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# ETHICAL FRAMEWORK

## THE JUSTICE OF PANDEMIC BIOMEDICAL RESEARCH PRIORITIES

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### Key Points

- From March to May 2020 non-COVID biomedical research was largely paused.
- In May 2020 there was a “restart” of normal research activity, but COVID-19 research was still prioritised.
- In May 2021 the aim changed from being a “restart” to being a question of “managed recovery.”
- This has had substantial implications for several stakeholder groups, with complex trade-offs and harmful consequences.
- A justice-based ethical framework provides the clearest lens to understand these implications.

*At the outset of the COVID-19 pandemic, a series of both practical and policy decisions led to the large-scale pausing of biomedical research in the UK. This document outlines a timeline of key events and some of their main consequences. It uses this to highlight key ethical considerations that should have been incorporated into policy and decision-making processes about pausing such research. I suggest that a justice-based framework is the best approach to framing and determining questions of biomedical research prioritisation, both contemporaneously and in hindsight, and show how the ethical considerations of the pandemic response of the biomedical research sector can be viewed against such framing.*

### Setting the Stage

In March 2020, when the WHO declared a pandemic in response to the SARS-CoV-2 outbreak (Ghebreyesus, 2020), there was a sudden impetus to develop and fund clinical research into the novel virus. Little was known about COVID-19, including in terms of diagnostics, treatment and vaccination. There followed a great swell of research across the globe, with governments, academics and the pharmaceutical industry all working together to develop

solutions to problems posed by COVID-19 (ABPI, 2021).

In the UK, as elsewhere, many clinical trials into other diseases were paused to prioritise COVID-19 research and ensure optimal management of COVID-19 patients. This allowed the UK to produce world-leading research on COVID-19, for example in the RECOVERY trial, which “represents a paradigmatic example of the way that well-designed research can be used to structure pandemic response and to generate the evidence needed to quickly eliminate unsafe or ineffective strategies and concentrate efforts on those with substantive clinical value” (London, 2022, p. xv).

But this decision to pause non-COVID-19 research was not without its consequences. By the end of April 2020, almost 90% of non-commercial research funded by the National Institute for Healthcare Research (NIHR)—the largest national clinical research funder in Europe—had been paused (Iacobucci, 2020). Non-COVID-19 research studies were paused in over 40% of NHS Trusts during the first wave of coronavirus (NIHR, 2020a).

Since summer 2020, the Department of Health and Social Care (DHSC), NHS England, NHS R&D Departments, the NIHR Clinical Research Network (CRN) and others across the clinical research sector have been working to return the UK's research portfolio to a position of balance and diversity (UK Clinical Research Recovery, Resilience and Growth programme, 2022). There has been some success in targeted areas, but unlike other countries, the UK struggled to recover research to pre-COVID levels (ABPI, 2021). Emphatically, the decision to prioritise COVID-19 was a values-based decision; a question of social justice. And it is one, as indicated, that has had a multitude of ethically-significant consequences; some foreseen, others not.

Below is a timeline of the decisions during the pandemic to prioritise COVID-19 research over research into all

other diseases and then to later try to “restart” UK clinical research. The timeline ends with the shift from “restart” to “recovery” rhetoric, an acknowledgement by the UK government that a multi-million-pound investment and long-term planning is necessary to secure the future of UK research and a new phase of closure of under-performing studies. The purpose of this ethics review is not to question the decisions, extemporary as they were, in a time of global crisis. Instead the aim is to highlight the ethical implications of the decisions, some only visible in hindsight, that should have formed the contextual background of the decision-making process. The review is accordingly intended both to assist understanding and evaluation of decisions that were made in the past, and to assist with ethical preparedness and decision-making in the future.

## Timeline

- |            |   |
|------------|---|
| 11/03/2020 | WHO declares Covid-19 a pandemic  |
| 16/03/2020 | NIHR prioritises nationally-sponsored COVID-19 research and asks health care professionals on NIHR-funded projects to prioritise frontline care (NIHR, 2020b).  |
| 17/03/2020 | NHS announces plan to ban elective surgeries and redeploy clinical academics from universities to frontline case (Stevens and Pritchard, 2020a).  |
| 19/03/2020 | NIHR Clinical Research Network pauses site set-up of any new or ongoing studies at NHS and social care sites that are not nationally prioritised COVID-19 studies (NIHR, 2020b).  |
| 20/03/2020 | The Health Research Authority and the Devolved Administrations are fast-tracking applications for COVID-19-related studies. All other applications are being accepted for review but are likely to be delayed (HRA, 2020a).<br>HRA stops applications for undergraduate and master's student projects until further notice. PhD student project applications to continue (HRA, 2020b).  |
| 23/03/2020 | Amanda Solloway MP, Minister for Science, Research and Innovation, writes to UK universities and other research institutions to encourage continuation of research where possible, especially: <ul style="list-style-type: none"> <li>• Science and research which is considered to be of critical urgency or importance – this may be for medical reasons or for reasons of national security</li> <li>• Science, research or technical work where the pausing of activity is either not possible or would severely impede research delivery</li> <li>• Science, research or technical work which requires ongoing maintenance and supervision activity – this may be for reasons of regulatory, legal or health and safety or other on-going requirements (Solloway, 2020)</li> </ul> |

