Rapid policy briefing

NUFFIELD COUNCIL ON BIOETHICS

Fair and equitable access to COVID-19 treatments and vaccines

29 May 2020

Overview

- The development of an effective treatment and vaccine for COVID-19 is key to ending the pandemic and resuming social and economic activity. An international research effort to this end is underway.
- The COVID-19 pandemic has disproportionately affected disadvantaged populations. Those inequalities will be exacerbated without consideration of the ways in which treatments and vaccines can be developed, accessed, and distributed in a fair and equitable way.
- Policies for fair and equitable access to treatments and vaccines need to be in place prior to or concurrent with their development and distribution.
- The key factors which affect fair and equitable access include where and how research is prioritised and funded; the distribution of the burden and benefits of research efforts between high and low income countries; prevailing structural and health inequalities which will further limit access; and public trust and engagement with the development and roll-out of any treatment or vaccine.
- Particular challenges arise through the interface between private and public interests, where commercial confidentiality laws, intellectual property rights, and pricing decisions can affect the way in which tests, treatments and vaccines are made available.
- In light of the truly global nature of the pandemic, international cooperation and collaboration across all different sectors working on COVID-19 to share the benefits of research and treatment is paramount.
- Key challenges for policy makers, regulatory bodies, industry, and research institutions include establishing harmonised regulatory regimes and ensuring transparency and data-sharing through research coalitions, to support and accelerate COVID-19 research efforts.

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INTRODUCTION

A global research effort is underway to develop effective treatments and vaccines for COVID-19.[1] The world hopefully awaits a safe and effective vaccine to end the pandemic and enable a revival of social and economic activity.

People within and across countries will have different levels of access to these products. This will not be a new problem. Structural, political, and power imbalances mean lack of access to medicines and vaccines already has a devastating effect on people throughout the world.

The COVID-19 pandemic is truly global. Populations who are not usually affected by inequitable access to medicines might now view this issue in a new light. However, this pandemic has disproportionately affected those who are already disadvantaged and will continue to do so, both within and between countries.[2] Without ethical leadership and changes to current systems, the effects will widen inequality, hitting disadvantaged populations and low-income countries hardest.[3]

This briefing encourages policy makers, regulators, companies, funders, and research institutions to consider ways in which COVID-19 treatments and vaccines can be developed, accessed, and distributed to those who need them in fair and equitable ways.[4]

HOW ARE DRUGS AND VACCINES DEVELOPED?

The pharmaceutical and biotechnology industries develop, produce, and market drugs and vaccines.[5] Companies work within an ecosystem that includes academic institutions and substantial public funding which facilitates early discovery and research.[6] The estimated costs of drug development vary according to products, with estimates ranging from USD$161 million to USD$2.6 billion.[7] Estimates of cost can account for opportunity costs and the cost of research and development which doesn't lead to viable products.[8] It takes, on average, 10-12 years to develop a drug from initial discovery to availability on the market.[9] The economic modelling upon which estimates are based relies on particular assumptions about the competitive and regulatory environments, which may change within the global context of COVID-19.

Regulatory and licensing bodies and approval processes for new drugs and medical products vary by country.[10] In the UK, once a new drug has completed clinical trials, the approval process consists of two stages before the drug is made available on the NHS. The first stage of licensing provides assurance from the regulatory authority (the European Medicines Agency and/or the Medicines and Healthcare products Regulatory Agency) that the drug or vaccine is effective, and is sufficiently well-tolerated that the potential benefit to patients outweighs the risk, and meets manufacturing quality standards to the extent that it should be made available for use by clinicians. After licensing, the product is appraised by the relevant bodies, such as the National Institute for Health & Care Excellence or the Joint Committee on Vaccination and Immunisation, to ensure that it is a cost-effective treatment or vaccine to provide on the NHS.[11]

Drugs can be patented to offer revenue protection to companies for the length of the patent, to enable them to recoup the cost of research and development and reward economic risk.[12] Patents can last up to 20 or exceptionally 25 years. Most drugs are often patented before being placed on the market, so the revenue life of the drug is usually shorter than the patent length. Patents are issued nationally, which means that drugs may be patented in one country but not in another. Drugs are priced and made available at differing costs across markets.

