WHO Collaborating Centre for Governance, Accountability and Transparency in the Pharmaceutical Sector

UNIVERSITY OF TORONTO
LESLIE DAN FACULTY OF PHARMACY

TRANSPARENCY INTERNATIONAL
Global Health

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For Whose Benefit?

Transparency

in the development

and procurement

of *COVID-19 vaccines*

Transparency International (TI) is the world's leading non-governmental anticorruption organisation, addressing corruption in its many forms through a network of more than 100 national chapters worldwide.

Transparency International Global Health's overall goal is to improve global health and healthcare outcomes for the benefit of all people, of all ages. It aims to achieve this by reducing corruption and promoting transparency, integrity and accountability within the pharmaceutical and healthcare sectors.

The World Health Organization Collaborating Centre (WHO CC) for Governance, Accountability, and Transparency in the Pharmaceutical Sector was established in 2015 at the Leslie Dan Faculty of Pharmacy, University of Toronto. The WHO CC assembles leading governance and related experts who have created a collaborative network to support WHO policy and country operations on the global problem of corruption.

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CONTENTS

KEY TERMS

Vaccine Developer	This refers to pharmaceutical companies, research institutes, clinical research organisations or other allied bodies that are developing or have developed and are marketing a COVID-19 vaccine.
Contract	An agreement, usually in writing, setting out the terms and conditions of the engagement. In our analysis, contracts are the documents that show the majority of the binding details of multi-lateral or bilateral agreements between a public entity and pharmaceutical developers.
Buyer	The entity paying for and using the vaccines.
Supplier	Those awarded the contract to provide the vaccines.
Clinical Trial Protocol	They contain important clinical trial information such as trial design, objectives, methodology and statistical analysis plans.
Clinical Trial Summary Results	These summarise the key features of a clinical trial: the drug or device being investigated, outcome measures used, patient characteristics, and the headline results.
Clinical Study Reports	These provide a detailed picture of the design, conduct, analysis, and outcomes of a trial, including details on the negative side effects experienced by patients.
Clinical Trials	Research studies conducted using human participants split into two groups, one group receiving the treatment or vaccine and the other a placebo group to measure the efficacy and any unintended side effects.
Indemnification Clause	These detail the scope and duration of the responsibility of one party (the indemnifying party) to cover losses of the other party (the indemnified party).
Price Per Dose	Price for each dose of a vaccine.
Redactions	The obfuscation of specific text through its removal or covering.

KEY FIGURES

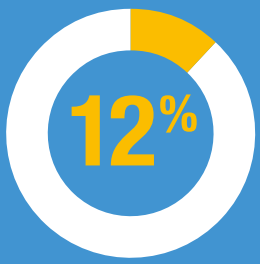
We analysed **86** registered clinical trials **across 20 different COVID-19 vaccines**

or **30%** of the total

are being made by developers based in countries that **do not align to best practice and require the reporting of clinical trial summary results within 12 months of trial completion.**

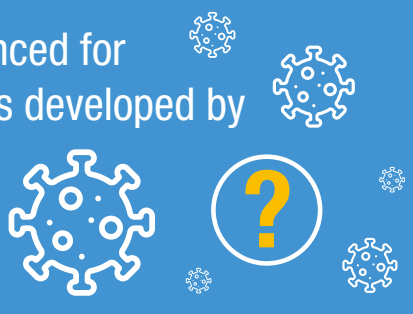
Clinical study reports are only made available in **two of the nine countries** where developers are based

We found the clinical trial protocols for just **10 trials**



There were no publicly accessible protocols for 88% of the registered trials in our analysis, meaning that we are missing key details of how the clinical trials have been ran.

At least some clinical trial results have been announced for **18 of the 20 vaccines** in our analysis. Two vaccines developed by **AnGes and Zydus Cadila have announced no trial results**



Results have been announced for **45% of the total registered clinical trials** in our analysis

Of these **41 per cent have no published data analysis**, meaning that **only top-level results were provided through a press release, press conference or media report, with minimal data**

We found a total of **182 agreements** for the purchase of **12 different COVID-19 vaccines**

Just 6% of vaccine contracts between developers and public buyers have been published through formal channels

Just one contract, or 0.5% of the total,

was published by buyers without [redacted] redaction. [redacted] The vast majority redact [redacted] large sections [redacted] that are of critical [redacted] public interest, price per dose and delivery timetables

For **AstraZeneca's** vaccine, upper-middle income countries like **South Africa** are paying an average of **25% more per contract** than high income countries like the **USA.**

High Income Economies	Lower-Middle Income Economies	Upper Middle Economies
$6.26 per contract	**$6.72** per contract	**$7.81** per contract

Amount in $USD

EXECUTIVE SUMMARY

The urgency of the COVID-19 pandemic has demanded rapid disbursements of public funds, quick decision-making, and unprecedented public health interventions. Our analysis reveals that the development of and contracting for the supply of COVID-19 vaccines has also been accompanied by a disturbing and dangerous lack of transparency.

Poor guidance and weak and inconsistent global policy mean that key information has only been shared because of the voluntary actions of certain vaccine developers, governments, and vaccine buyers. There is a pressing need for global policy reform to improve the current of standards of openness to embed transparency into development and contracting processes.

The case for transparency in vaccine development and contracts is clear: the huge global demand, the vast sums of public money already and still to be invested and spent, and the need to build public confidence in vaccines as the best way to bring the pandemic under control. Yet, our analysis of clinical contracting data across 20 of the leading COVID-19 vaccine candidates, a number of which are already in use around the world, uncovered an unsettling trend of poor transparency. For instance, 30 per cent of the COVID-19 vaccines being developed at the time of our research were made by developers based in countries that do not require the reporting of clinical trial summary results within 12 months.

Clinical Trial Transparency

Since March 2020, billions have been spent on the development of vaccines, with near-daily updates on new research findings. However, there is a lack of prescriptive guidance and legislation on the sharing of clinical trial results by pharmaceutical developers, funders, and drug regulatory agencies during a public health emergency. This has increased the risk of undue influence and manipulation in the clinical development process. Without legally mandated, harmonised, transparent processes and timelines for sharing clinical trial results, pharmaceutical developers can present their data in the most flattering and beneficial light or choose to withhold the data altogether. The immense pressure to rapidly produce treatments and vaccines, combined with the huge amounts of money on offer for effective products, only heightens these risks.

Further complicating the picture, clinical trial transparency requirements differ widely from country to country creating a confused global policy landscape. Depending on the location of clinical trials, where the vaccines are to be manufactured and the country applied to for approval, there are different levels of data sharing.

Together they have enabled a growing trend of 'science by press release' and the frequent use of media to announce clinical trial results without the accompanying publication of the associated data analysis. This facilitates potentially dangerous misinformation and misunderstanding.

Contract Transparency

Public procurement – the process whereby governments contract suppliers for products - in health is historically vulnerable to wastage and corruption, resulting in fewer life-saving products efficiently reaching those it is intended for.

Transparency in contracts to supply vaccines provides vital information such as price per dose that can ensure that public funds are spent as effectively as possible, saving more lives. Governments can improve their understanding of procurement processes, use pricing information in contracts to make informed choices. Civil society and journalists can monitor the process to identify irregularities and investigate corruption. Legislators can scrutinise the details of a deal, monitor its performance. This additional oversight reduces the risk of grand corruption or malfeasance such as state capture or illicit enrichment.

Despite these clear benefits, which have been recognised by governments around the world, robust guidance on contractual transparency in public health emergencies was not in place at the onset of the pandemic. As a result, there has been an extremely low publication rate of COVID-19 vaccine contracts worldwide. Even in published contracts there are significant redactions which hide key details of public interest and may play a part in explaining why many countries lost out in the initial race for vaccines.

Based on the limited information available, we also found that there is notable variability in pricing of vaccines. Some buyers are paying more than we would expect when compared to GDP per capita. Further, the inclusion of extensive indemnification clauses in the available contracts suggest that contracts are pushing financial risks onto national governments, and away from the developer.

INTRODUCTION

The COVID-19 pandemic has required an unprecedented public health response, with governments dedicating massive amounts of resources to their health systems at extraordinary speed. Governments have had to respond quickly to fast-changing contexts, with many competing interests, and little in the way of historical precedent to guide them. Transparency here is paramount; publicly available information is critical to reducing the inherent risks of such a situation by ensuring governmental decisions are accountable and by enabling non-governmental expert input into the global vaccination process.

Given the scope, rapid progression and complexity of the global vaccination process, this is not an exhaustive analysis. First, all the following analysis is limited to 20 leading COVID-19 vaccines that were in, or had completed, phase 3 clinical trials as of 11th January 2021. Second, we have concentrated on transparency of two of the initial stages of the process: clinical trial transparency and the public contracting for the supply of vaccines. The report provides concrete recommendations on how to overcome current opacity in order to contribute to achieving the commitment of world leaders to ensure equal, fair and affordable access to COVID-19 vaccines for all countries.

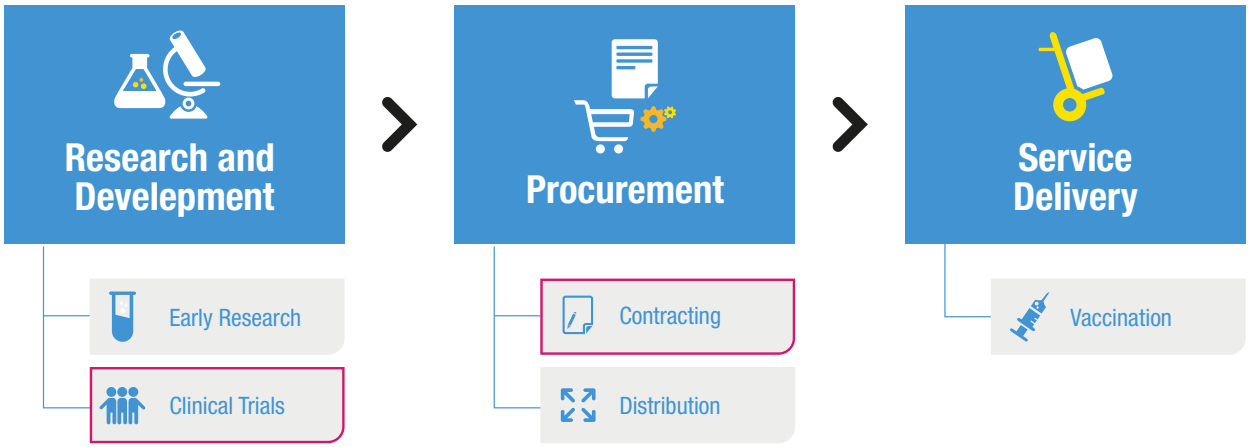


Image 1: Key stages in the COVID-19 global vaccination process

Transparency in these two stages of the global vaccination process has important implications, both for the development of COVID-19 medical technology, and for future health emergencies and the wider governance of pharmaceutical development and public contracting. The elements highlighted in this report are important in bringing COVID-19 vaccines to market whilst offering important opportunities to move the dial in wider conversations on transparency beyond COVID-19.

This report analyses transparency of two key stages of the vaccine development in chronological order: The development and subsequent buying of vaccines.

For development of the vaccines we focus on clinical trial transparency, detailing:

1. The clinical trial transparency policies of the jurisdiction in which the developers of the selected COVID-19 vaccines are based
2. Sharing of COVID-19 vaccine clinical trial protocols
3. Transparency of COVID-19 vaccine clinical trial results

For the buying of vaccines, we specifically focus on COVID-19 contractual transparency, detailing:

1. Publication of COVID-19 vaccine contracts: a global overview
2. Overview of the redactions in formally published COVID-19 vaccine contracts
3. COVID-19 vaccine prices: the need for transparency
4. Indemnification clauses: the need for transparency

RECOMMENDATIONS

The following recommendations should either be rapidly implemented to increase monitoring and transparency in the context of COVID-19 vaccines, or a more systematic manner to increase transparency, access to information, and accountability in the pharmaceutical industry, and pandemic-related research and development and public contracting.

Recommendations	Target Actor
The WHO should update its guidance on sharing clinical trial results to include an expanded amendment on public health emergencies, to be implemented by national governments.	WHO
National governments should adopt, fully implement and enforce broadened legislation which requires all clinical trials to be pre-registered, and make summary results public within 12 months of their completion on a trial registry.	National governments Drug regulatory agencies
Drug regulatory agencies should make complete clinical study reports available, after excluding individual participant identifiers if unavoidable, within 60 days of approval for all medical products, including COVID-19 vaccines.	National governments Drug regulatory agencies
COVID-19 vaccine developers that have not yet published their clinical trial protocols should do so on a publicly accessible clinical trial registry. In future they should publish them when the trial is approved, prior to participant recruitment. Any protocol amendments should be published at the time of results sharing.	Vaccine developers
All governments should revise clinical trial legislation to require the public sharing of clinical trial protocols when the trial is approved, on a publicly accessible platform which meets WHO standards, then updated with any amendments at the time of results sharing.	National governments Drug regulatory agencies
COVID-19 vaccine developers must publish all missing clinical trial data analysis.	Vaccine developers
Use of the media should only be used to announce clinical trial results in tandem with data analysis published in a peer-reviewed medical journal or as a pre-print article.	Vaccine developers
Further research is required to explore potential manipulation of key clinical trial information and trading activities of pharmaceutical developers.	WHO Research institutions
All buyers have an obligation to be transparent and accountable and should follow the lead of the USA and publish their remaining contracts. Brazil, the UK, and the EU should champion this given their relative wealth and number of doses already secured. The COVAX facility should reaffirm its commitment to equity by publishing all vaccine contracts, and if necessary, use redacted versions that are clearly and specifically justified.	The COVAX Facility

Recommendations	Target Actor
International NGOs should advocate for transparency and provide resources that assist with obtaining justifications for contractual secrecy by buyers. Where possible, these INGOs should combine efforts to also target regional and international decision-making bodies such as the African Union and COVAX.	International Non-Governmental Organizations
Governments and the WHO should provide guidance on public health emergency procurement which contains robust transparency rules, including when and how to publish contracts in a pandemic, in order to guarantee that transparency is not a casualty in future crises.	National governments and WHO
Buyers with already published and redacted contracts that are not marked with a justification - the UK, the EU and Brazil - should immediately republish with such details. Future publication of contracts should follow the CGD principle that "All redactions should be clearly marked with the reason for redaction".	The UK, the EU and Brazil. All public buyers of vaccines
Justification of redactions should detail the decision-making process that led the buyer to conclude that it is of a higher public interest to redact, or not redact at all. These should be specific to discrete sections of the contract rather than blanket explanations.	All public buyers of vaccines
All vaccine developers, and particularly AstraZeneca, should justify their commitment to broad and equitable access by releasing their price per dose of all their agreements, preferably within a contract.	Vaccine developers
The EU, the USA, the UK, Japan, Canada and Australia should champion pricing transparency, by releasing contracts without redaction of prices.	The EU, the USA, the UK, Japan, Canada and Australia
A pricing database should be established by the WHO with the general principle that all countries report their prices anonymously.	WHO
In the absence of full publications of contracts by buyers, suppliers should release the full extent of its agreed upon indemnification clauses.	National governments and public buyers of vaccines
The WHO should develop toolkit to promote good practice in pandemic vaccine agreements complete with template clauses and guidance.	WHO

WHY IS TRANSPARENCY KEY IN COVID-19 VACCINE DEVELOPMENT AND PROCUREMENT?

Three distinct features of the development processes of COVID-19 vaccines make clear the case for transparency: the large sums of public funding involved; every country's urgent need for the vaccines, and the need to enhance public confidence in them.

All Vaccines Have Received Some Form of Public Support

To different extents, and through different modalities, all vaccine candidates have received public resources for their development.

