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Structural Challenges in Deployment of an Open-Source Diagnostic by Independent Researchers During a Public Health Emergency

COLLECTION: BIOMED

ESSAY

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ABSTRACT

Open-source diagnostic products have the potential to address some of the major challenges of diagnostic access revealed during the COVID-19 pandemic. However, as it stands, the current approval model in the US is poorly suited for such tests. In March 2020, early in the COVID-19 pandemic, a small group of independent scientists with members located in Illinois, New York, and Georgia collaborated on developing an open-source, patent-free COVID-19 diagnostic test. Within a few short months, we had developed a reliable test and published the protocol online with the hope that this simple, yet sensitive test would be adopted for widespread testing in laboratories, schools, and workplaces. However, we encountered several unexpected barriers to deployment of the test. This essay describes our experience and proposes a novel solution to reduce the barriers that limit meaningful contributions by independent researchers to addressing healthcare challenges in the United States.

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INTRODUCTION

The idea of independent scientific research has its roots in the Renaissance, long before large institutions and governments provided funding for such work. In many disciplines, the idea of the independent researcher or inventor has continued to the present day. However, for the life sciences, this idea has been slow to mature. Modern life science research often requires sophisticated equipment and materials that can be prohibitively expensive. Additionally, even acquiring these materials can be difficult without affiliation with an institution. Nonetheless, groups of independent scientists from around the world have been building a global movement over the past two decades with the goal of democratizing life science research. Similar to the personal computing revolution in the 1970s, these groups, often existing under the umbrella of "do-it-yourself" Biology (DIYbio), create laboratories outfitted with used laboratory equipment in garages or old warehouses. Many of these laboratories are open to and supported by the public and allow anyone, regardless of background or formal training, to pursue research that interests them. Additionally, in our experience, most independent researchers have altruistic goals that are perhaps idealized, wishing to change the world for good without seeking patents or profits.

The Coronavirus Disease (COVID-19) pandemic provided a unique opportunity to test the resilience and resourcefulness of the independent research community. One of the many strengths of this community is its ability to rapidly mobilize across the globe. As news of a novel virus with pandemic potential began to spread, independent scientists were quick to act, sharing information and organizing meetings to determine how they might best help fight this emerging threat to global health.

One such effort emerged from Just One Giant Lab (JOGL), an online collaborative platform promoting open-source research that launched the OpenCovid19 Initiative in February 2020. JOGL's OpenCovid19 Initiative aimed to create a global community with the common goal of "developing open-source and low-cost tools and methodologies that are safe and easy to use in response to the COVID-19 pandemic" (JOGL, 2020). More than 4,000 volunteers from around the world, including lay people and experts, organized to address some of the main challenges of the COVID-19 pandemic, with efforts ranging from mitigation of personal protective equipment shortages to testing disparities. JOGL proved instrumental in uniting independent researchers around these efforts by providing a platform to connect, share ideas, and discuss results. In addition, JOGL provided community-vetted micro-grants which allowed teams to focus on the science rather than worry about how they would afford materials and reagents.

We joined the OpenCovid19 Initiative at launch, and seeing a severe lack of accessible and affordable diagnostic testing options early in the pandemic, sought to develop our own open and accessible test that could be used by anyone and anywhere it was needed. Our test was developed primarily by three independent scientists in Illinois, New York, and Georgia, and was supported by a global collaboration of independent researchers connected through the "nucleic acid amplification group" within JOGL. While each of us had formal training in life sciences, we worked independently of a formal institution; one of us worked in a community laboratory and one in a living room. Here, we discuss our development of an open-source COVID-19 diagnostic and experience attempting to deploy it for widespread use in the United States.

A DIAGNOSTIC CHALLENGE

Diagnostic testing early in the COVID-19 pandemic was fraught with many challenges that made it difficult for public health officials to truly understand the spread of the SARS-CoV-2 virus and for individuals to know whether or not they were infected or contagious. In the US, the Centers for Disease Control and Prevention (CDC) was quick to produce a molecular diagnostic test based on the polymerase chain reaction (PCR). The test was developed for use in connection with the CDC's existing nationwide influenza surveillance program and so was restricted to partner public health laboratories already qualified to perform similar testing. This resulted in limiting availability and accessibility of testing to the general public and also in introducing bottlenecks. Because all samples could be processed by only a few central laboratories, this led to delays in test results for days or weeks. Meanwhile, a potentially infectious individual could unknowingly be spreading the virus in their community. In addition to these limitations, early lots of the diagnostic oligonucleotide primers manufactured and disseminated by the CDC showed manufacturing defects, which rendered them unreliable (Lee et al. 2021). This further aggravated the challenge of surveillance of this new virus and shook the public's confidence in the US public health system.

