# Deutscher Ethikrat





# Immunity Certificates during the Covid-19 Pandemic

OPINION

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# 1 INTRODUCTION

The situation regarding the Covid-19 pandemic in late summer 2020 shows that the physical distancing strategy has proved successful – at least in Germany. The number of acutely infected people could be contained. The health care system has proved itself to be essentially robust. Intensive care capacity was not overstretched at any time. The number of people who died from or with Covid-19 has to some degree been limited. Meanwhile, the current renewed increase in infection numbers, due to the easing of various measures, indicates a need for caution as autumn and winter approach. The pandemic is not over.

In parallel – as far as can be seen at the present time – much of the feared political, social, economic or cultural collateral damage caused particularly by restrictive infection prevention and control measures, has already occurred. It is therefore ethically and legally imperative that the proportionality of restrictions be subjected to ongoing epidemiological and normative evaluation, and that measures be applied in an expedient and limited manner. This is precisely what the German Ethics Council had already called for in its Ad hoc Recommendation "Solidarity and Responsibility during the Coronavirus Crisis".

For some months now, the introduction of state-controlled immunity certificates<sup>2</sup> has also been under discussion. The possible introduction of these certificates is linked to strict scientific, legal, ethical and administrative requirements. The fulfilment, practicability and proportionality of these

<sup>1</sup> Cf. Deutscher Ethikrat 2020, 6.

In conjunction with this proposal, various terms are doing the rounds. In addition to "immunity documentation", they include "immunity passport", "immunity card" or "proof of immunity". In this Opinion the term "immunity certificates" is used. What is meant by this is the documentation of immunity – at the present time in a counterfactual manner – which is confirmed on the basis of sufficiently reliable, state-controlled tests and recorded in these certificates.

requirements is a subject of controversial debate, also within the Ethics Council.

Up to now, comparable instruments on this basis are to be found only on a very limited scale in current law. They may be used solely in very specific areas and only for designated workplaces, as far as this is necessary (see Sections 23, 23a IfSG<sup>3</sup> [Protection against Infection Act]). Their use across the entire health care system is no more feasible than their blanket use in other areas of application. In the context of legislative decisions on the Covid-19 pandemic, the Federal Minister of Health has asked the German Ethics Council to discuss the ethical prerequisites and implications of immunity certificates of this kind – provided that immunity can be proven with sufficient scientific and medical certainty.

At the same time, immunity certificates would have to rule out infectiousness, i.e. the possibility of infecting others. They could assume very different forms depending on the circle of persons who would be entitled to them and the scope of the acquired entitlements. For instance, immunity certificates could be issued to all persons whose immunity has been proven after infection with the SARS coronavirus 2, or SARS-CoV-2 in short, for the purpose of comprehensively exempting them from restrictions based on infection prevention and control. Another option is that this would apply only to specific groups who would be exempt from such restrictions entirely or only in specific areas. Finally, immunity certificates could lead not only to the lifting of restrictions of liberty but also conversely to special obligations in pandemic control.

In any case, the introduction of immunity certificates in the context of the Covid-19 pandemic would be dependent on two requirements: Firstly, there would have to be reliable evidence of the degree and duration of immunity, i.e. the protection of

<sup>3</sup> Gesetz zur Verhütung und Bekämpfung von Infektionskrankheiten beim Menschen (Act on the Prevention and Control of Infectious Diseases in Man) of 20 July 2000 (BGBI. I, 1045), last amended by Article 5 of the Act of 19 July 2020 (BGBI. I, 1385).

the persons concerned from infection and their non-infectiousness. This would necessitate serological tests that detect, with a minimum degree of certainty, not only a general but also a protective immune response to the SARS-CoV-2 pathogen for a certain minimum period of time. Secondly, the implications of such certificates for society as a whole would have to be ethically assessed not only from a medical (especially epidemiological) point of view, but also in terms of the various goods and rights of different groups of people. Against this backdrop, possibilities for individual exemptions from restrictions of basic rights when the justifiable pertinent ground of infectiousness has ceased to exist, should not be denied unless there were important reasons. In this Opinion, the German Ethics Council presents a discussion of these and other controversial, ethically relevant aspects.

In the opinion of all members of the Council, the current state of scientific and medical knowledge argues against recommending the introduction of immunity certificates at this point in time.

Beyond this, there are differing views within the Council as to whether and, if so, under what conditions the introduction of immunity certificates would be recommended, if future scientific and medical findings were to make it possible to provide more reliable proof of immunity and non-infectiousness, also with regard to their degree and duration.

According to **position A**, such a development would, under certain conditions and on the basis of ethical risk considerations, mean it would make sense to introduce immunity certificates in stages, both on a situation- and area-specific basis.

For **position B**, practical, ethical and legal reasons lead to a refusal to use state-controlled immunity certificates even if uncertainties regarding the state of scientific and medical knowledge no longer existed in the future.

### 2 SCIENTIFIC AND MEDICAL FOUNDATIONS

Covid-19 is a novel, highly infectious, currently pandemic viral disease<sup>4</sup> where the SARS-CoV-2 pathogen can also be transmitted by asymptomatic individuals (i.e. individuals presenting no obvious symptoms or complaints). Consequently, other people may also be infected prior to a discernible outbreak of the disease. The risk of infection is particularly high when large numbers of people are in close contact with each other indoors, for instance in community facilities, at large events or in factory buildings. Particularly severe courses of the disease, often with a fatal outcome, mainly occur in older people or in people with pre-existing conditions. All the same, severe courses are not limited to these groups of people. The symptoms affect a large number of organs to varying degrees. There is not yet sufficient scientific understanding of either the short or the long-term health effects of Covid-19 at this point in time. The following is a sketch of the situation at the time of publication.

### 2.1 Immunity and infectiousness

SARS-CoV-2, like the virus-induced disease Covid-19, was only identified at the end of 2019. Consequently, current scientific and medical knowledge about the underlying mechanisms of the disease is very limited. This also applies, amongst other things, to immunity, i.e. insensitivity or robustness to the pathogen, and infectiousness, i.e. the potential to infect other people. Immunity may occur to differing degrees ranging from merely increased resistance, where the possibility of a

<sup>4</sup> Cf. the continuously updated Covid-19 profile of the Robert Koch Institute: https://www.rki.de/DE/Content/InfAZ/N/Neuartiges\_Coronavirus/ Steckbrief.html [2020-06-12].

renewed illness with a milder course is not excluded, to the near impossibility of contracting the disease again. At present, it cannot be ruled out either that an immune response may make the body even more susceptible to the pathogen which would mean that renewed infection could lead to more severe courses of the disease (as is the case, for instance, with dengue fever). Depending on the pathogen, immunity may also take on different forms over time: from protection that lasts only a few months or years to lifelong immunity.

At the present time (August 2020) it has not yet been fully elucidated whether or to what extent immunity is acquired after recovering from a SARS-CoV-2 infection. No robust studies on the course of the disease over time or the manifestation of a protective immune response in humans are available as yet. Although the advancement of knowledge is rapid, any assumptions about immunity to SARS-CoV-2 at the present time are basically uncertain.

This is also due to the fundamental complexity of an immune response that is based on a complex combination of different physiological defence mechanisms. They include for instance various antibodies produced by certain immune cells (B cells) in response to an infection. Studies show that after recovering from a SARS-CoV-2 infection, individuals developed specific antibodies to the virus, including so-called neutralising antibodies that render the pathogen harmless.<sup>5</sup> However, it is not yet clear for how long such antibodies remain detectable, whether they are formed in every case and whether and in what quantity their presence offers reliable protection against reinfection. There is some evidence that the formation of antibodies to SARS-CoV-2, similar to that of other coronaviruses that cause colds for example, varies greatly from person to person, and that the concentration of protective antibodies can fall significantly after just a few months.6

<sup>5</sup> Cf. Kellam/Barclay 2020; Okba et al. 2020; Zhao et al. 2020; Wu et al. 2020.

