

Regulations & Exemptions during the COVID-19 Pandemic for New Medical Technology, Health Services & Data

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ABSTRACT

The rapid evolution of the COVID-19 pandemic has sparked a large unmet need for new or additional medical technology and healthcare services to be made available urgently. Healthcare, Academic, Government and Industry organizations and individuals have risen to this challenge by designing, developing, manufacturing or implementing innovation. However, both they and healthcare stakeholders are hampered as it is unclear how to introduce and deploy the products of this innovation quickly and legally within the healthcare system. Our paper outlines the key regulations and processes innovators need to comply with, and how these change during a public health emergency via dedicated exemptions. Our work includes references to the formal documents regarding UK healthcare regulation and governance, and is meant to serve as a guide for those who wish to act quickly but are uncertain of the legal and regulatory pathways that allow new a device or service to be fast-tracked.

INTRODUCTION

On 30 January, the World Health Organization (WHO) declared the outbreak a Public Health Emergency of International Concern. On March 11th, WHO characterized COVID-19 as a pandemic [1]. To address the shortfall and need for novel medical equipment, healthcare services and data access and processing, a cooperative innovation race to tackle COVID-19 has been triggered spanning healthcare, industry, academic and charity sectors, as well as many individuals. Taking these efforts to successful deployment is often hampered by perceived restrictions of healthcare regulations. To address this challenge, there are exemptions and processes that innovators and regulatory experts could be unaware of that can drastically accelerate these processes.

In the United Kingdom (UK), the devastating effects of the virus were reported by leading epidemiologists a week later [2], and the Coronavirus Emergency Bill became Act of Parliament on 25th March 2020 [3]. This activated special provisions in existing pieces of UK legislation that govern the powers and duties of regulators during public health emergencies. There are five regulatory authorities in the UK that are important to innovators looking to support the COVID-19 response:

- Medicines and Healthcare products Regulatory Agency (MHRA) is the Competent Authority which regulates safety, quality and efficacy of medical devices placed on the UK market. This includes clinical software, ventilators, equipment used to protect patients, and diagnostic tests.
- Care and Quality Commission (CQC) regulates quality and safety of health and social care services in England. There are similar organisations in Scotland, Wales and Northern Ireland that register and inspect health and care services.
- NHS Health Research Authority (HRA) grants or denies ethics approval for medical research, including clinical trials, often after review from a Research Ethics Committee (REC).
- Information Commissioner's Office (ICO) upholds information rights in the public interest.
- General Medical Council (GMC) and Nursing and Midwifery Council (NMC) regulate medical education and practice standards across the UK for doctors (GMS) and nurses (NMC).

This document will cover the provisions that allow each agency to function with greater flexibility during a public health crisis, and the steps the agencies have taken to facilitate innovation.

MEDICAL DEVICES AND EQUIPMENT

Medical devices and in vitro diagnostic medical devices, including software that has a medical purpose, are regulated by the MHRA, whose duties are set out in the Medical Devices Regulations 2002 [4] and amendments. This agency posts up-to-date guidance for industry [5], and facilitates contact with relevant teams [6].

Emergency Use Authorisations and CE Mark Derogation

Medical devices are CE (Conformité Européenne) marked before they are allowed to be placed on the market or made available (see Figure 1a). In order to do so, they require a clinical evaluation and often a clinical investigation. Medium and high-risk devices need to use a Notified Body to receive a certificate of conformity with the essential requirements of the device regulations [4] (or general safety and performance requirements in [7]). This conformity is often achieved through compliance with

harmonised standards –such as ISO13485 and ISO14971 – and relevant standards applicable to the specific type of device.

MHRA can, where it is in the interest of the protection of health, directly review what evidence is available and allow supply of medical devices that are not in conformity (see articles 12(5), 26(3) and 39(2) in [4]). This is known as CE mark derogation, and it will not change if the new Medical Device Regulations come into force during the pandemic (see Article 59(1) in [7]). In any case, the European Commission is working on postponing this date [8].