COVID-19 RESEARCH UNDERWAY

There is a significant effort towards global collaboration for the development of tests, treatments, and vaccines for COVID-19.[13] At present, there are over 200 authorised diagnostic tests to help detect COVID-19 and almost 100 drugs in human clinical trials.[14] Research is underway investigating the possibilities of repurposing existing drugs to treat COVID-19. Different treatments in development include antiviral drugs, immunosuppressants/immunomodulators to modify or suppress the immune response,[15] anti-inflammatory drugs, as well as cell and plasma-based therapies which use antibodies from the blood plasma of people who have recovered from COVID-19.[16]

Alongside efforts to develop treatments for COVID-19, there are over 100 vaccines in the early or preclinical development phase and ten in clinical trials.[17] No vaccines for other types of coronavirus (such as MERS-Cov or SARS-Cov) have been successfully developed and there is uncertainty concerning how long acquired immunity can last, with some evidence to suggest that immunity can be short-lived.[18] Two out of every three candidate vaccines for infectious diseases usually fails, which means there are significant obstacles to overcome before an effective vaccine can be discovered and made available.[19]

AN ETHICAL COMPASS

Our recent report on the ethics of research in global health emergencies[20] sets out an 'ethical compass' made up of three very widely shared values:

- **Equal respect**: treating others as moral equals, including respecting their dignity, humanity and human rights.
- **Helping reduce suffering**: acting in accordance with fundamental duties, founded on solidarity and humanity, to help those in need or suffering from disease.
- **Fairness**: including both duties of non-discrimination in the treatment of others, and of the equitable distribution of benefits and burdens.

The compass aims to inform policy approaches and help provide a common language and way of thinking through ethical dilemmas arising in research in health emergencies. It is similarly valuable in thinking through the ethical challenges of equitable access, and has informed the discussion that follows on factors that might affect access to treatments and vaccines for COVID-19.

FACTORS AFFECTING FAIR AND EQUITABLE ACCESS

Research funding and prioritisation

Most health research funders are based in high-income countries, though some middle-income countries are also investing in research and development. Governmental funders, in particular, are expected to prioritise the health security of their own citizens and those within their jurisdiction when determining their funding objectives. The current pandemic highlights that national interests are nevertheless closely related to threats which may be external and located abroad, and that risks to citizens should be considered within the global context.

Private sector priorities are inevitably strongly directed by commercial drivers, although priorities can also be influenced by regulatory requirements, corporate social responsibility policies, and involvement in public-private sector partnerships.

Governments of low- and middle-income countries (LMICs) facing global health emergencies may, at present, have little direct influence over the funding decisions of these external funding

bodies. The often-disadvantaged populations directly facing the consequences of emergencies are even less likely to be in a position to influence the decisions made elsewhere. The relative absence of voices representing these populations or communities carries the risk of important research being overlooked, or of research questions being ill-adapted to LMIC contexts, which often have less sophisticated health and research infrastructures.[21] Organisations such as the former Global Forum for Health Research, the Council on Health Research for Development, and Third World Network among others, have, however, contributed to the discourse, engaging civil society perspectives.

The global nature of the COVID-19 pandemic indicates strong reasons for all research funders to prioritise and feed into global efforts, in recognition of a moral responsibility towards others which extends beyond territorial boundaries. Governmental efforts to protect citizens within their country should not be viewed as being at odds with a responsibility to think globally and contribute to global efforts.

Accelerated development of drugs and vaccines

The development of drugs and vaccines can take up to a decade or more, although it is hoped that collaborative efforts and new technologies may reduce the time taken to develop new products for COVID-19.[22] Given the urgency posed by the global spread of COVID-19 and the critical need for drugs and vaccines, the timelines and processes for developing these products are being accelerated with the support of regulatory authorities. Previously approved drugs are being entered into late-stage clinical trials in efforts to discover treatments for COVID-19 in a shortened timescale.

