



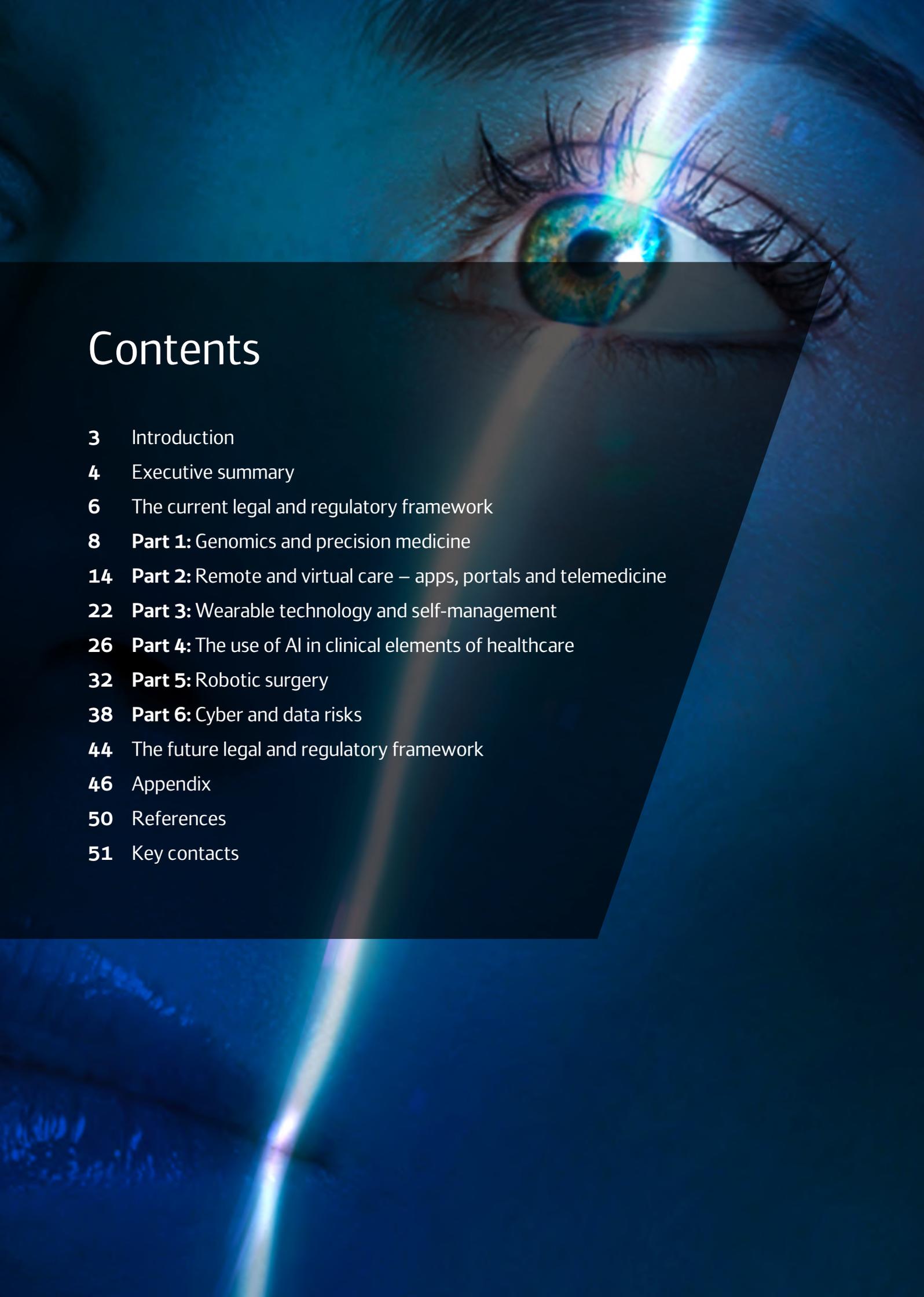
Healthtech in the future

The legal ramifications

May 2021



Kennedys



Contents

- 3 Introduction
- 4 Executive summary
- 6 The current legal and regulatory framework
- 8 **Part 1:** Genomics and precision medicine
- 14 **Part 2:** Remote and virtual care – apps, portals and telemedicine
- 22 **Part 3:** Wearable technology and self-management
- 26 **Part 4:** The use of AI in clinical elements of healthcare
- 32 **Part 5:** Robotic surgery
- 38 **Part 6:** Cyber and data risks
- 44 The future legal and regulatory framework
- 46 Appendix
- 50 References
- 51 Key contacts



Executive summary

Whilst the UK's current legal and regulatory framework provides a foundation for future healthtech developments, it will undoubtedly need to be modified as technological innovation and its application in healthcare continues to evolve.

