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DIAGNOSTIC JUSTICE: TESTING FOR COVID-19

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ABSTRACT

Diagnostic testing can be used for many purposes, including testing to facilitate the clinical care of individual patients, testing as an inclusion criterion for clinical trial participation, and both passive and active surveillance testing of the general population in order to facilitate public health outcomes, such as the containment or mitigation of an infectious disease. As such, diagnostic testing presents us with ethical questions that are, in part, already addressed in the literature on clinical care as well as clinical research (such as the rights of patients to refuse testing or treatment in the clinical setting or the rights of participants in randomized controlled trials to withdraw from the trial at any time). However, diagnostic testing, for the purpose of disease surveillance also raises ethical issues that we do not encounter in these settings, and thus have not been much discussed. In this paper we will be concerned with the similarities and differences between the ethical considerations in these three domains: clinical care, clinical research, and public health, as they relate to diagnostic testing specifically. Via an examination of the COVID-19 case we will show how an appeal to the concept of diagnostic justice helps us to make sense of the (at times competing) ethical considerations in these three domains.

Keywords: *diagnostic justice; philosophy of medicine; political philosophy; applied ethics*

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1. Introduction

The ongoing SARS-CoV-2/COVID-19 pandemic, now (August 2021) over 18 months old, has proved to be the greatest public health challenge and most significant global health event since the 1919 H1N1 influenza pandemic. This is so not just because of the scale, devastation, and human toll of the pandemic, but also because of some of the unique features of the disease itself. As has been well-documented, COVID-19 disproportionately causes severe illness among older adults, especially older males with certain underlying health conditions. The disease has entered the world at a unique time in human history, when large portions of the population are older and have age-related chronic conditions such as renal disease, diabetes, and hypertension, meaning that many more living individuals are susceptible to severe outcomes from this virus in a way that wouldn't have been the case a generation ago (Onder et al. 2020; Begley 2020). It has also exposed an existing and pernicious set of underlying, unjust inequalities, resulting in a distribution of mortality and morbidity that disproportionately impacts communities of color and low-income workers in developed countries (Hooper et al. 2020), as well as long-standing, pernicious inequalities in health care provision and access to medicines that exist between developed and developing countries.

One of the major challenges of the pandemic has been diagnostic testing for SARS-CoV-2 infection. Because of the danger of asymptomatic and pre-symptomatic transmission, testing is required in order to bring transmission of the disease under control, as it is the primary way in which to identify asymptomatic or pre-symptomatic cases and thus to control transmission via isolation of these individuals (Furukawa et al. 2020). Countries that have done well with testing (such as South Korea and Singapore) have fared better than other countries where testing has been more limited, such as the United States (Cheng et al. 2020). But testing in the context of this pandemic is, as in medicine and health care practice more generally, done for different purposes, and sorting through the rationale for COVID-19 testing, its different uses, and its relevance in different settings is a major conceptual and normative issue raised by the pandemic and the public health response to it.

Even aside from the COVID-19 considerations we will examine in detail here, it is not an overstatement to say that that the process of diagnosis—of which testing for infectious disease is an element—is the cornerstone of modern clinical medicine. This is because before the treatment or prognostic evaluation of any patient can begin, there must be at least a working diagnosis—some idea of what is causing the problem that brought the patient into the clinic in the first place. If a clinician does not begin the

clinical encounter by working to obtain an accurate, or at least close to accurate, diagnosis, then subsequent treatments prescribed for the patient are likely to be ineffective, and prognoses to be inaccurate. This means that clinicians must be concerned with the questions of when, how, and why to test their patients in order to best facilitate their individual health outcomes.

But diagnostic testing also has purposes beyond that of facilitating the clinical care of individual patients: it can also be used as an inclusion criterion for clinical trials, or in certain cases to surveil for, contain, and/or mitigate disease. In these cases, the goals of the testing are different from those of clinical care, and so are the ethical issues that arise when testing is conducted in these other domains. All of these different purposes for testing are present in the context of the COVID-19 pandemic, but they are not always carefully separated, and the running together of testing for clinical care and surveillance, in particular, has raised some important ethical and philosophical difficulties.

In this paper we will consider some of these difficulties via an exploration of the concept of *diagnostic justice* (Kennedy 2021) in the context of the COVID-19 pandemic, by examining the overlapping categories and the philosophical issues that arise out of diagnostic testing for clinical trial inclusion, public health surveillance, and testing to facilitate the clinical care of individual patients. In particular, we will focus on two areas of difficulty that require closer scrutiny: the possibility that individuals could confuse the goals of testing for public health surveillance with testing for clinical care, and the way that testing data is used to inform public health decision-making. We will argue that both of these areas raise issues of diagnostic justice regarding how testing is conducted and how testing data is utilized in managing the pandemic.[1] Our aim here is to point out two areas of difficulty that require further investigation and fine tuning of testing policy in the future. The COVID-19 pandemic is still, as of the writing of this paper, very much underway, and there remains much to be learned about the global response to it. This paper is thus written in the spirit of raising some questions that deserve reflection and analysis as the entire world endeavors to understand what has happened (and is happening) during this period, and to prepare for future global health emergencies.

[1] We refrain here from offering any judgment on whether testing policy for COVID-19 has failed to meet demands of diagnostic justice. The situation is still emergent, and we believe a sober judgment will need to be made retrospectively, once the pandemic is under control and there is more evidence available. We thank an audience at Georgetown University, for pushing us to clarify our aims here.