Whilst speeding up trials may promise faster access to suitable drugs, it will be essential to ensure that this is carefully balanced against appropriate consideration of risk to participants enrolling in trials, and that patient safety is given priority when investigating drugs which are in the trial phase.[23] The speed and urgency of trials should not compromise the safety of participants, quality of the trials or ethical standards. There needs to be significant patient engagement and involvement in research to ensure the results of the research are robust and relevant, as well as to ensure the research is feasible. Reducing patient involvement due to concerns about speed may result in research wastage.

Regulators in different countries are allowing the use of drugs, such as chloroquine and hydroxychloroquine, in hospitals or other treatment settings before they are licensed for use in COVID-19 infection, by granting emergency authorisation for their use in this indication, based on preliminary evidence.[24] The World Health Organisation has, however, halted a hydroxychloroquine COVID-19 trial over safety concerns and regulators will need to review the aforementioned emergency authorisations accordingly.[25] In addition to safety and efficacy concerns of these experimental treatments,[26] increased use of drugs such as chloroquine and hydroxychloroquine for COVID-19 are leading to shortages of these drugs and limiting availability for those for whom these drugs are proven to be effective with chronic inflammatory conditions or malaria.[27] Use of unlicensed or off-label medicines outside research settings may also compromise the ability to collect robust data for research and thus compromise the ability to assess if a medicine has an acceptable efficacy and safety profile.

Distribution of benefits and burdens

Much early research on disease which leads to the discovery of new treatments is conducted over many years by scientists in academic institutions (often publicly funded), and through

private-public partnerships involving government and industry. It is a widely held view that the benefits of health research that has received public investment should be harnessed for the public good and should meet patient need.

The research and development of medicines and vaccines involves clinical trials where potential products are tested on human participants. The participation of poorer people, particularly from LMICs, raises ethical concerns about exploitation and an unfair distribution of risk and benefit, particularly when medicines are not made available to populations who have contributed to their development through participation in trials at a significant personal cost. Past examples exist of clinical trials conducted in LMICs by private-sector companies with commercial interests that placed the burden of risk on vulnerable populations, whilst the benefits of such research were likely to accrue to those in high-income countries.[28]

The risks and ethical considerations of exporting clinical trials elsewhere need to be considered alongside the risks of exclusion of diverse participants from research. It will be important, particularly during conditions of social distancing and isolation, to ensure that research trial participants from various populations, especially those which are traditionally underrepresented, are engaging with research trials to ensure that drugs and vaccines are effective across diverse populations.[29] Should medicines and vaccines prove to be effective with acceptable safety, they should be made available to research participants and communities.

Commercial confidentiality

Pharmaceutical and biotech companies often rely on commercial confidentiality law and regulation to withhold information from the public domain, if sharing it would undermine their economic interests or competitive advantage. Article 39.3 of the World Trade Organisation's (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) offers protection for undisclosed information against unfair commercial use.[30] Additionally, in Europe, data and marketing exclusivity rights give companies approximately eight to eleven years of exclusive rights (dependent on the time taken from registering a patent to obtaining a licence) to compensate them for their research and development investment in a particular medicinal product.[31] This means that a company's data cannot be referenced as evidence in applications by any other companies seeking to produce similar products, such as generics.[32]

The type of information which companies can refuse to disclose based on commercial confidentiality includes details relating to pharmaceutical development, such as data about active substances, formulation and manufacturing, test procedures, validation and the names of manufacturers and suppliers of active substances. Company clinical trial data as well as 'negative' data can also be withdrawn or kept confidential under the EU trade secrets directive on the grounds that this information has commercial value because it is secret and disclosure could offer clues to competitors for avoiding drawbacks and help them towards successful drug development.[33]

Greater transparency and data sharing between companies and researchers is important for evaluating a drug's safety and efficacy but can also play an essential role in increasing access to medicines and vaccines.[34] Commercial confidentiality laws and data exclusivity may hinder global efforts to address the urgent need for vaccines and medicines in a timely and accessible way. The AllTrials initiative is a positive development on this front being increasingly adopted by industry, with companies registering past and present clinical trials and reporting their full methods and summary results. Industry commitment to disclosure can be found in the IFPMA code.[35] Unlike

patent laws, which are time-limited, commercial confidentiality laws and trade secret directives can offer protection for an indefinite period of time. However, emergency laws may offer options to force disclosure or the appropriation of goods and knowledge in the context of a pandemic.

