OPEN LETTER



REVISED COVID-19 vaccine delivery: an opportunity to set up

systems for the future [version 2; peer review: 2 approved]

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Abstract

The race to develop safe and effective SARS-COV-2 vaccines has moved with unprecedented speed. There are now multiple vaccines that have received emergency use authorization from the United States Food and Drug Administration and a host of candidates positioned for approval worldwide. Attention has now turned to allocation, distribution and verification of these vaccines, yet this focus exposes that the underlying infrastructure for global delivery and monitoring is threadbare and unevenly distributed. This presents both a barrier and an opportunity to deploy sustainable infrastructure. Major global stakeholders must convene quickly, collaborate, and collectively invest in global standards, legal models, common vocabularies and interoperable biometric-supported digital health technologies. As the COVID-19 vaccine effort scales, governments, private sector, and NGOs have the chance to place lasting resources needed for equitable and effective delivery that can pay dividends into the future.

Keywords

vaccine deliver, biometrics, identity, immunizations, health systems strengthening, health service deliver, COVID-19, COVID-19 vaccine, SARS-COV-2 vaccine, SARS-COV-2



Open Peer Review

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2. **Alan Gelb**, Center for Global Development, Washington, USA

Any reports and responses or comments on the article can be found at the end of the article.



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(COVID-19) collection.

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REVISED Amendments from Version 1

We are grateful for comments from our reviewers which are addressed in this new version. We have updated our text to reflect the surge of approved vaccines yet the continued underlying needs for a concerted approach to equitable and sustainable distribution. We have updated our text to reflect the need for realistic, incremental steps for identity systems to be in place. We have also taken heart from our reviewers comments that there is a global mismatch between vaccine systems meant to serve the very young while COVID-19 vaccines focus on older populations. We have also noted that "identity" may not be synonymous with national identification programs and alternatives exist for this issue. At the same time, we have added text to distinguish more clearly between stages of vaccine delivery as well as the conflicting pressures to roll-out quickly versus to capture good data on who has been vaccinated and what the efficacy and long term side effects of these vaccines are.

Any further responses from the reviewers can be found at the end of the article

With the launch of effective SARS-CoV-2 vaccine, policymakers, academics, and scientists around the globe are turning their attention to yet another fundamental challenge - how will governments monitor and verify vaccine delivery.

An effective vaccination program will falter if we don't invest in the information infrastructure for vaccine delivery in developed and low and middle-income countries alike. There is little evidence that we are ready for this. Glaring data gaps exist at numerous levels of global identity and health information exchange. Data on routine immunization already faces deep challenges. Studies show, for example, that despite WHO coverage estimates near 99%, up to 54% of children do not actually receive timely measles vaccinations in Bangladesh¹. Widespread gaps in data quality, reporting, and patient identification in routine vaccine delivery already exist, and risk wasting major investments like COVAX funding for COVID-19 vaccines in low and middle-income countries.

The supply of the first generation COVID-19 vaccines will be scarce, and each course must reach the intended recipient. Corruption, leakage, spoilage and even accidental duplications are deadly. Most current COVID-19 vaccine candidates require a two-dose course; patients will need to be reliably identified to ensure appropriate spacing of doses. Further, long-term efficacy remains to be seen and will require accurate, longitudinal patient data. Tracking patient data over time and across service delivery points requires patient identification systems. However, patient identification systems will be the hardest to achieve in the places they are needed most. Many low-income countries lack a foundational government-issued ID, and about one billion people lack any official civil registration.

We do have some options to face this disturbing scenario and one involves biometric digital identity. The foundational ID challenge will not be solved in time for the release of a COVID-19 vaccine. However, organizations like Gavi have identified biometric digital identity as a potential lever to bridge the identity gap and ensure accurate data². Done properly, these systems can be privacy preserving, interoperable, portable, secure, and capable of serving both adult and children's needs. In countries without foundational ID systems, biometrics are more reliable than identifiers like names and dates of birth, and less susceptible to loss or damage than paper vaccine cards³. Biometrics also have the advantage of being agnostic to use case, meaning they can connect different systems during or even after rollout. For example, governments will have different priorities behind ID for vaccine supply chain management, vaccine delivery, and international certification for travel. It will be essential to head off the creation of multiple, non-interoperable systems behind each of these priorities. Biometrics can connect these disparate systems because they are unique to an individual versus unique to a data system. Maintaining existing and well-tested biometric interoperability standards (e.g. ISO1974-2) will ensure biometric investments can plug into foundational ID programs as coverage expands over the next decade, and privacy-first architecture design is already underway in several projects⁴. Moreover, there is no need to solve the foundational ID problem before working at national levels. One can readily create registries that are regional yet not tied to citizenship, and these can continue in parallel or connect to national programs as they develop. Many such instances have been demonstrated on smaller scales such that the tools are poised for implementation, what remains lacking is the intention and coordination to apply these at scale.