Eventually, other laboratories began developing their own tests based on the CDC's PCR design, and while this did help alleviate some bottlenecks and increase testing capacity, tests were still hard to come by. Also, early in the pandemic, the use and availability of rapid antigen tests (RATs) had not yet become widespread; nearly all tests were nucleic acid amplification tests (NAATs). Because laboratories needed the same or very similar materials and reagents for processing samples and running these

types of tests, reagent shortages became a major problem. Meanwhile, private companies and start-ups began jumping on the diagnostics bandwagon seeking to make a quick profit from the testing scarcity. This culminated in a testing shortage that ultimately impacted low-income communities the most, as testing was either too expensive or inaccessible (Batista et al. 2021).

Addressing these shortcomings and the needs of the community was our primary motivation in developing a diagnostic test. Our goal was to develop a test that was open, meaning that the protocol and methodologies would be available to anyone who wanted to implement them and not require them to take a license. It was also important to us that the test allow the use of different reagents that were relatively inexpensive and readily available and otherwise have minimal equipment requirements. Additionally, the procedure had to be simple enough to be performed by a layperson with minimal training. And, of course, the test needed to be based on sound and validated science.

DEVELOPING AN OPEN DIAGNOSTIC TEST

When it comes to near-patient or point-of-care (POC) diagnostics, there are two main categories: nucleic acid amplification tests and antigen tests (Dolen et al. 2017). Antigen tests work by detecting specific antigen, which are parts of proteins of a particular pathogen, that are present in a sample. Lateral flow tests are the most common type of antigen test for POC applications. These tests have the advantage of being very fast; results are provided within 15 minutes of test administration. Antigen tests are also very easy to perform. Home antigen tests can even be administered by the individual taking the test without the supervision of a physician or laboratorian. The biggest disadvantage of these tests is lower sensitivity and specificity as compared to NAATs.

NAATs detect a specific target sequence of RNA or DNA through amplification of nucleic acid. NAATs based on PCR are the most common and variations on the technology, such as quantitative (qPCR) and reverse-transcription (RT-qPCR), allow for the highly sensitive detection of nucleic acid targets. All PCR tests must be run on an expensive machine called a thermal cycler. However, some NAATs are isothermal technologies that do not require thermal cycling (Oliveira, Veigas, and Baptista 2021). NAATs can be relatively simple to develop, usually only requiring synthetic oligonucleotide primers and off-the-shelf reagent kits. However, they can suffer from limitations including off-target amplification effects if primers are not adequately designed; carry-over contamination from previous tests or during nucleic acid extraction; and extremely high sensitivity resulting in positive results that may not be clinically relevant (Mina, Parker, and Larremore 2020).

While multiple approaches exist for developing NAAT-based and RAT-based diagnostics, few are accessible or affordable to the independent researcher. When considering which approach to pursue, we considered the following constraints: accessibility of regents and materials, equipment requirements, cost, ease of performing the test, and time to result. As mentioned above, our primary goal from the outset was to develop a test that was open-source and accessible and maintained high sensitivity and specificity under a variety of user conditions, both in formal laboratories and in more informal settings such as schools and workplaces. While antigen tests have some advantages that make them appealing for at-home or independent laboratory use, the need to identify antibodies specific to SARS-CoV-2 antigen was beyond our financial and laboratory capabilities – and likely would be for anyone else endeavoring to develop a test in an independent setting. Therefore, we chose to focus on NAATs.

Within the category of NAATs, we explored PCR and isothermal approaches, as some of our collaborators already had extensive experience with these technologies. PCR approaches proved to be both cost and resource prohibitive. Given the intensive testing being performed by public health, academic, and industrial laboratories based on this technology at that time, acquiring reagents was a challenge (Ratanghayra 2020). We did not want our test to rely on and further impact the limited reagent stocks already being used. Additionally, the cost and equipment requirements of performing an RT-qPCR test can be prohibitive in an independent environment. qPCR machines can retail from $10k to $100k USD and require trained laboratory personnel to operate and interpret results. It was clear that a PCR-based approach would not meet our goals of an accessible and easy-to-use test.

We found that the isothermal technique of loop-mediated isothermal amplification (LAMP) does not suffer from many of the shortcomings of PCR (Notomi et al 2000). LAMP would require us only to design, or to pull from existing literature, relatively inexpensive oligonucleotide primers and an enzyme mix that is easily acquired from commercial suppliers. Additionally, because it utilizes an isothermal approach, a LAMP-based test requires only a heat source, such as a water bath or heat block, rather than a thermal cycler, significantly lowering equipment costs. Finally, LAMP allows for many different end-point readouts from colorimetric to fluorometric, further simplifying interpretation and equipment needs.