Exceptional use authorisations by MHRA (see Figure 1b) are a temporary derogation of conformity that will last for the period of the pandemic. These authorisations are decided on a case by case basis, and confirmation from MHRA is explicitly required in advance to prevent manufacturers from placing unsafe devices on the market. Post-market surveillance still applies, and clinical safety continues to be monitored (e.g. through yellow card schemes [9]) to flag adverse effects and single out counterfeit and poor-performing devices. If necessary, MHRA may impose additional conditions to manage the risks involved, for example the duration or number of devices that may be made available. Devices supplied under an exceptional use authorisation cannot bear a CE mark and should ideally be marked as non-CE marked.

If you have certifications in place and are looking to change the intended use of a CE-marked device, you should not request derogation if the change is only minor and related to treating patients with COVID-19 such as, for example, changing indications from intensive care ward to the general ward. Instead, perform a risk assessment and go straight to your notified body (see Figure 1c).

Note that emergency derogations do not affect clinicians choosing to use devices off label, which is a matter for professional standards regulated by GMC and NMC. Also, it does not apply to custom-made devices or healthcare institution exemptions (see the In-house Manufacturing below), which can both be used as normal.

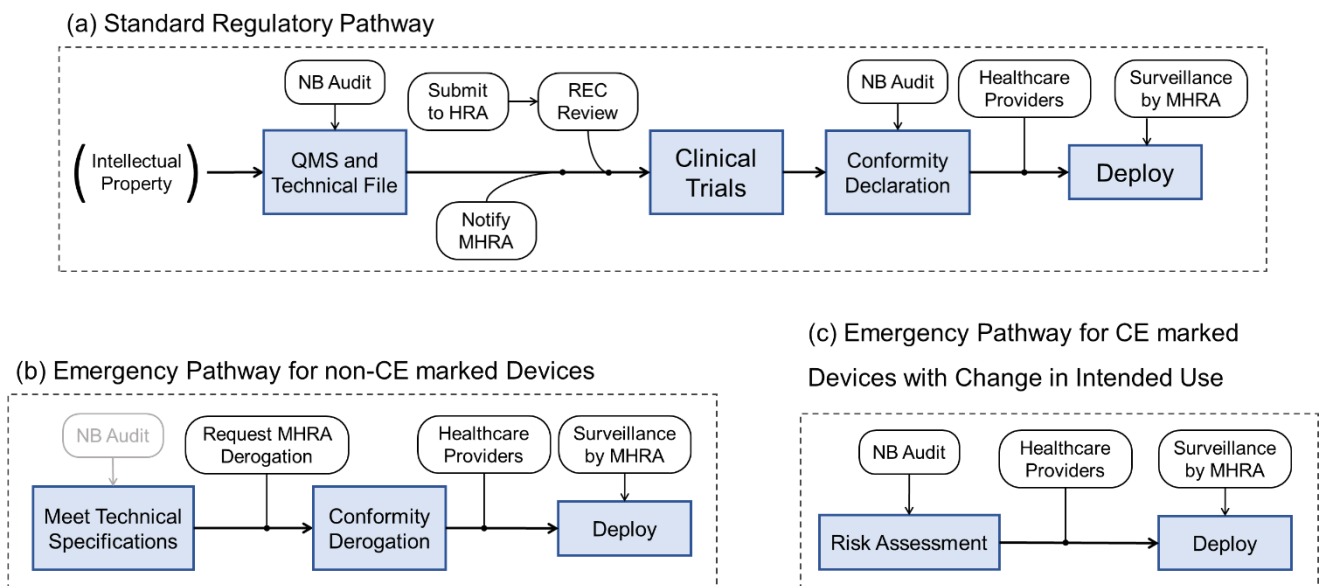


Figure 1. Medical device regulatory pathways. (a) The standard regulatory pathway for CE marking of medical devices. Note that some low-risk devices would not require a clinical study. (b) The pathway that applies during a public health emergency for new devices to be used during the emergency. (c) Emergency pathway for conforming devices with a change to their intended use (e.g. from ward to intensive care). QMS stands for “Quality Management System”. The acronym NB stands for “Notified Body”. It is shown in grey in (b) because it is optional.

