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OPEN LETTER

REVISED How science and policy came together and made a global impact: The EU common list of COVID-19 antigen tests

[version 2; peer review: 2 approved, 1 approved with reservations]

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Abstract

Science can play a pivotal role in providing support to public health policy making processes, and to ensure effective and efficient implementation of policies.

This work illustrates how science was integrated into policymaking during the peak of the COVID-19 pandemic, in relation to countries' COVID-19 antigen testing strategies as well as the implementation of Regulation (EU) 2021/953 on the EU Digital COVID Certificate. The lessons learnt during this process as well as the critical steps taken, and concrete recommendations, have been identified and capitalised and turned into a list of science-based advice. The availability of an already established mechanism that can be quickly adapted in case of need, is likely to be highly beneficial in case of a future public health emergency.

Plain language summary

This open letter illustrates how science was integrated into policymaking during the peak of the COVID-19 pandemic, in relation to countries' COVID-19 antigen testing strategies as well as the implementation of Regulation (EU) 2021/953 on the EU Digital COVID Certificate. The lessons learnt during this process as well as the critical steps taken, and concrete recommendations, have been identified and capitalised and turned into a list of science-based advice.

We consider that the availability of an already established mechanism that can be quickly adapted in case of need, is likely to be highly beneficial in case of a future public health emergency.

Open Peer Review

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

Keywords
COVID-19, policy support, science for policy

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Author roles: Raffael B: Conceptualization, Formal Analysis, Methodology, Writing – Original Draft Preparation, Writing – Review & Editing; **Petrillo M**: Formal Analysis, Methodology, Writing – Review & Editing; **Leoni G**: Formal Analysis, Writing – Review & Editing; **Wiesenthal T**: Writing – Review & Editing; **Kuipers Y**: Formal Analysis, Methodology, Writing – Review & Editing; **Querci M**: Conceptualization, Formal Analysis, Methodology, Supervision, Writing – Original Draft Preparation, Writing – Review & Editing

Competing interests: No competing interests were disclosed.

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REVISED **Amendments from Version 1**

The revised manuscript addresses all reviewer comments, enhancing clarity and widening its relevance to future pandemic preparedness and evidence-to-policy translation in public health. Among them: terms "accuracy" and "efficiency" are better defined; PCR-based methods and rapid antigen tests (RATs) are better contextualised, emphasising utility of RATs for detecting infectiousness.

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

Introduction

Since the outbreak of COVID-19 pandemic, testing strategies were a critical component in the EU's efforts to prevent, contain and mitigate the impact of the disease. Identifying infected individuals and preventing further virus transmission was essential to rapidly mitigate the pandemic, and for its subsequent control, allowing citizens to restart travelling and re-joining social activities and work-related tasks. The European Commission (EC) adopted various policy documents and legal acts to support Member States (MS) in the implementation of their COVID-19 testing strategies[1]. The EU Digital COVID Certificate (EUDCC) was introduced on July 1, 2021[2], serving as the digital proof that, amongst others, a person had received a negative COVID-19 test result.

To support EU level public health decision-making on COVID-19 antigen testing, a scientific process was put in place, consisting of three connected parts, for i) evidence identification and clarification, ii) evidence-based policymaking, and iii) policy implementation for citizen Benefit via the EUDCC. A graphical overview of the whole process for ensuring safe and reliable COVID-19 antigen testing is presented in Figure 1.

Policy outcomes and implications

Evidence identification and clarification

At the start of the pandemic, evidence on efficiency and reliability of COVID-19 antigen testing policies as well as available antigen devices was scarce. Later during the pandemic, the situation turned around and available information became extensive but scattered. There was therefore a need to create a platform to make information and data provided by the research community, as well as manufacturers, available in one place.

Testing strategies are a key element in the control of a pandemic event, in terms of identification of infected individuals and application of related measures, such as like self-isolation, controlling social interactions[3], or facilitating an early return to work after quarantine or isolation. Effective testing needs to be fast (to minimise the time an infected person can have contact with others), reliable (to avoid false negatives), at a low