<sup>6</sup> Cf. Long et al. 2020; Liu et al. 2020; Edridge et al. 2020.

Other immune cells (T cells) recognise, mark or destroy somatic cells infected with the virus. Some of them (as well as some of the antibody-producing B cells) "remember" for years, as so-called memory cells, the body's immune response to a certain pathogen and can quickly reactivate that response when they come into renewed contact with the pathogen. This immune memory can protect affected persons from a further onset of the disease or lead to a milder course – even if the antibody concentration in the blood has long since fallen. T cells that react to SARS-CoV-2 have already been identified but here too the questions remain open for the time being about how regularly they are formed and whether, how long and how comprehensively they develop protective action.<sup>7</sup>

There are signs that memory cells formed after previous contact with other, related coronaviruses can also recognise parts of SARS-CoV-2. This could lead to increased resistance to the new virus, known as cross-immunity, and explain the mild or completely symptom-free courses of Covid-19 in many individuals.<sup>8</sup> Here too, however, very little is known about possible mechanisms and interrelationships. It is unclear whether and, if so, how the detection of certain immune cells could be reliably used to document immunity.

Knowledge is likewise limited about non-infectiousness, i.e. the absence of the potential to (continue to) infect other people. In the case of other infectious diseases, immunity and non-infectiousness usually correlate. Evidence to date suggests that people who have recovered from Covid-19 are no longer contagious.<sup>9</sup> However, there is a lack of long-term observational studies in this area as well.

<sup>7</sup> Cf. Weiskopf et al. 2020; Mathew et al. 2020.

Cf. Nelde et al. 2020; Le Bert et al. 2020; Braun et al. 2020.

<sup>9</sup> Cf. Korea Centers for Disease Control and Prevention 2020.

### 2.2 Test methods for the detection of SARS-CoV-2 and immunity

Various test methods are currently available to detect a SARS-CoV-2 infection and the elicited immune response. From a practical point of view, antibody tests are of particular importance for a possible documentation of immunity.

While tests that detect an acute infection (PCR or antigen tests)<sup>10</sup> merely constitute a snapshot of the current, acute virus concentration, antibody tests reveal a longer-lasting response of the immune system to a pathogen. These tests can also be used to detect past infections. The tests detect antibodies that a sick person develops over the weeks and months following the infection, which can be detected in the blood for years to come. Should it become clear in the future that a certain concentration of specific antibodies affords sufficient protection from a renewed Covid-19 infection and transmission to other people, the corresponding detection of such antibodies could serve as the basis for some kind of immunity certificate.

However, up to now the validity of tests for antibodies to SARS-CoV-2 has been limited in several respects." Firstly, it depends on whether a test detects antibodies that actually have protective action against SARS-CoV-2. For example, a test could target antibodies that are actually produced to offer protection against widespread corona cold viruses and are less effective against SARS-CoV-2.<sup>12</sup> Hence, a positive test result could be obtained even without the presence of neutralising antibodies. The direct detection of the neutralising action of antibodies is possible but has been laborious up to now as it has to be tested directly in a virus-containing cell culture.

<sup>10</sup> PCR tests are used to examine a swab from the mouth, nose or throat to determine whether the genetic material of the SARS-CoV-2 pathogen can be detected, whereas antigen tests are used to detect proteins of the virus in the swabs.

<sup>11</sup> Cf. Cheng et al. 2020.

<sup>12</sup> Cf. Theel et al. 2020; Horvath et al. 2020.

This testing may only be done in biosafety level 3 laboratories (see Annex III GenTSV<sup>13</sup> [Genetic Engineering Safety Ordinance]).<sup>14</sup>

Furthermore, the degree of technical reliability that a test will produce a positive result when certain antibodies – and only those antibodies – are present, varies. In this context, sensitivity and specificity are particularly relevant parameters. Sensitivity indicates how reliably a test will perform within the groups of people who actually have antibodies in their blood. Errors in this category are called false negative results. Specificity indicates how reliably a test in a group of non-immune individuals not yet exposed to the virus can detect that the sample is actually negative, i.e. does not contain any antibodies. Errors in this category are called false positive results. A good test is characterised by high values for both indicators.<sup>15</sup>

In addition to antibody tests, it is also possible to directly detect specific immune cells that act against the virus.<sup>16</sup> However, these tests are not yet suitable for widespread use<sup>17</sup> as the necessary cultivation and identification of the cells concerned are much more complex than the comparatively simple detection of antibodies in a blood sample.

<sup>13</sup> Verordnung über die Sicherheitsstufen und Sicherheitsmaßnahmen bei gentechnischen Arbeiten in gentechnischen Anlagen (Ordinance on the biosafety levels and safety measures for genetic engineering work in genetic engineering facilities) of 14 March 1995 (BGBI. I, 297), last amended by Article 57 of the Ordinance of 31 August 2015 (BGBI. I, 1474).

<sup>14</sup> Current methodological developments hold the prospect of greater efficiency through testing in laboratories with a lower biosafety level 2 (cf. Krähling et al. 2020; Tan et al. 2020).

<sup>15</sup> Cf. on this topic also Deutscher Ethikrat 2013, 50 ff.

<sup>16</sup> Cf. Altmann/Boyton 2020.

<sup>17</sup> More widely applicable tests for the detection of cell-based immunity are currently being developed (cf. also https://www.biocentury.com/ article/305500 [2020-11-09] and https://www.bbc.com/news/ uk-wales-53764640 [2020-11-09]).

# 2.3 Requirements for immunity certificates

The use of antibody or other immunity tests in the context of immunity certificates would, due to the uncertainties described above, in any case require a review of detection methods that is monitored by public authorities and carried out independently of manufacturers. The aim here would be to guarantee tests of such a high quality that they could be used for this specific purpose beyond the general approval requirements. These tests would have to meet defined quality criteria for the suitability of the tested markers to prove immunity and non-infectiousness as well as for the sensitivity and specificity of the respective test.

A large number of readily available antibody tests are currently on the market. They differ greatly in terms of their working principle and quality, and often come with a very high degree of uncertainty.<sup>18</sup> Tests that do not reliably detect neutralising antibodies or deliver many false positive results due to lack of specificity may suggest immunity that is not actually present. If persons with a false positive or otherwise less robust test result were then to behave as if they were immune and refrain from taking steps to protect themselves and others, they would expose themselves (and potentially also people in their environment) to an increased risk of infection. Tests of insufficient reliability or robustness (including currently widely advertised rapid tests for private use) would not, therefore, be suitable as a basis for immunity certificates, as they could pose a significant risk to public health.

In addition, from the angle of the manifestation, duration and dynamics of immunity and non-infectiousness after recovering from Covid-19 and based on the current level of knowledge, repeat testing would probably be necessary. The period of validity prescribed for the approval of a test method

<sup>18</sup> Cf. Özçürümez et al. 2020.

and the efficacy criteria would have to be aligned from time to time with the latest scientific and medical findings. The possibility of viral mutations – i.e. changes in the viral genome that may but do not necessarily impact the transmissibility of the virus and the severity of the disease they cause – should also be taken into account. Here, it would be necessary to continuously monitor whether tests can also detect immune responses to any new emerging variants of the virus.<sup>19</sup>

In summary, the state of knowledge about immunity and infectiousness in the case of SARS-CoV-2 is evolving at a fast pace but these aspects are still far from being fully elucidated at the present time.

