Original

IN THE HIGH COURT OF SOUTH AFRICA

(GAUTENG DIVISION, PRETORIA)

Case number: 27477/2022

In the application of:

SAKELIGA NPC Applicant

and



MINISTER OF HEALTH First Respondent

DIRECTOR GENERAL: DEPARTMENT OF HEALTH Second Respondent

MINISTER OF COOPERATIVE GOVERNANCE AND TRADITIONAL AFFAIRS Third Respondent

THE PRESIDENT OF THE REPUBLIC OF SOUTH AFRICA Fourth Respondent

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NOTICE OF MOTION

KINDLY TAKE NOTICE THAT the Applicant intends to make application to the above Honourable Court on 14 June 2022 at 10:00 or on a date and a time to be allocated for an order in the following terms:

1. That the Rules of the above Honourable Court pertaining to notice and service be dispensed with and that this application be heard as a matter of urgency in accordance with Rule 6(12) of the Rules of Court and in a manner and timeframe and in accordance with such procedure as the Honourable Court may deem fit;

2. That the decision of the First Respondent to publish *Regulations Relating to the Surveillance and the Control of Notifiable Medical Conditions: Amendment 2022 published in Government Gazette No. 46319 of 4 May 2022* be reviewed and set aside and declared to be inconsistent with the Constitution and invalid;

3. That the *Regulations Relating to the Surveillance and Control of Notifiable Medical Conditions: Amendment 2022 published in Government Gazette No. 46319 of 4 May 2022* be reviewed and set aside and declared to be inconsistent with the Constitution and invalid;

4. That in the alternative to paragraphs 2 and 3 above, that an order be granted in terms of Section 172 of the Constitution that is just and equitable, and which has a remedial effect alleviating the Constitutional infringements, concerns and / or invalidities underlying this application and arising out of the aforesaid Regulations referred to above;

5. Directing the First Respondent to pay the costs of this application, including the costs occasioned by the appointment of two counsel were

so employed, and directing that the costs shall be paid jointly and severally by any remaining respondent who may oppose this matter;

6. Granting further and/or alternative relief.

KINDLY TAKE NOTICE FURTHER THAT the accompanying affidavit of **PIETER JACOBUS LE ROUX** with annexures thereto will be used in support of this application.

KINDLY TAKE FURTHER NOTICE THAT the Applicant has appointed Kriek Wassenaar & Venter Inc with address as set out hereunder as its attorneys of record herein, at which address it will accept notice and service of all process in these proceedings.

KINDLY TAKE FURTHER NOTICE THAT the First Respondent is called upon in terms of Rule 53(1)(a) to show cause why the aforementioned decision/s and / or provisions should not be reviewed and/ or set aside.

KINDLY TAKE FURTHER NOTICE THAT if the Respondents intend to oppose the relief sought, they are called upon to file a notice of opposition by 16:00 on Monday, 23 May 2022 and to appoint in the notice an address at which service of all proceedings are to be received.

KINDLY TAKE FURTHER NOTICE THAT the Respondents are called upon to dispatch to the Registrar by 16:00 on Friday, 27 May 2022 the record of all

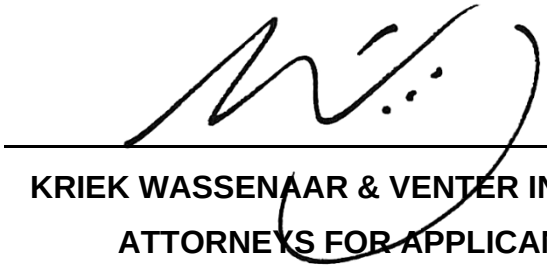
documents and of all electronic records (including any correspondence, contracts, memoranda, advices, recommendations, policies, valuations) that may relate to the making of the decision that is sought to be reviewed and set aside, together with such reasons as the Respondents are by law required or desire to give or make, and to notify the Applicant's attorneys that it has done so.

KINDLY TAKE FURTHER NOTICE THAT the Applicant may, in terms of Rule 53(4) amend, add to or vary the terms of the notice of motion and may supplement its founding affidavit in accordance with the Rules and that it intends to do so by Tuesday, 31 May 2022 (subject to timeous receipt of the record).

KINDLY TAKE FURTHER NOTICE THAT the Respondent will be called upon to file its answering affidavit by Tuesday, 7 June 2022 and that the Applicant intends to file its replying affidavit, if any, by Friday, 10 June 2022.

KINDLY ENROL the matter accordingly.

DATED at PRETORIA on 19 MAY 2022.



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REF: P.J. WASSENAAR/QB0952

TO: **THE REGISTRAR OF THE ABOVE HONOURABLE COURT**
PRETORIA

AND TO: **THE MINISTER OF HEALTH**

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AND TO: **DIRECTOR GENERAL: DEPARMENT OF HEALTH**

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AND TRADITIONAL AFFAIRS

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SERVICE BY SHERIFF

IN THE HIGH COURT OF SOUTH AFRICA

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Case number:

In the application of:

SAKELIGA NPC Applicant

and

MINISTER OF HEALTH First Respondent

DIRECTOR GENERAL: DEPARTMENT OF HEALTH Second Respondent

MINISTER OF COOPERATIVE GOVERNANCE AND TRADITIONAL AFFAIRS Third Respondent

THE PRESIDENT OF THE REPUBLIC OF SOUTH AFRICA Fourth Respondent

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FOUNDING AFFIDAVIT

I, the undersigned,

PIETER JACOBUS LE ROUX

do hereby state under oath as follows:

1. I am an adult male and Chief Executive Officer of Sakeliga NPC, the Applicant, which has its offices at Building A, 5th Floor, Loftus Park, 402 Kirkness Street, Arcadia, Pretoria, Gauteng Province.

2. The facts set out herein fall within my personal knowledge, save where the contrary is expressly stated or appears from the context, and such facts are true and correct. To the extent that any facts set out herein do not fall within my personal knowledge, I shall attempt to obtain confirmatory affidavits from persons with such personal knowledge. To the extent that I am unable to confirm such facts by means of confirmatory affidavits, I request the Court to admit such facts as evidence in terms of Section 3 of the Law of Evidence Amendment Act, Act 45 of 1988.

3. Where I make legal submissions herein, I do so based on the advice that I have received from the legal representatives of the Applicant.

4. I am duly authorised to depose to this affidavit and the Applicant has resolved to prosecute this application.

THE APPLICANT

5. The Applicant is **SAKELIGA NPC**, a non-profit company registered and incorporated in terms of the Laws of the Republic of South Africa with registration number 2012/043725/08, and with its principal place of business at Building A, 5th Floor, Loftus Park, 402 Kirkness Street, Arcadia, Pretoria, Gauteng Province.

6. The Applicant is a business-interest organisation with a support and donor base of more than 12 000 businesspeople, companies and business organisations and a network of more than 40 000 subscribers in South Africa supporting its causes and objectives.

7. The Applicant was established in the year 2011 and was incorporated and registered as a non-profit company in terms of the Companies Act, Act 71 of 2008 in the year 2012. The Applicant's main objective is the protection of constitutional rights, constitutional order, the rule of law, free-market principles, and a just and sustainable business environment within the Republic of South Africa.

8. Pursuant to its objectives, the Applicant lobbies to promote a free market and economic prosperity and to create a favourable business environment in the interest of its supporters and in the interest of the common good. Further, to achieve the Applicant's objectives and perform its functions and mandate, the

Applicant is *inter alia* mandated to act in the interest of its supporters and members of the public to protect their business and other constitutional rights.

9. The aforesaid is also evident from and confirmed by an extract of the Applicant's memorandum of incorporation, which I attach hereto marked **ANNEXURE PJLR 1**. I draw the Court's attention specifically to clause 4 of the memorandum of incorporation, which I confirm, and which sets out in more detail the objects, ancillary objects as well as the powers of the Applicant.

10. I do not attach a full copy of the memorandum of incorporation to these papers, because it will make these papers unnecessarily lengthy. The Applicant will make its full memorandum of incorporation available to the Court and to the respondents should same be requested.

THE RESPONDENTS

11. The First Respondent is **THE MINISTER OF HEALTH OF THE REPUBLIC OF SOUTH AFRICA**, a public office currently held by Dr J Phaahla, cited herein in his official capacity as the Cabinet member responsible for public health. The First Respondent has his office situated at Dr AB Xuma Building, 1112 Voortrekker Road, Pretoria, Gauteng Province and is referred to hereinafter as "**the Minister**".

12. The Second Respondent is **THE DIRECTOR GENERAL: NATIONAL DEPARTMENT OF HEALTH** and is referred to hereinafter as **"the Director**

General". In terms of the National Health Act, 61 of 2003 (also referred to hereinafter as "the Act" and / or "the National Health Act") the Director-General is the Head of the Department of Health and is responsible for the implementation of national health policies across the country. The duties of the Director-General in relation to the administration and implementation of the Surveillance Regulations referred to hereinbelow are set out in Regulation 3 of the National Health Act. The Director-General conducts business at 112 Voortrekker Road, Pretoria, Gauteng Province.

13. The Third Respondent is the **MINISTER OF COOPERATIVE GOVERNANCE AND TRADITIONAL AFFAIRS,** a public office currently held by Dr Nkosazana Dlamini-Zuma, cited herein in her official capacity as the Cabinet member responsible for cooperative governance and traditional affairs. The Third Respondent has her office at 87 Hamilton Street, Arcadia, Pretoria, Gauteng Province and is referred to hereinafter as "**the COGTA Minister**".

14. The Fourth Respondent is the **PRESIDENT OF THE REPUBLIC OF SOUTH AFRICA**, cited herein in his official capacity. Mr Matamela Cyril Ramaphosa currently holds the office of President. The Fourth Respondent is the head of the national executive and Cabinet. He is cited in these proceedings by virtue of the fact that section 85(1) of the Constitution vests the executive authority of the Republic in the President. The Fourth Respondent is joined in the event that he or any member of his Cabinet might have an interest in the litigation currently unknown to the Applicant or not foreseen by it. The Fourth Respondent has his office situated at the Union Buildings, Government

Avenue, Pretoria, Gauteng. I shall hereinafter refer to the Fourth Respondent as "**the President**".

15. A copy of this application will also be served on the office of the **State Attorney**, Pretoria at 316 Thabo Sehume Street, Pretoria Central, Pretoria, Gauteng.

16. The Director-General, COGTA Minister and the President are cited herein for the potential interest that they may have in this application. A cost order will only be sought in the event of opposition, subject to the discretion of the court.

17. Due to the urgent nature of this application, service will be effected via the office of the Sheriff, but also electronically to the known email addresses of the Respondents as well as the State Attorney. A service affidavit will be filled to confirm the method of service employed.

LOCUS STANDI

18. The Applicant has *locus standi* to launch this application and seek the relief that it does in this matter:

18.1 in its own interest as a party (as contemplated in Section 38(a) of the Constitution of the Republic of South Africa, Act 108 of 1996 (hereinafter referred to as "the Constitution")) directly affected by the Minister's regulations, as set out hereinbelow;

18.2 in the general public interest (as contemplated in Section 38(d) of the Constitution); and

18.3 in the interest of its members and supporters (as contemplated in Section 38(e) of the Constitution), who are also directly affected by the Minister's regulations.

19. Further argument insofar as may be necessary shall be advanced at the hearing of this application concerning the facts set out in the body of this application in support of the *Applicant's locus standi*.

JURISDICTION

20. This Court has jurisdiction to adjudicate this application by virtue of the Respondents' principal place of business and administration being situated within the Court's area of territorial jurisdiction.

21. This Court is further vested with the required jurisdiction to entertain this application on the basis that the Applicant's principal place of business is within the area of jurisdiction of this Honourable Court. The effect of the decision which is the subject of this application will be experienced by the Applicant at its principal place of business within the area of jurisdiction of this Court. In terms of the provisions of the Promotion of Administrative Justice Act 3 of 2000 ("PAJA") this Court accordingly enjoys jurisdiction to hear this matter.

INTRODUCTION AND OVERVIEW OF APPLICATION

22. On 4 May 2022 the Minister of Health amended the existing *Regulations Relating to the Surveillance and Control of Notifiable Medical Conditions, 2017* ("the 2017 surveillance regulations") published in terms of the National Health Act by way of the publication of a notice in Government Gazette No. 46319 of 4 May 2022. The amendment inserted substantive provisions into the 2017 surveillance regulations and, in particular, introduced:

    22.1 Regulation 16A which concerns the *"Wearing of face masks to contain the spread of Covid-19"*;

    22.2 Regulation 16B which concerns the *"Regulation of gatherings to contain the spread of Covid-19"*;

    22.3 Regulation 16C which concerns the *"Regulation of persons entering the country to contain the spread of Covid-19"*; and

    22.4 Covid-19 as a *"notifiable medical condition"* as Item 5A of Table 2 of Annexure A to the Regulations.

23. The newly inserted regulations above came into operation on 5 May 2022 and are hereinafter referred to as "the 2022 surveillance regulations".

24. This is an application to review and set aside the 2022 surveillance regulations and further to set aside the Minister's decision to publish the 2022 surveillance regulations.

25. There are several separate and independent grounds of review in this matter, which include:

25.1 The public participation process embarked upon by the Minister in respect of the 2022 surveillance regulations was unsatisfactory, inadequate, unlawful, irregular and stands to be set aside;

25.2 The Minister failed to comply with the peremptory provisions of Section 90(1) of the National Health Act in not consulting the National Health Counsel before publishing the 2022 surveillance regulations;

25.3 The 2022 surveillance regulations are both substantively and procedurally irrational;

25.4 The 2022 surveillance regulations are *ultra vires* the provisions of Section 90(1)(j), (k) and (w) of the National Health Act (which are the empowering provisions relied on by the Minister of Health to publish the Regulations) and are therefore unlawful and invalid;

25.5 The 2022 surveillance regulations were made for ulterior purposes, including:

25.5.1 To effectively extend the rules and restrictions which had been in place under the Disaster Management Act;

25.5.2 Continuing a public health containment strategy in respect of Covid-19 in a manner that is inappropriate and constitutionally impermissible.

25.5.3 Enforcing a covert vaccine mandate that effectively coerces the public into being vaccinated against Covid-19 by way of derogation of the Constitutional and public rights of unvaccinated persons;

25.5.4 To compel civil society to enforce the aforesaid vaccine mandate by creating mechanisms that will force civil society to discriminate between different classes of persons (namely vaccinated and unvaccinated persons);

25.6 The 2022 surveillance regulations impermissibly infringe various rights as set out in the Bill of Rights and are inconsistent with the Constitution and are invalid.

25.7 The Minister unlawfully delegates the obligation, risk and cost of enforcing a covert vaccine mandate to business, churches and other organisers of gatherings – to the detriment of a stable constitutional order.

26. Each of the above reasons alone constitutes a sufficient basis to review and set aside the 2022 surveillance regulations and declare them to be inconsistent with the Constitution and to be invalid.

27. These grounds of review may be supplemented in terms of Rule 53(4) of the Uniform Rules of Court after the Minister of Health dispatches to the Registrar of this Court the Rule 53 record of decisions sought by the Applicant in the notice of motion.

APPLICATIONS FOR SIMILAR RELIEF BY OTHER PARTIES

28. The Applicant has had the benefit of considering the similar applications filed in this Honourable Court under case numbers 25363/2022 (Solidariteit) and 25226/2022 (Afriforum NPC and Dear SA NPC) against the Minister and the Director-General (amongst others).

29. The Applicant supports the grounds and contentions generally in the similar applications and has considered seeking leave to be admitted as an *amicus curiae* in such matters.

30. Due to the substantive nature of the evidence and submission, which the Applicant feels is necessary to bring before the Court, the Applicant has been advised that it would not be possible or proper to do so as an *amicus curiae.*

31. The Applicant's grounds for relief, as set out below, traverses material and evidence that is not relied on by the applicants in the other matters mentioned above. Same cannot be dealt with through mere submissions. In addition to the grounds and material relied on by the applicants in the above-mentioned applications, the Applicant introduces new and substantially different grounds for the relief sought. It would be inappropriate for the Applicant to participate in the above applications as an *amicus curiae,* and a separate application is accordingly launched.

BACKGROUND

COVID-19 IN SOUTH AFRICA AND GOVERNMENT RESPONSE

32. The context in which this application arises is the well-known Covid-19 outbreak. Covid-19 has been traversed in various cases dealing with the legality of the government's response to the Covid-19.

33. On 15 March 2020, the Minister of Cooperative Governance and Traditional Affairs ("the COGTA Minister") declared a 'National State of Disaster' in response to Covid-19 in South Africa.



34. On 22 March 2020, the President declared a "national lockdown", initially with the aim of slowing the spread of Covid-19. This strategy was later replaced by a containment strategy focussing on managing infections and transmission. The lockdown was effected as of midnight on 26 March 2020. On 25 March 2020, the COGTA Minister made regulations to govern the lockdown in terms of Section 27(2) of the DMA ("the **DMA Regulations**").

35. The DMA Regulations were extensive and invasive of the public's basic constitutional rights and freedoms. The public, as well as the Applicant's, response to the limitation of constitutional rights and freedoms during the "National State of Disaster" should be measured within the context of the particular powers granted to the COGTA Minister under the DMA, which differs materially from the Minister's powers under the National Health Act.

36. The DMA Regulations were amended from time-to-time and extended one month at a time until the eventual termination of the "National State of Disaster".

ALERT LEVEL 1 DMA REGULATIONS: FROM 18 SEPTEMBER 2020 TO 30 DECEMBER 2021

37. During the "National State of Disaster" the scope of the DMA Regulations were continuously adjusted to reflect the perceived risk that Covid-19 posed.



38. Alert level 1 (the lowest or least restrictive level created) was provided for initially by way of an amendment of the DMA Regulations during or about September 2020. The regulations relating to Alert level 1 became increasingly less restrictive with each amendment thereof over time.

39. South Africa was effectively on a so-called Alert Level 1 from 1 October 2021.

40. On 30 September 2021, the COGTA Minister published amended DMA Regulations in Government Gazette 45253, providing for restrictions inter alia on mask wearing (Regulation 67), gatherings (regulation 69) and travel (Regulation 75) (which will henceforth be referred to as "the **September 2021 Regulations**"). A copy of the amendment notice is attached hereto as **ANNEXURE PJLR 2.**

41. The Applicant pauses to note that the September 2021 Regulations:

    41.1 did not introduce any provisions which discriminated between persons on the basis of their vaccination status for purposes of travel and/or gatherings, or attempted to limit any of a person's constitutional rights and freedoms for failing to comply with a public health policy in relation to vaccination;

    41.2 were applicable from October 2021 at a time when vaccinations had been freely available and administered to adults who sought to be vaccinated in South Africa;

41.3 were introduced at a time when citizens of almost every country in the world had access to vaccines and could chose to be vaccinated or not;

41.4 were introduced during or shortly after the peak of the Delta variant of Covid-19, which resulted in higher infection fatality rates than the later Omicron variant.

42. The September 2021 Regulations were amended by the COGTA Minister by way of amendments in Government Gazette 45297, 11 October 2021, Gazette 45697 of 21 December 2021, Gazette 45715 of 30 December 2021 and Gazette 43855 of 1 February 2022. None of the last-mentioned amendments to the regulations introduced vaccination status as a factor or means to contain Covid-19 in any way. The various amendments gradually reduced restrictions on gatherings and travel.

43. As of 30 December 2021 amendments, the position relating to gatherings was (in summary) that gatherings were restricted to no more than 1 000 people indoors and no more than 2 000 people outdoors. Where the venue was too small to accommodate these numbers with appropriate distancing, then no more than 50 per cent of the capacity of the venue could be used. No vaccination status condition was attached to the regulations.

44. The 1 February 2022 amendment to the September 2021 Regulations, in an apparent response to the reduced magnitude and severity of Covid-19, even

provided that persons who tested positive for Covid-19 but were asymptomatic were no longer required to isolate (Regulation 7(1)).

45. On 22 March 2022, the COGTA Minister introduced new regulations to amend Regulations 69 and 75, wherein she introduced (for the first time as far as the Applicant can establish) vaccination status conditions regarding gatherings and travel. A copy of the amendment notice is attached hereto as **ANNEXURE PJLR 3.**

46. In summary, the position relating to gatherings changed on 22 March 2022 to the following:

46.1 Fully Vaccinated persons and persons who tested negative for Covid-19 had no restrictions on their gatherings (indoor or outdoor) save that they were limited to 50% of the capacity of the venue if prescribed distancing could not be achieved; and

46.2 Persons not fully vaccinated and those who did not have a negative Covid Test could gather but were subject to a limit of 1000 persons indoors and 2000 outdoors, up to 50% of the capacity of the venue (with distancing of 1 meter);

46.3 The restrictions shifted from regulating the conduct of individuals in respect of gatherings, to holding business and organisers of gatherings if they do not discriminate between vaccinated and unvaccinated person.

END OF STATE OF DISASTER: 04 APRIL 2022 AND TRANSITIONAL PROVISIONS

47. On 4 April 2022, the "National State of Disaster" was terminated by way of a notice published in the Government Gazette (GG 46197) (the "**termination notice**"). A copy of the aforesaid notice is attached hereto as **ANNEXURE PJLR 4**.

48. In terms of the termination notice, all regulations and directions made in terms of Section 27(2) of the DMA were repealed, save for the regulations which dealt with mask-wearing (Reg 67), gatherings (Reg 69), travel (Reg 75), social relief and distress grants (Reg 4(5) and (10)) and various provisions relating to driver's licenses and motor vehicle licensing (Reg 4(7)(b)). Most of these provisions would, according to the notice, continue for a further month until midnight on 4 May 2022. A Covid-19 Vaccine Injury No-Fault Compensation Scheme created as part of the termination regulations would continue indefinitely.

49. Regulations 67, 69 and 75 continued in materially the same form as amended on 22 March 2022. I attach hereto the aforesaid regulations as published on 4 April 2022 as **ANNEXURE PJLR 5.**

50. On 5 April 2022, the Head of the National Disaster Management Centre, withdrew the classification of Covid – 19 as a "national disaster".

51. The applicant is of the view that the containment strategies deployed during the "National State of Disaster", were extremely harmful to both the economy and the social fabric of our society. The Applicant and its supporters hoped that the termination of the "National State of Disaster" would beckon a return to pre-Covid normality, as there is no current or likely public health emergency, public health risk or disaster in respect of Covid-19. The withdrawal of the classification of Covid-19 as a "national disaster" supports this.

MINISTERIAL ADVISORY COMMITTEE ON COVID -19

52. During the "National State of Disaster", a Ministerial Advisory Committee (MAC) was established to provide expert medical and other expert advice to the Minister and Cabinet on relevant issues relating to Covid-19. The committee was apparently comprised of over 50 members who the Minister considered to be leading experts in relevant fields, including virologists, epidemiologists, clinicians, and other relevant experts.

53. On 15 February 2022 the MAC on Covid-19 (having been requested to review the screening requirements for travel) advised the Minister by way of a written report (which is attached hereto as **ANNEXURE PJLR 6**) that:

> *"As the region moves to recognising COVID-19 as endemic, with a view to a mitigation strategy to address the health risk of infection, the MAC on COVID-19 therefore recommends that entry requirements for all international travellers to South Africa be reduced and even removed,*

opening the country to increased incoming travel, for economic and tourism purposes.

For entry into South Africa by air or sea (except from a neighbouring country) the following requirements should apply:

- *A completed Traveler Health Questionnaire at all border entry points according to Port Health data requirements; symptom screening is not recommended for travellers to prevent the transmission of COVID-19, but may remain in place to recognise other emerging infectious diseases;*

  Unvaccinated travellers in South African border and ports should be offered vaccinations in South Africa and where possible at the border. This vaccination program should be offered at no cost to the traveller..."

54. The MAC advised furthermore that the effect of vaccines was to *"reduce the risk of severe disease, hospitalisation and death."*[1] It referred to a study of September 2021 in which it was claimed that vaccines *"reduce transmission of the virus to some extent".*[2] The "extent" to which transmission is claimed to be reduced is unclear. The MAC accepts that vaccination against Covid-19

[1] At page 3 of MAC advice of 15 February 2022
[2] At page 3 of MAC advice of 15 February 2022

does not prevent transmission of Covid-19 and has advised measures in accordance with the limited effect of the vaccine.

55. On 16 February 2022, the MAC on Covid -19 (having been requested to review the requirements for gatherings) advised the Minister by way of a written report (which is attached hereto as **ANNEXURE PJLR 7**) at pages 1 and 2 thereof) that:

- *"The current restrictions applicable to outdoor gatherings be lifted;*

- *The current restrictions on the number of persons at indoor gatherings, the minimum physical distancing, and hence the 50% capacity rule, be lifted."*

56. It is patently clear from the contents of the MAC advisory of 16 February 2022 that the Minister was advised that no restrictions are required in South Africa for gatherings or mask-wearing in outdoor settings. The MAC recommended that wearing masks indoors *"be retained initially, but be re-assessed at regular intervals…. The ultimate aim should be lifting indoor mask mandates."*

57. Furthermore, the MAC advisory of 16 February 2022 provided reasoning for the recommendations, including that costly, large-scale containment efforts are inappropriate and that policies should be aimed at mitigation. The MAC advisories also state that while it is inevitable that easing restrictions on outdoor and indoor gatherings will allow for greater transmission of the virus,

the focus should now be on preventing severe disease ("mitigation"), rather than trying to prevent infections ("containment".)"

58. The MAC advisory of 16 February 2022 added:

- *"South Africa now has a high degree of population immunity to SARS-CoV-2, which can be expected to offer strong protection against severe disease and death, as was seen in the recent Omicron wave. SARS-CoV-2 seroprevalence exceeded 70% prior to the Omicron wave and is expected to be even higher now.*

- *Reducing unnecessary restrictions will allow society to return to normal functioning to the greatest possible degree and is expected to have significant economic and social benefits."*

59. The aforesaid MAC advisories indicated that the factual situation in South Africa no longer required mandatory mask-wearing outdoors, that indoor mask-wearing should be phased out and that no travel or gathering restrictions were required, i.e a return to normality.

NEW DRAFT REGULATIONS ANNOUNCED: 15 MARCH 2022

60. On 15 March 2022, the Minister gave notice in Government Gazette No 46048 of his intention to make four sets of regulations in terms of the National Health

Act and International Health Regulations Act 28 of 1974 (the **"draft health regulations"**).

61. The draft health regulations dealt with:

61.1 Regulations relating to Proposed Amendments of the Surveillance and Control of Notifiable Medical Conditions under Section 90(1)(j), (k) and (w) of the National Health Act ("the draft surveillance regulations");

61.2 Regulations relating to Public Health Measures in Points of Entry under Section 3(2) of the International Health Regulations Act 28 of 1974 ("the draft points of entry regulations");

61.3 The regulations relating to the Management of Human Remains under Section 68(1)(b) read with Section 90(4)(a) of the National Health Act ("the draft human remains regulations"); and

61.4 Regulations relating to Environmental Health in Section 90(1)(a), (n) and (w) of the National Health Act ("the draft environmental health regulations").

62. The draft health regulations included an invitation by the Minister to comment on the contents thereof within thirty days.

63. One needs only to glean the draft health regulations to see that they were clearly oblivious to the advice of the MAC reports of 15 and 16 February 2022. In contrast with the MAC's advice regarding devolution away from the draconian DMA Regulations and back to normality, the draft health regulations seek to introduce a permanent invasive public health regime of a nature never seen before in South Africa.

64. On 14 April 2022 (one day before the submissions were due), the Minister extended the period for public comments on the draft health regulations for a further week until 24 April 2022.

65. The Applicant responded to the Minister's invitation and made written representations on the draft health regulations. In its submissions, the Applicant raised several objections to the draft health regulations, including that it would be unlawful for the Minister to make the draft health regulations in terms of the National Health Act. The Applicant's submission is attached hereto as **ANNEXURE PJLR 8**. Due to the limited time available to consider the implication of such an extensive public health regime, the Applicant's submissions were limited in nature.

THE 2022 SURVEILLANCE REGULATIONS

66. On 4 May 2022 the Minister published the 2022 surveillance regulations, a copy of which is attached hereto as **ANNEXURE PJLR 9**. Notably, he did not adopt the draft health regulations (i.e. those regulations that he proposed

making in which he sought public comment). In summary the 2022 surveillance regulations dealt effectively with three topics namely a mask mandate (16A), limits on gatherings (16B) and regulation of entry at borders (16C).

67. Regulation 16A regulates the wearing of a face mask to contain the spread of Covid-19 and states as follows:

> *"(3) A person must, when entering and being inside an indoor public place, wear a face mask.*
>
> *(4) No person may use any form of public transport if they do not wear a face mask.*
>
> ...
>
> *(6) The Minister of Health may:*
>
> *(a) determine that the measures in this Regulation, in part or in their entirety, are no longer necessary to contain the spread of Covid-19 and give notice of this determination in the Government Gazette, whereupon the measures concerned will no longer be in operation; and*
>
> *(b) at any time after having made such a determination, determine that the measures concerned are once again necessary to contain the spread of Covid-19 and give notice of this determination in the Government*

Gazette, whereupon the measures concerned will resume operation."

68. Regulation 16B deals with gatherings and provides that:

"(2) For purposes of this regulation:

(a) A 'gathering' means a planned assembly or meeting at a particular venue involving more than one hundred persons, whether for faith-based, religious, social, political, cultural, sporting, economic or recreational purposes; and

(b) 'vaccinated against Covid-19' means having received at least one dose or a vaccine approved for use in respect of Covid-19 by the South African Health Products Regulatory Authority or listed for this purpose by the World health Organisation.

(3) For any indoor gathering, a maximum of 50% of the venue capacity may be occupied, provided that every attendee must:

(a) be vaccinated against Covid-19 and produce a valid vaccination certificate; or

(b) produce a valid certificate of a negative Covid-19 test, recognised by the World Health Organisation, which was obtained not more than 72 hours before the date of the gathering.

(4) Where sub-regulation (3) is not complied with, then attendance at the indoor gathering shall be limited to 1 000 people or 50% of the capacity, whichever is smaller.

(5) For any outdoor gathering, a maximum of 50% of the venue capacity may be occupied, provided that every attendee must:

(a) be vaccinated against Covid-19 and produce a valid vaccination certificate; or

(b) produce a valid certificate of a negative Covid-19 test, recognised by the World Health Organisation, which was obtained not more than 72 hours before the date of the gathering.

(6) Where sub-regulation (5) is not complied with, then attendance at the outdoor gathering shall be limited to 2 000 people or 50% of the capacity, whichever is smaller.

(7) An owner or operator of any indoor or outdoor facility where gatherings are held must display the certificate of occupancy which sets out the maximum number of persons the facility may hold.

(8) Hotels, lodges, bed and breakfast, timeshare facilities, resorts and guest houses are allowed full capacity of the available rooms for accommodation, with patrons wearing face masks when in common spaces.

(9) All registered basic education institutions are excluded from the operation of this regulation.

...

(11) The Minister of Health may:

(a) determine that the measures in this Regulation, in part or in their entirety, are no longer necessary to contain the spread of Covid-19 and give notice of this determination in the Government Gazette, whereupon the measures concerned will no longer be in operation; and

(b) at any time after having made such a determination, determine that the measures concerned are once again necessary to contain the spread of Covid-19 and give notice of this determination in the Government Gazette, whereupon the measures concerned will resume operation."

69. Regulation 16C, which deals with persons entering the country, requires of them, when entering at South African Ports of Entry to:

69.1 Be vaccinated against Covid-19 and produce a valid vaccination certificate; or

69.2 Produce a valid certificate of a negative PCR Covid-19 test, which was obtained not more than 72 hours before the date of departure; or

69.3 Produced a valid certificate of a negative antigen Covid-19 test performed by a medical practitioner, registered public health

authority or accredited/approved laboratory which was obtained no more than 48 hours before the date of departure; or

69.4 Produce a valid certificate of a positive PCR Covid-19 test, for a test date less than 90 days prior to the date of arrival and more than 10 days prior to the date of arrival, together with a signed letter from a health care provider stating that the person has fully recovered from Covid-19, is not experiencing any new symptoms, and is fit to travel.

70. Despite the new and invasive manner in which constitutional rights and freedoms would now be limited under the National Health Act, the regulations grant the Minister unchecked arbitrary power to invoke or terminate invasive public health interventions. Vaccination against Covid-19 can be a significant public health concern today (to such an extent as to strip a person of his ability to meet with others at large gatherings), only to be terminated by the Minister tomorrow.

71. While some of the topics set out in Regulations 16A, 16B and 16C were covered in the draft health regulations, the form in which they were ultimately adopted in the 2022 surveillance regulations did not accord with the draft health regulations. The 2022 surveillance regulations accord more with the transitional regulations contained in the termination notice under the DMA.



72. Simultaneously with the publication of the 2022 surveillance regulations, the Minister extended the period of public comment on the draft health regulations for three months.

73. The public had been given no notice or formal details of the contents of what the 2022 surveillance regulations would be before they were published, and which became law overnight. The approach adopted by the Minister has been incoherent, irrational and disingenuous for many reasons including:

73.1 The 2022 surveillance regulations came into effect merely hours before the DMA Regulations' transitional provisions were to expire at midnight on 4 May 2022;

73.2 Prior to the publication of the 2022 surveillance regulations, the public was not provided with any feedback on their comments or advised on changes thereto;

73.3 No notification was given that a wholly new version of particular differing provisions of the draft health regulations would be finally published and made law with immediate effect, and the public comment process extended in respect of the remaining draft health regulations;

73.4 No explanation was provided as to why the Minister only deemed it necessary to publish three discrete amendments to the surveillance regulations and not the other regulations proposed for adoption or why those provisions were not

adopted in the form in which they have been published in the draft health regulations;

73.5 No explanation was provided as to why the Minister completely disregarded the expert advice of his own MAC as set out in the advisories of 15 and 16 February 2022;

73.6 The process the Minister proposed to follow in applying the regulation and in particular in applying his sole and unfettered discretion to determine as to when and/or on what basis the Regulations are to be of force and effect or not is likewise unclear, vague and illegal.

MAC ADVISORY OF 25 APRIL 2022

74. The publication of the 2022 surveillance regulations is not only irrational in the light of the MAC advisories of 15 and 16 February 2022 referred to above but is impossible to reconcile with the further advice set out in a MAC on Covid-19 advisory of 25 of April 2022 (which is attached hereto as **ANNEXURE PJLR 10**). The advisory addresses the monitoring of Covid-19 between acute outbreaks and deciding on appropriate and timely responses. It states *inter alia* that:

> *"COVID-19 is most likely to become endemic, with periodic acute outbreaks. A mitigation approach is therefore needed, with the ability to pivot to a more interventional stance if needed."* [3]

[3] MAC 25 April 2022 Page 1 par 1 - background

75. In response to the question "What mitigation strategies are recommended if a high burden of severe disease is thought likely?"[4] the MAC states that:

> *"A rising caseload alone (as evidenced by total cases, percentage positivity, rising wastewater viral burden, or falling cycle threshold values) does NOT warrant further action in and of itself. However more intensive restrictions and enhanced mitigation efforts can be justified if a high burden of severe disease is shown to be likely. Should it be deemed that the integrity of the healthcare system is under threat, the following measures can be considered:"*

76. The MAC advisory of 25 April 2022 then lists nine recommended measures which are summarised as follows:

76.1 A Vaccination booster drive;

76.2 Strengthened linkage between vaccination coverage data, testing data and hospital admission data;

76.3 Securing of adequate quantities of essential medicines;

76.4 Strengthening of oxygen supplies;

[4] MAC 25 April 2022 page 6

76.5 Ordering sufficient consumables required for a severe COVID-19 outbreak;

76.6 Putting surge capacity strategies on standby;

76.7 Efficient public communication about mask-wearing, avoidance of large gatherings and ventilation and spacing in indoor venues with the focus on risk individuals with recommendations being favoured over mandates;

76.8 Restrictions on the sale of alcoholic beverages – to rapidly decongest ICU /High Care beds;

76.9 New restrictions on school attendance – a last resort.

77. The MAC does **not** advocate for a return to mandatory mask-wearing and does **not** call for restrictions on gatherings or travel in the event of an acute and serious outbreak of Covid -19. The Minister is advised to put other measures in place. Restricting unvaccinated persons access to gatherings is never advised as far as the Applicant can determine,

78. In any event, in the light of the fact that there is currently no acute or serious outbreak of Covid-19, it is completely irrational and unjustifiable that restrictions be placed on individuals such as those imposed by the 2022 surveillance regulations.

79. What is clear is that the approach taken by the Minister has not been transparent and open. He has not been open and transparent about his intention to effect the 2022 surveillance regulations instead of the published

draft health regulations. He has failed to explain why he did so or why he has elected to ignore the advice of his own MAC panel.

80. The intention of the rushed publication of the 2022 surveillance regulations was ostensibly to fill the gap that was perceived to be left by the lapsing of the DMA Regulations before midnight on 4 May 2022.

81. The Applicant and the public never participated in a consultation process for the enactment of the 2022 surveillance regulations. Had the public known that a separate set of regulations would be made instead of the draft health regulations, they would most likely have participated differently in the draft health regulations' consultation process. Instead of trying to comment on all-encompassing draft health regulations under pressure, the Applicant could have diverted its energy to the issues specifically relating to the intended 2022 surveillance regulations.

82. The Minister's conduct is unfortunate and regrettable and has tainted the whole public participation process with irrationality.

VACCINATION IN SOUTH AFRICA

83. South Africa's vaccination rollout commenced on 18 February 2021 under the auspices of the Department of Health. According to Government's SA Coronavirus Portal (sacoronavirus.co.za), as on 18 May 2022, approximately 35 617 595 vaccine doses have been administered. The Applicant refers to Figure X1 below taken from the SA Coronavirus Portal in support.

COVID-19 Total Vaccination Summary as at 17:00 18 May 2022
Total Number of Vaccines Administered
35,617,595

Figure **X1**

84. Disputes regarding safety, efficacy, and allocation have become divisive, polarising and far-reaching issues across the globe. South Africa's own track record concerning vaccination clearly shows a country divided (or at the least hesitant) on the issue. According to the SA Coronavirus Portal data, as on 18 May 2022, more than half of the adult population alone has decided to not have a Covid-19 vaccine administered. The Applicant refers to Figure X2 below, taken from the SA Coronavirus Portal that shows that only 45.25% of the population has been administered a full regiment of either one of the currently available vaccines.

COVID-19 Total Adults Fully Vaccinated Summary as at 17:00 18 May 2022 (Excluding 12 - 17 Years)	
Total Adult Population by Province [18 Years and Older] (1)	
39,798,201	
Total Number of Adults Fully Vaccinated (2)	Adults Fully Vaccinated as a % of the Adult Population (3)
18,010,428	45.25%

Figure **X2**

85. The data published by government on the SA Coronavirus Portal also clearly shows a steep and continued decline in vaccination rates since the vaccination drive peak at the end of August 2021. The Applicant refers to Figure X3 below, taken from the SA Coronavirus Portal in support.

