Canadian Journal of Bioethics Revue canadienne de bioéthique



Rapid Serological Tests and Immunity Policies: Addressing Ethical Implications for Healthcare Providers and the Healthcare System as a Priority

Marie-Alexia Masella, Hortense Gallois and Jean-Christophe Bélisle-Pipon

Volume 3, Number 3, 2020

URI: https://id.erudit.org/iderudit/1073796ar DOI: https://doi.org/10.7202/1073796ar

See table of contents

Publisher(s)

Programmes de bioéthique, École de santé publique de l'Université de Montréal

ISSN

2561-4665 (digital)

Explore this journal

Cite this document

Masella, M.-A., Gallois, H. & Bélisle-Pipon, J.-C. (2020). Rapid Serological Tests and Immunity Policies: Addressing Ethical Implications for Healthcare Providers and the Healthcare System as a Priority. *Canadian Journal of Bioethics / Revue canadienne de bioéthique*, 3(3), 177–179. https://doi.org/10.7202/1073796ar

Article abstract

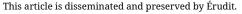
Healthcare providers (HCP) have been central actors in containing the COVID-19 pandemic. Although potentially very beneficial, the implementation of large-scale rapid serological tests raises ethical dilemmas and affects HCPs' capacity to work in optimal conditions. In this regard, we call for attention to address specific and urgent ethical issues distinctively affecting HCPs following the availability and possible mandatory use of rapid serological tests for COVID-19.

Copyright © Marie-Alexia Masella, Hortense Gallois and Jean-Christophe Bélisle-Pipon, 2020



This document is protected by copyright law. Use of the services of Érudit (including reproduction) is subject to its terms and conditions, which can be viewed online.

https://apropos.erudit.org/en/users/policy-on-use/



Érudit is a non-profit inter-university consortium of the Université de Montréal, Université Laval, and the Université du Québec à Montréal. Its mission is to promote and disseminate research.

https://www.erudit.org/en/





TÉMOIGNAGE / PERSPECTIVE

Rapid Serological Tests and Immunity Policies: Addressing **Ethical Implications for Healthcare Providers and the Healthcare System as a Priority**

Marie-Alexia Masella^a, Hortense Gallois^b, Jean-Christophe Bélisle-Pipon^{c,d,e}

Les prestataires de soins de santé (HCP) ont joué un rôle central dans l'endiguement de la pandémie de COVID-19. Bien que potentiellement très bénéfique, la mise en œuvre de tests sérologiques rapides à grande échelle soulève des dilemmes éthiques et affecte la capacité des HCP à travailler dans des conditions optimales. À cet égard, nous appelons l'attention sur les questions éthiques spécifiques et urgentes qui affectent de HCPs following the availability and possible mandatory use of manière distincte les HCP suite à la disponibilité et à l'éventuelle utilisation obligatoire de tests sérologiques rapides pour COVID-19.

Healthcare providers (HCP) have been central actors in containing the COVID-19 pandemic. Although potentially very beneficial, the implementation of large-scale rapid serological tests raises ethical dilemmas and affects HCPs' capacity to work in optimal conditions. In this regard, we call for attention to address specific and urgent ethical issues distinctively affecting rapid serological tests for COVID-19.

Mots-clés

sérologiques, COVID-19, éthique

Keywords

santé publique, prestataires de soins de santé, tests public health, healthcare providers, serological tests, COVID-19, ethics

Affiliations

- ^a Programmes de bioéthique, École de santé publique de l'Université de Montréal, Montréal, Canada
- ^b Center of Genomics and Policy, McGill University, Montréal, Canada
- ^e Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics, Harvard Law School, Cambridge, USA
- d Health Law Institute, Dalhousie University, Halifax, Canada
- e Centre de recherche en éthique, Montréal, Canada

Correspondance / Correspondence: Marie-Alexia Masella, marie-alexia.masella@umontreal.ca

BACKGROUND

The current COVID-19 pandemic has posed unprecedented public health challenges worldwide. Canada has approved a first rapid serological test (RST) for detecting antibodies for SARS-CoV-2 (DiaSorin LIAISON®) (1). This technology can detect individuals who have developed (some degree of) immunity to SARS-Cov-2 and assess herd immunity. If serological tests come with undeniable benefits, their limitations are still being explored, as are the associated ethical, legal and social issues. Further, the approval of this test is the first step towards large-scale immunity screening, as some countries have suggested or even planned (2). As frontline actors, healthcare professionals (HCPs) would likely be prioritized for serological testing (whether mandatory or not). Increased pressure on HCPs and the management of ethical challenges will have to be anticipated and addressed, as the impact on the overall healthcare system is central to containing the crisis (3).