<sup>19</sup> Cf. Day et al. 2020.

### **3 NORMATIVE POSITIONINGS**

In the German Ethics Council there is a consensus that, given the current level of scientific and medical knowledge, the introduction of immunity certificates cannot be recommended at this point in time. However, the members of the Council disagree on whether and, if so, under what conditions the introduction of immunity certificates should be recommended if future scientific and medical findings permit more reliable documentation of immunity to SARS-CoV-2 and its degree and duration.

The views expressed within the Council can be assigned to two basic positions: While position A recommends step-by-step measures that may be appropriate in connection with immunity certificates after recovery from this disease, position B considers the introduction of immunity certificates in the future to be unjustifiable even if the immunity and non-infectiousness of the person concerned could be reliably demonstrated. In the following, these positions are presented separately in order to render the reasoning behind them transparent.

### 3.1 Position A

# 3.1.1 Risk ethics considerations under pandemic conditions

The above comments in the medical-scientific section highlight numerous epistemic uncertainties surrounding the novel virus SARS-CoV-2. Supporters of position A are of the opinion that decisions must also be made under conditions of uncertainty and that the implementation of actions or the failure to take action must be judged on the basis of risk ethics principles.<sup>20</sup>

<sup>20</sup> Cf. Nida-Rümelin/Rath/Schulenburg 2012; Gethmann 2018.

At every point during the pandemic there were high-risk decisions that had to be made. At the beginning of the pandemic, the primary goal of political measures was to avoid the collapse of the health care system. It was by no means certain how successful these measures would be. This strategy also had to accept numerous forms of collateral damage.<sup>21</sup> From a risk ethics point of view, such considerations were and are nevertheless legitimate given the large gaps in knowledge.<sup>22</sup> The prerequisite here is that certain normative limits are maintained. The German Ethics Council has coined the term "deontological containment" to describe this.<sup>23</sup> This allows certain protected goods – such as the life or health of people – to be exposed to a risk, but requires the categorical defence of fundamental standards pertaining to the ethics of justice or human rights.

It follows on from the risk ethics classification that the admissibility of immunity certificates depends not only on the relevant level of knowledge about immunity and non-infectiousness, but also on the scale and concrete timeline for their use. Position A presupposes that a growing body of scientific and medical evidence will be available regarding a sufficiently reliable immune response and reliable non-infectiousness.

# 3.1.2 Opportunities associated with the use of immunity certificates

The use of immunity certificates would then be associated with a number of opportunities for both individuals and society.

<sup>21</sup> Cf. Deutscher Ethikrat 2020.

<sup>22</sup> Cf. Nida-Rümelin/Rath/Schulenburg 2012, 101 ff.; Deutscher Ethikrat 2014, 77 ff. To distinguish this from the so-called precautionary principle, cf. Gethmann 2018.

<sup>23</sup> Deontological ethics are characterised by the fact that the moral qualification of actions is based on the underlying reasons for them. Consequently, deontologically contained opportunity-risk analyses prohibit certain options for action even if their execution would lead to the greatest happiness of the largest number (cf. Deutscher Ethikrat 2019, 107 ff.; Deutscher Ethikrat 2014, 69 ff.).

Immunity certificates could make it possible to put an end to restrictions of rights. For example, restrictions of the basic rights of immune groups in the population in the interests of infection prevention and control could basically be lifted as the risk situation required by the Protection against Infection Act would no longer apply to them. This would even be required under constitutional law in principle provided that the entirety of the purpose of the respective anti-infection-measures would not be jeopardised.

Moreover, the use of immunity certificates could help to limit the negative economic consequences for both individuals and society as a whole. In addition, they could contribute to reducing the spread of infection as, in high-risk situations, knowledge of a proven immunity could be used to minimise the risks of virus transmission. Professional and private situations requiring physical proximity would be of relevance here which have to be maintained even during periods of an increased risk of infection, for instance during a second wave. This could also help to reduce repeated diagnostic testing of persons at such workplaces at short intervals (combined with corresponding time delays and the risk of incorrect test results).

Furthermore, the willingness to show voluntary social engagement could be strengthened, encouraged by the reassurance that when helping others, people will no longer fall seriously ill themselves or infect others. In addition, immunity certificates could reduce the psychological strain, for example, for people who either professionally or privately come into direct contact with potential carriers or have regular contacts with (chronically) ill individuals.

Furthermore, the possible stabilisation of the social environment of high-risk groups, i.e. people who are at increased risk of infection and/or are more susceptible to a severe to fatal course of the disease, must also be taken into account. For example, more extensive visiting rights could be granted to the immune relatives of residents in nursing homes or in other social institutions. Even people from high-risk groups outside of corresponding institutions (such as people of all ages with chronic diseases) could participate more freely in society if interactions with immune persons were made possible in their private and professional environment.

It would also be possible to improve the organisation of hospital procedures, especially during a new wave of the illness. Immune persons visiting a medical facility for the treatment of other illnesses could be moved immediately to a Covid-19-free ward without further testing upon presentation of the certificate. In addition, individuals with positive antibody status could be identified and when issued with the certificate, their attention drawn to the possibility of making a serum donation to convalescents as part of antibody therapies, thus potentially contributing to the recovery of others. Finally, the use of state-controlled tests that meet high quality standards would stem the spread of poorer quality tests from private suppliers.

# 3.1.3 Risks related to the use of immunity certificates

The opportunities outlined above would also carry risks. In some cases, the greater the scope of liberty-granting immunity certificates, the higher these risks would be. For individuals, the (re)attainment of liberty on the basis of their own immunity could act as an incentive for them to infect themselves and thus possibly acquire immunity. This would be counterproductive for the general control of the course of a pandemic and the goal of not overwhelming the health service.

Similarly, a comprehensive restoration of civil liberties would also entail risks for the observance of general infection prevention and control measures such as the wearing of mouth-and-nose coverings on public transport or when shopping. If holders of immunity certificates were exempted from such requirements, this could also diminish the willingness of the rest of the population to observe the rules. Since immunity is not recognisable from the outside, deviating behaviour based on it would appear to be a breach of the rules. This could influence the general acceptance of these requirements and, at the same time, make control measures in the public domain difficult to the point of being impracticable.

It is also feared that the introduction of immunity certificates could discriminate against or stigmatise those who cannot prove their immunity, for example people in precarious employment. This could also lead to new forms of exclusion and exacerbate social tensions.<sup>24</sup>

There would also be risks in the use of antibody tests of insufficient quality to permit a statement on immunity. Even with high quality test methods, it can never be ruled out in individual cases that false positive results may lead to risk-increasing behaviour. This could have dangerous repercussions, especially in contacts with vulnerable groups. As long as only a small proportion of the population actually possesses the immunity to be detected by a test and this proportion does not significantly exceed the expected false positive proportion of a test, the proportion of false positive results would be particularly significant.

Immunity certificates could also be tampered with, particularly in cases where they would secure significant personal benefits. There would likewise be a risk of misuse of the information recorded in them.

Finally, the effects of psychological relief already mentioned in the section on opportunities could also be reversed, and cause employees to worry that they would have to expose themselves to special dangers if they had an immunity certificate.

<sup>24</sup> Cf. Nuffield Council on Bioethics 2020, 3 f.

### 3.1.4 Normative considerations and conclusions

From the perspective of position A, the opportunities and risks must be factored into a concept of responsible liberty<sup>25</sup> on the basis of a well-founded weighing of interests. Consideration must be given not only to the relevant normative goods and values such as the restoration of freedom and liberties, health protection and pandemic control as well as responsibility, solidarity and damage limitation, but also to their respective ranking. Moreover, in view of the intertwining of the individual and social ethical levels, it would have to be ensured that a corresponding set of instruments was coherently integrated into the legal system and that deontological boundaries for the protection of the basic rights of the individual were strictly upheld.