Digital registries to document immunizations, their efficacy, and adverse events, while maintaining personal privacy can be readily developed and securely accessed using biometrics today. Such biometric linked immunization systems can be deployed for COVID-19 vaccines with little lead time *and* these could provide lasting infrastructure to serve routine immunizations, which are becoming less routine as the pandemics secondary effects become more prominent. We should have been developing these architectures months before the ramp up of vaccine delivery and before further lapses in basic primary health lead to explosions of other vaccine preventable illnesses. The opportunity remains, however missing this narrowing window could waste significant time, effort, and the chance to build forward-looking infrastructure that serves basic healthcare long into the future.

During the latest Ebola epidemic, a rush of technologies were hastily assembled to track and combat the disease, leading to massive duplication of efforts and half-built tools that were abandoned after the crisis⁵.

We know what is coming. In the next quarter all attention will be on the allocation, distribution and verification of COVID-19 vaccine delivery. Routine immunizations will be disrupted and there will be lapses in other public health and healthcare measures. Notably, while there has been much historic effort to support and monitor childhood vaccines in the developing world, there is substantially less global infrastructure for adults who will be the earliest recipients of COVID-19 vaccines. Investing in the infrastructure that can support COVID-19 vaccine delivery *and* routine immunizations, for everyone young and old, can ensure that we are taking advantage of this opportunity amidst the challenges and putting countries on track to fight not only this pandemic, but pressing public health needs for years to come.

Major global stakeholders must convene, collaborate, and collectively invest in global standards, legal infrastructure, common vocabularies and interoperable biometrically-supported digital health technologies. Within counties there will need to be concerted efforts to create standards that prevent siloed identity efforts, while across borders we must develop standards for mutual identification that respect the diversity of national systems. Biometrics must also work in concert with non-biometric identity methods where they are already successful, even as traditional methods can be leap-frogged in areas where the low cost, scalability and usability advantages of all digital identity are most relevant. This will pay dividends long after the world's attention has shifted. If done transparently, this infrastructure can enhance trust in vaccines, something critical to clinical trial enrolment and widespread public adoption.

There will be tradeoffs that must be navigated. Given that the vaccines have arrived, implementers must choose solutions that can be used immediately, broadly and at low enough cost that the ability to obtain and deliver vaccine is unhindered. While it may be infeasible to launch full scale biometric based programs today, thoughtfully architected systems could build trust with traditionally identify methods, and new technologies can be readily piloted then spread laterally with the potential to scale to or integrate with credible and trustworthy national identify programs or social registries as they become available.

We have a narrow opportunity to set the stage for such fair and sustainable infrastructure across the globe. If done well, we can ensure the promise of the COVID-19 vaccine portfolio leads to future widespread vaccination - and protection - for global populations.

Data availability

No data are associated with this article.

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Open Peer Review

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Kristin Nelson 匝

Department of Epidemiology, Rollins School of Public Health, Emory University, Atlanta, GA, USA

This version is improved. Establishing the details of how COVID-19 vaccines will be rolled out in LMIC remains a critical issue. I would still suggest that the authors provide a clear definition of what a biometric identification system would entail. (Scanning of fingerprints? Or other unique identifiers?) This is not clearly laid out and would help the reader understand what these systems would look like and the level of technology required to implement them.

Competing Interests: No competing interests were disclosed.

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

Reviewer Report 26 April 2021

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Alan Gelb

Center for Global Development, Washington, DC, USA

I have reviewed the revised paper and it has responded to the comments. The topic is one where we can expect a diversity of views, and the paper makes a useful contribution.