26/03/2020	COVID-19 Urgent Public Health Research is nationally centralised and prioritised through NIHR on behalf of the Department of Health and Social Care. Prioritisation decisions are to be made by Urgent Public Health Group. Research to be short-term, aiming to impact public health within 12 months (NIHR, 2020c).
29/04/2020	Second phase of NHS response to COVID-19 is announced. NHS request to restart non-COVID-19 urgent services and potentially some routine elective care (Stevens and Pritchard, 2020b).
21/05/2020	<p>NIHR publishes Restart Framework: The key aims of the framework are to guide the:</p> <ol style="list-style-type: none"> <li>1. Restart of paused NIHR research that was underway in the health and care system prior to the COVID-19 'surge',</li> <li>2. Commencement of 'new' NIHR research, and</li> <li>3. Prioritisation of resources in the NIHR Clinical Research Network (CRN) and NIHR infrastructure more broadly.</li> </ol> <p>Where restarting research leads to competition for scarce resources, COVID-19 is to still be prioritised accordingly: Level 1: Essential studies providing evidence for pandemic management, i.e. nationally prioritised COVID-19 Urgent Public Health (UPH) Research studies. Level 2: Studies where the research protocol includes an urgent treatment or intervention without which patients could come to harm. These might be studies that provide access to potentially life-preserving or life-extending treatment not otherwise available to the patient. Level 3: All other studies (including new COVID-19 studies not in Level 1). (NIHR, 2020d).</p>
28/05/2020	A UK-wide group of clinical academic trainee funders, including the NIHR, publishes a series of principles to support those returning to clinical academic roles (NIHR, 2020e).
7/07/2020	Guidance is issued by government and NHS England on how organisations can recover the cost of research staff who were loaned/redeployed at the beginning of the pandemic (NIHR, 2020f).
20/09/2020	UKRI issues advice on switching currently held research funding to COVID-19 priority areas (UKRI, 2020).
12/10/2020	As a second wave of coronavirus approaches, NIHR states staff on NIHR-funded projects should be redeployed to the front line only in exceptional circumstances. Restart Framework to continue unchanged in second wave (NIHR, 2020g).

23/03/2021	UK government sets out a “bold vision for the future of clinical research delivery” in its ‘Saving and improving lives: the future of UK clinical research delivery’ policy paper (DHSC, 2021a).
24/05/2021	NIHR moves away from Restart Framework, and issues new guidance on Managed Recovery, with an intention to ensure restoration of “a rich and balanced research portfolio.” COVID-19 research is to transition from being treated as a priority to being treated as “a speciality alongside others as part of a diverse portfolio”.
	The guidance “calls for a coordinated effort across all partners to support the recovery of the portfolio in the national interest.” (NIHR, 2021).
23/06/2021	UK government issues ‘The Future of UK Clinical Research Delivery: 2021 to 2022 implementation plan’ backed by over £64 million of dedicated investment (DHSC, 2021b).
22/03/2022	Letter from DHSC updating plan to ‘revitalise’ the NHS research by critically examining portfolios to identify studies which require closure because they “are not viable in the current context” in order to give as many studies as possible the chance of completing and yielding results (Chappell et al., 2022).
20/04/2022	HRA issues guidance for sponsors reviewing and closing studies in response to DHSC letter of 22/03/2022 (HRA, 2022).

## Asking Questions

Having broadly established what went on in biomedical research during 2020 and beyond, the remainder of this document asks what the ethical implications of these decisions were. The decisions of most relevance are those to pause non-COVID research and the reallocation of health care professionals to frontline care. These decisions triggered a need to actively attempt a “recovery” of the biomedical research industry as well as affecting countless patients and clinical staff on an individual level. In order to consider the ethics of these decisions, it is necessary to adopt a suitable ethical framework for biomedical research, particularly one that focuses on justifications for and potential obligations to undertake such research. Once a workable framework is identified, I go on to examine how it can be used to discern ethical considerations for the main stakeholder groups involved in biomedical research: the NHS, the patients and the researchers.