One such modality was through direct research grants, such as the sum of USD 2.48 billion that Moderna received from the United States (USA) government, through Operation Warp Speed[1]. The development of some COVID-19 vaccines was aided through publicly funded research conducted prior to the pandemic. For example, after receiving earlier funding from the USA government, a group of researchers developed foundational mRNA technology which they licensed to Moderna and BioNTech, forming the basis of their respective COVID-19 vaccines[2].

According to the United Kingdom National Audit Office report, the UK government agreed to upfront payments of GBP 914 million in the five contracts it signed up to 8th December 2020 to be used to cover clinical trial and manufacturing costs[3], which can then be used against future purchases once the vaccines are approved. Another form of public support is offering investment loans to vaccine developers. For example, BioNTech received a EUR 100 million investment from the European Investment Bank in a debt financing agreement in the summer of 2020, to support the development of its COVID-19 vaccine[4].

Public support has also been received in less quantifiable forms, such as in research collaborations with public institutions, for example, AnGes and the Japan Agency for Medical Research and Development who collaborated to conduct a phase I/II[5] and phase II/III trial[6]. Finally, some vaccines have been developed entirely by the public sector, as in the instance of Sinopharm, a Chinese state-owned enterprise, and the Gamaleya Research Institute, a Russian state institution.

As other leading global institutions have stated[7 8 9], the public has a right to know everything about the COVID-19 vaccines their taxes have significantly helped to fund.

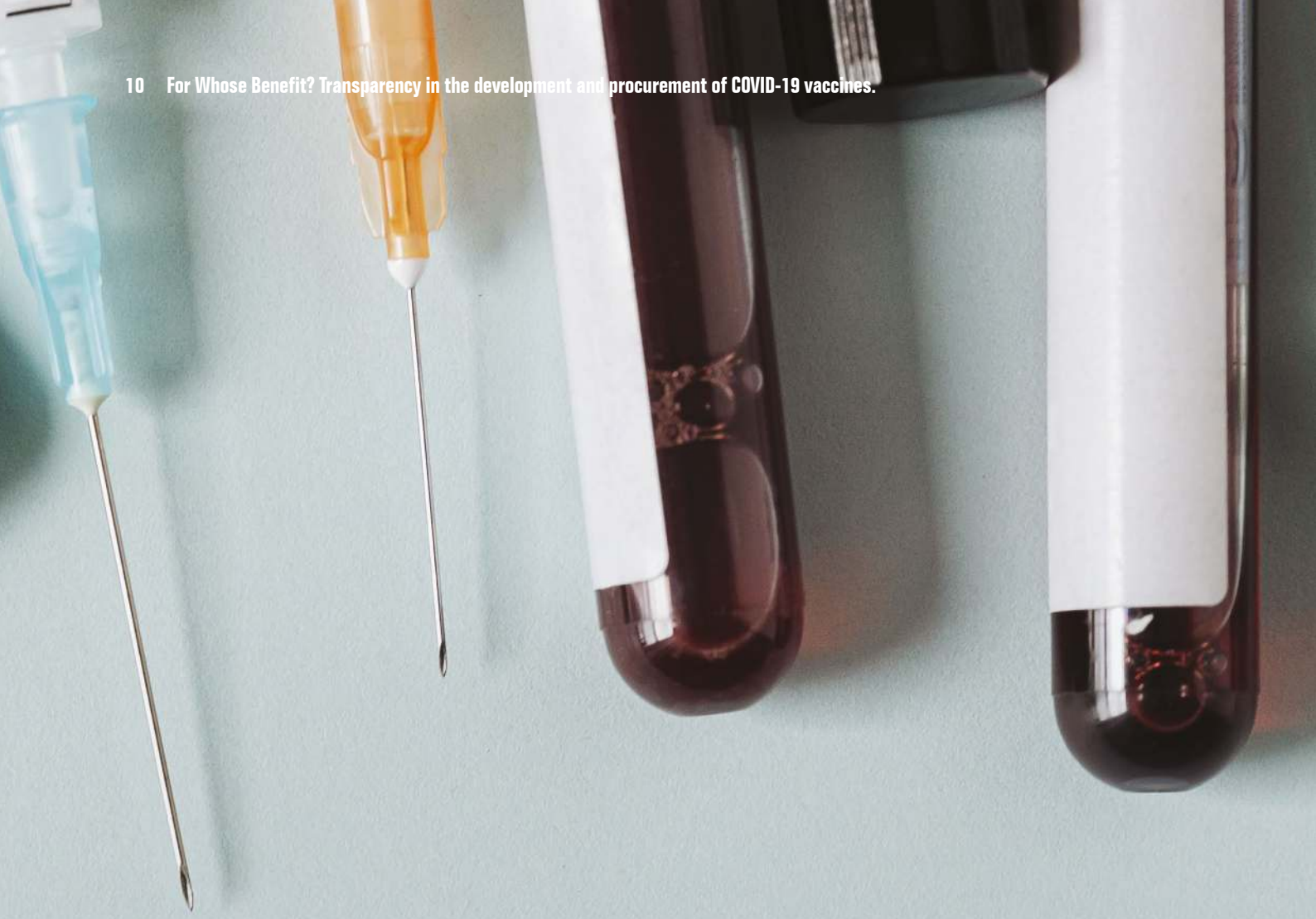
COVID-19 Vaccines are a Global Public Good

Citizens and institutions around the world are highly invested in the development and rollout of the COVID-19 vaccines. Many are hoping the deployments of vaccines will start to signal the end of a pandemic that has caused over 3.2 million deaths worldwide as of the 4th May 2021[10], in addition to chronic suffering of long-COVID, worsening inequalities and mental health impacts.

Early in the pandemic, COVID-19 vaccines were frequently referred to as "global public goods", a term generally used to describe "products, ideas, policies or issues with effects that could extend to everyone, everywhere"[11]. A WHO COVID-19 Resolution recognises, "the role of extensive immunisation against COVID-19 as a global public good for health in preventing, containing and stopping transmission in order to bring the pandemic to an end, once safe, quality, efficacious, effective, accessible and affordable vaccines are available"[12].

Public Confidence in COVID-19 Vaccines

When information regarding the development and supply of these vaccines is not published, the resulting evidence vacuum creates fertile ground for distrust in vaccines and hesitancy about inoculation. It is easy to see for example, how lack of information on the details of agreements between governments and suppliers may add confidence in conspiracy theories, such as the widely held belief that vaccines are being developed solely for the profit of pharmaceutical companies[13]. Similarly, opacity or vagary in clinical trial reporting of adverse effects has already led to distrust of vaccination. Such hesitancy, caused in part by the opacity around the global COVID-19 vaccination process, is directly linked to the 32 per cent of people worldwide who are unwilling to take the vaccine[14 15]. Uncertainty and misinformation can only be tackled by the sharing of factual and objective evidence. The more this is done, the more likely we are to have trust and therefore successful vaccination programmes.



CLINICAL TRIAL TRANSPARENCY

CLINICAL TRIAL TRANSPARENCY AND COVID-19 VACCINES

Clinical Trial Transparency: Background & Risks

Clinical trials are a key component of medical innovation and progress. Volunteers are enlisted to participate in trials to determine whether drugs, vaccines or other medical technologies are safe and efficacious. The efficacy of a drug, device or treatment is typically determined by testing it on volunteers and comparing the outcomes against a control group that receives a placebo, or the existing standard of care. Scientists monitor trial participants for changes in their health status, or for any negative side effects. By comparing data from the two groups of participants, researchers learn whether a drug, vaccine or technology is safe and efficacious.

There are four phases of in-human clinical trials. Phases I, II and III are normally required to be completed to confirm safety and efficacy of the medical product and allow for regulatory approval prior to distribution. A phase IV trial is ran once the product is already in use allowing for larger studies to confirm earlier findings. Each clinical trial phase can be repeated in different subsets of populations, such as different ages, health backgrounds and geographical location.

The case for transparency in this area is well established. Without access to clinical trial information, scientific advances are inhibited, creating research waste. Without legally mandated, transparent formats and timelines for sharing clinical trial results, clinical trial information can be manipulated, hidden or distorted, potentially in a manner that benefits the financial objective of the pharmaceutical developers. This can lead to public health consequences, as public, private, and medical communities will lack access to accurate information on potential benefits and risks of medicines[16]. Such issues contributed to the provision of the Helsinki Declaration that states "researchers, authors, sponsors, editors and publishers all have ethical obligations with regard to the publication and dissemination of the results of research"[17].

Here, we focus on transparency in three key elements of clinical trial transparency.

First are clinical trial protocols. Clinical trial protocols contain important information such as trial design, objectives, methodology and statistical analysis plans. Good practice is to share the protocol at the time of trial approval, prior to participant enrolment, and to publish any amendments made to the protocol at the time of results sharing. Transparency is important as the sharing of clinical trial protocols enables external expert scrutiny of methodology and design integrity to highlight potential bias. Making the sharing of protocols mandatory can also deter the selective reporting of results[18 19].

Second are summary results of clinical trials. Summary results take the form of a short table that summarises the key features of a clinical trial: the drug or device being investigated, outcome measures used, patient characteristics, and the headline results. They do not contain in-depth information on the design, conduct or findings of a trial but rather provide a picture of a trial's findings. Good practice is to share summary results on a publicly accessible clinical trial registry within 12 months of trial completion. Transparency here is important as summary results allow researchers to quickly and systematically share new findings without having to wait until publication in a peer-reviewed scientific journal, alongside reducing the potential for bias and evidence distortion in the reporting of results[20].

Third are clinical study reports (CSRs). CSRs make up a significant portion of the full reports submitted to drug regulatory agencies when a developer is seeking approval to distribute its medicine in that jurisdiction. Whilst summary results offer the valuable headline details of a clinical trial, the CSRs provide a much more detailed picture of the design, conduct, analysis, and outcomes of a trial, including details on the negative side effects experienced by patients. Additionally, whilst clinical trial results are often presented in peer-reviewed scientific journals as a primary method for sharing clinical data, this is often a representation of only a subset of data and thus still requires detailed CSRs. Good practice here is for drug regulatory agencies to make CSRs publicly available within 60 days of regulatory approval. Transparency is important as CSRs provide a much richer insight into the efficacy and safety of a medicine allowing researchers to independently verify the presented summary evidence from trials and how it was generated, and to re-evaluate the conclusions arrived at by pharmaceutical companies and regulatory agencies. Without access to CSRs, we cannot fully verify the accuracy, reliability, and validity of trial findings, or detect omissions, mistakes, misinterpretations, evidence distortion and misrepresentations in other forms of trial reporting[21].

This analysis first looks at existing clinical trial policies concerning these three elements to understand the basic level of transparency governments will be requiring when it comes to COVID-19 vaccine clinical trials. The jurisdictions selected for clinical trial policy analysis are

the headquarter locations of the vaccine developers leading the development of the selected 20 vaccines. Additionally, 80 per cent of the identified clinical trials have a minimum of one of their clinical trial locations in the selected jurisdictions.

Clinical Trial Transparency: Crises & COVID-19 Vaccines

Since March 2020, billions have been spent on the development of vaccines, with near-daily updates on new research findings. However, there is a lack of prescriptive guidance and legislation on the sharing of clinical trial results by pharmaceutical developers, funders, and drug regulatory agencies during a public health emergency. This increases the risks of undue influence and manipulation in the clinical development process. Without legally mandated, transparent formats and timelines for sharing clinical trial results, pharmaceutical developers can present the data in a manner that benefits their financial objectives or choose to withhold the data altogether. The immense pressure to rapidly produce treatments of vaccines, and potentially earn billions from them heighten such risks.

When vaccine developers apply for marketing authorisation, the clinical trial data is shared with national regulatory agencies, which are responsible for analysing and approving the medical technology under review for distribution. However, it is well-recognised[22] that in weak health systems, a lack of regulatory capacity and expertise can undermine a national regulatory agency's ability to spot suspicious clinical trial data. This can increase a country's vulnerability to substandard or unsafe medical products, whereas mandating the public sharing of clinical trial data would allow for both public and external expert scrutiny of results.

Governance of Clinical Trial Transparency

Improved guidance from the WHO, medical journals, clinical trial sponsors and drug regulatory agencies, alongside the introduction of new legislation over recent years have been instrumental in improving clinical trial transparency internationally. The WHO, in its role to set norms and provide technical guidance across the pharmaceutical development process and other areas of health, has been instrumental in facilitating international collaboration for setting clinical trial transparency standards over the past two decades[23 24]. While ultimately national governments are responsible for implementing robust legislation, a commitment from vaccine developers to comply with transparency is also important. However, regular monitoring and discussions around this issue are needed from governments, global health actors, civil society, and pharmaceutical developers to highlight how governance and legislation can be tightened to mitigate obstacles to global clinical trial transparency.

Discordant Legislation

We found that five out of nine jurisdictions require summary results to be shared within 12 months of trial completion. This means that six vaccines – or 30 per cent of the total - are being developed by developers based in jurisdictions that do not align to best practice in clinical trial summary results reporting. Furthermore, the public sharing CSRs is only mandated in two of the nine jurisdictions. As such we can expect that CSRs will only be made available for vaccines which have been applied for approval in Canada and the EU[i]. The same implication stands for clinical trial protocols as they are only required to be shared in two jurisdictions, the EU and USA.

Table 1. Summary of Clinical Trial Transparency Policies in the Selected Countries.

Jurisdictions	Summary results required to be shared within 12 months	Clinical study reports made available	Protocol sharing required
EU [25 26 27 ii]	X	X	X
Canada [28 iii 29]		X	
China [30]	X		
India [31]			
Russia [32]			

i The policies regarding CSR sharing in EU and Canada only applies to medicines which have been applied for approval to be distributed in the jurisdiction.

ii The EU has suspended its policy on prospective publication of clinical trial data with the exception of COVID-19 clinical trials as the European Medicines Agency (EMA) transfers to an EU base following the UK leaving the EU. 'Clinical Data Publication' (European Medicines Agency, 17 September 2018) <https://www.ema.europa.eu/en/human-regulatory/marketing-authorisation/clinical-data-publication> accessed 9 April 2021.

iii Registration is not legally mandated in Canada but its ethical benchmark policy states that clinical trials must be registered.

Jurisdictions	Summary results required to be shared within 12 months	Clinical study reports made available	Protocol sharing required
UK [33]	X		
USA [34 35]	X		X
Kazakhstan [36]			
Japan [37 38]	X		

Even in jurisdictions where transparency aligns to good practice, these policies are not globally uniform. For example, different jurisdictions can have different inclusion and exclusion criteria as to what type of clinical trials must be registered and results shared. Additionally, even with a legal requirement for all results to be shared, compliance is not guaranteed, nor is active monitoring or penalisation of non-compliance by a relevant regulatory body[39 40].

Mixed Global Leadership

Certain countries and global institutions have maintained high standards of transparency during the COVID-19 pandemic. For example, in 2020, the UK announced a new clinical trial transparency strategy which calls for all UK clinical trials to be registered and results shared, seemingly without exceptions[41]. The European Medicines Agency did introduce exceptional transparency measures for COVID-19 vaccines and therapeutics by resuming its suspended policy on clinical trial transparency[42]. Yet there still is much room for improvement.

During public health emergencies, the WHO recommends that quality-controlled interim results be shared prior to clinical trial completion[43]. This recommendation was made in 2015, but our analysis did not find that this was implemented in national policies. Furthermore, it also does not specify timing or in what format the results should be shared[44]. Similarly, the USA National Institutes of Health called upon researchers to "share their results as swiftly as possible… ahead of regulatory and policy deadline requirements to ClinicalTrials.gov" but did not specify any exact timings[45].

SUMMARY OF RECOMMENDATIONS

- The WHO should update its guidance on sharing clinical trial results to include an expanded amendment on public health emergencies, to be implemented by national governments.
- National governments should adopt, fully implement and enforce broadened legislation which requires all clinical trials to be pre-registered, and make summary results public within 12 months of their completion on a trial registry.
- Drug regulatory agencies should make complete clinical study reports available, after excluding individual participant identifiers if unavoidable, within 60 days of approval for all medical products, including COVID-19 vaccines.