Ultimately, we settled on LAMP as the method of choice and developed the One Hour COVID Test (Monaco,

Jorgensen, and Ware 2021). To aid in the rapid development of our test, we chose to evaluate several different published primer sets rather than design our own. We also chose to use a pH-based, colorimetric read-out, which would allow the test results to be easily interpreted with the naked eye. Furthermore, we utilized a commercially available sample collection device with a novel RNA processing step that requires very little equipment and training. We chose commercial sources for reagents and materials where necessary to speed up production. The sample collection device had several advantages over a custom solution; specifically, it had been tested and shown to work, had a US Food and Drug Administration (FDA) Emergency Use Authorization (EUA), and was in ample supply. The LAMP reagents had similar advantages in that they were shown by others to work well and were readily available (Zhang, et al. 2020). We believed that the use of commercial materials and reagents would not undermine the open-source nature of the test because all of the selected products were used in accordance with the manufacturer's instructions. It further allowed us to focus our efforts into developing and optimizing the overall test. Finally, to validate our test, we selected known amounts of an inactivated culture of SARS-CoV-2 in human buccal cells from the American Type Culture Collection (ATCC) via BEI Resources to generate contrived samples. Within a few months, we had developed and validated a complete testing protocol.

BARRIERS TO DEPLOYMENT

We then turned our attention to clinical testing of the test and to deployment. Little did we know how challenging these next steps would prove. Indeed, overcoming nearly all of them required skill sets and knowledge unrelated to the basic sciences.

In the US during non-emergency times, there exist two main designations for diagnostic tests: in vitro diagnostics (IVDs) and laboratory-developed tests (LDTs). IVDs are regulated by the FDA as medical devices under the Medical Devices Amendments of 1976 (FDA, 2021a). To obtain FDA approval, IVD developers must submit both analytical and clinical testing information to prove product safety and efficacy (Pew Charitable Trust 2019). During emergencies, such as the COVID-19 pandemic, the FDA can grant Emergency Use Authorization (EUA) for IVDs that meet criteria in Section 564 of the Federal Food, Drug and Cosmetic Act (FDA, 2018). An IVD can be approved for EUA with less analytical and clinical data, but the EUA will expire once the emergency is declared over (FDA 2021b).

To generate data to support approval of the test as an IVD, we worked to establish partnerships for clinical trials. Connections through JOGL with physicians in Germany and France initially seemed promising but did not lead to lasting partnerships. We also attempted to partner with a local Chicago-area hospital, but we were informed that this hospital was too inundated with COVID-19 cases to support a COVID-19 clinical trial. We then offered to assemble test kits at cost to enable a university in Chicago to perform weekly screening of its students with an invitation to opt in to a clinical study, but the university administrators elected not to conduct regular screening. Finally, we were approached by a small diagnostics start-up company that offered access to clinical samples in exchange for exclusive licensing of the test, but this option undermined our objective of keeping the test open-source. Thus, despite our best efforts, we did not gain access to clinical samples and, as a result, we were never able to clinically validate our test.

Although the guidelines for FDA EUA during the COVID-19 pandemic indicated that it might be possible to obtain an EUA without clinical data, we did not pursue this option based on information from other colleagues and collaborators that the approval process had stalled; some groups were still waiting for approval six months after submitting their application. We also were informed that the FDA was shifting its focus to approving only high-throughput tests for companies with existing markets.

We therefore turned our attention to offering the test as an LDT. LDTs are neither regulated by the FDA nor required to undergo clinical trials. However, both IVDs and LDTs can be used only in facilities with certification under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), with oversight from the Centers for Medicare & Medicaid Services (CMS). Whereas IVDs can be used in any CLIA-approved facility that is certified for the complexity level of the test, LDTs can only be used in the CLIA-approved facility in which they were developed.

Our new plan was to obtain CLIA certification for and then run the test in an independent biosafety level II (BSL-2) laboratory, managed by one of us in the Chicago suburbs, that was a primary site of test development. Although we all have research and development backgrounds, none of us had experience setting up or operating a CLIA laboratory and so we were faced with a new challenge. We searched for a laboratory director who had supervisory experience in a CLIA-certified laboratory, and after many months, we connected with a laboratory director through a contact at a local university. The process of applying for CLIA certification for that laboratory was daunting, but CLIA certification was eventually obtained.

To deploy our test for widespread use, however, additional expertise in medical software, marketing, insurance billing, test reporting, and related legal and regulatory matters

was required. Considering just the first hurdle, we needed to acquire software for securely storing patient information under federal law by the Health Insurance Portability and Accountability Act (HIPAA). HIPAA compliance requires a Laboratory Information Management System (LIMS) that includes Electronic Medical Software (EMS), but for our team, this software was cost-prohibitive at thousands of dollars per month.