## What are the justifications for clinical research? Is there an obligation to conduct research?

Forgetting the pandemic for a moment, in order to properly think about questions of prioritisation, it is first important to understand the ethics of clinical research on a broad scale. Modern standards of research on human subjects can be traced back to the Nuremberg Code. This was the first international code of ethics for research on human subjects, adopted in 1947 in response to Nazi atrocities (BMJ, 1996a). This, and the following Helsinki Declaration (BMJ, 1996b), both lay down guidelines that aim to ensure that any given piece of biomedical research is conducted ethically. The main ethical considerations are accordingly the concerns that are more familiar within medical- and research ethics: risk to the patient/participant, informed consent, use of appropriate scientific method and so on. Codes of biomedical research need to balance tensions between employing the scientific method and not treating humans merely as objects of scientific inquiry. As such, the focus of most biomedical ethical literature is concerned with how to conduct

research. However, it cannot be inferred from such rules whether or not the research ought to be carried out at all, the question of why rather than how. Their silence regarding the justifications (or lack thereof) of biomedical research therefore means standard biomedical research ethics do not give any hints as to how to prioritise between different subjects for research.

Whether there is an ethical imperative to do medical research on humans has been a question in the background of research ethics over the last century. The idea of such an imperative formed part of the proposed but rightly rejected defence of Nazi doctors. For example, Dr. Karl Brandt argued that human experimentation must be undertaken for the common good, that “the demands of society are placed above every individual human being as an entity, and this entity, the human being, is completely used in the interests of that society” (Tribunals 1949, 29). Partly in backlash to this, orthodox research ethics in the last 70 years has largely rejected the idea that there is a social imperative to undertake biomedical research. It is permitted; but it is not based on a duty that can be used to justify the subjugation of individual rights such as autonomy.

Hans Jonas was influential in expounding this view and his reasoning is highly relevant to the question of research prioritisation. Central to Jonas’s argument is that most common illnesses, such as “cancer, heart disease, and other organic, noncontagious ills,” do not pose a threat to the common good but are part of the normal fabric of human life on which society is predicated (Jonas, 1969). Any one individual is threatened by illnesses, but not society as a whole. Therefore, he concludes that while individuals may privately desire medical progress for their own purposes, it is an individual rather than a common good and thus there is no societal obligation to pursue research into cancer, heart disease and other noncontagious ills.

It is notable how this argument only applies to noncontagious conditions. Jonas suggests that these are fundamentally different to contagious conditions wherein an individual poses a threat to “the whole condition, present and future, of the community.” A pandemic then, may create a state of emergency “thereby suspending certain otherwise inviolable prohibitions and taboos” (Jonas 1969, 229). On this basis it would have been justified, indeed potentially essential, to stop most biomedical research (which society was not under a duty to undertake) to address the pandemic which does threaten the common good; society “cannot afford to let an epidemic rage unchecked.”

There is a clear tension in the position explained above. There is a genuine and reasonable fear of using the common good to justify a moral imperative to undertake biomedical research, given the historical context of such claims. But there are also genuine circumstances where social order can only be saved from threats by such research. The ethical strength of “common good” arguments for biomedical research stands and falls on who and what is defining ‘the common good’, if it can be antithetical to individual interests then it is a powerful and dangerous tool. In the current English context, it is worth noting that research is acknowledged within the NHS constitution as integral to achieving its goals and standards (DHSC, 2021c) and there was a call in the Cross sector Health and Care Bill Committee Stage briefing to enhance this to a statutory duty to conduct research. The new Health and Care Act 2022 therefore includes a duty to “facilitate or otherwise promote” health research. The inclusion of such a duty was justified by appeal to the many public benefits of biomedical research within the NHS, such as improved patient outcomes and economic benefits. This represents a very wide conception of the “common good” adopted by the current Westminster legislature, much wider than Jonas’s approach.