Sharing of Clinical Trial Protocols

Clinical trial protocols contain important information such as trial design, objectives, methodology and statistical analysis plans. Trial protocols are submitted to local or national ethics committees or institutional review boards. Once approved, the trials can be initiated. Providing public access to trial protocols allows researchers to better understand the trial design, any potential limitations. They can also help accelerate R&D through parallel trial designs if others can understand the types of innovative trials designs being used in the pandemic setting. The Trial Registration Data Set defined by the WHO ensures that clinical trial registries offer a brief description of the clinical trial design. But this does not provide enough information to effectively appraise a study's design or identify selective reporting[46]. However, public sharing of protocols is generally not mandated - at least not prior to trial completion. When protocols are shared, they do not always include details of amendments made. This risks potential bias in changes made to the protocol (for example to the primary endpoint – the measurement taken to indicate whether the tested product is safe or efficacious) upon viewing interim data. As such, it is often left to the discretion of the pharmaceutical company whether or not to make them publicly available.

The WHO recommends that protocols should be shared no later than the sharing of summary results in order to effectively interpret the results[47]. The European Medicines Agency makes available the protocols for products it has approved[48] and USA legislation requires that protocols be submitted alongside results[49].

The sharing of clinical trial protocols is important, as it enables external expert scrutiny of methodology and design integrity to highlight potential bias. Making the sharing of protocols mandatory can also deter the

selective reporting of results[50] [51]. Protocols should be shared prior to participant enrolment and to be followed up by a final version highlighting any amendments at the time of results sharing. This early sharing would minimise the risk of undue influence and bias in the trial design[52]. Sharing of protocols could give other developers a competitive advantage[53]. But the low level of confidential information in protocols minimises any risk of that[54].

Promising Action: Proactive Disclosure in Clinical Trial Protocols

Our analysis identified 86 registered clinical trials across the 20 vaccines. Of these, we found the clinical trial protocols for only 10 trials, two of which were shared alongside the publication of data analysis. This means that protocols were only made publicly accessible for just 12 per cent of clinical trials[iv].

Protocols were shared prior to trial completion in few clinical trials. Whilst those developers who did share protocols made positive steps towards increasing transparency, on a wider scale, especially during a health emergency, its importance is still under not sufficiently recognised.

SUMMARY OF RECOMMENDATIONS

- COVID-19 vaccine developers that have not yet published their clinical trial protocols should do so on a publicly accessible clinical trial registry. In future they should publish them when the trial is approved, prior to participant recruitment. Any protocol amendments should be published at the time of results sharing.
- All governments should revise clinical trial legislation to require the public sharing of clinical trial protocols when the trial is approved, on a publicly accessible platform which meets WHO standards, then updated with any amendments at the time of results sharing.

Clinical Trial Results Sharing During The COVID-19 Pandemic

COVID-19 vaccine trial information has been disseminated through press releases, media conferences, and even personal Twitter accounts. Typically, results are shared through peer reviewed articles in medical journals or on clinical registry sites, but the significant level of media and public interest has meant an increased appetite for quick, proactive, and easy to understand updates on the progress of COVID-19 vaccines. Whilst this increased appetite seemingly might strengthen the argument for announcing clinical trial results without having to wait for the publication of a peer-reviewed article, or preferably a CSR, we would argue that no results should be shared until the data analysis is also ready to be shared. These early announcements of headline results have led to the selective sharing of results, and a failure to explain methodological details that are key to interpreting the results. The way in which information is published can distort public trust, political responses, and ongoing evaluations.[55] This risks negatively impacting vaccine distribution and acceptance.[56]

Although no evidence of data manipulation has been identified, it is important to understand the potential risks to prevent any possibility of corruption, and to ensure that public trust is not undermined. Announcing clinical trial findings without the clinical trial data and analysis should not be allowed. The WHO recommends for interim clinical trial results to be shared during health emergencies. But more specific guidance, such as what data should be shared and in what format, is lacking, as are specific country policies for such exceptional circumstances.

An Unclear Picture: Absence of Meaningful Data Analysis

Our analysis of 20 COVID-19 vaccines investigated whether a vaccine developer announced any clinical trial results, if so, then in what format and did they publish any data analysis[v] beyond the headline results.

We found 86 clinical trials are registered across the 20 COVID-19 vaccines. At least some clinical trial results had been announced for 18 vaccines, meaning that two vaccines developed by AnGes and Zydus Cadila had announced no trial results. Only 45 per cent of registered clinical trials had announced any clinical trial results[vi]. Of these trials with announced clinical trial results, 41 per cent have no published data analysis, meaning that only top-level results were provided through a press release, press conference or media report, with minimal data[vii].

We found that Sinovac Biotech and the Vector Institute published no clinical trial data analysis for their vaccines at all, for reasons unknown, despite both vaccines having been administered to populations since July 2020 and October 2020, respectively.

In November 2020, AstraZeneca announced preliminary results of its phase III trial by press release which created confusion due to differences in dosing, where a lower

iv Full dataset can be found in Annex 2.

v Whilst CSRs are the more optimal format of data analysis sharing we did not find any CSRs that have been shared so in this context the publication of data analysis refers to pre-print or peer-reviewed scientific articles.

vi Note that due to the difficulty in obtaining accurate updates on individual trial progression, our analysis does not take into account trial timelines (for example, some registered trials might not have commenced dosing of participants or have yet to produce any results) which would explain why no results have been made available.

vii Full dataset can be found in Annex 2.

Results have been announced for **45% of the total registered clinical trials** in our analysis

Of these **41 per cent have no published data analysis**, meaning that **only top-level results were provided through a press release, press conference or media report, with minimal data**

dose led to a nearly 30 per cent higher efficacy rate. Further explanatory details were privately shared with industry experts and selected media. But the lack of public disclosure raised doubts and potentially risked undermining confidence in the vaccine[57]. Concerns were raised in March 2021 by the USA National Institute of Allergy and Infectious Disease (NIAID) that a press release reporting an efficacy rate of 79 per cent based on an interim analysis "may have provided an incomplete view of the efficacy data," leading to further confusion. A few days later AstraZeneca published a further press release reporting an efficacy rate of 76 per cent based on final analysis[58]. Given the primary analysis was close to complete and the additional data apparently having been seen by NIAID prior to the announcement of the interim analysis, it is unclear why AstraZeneca took such an approach. Particularly when such actions can give an impression of hiding data which indicates a lower efficacy, further risking damage to public trust. This risk of lowered trust was then compounded by the concerns about the vaccine's side effects and use in elderly age groups leading governments to suspend or curtail the use of the vaccine[59 60].

A further example is the varying efficacy results that were released from Sinovac Biotech's phase III trials, all announced either by press release, press conference or state media reports without publishing any data analysis. The announced results across different trial locations greatly differed in reported efficacy, ranging from 50.4 – 97 per cent[61 62]. These were explained retrospectively by Sinovac Biotech as partly due to methodological differences in trials[63]. However, given the lack of impartiality and limited information that press releases and press conferences permit, confusion can be expected when they announce clinical trial results without the concurrent publication of a data analysis. We do not yet know whether this discrepancy will have negative impacts on the rollout and uptake of Sinovac Biotech's vaccine.

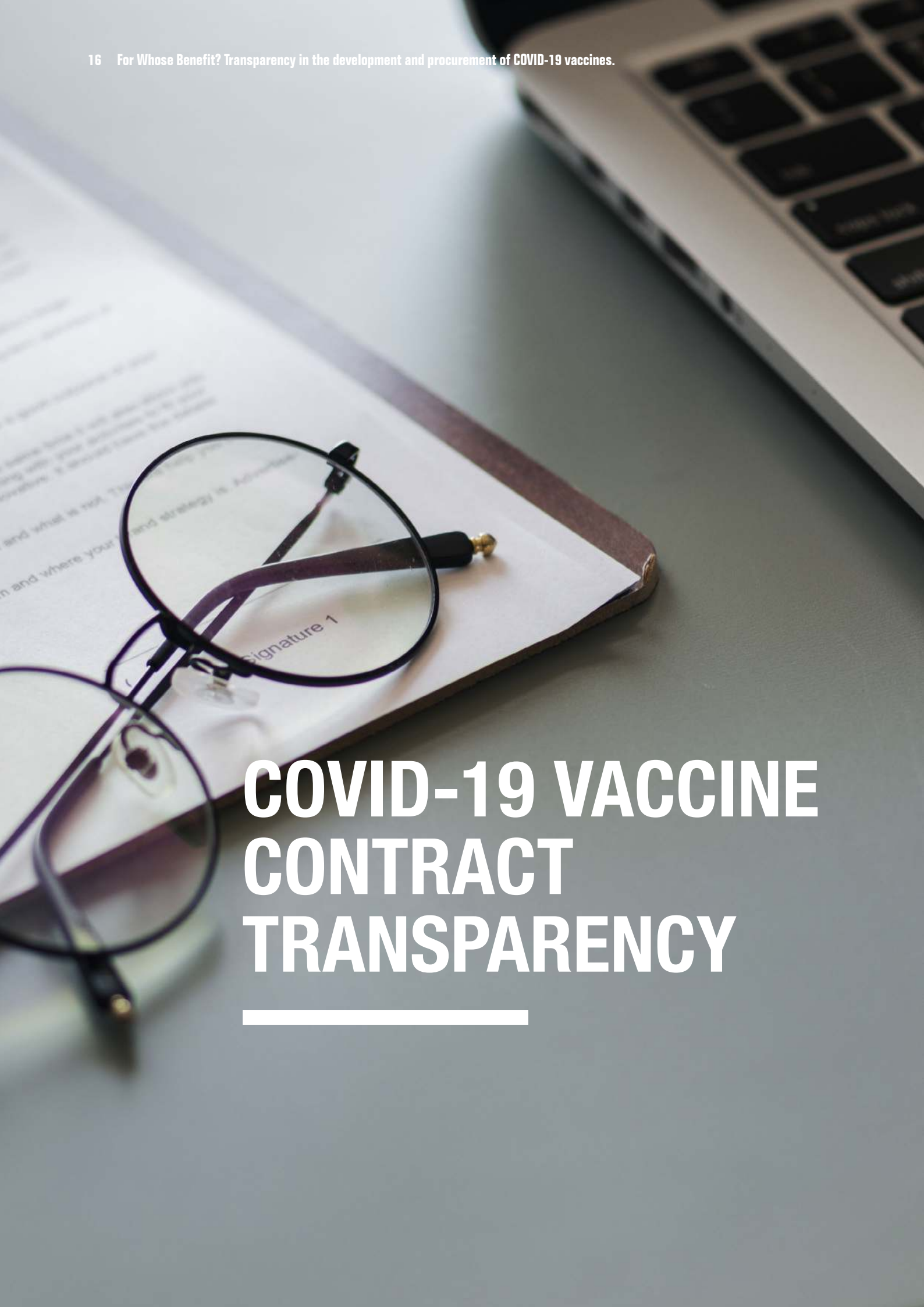
Furthermore, press releases enable companies to sequence information releases alongside stock movements, gaining a potential opportunity for private profit. Correlations between the publication of clinical trial results and stock selling patterns by top pharmaceutical executives have been observed during announcements by Moderna[64] and Pfizer[65]. USA executives at both companies are reported to have had adopted or amended pre-scheduled stock trading plans (known as 10b5-1 plans) just days before significant announcements regarding the successful progress of their COVID-19 vaccines were made public. Such trading plans, for example instructions to buy or sell stocks, are legal, providing the person(s) involved did not hold any non-public information, such as trial results or investments, at that time.

Whilst there is no evidence of malpractice in the cases of Moderna and Pfizer, such activities can raise suspicions and highlight the risk of pharmaceutical companies using important public health announcements to make personal gains, especially significant in the case of Moderna, whose vaccine received large amounts of USA government funding. Spokespersons for both Moderna[66] and Pfizer[67] have publicly denied that their respective executives' stock trading decisions were based on material non-public information.

There has been a move towards increased clinical trial transparency by certain vaccine developers, perhaps signalling a shift toward transparency efforts for the pharmaceutical sector. Perhaps press releases are a proactive way for vaccine developers to engage the public in important research updates. However, it could be argued that these vaccine developers have only superficially embraced transparency, and in fact, have distorted its progress. In order to alleviate further concerns, vaccine developers and governments should seek to regulate the process of publishing information in public online spaces.

SUMMARY OF RECOMMENDATIONS

- COVID-19 vaccine developers must publish all missing clinical trial data analysis.
- Use of the media should only be used to announce clinical trial results in tandem with data analysis published in a peer-reviewed medical journal or as a pre-print article.
- Further research is required to explore potential manipulation of key clinical trial information and trading activities of pharmaceutical developers.



COVID-19 VACCINE CONTRACT TRANSPARENCY

PUBLICATION OF COVID-19 VACCINE CONTRACTS: A GLOBAL OVERVIEW

Public procurement – the process whereby governments contract suppliers for products - in health is historically vulnerable to inefficiencies meaning potentially less lifesaving products are delivered to populations and in a suboptimal sequence. The WHO has suggested that 20-40 per cent (or USD 1.7 – USD 3.4 trillion yearly[68 69]) of total spending does "little to improve people's health"[70]. Of the ten leading causes for this inefficiency, five are fully or partially procurement related.

There are many causes for this inefficiency. Corruption, for instance, can undermine the value of a procurement process by 10-25 per cent[71]. This can occur, for example, if collusion or preferential treatment results in an unqualified supplier[72] producing medical products; or if a supplier reduces the quality of products to cut costs – sometimes rendering it medically useless[73]. Grand corruption can result in monopolies or state capture that reduce the number of suppliers and products governments have available, leaving the system open to cartels, collusion, and price-fixing[74]. Corruption in procurement has been deemed as the number one corruption risk in the public sector by the OECD[75]. Another explanation for inefficiency is mismanagement or lack of capacity[76]. Inability of procuring entities to benchmark prices, negotiate effectively and properly assess a need for products results in suboptimal buying practices which may lead to an oversupply of unneeded equipment for excessive prices[77].

Contractual transparency provides information needed to help disentangle the causes of such inefficiencies and target them directly, leading to better utilisation of public funds and better health outcomes. Contracts for the supply of products in general show who gets what, when, and for how much, by including information on prices paid, number of products to be supplied, and timetables for delivery. When this information is made accessible through the publication of contracts, businesses have more information which they can use to win contracts fairly[78], and civil society and journalists can monitor the process to identify irregularities and investigate corruption[79]. Legislators can scrutinise the details of a deal, monitor its performance, reducing the risk of grand corruption or malfeasance such as state capture or illicit enrichment. Governments can improve their understanding of procurement processes, use pricing information in contracts to make informed choices[80], correct markets through regulatory changes, and punish corrupt actors through enforcement[81].

Vaccines are being utilised as a key tool in ending the pandemic. Yet this is at risk of being undermined by wealthy countries stockpiling vaccines, corruption, pricing disparities and inefficiencies. Furthermore, the publication of contractual information could be of critical importance in tackling the virus. Information held in contracts such as the number of doses secured and timetables for delivery per country can for example be used by public health researchers to refine models for the likely spread of the disease. In this context the need for contractual transparency and accountability becomes paramount. The benefits detailed above can lead to better and more honest buying practices, which in turn result in more supplies, more efficiency and more access to life saving services.

The Scarcity of Transparently Published COVID-19 Vaccine Contracts

Of the 20 vaccine candidates we have analysed, our research approach returned a total of 182 agreements for the purchase of the 12 different COVID-19 vaccines[viii] which have been concluded between 75 buyers and 13 suppliers globally[ix]. We found that only 13 of these contracts are publicly available. Out of these 13 contracts, 11 were formally published[x], while the remaining two were unofficially leaked. This means that only six per cent of the 182 concluded agreements were formally published.