In-house Manufacturing

In-house manufacturing refers to the medical devices made by a healthcare institution to be used on its own patients (see Figure 2). The definition of “healthcare institutions” includes hospitals and, in very few cases, institutions that support the healthcare system such as laboratories and public health institutes. Healthcare institutions are not defined as a manufacturer [10], and these are able to build, modify and use devices in-house to address, without commercial application, specific patient needs which cannot be met otherwise ([11], and Article 5(4, 5) in [7]). In particular, when an equivalent CE-marked medical device that could fulfil the necessary function is not available.

To be put into service, an in-house device does not require – and cannot bear – a CE mark but should be managed in the context of clinical governance (i.e., quality and risk management, and performance monitoring) [12]. When the Medical Devices Regulations come into force, in-house manufacturers must meet the relevant general safety and performance requirements set (see Annex I in [7]). Briefly, this annex highlights the importance of the risk-benefit gain for the patient and the device’s conformity to safety principles.

We believe the in-house device regulation route can play a major role in university hospitals with high levels of research, especially for software and 3D-printed devices that can be quickly designed. This would allow innovators within a single university hospital to deploy diagnostic software and 3D-printed visors within its own healthcare institution, as code and raw CAD files can be easily distributed.

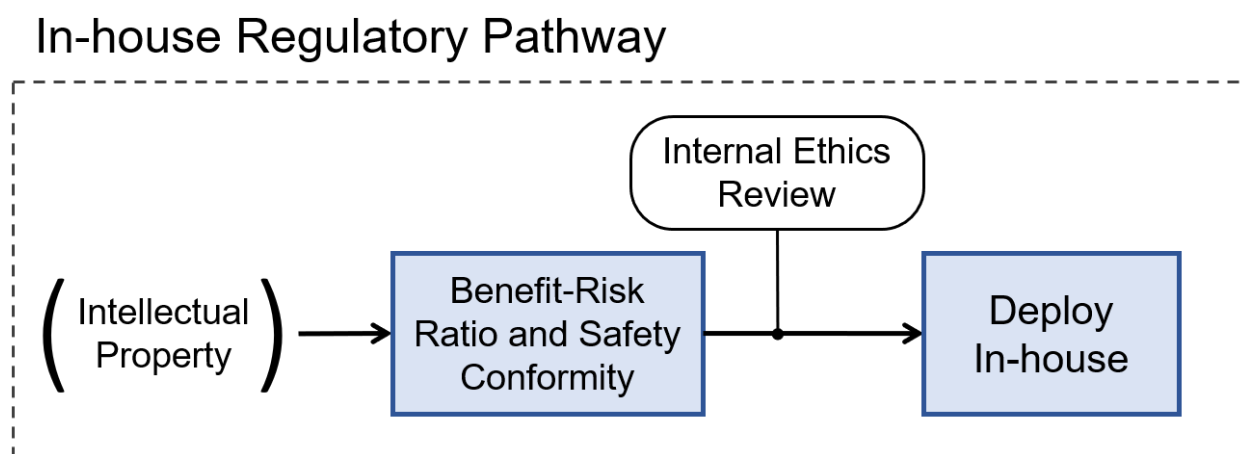


Figure 2. The medical device in-house manufacturing regulatory pathway. This applies regardless of a public health emergency.

Intellectual Property Concerns

One of the main legal concerns of innovators surrounding intellectual property is freedom to operate (i.e. violating the intellectual property of someone else). In the current context, open-source solutions are dominating the machine learning and 3D-printed device / equipment landscape. In the area of software, which is rarely protected, predictive algorithms in medicine are most likely published. Innovators designing basic protective devices and equipment (like gloves and visors) are unlikely to infringe.

However, you are likely to infringe if you reverse-engineer some of the existing ventilators. Although the first ventilators were built in the 1950s and those patents are long expired, these designs are unlikely to meet current safety requirements. If you find yourself potentially infringing in the UK, you should request a license from the owner for the period of the pandemic.

The Patent Act (§60(5)(a) in [13]) does allow for non-commercial private (i.e. personal) use of a patented invention. As a healthcare establishment, if you cannot find an available product on the market you might be able to manufacture it in-house under those grounds.