The inclusion of a duty to research in recent legislation therefore suggests a very different way of conceptualising the question of research and the common good. Alex John London has convincingly argued that a view such as Jonas’s is based on a fundamental misunderstanding of the relationship between research and the ‘common good’. London accepts Jonas’s argument that there is no moral imperative to undertake medical research as a way of promoting the common good if we think of the common good as some kind of entity that exists in its own right, with interests that can compete with those of individual members of the community. To ground a moral imperative to research, London argues we need to understand ‘the common good’ differently. He points to Rawls’ view that all members of society have the same basic interests and the ‘common good’ is whatever best promotes these. This basic or “higher-order” interest that each person has is to be able to develop and exercise their basic intellectual, affective, social, and physical capacities in order to be able to formulate, pursue, and revise a meaningful life plan, including forming and maintaining relationships of significance with others (Rawls, 2020). More simply put, Rawls’ theory conceptualises justice as fairness, which means that each individual ought to have equal opportunity to develop themselves, plan their lives and pursue those plans. The common good is not in competition with individuals’ interests, instead the common good is the pursuit of fairness.

London takes an approach to health that is strongly influenced by Rawls' theory of justice, like Norman Daniels does (Daniels, 2008):

*"The loss of function associated with disease and disability reduces the range of opportunities open to us compared to what it would be were we healthy or fully functional. By keeping people functioning normally, we protect their range of opportunities."*

Since ill health can hinder an individual's capacity to develop themselves, plan their lives and pursue those plans—since it limits a person's opportunities—it is a matter of justice. Health infrastructure is, therefore, an essential component of a just society. As Rawls himself puts it, provision of medical care is a primary good (Rawls, 2001, p. 174).

Because, therefore, health and health infrastructure are of public interest as vehicles of justice, London suggests that focus on interaction between researchers, participants and governing bodies is too narrowly constrained a view of research ethics (London, 2022, p. 7). He argues that much of the discourse about biomedical research ethics is based on a false and "ineliminable moral dilemma, a conflict between the good of the individual and the good of society, and the belief that an imperative to carry out research threatens the rights and welfare of individuals" (London, 2022, p. 30). While it is generally accepted that the guiding principles of medical ethics: autonomy, non-maleficence, beneficence and justice (Beauchamp and Childress, 2013) are translated across to biomedical research, London argues that within the research ethics literature, justice is minimized and subsumed into the other principles.

By focusing closely on researchers and how they treat their participants, orthodox research ethics has treated research as a largely private activity, (See Jonas, 1969). London suggests this view severs biomedical research from its larger social purposes and the moral obligations of the state to pursue and uphold a just social order. It also obfuscates factors that are relevant to prioritisation decisions in an emergency situation, since those are rooted in the very social purposes and moral obligations that are neglected by this approach. Furthermore, it relies on the idea that health is a fundamentally private concern, and only public if certain limited conditions are met wherein 'the common good', whatever definition is taken by those in power, is threatened. As explained above though, London instead argues for a different, higher-order, understanding of the common good, and thus health, that restores its place in the public sphere but avoids the dangers of subjugating individual interests and rights to it.

London goes on to explain how on this view there is a moral imperative to undertake biomedical research as it is not enough to merely intend the provision of medical care to promote equality, but it must be supported by possession of "the knowledge and the means of intervening in the world to bring about these ends in actual practice" (London, 2022, p. 151). But unlike arguments from the "common good" above, this framework preserves the role of autonomy and beneficence as they flow from an understanding of justice that aims to protect individual's ability to make and carry out life plans.

There is an imperative to undertake biomedical research, generally speaking, in order to ensure medical provision is being provided by society in as effective way possible and it not wasting resources that could be distributed differently. If a doctor does not know whether treatment A or treatment B is more effective, it is better to treat against a background of experiments having taken place and proven efficacy (i.e. practise evidence-based medicine), rather than have half the doctors in the country using the worse treatment through guess work. It is not fair, either to the group who end up receiving the worse treatment by chance, or to others who may miss out on doctors' care because resources were wasted through this inefficient treatment regime. Knowledge is a public good.

Once the focus of ethical investigation of biomedical research is shifted to a justice framework rather than one of individual rights and duties, it becomes possible to consider questions of priority in a much clearer way

## Summary

- Traditionally, research ethics have focused predominantly on how to conduct research ethically, rather than whether there is an ethical imperative to do research. This was partly based on a view of ill-health as a primarily individual matter.
- From this came a received wisdom that while general biomedical research was permissible provided it was conducted ethically, it was not obligatory.
- However, there are reasons to argue both that through coordinated societal efforts we should do research, and that if this is so that we should have methods, based on justice, of saying which research matters more and thus should be prioritised.