Table 2. List of Contractual Agreements Between Public Buyers and Pharmaceutical Suppliers[82]

Public Buyer	Supplier	Formal Publication
Brazil	AstraZeneca	Yes
Dominican Republic	Pfizer	Yes
EU	CureVac	Yes
EU	AstraZeneca	Yes
UK	AstraZeneca	Yes
USA	AstraZeneca	Yes
USA	AstraZeneca	Yes
USA	Johnson & Johnson (Janssen)	Yes
USA	Moderna	Yes
USA	Pfizer/BioNTech	Yes
USA	Novavax/BioNTech	Yes
Albania	Pfizer	No - Draft leaked
EU	AstraZeneca	No - leaked

viii that had either completed or were currently in phase III clinical trials by 11th January 2021

ix This is of 5th March 2021 and based on UNICEF'S Market Analysis Dashboard: https://www.unicef.org/supply/covid-19-vaccine-market-dashboard

x Formally published is defined as the hosting of the contract on an institutional web platform. This can either be published proactively or through Freedom of Information requests.

The 11 formally published contracts were provided by five different procuring entities: the European Union, the United Kingdom, Brazil, Dominican Republic, and the USA. These entities entered into multiple agreements and did not formally publish every contract. They formally published an average of 23 per cent of their concluded agreements. The USA is an exception to this, as it formally published all six of the contracts it signed.

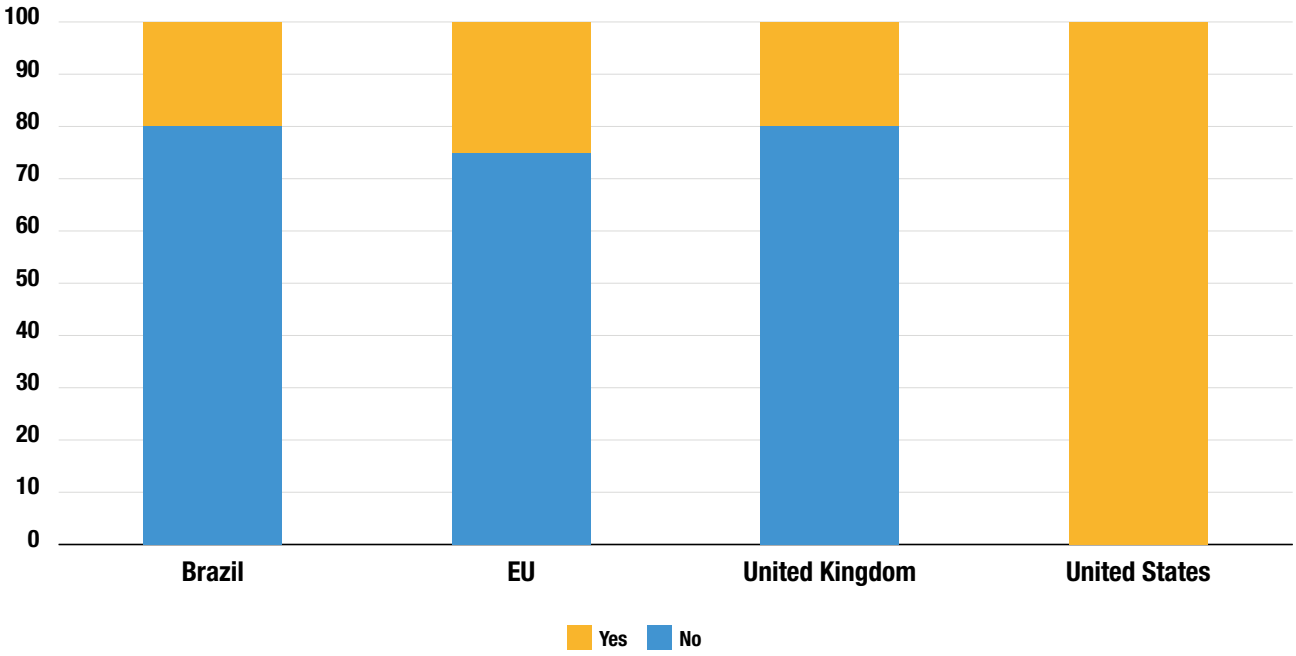
The formal publication of only six per cent of the total number of concluded COVID-19 vaccine contracts is strikingly low and holds significant implications – not only in terms of lack of accountability and risks of inefficiency, but also for the concept of open government[83]. As more and more governments, including Uganda, Kenya, Bangladesh, the UK and the EU have been introducing transparency in public procurement regulations and publishing contracting information this lack of transparency of COVID-19 vaccine contracts goes against this nascent norm[84]. It seems then that over a period of few months, and for perhaps the most important procurement process of our lifetime, the publication of COVID-19 contracts has become a casualty in the race to secure doses.

Justifications by Buyers for Poor Transparency

Justifications by buyers as to the lack of publication of COVID-19 vaccine contracts have been sporadic. COVAX is led by The Global Alliance for Vaccines and Immunizations (GAVI), the WHO, and the Coalition for Epidemic Preparedness Innovations (CEPI) and is the global pooled procurement mechanism for COVID-19 vaccines. It boasts "the largest and most diverse COVID-19 vaccine portfolio in the world" with the aim of delivering two billion vaccines worldwide by the close of 2021 to low- and middle-income countries[85]. Despite the scale of the roll out, COVAX has not released a single contract, and has reportedly justified this lack of transparency by noting that it "could be detrimental to [our] future deals", because they "contain proprietary information"[86]. Media reports[87] [88] and official statements[89] indicate that this line of argument, which is also fairly standard within the industry[90], is generally accepted as a justification for the lack of transparency by buyers worldwide.

This reasoning, however, does not justify the complete lack of publication of contracts. Even if we ignore the public interest argument for transparency, the need to secure the secrecy of proprietary information can be achieved by publishing a redacted version of the contract. Such redactions must be clearly justified and explained to ensure that the redaction process is not arbitrarily applied and open to abuse.

Chart 1. Percentage of Contracts Released by Each Procuring Entity[xi]



xi The procuring entities which are included are only those which formally published at least one contract.

RECOMMENDATIONS

Probing the rationales and justification for a lack of transparency allows civil society organisations to challenge such justifications, holding the procuring entities accountable to their responsibility to public citizens. Accordingly, it is necessary for procuring entities to provide such justifications and for civil society actors to pressure their disclosure. Important here is the role International Non-Governmental Organisations (INGOs), such as Transparency International, can play in the development of advocacy templates and tools. This is particularly true of that enable the use of Freedom of Information requests, which can be used to pressure national governments through their downstream partners and offices.

The aim of COVAX is to increase the equitability of vaccine distribution – a process that is enabled by contractual transparency. Given this context, COVAX should publish all their contracts, and if necessary, redact certain information with sufficient justification.

Given the arguments for contract transparency generally, but also specifically in this context we call for all governments worldwide to publish COVID-19 vaccine contracts. However, given the current extent of secrecy around COVID-19 vaccine contracts and the need for timeliness in this context, it is prudent to make smaller scale recommendations that provide potential initial steps that may hasten the realisation of this lofty aim. An understanding of the current vaccine market may provide a way to appropriately achieve this. Currently demand for COVID-19 vaccines outstrips supply, meaning there is no market equilibrium, and suppliers have market and price setting power.[91] This implies that buyers are sacrificing standards of transparency in order to secure doses. Consequently, other buyers are likely to do the same in order to avoid losing bargaining power relative to other buyers. Such an insight can assist in making two further actionable recommendations.

Those governments which have already shown a willingness to publish contracts, the UK, EU, Brazil and USA should continue to do so and publish all of COVID-19 vaccine contracts, becoming champions of contractual transparency. Given the large supplies of vaccines already procured across these economies[xii], the argument that publishing contracts would undermine efforts to procure vaccines is particularly difficult to justify.

Robust guidance on contractual transparency in a pandemic did not exist at the onset of the crisis, enabling the process whereby openness was underappreciated in the race to secure better deals. This is highlighted by the calls for a pandemic treaty that includes commitments to transparency[92]. National governments and the WHO should aim to establish a new norm whereby contractual transparency is mandated and provide clear guidelines for how and when to publish contractual texts.

SUMMARY OF RECOMMENDATIONS

- All buyers have an obligation to be transparent and accountable and should follow the lead of the USA and publish their remaining contracts. Brazil, the UK, and the EU should champion this given their relative wealth and number of doses already secured. The COVAX facility should reaffirm its commitment to equity by publishing all vaccine contracts, and if necessary, use redacted versions that are clearly and specifically justified.
- International NGOs should advocate for transparency and provide resources that assist with obtaining justifications for contractual secrecy by buyers. Where possible, these INGOs should combine efforts to also target regional and international decision-making bodies such as the African Union and COVAX.
- Governments and the WHO should provide guidance on public health emergency procurement which contains robust transparency rules, including when and how to publish contracts in a pandemic, in order to guarantee that transparency is not a casualty in future crises.

xii According to the UNICEF dashboard and World Bank data and only including vaccines in our subset: High Income and with the 6th highest GDP in the world, the UK has 269,000,000 secured and optional doses or one dose for 245% of its population. Upper-Middle Income and with the 9th highest GDP in the world, Brazil has secured 445,400,000 doses, or one dose for 211% of its population. The EU has 2,390,000,000 secured and optional doses enough to provide one dose to 628% of its population when subtracting the UKs population from World Bank Figures. It is also High Income and a GDP that is only second to the USA.

REDACTIONS IN COVID-19 VACCINE CONTRACTS

The benefits of contractual transparency rely on the ability of the public to look at unaltered contractual information. It thus becomes important to look at the extent of redactions in the formally published COVID-19 contracts to assess their value to the public.

Redaction is a commonly used tool that covers or removes elements of text that may be sensitive. A common reason for redaction in formally published COVID-19 contracts is to obscure "commercially sensitive provisions", information that could prejudice a supplier's commercial interests. Commercially sensitive information in this context is often argued to be information regarding manufacturing capacity, prices per dose, indemnification clauses and intellectual property[93]. However, such details are important in improving accountability and the global response to the virus.

These are two competing interests. On one side, there is the public interest of releasing such information unredacted. On the other, the commercial interest in not doing so. Many countries' Freedom of Information laws – often vital in obtaining secretive data – incorporate ways to weigh these interests against each other including those in the UK, New Zealand, and India[94]. These exist in many different variations around the globe, but universal "good practice" is provided by The Centre for Global Development (CGD). In their "Principles of Commercial Confidentiality", [95] they state that "Full Contract Publication" should be the norm, and that redactions can be justified under certain conditions:

- Information should only be redacted for reasons of commercial sensitivity when the public interest in withholding information outweighs the public interest in disclosure.
- The public interest test should take into account the wider economic benefits of the sharing of commercial information, as well as the case for accountability and the public's right to know.
- All redactions should be clearly marked with the reason for redaction.

CGD's Principles provide a way in which the benefits of contractual transparency can be obtained whilst still allowing for commercial confidentiality. These provide a framework for assessing the redactions.

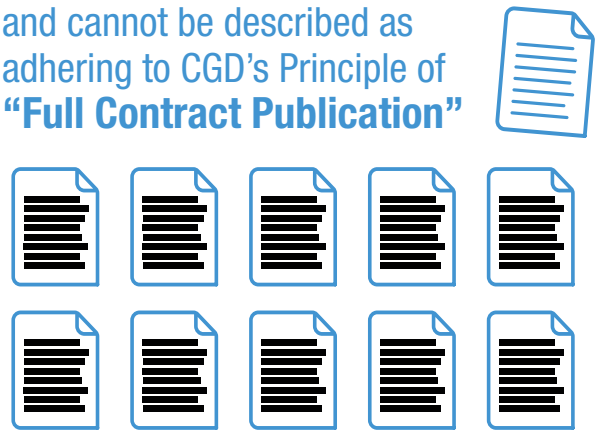
Omission by Redaction: Redactions in COVID-19 Vaccine Contracts

Out of the 11 formally published contracts, 10 were published with a high number of redactions and cannot be described as adhering to CGD's Principle of "Full Contract Publication". These redactions often covered entire pages and sections. Quantifying the exact extent in the remaining 10 is difficult, because we do not know how many words are obscured. However, analysis of the amount of space blocked by redactions in the EU – CureVac contract showed that 24 per cent was redacted[96], whilst a comparison of the unredacted and redacted versions of the EU – AstraZeneca contract showed that 12 per cent of the words were obscured[97].

In the year prior to the onset of the pandemic[xiii] the UK published three comparable[xiv] non-COVID-19 contracts with AstraZeneca and Pfizer for the supply of vaccines. Whilst these contracts were agreed in vastly different contexts to the UK-AstraZeneca COVID-19 vaccine contract, comparing the number of redactions is striking. Table 3 shows the number of redactions in the comparable contracts and alongside the UK-AstraZeneca COVID-19 contract.

Out of the 11 formally published contracts, 10 were published with a high number of redactions

and cannot be described as adhering to CGD's Principle of **"Full Contract Publication"**



xiii March 2019 to March 2020

xiv Comparable is defined as a bilateral agreement between a developer and the UK for the supply of vaccines. Based on contract transparency resource opentenders.eu.

Table 3. Comparison of Number of Redactions in UK-AstraZeneca Contract Versus Comparable Contracts

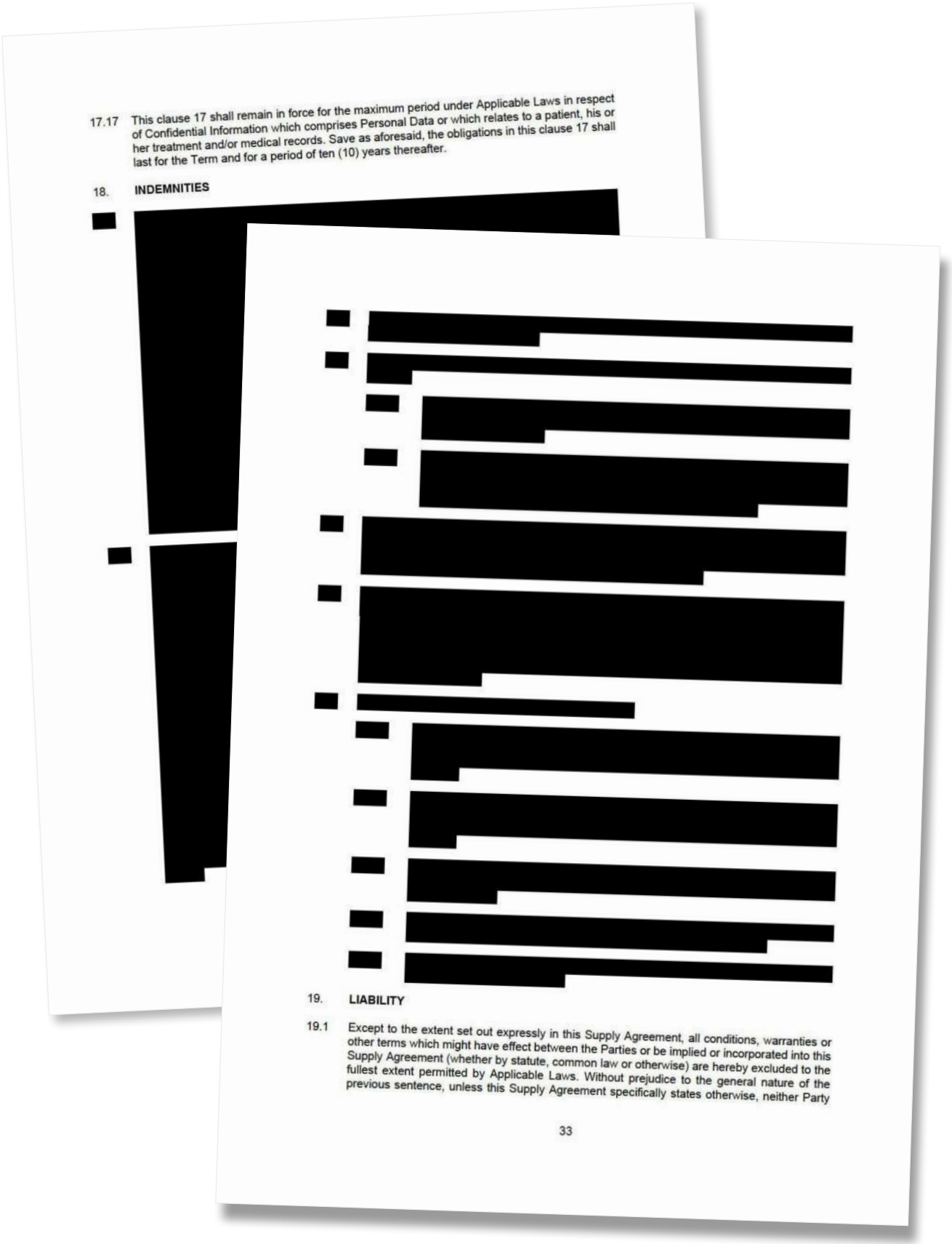
Contract ID	Supplier	Vaccine type	Number of Redactions	Pages with Redactions
CM/PHV/16/5504	Pfizer	Meningococcal	2	2
CM_PHV_12_5354	Pfizer	Influenza	2	2
CM_PHV_14_5433	AstraZeneca	Pneumococcal Conjugate	8	4
AZD1222 supply agreement	AstraZeneca	COVID-19	98	22

Redactions in the UK-AstraZeneca COVID-19 contract also routinely cover large portions of text, sometimes obscuring entire sections that were totally unredacted in the comparable contracts, such as the indemnification section. Image 2 below provides a visual comparison of the AstraZeneca – UK COVID-19 vaccine contract indemnification section against the redactions in the non-COVID, comparable AstraZeneca – UK Influenza contract.

