

TELEMEDICINE: A GLOBAL APPROACH TO TRENDS AND PRACTICES
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LAWS AND REGULATIONS ON TELEMEDICINE
1. Is telemedicine allowed in your country? If so, how is it defined?
<p>Telemedicine is not defined or regulated as such in the UK. The provision of healthcare remotely (including digitally) is seen as one of many means of providing healthcare in the UK. Telemedicine is therefore regulated as an aspect of healthcare provision rather than as a separate activity, although through NHS Digital and other government bodies there is an increasing amount of guidance and standardisation to be mindful of.</p> <p>The lack of direct structured regulation has allowed the provision of healthcare in the UK to adapt to providing telephone and video consultations as a matter of course. The use of apps and texts to patients with links to forms and authorisations for consultations and treatments, as well as ordering repeat prescriptions and the provision of digital prescriptions directly to pharmacies is now built into the UK healthcare system for those able to use a mobile phone.</p>
2. Please provide a high-level overview of the legal framework regarding telemedicine in your country.
<p>The statutory basis for structure of the National Health Service (NHS) is mainly found in the Health and Social Care Acts 2008 and 2012 and amending provisions (HSCA). The HSCA does not though dictate the methods of providing the health service, which can be determined by the providers themselves. The HSCA mandates that the clinical safety standards DCB0129 and DCB0160 must be complied with to sell products into the NHS. These require manufacturers to have a systematic approach to clinical risk management and documents and processes for documenting and reporting hazards. The manufacturer must have a Clinical Safety Officer (CSO) who is involved in the clinical risk management, who is clinically qualified and has undergone specific training with NHS Digital. If the product requires clinicians to operate it, then all involved clinicians must be notified to NHS Digital together with the professional registration details. It is also necessary to supply evidence of the origin of clinical reference sources.</p> <p>The provision of healthcare as a service is regulated in the UK by the Care Quality Commission (CQC).</p> <p>Pharmacies dispensing medicines via electronic prescriptions without seeing either the patient or the prescriber are said to be 'providing services at a distance'. All pharmacies, including services provided at a distance, are regulated by the General Pharmaceutical Council (GPhC). Individuals providing healthcare are regulated by their professional bodies as follows:</p> <ul style="list-style-type: none">• doctors are regulated by the General Medical Council;• nurses are regulated by the Nursing and Midwifery Council;• pharmacists are regulated by the GPhC; and• dentists are regulated by the General Dental Council (GDC) <p>Each of the CQC, the GPhC and the professional bodies have provided guidance on the provision of services via telehealth or distance services.</p> <p>If the means for providing telemedicine or any part fits the definition of a medicine or a medical device, they must comply with the UK laws relating to medicines or medical devices, as applicable, or EU laws with respect to their use in Northern Ireland.</p>

3. Briefly identify the key licensing bodies for telemedicine and outline their responsibilities.
As stated above, telemedicine is not separately regulated and therefore the licensing bodies for the provision of healthcare and the individuals providing that care are those set out at Question 2.
4. Was telemedicine authorized during the Covid-19 pandemic?
Telemedicine was already operating in the UK prior to the Covid-19 pandemic, which has accelerated its use both in general practice and in hospital medicine. The NHS provides its own app through which the individual's Covid vaccination status can be downloaded for travel, appointments can be made with their general practice (GP) doctor, and repeat prescriptions ordered. It also contains a record of more recent healthcare interactions, including prescriptions since 2000, test results, GP notes and documents such as letters from consultants and allows the booking of Covid-19 vaccinations.
5. Is there any possibility of the regulatory landscape being changed in the post-pandemic scenario? Or has there been already a change in the regulation in the post-pandemic scenario?
<p>Because telemedicine was already in use in the NHS, no changes were required to regulations in order to provide healthcare via telemedicine solutions. In January 2021, the Department of Health and Social Care published a guide to good practice for digital and data-driven health technologies: A guide to good practice for digital and data-driven health technologies (https://www.gov.uk/government/publications/code-of-conduct-for-data-driven-health-and-care-technology/initial-code-of-conduct-for-data-driven-health-and-care-technology#principle-1-understand-users-their-needs-and-the-context).</p> <p>However, the government through the Medicines and Healthcare products Regulatory Authority (MHRA) is currently consulting on the use of medical devices to provide healthcare services from outside the UK (distance selling). It is possible that there might be changes in that area, potentially adding some restrictions.</p>
6. What types of teleservices are allowed? (e.g. second opinion, teleconsultation, telediagnosis, telesurgery, among others)
Physicians are permitted to use their own judgement on the methodology for the provision of their services. They are required to assess that methodology according to the General Medical Council (GMC) standards of good medical practice.
7. Who can use telemedicine services? Please indicate if whether only doctor-doctor or also patient-doctor remote medical services are allowed.
<p>General practice doctors and hospital doctors frequently engage with patients by telephone. Indeed, unless there is a reason to see a patient in person, a telephone call is often the preference.</p> <p>The provision of doctor-doctor services, for example, the reading of images overnight by radiologists in another country, has been commonplace for some years. Doctors providing this service to patients in the UK from other countries must be GMC registered.</p> <p>Remote services by video call are also offered by private providers of GP services, some of whom have been contracted to provide this service to NHS patients.</p>
8. Please outline the funding model for telemedicine. Is it available in your jurisdiction public health system? Is telemedicine under mandatory insurance coverage? Please indicate what legislation applies.
<p>The UK's NHS is free of charge at point of use if UK residency requirements for the patient are met. Where telemedicine is used in the NHS, it is provided in the same way as any other NHS medical service.</p> <p>Apps, software and online platforms intended to benefit people's health or care with medical, health or wellness or system efficiency goals can be subject to review by the National Institute</p>