The other main concern for innovators is how to protect their own inventions. As we have mentioned, the most innovative areas in the COVID-19 pandemic have been extensively and publicly explored, so the scope of protection could be very limited. For a fast and cheap way of obtaining protection, you should consider filing electronically a provisional patent application through the United States Patent and Trademark Office (§111(b) in [14]). For a small fee, this method provides an early effective filing date, allowing you 12 months to convert it to a U.S. patent application and file internationally in the UK.

Regulations in the European Union

Most of the exemptions and requirements covered in this writing stem from European directives/regulations. The MHRA is the Competent Authority in the UK for medical devices, but each Member State has its own authority with similar powers. Most of the things outlined in this document are also applicable to innovators in the European Union.

For more EU-related information, the European Commission has issued a guidance document [15] that touches on many of the same aspects covered by the MHRA and HRA.

Innovation Post-Covid

Bear in mind that when applying for exceptional use authorisation, you must inform MHRA what is the expected time to gain CE certification, so keep in mind the whole device development pipeline.

Devices that enter the UK market by receiving MHRA derogation through an exceptional use authorisation will not be usable when the pandemic has passed unless they are CE marked, including devices which are CE marked that have been modified or whose intended purpose has changed. Of course, if your device is deployed during the pandemic and you have gathered sufficient clinical data, it should be relatively easy to get HRA approval and run a successful trial.

Still, notified bodies have been urged to prioritize and speed conformity assessments for equipment being used to help prevent the transmission of COVID-19, so it could be a good moment to get certifications in place fast.

HEALTH AND CARE SERVICES

The response to COVID-19 requires new registrations of often quite unfamiliar health and social care services. The Care Quality Commission (CQC) regulates organisations providing health and care. They register, monitor, inspect and report on the quality of services by using five key questions: are services safe, effective, caring, well-led, and do they respond to people's needs.

The CQC – and its counterparts in Wales, Scotland and Northern Ireland – have responded by adapting their approach to regulation [16] and most have ceased routine inspections and established fast track registration processes so that they are not a barrier to increasing capacity to care at this critical time. Providers seeking to expand their services in new sites or those seeking to establish a health or social care service will be prioritised according to the needs of commissioners seeking to increase capacity to care.

The CQC is also developing an emergency support framework that reflects its stated mission to “support providers to provide high quality care and keep people safe”. The emergency support framework will focus on services being Safe and Well-Led. The CQC has also released paid staff to work directly on the public health response to COVID-19 or in the health and care system, and is working with national and regional incident centres to aggregate insights from across the sector. This insight is used to support health and social care systems as well as to inform the regulatory response. Counterpart regulators across Scotland, Northern Ireland and Wales are taking similar approaches to supporting their health and care systems.

CLINICAL STUDIES

The important take home message for innovators is that clinical study for a new device is not necessary if MHRA approves conformity derogation. The urgent clinical need the device meets must be justified, for example, with a firm order from a healthcare institution, or advice from the DHSC and other national healthcare bodies. In these cases, MHRA will likely accept a lower level of clinical evidence than it is usually required, like an expert’s opinion or similarity to existing devices. This does not mean that you are exempt from following ethical principles. Quality and safety standards must be in place, and any adverse events should be reported to MHRA when they occur [8].

Any clinical investigation that involves patients will require some form of ethics review before it can be obtained. If this is the case, assessments directly related to the treatment of COVID-19 will receive priority, and authorisation could be granted within a week. For studies not related to coronavirus, MHRA might object to trials starting now if they can place participants at risk of infection. More up-to-date information on clinical trial applications [17] and management [18] can be found on the MHRA website [5].

Research Ethics Committee Requirements

To undertake research in the NHS you must apply to HRA [19] and receive a favourable opinion from a REC to make sure the clinical trial is safe, legal, ethical and fair [20]. The ethical review and the notification to MHRA can progress in parallel via the Integrated Research Application System [21]. In cases related to COVID-19, the HRA can fast-track the review of a study so the REC can scrutinize the trial as quickly as possible (see Expedited Review section below).

Certain types of clinical research can be conducted without REC review. This is the case for research involving information that has been anonymised [22] by an intermediary (§1.3.4(b) in [20]), which highlights the important role that NHS Digital and the health informatics teams in hospital trusts play in making anonymized data available to innovators. Similarly, research involving only staff of health or social care services as professionals (and not as patients) is often excluded from REC review (§2.3.14 in [20]).

