Rapid EUnetHTA assessment on coronavirus diagnostics supported by IQWiG

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As a founding member, the Institute for Quality and Efficiency in Health Care (IQWiG) has been involved in EUnetHTA, a European network for Health Technology Assessment (HTA), since 2006. The European Union

supports the network. Following the outbreak of the corona pandemic, the EU Directorate of Health called on the EUnetHTA partners to make a scientific commitment to combating the pandemic. Against this background, IQWiG has now supported the Health Agency of the Emilia Romagna region in Bologna in an initial assessment of coronavirus diagnostics. Initiator of the HTA report was the Italian partner organization, which also defined the topic. A Welsh partner co-authored the report in addition to IQWiG.

Two types of Corona tests

RT-PCR test: Rapidly after the outbreak of the corona pandemic, researchers developed methods to detect the virus directly. For this purpose, a smear is taken from the mouth, nose or throat area and examined for genetic traces of the virus. This method is known under the abbreviation RT-PCR and has a high accuracy. However, a few days after infection the body reacts to the virus. If the body's immune defense fights and destroys the virus, it is difficult or impossible to detect it with the RT-PCR test.

Antibody test: This second type of coronavirus test measures the body's immune response. The antibodies produced by the body are detected—usually by measuring the immunoglobulins M and G. Since the body needs several days to produce a measurable immune response, antibody tests only react with a strong delay after an infection. Antibody tests for the coronavirus are therefore too slow to detect or rule out an acute infection when relevant symptoms occur. However, antibody tests can be used in field studies to determine the proportion of the population having undergone a coronavirus infection (seroprevalence).

Neither immunity nor non-infectivity can be reliably detected

Having analyzed a total of 40 studies worldwide, the authors of the EUnetHTA report conclude that antibody tests can detect a past infection with the SARS coronavirus 2. However, the accuracy of the tests is not yet sufficient. Above all, it is still questionable whether a positive test result can be interpreted as a sign of immunity against re-infection. Moreover, a positive test result after recovery from an infection is no reliable proof that the person can no longer transmit the virus to other people.

Using corona diagnostics correctly

Due to the urgency of the matter, the EUnetHTA report that is now available was drawn up unusually quickly (within 6 weeks). As new study results are to be expected almost weekly, the assessment of the antibody tests will presumably be updated in about 3 months—again under the leadership of the Health Agency in Bologna and with the support of IQWiG.

The report results shall help to ensure that coronavirus diagnostics are properly used and developed in Europe and worldwide. However, the current EUnetHTA report has no direct consequences for the question of whether coronavirus antibody tests in Germany are paid for by the statutory health insurance (Gesetzliche Krankenversicherung [GKV]). At present, the tests are available as a benefit of the GKV, but the necessity of testing must be justified in each individual case. A positive test result must be reported.

More information: EUnetHTA report: www.iqwig.de/download/RCR_OT_0 … CoV-2_23-06-2020.pdf

Provided by Institute for Quality and Efficiency in Health Care