In the following section we will survey the different forms of testing for COVID-19 and then in section 3 we will outline some of the ethical issues that arise when these testing methods are employed. In section 4 we will discuss the idea of diagnostic justice and argue that issues of justice are generated by the uses of diagnostic testing in different settings. In section 5 we will raise two ethical difficulties regarding diagnostic justice for COVID-19 testing. We will then draw out some implications of this discussion for diagnostic justice, testing, and global public health policy in section 6, before a brief conclusion in section 7.

2. COVID-19 Testing Methods

Types of tests

There are three main types of tests currently in use for the diagnosis/detection of COVID-19 infection. Two of them (PCR testing and antigen testing) are used to detect active infection, while the third (antibody testing) is used to detect past infection with the SARS-CoV-2 virus. The PCR test for COVID-19 infection is considered to be highly accurate, but at this time no data on the exact sensitivity or specificity of the test is available, because there is no gold standard to compare it to. However, estimates based on similar PCR tests for other diseases put the specificity of the COVID-19 test very high (close to 100 percent, barring lab or technician error), but sensitivity only at around 70 percent, due to the relative frequency of inadequate sampling as well as the disease's variable incubation period (estimated as 2-14 days). Antigen testing, on the other hand, has the benefit of delivering results quickly (usually in about 15-20 minutes), which can be useful in point-of-care treatment for patients, but it is less sensitive than PCR testing and thus delivers more false negative results.

Antibody testing, in contrast to PCR and antigen testing, is used to confirm a past infection with the SARS-CoV-2 virus. Because measuring antibody levels in a large segment of the population can help to determine how much of the population is or was infected with the virus, which in turn allows for an estimation of the level of herd immunity present in that population, antibody testing can be very useful for public health surveillance. Of course, measuring antibody levels in a population in order to estimate herd immunity is useful only if naturally derived antibodies do indeed provide immunity to the disease. Given preliminary data, this does seem to be a reasonable assumption (Spellberg et. al. 2021) in the case of COVID-19.

Test Uses

In the clinical setting, COVID-19 testing is conducted on individuals for the purpose of diagnosing those patients who are either symptomatic, or who have had recent exposure to the virus, in order to facilitate their individual case management. In the context of a research trial, on the other hand, potential participants are tested as an inclusion criterion for the trial, in order to make sure that symptoms are due to COVID-19, rather than other respiratory infections or disorders. In the public health domain, there are at least three reasons why a COVID-19 test might be conducted: for screening, for passive surveillance, or for active surveillance. According to the CDC,

> The primary purpose of screening is to identify early signs and symptoms of a disease or health problem to implement early treatment or program intervention to reduce the likelihood of the emergence of disease or health problem and/or mortality from the disease in an individual. (Oleske 2009, 131)

So far, COVID-19 tests have not been used for this purpose, although it is possible that in the future, especially if early treatment or prevention measures become available, that they might be. COVID-19 tests can also be used for the purpose of passive surveillance, which "is intended to monitor community- or population-level outbreak of disease, or to characterize the incidence and prevalence of disease" (Center for Disease Control and Prevention 2020). Surveillance testing is performed on de-identified specimens, usually via antibody titer on samples obtained from clinics or hospitals, and thus the results are not linked to individual patients or participants. Because of this, surveillance testing cannot be used for individual patient care, however it is often used as decision-input for population level health interventions (Oleske 2009). The sort of testing for COVID-19 that is most often conducted in the public health domain is for the purpose of active surveillance. Confusingly, sometimes the literature (and the CDC) refers to this also as "screening". However, the purpose of this kind of testing is different than screening, because the goal is not to treat or prevent disease in individuals, but rather to

> identify infected persons who are asymptomatic and without known or suspected exposure to SARS-CoV-2. [It] is performed to identify persons who may be contagious so that measures can be taken to prevent further transmission. (Oleske 2009, 139)

In practice, however, this theoretically strict separation of goals often becomes blurred, and both participants in trials and the researchers that conduct them are forced to navigate potentially complicated situations. As an example, consider the role of testing in AIDS vaccine trials. Testing during AIDS vaccine field trials is essential in order to collect data on the efficacy of vaccine candidates. There is, quite simply, no way to know whether a vaccine is working or not without the testing of the subjects in the trial. Further, because of the manner of presentation and progressive nature of the disease, testing for HIV infection is necessary for the diagnosis of AIDS. What this means in practice is that while subjects can of course refuse to participate in the trial altogether, or to withdraw from the trial at any time, they cannot refuse testing and at the same time remain in the trial; if they are not able to consent to testing, then they cannot participate. However, during AIDS vaccine trials, testing also often ends up serving a de facto clinical function. Because these trials are mostly staged in developing countries with high baseline transmission rates, or in populations with a high risk of HIV infection, there is a significant chance that, even despite counseling, provision of different services, and of course some individuals getting the vaccine candidate itself, individuals in (but not only in) control groups will become HIV positive. There has been a longstanding debate about the obligations researchers have to subjects in these trials who become HIV positive during the course of the research (Berkley 2003). It is now generally accepted that researchers have *some* obligations to provide some form of care and support for HIV positive research subjects enrolled in clinical trials for HIV/AIDS therapeutics, such as the provision of antiretroviral medication and financial support for health infrastructure in communities from which participants are drawn (Richardson 2007). This means that in the course of conducting diagnostic testing for HIV infection for research purposes, data from this testing also has a clinical function, in that it identifies individuals that are (potentially) owed some form of care as part of the duty researchers owe to participants. So, while superficially similar to the ethical issues involved with diagnostic testing in clinical care, testing as part of clinical research raises different concerns.