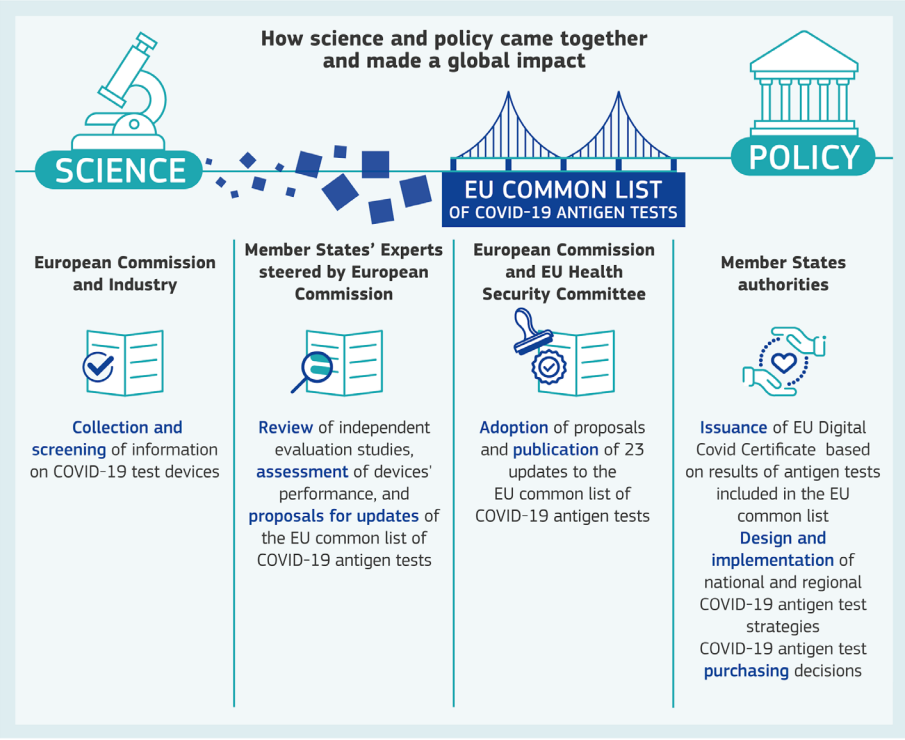


Figure 1. Science and policy together. Visual of how science and policy came together and made a global impact for ensuring safe and reliable COVID-19 antigen testing.

cost (to be accessible across different population groups), and widely deployable (to be available to the whole population).

The COVID-19 in Vitro Diagnostic Devices and Test Methods Database (DB) was developed[4] to meet this need. It stands as one of the most comprehensive inventories of COVID-19 testing devices and methods globally. It makes relevant information on the performance of in vitro diagnostic medical devices and laboratory-developed methods for COVID-19 publicly available and up to date. With more than 2 600 testing devices and methods stored, it has been accessed by visitors from more than 168 countries[5]. The information and metadata collected in the database remain publicly accessible and available for eventual studies needs on methods and devices.

Evidence-based policymaking

Among the testing possibilities, rapid antigen tests (RATs), despite being less accurate than PCR tests in identifying presence of viral RNA and thus infection, are more suitable to detect infectiousness, being much faster, cheaper, and easy to use, enabling immediate interventions and guiding quarantine and mobility decisions[6,7]. Consequently, the role played by COVID-19 RATs became significant, and the number of devices available on the EU market increased exponentially during the pandemic.

In September 2020, the EU Health Security Committee (HSC) began gathering data on RATs performance from evaluation studies conducted within MS.

Following this, the Council of the European Union issued a Council Recommendation[8] in January 2021. This recommendation called upon EU MS to agree on and maintain a common list of COVID-19 antigen tests, and to mutually recognise the result of those tests included. As a result, the first EU common list of COVID-19 antigen tests was published in February 2021.

Initially, device inclusion in the list was based on market availability and manufacturer's claims. However, RATs efficacy was vital for the effectiveness of the EUDCC implementation, needing an efficacy verification system, through a transparent evaluation procedure with well-defined scientific criteria. For this, in May 2021, the HSC set up a specialised Technical Working Group on COVID-19 diagnostic tests (TWG). The purpose of the TWG was to evaluate submissions from countries and manufacturers for devices to be included to the EU common list, based on the criteria established by the Council Recommendation of January 2021 (CE marking, minimum performance requirements of $\geq$ 90% sensitivity and $\geq$ 97% specificity, and validated by at least one Member State). These criteria were updated and expanded by the TWG and underwent a constant verification process to ensure their correspondence to the fast changing scientific and epidemiological situation[9].

Furthermore, the TWG, along with the Commission and the European Centre for Disease Prevention and Control, was tasked with drafting a technical guidance for the independent validation of the devices.

A dedicated system (based on EUSurvey, CIRCABC and the DB) was developed and used by manufacturers to upload applications, and by the TWG to collect relevant information and data to be reviewed for their devices assessment for possible inclusion in the EU common list. The system ensured confidentiality and expert anonymity while swiftly managing sensitive information. This workflow facilitated the integration of science into policy. It allowed for the responsibility of EU common list modifications to remain in MS' hands, through the HSC, while ensuring that decisions were based on scientifically solid evaluations.

Since its first publication, the EU common list and the list of criteria have undergone 23 revisions, taking into account the results of new validation studies, the introduction of new devices to the market, the epidemiological developments, and the emergence of new SARS-CoV-2 variants. Around 50% of the submitted applications of devices were successful and thus included in the EU common list[10]. The latest version of the list can be found on the TWG COVID-19 diagnostic tests webpage[11].

As of 1 July 2021, under the EUDCC Regulation (EU) 2021/953, all devices enclosed in the EU common list and carried out by health professionals or qualified testing personnel could be used by MS to issue EUDCC test certificates, and (as of 22 February 2022) EUDCC recovery certificate.

Policy implementation for citizen benefit via the EUDCC

The DB was updated and adapted to include the evolving EU common list. The list was automatically extracted from the database on daily basis. The extracted information, converted into a language-independent data format file (JSON), was and still is accessible at a static URL[12].