Although REC review is not necessary in the above situations, all research involving the NHS in England and Wales will require HRA approval. Some research might also require review of funding, recruitment and study protocols.

Expedited Review

The HRA recognises that research for new studies relating to COVID-19 may require expedited review (§5.5.1 [20]). The HRA Director of the Approvals Service directly oversees the process to ensure that studies are expedited proportionately. Some of the projects expedited by HRA [23] will also have been

categorised as Urgent Public Health Research Studies [24] by the Chief Medical Officer of the National Institute for Health Research (NIHR). These processes are not interdependent.

Most NIHR expedited COVID-19 research so far has focused on public health studies involving vaccines, drugs and epidemiology [24] as it happened with Ebola [25]. In light of this, we advise medical device researchers not to expect a successful request for an expedited review.

For existing studies, covid-related amendments are reviewed for urgency and expiated appropriately [26]. Non-substantial amendments only require the authorization of the sponsor, marking them as COVID-19 amendments for expedited review. Everyone involved (researchers, sponsors, and healthcare providers) should examine their processes carefully and decide if recruitment should be paused or if trial visits be continued safely for already-recruited patients.

Informed Consent

In the context of a public health emergency, the General Data Protection Regulation (GDPR) has provisions for processing special category data without the need for explicit consent (Chapter II, Article 9(2)(h) and (i) in [27]). The HRA has published guidance on seeking consent for COVID-19 research [28].

To carry out an intervention in a clinical emergency situation without prior consent (note this is not the same as a public health emergency), a number of conditions must be met (see Article 68(1) in [7]). Many of these will not apply to the devices commonly seen in the COVID-19 epidemic, except for when the patient requires urgent use of assisted ventilation. Generally, after the intervention, the subject still has a right for their data to be excluded from the investigation. However, this right to data erasure does not necessarily apply for public health threats, as covered in the Data Governance section below.

With respect to the means of obtaining participant consent, the MHRA and HRA have published a joint statement on seeking consent by electronic methods [29]. Electronic methods may be used to confirm and document informed consent, and information sheets can be provided electronically. This method of communication is particularly useful for developers of software apps, and from a public health perspective to help reduce transmission.

DATA GOVERNANCE

Due to the COVID-19 health emergency, the ICO has recognized that the need to share information quickly could lead to data protection practices that do not meet the usual standards [30]. Taking into account the interest of public health, it has clarified that data protection law and enforcement will not be directed to penalise organisations.

Furthermore, data protection and electronic communication laws do not stop the NHS or health professionals contacting individuals in relation to COVID-19 without prior consent. Also, the General Data Protection Regulation (GDPR) (Article 9(2)(h) and (i) in [27]) and the Data Protection Act (DPA) [31] allow healthcare providers to collect and share personal data to protect against serious threats to public health, and to use technology to facilitate diagnosis or treatment.

The ICO and NHSX guidance indicates that the risk of damage, harm or distress being caused to individual patients and service is to be balanced with the benefits of the use of that data for improved services [30], [32]. They strongly encourage those dealing with personal confidential data to conduct a Data Protection Impact Assessment [33], even if it is just the general principles of how they will use

and store that information to make sure it is safe. They also state that the principles of the GDPR (Article 5 in [27]) should continue to be followed.

For the social care sector [34], NHSX has pointed out that mobile messages (including commercial messaging apps), videoconferencing, and working from home with your own device are allowed. Caregivers should try their best to use secure emails provided by NHS and encrypted communication channels, and avoid storing people's personal/confidential information in their own hard drives. This information, related or not to COVID-19, must be transferred to the health record as soon as possible and be deleted from personal servers.

Furthermore, individuals' requests for personal data erasure do not apply when the data is being used for their own medical benefit and/or the benefit of public health (Article 17(3)(c) in [27]). Note that these exceptions to data rights only apply to healthcare providers and government bodies, which again stresses the need for innovators in data science to work closely and in good relationship with hospital trusts.