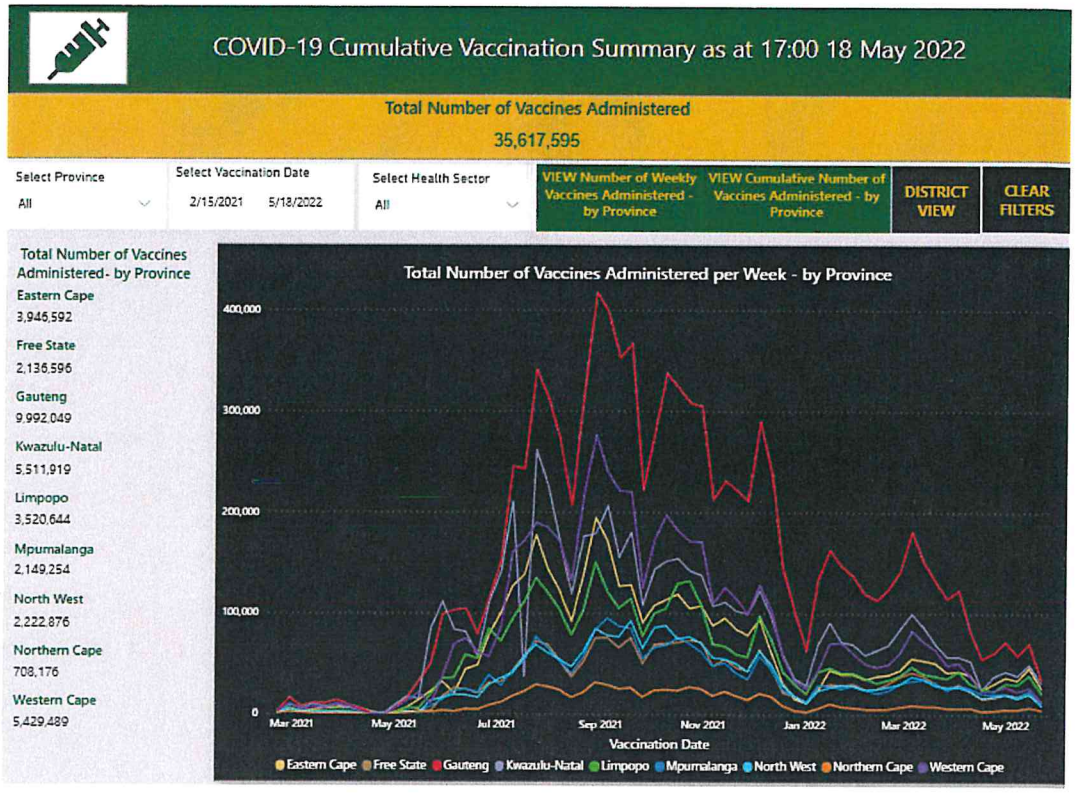


Figure **X3**

86. People are also not returning for what is called booster shots at even remotely the same rate as at the vaccination peak of the 2021 vaccination drive. According to the SA Coronavirus Portal, only 3 026 816 people have, as at 18 May 2022 returned for a booster shot. According to the SA Coronavirus Portal, at least 6 354 669 adults received a full vaccine regimen by 31 July 2021 (I refer to Figure **X4** below).

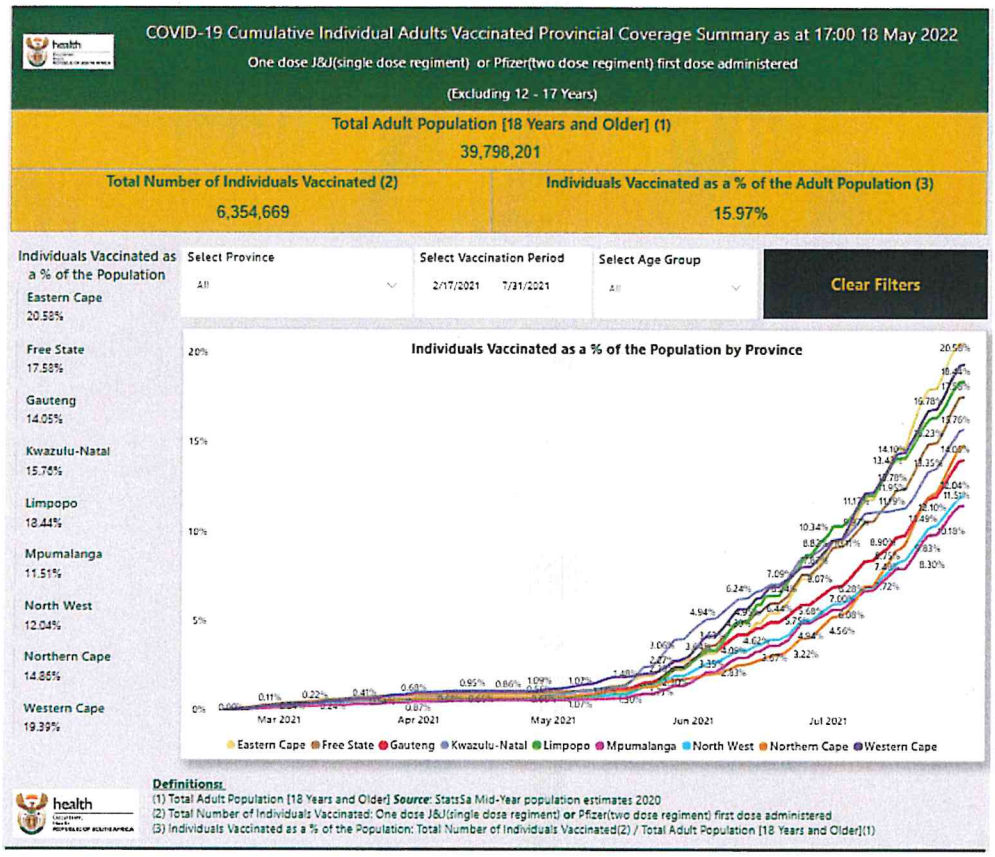


Figure **X4**

87. Logic would dictate that at least that number of people would have started to return for a booster shot, as is recommended by the Minister (in most cases after 180 days), somewhere between January 2022 until May 2022. This is simply not happening at this stage, indicating a potentially larger number of people who will not be "fully vaccinated" (i.e. vaccinated and with all booster shots subsequently received at recommended intervals) in the future. That only 3 026 816 people have received a booster shot by 18 May means that the "fully vaccinated and boosted" rate for the adult population in South Africa was at most 7,6% at this date.

88. People's response to vaccination has been clearly motivated by a myriad of different considerations. The ability of adults to apply their own minds to the

issue of vaccination, has been a key theme in the public position taken by the National Executive. During an address on 1 February 2021, the President stated the following:

> *"Nobody will be forced to take this vaccine. Nobody will be forbidden from travelling, from enrolling at school,* ***or from taking part in any public activity if they have not been vaccinated.*** *Nobody will be given this vaccine against their will, nor will the vaccine be administered in secret." [Own emphasis]*

89. As recently as 31 March 2022, the Deputy President, Mr David Mabuza, confirmed the following in a question-and-answer session before Parliament:

> *"One thing we are not going to do is force people to go and vaccinate,"*
> *[...]*
> *"We think (that) would be crossing the 'red line'. All we can do is encourage our people to go and vaccinate."*

90. The Applicant can also note that, as far as it is aware, no legislation has been tabled before Parliament which seeks to introduce any form of mandatory vaccination or which will seek to penalise persons who refuse to be vaccinated.

91. Viewed in the light of the above, the Minister's regulations are not only out of touch with the advice of the Minister's own experts but also:

89.1 in direct contradiction to the official position of the National Executive as represented by the President and Deputy-President on the issue (as declared in public and before Parliament);

89.2 exclusionary of a majority of the country's residents;

89.3 in direct opposition to the majority public sentiment in respect of vaccination.

LEGAL FRAMEWORK

THE NATIONAL HEALTH ACT

92. The Preamble of the National Health Act recognises that the State "must", in compliance with Section 7(2) of the Constitution, respect, protect, promote, and fulfil the rights in the Bill of Rights, which is the cornerstone of democracy in South Africa.

93. According to the Preamble of the National Health Act, the statute was enacted *inter alia* in order to:

93.1 Provide for a system of cooperative governance and management of health services within national guidelines, norms and standards, in which each province, municipality and health district must address questions of health policy and delivery of quality health care services; and



93.2 Establish a health system based on decentralised management, principles of equity, efficiency, sound governance, internationally recognised standards of research and a spirit of enquiry and advocacy which encourages participation.

94. Section 4 of the National Health Act imposes the obligation upon the Minister to *inter alia*:

94.1 Endeavour to protect, promote, improve, and maintain the health of the population;

94.2 Determine the policies and measures necessary to protect, promote, improve, and maintain the health and well-being of the population.

95. Section 21 of the National Health Act sets out the general functions of the Director-General. These include:

95.1 Ensuring that the National Health Policy is implemented;

95.2 Issuing guidelines for the implementation of the National Health Policy;

95.3 Coordinating health and medical services during national disasters; and



95.4 Facilitating and promoting the provision of health services for the management, prevention, and control of communicable and non-communicable diseases.

96. Section 22 of the National Health Act deals with the establishment and composition of the National Health Council. Section 23 sets out the functions of the National Health Council and states that the Council must advise the Minister amongst other things of the following:

> *"(a) Policy concerning any matter that will protect, promote, improve and maintain the health of the population, including ...*
>
> *(ix) epidemiological surveillance and monitoring of national and provincial trends with regard to major diseases and risk factors for disease."*

97. In terms of Section 23(3) of the National Health Act, the Council must try to reach its decisions by consensus but where a decision cannot be reached by consensus, the decision of the majority of the members of the National Health Council is the decision of such Council.

98. Section 90(1) of the National Health Act confirms that the Minister, after consultation with the National Health Council or the Officer, Health Standard Compliance as the case may be, may make regulations regarding amongst other things:



"(j) Communicable diseases;

(k) Notifiable medical conditions;

(w) Generally any other matter which it is necessary or expedient to prescribe in order to implement or administer this Act."

99. Section 90(3) states that the Minister may, in regulation made under the National Health Act:

"(a) Designate as authoritative any methodology, procedure, practice or standard that is recognised as authoritative by internationally recognised health bodies within the relevant profession; and

(b) Require any person or body to comply with the designated methodology, procedure, practice or standard."

100. Section 90(4) prescribes the conditions relating to the publishing of regulations and states that:

"(4)(a) The Minister must publish all regulations proposed to be made under the Act in the Gazette for comment at least three months before the date contemplated for their commencement.

(b) If the Minister alters the draft regulations, as a result of any comment, he or she need not publish those alternations before making the regulations.

(a) The Minister may, if circumstances necessitate the immediate publication of a regulation, publish that regulation without the consultation contemplated in paragraph (a)."

THE 2017 REGULATIONS

101. As indicated above, the 2017 Regulations were published on 15 December 2017.

102. The 2017 Regulations defines four categories of notifiable medical conditions and sets out specific and distinct timeframes within which the Health Department must be notified of such conditions.

103. The May 2017 Regulations define a "notifiable medical condition" as a medical condition, disease or infection of public health importance that is classified as notifiable in terms of Regulation 12 thereof. The National Health Act does not provide a definition of such term.

104. The 2017 Regulations further define a "*public health risk*" as a likelihood of an event that may adversely affect the health of human populations, with the emphasis on one which may spread internationally or may present a *"serious and direct danger"*.

105. Regulation 12 provides for "the declaration of notifiable medical conditions":

105.1 Sub-regulation 12(1) confirms that medical conditions listed in Annexure A, Tables 1, 2 and 3 are declared to be notifiable medical conditions;

105.2 Sub-regulation 12(2) states that:

"The Health Minister may declare by Notice in the Government Gazette, a medical condition not listed in Annexure A, as notifiable if in his or her opinion the medical condition:

(a) *poses a public health risk to a population of a particular community, district, municipality, province or the country;*

(b) *may be regarded as a public health risk or has a potential for regional or international spread; and*

(c) *may require immediate, appropriate and specific action to be taken by the national department, one or more provincial departments or one or more municipalities."*

106. Sub-regulation 12(3) further provides that:

"The Health Minister may determine, by notice in the Government Gazette, that:

(a) certain diseases or medical conditions be notifiable in certain provinces, districts or municipalities, for a period specified in the notice or until the notice is withdrawn;

(b) certain diseases or medical conditions be notifiable by certain categories of health care providers, pathologists or laboratory personnel; and

(c) specific diagnostic or laboratory criteria apply to specific diseases or medical conditions."

Regulation 13 of the 2017 Regulations requires that the diagnosis of a patient with a notifiable medical condition listed in Annexure A, Table 2 be notified to the focal person at the health sub-district within 7 (seven) days of diagnosis.

107. Regulation 15 deals with "mandatory medical examination, prophylaxis, treatment, isolation and quarantine":

107.1 Sub-regulation 15(1) states that:

"The required mandatory medical examination, prophylaxis, treatment, isolation or quarantine procedures must be determined on a case-by-case basis and tailored depending on

the public health risk and individual circumstances of the person in question."

107.2 Sub-regulation 15 (2) is exceptionally sensitive about the fundamental rights of citizens and provides for extremely limited circumstances in which an invasion of an individual's rights to *inter alia* freedom and security of the person, privacy, movement, and dignity may be allowed so as to subject a person to a mandatory medical examination, prophylaxis, treatment, isolation, and quarantine. The entire process is regulated on a case-by-case basis and a Court order is required.

108. Regulation 16 of the 2017 Regulations deals with the "Control of spread of notifiable medical conditions": Sub-regulation 16(1) requires that:

"The district health manager must ensure that health care providers, the case, contact or carrier comply with the specified disease prevention, management and control measures stipulated in the national department guidelines."

PUBLIC COMMENTS ON DRAFT REGULATIONS

109. Despite the Minister providing an exceptionally limited period for comment on the draft health regulations, the public sent in excess of 300 000[5] comments to his office.

110. The Minister assured the public that all comments would be considered and reviewed before the 5th of May 2022. I attach a copy of the speaking notes of the Minister on 29 April 2022 hereto as **ANNEXURE PJLR 11.**

111. I point out that the Minister specifically informed the public that he had sufficient resources and officials available to properly consider the comments by the public.

112. Having called for comments, a legitimate expectation was created that the Minister would only publish regulations once he had completed his consultation process with the public. The Minister's silence on the public comments received before publishing the 2022 surveillance regulations and extending the consultation process for his draft regulations is alarming.

THE MINISTER'S CONCERN ABOUT A FIFTH WAVE AND A DISTINCT NEW VARIANT

113. In a speech on 29 April 2022, the Minister expressed hesitancy to terminate the DMA Regulation style restrictions due to the apparent risk of a fifth Covid-

[5] As per speaking notes of Minister of Health on 29 April 2022

19 wave and the possibility of a distinct new Covid-19 variant. He indicated that South Africa would know if this risk would materialise by 6 May 2022. As of date of signature of this affidavit, the Minister has yet to publicly show that a new distinct variant that exceeds the magnitude and severity of the previous Covid-19 variants has materialised.

114. The Applicant submits that it would not be rational for the Minister to base his regulations on the mere possibility of future variations of Covid-19. Viruses are constantly mutating. The risk of mutation or variation does not imply that a real public health risk exists or that there is a serious or direct danger to public health.

115. Furthermore, the probability and high likelihood of a fifth wave was predicted by the MAC on Covid-19, with no concern being raised about it becoming an increased public health risk. The mere development of a fifth Covid-19 wave does not in itself pose a rational threat of risk to public health.

116. No justifiable basis exists for the continuation of restrictions on gatherings, travel and mask-wearing. The 2022 surveillance regulations are clearly out of step with the advice of the Minister's own MAC on Covid-19, who have called for an end to the restrictions and measures that aim to "contain" Covid-19. No alternative scientific evidence has been presented to the public to explain the Minister's divergence from the advice of his own MAC.

DEMANDS OF THE APPLICANT

117. On 12 May 2022 the Applicant, caused a letter of demand to be sent to the Minister, which is attached hereto as **ANNEXURE PJLR 12**. In the above letter of demand, the Applicant sought an audience of the President and the Minister to make proposals and suggestions so as to avoid litigation. To date there has been no response to the above letter and there has been no engagement by the President and/or the Minister.

GROUNDS FOR RELIEF SOUGHT

118. The decision to promulgate the 2022 surveillance regulations constitutes administrative action under PAJA. The amended regulations may be reviewed and set aside under that statute or on the basis of constitutional invalidity and illegality.

119. The promulgation of the 2022 surveillance regulations must be declared unlawful and unconstitutional and should be reviewed and set aside on at least the following grounds:

    119.1 Section 6(2)(b) of PAJA since the mandatory condition of consultation with the National Health Council as provided for in Section 90(1) of the Act was not complied with;

    119.2 Section 6(2)(e)(i) and (ii) of PAJA, since the decision arose out of a misconception of the proper scope and powers of the

Minister under the Act and was made for an improper and /or ulterior purpose and motive;

119.3 Section 6(2) (d) of PAJA since the decision was materially influenced by an error of law and an excess of jurisdiction;

119.4 Section 6(2)(e)(i) of PAJA, since the limitations imposed by the 2022 surveillance regulations are not authorised by the National Health Act;

119.5 Section 6(2)(e)(iii) of PAJA, since the Minister of Health brought irrelevant considerations into account in deciding to publish the 2022 surveillance regulations and further failed to take into account relevant material considerations including scientific evidence and the advice of the MAC;

119.6 Section 6(2)(e)(vi) of PAJA, in that the mandatory requirements to wear face masks and the limitations imposed on gatherings and travel based on vaccination status, are unlawful and arbitrary;

119.7 Section 6(2)(h) of PAJA, in that the regulations, if objectively viewed, are unreasonable ;

119.8 Section 6(2)(i) of PAJA, in that the amended regulations are impermissibly vague and cause uncertainty.



120. For the same reasons as set out above the decision to publish the 2022 surveillance regulations falls to be set aside on the basis of illegality.

IMPROPER AND MATERIALLY DEFECTIVE PROCEDURE

FAILURE TO CONSULT WITH THE NATIONAL HEALTH COUNCIL – SECTION 90(1) OF ACT

121. As set out above, Section 90(1) of the National Health Act empowers the Minister to make regulations regarding matters listed in Section 90(1) after consultation with the National Health Council. The power to make regulations is given in respect of medical diseases, notifiable medical conditions and other matters which are necessary or expedient to prescribe in order to implement and administer the National Health Act.

122. The notice in terms of which the 2022 surveillance regulations were published does not state that the National Health Council had been consulted by the Minister or indicate in any other manner that the Minister of Health in fact consulted with the National Health Council.

123. The Minister must show that he has properly consulted the National Health Council before promulgating his regulations under the National Health Act.

124. In the event that the Minister asserts that he did in fact consult with the National Health Council, the Minister is required to provide a full record of the consultation process and the feedback and advice received.

125. Failing proper consultation with the National Health Council, the amended regulations fall to be set aside on this basis alone.

FAILURE TO PUBLISH REGULATIONS FOR COMMENT ON THREE MONTHS' NOTICE

126. Section 90(1)(a) of the National Health Act, expressly requires that the Minister must publish all regulations proposed to be made under the National Health Act in the Gazette for comment at least three months before the date contemplated for the commencement.

127. The above provisions of Section 90(4)(a) are obligatory.

128. Section 90(4)(c) of the National Health Act provides a single exception to the rule, and that is that "if circumstances necessitate the immediate publication of a regulation, it may be published without the consultation contemplated in Section 90(4)(a)".

129. In terms of the promulgation notice of 4 May 2022, the Minister declares to have issued his regulations under Sections 90(1)(j), (k) and (w) of the National Health Act. The Minister does not state any special or exceptional

circumstances that would comply with Section 90(4)(c). In fact, the Minister does not even rely on Section 90(4)(c) in his promulgation notice.

130. The Applicant submits that failing reliance on Section 90(4)(c), any regulation published by the Minister that fails to strictly comply with Section 90(4)(a), is procedurally irrational and should be reviewed and set aside.

131. The notice and comment procedure regarding the proposed regulations cannot constitute a dual consultation process for regulations devised of separately. The 2022 surveillance regulations were clearly devised and published in circumstances where no notice or public participation process was followed. At best, it can be argued that the 2022 surveillance regulations are an improper and irregular offshoot of the Minister's draft regulations in respect of which the actual consultation and public participation process remains open.

132. Insofar as the Court may be prepared to accept that the limited notice and comment procedure in respect of the proposed regulations up to 24 April 2022 may be regarded as notice and comment in respect of the 2022 surveillance regulations (which contention is not correct), the Applicant contends that such process was unfair on the same grounds as contended for by Solidariteit in their application namely because:

132.1 The public was not provided with sufficient time to comment on the extensive regulations of more than 150 pages;



132.2 The 2022 surveillance regulations were substantively different from the proposed regulations in respect of which comments had been invited;

132.3 It is improper for the Minister to select limited provisions of the proposed regulations to give effect to whilst the notice and comment procedure are still ongoing, particularly in the light of the fact that the notice and comment procedure in respect of the proposed regulations was inadequate;

132.4 It is noteworthy that the Minister has recognised that the period initially provided for the submissions of comments was insufficient and non-compliant with the requirements of the National Health Act. It cannot be that the Health Minister at once accepts that the notice and comment procedure was insufficient, but then relies on that notice and comment procedure to assert that the required process and processes have been followed in respect of the 2022 surveillance regulation;

132.5 The failure to provide for a notice and comment procedure coupled with the failure to invoke Section 90(4)(c), raises a substantive consideration in addition to a procedural one. If the Minister has not invoked the power under Section 90(4)(c) in making the regulations without first allowing for a notice and comment procedure, then he has acted outside his powers to make regulations. The Minister's powers to make regulations through immediate publication are confined to the circumstances in Section 90(4)(c). He could only

have made regulations with immediate effect if he invoked that power. Since he did not invoke such power, he made regulations with immediate effect in a manner outside the powers conferred upon him by Section 90(1) read with Section 90(4).

133. The 2022 surveillance regulations accordingly fall to be set aside on this basis, as set out above.

ULTERIOR PURPOSE OF REGULATIONS

134. The Applicant submits that the actual intention of the Minister in promulgating the 2022 surveillance regulations was twofold, namely: 1) to revive and extend the DMA Regulations (despite the termination of the "National State of Disaster") and 2) to coerce the public into being vaccinated by introducing measures which amount to a covert vaccine mandate.

135. The powers granted to the Minister under the Health Act cannot be used for purposes of extending the DMA Regulations. The regulatory function of the Minster can only be validly performed within the strict authority delegated to him by the National Health Act itself. Parliament did not provide for an extension of regulations issued in terms of the DMA, under the National Health Act. The use of discretionary power to make regulations by the Minister in this context is invalid if done for a purpose not expressly authorised by the empowering statutory enactment.

136. The Minister's attempts to essentially extend and create powers for himself to address Covid-19, which are similar to the powers ostensibly enjoyed under

the DMA, are invalid and unconstitutional. The National Health Act does not operate within the same confines as the DMA. The Applicant will if necessary, raise argument in this respect at the hearing of the matter.

137. The way that the 2022 surveillance regulations were considered and published simply does not comply with the framing of or requirements of the National Health Act. The Minister's conduct is more reminiscent of the continued and unpredictable publication of 'emergency' regulations under the "National State of Disaster", than the considered and structured process prescribed by the National Health Act.

138. Instead of deferring to the appropriate legislative forum, being Parliament, to debate an unforeseen problem facing society, the Minister elected to fashion himself a new permanent regulatory medical regime that 1) limits the constitutional rights and freedoms ordinarily available to the public, 2) penalises individuals who fail to act in a manner preferred by the Minister and 3) goes far beyond the framing, wording, intents and purposes of the National Health Act.

139. Parliament has the general authority to augment current legislation in order to adapt to new social challenges. Failing appropriate augmentation of current legislation, Parliament can introduce new legislation. Unlike Parliament, the Minister can only introduce regulations within the strict confines of the empowering legislation, being the National Health Act in this case.

140. The Director-General is reported to have explained in a press report of 4 May 2022 that the 2022 surveillance regulations were created to *"keep in place South Africa's mask mandates and other remaining Covid-19 rules"*. It is manifest that the Minister expressly exercised his authority to make regulations under Section 90(1), not for the particular purpose identified under the National Health Act, but to keep the so-called DMA Regulations in place. A copy of the press report is attached hereto as **ANNEXUR PJLT 13**.

ULTERIOR PURPOSE: COVERT VACCINE MANDATE

141. The introduction of vaccination status as a criterion to determine the attendance of gatherings and travel regulations in the 22 March 2022 DMA regulations came as a surprise. This criterion was introduced at a time when the fourth wave of Covid-19 had died down and there was no increased public health risk posed by Covid-19. Furthermore, the MAC advice at that time was clear that restrictions should be lifted. Despite the irrationality of the then restrictions, the Applicant and the public, especially considering the MAC advisories being circulated, assumed that these regulations will wither as the preference to manage Covid-19 shifted away from the DMA under the COGTA Minister, to the Minister under the National Health Act.

142. The importation of the DMA regulations, regarding vaccination status and masking, into the National Health Act's regulations without any consideration and augmentation of the empowering legislation by Parliament to cater for the specific aims of the Minister, is *ultra vires,* unreasonable and irrational.

143. One rationale for distinguishing between vaccinated and unvaccinated persons is that the Minister appears to believe that vaccinated persons are less likely to be infected with Covid-19 and/or do not transmit Covid-19. At the least, the motivator seems to be that vaccination will materially contribute to the safety of public spaces. This is incorrect and irrational.

144. A person should consider the real-world data from countries with some of the highest vaccination rates in the world that have continued to experience waves of infections and transmission. Israel is a prime example of a country that, according to data from the World Health Organization (WHO) website as on 18 May 2022, has a vaccination rate among its population of more than 70%. Despite being one of the earliest countries to roll out vaccines, the country continues to experience spikes in infections, having exited its so-called fifth wave of infections at the start of 2022. I refer in support to the data found on the World Health Organization website, Figure **X5** below.

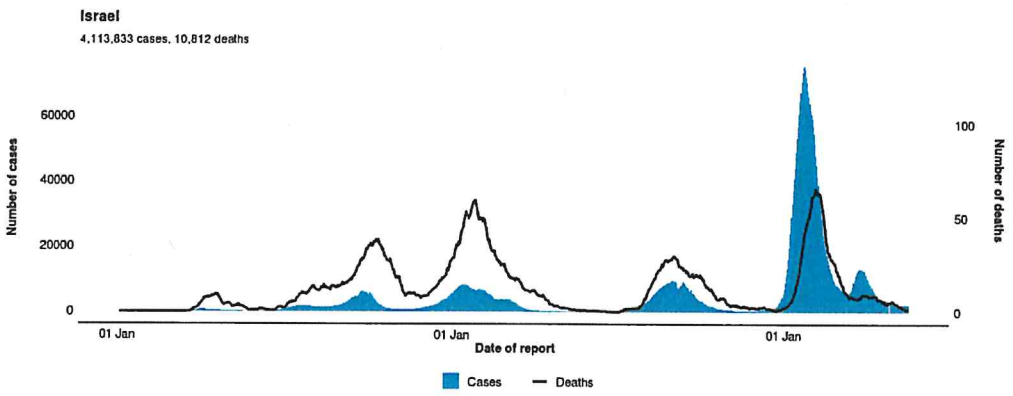


Figure **X5** below.

145. The data shows high levels of infection (cases), despite very high vaccination rates. Comparable data is available on the WHO website on other countries that all have vaccination rates in excess of 70% of their populations.

146. It is impossible to have high infection levels unless both transmission and infection have taken place amongst the vaccinated. The Applicant refers to a UK study where researchers concluded that:

> *"Nonetheless, fully vaccinated individuals with breakthrough infections have peak viral load similar to unvaccinated cases and can efficiently transmit infection in household settings, including to fully vaccinated contacts."*

A copy of the study is attached hereto as **ANNEXURE PJLR 14**.

147. It is apparent that vaccination status does not *per se* have an effect on the transmission of the virus or infection rates, and that its possible benefits are limited to preventing severe disease in the case of infection.

148. In a similar vein to the complexities relating to transmission and infection, the question of the personal health benefits of vaccination is similarly complex, as a case can be made out for and against vaccine created versus natural infection related immunity (not even accounting for wide variations in apparent natural resistance, pre-infection, to the pathogen, given how most people experience no severe symptoms at first infection).

149. A South African study published on 23 February 2022 found that:

> *"[P]eak incidences of hospitalization, recorded death, and excess death in the fourth wave were lower than the peak incidences in previous waves. The fourth wave contributed 11.2%, 3.9%, and 3.3% of overall hospitalizations, recorded deaths, and excess deaths due to Covid-19, respectively, whereas the third wave, in which the delta variant was dominant, contributed 43.6%, 49.3%, and 52.7%."*
>
> *"[W]e observed a dramatic decoupling of hospitalizations and deaths from infections during the fourth wave of Covid-19, as compared with the proportions seen during the three previous waves. The biologic basis for this decoupling could be the extensive cell-mediated immunity in the population that was induced by previous natural infection and vaccination."*
> *"The researchers found that seropositivity for Covid-19, was prevalent in at least 85% of cases."*

A copy of the study is attached hereto as **ANNEXURE PJLR 15.**

150. According to Professor Shabir Madhi, the Dean of Health Sciences and professor of vaccinology at the University of the Witwatersrand, writing on the Conversation on 1 March 2022:

"The omicron wave was associated with 10% of all hospitalisations since the start of the pandemic, whereas 44% of hospitalisations had transpired during the course of the Delta variant wave. More impressively, only 3% of COVID deaths since the start of the pandemic occurred during the omicron wave, compared with 50% during the delta dominant wave."

"Our findings also show that natural infection has been high and is playing a major role in how the pandemic has unfolded especially in countries with low to moderate COVID-19 rollout."

"Another resurgence is likely, and there might well be another variant. But it would be very surprising if further variants are able to evade the T-cell arm of the immune system ***which is stimulated by vaccines and natural infection****." [own emphasis]*

"So why do I believe that we are at the tail end of this pandemic? It depends what metric you use. If it's about infections, we're not at the tail end. If it's about the number of deaths that will transpire from COVID-19 during 2022, relative to the number of deaths that will transpire from other preventable causes of death in countries such as South Africa, then I believe the country has pretty much arrived towards the end of this pandemic."



"In South Africa about 10,000 to 11,000 people die of seasonal influenza every year. In 2019 tuberculosis killed 58 000 in 2019. But we are not declaring an emergency in South Africa to deal with flu or tuberculosis. Deaths from HIV, and complications from HIV, are about 70,000. But South Africa isn't shutting down the country to prevent deaths and infections from these diseases."

A copy of the article is attached hereto as **ANNEXURE PJLR 16.**

151. It is also relevant to note that during November 2021, the country successfully completed a nationwide municipal election without any surge in case numbers. Despite the fears of the Independent Electoral Commission, who had brought an unsuccessful application to postpone the election (fearing that this massive nationwide gathering presented an unacceptable public health risk), the largest public gathering since March 2020 was successful. According to the Chief Electoral Officer's report on the 2021 municipal elections published on 13 May 2022, more than 93% of surveyed voters were satisfied that Covid-19 was sufficiently managed at voting stations. A successful gathering with people standing in close proximity, sometimes for hours, could be completed without ever having to exclude the unvaccinated from the process. The report is attached as **ANNEXURE PJLR 17.**

152. There is no logical or rational basis for arguing that a vaccinated person presents such a materially higher public health risk as to exclude that person from access to public spaces, as is the case under the 2022 surveillance

regulations. The facts simply do not support any rational link between vaccination (or rather the lack thereof) and increased general public health risks.

153. The only conclusion that can be reached is that the purpose of referring to vaccine status in the DMA regulations of 22 March 2022 and in the 2022 surveillance regulations was to coerce citizens into being vaccinated by creating two distinct classes of citizens namely: 1) those who could participate in larger gatherings and travel without fear of having to render a positive Covid-19 test at a port of entry and 2) those who could not attend larger gatherings or who had to incur the cost of Covid-tests (with the risk of being prevented from gathering or travelling if the test was positive.) The vaccinated are effectively rewarded with fewer restrictions and the unvaccinated punished in turn. The irony of the above is that vaccinated persons who are asymptomatically - and even symptomatically - positive with Covid-19 (and are accordingly potentially infecting people around them) can travel with no restrictions or testing and attend large gatherings of people while an unvaccinated person who does not have Covid-19 cannot travel without restriction and cannot attend large gatherings. This makes no sense and is irrational.

154. The only reason why vaccine status has now been included in travel and gathering regulations is that the Minister seeks to coerce South Africans into being vaccinated by making the rewards of an unrestricted society available to the vaccinated and restraining the unvaccinated from enjoying such

freedoms. The Minister wants to make life so unbearable for unvaccinated (and potentially, unboosted) persons that they will vaccinate themselves, indirectly forcing them to comply. Put differently, he wants to infringe on people's freedoms to such a degree that even being vaccinated against their will is a lesser – and therefore "preferred" - penalty.

155. Regulations 16B and 16C were accordingly published by the Minister with the further ulterior motive of coercion and a covert vaccine mandate. This is irrational, unreasonable, irregular, and unconstitutional, and fall to be set aside on this ground alone.

THE REGULATIONS ARE ULTRA VIRES THE PROVISIONS OF THE NATIONAL HEALTH ACT

156. The National Health Act was not enacted to respond to National Disasters or public health emergencies.

157. The overall purpose of the National Health Act and the system of healthcare regulation established thereunder is that the Act is supposed to be employed to ensure proper regulation of the healthcare sector. The primary aim of the National Health Act is not to regulate public health emergencies. The National Health Act does not endow the Minister with the power to simply make broad regulations unrelated to providing health care services.

158. The Minster does not have the power under the Act to limit gatherings, regulate travel and impose mask and vaccine mandates on the public.

UNFETTERED POWER GRANTED BY MINISTER

159. The 2022 surveillance regulations do not specify what conditions will need to be met to implement the restrictions set out in Regulations 16A, 16B and 16C. Likewise, it is unclear under what conditions the public will be entitled to claim the return of their general rights and freedoms affected by a restriction imposed by the Minster.

160. The Minister has granted himself unfettered and unchecked discretion to impose the 2022 surveillance regulations. There are no guidelines or checks or balances to the powers that the Minister has granted himself.

161. The 2022 surveillance regulations must be found to be *ultra vires,* arbitrary and unlawful.

GENERAL IRRATIONALITY

162. There is no rational, scientific or other basis for:

162.1 distinguishing between assemblies of people in public places from "planned" gatherings. For example, a Shopping Mall with a capacity of 30 000 people (where people gather in confined indoor spaces) will be allowed to operate at full capacity since it is not a "planned" gathering. At the same time, an assembly

of spectators in a sports stadium with a capacity of 30 000 people will be viewed as a "planned gathering" and may not operate at more than 50% of its capacity for vaccinated persons and capped at 2000 persons if even one unvaccinated person is admitted. This is irrational;

162.2 still requiring that face masks be worn indoors (particularly when the MAC on Covid-19 indicated in February 2022 that this should be phased out);

162.3 requiring only one dose of a Covid-19 vaccine, even if the prescribed regiment is two, to be considered vaccinated against Covid-19.

162.4 to restrict an unvaccinated person's rights and freedoms, but to reward a person with his rights and freedoms immediately upon receiving a first dose even if he has not completed a prescribed regiment;

162.5 distinguishing between hotels, lodges, bed and breakfast, timeshare facilities, resorts and guest houses and other public places;



162.6 compelling unvaccinated persons entering South Africa to undergo Covid testing while not requiring vaccinated persons to undergo testing.

THE AMENDED REGULATIONS INFRINGE UPON RIGHTS CONFERRED BY THE CONSTITUTION

163. The 2022 surveillance regulations make drastic inroads into and unjustifiably infringe on the basic constitutional rights of South Africans.

DIGNITY

164. The right to human dignity affirms the intrinsic worth of every person, and is foundational to several other rights in the Bill of Rights. The right to dignity informs constitutional interpretation and adjudication.

165. The approach of the 2022 surveillance regulations, especially in as far as it speaks to the vaccination status of a person, stigmatises and excludes unvaccinated persons from a large part of public life. An unvaccinated person, relying on constitutional rights when refusing to vaccinate, is deemed to have made a selfish and foolish choice. Ostensibly, such a person becomes deserving of exclusion from public life.

166. In public discourse, a narrative has emerged branding the unvaccinated (or even unboosted) as irresponsible and careless. The vaccination mandate

enshrined in the 2022 surveillance regulations makes this narrative part of the law. It is dehumanising as its moves a large part of the public to the fringes of public life, based solely on an individual medical choice.

167. The 2022 surveillance regulations further shift the duty, to exclude more than half of the population from general public life, onto owners and operators of venues. Businesses that would prefer to uphold and respect the constitutional rights and freedoms of others are effectively penalised (including being held criminally liable) by a hard cap on the number of persons who can visit or gather at their place of business.

168. The 2022 surveillance regulations question the intelligence, integrity, and ability of adult human beings to make their own decisions in respect of their health, safety in public and bodily integrity.

169. Ngcobo J in the matter of Barkhuizen v Napier 2007 (5) SA 323 CC, stated at paragraph 57 that "self-autonomy, or the ability to regulate one's own affairs, even to one's own detriment, is the very essence of freedom and a vital part of dignity". The statement especially applies to the most intimate of matters, such as the right to make your own informed medical decisions.

170. The penalising of a person relying on a fundamental constitutional right is constitutionally unacceptable.

PRIVACY

171. The vaccination policy of the 2022 surveillance regulations compels an unvaccinated person to disclose personal medical information and her/his vaccination status if they want to attend a Regulation 16B(3) gathering or if they want to enter South Africa.

172. This infringes upon the privacy of the unvaccinated person in circumstances where the limitation is not reasonable or justified.

173. The right to privacy intends to restrain both governmental and private actions that threaten an individual's privacy. The requirement to disclose intimate medical information infringes directly upon that right.

BODILY INTEGRITY

174. The right to bodily and psychological integrity is guaranteed by section 12(2)(b) of the Constitution. It is a component of the broader fundamental rights, which generally deals with 'freedom' and 'security of person'. The relevant text reads as follows:

> *"2. Everyone has the right to bodily and psychological integrity, which includes the right –*
>
> *a) to make decisions concerning reproduction;*
>
> *b) to security in and control over their body; and*
>
> *c) not to be subjected to medical or scientific experiments without their informed consent."*

175. This right is self-explanatory and entails the right of adults to make autonomous decisions regarding their body.

176. A covert mandatory vaccination policy and /or a vaccination status discrimination policy limits and violates unvaccinated persons' right to bodily integrity by denying them control over their bodies, with the threat that should they refuse vaccination, their ability to participate freely in normal activities in society will be curtailed.

177. The limitation of this right under the current circumstances is unreasonable and unjustified in an open and democratic society based on human dignity, equality, and freedom.

FREEDOM OF CONSCIENCE, FREEDOM OF RELIGION, BELIEF AND OPINION

178. The situation described above amounts to societal pressure, which has the effect of limiting the right of the unvaccinated person to freedom of conscience, belief, and opinion.

179. Many members of society hold a sincere, well-founded belief and informed opinion that the several known and unknown side effects of available vaccinations do not outweigh the risk of Covid-19 for them and have therefore taken one or more regiments of such vaccines. At the same time, many members of society, having had Covid-19 or even not having had Covid-19, hold a sincere, well-founded and informed opinion that the risk of future

contraction of the disease does not pose a serious adverse health risk that outweighs the effort of vaccination and boosting or the several known and unknown side-effects of the vaccination.

180. A system that effectively penalises people who hold sincere beliefs and opinions regarding the risks and benefits, of recently developed vaccines, whereof knowledge of the short, medium, and long-term side-effects remain unclear and whereof recommendations and even approvals by different health authorities in different countries keep changing and being revoked or reinstated, infringes upon section 15 rights of the Constitution. It imperils social cohesion and stability and drives a wedge between people, organisations and sections of society. This is particularly so where one encounters such an issue as divisive as mandatory medical intervention.

181. Mandatory vaccination policies, directly and indirectly, restrict how the beliefs of persons who oppose this type of coercion find expression. Freedom of conscience favours a non-coercive position.

182. In contrast with a non-coercive position, the threat of exclusion or penalties in the case of owners or operators of venues who refuse to adopt or apply a covert mandatory vaccination policy and/or a vaccination status discrimination policy may eventually become so pressing that persons who oppose mandatory vaccination on moral, religious, and factual grounds act against their conscience and held beliefs or opinions and subject themselves to committing or subjecting to such infringements.

FREEDOM OF ASSEMBLY

183. In terms of Section 17 of the Constitution, everyone has the right to assemble with other persons. This is not only a basic human right but a social need and forms part of normal society where people gather and assemble for numerous purposes. The 2022 surveillance regulations limit and restrict such right irrationally, unreasonably, and without justification.

LAW OF GENERAL APPLICATION

184. A fundamental right may only be limited by way of a law of 'general application'. Furthermore, the law so limiting must be sufficiently clear, accessible, and precise so that those who are affected by it can ascertain the extent of their rights and obligations.