This served as the foundation for the information displayed on the EUDCC test and recovery certificates that were based on antigen testing. The EUDCC facilitated safe travel for citizens across the European Union, enabled the establishment of mitigation measures, and allowed to coordinate the lifting of restrictions when possible.

The EUDCC has also been a success worldwide: it has set a global standard for international travel and has been the only system in operation at international level. An example of digital EUDCC is presented in Figure 2.

Actionable recommendations

The capitalization of lessons learned in the context of the EU common list and its related evaluation process by experts can be precious for future needs, as they can facilitate the development of a workflow in case of future public health emergencies, such as reflected also by other multi-stakeholder communities[13].

The work that was carried out by the TWG came with a heavy workload that required proper and efficient management. In total, the TWG reviewed over 1 100 manufacturer applications, declining over time without reaching a plateau. To support their work, the Commission screened

applications for compliance before transmitting them to TWG experts, significantly reducing the TWG workload by approximately 40%. For future needs, it is recommended to foresee a screening process with dedicated personnel.



Figure 2. Example of digital EUDCC. The figure is the mobile screenshot of an EUDCC issued in Italy after testing, in which "RAT Test name and manufacturer" are expressed as the numerical code (1610) assigned to the antigen tests in the COVID-19 in Vitro Diagnostic Devices and Test Methods Database.

EC platforms were used for information exchange and document management. When the amount of documents to be included in the manufacturer's applications increased, due to evaluation criteria becoming stricter, the limits of the platforms capacity became a limiting factor. Future systems should be more flexible or anticipate increased documentation load.

Dedicated mailboxes were established for communication with manufacturers and TWG: the volume of non-compliant applications and support requests reached an overwhelming amount of over 18 000 emails. Thus, adequate resources for help-desk staff are recommended for future needs.

The TWG conducted independent evaluations of applications, with plenary meetings both for reaching consensus and for revising requirements. While written procedures were employed when a meeting could not be arranged, meetings demonstrated to be essential for discussing device performance and revising guidelines and criteria. Adequate resources for the organisation of regular meetings are recommended for future planning.

The initial version of the common list featured 26 devices, reaching 279 devices by the end of the exercise. The dynamic list required a comprehensive management approach, leading to the adoption of a "master file" for discussions and assessments. Future planning should anticipate such solution and allocate necessary resources accordingly.

Challenges, solutions, and recommendations are summarised in Table 1.

Conclusions/Discussion

The crisis prompted the development of an action protocol that had a direct impact on the health and well-being of EU citizens. It facilitated secure information exchange between manufacturers and experts, with swift adaptability and robust security measures. Within the EU, it allowed to agree on a list of antigen tests that were meeting common criteria. This supported countries in developing and implementing

Table 1. Challenges, solutions and recommendations.

Challenge	Adopted solution	Recommendation
High and irregular workload for experts	Initial screening of data	Foresee skilled support staff
High volume of confidential data	Platforms for information exchange and for document management and storage	Foresee a flexible and scalable system since the beginning
Need for constant exchange of information with manufacturers	E-mail help desk	Foresee flexible staff for secretarial support
Need to discuss data and criteria	Written procedure and organisation of meetings	Foresee organization of regular meetings
Enormous amount of data processed, re-processed and adjusted, and relative discussions, outcomes and assessments	Creation of a master-file	Allocation of resources for file management

COVID-19 testing strategies as well as issuing the relevant EUDCC test and recovery certificates, allowing the introduction of societal measures to contain the infectiousness and curb the infection. In preparation for potential future pandemics, a list of agreed rapid tests is crucial for the implementation of quarantine measures. In addition, the EU common list provided support to MS procurement procedures and national insurance and reimbursement schemes.

At the global level, the EU common list also facilitated travelling through the EUDCC, and indirectly provided quality standards to be used as a global reference. In total, 51 countries across four continents have benefited from the EUDCC system, lately adopted (including its links to the DB) as the first building block of the WHO Global Digital Health Certification Network that will develop digital products "*to deliver better health for all*"[14], potentially widening the use of digital certificates.

A unified evaluation framework by Member State experts reduced duplication of efforts and ensured uniform decisions, benefiting all. Furthermore, industry had to follow guidelines based on the scientific criteria set by the TWG.

The coordinated EU response minimized duplication and conflicting standards among Member States, enabling faster citizen-centric actions and knowledge sharing. To ensure a swift and effective response to future emergencies, key proposed actions include the immediate nomination of a Team of Experts, the establishment of an independent management team, the development of working procedures and performance criteria, and the creation of detailed guidance and of a solid information exchange system.

Lessons learnt are crucial for future preparedness.

This knowledge can help minimise delays between evidence availability and policy implementation across various critical public health issues.

The universality of the scientific method transcends political boundaries, ensuring its applicability across diverse contexts. As evidenced by the adoption of the EUDCC not only in Europe but also in nations worldwide, our reliance on the scientific method underscores its efficacy in informing evidence-based policy decisions globally.

Disclaimer

The views expressed in this article are those of the author(s). Publication in Open Research Europe does not imply endorsement of the European Commission.

