support data sharing initiatives to create large scale national level databases;

- Empower patients to be part of governance around data stewardship. Trusted research environments (TREs) have been suggested as a route for increasing trust around security and privacy of data. Participants suggested that involving patients and the public in the design and governance of TREs might help to increase trust further;

- Develop more flexible and agile research infrastructure and proportionality in regulations – further investing in diversifying the actors in charge of developing TREs[4];

- Develop training for researchers on early and targeted interventions to improve communication with underrepresented and marginalised audiences. For example, making sure that information is accessible (providing non-digital options if necessary), and making it easier for patients that are willing to be involved with data research to do so;

- Devise systems to disseminate and implement health dataset standards, including an active voice of patients, clinicians, researchers and policy makers.

[4] Data and Analytics Research Environments UK (https://dareuk.org.uk/)

Public and patient concerns and trust regarding digital technologies

Participants reported that although there is not enough public involvement in medical research in general, artificial intelligence is a highly complex, technical field, and it can be hard to bring everyone 'up to speed'. This may make it even harder to deliver effective public engagement on Artificial Intelligence topics.

The population in the UK is very diverse and contains multiple cultures, nationalities, religions and ethnicities. There may be different appetites for using AI technologies between groups, leading some to miss out on potential benefits if they 'opt out'. For example, if information for patients is not accessible or if there is not enough support for people with disabilities, some people may not feel comfortable with AI technologies being used.

Even for some healthcare professionals, there may be a fear that engagement with new technologies will negatively impact on service delivery. This in turn also affects how patients react to AI.

We also set out to discuss current and future concerns that patients and the public have towards these technologies.

CURRENT CONCERNS

- **Lack of transparency:** there are concerns about the lack of transparency in institutions regarding the use of data, its anonymisation, ownership and distribution;

- **Insufficient regulations:** there are also worries that there are insufficient checks and evaluations of how data is collected and how private information is kept secure, as well as common standards to regulate and support the safe application of new technologies.
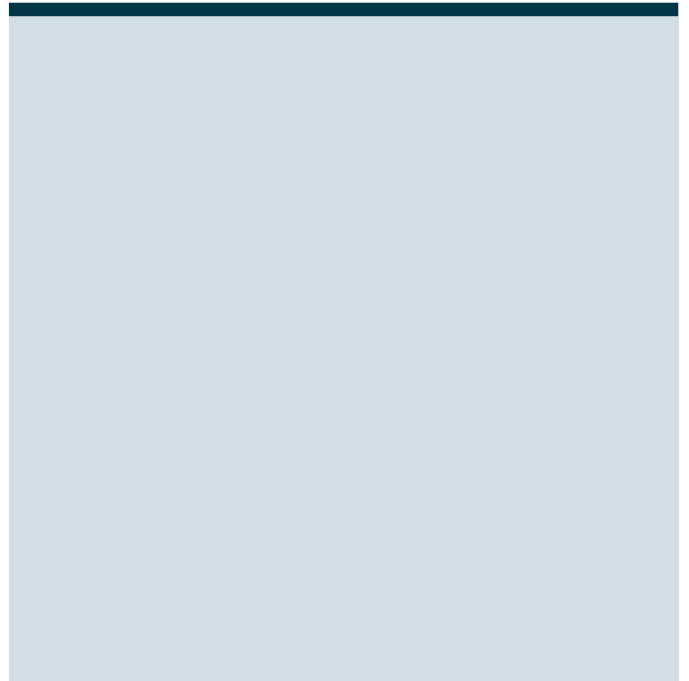
Annex 1: Summary of resources and initiatives

Research and statistics

- European Health Data Space
  https://ec.europa.eu/health/publications/
  communication-commission-european-health-data-
  space-harnessing-power-health-data-people-patients-
  and_en

- Open Data Institute projects on AI
  https://theodi.org/topic/emerging-tech/

- Standing Together
  https://www.health.org.uk/funding-and-partnerships/
  programmes/artificial-intelligence-and-racial-and-ethnic-
  inequalities)
  https://www.datadiversity.org/

Policy Papers and Consultations

- Data storage and processing infrastructure security and
  resilience – call for views
  https://www.gov.uk/government/publications/data-
  storage-and-processing-infrastructure-security-and-
  resilience-call-for-views/data-storage-and-processing-
  infrastructure-security-and-resilience-call-for-views