Whilst the number of redactions provides a limited insight into which important information is obscured, it raises the question as to why so much – and seemingly more than usual – needs to be secret.

Image 2. Visual comparison of redactions in the AstraZeneca – UK COVID-19 Contract and the non-COVID-19 UK-AstraZeneca influenza vaccine supply contract

AstraZeneca – UK COVID-19 vaccine contract redactions



17.17 This clause 17 shall remain in force for the maximum period under Applicable Laws in respect of Confidential Information which comprises Personal Data or which relates to a patient, his or her treatment and/or medical records. Save as aforesaid, the obligations in this clause 17 shall last for the Term and for a period of ten (10) years thereafter.

18. **INDEMNITIES**

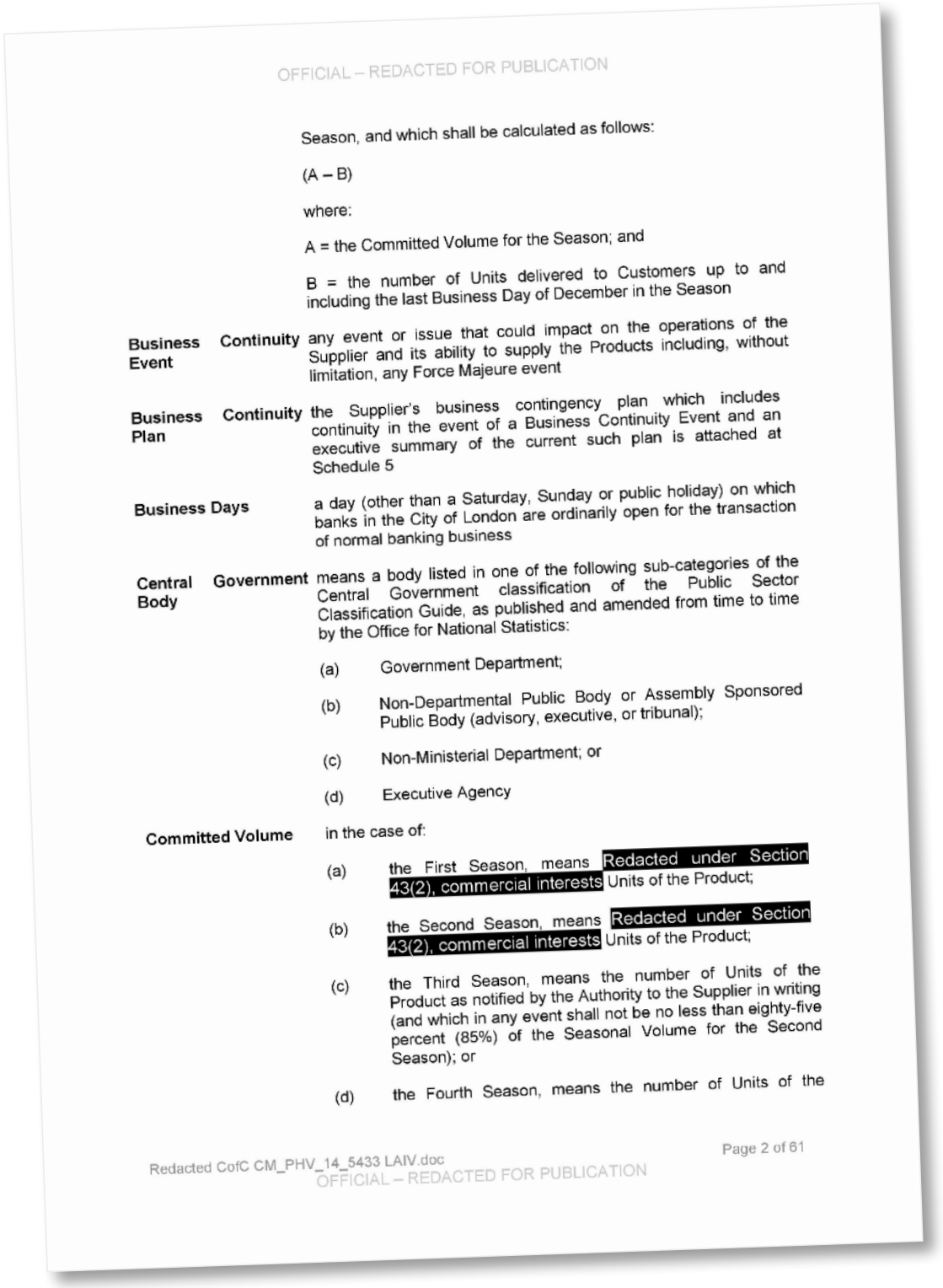
[redacted]

19. **LIABILITY**

19.1 Except to the extent set out expressly in this Supply Agreement, all conditions, warranties or other terms which might have effect between the Parties or be implied or incorporated into this Supply Agreement (whether by statute, common law or otherwise) are hereby excluded to the fullest extent permitted by Applicable Laws. Without prejudice to the general nature of the previous sentence, unless this Supply Agreement specifically states otherwise, neither Party

33

Non-COVID-19, comparable AstraZeneca – UK Influenza contract redactions



Season, and which shall be calculated as follows:

(A – B)

where:

A = the Committed Volume for the Season; and

B = the number of Units delivered to Customers up to and including the last Business Day of December in the Season

Business Continuity Event any event or issue that could impact on the operations of the Supplier and its ability to supply the Products including, without limitation, any Force Majeure event

Business Continuity Plan the Supplier's business contingency plan which includes continuity in the event of a Business Continuity Event and an executive summary of the current such plan is attached at Schedule 5

Business Days a day (other than a Saturday, Sunday or public holiday) on which banks in the City of London are ordinarily open for the transaction of normal banking business

Central Government Body means a body listed in one of the following sub-categories of the Central Government classification of the Public Sector Classification Guide, as published and amended from time to time by the Office for National Statistics:

(a) Government Department;

(b) Non-Departmental Public Body or Assembly Sponsored Public Body (advisory, executive, or tribunal);

(c) Non-Ministerial Department; or

(d) Executive Agency

Committed Volume in the case of:

(a) the First Season, means Redacted under Section 43(2), commercial interests Units of the Product;

(b) the Second Season, means Redacted under Section 43(2), commercial interests Units of the Product;

(c) the Third Season, means the number of Units of the Product as notified by the Authority to the Supplier in writing (and which in any event shall not be no less than eighty-five percent (85%) of the Seasonal Volume for the Second Season); or

(d) the Fourth Season, means the number of Units of the

Information of Public Interest Routinely Obscured by Redaction

According to CGD's Principles, the lack of "Full Contract Publication" of 10 of the 11 contracts signals that an investigation is required to determine what aspects of public interest have been redacted. The nature of redactions makes this difficult, as we do not know exactly what has been obscured. Table 4 summarises whether information considered to be of public interest[xv] is available in a sample of the COVID-19 vaccine contracts.

The table below highlights an information deficit in several areas of heightened public interest. Important here is that "partial" transparency, or elements of a contract that are partially redacted, can lead to false assumptions based on the unredacted text. The meaning of this unredacted text could be, to differing extents, qualified, reduced or in certain situations overturned by the redacted text that we can see. As stated in the previous section, contract transparency is about making accessible a shared evidence base. This then suggests that aspects of high public interest have been heavily redacted in COVID-19 vaccine contracts, drawing into question how – if at all – public interest has been weighed against commercial confidentiality.

Table 4. What Information is Forthcoming in a Sample of Contracts (1 per buyer) Against Our Adapted List of Important Areas of the COVID-19 Contracts. [xvi]

Aspects in a contract of heightened public interest	USA Janssen	EU CureVac	Brazil AstraZeneca	UK AstraZeneca
Simple				
The entire contract value	Full	None	None	None
Timetables for delivery	Full	None	None	None
The quantity of vaccines bought	Full	Full	Full	Full
Price per vaccine dose	Full	None	None	None
Complex				
Whether governments have "march-in-rights" which allow governments to license the product to other suppliers if certain conditions are met	Substantial	Limited	Limited	Limited
Whether the buyer can send vaccines to a different country	Substantial	Substantial	Limited	Partial
Whether there are, and to what degree, penalties for non-performance	Substantial	Partial	Partial	Partial
Who owns the rights of and processes to develop vaccines	Substantial	Substantial	Partial	Substantial
Scope and duration of Indemnification	Substantial	Partial	Limited	Limited

xv Based on the elements of a contract the European Parliament's Committee on the Environment, Public Health and Food Safety has called to be made public and a list from eyeonglobaltransparency.net available here: https://eyeonglobaltransparency.net/2021/01/29/transparency-becomes-a-casualty-for-contracts-to-buy-covid-19-vaccines/

xvi The simple aspects are those that are almost certainly in every contract. "Full" denotes that the contract contains the key information within these aspects in unredacted form, "None" denotes that they are not present. Complex aspects are those that could be split across multiple different sections. The scoring for these is a judgement based on 1) what key information points are unredacted and present in the contract 2) the volume of the redactions in relevant sections. For more detail on these assessments see the full scoring table in Annex 4

Justifications by Buyers for Poor Transparency

Almost all contracts were not "clearly marked with the reason for redaction". The exception to this is contracts entered into by the USA, which noted alongside each of its redactions the legal provisions which allow for said redaction. Thus, all buyers except for the USA are not following good practice in transparency as defined by CGD principles.

Whilst lacking in the contractual text, justifications for redactions have sporadically come from different buyers, such as the EU. These generally use the blanket justification of "commercial confidentiality"[98]. This means that we cannot properly assess the justifiability of such redactions without explanation as to how it is weighed against public interest. The lack of sufficient justification creates the impression that one or both parties have something to hide and can raise suspicion at a time where trust in vaccines is more important than ever.

RECOMMENDATIONS

Without justifications of redactions, it is impossible to properly assess whether the balance between commercial confidentiality versus public interests has been met. Additionally, justifications have thus far proved insufficient by only stating "commercial confidentiality". It is therefore necessary for all buyers to follow the principles of commercial confidentiality set by CGD. This requires that full publication of contracts should be the norm, and that any redactions should be specifically marked with a justification. This should be applied to each discrete section of the contract individually, with different explanations for their weighing process allowing the public to construct counter arguments if necessary.

SUMMARY OF RECOMMENDATIONS

- Buyers with already published and redacted contracts that are not marked with a justification - the UK, the EU and Brazil - should immediately republish with justifications added. Future publication of contracts should follow the CGD principle "All redactions should be clearly marked with the reason for redaction".
- Justification of redactions should detail the decision-making process that led the buyer to conclude that it is of a higher public interest to redact, or not redact at all. These should be specific to discrete sections of the contract rather than blanket explanations.

COVID-19 VACCINE PRICES

Vaccine pricing transparency is the formal publication of the cost per vaccine dose that has been legally agreed to in a contract between and buyer and supplier. Vaccine pricing transparency has historically received considerable attention, with studies highlighting its role in generating sustainable access in low- and middle-income Economies (LMIEs)[xvii] exposing price gouging and inflated costs[99]. Eighty-five per cent of the world's population lives in LMIEs, many of which are unable to afford sufficient COVID-19 vaccine doses even at a low price. Inflated prices for specific economies could undermine global access, as many will not be able to afford sufficient quantities quickly, even at a low price per dose. Such a situation will result in more deaths and prolonged impact upon health systems in countries with low access, while potentially costing the global economy an estimated USD 9.2 trillion, half of which would come at a cost to wealthy countries[100].

Furthermore, transparency in vaccine and medicine pricing can increase equitable access to life-saving products. Studies have highlighted the link between pricing and procurement data, and the ability for countries to improve budget analyses, purchase choices, and negotiation for equitable prices[101 102]. For example, in 2012, health authorities of Latvia, Estonia, and Lithuania used pricing data sourced from the Market Information for Access to Vaccines (MI4A) database to inform their joint tender for the rotavirus vaccine. This resulted in a lower price of 17–25 per cent for each immunisation course than what the countries had paid previously[103]. Such benefits are being better recognised by governments worldwide, as reflected in a 2019 WHO resolution which urged [104] national governments to publicly share information on net prices of health products to increase equitable access[105].

Pricing information can also enable accountability, allowing the public to scrutinise a government's fiscal decisions. At a national level, without transparency the public cannot know if procuring entities are overpaying for vaccines - an aspect especially important considering that overpayment may reduce some governments' ability to secure more doses. At a global level, the mapping of prices allows the public to assess the extent to which prices are proportionate to a buyer's ability to pay, revealing the equitability of distribution. Richer countries have stockpiled vaccines which could lead to high prices for other countries, while in some cases the same vaccine has been sold at a higher price to less wealthy countries, so the public's role in scrutinising information is critical.

This analysis provides an overview of the extent to which prices are detailed in formally published COVID-19 contracts. It then uses analysis of secondary data sources to assess what information on prices may tell us to illustrate the importance of transparency in this area.

Near Universal Obfuscation of Prices in COVID-19 Contracts

Despite the stated advantages to vaccine distribution, price per dose - the contractual information perhaps most highly valued by the global community - has also been the most systematically unpublished. Whilst there have been reports from parties involved in agreements, information on pricing is incomplete in all formally published contracts other than those of the Dominican Republic and USA.

Concerning Variance in Reported Prices Paid for COVID-19 Vaccines

The most comprehensive database on COVID-19 vaccine prices is led by UNICEF whose COVID-19 Vaccine Market Dashboard uses secondary sources such as media reports and press statements[106]. Whilst imperfect compared to sourcing information directly from contracts, it allows for high-level trends or anomalies in prices between countries to be identified. Using UNICEF'S data, it is possible to assess regional and country trends in prices per dose. When compared to indicators of a country's ability to purchase vaccines (indicated by GDP per capita), the data indicates concerning trends that highlight the need for pricing transparency.

Whilst variance in pricing across countries is to be expected somewhat due to the different costs for different vaccines, one would expect that in an equitable pricing system, prices would broadly increase at the same rate as a buyer's ability to afford and that in general lower- and middle-income countries would have access to the cheapest vaccines. However, the available data indicates that this may not be the case. The below graph shows that Upper-Middle Income Economies (UMIE) on average paid the most for a single course of a COVID-19 vaccine, at USD 32. High Income Economies (HIE)[xviii] paid less, USD 20 on average [xix], with LMIEs paying USD 14 on average. It also shows several anomalous results where buyers are paying higher than what we expect when compared to GDP per capita, for instance in the cases of Senegal and Ukraine. Senegal's purchasing of the Beijing

xvii Based on World Bank lending groups. Available here: https://datahelpdesk.worldbank.org/knowledgebase/articles/906519-world-bank-country-and-lending-groups

xviii "Economies" is used here because certain buyers in this analysis are not countries but is aligned to World Bank Lending Groups.