for Health and Care Excellence (NICE) which has published <i>Evidence standards framework for digital health technologies</i> . This is essentially a health technology assessment, but its use is optional.
9. Please indicate whether any insurance requirements applicable to telemedicine services providers.
<p>The UK has no insurance requirements that are specifically applicable to telemedicine services providers. However, there is a statutory requirement for individual doctors and nurses to have insurance or indemnity provision. For doctors and nurses working in the NHS there is indemnity coverage provided by the following bodies:</p> <ul style="list-style-type: none"> • In England, through the Clinical Negligence Scheme for Trusts (CNST), administered by the NHS Litigation Authority. • In Wales, indemnity is provided by Welsh Risk Pool Services. • In Scotland, indemnity is provided by the Clinical Negligence and Other Risks Indemnity Scheme. • In Northern Ireland each HSC Trust assumes the role, funded by the Department of Health, Social Security and Public Safety. <p>Doctors and nurses providing their services privately must have insurance or indemnity provisions in place.</p>
REQUIREMENTS APPLICABLE TO HEALTHCARE PROFESSIONALS AND INSTITUTIONS
10. Who can practice telemedicine in your country? Please indicate whether other healthcare professionals are authorized to provide remote health services under the applicable rules (e.g. nurses, psychologists, nutritionists, alternative health therapies providers, etc.)
As telemedicine is an integrated part of the healthcare system its use is applied by any healthcare professional where the technology is suitable for their practice.
11. Are there any specific education requirements or trainings that healthcare professionals need to meet or attend to provide telemedicine services?
<p>The usual professional requirements apply to the provision of healthcare via telemedicine services as with any other type of healthcare. By way of example, the GMC requires that registered doctors: keep their professional knowledge and skills up to date; and recognise and work within the limits of their competence.</p> <p>Therefore, if the telehealth service or technology necessitates training or additional knowledge for proper use or application, it is for the individual physician to ensure that they obtain that training or knowledge before using the service or technology.</p>
12. Is there any registration requirement applicable to physicians that provide telemedicine services?
All physicians providing healthcare to patients in the UK must be registered with the GMC. There are no additional requirements for physicians that provide telemedicine services.
13. Please indicate whether special licenses or authorizations are mandatory for institutional healthcare providers engaged in telemedicine services.
Under the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014, 'transport services, triage and medical advice provided remotely' are regulated activities. In England the CQC considers the activities of telemedicine providers to fall under this. Providers must register with the CQC and satisfy it that they meet the requirements of the relevant regulations. This effectively means that telemedicine providers in England are regulated in the same way as face-to-face providers. Registration and inspection in the devolved nations are the responsibility of the following bodies:

