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Aspects of Testing for and Vaccinations against Coronavirus in Germany and Worldwide

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Abstract

Introduction: Coronavirus has become an important topic of conversation once more. Every day, we follow the news, essentially to be able to assess how high the risk is in everyday life.

Targets: This report aims to provide information on the current situation in Germany, simply what people can and should know.

Method: The approach includes the investigation and evaluation of literature, analysis and interpretation in the context of the research issue.

Results: It appears that a consistently implemented lockdown, together with testing and vaccinations, would be able to curb the effects of the COVID-19 virus.

Conclusions: These precautionary measures must be taken and each individual must behave responsibly in order to prevent infection with coronavirus. Vaccinations and tests must be carried out consistently.

Outlook: As can be seen, basic immunisation of the population has taken place in Germany.

Keywords: Coronavirus; Robert Koch Institute; Pandemic planning; Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2); Vaccinations; COVID-19 tests

Introduction

Tests are among the most important tools in the fight against the novel coronavirus. For this reason, Germany has been rapidly establishing and expanding test capacities since the beginning of the pandemic.

- Who is being tested?
- Adaptation of the national testing strategy for the autumn/winter season 2020/2021.
- How to react if you suspect you are infected.
- How a SARS-CoV-2 test is carried out.

Who is Being Tested

When testing, a targeted approach is important. Testing without cause leads to a false sense of security. Even a negative test is also merely a snapshot of a moment and does not absolve the individual from hygienic and preventive measures (keyword AHA+L [keeping distance, hygienic measures, wearing a mask, airing]). Testing without a reasonable suspicion also increases the risk of false positive

results and puts strain on the existing test capacity. For this reason, we should test more intensively, but also in a targeted manner [1].

Adaptation of the National Testing Strategy for the Autumn/Winter Season 2020/2021

Those with minor cold symptoms who do not belong to a risk group or have not had contact to someone infected with SARS-CoV-2 will not be tested initially. This decision is to be made by the doctor treating them or contacted by them. These individuals should isolate themselves at home in order to reduce their number of contacts. The RKI recommends that this self-isolation last five days plus two days without symptoms. Those affected should clarify with their employer whether it is possible for them to work from home during this period. If necessary, they should discuss sick leave with their doctor.

The Following Groups of People are Only Entitled to Testing with Near-Patient Antigen Rapid Tests (Poc Antigen Tests) Within the Facility and Business Testing Concept

- Patients, those in assisted living facilities, those requiring care, above all in medical facilities for in-patient and out-patient care (excluding human medical, dental or other medical practices), in in-patient or day patient facilities for the care and accommodation of old, disabled and care-dependent people, of out-patient nursing services and integration assistance services and in day-care hospitals; without COVID-19 cases, according to the facility's testing concept [1].
- Visitors above all in medical facilities for in-patient and out-patient care (excluding human medical, dental or other medical practices), in in-patient or day patient facilities for the care and accommodation of old, disabled and care-dependent people; immediately before visiting the facility.

Those entering Germany who have spent time in a high-risk area within ten days before entering the country must prove that they are not infected with coronavirus within 48 hours after entering the country. The public health authority responsible or another authority determined by the state can request submission of a negative test result up to ten days after entrance to the country. Those entering from areas with a particularly high risk of infection must provide a negative test result before entering the country.

A negative test result regarding direct pathogen detection of coronavirus SARS-CoV-2 is deemed proof of testing. This proof of testing can be submitted in paper form or in an electronic document in German, English or French. In general, those entering Germany who have spent time in a high-risk area within ten days before entering the country must isolate at home immediately after entering the country. This isolation can also be ended with a negative test result after a minimum of five days. The details depend on the relevant regulations of the federal states.

Antigen tests which verify the presence of the SARS-CoV-2 protein structures work using a similar principle to that of pregnancy tests. A sample of a swab from the nose and throat is placed on a test strip. If the sample contains the SARS-CoV-2 virus, the protein components of the virus react with the test strip and a change in colour is seen on the test strip. The advantages of antigen tests are the comparatively low costs and the prompt test result (in less than 30 minutes). The ease of use of a point-of-care (PoC) antigen test makes testing also possible outside a laboratory, for example in a care facility or in medical facilities and medical practices without a diagnostic laboratory. Here, a PoC antigen test can help to easily identify asymptomatic and potentially infectious people and to prevent transmission of the virus with suitable measures such as temporary isolation at home. Generally, antigen tests are less sensitive than PCR tests, meaning that a larger quantity of the virus is required for the antigen test to show a positive result. This means that a negative antigen test result does not rule out the possibility of infection with SARS-CoV-2. An antigen rapid test is also not as specific as a PCR test, meaning that positive test results occur when the person is not infected more frequently than with PCR tests. For this reason, a positive antigen test must be confirmed with a PCR test [1].