185. As already shown above, this is not the case with 2022 surveillance regulations.

LIMITATIONS ANALYSIS

186. The limitation of a constitutional right in the Bill of Rights is permissible only to the extent that the limitation is reasonable and justifiable in an open and democratic society based on dignity, equality, and freedom. The advantage

and benefit to be gained by limiting the right must be compelling, tangible, and substantive.

187. The limitation must consider all relevant factors, such as the nature of the right, the importance of the purpose of the limitation, the nature and extent of the limitation, the relation between the limitation and its purpose and less restrictive means to achieve the purpose.

188. The 2022 surveillance regulations do not strike an appropriate balance between the relevant facts of the matter and the objectives of the regulations as to warrant the limitation of the constitutional rights of the public.

189. No evidence exists that any of the available vaccines prevent the spread of Covid-19. Differentiating between persons on the basis of vaccination choice or status does not make society safer.

190. Therefore, the limitation of constitutional rights and freedoms in the 2022 surveillance regulations is not justified.

CONTRA BONOS MORES

191. The Applicant contends that there is no justice or morality under these circumstances in coercing an autonomous individual into receiving medical treatment against his will, convictions, and beliefs. Equally, there is no justice or morality in excluding such a person from public life. This is even more important to remember where 1) no benefit for excluding such a person from

public life can be shown and 2) the exclusion is a direct result of an intimate and personal choice made in terms of a freedom guaranteed by the Constitution.

192. A vaccination mandate of any nature (covert, express, tacit or implied) is and generally should be found to be against the morals and convictions of a society based on mutual respect and dignity.

193. The currently available data demonstrate that the public is not in favour of mandatory vaccination and is generally not eager to be vaccinated, and even more so not willing to take booster shots.

194. The 2022 surveillance regulations do not seek to exclude a small section of society or one little group from general public life, it seeks to effectively exclude the majority of the population.

195. The Applicant submits that the vaccination status provisions of the 2022 surveillance regulations are *contra bonos mores*.

FURTHER GROUNDS OF REVIEW

196. It is noteworthy that notwithstanding that Regulation 16B makes no mention of past infections (and the consequent extension of natural immunity beyond the normally sufficient *ex ante* natural ability to combat the disease), the efficacy of natural disease-acquired immunity is clearly recognised in Regulation 16C (3)(d) for those entering the country. If natural disease-acquired immunity is good enough for travel and is not a threat to the country,

then surely it must be good enough for gatherings. At the very least, the failure to provide in the 2022 surveillance regulations for persons who have natural disease-acquired immunity due to past infections when attending gatherings is irrational and unjust.

197. Furthermore no provision is made for venues or premises which can "safely" accommodate more than 50% of their capacity – even if prescribed distancing is followed (and even if vaccination discrimination is allowed). A number of businesses are able to safely accommodate 100% of their capacity (outdoor and indoor). This should be provided for in the regulations and has been irrationally omitted.

198. The managing of "vaccinated" versus "unvaccinated" gatherings is practically impossible (or at the least extremely burdensome). Businesses and gatherings that do not want to exclude more than half of their patrons will need to either cut their service capacity in half or create duplicate gatherings. Businesses and civil society institutions, including inter alia schools, churches, sport stadia, expos, etc., are placed between a rock and a hard place. They need to either cut their ability to service the public in half or incur double costs in order to service everybody. The impact on businesses (including costs to "police" and administer the regulations) is unreasonably burdensome.

199. It cannot be expected of businesses and civil society to carry the costs and risks associated with the 2022 surveillance regulations.

200. Non-compliance with the 2022 surveillance regulations is a criminal offence with a penalty of up to 10 years imprisonment (Regulation 20). This is a particularly severe punishment which far exceeds any sanction imposed for failure to comply with regulations under the former "National State of Disaster".

201. In the premises the limitations imposed by the 2022 surveillance regulations cannot be justified. They fall to be set aside.

URGENCY AND NECESSITY OF EXPEDITED REVIEW

202. There is only one just and equitable order available to a Court in the current circumstances. The 2022 surveillance regulations must be set aside in *toto.*

203. The 2022 surveillance regulations constitute a continuing and daily risk to the rule of law, the public, the economy, and individual freedoms. The infringement of the rights of individuals is continuous and ongoing and the application must be heard as soon as possible.

204. The Applicant (and clearly other interested parties) did not anticipate that the Minister would simply adopt the 2022 surveillance regulations of 4 May 2022. Knowing that other parties were already bringing similar challenges, the Applicant elected to first consider their papers, as to avoid unnecessary burdening this Court. The applicant called for discussions with the Minister and the President with the hope that litigation could be avoided. The Applicant has acted with all reasonable haste in launching this application.

205. This matter is urgent and the Applicant seeks an order that the Rules relating to time frames, forms and service be dispensed with in terms of Rul 6(12) of the Rules of Court.

206. The 2022 surveillance regulations are fully operational. Failure to comply exposes the public to severe criminal sanction. Individuals furthermore face the continued infringement of their various rights as set out hereinabove for as long as the 2022 surveillance regulations are allowed to remain in force and effect.

207. Urgent intervention from the Court is required to prevent the ongoing illegal and unlawful limitation of constitutional rights and freedoms. The prejudice that will be suffered by the Applicant, its supporters as well as the general public, should the order prayed for not be granted, is immense. The Applicant has no other remedy available to it other than to approach this Court for relief.

208. In the above circumstances, the Applicant has set expedited timelines in the notice of motion in line with the expedited timelines set by Solidariteit (case number 25363/2022). Should alternative truncated timelines not be agreed between the parties, or the matter be subjected to specific directions from the Judge President, the matter will be set down as per the notice of motion.

CONCLUSION

209. The Applicant will file its supplementary affidavit in terms of Rule 53(4) of the Rules of Court after receipt of the record in line with the time frames set out in

notice of motion or as directed by the Judge President. I submit that the truncated time period for the filing of the record is reasonable in the circumstances of this matter since this matter is urgent and the Minister is bound to prepare and make such record available in other cases which are serving before Court already.

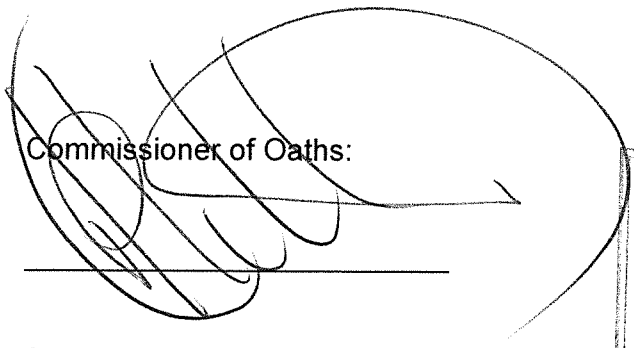
210. I have set out hereinabove the basis for the review of the amended regulations. These grounds of review may be supplemented in terms of Rule 53(4) of the Uniform Rules of Court after receipt of the Rule 53 record sought by the Applicant.

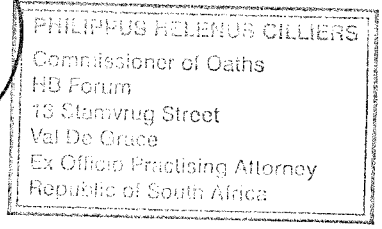
WHEREFORE the Applicant prays for relief on the terms as set out in the notice of motion attached hereto.

P J LE ROUX

Signed and sworn/affirmed to before me at PRETORIA on this 19th day of May 2022, the deponent having acknowledged that he knows and understands the contents of this affidavit; which is deposed to in accordance with the regulations governing the administration of an oath as more fully set out in Government Notice R1258 of 21 July 1972, as amended by Government Notice 1648 dated 19 August 1977 and Government Notice 903 dated 10 July 1998.

Commissioner of Oaths:





Signature

Full names: _____

Status: _____

Street address: _____

teenstrydigheid effektiewelik aan te spreek, en

3.3.3. Die aksies neem wat binne hul uitsluitlike diskresie nodig is om die oortreding, botsing en/of teenstrydigheid aan te spreek, wat insluit maar nie beperk is tot die voorstel van wysigings tot die Akte en die belê van 'n spesiale Ledevergadering ten einde daardie wysigings goed te keur.

4. DOELSTELLINGS EN MAGTE VAN DIE MAATSKAPPY

4.1. Ter nakoming van artikel 1 van bylaag 1 tot die Wet, verklaar die Maatskappy hiermee die volgende hoofdoelstellings:

4.1.1. Die bevordering van konstitusionele orde, vryemarkbeginsels en 'n kapitaalkragtige, regverdige, en volhoubare sake-omgewing in die Republiek;

4.1.2. Die skepping van 'n selfstandige sakegemeenskap in die Republiek;

4.1.3. Die behoud van eiendomsreg, holisties gesien, ooreenkomstig die Grondwet van die Republiek;

4.1.4. Om, sonder inperking, bydraes en skenkings te doen tot die Helpende Hand Beursfonds en/of die Solidariteit Helpende Hand NPC;

4.1.5. Om kollektief namens Lede, ondersteuners en die publiek met Owerhede te onderhandel en verhoudinge met Owerhede asook plaaslike, nasionale en internasionale instansies en persone te beding te einde die doelstellings van die Maatskappy te bevorder;

4.2. Die Maatskappy verklaar hiermee die volgende aanvullende doelstellings, maar sonder inperking van die algemene aard van die Maatskappy hoofdoelstellings:

4.2.1. Om as 'n openbare sakewaghond wat fokus op die regte en belange van sy Lede, ondersteuners en lede van die publiek in die algemeen, op te tree;

4.2.2. Om ondersoek in te stel oor gevalle waar die regte van Lede, ondersteuners asook die publiek oor die algemeen, geskend en/of ingeperk word, en om waar nodig ook op te tree ten einde daardie regte te beskerm of te bevorder.

4.3. Die volgende magte word ook, sonder inperking van die algemene magte van die Maatskappy soos uitgeoefen Direksie kragtens die Wet, aan die Maatskappy verleen:

4.3.1. Om deur selfregulering en privaat institusionele infrastruktuur 'n alternatiewe

Extract of memorandum of incorporation

SAKELIGA

sake-omgewing te skep waarbinne ekonomiese aktiwiteit voortgesit kan word;

4.3.2. Om die Maatskappy se Lede, ondersteuners en lede van die publiek in die uitoefen van hul belange en regte, hetsy op plaaslike, nasionale of internasionale vlak, by te staan, te adviseer, te ondersteun en/of te verteenwoordig.

4.3.3. Om die publiek oor die algemeen by te staan met die bevordering van hul regte op 'n plaaslike, nasionale en internasionale vlak;

4.3.4. Om 'n vrye, onafhanklike en goedgunstige sake-omgewing in die Republiek te beskerm, stimuleer en waar nodig te skep;

4.3.5. Om regsgedinge in te stel, daartoe toe te tree, om sake te opponeer en/of te verdedig, om as *amicus curiae* in sake op te tree, deel te neem aan appèlle, hersienings, en om voor enige Owerheid te verskyn, submissies te maak, te argumenteer, op te tree, teen te staan en/of te ondersteun.

4.3.6. Om met die Owerhede, politieke partye, lede van die sakewêreld, die media asook enige ander lid van die publiek te kommunikeer, te onderhandel, in te debat te tree en om ook waar nodige daardie persone en/of instansies te voorsien met voorstelle, vertoë, submissies, verslae, argument en/of inligting.

4.3.7. Om navorsing ter bevordering van hierdie doelstellings te doen asook om inligting in te samel, statistiek op te bou, te verwerk en te publiseer;

4.3.8. Om onafhanklike regsadvies oor enige saak wat enige doelstelling van hierdie Akte raak, te bekom en waar nodig om ook regsverteenwoordiging aan te stel om die Maatskappy te verteenwoordig in die bevordering van hierdie doelstellings.

4.3.9. Om met ander organisasies of persone met soortgelyke doelstellings te onderhandel, ooreenkomste te sluit, projekte te hardloop, sake te bevorder, befondsing te voorsien, befondsing te ontvang, ondersteuning te bied en/of te affilieer.

4.3.10. Om deel te neem in die bestuur, beheer of aktiwiteite van enige ander organisasie wat soortgelyke doelstellings as die van die Maatskappy het en om in hulle te belê, belange te bekom en/of om vennootskappe of samewerkingsooreenkomste met hulle aan te gaan.

4.3.11. Om enige persoon of organisasie te vergoed vir hul dienste gelewer aan of

PJLR02

DEPARTMENT OF CO-OPERATIVE GOVERNANCE

NO. R. 960 **30 September 2021**

DISASTER MANAGEMENT ACT, 2002: AMENDMENT OF REGULATIONS ISSUED IN TERMS OF SECTION 27(2)

I, Dr Nkosazana Dlamini Zuma, Minister of Cooperative Governance and Traditional Affairs, designated under section 3 of the Disaster Management Act, 2002 (Act No. 57 of 2002), having declared a national state of disaster published by Government Notice No. 313 of 15 March 2020, and extended by Government Notices Nos. 646 of 5 June 2020, 765 of 13 July 2020, 889 of 15 August 2020, 995 of 14 September 2020, 1090 of 14 October 2020, 1225 of 14 November 2020, No.1341 of 11 December 2020, No. R. 15 of 13 January 2021, No. R. 86 of 11 February 2021, No. R. 193 of 11 March 2021, No. 333 of 14 April 2021, No. R. 424 of 14 May 2021, No. R. 476 of 30 May 2021, No. R. 493 of 11 June 2021, No. R. 611 of 12 July 2021, No. R. 733 of 12 August 2021 and No. R. 867 of 12 September 2021, hereby in terms of section 27(2) of the Disaster Management Act, 2002, after consultation with the relevant Cabinet members, make the Regulations in the Schedule.

NC Nzuma

DR NKOSAZANA DLAMINI ZUMA, MP
MINISTER OF COOPERATIVE GOVERNANCE AND TRADITIONAL AFFAIRS
DATE: 30.09.2021.

SCHEDULE

Definitions

1. In these Regulations, "the Regulations" means the regulations published by Government Notice No. R. 480 of 29 April 2020 as amended by Government Notices Nos. R. 608 of 28 May 2020, R. 714 of 25 June 2020, R.763 of 12 July 2020, R. 846 of 31 July 2020 R. 891 of 17 August 2020, No. 999 of 18 September 2020, No. 1011 of 20 September 2020, No. 1053 of 1 October 2020, No. 1104 of 21 October 2020, No. 1199 of 11 November 2020, No. 1290 of 3 December 2020, No. 1346 of 15 December 2020, No.1370 of 17 December 2020, No. 1421 of 24 December 2020, No. 1423 of 29 December 2020, No 1435 of 29 December 2020, No. R. 11 of 11 January 2021, No. R. 69 of 1 February 2021, No. R. 92 of 13 February 2021, No. R. 93 of 13 February 2021, No. R. 152 of 28 February 2021, No. R. 284 of 30 March 2021, No. 376 of 22 April 2021, No. R. 477 of 30 May 2021, No. R. 530 of 15 June 2021, No. R. 532 of 17 June 2021, No. R. 565 of 27 June 2021, No. R. 567 of 29 June 2021, R. No. R. 610 of 11 July 2021, R. No. 612 of 14 July 2021 and R. No. 614 of 14 July 2021, No. R. 651 of 25 July 2021, No. 669 of 30 July 2021, No. R. 869 of 12 September 2021 and No. R.953 of 26 September 2021.

Amendment of Classification of Regulations

2. The Classification of the Regulations is hereby amended by—

(a) the substitution for Chapter 6 of the following Chapter:

"CHAPTER 6
ADJUSTED ALERT LEVEL 1

65. Application of Alert Level

65A. Notification by district municipalities
66. Movement of persons
66A. Opening and closure of schools, early childhood development centres and institutions of higher education
67. Mandatory protocols when in a public place
68. Attendance of funerals and cremations
69. Gatherings
70. Eviction and demolition of places of residence
71. Rental housing
72. Places and premises closed to the public
73. Initiation practices
74. Controlled visits by members of the public
75. Partial re-opening of borders
75A. Transportation of cargo
76. Public transport
77. Sale and dispensing of liquor
78. Operation of economic sector
79. Compliance officers
80. Offences and penalties"; and

(b) the substitution for Table 4 of the following Table:

"**TABLE 4**

Adjusted Alert Level 1".

Substitution of Chapter 6 of the Regulations

3. Chapter 6 of the Regulations is hereby substituted for the following Chapter:

"**CHAPTER 6**
ADJUSTED ALERT LEVEL 1

Application of Adjusted Alert Level

65. The regulations set out in this Chapter apply during Adjusted Alert Level 1.

Notification by district municipalities

65A. All district municipalities must, after consultation with its local municipalities in its area—

(a) alert communities within that district of the increasing number of infections;
(b) publish on their websites and in the local media, areas with high infection rates within the district; and
(c) update the information as and when it becomes available.

Movement of persons

66. (1) Every person is confined to his or her place of residence from 00H00 until 04H00 daily, unless a person—

(a) has been granted permission through directions issued by the relevant Cabinet member or a permit, which corresponds with Form 7 of Annexure A, to perform a service other than a service related to an activity listed under Table 4;

(b) is attending to a security or medical emergency; or

(c) arrives on a flight or is travelling to or from an airport which necessitates travelling during restricted hours of movement: Provided that the person traveling is in possession of a valid boarding pass as proof of flight or a copy of the airline ticket.

(2) Any person who fails to abide by the curfew referred to in subregulation (1) commits an offence and is, on conviction, liable to a fine or a period of imprisonment not exceeding six months, or to both such fine and imprisonment.

(3) Closing time for the following establishments, whether indoors or outdoors, is 23H00:

(a) cinemas;

(b) theatres;

(c) casinos;

(d) museums, galleries and archives;

(e) public swimming pools;

(f) beaches and public parks;

(g) game parks, botanical gardens, aquariums and zoos;

(h) gyms and fitness centres;

(i) restaurants bars, shebeens and taverns;

(j) venues hosting auctions;

(k) venues hosting professional sport; and

(l) venues hosting faith-based, or religious gatherings; and

(m) social, political and cultural gatherings.

(4) Inter-provincial travel is permitted.

Opening and closure of schools, early childhood development centres and institutions of higher education

66A. (1) The Cabinet member responsible for basic education may, by directions contemplated in regulation 4(3), announce further measures related to the management and reduction of risk at schools in the basic education sector, in order to address, prevent and combat the spread of COVID-19.

(2) The Cabinet member responsible for higher education may by directions contemplated in regulation 4(3), announce further measures related to the management and reduction of risk at institutions in the higher education sector, to address, prevent and combat the spread of COVID-19.

(3) Early childhood development centres will remain open.

(4) *(a)* The social distancing measures in primary schools is reduced to one metre.

(b) Strict adherence to all health protocols including the wearing of face masks, the washing of hands and hand sanitisation must be observed.

Mandatory protocols when in a public place

67. (1) For the purposes of these Regulations, a **'face mask'** means a cloth face mask or a homemade item that covers the nose and mouth, or another appropriate item to cover the nose and mouth.

(2) The wearing of a face mask is mandatory for every person when in a public place, excluding a child under the age of six years, and any person who fails to comply with a verbal instruction by an enforcement officer to wear a face mask, commits an offence and is, on conviction, liable to a fine or a period of imprisonment not exceeding six months, or to both such fine and imprisonment.

(3) No person will be allowed to—

(a) use, operate, perform any service on any form of public transport;

(b) enter or be in a building, place or premises, including government buildings, places or premises, used by the public to obtain goods or services; or

(c) be in any public open space,

if he or she is not wearing a face mask.

(4) The prohibition in subregulation (3)*(c)* shall not apply to a person who undertakes vigorous exercise in a public place, provided that the person maintains a distance of at least one and a half metres from any other person, and subject to directions on what is considered to be vigorous, issued by the Cabinet member responsible for health.

(5) An employer may not allow any employee to perform any duties or enter the employment premises if the employee is not wearing a face mask while performing his or her duties.

(6) Every business premises, including, but not limited to, a supermarket, shop, grocery store, retail store, wholesale produce market or pharmacy shall—

(a) determine their area of floor space in square metres;

(b) based on the information contemplated in paragraph *(a)*, determine the number of customers and employees that may be inside the premises at any time with adequate space available, on the basis of providing for a social distance of one and a half metres between persons;

(c) take steps to ensure that persons queuing inside or outside the premises are able to maintain a distance of one and a half metres from each other;

(d) provide hand sanitisers for use by the public and employees at the entrance to the premises; and

(e) assign, in writing, an employee or any other suitable person, as the compliance employee, who must ensure—

(i) compliance with the measures provided for in paragraphs *(a)* to *(d)*; and

(ii) that all directions in respect of hygienic conditions and limitation of exposure to persons with COVID-19 are adhered to.

(7) Any business whose premises exceeds the maximum number of customers and employees determined in subregulation (6) commits an offence and is, on conviction, liable to a fine or to imprisonment for a period not exceeding six months or to both such fine and imprisonment.

(8) All employers must, adopt measures to promote physical distancing of employees, including—

(a) enabling employees to work from home or minimising the need for employees to be physically present at the workplace;

(b) the provision for adequate space;

(c) restrictions on face to face meetings;

(d) special measures for employees with known or disclosed health issues or comorbidities, or with any condition which may place such employees at a higher risk of complications or death if they are infected with COVID-19; and

(e) special measures for employees above the age of 60 who are at a higher risk of complications or death if they are infected with COVID-19.

(9) The requirements as set out in subregulation (6) apply with the necessary changes, to any other building that is not provided for by subregulation (6).

(10) All courier and delivery services shall provide for minimal personal contact during delivery.

(11) All banks as defined in the Banks Act, 1990 (Act No. 94 of 1990) and non-bank financial institutions as defined in the Financial Sector Regulation Act, 2017 (Act No. 9 of 2017), must—

(a) (i) ensure that all automated teller machines located at their premises and branches that bears the name of that bank or a non-bank financial institution, have hand sanitisers for use by the public at each automated teller machine;

(ii) take reasonable steps to ensure that persons queuing at the automated teller machine on their premises and branches maintain a distance of one and a half metres from each other; and

(b) take reasonable steps to ensure implementation of these provisions by third parties hosting automated teller machines of a bank or non-bank financial institution through appropriate agreements.

Attendance of funerals and cremations

68. (1) Attendance of a funeral and cremation is limited to 100 persons or less and if the venue is too small to hold the prescribed number of persons observing a distance of at least one and a half metres from each other, then not more than 50 percent of the capacity of the venue may be

used, subject to strict adherence to all health protocols and all persons maintaining a distance of one and a half metres from each other.

(2) Night vigils are not allowed.

(3) After-funeral and cremation gatherings, including "after-tears" gatherings, are not allowed.

(4) During a funeral and cremation, a person must wear a face mask and adhere to all health protocols and social distancing measures.

(5) The duration of a funeral or cremation service is restricted to a maximum of two hours.

Gatherings

69. (1) Every person, when attending a gathering and in order to limit exposure to COVID-19, must—

(a) wear a face mask;

(b) adhere to all health protocols;

(c) maintain a distance of at least one and a half metres from each other;

(d) adhere to the curfew hours as provided for in regulation 66; and

(e) adhere to any other health protocols and social distancing measures as provided for in directions issued by the relevant Cabinet member after consultation with the Cabinet member responsible for health.

(2) An owner or operator of any indoor or outdoor facility where gatherings are held must display the certificate of occupancy which sets out the maximum number of persons the facility may hold.

(3) An owner or operator of any indoor or outdoor facility where gatherings are held and who fails to display the certificate of occupancy as contemplated in subregulation (2), commits an offence and is, on conviction, liable to a fine or imprisonment for a period not exceeding six months or to both such fine and imprisonment.

(4) All—

(i) faith-based or religious gatherings; and

(ii) social, political and cultural gatherings;

are permitted but limited to 750 persons or less for indoor venues and 2000 persons or less for outdoor venues and if the venue is too small to hold the prescribed number of persons observing a distance of at least one and a half metres from each other, then not more than 50 percent of the capacity of the venue may be used, subject to strict adherence to all health protocols and social distancing measures.

(5) A convener of a faith based, religious, social, political or cultural gathering must ensure compliance with the limitation on the number of persons attending such a gathering contemplated in subregulation (4).

(6) A convener of a faith based, religious, social, political or cultural gathering who fails to comply with subregulation (5), commits an offence and is, on conviction, liable to a fine or imprisonment for a period not exceeding six months or to both such fine and imprisonment.

(7) Any person who attends a faith based, religious, social, political or cultural gathering and who knows or ought reasonably to have known or suspected that the number of persons exceeds the limitation

provided for in subregulation (4), commits an offence and is, on conviction, liable to a fine or imprisonment for a period not exceeding six months or to both such fine and imprisonment.

(8) Gatherings at a workplace for work purposes are allowed, subject to strict adherence to all health protocols and social distancing measures.

(9) *(a)* Hotels, lodges, bed and breakfasts, timeshare facilities, resorts and guest houses are allowed full capacity of the available rooms for accommodation, with patrons wearing face masks and observing a distance of at least one and a half metres from each other when in common spaces.

(b) Restaurants, bars, shebeens and taverns are allowed, subject to a limitation of a maximum of 750 persons or less for indoor venues and 2000 persons or less for outdoor venues and if the venue is too small to hold 750 persons indoors or 2000 persons outdoors observing a distance of at least one and a half metres from each other, then not more than 50 percent of the capacity of the venue may be used.

(c) An owner or manager of a restaurant, bar, shebeen or tavern must ensure compliance with the limitation on the number of persons attending such a restaurant, bar, shebeen or tavern contemplated in paragraph *(b)*.

(d) An owner or manager of a restaurant, bar, shebeen or tavern who fails to comply with paragraph *(c)*, commits an offence and is, on conviction, liable to a fine or imprisonment for a period not exceeding six months or to both such fine and imprisonment.

(e) Any person who attends a restaurant, bar, shebeen or tavern and who knows or ought reasonably to have known or suspected that the number of persons attending exceeds the limitation provided for in paragraph *(b)*, commits an offence and is, on conviction, liable to a fine or imprisonment for a period not exceeding six months or to both such fine and imprisonment.

(f) Conferencing, exhibitions, dining, gyms, fitness centres, casinos and entertainment facilities are subject to a limitation of a maximum of 750 persons or less for indoor venues and 2000 persons or less for outdoor venues and if the venue is too small to hold 750 persons indoors or 2000 persons outdoors observing a distance of at least one and a half metres from each other, then not more than 50 percent of the capacity of the venue may be used.

(g) An owner or operator of a conferencing, exhibition, dining, gym, fitness centre, casino or entertainment facility must ensure compliance with the limitation on the number of persons attending such a conferencing, exhibition, dining, gym, fitness centre or entertainment facility contemplated in paragraph *(f)*.

(h) An owner or manager of a conferencing, exhibition, dining, gym, fitness centre, casino and or entertainment facility who fails to comply with paragraph *(g)*, commits an offence and is, on conviction, liable to a fine or imprisonment for a period not exceeding six months or to both such fine and imprisonment.

(i) Any person who attends a conferencing, exhibition, dining, gym, fitness centre, casino or entertainment facility and who knows or ought reasonably to have known or suspected that the number of persons attending exceeds the limitation provided for in paragraph *(f)*, commits an offence and is, on conviction, liable to a fine or imprisonment for a period not exceeding six months or to both such fine and imprisonment.

(10) Sporting activities, including both professional and non-professional matches, by recognised sporting bodies are allowed, subject to strict adherence to the times of operation as provided for in regulation 66(3) and the following:

(a) Directions for sports matches issued by the Cabinet member responsible for sport after consultation with the Cabinet member responsible for health;

(b) only journalists, radio, television crew, security personnel, emergency medical services, and the necessary employees employed by the owners of the venue of the sport match, are allowed at the venue of the sport match;

(c) only the required number of players, match officials, support staff and medical crew required for the sport match, are allowed at the venue of the sport match;

(d) no spectators are allowed at the venue of the sports match; and

(e) international sport events involving countries with a low or medium COVID-19 infection and transmission rate are allowed.

(11) An owner or operator of a sporting facility or an organiser of a sporting event referred to in subregulation (10) must, when such sporting activities take place, ensure compliance with the prohibition on spectators contemplated in subregulation (10)*(d)*.

(12) An owner or manager of a sporting facility or an organiser of a sporting event referred to in subregulation (10) who fails to comply with subregulation (11), commits an offence and is, on conviction, liable to a fine or imprisonment for a period not exceeding six months or to both such fine and imprisonment.

(13) Any person who, as a spectator, attends a sporting facility must, when sporting activities contemplated in subregulation (10) take place, commits an offence and is, on conviction, liable to a fine or imprisonment for a period not exceeding six months or to both such fine and imprisonment.

(14) An enforcement officer must, where a gathering in contravention of the regulations takes place—

(a) order the persons at the gathering to disperse immediately; and

(b) if the persons refuse to disperse, take appropriate action, which may, subject to the Criminal Procedure Act, 1977 (Act No. 51 of 1977), include the arrest and detention of any person at the gathering.

Eviction and demolition of places of residence

70. (1) A person may not be evicted from his or her land or home or have his or her place of residence demolished for the duration of the national state of disaster unless a competent court has granted an order authorising the eviction or demolition.

(2) A competent court may suspend or stay an order for eviction or demolition contemplated in subregulation (1) until after the lapse or termination of the national state of disaster unless the court is of the opinion that it is not just or equitable to suspend or stay the order having regard, in addition to any other relevant consideration, to—

(a) the need, in the public interest for all persons to have access to a place of residence and basic services to protect their health and the health of others and to avoid unnecessary movement and gathering with other persons;

(b) any restrictions on movement or other relevant restrictions in place at the relevant time in terms of these Regulations;

(c) the impact of the disaster on the parties;

(d) the prejudice to any party of a delay in executing the order and whether such prejudice outweighs the prejudice of the persons who will be subject to the order;

(e) whether any affected person has been prejudiced in their ability to access legal services as a result of the disaster;

(f) whether affected persons will have immediate access to an alternative place of residence and basic services;

(g) whether adequate measures are in place to protect the health of any person in the process of a relocation;

(h) whether any occupier is causing harm to others or there is a threat to life; and

(i) whether the party applying for such an order has taken reasonable steps in good faith, to make alternative arrangements with all affected persons, including but not limited to payment arrangements that would preclude the need for any relocation during the national state of disaster.

(3) A court hearing an application to authorise an eviction or demolition may, where appropriate and in addition to any other report that is required by law, request a report from the responsible member of the executive regarding the availability of emergency accommodation, or quarantine, or isolation facilities pursuant to these Regulations.

Rental housing

71. (1) During the national state of disaster, the Rental Housing Tribunals established under the Rental Housing Act, 1999 (Act No. 50 of 1999)—

(a) must determine fair procedures for the urgent hearing of disputes; or

(b) may grant an urgent *ex parte* spoliation order including to restore the occupation of a dwelling or access to services provided that an affected party may, on 24 hours' notice, require that a hearing be promptly convened.

(2) During the national state of disaster and without derogating from the protections afforded by the Rental Housing Act, 1999 or any provincial unfair practice regulation in place or the duty to consider the interests of both the landlord and tenant on a just and equitable basis, the following conduct is presumed to be an unfair practice for purposes of the Act:

(a) The termination of services in circumstances where—

(i) the landlord has failed to provide reasonable notice and an opportunity to make representations;

(ii) the landlord has failed, reasonably and in good faith, to make the necessary arrangements including to reach an agreement regarding alternative payment arrangements, where applicable; or

(iii) no provision has been made for the ongoing provision of basic services during the national state of disaster.

(b) The imposition of any penalty for the late payment of rental where the default is caused by the disaster, whether or not the penalty takes the form of an administrative charge or any other form other than interest.

(c) The failure of a landlord or tenant to engage reasonably and in good faith to make arrangements to cater for the exigencies of the disaster.

(d) Any other conduct prejudicing the ongoing occupancy of a place of residence, prejudicing the health of any person or prejudicing the ability of any person to comply with the applicable restrictions on movement that is unreasonable or oppressive having regard to the prevailing circumstances.

(3) Where the protections afforded by any Unfair Practice Regulations in force in any province are greater than those provided in this regulation, the provisions of the provincial Unfair Practice Regulations shall apply.

(4) The Cabinet member responsible for human settlements must, after consulting with the Rental Housing Tribunals, issue directions disseminating information about the manner in which the Tribunals will conduct their proceedings during the national state of disaster including, but not limited to—

(a) the manner in which Tribunals will facilitate expeditious access to any aggrieved person; and

(b) the convening of remote hearings or the convening of hearings at any suitable place.

Places and premises closed to the public

72. (1) Night clubs are closed to the public.

(2) An owner or manager of a nightclub must ensure compliance with subregulation (1).

(3) An owner or manager of a night club who fails to comply with subregulation (2), commits an offence and is, on conviction, liable to a fine or imprisonment for a period not exceeding six months or to both such fine and imprisonment.

(4) The Cabinet member responsible for cooperative governance and traditional affairs may, by directions, determine a place or premises that must be closed, if there is a risk of any members of the public being exposed to COVID-19 at such a place or premises.

Initiation practices

73. (1) Initiation practices are permitted, subject to the submission of a risk adjusted plan for the conducting of initiation practices to the relevant Cabinet members by the provincial executive responsible for traditional affairs and strict adherence to all health protocols and social distancing measures as provided for in directions issued by the relevant Cabinet member after consultation with the Cabinet member responsible for health.

(2) Post-initiation celebrations ("*imigidi*") are permitted.

(3) The National House of Traditional Leaders and provincial houses of traditional leaders must take steps to ensure that traditional leaders are aware of the content of this regulation.

(4) Failure to adhere to these regulations and any directions that are issued in respect of initiation schools will result in the closure of initiation schools by the relevant authorities.

Controlled visits by members of the public

74. (1) All visits by members of the public to—

(a) correctional centres;
(b) remand detention facilities;
(c) police holding cells;
(d) military detention facilities;
(e) health establishments and facilities, except to receive treatment or medication, subject to strict adherence to health protocols; and
(f) older persons' residential facilities,

are permitted to the extent and in the manner directed by the relevant Cabinet member.

(2) The Independent Electoral Commission will be allowed to visit the institutions referred to in subregulation (1), where required for the purposes of voter registration, or special voting, to the extent and in the manner set out in Directions by the relevant Cabinet member.

Partial re-opening of borders

75. (1) The 20 land borders which are fully operational, will remain as such and the 33 land borders which were closed, will remain closed.

(2) Traveling to and from the Republic is allowed, subject to subregulation (3).

(3) Daily commuters from neighbouring countries who attend or teach at a school in the Republic, and who are allowed entry into

and exit from the Republic, are subject to compliance with protocols relating to—

(a) screening for COVID-19 and quarantine or isolation, where necessary;
(b) the wearing of a face mask;
(c) transportation; and
(d) sanitisation and social distancing measures as per the relevant health protocols on safety and prevention of the spread of COVID-19.

(4) *(a)* International air travel is restricted to the following airports—

(i) OR Tambo International Airport;
(ii) King Shaka International Airport;
(iii) Cape Town International Airport;
(iv) Lanseria International Airport; and
(v) Kruger Mpumalanga International Airport.

(b) Long-haul flight departures and landings at the airports listed in paragraph *(a)* are permitted during the hours of curfew as provided for in regulation 67(1).

(c) All international travellers arriving at the airports listed in paragraph *(a)* must provide a valid certificate of a negative COVID-19 test, recognised by the World Health Organisation, which was obtained not more than 72 hours before the date of travel.

(d) In the event of the traveller's failure to submit a certificate as proof of a negative COVID-19 test, the traveller will be required to do an antigen test on arrival at his or her own cost and in the event of a traveller testing positive for COVID-19, he or she will be required to isolate him or herself at his or her own cost, for a period of 10 days.

(5) All commercial seaports will remain open and small crafts, and all passenger ships, including cruise ships, will be allowed entry into seaports, in-line with all health and border law enforcement protocols.

Transportation of cargo

75A. (1) Rail, ocean, air and road transport is permitted for the movement of cargo to and from other countries and within the Republic, subject to national legislation and any directions issued in terms of subregulation (2), for the transportation of goods for export and for import.

(2) The Cabinet member responsible for trade, industry and competition may, after consultation with the Cabinet members responsible for transport and finance, issue directions that provide for the management, administration and prioritisation of exports or imports, taking into account the need to prevent and limit the spread of COVID-19 and to deal with the destructive and other effects of the COVID-19 pandemic.

(3) The Cabinet member responsible for transport may, after consultation with the Cabinet members responsible for cooperative governance and traditional affairs, trade, industry and competition, health, justice and correctional services, finance and public enterprises, issue directions relating to health protocols applicable to sea cargo operations and air freight operation.

Public transport

76. (1) For purposes of this regulation "long distance travel" is a trip of 200 km or more.

(2) The Cabinet member responsible for transport must, after consultation with the Cabinet members responsible for cooperative governance and traditional affairs, health, police, trade, industry and competition, and justice and correctional services, issue directions for the resumption of different modes of public transport to cater for the gradual return to work of people, in respect of—

(a) domestic air travel;
(b) rail, bus services, taxi services;
(c) e-hailing services;
(d) private vehicles; and
(e) passenger ships, including cruise ships.

(3) Bus and taxi services—

(a) may not carry more than 70 percent of the licensed capacity for long distance travel; and
(b) may carry 100 percent of the licensed capacity for any trip not regarded as long distance travel in terms of subregulation (1).

(4) A driver, owner or operator of public transport may not allow any member of the public who is not wearing a face mask, to board or be conveyed in a public transport owned or operated by him or her.

(5) The directions to be issued by the Cabinet member responsible for transport must set out the health protocols that must be adhered to and the steps to be followed for the limitation of the exposure of members of the public using public transport to COVID-19.

Sale, dispensing and transportation of liquor

77. (1) The sale of liquor—

(a) by a licensed premises for off-site consumption, is permitted during licensed trading hours, subject to the laws governing such licenses; and
(b) by a licensed premises for on-site consumption is permitted, subject to strict adherence to the curfew contemplated in regulation 66.

(2) The consumption of liquor in public places, except in licensed on-site consumption premises, is not permitted.

(3) The transportation of liquor is permitted.

(4) The sale and consumption of liquor in contravention of subregulations (1) and (2) is an offence.

Operation of economic sector

78. (1) Businesses may operate except for those set out in Table 3.

(2) Relevant health protocols and social distancing measures for persons employed in private residences must be adhered to.

(3) Relevant health protocols and social distancing measures set out in directions must be adhered to, in addition to the occupational health and safety directions issued by the Cabinet member responsible for employment and labour, and applicable labour legislation.

(4) *(a)* Firms must adhere to any sector-specific health protocols intended to limit the spread of COVID-19 in the sector concerned.

(b) Sector-specific health protocols may address matters such as work rotation, staggered working hours, shift systems, remote working arrangements, special measures affecting persons with greater vulnerabilities or similar measures, in order to achieve social distancing, protect employees or limit congestion in public transport and at the workplace.

(c) Sector-specific health protocols where these are still to be developed, must be developed and issued by Cabinet members responsible for a sector in consultation with the Cabinet member responsible for health.

Compliance officers

79. (1) Industries, businesses and entities, both private and in the public sector, must—

(a) designate a COVID-19 compliance officer who must oversee—
  (i) the implementation of the plan referred to in paragraph *(b)*; and
  (ii) strict adherence to the standards of hygiene and health protocols relating to COVID-19 at the workplace;

(b) develop a plan containing measures to ensure that the workplace meets the standards of health protocols, adequate space for employees and social distancing measures for the public and service providers, as required; and

(c) retain a copy of the plan for inspection, which plan must also contain the details of the COVID-19 compliance officer.

(2) A person in control of a retail store or institution must—

(a) take steps to ensure that customers keep a distance of at least one and a half metres from each other and that all directions in respect of health protocols and social distancing measures are strictly adhered to; and

(b) designate a compliance officer to ensure that safety controls are strictly adhered to and display the name of the compliance officer prominently in the store or institution in a visible area.

Offences and penalties

80. (1) For the duration of the national state of disaster, any person who hinders, interferes with, or obstructs an enforcement officer in the exercise of his or her powers, or the performance of his or her duties in terms of these Regulations, is guilty of an offence and, on conviction, liable to a fine or to imprisonment for a period not exceeding six months or to both such fine and imprisonment.