<ul style="list-style-type: none"> Healthcare Improvement Scotland (HIS) Healthcare Inspectorate Wales (HIW) Regulation and Quality Improvement Authority in Northern Ireland (the RQIA).
REQUIREMENTS APPLICABLE TO TELEMEDICINE SERVICES
14. Are there specific requirements applicable to the telemedicine platform?
There are no specific requirements applicable to any telemedicine platform as such. There are however standards on data privacy and security (see questions 20 to 23), on data standards for interoperability (see Question 19), on security of patient data (see Question 16).
15. Are there any requirements regarding electronic equipment and internet speed for telemedicine services?
There are no requirements regarding electronic equipment and internet speed for telemedicine services.
16. Does the legislation provide for specific rules concerning patients' medical records?
<p>If patient medical records are to be accessed to supply the telemedicine services, then it is a requirement that the provider provides assurance on data security and the handling of personal information by compliance with the NHS Digital Data Security and Protection Toolkit (NHS Toolkit), which is an online self-assessment tool against the National Data Guardian's ten data security standards. NHS Digital provides a guide on Data Security Standards which is a helpful starting point. The Department of Health and Social Care (DHSC) has also published five guiding principles to ensure that the NHS, patients and the public gain fair benefit from agreements involving the use of patient data.</p> <p>To access the NHS Toolkit assessment organisations must first register and obtain an organisation code (ODS code) via the ODS Portal. Note that this does not apply to telehealth services provided privately. The National Data Guardian has ten data security standards that form part of the NHS Standard Contract with all providers. Completing the NHS Toolkit provides evidence that these ten standards have been met. For web applications, the product should meet the OWSAP Application Security Verification Standard.</p> <p>Most UK healthcare is provided through a central hub of the GP. Any doctor providing a private consultation via telehealth should ask the patient to consent to their contacting that patient's GP to obtain the patient's history and to provide a copy of their advice to the GP. If the patient does not consent to this exchange of information, then the telehealth provider has to consider whether it is safe to provide the treatment.</p>
17. Are there geographic location requirements applicable to the provision of telemedicine services?
<p>There are no specific geographic location requirements applicable to the provision of telemedicine services. However, professional qualification requirements apply so that individuals providing their professional healthcare services to UK residents must be registered with the applicable professional body in the UK (see Question 2).</p> <p>The Academy of Medical Royal Colleges, CQC, Faculty of Pain Medicine, GDC, GMC, General Optical Council, General Pharmaceutical Council, Healthcare Improvement Scotland, Healthcare Inspectorate Wales, NMC, Pharmaceutical Society of Northern Ireland, Royal Pharmaceutical Society, Regulation and Quality Improvement Authority published a joint statement in September 2019. This targets online primary care providers and expresses concern about the provision of online services that might be configured to take the providers of healthcare services to UK residents out of the jurisdiction of the UK regulators.</p> <p>The GPhC notes that for UK pharmacies there are additional risks in working with prescribers who are not registered with the relevant UK professional regulator, but has not prohibited them</p>

from doing so. A UK pharmacy is however required to note and mitigate the additional risks of such an activity, and they are expected to manage these risks. If they are found to be failing in this, regulatory action can follow.

Similarly, the GPhC does not restrict UK pharmacies from supplying individuals in other countries, but states that they should comply with the laws of those countries. The GPhC does not know the overseas rules but would expect to inspect any correspondence on sanctions imposed by regulators in other countries and could act upon this.

Were pharmacies in other countries to supply UK residents with prescription or pharmacy only products they would need to be registered with the GPhC. We have not found any foreign pharmacies to be so registered. This is likely to be because the system of funding pharmaceutical products provided by the NHS makes it uncompetitive to supply such products from abroad without NHS funding.

18. Does the healthcare professional need to obtain patient's consent to engage in a telehealth?

In the UK professional codes are principle based and the same principles of consent and ensuring that the service is appropriate to the needs of the patient apply whatever the method for providing the healthcare service. The GMC has issued guidance on remote consultations. This includes a flow chart to help doctors determine whether remote treatment is appropriate. The GMC highlights that if prescribing remotely is not safe, there should instead be a face-to-face consultation and the patient's consent should be sought on the type of consultation.

19. Is there any other important requirement that should be highlighted?

The GDC has noted the increasing provision of orthodontic treatment directly to patients, with orthodontic appliances being sent directly to the patient's home. The GDC notes that remote consultations are increasingly being provided and states that anyone providing remote consultations must be registered with the GDC. It also notes that a face-to-face interaction or physical clinical assessment is likely to be necessary, but nevertheless the GDC leaves it to the dentist providing the treatment to determine whether they have a full assessment of the patient's oral health and to take responsibility for the patient's treatment.