Modern healthcare is built on the premise that treatment is a shared decision between a doctor and a patient, with the role of technology now increasingly a part of that conversation, with a definite shift towards greater patient autonomy with new virtual healthcare initiatives.

This report considers emerging areas of healthcare and new technology that offer significant opportunities and benefits in the delivery of healthcare, but also present new and significant risks for the healthcare sector. In doing so, we offer our recommendations to help safeguard patients and healthcare professionals against the potential risks that these developments present. Knowledge of the approach being taken by healthcare providers with regard to these developments is essential to ensure the right questions are being asked now to address potential risks.

We anticipate that the role of UK healthcare regulators will need to change, as the use of healthtech within the healthcare sector develops. The Care Quality Commission, NHS Digital, and the Medical and Healthcare Products Regulatory Agency are likely to have a major and collaborative role to play, alongside the newly created NHSX.

Knowledge of the approach being taken with regard to these developments is essential to ensure the right questions are being asked now to address potential risks.



The **complex chain of causation in healthtech** means that the identification of the cause of any harm to a patient is likely to become more challenging.

For the healthcare sector, the key question is the extent to which technological advancements utilised to treat and care for patients will challenge the underlying basis of the legal obligations it currently owes.

For the foreseeable future at least, clinicians are still likely to be making clinical judgements as to patient care and treatment alongside healthtech. The duty of care that will attach to clinicians who utilise healthtech in treating patients is likely to be an issue to be determined by the courts in due course. We anticipate the laws on non-delegable duties of care becoming more sophisticated.



Future proofing to mitigate against the risks that these technological developments bring will require a **multi-faceted approach**.

The complex chain of causation in healthtech means that the identification of the cause of any harm to a patient is likely to become more challenging. We may therefore also see development in the law on causation to facilitate patient redress in circumstances where there are a number of potential defendants, to include healthcare providers such as the NHS and private healthcare providers, and where the exact cause of harm cannot be identified.

Increasing implementation of genetic profiling for precision medicine; the delivery of care remotely in both the primary and secondary care setting; the use of artificial intelligence both in primary care and clinical elements of healthcare; wearable technology; and robotic assisted surgery – require a new focus on legal liability.

Summary of recommendations

Future proofing to mitigate against the risks that these technological developments bring will require a multi-faceted approach, including:

- The need for increased training for healthcare provider staff to ensure that risks to patients are anticipated and minimised.
- A robust approach to limitation of liability through the negotiation of contracts and license agreements with developers/producers/manufacturers/other third parties, to ensure appropriate indemnities are in place.
- Investment in IT infrastructure and cyber protection to minimise risk of data breaches and unauthorised data capture.
- Increased investment in healthcare provider's hardware and infrastructure at every level.
- Appropriate regulation and accreditation will be required for the safe use of new apps, artificial intelligence, wearables and robotics in the treatment of patients.

It is hoped that the UK government will take steps through appropriate regulation to help protect healthcare providers from significant exposure to risk and compensation payments due to healthtech. However, balance will need to be found to ensure that patients have protection and clear rights of redress where harm arises from a situation in which healthtech has been utilised to treat a patient.

Anticipating the legal risks and planning ahead is essential, particularly as technology moves on apace, and implementation of a regulatory framework that can evolve and adapt as the technology develops, is likely to be a slower process.



Rob Tobin
Partner, Cambridge

t +44 1223 533 095
e rob.tobin@kennedyslaw.com

Kennedys

 kennedyslaw.com

 [Kennedys](#)

 [KennedysLaw](#)

 [KennedysLaw](#)

Kennedys is a global law firm operating as a group of entities owned, controlled or operated by way of joint venture with Kennedys Law LLP. For more information about Kennedys' global legal business please see kennedyslaw.com/regulatory

kennedyslaw.com/healthtech