BENEFITS OF TESTING

The responsiveness and effectiveness of public healthcare systems are critical to containing the current COVID-19 crisis. The benefits of equitable availability and effective use of such tests are multiple. They could contribute to a return to a "new" normalcy, but also reduce the demand on healthcare facilities. Containing the pandemic starts with ensuring that the health workforce is healthy and those who have contracted the virus no longer represent vectors of infection. The same applies to patients and their families for the health system to resume its regular activities, e.g., with the suspension of most non-COVIDrelated care. For HCPs, knowing their immune status could enable them to reduce the risk of infection among colleagues, and maybe even reduce the pressure they may feel while working with patients with COVID-19 symptoms (4). The general population will also benefit from RSTs as people who are immune would be allowed to return to healthcare institutions (e.g., fathers allowed in the delivery room, access to important care for people with cancer or requiring surgery, visits to elderly people in residence).

ETHICAL IMPLICATIONS FOR HCP

Immunity policies entail significant ethical concerns for HCPs, including respect for professional autonomy, privacy concerns, and increased risk of moral distress. Public health authorities' plans to conduct large-scale rapid serological screening will require significant testing capacity that may be limited by practical (mass production or import of tests), logistical (rapid deployment of testing infrastructure) and economical (steep pricing) constraints that, at-first, will require triaging access to RSTs. Canada's COVID-19 Immunity Task Force plans on testing at least one million Canadian over the next two years to track the virus and assess the herd immunity (1).

Considering their essential role, HCPs would be prioritized (5,6) and may even be required to undergo testing, meaning that consent may become a worthless formality, compromising HCPs' right to autonomy. Respect of privacy is also at stake, as mandatory testing in the workplace would imply disclosure of results, especially if the immunity status is used to determine who is deployed in hotspots (i.e., with COVID-19 patients), something that may affect confidentiality and privacy expected for such personal medical information. Additionally, being mandated to work in higher risk contexts may further affect HCPs overall mental and physical health (by being more directly or frequently confronted with the disease, anxiety, moral distress and fatigue can greatly increase). HCPs are already facing extraordinary pressure in the context of the pandemic (3), working even longer shifts and feeling compelled to contribute despite their personal situations (e.g., the presence of a vulnerable relative or loved one at home which does not allow them to obtain an exemption from reporting to work). Mandatory testing and consequent deployment of immune individuals to hotspots may pose an additional source of concern for immune HCPs' families as it is not clear that they too would be prioritized (and reimbursed) for serological testing, although they would be put at greater risk.

IMPLEMENTING LARGE-SCALE USE OF UNRELIABLE TESTS: A COUNTERPRODUCTIVE MEASURE FOR THE HEALTHCARE SYSTEM?

All the potential benefits of serological tests rest on there being sufficient reliability of the results (7). International examples show that RSTs for COVID-19 are associated with risks of false positive and false negative results, as well as of unintended behaviours and inequalities (4). The World Health Organization (WHO), among others, has warned against the limitations of RSTs' effectiveness and reliability and called for caution on the part of public authorities (8). As stated by Health Canada, "serological testing will contribute to a better understanding of whether people who have been infected by COVID-19 are immune to the virus. Further research will also help us fully understand the relationship between positive antibody tests and protection against re-infection" (1). Currently no evidence can clearly determine for how long a person will maintain her immunity status, and whether immunity status prevents the person from being contagious (7).

Uncertainty regarding test results will directly affect HCPs' work. A significant number of incorrect test results will disrupt care management and put pressure on HCPs. In the United States, where numerous RSTs are in use, the Food and Drug Administration (FDA) warned HCPs about the limitations of the tests (9). For instance, a false immunity may be counterproductive to limiting the spread of the virus in healthcare facilities, by putting both non-immune HCPs and patients at risk, while a patient whose immune status has not been properly detected could be deprived of necessary care (chemotherapy, dialysis). Overreliance on test results, in a context of uncertainty regarding their actual reliability and the duration of immunity, can impede HCPs from fulfilling their deontological duty to provide the best care possible to their patients.