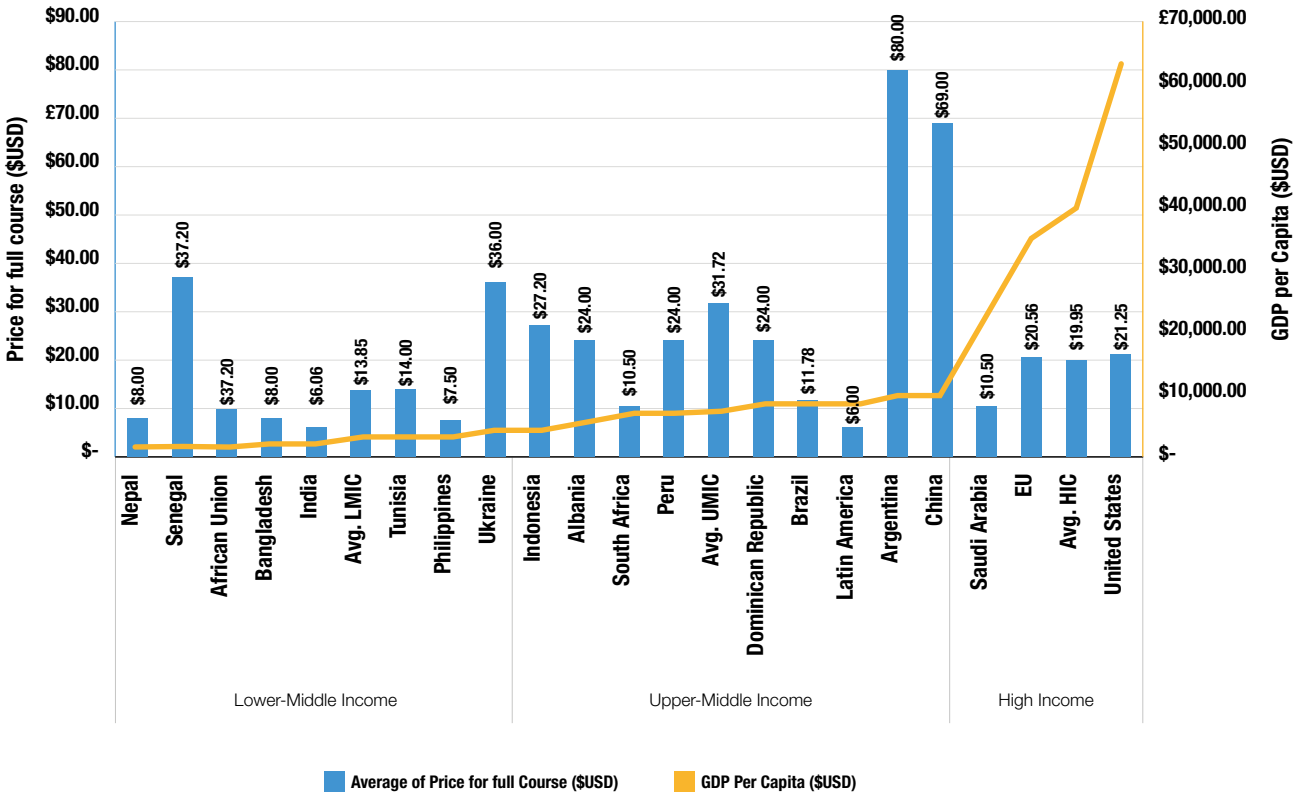
xix This is calculated by averaging the price paid per agreement, not per amount of doses secured.

Institute of Biological Products (CNBG) vaccine, which is significantly more expensive, has pushed up the average price paid. Such an observation. Considering that HIEs have secured 41 per cent of AstraZeneca's (who provide the cheapest vaccines) total committed stock, this raises questions as to whether market dynamics, such as lack of available cheap vaccines for Senegal, played a part in such procurement decisions.

For the AstraZeneca developed vaccine[xx], the USA and EU pay the third and second lowest prices respectively, despite being the two highest income entities per capita.

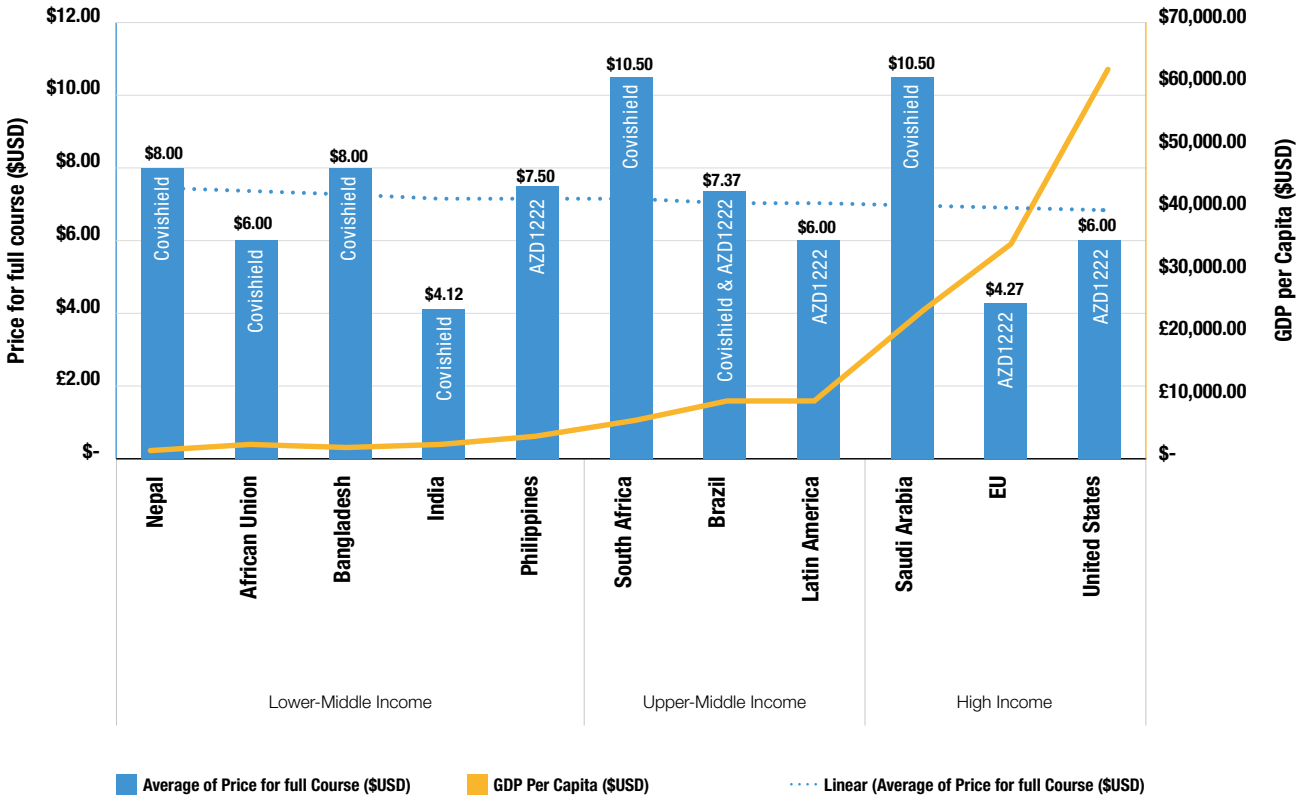
Conversely, Nepal pays the second highest amount, despite having the lowest GDP per capita. Proportional to GDP per capita and in real terms, HIE's are paying the least of the three groups at on average USD 6.26 per contract, second is the LMIE grouping with USD 6.72 per contract, and the most spent on vaccines is by UMIE's at USD 7.81. Of all the other vaccines in our subset with more than three agreements, none showed a negative correlation between GDP per capita and vaccine prices. Such analysis appears to be particularly damning for AstraZeneca, drawing into question the veracity of their "commitment to ensure broad and equitable access"[107].

Chart 2. Price Paid by Economies, Ordered by GDP per Capita, for One Full Course of a Vaccine ($USD)



xx AstraZeneca reached a licensing agreement with the Serum Institute of India to allow the AZD1222 vaccine to be manufactured in India under the alternative brand name, Covishield.

Chart 3. Covishield and AZD1222 (AstraZeneca) Prices per Economy, Ordered by GDP per Capita



RECOMMENDATIONS

All buyers, such as national governments and international organisations should release contracts with key information on price per dose. This will help ensure consistent and equitable pricing structures worldwide. However, with almost no contractual transparency in this area, it seems that the prevailing logic here is commercial confidentiality. But initial steps to champion this cause can be taken by those with less of an urgent need for better deals. These are most obviously entities who have secured a high number of doses relative to their population. Of those that have secured more than 100 million doses, the EU, the USA, the UK, Japan, Canada and Australia are the only entities to have secured more than double their population[108].

The development of a relatively complete database on pricing of COVID-19 contracts will likely take time, meaning that it will not be available to those countries currently in negotiation for vaccines. Given this context, one could look to the example set by the WHO Market Information for Access to Vaccines (MI4A) which "aims to identify and address affordability and shortage issues for self-funding and self-procuring countries"[109] by providing a database on vaccine pricing. Within this data, countries are not named, but rather categorised by region and income level. If adhered to widely, such anonymity could lessen the concern of buyers and suppliers who are worried about commercial confidentiality and seeking a better deal, because pricing information could not be as easily linked to specific buyers or suppliers. This would still generate accessible information on pricing that could be used by negotiating buyers to make evidence-based decisions on appropriate pricing of vaccines.

SUMMARY OF RECOMMENDATIONS

- All vaccine developers, and particularly AstraZeneca, should justify their commitment to broad and equitable access by releasing their price per dose of all their agreements, preferably within a contract.
- The EU, the USA, the UK, Japan, Canada and Australia should champion pricing transparency, by releasing contracts without redaction of prices.
- A pricing database should be established by the WHO with the general principle that all countries report their prices anonymously.

INDEMNIFICATION CLAUSES

The development of vaccines poses significant risk - the possibility exists that rare adverse effects may occur, and developers may be held liable. In the context of COVID-19 the risk of litigation could be exacerbated due to the expedited nature of clinical trial research, the scale of distribution, as well as the levels of low trust in vaccines in particular countries.

To ensure a steady supply of vaccines, governments use two tools to limit the risk for the developer [110]. The first, is the use of regulation to create a "no fault" basis for injuries resulting from vaccines which can be resolved out of court. For example, COVAX and the WHO are developing a "no-fault compensation scheme for indemnification and liability issues"[111]. Similar mechanisms operate in the USA[112] and the UK[113]. The second entails the use of "indemnity clauses" in contracts. An indemnification clause is often referred to as a "hold harmless provision", which details the level of security against legal liability for a particular party's actions. Essentially, the clause may protect an indemnified party against future losses or claims resulting from the contract. For example, should there be an adverse reaction to a COVID-19 vaccine that results in a civil claim, many contracts stipulate that the government will "indemnify" the developer, meaning that the "indemnifying party", a government in this case, pay for settlements and/or legal expenses.

Such clauses are commonly used to cover adverse effects in pandemics or situations with pandemic potential[114] to ensure that the developers are not discouraged from deploying vaccines. However, recent media reports have noted that some developers are requesting more extensive indemnity clauses[115] that could contractually oblige buyers to cover losses in many more circumstances. This is concerning because due to the lack of transparency in this area detailed previously, we do not know for certain how extensive these clauses may be.

We will now consider transparency and scope of indemnification clauses included in the formally published vaccine contracts. First, by providing an overview on what information is available, and then, through interrogating clauses that may be described as "extensive". Out of this interrogation, we highlight areas for concern for citizens and apply them more generally to what it may mean if such clauses are representative of agreements that we cannot scrutinise.

The Content of Indemnification Clauses in COVID-19 Vaccine Contracts

Out of the 13 published and leaked vaccine contracts, three had indemnity clauses which contained substantial or partially unredacted information. These are the EU - AstraZeneca contract and the two Pfizer contracts. All three showed that developers were indemnified from any and all damages and liabilities in the case of specific adverse effects from the vaccine. In the case of the EU-AstraZeneca vaccine contract, the EU will cover all liabilities, damages, and legal costs "resulting from or associated with claims for death, physical, mental, or emotional injury, illness, disability, or condition, fear of the foregoing, property loss or damage, and business interruption".

However, as evidenced by the Pfizer contracts with the Governments of the Dominican Republic and Albania, some contracts cover additional liabilities. The Dominican Republic contract states that the governments will "indemnify, defend, and hold harmless Pfizer, its partner BioNTech and its affiliates" from both costs and legal cases "arising out of, relating to, or resulting from the Vaccine, including but not limited to any stage of design, development, investigation, formulation, testing, clinical testing, manufacture, labelling, packaging, transport, storage, distribution, marketing, promotion, sale, purchase, licensing, donation, dispensing, prescribing, administration, provision, or use of the vaccine". This clause goes much further than comparative clauses by seeking to push the risk onto national governments, and away from the developer, even if missteps are made by the developer or supply chain partners, and not just if there is a rare adverse effect of the vaccines.

The number of agreements, the number of countries the vaccine is distributed through and/or to, and the number of stages covered by this provision (which include the highly technical "cold chain" stages of manufacture, storage, and transportation) mean governments may struggle to understand the full picture of likely risk.

The "Indemnification of Government" clauses in the Pfizer contracts with the Dominican Republic and Albania, are almost the same. The only difference between them is that the Albanian contract covers the additional provisions of reasonable legal expenses "without limitation" as well as covering additional losses if they should arise through "marketing, promotion, sale, purchase". Although the Albanian contract was in draft form, the similarity raises questions as to where the power lies in drawing up contracts, and whether indemnity clauses are more extensively applied to countries with less negotiating power.

Applying Learnings to Contracts We Cannot Scrutinise

The Pfizer example above raises the possibility that indemnity clauses may be as extensive or even more so the other non-published vaccine contracts. Time will truly tell whether this would be the case but theoretically if the inclusion of extensive indemnity clauses is representative of the global situation, governments could end up paying huge amounts for losses over an extended period. Beyond the pandemic, citizens may also have a justifiable concern in how the allocation of risk affects the relationship between the pharmaceutical industry and government in the long term.

The contracts that we cannot scrutinise also indicate that extensive indemnification clauses may be disproportionately present in contracts signed by LMIEs. Our analysis, supported by media and NGO reports[116] [117], indicates a "pandemic norm" where a priority aspect of negotiation for suppliers has been limiting the level of financial risk should something go wrong in the development and distribution of vaccines. In turn, such aspects of a contract become more commercially sensitive, creating a higher incentive on behalf of the supplier to redact or not publish such information. This situation is compounded, particularly in LMIEs, as many do not have the administrative or legal capacity to adapt quickly, and procurement systems may already be overstretched due to the pandemic. Suppliers however are more specialised; they have access to a range of legal and administrative resources and can draw on a global knowledge pool generated by their other negotiations. Applying this perspective alongside the fact that, as far as the public can tell, extensive indemnification clauses only exist in contracts with UMIEs suggests that extensive indemnity clauses disproportionately effect non-HIEs. This would mean that non-HIEs would more often be contractually obliged to cover a wider set of risks than HIEs, despite their lesser ability to absorb more costs.