(2) For the purposes of this Chapter, any person who fails to comply with or contravenes a provision of regulations 66(1) and (3), 67(2),

(3) and (7), 76(3)*(a)*, and 77(1) and (2) of these Regulations commits an offence and is, on conviction, liable to a fine or to imprisonment for a period not exceeding six months or to both such fine and imprisonment.".

Substitution of Table 4 of the Regulations

4. Table 4 of the Regulations is hereby substituted for the following Table:

"TABLE 4
ADJUSTED ALERT LEVEL 1

All persons who are able to work from home must do so. However, persons will be permitted to perform any type of work outside the home, and to travel to and from work and for work purposes under Adjusted Alert Level 1, subject to—

(a) strict adherence to health protocols and social distancing measures;

(b) the return to work being phased-in in order to put in place measures to make the workplace COVID-19 ready;

(c) the return to work being done in a manner that avoids and reduces risks of infection; and

(d) the work not being listed under the specific exclusions in this Table.

	SPECIFIC EXCLUSIONS
1.	Night vigils.
2.	After-funeral and cremation gatherings including "after-tears" gatherings.
3.	Night clubs.
4.	The land borders that remain closed, excluding the land borders contemplated in regulation 75(1).
5.	Attendance of any sporting event by spectators.
6.	Exclusions relating to public transport services as set out in the directions issued by the Cabinet member responsible for transport.
7.	Exclusions relating to education services as set out in the directions issued by the Cabinet members responsible for education.".

Form 7 of Annexure A

5. Form 7 of Annexure A:

"FORM 7
PERMIT TO TRAVEL TO PERFORM A SERVICE

- *Please note that the person to whom the permit is issued must at all times present a form of identification together with this permit. If no identification is presented, the person to whom the permit is issued will have to return to his or her place of residence.*

I, being the head of institution, with the below mentioned details,

Surname:				
Full names:				
Identity number:				
Contact details:	**Cell nr.**	**Tel nr(w)**	**Tel nr(h)**	**E-mail address**
Physical Address of Institution:				

hereby certify that the below mentioned official/employee is performing services in my institution

Surname:	
Full names:	
Identity number:	
Place of residence of employee:	

Signed at _____, on this the _____ day of _____ 20_____.

_____
Signature of Head of Institution".

Official stamp of Institution

Commencement

6. This amendment to the Regulations will come into operation on publication in the *Gazette*.

PJLR03

DEPARTMENT OF CO-OPERATIVE GOVERNANCE

NO. R. 1915 **22 March 2022**

DISASTER MANAGEMENT ACT, 2002: AMENDMENT OF REGULATIONS ISSUED IN TERMS OF SECTION 27(2)

I, Dr Nkosazana Dlamini Zuma, Minister of Cooperative Governance and Traditional Affairs, designated under section 3 of the Disaster Management Act, 2002 (Act No. 57 of 2002), having declared a national state of disaster published by Government Notice No. 313 of 15 March 2020, and extended by Government Notices Nos. 646 of 5 June 2020, 765 of 13 July 2020, 889 of 15 August 2020, 995 of 14 September 2020, 1090 of 14 October 2020, 1225 of 14 November 2020, No.1341 of 11 December 2020, No. R. 15 of 13 January 2021, No. R. 86 of 11 February 2021, No. R. 193 of 11 March 2021, No. 333 of 14 April 2021, No. R. 424 of 14 May 2021, No. R. 476 of 30 May 2021, No. R. 493 of 11 June 2021, No. R. 611 of 12 July 2021, No. R. 733 of 12 August 2021, No. R. 867 of 12 September 2021, No. R. 1031 of 13 October 2021, No. R. 1501 of 13 November 2021, No. R. 1598 of 10 December 2021, No. R. 1672 of 14 January 2022, No. R. 1758 of 14 February 2022 and No. R.1875 of 14 March 2022 hereby in terms of section 27(2) of the Disaster Management Act, 2002, after consultation with the relevant Cabinet members, make the Regulations in the Schedule.

NC Zuma

DR NKOSAZANA DLAMINI ZUMA, MP
MINISTER OF COOPERATIVE GOVERNANCE AND TRADITIONAL AFFAIRS
DATE: 22 03 2022

SCHEDULE

Definitions

1. In these Regulations, "the Regulations" means the regulations published by Government Notice No. R. 480 of 29 April 2020 as amended by Government Notices Nos. R. 608 of 28 May 2020, R. 714 of 25 June 2020, R.763 of 12 July 2020, R. 846 of 31 July 2020 R. 891 of 17 August 2020, No. 999 of 18 September 2020, No. 1011 of 20 September 2020, No. 1053 of 1 October 2020, No. 1104 of 21 October 2020, No. 1199 of 11 November 2020, No. 1290 of 3 December 2020, No. 1346 of 15 December 2020, No.1370 of 17 December 2020, No. 1421 of 24 December 2020, No. 1423 of 29 December 2020, No 1435 of 29 December 2020, No. R. 11 of 11 January 2021, No. R. 69 of 1 February 2021, No. R. 92 of 13 February 2021, No. R. 93 of 13 February 2021, No. R. 152 of 28 February 2021, No. R. 284 of 30 March 2021, No. 376 of 22 April 2021, No. R. 477 of 30 May 2021, No. R. 530 of 15 June 2021, No. R. 532 of 17 June 2021, No. R. 565 of 27 June 2021, No. R. 567 of 29 June 2021, R. No. R. 610 of 11 July 2021, R. No. 612 of 14 July 2021 and R. No. 614 of 14 July 2021, No. R. 651 of 25 July 2021, No. 669 of 30 July 2021, No. R. 869 of 12 September 2021; No. R.953 of 26 September 2021; No. R.960 of 30 September 2021, No. R. 1024 of 11 October 2021, No. R. 1633 of 17 December 2021, No. R. 1646 of 21 December 2021, No. R. 1659 of 30 December 2021, No. R. 1715 of 1 February 2022 and No. R. 1759 of 15 February 2022.

Amendment of regulation 67 of the Regulations

2. Regulation 67 of the Regulations is hereby amended by—

(a) the substitution for subregulations (2), (3) and (4) of the following subregulations:

"(2) The wearing of a face mask is mandatory for every person when in an indoor public place, excluding a child under the age of six years, and any person who fails to comply with a verbal instruction by an enforcement officer to wear a face mask, commits an offence and is, on conviction, liable to a fine or a period of imprisonment not exceeding six months, or to both such fine and imprisonment.

(3) A person not wearing a face mask will not be allowed to—

(a) use, operate, perform any service on any form of public transport; or

(b) enter or be in a building, place or premises, including government buildings, places or premises, used by the public to obtain goods or services.

(4) (a) All persons in an open public space need not wear a mask but must maintain a distance of at least one metre from another person.

(b) The school environment is excluded from the requirement of maintaining a distance of at least one metre from another person.";

(b) the substitution for paragraphs *(b)* and *(c)* of subregulation (6) of the following paragraphs:

"(b) based on the information contemplated in paragraph *(a)*, determine the number of customers and employees that may be inside the premises at any time with adequate space available, on the basis of providing for a social distance of one metre between persons;

(c) take steps to ensure that persons queuing inside or outside the premises are able to maintain a distance of one metre from each other;" and

(c) the substitution for subparagraph (11)*(a)*(ii) of the following subparagraph:

"(ii) take reasonable steps to ensure that persons queuing at the automated teller machine on their premises and branches maintain a distance of one metre from each other; and".

Amendment of regulation 68 of the Regulations

3. Regulation 68 of the Regulations is hereby substituted of the following subregulation:

"Attendance of funerals and cremations

68. (1) Attendance of a funeral and cremation is limited to 200 persons or less and if the venue is too small to hold the prescribed number of persons observing a distance of at least one metre from each other, then not more than 50 percent of the capacity of the venue may be used, subject to strict adherence to all health protocols.

(2) Night vigils are not allowed.

(3) After-funeral and cremation gatherings, including "after-tears" gatherings, are not allowed.

(4) During a funeral and cremation, a person must wear a face mask and adhere to all health protocols and social distancing measures.

(5) The duration of a funeral or cremation service is restricted to a maximum of two hours.".

Substitution of regulation 69 of the Regulations

4. Regulation 69 of the Regulations is hereby substituted of the following regulation:

"Gatherings

69. (1) All gatherings, including faith-based or religious, social, political and cultural, gatherings at restaurants, bars, shebeens and taverns; gatherings at conferencing, exhibitions, dining, gyms, fitness centres, casinos and entertainment, facilities, gatherings at venues hosting auctions including agricultural auctions, sporting activities, including both professional and non-professional matches, by recognised sporting bodies, where persons who are—

(a) fully vaccinated and in possession of a valid vaccination certificate; or

(b) unvaccinated but in possession of a valid certificate of a negative COVID-19 test, recognised by the World Health Organisation, which was obtained not more than 72 hours before the date of the gathering,

are allowed at up to 50% of the capacity of the venue: Provided that entry to the venue is conditional upon production of a valid certificate as referred to in paragraph *(a)* or *(b)* and subject to strict adherence to all health protocols and social distancing measures.

(2) All gatherings, including faith-based or religious, social, political and cultural, gatherings at restaurants, bars, shebeens and taverns; gatherings at conferencing, exhibitions, dining, gyms, fitness centres, casinos and entertainment facilities, gatherings at venues hosting auctions including agricultural auctions, sporting activities, including both professional and non-professional matches, by recognised sporting bodies, where persons who are—

(a) not fully vaccinated or in possession of a valid vaccination certificate; or

(b) unvaccinated and not in possession of a valid certificate of a negative COVID-19 test, recognised by the World Health Organisation, which was obtained not more than 72 hours before the date of the gathering,

are allowed but limited to 1000 persons or less for indoor venues and 2000 persons or less for outdoor venues and if the venue is too small to hold the prescribed number of persons observing a distance of at least one metre from each other, then not more than 50 percent of the capacity of the venue may be used, subject to strict adherence to all health protocols and social distancing measures.

(3) An owner or operator of any indoor or outdoor facility where gatherings are held must display the certificate of occupancy which sets out the maximum number of persons the facility may hold.

(4) An owner or operator of any indoor or outdoor facility where gatherings are held and who fails to display the certificate of occupancy as contemplated in subregulation (3), commits an offence and is, on conviction, liable

to a fine or imprisonment for a period not exceeding six months or to both such fine and imprisonment.

(5) A convener of a gathering who fails to comply with subregulation (1) or (2), commits an offence and is, on conviction, liable to a fine or imprisonment for a period not exceeding six months or to both such fine and imprisonment.

(6) Gatherings at a workplace for work purposes are allowed, subject to strict adherence to all health protocols and social distancing measures.

(7) Hotels, lodges, bed and breakfasts, timeshare facilities, resorts and guest houses are allowed full capacity of the available rooms for accommodation, with patrons wearing face masks and observing a distance of at least one metre from each other when in common spaces.".

Amendment of regulation 75 of the Regulations

5. Regulation 75 of the regulations is hereby amended by—

(a) the substitution for subregulation (2) of the following subregulation:

"(2) Traveling to and from the Republic from neighbouring countries is allowed, subject to subregulation (3): Provided that travellers who are—

(a) fully vaccinated must upon arrival at the land border, produce, a valid vaccination certificate; and

(b) unvaccinated must upon arrival at the land border, provide a valid certificate of a negative COVID-19 test, recognised by the World Health Organisation, which was obtained not more than 72 hours before the date of travel."; and

(b) the substitution for paragraph (4)*(c)* of the following paragraph:

"(c) All international travellers arriving at the Ports of Entry listed in paragraph *(a)* who are—

(i) fully vaccinated must upon arrival at the Port of Entry, produce a valid vaccination certificate; and

(ii) unvaccinated must upon arrival at the Port of Entry, provide a valid certificate of a negative COVID-19 test, recognised by the World Health Organisation, which was obtained not more than 72 hours before the date of travel.".

(c) the addition in subregulation 4 of the following paragraph:

"*(e)* Outbound travellers from South Africa must comply with the requirements of the country of destination."

Amendment of regulation 79 of the Regulations

6. Regulation 79 of the Regulations is hereby amended by the substitution for subregulation (2) of the following subregulation:

"(2) A person in control of a retail store or institution must—

(a) take steps to ensure that customers keep a distance of at least one metre from each other and that all directions in respect of health protocols and social distancing measures are strictly adhered to; and".

Commencement

7. The amendment to Regulations will come into operation on publication in the *Gazette*.

GOVERNMENT NOTICES • GOEWERMENTSKENNISGEWINGS

DEPARTMENT OF CO-OPERATIVE GOVERNANCE

NO. R. 1988 **4 April 2022**

TERMINATION OF THE NATIONAL STATE OF DISASTER (COVID-19)

DISASTER MANAGEMENT ACT, 2002: (ACT NO. 57 OF 2002):

On 15 March 2020, I declared a national state of disaster (Covid-19) in terms of my powers under section 27(1)(*a*) of the Disaster Management Act, 2002 (the Act). This was extended in terms of section 27(5)(*c*) of the Act at one-month intervals to 15 April 2022.

I have, together with Cabinet, considered the current situation and the steps taken to augment existing legislation and contingency arrangements, and have decided to terminate the national state of disaster.

In determining precisely when each of the Regulations and Directions should be repealed, I have given consideration to, inter alia, the need for post-disaster recovery and rehabilitation, including the need to anticipate future disaster risk, reduce exposure, improve resilience, mitigate the effects of the disaster, create circumstances that will reduce the risks of a similar disaster and deal with the destructive and other effects of the disaster.

Therefore, I, Dr Nkosazana Dlamini Zuma, Minister of Cooperative Governance and Traditional Affairs, designated under section 3 of the Act, in terms of section 27(5)(*b*) of the Act hereby terminate the national state of disaster which I declared on 15 March 2020 as published in Government Gazette No. 43096 in Notice No.313 and which, in terms of section 27(5)(*c*) of the Act, I extended at one month intervals to 15 April 2022 and published in Government Gazette No. 46042 in Notice R. 1875.

(1) All regulations and directions made in terms of section 27(2) of the Act pursuant to the declaration of the national state of disaster to deal with Covid-19, are hereby repealed with immediate effect, save for the following:

(*a*) Regulation 67;

(*b*) Regulations 69;

(*c*) Regulations 75;

(*d*) Directions, as amended, issued in terms of Regulation 4(5) and (10), which provide for Social Relief of Distress Grant;

(*e*) Directions, as amended, issued in terms of Regulation 4(7)(*b*), which provide for the extension of the validity period of a learner's license, driving licence card, licence disc, professional driving permit and registration of a motor vehicle; and

(*f*) The Regulations in Chapter 8 and the Directions in terms thereof, which provide for the COVID-19 Vaccine Injury No-Fault Compensation Scheme.

(2) The Regulations and Directions referred to in subsection (1)(*a*) to (*e*) shall -

(*a*) not cease to operate or cease to be of force and effect due to the termination of the national state of disaster; and

(*b*) continue to operate and be of force and effect for a period of one month from today, whereupon they will automatically lapse.

(3) The Regulations and Directions referred to subsection (1)(*f*) shall -

(*a*) not cease to operate or cease to be of force and effect due to the termination of the national state of disaster; and

(*b*) continue to operate and be in force until terminated in terms of Regulation 100 of Chapter 8.

NZuma

DR NKOSAZANA DLAMINI ZUMA, MP

MINISTER OF COOPERATIVE GOVERNANCE AND TRADITIONAL AFFAIRS

DATE: 04.04.2022.

GOVERNMENT NOTICES • GOEWERMENTSKENNISGEWINGS

DEPARTMENT OF CO-OPERATIVE GOVERNANCE

NO. R. 1986 **4 April 2022**

DISASTER MANAGEMENT ACT, 2002: AMENDMENT OF REGULATIONS ISSUED IN TERMS OF SECTION 27(2)

I, Dr Nkosazana Dlamini Zuma, Minister of Cooperative Governance and Traditional Affairs, designated under section 3 of the Disaster Management Act, 2002 (Act No. 57 of 2002), having declared a national state of disaster published by Government Notice No. 313 of 15 March 2020, and extended by Government Notices Nos. 646 of 5 June 2020, 765 of 13 July 2020, 889 of 15 August 2020, 995 of 14 September 2020, 1090 of 14 October 2020, 1225 of 14 November 2020, No.1341 of 11 December 2020, No. R. 15 of 13 January 2021, No. R. 86 of 11 February 2021, No. R. 193 of 11 March 2021, No. 333 of 14 April 2021, No. R. 424 of 14 May 2021, No. R. 476 of 30 May 2021, No. R. 493 of 11 June 2021, No. R. 611 of 12 July 2021, No. R. 733 of 12 August 2021, No. R. 867 of 12 September 2021, No. R. 1031 of 13 October 2021, No. R. 1501 of 13 November 2021, No. R. 1598 of 10 December 2021, No. R. 1672 of 14 January 2022, No. R. 1758 of 14 February 2022 and No. R.1875 of 14 March 2022 hereby in terms of section 27(2) of the Disaster Management Act, 2002, after consultation with the relevant Cabinet members, make the Regulations in the Schedule.

NC Zuma

DR NKOSAZANA DLAMINI ZUMA, MP
MINISTER OF COOPERATIVE GOVERNANCE AND TRADITIONAL AFFAIRS
DATE: 04.04.2022.

SCHEDULE

Definitions

1. In these Regulations, "the Regulations" means the regulations published by Government Notice No. R. 480 of 29 April 2020 as amended by Government Notices Nos. R. 608 of 28 May 2020, R. 714 of 25 June 2020, R.763 of 12 July 2020, R. 846 of 31 July 2020 R. 891 of 17 August 2020, No. 999 of 18 September 2020, No. 1011 of 20 September 2020, No. 1053 of 1 October 2020, No. 1104 of 21 October 2020, No. 1199 of 11 November 2020, No. 1290 of 3 December 2020, No. 1346 of 15 December 2020, No.1370 of 17 December 2020, No. 1421 of 24 December 2020, No. 1423 of 29 December 2020, No 1435 of 29 December 2020, No. R. 11 of 11 January 2021, No. R. 69 of 1 February 2021, No. R. 92 of 13 February 2021, No. R. 93 of 13 February 2021, No. R. 152 of 28 February 2021, No. R. 284 of 30 March 2021, No. 376 of 22 April 2021, No. R. 477 of 30 May 2021, No. R. 530 of 15 June 2021, No. R. 532 of 17 June 2021, No. R. 565 of 27 June 2021, No. R. 567 of 29 June 2021, R. No. R. 610 of 11 July 2021, R. No. 612 of 14 July 2021 and R. No. 614 of 14 July 2021, No. R. 651 of 25 July 2021, No. 669 of 30 July 2021, No. R. 869 of 12 September 2021; No. R.953 of 26 September 2021; No. R.960 of 30 September 2021, No. R. 1024 of 11 October 2021, No. R. 1633 of 17 December 2021, No. R. 1646 of 21 December 2021, No. R. 1659 of 30 December 2021, No. R. 1715 of 1 February 2022, No. R. 1759 of 15 February 2022, and

No. R 1915 of 22 March 2022.

Amendment of the Classification of the Regulations

2. The Classification of the Regulations is hereby amended by the substitution for Chapter 8 of the following Chapter:

"88. Definitions
89. Establishment of COVID-19 Vaccine Injury No-Fault Compensation Scheme:
90. Administration of the Scheme
91. Financial management and oversight of the Scheme
91A. Governance and Oversight
92. Adjudication Panel and Appeal Panel
93. Eligibility
94. Compensation
95. Submission of claims and procedure
96. Effect of submission of claims on right to claim damages in court proceedings
97. Causality determination
98. Adjudication of claims
99. Appeal
100. Duration and termination of Scheme
101. Condonation
102. Contact details of Scheme.".

Amendment of regulation 67 of the Regulations

3. Regulation 67 of the Regulations is hereby substituted by the following regulation:

"Mandatory protocols when in a public place

67. (1) For the purposes of these Regulations, a 'face mask' means a cloth face mask or a homemade item that covers the nose and mouth, or another appropriate item to cover the nose and mouth.

(2) The wearing of a face mask is mandatory for every person when in an indoor public place, excluding a child under the age of six years.

(3) No person will be allowed to—

(a) use, operate, perform any service on any form of public transport; or

(b) enter or be in a building, place or premises, including government buildings, places or premises, used by the public to obtain goods or services,

if he or she is not wearing a face mask.

(4) *(a)* All persons in an open public space need not wear a face mask but must maintain a distance of at least one metre from another person.

(b) The school environment is excluded from the requirement of maintaining a distance of at least one metre from another person.

(5) An employer may not allow any employee to perform any duties or enter the employment premises if the employee is not wearing a face mask while performing his or her duties.

Substitution of regulation 69 of the Regulations

4. Regulation 69 of the Regulations is hereby substituted of the following regulation:

"Gatherings

69. (1) All gatherings, including faith-based or religious, social, political and cultural, gatherings at restaurants, bars, *shebeens* and taverns; gatherings at conferencing, exhibitions, dining, gyms, fitness centres, casinos and entertainment, facilities, gatherings at venues hosting auctions including agricultural auctions, sporting activities, including both professional and non-professional matches, by recognised sporting bodies, where persons who are—

(a) fully vaccinated and in possession of a valid vaccination certificate; or

(b) unvaccinated but in possession of a valid certificate of a negative COVID-19 test, recognised by the World Health Organisation, which was obtained not more than 72 hours before the date of the gathering,

are allowed at up to 50% of the capacity of the venue: Provided that entry to the venue is conditional upon production of a valid certificate as referred to in paragraph *(a)* or *(b)* and subject to strict adherence to all health protocols and social distancing measures.

(2) All gatherings, including faith-based or religious, social, political and cultural, gatherings at restaurants, bars, *shebeens* and taverns; gatherings at conferencing, exhibitions, dining, gyms, fitness centres, casinos and entertainment facilities, gatherings at venues hosting auctions including agricultural auctions, sporting activities, including both professional and non-professional matches, by recognised sporting bodies, where persons who are—

(a) not fully vaccinated or in possession of a valid vaccination certificate; or

(b) unvaccinated and not in possession of a valid certificate of a negative COVID-19 test, recognised by the World Health Organisation, which was obtained not more than 72 hours before the date of the gathering,

are allowed but limited to 1000 persons or less for indoor venues and 2000 persons or less for outdoor venues and if the venue is too small to hold the prescribed number of persons observing a distance of at least one metre from each other, then not more than 50 percent of the capacity of the venue may be used, subject to strict adherence to all health protocols and social distancing measures.

(3) An owner or operator of any indoor or outdoor facility where gatherings are held must display the certificate of occupancy which sets out the maximum number of persons the facility may hold.

(4) Gatherings at a workplace for work purposes are allowed, subject to strict adherence to all health protocols and social distancing measures.

(5) Hotels, lodges, bed and breakfasts, timeshare facilities, resorts and guest houses are allowed full capacity of the available rooms for accommodation, with patrons wearing face masks and observing a distance of at least one metre from each other when in common spaces.".

Amendment of regulation 75 of the Regulations

5. Regulation 75 of the regulations is hereby substituted of the following regulation:

"Partial re-opening of borders

75. (1) *(a)* The 21 land borders which are fully operational, will remain as such and the 32 land borders which were closed, will remain closed.

(b) The Cabinet member responsible for Home Affairs may, from the date of commencement of this amendment to the Regulations, issue directions regarding the opening and closing of any further Ports of Entry.

(2) Traveling to and from the Republic from neighbouring countries is allowed: Provided that travellers who are—

(a) fully vaccinated must upon arrival at the land border produce a valid vaccination certificate; and

(b) unvaccinated must upon arrival at the land border, provide a valid certificate of a negative COVID-19 test, recognised by the World Health Organisation, which was obtained not more than 72 hours before the date of travel.

(3) *(a)* International air travel is restricted to the following airports—

(i) OR Tambo International Airport;
(ii) King Shaka International Airport;
(iii) Cape Town International Airport;
(iv) Lanseria International Airport; and
(v) Kruger Mpumalanga International Airport.

(b) All international travellers arriving at the Ports of Entry listed in paragraph *(a)* who are—

(i) fully vaccinated must upon arrival at the Port of Entry, produce a valid vaccination certificate; and

(ii) unvaccinated must upon arrival at the Port of Entry, provide a valid certificate of a negative COVID-19 test, recognised by the World Health Organisation, which was obtained not more than 72 hours before the date of travel.".

(c) Outbound travellers from South Africa must comply with the requirements of the country of destination.

(4) All commercial seaports will remain open and small crafts, and all passenger ships, including cruise ships, will be allowed entry into seaports, in-line with all health and border law enforcement protocols.".

Substitution of Chapter 8 of the Regulations

6. Chapter 8 of the Regulations is hereby substituted of the following Chapter:

"CHAPTER 8
COVID-19 VACCINE INJURY NO-FAULT COMPENSATION SCHEME

Definitions

88. For the purposes of this Chapter, unless the context otherwise indicates—

'AEFI' means any untoward medical occurrence that may present after vaccination, whether or not it has a causal relationship to the administration of the vaccine concerned;

'claim' means a claim made in terms of regulation 95;

'claimant' means a person who makes a claim in terms of regulation 95;

'COVID-19 Vaccine Injury' means a serious injury as referred to in regulation 93(1) and specified as contemplated in regulation 93(3);

'dependant' means the spouse of the deceased person; the permanent life partner of the deceased person; the child of the deceased person; a person to whom the deceased person is legally liable for maintenance; or a person who is factually dependent upon the deceased person for maintenance;

'NISEC' means the National Immunisation Safety Expert Committee, a non-statutory, standing, advisory committee of independent experts, appointed by the Cabinet member responsible for Health;

'Promotion of Administrative Justice Act, 2000' means the Promotion of Administrative Justice Act, 2000 (Act No. 3 of 2000);

'Public Finance Management Act, 1999' means the Public Finance Management Act, 1999 (Act No. 1 of 1999); and

'the Scheme' means the COVID-19 Vaccine Injury No-Fault Compensation Scheme established by regulation 89.

Establishment of the COVID-19 Vaccine Injury No-Fault Compensation Scheme

89. (1) A COVID-19 Vaccine Injury No-Fault Compensation Scheme is hereby established in terms of section 27(2)*(c)*, *(m)* and *(n)* of the Act.

(2) The Scheme is an essential part of the COVID-19 vaccination roll-out, which is a critical component of the national plan and response to alleviate, contain and minimise the effects of the disaster, and ultimately to end the national state of disaster.

(3) The purpose of the Scheme is to provide expeditious and easy access to compensation, for persons who suffer from a COVID-19 Vaccine Injury caused by the administration of an approved COVID-19 vaccine, which was administered at an authorised facility within the Republic, as specified in directions issued by the Cabinet member responsible for Health in terms of regulation 93(3), without having to establish fault.

(4) In order to ensure the effective and efficient administration of the Scheme in a manner that ensures fairness in the assessment and administration of claims, and respects the constitutional rights of claimants, the Cabinet member responsible for Health must issue directions in consultation with the Cabinet member responsible for Finance in respect of—

(a) the requirements relating to the administration of the Scheme;

(b) the policy in respect of the administration of the Scheme;

(c) the reporting of a COVID-19 Vaccine Injury;

(d) the claims system;

(e) the eligibility requirements of the Scheme;
(f) the size of the Adjudication Panel, and the Appeal Panel;
(g) the qualifications for appointment of members of the Adjudication Panel, and members of the Appeal Panel; and
(h) any other matter relevant to the effective, efficient and fair administration of the Scheme.

Administration of the Scheme

90. (1) The National Department of Health is responsible for the administration of the Scheme and its funds.

(2) The Director-General of the National Department of Health must establish administration of the scheme and its funding arrangements, in consultation with the National Treasury.

Financial management and oversight of the Scheme

91. (1) The funds of the Scheme consist of—
(a) funds appropriated by an Act of Parliament to the vote of Health or from contingencies in terms of appropriation legislation or the Public Finance Management Act; and
(b) funds donated to the Scheme in accordance with existing donor procedures and requirements.

(2) The Cabinet member responsible for Finance may, in consultation with the Cabinet member responsible for Health, issue directions in respect of the requirements relating to the financial management and oversight of the Scheme that are in accordance with the Public Finance Management Act, 1999.

(3) The funds identified for the Scheme may not be utilised for purposes other than payment of compensation in terms of the Scheme; the implementation and administration of the Scheme; and as provided in regulation 100(3).

Governance and Oversight

91A. The Director General of Health, as the accounting officer, is responsible for overseeing the implementation of the Scheme in terms of this Chapter and the directions issued in terms hereof, and to provide advice to the Cabinet member responsible for Health and the Cabinet member responsible for Finance in respect of the implementation of the Scheme.

Establishment of the Adjudication Panel and Appeal Panel

92. (1) The functionaries of the claims adjudication process of the Scheme hereby established are—
(a) the Adjudication Panel; and
(b) the Appeal Panel.

(2) *(a)* The Adjudication Panel shall comprise of at least 3, but no more than 5 members.

(b) The Cabinet member responsible for Health must appoint the members of the Adjudication Panel, following a nomination process, and subject to the criteria set out in directions and the call for nominations, relating to qualifications, expertise and experience.

(c) The members of the Adjudication panel must between them have appropriate medical expertise, financial expertise, and expertise in the adjudication of compensation of injuries.

(3) *(a)* The Appeal Panel shall comprise of 3 or more permanent members and 2 additional members, who may be appointed if additional expertise is required, who all may be appointed by the Cabinet member responsible for Health following a nomination process, and subject to the criteria set out in the directions and the call for nominations, relating to qualifications, expertise and experience.

(b) The Appeal Panel must be chaired by an advocate or attorney with at least 15 years' experience.

(c) At least one of the permanent members of the Appeal Panel must have medical expertise and at least one of the permanent members of the Appeal Panel must have expertise in finance or in the assessment of damages.

(4) *(a)* The members of the Adjudication Panel and Appeal Panel must be independent from each other and possess appropriate expertise to fulfil their functions in respect of the implementation of the Scheme.

(b) The members of the Adjudication Panel and the permanent and additional members of the Appeal Panel are appointed for the period, and on the terms and conditions, determined in writing by the Cabinet member responsible for Health.

(c) The Director-General of the National Department of Health must provide necessary administrative support to the Adjudication Panel and Appeal Panel.

(d) The Adjudication Panel and Appeal Panel shall take their decisions independently in terms of these Regulation and the Directions thereunder, and no person shall interfere with their decisions.

(5) The Adjudication Panel and Appeal Panel must take decisions and make assessments in accordance with—

(a) the requirements contained in regulation 93 and the directions issued in terms of regulation 93(3); and

(b) the directions issued in terms of regulation 94.

(6) The Adjudication Panel must further comply with regulation 98 in the adjudication of claims.

(7) The Appeal Panel must further comply with regulation 99 in the adjudication of appeals.

Eligibility

93. (1) A person—

(a) who was vaccinated with a COVID-19 vaccine that was procured and distributed by the National Government and administered as part of the national vaccination programme as specified in directions as contemplated in subregulation (3)*(c)*; and

(b) who suffers from or has suffered from a serious COVID-19 Vaccine Injury as specified in directions as contemplated in subregulation (3); and

(c) whose serious COVID-19 vaccine injury is determined by NISEC to be causally related to the administration of the COVID-19 vaccine concerned,

is eligible for compensation from the Scheme subject to the provisions of regulation 94 and the directions issued in terms of these regulations, and in particular directions contemplated in subregulation (3) and regulation 94.

(2) A dependant of a deceased person, whose death was caused by a COVID-19 Vaccine Injury, where the requirements of subregulations 93(1)*(a)* to *(c)* are met, is eligible for compensation from the Scheme, subject to the provisions of regulation 94 and the directions issued in terms of these regulations, and in particular directions contemplated in subregulation (3) and regulation 94.

(3) The Cabinet member responsible for Health, in consultation with the Cabinet member responsible for Finance, must issue directions specifying—

(a) the types of injury that constitute a COVID-19 Vaccine injury that is covered by the Scheme;

(b) the types of loss or damage covered;

(c) the specific approved vaccines to be covered, which must be registered or otherwise approved by the South African Health Products Regulatory Authority and initially procured and distributed by the National Government;

(d) authorised sites in the Republic where COVID-19 vaccinations are officially administered;

(e) the duration of the COVID-19 Vaccine Injury after the administering of the vaccination that the Scheme will cover; and

(f) the period in respect of which claims for compensation may be submitted to the Scheme.

(4) A person who has submitted a claim for compensation under the Compensation for Occupational Injuries and Diseases Act, 130 of 1993 for an AEFI arising from vaccination is not eligible for compensation under the Scheme.

Compensation

94. (1) The Cabinet member responsible for Health, in consultation with the Cabinet member responsible for Finance, must issue directions specifying the compensation that will be provided under the Scheme.

(2) Such compensation shall—

(a) be a capped amount to be outlined in the directions, in respect of the type of injury listed under a COVID-19 Vaccine Injury; and

(b) make provision for lump sum compensation payments.

(3) The categories of compensation which may be awarded are for:

(a) death;

(b) permanent disability; and

(c) temporary disability.

(4) Compensation in terms of the Scheme shall only include those types of compensation specified in terms of directions.

Submission of claims and procedure

95. (1) Any person who maintains that he or she meets the requirements for claiming compensation from the Scheme in terms of regulation 93(1) or regulation 93(2) must report the AEFI in the manner and within the time period set by the directions, so as to allow for a causality determination by NISEC in terms in terms of regulation 97.

(2) Where a person seeks to claim from the Scheme without complying with regulation 95(1), the Scheme must direct the person's attention to the provisions of regulation 95(1) and provide the details of the process to report the AEFI.

(3) Following the communication of a causality determination by NISEC in terms of regulation 97, a claim to the Scheme must be submitted by an eligible person, or a person duly authorised to act on behalf of an eligible person, to the Scheme and must be submitted in the manner and within the time period set by the directions.

(4) The Cabinet member responsible for Health must, after consultation with the Director General of the National Department of Health, issue directions specifying—

(a) procedures for instituting and submitting claims to the Scheme, including the form to be used for submitting claims;

(b) procedures for claims to be adjudicated by the adjudication panel, including the period in which a claim must be adjudicated; and

(c) procedures for appealing any decision of the adjudication panel or any determination of NISEC, including the periods in which a claim must be appealed and in which the appeal must be decided.

Effect of submission of claims on right to claim damages in court proceedings

96. (1) Any person who elects to submit a claim to the Scheme in terms of these Regulations thereby agrees to follow and abide by the procedure for the adjudication and appeal of claims set out in these regulations.

(2) Any person who elects to submit a claim to the Scheme in terms of these regulations and is awarded compensation from the Scheme thereby abandons their right to institute a damages claim in a Court against any party arising from harm, loss or damage allegedly caused by a COVID-19 Vaccine Injury.

(3) The provisions of this regulation shall not affect the right of any claimant to review an adverse decision in the High Court in terms of the Promotion of Administrative Justice Act, 2000.

(4) The Cabinet member responsible for Health must ensure that the form for submitting a claim contemplated in regulation 95(4)(a) explains in plain language the effect of regulations 96(1) to 96(3).

Causality determination

97. (1) NISEC must determine the causality between the administration of a COVID-19 vaccine and the injury allegedly caused by the COVID-19 vaccine.

(2) To determine causality, NISEC must apply the World Health Organisation Methodology for Causality assessment of adverse events following immunisation, as may be published from time to time by the World Health Organisation.

(3) *(a)* The determination on causality on an AEFI and relevant information by NISEC must be communicated to the person concerned in terms of the directions.

(b) In the event of NISEC finding causality, the Scheme must refer the claim to the Adjudication Panel for adjudication in terms of regulation 98.

(c) If NISEC makes a determination of non-causality, the claimant may refer the matter to the Appeal Panel in terms of regulation 99(1)*(a)*.

Adjudication of claims

98. A claim contemplated in regulation 97(3)*(a)* will be adjudicated by the designated members of the Adjudication Panel, who must determine compensation in accordance with regulation 94 and the directions issued by the Cabinet member responsible for Health.

Appeals

99. (1) A claimant who is dissatisfied by—

(a) a determination of non-causality by NISEC as contemplated by regulation 97(3)*(b)*; or

(b) a decision of the adjudication panel as contemplated by regulation 98,

may appeal such decision to the Appeal Panel within the specified period.

(2) The Appeal Panel hearing an appeal in terms of subregulation (1) may—

(a) confirm, vary or set aside the determination of NISEC or the decision of the Adjudication Panel, whichever is applicable;

(b) where it deems it is necessary for the proper adjudication of an appeal, call for and receive new information or evidence relevant to the claim; and

(c) where it deems it is necessary for the proper adjudication of an appeal, appoint appropriately qualified persons (if already not part of the panel) to assist in the determination of the claim.

(3) Any decision of the Appeal Panel is final and binding, but may be reviewed under the Promotion of Administrative Justice Act, 2000.

Duration and termination of Scheme

100. (1) This Chapter, the directions issued in terms hereof, and the existence of the Scheme—

(a) will not cease to operate or cease to be of force and effect merely because the national state of disaster comes to an end; and

(b) will continue to operate and be of force and effect until a notice is published by the Cabinet member responsible for Health, in consultation with the Cabinet member responsible for Finance, in the *Gazette* terminating the Scheme.

(2) The Scheme shall not be terminated until—

(a) the period prescribed in the directions for the submissions of claims to the Scheme has expired; and

(b) all claims lodged with the Scheme within the period prescribed in the directions have been finalised.

(3) Any funds which remain in the Scheme immediately before it is terminated shall be deposited into the National Revenue Fund, or shall otherwise be dealt with in terms of an Act of Parliament.

Condonation

101. (1) A person who-

(a) is affected by a vaccine injury which manifested on or before the date of publication of this amendment to the Regulations; and

(b) contends that he or she has been unfairly precluded from obtaining compensation from the Scheme by virtue of these amendments to the Regulations,

may apply to the Appeal Panel for condonation in order to have his or her claim fairly dealt with and adjudicated.

(2) The Appeal Panel may grant condonation to a person envisaged in subregulation (1) where it is of the view that to do so would be justified in all the circumstances and would promote the aims of the Scheme.

(3) In cases other than those envisaged in sub-regulations (1) and (2) above, the Appeal Panel may grant condonation for a failure to comply with a time period set by these Regulations or the Directions issued thereunder where:

(a) good cause has been shown for the failure to comply with the time period;

(b) granting condonation would not preclude a proper assessment of the claim, including the question of causality; and

(c) granting condonation would promote the aims of the Scheme.

Contact details of Scheme

102. The contact details of the Scheme are as follows:

The Director General
National Department of Health
A B Xuma Building
128 Voortrekker Rd
Raslouw AH
PRETORIA
0157
eMail: dg@health.gov.za
Tel (012) 395 8402".

Transitional provisions

7. (1) The regulations and directions specified in sub-regulation (2) will—

(a) not cease to operate or cease to be of force and effect merely because the national state of disaster is terminated; and

(b) continue to operate and be of force and effect until one month after the national state of disaster is terminated, whereupon the regulations and directions concerned will automatically lapse.

(2) The regulations and directions specified in sub-regulation (1) are as follows:

(a) Regulation 67;

(b) regulations 69;

(c) regulations 75;

(d) directions, as amended, issued in terms of Regulation 4(5) and (10), which provide for Social Relief of Distress Grant; and

(e) directions, as amended, issued in terms of Regulation 4(7)*(b)*, which provide for the extension of the validity period of a learner's license, driving licence card, license disc, professional driving permit and registration of a motor vehicle.

(3) The Regulations in Chapter 8 and the Directions in terms thereof, which provide for the COVID-19 Vaccine Injury No-Fault Compensation Scheme will—

(a) not cease to operate or cease to be of force and effect merely because the national state of disaster is terminated; and

(b) continue to operate and be of force and effect until terminated in terms of Regulation 100 of Chapter 8.

Commencement

8. (1) Subject to sub-regulation (2), the amendments to the Regulations will come into operation on publication in the *Gazette.*

(2) The amendments to Chapter 8 of the Regulations shall be deemed to have come into operation on 22 April 2021.