Whilst platforms like the cross-pharma Transcelerate project are enabling the sharing of datasets between Transcelerate companies to help inform and accelerate drug development, the COVID-19 pandemic requires global cooperation between industry, academic, and research institutions, and governments to speed the discovery of drugs and vaccines.[36] The COVID-19 Clinical Research Coalition is an example of a global coalition that has been established to accelerate COVID-19 clinical research.[37] Not-for-profit organisations like Vivli have expanded their offering by waiving fees, in order to serve as a hub for the sharing of clinical study datasets, to make data from coronavirus studies available to qualified researchers in an expedited manner.[38]

Patents and licensing

Patents are intellectual property rights which give companies protection over a novel product, process or material. The patent system is based on a quid pro quo: the inventor is granted exclusive use of the invention, subject to disclosing how to use the invention. The purpose of the system is to create incentives for individuals and firms to invest in creating and publishing useful inventions, which can involve lengthy, complex, and risky processes for developing new products.

Patents give companies exclusive use of the claimed invention, and in some cases this creates market power, enabling the patentee to set high prices on patented drugs and medical products such as diagnostic tests, ventilators, computer models, and masks. Patents nominally allow for a 20-year term, but the system is complex, and there are additional tools for supporting and extending exclusivity, including data exclusivity, market exclusivity, and Supplementary Protection Certificates.[39] Effective exclusivity for new drugs averages around 12.5 years in the US.[40] However, in some cases exclusivity can be much longer. Generic and biosimilar competitors can only enter and compete with lower prices after exclusivity has ended. In some cases, effective exclusivity can be lengthened with modifications to the patented drug or product, through 'evergreening' so that subsequent patents relating to the same drug are issued.

The monopoly created by patents (and similar instruments) carries ethical implications for access to life-saving treatments and vaccines by restricting the production of these to patent holders. The extraordinary circumstances that have resulted from the global pandemic raise questions about the appropriateness of these regulatory regimes, and the current system of ownership rights, to the global challenges that have emerged and continue to evolve.[41]

The search for drugs and vaccines for COVID-19 involves some clinical trials on already patented drugs. Access to information about these drugs is currently restricted to patent holders. Once discovered, access to COVID-19 drugs and vaccines will be determined by intellectual property rights and international trade laws, the former potentially dictating whether cheaper generics or biosimilars can be produced. There have been several proposals to ensure that the development of drugs and vaccines can be accelerated, by lifting patent-related monopolies through voluntary or compulsory licensing to share intellectual property of existing patent-protected medicines. Licences give third parties permission to use the intellectual property through purchasing rights of production, distribution and sales. The Open COVID Pledge encourages companies holding rights to publicly commit to sharing their intellectual property for free, in the fight against COVID-19, by adopting and publishing an Open COVID Licence (OCL) or issuing a custom licence which is

consistent with the OCL.[42]

Most countries have compulsory licensing provisions in their patent laws.[43] Some governments have already acted on public health grounds to issue compulsory licences to support research efforts underway for COVID-19.[44] This allows patents on a product to be suspended, enabling others to produce a patented product or process without the consent of the patent owner.[45] In the UK, the 'Crown use' provision of patent law could grant authorisation for the use of patent rights without the need for obtaining a voluntary agreement with the patent owner.[46] Patent pooling, as in the example of the Medicines Patent Pool, is another option for sharing information to prevent exclusive licensing.[47] WHO and Costa Rica are launching a global COVID-19 technology pool,[48] collecting patent rights, regulatory data, software, designs, and trade secrets to make them available globally. Whilst many scientists and companies are pooling resources and collaborating in the fight against COVID-19,[49] adapting the regulatory environment to align regulatory regimes across countries might offer further mechanisms for facilitating equitable access to treatments and vaccines.

