1. Introduction

The Novel Coronavirus 2019 (C-19) pandemic, and its impact on people, communities, the economy and health and care services has been unparalleled since the birth of the NHS.

Health and care services are working at a new speed, in new ways, to provide capacity to care and to keep people safe.

As a part of this, we have seen innovators, communities and companies coming together and putting material interests aside to seeking to support the national and international effort. However, we have also seen opportunists trying to profit from the situation in a way that puts people at risk.

We wanted to set out how people can innovate, manufacture, provide services and introduce technologies to support the response in a way that is coordinate, legal and safe.

The Department for Health and Social Care have published an ethical framework for adult social care with 8 principles that we think apply well to the wider national collaboration and mobilisation to support with COVID-19.

Mobilising our collective skills, resources and capabilities is going to be important in how far we can limit the harm from this epidemic, and how quickly we control it. However, we need to mobilise in a way that is coordinated, deploying resources where they will be used best, and focusing energies on what will make the biggest difference. Otherwise, we risk further confusion and complication in our efforts to control the pandemic.
2. How you can help as an individual

If you are an individual, look to your professional networks, the institution you work for, advertised jobs, or volunteer networks either locally or nationally. Advice on how to help safely and local and national opportunities can be found here:


If you have had clinical training in any healthcare profession, NHS bodies have called on you to return to practice during Coronavirus. Details here:

https://www.england.nhs.uk/coronavirus/returning-clinicians/

Returning to work has been made easier by the relevant Professional Regulators (General Medical Council, Nursing and Midwifery Council, Health and Care Professions Council and General Pharmaceutical Council).

3. How you can help as a business

Offering your support through central coordinating bodies will help the government to put resource in the right place in the right way. Where this offer is not taken, coordinate through a local or regional body, or provider of health and care services that appropriate to what you have to offer.

If you are an organisation with capacity or intellectual property that you are offering to government, then use this central form to make your offer clear to decision makers:

https://www.gov.uk/coronavirus-support-from-business
4. Regulation and coordination for new services, devices and technologies

Health and care, and the products, equipment and technologies that support it, are safety-critical. One mistake and someone can be seriously hurt. It is therefore important that we work with our legal and regulatory framework that governs how we provide care in the UK and how we ensure that the products and technologies involved are safe. Regulators are aware that innovation is time critical in the context of COVID-19, and most have made rapid and widespread changes to accommodate this.

4.1 Establishing a new service or site delivering clinical or personal care

NHS health services are commissioned (paid for and organised) by national and local commissioning bodies such as NHS England and Clinical Commissioning Groups.

Social care services that support people with personal care in a home or residential setting, are funded privately or through local government.

All services delivering Regulated Activity must register with the relevant health and care services regulator.

<table>
<thead>
<tr>
<th>Nation</th>
<th>Type of care</th>
<th>Regulator</th>
<th>Exceptions and processes during COVID-19</th>
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<tr>
<td>England</td>
<td>Clinical and personal</td>
<td>Care Quality Commission</td>
<td>Ceasing routine inspections Fast-track process for registering new services for COVID-19 The provision of paid secondments and emergency support for providers</td>
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<td>Northern Ireland</td>
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<td>See here for how to register a service in Northern Ireland</td>
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<tr>
<td>Scotland</td>
<td>Clinical</td>
<td>Healthcare Improvement Scotland</td>
<td>Adapting their approach to regulation, including providing key guidance to services and releasing resource for direct support to services. See here for how to register an independent healthcare service in Scotland</td>
</tr>
<tr>
<td></td>
<td>Personal</td>
<td>Care inspectorate</td>
<td>Ceased inspection activity Accelerated registration processes with a 6 month certificate See here and here for how to register a care service in Scotland</td>
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<tr>
<td>Wales</td>
<td>Clinical</td>
<td>Health Inspectorate Wales</td>
<td>Ceasing routine inspections See here for how to register a healthcare service in Wales</td>
</tr>
<tr>
<td></td>
<td>Personal</td>
<td>Care Inspectorate Wales</td>
<td>Ceasing routine inspections Fast track registration process Relaxing recruitment checks for providers Enabling urgent, temporary social care provision in response to COVID-19</td>
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</table>
4.2 Putting a new medicine or vaccine on the market

The MHRA is the regulator for medicines and vaccines, and they are prioritising work to support and authorise the development of vaccines, clinical trials of new medicines, and helping to manage the supply of medicines and other healthcare products.

The MHRA includes the National Institute for Biological Standards and Control (NIBSC) which plays a role in assuring the quality of biological medicines worldwide. It is developing biological reference materials to support the diagnosis of infection, and evaluate vaccines and treatments.