List of abbreviations

CIRCABC: Communication and Information Resource Centre for Administrations, Businesses and Citizens.

DB: COVID-19 in Vitro Diagnostic Devices and Test Methods Database

EU: European Union

EUDCC: EU Digital COVID Certificate

EUSurvey: European Union Survey management system

HSC: Health Security Committee

MS: Member States

RATs: Rapid antigen tests

TWG: Technical Working Group on COVID-19 diagnostic tests

Data availability

No data are associated with this article.

Contributions

BR, MP drafted the manuscript. BR, MP, GL, MQ provided technical comments to improve the manuscript. BR, MP, GL, MQ reviewed & edited. All authors read and approved the final manuscript.

Acknowledgements

We would like to acknowledge Veronique Vanherck for her great graphic skills that managed to summarise a complex process into the nice visual we used as Figure 1.

References

1. **Commission Recommendation (EU) 2020/1595 of 28 October 2020 on COVID-19 testing strategies, including the use of rapid antigen tests**. OJ L 360, 30.10.2020; 43.
Reference Source

2. **Regulation (EU) 2021/953 of the European parliament and of the council of 14 June 2021 on a framework for the issuance, verification and acceptance of interoperable COVID-19 vaccination, test and recovery certificates (EU Digital COVID Certificate) to facilitate free movement during the COVID-19 pandemic**. OJ L 211, 15.6.2021; 1–22.
Reference Source

3. Burnside G, Cheyne CP, Leeming G, *et al.*: **COVID-19 risk mitigation in reopening mass cultural events: population-based observational study for the UK Events Research Programme in Liverpool City Region.** *J R Soc Med.* 2024; **117**(1): 11–23.
PubMed Abstract | **Publisher Full Text** | **Free Full Text**

4. Petrillo M, Querci M, Tkachenko O, *et al.*: **The EU one-stop-shop collection of publicly available information on COVID-19 *in vitro* diagnostic medical devices [version 1; peer review: 2 approved].** *F1000Res.* 2020; **9**: 1296.
PubMed Abstract | **Publisher Full Text** | **Free Full Text**

5. Raffael B, Munoz-Pineiro MA, Petrillo M, *et al.*: **JRC: the one-stop-shop for COVID-19 test information**. European Commission, 2023; JRC128837.
Reference Source

6. Mina MJ, Peto TE, García-Fiñana M, *et al.*: **Clarifying the evidence on SARS-CoV-2 antigen rapid tests in public health responses to COVID-19.**

Lancet. 2021; **397**(10283): 1425–1427.
PubMed Abstract | **Publisher Full Text** | **Free Full Text**

7. Crozier A, Rajan S, Buchan I, *et al.*: **Put to the test: use of rapid testing technologies for COVID-19.** *BMJ.* 2021; **372**: n208.
PubMed Abstract | **Publisher Full Text**

8. **Council Recommendation on a common framework for the use and validation of rapid antigen tests and the mutual recognition of COVID-19 test results in the EU 2021/C 24/01**. OJ C 24, 22.1.2021; 1–5.
Reference Source

9. **EU Common list of COVID-19 antigen tests - Agreed by the Health Security Committee**.
Reference Source

10. Raffael B, Petrillo M, Leoni G, *et al.*: **How science supported EU policy making in ensuring safe and reliable COVID-19 antigen testing.** Publications Office of the European Union, Luxembourg, 2024.
Publisher Full Text

11. **Technical working group on COVID-19 diagnostic tests**.
Reference Source

12. **https://covid-19-diagnostics.jrc.ec.europa.eu/devices/hsc-common-recognition-rat**

13. **Community Testing Review**.
Reference Source

14. **https://www.who.int/initiatives/global-digital-health-certification-network**

Open Peer Review

Current Peer Review Status: ✔ ✔ ?

Version 2

Reviewer Report 23 January 2025

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The revised manuscript addresses reviewer comments to enhance its clarity and relevance for public health decision-making, particularly in future pandemic preparedness. It focuses on the EU's COVID-19 antigen testing strategies and evidence-to-policy translation, emphasizing the utility of rapid antigen tests (RATs) for detecting infectiousness.
Testing strategies were pivotal in mitigating COVID-19's spread, enabling individuals to resume social and economic activities. The European Commission (EC) introduced policies like the EU Digital COVID Certificate (EUDCC) to standardize and implement testing across Member States (MS). A scientific workflow comprising evidence identification, policymaking, and implementation was established, supported by a comprehensive database of in vitro diagnostic devices and methods.
RATs, though less precise than PCR tests, provided faster, cheaper, and widely deployable testing. To evaluate and maintain a common list of RATs, the EU established a Technical Working Group (TWG), which assessed over 1,100 manufacturer applications using criteria like sensitivity, specificity, and validation by at least one MS. The list underwent 23 updates, reflecting new scientific data and market developments.
The EUDCC, enabled by this process, became a global standard for travel and public health coordination, adopted by 51 countries and forming a foundation for the WHO Global Digital Health Certification Network. Lessons learned include the need for scalable systems, expert support, and efficient communication. These findings are vital for future preparedness, emphasizing the importance of evidence-based, globally coordinated public health policies to address emerging crises.