National Vaccination Strategy

In this document, the essential components of a national vaccination strategy against COVID-19 will be described, as well as the systems with which vaccination of the population in Germany according to consistent standards and prompt evaluation of vaccines in the course of broad usage can be ensured. This document is intended to provide orientation and planning, as well as aid the responsible participants to address any existing omissions. Table 1 provides an overview of the elements and participants involved in the vaccination strategy.

After production of a potential vaccine candidate in the research laboratory, initial animal and cell culture experiments are carried out to examine whether the vaccine candidate, besides its tolerability, is suitable for evoking a protective effect against the target virus or the infectious disease it causes, if there is an animal model

for this. Subsequently, toxicological and pharmacological properties are examined in various animal models. Only when there are no concerns regarding use in humans is the tolerability examined in a first clinical trial on healthy adult volunteers (Phase 1). In the subsequent clinical phases, the optimal dosage and vaccination scheme is examined in a larger number of volunteers (several hundred) (Phase 2) and finally the effectiveness and side-effect profile of the vaccine are determined in a large randomised controlled clinical study with several thousand volunteers in various age groups (Phase 3). Various new vaccine candidates (e.g. mRNA and DNA vaccines) are currently being developed and tested in clinical trials on various manufacturing platforms. The federal government sponsors research into vaccines and the production of vaccines, and is advocating for fair global distribution of vaccines in the spirit of global responsibility. Table 2 shows in particular the COVID-19 vaccine candidates for which EU market authorisation is, according to current information, aspired to, and for which early availability could be possible or where a sufficiently large quantity of vaccine doses could be provided for the beginning of a nationwide vaccination campaign in prioritised groups.

Elements	Participants
Vaccine development	Federal Ministry of Education and Research [Bundesministerium für Bildung und Forschung (BMBF)], universities, pharmaceutical companies
Vaccine authorisation	Paul Ehrlich Institute [Paul-Ehrlich-Institut (PEI)], European Medicines Agency (EMA) and European Commission, pharmaceutical companies
Vaccination recommendations and prioritisation	Standing Committee on Vaccination [Ständige Impfkommission (STIKO)], Robert Koch Institute [Robert- Koch-Institut (RKI)], Leopoldina National Science Academy [Nationale Akademie der Wissenschaften], German Ethics Council [Deutscher Ethikrat]
Production and procurement	European Commission, EU member states, BMBF, Federal Ministry for Economic Affairs and Climate Action [Bundesministerium für Wirtschaft und Energie (BMWi)], BMG, pharmaceutical companies
Distribution, storage and logistics	BMG, Federal Ministry of Defence [Bundesministerium der Verteidigung (BMVg)]/Federal Armed Forces [Bundeswehr], federal states, logistics specialists, pharmaceutical wholesalers, (hospital) pharmacies
Organisation and provision of vaccinations	Federal states, public health service [Öffentlicher Gesundheitsdienst (ÖGD)], National Association of Statutory Health Insurance Physicians [Kassenärztliche Bundesvereinigung (KBV)], Associations of Statutory Health Insurance Physicians in the federal states [Kassenärztliche Vereinigungen der Länder (KVs)], medical personnel
Financing	BMG, federal states, GKV, PKV
Communication, professional training and public education	Federal Centre for Health Education [Bundeszentrale für gesundheitliche Aufklärung (BZgA)], RKI, PEI, BMG, federal states, Academy of Public Health Services [Akademie für das Öffentliche Gesundheitswesen], professional societies
Vaccination coverage monitoring	RKI
Surveillance: Monitoring of vaccine effectiveness and vaccine safety in the course of broad usage	RKI, PEI, EMA, pharmaceutical companies
International coordination and cooperation	Federal Government, EU, scientific forums
Evaluation of overall process	BMG

Table 1: Overview of elements and potential participants of the vaccination strategy [1].