They have a helpline for COVID-19 applications for clinical trials of new medicines in the UK: clintrialhelpline@mhra.gov.uk

A summary of guidance on marketing authorisations, variations and licensing can be found here.

4.3 Emergency Authorisations for Medical Devices (including clinical software)

The MHRA regulates medical devices across the UK. All medical devices require a clinical evaluation; in many cases, this may require a clinical investigation. Medium and high-risk devices need to use a Notified Body to provide a conformity assessment when placed on the European market. Harmonised standards (European adoptions of ISO standards) may help to show conformity with the essential requirements of the device regulation. Software intended to provide diagnostic or therapeutic information is usually regulated as a medical device.

In the exceptional situation during COVID-19, the MHRA may authorise you to supply a non-CE marked device in the interest of the protection of health. Details including for Personal Protective Equipment (PPE), ventilators, and which government departments to liaise with are here. The MHRA will prioritise applications based on the needs of healthcare providers to increase the supply of critical devices and tests.

Up to date guidance, including specifications for priority devices to be manufactured, and quick guides to placing key devices to support with COVID-19 on the market can be found here.

Where you are seeking to introduce a novel software based medical device to support the response to COVID-19, also email NHS X, who are coordinating technology and software support, at dnhsx@nhsx.nhs.uk

The following medical devices and equipment are in high demand:

<table>
<thead>
<tr>
<th>Type of Device</th>
<th>Contact</th>
<th>Specifications</th>
</tr>
</thead>
</table>
| Ventilators    | ventilation.challenge@dhsc.gov.uk (1st)
devices.compliance@mhra.gov.uk (2nd) | Here, and Summary. |
| CPAP Systems   | OPSS.enquiries@beis.gov.uk | Here. |
| PPE for staff  | devices.compliance@mhra.gov.uk | Here. |
| PPE for patients | OPSS.enquiries@beis.gov.uk | Here. |
| Test kits      | Devices.Regulatory@mhra.gov.uk | Here. |
4.4 Working across services to improve and reconfigure care in response to COVID-19

Local government officials, members of local health funding bodies, and leaders across health and social care organisations have historically faced constraints to pooling resources, information and problems in order to improve the way that services work.

Local Resilience Forums and Academic Health Science Networks are available in each area to coordinate the local response and efforts to provide care and protect people from harm.

National resources may be forthcoming from places like the Health Foundation where they are considering how they can best support the system to adapt.

Finally, the Information Commissioners Office (ICO) have clarified that people should take a proportionate approach, rather than let legalistic approaches to data protection frustrate an important response to COVID-19. They have a contact number 03031231113 to discuss people’s concerns, and a blog to discuss information governance for new community and voluntary groups.

In this context the flow of data becomes a critical factor in lubricating the COVID-19 response to COVID-19. In this context the GDPR has provisions for processing special category data without the need for explicit consent in article 9 (2), including when it is necessary for the purposes of preventative or occupational medicine, or for reasons of public interest in the area of public health. The NHS-X information governance board has acknowledge that data regarding the Covid-19 outbreak should be shared as needed to support individual care and to help tackle the disease through research and planning during the Covid-19 situation. 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 (https://www.nhsx.nhs.uk/key-information-and-tools/information-governance-guidance). Similarly the ICO recognises the unprecedented of the COVID-19 pandemic that a proportion response should be considered and risks balanced with benefits (https://ico.org.uk/for-organisations/data-protection-and-coronavirus/).

4.5 Offering professional services to support the response

Professional services to support with the management, coordination and delivery of national and local efforts to respond to COVID-19 are being offered and accepted across government. These can come in the form of voluntary or trades associations, or paid staff secondments from your organisation where there are transferrable skills. This can be offered locally or nationally, for example to NHS X for technology and software deployment support through dnhsx@nhsx.nhs.uk.

4.6 Conducting applied scientific or public health research

The NIHR has established a single, national prioritisation process for COVID-19 research to prevent duplication and ensure that health and care resources are protected, and maintain a live list of COVID-19 studies that have been given urgent public health research status by the Chief Medical Officers for England.

The Health Research Authority grants ethical approvals for health research in the United Kingdom. They have established an expedited review process for studies relating to COVID-19 for ethical approval and for review from the Confidential Advisory Group on studies that will involve using confidential patient information without consent. Existing studies that can be amended to address COVID-19 elements.
Conclusion

We are faced by a fast spreading and deadly virus that has disrupted and touched everyone’s life in our country. In order to protect people, we will need to mobilise resources effectively. To do this, we encourage people to step forward, and to do so in a way that helps to keep people safe, and best supports the national response.

This document was prepared with the help of Ignacio Albert Smet and Aldo Faisal at the UKRI Centre in AI for Healthcare at Imperial College. Aldo Faisal acknowledges funding from NIHR Imperial College BRC, UKRI and Research England towards this project.