NHS Digital as the Data Controller

In a notice from the Secretary of State [35], and following the National Health Service Control of Patient Information Regulations (§3 in [36]), NHS Digital has been given the permission and responsibility to disseminate confidential patient information in respect of which it is a controller of that data.

Additionally, the NHS has been tasked with collecting and analysing data, and develop systems to deliver services in connection with COVID-19 [37] according to the Health and Social Care Act 2012 (§254(1) and (6), §260 (2)(d), and §261(1) and (2)(e) in [38]). Following this notice, HRA has issued guidance on how use this patient data without consent [39].

Finally, although unlikely to happen, the UK can legally restrict the scope of the data obligations and rights to protect against serious public health threats (Article 23(1)(e) in [27]).

CASE STUDIES

Ventilators and CPAP Systems

A set of devices that are in short supply are systems for assisted ventilation. Manufacturers of these devices will first require approval from the Department of Health and Social Care (DHSC) by contacting ventilation.challenge@dhsc.gov.uk. Once the DHSC has granted approval, you can apply to MHRA for exemption from conformity assessment.

During the design process, innovators should address the technical specifications set by the DHSC for ventilators [40] and continuous positive airway pressure (CPAP) systems [41]. These specifications refer to IEC and ISO standards, which the British Standards Institution (BSI) has made freely available [42].

The specifications set ensure the devices meet the essential safety and quality requirements, e.g., the basic ventilation modes and parameter settings, and the use of compatible connectors. With regard to testing, prototypes and final products will require usability testing following ISO62366 (Formative Usability Test), ideally performed by a clinician, which raises the next point.

Innovators should work closely with clinicians in hospitals from the very beginning and throughout the design process. This is not stressed only because it is good design practice, but because they can provide the arguments for clinical need to support the exceptional use authorisation by MHRA.

With respect to 3D printed ventilators, there are significant biological safety and pressurised gas safety concerns. Specifically, the types of plastic and release agents are not known to be safe and the variation in layer adhesion can cause unpredictable weaknesses that are not safe in the presence of pressurised gas. MHRA has mostly ruled out 3D-printed parts in ventilators, certainly in the patient gas pathway.

Protective Equipment

Protective equipment to protect the patient falls within the definition of a medical device [4],[7], including surgical face masks and examination gloves (Class I), surgical gloves (Class IIa), and antimicrobial-coated gloves (Class III). Health innovators should seek exceptional use authorisation by contacting MHRA and showing that the device performs as intended with evidence of bench testing, compliance with recognised standards, and any performance data.

Other equipment to protect the worker, such as general face masks and protective gloves to be used by medical staff, is considered personal protective equipment (PPE) [43] and is regulated by the Health and Safety Executive, not by MHRA. In the current emergency, a CE mark exemption for PPE can be requested to the Department for Business, Energy and Industry Strategy (BEIS).

The required specifications that PPE must follow to receive a derogation have been published by MHRA [44] and by Office for Product Safety and Standards [45]. In addition, the European Commission has made the specifications for medical supplies and protective gear (like masks, gloves, clothing, and filters) freely available [46].

Innovators from hospitals that are in short supply of visors or goggles can rely on in-house additive manufacturing (3D printing) to supply their staff. The design templates and specifications (for example, an STL file for a 3D printed surgical visor) can be designed or downloaded by the hospital which can make the devices on site. The use of this non-certified equipment should be temporary until better alternatives are available. In-house manufacturers should be aware that uncertified equipment cannot claim an intended use (e.g. proper protection of staff).

Some innovators have tried to extend the idea of in-house 3D printing to mechanical parts for device modifications. For ventilator connectors and adaptors, see the Case Study on ventilators above.

Algorithms for Diagnosis and Prognosis

Prognosis and diagnosis tasks include mortality and admission prediction, and rapid diagnosis and triage applications using demographic data in combination with clinical data from chest X-ray images, blood tests and vital signs. We believe that more ambitious devices (e.g. decision-support for adjustment of ventilation settings) might be too complex to design, validate and deploy within the time frames of the emergency.

As a precedent, the MHRA approved a CE-mark derogation for a self-diagnosis algorithm built by the Department of Health [47] during the H1N1 swine flu pandemic of 2009. This diagnostic algorithm, classified as a medical device, was successfully deployed in the UK.