POLR06

health
Department:
Health
REPUBLIC OF SOUTH AFRICA

Date:	15 February 2022		
To:	**Dr MJ Phaahla, MP** **Honourable Minister of Health**	From:	**Ministerial Advisory Committee (MAC) on COVID-19**

REVISED COVID-19 SCREENING REQUIREMENTS AT BORDERS AND PORTS OF ENTRY

Problem Statement and Task to Committee

- The MAC on COVID-19 was requested to review the current COVID-19 screening requirements for land, air and sea ports of entry (with reference to the advisory on *Screening Requirements at Borders and Ports of Entry (Land, Sea and Air),* dated 15th October 2021).

Background/ Current Information

- COVID-19 incidence has declined in all nine provinces, and the fourth wave of the pandemic in South Africa has been declared over. Together with regional reductions in case numbers, this suggests that a change in the current COVID-19 screening requirements at the borders is warranted. Concern has been expressed by the MAC on COVID-19 about the excessive resources allocated to testing strategies in asymptomatic and mild disease, contact tracing, and screening requirements at ports of entry. These resources should rather be redirected to reaching the desired vaccination target, maximizing the infrastructure and personnel available for enhanced vaccination service delivery models.

- Current regulations gazetted on 15 December 2020[1] require that a person entering the Republic must:
  - Be subjected to screening on arrival at the point of entry and must present a completed traveller health questionnaire to a port health official; and
  - Provide to the port health official a valid negative COVID-19 Polymerase Chain Reaction (PCR) test result, performed not more than 72 hours before date of departure from the country of origin; or
  - If not in possession of a valid negative COVID-19 PCR test result, be subjected to antigen testing at the point of entry.

- Those who test positive on arrival may be subjected to isolation at an approved facility at their own cost.

- It is further noted that the applicable regulations covering quarantine and isolation have recently been amended.[2] All mention of quarantine has been removed, and the period of

[1]Disaster Management Act, 2002: Amendment of Regulations issued in terms of section 27(2). Government Gazette No 44004, 15 December 2020

[2] Disaster Management Act, 2002: Amendment of Regulations issued in terms of section 27(2). Government Gazette No 45855 1 February 2022

isolation for symptomatic cases reduced to 7 days. No isolation is required for asymptomatic cases.

- The MAC on COVID-19 Advisory on *Screening Process for Land Border Crossings During the Festive Season* dated 30th December 2020, made the following recommendations, among others:
    - To discontinue COVID-19 testing requirements for land-border entry into South Africa.
    - To implement a "travel bubble" with selected neighbouring countries (Botswana, Eswatini, Lesotho, Mozambique, Namibia, Zimbabwe).

- These recommendations were, however, contingent on certain criteria being met by the selected countries (e.g. local transmission remaining below a specified threshold). Travellers from any country that was not part of the proposed "travel bubble" would need to provide proof of a negative PCR test or undergo antigen testing on arrival at their own cost.

- The MAC on COVID-19 advisory on *COVID-19 Screening Requirements at Borders and Ports of Entry (Land, Sea and Air)* dated 15th October 2021 reiterated this recommendation but stratified the ports of entry strategy to differentiate the travelers by risk of point of origin. This approach was not adopted by the Department of Health nor Department of Home Affairs due to concerns raised about the validity of vaccine passports and recognition of vaccine types, and ongoing concern about occupational health exposure to the essential personnel working at border crossings.

- The National Health Laboratory Service (NHLS) and private laboratories have raised concerns about capacity constraints and the cost implications of providing antigen testing at ports of entry. During a peak in incidence, the positivity rates for travelers rises to approx. 5%. The in-bound traveler numbers do not contribute to the overall incidence of COVID-19 inside South Africa, and the result of the test is only used to provide isolation guidance, which guidance has recently been modified. The NHLS has recommended that testing at all borders ceases.

- In addition, it has been pointed out that a PCR test is prohibitively expensive in some countries, making it unaffordable to many travelers, with a significant impact on economic and tourist travel.

- Vaccines still have limited availability in neighboring countries, with vaccine coverage varying from 14% to 47% (fully vaccinated). To enable comparative data between countries the total population vaccination coverage rates for selected Southern African Countries is shown below[3]:

Country	Vaccinated	Fully Vaccinated	Additional Doses	Per 100 people	Total Doses
Botswana	52%	47%		49	1128095
Eswatini	32%	29%		40	462652
Mozambique	35%	30%		65	19788759
Namibia	17%	14%		31	773702
South Africa	33%	28%	1%	51	29812348
Zimbabwe	29%	23%		52	7564190

[3] Ref: Tracking Coronavirus Vaccination Around the World. https://www.nytimes.com/interactive/2021/world/covid-vaccinations-tracker.html accessed on 31st January 2022.

Evidence Review

- With the advent of the COVID-19 pandemic and the approach to containment of a novel highly transmissible respiratory infection, countries imposed travel restrictions and requirements as a way of excluding travellers that were infected with COVID-19. According to the United Nations World Tourism Organisation, international tourist arrivals declined by about 1 billion or 74% between January and December 2020. In the first quarter of 2021, the United Nations World Tourism Organisation (UNWTO) World Tourism Barometer shows a decline of 88%.[4]

- Despite these measures, transmission of COVID-19 variants has not been prevented, with global distribution of the Delta and Omicron variants in particular demonstrated worldwide. Fourth/Fifth waves have been recorded in France, the Middle East, and several African countries.[5] World Health Organisation (WHO) and country policy is shifting towards an endemic COVID-19 response, with health care mitigation and increasing economic activity with open international movement.

- A recent meta-analysis based on both modelling and observational studies[6] noted that "the certainty of the evidence for most travel-related control measures and outcomes is very low". Nonetheless, the authors concluded that, "Broadly, (during an early containment phase) travel restrictions may limit the spread of disease across national borders. Symptom/exposure-based screening measures at borders on their own are likely not effective; PCR testing at borders as a screening measure likely detects more cases than symptom/exposure-based screening at borders, although if performed only upon arrival this will likely also miss a meaningful proportion of cases. Quarantine is likely to largely avoid further transmission from travellers. Combining quarantine with PCR testing at borders will likely improve effectiveness." In addition, the authors noted that any estimates of effectiveness would be dependent on a combination of factors such as the "levels of community transmission, travel volumes and duration, other public health measures in place, and the exact specification and timing of the measure".

- A personal communication report suggests that pre-travel testing performed in a South African private laboratory showed an overall PCR test positivity rate of 3.3% in the period October 2020-October 2021. Fluctuations in the PCR test positivity rate mimicked the waves of the pandemic, with a peak of 7.1% in January 2021 (second-wave) and 6.22% in July 2021 (third-wave). The data for January 2022 demonstrates a positivity rate of 5.2% amongst travellers.

- Vaccines against COVID-19 have been added to the existing public health and social measures (PHSM) as a way of managing the pandemic. Vaccines reduce the risk of severe disease, hospitalisation and death. Research also shows that vaccines reduce transmission of the virus to some extent.[7]

- With high rates of vaccination coverage in most of South Africa's trade partner countries outside Africa, international travel is opening up as vaccination is seen to reduce the risk of infection. Additional requirements have been applied in some countries for those that are not vaccinated.

[4] UNCTAD, 2021. *Global economy could lose over $4 trillion due to COVID-19 impact on tourism.* https://unctad.org/news/global-economy-could-lose-over-4-trillion-due-covid-19-impact-tourism

[5] Africa CDC, 2021. Outbreak Brief 87: Coronavirus Disease 2019 (Covid-19 Pandemic). (https://africacdc.org/download/outbreak-brief-87-coronavirus-disease-2019-covid-19-pandemic/

[6] Burns, Movsisyan et al, 2021. *International travel-related control measures to contain the COVID-19 pandemic: a rapid review.* Cochrane Database Syst Rev. 2021 Mar 25;3(3):CD013717. https://pubmed.ncbi.nlm.nih.gov/33763851/

[7] CDC, 2021. Science Brief: COVID-19 Vaccines and Vaccination, 15 September 2021. https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/fully-vaccinated-people.html

Several countries now categorise travel requirements according to vaccination status. Persons who are vaccinated are no longer required to provide viral tests while unvaccinated travellers must provide proof of a negative COVID-19 viral test (nucleic acid or antigen detection) prior to departure and may be required to isolate. Various permutations for further categorization of countries exist where countries are categorized as high-risk or having variants of concern. [8]

- South Africa and its neighbours are currently in inter-wave period of transmission of the virus, although daily infection rates remain high, the overall rate is stable or declining. At present, most European countries and the US are experiencing higher rates of transmission. Vaccination rates in European countries and the US are high, while southern Africa still has significantly lower vaccination rates.

- Recent changes to regulations (Gazette 45855 of 1 February 2022) have removed the need for quarantine in the event of close contact with a COVID-19 positive patient. Isolation for asymptomatic COVID-19 positive individuals is no longer required. Isolation for symptomatic COVID-19 positive persons is required for 8 days.

- All the above developments and evidence necessitate a review of the current COVID-19 screening requirements for land, air and sea ports of entry.

Recommendations

The risk of presentation of a case of COVID-19 and the contribution to the overall incidence of the disease in South Africa remains very low. With the prevalence of COVID-19 in South Africa, high exposure and vaccine related immunity, the risk of transmission to a South African resident is at very low levels. The documented incidence of COVID-19 is higher in South Africa than in neighbouring countries with South Africa contributing the most to the number of cases in the region.

As the region moves towards recognizing COVID-19 as endemic, with a view to a mitigation strategy to address the health risk of the infection, the MAC on COVID-19 therefore recommends that entry requirements for all international travelers to South Africa be reduced and even removed, opening the country to increased incoming travel, for economic or tourism purposes.

For entry into South Africa by air or sea (except from a neighbouring country), the following requirements should apply:

- A completed Traveler Health Questionnaire at all border entry points according to Port Health data requirements; symptom screening is not recommended for travelers to prevent the transmission of COVID-19, but may remain in place to recognize other emerging infectious diseases.
- Unvaccinated travelers in South African border and ports should be offered vaccinations in South Africa and where possible at the border. This vaccination program should be offered at no cost to the traveler, and can be used to enhance the vaccination numbers in the region amongst the highly mobile population.

For land borders with neighbouring countries (Botswana, Eswatini, Lesotho, Mozambique, Namibia, and Zimbabwe), only the following requirements should apply:

- A completed Traveler Health Questionnaire at all border entry points according to Port Health data requirements. Symptom screening is not recommended for travelers to prevent

[8] Covid-19 and EU Travel Restrictions, 2021. https://www.schengenvisainfo.com/news/covid-19/

transmission of COVID-19, but may remain in place to recognize other emerging infectious diseases.

- Unvaccinated travelers arriving at South African ports of entry should be offered vaccinations in South Africa, and where possible at the border. This vaccination program should be offered at no cost to the traveler and can be used to enhance the vaccination numbers in the region amongst the highly mobile population.

If Port Health Authorities wish to continue testing for COVID-19 against this advice, it is recommended that both PCR and Antigen Test results performed by an accredited laboratory, either 72 hours before travel or on arrival, be considered as valid.

The use of the COVID-19 Alert Application should be discontinued as there is very little uptake and movement data available to enable any reliance on the application.

Current symptom screening measures should continue at all ports of entry, with public health interventions to reduce transmission continued. The recommendation may change to align with the advice provided on gathering and masking recommendations in future.

Rationale for Recommendations

1. As many countries enter the mitigation phase of the pandemic with a shift towards an endemic COVID-19 response, are adopting measures to ensure a return to normal life and economic activities. This can be achieved through continuing with current PHSMs and increasing vaccination rates. As quarantine and isolation regulations have changed, the response to a traveler with a COVID-19 positive test has changed, with no action required. This makes the testing requirement an unnecessary burden on the health system, traveler and economic activity.

2. The World Health Organization (WHO) recommends that Member States consider a risk-based approach to the facilitation of international travel by lifting measures, such as testing and/or quarantine requirements, to individual travellers who:
   - were fully vaccinated, at least two weeks prior to travelling, with COVID-19 vaccines listed by WHO for emergency use or approved by a stringent regulatory authority; or
   - have had previous SARS-CoV-2 infection as confirmed by PCR within the 6 months prior to travelling and are no longer infectious as per WHO criteria for releasing COVID-19 patients from isolation.
   - If testing and/or quarantine requirements are lifted for travellers who meet the above-mentioned criteria, individuals who are unvaccinated or do not have proof of past infection should be offered alternatives, such the use of negative PCR tests, or antigen tests.[9]

3. The WHO further recommends that Member States not treat international travelers as a priority group for SARS-CoV-2 testing. In resource limited contexts, diverting testing resources from settings where testing can have a higher public health impact should be avoided.

4. Over the course of the pandemic, possibly due to more testing capacity in South Africa than surrounding nations, it appears that the impact of neighbouring countries on the South African epidemic is minimal, yet the economic impact of travel restrictions is significant.

[9] WHO, 2020. *Considerations for implementing a risk-based approach to international travel in the context of COVID-19. Interim guidance 16 December 2020.* Available on https://www.who.int/publications/i/item/WHO-2019-nCoV-Risk-based-international-travel-2020.1.

5. Testing measures instituted are not cost effective or affordable, neither for the National Health Laboratory Service/ Department of Health nor for travelers entering South Africa. This has impacted negatively on tourism, business travel, and economic activity in the region. Workers and small business owners such as taxis crossing the border cannot afford the cost of testing for each border crossing. Instances of travelers fraudulently crossing the border without valid PCR tests have the potential to increase the opportunities for bribery and corruption.

Thank you for consideration of this advisory.

Kind regards

PROF KOLEKA MLISANA **PROF MARIAN JACOBS**
CO-CHAIRPERSONS: MINISTERIAL ADVISORY COMMITTEE ON COVID-19
DATE:
CC:

- **Dr SSS Buthelezi (Director-General: Health)**
- **Dr N Crisp (Deputy Director-General: National Health Insurance)**

Disclaimer: As stipulated in its Terms of Reference, the MAC on COVID-19 is an advisory Committee to the Minister of Health and does not have any delegated powers to act on behalf of, or to commit, the Minister or Government to any actions. Recommendations offered by the MAC on COVID-19 constitute evidence-informed advice only and do not represent final decisions of the Minister of Health or government.

PJLR07

health
Department:
Health
REPUBLIC OF SOUTH AFRICA

Date:	16 February 2022		
To:	**Dr MJ Phaahla, MP** **Honourable Minister of Health**	From:	**Ministerial Advisory Committee (MAC) on COVID-19**

RESTRICTIONS ON GATHERINGS

Problem Statement and Task to Committee

Whether restrictions on indoor and/or outdoor gatherings can be amended or relaxed, given the current state of the pandemic.

Background/Current Information

- Currently, the regulations for adjusted alert level 1 (as updated on 30th December 2021) restrict gatherings to no more than 1000 people indoors and no more than 2000 people outdoors, provided a distance of 1.5 metres between people can be sustained. Where this is not possible, venues are permitted to fill to no greater than 50% of their maximum capacity. Furthermore, everyone attending a gathering is required to wear a mask.
- The current regulations apply to all gatherings, including religious gatherings, restaurants, bars, shebeens, taverns, conferences, exhibitions, gyms, and other entertainment facilities, amongst others.

Evidence review

- The evidence and rationale for moving towards a "mitigation" strategy rather than a "containment" strategy have been outlined in recent communication from the MAC ("Mitigating COVID-19 in South Africa: Going Forward Position Paper", 8th Feb 2022).
- The MAC position paper highlighted the principles for implementing public health and social measures (PHSMs) which have been advanced by the World Health Organization (WHO):
    - That, measures with the highest level of acceptability and feasibility and proven effectiveness, and which minimize the negative consequences on health and wellbeing of all members of society and the economy, should be adopted.
    - That the decisions to apply PHSMs must be weighed against the wider impact of these measures on health and well-being.
- The risk of SARS-CoV-2 transmission is much lower outdoors than indoors, owing primarily to better ventilation. It has been estimated that only ~1% of SARS-CoV-2 transmissions occur outdoors.[1]

Recommendations

- **That the current restrictions applicable to outdoor gatherings be lifted.**
    - In accordance with the previous MAC on COVID-19 position paper, the wearing of masks outdoors and physical distancing should no longer be mandatory. Good ventilation continues to be recommended where possible.

- **That the current restrictions on the number of persons allowed at indoor gatherings, the minimum physical distancing, and hence the 50% capacity rule, be lifted.**
    - In accordance with the previous MAC on COVID-19 position paper, the wearing of masks indoors should be retained initially, but be re-assessed at regular intervals. On a monthly basis, the need for mandatory mask-wearing at indoor gatherings should be assessed in relation to the COVID-19 caseload, and the extent to which any changes in caseload are attributable to the relaxation of the above restrictions. The ultimate aim should be lifting of indoor mask mandates.
    - Regardless of any decision on mandatory mask-wearing at indoor gatherings, high-risk individuals, such as the elderly, those who are immunocompromised, those with comorbid conditions and those with whom they have close contact (e.g. caregivers), should be encouraged to wear quality masks (preferably surgical masks rather than cloth masks) in such venues, particularly if the COVID-19 caseload in the area is high.
- If a new wave of COVID-19 infections leads to, or is expected to lead to, high rates of severe disease or death, then consideration can be given to reinstituting limits on gatherings, particularly indoor gatherings.
- Communication of this relaxation of the current Alert Level 1 restrictions needs to emphasize vaccination as being even more important at this stage in the pandemic response. Vaccination (including booster doses) remains a critical mitigation tool. High levels of vaccination coverage, particularly in vulnerable groups, contribute to the rationale for lifting restrictions such as those on gatherings.

Rationale for recommendations

- COVID-19 is expected to persist globally for years, possibly indefinitely. Costly, large-scale containment efforts are therefore inappropriate, and policies should be aimed at mitigation. While it is inevitable that easing restrictions on outdoor and indoor gatherings will allow for greater transmission of the virus,[2,3] the focus should now be on preventing severe disease ("mitigation") by promoting vaccination and focusing protective measures on high-risk individuals, rather than trying to prevent infections *per se* ("containment").
- South Africa now has a high degree of population immunity to SARS-CoV-2, which can be expected to offer strong protection against severe disease and death, as was seen in the recent Omicron wave.[4,5] SARS-CoV-2 seroprevalence exceeded 70% prior to the Omicron wave, and is expected to be even higher now. The virulence of future variants of SARS-CoV-2 and the degree to which prior immunity will confer protection from severe disease and death are uncertain however, and restrictions on gatherings may be reinstated in the future if necessary to reduce rates of hospitalisations and death attributable to COVID.
- The WHO paper on PHSMs (*see above*) states that "measures should have the highest level of acceptability and feasibility". Noting that many people are now choosing not to wear masks outside and that this is unlikely to significantly increase spread, removing this measure may in addition promote the wellbeing and goodwill of citizens.
- Reducing unnecessary restrictions will allow society to return to normal functioning to the greatest possible degree, and is expected to have significant economic and social benefits.

Process for implementation

- Regulation 69, related to "Gatherings", amended by Government Notice No. R1659 (Government Gazette No. 45715, 30 December 2021) will need to be amended in order to give effect to the changes recommended above.
- In particular, attention needs to be paid to the specific restrictions currently imposed on faith-based or religious gatherings, social, political and cultural gatherings, workplace gatherings, accommodation facilities, restaurants, bars, shebeens and taverns, conferencing, exhibition, dining, gym, fitness centre, casino and entertainment facilities.

Thank you for consideration of this advisory.

Kind regards

PROF KOLEKA MLISANA **PROF MARIAN JACOBS**
CO-CHAIRPERSONS: MINISTERIAL ADVISORY COMMITTEE ON COVID-19
DATE:
CC:

» **Dr SSS Buthelezi (Director-General: Health)**
» **Dr N Crisp (Deputy Director-General: National Health Insurance)**

Disclaimer: As stipulated in its Terms of Reference, the MAC on COVID-19 is an advisory Committee to the Minister of Health and does not have any delegated powers to act on behalf of, or to commit, the Minister or Government to any actions. Recommendations offered by the MAC on COVID-19 constitute evidence-informed advice only and do not represent final decisions of the Minister of Health or government.

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PJ4R08

SAKELIGA

SELFSTANDIGE SAKEGEMEENSKAP

21 April 2022

TO: Department of Health
ATTENTION: Tsakani Furumele
DELIVERED: **By email:** tsakani.furumele@health.gov.za

To whom it may concern,

SUBMISSION: AMENDMENTS TO THE REGULATIONS RELATING TO THE SURVEILLANCE AND THE CONTROL OF NOTIFIABLE MEDICAL CONDITIONS, 2022

This submission constitutes Sakeliga's comment on the proposed Regulations Relating to the Surveillance and the Control of Notifiable Medical Conditions (published for comment on 15 March 2022).

About Sakeliga

Sakeliga is a business group and public benefit organisation with more than 11,000 members in various enterprises across South Africa. Sakeliga promotes a favourable business environment in the public interest.

Submission

Sakeliga finds the proposed regulations to be detrimental to public health, unsound in law, and economically and socially harmful. The regulations constitute an attempt to give the public the impression that the national state of disaster on Covid-19 is being lifted when, in fact, it continues by another name. We maintain that the proposed regulations are so severely flawed – *inter alia* also with regard to process, assumptions, and construction – that they are irreparable and should be abandoned in their entirety.

While the regulations are of more general application than only to Covid-19, government has made it clear that the proposed regulations were crafted specifically for the purposes of giving the Minister of Health the power to continue with heretofore impermissible public health interventions, similar to what was implemented under the national state of disaster on Covid-19. Problematically, the regulations will not be limited in their application to matters relating to Covid-19, but to all matters relating to notifiable medical conditions – a list of conditions that is determined by the Minister by regulation. This creates the grave danger for the public of suffering the harmful effects of permanent Covid-19-type regulations not just for Covid-19 (regardless of Covid-19 constituting a disaster or not), but in their daily walks of life for a multitude and open-ended list of other diseases.

We are concerned that with the adoption of these regulations, the exigent-circumstances-requirement that is associated with states of disaster will be replaced with a default,

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entrenched state of health monitoring. This would entail various deleterious consequences for privacy, freedom, social harmony, and commercial flourishing.

We have, as a result, sought advice on the scope of the Minister's powers under the National Health Act (61 of 2003), and have been advised that the draft regulations, if adopted, will most likely be found to be *ultra vires* the empowering provisions of the Act. The Minister does not have the administrative authority to create a new system of law via regulations that will infringe upon the rights and freedoms of the public. We have been advised that the Minister's approach in framing the draft regulations undermines the rule of law, the separation of powers between the executive and the legislature, and is therefore unconstitutional. The Minister has seemingly conferred on himself the authority to regulate matters for which the legislature has failed to provide any authority or guidance on.

With regard to the regulations' merits as public health interventions, Sakeliga has considered the comments of several and diverse public health and medical researchers and scientists. We attach two documents in this regard, in which the authors scathingly reject the proposed regulations. In one, the researchers call the proposed regulations "an ill-conceived and misdirected attempt to continue preventing SARS-CoV-2 infections" and "oblivious to the new realities of Covid-19, two years into a pandemic."[1] In the other, the researchers on similar and other grounds conclude as well that "the Proposed Regulations are not grounded in science, and are unnecessary, illegal and disproportionate to the risks society faces."[2] We find these analyses comprehensive and significant in that, even while they were done independently and while there are differences between them, both reject the proposed regulations *in toto*, and consider it too flawed for remedy.

Notably, Medelson *et al* remarks that "influenza is not an NMC [notifiable medical condition], and like the "swine flu" (H1N1pdm09) pandemic influenza virus of 2009, the way forward for Covid-19 is to be considered in the same light..." They then proceed to recommend that Covid-19 could simply be added to current influenza community and hospital surveillance programmes. They explicitly reject several remaining compulsory public interventions relating to Covid-19, such as border and travel restrictions, hand hygiene, masking, etc., leaving room only for public health recommendations, rather than instructions. Similarly, Panda concludes that "no new legislation is required. Between the existing health regulations and the Disaster Management Act, government is able to adequately respond to pandemics."

It is common cause that the proposed Regulations Relating to the Surveillance and the Control of Notifiable Medical Conditions spring from a desire to replace the supposedly temporary measures under the regulations of the national state of disaster with standing measures under the National Health Act. Were it not for this desire, no new regulations would have been proposed at this time or of this sort. However, since Covid-19 cannot appropriately be considered a notifiable medical condition, none of the proposed regulations are fit for purpose or appropriate to replace existing regulations on notifiable medical conditions.

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[1] Mendelson, Madhi, Nel, Gray, Osih, & Venter. 22/03/2022. *The incoherent and illogical new government Covid-19 regulations are the real state of disaster.* Daily Maverick. Available online at https://www.dailymaverick.co.za/article/2022-03-22-the-incoherent-and-illogical-new-government-covid-19-regulations-are-the-real-state-of-disaster/

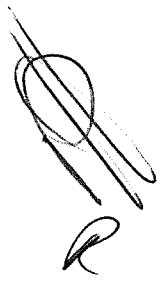
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Our position is as follows:

1. Covid-19 is not fit for classification as a notifiable medical condition.
2. There is no need to alter the existing regulations to deal with Covid-19, so the proposed regulations, having been developed for that purpose, lack a reasonable basis.
3. The extension of the draconian powers used to deal with Covid-19 to a long list of other conditions on a permanent basis would turn South Africa into a monitored society where freedom, privacy, and commerce would be unduly hindered and deprived.
4. The powers which the Minister affords himself in the regulations (in respect of any current or future notifiable medical conditions) are *ultra vires,* draconian, and unconstitutional.
5. The proposed regulations should be withdrawn.

We insist that the proposed regulations should not be promulgated and have instructed our legal team to prepare for litigation (or to assist others in litigation where appropriate), in the event that a version of the proposed regulations were to be promulgated.

Given the (unlawfully) limited timeframe offered to the public for comments on these proposed regulations, the above comments will have to suffice. We reserved all our rights.



PJLR 69

GOVERNMENT NOTICES • GOEWERMENTSKENNISGEWINGS

DEPARTMENT OF HEALTH

NO. 2060 **4 May 2022**

NATIONAL HEALTH ACT, 2003

REGULATIONS RELATING TO THE SURVEILLANCE AND THE CONTROL OF NOTIFIABLE MEDICAL CONDITIONS: AMENDMENT

The Minister of Health has, in terms of sections 90(1)(j), (k) and (w) of the National Health Act, 2003 (Act 61 of 2003), made the regulations in the Schedule.

DR M.J. PHAAHLA, MP
MINISTER OF HEALTH
Date: 04/05/2022

SCHEDULE

Definitions

1. In this Schedule "the Regulations" means the Regulations relating to the Surveillance and the Control of Notifiable Medical Conditions made under the National Health Act, 2003 (Act No. 61 of 2003), and published under Government Notice No. 1434 of 15 December 2017.

Insertion of Regulations 16A to 16C

2. The Regulations are hereby amended by the insertion, after regulation 16, of the following regulations:

"Wearing of face masks to contain the spread of COVID-19

16A. (1) Subject to the provisions of subregulations (5) to (6), the measures stipulated in subregulations (2) to (4) must be adhered to.

(2) For the purposes of this Regulation, a 'face mask' means a cloth face mask or a homemade item that covers the nose and mouth, or another appropriate item to cover the nose and mouth.

(3) A person must, when entering and being inside an indoor public place, wear a face mask.

(4) No person may use any form of public transport if they do not wear a face mask.

(5) The measures in this Regulation shall come into operation upon publication of this regulation in the Government Gazette.

(6) The Minister of Health may:

(a) determine that the measures in this Regulation, in part or in their entirety, are no longer necessary to contain the spread of COVID-19 and give notice of this determination in the Government Gazette, whereupon the measures concerned will no longer be in operation; and

(b) at any time after having made such a determination, determine that the measures concerned are once again necessary to contain the spread of COVID-19 and give notice of this determination in the Government Gazette, whereupon the measures concerned will resume operation.

Regulation of gatherings to contain the spread of COVID-19

16B. (1) Subject to the provisions of subregulations (10) to (11), the measures stipulated in subregulations (2) to (9) must be adhered to.

(2) For purposes of this regulation:

(a) a "gathering" means a planned assembly or meeting at a particular venue involving more than one hundred persons, whether for faith-based, religious, social, political, cultural, sporting, economic or recreational purposes; and

(b) "vaccinated against COVID-19" means having received at least one dose of a vaccine approved for use in respect of COVID-19 by the South

African Health Products Regulatory Authority or listed for this purpose by the World Health Organization.

(3) For any indoor gathering, a maximum of 50% of the venue capacity may be occupied, provided that every attendee must:
  (a) be vaccinated against COVID-19 and produce a valid vaccination certificate; or
  (b) produce a valid certificate of a negative COVID-19 test, recognised by the World Health Organization, which was obtained not more than 72 hours before the date of the gathering.

(4) Where sub-regulation (3) is not complied with, then attendance at the indoor gathering shall be limited to 1000 people or 50% of the capacity, whichever is smaller.

(5) For any outdoor gathering, a maximum of 50% of the venue capacity may be occupied, provided that every attendee must:
  (a) be vaccinated against COVID-19 and produce a valid vaccination certificate; or
  (b) produce a valid certificate of a negative COVID-19 test, recognised by the World Health Organisation, which was obtained not more than 72 hours before the date of the gathering.

(6) Where sub-regulation (5) is not complied with, then attendance at the outdoor gathering shall be limited to 2000 people or 50% of the capacity, whichever is smaller.

(7) An owner or operator of any indoor or outdoor facility where gatherings are held must display the certificate of occupancy which sets out the maximum number of persons the facility may hold.

(8) Hotels, lodges, bed and breakfasts, timeshare facilities, resorts and guest houses are allowed full capacity of the available rooms for accommodation, with patrons wearing face masks when in common spaces.

(9) All registered basic education institutions are excluded from the operation of this regulation.

(10) The measures in this Regulation shall come into operation upon publication of this regulation in the Government Gazette.

(11) The Minister of Health may:
  (a) determine that the measures in this Regulation, in part or in their entirety, are no longer necessary to contain the spread of COVID-19 and give notice of this determination in the Government Gazette, whereupon the measures concerned will no longer be in operation; and
  (b) at any time after having made such a determination, determine that the measures concerned are once again necessary to contain the spread of COVID-19 and give notice of this determination in the Government Gazette, whereupon the measures concerned will resume operation.

Regulation of persons entering the country to contain the spread of COVID-19

16C. (1) Subject to the provisions of subregulations (6) to (7), the measures stipulated in subregulations (2) to (5) must be adhered to.

(2) For purposes of this regulation, "vaccinated against COVID-19" means having received at least one dose of a vaccine approved for use in respect of COVID-

19 by the South African Health Products Regulatory Authority or listed for this purpose by the World Health Organization.

(3) All international travellers arriving at South African Ports of Entry must:

(a) be vaccinated against COVID-19 and produce a valid vaccination certificate; or

(b) produce a valid certificate of a negative PCR COVID-19 test, recognised by the World Health Organization, which was obtained not more than 72 hours before the date of departure; or

(c) produce a valid certificate of a negative antigen COVID-19 test performed by a medical practitioner, registered public health authority or accredited/approved laboratory which was obtained not more than 48 hours before the date of departure; or

(d) produce a valid certificate of a positive PCR COVID-19 test, recognised by the World Health Organization, for a test date less than 90 days prior to the date of arrival and more than 10 days prior to the date of arrival, together with a signed letter from a health care provider, registered in the country of origin, stating that the person has fully recovered from COVID-19, is not experiencing any new symptoms and is fit to travel.

(4) If an international traveller does not comply with subregulation (3):

(a) the traveller must undergo antigen testing for COVID-19 at the Port of Entry; and

(b) if the traveller tests positive for COVID-19 in the antigen test, the traveller will still be admitted into the Republic but, if the traveller is experiencing symptoms of COVID-19, the traveller must self-isolate for ten days after admission into the Republic.

(5) Subregulations (3) and (4) do not apply to:

(a) travellers who are under 12 years old; and

(b) daily commuters from neighbouring countries.

(6) The measures in this Regulation shall come into operation upon publication of this regulation in the Government Gazette.

(7) The Minister of Health may:

(a) determine that the measures in this Regulation, in part or in their entirety, are no longer necessary to contain the spread of COVID-19 and give notice of this determination in the Government Gazette, whereupon the measures concerned will no longer be in operation; and

(b) at any time after having made such a determination, determine that the measures concerned are once again necessary to contain the spread of COVID-19 and give notice of this determination in the Government Gazette, whereupon the measures concerned will resume operation.

Amendment of Annexure A to the Regulations

3. Table 2 of Annexure A to the Regulations is amended by inserting the following item between existing items 5 and 6:

5A	Coronavirus disease (COVID-19)

Commencement

4. These amendments to the Regulations will come into operation on publication in the *Gazette*.

Short Title

5. These Regulations are called Regulations Relating to the Surveillance and the Control of Notifiable Medical Conditions: Amendment, 2022.

PJLR10

health
Department:
Health
REPUBLIC OF SOUTH AFRICA

Date:	25 April 2022		
To:	**Dr MJ Phaahla, MP** **Honourable Minister of Health**	From:	**Ministerial Advisory Committee (MAC) on COVID-19**

MONITORING COVID-19 BETWEEN ACUTE OUTBREAKS AND DECIDING ON APPROPRIATE AND TIMELY RESPONSES

Problem Statement and Task to Committee

1. What are the most sensitive and feasible indicators that would identify an acute COVID-19 outbreak at the earliest possible time point?
2. Once a potential new acute outbreak is identified, how can the likely clinical impact (particularly in terms of severe disease) be determined in a timely manner?
3. If a new acute outbreak does occur, what actions should be taken to mitigate the severity of the outbreak? Can this be done without declaring a national state of disaster?

Background/Current Information

Although the possibility of a new variant of SARS-CoV-2 with increased transmissiblity, immune escape characteristics, and/or increased virulence, cannot be discounted entirely, future planning needs to be based on the most likely scenarios. COVID-19 is most likely to become endemic, with periodic acute outbreaks. A mitigation approach is therefore needed, with the ability to pivot to a more interventional stance if needed.

In the mitigation phase of the epidemic, the primary focus needs to be on identifying an **acute outbreak of COVID-19 that is of national importance**. An acute outbreak of this nature may be defined as "*widespread transmission of SARS-CoV-2, causing a high burden of severe disease, hospitalisation or death, including amongst those with prior infection or vaccination.*" Although a high caseload may be associated with a high number of cases of severe disease, recent experience with the Omicron variant has shown that this is not inevitable.[1-3] Given the high levels of population immunity to COVID-19 in South Africa – a consequence of both vaccination and past infections - a future acute outbreak may not necessarily be associated with a high burden of severe disease. Although a high caseload should prompt some public health actions (e.g. focusing on health systems preparedness), it is the early evidence of an increased burden of severe disease that should trigger immediate action.

In keeping with a "mitigation" approach, it is critical to have a clear plan of action for the period between acute outbreaks, in order that future outbreaks can be detected and responded to in the shortest time possible, and that a response can be tailored to the likely national importance of the outbreak. The capacity to mount an even more rigorous response, if warranted, must also be ensured in the longer term.

Evidence review and recommendations

QUESTION 1: What indicators would indicate an acute outbreak of national importance?

An intrinsic difficulty with the choice of indicators is that measures of severe disease lag behind increased caseload by 1-2 weeks. Thus the earliest indicators of an acute outbreak (see table below) are paradoxically the least useful in establishing whether further action needs to be taken, and later indicators of severity, while more useful, may not provide sufficient time to act effectively. The various indicators therefore need to be analysed as a group, understanding their advantages and disadvantages.

Bearing this in mind, the following indicators need to be considered at a subdistrict (if possible), district, provincial and national level:

INDICATOR	ADVANTAGES	DISADVANTAGES
Total COVID-19 caseload	Easy to monitor, provided that private and state laboratories continue to submit data to the National Institute for Communicable Diseases (NICD) or an equivalent body on a regular basis. COVID-19 is listed as a category 1 notifiable medical condition, so reporting should be done within 24 hours of a diagnosis.	A rising caseload does not necessarily indicate that a high burden of severe disease is likely. This indicator is also vulnerable to changes in testing volumes and strategies.
Percentage SARS-CoV-2 test positivity	Easy to calculate provided that private and state laboratories continue to submit data to the NICD or an equivalent body on a regular basis.	A rising percentage does not necessarily indicate that a high burden of severe disease is likely. This indicator is also vulnerable to changes in testing strategies, as well as changes in reporting practices (e.g. if positive tests are more likely to be reported than negative results, or if only polymerase chain reaction (PCR) and not antigen rapid diagnostic tests (Ag RDTs) are reported). The rate of change in the percentage test positivity over a 7 day period may be a more sensivity indicator, but cutoff values would need to be agreed. Monitoring within a province where there is consistency of testing strategies may give a more accurate indication of caseload change.

Changes in cycle threshold (Ct) value of SARS-CoV-2 PCR tests	This is a standard component of RT-PCR test reporting, but needs to be tracked nationally, and at disaggregated levels of the health system.	A falling Ct, which indicates rising viral loads, does not necessarily indicate that a high burden of severe disease is likely. As this is a new method, it is not well validated and thresholds have not been well established. It is also vulnerable to changes in testing strategies. It is only applicable to RT-PCR test results.
Wastewater surveillance of SARS-CoV-2 RNA levels[4]	This is an efficient sampling technique, as a single test gives a snapshot of SARS-CoV-2 burden from the community, town or city. Variants can be sampled *en masse*.	A rise in SARS-CoV-2 in wastewater does not necessarily indicate an increase in the burden of severe disease. This approach requires a dedicated surveillance programme (currently led by South African Medical Research Council). Only certain sites are sampled, and some houses are not connected to sewerage, so there is a risk of selection bias and patchy coverage. Single individuals may contribute to more than one catchment area through travel. Thresholds are not well defined, so interpretation of results is difficult due to uncertainties in viral shedding patterns. At present only 88 facilities are being sampled, using varying methods. Interpretation is also vulnerable to environmental changes, including dilution by rain run-off.
COVID-19 hospitalisations and Intensive Care Unit (ICU) admissions	This metric may indicate the burden of severe disease. Currently, all hospitalisations are reported on a voluntary basis to DATCOV, and all public and private hospitals are reporting.	These data are vulnerable to changes in testing strategies and volumes in hospitals. They also do not necessarily distinguish between admission *due to* COVID-19 and admission *with* (incidental) COVID-19 infection. Although DATCOV is reported to cover 100% of hospitals, the completeness and accuracy of data has been questioned.

Total hospitalisations & ICU admissions	This metric can offer a compelling indication of burden of severe disease, if paired with a contemporaneous rise in caseload.	This measure may underestimate disease burden in an acute outbreak, if other competing diagnoses are not being admitted to hospital. It also requires a dedicated hospital surveillance system with quick reporting of all admissions, something which is not currently reported to DATCOV. Private hospitals have not always been open to reporting on all admissions.
Oxygen utilisation trends	Offers a sensitive and specific marker of COVID-related severe disease burden.	This requires centralised reporting, but also needs to take into account the variety of oxygen supply mechanisms across different types of facilities and locales. It also assumes that oxygen therapy remains a sensitive indicator of severe COVID-19 disease with a new variant. Its specificity may be suboptimal in the face of outbreaks of other respiratory viruses (e.g. influenza).
Genomic surveillance programmes	A new variant detected at rapidly rising frequency may offer early indication of a possible new variant of concern or a new sublineage. Analysis may also provide early indications of variants or sublineages which may be at high risk of immune escape (when combined with an analysis of reinfection hazards) or increased transmissibility.	A rise in frequency of a new variant or sublineage does not necessarily indicate that a high burden of severe disease will occur. Such surveillance programmes may be vulnerable to delays in processing and are expensive. Limited sampling may bias interpretation of the results. Early extrapolation of genotypic characteristics to phenotypic effects in a human population is currently difficult and potentially inaccurate.
Analysis of *in vitro* immune response to new variants	*In vitro* data can provide an indication of immune escape from either vaccination or past infection.[5-7]	Antibody neutralization assays correlate moderately well with protection from infection, but not protection from severe disease. T-cell assays do not correlate well with severe disease protection.[8]

The indicators of disease burden should be stratified by age and geographic level, in order to optimally define the characteristics of the outbreak. An increase in caseload should be communicated as not being a concern unless there are also indications of increased severity.