One seeming anomaly to the traditional IVD and LDT routes came to light during the COVID-19 pandemic. Yale University developed a testing protocol called SalivaDirect, and it was the protocol, not the test, that was granted an FDA EUA (Vogels et al 2021). The SalivaDirect protocol is now being used by third parties. However, these parties must have CLIA authorization for high-complexity testing, and they must request authorization from Yale and perform validation by running sample test reactions. This approach, which likely required intensive support from Yale's legal team, would not have been feasible for our independent group of three scientists working unrelated full-time jobs and volunteering our time.

Despite our best intentions and the development of an open-source COVID-19 test, our test did not become widely adopted for use in schools, hospitals, workplaces, and independent laboratories. It did not become adopted for use anywhere.

OVERCOMING BARRIERS FOR INDEPENDENT RESEARCHERS

Our largest challenges were lack of resources and expertise outside of scientific research. The stringent requirements and need for clinical validation required for the IVD proved too much of a hurdle for our small group of independent researchers. The LDT route presented the different challenge of requiring a CLIA-certified laboratory and restricted our test's use strictly to one CLIA laboratory.

We believe giving independent researchers access to resources such as healthcare partners for clinical trials and expertise in marketing and law would reduce the barriers to entry for IVD or LDT certifications and allow this important work to reach those who need it. We recognize, however, that these resources can come at a steep financial cost. Furthermore, how might experts willing to help connect with legitimate independent scientists to donate their time?

To help make these resources available to independent researchers, we propose the creation of a new not-for-profit entity we are calling JOGL Fitz, named for John G. FitzGerald, a Canadian physician who produced and freely distributed an open-source antitoxin to diphtheria (JOGL 2022). JOGL Fitz would act as a central body to help lend credibility to independent scientists by ensuring they are conducting ethical, safe, and sound scientific research through access to expert resources, including resources specific to regulatory matters of which independent researchers may not be familiar. For example, this entity would provide assistance with obtaining CLIA certification and/or FDA or FDA EUA approval and setting up patient portals and medical billing software. JOGL Fitz would facilitate partnerships with physicians, hospitals, and other healthcare entities so that independent scientists have access to clinical samples for trialing of healthcare-related products, as well as partnerships with marketing and manufacturing companies. Further, JOGL Fitz would form an Institutional Review Board (IRB) to guide the work of independent scientists.

Finally, we believe an entity like JOGL Fitz could play an important role in helping to secure funding for independent researchers—one of the most difficult hurdles for any independent scientist. By acting as a central organization, JOGL Fitz could secure larger amounts of funding than any small group of independent scientists. The entity would also work to ensure funding disbursements are made to individuals or groups that align with JOGL Fitz's mission and demonstrate the capacity for high-quality scientific work.

JOGL Fitz remains within the framework of open science by promoting the work of independent researchers based on criteria other than degrees, institutional affiliations, or infrastructure. The entity would seek to ensure independent researchers are conducting their work in an ethical, safe, and scientifically sound manner. With JOGL Fitz, we seek to establish an organization that can act as a bridge between independent scientists, regulators, and the general public in a way that would spur greater innovation and acceptance of open, independent scientific research.

THE BENEFITS OF OPEN DIAGNOSTICS

Some may wonder if it is a good idea to promote open in vitro diagnostics in the first place. Can tests developed by independent researchers be trusted? And will people even use these tests if they are also available from established companies? We believe the COVID-19 pandemic has shown weaknesses in the US diagnostic infrastructure that open diagnostics could address. As mentioned above, early reliance on slow-moving public health entities resulted in test scarcity and result delays. These entities, like the CDC, have a focus on population surveillance, and so are not interested in developing the point of care tests that allow individuals to monitor their own health. Typically, this is left to private companies, whose efforts

are often driven by shareholders and profit margins. In combination, these factors lead to testing deficits that ultimately impact the most vulnerable communities in our country. We believe that, with the right supports, independent researchers can provide reliable testing options to the people and communities that need them the most.

CONCLUSIONS

The COVID-19 pandemic has revealed a clear need for new ways of thinking about how diagnostic testing can be rapidly developed and deployed. Independent researchers could play an important role in addressing some of these challenges if barriers to approval and adoption of independently developed tests are reduced. We have demonstrated that independent researchers can successfully create a scientifically sound, open diagnostic test, but numerous regulatory and other barriers prevented its widespread use. We propose a centralized body that will support independent scientists in achieving their goal of developing open-source healthcare-related products to benefit all mankind.

COMPETING INTERESTS

The authors have no competing interests to declare.

AUTHOR CONTRIBUTIONS

Both authors contributed equally to all aspects of the manuscript.

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