- Inclusive Britain
  https://www.gov.uk/government/publications/
  inclusive-britain-action-plan-government-response-
  to-the-commission-on-race-and-ethnic-disparities/
  inclusive-britain-government-response-to-the-
  commission-on-race-and-ethnic-disparities

- https://www.bennett.ox.ac.uk/blog/2022/07/bennett-
  insights-an-overview-of-uk-data-policy-developments/

- Common Regulatory Capacity for AI
  https://www.turing.ac.uk/research/publications/
  common-regulatory-capacity-ai

- Secure data environment for NHS health and social
  care data
  https://www.gov.uk/government/publications/secure-
  data-environment-policy-guidelines/secure-data-
  environment-for-nhs-health-and-social-care-data-
  policy-guidelines

- Government response to consultation on the future
  regulation of medical devices in the United Kingdom

Guidance and Regulation

- HDRUK 5 safes
  https://www.hdruk.ac.uk/news/building-a-robust-and-
  trustworthy-approach-to-health-data-research-and-
  innovation-across-the-uk/

- 2022 artificial intelligence (AI) update publication
  https://www.nice.org.uk/about/what-we-do/our-
  programmes/evidence-standards-framework-for-digital-
  health-technologies#ai-update

- National AI strategy
  https://www.gov.uk/government/publications/national-
  ai-strategy

- Data protection and digital information bill
  https://bills.parliament.uk/bills/3322

- BSI White Paper – Overview of standardization
  landscape in artificial intelligence

- EU AI Act
  https://artificialintelligenceact.eu/the-act/

- AI international standards collaborations

- Software and AI as a Medical Device Change
  Programme – Roadmap
  https://www.gov.uk/government/publications/software-
  and-ai-as-a-medical-device-change-programme/
  software-and-ai-as-a-medical-device-change-
  programme-roadmap

Annex 2: Summary institutions and participants engaged in the project

1. **Dan Stoyanov**, WEISS Director

3. **Laurence Lovat**, WEISS Clinical Director

4. **Evangelos Mazomenos**, WEISS Deputy Director for Engagement

5. **Matt Clarkson**, WEISS Deputy Director for Education

4. **Hani Marcus**, WEISS Deputy Director for Translation

6. **Rachael Rodell**, WEISS Quality Assurance Manager

7. **Simon Watt**, WEISS Public Engagement Manager

8. **Phil Wiles**, WEISS Public Engagement Coordinator

9. **Michelle McGrath**, WEISS Communication Manager

10. **Rawen Kader**, Clinical Research Fellow, WEISS

11. **Hannah Spiro**, Head of Public Attitudes, Centre for Data Ethics and Innovation

12. **Aleksandra Herbec**, Scientific Secretary and Head of Secretariat for Independent Review on Equity in Medical Devices, Department of Health and Social Care

13. **Nathalie Carter**, Patient and Public Involvement Manager, NHS England and NHS Improvement

14. **Julian Louis**, Project Support Officer, NHS England and NHS Improvement

15. **Sandra Nwokeoha**, Manager, AI Award, NHS England and NHS Improvement

16. **Georgious Onisiforou**, Research Manager, NHS AI Lab

17. **Nisha Shah**, Researcher in Social Science, Centre for Health, Law and Emerging Technologies (HeLEX) at University of Oxford

18. **Xiaoxuan Liu**, Clinical Researcher, Institute of Inflammation and Ageing

19. **Joe Alderman**, AI and Digital Health Clinical Research Fellow, Institute of Inflammation and Ageing

20. **Ellen Coughlan**, Programme Manager, Health Foundation

21. **Lara Grooves**, Researcher, Ada Lovelace Institute

22. **Pritesh Mistry**, Fellow, Digital Technologies, The King's Fund

23. **Lesley Booth**, Director of Research and Patient & Public Involvement/Engagement, Bowel Research UK

24. **Urte Macikene**, Policy and External Affairs Manager, Healthwatch England

25. **Rebecca Moore**, Senior Policy Analyst, Healthwatch England

26. **Dee Davison**, Public Engagement Manager, University of Edinburgh

27. **Robin Carpenter**, Senior Research Data Governance Manager, London Medical Imaging & Artificial Intelligence Centre for Value Based HealthomL5c1 Tf⫪f⫪f.R 0 p0 Inflammation and Ageing

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