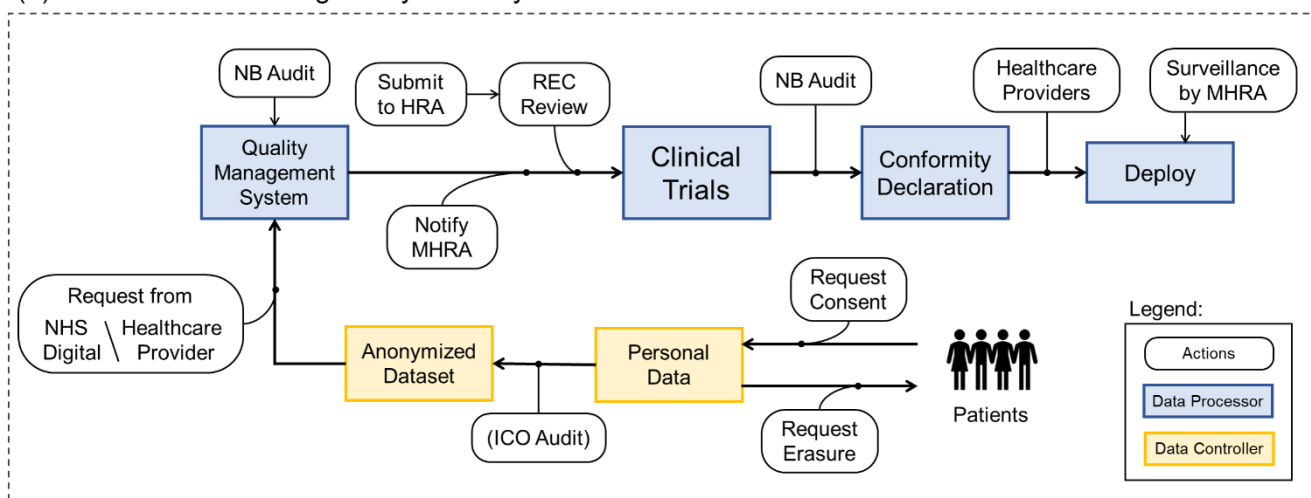
Many times, algorithm development requires access to data. Applicable data regulations have been covered in the Data Governance section above. Under serious threats to public health, data protection

laws allow greater flexibility when it comes to collecting and sharing personal medical information. After internal ethics review, hospital trusts can share their data with innovators that comply with data protection laws to build diagnostic and prognostic tools.

For clinical research involving information anonymised [22] by an intermediary before its onward release to the researchers is excluded (§1.3.4(b) in [20]) from ethics review. If you have this data and have developed a software device (for software classification rules, see Annex VIII 6(1) in [7]), contact MHRA for conformity derogation.

Depending on the claims made and instructions for use, untrained machine learning models could be sent to hospitals which would train them on their own data, therefore “manufacturing”, in-house, their own device. For example, a neural network architecture *per se* is not a medical device as long as it is not intended to be used specifically for medical purposes, but can become one when its weights are adjusted to perform a specific function regarding treatment or diagnosis of a disease.

(a) Software Devices Regulatory Pathway



(b) Emergency Software Devices Pathway

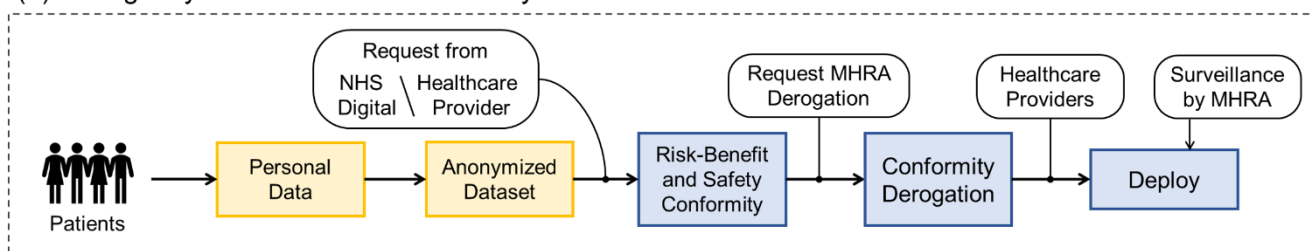


Figure 3. Software as a medical device regulatory pathway. (a) The standard regulatory pathway for CE marking of software devices, including accessing clinical data to build the algorithm. (b) The pathway that applies during a public health emergency. The acronym NB stands for “Notified Body”.