Aside from these necessary limits, different strategies are conceivable for the concrete framing of immunity certificates under the conditions outlined here. In summary, position A attaches particular importance to the restoration of individual civil liberties, especially if they can also contribute to the common good. Health protection must be maintained. The risks mentioned above, such as social exclusion and the perverse incentive to self-infect, must be prevented by means of a careful and context-related examination of the selection of restored civil liberties. Consideration could also be given, where appropriate, to attaching certain obligations to the issuing of immunity certificates.

#### Facilitating the restoration of liberty and damage limitation

In contrast to the general easing of restrictions – for example in certain areas or regions – the instrument of immunity certificates would serve the purpose of initially allowing the individual lifting of restrictive measures that were necessarily designed without any exemptions. Like other easing measures,

<sup>25</sup> Cf. Bormann 2014.

this instrument would be aligned with an improved knowledge base. Since these measures would be linked to individuals, they would only allow corresponding individual easing of existing constraints. Such a procedure would be in accordance with the general rule of law that there is a need to justify not the individual exercise of liberty but top-down restrictions of liberty. Where the previous justification has ceased to apply – for example, because a person can be shown to no longer pose a risk of infection – a restriction must not be upheld. A lifting of restrictions of liberty is not therefore per se discriminatory. Proof of immunity and the resulting relative non-harm to oneself and others would, in principle, justify unequal treatment, subject to their being further grounds for upholding the measure.

At the same time, this restoration of liberty would be linked to damage limitation. Since their introduction, the anti-infection measures have led to considerable constraints for almost all members of society and, in many cases and with increasing duration, even to serious collateral damage.<sup>26</sup> This encompasses not only considerable restrictions of elementary individual and political liberties. There are also negative consequences from the educational, psycho-social, cultural and economic perspective. Even direct collateral damage to health must be taken into account in this context, for example, postponed operations, failure to undergo medical treatment, inadequate medical-therapeutic care for persons in institutions for the elderly and disabled coupled with greater access restrictions, isolation and loneliness of persons living alone in the domestic environment, stress-induced domestic violence, etc. The occasional attempt to distinguish between health protection on the one hand and economic protection on the other is misguided, because economic, health and other social goods cannot be viewed separately. Consequently, protection of health and life are always affected.27

<sup>26</sup> Cf. Deutscher Ethikrat 2020.

<sup>27</sup> Cf. Dorn et al. 2020.

# Avoiding the social effects of self-endangerment and extending protection from social exclusion

The social debate also reflects the concern, which must be taken seriously from a socio-ethical point of view, that the introduction of immunity certificates could increase social tensions. This could lead to discrimination and stigmatisation of those individuals who are unable to prove their immunity. In the long term, there are fears of a division in society. There could be pressure for people in certain private or professional contexts to acquire immunity as quickly as possible. This would carry the risk that employers would give preference to seropositive employees or introduce segregated working environments and that employees would indirectly have perverse incentives to infect themselves or falsify immunity certificates. Groups that are already disadvantaged would be particularly affected by such developments.

However, not all differentiating treatments are discriminatory. Problematic processes of exclusion, inter alia by making access conditions more difficult, are to be feared in particular if immunity certificates are used nationwide in almost all areas of society resulting in non-immune persons being virtually excluded from social life. For example, immunity certificates should not be used in such a way as to cause significant disadvantages for individuals who do not possess such a document, unless this could be justified primarily on the grounds of infection prevention and control.

The effects on pandemic control that could result from incentives for self-endangerment are equally problematic. Care should, therefore, be taken to systematically counteract such secondary effects. The coherence of the overall pandemic containment strategy must be ensured. The power of an incentive for self-infection and its societal consequences could not be reliably assessed in advance, especially since they depend on many factors, such as the current state of knowledge about the expected long-term effects after contracting Covid-19. Consequently, the group of persons entitled to immunity certificates and the liberties they restore would have to be examined on an ongoing, situation-specific basis to allow intervention if needed. In order to counter the risk of self-infection, the introduction of immunity certificates would also have to be combined with a nationwide awareness-raising campaign about the risks of Covid-19.

#### Factoring in special obligations and their limits

Immunity – even if it is limited or only exists with a certain degree of probability – does not just imply the possibility of lifting restrictions of liberty. Under certain strictly understood conditions, it may be permitted or even necessary to oblige people to expose themselves to a risk or to set aside the exercise of personal (basic) liberties in the interest of defending a collective good. It is conceivable, for example, that immunity certificates may also oblige people to take on special tasks for the benefit of others, for instance in the context of a renewed exponential rise in the number of infections and an acute risk of infection.

Pandemics are indisputably one of the contexts in which there is justification for restricting individual rights and imposing obligations on people based on a balance between encroachment of individual liberties, the imperative to manage the consequences, the interests and liberties of third parties, and the protection of collective goods. However, this specific obligation may only apply to people exposing themselves to a hazardous situation because of their immunity. An obligation to sacrifice their health or even their lives can never be justified.

#### Laying down possible areas and conditions of use

In view of the risks discussed and the epistemic uncertainty of the state of knowledge mentioned in chapter 2, it does not currently appear justifiable to use immunity certificates in any area of life. It is possible, however, to identify areas of society in which the use of immunity certificates could make sense in the future. In this case, a step-by-step approach that reflects the importance of the areas concerned would be appropriate.

Initially, as illustrated by the opportunities outlined above, immunity certificates could help to mitigate the negative effects of the pandemic and facilitate a faster exit from the crisis situation. For example even if the number of infections were to rise sharply again, people with immunity certificates could continue to work full-time in areas where there is a specific societal need for their reliable operation, for instance child day care centres and schools. Gradually, other areas of society could then be considered and, finally, immunity certificates could also be used to reverse individual restrictions of liberties. It would be for the legislator to determine in which areas and on which occasions proven immunity or other protective measures appropriate to the situation could lead to individual exemption from an infection and control measure.

Given the otherwise limited alternatives to the existing contact-restricting measures - vaccines and medicinal products to treat Covid-19 will not be available in the short term - a case could be made for the use of immunity certificates, at least in certain areas of life defined by law. Against this backdrop, contacts with vulnerable persons, for example in hospices or care institutions, and forms of professional practice with unavoidable spatial and physical proximity should be considered, depending on the context and subject to specific requirements. The lifting of contact restrictions should not, however, indiscriminately be made dependent on certified immunity. Consideration would have to be given to whether risks could not also be effectively averted by other anti-infection measures appropriate to the situation, for example personal protective equipment, special visiting rooms or sufficiently reliable on-site tests to determine current infection status, for example, during visits to nursing homes. In order to prevent the discrimination of persons who are not immune, appropriate measures should still be allowed as an alternative in such cases. This would apply in particular to situations in which it is not possible to issue immunity certificates or at least not immediately.

Since the lifting of liberty-restricting measures for a few may influence the general acceptance of norms and, at the same time, hamper control measures in public places, there would have to be careful examination of the areas in which restrictive measures could be lifted or, conversely, where this would jeopardise effective infection prevention and control. For example, immunity certificates should not exempt the holders from the obligation to wear a face covering on public transport.

The taking of tests to obtain immunity certificates should normally be voluntary. Their use should be based on a well-informed decision. Beyond the awareness-raising measures for individuals required in this respect, the population should also be informed about existing residual uncertainties in a quality-assured manner. The problem of over-the-counter tests would also have to be elucidated.