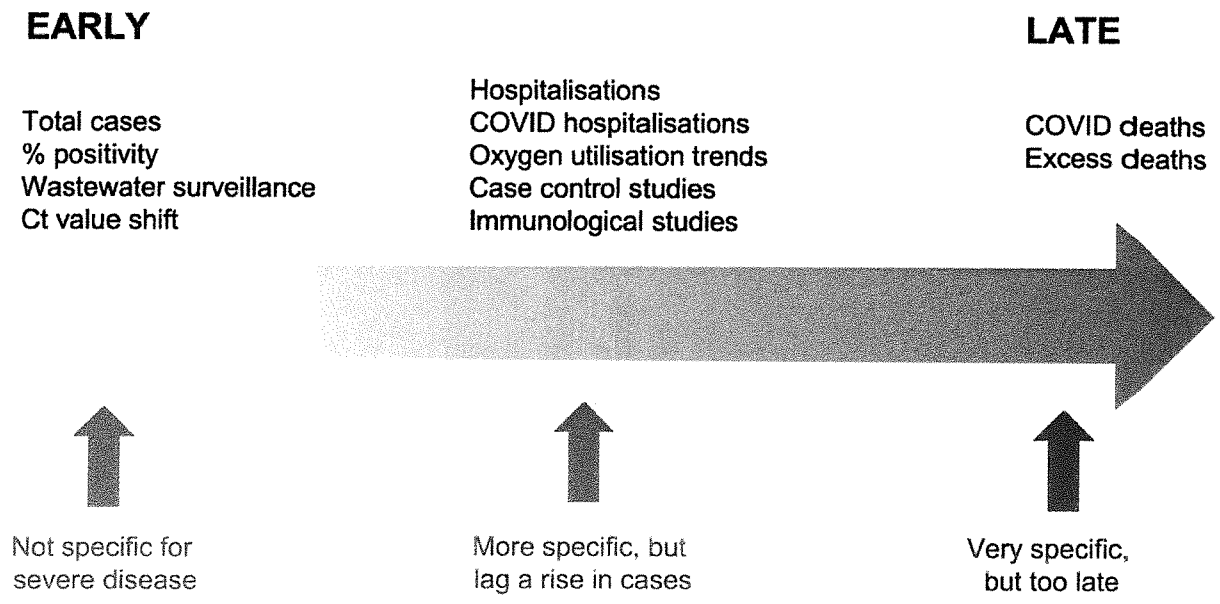


Figure 1 – Range of indicators

QUESTION 2: What response is needed if an acute outbreak is thought to be likely?

The priority at this stage would be to determinate the likely burden of severe disease as rapidly as possible. Some indications may be gleaned from national and international data:

1. **National** – COVID hospitalisations, total hospitalisations, oxygen utilisation trends, deaths.
2. **International** – where a variant has first been described in another part of the world, data on severity may already be available, and should be used.

If the available national and international data are deemed insufficient, a rapid **case-control study** can be considered to establish disease severity and potential immune escape of the new variant compared to the previous one. Linkage between national databases of tests, hospitalisations and vaccinations is essential for this task.

Another key aspect of the acute response should be to **rapidly scale up the volume and speed of SARS-CoV-2 genomic surveillance**, targeting the geographical areas where the caseload is rising. Although a new variant or sublineage's arrival does not necessarily portend a substantial burden of severe disease, understanding whether a change in genomics is driving the acute outbreak is important for many reasons. These include allowing for speculative extrapolations from genotype to phenotype and indicating the need to perform immunological studies on the new variant (e.g. antibody neutralization assays). Sustainable funding needs to be provided to maintain the capacity to do genomic sequencing on sufficient numbers of COVID-19 cases within a timeframe that is likely to be useful in an acute outbreak (ideally less than 1 week from the time of testing).

COVID-19 surveillance should be incorporated in a sustainable way into routine respiratory pathogen surveillance systems (e.g. SARI surveillance, currently conducted by NICD) to provide unbiased data that is not vulnerable to changes in testing volumes, strategies and practices. If the SARI network is used, sustainable funding should be provided to expand this surveillance system to all provinces.

Furthermore, if a new variant is detected, it is vital to **establish whether the sensitivity of the RT-PCR and rapid antigen tests is impaired**, if this is not already known.

QUESTION 3: What mitigation strategies are recommended if a high burden of severe disease is thought to be likely?

A rising caseload alone (as evidenced by total cases, percentage positivity, rising wastewater viral burden, or falling cycle threshold values) does NOT warrant further action in and of itself. However, more intensive restrictions and enhanced mitigation efforts can be justified if a high burden of severe disease is shown to be likely. Should it be deemed likely that the integrity of the healthcare system is under threat, the following measures can be considered:

1. **Vaccination booster drive according to immunsation guidelines** –primarily targeting those individuals at the highest risk of severe disease (age >50 and/or comorbidities). Given that it may take ~2 weeks for a protective effect to be seen, this should occur as soon as possible, and can be promoted as soon as an acute outbreak is thought to be likely, even before the clinical effects on severe disease are known.
2. Linkage between vaccination coverage data (EVDS), testing data (as reported to NICD) and hospital admission data (DATCOV) should be strengthened so that the designated agency has access to all components in an acute COVID-19 outbreak to rapidly assess the likely severity of disease and the likely importance of a new outbreak.
3. **Securing of adequate quantities of essential medicines** – as identified by National Essential Medicines List MAC on COVID-19 Therapeutics. Currently, the key medicines for severe cases would be systemic corticosteroids, low-molecular weight heparins and baricitinib, but other medicines may be considered (e.g. tocilizumab, antivirals).
4. **Strengthening of oxygen supplies and oxygen supply chain** – maintaining an effective oxygen supply monitoring system and close liaison with suppliers is also key.
5. **Ordering of sufficient consumables required for a severe COVID-19 outbreak** – e.g. personal protective equipment (PPE), oxygen delivery tubing and masks.
6. **Putting surge capacity strategies on standby** – e.g. additional beds, redeployment of staff, reduction of elective surgeries, public-private partnerships to alleviate bed capacity shortfalls.
7. **Efficient public communication about mask wearing, avoidance of large gatherings, and ventilation and spacing in indoor venues.** The focus should primarily be on high risk individuals, with recommendations being favoured over mandates – e.g. high risk individuals to consider a mask in public (preferably a surgical or N95 mask), and to avoid large public gatherings and public transport if possible. If the severity of the acute outbreak is thought sufficient to justify additional measures, the above advice can be extended to all members of the public, and/or be made mandatory.
8. **Restrictions on the sale of alcoholic beverages** – this should ONLY be considered to rapidly decongest the ICU/high care beds available if these are becoming overwhelmed during an acute COVID outbreak.
9. **New restrictions on school attendance** - should be introduced as an intervention of last resort, noting the negative impact of such restrictions on children's education, development and mental health.

Can the actions listed be implemented without declaring a national state of disaster?
Draft Regulations issued in terms of the National Health Act and International Health Regulations Act are currently awaiting public comment. Where possible, restrictions and responses should be enabled without the declaration of a state of disaster. However, that option of reinstatement remains available, if needed. A state of disaster can also be declared at a district or provincial, rather than a national level, although this introduces new complexities. Restrictions on the sale of alcoholic beverages and significant restrictions on business and educational activities, or mandatory interventions at a population-wide level require intergovernmental action and co-ordination, and would seem to warrant invocation of the Disaster Management Act. Any restrictions in citizen's rights need to pass the test posed by section 36 of the Constitution.

Rationale for recommendations

- Although the emergence of a new variant of SARS-CoV-2 cannot be ruled out, COVID-19 is expected to become endemic. Endemicity implies continued transmission of the virus, possibly with seasonal or other acute outbreaks.
- In the face of considerable population immunity, a rising caseload by itself does not necessarily indicate that an outbreak will lead to a substantial amount of severe disease (hospitalisations and deaths - i.e. to an "acute outbreak of national importance"). The primary focus for any public health measures should be to mitigate the burden of severe disease due to COVID.
- Early warning of the possibility of an acute outbreak of national importance is crucial, but no single indicator suffices in this regard. Combining information from a range of indicators can help to identify an acute outbreak of national importance, and to respond in a timely and effective manner.
- Maintaining the capacity to provide timely indicators of severe disease is crucial, as is the ability to rapidly activate additional resources to manage an acute outbreak of national importance.

Thank you for consideration of this advisory.

Kind regards

PROF KOLEKA MLISANA **PROF MARIAN JACOBS**
CO-CHAIRPERSONS: MINISTERIAL ADVISORY COMMITTEE ON COVID-19
DATE: 22 April 2022
CC:

» **Dr SSS Buthelezi (Director-General: Health)**
» **Dr N Crisp (Deputy Director-General: National Health Insurance)**

Disclaimer: As stipulated in its Terms of Reference, the MAC on COVID-19 is an advisory Committee to the Minister of Health and does not have any delegated powers to act on behalf of, or to commit, the Minister or Government to any actions. Recommendations offered by the MAC on COVID-19 constitute evidence-informed advice only and do not represent final decisions of the Minister of Health or government.

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PJLR11

Minister Joe Phaahla: Covid-19 and vaccination rollout programme

29 Apr 2022

Speaking notes by Health Minister, Dr MJ Phaahla during virtual briefing on Covid-19 and vaccination rollout programme

Thank you, Programme Director,
Greetings to my colleague and Deputy Minister Dr Sibongiseni Dhlomo Dr Waasila Jassat, from NICD
Dr Richard Lessells, from Genomic Sequence Network
Deputy Vice-Chancellor from the UKZN, Prof Mosa Moshabela Director General, Dr Sandile Buthelezi and Departmental officials Members of the Media
Viewers and Listeners at home Good morning

It has been some time since we shared with South Africans how the Covid- 19 pandemic is progress in our country and its impact on our society. A major focus over the almost two months has been on the exit from the State of Disaster as a tool for managing the pandemic du. Over this period there has been a sense of stability charaterised by low infection rates. At the same time we have been witnessing very low uptake of vaccination.

During this time where the regulatory regime around containment of the Covid-19 dominated the public discourse, we continued to warn that this was not the time to lower our guards as we have been noticing serious spikes of infections in other parts of the world with

dire consequences. Over the last 2 weeks we started to notice a continuous rise in daily infections led in the main by Gauteng, Western Cape and Kwazulu-Natal.

The rise in daily infections took a sharper upstick as we got to the end of on the week ending Saturday, 23rd April, and has been sustained during the week starting on Monday 25th April reaching up to over 6000 on Wednesday 27th April, which are tests done on Tuesday 26th April. We witnessed a slight decline to just above 4000 on Thursday 28th April, but these are tests done on a public holiday, 27th April. But positivity rate remains high at 17% with Gauteng and KzN above 20%.

We decided to wait a bit long to observe for more than seven days to see if the upward trend is sustained and the answer is yes. Nationally, as of 25th April, there has been a 137% increase in new cases compared to 7 days earlier, which on the curve shows a steep rise. The new steep rise driven mainly by higher rates of infection in Gauteng, KzN and Western Cape – the three account for 85% of the cases in the last 7 days.

Yesterday and last 7 days the average breakdown is Gauteng 53%, KZN 23% and Western Cape 11% of all the cases. The rate at yesterday were Gauteng 23%, KzN 23%, Western Cape 16% and Northern Cape 18%. Active cases have risen from lows of 15 000 few weeks ago to 39 000 yesterday. The R – number = 1.56 on 21/4/2022, the highest incidence per 100 000 population is:

Gauteng = 76
KZN = 47.6
WC = 46.5
So in terms of rapid rise of rates of infections there is no doubt. What remains stable even though with some change in hospital admissions including into ICU.

28/4 = 2027 total admission of 192 in ICU.

In absolute numbers – this was admissions in week 18 – 24 April from 346 admissions previous week to 108 – but this far from threatening capacity. There was a rise in deaths but from a low base = from 51 previous 7 days to 150 in week 18 – 24 April. The question which is now top of our minds si whether we have entered the 5th Wave earlier than was expected. Prof Abdul Karim, in his weekly analysis published every Tuesday argues that from a technical definition of 75 cases/100 000 population daily – we have entered the 5th in most provinces. From another definition it is proposed that if we reach > 6 237 cases per day on 7 days average = 5th Wave. Either way, we went to 6372 cases on Wednesday, which means its possible that the 5th Wave will qualify in next four days.

What is still uncertain is that our scientists also tell us that a new wave will come through a new variant nicknamed Pi, which will need to be more transmissible and escape immunity. But at this stage what is confirmed to be dominant are sub-variants of Omicron called B.4 and B.5, which have changes to the original B.1 but not enough to be new variants of concern.

Whilst these are the scientific analysis which the NICD and Krisp colleagues, will say more about, what is clear is that we are still at great risk of Covid-19 – especially as we go into a long winter than normal where we spend more time indoors including in gatherings. Because of the lack of a clear driver of the spiking infections, there is also an analysis that because of the Easter weekend, which also coincided with Ramadan for Muslims and Passover for Jewish faith, the related gatherings may be the tricker.

The next 7 days until 6th May will give a clearer picture as to where we are going i.e. whether the 5th Wave started earlier without distinct new variant

but driven by sub-variants or its just an early spike driven by Easter weekend. Our message again is that Covid-19 remains a threat and we cannot afford to drop all prevention measures. We do not believe that it is a correct public health approach to say because there is lot of immunity driven by high levels of previous infections and vaccination we should drop all prevention measures.

We again urge all those who are still not vaccinated to come forward and take the jab. We are still under 50% of adults with at least one jab and that's not good. We urge young adults especially to come forward. Natural immunity wanes after time and unlike vaccination it cannot be booked. We urge all those who qualify for boosters to all take the opportunity before deep winter.

In terms of the Regulations, we thank all South Africans who responded. We are processing the more than 300 000 comments received and will conclude before 5th May when the Disaster Recovery Regulations expire.

Thank you

Issued by: Department of Health
More from: Department of Health
More on: Health

PJLR 12

KRIEK WASSENAAR & VENTER ING
PROKUREURS - ATTORNEYS

Our Ref: PJ Wassenaar/es/QB0952
Your ref:

12 May 2022

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President/Minister/Sir/Madam

URGENT: NATIONAL HEALTH ACT REGULATIONS: 4 MAY 2022

URGENT MEETING SOUGHT WITH PRESIDENT AND/OR MINISTER OF HEALTH

1. We act on instructions of Sakeliga NPC ("our client").

2. Our client's main objective is the protection of a constitutional order, the rule of law, market principles, and a just and sustainable business environment within the Republic of South Africa. Pursuant to its objectives, our client lobbies for reforms and supports institutional initiatives to

create a favourable business environment and flourishing society in the interest of its supporters and for the common good.

3. Our client has had the opportunity to consider and consult as widely as possible with its various supporters and stakeholders on the National Health Act Regulations of 4 May 2022 ("the Regulations") that have been published. Our client is of the view that the Regulations are exceedingly burdensome on civil society, infringe unreasonably on constitutional rights and freedoms, are unnecessary and should be repealed with immediate effect.

4. Our client emphasises that the Regulations, even beyond their specific restrictions on masking, gathering, and so forth will harm social stability, levels of trust, and cohesion on an additional level: By transferring responsibility for enforcement of these restrictions, compulsions, and discrimination from the executive branch of the state to organisations in civil society such as businesses, churches and other religious groups, educational institutions, and more, these elements of organised society are turned into executive agents of the state. Besides the constitutional impermissibility of this development, it has the further consequence of driving deep wedges between, on the one hand, a public which overwhelmingly rejects in one way or another the regulations and, on the other hand, the organisations that make up organised society. In the case of businesses, this risk is especially pertinent, given the frequency and scale by which they are victims of crime and targeted during social unrest. The breakdown of civil co-operation from these regulations will structurally raise the cost of operating as organised civil society, including of doing business, in South Africa, to lasting detriment of public welfare.

5. We note that the Regulations published differ drastically from the Draft Regulations which were published for comment and to which our client submitted submissions.

6. We have taken legal advice on the Regulations and have been advised that the Regulations are *ultra vires,* unconstitutional and fall to be set aside on various grounds including:

   6.1 an inadequate and unlawful public participation process;

   6.2 the regulations are substantively and procedurally irrational;

   6.3 the regulations are *ultra vires* section 90(1) of the Act;

   6.4 the regulations were published for an ulterior purpose;

   6.5 the regulations impermissibly infringe various constitutional rights and freedoms; and

6.6 the regulations will continue to cripple the economy and infringe on economic activity.

7. We have also noted and perused the applications already brought by various organisations including AfriForum and Solidariteit in which the urgent review and setting aside of the Regulations is sought. Even though the applicants' various positions on the Regulations differ slightly from each other, and in turn too ours from theirs, the aforesaid applications are well-founded and the Regulations will not stand constitutional scrutiny.

8. The Regulations seek to create an unlawful regime of coercion based on a person's medical decisions. This is even more concerning in view of the lifting of the 'state of disaster' and a decrease in the effect of COVID-19 on the health care system. We stress that it is clear from the documentation available in the public domain and recommendations of leading medical experts (including the Ministerial Advisory Committee on COVID-19) that there is currently no serious public health risk anticipated from COVID-19.

9. The time to return to pre-Covid normality has arrived but the Regulations constitute an astounding about-turn in policy and a rejection of what should be the natural direction of change toward restored constitutional rights and freedoms. The Regulations regrettably seek to keep the public enchained by the excessive powers that the government has tasted during the 'state of disaster'. The cost to the government in the loss of trust and faith by the general population as a result of the policies deployed over the last two years is immeasurable.

10. Our client works toward positive solutions and wants to engage with the government on the best way forward. Our client is willing to meet with the President and / or the Minister of Health to in order to avoid litigation.

11. Kindly advise if you are prepared to engage with our client in a proposed meeting at your earliest convenience, but to be held no later than 18 May 2022 at 12h00.

12. Should you not be prepared to meet with our client or withdraw the Regulations, we hold instructions to join other litigants in approaching the Courts to uphold the constitutional rights and freedoms of our client, its supporters and the general public. To this end we point out that (in addition to the grounds referred to above) the regulations fall to be set aside on *inter alia* the following further considerations:

12.1 Regulations 16B and 16C contain unconstitutional provisions based on vaccination status. There do not appear to be any rational grounds to discriminate between vaccinated and unvaccinated persons. The purpose of the regulations is said to be to "contain" the disease. It appears now to be common cause that vaccinations do not prevent infection, illness or the spread of COVID-19. The distinction between vaccinated and unvaccinated persons is accordingly irrational and without foundation.

12.2 Furthermore, persons who have natural immunity / protection against serious illness due to previous infection are not provided for in Regulation 16B. It appears that natural immunity has been overlooked and that the State only relies on vaccination for its containment strategy. (The "containment" strategy is also in conflict with the MAC and recent medical advice to the State.)

12.3 The limitation of public freedoms, based on vaccination status, is effectively a government vaccine mandate. Businesses or those in charge of public gathering places are called on to enforce this policy on behalf of the government in order to coerce the public into vaccinating. This is unconstitutional and unlawful.

12.4 The approach of the State in the Regulations infringes the individual rights and choice of members of the public to elect their own medical treatment and preventative measures (including the right to contract COVID -19 so as to build up antibodies in a natural manner as opposed to vaccination).

12.5 Notwithstanding that Regulation 16B makes no mention of past infections (and the consequent natural immunity arising), the efficacy of natural immunity is clearly recognised by the Minster of Health in Regulation 16C (3)(d) for those entering the country. If natural immunity is good enough for travel and is not a threat then it must be good enough for gatherings which should no longer be limited or prevented on the basis of vaccination status.

12.6 The monitoring of people for the purposes of maintaining "vaccinated" versus "unvaccinated" gatherings is practically impossible. The impact on businesses (including costs to "police" and administer this policy of government) is unreasonably burdensome.

12.7 Society cannot be expected to enforce what is unfair, unreasonable, and unconstitutional.

12.8 As you are aware, non-compliance with the Regulations is a criminal offence with a penalty of up to 10 years imprisonment (Regulation 20). This is a particularly severe punishment which far exceeds the sanction for failure to comply with regulations under the former 'state of disaster'. Our client opposes any attempt to penalise or prosecute persons who rely on their constitutional freedoms.

13. Should you fail to engage with our client as suggested above and / or should the Regulations not be withdrawn 12h00 on Wednesday 18 May 2022, we hold instructions to launch an application on an urgent basis to have the decision to publish same reviewed and the Regulations set aside.

14. We await your urgent response.

15. All our client's rights are reserved.

Yours faithfully,

KRIEK WASSENAAR & VENTER INC
PÉTER WASSENAAR – DIREKTEUR / DIRECTOR
(f) 086 596 8516
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Electronically signed

Elbie Swanepoel

From:	Elbie Swanepoel
Sent:	13 May 2022 09:59
To:	'president@po.gov.za'; 'malebo@presidency.gov.za'; 'yasmeen@presidency.gov.za'; 'Musi@dpme.gov.za'; 'Lumko@dpme.gov.za'; 'manduy@health.gov.za'; 'MajaP@health.gov.za'; 'Rabots@health.gov.za'; 'dg@health.gov.za'; 'AndreG@health.gov.za'; 'Foster.mohale@health.gov.za'
Cc:	NJ Nel
Subject:	URGENT: NATIONAL HEALTH ACT REGULATIONS: 4 MAY 2022 - URGENT MEETING SOUGHT WITH PRESIDENT AND/OR MINISTER OF HEALTH
Attachments:	Minister of Health sent 2022-05-12.pdf
Sensitivity:	Private

Good day,

We refer to the above and attach hereto a letter for your attention.

Regards,

ELBIE SWANEPOEL

Kriek Wassenaar & Venter Inc

Regsekretaresse / Legal Secretary

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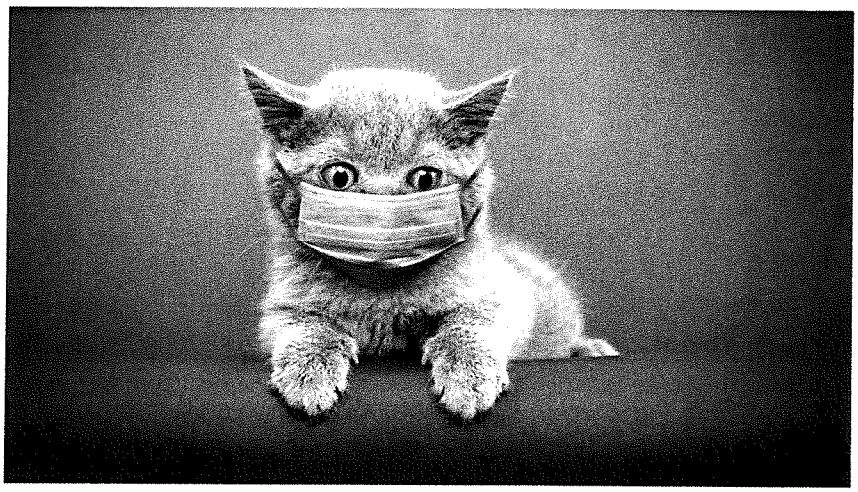
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PJCR 13

TRENDING

Covid-19 rules – and SA's mask mandate – won't be allowed to lapse tonight, DoH says

Business Insider SACompiled by Phillip de Wet,



(Getty

South Africa's mask mandate – and all remaining Covid-19 rules – expire tonight.

But a last-minute update is due, the department of health said on Wednesday.

The sudden dismantling of the state of disaster left a 30-day window for new health regulations to be finalised.

They turned out to be controversial.

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UPDATE | SA's new Covid-19 rules: Masks stay on until the minister of health says otherwise

A last-minute update to national regulations on Wednesday night should keep in place South Africa's mask mandate, and the other remaining Covid-19 rules, the department of health says.

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All remaining restrictions, originally imposed via a national state of disaster, are due to expire at midnight.

But before that, there will be new regulations, Nicholas Crisp, deputy director-general at the department of health, said late Wednesday morning.

Crisp did not provide further detail, and it was not yet clear whether the Wednesday update would be a stop-gap measure, or if the department intended to publish and activate amendments to regulations on communicable disease more broadly.

The department gave itself seven working days to consider public comment on those communicable-disease rules, which had a controversial reception.

Like the state of disaster under which Covid-19 was previously managed, the communicable disease rules would allow for the imposition of booze bans, or mask mandates, during any pandemic. Some groups have argued that entire approach is unconstitutional, with various implied threats of legal action should the minister of health go ahead with publication.

President Cyril Ramaphosa announced the end of the national state of disaster on Covid-19 on 4 April. That dismantled the legal authority under which mass gatherings were banned and masks were mandated on public transport and in public-access buildings.

A set of "transitional measures" kept those rules in place until now, but were set to automatically lapse after 30 days.

Should there be no replacement rules, there will be no legal authority to require anyone to wear a mask, anywhere, or to prevent

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stadiums or concert halls from being packed to their safety limits determined before the pandemic, whether or not attendees are vaccinated.

UPDATE | SA's new Covid-19 rules: Masks stay on until the minister of health says otherwise

Beijing restricts public transport as COVID spreads

REUTERS

Around 15% of the public transport network has been closed as the Chinese capital tries to stop the spread of COVID-19 and avoid the fate of Shanghai where millions of residents have been under strict lockdown for more than a month. Rachel Judah has more.

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PJCR14

Community transmission and viral load kinetics of the SARS-CoV-2 delta (B.1.617.2) variant in vaccinated and unvaccinated individuals in the UK: a prospective, longitudinal, cohort study

Anika Singanayagam, Seran Hakki*, Jake Dunning*, Kieran J Madon, Michael A Crone, Aleksandra Koycheva, Nieves Derqui-Fernandez, Jack L Barnett, Michael G Whitfield, Robert Varro, Andre Charlett, Rhia Kundu, Joe Fenn, Jessica Cutajar, Valerie Quinn, Emily Conibear, Wendy Barclay, Paul S Freemont, Graham P Taylor, Shazaad Ahmad, Maria Zambon, Neil M Ferguson†, Ajit Lalvani†, on behalf of the ATACCC Study Investigators‡*

Summary

Background The SARS-CoV-2 delta (B.1.617.2) variant is highly transmissible and spreading globally, including in populations with high vaccination rates. We aimed to investigate transmission and viral load kinetics in vaccinated and unvaccinated individuals with mild delta variant infection in the community.

Methods Between Sept 13, 2020, and Sept 15, 2021, 602 community contacts (identified via the UK contract-tracing system) of 471 UK COVID-19 index cases were recruited to the Assessment of Transmission and Contagiousness of COVID-19 in Contacts cohort study and contributed 8145 upper respiratory tract samples from daily sampling for up to 20 days. Household and non-household exposed contacts aged 5 years or older were eligible for recruitment if they could provide informed consent and agree to self-swabbing of the upper respiratory tract. We analysed transmission risk by vaccination status for 231 contacts exposed to 162 epidemiologically linked delta variant-infected index cases. We compared viral load trajectories from fully vaccinated individuals with delta infection (n=29) with unvaccinated individuals with delta (n=16), alpha (B.1.1.7; n=39), and pre-alpha (n=49) infections. Primary outcomes for the epidemiological analysis were to assess the secondary attack rate (SAR) in household contacts stratified by contact vaccination status and the index cases' vaccination status. Primary outcomes for the viral load kinetics analysis were to detect differences in the peak viral load, viral growth rate, and viral decline rate between participants according to SARS-CoV-2 variant and vaccination status.

Findings The SAR in household contacts exposed to the delta variant was 25% (95% CI 18–33) for fully vaccinated individuals compared with 38% (24–53) in unvaccinated individuals. The median time between second vaccine dose and study recruitment in fully vaccinated contacts was longer for infected individuals (median 101 days [IQR 74–120]) than for uninfected individuals (64 days [32–97], p=0·001). SAR among household contacts exposed to fully vaccinated index cases was similar to household contacts exposed to unvaccinated index cases (25% [95% CI 15–35] for vaccinated *vs* 23% [15–31] for unvaccinated). 12 (39%) of 31 infections in fully vaccinated household contacts arose from fully vaccinated epidemiologically linked index cases, further confirmed by genomic and virological analysis in three index case–contact pairs. Although peak viral load did not differ by vaccination status or variant type, it increased modestly with age (difference of 0·39 [95% credible interval −0·03 to 0·79] in peak $\log_{10}$ viral load per mL between those aged 10 years and 50 years). Fully vaccinated individuals with delta variant infection had a faster (posterior probability >0·84) mean rate of viral load decline (0·95 $\log_{10}$ copies per mL per day) than did unvaccinated individuals with pre-alpha (0·69), alpha (0·82), or delta (0·79) variant infections. Within individuals, faster viral load growth was correlated with higher peak viral load (correlation 0·42 [95% credible interval 0·13 to 0·65]) and slower decline (−0·44 [−0·67 to −0·18]).

Interpretation Vaccination reduces the risk of delta variant infection and accelerates viral clearance. Nonetheless, fully vaccinated individuals with breakthrough infections have peak viral load similar to unvaccinated cases and can efficiently transmit infection in household settings, including to fully vaccinated contacts. Host–virus interactions early in infection may shape the entire viral trajectory.

Funding National Institute for Health Research.

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Introduction

While the primary aim of vaccination is to protect individuals against severe COVID-19 disease and its consequences, the extent to which vaccines reduce onward transmission of SARS-CoV-2 is key to containing the pandemic. This outcome depends on the ability of

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This online publication has been corrected. The corrected version first appeared at thelancet.com/infection on November 2, 2021

See **Comment** page 152

*Joint first authors

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Research in context

Evidence before this study

The SARS-CoV-2 delta variant is spreading globally, including in populations with high vaccination coverage. While vaccination remains highly effective at attenuating disease severity and preventing death, vaccine effectiveness against infection is reduced for delta. Determining the extent of transmission from vaccinated delta-infected individuals to their vaccinated contacts is a public health priority. Comparing the upper respiratory tract (URT) viral load kinetics of delta infections with those of other variants gives insight into potential mechanisms for its increased transmissibility. We searched PubMed and *medRxiv* for articles published between database inception and Sept 20, 2021, using search terms describing "SARS-CoV-2, delta variant, viral load, and transmission". Two studies longitudinally sampled the URT in vaccinated and unvaccinated delta variant-infected individuals to compare viral load kinetics. In a retrospective study of a cohort of hospitalised patients in Singapore, more rapid viral load decline was found in vaccinated individuals than unvaccinated cases. However, the unvaccinated cases in this study had moderate-to-severe infection, which is known to be associated with prolonged shedding. The second study longitudinally sampled professional USA sports players. Again, clearance of delta viral RNA in vaccinated cases was faster than in unvaccinated cases, but only 8% of unvaccinated cases had delta variant infection, complicating interpretation. Lastly, a report of a single-source nosocomial outbreak of a distinct delta sub-lineage in Vietnamese health-care workers plotted viral load kinetics (without comparison with unvaccinated delta infections) and demonstrated transmission between fully vaccinated health-care workers in the nosocomial setting. The findings might therefore not be generalisable beyond the particular setting and distinct viral sub-lineage investigated.

Added value of this study

The majority of SARS-CoV-2 transmission occurs in households, but transmission between fully vaccinated individuals in this setting has not been shown to date. To ascertain secondary transmission with high sensitivity, we longitudinally followed index cases and their contacts (regardless of symptoms) in the community early after exposure to the delta variant of SARS-CoV-2, performing daily quantitative RT-PCR on URT samples for 14–20 days. We found that the secondary attack rate in fully vaccinated household contacts was high at 25%, but this value was lower than that of unvaccinated contacts (38%). Risk of infection increased with time in the 2–3 months since the second dose of vaccine. The proportion of infected contacts was similar regardless of the index cases' vaccination status. We observed transmission of the delta variant between fully vaccinated index cases and their fully vaccinated contacts in several households, confirmed by whole-genome sequencing. Peak viral load did not differ by vaccination status or variant type but did increase modestly with age. Vaccinated delta cases experienced faster viral load decline than did unvaccinated alpha or delta cases. Across study participants, faster viral load growth was correlated with higher peak viral load and slower decline, suggesting that host–virus interactions early in infection shape the entire viral trajectory. Since our findings are derived from community household contacts in a real-life setting, they are probably generalisable to the general population.

Implications of all the available evidence

Although vaccines remain highly effective at preventing severe disease and deaths from COVID-19, our findings suggest that vaccination is not sufficient to prevent transmission of the delta variant in household settings with prolonged exposures. Our findings highlight the importance of community studies to characterise the epidemiological phenotype of new SARS-CoV-2 variants in increasingly highly vaccinated populations. Continued public health and social measures to curb transmission of the delta variant remain important, even in vaccinated individuals.

vaccines to protect against infection and the extent to which vaccination reduces the infectiousness of breakthrough infections.

Vaccination was found to be effective in reducing household transmission of the alpha variant (B.1.1.7) by 40–50%,[1] and infected, vaccinated individuals had lower viral load in the upper respiratory tract (URT) than infections in unvaccinated individuals,[2] which is indicative of reduced infectiousness.[3,4] However, the delta variant (B.1.617.2), which is more transmissible than the alpha variant,[5,6] is now the dominant strain worldwide. After a large outbreak in India, the UK was one of the first countries to report a sharp rise in delta variant infection. Current vaccines remain highly effective at preventing admission to hospital and death from delta infection.[7] However, vaccine effectiveness against infection is reduced for delta, compared with alpha,[8,9] and the delta variant continues to cause a high burden of cases even in countries with high vaccination coverage. Data are scarce on the risk of community transmission of delta from vaccinated individuals with mild infections.

Here, we report data from a UK community-based study, the Assessment of Transmission and Contagiousness of COVID-19 in Contacts (ATACCC) study, in which ambulatory close contacts of confirmed COVID-19 cases underwent daily, longitudinal URT sampling, with collection of associated clinical and epidemiological data. We aimed to quantify household transmission of the delta variant and assess the effect of vaccination status on contacts' risk of infection and index cases' infectiousness, including (1) households with unvaccinated contacts and index cases and (2) households with fully vaccinated contacts and fully vaccinated index cases. We also compared sequentially sampled

URT viral RNA trajectories from individuals with non-severe delta, alpha, and pre-alpha SARS-CoV-2 infections to infer the effects of SARS-CoV-2 variant status—and, for delta infections, vaccination status—on transmission potential.

Methods

Study design and participants

ATACCC is an observational longitudinal cohort study of community contacts of SARS-CoV-2 cases. Contacts of symptomatic PCR-confirmed index cases notified to the UK contact-tracing system (National Health Service Test and Trace) were asked if they would be willing to be contacted by Public Health England to discuss participation in the study. All contacts notified within 5 days of index case symptom onset were selected to be contacted within our recruitment capacity. Household and non-household contacts aged 5 years or older were eligible for recruitment if they could provide written informed consent and agree to self-swabbing of the URT. Further details on URT sampling are given in the appendix (p 13).

The ATACCC study is separated into two study arms, ATACCC1 and ATACCC2, which were designed to capture different waves of the SARS-CoV-2 pandemic. In ATACCC1, which investigated alpha variant and pre-alpha cases in Greater London, only contacts were recruited between Sept 13, 2020, and March 13, 2021. ATACCC1 included a pre-alpha wave (September to November, 2020) and an alpha wave (December, 2020, to March, 2021). In ATACCC2, the study was relaunched specifically to investigate delta variant cases in Greater London and Bolton, and both index cases and contacts were recruited between May 25, and Sept 15, 2021. Early recruitment was focused in West London and Bolton because UK incidence of the delta variant was highest in these areas.[10] Based on national and regional surveillance data, community transmission was moderate-to-high throughout most of our recruitment period.

This study was approved by the Health Research Authority. Written informed consent was obtained from all participants before enrolment. Parents and caregivers gave consent for children.

Data collection

Demographic information was collected by the study team on enrolment. The date of exposure for non-household contacts was obtained from Public Health England. COVID-19 vaccination history was determined from the UK National Immunisation Management System, general practitioner records, and self-reporting by study participants. We defined a participant as unvaccinated if they had not received a single dose of a COVID-19 vaccine at least 7 days before enrolment, partially vaccinated if they had received one vaccine dose at least 7 days before study enrolment, and fully vaccinated if they had received two doses of a COVID-19 vaccine at least 7 days before study enrolment. Previous literature was used to determine the 7-day threshold for defining vaccination status.[11–13] We also did sensitivity analyses using a 14-day threshold. The time interval between vaccination and study recruitment was calculated. We used WHO criteria[14] to define symptomatic status up to the day of study recruitment. Symptomatic status for incident cases—participants who were PCR-negative at enrolment and subsequently tested positive—was defined from the day of the first PCR-positive result.

Laboratory procedures

SARS-CoV-2 quantitative RT-PCR, conversion of ORF1ab and envelope (E-gene) cycle threshold values to viral genome copies, whole-genome sequencing, and lineage assignments are described in the appendix (pp 13–14).

Outcomes

Primary outcomes for the epidemiological analysis were to assess the secondary attack rate (SAR) in household contacts stratified by contact vaccination status and the index cases' vaccination status. Primary outcomes for the viral load kinetics analysis were to detect differences in the peak viral load, viral growth rate, and viral decline rate between participants infected with pre-alpha versus alpha versus delta variants and between unvaccinated delta-infected participants and vaccinated delta-infected participants.

See Online for appendix

We assessed vaccine effectiveness and susceptibility to SARS-CoV-2 infection stratified by time elapsed since receipt of second vaccination as exploratory analyses.

Statistical analysis

To model viral kinetics, we used a simple phenomenological model of viral titre[15] during disease pathogenesis. Viral kinetic parameters were estimated on a participant-specific basis using a Bayesian hierarchical model to fit this model to the entire dataset of sequential cycle threshold values measured for all participants. For the 19 participants who were non-household contacts of index cases and had a unique date of exposure, the cycle threshold data were supplemented by a pseudo-absence data point (ie, undetectable virus) on the date of exposure. Test accuracy and model misspecification were modelled with a mixture model by assuming there was a probability p of a test giving an observation drawn from a (normal) error distribution and probability $1-p$ of it being drawn from the true distribution.