CONCLUSION

RSTs are developed to provide a way out of the current pandemic. Although their benefits are manifold and technological and scientific advances will improve RSTs' effectiveness, important ethical issues remain, notably regarding their use and the implementation of immunity policies. In particular, the emotional and moral burden that can be placed on HCPs should not be forgotten. The uncertainty regarding the reliability of current tests is also worrisome. As front-line actors, HCPs will have a proactive role to play in RSTs' deployment by testing the general population. Although their intervention is essential to slow the transmission of the virus and to protect public health, they remain subject to their professional ethical obligations and must, even in times of health emergency, obtain the voluntary and informed consent of individuals before administering the test. Their role is all the more important since they are ideally placed (close to the population) to inform patients about the scientific limitations inherent to serological tests, especially regarding their limited reliability and the fact that a positive result does not mean that the individual cannot transmit the virus.

Therefore, we urge that ethical issues related to HCPs (consent, privacy, risks of infection to families, and avoiding increasing immune HCPs' burden of care to COVID-19 patients) be considered and addressed. We stress that federal and provincial health authorities ensure fair access to RSTs to the broad healthcare workforce (e.g., from cleaning staff and orderlies to physicians and nurses) in all care settings (e.g., hospitals, clinics, long-term care centres) and consider the broad range of implications of these tests on HCPs and their relatives.

KEY POINTS

- Canada approved a first rapid serological test (RST) to detect antibodies for COVID-19 in May 2020.
- Rapid knowledge of the serological status may allow immune individuals to regain access to healthcare facilities and help mitigate the negative effects of the pandemic on the healthcare system.
- Immunity policies using RSTs are being contemplated worldwide to hasten deconfinement and help contain the pandemic despite concerns about RSTs' reliability and potential adverse effects in the context of care.
- The pressure on the healthcare system has already taken a toll on the ability of some HCPs to work efficiently, thus
 policymakers should consider these ethical issues when adopting immunity policies in Canada.

- The (systematic) implementation of RSTs and immunity policies raises its share of ethical dilemmas, especially for COVID-19 frontline actors (linked to issues of privacy, autonomy and dignity).
- Implementing beneficial immunity policies based on serological tests requires first addressing these ethical issues along with the technological limitations of the test itself.

Reçu/Received: 04/06/2020 Publié/Published: 16/11/2020
Conflits d'intérêts Conflicts of Interest

Aucun à déclarer None to declare

Édition/Editors: Hazar Haidar & Aliya Affdal

Les éditeurs suivent les recommandations et les procédures The editors follow the recommendations and procedures décrites dans le <u>Code of Conduct and Best Practice Guidelines</u> outlined in the COPE <u>Code of Conduct and Best Practice for Journal Editors</u> de COPE. Plus précisément, ils travaillent <u>Guidelines for Journal Editors</u>. Specifically, the editors will work pour s'assurer des plus hautes normes éthiques de la to ensure the highest ethical standards of publication, including: publication, y compris l'identification et la gestion des conflits the identification and management of conflicts of interest (for d'intérêts (pour les éditeurs et pour les auteurs), la juste editors and for authors), the fair evaluation of manuscripts, and évaluation des manuscrits et la publication de manuscrits qui the publication of manuscripts that meet the journal's standards répondent aux normes d'excellence de la revue.

REFERENCES

- Health Canada. <u>Statement from Health Canada on COVID-19 Serological Tests</u>. Government of Canada; 12 May 2020
- Altmann DM, Douek DC, Boyton RJ. What policy makers need to know about COVID-19 protective immunity. The Lancet. 2020;395:1527-9.
- Adams JG, Walls RM. Supporting the health care workforce during the COVID-19 global epidemic. JAMA. 2020;323:1439-40.
- 4. Abbasi J. The promise and peril of antibody testing for COVID-19. JAMA. 2020;323(19):1881-1883.
- Jecker NS, Wightman AG, Diekema DS. <u>Prioritizing frontline workers during the COVID-19 pandemic</u>. The American Journal of Bioethics. 2020;7:128-132.
- 6. Emanuel EJ, Persad G, Upshur R, et al. <u>Fair allocation of scarce medical resources in the time of Covid-19</u>. New England Journal of Medicine. 2020;382:2049-2055.
- 7. Mallapaty S. Will antibody tests for the coronavirus really change everything? Nature. 2020;580:571-2.
- 8. World Health Organization. <u>Scientific Brief Advice on the use of point-of-care immunodiagnostic tests for COVID-19</u>. World Health Organization; 2020.
- Food and Drug Administration. <u>Important Information on the Use of Serological (Antibody) Tests for COVID-19</u>
 Letter to Health Care Providers. FDA; 2020.