Public Health

Diagnostic testing for public health reasons is subject to a seemingly similar issue as is testing that is used in the context of clinical research, in that its primary goal is not (necessarily) to benefit the individuals submitting to the testing, but rather to protect the public health as a whole. But, as in the case of clinical research, there is, in practice, often a blurring of these goals. For example, submitting to testing to provide pieces of aggregate data for public health purposes can also have an important

clinical benefit for individuals, as it allows them to also provide information to their providers that can help to facilitate their own care. However, this blurring of clinical medicine vs. public health raises some difficulties for the ethics of COVID-19 testing, which we will discuss in section 5 below.

When it comes to the question of whether individuals can refuse testing for public health purposes, the situation is far murkier than it is with clinical research. With passive surveillance, individuals can refuse testing without compromising the public health goals of collection of data, as long as there is a sufficient sample who will submit to testing (or some form of proxy data that can be gathered instead). But with active surveillance, the situation is different. This sort of testing, for example, is often required for things like crossing borders where mandatory quarantine orders or travel restrictions are in effect. Refusing to submit to testing in this kind of context can be grounds for the barring of entry or even for forcing individuals into mandatory quarantine. Active surveillance requires a high volume of testing; during the COVID-19 pandemic, different countries have taken different tacks when it comes to mandating testing during active surveillance. Though compelling testing (as in China) raises some serious ethical questions, leaving testing voluntary (as has been the case in the United States) raises its own difficulties (which we will also discuss in section 5 below).

There is an enduring question here about whether testing for public health surveillance can be compelled. On the one hand, there is a clear public health rationale based on prevention of harms to others for making testing mandatory, at least in certain circumstances.

On the other hand, as we will argue in the next two sections, the way testing data is used is not morally inert. Compelling individuals to submit to testing, and then using data in ways that either results in an inequitable distribution of the burdens of mitigation or neglects obligations of care to individuals would raise serious concerns. Whether compelling testing is justifiable, then, depends on a number of factors. Some of these factors are unique to the situation of testing for disease surveillance in public health, and some are shared with other domains in which diagnostic testing is employed (as we've noted, with testing for clinical research, where compelling testing as a condition of participation also raises questions about ancillary duties of care).[2] So, the ethics of diagnostic testing for an

[2] We offer here no opinion on whether testing for COVID-19 in situations where it was left voluntary (such as in community testing in the United States) should have been mandatory. No general opinion

infectious disease such as COVID-19, while it raises some common questions in all scenarios (such as questions about a right to refuse a test as well as about balancing different goals of testing), is sensitive to differences in context between clinical care, clinical research, and public health settings. Understanding these differences is crucial to understanding the concerns of diagnostic justice raised by testing for public health purposes.

3. Diagnostic Justice

In biomedical ethics much has been written about the idea of justice as fairness, particularly as it relates to the allocation of treatments to patients, especially when these treatments are scarce resources in the community (Beauchamp and Childress 2020; Emanuel, et. al. 2020; Truog et. al 2020). However, at least to our knowledge, this concept has not been discussed in regard to diagnostic testing. It is our view, however, that in the case of diagnostic testing, as with health care generally, there are multiple, and sometimes competing, moral considerations that come into play when making decisions about allocating testing resources, using data, and compelling (or not compelling) individuals to submit to testing. In some instances, there are not enough diagnostic tests to go around (as was the case in the early days of the COVID-19 pandemic in the United States), while in other cases, even when there is an adequate supply of tests, the act of testing itself can have differential impacts on the individuals being tested (this is further discussed in section 5, below) and thus there arise distributive considerations in how testing should be used and what resources should made available to those who submit to testing. In our view, what this means is that diagnostic testing is subject to demands of *diagnostic justice* (Kennedy 2021). That is, diagnostic justice requires both that the burdens and benefits of testing be distributed equitably and that diagnostic resources be allocated fairly. Thus, diagnostic justice, like other forms of justice,

is possible, as the rationale for compelling testing is sensitive to highly local factors—any justification for compelling testing will depend at least to some degree on how much harm results from a voluntary testing regime, and this will always be something that must be settled on a case-by-case basis. All we want to argue here is that, unlike in testing for clinical care, testing as part of public health surveillance *could* in principle be compelled, and that the differences between these circumstances make a moral difference on this issue of compelling diagnostic testing. Further, there is more going on here than just a trade-off between patient autonomy and prevention of harms to others. Adjudicating whether testing can be made mandatory requires considering issues about how data is used and whether there are ancillary obligations owed to test subjects—or in short, requires considering diagnostic justice. Thanks to an anonymous referee for pushing for clarification on this point.

> requires equality by default if: (a) there are not any relevant distinguishing feature between people that legitimate unequal distribution of advantages and disadvantages or (b) we do not have reliable ways of identifying and measuring the unequal claims people may have. (Lysdahl and Hoffman 2021, 21)

For our purposes, what is considered just or unjust when it comes to the ethical considerations of diagnostic testing will depend on the primary context in which the test is being used or conducted. That is, the purpose of testing in clinical settings, as we have seen, differs from the purpose of testing in the research trial setting, which in turn also differs from the purpose of testing in the public health setting, and these differences give rise to different ethical considerations. The ethical considerations and implications differ between these domains because the considerations of *why to test* as well as *whom to test* differ.