## Research Responsibilities and Priorities with Pandemics

Novel situations, like pandemics caused by new viruses, inevitably create large knowledge gaps. As established above, such knowledge gaps concerning medical best practice generate a moral duty for society to undertake biomedical research. Doctors (and governments) are unable to fulfil their duty to act in their patients' (or citizens') best interests if it is unknown what would make a situation better or worse. This is not a new realisation, and is reflected in global research ethics guidelines that preceded the arrival of COVID-19: 'In order to identify effective ways of mitigating the health impact of disasters and disease outbreaks, health-related research should form an integral part of disaster response' (CIOMS and WHO, 2016, p. 75). This need was likewise recognised by the Nuffield Council on Bioethics in their recent report on research ethics in global health emergencies (Nuffield Council on Bioethics, 2020). Accordingly, some sort of emergency COVID-19 research was the ethically-required response to the pandemic. The difficult question this paper aims to shed some light on is whether or not this duty needed to be balanced against duties to undertake other biomedical research, and if such other duty exists, what factors justify prioritisation of one over the other?

The existence of a moral duty to research COVID-19 in the early stages of the pandemic is clear on all of the accounts considered in the previous section. For example, within Jonas's framework a pandemic affects society in a way that is fundamentally different to illnesses such as cancer, and thus constitutes a threat to the common good. There are still ethical considerations to this decision, but they relate more to how to define a threat to the common good, rather than the decision to prioritise COVID-19 research itself. The Nuffield Council's report identifies this ethical responsibility and several "duty-bearers", without extensive examination into what grounds this duty. That is to be expected as the report is largely concerned with how to conduct research ethically. It is taken as a given that there is a responsibility to research global health emergencies, and attention is paid to how to distribute this responsibility across potential duty-bearers was identified, including national governments and local community leaders, intergovernmental organisations, NGOs, Research funders and institutions, and Research Ethics Committees.

The Nuffield Council's report highlights a justice-based approach to allocation of responsibility (See Sen, 2010), however that is only tangentially linked to the question of prioritisation. It can be argued that if you are concerned with prioritisation, you are concerned with justice. Prioritisation can be thought of as asking how the research infrastructure is organised in light of which goals it is pursuing.

*"How the research enterprise is organized is a question of justice because that enterprise calls into action the social authority, institutions, and resources of the state to create a division of social labor that must advance a particular social purpose." (London, 2022)*

Hence it is useful to turn to London's justice-based framework for research ethics. According to London's schema, there is a moral obligation to undertake biomedical research in order to close a particular sort of knowledge gap, and thus to best promote an equitable societal system. There was and is a moral obligation to undertake COVID-19 research, as the illness was and is disrupting the social order to such a degree that, as well as the direct harms of contracting the virus itself, people's ability to plan their lives is compromised. The disruption to each specific person when their life is unsettled or ended by contracting the virus is also part of the equation. Under a justice-based framework, the moral imperative to research other illnesses remains. They must be balanced against each other. This is in contrast to the view afforded by Jonas's approach, wherein there is no imperative to research non-contagious diseases. Therefore, London's scheme offers a better framework for prioritisation decisions in a pandemic because it allows us to compare like with like—duty with duty—as opposed to permissible action compared to duty. Going forwards, I therefore suggest attributing moral value to research decisions based on how they affect access to justice (understood in the widest sense).

### Summary

- The COVID-19 pandemic represented a global health emergency and there was a lack of evidence or knowledge about how best to respond to it, especially given it was a novel virus.
- This sort of lack of knowledge generates a moral imperative to research, that must nevertheless be balanced against the existing need/desire to research other health issues.
- Adopting a justice-based framework means there is a moral imperative to research in all areas of health and makes it easier to compare this duty with the novel duty generated by the pandemic.

## A Framework of Ethical Questions to Consider when Prioritising Research

Against the history of decision-making given above about research priorities, and in line with the reflections given on questions of justice, in this section I highlight some of the ethical consequences of the decisions taken throughout the pandemic that affected biomedical research. In addition, I articulate some questions that might have been useful to ask at the time. I do not try to offer answers, but rather show how these questions might fit into and facilitate a justice-based framework for research prioritisation. The questions can help frame our ethical analysis, both in evaluating past practices and in considering ethical matters that will arise in the future.

While I suggest three key questions and areas to consider, all the questions below can be subsumed in the single over-arching question, “What resource allocation best promotes equality of opportunity for human flourishing?” This is the question that is at the heart of all questions of priority for (biomedical) research. It is also the crux of questions about healthcare more generally. Both pandemic and non-pandemic illnesses have knowledge gaps that create an obligation to research them, but resources are not infinite. To consider allocations of resources, as the question asks, it needs to be known what the relevant resources are. Clinical research has many limiting factors such as existing research staff, existing medical staff, medical equipment resources, limited pool of healthy control subjects, hospital beds for clinical trials, and of course, funding to pay for these resources. It is important to say “existing staff” because in an emergency pandemic situation, we cannot just increase the country’s stock of scientists and doctors since they are roles that take years and years of training and experience. In addition, existing staff may be redeployed to the front line, as seen in the COVID-19 pandemic. But the pandemic of course adds an extra lens, that of sudden emergency.