Tests entitling people to the issuing of immunity certificates should be carried out in accredited, quality-assured laboratories. The instrument would have to be designed and used in accordance with data protection law and data security requirements. Given the temptation of falsification, the certificate would have to be sufficiently secure from a technical point of view. A simple entry in existing vaccination cards would not, therefore, be sufficient. Not least because of the supra-regional implications of the decisions to be taken with immunity certificates, the objective should be uniform nationwide regulation.

It would also seem necessary to make the legal regulation of immunity certificates not indefinite but limited in time. The legislator should introduce an obligation to monitor and rectify their effectiveness and possible undesirable side effects. This should be supplemented by an overall evaluation of the experience gained in handling immunity certificates after the specified duration. A temporary regulation would also take into account the highly dynamic development of scientific and medical knowledge about immunity and immunity testing. On this basis of knowledge and experience, it could then be examined whether the permanent standardisation of immunity certificates that goes beyond the current legal options would be scientifically and medically viable, ethically justified and constitutionally acceptable.

In the future, immunity certificates could also be used in cross-border contexts. Mutual recognition should therefore be promoted, particularly between the member states of the European Union and the countries that belong to the Schengen area.

The step-by-step introduction of immunity certificates, as outlined above, would be dependent on sufficient testing capacity. This could lead to a distribution problem, which should be solved by legally defined but sufficiently flexible access or prioritisation criteria. The parliamentary legislator should strive for uniform regulations throughout Germany. The prioritisation of initially scarce test capacities should be based on the social relevance of the areas of application. For this purpose, the legal ordinances of the federal states issued on the basis of the Protection against Infection Act furnish the initial criteria that could be implemented.

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#### 3.1.5 Supplemental normative positioning

In the following, three aspects are accentuated in different ways: the characteristics of the risk ethics perspective (1.), the significance of basic liberty (2.) and the possibilities of a legal regulation that is sensitive to liberty and oriented towards the common good (3.).

1. In response to the question whether it is ethically justifiable to introduce immunity certificates, epistemic safety (along the lines of scientific-medical indicators) is not the only or even the primary consideration. A risk ethics approach to normative questions of pandemic control should rather be based on the insight that epistemic and normative aspects are closely interwoven. The actions we should take depend unquestionably on what we can know. How we should act in spite of a lack of or dynamically evolving knowledge is not, therefore, determined by the respective state of (non-)knowledge, but results from a normative assessment that seeks to identify the reasons which make risky behaviour appear justifiable. The circumstances under which potential immunity certificates are sufficiently secure and justifiable are, therefore, a question of reflexive and communicative judgement in which social, political and legal stakeholders are involved, in addition to research circles.

Rather than assuming that there will be clarity in the medium to long term, it is essential to formulate conditions under which the use of immunity certificates may be permissible despite constantly evolving knowledge but also new uncertainties. Ethical reflection must distinguish between what is only feared and what can be expected on the basis of experience, between scepticism justified by arguments and exaggerated safety concerns. Neither the description of risks nor the expectations of risk management can simply be carried over from other areas to "new" situations. A comparative look at evidence-based medicine, for example, illustrates why absolute certainty cannot be demanded, but only a procedural, situationally adaptive approach to it (degrees of certainty).

For this reason, a distinction should be made between risk perceptions and risk assessments, as well as between hopes of salvation and realistic possibilities. Opportunities and risks must not only be listed and compared, but weighed on the basis of explicit criteria and contrasted with the possible consequences of actions and decisions. Particular attention must be paid to the existential challenges to which people are exposed during the pandemic. As much as it is right to keep the economic consequences of pandemic control in mind, it is just as important to examine whether the measures help to avoid borderline situations that are difficult for individuals to bear.

2. The risk ethics assessment required here is only plausible if it incorporates fundamental constitutional-normative requirements into the weighing up process. This touches on perhaps the most noble and urgent function of immunity certificates: to reduce as far as possible what are, in some cases, considerable restrictions of the individual civil liberties of people who have had Covid-19. Since, under the Basic Law, it is not the liberty of the individual but limitation of that liberty by the state that requires legitimation, the burden of justification shifts: The (in principle forbidden) state restriction of basic liberty must be judged more strictly than the (in principle required) restoration of this liberty. The risk assessment must also be based on the assumption that, in cases of doubt, the decision must be made in favour of individual liberty. This need not be at the expense of the community and its goods. Collective goods may not, in principle, be placed in opposition to civil liberties. Rather, more trust should be placed in people's ability to assume responsibility for others, which is part of the promise of dignity enshrined in the Basic Law. Weighing up processes must therefore resist the temptation to subordinate individual civil liberties overly quickly to a supposedly higher good.

Allegations of discrimination are not appropriate where a measure limited in time and place is based on a factual reason, such as the presumed absence of infectiousness in the case of immunity certificates. Furthermore, action to benefit others should not be attributed blanket priority over other interests in liberty. Moreover, what is considered to be of benefit to a third party is not self-evident and cannot always be clearly distinguished from self-serving motives. Altruistic motivations, in the same way as egotistical ones, can lead to erroneous actions. The concern that people could misuse a possible documentation of their immunity can be countered by the argument that people with proven immunity could, for example, engage with greater peace of mind in voluntary work in the cultural sector, in sports, in religious communities or associations.

3. Against this backdrop, it seems justifiable to introduce carefully monitored and regulated immunity certificates. This is especially true as such an instrument cannot be a sufficient means on its own, but must always be discussed in combination with other anti-infection measures. Of course, possible negative effects must also be taken into account. The reservations listed, some of which are formulated as rather distant fears, can, however, be contained by means of insightful regulation, which may also need to be readjusted legally in the light of new experiences with the implementation of measures.

For the rest, the following must apply: If it is possible to anticipate negative consequences, this must also apply to positive consequences. The necessary "tentative" action of the state in a crisis situation, based on more or less well-founded assumptions, model calculations and preliminary risk assessments, is clearly at odds with a rigid and excessive demand for safety. This applies not only to consideration of the increased resistance to Covid-19 after recovering from the illness when planning risk-adapted in-house duty rosters. The practical value of such an approach is likely to be limited at the present time. However, the combination of antibody tests with PCR results (or additional neutralisation tests) and the maintenance of anti-infection measures ensure that there is at least no threat of negative effects, i.e. only additional protection is provided. This also applies to the immunity certificates themselves. Self-critical, adaptive regulation is equivalent to a risk ethics assessment that responds flexibly and in line with the dynamics of the pandemic. Uncertainty does not result in a prohibition to act - which produces particular consequential costs - but above all in the obligation to continuously verify whether the original assumptions continue to hold and, if not, to make adjustments.

Through consistent monitoring and risk impact assessments that are open to repeated review, potential unintended

side effects can be identified and corrected. In addition to the expertise of political, administrative and judicial circles, the diverse experiences from various areas of society should also be taken into account, differentiated according to life situation and degree of affectedness (e.g. family, work, economy, health and social services, education and culture). A wise and responsible strategy for dealing with the pandemic is dependent on this review-based monitoring process, in which experience-based and appropriately formulated criticisms can provide the impetus for corrections to instruments and strategies. As long as neither efficacious medicinal products nor vaccines are available, test strategies have to be constantly readjusted given the limited resources available, and as long as the dynamics of the epidemiological situation continue to be as unpredictable as they are at present, every option should be explored and, where appropriate, exploited to enable as many people as possible to lead their lives in liberty and good health.