Pricing

The price of medicines and vaccines can be a barrier to access for people, healthcare systems and governments who are unable to afford them.[50] Price is particularly an issue for specialty drugs (often biologics) and orphan drugs which are used to treat rare diseases. Whilst the issue of affordability is a universal one affecting all countries, the extent of the challenges this poses for access to medicines varies according to healthcare systems, governmental decisions on investment in health and medicines, and the economic status of countries. The challenge is also complicated by the extent of co-payments that exist between governments, insurance companies, health systems, and individuals.

There is lack of transparency and a degree of complexity in the drug buying process, which enables varied prices for the same drugs for different buyers. Companies can use commercial confidentiality criteria to withhold pricing information across markets. The final prices may reflect a country's ability to negotiate the best price, rather than its ability to afford the drugs. Such practices can lead to greater inequity in access to medicines.

During the patented lifetime of a drug, companies can exercise greater freedom to set prices for necessary medicines for which there may be no identical competition. Once patents expire, generic medicines play an important role in driving efficiency and increasing access, as they enter the market at a much lower price.

The global economic downturn that is resulting from the COVID-19 pandemic combined with health budgets being stretched in many directions, will make it harder for governments to subsidise medicines and vaccines, and for many people impossible to afford if they are forced to pay out-of-pocket.[51] Reducing market monopolies and ensuring earlier competition, as well as pooled procurement of drugs by low- and middle- income countries can increase access through affordably priced drugs.[52] The COVID-19 pandemic offers an opportunity to review innovation policy regarding just compensation and reward mechanisms. Models which account for risks and costs may encourage investments in rapid industry research and development efforts for COVID-19, whilst ensuring fair and equitable access to treatments and vaccines.[53]

There is growing international support for the recent proposal, organised by Oxfam and UNAIDS, calling for a global agreement on COVID-19 diagnostics, treatments, and vaccines, which

includes a patent-free 'people's vaccine' as a global public good.[54] This would ensure that, once developed, the mass production and distribution of COVID-19 vaccines is funded by rich nations and rapidly made available to people, in all countries, free of charge. They have similarly called for diagnostics, tests, and treatments to be provided free of charge.[55]

Infrastructure issues

Global health emergencies disproportionately affect those who are already disadvantaged. In some cases, this will be a consequence of living in places with inadequate or poorly maintained infrastructure with a lack of access to water, sanitation and hygiene (WASH) and basic healthcare, living in overcrowded situations making social distancing impossible, socioeconomic inequality and political marginalisation.[56] Such populations are less likely to have access to well-resourced health services or to have production facilities in place for manufacturing medicines and vaccines.[57] In countries like Liberia, South Sudan, and Central African Republic, there are three or four ventilators for the entire country.[58] In countries, such as Uganda, there is only one equipped intensive care bed per million people.[59]

According to WHO, 30% of the world's population, mostly in low and middle-income countries, do not have access to essential medicines.[60] This access is limited not only by availability and affordability, but also due to the shortage and scarcity of medicines, arising from a lack of research and development for medicines or issues with supply chain management.[61] Such countries face additional logistical challenges related to the production, storage and delivery of medicines, which can contribute further to the lack of access to medicines and vaccines. Oxfam International has warned that a further half a billion people in poorer countries could be pushed into poverty by the pandemic, which could exacerbate these challenges further.[62]

Limited supplies and purchasing monopolies

The global nature of the COVID-19 crisis is creating challenges for supply and production with an ever-increasing demand for testing and protective equipment. It is likely that once drugs and vaccines are developed, there will be a similar challenge for production seeking to meet global demand. Ethical challenges are surfacing with reports of richer countries paying a higher market price to private manufacturers for masks and testing equipment. This means that supplies are being channelled to Europe and America, with poorer countries in Africa and Latin America unable to access the market and secure what they need for their COVID-19 response efforts.[63] Countries like Brazil and South Africa, which have tried to source chemical reagents needed for testing are being given two month wait times, since richer countries have purchased supplies spanning months of production. Further reports estimate that over 50 countries have limited the export of medical goods to secure them for national use.[64] The lack of access to testing kits and protective equipment carries consequences for the COVID-19 treatment pathway.