Therefore, in addition to the above question, one must ask, “How do you weigh the emergency against established problems?” This question reveals a final crucial resource: time. In a pandemic, time is everything. Staff have finite time, meanwhile the virus continues to spread exponentially. How is time best spent? This question was clearly in the minds of policymakers when they prioritised only COVID-19 research that would impact public health within 12 months.

In order to anchor the ethical questions to facts, the rest of this review focuses on three different stakeholders who are identified as being impacted when a prioritisation decision is made: the NHS, the patient/trial participant, and the researcher. A broadly framed question is asked regarding each of these:

1. Within the NHS, how will a decision impact other parts of the biomedical ecosystem?
2. Would re-prioritisation of research in a pandemic breach patients’/research participants’ rights? If so, could it nonetheless be justified?
3. What concerns, in justice, are raised for the researchers themselves?

The sections below take these wide-reaching questions and unpack them in order to explore in more practical terms what it might mean to engage with them as a framework. This enables us to see what actual factors might be involved in coming to an answer that is useful for setting research priorities or evaluating such decisions in the aftermath.

### 1. Within the NHS, how will a decision impact other parts of the biomedical ecosystem?

One of the first things to consider is that clinical research does not take place in a vacuum. Instead it is part of a complex biomedical ecosystem. This is most obvious when we consider the decision by the NHS, on 17th March, 2020, to redeploy clinical academics to frontline care. This decision affected the stock of research resources, albeit of course limiting research was not the primary aim of that decision. It was not a question of deciding which knowledge gap needed to be closed more urgently, but whether closing the knowledge gap around cutting-edge treatment for other diseases was more important than getting basic care for people suffering from COVID-19.

There is not a great deal of data available, but there is one very interesting study of the effect of the policy on a single London NHS Trust (Wyatt et al., 2021). The prioritisation of research was important because of the reduction in available research delivery staff. The Trust’s clinical research delivery workforce, which totalled 165 on 14th April, 2020, was reduced by 79% or 131 staff members during the peak of the first wave due to redeployment to frontline care. A further 52 non-clinical research staff were redeployed to support other Trust activity. If studies had not been officially paused, there would not have been the staff required to run them.

A final point on the complex interplay of factors within the UK’s health system is the financial effect the pausing of clinical trials had on the NHS. Is this financial burden on the NHS a reasonable cost for trying to minimise the effect of COVID-19? The loss of commercial research across NHS Trusts during the pandemic is estimated to have generated a deficit of up to £447 million in total in the financial year 2020/2021 (ABPI, 2021, p. 6).

Coggon reminds us of the complexity of the trade-offs involved here: 'We should not suppose that we can reduce our evaluations to "health versus the economy". Indeed, because economic decline leads to catastrophic, and avoidable, health harms we need to aim for shared gains in economic and public health protections' (Coggon, 2021).

Moreover, due to the slower recovery of the UK's research portfolio compared to Europe (ABPI, 2021, p. 15), a question mark remains over the future of the industry in the UK. How important is it, in terms of justice, to be and continue to be, a world-leader in biomedical research? How important is it that our citizens have opportunities to take part in cutting-edge medical research?

The existence of a clinical trial infrastructure depends on having capacity within the health system to support it. It was important to consider, without prioritising intense COVID-19 research, how long the health system would have been overwhelmed by the pandemic to an extent that other research was impossible anyway. These are complicated issues and counterfactuals to play off against each other. There needs to be further research on this if the prioritisation decisions highlighted above can be fully evaluated.

## [2. Would re-prioritisation of research in a pandemic breach patients'/research participants' rights?](#)

Another key area for consideration is patients themselves; both COVID-19 patients and people on clinical trials that were paused. One essential question that needs unpacking is "Do people have a right to be on clinical trials?" If the answer is yes, then pausing/cancelling trials goes against this right and would need clear justification. If no, the decision to pause trials would be less contentious as regards research participants. With research ethics frameworks that focus on autonomy and beneficence it is easier to imagine a right to clinical trials that might be founded on an individual's liberty to freely contract with whoever they want and not have this interfered with by the state. However, London sees participation in clinical trials through quite a different lens:

*"[T]here is an imperative to treat study participation ... not as a career but as a social opportunity open to community members through which they can contribute to the common good with credible public assurance that, in doing so, their own basic interests will not be knowingly compromised in the process."* (London, 2022, p. 138)

People often view trials as a way to access cutting-edge, life-saving treatment. Sometimes that is indeed the effect of being in a clinical trial. But there is no guarantee that the treatment being tested is better than the standard care you would otherwise be offered, or would get if

you were in the control group of a trial. This is essential for a trial to run ethically and maintain equipoise (Ashcroft, 1999). If it is known that a given new treatment is better, then it would not be a true trial.