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### 3.1.6 Supplemental proposal for action

The reflections in position A are based on the currently unconfirmed assumption that, in the future, immunity tests could be available that document a person's non-infectiousness and immunity with sufficient certainty for a specific period of time. Already today it can be assumed that there is an increased resistance after contracting Covid-19. After recovering, sick patients have a very low risk of reinfection at least for a period of several months.<sup>28</sup> This regularly prompts people in certain

<sup>28</sup> Cf. the continuously updated Covid-19 profile of the Robert Koch Institute: https://www.rki.de/DE/Content/InfAZ/N/Neuartiges\_Coronavirus/ Steckbrief.html [2020-06-12].

professional groups who have recovered from this disease to voluntarily take on tasks with a higher risk of infection – for example, contact with Covid-19 patients or particularly intensive interaction with the general public.

Some members of the Council suggest that this common but informal and therefore very heterogeneous practice should be made possible in general and placed on a reliable foundation in the context of the planning of in-house duty rosters. It is a limited instrument which can already be used today from an ethical point of view. It does not necessitate immunity certificates and should not be confused with them. It could support in-house decisions to make more use of employees who have recovered from Covid-19 in positions that carry a higher risk of infection. The proof of increased resistance should be confirmed by a high quality antibody test, in addition to proof of recovery from a SARS-CoV-2 infection.<sup>29</sup> The risk of false positive antibody test results is minimised by the simultaneous requirement of direct detection of the virus at the time of contracting the disease. Antibody status should be checked regularly by retesting.

Potential areas of application are work environments where there is a risk of infection, for example in the medical and educational sector, but also in public administration. Such an approach is an opportunity to reduce the risk of further infections by deploying staff members with an individual reduced risk profile, thereby contributing to pandemic containment. Moreover, this could reduce the physical risk but also the mental strain of previously uninfected colleagues of individuals who have recovered from this illness, who would then have to be deployed less at exposed locations. In order to avoid additional risks, the persons concerned should be

<sup>29</sup> With advancing scientific knowledge, other detection methods could also be considered, for example T cell mediated immunity. If direct detection of the virus is not possible during the infection period, a positive antibody test result could alternatively be confirmed by an additional neutralisation test to ensure greater certainty.

absolutely prohibited from abstaining from general or job-specific anti-infection measures (such as face coverings or personal protective equipment) at work or in private life. In this scenario there would be no increased risk for contact persons; it is therefore irrelevant whether the increased resistance of the individuals who have recovered from this illness also results in reduced infectiousness.

Participation in such in-house planning constitutes an altruistic act on the part of those who have recovered from this illness. As such this act imposes additional obligations on those affected and serves exclusively the welfare of others. Consequently, such planning should only be done on a voluntary basis. Employees should be free to withdraw from the willingness to volunteer for particularly vulnerable positions at a later date. If the employer makes use of health data within the company, the requirements of data protection law would have to be strictly adhered to, in addition to those of labour law and public service law. In particular, voluntary consent to participation in a test and to the use of the associated health data would be required. Inappropriate pressure on employees' freedom of choice and discrimination by the employer would have to be effectively countered. In order to counteract possible misconceptions, it would also be necessary to inform tested persons in a comprehensive manner that, according to the latest findings available up to now, neither recovery from Covid-19 nor elevated antibody status guarantees immunity or non-infectiousness. The measure would have to be regularly reviewed in the light of the latest findings.

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### 3.2 Position B

### 3.2.1 Basic principles of ethical evaluation

To begin with, position B differs from position A in that, based on the latest available findings, it does not assume that a SARS-CoV-2 infection leads to sufficiently long and reliable immunity. Consequently, there is no empirical basis for test methods that could be used in the future to certify individual non-infectiousness with sufficient certainty. Therefore, position B is much more reticent about the willingness to accept health risks for the general public and especially for vulnerable groups, which could result from the use of immunity certificates.

Even if reliable proof of longer-lasting immunity and sufficiently reliable tests to prove immunity and non-infectiousness were to become available in the future, weighty practical, ethical and legal arguments are presented against the introduction of state-controlled immunity certificates. It is therefore not only the varying assessments of scientific progress but above all the different normative foundations of positions A and B that result in them reaching different conclusions about the instrument of immunity certificates, and consequently in them making differing recommendations. The main reason for rejection of this instrument is the weighing of fundamental individual and social protected goods and the interrelationships between them.

#### 3.2.2 Individual and social protected goods

Individual and social goods must be taken into account in the ethical assessment of whether immunity certificates can be an effective means of restoring civil liberties or even imposing specific obligations. Life, health and liberty are such fundamental goods and people have a legal entitlement to their protection by the state. In order to protect the life and health of others, it may be necessary to restrict individual civil liberties. However, such restrictions of individual rights by the state must always be justified; they must be proportionate and undergo constant review.

At the beginning of the Covid-19 pandemic and under conditions of very limited knowledge about the virus, the consequences of infection and the effectiveness of anti-infection measures, there was certainly justification for restricting the civil liberties of people in general. Overstretching the health care system would not only have cost many people their lives, but would also have led to far greater social and economic damage than was caused in this country by the lockdown.

In the ethical justification of restrictions of liberty but also in the assessment of the means to mitigate or even abolish them, people's individual rights and obligations alone must not be moved centre stage. Issues pertaining to the just distribution of benefits, solidarity obligations, burdens, restrictions, potential exclusion and discrimination must also become the focus of attention and their importance duly taken into account.

It is undisputed that liberty-restricting measures, which limit individual rights in favour of the general public, can only be considered as a last resort in very limited exceptional cases. Should more specific and effective means of achieving an objective - in this case, containment of the Covid-19 pandemic - become available, the previous general restrictions of liberty would have to be lifted in favour of more specific anti-infection measures. This also applies if a risk - such as the overstretching of the health care system with all its consequences - had been averted. However, whether state-imposed immunity certificates could be just such a more specific means depends crucially on whether, compared with other measures, they are indeed suitable for lifting restrictions of individual liberty without, in return, unduly jeopardising the protection of the rights to life, health, self-determination and social participation of other people. This is doubtful.

#### 3.2.3 Societal and systemic consequences of state-controlled immunity certificates

With regard to questions of justice, when liberties or obligations are linked to the status of immunity, unfair distributions of opportunities but also of risks, burdens and restrictions, can go in two directions: On the one hand, when persons with no immunity certificates would be denied opportunities (for example, attendance at a training centre); on the other hand, when persons with immunity certificates would be specifically required to perform certain activities (for example, as medical staff, cleaning staff, sales personnel, staff in child day care centres or schools). In this context, attention should be drawn more particularly to the danger of an exacerbation of existing disadvantages and the risk dispositions of certain groups of people. Not least because of the possibility of misuse or fraudulent acquisition of immunity certificates, particularly by private actors, there is also a danger of the emergence of a twotier society, where, for example, access to a department store or to cultural and sporting events, freedom of travel or even the conclusion of an employment contract would only be granted to persons with immunity certificates.

A sceptical view is therefore taken of whether the liberty-granting and, where appropriate, specific obligations that are to go hand in hand with immunity certificates, can be properly limited and thus prevent problematic societal and systemic consequences.

### 3.2.4 Conclusions of position B

#### Limited practical benefits of immunity certificates

Advocates of position B are very cautious in their estimation of whether any reliable methods or methods with a sufficiently predictive timeline for the detection of immunity in the context of Covid-19 will be available at all in the future. Caution should, therefore, be exercised when anticipating such a development or basing reflections on the introduction of immunity certificates on this. On the contrary, more recent virological findings seem to indicate that it is possible and perhaps even probable that it cannot be reliably assumed that people who have recovered from a SARS-CoV-2 infection will have prolonged immunity and not be infectious. After an infection, people would probably not be protected for a longer period of time against renewed infection.