There are NHS England Interoperability standards hosted by NHS Digital to ensure the ability to provide joined up care. There are also standards on patient/clinical records as set out by the Professional Record Standards Body as well as references for coding clinical data and other datasets used in the healthcare system, including standards mandated for use in the NHS in England through an information standards notice. The NHS has also published the NHS Data Model and Dictionary.

DATA PRIVACY ASPECTS

20. Are there data privacy issues should be considered for the exploitation of such market? If your answer is positive, please provide a short description.

While the UK is no longer part of the EU, its current data privacy laws are a near copy of the EU GDPR, with some differences. Therefore, any telemedicine service must comply with the data protection principles under the UK GDPR. The UK GDPR is supplemented by the Data Protection Act 2018.

Any electronic communications are regulated under the Privacy and Electronic Communications (EC Directive) Regulations 2003 (as amended) which regulate aspects such as use of cookies and e-marketing. Additionally, if the telemedicine service records calls, there is a requirement to comply with the Investigatory Powers (Interception by Businesses etc for Monitoring and Record-keeping Purposes) Regulations 2018/356.

The UK regulator, the Information Commissioner's Office, has issued guidance on compliance as well as codes such as the Data Sharing Code which regulates the sharing of personal data between two or more controllers. The NHS also has a National Data Guardian who oversees the application of the seven Caldicott Principles governing the use of confidential patient data.
21. Does the applicable regulation provide for criteria and requirements for the security systems to protect the patient's information?
See answers to Question 16 in relation to NHS patient data.
22. Does the applicable regulation provide for requirements for the transfer of information abroad?
Personal data may be transferred outside the UK in accordance with the transfer framework set out under the UK GDPR. In most circumstances, where personal data is being transferred between organisations, this will require the parties to enter into a set of approved standard contractual clauses. UK law recognises reliance on the European Commission approved standard contractual clauses so long as the UK Addendum (drafted by the ICO) is appended.
23. Is there any registration of databases requirement that companies must observe? Are there requirements regarding the recording of data in the patient's medical records?
There is a registration requirement on controllers (not databases) to pay a fee under UK law. There is a register of fee payers, but the register does not include a detailed description of data processing that the controller carries out.
See the answer to Question 16 on patient records.
LIABILITIES
24. Please provide a high-level overview of the liability of healthcare professionals and institutions involved in telemedicine practices.
<p>Healthcare professionals' and institutions' potential liabilities include:</p> <ul style="list-style-type: none"> • for death or personal injury due to negligence if they are found to have a duty of care to the patients/users, to have breached that duty of care and which breach has caused the harm; • criminal liability for professionals providing regulated healthcare services to persons in the UK without the required UK professional registration; • criminal liability for the provider and/or its directors for failure to register with the CQC and for other breaches of the rules on the provision of healthcare services; • fines imposed by the UK Information Commissioner for serious data privacy breaches – individuals and organisations can bring third party damages claims if the damage is sufficiently serious. <p>Where services are provided to the NHS, there is a duty of candour imposed on the government/NHS provider to inform every person whose diagnosis or treatment has been potentially affected by breaches of law or duties of care.</p>
TELEMEDICINE NUMBERS AND TRENDS
25. Is there any public disclosed information concerning the use and acceptance of telemedicine in your country?
<p>Statista, 'To what extent would you consider using a digital health service instead of visiting your doctor in person?' 2023 www.statista.com/statistics/1106683/use-of-digital-health-services-in-the-uk/#:~:text=A%20survey%20carried%20out%20in%20the%20United%20Kingdom,with%20doctor%20online%20instead%20of%20face-to%20face%20appointments.</p>

UK Government, 'Telehealth trial shows early success', Department of Health and Social Care', 16 December 2011 www.gov.uk/government/news/telehealth-trial-shows-early-success.

26. What are the perspectives and trends in relation to the matter for the next few years? Please outline any unresolved issues, proposed changes or trends for the telemedicine sector and briefly indicate how these may foreseeably affect medical practice in the near future.

See answer to Question 5.

New legislation regulating medical devices is to be published in spring 2023. We have been promised new and different regulation for software that is used as a medical device and is likely to be a departure from the EU MDR.

UK data privacy laws are continuing to develop independently since Brexit and we are likely to see a revised Data Protection and Digital Information Bill during 2023 which will amend the existing data protection legal framework. Additionally, the UK Government is due to introduce a White Paper on AI regulation during the course of 2023. Assuming such regulation is implemented, it would likely have an impact on any telemedicine services that use AI systems given AI systems that process health data are likely to be considered riskier.