The answer to the *why* and *whom* questions in the clinical setting is that tests should be performed on symptomatic patients in whom the test result would be likely to change the course of their clinical care (in terms of either treatment or supportive measures). If tests are scarce, however, and there are not enough such that all symptomatic patients can receive one, then distribution decisions should be made as fairly as possible. In the context of a research trial, on the other hand, the demands of diagnostic justice differ: testing should be conducted only on symptomatic patients in this context when it is *not known* whether or not the test results would change the course of their clinical care in any significant way.[3]

Finally, in the context of public health, the answer to the *why* and *whom* to test questions is that the goal of testing is to contain the disease and testing should therefore be performed as widely, and on as many individuals, as possible (or at least, as is necessary for mitigation or successful surveillance). Further, the idea behind requiring testing in this context is that it would further the goal of mitigation or containment measures: the more people who are tested, the more likely it is that the disease will be successfully contained, especially if those in the population who test positive for active infection can be effectively isolated from others. This

[3] This epistemic requirement that it not be known ahead of time whether or not the treatment is effective is known as the *principle of equipoise* (Freedman 1987). According to Freedman, equipoise is the state of genuine uncertainty within the expert medical community on the best treatment for a condition. Thus it is a state that exists when some physicians or researchers favor one treatment (or expect it to work) while others favor another (or do not expect the one being tested to work). The idea is that this epistemic principle should be adhered to because if it is already known prior to the trial that the treatment works, then running the trial is a waste of time and financial resources, while, on the other hand, if it is already known prior to the trial that the treatment does not work, then the trial participants will be put at potential risk for no reason.

raises different distribution and allocation questions than in the case of clinical uses of testing for treatment. By way of partial analogy, in the context of justice in *treatment* allocation, in general, there are few restrictions on a competent adult patient's right to refuse a treatment measure or intervention (Flanigan 2017), although there might be restrictions on a patient's right to request these things. However, this is not as clearly the case when it comes to diagnostic testing for active surveillance purposes. In this situation, diagnostic testing is conducted not (solely) for the benefit of the individual being tested, but also to protect others in the society of which the infected person is a part.[4]

Thus the answer to the question of whether it is sometimes, always, or never acceptable to force individuals to be tested in the public health context will depend on how one settles distributive questions about the burdens of testing *when it comes to containment/mitigation measures specifically*. In considering how testing resources are allocated and how the burdens and benefits of testing are distributed, the concept of diagnostic justice provides a lens through which to evaluate how these tensions can be resolved and how the different moral demands on testing can be balanced. For example, imagine that you (unfortunately) find yourself in the emergency department of your local hospital with a diagnosis of sepsis. The treatment for this condition is intravenous antibiotic therapy, generally with two or three agents (Schmidt and Mandel 2020). But suppose that the attending physician in this case decides not to treat you because she is aware that the more often any given antibiotic is prescribed, the more likely it is that bacteria in the community will develop resistance to it. So, she decides not to treat you in order to preserve the antibiotics' effectiveness (Kennedy 2021). We might or might not agree with this physician's decision, however, what we can agree on is that she is, in the process of making this decision, weighing the benefit of the intervention to the individual vs. the risk of the intervention to society at large. That is, what she is doing is weighing in on what is the most just all-things-considered action to take in the situation. This is the sort of normative reasoning that is also required when making testing/diagnostic decisions in the clinical, research and public health settings. And, in our view, this reasoning can be facilitated by taking into consideration the principle of diagnostic justice.

[4] This is similar to the situation with vaccination—which is done not just for the benefit of the individual, but also for the benefit of the society in which that person resides.

4. Two Outstanding Difficulties in COVID Testing

Testing for COVID-19 that is part of active surveillance and mitigation efforts, as well as screening for the disease to inform quarantine decisions or travel restrictions, raises two difficulties when it comes to diagnostic justice. These difficulties are outstanding, in the sense that they have not been adequately addressed in testing policy and thus different kinds of COVID-19 testing policies may fail to meet the demands of diagnostic justice. Though testing for COVID-19 as part of the response to the pandemic was put together on the fly in the face of the global health emergency posed by the disease, it is important to understand these difficulties so as to fine tune testing policy for future public health emergencies.

A Diagnostic Misconception?[5]

A central tenet of the ethics of clinical research since the Belmont Report has been the separation of therapy from research (Emanuel et al. 2000). Revelations about the deeply unethical Tuskegee Syphilis studies in the United States showed that blurring boundaries between research and therapy can cause enormous difficulties, making exploitation of subjects much easier and complicating the exercise of an individual's right to withdraw from an experiment, among other issues.[6] It is generally accepted that, in order for clinical research to be ethical, therapy must be detached from research, in practice and in the understanding of research subjects.

Public health surveillance is similarly detached from therapy, in that the goals of public health surveillance are different from the goals of individual patient therapy. However, as happens in clinical research, individuals may not understand this difference. Patients' participation in research because they mistake it for therapy is known as the *therapeutic misconception* (Applebaum et al. 1987; Miller and Rosenstein 2003). The therapeutic misconception raises significant problems for clinical research; it may compromise informed consent, particularly in cases where participants may believe that participation in the trial is actually tantamount to a novel form of treatment, when in fact they may be assigned to a control group

[5] We owe Peter Jaworski for suggesting this term to us.

[6] It is necessary to note that a complicating factor in this case is the deep and abiding systemic racism present in the United States, which shaped the Tuskegee case and was responsible for so many of its features. The issue in Tuskegee was not just that there was a blurring of the researcher/clinician roles, it was that Black individuals were preyed upon and treated as research materials in the guise of providing them with "care".

and may receive little to no (medical) benefit from the trial at all.[7] How to deal with the therapeutic misconception in clinical trials has been a significant subject of debate (Applebaum et al. 1987).