While patients on trials may or may not receive novel and superior treatment, it is nonetheless interesting to note that it is known that clinical research benefits patients in other ways. Patients benefit from receiving care in research-active hospitals with improved outcomes and improved survival rates as it appears to drive better information provision to inpatients—particularly around medicine management—and contribute to a better inpatient experience overall (Jonker et al., 2020). While there may not be a right to treatment on a trial, or even in a specific hospital, there are clear benefits to patients in promoting research and it may not be fair to suddenly and unexpectedly withdraw this opportunity.

As such, a justice-based framework does highlight a clear ethical consideration in pausing/cancelling trials. Justice is here defined as a state of affairs where everyone has equal and "real opportunity to exercise their moral powers, free from arbitrary social interference, to formulate, pursue, and revise a reasonable life plan." (London, 2022) Stability of expectation is therefore a crucial component of a just system: if you make a plan, it is not fair if it unexpectedly becomes impossible to see it through. If someone has been told they will be part of a clinical trial, and they have integrated that into their life plan, it is contrary to justice to frustrate that expectation. Of course, it may still be justified, given the circumstances, it merely must not be "arbitrary". There might be a very good reason for no longer allowing that plan to happen, but the disappointment of a foiled plan remains. On an individual level, the decisions above led to people expecting to be on clinical trials and then having that chance taken away. Over the last two years it is inevitable that people who were going to be involved in clinical trials will have died. It is not necessarily true that they will have died because of the withdrawal of trial treatment, but it is true that that was not part of their plan. If there was no good justification for cancelling the trials, it is open to argument whether such a decision was arbitrary, and thus contrary to justice.

However, there are further factors to bear in mind in relation to this. A decision was made to prioritise COVID-19 research. However, as a counter-factual, what would have been the practicalities and ethics of attempting to continue clinical trials as normal in the coronavirus pandemic? In 2020, the world was self-isolating. The aim was to keep contact with infected populations as low as possible. This was considered especially important for those considered "vulnerable". Hospitals were massive hubs of people with COVID-19. To have continued with clinical trials as normal would have necessitated actively bringing vulnerable people into high-risk environments.

Depending on the trial, participants may even have a suppressed immune system for trial purposes, leaving them even more vulnerable to COVID-19. This is an issue both in light of the effect on the individual if they contracted COVID-19, but also for the wider ethics of the trial itself. Data collection would be skewed if people on the study started having extra medical problems. Phase II trials especially rely on having healthy participants in order to assess the effects of drugs on the normal functioning of the human body. These more practical questions needed to have been considered as a starting point. Only if it were prima facie appropriate to continue the studies, would the next question of prioritisation policy arise.

To minimise the impact of the pandemic on trial participants, having decided trials cannot continue as normal, one should then ask, "Can trials be continued with an altered protocol?" As the pandemic continued over the years, this did start happening, but it was not immediate. A consideration here is whether it would be an effective use of resources to spend the time and money on altering protocols and develop technological solutions. One would also have to consider whether doing so in a rush might compromise the careful scientific method of the trials, which is essential to keeping any clinical trial ethical (Francis and Wydenbach, 2020).

### 3. What concerns, in justice, are raised for the researchers themselves?

There are also ethical questions to consider from the researcher's point of view. What was the effect on their research skills? It is striking that guidance had to be specifically issued to help them adjust to a return to their academic roles. What is the financial effect? Research funding is a complicated process and researchers employed on projects were suddenly redeployed to entirely different jobs. The logistics of paying their wages was complicated and guidance was only issued on it in July 2020, as discussed above, on London's account of justice, economic inefficiency is unjust as it represents a waste of resources that could have been better allocated. That is not to say that was in fact the result of this decision, in fact, I merely mean to highlight how it ought to be considered when doing the grand ethical calculus of pandemic response.

Undertaking research is good for patients' experience, as explored above, but it is also beneficial for the NHS as a whole. It has been shown that research participation helps the NHS through improving job satisfaction for clinicians, by helping morale and supporting the retention of staff (RCP, 2019). Outside of pandemic conditions, doctors hugely value research as an important part of their job but are hampered by a lack of protected time for patient-facing research.