Furthermore, the proven case numbers of a SARS-CoV-2 infection in Germany are comparatively low. Consequently, the economic and social benefits of state-controlled immunity certificates can be classed as limited in terms of society as a whole. Given the low number of previously infected persons, the expected short duration of immunity and the high number of unreported cases, only a small number of documentable immune and non-infectious persons would potentially be available who could be deployed primarily in critical economic and social areas.

The desire for (roster) planning reliability through immunity certificates in health and care areas or in schools and child day care centres is basically understandable. However, it can be assumed that considerable pressure would be placed on staff in these facilities to undergo antibody testing in order to obtain immunity certificates which would enable them to take on tasks with a higher risk potential. The self-image of caregivers and their perceived responsibility for people with disabilities or in need of care would probably also lead to them feeling obliged to undergo a test.

Undoubtedly, confirmation of immunity and non-infectiousness would be a great relief for everyone. This is particularly true for people who are inevitably exposed to a particular risk of infection in their professional or everyday lives. However, if immunity certificates did not have a sufficiently secure foundation, they would lull these persons into a dangerous false sense of security, and entail considerable risks for them and others.

#### Use of proof of non-infectiousness by caring communities for the benefit of particularly vulnerable groups

If, contrary to expectations, antibody tests prove to be sufficiently reliable in the future, they should only be used in strictly defined individual cases to restore individual liberties or to impose specific obligations. Based on sound knowledge of their immunity and non-infectiousness, exemptions would only be granted to the dependents and close relatives of particularly vulnerable groups, such as residents in facilities for the elderly or disabled who suffer badly from the strict isolation measures, and, where appropriate, to voluntary or full-time members of accompanying external services (pastoral care, hospice services, etc.). Such measures do not, however, need state immunity certificates. They could be regulated in a binding manner in the Protection against Infection Act, for example by a clause authorising doctors to issue a corresponding certificate of - highly probable - non-infectiousness for this group of persons on the basis of either a sufficiently reliable up-todate PCR test or a sufficiently reliable antibody test which may become available in the future. However, this would not be a state-controlled document similar to a vaccination card.

Balancing the right to self-determination and social participation against the protection of health in community facilities would nonetheless necessitate, irrespective of the availability of sufficiently reliable proof of immunity, a search for ways to relax the strict isolation measures in community facilities. Rather than hoping for the development of reliable immunity tests, it would be more appropriate, for example, to work towards regular testing using approved, reliable PCR tests.

Apart from the narrow area mentioned here, the protection of the public interest generally argues against the use of any kind of immunity certificate for the reasons set out below.

# Immunity certificates may jeopardise the success of the pandemic control strategy

In Germany, a pandemic control strategy seeking to keep the infection rate as low as possible during the Covid-19 pandemic has been successfully pursued to date. In view of the still comparatively low number of cases, it is illusory to assume that the use of immunity certificates would have a relevant impact on the recovery of the economy or the provision of services in the social and health care systems. Against this backdrop, this use would not be effective as long as the number of infections remained low.

In general, proof of immunity could lead to greater carelessness not only on the part of the tested persons themselves regarding compliance with proven anti-infection measures, such as in particular distancing rules or the wearing of mouthand-nose protection. Seeing other people who no longer comply with these anti-infection measures could also lead to unfounded carelessness by those who are not immune.

The introduction of immunity certificates would also create perverse incentives that could run counter to the current successful strategy. For instance, people could deliberately expose themselves to the risk of infection, for example out of economic hardship or to secure individual advantages. Especially in fields of work with precarious working conditions and/or special infection risks, this would be a consequence that would be both dangerous and unfair. Last but not least, warnings must be issued against erosion effects which the widespread use of liberty-granting immunity certificates might have on the willingness to comply with general anti-infection measures.

Against the backdrop of the uncertain prospects of success and the limited resources available in the health care sector – not only from an economic point of view – it does not seem responsible to invest considerable resources in the drawing up and legal anchoring of immunity certificates. The following steps, among others, would be necessary for this: the development of reliable tests to confirm protective immunity and simultaneous non-infectiousness; the definition of parameters to be laid down in such a document; state approval of immunity certificates and the development of testing capacities. This would tie up resources that would then no longer be available for other, possibly more promising, measures (for example, improved supply of personal protective clothing and masks in nursing homes or regular testing for non-infectiousness using reliable PCR tests in hospitals or large research facilities).

# Subsequent legal problems of state-controlled immunity certificates

The above-mentioned problems linked to the introduction of liberty-granting immunity certificates constitute a major challenge for an appropriate legal framework, which it would be almost impossible to tackle in practical and political terms. This is partly due to the dynamics of democratic decision-making processes, but also to the particular interests of those who would benefit from immunity certificates. At the same time, the people who would be affected by the risks and disadvantages of the instrument are less represented politically. This applies, for example, to the necessary legal adjustments with regard to the risks of abuse in the private sector regarding data protection and labour law. Therefore, the subsequent legal problems are also an argument against the introduction of state-controlled immunity certificates.

# 3.2.5 The supplemental proposal for action in position A

Position B deems the use of proof of increased resistance after recovery from a Covid-19 infection, as presented in the supplementary proposal for action in position A, to be irresponsible. Due to the unreliability of the immunity tests available at the present time and the dangers of false positive test results, this is strongly discouraged. This applies even if antibodies are detected after recovery from the disease as this is not a guarantee either of long-term immunity or non-infectiousness. It would also be obvious that not all persons with such proof would continue to comply with infection prevention and control measures with the necessary rigour. In addition, employers might be tempted to no longer take other necessary protective measures for persons, especially those in precarious employment, if these employees had proof of increased resistance. This could lead not only to harm to the person concerned but also to super-spreader effects with fatal consequences for vulnerable persons, especially in critical contexts such as hospitals, nursing homes or food production facilities.

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### 4 **RECOMMENDATIONS**

### 4.1 Joint recommendations

- 1. At this point in time, the German Ethics Council does not recommend the use of immunity certificates given the major uncertainties surrounding the manifestation and course over time of immunity, infectiousness and the robustness of antibody tests for SARS-CoV-2. This reinforces the need to rely on other measures for effective infection prevention and control.
- 2. Comprehensive efforts should be undertaken to raise awareness about the possible consequences of behaviour that disregards both a person's own protection and the protection of others from infection. These awareness-raising efforts should be coupled with the appeal to always have one's fellow human beings and the common good in mind. In addition, the public should be comprehensively informed about the robustness of antibody tests, for example by the Bundeszentrale für gesundheitliche Aufklärung (Federal Centre for Health Education).
- 3. Targeted and coordinated research into the infectious and immunological properties of the novel coronavirus should be intensified. Appropriate medical research should be supported and promoted to increase understanding of the development, duration and course of immunity to SARS-CoV-2, and to elucidate the links to infectiousness in a comprehensible manner.
- 4. Given their doubtful reliability and the resulting potential risks, over-the-counter tests for the detection of immunity to SARS-CoV-2 should be more strictly regulated.