Competing Interests: Some of the contributing authors are with Simprints. I am on the Advisory Board of that company. I do not believe that this constitutes a conflict of interest but am flagging

it for transparency.

Reviewer Expertise: ID systems and economic development

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

Version 1

Reviewer Report 20 January 2021

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? Alan Gelb

Center for Global Development, Washington, DC, USA

The paper addresses an important issue: the pace of Covid-19 vaccine deployment is outstripping the data systems needed to manage and document it. There is a risk of ending up with multiple, disconnected systems, many of low quality, especially in countries that do not have a strong and widely held national ID credential. Accurate identification of those receiving vaccines (and also of those administering them) is an essential part of such systems.

My first suggestion is to: distinguish more clearly between the stages -- national vaccine supply chain management, national vaccination rollout management, and international certification. The priorities for ID are different across these stages;

A second suggestion is to be clear on the role of inter-operability and standards for each stage. Within countries, it is important to head off the growth of multiple, non-interoperable, systems; therefore some national standards will be needed, including for identification. A successful "global vaccination passport" will require the capability for mutual recognition, but will almost surely have to be built on the basis of differing national systems, just as the current passport system is built on very different registration and ID systems.

The third suggestion is to flag some major tradeoffs that will need to be negotiated. One concerns the time and access to technology needed to enroll people for a vaccination program in a way that would be interoperable with a national ID. Mass vaccination needs to be fast and inclusive. It can be a driver for increasing registration, but only if this is managed well and if there is trust in the system. Another is the potential tradeoff between digital vaccination systems and privacy. Technical approaches are being proposed to give people control over their data (see the article in The Guardian, January 15) but the big concern is the credibility of many governments. It may be that privacy and surveillance concerns slow the emergence of an international consensus on national registration systems. Nevertheless, countries will need to move forward in developing

effective national vaccination management programs. .

Is the rationale for the Open Letter provided in sufficient detail?

Yes

Does the article adequately reference differing views and opinions? Partly

Are all factual statements correct, and are statements and arguments made adequately supported by citations?

Yes

Is the Open Letter written in accessible language?

Yes

Where applicable, are recommendations and next steps explained clearly for others to follow?

Partly

Competing Interests: Some of the contributing authors are with Simprints. I am on the Advisory Board of that company. I do not believe that this constitutes a conflict of interest but am flagging it for transparency.

Reviewer Expertise: ID systems and economic development.

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.

Reviewer Report 15 January 2021

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? Kristin Nelson 匝

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This is a timely article that describes a key barrier to successful SARS-CoV-2 vaccine rollout globally – the lack of effective systems to record vaccinations. The authors propose the use of biometric digital identifiers to identify vaccinated individuals and monitor progress of vaccine administration. The rationale is clearly laid out, but several comments to improve the letter are below.

Major comments:

The authors recommend the use of biometric immunization registries, but do not clearly explain what they are and how they would work. A description of this system for the uninitiated reader is necessary.

Can the authors comment on the feasibility of implementing biometric ID programs on national level (would they be implemented on a national level?) with only several months' lead time? Are projects to implement these systems already underway that could be accelerated? The authors make the case that there is a problem that needs to be solved, but not that these tools are well-positioned to solve it in the short time required.

It may be relevant to include how these concerns are magnified given that a vaccine for COVID-19 will likely be targeted towards adults and many immunization programs in LMIC are set up primarily to administer childhood vaccinations. There is a significant disconnect here between the current structure and function of national immunization programs and what they would asked to do to widely administer a COVID-19 vaccine.

Minor comments:

The abstract and first paragraph should be updated to reflect the recent approval and rollout of several vaccines in high-income countries.

Are there alternatives to these systems for the ID challenge? If so, please briefly mention and explain why biometric identifiers are a better solution.

Is the rationale for the Open Letter provided in sufficient detail?

Yes

Does the article adequately reference differing views and opinions? No

Are all factual statements correct, and are statements and arguments made adequately supported by citations?

Yes

Is the Open Letter written in accessible language?

Yes

Where applicable, are recommendations and next steps explained clearly for others to follow?

Yes

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: infectious disease epidemiology, respiratory infections, vaccines

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have

significant reservations, as outlined above.