During the pandemic, this already limited time disappeared for many as pressures of the front-line increased. Greater consideration might have been paid to the potential psychological effects of research policy decisions on research staff; both those redeployed to the front line and those left in research roles. The potential of inflicting psychological harm on clinical researchers must be carefully justified. Consider these comments gathered from interviews in the Wyatt study:

*"Others warned that the pace of research during the first wave of the pandemic came at a human cost. Some researchers had vastly increased workloads, "going at max [...] for 5 months" (R-1), where in some cases "there's not been a single day when [they've] not been working in the laboratory including all Sundays and Saturdays, Easter and so on" (R-4). Whilst some enjoyed this fast-paced moment, for those closer to the frontline it has caused anxiety. As one participant (G-5) explained, "we've been fire-fighting"; and at least one member of staff, another explained, "can't come near the hospital. She has panic attacks" (D-3). Whilst it has already been documented that critical care staff's mental health has suffered in the pandemic, these participants suggest there may also be concern for the staff involved in the research response." (Wyatt et al., 2021)*

More nebulous and harder to quantify is the question "Is this the best use of our scientists?" As above, this goes to the question of efficiency, though in a somewhat unquantifiable manner. This question was notably raised by Sir Peter Ratcliffe, winner of the 2019 Nobel prize in medicine, in October 2020. He noted there was "a belief in some quarters that the whole world of science should stop what it's doing and work on coronavirus" (Havergal, 2020). But he argued that instead research must be driven by an individual scientist's passions:

*"The investigator has a passion for what they do, they have self-belief that they can solve a particular problem, and they have some belief that the problem is important, and that's what drives us all on... That's what you're harnessing in science; it's that human passion that some people have to push themselves and to find things out." (Havergal, 2020)*

It might also have been worth considering the longer-term implications of the decision in March 2020 by the HRA to stop applications for undergraduate and master's student projects until further notice. There are several points to unpack here. Access to education is a key element of assuring a just society.

*“Restrictions on access to education, for example, prevent individuals in targeted classes from developing their basic intellectual, affective, and social capabilities and also deprive them of access to a social space in which the exercise of those abilities is a gateway to additional social, economic, and political opportunity.” (London, 2022)*

While London is here talking more broadly about issues of structural discrimination, I suggest the point still stands when thinking about the young people whose education was disrupted by this policy. What impact will this have on our stock of scientists in the future? As I hope has been made clear throughout this piece, the existence of a biomedical infrastructure is more than a question of individual rights and interests. Contrarily, if these projects had not been stopped, would it have been justifiable to allow students into high-risk environments for projects that were not essential, merely formative experiences which could be substituted with other pedagogic tools? Within our biomedical research infrastructure, the human element of researchers is perhaps easy to overlook but without them the system crumbles. Our stock of biomedical researchers needs upkeep and good management just as much as the clinical staff doing front-line care.

## Conclusion

There are so many factors relevant to the ethical rights and wrongs of decisions made about research priorities throughout the pandemic. This review has considered a brief selection of them. It must also be remembered that these are not independent questions, and to view them as such would be to make a categorical error. As Coggon (2021) makes clear, these sorts of ethical issues form a complex web of trade-offs which are all deeply interconnected. What looks like an individual decision about a single trial or staffing in a single hospital actually fits into a wide matrix with cascading results impacting many different stakeholders. I hope to emphasize this element of interdependence by suggesting that all the specific, circumstantial questions suggested can in fact come under a greater heading: how best can we promote equality of opportunity, given the resources we have and given the desperate times we find ourselves in? I accept that not all consequences of the policy decisions identified can be thought of in terms of justice; there will be many occasions simply in which an individual's interests were harmed, when this is in pursuit of a moral duty that can be justified. But I do argue that many more consequences than perhaps first realised can be seen in terms of justice, thereby allowing a clearer comparison of the various effects and consequences of policy decisions.

For this view, we first need to view biomedical research as a duty founded in social justice. We may then identify a framework of questions, such as those presented in the previous section, to help us explore the demands of justice given the interests, expectations, rights, and duties, of stakeholders in society and biomedical research.

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## About this submission

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## About the UK Pandemic Ethics Accelerator

The UK Ethics Accelerator is a UKRI/AHRC-funded initiative that aims to bring UK ethics research expertise to bear on the multiple, ongoing ethical challenges arising during a pandemic emergency. We provide rapid evidence, guidance, and critical analysis to decision-makers across science, medicine, government, and public health. We also facilitate public stakeholder deliberation around key ethical challenges.