## **4.2** Recommendations of position A<sup>30</sup>

- A1. While immunity certificates may, in principle, be an appropriate means of correcting interventions related to infection prevention and control in basic rights or of justifying specific obligations, they may only be introduced once immunity to SARS-CoV-2 and the non-infectiousness of those affected can be demonstrated with sufficient certainty. Determining when an adequate level of certainty has been reached is not a purely scientific-medical question, but must be clarified within the framework of normative considerations. The latter must place the risks resulting from incomplete knowledge in relation to the expected benefits and restrictive conditions.
- A2. The further development of reliable tests to confirm immunity and non-infectiousness should be encouraged. If the advancement of scientific knowledge were to provide more reliable information on immunity and infectiousness in the foreseeable future, a limited use of immunity certificates, as specified below, would be justifiable on the basis of a normative risk evaluation.
- A3. The use of immunity certificates should not be solely considered as a strict imperative in terms of civil liberties or as a priori discrimination. The need to weigh the advantages and disadvantages associated with them is an argument, within the framework of a step-by-step approach, in favour of using them in specific contexts and areas regulated by law, particularly for the purpose of safeguarding the interests of persons who are especially susceptible to Covid-19, and for the exercise of professions requiring spatial or physical proximity to other

<sup>30</sup> These recommendations are backed by the following Council members: Steffen Augsberg, Petra Bahr, Franz-Josef Bormann, Alena Buyx, Hans-Ulrich Demuth, Helmut Frister, Carl Friedrich Gethmann, Volker Lipp, Julian Nida-Rümelin, Stephan Rixen, Kerstin Schlögl-Flierl, Susanne Schreiber.

persons. The wider the scope of application, the more the risks would have to be weighed up.

- A4. Immunity certificates must not jeopardise the overall purpose of the anti-infection measure from which exemption is granted in individual cases (as would be the case, for example, if their holders were exempted from the obligation to wear masks and respect physical distancing in public places). Consequently, their use must not constitute an automatism that lifts restrictions of liberty. Rather, the authorities must examine their proportionality in the concrete context of their use. Immunity certificates must not be a blanket replacement for existing anti-infection concepts geared to the respective situation. Rather, in order to prevent discrimination, such measures should be maintained alongside immunity certificates.
- A5. When assessing proportionality, special attention must be paid to the possible consequences for persons who are either exposed to an increased risk of morbidity and mortality or whose (health) situation may be particularly impaired by the negative consequences of anti-infection measures (particularly vulnerable groups).
- A6. The corona pandemic seems to justify imposing special obligations on people on the grounds of their immunity. However, this specific obligation may only apply to people exposing themselves to a hazardous situation because of their immunity. It must be ruled out that this would entail an obligation to sacrifice their health or even their lives.
- A7. The requirements for the approval of detection methods of immunity and non-infectiousness, for instance relating to their sensitivity and specificity, are to be established and regularly reviewed by the competent bodies. It must be ensured that immunity certificates can only be legitimised by tests of a sufficiently high standard.

- A8. It is also necessary to ensure a conservative validity of immunity certificates in line with emerging medical knowledge concerning the duration of immunity, which must keep pace with scientific progress.
- A9. The legal regulation of immunity certificates should not be permanent but limited in time. The legislator should provide for an obligation to monitor and rectify their effectiveness and possible adverse side effects. This should be supplemented by an overall evaluation on expiry of their period of validity.
- A10. In principle, efforts to introduce immunity certificates may only be undertaken on the basis of voluntary decisions. Unacceptable pressure, for example from employers or insurance companies, must be resolutely countered.
- A11. The protection of data entered in immunity certificates and their tamper-proofness must be ensured. A simple entry, for example in the vaccination card, is not sufficient for this purpose.
- A12. Steps are to be taken to achieve reciprocal recognition of immunity certificates within the European Union and the Schengen area.
- A13. When immunity certificates are issued, the persons tested must be informed about unavoidable residual uncertainties of test results (including the possibility of false positive results) and the associated risks.
- A14. In order to limit prioritisation decisions, comprehensive capacities for reliable testing must be put in place as quickly as possible. Under the initially expected conditions of relatively limited test capacities, legally defined but sufficiently flexible access and prioritisation criteria are needed. They should be oriented towards societal relevance.

# Recommendation of supplemental normative positioning (section 3.1.5)<sup>31</sup>

A15. In addition to recommendation A3, a wider use of immunity certificates to restore liberty should be sought. Undesirable consequences must be effectively countered through intelligent regulation and ongoing monitoring processes.

# Recommendation of the supplemental proposal for action (section 3.1.6)<sup>32</sup>

A16. Since, based on the latest findings, increased resistance to SARS-CoV-2 is plausible after recovering from this illness, consideration should be given to using this information in a quality-assured and voluntary procedure for the risk-optimised planning of in-house procedures. Persons who have recovered from Covid-19 and have tested positive for antibodies could thus be given priority in positions that carry a higher risk of infection; this would not entail any exemption from anti-infection measures. It would be necessary to define by law which occupational groups are covered and how safety, time limits, voluntariness, awareness-raising and data protection are to be guaranteed.

<sup>31</sup> This recommendation is backed by the following Council members: Steffen Augsberg, Petra Bahr, Alena Buyx, Carl Friedrich Gethmann, Julian Nida-Rümelin, Stephan Rixen, Susanne Schreiber.

<sup>32</sup> This recommendation is backed by the following Council members: Steffen Augsberg, Petra Bahr, Alena Buyx, Carl Friedrich Gethmann, Volker Lipp, Susanne Schreiber.

# **4.3** Recommendations of position B<sup>33</sup>

- B1. In view of the scientific, ethical and practical reasons set out above, state-controlled immunity certificates in the context of the Covid-19 pandemic should not be used to restore civil liberties or to impose specific obligations.
- B2. Instead of introducing immunity certificates, the successful pandemic control strategy of the Federal Government and the federal states should be continued and differentiations undertaken within this strategy in order to restore the basic rights and liberties of the population as quickly as possible and, at the same time, combat the Covid-19 pandemic and its consequences. The following measures are recommended:

a) Significant increase in testing for SARS-CoV-2 infections; ensuring access to sufficiently reliable PCR tests for everyone with reliable and timely reporting of results; cost coverage regardless of symptoms.

- b) Consistent recording of chains of infection; quarantine of currently infected persons and their contact persons.
- c) Restructuring of or alternatives to institutions with special, structurally based infection risks in order to facilitate contact restrictions and compliance with physical distancing and hygiene rules (asylum seekers' hostels, nursing homes, day care centres, workshops, slaughterhouses, parcel distribution centres, etc.).
- d) Regional and event-related tightening of pandemic protection measures in the event of infection.
- e) Systematic verification of the effectiveness of anti-infection measures and their optimisation.

<sup>33</sup> These recommendations are backed by the following Council members: Elisabeth Gräb-Schmidt, Sigrid Graumann, Wolfram Henn, Ursula Klingmüller, Stephan Kruip, Andreas Kruse, Andreas Lob-Hüdepohl, Annette Riedel, Frauke Rostalski, Josef Schuster, Judith Simon, Muna Tatari.

- f) Extension of the use of the *Corona-Warn-App* (by changing the operating systems for older mobile phones, if possible, multilingualism, bug fixing, etc.).
- g) Expansion of antibody testing for research purposes; promotion of research on immunity to SARS-CoV-2 and on medicinal products and vaccines.
- h) Comprehensive awareness-raising about the possible consequences of behaviour that disregards a person's own protection and the protection of others from infections. These awareness-raising efforts should be coupled with the appeal to always keep one's fellow human beings and the common good in mind.
- i) A ban on the manufacture, the placing on the market and the use of privately issued immunity certificates.
- j) Supplementing the Protection against Infection Act with an enabling clause that allows relatives and friends of vulnerable persons and voluntary or fulltime members of accompanying external services (pastoral care, hospice services, etc.) to have contacts with vulnerable persons provided their immunity and non-infectiousness are confirmed by a medical certificate based on approved test methods. Sufficiently up-to-date and sufficiently reliable PCR tests can already be used for this purpose. Care should be taken to ensure that the test capacities are available for this and that the costs are covered.

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