Key

Elements participants	BMBF
Vaccine development	
Federal Ministry of Education and Research	
Universities, pharmaceutical companies	PEI
Vaccine authorisation Paul Ehrlich Institute	
European Medicines Agency	EMA
European Committee, pharmaceutical companies	STIKO
Vaccine recommendations and prioritisation	
Standing Committee on Vaccination	
Robert Koch Institute	RKI
Leopoldina	National Science Academy
German Ethics Council Production and procurement	BMBF
European Commission, EU member states	
Federal Ministry for Economic Affairs and Climate Action	BMWi, BMG
Pharmaceutical companies	BMG
Distribution, storage and logistics	
Federal Ministry of Defence/Federal Armed Forces, federal states, logistics specialists, pharmaceutical wholesalers, (hospital) pharmacies	BMVg
Organisation and provision of vaccinations Federal states	
Public health service	ÖGD
National Association of Statutory Health Insurance Physicians, Associations of Statutory Health Insurance Physicians in the federal states, medical personnel Financing, federal states, Federal Ministry of Health, statutory health insurance, private health insurance	KBV
	KVs
	BMG
	GKV
	PKV
Communication, professional training and public education Federal Centre for Health Education	BZgA, RKI, PEI, BMG,
Federal states, Academy of Public Health Services, professional societies Vaccine coverage monitoring	RKI
Surveillance: Monitoring of vaccine effectiveness and vaccine safety in the course of broad usage	RKI, PEI, EMA
Pharmaceutical companies International coordination and cooperation Federal Government	EU
Scientific forums	BMG
Evaluation of overall process	

COVID-19 Vaccines

Overview of COVID-19 vaccines and vaccine development.

The development of vaccines takes place over various stages, from the explorative and the pre-clinical phase with tests on laboratory animals via clinical phases 1, 2 and 3 with tests on humans to market authorisation.

Figure 1: Overview of phases of vaccine development [1].

Pharmaceutical companies and research institutes develop vaccines.

Company	Vaccine type	Number of doses vaccination interval	Vaccination volume per use	State of per clinical development	Planned submission for EU authorisation
Oxford/ Astra Zeneca	Vector-based ChAdOx1, non-replicating	(1–)2 doses 0.28 days	1 vaccine dose of 0.5ml IM	Phase 1/2: UK Phase 3: UK, Brazil, South Africa, India; USA	Start Rolling Review October 2020
BioN- Tech/Pfizer	mRNA enclosed in lipid nanoparticles	2 doses 0.21 days	1 vaccine dose of 0.3ml IM	Phase 1/2: Germany, USA Phase 3: USA, Brazil, Argentina, Turkey, Germany	Start Rolling Review 10/1/2020
J&J/Jans-sen	Vector-based Ad 26, non-replicating	(1–)2 doses 0.56 days	1 vaccine dose of 0.5ml IM	Phase 1/2: Belgium, USA, Phase 2: Germany, Phase 3: global	2021
SP/GSK	Recombinant, adjuvanted	2 doses 0.28 days	1 vaccine dose of 0.5ml IM	Phase 1/2: USA, Phase 3: USA	2021
Moderna/Lonza	mRNA enclosed in lipid nanoparticles	2 doses 0.28 days	1 vaccine dose of 0.5ml IM	Phase 3: USA	Possibly end of 2020
Novavax	Recombinant, adjuvanted	2 doses 0.21 days	1 vaccine dose of 0.5ml IM	Phase 1: Australia, Phase 2: USA, Australia, South Africa Phase 3: UK	Possibly end of 2020
Curevac	mRNA enclosed in lipid nanoparticles	2 doses 0.28 days	1 vaccine dose of 0.6ml IM	Phase 1: Belgium, Germany, Phase 2: Peru, Panama	Unknown
***Note:** Preliminary information based on current state of knowledge					

Table 2: Overview of vaccine candidates and the current state of their development (manufacturer information, last updated November 2020) Information supplied without guarantee [2].

What are the New Covid-19 Variants

The fact that more people are talking about COVID-19 again is also due to new Sars-CoV-2 variants. This focus is currently particularly on two new Omicron variants: initially, the World Health Organisation (WHO) advanced EG.5, also known as Eris, to one of now three "virus variants of interest". According to the WHO, Eris could lead to cases increasing once more, and could become dominant in some countries or even worldwide.

The variant BA.2.86 is significantly more mutated than Eris, but has not yet been identified in Germany. Some scientists feel that BA.2.86 is reminiscent of the early days

of Omicron. At the time, Omicron spread extremely quickly worldwide. But this will not necessarily happen again [3].

Conclusion

In principle, it seems that the only rational hope during the first wave of the dangerous coronavirus or COVID-19 was that a vaccine would be developed. Now that the vaccine has arrived, those affected are focussing on new problems, and in all probability, everyone is affected. How much vaccine is available and how it is distributed depends to a high degree on politics. Furthermore, it needs to be established who is to be vaccinated first (vaccine prioritisation). The effectiveness and vaccine safety are other concepts which people need to address. Mutations of the dangerous coronavirus must also be observed and analysed with regard to their effects on the vaccine. However, it is not only vaccination that has gained importance, but also testing, which has been possible for some time. Here, as with vaccinations, there are country-specific differences. National testing strategies are developed and implemented. A multitude of organisations participate, or rather are involved, in these processes, as shown by the example of Germany.