Operations Technology Software

Software that does not act as a medical device, such as video-conferencing solutions, data capture, care records and robotic process automation can be deployed artfully in order to increase capacity. There are no medical device regulatory requirements, but there are standards.

NHS Digital’s Clinical Safety Team establishes guidance for software deployments, DCB0129 and DCB0160 for manufacturers and service providers, that help Clinical Safety Officers in the NHS to ensure that technologies are deployed safely with proportionate governance. These standards require

anticipating and logging risks, monitoring issues during deployment, and listening to concerns so that these issues are resolved.

Further, there are within industry standards that work to protect people. Information Governance toolkits or ISO27001 provide a governance framework that helps organisations to handle people's information appropriately. Cyber Security Essentials [48] helps organisations to prepare for and defend against malicious attacks.

Finally, there are common languages for software used in services (such as HL7) and common data structures (such as SNOMED codes), and a need to integrate systems to support better communication across clinical areas and better coordination of operations.

Social Care Organizations

Social care organisations are not always as digitally mature as their counterparts in health. However, some organisations have demonstrated remarkable improvements to people's health and the efficiency of how care professionals' time is used by digitising and then using the data to drive and monitor service innovation. Interventions have been as simple as ordering glow in the dark markers to reduce the number of slips and trips at night.

Audio monitoring can be an effective way of supporting people at night where they may be struggling in their room and has been used by care homes to improve their sleep and reduce the number of staff required at night. These technologies involving surveillance require careful consultation and implementation in order to be used openly. Covert surveillance is unlikely to be appropriate [49].

CONCLUSION

Our efforts have focused on giving an overview of the changes across the entire regulatory landscape in services and medical devices, two areas where a lot of companies, researchers and volunteers are contributing to from different angles. We have purposefully left out drugs and vaccines: our judgement indicates that this field is under control by experienced researchers in partnership with the clinical trials agencies and big industry.

There are a number of exceptional regulatory provisions that allow for quick deployment of equipment and services required in a public health emergency. These provisions allow the authorities to determine which rules to follow, to where they apply, and the period they are valid for. The agencies have the public's best interest in mind and, because the situation evolves rapidly, innovators of healthcare services and medical devices need to keep up to date with the regulatory changes as they occur.

Government authorities have made themselves available to innovators helping in the COVID-19 emergency. As a result, they are receiving an overwhelming amount of applications. Before reaching out, check if you comply with the established standards and procedures, and applicable regulations. Time is of the essence now.

TABLE OF ABBREVIATIONS

| Abbreviation | Full Name |
|---------------------|---|
| BSI | British Standards Institution |
| CAD | Computer-Aided Design |
| CE | Conformité Européenne |
| COVID-19 | Coronavirus Disease 2019 |
| CPAP | Continuous Positive Airway Pressure |
| CQC | Care and Quality Commission |
| DCB | Data Center Bridging |
| DHSC | Department of Health and Social Care |
| DPA | Data Protection Act 2018 |
| EU | European Union |
| GDPR | General Data Protection Regulation |
| GMC | General Medical Council |
| H1N1 | Influenza A virus subtype H1N1 |
| HL7 | Health Level 7 |
| HRA | NHS Health Research Authority |
| ICO | Information Commissioner's Office |
| ISO | International Organization for Standardization |
| MHRA | Medicines and Healthcare products Regulatory Agency |
| NHS | National Health Service |
| NIHR | National Institute for Health Research |
| NMC | Nursing and Midwifery Council |
| PPE | Personal Protective Equipment |
| QMS | Quality Management System |
| REC | Research Ethics Committee |
| SNOMED | Systematized Nomenclature of Medicine |
| STL | Stereolithography |
| UK | United Kingdom |
| WHO | World Health Organization |

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