Review: Where is the Global Impact of the EU?
By a narrow focus on the EU common list of Antigen tests the authors ignore the critiques of the public health responses to the COVID-19 pandemic, often dealing with a lack of coordination at the EU level. For example, differences in preparedness, political decision-making, and public health infrastructure. Here are some insights drawn from the research:
Lack of Consistent Preparedness: Many countries faced challenges in testing, contact tracing, and communication with the public, leading to a fragmented response. An analysis of 28 countries highlighted resilience in some areas but underscored gaps in coordination and timely implementation of public health measures (Haldane et al. Ref 1).
Delayed Responses: Delays in lockdowns, inconsistent enforcement of social distancing measures, and inadequate initial responses to outbreaks were frequently criticized. For example, countries like Italy and Spain faced criticism for failing to act swiftly, amplifying the impact of early outbreaks (Carta et al. Ref 2).
Communication Failures: Effective public health communication was inconsistent across EU members. Research into the use of social media platforms by public health authorities showed inequities in reaching diverse populations effectively, which hampered public trust and adherence to guidelines (Raamkumar et al. Ref 3).
Equity and Access Issues: vaccination rollouts and access to healthcare resources revealed significant inequalities. In some countries, deprived and discriminated populations faced systemic barriers to testing and vaccination (Edwards & Ott Ref 4).
Overreliance on Centralized Approaches: Critiques of centralized strategies in regions such as the EU pointed to inefficiencies and failures in coordinating cross-border health measures. A review highlighted how health governance was strained under the demands of the pandemic (Greer et al. Ref 5).
Failure to learn from lessons from comparative analysis: Countries with robust prior investments in public health infrastructure, such as South Korea, managed testing and contact tracing more effectively during the first wave. This highlighted how pre-existing systems and rapid mobilization were crucial in mitigating the pandemic's effects (Assefa et al. Ref 6).
Global inequities: the pandemic is a case study to illustrate how misplaced priorities—emphasizing market values over human ones—left societies vulnerable. The EU did not prioritize equity, resilience, and sustainability, highlighting the lack of interconnectedness of health, economics, and global cooperation with low-income countries lacking acces to vaccines (Carney, M Value(s): Building a Better World for All Penguin Canada)
These critiques underscore the need for enhanced global preparedness, equitable healthcare access, and improved communication strategies for managing future public health crises.

References

1. Haldane V, De Foo C, Abdalla SM, Jung AS, et al.: Health systems resilience in managing the COVID-19 pandemic: lessons from 28 countries.*Nat Med*. 2021; **27** (6): 964-980 PubMed Abstract | Publisher Full Text
2. Carta MG, Orrù G, Littera R, Firinu D, et al.: Comparing the responses of countries and National Health Systems to the COVID-19 pandemic: a critical analysis with a case-report series.*Eur Rev Med Pharmacol Sci*. 2023; **27** (16): 7868-7880 PubMed Abstract | Publisher Full Text
3. Sesagiri Raamkumar A, Tan SG, Wee HL: Measuring the Outreach Efforts of Public Health Authorities and the Public Response on Facebook During the COVID-19 Pandemic in Early 2020: Cross-Country Comparison.*J Med Internet Res*. 2020; **22** (5): e19334 PubMed Abstract | Publisher Full Text
4. Edwards F, Ott J: Governments' Responses to the COVID-19 Pandemic. *International Journal of*

Public Administration. 2021; **44** (11-12): 879-884 Publisher Full Text
5. Elsayed H, Al Disi ZA, Naja K, Strakhov I, et al.: Do coastal salt mudflats (sabkhas) contribute to the blue carbon sequestration?. *Biogeochemistry*. 2025; **168** (1): 15 PubMed Abstract | Publisher Full Text
6. Assefa Y, Gilks CF, Reid S, van de Pas R, et al.: Analysis of the COVID-19 pandemic: lessons towards a more effective response to public health emergencies.*Global Health*. 2022; **18** (1): 10 PubMed Abstract | Publisher Full Text

Is the rationale for the Open Letter provided in sufficient detail? (Please consider whether existing challenges in the field are outlined clearly and whether the purpose of the letter is explained)
Partly

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?
Partly

Is the Open Letter written in accessible language? (Please consider whether all subject-specific terms, concepts and abbreviations are explained)
No

Where applicable, are recommendations and next steps explained clearly for others to follow? (Please consider whether others in the research community would be able to implement guidelines or recommendations and/or constructively engage in the debate)
Yes

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Social inequalities in health, health equity

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

Author Response 24 Jan 2025

Barbara RAFFAEL

Dear Reviewers,

Thank you for your detailed comments on our open letter. We appreciate the time and effort you have taken to provide this feedback. We would like to clarify that the primary focus of our open letter is the analysis of the path towards the formulation of the EU common list of COVID-19 antigen tests.