RECOMMENDATIONS

Whilst some level of indemnification is expected, our research has uncovered that at least some of these contracts contain clauses that can be described as extensive. Given the small sample size, we do not know the extent of this in other COVID-19 vaccine contracts or how indemnity clauses are being formulated during the pandemic. A comprehensive analysis is impossible without the requisite transparency of these clauses and the broader agreements. Given the indications in the information available, it is of the utmost importance that these clauses are published unredacted within a contract. However, given current unwillingness to be transparent it is unlikely that this will happen in a short timeframe. Our recommendations target more feasible initial steps that should lead to greater transparency in the long term.

Given the indications presented in this analysis, in the absence of full contract publication it is prudent that suppliers take the first step towards transparency and publish indemnification clauses if agreed to by the buyer. Until this happens, they will be unable to sufficiently curtail lingering concerns of "bullying"[118 119] of UMIE's for more extensive indemnity clauses.

In the absence of more concrete contractual transparency to disprove the claim that more extensive clauses are being pushed onto countries with relatively less bargaining power, resources need to be directed at improving the standardisation and capacity in the development of important clauses, such as indemnification. The development of a toolkit, complete with template clauses and guidance on good practice could solve these challenges. A similar resource was provided by the WHO during the H1N1 pandemic and was relied on extensively by non-HIEs[120]. This would provide a standard that buyers and developers could use as a benchmark. Such a resource should be developed by the WHO.

Given the indications presented in this analysis, in the absence of full contract publication it is prudent that **suppliers take the first step towards transparency and publish indemnification clauses if agreed to by the buyer.**

SUMMARY OF RECOMMENDATIONS

- In the absence of full publications of contracts by buyers, suppliers should release the full extent of its agreed upon indemnification clauses.
- The WHO should develop toolkit to promote good practice in pandemic vaccine agreements complete with template clauses and guidance.

OVERALL CONCLUSION

Our macro analysis of two key stages of the COVID-19 vaccine development and distribution process has highlighted a mixed picture, which raises concerns regarding the global governance of clinical trials and contracting in the context of public health emergencies.

We found that where robust transparency standards do exist, they are driven by individual proactive actions of governments, institutions and vaccine developers. In no area of our analysis – whether contracts, redactions, or clinical data - is there a cohesive global approach to transparency. This has considerable implications because global crises require global solutions. In a time where clinical development and procurement processes have become the most important of our lifetime, it is concerning to see transparency being accorded so little importance.

Overall, our analysis of the global COVID-19 vaccination process indicates a lack of quality governance in the areas of clinical trials and contracting in pandemic situations. Whilst initial steps can be taken to immediately improve this, it is vital that governments work together to create a regulatory framework which removes the opportunity for the degradation of standards of openness. Early discussions around a new pandemic treaty provides an opportunity for this, with several countries, including the UK and South Africa, already pushing for robust transparency provisions. We look forward to following and inputting into these discussions using the findings and recommendations of this report to ensure that transparency becomes a norm, and not an exception.

ANNEX 1. METHODOLOGY

Data Retrieval

In order to capture meaningful data for analysis, we selected vaccine candidates that had either completed or were currently in phase III clinical trials as of 11th January 2021 based on the New York Times COVID-19 vaccine tracker[121]. This resulted in a pool of 21 candidates. We excluded the Bacillus Calmette–Guérin (BCG) vaccine sponsored by Murdoch Children's Research Institute's as the BCG is a well-established vaccine used primarily against TB and its use against COVID-19 is being explored by many organisations. As a result, 20 vaccines were included in the analysis.

The vaccine candidates selected for analysis are contained in the below table, in no specific order:

Table 5. Details of the 20 COVID-19 Vaccine Candidates Included in the Analysis.

Name of vaccine developer	HQ location	Name of vaccine	First regulatory approval
Moderna	USA	mRNA-1273	December 2020 (USA)
Pfizer/BioNTech	USA / Germany	Comirnaty (BNT162b2)	December 2020 (UK)
Medicago (w/GSK adjuvant)	Canada (/UK)	CoVLP	Q4 2021 (Expected)
Anhui Zhifei Longcom	China	ZF2001	March 2021 (Uzbekistan)
Bharat Biotech	India	Covaxin (BBV152)	January 2021 (India)
CureVac	Germany	CVnCoV	Q2 2021 (Expected)
Clover Biopharmaceuticals (w/GSK adjuvant)	China (/UK)	SCB-2019	TBC
Sinopharm (Beijing)	China	BBIBP-CorV	July 2020 (Emergency use China)
AstraZeneca	UK	AZD1222 / Covishield (ChAdOx1 nCoV-19)	January 2021 (UK)
CanSino Biologics	China	Convidicea (Ad5-nCoV)	TBC
Johnson & Johnson	USA	Ad26.COV2.S	TBC
Novavax	USA	NVX-CoV2373	Q3 2021 (Expected)
Sinovac Biotech	China	CoronaVac	July 2020 (Emergency use China)
Gamaleya Research Institute	Russia	Sputnik V	September 2020 (Russia)
AnGes	Japan	AG0302-COVID19	TBC
Zydus Cadila	India	ZyCoV-D	Q2 2021 (Expected)
Vector Institute	Russia	EpiVacCorona	October 2020 (Russia)
Chinese Academy of Medical Sciences	China	Unnamed Inactive Vaccine - Yunnan	TBC
Research Institute for Biological Safety Problems	Kazakhstan	QazCovid-in	January 2021 (Temporary 9 month registration Kazakhstan)
Sinopharm (Wuhan)	China	Unnamed Inactive Vaccine - Wuhan	December 2020 (China)

Clinical Trial Policies and COVID-19 Clinical Trials Analysis

The aim of analysing clinical trial policies in the nine selected jurisdictions was to identify inclusions of best practice related to summary results sharing, protocol sharing and clinical study report sharing. This indicates the standards of transparency expected in that jurisdiction. The PHUSE clinical trial transparency country level worksheet[122] was used to identify clinical trial policies and was confirmed through manual searches.

The aim of analysing COVID-19 vaccine clinical trials was to identify how many clinical trials are being held across the 20 vaccines in order to identify the proportion of which had any results announced, protocol shared and data analysis published. This provides an indication of the level of actual clinical trial transparency in COVID-19 vaccine clinical trials. The BioRender COVID-19 Vaccine & Therapeutics Tracker[123] was utilised to identify registered trials. The following types of clinical trials were excluded: phase IV trials and combined or comparative studies of different vaccines.

Data was derived from peer-reviewed articles using Google Scholar, media reports, government legislation and developer websites. This information was obtained through internet searches and was collected between December 2020 and March 2021.

The search guide can be found in Annex 2.

Contract Sourcing

Our approach here was to get an indication of the number of COVID-19 vaccine contracts available online and thereby understand in general transparency of publication from a global perspective. Identifying common publication portals for contracts in each country and then investigating the presence of COVID-19 vaccine contracts would be resource intensive, but more importantly, there is no guarantee that these portals would have been used in this context. For example, the EU released contracts on a separate web pages different from their normal platform: Tenders Electronic Daily. Thus, it was important to develop a methodology that searched widely across the internet and enabled us not only to find which contracts were available but provided evidence that they were not made available by certain countries.

In order to source the vaccine contracts, a script was developed that searched Google using keywords in English as well as, where possible, local languages on the 5th March 2021. Languages searched in included only those that could be translated using Google: English, Albanian, Arabic, Spanish, Azerbaijani, Bengali, Bosnian, Portuguese, Khmer, Chinese (PRC), French, German, Hungarian, Hindi, Indonesian, Persian, Hebrew, Italian, Javanese, Kazakh, Macedonian, Malay, Nepali, Urdu, Tagalog, Serbian, Zulu, Sinhala, Thai, Twi, Ukrainian, Uzbek and Vietnamese. Whilst translators would have been preferred, resource limitations meant that we relied heavily on Google Translate.

This script searched for every vaccine within the table above alongside every multilateral and bilateral agreement on the UNICEF COVID-19 vaccine market analysis dashboard. For each search it matched, using Boolean operators ("AND" and "OR"), the name of the buying entity with that of the supplier with keywords denoting a contract as well as Google search terms to specify the query to only return the top five documents as opposed to webpages. The subsequent pattern, which was then run 201 times in English and other languages, was as follows:

<buying entity of vaccine> AND <supplier of vaccine> AND ("contract" OR "agreement") AND filetype:pdf OR filetype:docx OR filetype:doc

This returned over 1,000 results which were sifted through by researchers to obtain contractual agreements and was added to from Knowledge Ecology International's online database[124]. This returned two "Term Sheets", detailing some of the agreement between Peru and Pfizer and between Malaysia and Duopharma Biotech. However, both are excluded from our analysis, as the former does "not describe all the terms and conditions that would be included in the Definitive Agreement" and the latter does not appear to be legally binding.

Pricing data was sourced via exporting from the pricing section of the UNICEF COVID-19 vaccine market dashboard[125]. This resource includes likely price per dose in over 100 agreements worldwide and is sourced from media reports and official statements. Where possible, we appended this data set with information in contractual documents and term sheets that appeared in our search.

All data sourced as well as the script used to find them is available on the Transparency International Global Health Website here: http://ti-health.org/covid-19-vaccine-contract-data/

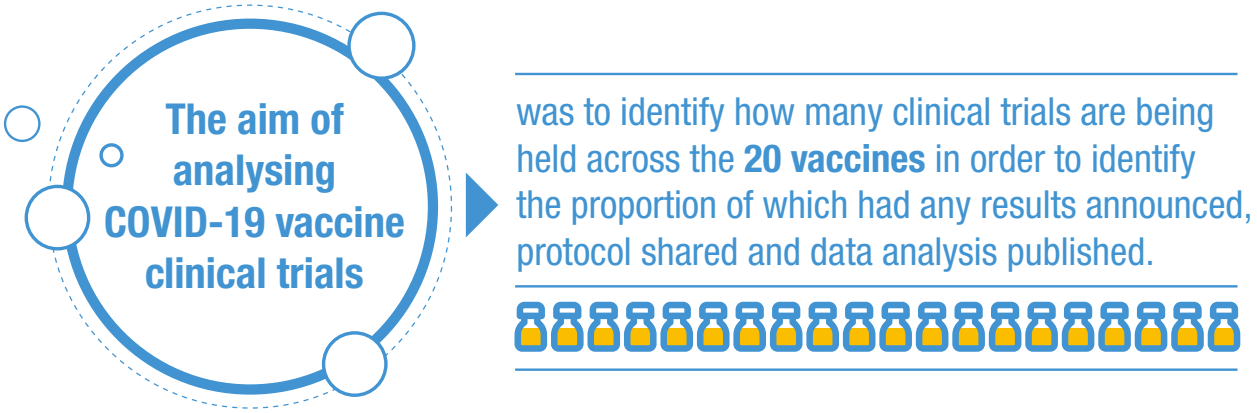
Limitations to the Collection and Analysis Process

Using Google to search for contracts is an imperfect method for constructing an exhaustive list of those hosted online. Certain contracts could conceivably be hosted on platforms without, for example, sufficient Search Engine Optimisation or indexing. Using this approach however has two benefits. First, Google is a powerful search engine and will likely result in a relatively accurate picture of what is available on the internet. Second, accessibility is an important tenet of transparency and given Google is by far the most used search engine worldwide, this approach emulates somewhat one method of how the public are likely to try and find contracts.

One further limitation is that the researchers involved in the data collection process are predominantly English speakers. Whilst every effort was made to ensure no English language bias, misunderstandings of the foreign language text may have led to omissions in the analysis

Textual Analysis of Contracts

When quantifying redactions in a contract, pytesseract, an optical character recognition software, was used to scan and recognise scanned pdfs and to convert them automatically into text.



ANNEX 2. SEARCH TERM GUIDE

National CTT Legislation / Policies:

a. Clinical trial registration:

- **i.** 'country/national or regional drug regulatory agency name + clinical trial policy' 'country/ national or regional drug regulatory agency name + clinical trial registration'

b. Clinical trial results sharing:

- **i.** 'country/national or regional drug regulatory agency name + clinical trial results sharing'

c. Clinical study reports sharing:

- **i.** 'country/national or regional drug regulatory agency name + clinical trial study reports'

d. Clinical trial protocols sharing:

- **i.** 'country/national or regional drug regulatory agency name + clinical trial protocols

Research Transparency

a. Clinical trial protocol published

- **i.** 'developer name + COVID-19 vaccine clinical trial protocol'
- **ii.** Vaccine developer website also hand searched.

b. Clinical trial results sharing

- **i.** 'developer name + COVID-19 + results'
- **ii.** Vaccine developer website also hand searched.

ANNEX 3. OVERVIEW OF REGISTERED CLINICAL TRIALS, PROTOCOL SHARING, RESULTS AND METHODS OF SHARING OF THE SELECTED 20 VACCINE CANDIDATES.

Name of vaccine developer	Name of vaccine	Clinical trials registered	Clinical trial locations	Clinical trial protocol shared	Clinical trial results shared		
					Phase [xxi]	Method of sharing	Date
Moderna	mRNA-1273	Phase I [126]	USA	Yes (Phase III) [127]	Phase I [128]	Press release (interim analysis)	May 18 2020
		Phase IIa [129]	USA				
		Phase II/III [130]	USA		Phase I [131]	Peer reviewed article (interim analysis)	Jul 14 2020
		Phase III [132]	USA		Phase I [133]	Peer reviewed article (additional data, interim analysis)	Sep 29 2020
					Phase III [134]	Press release (interim analysis)	Nov 16 2020
					Phase III [135]	Press release	Nov 30 2020
					Phase III [136]	Peer reviewed article	Dec 30 2020
Pfizer/ BioNTech	Comirnaty (BNT162b2)	Phase I [137] [138]	China	Yes (Phase I/II/ III) [139]	Phase I/II/III [140] [141]	Press release and pre-pint article (Phase I/II data only)	Jul 1 2020
		Phase I/II [142] [143]	Germany				
		Phase I/II [144] [145]	Japan				
		Phase I/II [146] [147]	Germany				
					Phase I/II (NCT04 380701) [148] [149]	Press release and pre-print article (BNT162b1 vaccine candidate data only)	Jul 20 2020
		Phase II [150]	China				
		Phase I/II/III [151] [152]	Argentina, Brazil, Germany, South Africa, Turkey, USA				
		Phase II/III [153]	USA				
		Phase III [154]	USA		Phase I/II/ III [155]	Peer reviewed article (Phase I/II data only)	Aug 12 2020
					Phase I/II/III [156] [157]	Press release and pre-print article (additional Phase I data, interim analysis)	Aug 20 2020

xxi Where possible, trial registration IDs have been specified in cases where there a more than trials of the same phase.