The hierarchical structure was represented by grouping participants based on the infecting variant and their vaccination status. A single-group model was fitted, which implicitly assumes that viral kinetic parameters vary by individual but not by variant or vaccination status. A four-group model was also explored, where groups 1, 2, 3, and 4 represent pre-alpha, alpha, unvaccinated delta, and fully vaccinated delta, respectively. We fitted a correlation matrix between

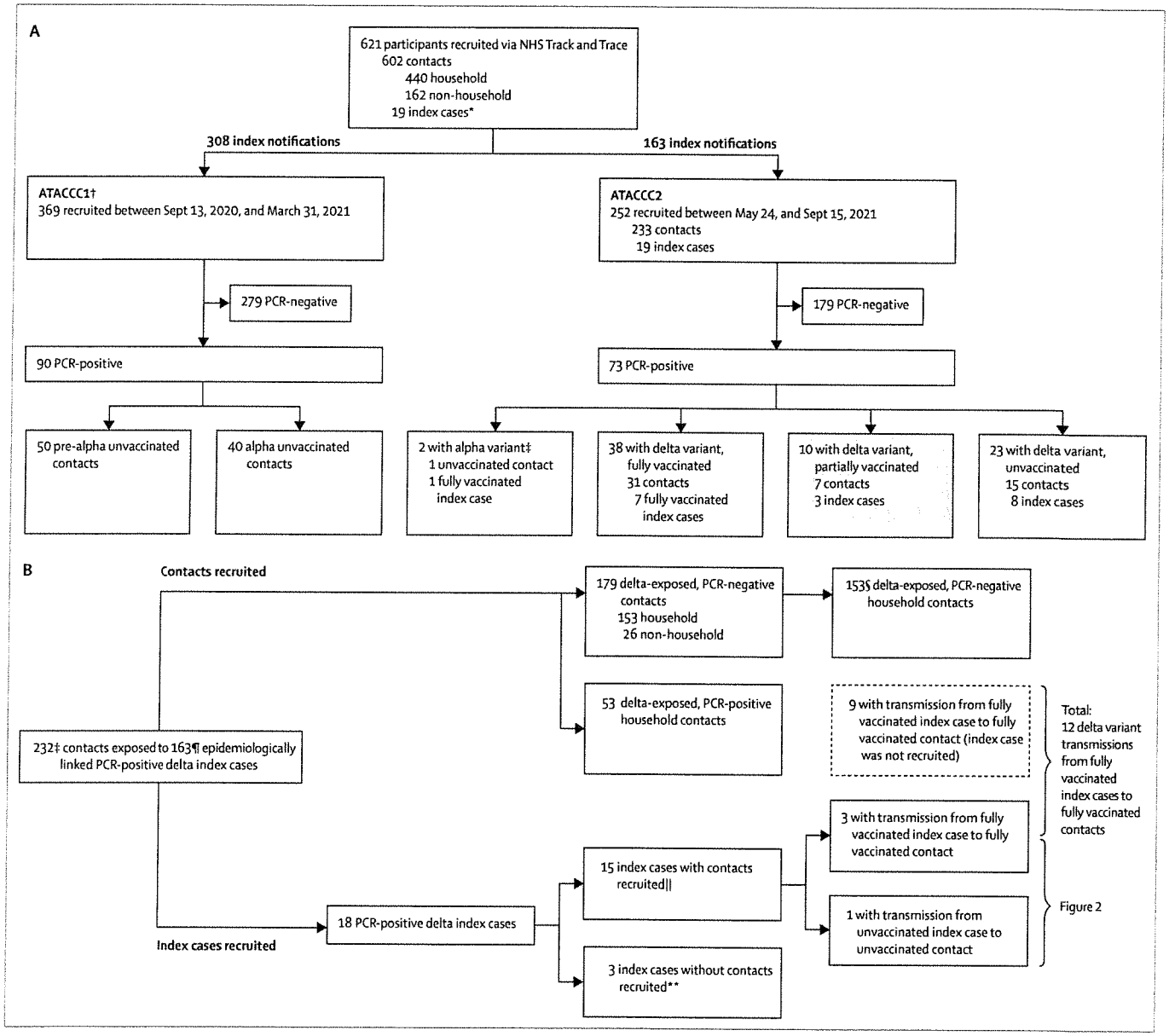


Figure 1: **Recruitment, SARS-CoV-2 infection, variant status, and vaccination history for ATACCC study participants**
(A) Study recruitment and variant status confirmed by whole-genome sequencing (ATACCC1 and ATACCC2 combined). (B) ATACCC2: delta-exposed contacts included in secondary attack rate calculation (table 1) and transmission assessment (table 2). NHS=National Health Service. *All index cases were from ATACCC2. †All contacts. ‡The two earliest PCR-positive cases from the ATACCC2 cohort (one index case and one contact) were confirmed as having the alpha variant on whole-genome sequencing (recruited on May 28, 2021). This alpha variant-exposed, PCR-positive contact is excluded from figure 1B. §One PCR-negative contact had no vaccination status data available and one PCR-negative contact's index case had no vaccination data available. ¶Vaccination data were available for 138 index cases of 163. ||The contacts of these 15 index cases are included within the 232 total contacts. **These three index cases without contacts are only included in the viral load kinetics analysis (figure 3) and are not included in tables 1 and 2.

participant-specific kinetic parameters to allow us to examine whether there is within-group correlation between peak viral titre, viral growth rate, and viral decline rate. Our initial model selection, using leave-one-out cross-validation, selected a four-group hierarchical model with fitted correlation coefficients between individual-level parameters determining peak viral load and viral load growth and decline rates (appendix p 5). However, resulting participant-specific estimates of peak viral load (but not growth and decline rates) showed a marked and significant correlation with age in the exploratory analysis, which motivated examination of models where mean peak viral load could vary with age. The most predictive model overall allowed mean viral

load growth and decline rates to vary across the four groups, with mean peak viral load common to all groups but assumed to vary linearly with the logarithm of age (appendix p 5). We present peak viral loads for the reference age of 50 years with 95% credible intervals (95% CrIs). 50 years was chosen as the reference age as it is typical of the ages of the cases in the whole dataset and the choice of reference age made no difference in the model fits or judgment of differences between the groups.

We computed group-level population means and within-sample group means of log peak viral titre, viral growth rate, and viral decline rate. Since posterior estimates of each of these variables are correlated across groups, overlap in the credible intervals of an estimate for one group with that for another group does not necessarily indicate no significant difference between those groups. We, therefore, computed posterior probabilities, *pp*, that these variables were larger for one group than another. For our model, Bayes factors can be computed as $pp/(1-pp)$. We only report population (group-level) posterior probabilities greater than 0·75 (corresponding to Bayes factors >3) as indicating at least moderate evidence of a difference.

For vaccine effectiveness, we defined the estimated effectiveness at preventing infection, regardless of symptoms, with delta in the household setting as 1 – SAR (fully vaccinated) / SAR (unvaccinated).

Role of the funding source

The funder of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report.

Results

Between Sept 13, 2020, and Sept 15, 2021, 621 community-based participants (602 contacts and 19 index cases) from 471 index notifications were prospectively enrolled in the ATACCC1 and ATACCC2 studies, and contributed 8145 URT samples. Of these, ATACCC1 enrolled 369 contacts (arising from 308 index notifications), and ATACCC2 enrolled 233 contacts (arising from 163 index notifications) and 19 index cases. SARS-CoV-2 RNA was detected in 163 (26%) of the 621 participants. Whole-genome sequencing of PCR-positive cases confirmed that 71 participants had delta variant infection (18 index cases and 53 contacts), 42 had alpha variant infection (one index case and 41 contacts), and 50 had pre-alpha variant infection (all contacts; figure 1A).

Of 163 PCR-positive participants, 89 (55%) were female and 133 (82%) were White. Median age was 36 years (IQR 26–50). Sex, age, ethnicity, body-mass index (BMI) distribution, and the frequency of comorbidities were similar among those with delta, alpha, and pre-alpha infection, and for vaccinated and unvaccinated delta-infected participants, except for age and sex (appendix pp 2–3). There were fewer unvaccinated females than males (p=0·04) and, as expected from the age-prioritisation of the UK vaccine roll-out, unvaccinated participants infected with the delta variant were significantly younger (p<0·001; appendix p 3). Median time between exposure to the index case and study enrolment was 4 days (IQR 4–5). All participants had non-severe ambulatory illness or were asymptomatic. The proportion of asymptomatic cases did not differ among fully vaccinated, partially vaccinated, and unvaccinated delta groups (appendix p 3).

	Total	PCR positive	PCR negative	SAR (95% CI)	p value
Contacts					
All	231	53	178	23 (18–29)	NA
Fully vaccinated	140	31	109	22 (16–30)	0·16
Unvaccinated	44	15	29	34 (22–49)	..
Partially vaccinated	47	7	40	15 (7–28)	NA
Household contacts					
All	205	53	152	26 (20–32)	NA
Fully vaccinated	126	31	95	25 (18–33)	0·17
Unvaccinated	40	15	25	38 (24–53)	..
Partially vaccinated	39	7	32	18 (9–33)	NA

χ^2 test was performed to calculate p values for differences in SAR between fully vaccinated and unvaccinated cases. One PCR-negative contact who withdrew from the study without vaccination status information was excluded. NA=not applicable. SAR=secondary attack rate.

Table 1: **SAR in contacts of delta-exposed index cases recruited to the ATACCC2 study**

No pre-alpha-infected and only one alpha-infected participant had received a COVID-19 vaccine before study enrolment. Of 71 delta-infected participants (of whom 18 were index cases), 23 (32%) were unvaccinated, ten (14%) were partially vaccinated, and 38 (54%) were fully vaccinated (figure 1A; appendix p 3). Of the 38 fully vaccinated delta-infected participants, 14 had received the BNT162b2 mRNA vaccine (Pfizer–BioNTech), 23 the ChAdOx1 nCoV-19 adenovirus vector vaccine (Oxford–AstraZeneca), and one the CoronaVac inactivated whole-virion vaccine (Sinovac).

It is highly probable that all but one of the 233 ATACCC2 contacts were exposed to the delta variant because they were recruited when the regional prevalence of delta was at least 90%, and mostly 95–99% (figure 1B).[10] Of these, 206 (89%) were household contacts (in 127 households), and 26 (11%) were non-household contacts. Distributions of age, ethnicity, BMI, smoking status, and comorbidities were similar between PCR-positive and PCR-negative contacts (appendix p 4). The median time between second vaccine dose and study recruitment in fully vaccinated contacts with delta variant infection was 74 days (IQR 35–105; range 16–201), and this was significantly longer in PCR-positive contacts than in PCR-negative contacts (101 days [IQR 74–120] *vs* 64 days [32–97], respectively, p=0·001; appendix p 4). All 53 PCR-positive contacts were exposed in household settings and the SAR for all delta variant-exposed household contacts was 26% (95% CI 20–32). SAR was

	All household contacts (n=204)*	Fully vaccinated contacts (n=125)		Partially vaccinated contacts (n=39)		Unvaccinated contacts (n=40)	
		PCR positive (n=31)	PCR negative (n=94)	PCR positive (n=7)	PCR negative (n=32)	PCR positive (n=15)	PCR negative (n=25)
Fully vaccinated index cases (n=50)	69	12	31	1	8	4	13
Partially vaccinated index cases (n=25)	35	7	12	3	10	3	0
Unvaccinated index cases (n=63)	100	12	51	3	14	8	12

Non-household exposed contacts (n=24, all PCR negative) were excluded. One PCR-negative household contact who withdrew from the study without vaccination status information was excluded. One PCR-negative household contact who could not be linked to their index case was also excluded. *The rows below show the number of contacts exposed to each category of index case.

Table 2: **Comparison of vaccination status of the 138 epidemiologically linked PCR-positive index cases for 204 delta variant-exposed household contacts**

not significantly higher in unvaccinated (38%, 95% CI 24–53) than fully vaccinated (25%, 18–33) household contacts (table 1). We estimated vaccine effectiveness at preventing infection (regardless of symptoms) with delta in the household setting to be 34% (bootstrap 95% CI −15 to 60). Sensitivity analyses using a 14 day threshold for time since second vaccination to study recruitment to denote fully vaccinated did not materially affect our estimates of vaccine effectiveness or SAR (data not shown). Although precision is restricted by the small sample size, this estimate is broadly consistent with vaccine effectiveness estimates for delta variant infection based on larger datasets.[9,16,17]

The vaccination status of 138 epidemiologically linked index cases of 204 delta variant-exposed household contacts was available (figure 1B, table 2). The SAR in household contacts exposed to fully vaccinated index cases was 25% (95% CI 15–35; 17 of 69), which is similar to the SAR in household contacts exposed to unvaccinated index cases (23% [15–31]; 23 of 100; table 2). The 53 PCR-positive contacts arose from household exposure to 39 PCR-positive index cases. Of these index cases who gave rise to secondary transmission, the proportion who were fully vaccinated (15 [38%] of 39) was similar to the proportion who were unvaccinated (16 [41%] of 39). The median number of days from the index cases' second vaccination to the day of recruitment for their respective contacts was 73 days (IQR 38–116). Time interval did not differ between index cases who transmitted infection to their contacts and those who did not (94 days [IQR 62–112] and 63 days [35–117], respectively; p=0·43).

18 of the 163 delta variant-infected index cases that led to contact enrolment were themselves recruited to ATACCC2 and serial URT samples were collected from them, allowing for more detailed virology and genome analyses. For 15 of these, their contacts were also recruited (13 household contacts and two non-household contacts). A corresponding PCR-positive household contact was identified for four of these 15 index cases (figure 1B). Genomic analysis showed that index–contact pairs were infected with the same delta variant sub-lineage in these instances, with one exception (figure 2A). In one household (number 4), an unvaccinated index case transmitted the delta variant to an unvaccinated contact, while another partially vaccinated contact was infected with a different delta sub-lineage (which was probably acquired outside the household). In the other three households (numbers 1–3), fully vaccinated index cases transmitted the delta variant to fully vaccinated household contacts, with high viral load in all cases, and temporal relationships between the viral load kinetics that were consistent with transmission from the index cases to their respective contacts (figure 2B).

Inclusion criteria for the modelling analysis selected 133 participant's viral load RNA trajectories from 163 PCR-positive participants (49 with the pre-alpha variant, 39 alpha, and 45 delta; appendix p 14). Of the 45 delta cases, 29 were fully vaccinated and 16 were unvaccinated; partially vaccinated cases were excluded. Of the 133 included cases, 29 (22%) were incident (ie, PCR negative at enrolment converting to PCR positive subsequently) and 104 (78%) were prevalent (ie, already PCR positive at enrolment). 15 of the prevalent cases had a clearly resolvable peak viral load. Figure 3 shows modelled viral RNA (ORF1ab) trajectories together with the viral RNA copy numbers measured for individual participants. The E-gene equivalent is shown in the appendix (p 2). Estimates derived from E-gene cycle threshold value data (appendix pp 5, 7, 9, 11) were similar to those for ORF1ab.

Although viral kinetics appear visually similar for all four groups of cases, we found quantitative differences in estimated viral growth rates and decline rates (tables 3, 4). Population (group-level) estimates of mean viral load decline rates based on ORF1ab cycle threshold value data varied in the range of 0·69–0·95 $\log_{10}$ units per mL per daxes 4; appendix p 10), indicating that a typical 10-day period was required for viral load to decline from peak to undetectable. A faster decline was seen in the alpha (pp=0·93), unvaccinated delta (pp=0·79), and fully vaccinated delta (pp=0·99) groups than in the pre-alpha group. The mean viral load decline rate of the fully vaccinated delta group was also faster than those of the alpha group (pp=0·84) and the unvaccinated delta group (pp=0·85). The differences in decline rates translate into a difference of about 3 days in the mean duration of the decline phase between the pre-alpha and delta vaccinated groups.

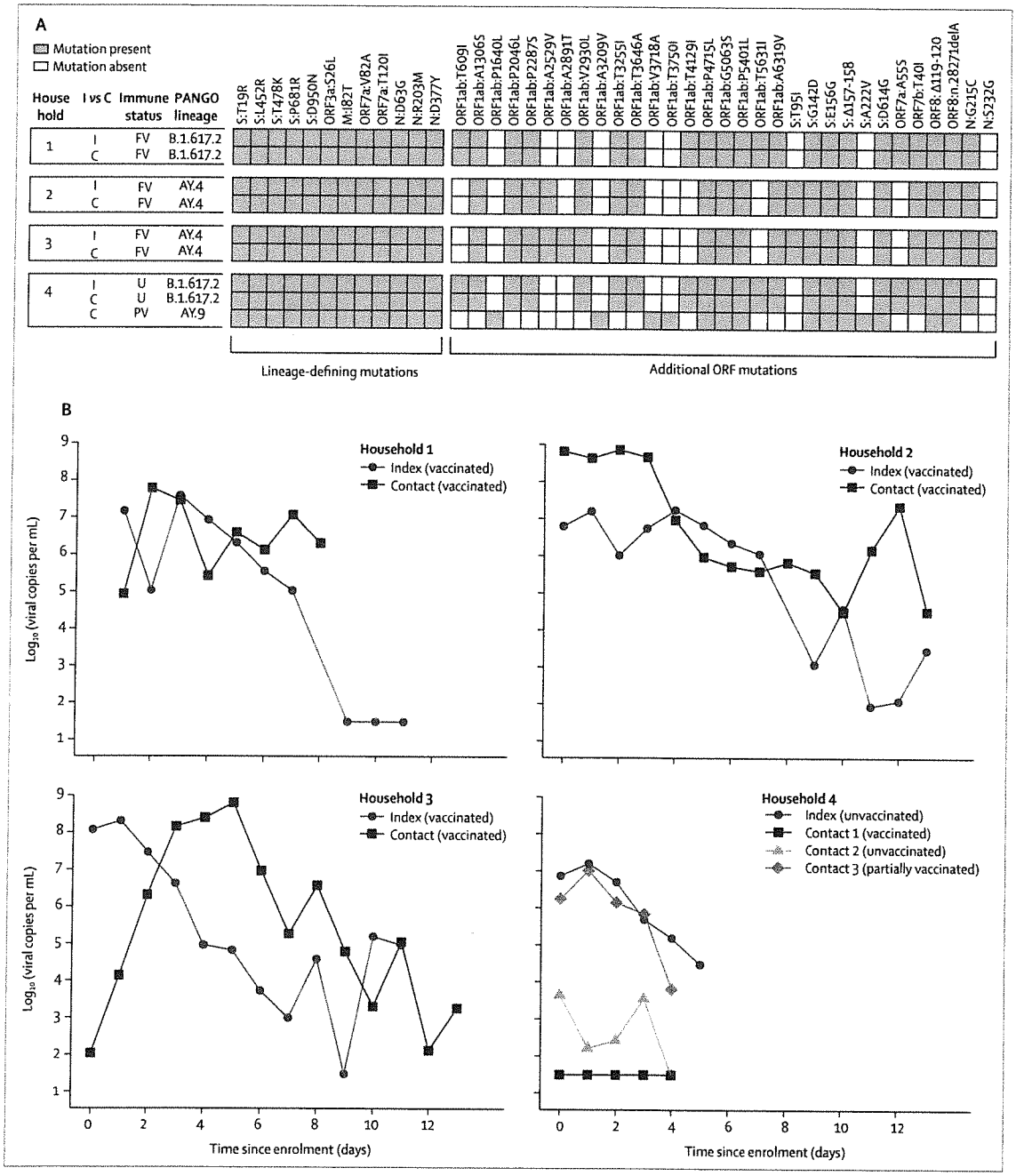
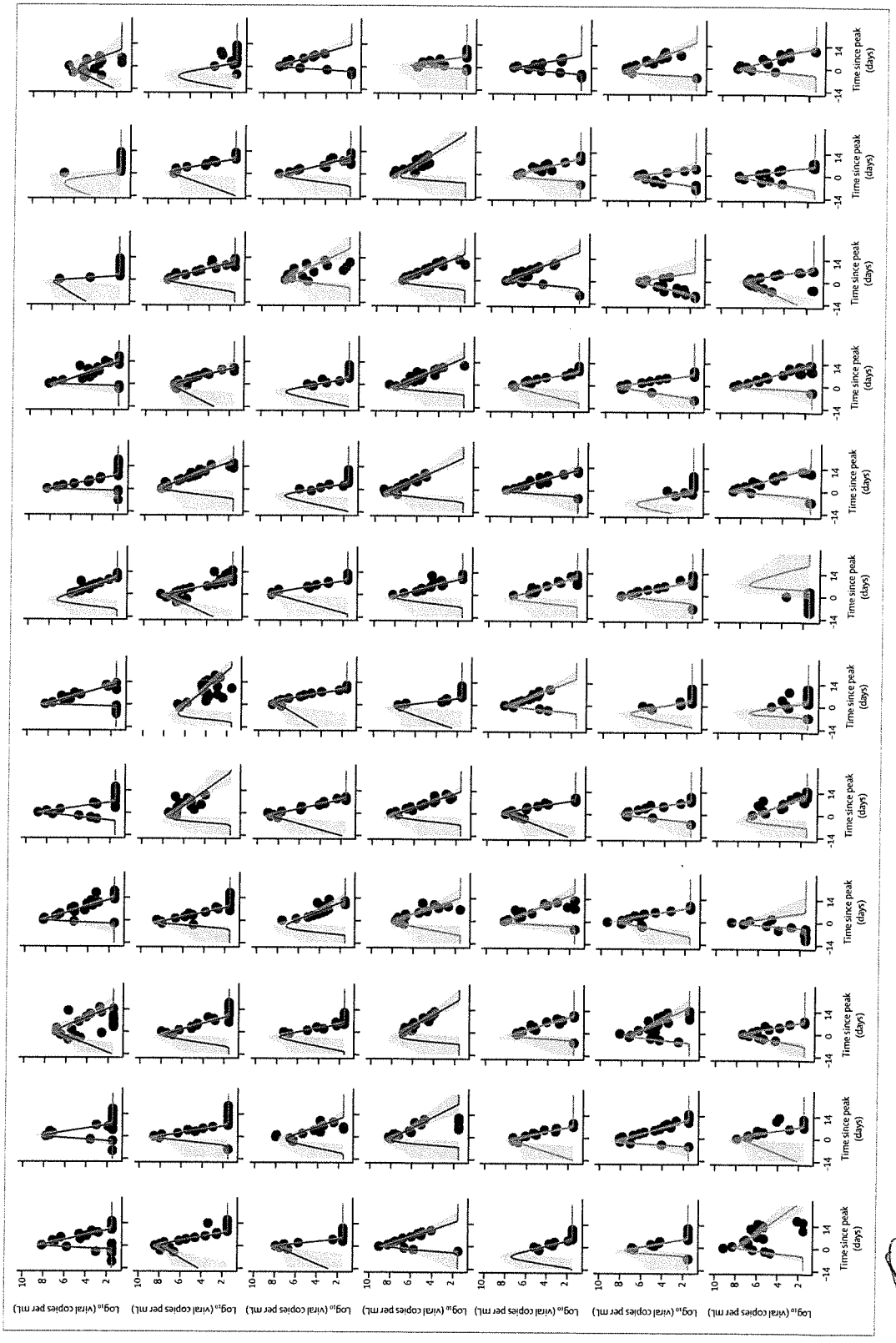


Figure 2: **Virological, epidemiological, and genomic evidence for transmission of the SARS-CoV-2 delta variant (B.1.617.2) in households**
(A) Genomic analysis of the four households with lineage-defining mutations for delta[18] and additional mutations within ORFs displayed to give insight into whether strains from individuals within the household are closely related. Lineages AY.4 and AY.9 are sub-lineages of delta. (B) Viral trajectories and vaccination status of the four index cases infected with the delta variant for whom infection was detected in their epidemiologically linked household contacts. All individuals had non-severe disease. Each plot shows an index case and their household contacts. Undetectable viral load measurements are plotted at the limit of detection ($10^{2\cdot49}$). C=contact. I=index case. FV=fully vaccinated. ORF=open reading frame. PV=partially vaccinated. U=unvaccinated.

Viral load growth rates were substantially faster than decline rates, varying in the range of $2\cdot69$–$3\cdot24$ $\log_{10}$ units per mL per day between groups, indicating that a typical 3-day period was required for viral load to grow from undetectable to peak. Our power to infer differences in growth rates between groups was more restricted than for viral decline, but there was moderate evidence (pp=0·79) that growth rates were lower for



(Figure 3 continues on next page)

Figure 3: **ORF1ab viral load trajectories from 14 days before to 28 days after peak for 133 participants infected with pre-alpha or alpha variants (uncaccinated), or the delta variant (vaccinated and unvaccinated) variants**
Black circles are measured values, with the first datapoint for each participant being taken to the day of enrolment. Plots are rooted on the day of peak viral load for each participant, denoted as day 0 on the x-axis. Curves show the model posterior median estimate, with a 95% credible interval shading. 133 infected participants, comprising 114 contacts and 19 index cases. *Index cases.

	VL growth rate (95% CrI), log_{10} units per day	Posterior probability estimate is less than pre-alpha	Posterior probability estimate is less than alpha	Posterior probability estimate is less than delta (unvaccinated)	Posterior probability estimate is less than delta (fully vaccinated)
Pre-alpha (n=49)	3·24 (1·78–6·14)	..	0·44	0·27	0·21
Alpha (n=39)	3·13 (1·76–5·94)	0·56	..	0·32	0·25
Delta, unvaccinated (n=16)	2·81 (1·47–5·47)	0·73	0·68	..	0·44
Delta, fully vaccinated (n=29)	2·69 (1·51–5·17)	0·79	0·75	0·56	..

VL growth rates are shown as within-sample posterior mean estimates. Remaining columns show population (group-level) posterior probabilities that the estimate on that row is less than an estimate for a different group. Posterior probabilities are derived from 20 000 posterior samples and have sampling errors of <0·01. VL=viral load. CrI=credible interval.

Table 3: **Estimates of VL growth rates for pre-alpha, alpha, and delta (unvaccinated and fully vaccinated) cases, derived from ORF1ab cycle threshold data**

	VL decline rate (95% CrI), log_{10} units per day	Posterior probability estimate is larger than pre-alpha	Posterior probability estimate is larger than alpha	Posterior probability estimate is larger than delta (unvaccinated)	Posterior probability estimate is larger than delta (fully vaccinated)
Pre-alpha (n=49)	0·69 (0·58–0·81)	..	0·07	0·21	0·01
Alpha (n=39)	0·82 (0·67–1·01)	0·93	..	0·60	0·16
Delta, unvaccinated (n=16)	0·79 (0·59–1·04)	0·79	0·40	..	0·15
Delta, fully vaccinated (n=29)	0·95 (0·76–1·18)	0·99	0·84	0·85	..

VL decline rates are shown as within-sample posterior mean estimates. Remaining columns show population (group-level) posterior probabilities that the estimate on that row is less than an estimate for a different group. Posterior probabilities are derived from 20 000 posterior samples and have sampling errors of <0·01. VL=viral load. CrI=credible interval.

Table 4: **Estimates of VL decline rates for pre-alpha, alpha, and delta (unvaccinated and fully vaccinated) cases, derived from ORF1ab cycle threshold data**

those in the vaccinated delta group than in the pre-alpha group.

We estimated mean peak viral load for 50-year-old adults to be 8·14 (95% CrI 7·95 to 8·32) log_{10} copies per mL, but peak viral load did not differ by variant or vaccination status. However, we estimated that peak viral load increases with age (*pp*=0·96 that the slope of peak viral load with log[age] was >0), with an estimated slope of 0·24 (95% CrI −0·02 to 0·49) log_{10} copies per mL per unit change in log(age). This estimate translates to a difference of 0·39 (−0·03 to 0·79) in mean peak log_{10} copies per mL between those aged 10 years and 50 years.

Within-group individual participant estimates of viral load growth rate were positively correlated with peak viral load, with a correlation coefficient estimate of 0·42 (95% CrI 0·13 to 0·65; appendix p 8). Hence, individuals with faster viral load growth tend to have higher peak viral load. The decline rate of viral load was also negatively correlated with viral load growth rate, with a correlation coefficient estimate of −0·44 (95% CrI −0·67 to −0·18), illustrating that individuals with faster viral load growth tend to experience slower viral load decline.

Discussion

Households are the site of most SARS-CoV-2 transmission globally.[19] In our cohort of densely sampled household contacts exposed to the delta variant, SAR was 38% in unvaccinated contacts and 25% in fully vaccinated contacts. This finding is consistent with the known protective effect of COVID-19 vaccination against infection.[8,9] Notwithstanding, these findings indicate continued risk of infection in household contacts despite vaccination. Our estimate of SAR is higher than that reported in fully vaccinated household contacts exposed before the emergence of the delta variant.[1,20,21] The time interval between vaccination and study recruitment was significantly higher in fully vaccinated PCR-positive contacts than fully vaccinated PCR-negative contacts, suggesting that susceptibility to infection increases with time as soon as 2–3 months after vaccination—consistent with waning protective immunity. This potentially important observation is consistent with recent large-scale data and requires further investigation.[17] Household SAR for delta infection, regardless of vaccination status, was 26% (95% CI 20–32), which is higher than estimates of UK national surveillance data (10·8% [10·7–10·9]).[10] However, we sampled contacts daily, regardless of symptomatology, to actively identify infection with high sensitivity. By contrast, symptom-based, single-timepoint surveillance testing probably underestimates the true SAR, and potentially also overestimates vaccine effectiveness against infection.

We identified similar SAR (25%) in household contacts exposed to fully vaccinated index cases as in those exposed to unvaccinated index cases (23%). This finding indicates that breakthrough infections in fully vaccinated people can efficiently transmit infection in the household setting. We identified 12 household transmission events between fully vaccinated index case–contact pairs; for three of these, genomic sequencing confirmed that the index case and

contact were infected by the same delta variant sub-lineage, thus substantiating epidemiological data and temporal relationships of viral load kinetics to provide definitive evidence for secondary transmission. To our knowledge, one other study has reported that transmission of the delta variant between fully vaccinated people was a point-source nosocomial outbreak—a single health-care worker with a particular delta variant sub-lineage in Vietnam.[22]

Daily longitudinal sampling of cases from early (median 4 days) after exposure for up to 20 days allowed us to generate high-resolution trajectories of URT viral load over the course of infection. To date, two studies have sequentially sampled community cases of mild SARS-CoV-2 infection, and these were from highly specific population groups identified through asymptomatic screening programmes (eg, for university staff and students[23] and for professional athletes[24]).

Our most predictive model of viral load kinetics estimated mean peak $\log_{10}$ viral load per mL of 8·14 (95% CrI 7·95–8·32) for adults aged 50 years, which is very similar to the estimate from a 2021 study using routine surveillance data.[25] We found no evidence of variation in peak viral load by variant or vaccination status, but we report some evidence of modest but significant (pp=0·95) increases in peak viral load with age. Previous studies of viral load in children and adults[4,25,26] have not used such dense sequential sampling of viral load and have, therefore, been restricted in their power to resolve age-related differences; the largest such study[25] reported a similar difference between children and adults to the one we estimated. We found the rate of viral load decline was faster for vaccinated individuals with delta infection than all other groups, and was faster for individuals in the alpha and unvaccinated delta groups than those with pre-alpha infection.

For all variant vaccination groups, the variation between participants seen in viral load kinetic parameter estimates was substantially larger than the variation in mean parameters estimated between groups. The modest scale of differences in viral kinetics between fully vaccinated and unvaccinated individuals with delta infection might explain the relatively high rates of transmission seen from vaccinated delta index cases in our study. We found no evidence of lower SARs from fully vaccinated delta index cases than from unvaccinated ones. However, given that index cases were identified through routine symptomatic surveillance, there might have been a selection bias towards identifying untypically symptomatic vaccine breakthrough index cases.

The differences in viral kinetics we found between the pre-alpha, alpha, and delta variant groups suggest some incremental, but potentially adaptive, changes in viral dynamics associated with the evolution of SARS-CoV-2 towards more rapid viral clearance. Our study provides the first evidence that, within each variant or vaccination group, viral growth rate is positively correlated with peak viral load, but is negatively correlated with viral decline rate. This finding suggests that individual infections during which viral replication is initially fastest generate the highest peak viral load and see the slowest viral clearance, with the latter not just being due to the higher peak. Mechanistically, these data suggest that the host and viral factors determining the initial growth rate of SARS-CoV-2 have a fundamental effect on the trajectory throughout infection, with faster replication being more difficult (in terms of both peak viral load and the subsequent decline of viral load) for the immune response to control. Analysis of sequentially sampled immune markers during infection might give insight into the immune correlates of these early differences in infection kinetics. It is also possible that individuals with the fastest viral load growth and highest peaks contribute disproportionately to community transmission, a hypothesis that should be tested in future studies.

Several population-level, single-timepoint sampling studies using routinely available data have found no major differences in cycle threshold values between vaccinated and unvaccinated individuals with delta variant infection.[10,27,28] However, as the timepoint of sampling in the viral trajectory is unknown, this restricts the interpretation of such results. Two other studies longitudinally sampled vaccinated and unvaccinated individuals with delta variant infection.[23,29] A retrospective cohort of hospitalised patients in Singapore[29] also described a faster rate of viral decline in vaccinated versus unvaccinated individuals with delta variant, reporting somewhat larger differences in decline rates than we estimated here. However, this disparity might be accounted for by the higher severity of illness in unvaccinated individuals in the Singaporean study (almost two-thirds having pneumonia, one-third requiring COVID-19 treatment, and a fifth needing oxygen) than in our study, given that longer viral shedding has been reported in patients with more severe illness.[30] A longitudinal sampling study in the USA reported that pre-alpha, alpha, and delta variant infections had similar viral trajectories.[24] The study also compared trajectories in vaccinated and unvaccinated individuals, reporting similar proliferation phases and peak cycle threshold values, but more rapid clearance of virus in vaccinated individuals. However, this study in the USA stratified by vaccination status and variant separately, rather than jointly, meaning vaccinated individuals with delta infection were being compared with, predominantly, unvaccinated individuals with pre-alpha and alpha infection. Moreover, sampling was done as part of a professional sports player occupational health screening programme, making the results not necessarily representative of typical community infections.

Our study has limitations. First, we recruited only contacts of symptomatic index cases as our study recruitment is derived from routine contact-tracing notifications. Second, index cases were defined as the first household member to have a PCR-positive swab, but we cannot exclude the possibility that another household member might already have been infected and transmitted

to the index case. Third, recording of viral load trajectories is subject to left censoring, where the growth phase in prevalent contacts (already PCR-positive at enrolment) was missed for a proportion of participants. However, we captured 29 incident cases and 15 additional cases on the upslope of the viral trajectory, providing valuable, informative data on viral growth rates and peak viral load in a subset of participants. Fourth, owing to the age-stratified rollout of the UK vaccination programme, the age of the unvaccinated, delta variant-infected participants was lower than that of vaccinated participants. Thus, age might be a confounding factor in our results and, as discussed, peak viral load was associated with age. However, it is unlikely that the higher SAR observed in the unvaccinated contacts would have been driven by younger age rather than the absence of vaccination and, to our knowledge, there is no published evidence showing increased susceptibility to SARS-CoV-2 infection with decreasing age.[31] Finally, although we did not perform viral culture here—which is a better proxy for infectiousness than RT-PCR—two other studies[27,32] have shown cultivable virus from around two-thirds of vaccinated individuals infected with the delta variant, consistent with our conclusions that vaccinated individuals still have the potential to infect others, particularly early after infection when viral loads are high and most transmission is thought to occur.[30]

Our findings help to explain how and why the delta variant is being transmitted so effectively in populations with high vaccine coverage. Although current vaccines remain effective at preventing severe disease and deaths from COVID-19, our findings suggest that vaccination alone is not sufficient to prevent all transmission of the delta variant in the household setting, where exposure is close and prolonged. Increasing population immunity via booster programmes and vaccination of teenagers will help to increase the currently limited effect of vaccination on transmission, but our analysis suggests that direct protection of individuals at risk of severe outcomes, via vaccination and non-pharmacological interventions, will remain central to containing the burden of disease caused by the delta variant.

Contributors

AS, JD, MZ, NMF, WB, and ALal conceptualised the study. AS, SH, JD, KJM, AK, JLB, MGW, ND-F, RV, RK, JF, CT, AVK, JC, VQ, EC, JSN, SH, EM, TP, HH, CL, JS, SB, JP, CA, SA, and NMF were responsible for data curation and investigation. AS, SH, KJM, JLB, AC, NMF, and ALal did the formal data analysis. MAC, AB, DJ, SM, JE, PSF, SD, and ALac did the laboratory work. RV, RK, JF, CT, AVK, JC, VQ, EC, JSN, SH, EM, and SE oversaw the project. AS, SH, JD, KJM, JLB, NMF, and ALal accessed and verified the data. JD, MZ, and ALal acquired funding. NMF sourced and oversaw the software. AS and ALal wrote the initial draft of the manuscript. AS, JD, GPT, MZ, NMF, SH, and ALal reviewed and edited the manuscript. The corresponding author had full access to all the data in the study and had final responsibility for the decision to submit for publication.

The ATACCC Study Investigators

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Declaration of interests

NMF reports grants from UK Medical Research Council, UK National Institute of Health Research, UK Research and Innovation, Community Jameel, Janssen Pharmaceuticals, the Bill & Melinda Gates Foundation, and Gavi, the Vaccine Alliance; consulting fees from the World Bank; payment or honoraria from the Wellcome Trust; travel expenses from WHO; advisory board participation for Takeda; and is a senior editor of the *eLife* journal. All other authors declare no competing interests.

Data sharing

An anonymised, de-identified version of the dataset can be made available upon request to allow all results to be reproduced. Modelling code will also be made publicly available on the GitHub repository.

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The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Population Immunity and Covid-19 Severity with Omicron Variant in South Africa

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Abstract

BACKGROUND

The B.1.1.529 (omicron) variant of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) was first identified on November 25, 2021, in Gauteng province, South Africa. Data regarding the seroprevalence of SARS-CoV-2 IgG in Gauteng before the fourth wave of coronavirus disease 2019 (Covid-19), in which the omicron variant was dominant, are needed.

METHODS

We conducted a seroepidemiologic survey from October 22 to December 9, 2021, in Gauteng to determine the seroprevalence of SARS-CoV-2 IgG. Households included in a previous seroepidemiologic survey (conducted from November 2020 to January 2021) were contacted; to account for changes in the survey population, there was a 10% increase in the households contacted, with the use of the same sampling framework. Dried-blood-spot samples were tested for IgG against SARS-CoV-2 spike protein and nucleocapsid protein with the use of quantitative assays. We also evaluated Covid-19 epidemiologic

trends in Gauteng, including cases, hospitalizations, recorded deaths, and excess deaths from the start of the pandemic through January 12, 2022.

RESULTS

Samples were obtained from 7010 participants, of whom 1319 (18.8%) had received a Covid-19 vaccine. The seroprevalence of SARS-CoV-2 IgG ranged from 56.2% (95% confidence interval [CI], 52.6 to 59.7) among children younger than 12 years of age to 79.7% (95% CI, 77.6 to 81.5) among adults older than 50 years of age. Vaccinated participants were more likely to be seropositive for SARS-CoV-2 than unvaccinated participants (93.1% vs. 68.4%). Epidemiologic data showed that the incidence of SARS-CoV-2 infection increased and subsequently declined more rapidly during the fourth wave than it had during the three previous waves. The incidence of infection was decoupled from the incidences of hospitalization, recorded death, and excess death during the fourth wave, as compared with the proportions seen during previous waves.

CONCLUSIONS

Widespread underlying SARS-CoV-2 seropositivity was observed in Gauteng before the omicron-dominant wave of Covid-19. Epidemiologic data showed a decoupling of hospitalizations and deaths from infections while omicron was circulating. (Funded by the Bill and Melinda Gates Foundation.)

Introduction

THE B.1.1.529 (OMICRON) VARIANT OF SEVERE ACUTE RESPIRATORY SYNDROME coronavirus 2 (SARS-CoV-2) was first identified on November 25, 2021, in Gauteng province, South Africa.[1] The World Health Organization designated omicron as a variant of concern because of its predicted high transmissibility and its potential to evade immunity from neutralizing antibodies induced by vaccination or natural infection with wild-type virus.[2] The omicron variant contains mutations that indicate that it could be more infectious, more transmissible, and possibly better able to evade innate immunity and neutralizing antibody activity than wild-type virus.[3-5] In addition to having at least 32 mutations affecting the spike protein,[6] the omicron variant harbors 3 mutations involving the membrane protein and 6 involving the nucleocapsid protein, whereas the antibody-evasive B.1.351 (beta) variant has only 7 spike-protein mutations and 1 nucleocapsid-protein mutation.[7]

The omicron variant outcompeted the B.1.617.2 (delta) variant in Gauteng and was responsible for 98.4% of new cases sequenced in South Africa in December 2021.[8] This fourth wave of coronavirus disease 2019 (Covid-19) arose in the context of the rollout of Covid-19 vaccines, which began on May 17, 2021, in South Africa. We previously conducted a population-wide seroepidemiologic survey in Gauteng that was completed on January 22, 2021.[9] We found that 19.1% of the population was seropositive for SARS-CoV-2, as assessed by the detection of IgG against the receptor-binding domain; the seroprevalence ranged from 5% to 43% across provincial subdistricts.[9] After that survey was completed, South Africa faced a third wave of Covid-19, from approximately April 7 to November 1, that was largely due to the delta variant, which outcompeted the beta variant.[10]

We report the results of a follow-up seroepidemiologic survey in Gauteng that was completed on December 9, 2021, and thus provides seroprevalence data largely from before the fourth wave of Covid-19. Furthermore, we report data regarding Covid-19 epidemiologic trends in Gauteng, including cases, hospitalizations, recorded deaths, and excess deaths from the start of the pandemic through January 12, 2022.