Something very much like the therapeutic misconception may be operating in instances of disease surveillance as well. Individuals who consent to testing may not fully understand how their testing data will be used by public health decision-makers, may not understand procedures such as the deidentification of data or its use in contact tracing, and may believe that by submitting to testing, they will be facilitating their own clinical care. As an analogy, consider a study of adults in the UK about their attitudes towards contact tracing via smartphone (Williams et al. 2021). In this study researchers found that misconceptions about contact tracing data were widespread; individuals believed that contact tracing data would allow others to identify themselves, believed that contact tracing data had a kind of diagnostic function (to identify close contacts with COVID-19 so that they could understand their own risk of exposure), and did not understand how the data was being used by the government. What attitudes individuals have towards testing is an empirical question, and no doubt there will be significant research on this in the future; but it is not hard to imagine that similar misconceptions are involved with COVID-19 testing, at least at the present time.

This poses a difficulty relating to diagnostic justice for three reasons. First, individuals may be submitting to testing based on mistaken understandings of the use of the data and the purpose of the testing. As in the case of the therapeutic misconception in research ethics, this may compromise individuals' ability to give informed consent. Second, these misconceptions may be playing a part in motivating participation in testing in ways that raises worries about exploitation. In countries such as the United States where testing has been voluntary, it is possible that beliefs about the clinical relevance of testing data have played a part in individuals submitting to testing. And third, the opposite may be occurring—misconceptions about testing may play a part in keeping some individuals from submitting to testing at all, thus complicating the active surveillance measures necessary to mitigate the pandemic.

Added together, this raises a question about whether testing policy is exploiting these misconceptions to gather data. If that is the case, then testing policy, in order to be effective for active surveillance, would be

[7] They may be benefited in that they identify with the goals of the trial, and so even if participation doesn't impact their health, they may consider it a benefit to have helped further the goals of the trial. Hans Jonas famously argued that identification with the goals of a clinical trial in this strong sense was a necessary condition for a clinical trial to be morally acceptable (Jonas 1969).

depending on a widespread diagnostic misconception—to perform active surveillance, testing policy is intentionally leaving a fuzzy line between clinical and public health uses of testing, and depending on the fuzziness of the situation to leave a gap in which individuals are motivated to seek testing under mistaken pretenses. This is an issue of diagnostic justice because it raises a major concern about fairness—if individuals are seeking testing because they believe it is part of getting care, and yet it neither furthers their own care goals nor is necessary for individual care, individuals are taking on the burden (however minimal that burden is) of testing without any benefit.[8]

As with some forms of clinical research, testing for COVID-19 surveillance also involves blurred lines between the collecting of data for research and the collecting of data for therapeutic purposes. Ideally, these two domains, along with their differing aims and ethical considerations should be kept separate. However, during public health emergencies, these lines are almost necessarily blurred. Clinicians become researchers and *vice versa* and are suddenly tasked with the considerations of both knowledge acquisition and patient care. We have seen this in the current pandemic, as data gathered in the course of the clinical care of COVID-19 patients has both been made public and has been used to inform public health decision-making. For example, testing data from clusters identified at the beginning of the pandemic were instrumental in establishing that the disease is spread via aerosol transmission (Hamner et al. 2020). Unlike in (well-designed) clinical trials, there are no clear protocols on how to keep these roles separate. Further, this blurring of clinical and public health surveillance roles for testing and data gathering, both in the understanding of individuals submitting to testing and in the practices of both clinicians and researchers, could pose significant problems in the future. This is an area that requires further investigation and would greatly benefit from the development of clear protocols.

Use of Data and Impacts on Communities

It is well recognized that participation in research does not always benefit the individual participants involved, and because of this, what benefits are owed to research subjects has itself been a subject of intense debate within the ethics of clinical research (Richardson 2012).

Similarly, participation in active surveillance by submitting to testing does not always benefit individuals or even their communities, and in fact can be used to inform decision-making that could potentially *harm* these

[8] Thanks to an anonymous referee, for pushing us to clarify this point.

communities. One of the major features of the COVID-19 pandemic has been the significant disparities in morbidity/mortality rates among different communities, with Hispanic, Latinx, Black, Indigenous, and Pacific Islander populations disproportionately affected by the disease (Hooper et al. 2020). These dynamics were noticed very early on in the pandemic, and yet data gathered from surveillance has done little to make a dent in this disparity. This is a significant concern for diagnostic justice; if testing as part of active surveillance reveals such significant and morally arbitrary disparities, it should, ideally, also inform policies that address these problems. Yet in the case of COVID-19, the opposite has been the case; upticks in infections revealed by active surveillance testing informed policies that seemed to have little to no impact on these disparities. A vivid example of this has been the US state of California, where an early lockdown likely mitigated the impact of the pandemic in the early months of the pandemic (Friedson et al. 2021), but where there have been massive disparities between lower-income and higher-income communities and white and Latinx communities in their respective burdens of COVID-19 morbidity and mortality (Hsu and Hayes-Bautista 2021). Why data revealed from active surveillance indicated these disparities but policy did not adjust accordingly is a major issue that must be addressed in the wake of the pandemic. If active surveillance reveals such a disparity, but policy does nothing to ameliorate it, this looks like a significant failure of diagnostic justice, as the public health purposes of testing and compliance with testing requirements by community members did not result in any action that ameliorated the effects of the pandemic.