Our aim is to highlight the importance of the scientific input in the implementation of policy decisions. Our document intends to provide only scientific advice and practical recommendations that may help in addressing future health crises, in the field of testing. It is not meant to address broader critiques of public health responses, political decision-making, or the management of public health and public health infrastructure at either the EU or Member States level.

Consequently, we believe that your concerns fall outside the scope of our current study. Thus, our intention is to maintain a focused analysis on the procedural aspects that led to the EU common list of antigen tests, without incorporating political considerations or broader public health issues.

We hope this clarifies the scope and intent of our open letter. Thank you once again for your feedback.

Sincerely,

Barbara Raffael, on behalf of all the authors

Competing Interests: No competing interests were disclosed.

Reviewer Report 08 January 2025

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Benjamin Vallejo
University of the Philippines Diliman, Quezon City, Philippines

Thank you. The references to the information on how accurate RAT tests in the EU will be useful for public health authorities.

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Science advice and policy, marine environmental science, science, technology and society

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 27 December 2024

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Iain Buchan
University of Liverpool, Liverpool, UK

Thank you for addressing all of the points raised in my review of Version 1. This version of the paper reads well and concisely conveys an important message about trans-national preparedness for pandemic testing.

Competing Interests: Member of the UK COVID-19 Testing Initiatives Evaluation Board; data science adviser to AstraZeneca 2019-2023; member of The Pandemic Institute that received a gift from Innova Medical rapid antigen test manufacturer after evaluations of their technology had been reported to policymakers.

Reviewer Expertise: Public Health, Data Science, COVID-19/pandemic testing

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 05 December 2024

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Benjamin Vallejo
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Rapid antigen tests (RAT) while less accurate, proved valuable in detecting COVID-19 positive patients so that interventions can be done immediately. This proved important in determining quarantine status and whether to relax or maintain travel and mobility restrictions. I would suggest the authors to present an estimate of how accurate the RAT tests used in the EU are and the general criteria used to determine which are acceptable and which are not. That's because the

EU agreed on a list of RAT tests. This information has to be presented as it is important in implementing quarantine methods just in case another global pandemic happens.

Is the rationale for the Open Letter provided in sufficient detail? (Please consider whether existing challenges in the field are outlined clearly and whether the purpose of the letter is explained)
Yes

Does the article adequately reference differing views and opinions?
Yes

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

Is the Open Letter written in accessible language? (Please consider whether all subject-specific terms, concepts and abbreviations are explained)
Yes

Where applicable, are recommendations and next steps explained clearly for others to follow? (Please consider whether others in the research community would be able to implement guidelines or recommendations and/or constructively engage in the debate)
Yes

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Science advice and policy, marine environmental science, science, technology and society,

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.

Author Response 12 Dec 2024

Mauro PETRILLO

Thank you for your thoughtful comments on our paper. We agree that providing an estimate of the accuracy of RAT tests used in the EU and the criteria for determining their acceptability would be a valuable addition. We addressed this point in the section “Evidence-based Policymaking” by adding information on the acceptance criteria and the percentage of devices that did not meet the agreed standards, to highlight the importance of the evaluation exercise in maintaining a suitable level of accuracy for the devices used to issue the EUDCC. More detailed information on these topics can also be found in the referenced JRC Science for Policy Report (doi:10.2760/573813).

Competing Interests: No competing interests were disclosed.

Reviewer Report 25 November 2024

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Important topic. Lessons from rapid antigen testing in COVID-19 responses that are key to future pandemic preparedness. The learning is also applicable to minimising avoidable gaps between evidence availability and policy implementation across a wide range of topics of public health importance.

The article might better draw upon related multi-stakeholder reflections such as: https://www.thepandemicinstitute.org/collaborate/academics/community-testing-review/, where experts (mostly from the UK COVID-19 Testing Initiatives Evaluation Board) reflected on SARS-CoV-2 rapid antigen testing uses, evaluations and impacts.

The article needs to make the purposes for testing (e.g. Ref 1, 9) clearer. Terms "effectiveness" "efficiency" "reliability" "accuracy" need a context of use and a defined utility e.g. for minimising the time taken to identify that a person is likely infectious and to inform their (or other person's) actions such as self-isolation, minimising social mixing, early return from quarantine or isolation to work...

The three stages of "information rationalisation", "integration of science into policy" and "benefits for citizens via EUDCC" could be made clearer as 1) Evidence Identification and Clarification; 2) Evidence-based Policymaking; 3) Policy Implementation for Citizen Benefit. The need for agility through timely, actionable information from science and field surveillance/monitoring of policy impacts could be emphasised more.

The assertion that rapid antigen tests are less accurate than PCR tests is not true if the purpose is to identify people likely infectious across the whole infection course. PCR tests pick up infectiousness slightly earlier than antigen tests but go on to misclassify (as infectious) people who are no longer infectious. PCR is the gold standard test of having been infected but not the gold standard test of likely infectiousness. This is important if there is a societal cost to misclassifying non-infectious individuals as infectious, for example if it prevents a key worker maintaining critical infrastructure/services. See Mina, Michael J et al. (2021 [Ref 2]), which dealt with this misconception at the height of COVID-19 policy pressure (requiring rapid identification of likely

infectious individuals). And see https://www.thepandemicinstitute.org/collaborate/academics/community-testing-review/ for reflections on clarifying evidence in this way across multiple testing purposes.