Methods

STUDY SETTING

Gauteng is divided into five health districts (Johannesburg, Ekurhuleni, Sedibeng, Tshwane, and West Rand) that comprise 26 subdistricts.[11] Gauteng constitutes 1.5% of the landmass in South Africa but contains 26% of the population (15.5 of 59.6 million persons).[11] The overall population density in Gauteng is 737 persons per square kilometer, with the value ranging from 3400 in Johannesburg, where 36.9% of the population lives, to 200 in West Rand, where 6.2% of the population lives (Table S1 in the **Supplementary Appendix**, available with the full text of this article at NEJM.org).

STUDY SURVEY

This survey included the same households that were sampled during our previous survey, which was undertaken from November 4, 2020, to January 22, 2021.[9] The previous survey was started 9 weeks after the onset of the second wave of Covid-19 in Gauteng, which was dominated by the beta variant. Details regarding the previous survey, including the sampling framework used, have been published[9] and are summarized in the Supplementary Methods section of the **Supplementary Appendix.**

This survey was conducted from October 22 to December 9, 2021. To account for possible nonparticipation, out-migration, and death since the previous survey, there was a 10% increase in the households that were sampled; the additional households were sampled in the same clusters used previously. The survey was powered to evaluate seropositivity for SARS-CoV-2 at the district and subdistrict levels. Demographic and epidemiologic data were collected with the use of an electronic questionnaire.[9] Details regarding the questionnaire are provided in the **Supplementary Appendix.**

The Human Research Ethics Committee at the University of the Witwatersrand granted a waiver for ethics approval of the survey, which was performed at the behest of the Gauteng Department of Health as part of public health surveillance. Nevertheless, all participants provided written informed consent; those who were approached to participate were free to decline participation. The authors designed the study, collected and analyzed the data, and vouch for the completeness and accuracy of the data and the fidelity of the study to the protocol. The authors wrote the manuscript; no one who is not an author contributed to the writing of the manuscript.

SEROLOGIC ANALYSIS

Dried-blood-spot samples were obtained from participants and tested for IgG against SARS-CoV-2 spike protein and nucleocapsid protein with the use of quantitative assays on the Luminex platform. Anti-nucleocapsid IgG was included to identify persons who were seropositive from natural infection rather

than vaccination. Details regarding the serologic assays have been published[12,13] and are summarized in the **Supplementary Appendix.**

COVID-19 DATA SOURCES

Data regarding daily cases, hospitalizations, and recorded deaths were sourced from the South African National Institute for Communicable Diseases daily databases, including the DATCOV database, through January 12, 2022.[14,15] Data regarding weekly excess deaths attributable to Covid-19 were defined by and sourced from the South African Medical Research Council through January 8, 2022.[16] We analyzed these epidemiologic data for Gauteng and its five health districts, both overall and with stratification according to age group and sex when granular data were available.

Cases included asymptomatic and symptomatic infections with SARS-CoV-2 confirmed by either a nucleic acid amplification assay or a rapid antigen test. Hospitalizations included admissions for SARS-CoV-2 infection, as well as admissions for other illnesses in which SARS-CoV-2 infection was incidentally identified on routine screening at the time of admission. Definitions of recorded death and excess death attributable to Covid-19 are provided in the **Supplementary Appendix.**

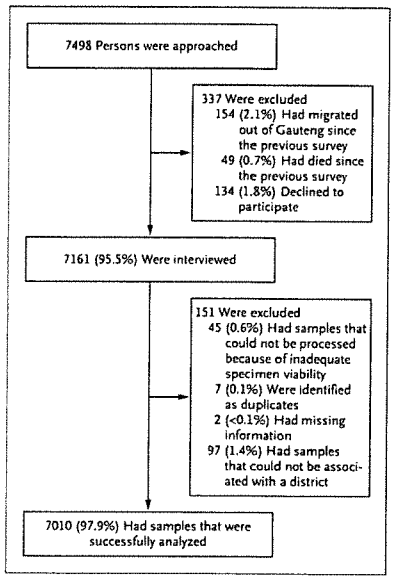
STATISTICAL ANALYSIS

The sample-size justification and the methods for repeated random sampling of households that were used in our previous survey have been published[9] and are summarized in the **Supplementary Appendix,** together with the methods for analyses of associations with seropositivity, which were performed with the use of generalized linear models with log link to estimate risk ratios. These were unadjusted, univariable analyses for each risk factor. Data regarding daily cases, hospitalizations, and recorded deaths and weekly excess deaths were converted to incidences with the use of population denominators from Statistics South Africa mid-2020 projections for South Africa and its provinces.[11]

Results

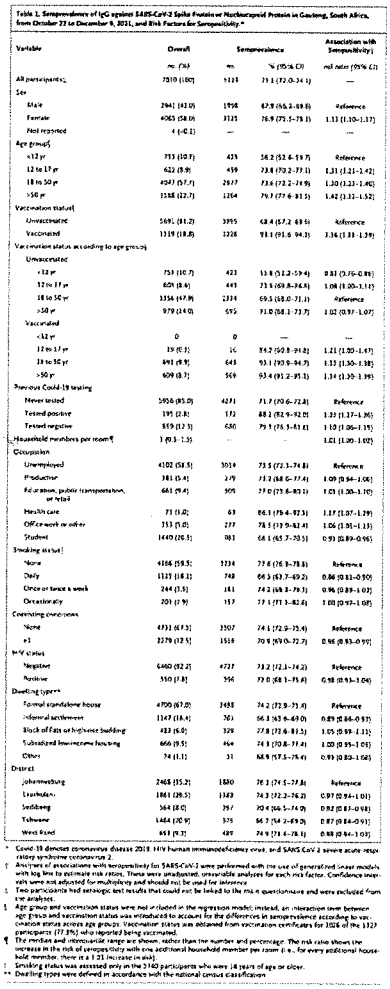
PARTICIPANTS

Figure 1.



Survey Participants.

Table 1.



Seroprevalence of IgG against SARS-CoV-2 Spike Protein or Nucleocapsid Protein in Gauteng, South Africa, from October 22 to December 9, 2021, and Risk Factors for Seropositivity.

We obtained samples that were adequate for serostatus evaluation from 7010 of 7498 participants from 3047 households (**Figure 1**); 83% of the samples had been obtained by November 25, 2021, when the

omicron variant was first identified (Fig. S1). Demographic and household characteristics, known underlying medical conditions and participant-reported human immunodeficiency virus status, and vaccination status of the survey participants are shown in **Table 1**. The degree to which the survey population was representative of the general population of Gauteng and of South Africa is described in Table S2. Vaccination in Gauteng according to district, age, and vaccine is summarized in Table S3. As of November 25, 2021, of the total population of 12,191,569 persons 12 years of age or older (who were eligible for vaccination), 4,386,646 (36.0%) had received at least one dose of BNT162b2 or Ad26.COV2.S, and 2,452,017 (20.1%) had received two doses. Of the 2,416,045 persons older than 50 years of age, 1,074,303 (44.5%) had received two doses of BNT162b2.

SEROPREVALENCE

Among unvaccinated participants, the overall prevalence of anti-spike or anti-nucleocapsid IgG seropositivity was 68.4% (95% confidence interval [CI], 67.2 to 69.6), whereas the prevalence of anti-nucleocapsid IgG seropositivity was 39.7% (95% CI, 38.4 to 41.0), a finding that indicates a lack of sensitivity of anti-nucleocapsid IgG for the detection of previous infection. We thus focused on the overall prevalence of anti-spike or anti-nucleocapsid IgG seropositivity.

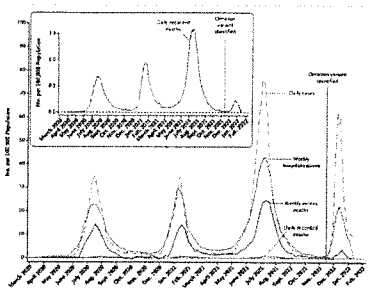
Among all participants, the overall seroprevalence was 73.1% (95% CI, 72.0 to 74.1) (**Table 1**). The seroprevalence was heterogeneous across provincial districts, ranging from 66.7% (95% CI, 54.2 to 69.0) in Tshwane, where the omicron variant was first identified, to 76.2% (95% CI, 74.5 to 77.8) in Johannesburg (Fig. S2). In addition, the seroprevalence was heterogeneous across subdistricts, ranging from 72.7% to 85.8% within Johannesburg and from 58.9% to 77.4% within Tshwane (Table S4).

Female participants were more likely to be seropositive than male participants (76.9% vs. 67.9%; risk ratio, 1.13; 95% CI, 1.10 to 1.17). The seroprevalence varied according to age group; it was lowest among children younger than 12 years of age (56.2%) and highest among adults older than 50 years of age (79.7%). Children 12 to 17 years of age were more likely to be seropositive than children younger than 12 years of age (73.8% vs. 56.2%; risk ratio, 1.31; 95% CI, 1.21 to 1.42). Participants who had received a Covid-19 vaccine were more likely to be seropositive than unvaccinated participants (93.1% vs. 68.4%; risk ratio, 1.36; 95% CI, 1.33 to 1.39). Among vaccinated participants, the seroprevalence was consistently high across age groups; among adults 18 to 50 years of age, those who were vaccinated had a higher seroprevalence than those who were unvaccinated.

Participants who had previously tested positive for SARS-CoV-2 infection were more likely to be seropositive than participants who had never been tested (88.2% vs. 71.7%; risk ratio, 1.23; 95% CI, 1.17 to 1.30). Participants living in an informal settlement had a lower seroprevalence than participants living in a standalone house (66.3% vs. 74.2%; risk ratio, 0.89; 95% CI, 0.86 to 0.93). Daily smoking was associated with a lower seroprevalence than was not smoking (66.5% vs. 77.6%; risk ratio, 0.86; 95% CI, 0.82 to 0.90).

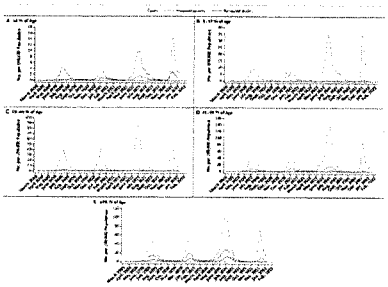
COVID-19 TRENDS

Figure 2.



Cases, Hospitalizations, Recorded Deaths, and Excess Deaths Attributable to Covid-19 in Gauteng, South Africa, from the Start of the Pandemic through January 12, 2022.

Figure 3.



Covid-19 Cases, Hospitalizations, and Recorded Deaths in Gauteng, South Africa, According to Age Group.

Daily cases, weekly hospitalizations, daily recorded deaths, and weekly excess deaths attributable to Covid-19 in Gauteng are shown in **Figure 2**. Daily cases, hospitalizations, and recorded deaths are also shown with stratification according to age group (**Figure 3**) and according to sex (Fig. S3).

During the fourth wave of Covid-19, in which the omicron variant was dominant, the daily case incidence increased more rapidly and also appeared to be decreasing more quickly than it had during the three previous waves (**Figure 2**). The time from the onset to the peak of the wave was 1 month in the fourth wave, as compared with 2 months in the third wave. As of January 12, 2022, the case incidence had not yet fully returned to the level before the onset of the fourth wave, but the wave was nearing its end, on the basis of the trajectory shown in **Figure 2**. At that time, there were almost no recorded or excess deaths attributable to Covid-19 per 100,000 population.

Table 2.

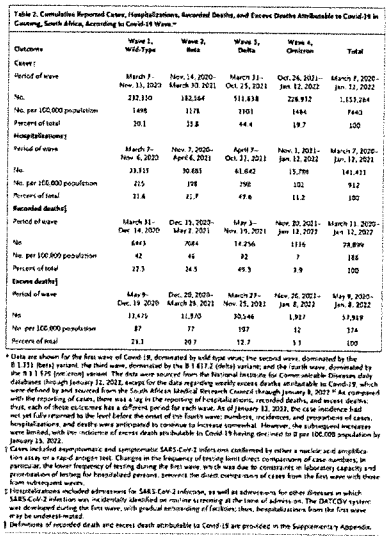


Table 2. Cumulative Reported Cases, Hospitalizations, Recorded Deaths, and Excess Deaths Attributable to Covid-19 in Gauteng, South Africa, According to Covid-19 Wave.*

Outcome	Wave 1, Wild-Type	Wave 2, Beta	Wave 3, Delta	Wave 4, Omicron	Total
Cases†					
Period of wave	March 7–Nov. 13, 2020	Nov. 14, 2020–March 13, 2021	March 31–Oct. 25, 2021	Oct. 26, 2021–Jan. 12, 2022	March 7, 2020–Jan. 12, 2022
No.	232,350	182,564	511,638	226,932	1,153,284
No. per 100,000 population	1498	1178	3301	1464	7443
Percent of total	20.1	15.8	44.4	19.7	100
Hospitalizations‡					
Period of wave	March 7–Nov. 6, 2020	Nov. 7, 2020–April 6, 2021	April 7–Oct. 31, 2021	Nov. 1, 2021–Jan. 12, 2022	March 7, 2020–Jan. 12, 2022
No.	33,315	30,683	61,642	15,799	141,421
No. per 100,000 population	215	198	398	102	912
Percent of total	23.6	21.7	43.6	11.2	100
Recorded deaths§					
Period of wave	March 11–Dec. 14, 2020	Dec. 15, 2020–May 2, 2021	May 3–Nov. 19, 2021	Nov. 20, 2021–Jan. 12, 2022	March 11, 2020–Jan. 12, 2022
No.	6443	7044	14,256	1116	28,859
No. per 100,000 population	42	45	92	7	186
Percent of total	22.3	24.5	49.3	3.9	100
Excess deaths§					
Period of wave	May 9–Dec. 19 2020	Dec. 20, 2020–March 29, 2021	March 27–Nov. 25, 2021	Nov. 26, 2021–Jan. 8, 2022	May 9, 2020–Jan. 8, 2022
No.	13,475	11,590	30,546	1,917	57,919
No. per 100,000 population	87	77	197	12	374
Percent of total	23.3	20.7	52.7	3.3	100

* Data are shown for the first wave of Covid-19, dominated by wild-type virus; the second wave, dominated by the B.1.351 (beta) variant; the third wave, dominated by the B.1.617.2 (delta) variant; and the fourth wave, dominated by the B.1.1.529 (omicron) variant. The data were sourced from the National Institute for Communicable Diseases daily databases through January 12, 2022, except for the data regarding weekly excess deaths attributable to Covid-19, which were defined by and sourced from the South African Medical Research Council through January 8, 2022.† As compared with the reporting of cases, there was a lag in the reporting of hospitalizations, recorded deaths, and excess deaths. First, each of these outcomes has a different period for each wave. As of January 12, 2022, the case incidence had not yet fully returned to the level before the onset of the fourth wave; numbers, incidences, and proportions of cases, hospitalizations, and deaths were anticipated to continue to increase somewhat. However, the subsequent increases were limited, with the incidence of excess death attributable to Covid-19 having declined to 8 per 100,000 population by January 13, 2022.

‡ Cases included asymptomatic and symptomatic SARS-CoV-2 infections confirmed by either a nucleic acid amplification assay or a rapid antigen test. Changes in the frequency of testing limit direct comparisons of case numbers, in particular, the lower frequency of testing during the first wave, which was due to constraints in laboratory capacity and prioritization of testing for hospitalized persons, prevents the direct comparisons of cases from the first wave with those from subsequent waves.

§ Hospitalizations included admissions for SARS-CoV-2 infection, as well as admissions for other diseases in which SARS-CoV-2 infection was incidentally identified on routine screening at the time of admission. The DATCOV system was developed during the first wave, with gradual networking of facilities; thus, hospitalizations from the first wave may be underestimated.

¶ Definitions of recorded death and excess death attributable to Covid-19 are provided in the Supplementary Appendix.

Cumulative Reported Cases, Hospitalizations, Recorded Deaths, and Excess Deaths Attributable to Covid-19 in Gauteng, South Africa, According to Covid-19 Wave.

The number of documented Covid-19 cases in the fourth wave (226,932) was higher than that in the second wave (182,564) and lower than that in the third wave (511,638), whereas the incidences of hospitalization, recorded death, and excess death attributable to Covid-19 in the fourth wave were consistently lower than the incidences in earlier waves (**Table 2**). In addition, the peak incidences of hospitalization, recorded death, and excess death in the fourth wave were lower than the peak incidences in previous waves. The fourth wave contributed 11.2%, 3.9%, and 3.3% of overall hospitalizations, recorded deaths, and excess deaths due to Covid-19, respectively, whereas the third wave, in which the delta variant was dominant, contributed 43.6%, 49.3%, and 52.7%. Similar trends were observed across all districts (Fig. S4). Although there is a lag in the reporting of weekly excess deaths, the incidence in the fourth wave as of January 8, 2022 (12 per 100,000 population), was lower than the incidence in the third wave (197 per 100,000 population). As of January 12, 2022, incidences were on an ongoing downward trajectory, with a 7-day moving average of 7.28 cases, 0.96 hospitalizations, and 0.11 recorded deaths per 100,000 population — a decrease by a factor of 9.3, 3.3, and 2.4 from the peak incidence of 67.56 cases, 3.18 hospitalizations, and 0.26 recorded deaths per 100,000 population, respectively. The incidences were nearing prewave levels (as of October 25, 2021) of 0.46 cases, 0.15 hospitalizations, and 0.04 recorded deaths per 100,000 population.

During the fourth wave, decreased incidences of hospitalization and recorded death were evident across all age groups older than 17 years and among both men and women. The incidences of hospitalization and recorded death among children 17 years of age or younger, which have consistently been markedly lower than the incidences in older age groups, were similar to the incidences during earlier waves, except for a lower mortality among children 5 to 17 years of age during the fourth wave than during the third (delta-dominant) wave (**Figure 3** and Tables S5, S6, and S7).

Discussion

In Gauteng, the resurgence of Covid-19 that was dominated by the omicron variant evolved at a time when Covid-19 vaccine coverage was 36.0% among persons 12 years of age or older, with only 20.1% having received at least two doses of a Covid-19 vaccine as part of the national vaccine rollout program. Nevertheless, the results of our survey showed widespread underlying SARS-CoV-2 seropositivity across the province (73.1%), including a prevalence at the subdistrict level of up to 85.8%, before the onset of the omicron-dominant wave. This high seroprevalence was primarily induced by previous SARS-CoV-2 infection, as evidenced by the 68.4% seroprevalence among participants who had not received a Covid-19 vaccine. The methods used for selecting the random sample of households in the survey, with a distribution proportionate to subdistrict population sizes, ensured that the sample was representative of the general population of Gauteng.

In this context, we observed a dramatic decoupling of hospitalizations and deaths from infections during the fourth wave of Covid-19, as compared with the proportions seen during the three previous waves. The biologic basis for this decoupling could be the extensive cell-mediated immunity in the population that was induced by previous natural infection and vaccination. At least one vaccine dose had been administered to 61.2% of adults older than 50 years of age (1,479,288 of 2,416,045), who had accounted for 81.0% of all deaths (22,269 of 27,500) due to Covid-19 in Gauteng through the end of the third wave.[17] Although we did not evaluate cell-mediated immunity, other studies have shown that natural infection induces a diverse polyepitopic cell-mediated immune response that targets the spike protein, nucleocapsid protein, and membrane protein.[18] Consequently, cell-mediated immunity is likely to be more durable than neutralizing antibody–mediated immunity in the context of small mutations,[19] particularly those mainly affecting the spike protein, such as those in the omicron variant. Furthermore, natural infection induces robust memory T-cell responses, including long-lived cytotoxic (CD8+) T cells, which have a half-life of 125 to 255 days.[20]

We think that the evolution of cell-mediated immunity from previous natural infection and vaccination has resulted in the decoupling of the high case incidence seen with the omicron variant from the incidence of severe disease (hospitalizations and deaths). This decoupling has occurred despite evidence that the omicron variant evades neutralizing antibody activity induced by spike-protein–based vaccines and by previous infection with other variants that did not harbor the same full set of putatively antibody-evasive mutations. Our hypothesis is supported by two recent preprint publications, which indicated that most of the T-cell response induced by vaccination or natural infection cross-recognizes the omicron variant, thereby probably contributing to protection against severe disease.[21,22] An alternative or additional mechanism by which protection against severe disease may be conferred, despite the reduced neutralizing antibody activity against the omicron variant, is through Fc-mediated effector functions of non-neutralizing antibodies that induce antibody-mediated cellular phagocytosis, complement deposition, and natural killer–cell activation.[19,23] In addition, the omicron variant may be less potent in causing serious illness.

We saw a high incidence of Covid-19 cases due to the omicron variant despite the high seroprevalence of humoral immune responses, a finding consistent with the antibody-evasive nature of the omicron variant. Reports have indicated that the omicron variant is more capable of evading neutralizing antibody activity than even the beta variant.[7,24-26] Neutralizing antibody activity against the omicron

variant after two doses of BNT162b2 or AZD1222 (also known as ChAdOx1 nCoV-19) was shown to be substantially lower than vaccine-induced neutralizing antibody activity against wild-type virus.[27,28] Nevertheless, the majority of persons with hybrid immunity from natural infection and BNT162b2 or AZD1222 vaccination have measurable neutralizing antibody activity against the omicron variant, albeit a lower level than that against the wild-type virus.[24] In this context, a high incidence of breakthrough cases and reinfections with the omicron variant was to be expected in South Africa, where the majority of persons had immunity from natural infection, which induces a lower magnitude of anti-spike neutralizing and binding antibody responses than vaccination.[25] Furthermore, as part of its vaccine rollout at the time of the evolution of the fourth wave, South Africa was providing only a single dose of Ad26.COV2.S, which induces lower titers of neutralizing and blocking antibodies than two doses of BNT162b2[25]; the third (booster) dose of BNT162b2 had not been introduced in South Africa at that time.

This clinical evidence of the antibody-evasive nature of the omicron variant is corroborated by early studies that showed limited vaccine effectiveness against omicron at 25 weeks after two doses of AZD1222 or BNT162b2.[29] However, vaccine effectiveness was substantially increased at 2 weeks after a booster dose of BNT162b2,[29] which results in much higher neutralizing antibody titers than two doses of the vaccine[30] and thus may partly mitigate the relative antibody-evasiveness of the omicron variant. In addition, in South Africa, vaccine effectiveness against hospitalization was 70% with the omicron variant, as compared with 93% with the delta variant.[31] These data, together with the very limited neutralizing antibody activity against the omicron variant after two doses of AZD1222 or BNT162b2, further corroborate the evidence that protection against severe Covid-19 due to the omicron variant is probably mediated by much lower neutralizing antibody titers than those required to protect against SARS-CoV-2 infection or mild Covid-19[25] or is provided by cell-mediated immunity or the Fc-effector functions of non-neutralizing antibodies (or a combination of these mechanisms).[19,23]

The antibody-evasive nature of the omicron variant is analogous to the antibody-evasiveness of the beta variant in recipients of AZD1222, the AstraZeneca chimpanzee adenovirus–based vaccine. AZD1222 was shown to have no effectiveness against mild-to-moderate Covid-19 due to the beta variant.[32] However, vaccine effectiveness against hospitalization or death due to the beta or P.1 (gamma) variant was 80% in a report from Canada.[33] Although AZD1222 induced nominal neutralizing antibody activity against the beta variant, only 11 of the 87 spike-protein epitopes targeted by T-cell immune responses induced by AZD1222 were affected by mutations in the beta variant.[32] The dissociation between the lack of AZD1222-induced neutralizing antibody activity and the protection against severe disease involving the lower respiratory tract was also observed in a challenge study with AZD1222 against the beta variant in a Syrian golden hamster model.[34]

Evidence of the high transmissibility of the omicron variant is corroborated by the rapid rise in reported Covid-19 cases in Gauteng during the fourth wave. Indeed, the increase in the case incidence during the fourth wave occurred faster than that during any previous wave, a finding that indicates that the omicron variant is more transmissible than even the delta variant, which had an estimated reproductive number (R_0) of 5 to 6.[35]

Our study has some limitations. First, we used publicly available data regarding Covid-19 morbidity and mortality that were collated in surveillance systems and could have changed over time, which could affect comparisons across the four waves. The DATCOV database does not distinguish between patients hospitalized for SARS-CoV-2 infection and patients hospitalized for other illnesses who incidentally had a positive test for SARS-CoV-2 on routine screening. Nevertheless, data from these systems are unlikely to have changed since the third wave. Second, changes in the frequency of testing over time limit head-to-head comparisons of case numbers across waves, although the criteria for testing have been similar since the start of the second wave. Finally, the fourth wave had not fully subsided at the time of this analysis. The numbers, incidences, and proportions of total cumulative cases, hospitalizations, and deaths attributable to this wave — in particular, the data for hospitalizations and deaths, because there is a lag in the reporting of these data — were anticipated to continue to increase somewhat. However, the subsequent increases were limited, with the incidence of excess death attributable to Covid-19 having declined to 0 per 100,000 population by January 15, 2022.

Our hypothesis that cell-mediated immunity primarily due to natural infection, with or without Covid-19 vaccination, has resulted in the decoupling of cases from severe disease remains to be investigated. In particular, the extent to which the polyepitopic T-cell response induced by vaccination against the spike protein — as well as the even more diverse polyepitopic T-cell response stimulated by natural infection, with or without vaccination — remains cross-reactive against the omicron variant warrants further investigation.[21,22] Another possible contributing factor to the decoupling of cases from severe disease with the omicron variant, as compared with the proportions seen with previous variants, is that the omicron variant may be more adept at infecting the upper airways and less adept at infecting the lower airways, which could result in reduced virulence.[36] The difference in the prevalence of immunity across waves limits our ability to draw any conclusions regarding the relative roles of reduced virulence and higher prevalence of underlying cell-mediated immunity in contributing to the decoupling of cases from severe disease observed with the omicron variant in our study.

We think that the decoupling of the incidence of Covid-19 cases from the incidences of hospitalization and death during the omicron-dominant wave in South Africa heralds a turning point in the Covid-19 pandemic, if the primary goal is protection against severe disease and death rather than prevention of infection. The 70% vaccine effectiveness against severe disease with BNT162b2 in South Africa[31] might well be due to the hybrid cell-mediated immunity induced by vaccination and natural infection. Whether the same protection against severe Covid-19 due to the omicron variant will be seen in countries in which immunity is mainly from vaccination remains to be determined.

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Data are available at www.wits-vida.org; requests for data sharing should be directed to Dr. Madhi at shabir.madhi@wits.ac.za.

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Supplementary Material

Supplementary Appendix	PDF	1557KB
Disclosure Forms	PDF	299KB

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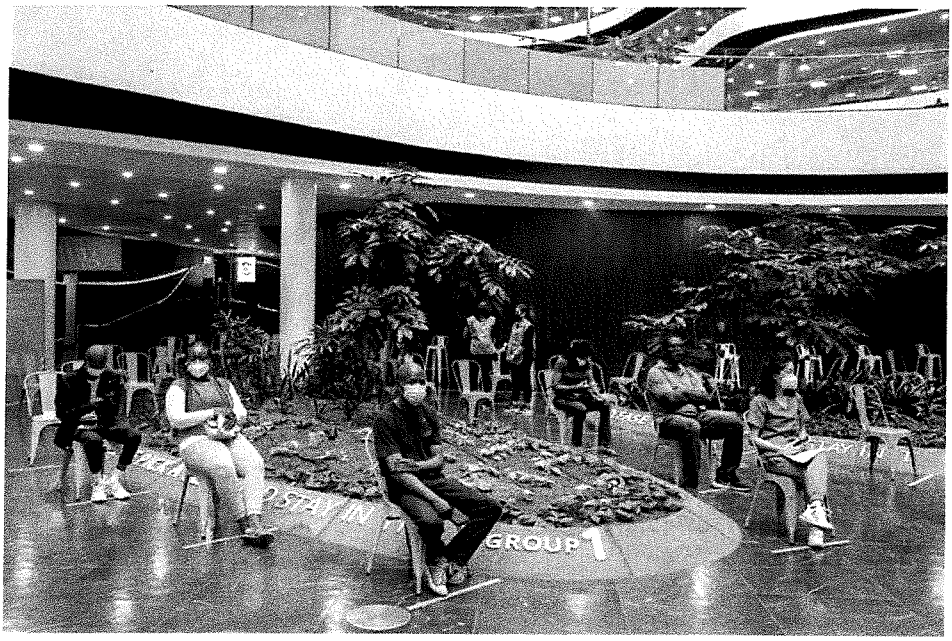
Academic rigour, journalistic flair

New COVID data: South Africa has arrived at the recovery stage of the pandemic

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People wait to be vaccinated against COVID-19. Luca Sola/AFP via Getty Images

A recently published South African study set out to determine sero-positivity against SARS-CoV-2 before the fourth wave of COVID-19, in which the omicron variant was dominant. Sero-positivity measures the presence of antibodies against the virus; it indicates past infection. The study focused on Gauteng, the country's economic hub. Ozayr Patel asked Shabir Madhi to unpack the results and explain why the findings suggest that South Africa has reached a turning point in the pandemic.

What we found

The results show the levels of sero-positivity – in other words what percentage of people have antibodies to the virus – among just over 7,000 people from whom samples were taken. From these results the following rates were calculated:

- In those under 12 years of age, none of who received a COVID-19 vaccine, 56% showed presence of antibodies to SARS-CoV-2

- In those over 50 it was 80%, including 70% if unvaccinated and 93% if vaccinated
- In high density inner city areas the sero-positivity prevalence was 85%

Using the seroprevalence data, together with COVID-19 attributable deaths using excess mortality data from the South African Medical Research Council, the study was also able to impute the risk of dying following infection by SARS-CoV-2 prior to the Omicron wave in South Africa. This infection fatality risk for COVID-19 was 0.57% pre-omicron in Gauteng. This is substantially higher than 0.019% imputed for seasonal flu, which infected one-third of the population each year pre-COVID, calculated using similar methods.

Vaccination coverage: We discovered high levels of hybrid immunity: that is immunity gained from a combination of previous infections plus vaccinations.

At the time of the onset of the omicron wave, 36% of people in Gauteng had at least one dose of the vaccine. This was higher – 61% – in those over the age of 50. (This cohort was responsible for more than 80% of deaths pre-omicron.)

Based on sero-survey, 70% of vaccinated people were also infected pre-omicron. Hence they would have had substantial hybrid immunity, which has been shown to induce a broader repertoire of immune responses against the virus. Such hybrid immunity in South Africa has, however, come at the cost of loss of 300,000 lives based on South African Medical Research Council excess mortality estimates. These are three-fold higher than the official recorded number of deaths.

Based on another study, the hybrid immunity is expected to confer greater protection against infection and mild COVID-19 compared with immunity only from vaccine or natural infection.

Hospitalisations and death rates: Our study also analysed the temporal trends in COVID-19 cases, hospitalisations and deaths (recorded and COVID attributable from excess mortality) from the start of the pandemic up until the tail end of the Omicron wave. The study found a massive decoupling between the number of people becoming infected with the virus relative to COVID hospitalisation and death rates during the course of omicron compared with earlier waves. This was true across all adult age groups.

The omicron wave was associated with 10% of all hospitalisations since the start of the pandemic, whereas 44% of hospitalisations had transpired during the course of the Delta variant wave. More impressively, only 3% of COVID deaths since the start of the pandemic occurred during the omicron wave, compared with 50% during the delta dominant wave.

The findings of decoupling of infections and severe or fatal COVID-19 were similar in the 50-59 year age group. In this group the omicron wave contributed to 15% of recorded COVID hospitalisations and 2% of deaths since the start of pandemic. This compares with 46% of hospitalisations and 53% of deaths occurring in the third wave, dominated by delta. The data for people over 60 years old was similar.



The survey also found that 58% of children under 12 years of age (all unvaccinated) were sero-positive. They were not more heavily affected during the Omicron wave.

The delta dominant wave which was the most severe in South Africa, coincided with South Africa's belated COVID vaccine rollout. The high death rate during that wave is an indictment of the missed opportunities that could have prevented a large percentage of the deaths which transpired. In particular, the delayed procurement and roll out of COVID-19 vaccines in South Africa, as well as the ill-informed decision to against the WHO recommendation on the continued use of the AstraZeneca vaccine which was available to in South Africa when the Beta variant was circulating in South Africa.

In summary, the omicron wave contributed to less than 5% of all COVID-19 deaths in Gauteng. Since the start of the pandemic, the delta variant wave contributed to 50% of all of the deaths. The balance is split roughly equally between the first and second waves caused by ancestry and the beta variant.

Our findings also show that natural infection has been high and is playing a major role in how the pandemic has unfolded especially in countries with low to moderate COVID-19 rollout. These high levels of infections have, however, resulted in a massive loss of lives; which to date is likely under-estimated in low and middle income countries as shown from the South African data.

What the findings tell us

The findings indicate that South Africa is moving into the convalescent phase of the COVID pandemic – the recovery phase. This is likely to be the same in other countries with low or modest vaccine uptake, but high force of past infections. As such, South Africa needs to recaliberate its approach to the pandemic and to start managing it as we would do for other respiratory infections which too cause large number of hospitalisations and deaths.

There are still a few unknowns. Another resurgence is likely, and there might well be another variant. But it would be very surprising if further variants are able to evade the T-cell arm of the immune system which is stimulated by vaccines and natural infection. The T-cell (cell mediated immunity) arm of the immune system, appears to be the main mediator of protecting against severe COVID-19, even when there are breakthrough infections in vaccinated people or reinfections.

So why do I believe that we are at the tail end of this pandemic? It depends what metric you use. If it's about infections, we're not at the tail end. If it's about the number of deaths that will transpire from COVID-19 during 2022, relative to the number of deaths that will transpire from other preventable causes of death in countries such as South Africa, then I believe the country has pretty much arrived towards the end of this pandemic.

In South Africa about 10,000 to 11,000 people die of seasonal influenza every year. In 2019 tuberculosis killed 58 000 in 2019. But we are not declaring an emergency in South Africa to deal with flu or tuberculosis. Deaths from HIV, and complications from HIV, are about 70,000. But South Africa isn't shutting down the country to prevent deaths and infections from these diseases.

Now what?

Only 12% of people across the continent have received one dose of vaccination. The implications of our findings are that:

- Vaccine coverage must be enhanced by ensuring that adequate booster doses are given to those who require it. We might need to continue boosting. This might need to be on an annual basis for the next two to three years, especially for high risk individuals. The time line for this is until we have more experience on the durability of protection of vaccines, particularly in settings with a high prevalence of hybrid immunity (where protection may be even longer lasting.)

Campaigns should be focused primarily on high risk groups, including getting over 90% of people over 50 years of age vaccinated before the next resurgence anticipated. This should be the focus rather than the current arbitrary target of vaccinating 40%-70% of the population.

- It's still beneficial to expand vaccinations in settings with high sero-positivity. Studies on hybrid immunity show this delivers more robust and broader repertoire immune responses that could heighten protection against infection, and reduce the magnitude of future resurgences.

- It's also important that key non-pharmacuetical interventions are kept in place. This includes wearing masks in crowded poorly ventilated indoor places, and particularly high risk individuals when there is an increase in virus transmission activity.

Our findings support the optimism expressed at the beginning of 2022 in South Africa that a turning point had been reached in the pandemic. Many in high income countries dismissed this view as not applicable to their settings despite high vaccine coverage. But their experience has since generally aligned with South Africa's.

Read more: South Africa has changed tack on tackling COVID: why it makes sense

Lastly, better COVID vaccines are required. But the world is no longer at "code red". And it's time to rebuild livelihoods, economies and all other facets of life that were affected over the past two years. This is particularly true in fragile low and middle income countries.

OVERVIEW BY THE CHIEF ELECTORAL OFFICER

The Electoral Commission is honoured to present the 2021 Municipal Elections Report, which covers elections that were challenging, exciting and historic.

This report is presented in pursuance of Section 14(3) of the Electoral Commission Act (Act No 51 of 1996) and sets out the activities undertaken during the total electoral cycle for the 2021 Municipal Elections held on 1 November 2021.

These elections were historic in that they were held under conditions imposed by COVID-19. This public health crisis posed many unprecedented challenges in the preparation for and holding of elections. Faced with these challenges, our duty was to preserve the integrity of the Commission, the electoral process, and election outcomes as required in terms of the Constitution of the Republic of South Africa. We were able to do so with pleasing efficiency, because our focus was on delivering the best elections possible, despite the challenges.

The decision that the Commission took to create a transparent process – chaired by retired Deputy Chief Justice Dikgang Moseneke – on whether free and fair elections were possible within the COVID-19 context, was a necessity.

We are proud to report that, throughout the disruptions brought about by COVID-19, the Commission continued to function in compliance with prescripts. Therefore, once the legal challenges were dispensed with, it was possible to deliver elections in 42 days – the shortest period in the history of our electoral democracy.

With so many challenges, we experienced inexcusable ills, but they are part of the elections environment. However, delivering, as we did, a registration weekend in 14 days was a major achievement. Equally, delivering an election in 42 days was the second major positive landmark.

For the staff at the Commission, delivering these elections was a big call and it is one that they answered with aplomb. For that, the Commission remains eternally grateful to each one of them.



Electoral Commission Chief Electoral Officer, Simon Mamabolo

In keeping with our constitutional commitment of being inclusive, our electoral engagement had a social consciousness and was thus alive to the fact that we have, among us, those who are infirm or with impaired mobility. Hence, South Africans in special circumstances were offered an opportunity to cast special votes on 30 and 31 October 2021.

Special votes served a twin purpose: on the one hand, they enfranchised people in special circumstances and assisted with the depopulation of voting stations on Elections Day in line with COVID-19 protocols. They also offered the Commission an opportunity to sharpen the proficiency of its operations ahead of Voting Day.

Without a doubt, the 2021 Municipal Elections will go down in history as the most innovative. The use of voter management devices (VMDs) catapulted electoral management in our country to new heights, setting a foundation for future innovations. Yes, operational challenges were encountered, but despite that, the VMDs were a success we can all be proud of.

The Commission deployed 30 387 VMDs, which were centrally connected through an Access Point Network.

This digital connection enabled the strengthening of controls in the voting process. Once ballots had been issued to a voter, voters could not present themselves at another voting station without detection. In use at the voting stations was a live, centrally connected voters' roll. This capability will decisively lay to rest allegations of double voting.

With the VMD, possibilities abound. The prospect of building additional engines and reports will enable the real-time monitoring of the quantities of ballot papers issued and on hand at each voting station. This will remedy the reports of voting stations running out of ballot papers.

Therefore, the introduction of VMDs can only serve to fortify controls in the voting process and enhance the capability to manage the voting process efficiently. The challenges of the moment, as we experienced, should not cloud our desire to exploit digital innovations to improve our electoral programmes. We dare not retard the progress we have made.

Our electoral enterprise is about people and their well-being. So, the views expressed by voters through a survey conveyed by the Human Sciences Research Council (HSRC) are important.

The HSRC interviewed 12 189 randomly sampled voters in 300 voting stations across the country during different time segments throughout Voting Day. By acceptable standards, this is a representative sample that enables us to make generalisations of the whole voter population.

Some 97% of the sampled voters found the voting procedures inside our voting stations easy to understand, while 94% was satisfied with the ballot papers used in the elections. In other words, the identifiers used in the ballot design were clear and not confusing to voters.

This survey further indicated that 96% was satisfied with the secrecy of the ballot, while 93% was satisfied with the safety and security at voting stations. Some 84% expressed confidence in the accuracy of the counting and tallying processes. Most importantly, 95% experienced the elections as being free and fair.

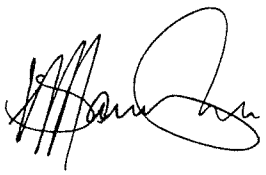
We are also glad that this survey reflects that 93% of the voters commended the Commission's efforts to mitigate the risk of COVID-19 at the voting stations.

Overall, voters said their lived electoral reality was positive and consistent with their expectations of integrity standards in the voting process.

The people have indeed spoken.

This is a solid foundation on which we will build future electoral operations. The Commission will continue to work with all its stakeholders to improve the voter experience.

I echo the gratitude expressed by the Vice-Chairperson to all stakeholders and our staff for the role they played in delivering good-quality, free and fair municipal elections in South Africa.



Simon Mamabolo
Chief Electoral Officer
Electoral Commission of South Africa