The primary function of data gathered from active surveillance has, so far, been to inform when to impose different restrictions on businesses, schools, and other public activities. Different communities have experimented with various metrics in an effort to determine when it is safe to permit school openings, religious services, dine-in service at restaurants, and the like. As an example, New York City, in the United States, established fairly early on in the pandemic a metric of a 3% test positivity rate for opening public schools (Shapiro 2020). These restrictions, however, do not benefit or harm everyone equally; in New York City, the effects of closing public schools have primarily been felt by lower-income communities (Agostinelli et al. 2020). There are also worries about the disproportionate long-term effects of lockdowns from lost income, mental health impacts, and the like (Winsberg et al. 2020).[9] During the COVID-19 pandemic, testing data has informed these policies. Testing data, then,

[9] We bracket here any comment on Winsberg et al.'s claim that these long-term effects show that trade-offs from lockdowns raise a high epistemic barrier to imposing such lockdowns, and that this barrier was not met in the early months of the pandemic (Winsberg et al. 2020).

can be used in such a way that informs policy-decisions that impose burdens, but in which burdens are not distributed equitably, in which burdens fall disproportionately on some communities and not others. If testing data gathered during active surveillance informs policies that not only do not ameliorate the impacts of the pandemic on disproportionately affected communities, but actually generate some significant harms of their own, then this also looks like a significant failure of diagnostic justice.

5. Implications

Our discussion of diagnostic testing and diagnostic justice has implications not just for COVID-19 testing but for testing policy for future public health emergencies. As we have seen, testing for COVID-19 as part of active surveillance efforts can involve a blurring of the boundaries between public health and clinical medicine. Since test results are obviously relevant for an individual's health, testing as part of active surveillance and mitigation efforts at least has some relevance for individuals, even if that is not the primary goal of the testing. Given this, it may be that testers have obligations to individuals who report for testing as part of active surveillance efforts, even if the primary aim is not clinical but is to provide data for mitigation efforts. These obligations, for testing as part of active surveillance, may be minimal: timely return of results, clinical advice and direction to care resources, communication of results to individuals in a clear fashion, and the like may be sufficient to discharge the duties resulting from the partial entrustment of individuals' health to testers. However minimal, meeting these requirements may be necessary to ensure that benefits from testing are distributed equitably. Some individuals may be better placed to take advantage of information gained from testing without additional resources or aid from public health officials. Building in resources to meet obligations of care to those who submit to testing may be necessary to help remove these inequities, and ensure that those who submit to testing receive some (clinical) benefit from doing so, as well as those who benefit from mitigation efforts.

Though minimal, this hasn't always been the case with active surveillance measures during epidemics. During the 2013-2016 Upper West Africa Ebola epidemic, the focus throughout, from the very earliest days, was on containment, instead of care (Farmer 2020). Pressure from the world community on Guinea, Sierra Leone, and Liberia led to a channeling of resources into identification and isolation of cases, in the hopes of breaking transmission chains, and this extended as well to testing and contact tracing. Much of the containment and mitigation effort was put in the hands of the military, which employed coercive measures aimed at containment

(such as the infamous *cordon sanitaire*) (McNeill 2014). As the medical historian Frank Snowden argues, the response to Ebola involved a resurrection of the tactics used to fight infectious disease in the dark ages of medicine, rather than a 21st century, biomedically sophisticated effort aimed at both care and mitigation:

> Many of the coercive means adopted echoed early modern Europe's effort to defend itself against bubonic plague (…). Compulsory treatment facilities surrounded by troops even closely resembled lazarettos. Daniel Defoe would have found the response familiar. (Snowden 2019, 495).

Besides the obvious wrong of failing to provide even minimal supportive care to those suffering from Ebola Virus Disease, this also hampered mitigation efforts, as the (correct) perception that public health authorities (including some, but not all, foreign support) were more interested in containment than in caring for the sick sowed distrust and resentment, and led to (sometimes violent) backlash among the population of the three most affected countries. Though testing during the Upper West African Ebola epidemic was not nearly on the scale of the current worldwide efforts to test for SARS-CoV-2, and there are many relevant differences in the dynamics of the two epidemics, the contrast between the two events shows how employing active surveillance without providing any clinical support leads not just to serious harms but is counterproductive to mitigation.[10] This has important implications for global health ethics and public health policy looking forward: the separation of care from mitigation is neither normatively nor practically possible, and active surveillance measures, including testing for this purpose, must recognize the requirements of care to the individuals being tested in order to equitably distribute the burdens and benefits of testing, even if the primary goals of surveillance are not clinical.

6. Conclusion

We have argued in this paper that considerations of diagnostic justice generate moral demands on testing policy as part of public health

[10] There are many reasons, of course, for the differences between the two events: the Upper West Africa Ebola epidemic occurred in a region with minimal clinical resources (Farmer 2020), the epidemic was concentrated in Upper West Africa despite some sporadic imported infections (and limited secondary transmission) elsewhere in Africa, Europe, and the United States, and the different stigmas, biases, and prejudices about Ebola and those suffering most from it during the epidemic made it far easier to "other" those in need of care and thus to direct resources elsewhere than has been the case with COVID-19, although there is also plenty of stereotyping of individuals susceptible to the disease in the latter case as well (Aronson 2020).

surveillance during infectious disease epidemics. The current and ongoing SARS-CoV-2/COVID-19 pandemic has revealed many of the dynamics involved with testing as part of active surveillance during these events and provided important lessons for the general question of what would constitute an ethical testing regime for active surveillance during epidemics. This, unfortunately, looks likely to be a significant question for global health in the foreseeable future. The first two decades of the 21st century have already seen a number of significant public health events involving novel and emerging pathogens—SARS, H1N1, Ebola, and now COVID-19. Collectively, these have already cost the lives of millions of people, in the form of premature death from infection and illness. There are plenty of reasons to believe this is not just bad luck; some of the dynamics of our world—further encroachment into the wildland-urban interface (which provides increased opportunities for zoonosis), intensifying urbanization of the world's population, the high volume of international air travel, and continuing, morally pernicious disparities in access to basic health care resources in many parts of the world—all provide ample opportunities for emerging pathogens to spark epidemics (Bollyky 2018).[11] A just and sustainable world will require just and sustainable global health policy, which includes testing protocols for public health surveillance that meet the demands of diagnostic justice.