The competition for resources and the steep increase in prices means that already disadvantaged countries will be placed in an impossible situation. The global nature of this pandemic requires responses to be guided by values such as global solidarity and equal respect for lives. Purchasing monopolies or the prevention of medical exports are likely to have a humanitarian impact on countries whose economies and health systems are already fragile.[65] More prosperous countries have an ethical responsibility to ensure that their responses to fighting the pandemic are measured and globally responsible. For example, sharing patents on niche medical products, such as testing reagents and mask designs, would enable production to be taken up by other manufacturers to help meet demand.

Prevailing health inequalities and vulnerable groups

Health inequalities refer to the differences in health between people or groups due to socio-economic, geographical, biological or other factors. Such differences are having a huge impact during the pandemic because people who are worse off are experiencing poorer health and shorter lives. Evidence is emerging highlighting the disproportionate impact of COVID-19 on groups already affected by unmet health needs such as poorer and BAME communities in the UK.[66] The latter may be also be compounded due to the predominance of frontline workers in such groups. Additionally, with social distancing and isolation measures in place, people who already face challenges when accessing treatment, either due to structural inequalities or language barriers, may have their struggles exacerbated and feel disempowered to seek treatment for COVID-19 and other conditions or to have other non-health care needs met.

Furthermore, undocumented migrants, who are unable to access medical help for COVID-19, are also likely to be in communities at higher risk due to the social, political, and administrative obstructions preventing access to necessary support, protective measures, and treatment. Addressing health inequalities will contribute to closing of the health and well-being gap experienced by those at risk of vulnerability and ensuring that they have fairer access to treatments and vaccines. Provisions to mitigate the impact of COVID-19 on such groups may include interventions such as occupational risk assessments and priority testing.

The pandemic has also had a devastating impact on vulnerable groups such as residents of nursing homes and care homes, highlighting gaps in social care as well as delays in provision of adequate protective equipment and timely treatment.[67]

Public trust

Public trust in the safety and efficacy of treatments and vaccines will play a key role in ensuring access and uptake. Opportunities for scientists to engage with public concerns and expectations in the early research and development phase, can lead to greater trust. In recent years, concerns about the safety of vaccines for children – so-called 'vaccine hesitancy' – has led in some areas to a dramatic and damaging decrease in uptake by parents and carers. Early public engagement using sensitive and appropriate language, carefully planned programme designs,[68] sharing information, and countering misinformation about vaccines and treatments can all contribute to public trust and acceptance. Policy makers should be aware of the range of factors that affect people's decisions about vaccination and treatments, such as attitudes to healthcare, social norms, identity, culture and cultural norms, and structural barriers.[69]

Public perceptions and trust in healthcare systems may be impacted by COVID-19 related fears, affecting health seeking-behaviours and causing reluctance in accessing treatment.[70] There are reports of almost half of hospital beds being empty and the lowest levels of A&E admissions in UK hospitals on record. Policy makers and healthcare institutions may need to address underlying concerns and alleviate public anxiety to facilitate access to timely treatment for COVID-19 and other healthcare needs.