The data and information systems focus of the article is useful. The authors might emphasise more the need to link digital workflows around certification. Burnside G et al. (2024 [Ref 8]) gives the example of a need to link test results with ticket (de)activation for entry to mass cultural events. Again, the purpose (for testing or certification) is key to optimising the policy. For example, the EU Digital Covid Certificate, is relevant to more than travel, and the wider uses of digital certificates may be important in the next pandemic.

The authors might want to note how the EU Common List of COVID-19 Antigen Tests could have accumulated metadata from end-to-end testing evaluations - very few (e.g. Zhang X [2024 (Ref 3)] compare different manufacturer's devices after basic approvals - and there was very little information on novel uses (such as combinations) of devices in response to real-world pressures using readily available stocks. The authors might recommend surfacing natural experiments of pandemic testing.

References

1. Crozier A, Rajan S, Buchan I, McKee M: Put to the test: use of rapid testing technologies for covid-19.*BMJ*. 2021; **372**: n208 PubMed Abstract | Publisher Full Text
2. Mina MJ, Peto TE, García-Fiñana M, Semple MG, et al.: Clarifying the evidence on SARS-CoV-2 antigen rapid tests in public health responses to COVID-19.*Lancet*. 2021; **397** (10283): 1425-1427 PubMed Abstract | Publisher Full Text
3. Zhang X, Cheyne C, Jones C, Humann M, et al.: Can self-testing be enhanced to hasten safe return of healthcare workers in pandemics? Random order, open label trial using two manufacturers' SARS-CoV-2 lateral flow devices concurrently and nested viral culture study. *BMC Infectious Diseases*. 2024; **24** (1). Publisher Full Text
4. García-Fiñana M, Hughes DM, Cheyne CP, Burnside G, et al.: Performance of the Innova SARS-CoV-2 antigen rapid lateral flow test in the Liverpool asymptomatic testing pilot: population based cohort study.*BMJ*. 2021; **374**: n1637 PubMed Abstract | Publisher Full Text
5. Green MA, García-Fiñana M, Barr B, Burnside G, et al.: Evaluating social and spatial inequalities of large scale rapid lateral flow SARS-CoV-2 antigen testing in COVID-19 management: An observational study of Liverpool, UK (November 2020 to January 2021).*Lancet Reg Health Eur*. 2021; **6**: 100107 PubMed Abstract | Publisher Full Text
6. Petersen I, Crozier A, Buchan I, Mina MJ, et al.: Recalibrating SARS-CoV-2 Antigen Rapid Lateral Flow Test Relative Sensitivity from Validation Studies to Absolute Sensitivity for Indicating Individuals Shedding Transmissible Virus.*Clin Epidemiol*. 2021; **13**: 935-940 PubMed Abstract | Publisher Full Text
7. Zhang X, Barr B, Green M, Hughes D, et al.: Impact of community asymptomatic rapid antigen testing on covid-19 related hospital admissions: synthetic control study.*BMJ*. 2022; **379**: e071374 PubMed Abstract | Publisher Full Text
8. Burnside G, Cheyne CP, Leeming G, Humann M, et al.: COVID-19 risk mitigation in reopening mass cultural events: population-based observational study for the UK Events Research Programme in Liverpool City Region.*J R Soc Med*. 2024; **117** (1): 11-23 PubMed Abstract | Publisher Full Text

Is the rationale for the Open Letter provided in sufficient detail? (Please consider whether

existing challenges in the field are outlined clearly and whether the purpose of the letter is explained)
Partly

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?
Partly

Is the Open Letter written in accessible language? (Please consider whether all subject-specific terms, concepts and abbreviations are explained)
Partly

Where applicable, are recommendations and next steps explained clearly for others to follow? (Please consider whether others in the research community would be able to implement guidelines or recommendations and/or constructively engage in the debate)
Partly

Competing Interests: Member of the UK COVID-19 Testing Initiatives Evaluation Board; data science adviser to AstraZeneca 2019-2023; member of The Pandemic Institute that received a gift from Innova Medical rapid antigen test manufacturer after evaluations of their technology had been reported to policymakers

Reviewer Expertise: Public Health, Data Science, COVID-19/pandemic testing

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.

Author Response 25 Nov 2024

Mauro PETRILLO

Dear Prof. Buchan, Thanks a lot for your valuable comments and suggestions that you have provided in the report. We will surely implement them, and wait for those of other reviewers, to provide a revised version of the manuscript. Best regards, Mauro Petrillo, on behalf of the authors.

Competing Interests: No competing interests were disclosed.