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[11] The causal claims involved in theories about the vulnerability of the contemporary world to infectious disease generate interesting questions in the philosophy of science in their own right; but some of the narratives and rhetoric in the presentation of these claims can echo problematic ideas about developing countries from past decades. Some of this is the case with Bollyky's treatment, especially his discussion of the role of urbanization in developing countries and population increases due to progress in combating childhood mortality (Bollyky 2018). Others draw different lessons; Deaton (2013) and Farmer (2020), for instance, see the unique zoonotic opportunities provided by urbanization and encroachment on the urban-wildland interface in developing countries as evidence of the severe risks and injustices posed by lack of public health infrastructure and clinical resources; or rather, as evidence not that, as Bollyky puts it, "the world is getting healthier in worrisome ways", but rather that persistent injustices in access to health care and other basic goods create significant risks for all.

REFERENCES

Agostinelli, Francesco, Matthias Doepke, Giuseppe Sorrenti, and Fabrizio Zilibotti. 2020. "When the Great Equalizer Shuts down: Schools, Peers, and Parents in Pandemic Times." w28264. Cambridge, MA: National Bureau of Economic Research. https://doi.org/10.3386/w28264.

Appelbaum, P. S., L. H. Roth, C. W. Lidz, P. Benson, and W. Winslade. 1987. "False Hopes and Best Data: Consent to Research and the Therapeutic Misconception." *The Hastings Center Report* 17 (2): 20–24.

Aronson, Louise. 2020. "Age, Complexity, and Crisis — a Prescription for Progress in Pandemic." *New England Journal of Medicine* 383 (1): 4–6. https://doi.org/10.1056/NEJMp2006115.

Beauchamp, Tom L., and James F. Childress. 2020. *Principles of Biomedical Ethics*. 8th ed. New York: Oxford University Press.

Begley, Sharon. 2020. "Who Is Getting Sick? A Breakdown of Coronavirus Risk by Demographic Factors." *STAT* (blog). March 3, 2020. https://www.statnews.com/2020/03/03/who-is-getting-sick-and-how-sick-a-breakdown-of-coronavirus-risk-by-demographic-factors/.

Berkley, Seth. 2003. "Thorny Issues in the Ethics of AIDS Vaccine Trials." *Lancet* 362 (9388): 992. https://doi.org/10.1016/S0140-6736(03)14371-1.

Bollyky, Thomas J. 2018. *Plagues and the Paradox of Progress: Why the World Is Getting Healthier in Worrisome Ways*. Cambridge, MA: MIT Press.

Center for Disease Control and Prevention. 2020. "Testing Strategies for SARS-CoV-2." Center for Disease Control and Prevention. February 11, 2020. https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/sars-cov2-testing-strategies.html.

Cheng, Matthew P., Jesse Papenburg, Michaël Desjardins, Sanjat Kanjilal, Caroline Quach, Michael Libman, Sabine Dittrich, and Cedric P. Yansouni. 2020. "Diagnostic Testing for Severe Acute Respiratory Syndrome–Related Coronavirus-2." *Annals of Internal Medicine*, M20-1301. https://doi.org/10.7326/M20-1301.

Deaton, Angus. 2013. *The Great Escape: Health, Wealth, and the Origins of Inequality*. Princeton: Princeton University Press.

Emanuel, E. J., D. Wendler, and C. Grady. 2000. "What Makes Clinical Research Ethical?" *JAMA* 283 (20): 2701–11. https://doi.org/10.1001/jama.283.20.2701.

Emanuel, Ezekiel J., Govind Persad, Ross Upshur, Beatriz Thome, Michael Parker, Aaron Glickman, Cathy Zhang, Connor Boyle, Maxwell Smith, and James P. Phillips. 2020. "Fair Allocation of Scarce Medical Resources in the Time of Covid-19." *New England Journal of Medicine* 382 (21): 2049–55. https://doi.org/10.1056/NEJMsb2005114.

Farmer, Paul. 2020. *Fevers, Feuds, and Diamonds: Ebola and the Ravages of History*. New York: Farrar, Straus and Giroux.

Flanigan, Jessica. 2014. "A Defense of Compulsory Vaccination." *HEC Forum: An Interdisciplinary Journal on Hospitals' Ethical and Legal Issues* 26 (1): 5–25. https://doi.org/10.1007/s10730-013-9221-5.

———. 2017. *Pharmaceutical Freedom: Why Patients Have a Right to Self-Medicate*. New York: Oxford University Press.

Freedman, B. 1987. "Equipoise and the Ethics of Clinical Research." *The New England Journal of Medicine* 317 (3): 141–45. https://doi.org/10.1056/NEJM198707163170304.

Friedson, Andrew I., Drew McNichols, Joseph J. Sabia, and Dhaval Dave. 2021. "Shelter-in-place Orders and Public Health: Evidence from California during the Covid-19 Pandemic." *Journal of Policy Analysis and Management* 40 (1): 258–83. https://doi.org/10.1002/pam.22267.

Furukawa, Nathan W., John T. Brooks, and Jeremy Sobel. 2020. "Evidence Supporting Transmission of Severe Acute Respiratory Syndrome Coronavirus 2 While Presymptomatic or Asymptomatic - Volume 26, Number 7—July 2020 - Emerging Infectious Diseases Journal—Cdc." Accessed November 9, 2021. https://doi.org/10.3201/eid2607.201595.