Name of vaccine developer	Name of vaccine	Clinical trials registered	Clinical trial locations	Clinical trial protocol shared	Clinical trial results shared		
					Phase [xxi]	Method of sharing	Date
					Phase I/II/III [158]	Peer reviewed article (additional Phase I data, interim analysis)	Oct 14 2020
					Phase I/II/III [159]	Press release (Phase III data, interim analysis)	Nov 9 2020
					Phase I/II/III [160]	Press release (Phase III data)	Nov 18 2020
					Phase I/II/III [161] [162]	Press release and peer reviewed article (Phase III data)	Dec 10 2020
					Phase I/II (NCT04380701) [163]	Pre-print article (BNT162b2 vaccine candidate data only)	Dec 11 2020
					Phase I/II (NCT04380701) [164]	Press release (BNT162b2 vaccine candidate data only)	Dec 14 2020
Medicago (w/GSK adjuvant)	CoVLP	Phase I [165]	Canada	No	Phase I [166]	Pre-print article	Nov 6 2020
		Phase II/III [167]	Canada, UK, USA		Phase I [168]	Press release	Nov 10 2020
Anhui Zhifei Longcom	ZF2001	Phase I [169]	China	No	Phase I and II [170]	Pre-print article	Dec 22 2020
		Phase I [171]	China				
		Phase II [172]	China				
		Phase III [173]	China, Ecuador, Indonesia, Pakistan, Uzbekistan				
Bharat Biotech	Covaxin (BBV152)	Phase I/II [174]	India	No	Phase I/II [175]	Pre-print article (Phase I data only)	Dec 15 2020
		Phase III[176]	India		Phase I/II [177]	Peer reviewed article (Phase I data only)	Jan 21 2021
					Phase I/II [178]	Pre-print article	Dec 22 2020
					Phase I/II [179]	Peer reviewed article	Mar 8 2021
					Phase III [180]	Press release (interim analysis)	Mar 3 2021
CureVac	CVnCoV	Phase I [181]	Belgium, Germany	Yes (Phase IIb/III) [182]	Phase I [183]	Press release	Nov 2 2020

Name of vaccine developer	Name of vaccine	Clinical trials registered	Clinical trial locations	Clinical trial protocol shared	Clinical trial results shared		
					Phase [xxi]	Method of sharing	Date
		Phase IIa [184]	Panama, Peru				
		Phase IIb/III[185]	Belgium, Germany, The Netherlands, Mexico, Peru, Spain		Phase I [186]	Pre-print article	Nov 10 2020
		Phase III [187]	Germany				
Clover Biopharma-ceuticals (w/GSK adjuvant)	SCB-2019	Phase I [188]	Australia	No	Phase I [189] [190]	Press release and pre-print article	Dec 4 2020
		Phase II/III [191]	Belgium, Brazil, Colombia, Dominican Republic, Germany, Nepal, Panama, Philippines, Poland, South Africa		Phase I [192]	Peer-reviewed article	Jan 29 2020
Sinopharm (Beijing)	BBIBP-CorV	Phase I/II [193]	China	No	Phase I/II [194]	Press release	Jun 17 2020
		Phase III [195]	Bahrain, Egypt, UAE				
		Phase III [196]	Argentina		Phase I/II [197]	Peer-reviewed article	Oct 15 2020
		Phase III [198]	Bahrain, Egypt, Jordan, UAE		Phase III (NCT045 10207) [199]	Press release (interim analysis)	Dec 9 2020
					Phase III [200]	Press release (interim analysis)	Dec 30 2020
AstraZeneca	AZD1222 (ChAdOx1 nCoV-19)	Phase I/II [201]	UK	Yes (Phase III, NCT0451 6746) [202]	Phase I/II (NCT043 24606) [203] [204]	Press release and peer reviewed article (interim analysis)	Jul 20 2021
		Phase I/II [205]	South Africa				
		Phase I/II [206] [207]	Japan				
		Phase II/III [208]	UK		Phase II/III, Phase III (NCT0453 6051) [209]	Press release (interim analysis)	Nov 23 2020
		Phase III [210]	Argentina, Chile, Colombia, France, Peru, USA				
		Phase III [211] [212]	Brazil				
					Phase I/II (NCT04 324606), Phase I/II (NCT04 444674), Phase II/III, Phase III (NCT04 536051) [213] [214]	Press release and peer reviewed article (interim analysis)	Dec 8 2020

Name of vaccine developer	Name of vaccine	Clinical trials registered	Clinical trial locations	Clinical trial protocol shared	Clinical trial results shared		
					Phase [xxi]	Method of sharing	Date
		Phase III [215]	Russia		Phase I/II (NCT04324606), Phase I/II (NCT04444674), Phase II/III, Phase III (NCT04536051) [216]	Pre-print article	Feb 1 2021
					Phase I/II (NCT04324606), Phase I/II (NCT04444674), Phase II/III, Phase III (NCT04536051) [217]	Press release	Feb 3 2021
					Phase III (NCT04516746) [218]	Press release (interim analysis)	Mar 22 2021
					Phase III (NCT04516746) [219]	Press release	Mar 25 2021
CanSino Biologics	Convidicea (Ad5-nCoV)	Phase I [220]	China	No	Phase I (NCT04313127) [221]	Peer reviewed article	May 22 2020
		Phase I [222]	China				
		Phase I [223]	China				
		Phase I/II [224]	Canada		Phase II [225]	Peer reviewed article	Jul 20 2020
		Phase II [226] [227]	China				
		Phase IIb [228]	China				
		Phase III [229]	Argentina, Chile, Mexico, Pakistan, Russia		Phase III [230]	Twitter account of Pakistan Government Health Advisor [xxii]	Feb 8 2021
		Phase III [231]	Russia				
Johnson & Johnson	Ad26.COV2.S	Phase I/IIa [xxiii]	Belgium, USA	Yes (Phase III NCT04505722, Phase I/IIa with results) [232] [233]	Phase I/IIa [234]	Peer reviewed article (interim analysis)	Jan 13 2021
		Phase IIa [235]	Brazil, Canada, Germany, The Netherlands, Spain, UK, USA				
		Phase II [236]	Australia, Brazil, Canada, Finland, South Africa, Spain, UK, USA		Phase I/IIa	Peer reviewed article	Mar 11 2021
		Phase III [237]	Argentina, Brazil, Chile, Colombia, Mexico, Peru, South Africa				
		Phase III [238]	Australia, Brazil, Canada, Finland, South Africa, Spain, UK, USA		Phase III (NCT04505722) [239]	Press release (interim analysis)	Jan 29 2021

xxii These results have been widely reported in global media with no objections from CanSino Biologics, therefore allowing the assumption that they are accurate.

xxiii 'A Randomized, Double-Blind, Placebo-Controlled Phase 1/2a Study to Evaluate the Safety, Reactogenicity, and Immunogenicity of Ad26COVS1 in Adults Aged 18 to 55 Years Inclusive and Adults Aged 65 Years and Older' (clinicaltrials.gov 2021) Clinical trial registration NCT04436276 <https://clinicaltrials.gov/ct2/show/NCT04436276> accessed 24 March 2021.

Name of vaccine developer	Name of vaccine	Clinical trials registered	Clinical trial locations	Clinical trial protocol shared	Clinical trial results shared		
					Phase [xxi]	Method of sharing	Date
Novavax	NVX-CoV2373	Phase I/II [240]	Australia, USA	Yes (Phase II, Phase III NCT04 583995, NCT0 4611802) [241]	Phase I/II [242]	Press release with downloadable slides (phase I data only)	Aug 4 2020
		Phase II [243]	Australia, USA				
		Phase III [244]	UK		Phase I/II [246]	Pre-print article (phase I data only)	Aug 6 2020
		Phase III [245]	Mexico, Puerto Rico, USA		Phase I/II [247]	Peer reviewed article (phase I data only)	Sep 2 2020
					Phase II and Phase III (NCT04 583995) [248]	Press release (interim analysis)	Jan 28 2021
					Phase I/II [249]	Pre-print article (phase II data only)	Mar 1 2021
					Phase II [250]	Pre-print article (interim analysis)	Mar 3 2021
Sinovac Biotech	CoronaVac	Phase I/II [251]	China	No	Phase I/II (NCT043 52608) [252]	Press release	Jun 13 2020
		Phase I/II [253]	China				
		Phase I/II [254]	China				
		Phase III [255]	Brazil		Phase I/II (NCT043 83574) [256]	Press release	Sep 9 2020
		Phase III [257]	Indonesia				
		Phase III [258]	Turkey				
		Phase III [259]	China		Phase I/II (NCT045 51547) [260]	Press release	Sep 23 2020
		Phase III [261]	Chile		Phase III (NCT045 08075) [262]	PT Bio Farma press conference (Indonesia partner)	Dec 8 2020
					Phase III (NCT045 82344) [263]	Turkish government press conference (interim analysis)	Dec 24 2020
					Phase III (NCT044 56595) [264]	Butantan Institute press conference (Brazil partner	Jan 7 2021
					Phase III (NCT044 56595) [265]	Butantan Institute press conference (Brazil partner)	Jan 12 2021
					Phase III (combined analysis) [266]	Press release	Feb 5 2021
					Phase III (NCT045 82344) [267]	Turkish state media report	Mar 3 2021

Name of vaccine developer	Name of vaccine	Clinical trials registered	Clinical trial locations	Clinical trial protocol shared	Clinical trial results shared		
					Phase [xxi]	Method of sharing	Date
Gamaleya Research Institute	Sputnik V[xxiv]	Phase I/II [268]	Russia	No	Phase I/II [269]	Peer reviewed article	Sep 4 2020
		Phase I/II [270]	Russia		Phase III (NCT045 30396) [271]	Press release (first interim analysis)	Nov 11 2020
		Phase II [272]	Russia				
		Phase II/III [273]	India		Phase III (NCT045 30396) [274]	Press release (second interim analysis)	Nov 24 2020
		Phase III [275]	Not provided				
		Phase III [276]	Not provided				
		Phase III [277]	Belarus				
		Phase III [278]	Russia				
					Phase III (NCT045 30396) [279]	Press release (third interim analysis)	Dec 14 2020
					Phase III (NCT045 30396) [280]	Peer reviewed article (interim analysis)	Feb 2 2021
AnGes	AG0302-COVID19	Phase I/II[281]	Japan	No	No results shared		
		Phase I/II[282]	Japan				
		Phase II/III[283]	Japan				
Zydus Cadila	ZyCoV-D	Phase I/II [284]	India	No	No results shared		
		Phase III [285]	India				
Vector Institute	EpiVacCorona	Phase I/II [286]	Russia	No	Phase I/II [287]	Media report	Jan 19 2021
		Phase III [288]	Russia				
Chinese Academy of Medical Sciences	Unnamed Inactive Vaccine - Yunnan	Phase Ia/IIa [289]	China	No	Phase I/IIa (NCT044 12538) [290]	Pre-print article (phase Ia data only)	Oct 6 2020
		Phase Ib/IIb [291]	China				
		Phase III [292]	Brazil, Malaysia				
					Phase Ia/IIa (NCT0441 2538) [293]	Peer reviewed article (phase IIa data only)	Nov 9 2020
Research Institute for Biological Safety Problems	QazCovid-in	Phase I/II [294]	Kazakhstan	No	Phase I/II [295]	Government article	Dec 19 2020
		Phase III [296]	Kazakhstan				
		Phase I/II [297]	China		Phase I/II [298]		Aug 13 2020
Sinopharm (Wuhan)	Unnamed Inactive Vaccine - Wuhan	Phase III [299]	China, Bahrain, Egypt, UAE	Yes (phase I/II shared with results)		Peer reviewed article (interim analysis)	
		Phase III [300]	Peru		Phase III [301]	Press release	Feb 24 2021
		Phase III [302]	China, Morocco				

xxiv The analysis only included clinical trials of the original Sputnik V and excluded Sputnik V Light and oral formulations.

ANNEX 4. FULL JUSTIFICATION FOR SCORING IN TABLE 4

Aspects in a contract of heightened public interest	USA Janssen	EU CureVac	Brazil AstraZeneca	UK AstraZeneca
Simple				
The entire contract value	Page 17/89: Milestone payment schedule table contains number of regimens against value. Page 15/89: Provides more information about the definition and cost of each regimen	No information on prices. "Product Price" is redacted on page 19	No total cost information is present in the contract, with large parts of CLAUSE 9 redacted on page 22.	No contract value with the "Cost of goods" section almost entirely redacted
Timetables for delivery	page 17/89: Schedule table shows when deliveries are to be expected	Schedule of delivery is entirely redacted on page 16	No timetables present	the values in Schedule 3 which shows the proposed delivery schedule are all redacted
The quantity of vaccines bought	Page 17/89: Milestone payment schedule table contains number of regimens	Page 12: details how many initial and additional doses have been secured by the EU	Contract states that 100.4 million doses of the Active Ingredient has been bought	Page 15 shows 100 million doses would be ordered
Complex				
Whether governments have "march-in-rights" which allow governments to license the product to other suppliers if certain conditions are met	Key Information points: Page 34 shows that the government have march in rights and their scope in the "March-in Rights" section. As per Knowledge Ecology International's spreadsheet: For failure to achieve practical application (35 USC 203(a)(1)), march-in rights are limited to "intent of this agreement". Also, the government cannot march-in to address practical application if J&J completed a Phasella clinical trial of the vaccine or the subject invention is a method of use invention and was used in a Phase IIa clinical trial. Health and saftey grounds (35 USC 203(a)(2))seem to be limited to determinations of emergencies. The contract states that J&J and the government will negotiate the march-in license Redactions: None	No mention of march-in-rights in the contract and limited information on licencing. Unclear whether this is due to redaction or not covered in the agreement	No mention of march-in-rights in the contract and limited information on licencing. Unclear whether this is due to redaction or not covered in the agreement	No mention of march-in-rights in the contract and limited information on licencing. Unclear whether this is due to redaction or not covered in the agreement

Aspects in a contract of heightened public interest	USA Janssen	EU CureVac	Brazil AstraZeneca	UK AstraZeneca
Whether the buyer can send vaccines to a different country	Key Information points: The USA cannot sent vaccines to other countries as per "Article IV. "PREP ACT" Coverage" on page 25 Redactions: None	Key information points: on pages 15-16 the section "RIGHT OF THE PARTICIPATING MEMBER STATES TO RESELL, EXPORT AND/ OR DISTRIBUTE THE PRODUCT" it details that the EU can donate or resell under specific circumstances Redactions: None	Key Information Points: The contract in Clause one (starting page 7) states that there is an option to expand the "territory" beyond the Brazilian Public Health System. Unfortunately whether this includes donations or re-selling outside of the country is unclear because redactions cover entire paragraphs. Redactions: Several paragraphs redacted making it impossible to understand the extensivity of this clause in relation to this aspect	Key Information Points: The contract states on page 14, clause 3.9, that AstraZeneca agrees to the provision that the Purchaser may donate or transfer vaccines that are in excess of requirements. Redactions: More than half of clause 3.9 is redacted
Whether there are, and to what degree, penalties for non-performance	Key Information points: Split over a number of sections, notably "Section XIX.7 Failure to Provide Prototype Product" and "Section IX.8 March-in Rights", the contract details the process should certain problems arise Redactions: None	Key Information points: Information on the process of delays, recalls and defects in the product on page 17 and 18. No information on fines or penalties present Redactions: Two multi-line redactions on page 17-18	Key Information Points: Clause 18, starting on page 38 provides information on Administrative Sanctions and shows that fines may be used in certain circumstances. Redactions: However Large parts of clause 18 appear to be redacted including 3 entire pages	Key Information Points: the "Consequences of Termination" Section (starting page 37) details some of the processes should the agreement be cancelled including that the parties should "use best reasonable efforts" to mitigate costs/damages. Redactions: Almost the entirety of the clause that details what happens on the termination of the agreement is redacted
Who owns the rights of and processes to develop vaccines	Key Information Points: Page 30-35 in various rights are detailed. Janssen has principle rights and retains a nonexclusive, royalty-free licence. Redactions: two redactions that obscure serial numbers of patent applications	Key Information Points: Covered fully on page 22 in "1.20. EXPLOITATION OF THE RESULTS OF THE APA" which states that controcator is the sole owner of all intellectual property Redactions: None	Key Information Points: Clause 15 (starting on page 33) contains many details on Intellectual property, including how FIOCRUZ will receive Information and Intellectual property on the vaccine. Redactions: An entire page is redacted in this clause as well as paragraph 15.6	Key Information Points: The Intellectual Property Section (starting page 27) shows that intellectual property stays with the supplier Redactions: None
Scope and duration of Indemnification	Key Information Points: although no specific indemnity clause is present, liability is detailed from page 24 in "Article IV. "PREP ACT" Coverage" Redactions: None	Key information Points: The Indemnification section on page 23-24 gives the general scope of indemnity detailing which stages of distribution it applies to. Redactions: two multiline redactions which cover when indemnity is not available and an entire paragraph the content of which is unclear	Key Information Points: Clause 18 (starting page 38) likely includes a section on indemnification as it is titled "CLAUSE 18 - ADMINISTRATIVE SANCTIONS AND INDEMNIFICATION". However, the scope and duration of indemnity do not appear in that section which is heavily redacted. Redactions: However Large parts of clause 18 appear to be redacted including 3 entire pages	Key Information Points: None Redactions: Entire Indemnification section (starting page 32)

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