Outlook and Actual Tendencies

Vaccination Dashboard

Vaccination Status: up to 8 April 2023. 64.9 million people (77.9% of the population) have received one dose of vaccine. Of these, 63.6 million people (76.4%) have primary immunisation. 52.1 million people (62.6%) have also received a booster vaccination. 12.7 million people (15.2%) received at least two booster vaccinations. 18.4 million people have not been vaccinated (22.1% of the population).

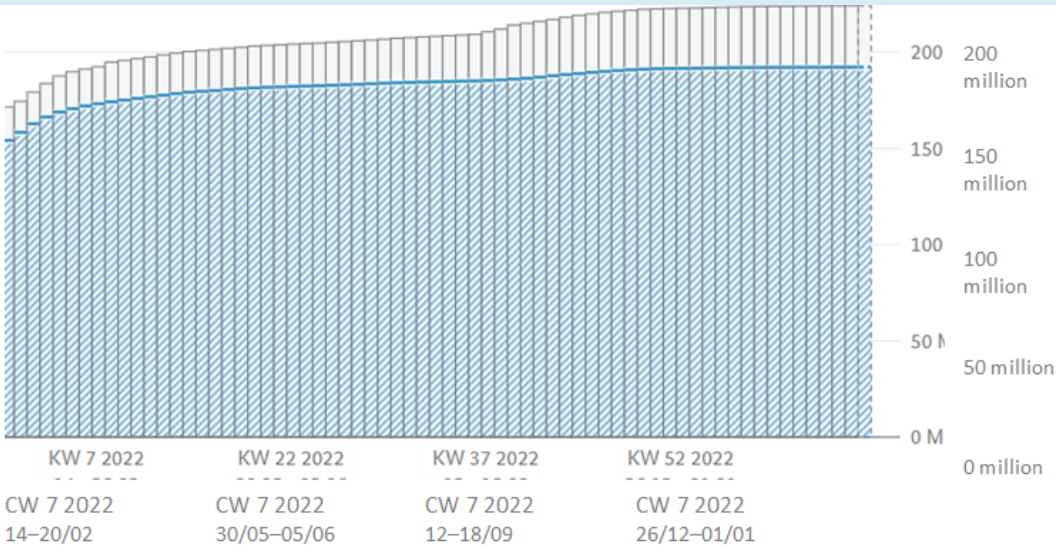


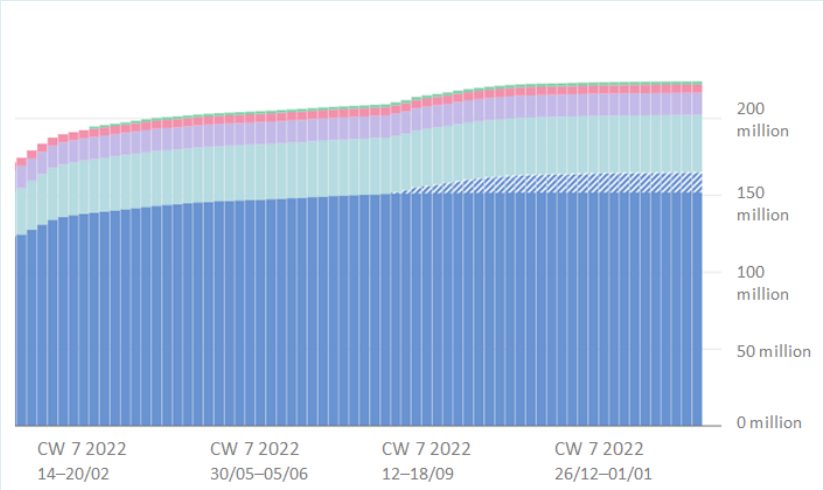
Figure 2: Vaccination dashboard (extract) [4].

As can be seen in Figure 2 above, basic immunisation of the population has taken place in Germany.

Vaccine Manufacturers

Deliveries by manufacturer and vaccine type

- By 8 April 2023, 224.1 million doses of vaccine had been delivered.
- The deliveries were from the manufacturers BioNTech/ Pfizer
- (164.7 million doses), Moderna (37.7 million doses), AstraZeneca
- (14.4 million doses), Johnson & Johnson (5.4 million doses), Novavax
- (1.9 million doses), Valneva (100 thousand doses) and Sanofi (6 thousand doses).
- The deliveries also included 13.6 million doses of adapted Omicron vaccine.



■ BioNTech/Pfizer ■ Moderna ■ AstraZeneca ■ Johnson & Johnson ■ Novavax ■ Valneva ■ Sanofi
Vaccines adapted to the Omicron virus variants

Figure 3: Administered doses by manufacturing company [4-7].

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