Hamner, Lea, Polly Dubbel, Ian Capron, Andy Ross, Amber Jordan, Jaxon Lee, Joanne Lynn, et al. 2020. "High Sars-CoV-2 Attack Rate Following Exposure at a Choir Practice—Skagit County, Washington, March 2020." *MMWR. Morbidity and Mortality Weekly Report* 69 (19): 606–10. https://doi.org/10.15585/mmwr.mm6919e6.

Hsu, Paul, and David E. Hayes-Bautista. 2021. "The Epidemiology of Diversity: Covid-19 Case Rate Patterns in California." *Journal of Immigrant and Minority Health* 23 (4): 857–62. https://doi.org/10.1007/s10903-021-01159-x.

Jonas, Hans. 1969. "Philosophical Reflections on Experimenting with Human Subjects." *Daedalus* 98 (2): 219–47.

Jr, Donald G. McNeil. 2014. "Using a Tactic Unseen in a Century, Countries Cordon off Ebola-Racked Areas." *The New York Times*, 2014, sec. Science.

https://www.nytimes.com/2014/08/13/science/using-a-tactic-unseen-in-a-century-countries-cordon-off-ebola-racked-areas.html.

Karlsson, Annika C., Marion Humbert, and Marcus Buggert. 2020. "The Known Unknowns of T Cell Immunity to COVID-19." *Science Immunology* 5 (53): eabe8063. https://doi.org/10.1126/sciimmunol.abe8063.

Larijani, Mona Sadat, Amitis Ramezani, and Seyed Mehdi Sadat. 2019. "Updated Studies on the Development of HIV Therapeutic Vaccine." *Current HIV Research* 17 (2): 75–84. https://doi.org/10.2174/1570162X17666190618160608.

Lasagna, L. 1968. "Some Ethical Problems in Clinical Investigation." *South African Medical Journal* 42 (1): 2–5.

Lysdahl, Kristin Bakke, and Bjørn Hofmann. 2020. "Overutilization of Imaging Tests and Healthcare Fairness." In *Philosophy of Advanced Medical Imaging*, edited by Elisabetta Lalumera and Stefano Fanti, 99–111. SpringerBriefs in Ethics. Cham: Springer International Publishing. https://doi.org/10.1007/978-3-030-61412-6_8.

Miller, Franklin G., and Donald L. Rosenstein. 2003. "The Therapeutic Orientation to Clinical Trials." *New England Journal of Medicine* 348 (14): 1383–86. https://doi.org/10.1056/NEJMsb030228.

Oleske, Denise M. 2010. "Screening and Surveillance for Promoting Population Health." In *Epidemiology and the Delivery of Health Care Services: Methods and Applications*, 131–50. Boston, MA: Springer. https://doi.org/10.1007/978-1-4419-0164-4_5.

Onder, Graziano, Giovanni Rezza, and Silvio Brusaferro. 2020. "Case-Fatality Rate and Characteristics of Patients Dying in Relation to Covid-19 in Italy." *JAMA*. https://doi.org/10.1001/jama.2020.4683.

Paltiel, A. David, Amy Zheng, and Rochelle P. Walensky. 2020. "Assessment of SARS-CoV-2 Screening Strategies to Permit the Safe Reopening of College Campuses in the United States." *JAMA Network Open* 3 (7): e2016818. https://doi.org/10.1001/jamanetworkopen.2020.16818.

Richardson, Henry S. 2007. "Gradations of Researchers' Obligation to Provide Ancillary Care for HIV/AIDS in Developing Countries." *American Journal of Public Health* 97 (11): 1956–61. https://doi.org/10.2105/AJPH.2006.093658.

———. 2012. *Moral Entanglements: The Ancillary-Care Obligations of Medical Researchers*. Oxford: Oxford University Press.

Shapiro, Eliza. 2020. "New York City to Close Public Schools Again as Virus Cases Rise." *The New York Times*, 2020, sec. New York.

https://www.nytimes.com/2020/11/18/nyregion/nyc-schools-covid.html.

Sharfstein, Joshua M., Scott J. Becker, and Michelle M. Mello. 2020. "Diagnostic Testing for the Novel Coronavirus." *JAMA* 323 (15): 1437–38. https://doi.org/10.1001/jama.2020.3864.

Snowden, Frank M. 2019. *Epidemics and Society: From the Black Death to the Present*. Open Yale Courses Series. New Haven: Yale University Press.

Spellberg, Brad, Travis B. Nielsen, and Arturo Casadevall. 2021. "Antibodies, Immunity, and COVID-19." *JAMA Internal Medicine* 181 (4): 460. https://doi.org/10.1001/jamainternmed.2020.7986.

Truog, Robert D., Christine Mitchell, and George Q. Daley. 2020. "The Toughest Triage — Allocating Ventilators in a Pandemic." *New England Journal of Medicine* 382 (21): 1973–75. https://doi.org/10.1056/NEJMp2005689.

Webb Hooper, Monica, Anna María Nápoles, and Eliseo J. Pérez-Stable. 2020. "Covid-19 and Racial/Ethnic Disparities." *JAMA* 323 (24): 2466. https://doi.org/10.1001/jama.2020.8598.

Williams, Simon N., Christopher J. Armitage, Tova Tampe, and Kimberly Dienes. 2021. "Public Attitudes towards COVID-19 Contact Tracing Apps: An UK-based Focus Group Study." *Health Expectations* 24 (2): 377–85. https://doi.org/10.1111/hex.13179.

Winsberg, Eric, Jason Brennan, and Chris W. Surprenant. 2020. "How Government Leaders Violated Their Epistemic Duties during the SARS-CoV-2 Crisis." *Kennedy Institute of Ethics Journal* 30 (3): 215–42. https://doi.org/10.1353/ken.2020.0013.