Distributive justice

Resource allocation and distributive justice considerations are being brought into sharp focus by the current global health emergency. The question of who should be prioritised for treatment and resources has already surfaced in the case of limited ventilators and intensive care beds on COVID-19 hospital wards as well as identifying and giving effect to who can and should be

tested for the virus given the finite testing capacities. Once COVID-19 drugs and vaccines are available, given the global demand, it is likely that there will be limited supplies available initially. Determining who should be given priority for treatment or be vaccinated first will require careful deliberation and informed planning with learning from past pandemics.[71] Factors to consider when prioritising will include understanding which populations are at greater risk and more vulnerable, and how transmission takes place. Governments should be transparent about their prioritisation strategies for delivering treatments and vaccines and communicate the values underlying their preferred approach, so that the public are aware of why certain sub-groups may be prioritised for treatment or vaccination, in the case of limited supplies.[72] International cooperation to develop responses and share resources will facilitate a collective global transition out of the current pandemic.

EFFECTS ON OTHER AREAS OF RESEARCH AND TREATMENT

Major funders, industry and governments have strategically redirected their priorities to COVID-19 related research, pausing many existing research studies and clinical trials.[73] Clinical scientists have been asked to pause their research activities and return to frontline service. Measures introduced to curtail the spread of COVID-19 have caused some university and research centers to close.[74] These changes will have implications on other areas of health-related research and on patients, especially those who are enrolled on trials. Further ethical issues are arising in the clinical setting related to clinical decision-making and prioritisation of COVID-19 patients over other patients.

It will be important to justify the extent to which the emergency response to COVID-19 should take priority over other areas of health research and services, and to plan for how research activities can continue beyond COVID-19.

KEY CHALLENGES

Policy makers, regulatory bodies, industry, research institutions, and funders should create timely strategies for ensuring fair and equitable access to COVID-19 tests, treatments, and vaccines through consideration of the key challenges outlined below.

Underlying all activities in this area should be:

- Recognition of the need for international solidarity and collaboration to share the benefits of research and treatment by avoiding purchasing monopolies.
- Effective mechanisms for collaboration across different sectors working on COVID-19 treatment and vaccine efforts, including industry, government, academia, and charity.
- Strategies for early public engagement and research governance that ensure participant safety.
- Efforts to promote access initiatives such as WHO's COVID-19 technology pool.

Key challenges for regulatory bodies include:

- Harmonised regulatory regimes that ensure alignment of approaches across different countries to support and accelerate COVID-19 research efforts.
- National and international regulatory environments that facilitate timely and equitable access to treatments by addressing laws and regulation such as commercial confidentiality, data and market exclusivity.
- Robust regulatory reviews that ensure the safety of research participants is not compromised in the accelerated and pressured environment of COVID-19.

- Ensuring that the benefits of health research that has received public investment is harnessed for the public good and meets patient need.

Key challenges for policy makers include:

- Fair and transparent strategies for prioritising and allocating COVID-19 treatments and vaccines.
- Addressing prevailing health inequalities, and the needs of vulnerable groups, to ensure timely and equitable access to treatment.
- Timely identification of vulnerable groups to enable rapid risk assessment and testing to facilitate access to treatment.
- Support for countries with existing structural barriers to essential healthcare and broader infrastructural problems for public health.
- Review innovation policy regarding just compensation and reward mechanisms that account for risks and costs to encourage investments in rapid industry research, whilst ensuring fair and equitable access to treatments and vaccines.

Key challenges for industry include:

- Patenting policies and intellectual property licensing that focuses on fairness and global public good.
- Transparency and data-sharing through research coalitions to support global efforts to develop safe and efficacious treatments.
- Commitment to initiatives like the Open COVID Pledge to share intellectual property.
- Joining the COVID-19 technology pool established by WHO.
- Transparency in policy-making around drug pricing that ensure fair policies and pricing.

Key challenges for research institutions include:

- Robust research and governance to ensure the safety of research participants is not compromised in the accelerated and pressured environment of COVID-19.
- Early public participation and involvement in COVID-19 research efforts, especially from underrepresented groups.
- Community engagement and initiatives to build public trust for COVID-19 drugs and vaccines, with conversations around public expectations.

Key challenges for other funders of research include:

- Research prioritisation to reflect international need and to contribute to global efforts, in recognition of a moral responsibility towards others which extends beyond territorial boundaries.
- Aligning research questions to meet locally informed needs, especially in LMIC contexts.

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