Author Response 12 Dec 2024

Mauro PETRILLO

Important topic. Lessons from rapid antigen testing in COVID-19 responses that are key to

future pandemic preparedness. The learning is also applicable to minimising avoidable gaps between evidence availability and policy implementation across a wide range of topics of public health importance.
Author Response: *Thank you for your kind words and for recognising the importance of our topic. We are glad you agree that the lessons learned from rapid antigen testing in COVID-19 responses can inform future pandemic preparedness and have broader implications for public health policy.*

The article might better draw upon related multi-stakeholder reflections such as: https://www.thepandemicinstitute.org/collaborate/academics/community-testing-review/, where experts (mostly from the UK COVID-19 Testing Initiatives Evaluation Board) reflected on SARS-CoV-2 rapid antigen testing uses, evaluations and impacts.
Author Response: *Thank you for bringing to our attention the valuable work and reflections of the Pandemic Institute and the UK COVID-19 Testing Initiatives Evaluation Board on SARS-CoV-2 rapid antigen testing. We appreciate the relevance of this work and acknowledge the importance of considering the broader perspectives of multiple stakeholders in the field. However, as our paper focuses on the integration of science into policy in the context of rapid antigen testing during the COVID-19 pandemic at European Commission level, and the lessons learnt in the process, a detailed comparison of these reflections is outside the scope of our current work. Nevertheless, we have taken the opportunity to mention your suggested reference in our paper in the "Actionable recommendations" section, as it can be useful for the readers of the paper.*

The article needs to make the purposes for testing (e.g. Ref 1, 9) clearer. Terms "effectiveness" "efficiency" "reliability" "accuracy" need a context of use and a defined utility e.g. for minimising the time taken to identify that a person is likely infectious and to inform their (or other person's) actions such as self-isolation, minimising social mixing, early return from quarantine or isolation to work.
Author Response: *Thank you for your comment. We agree that clarifying the purposes for testing and providing context for the terms 'effectiveness', 'efficiency', 'reliability', and 'accuracy' is relevant. We revised different sections across the paper to better specify the importance of testing in specific scenarios, such as identifying infectious individuals and developing mitigation measures.*

The three stages of "information rationalisation", "integration of science into policy" and "benefits for citizens via EUDCC" could be made clearer as 1) Evidence Identification and Clarification; 2) Evidence-based Policymaking; 3) Policy Implementation for Citizen Benefit. The need for agility through timely, actionable information from science and field surveillance/monitoring of policy impacts could be emphasised more.
Author Response: *Thank you for suggesting new titles for the three stages of the process. We agree that rephrasing them according to your suggestion provides a clearer and more concise structure.*

The assertion that rapid antigen tests are less accurate than PCR tests is not true if the purpose is to identify people likely infectious across the whole infection course. PCR tests pick up infectiousness slightly earlier than antigen tests but go on to misclassify (as infectious) people who are no longer infectious. PCR is the gold standard test of having been infected but not the gold standard test of likely infectiousness. This is important if

there is a societal cost to misclassifying non-infectious individuals as infectious, for example if it prevents a key worker maintaining critical infrastructure/services. See Mina, Michael J et al. (2021 [Ref 2]), which dealt with this misconception at the height of COVID-19 policy pressure (requiring rapid identification of likely infectious individuals). And see https://www.thepandemicinstitute.org/collaborate/academics/community-testing-review/ for reflections on clarifying evidence in this way across multiple testing purposes.
Author Response: *Thank you for pointing out the important distinction between PCR and antigen tests in identifying infectious individuals. We appreciate your clarification that PCR tests, while sensitive to early detection, can misclassify non-infectious individuals as infectious, whereas antigen tests may be more accurate in identifying those likely to be infectious across the course of the disease. We revised our text, across different sections, to reflect this nuance. We also appreciate the references you provided, including the work by Mina et al. (2021) and Crozier et al. (2021), which help inform our discussion on this topic.*

The data and information systems focus of the article is useful. The authors might emphasise more the need to link digital workflows around certification. Burnside G et al. (2024 [Ref 8]) gives the example of a need to link test results with ticket (de)activation for entry to mass cultural events. Again, the purpose (for testing or certification) is key to optimising the policy. For example, the EU Digital Covid Certificate, is relevant to more than travel, and the wider uses of digital certificates may be important in the next pandemic.
Author Response: *Thank you for highlighting the importance of optimising the use of certifications, particularly in high-risk settings such in social events, (as illustrated by Burnside et al. (2024). We implemented your suggestion in the Evidence Identification and Clarification, Policy Implementation for Citizen Benefit via the EUDCC and in the Conclusions chapters of the paper.*

The authors might want to note how the EU Common List of COVID-19 Antigen Tests could have accumulated metadata from end-to-end testing evaluations - very few (e.g. Zhang X [2024 (Ref 3)] compare different manufacturer's devices after basic approvals - and there was very little information on novel uses (such as combinations) of devices in response to real-world pressures using readily available stocks. The authors might recommend surfacing natural experiments of pandemic testing.
Author Response: *We appreciate your suggestion to view the EU Common List of COVID-19 Antigen Tests as a potential source of metadata. You raise a crucial point on the lack of comparative studies between different manufacturers' devices beyond basic approvals, as well as limited information on innovative uses of devices in response to real-world challenges. We addressed this comment at the end of the chapter "Evidence Identification and Clarification".*

Competing Interests: No competing interests were disclosed.