

Pulse oximetry screening in newborns: Hint of benefit for critical congenital heart defect

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There is a hint of a benefit of pulse oximetry screening as an add-on test to existing standard examinations for detection of critical congenital heart defects in newborns: More cases are detected by additional screening than by the two clinical examinations U1 and U2 alone. This means that newborns can be treated at an early stage and may be protected from severe late complications.

There is an insufficient evidence base to weigh benefit and harm with regard to the diagnosis of other diseases additionally detected by pulse oximetry [screening](#). This is the result of a final report published on 6 May 2015 by the German Institute for Quality and Efficiency in Health Care (IQWiG) after commissioning by the Federal Joint Committee (G-BA).

The earlier the diagnosis, the better the chances

Some [congenital heart defects](#), that is, deformities of the heart or of blood vessels close to heart, can quickly lead to life-threatening dysfunctions of the cardiovascular system after birth. Such critical congenital heart defects (CCHD) occur in about 1 in 1000 children per year in Germany. The earlier this condition is diagnosed, the better late complications and deaths can be prevented by early treatment.

In Germany, in the first and second clinical examination after birth (U1 and U2) the heart and [pulse rate](#) of [newborns](#) are also routinely checked.

In the event of a conspicuous finding, an ultrasound test is performed to clarify a potential heart defect.

Add-on pulse oximetry is supposed to decrease diagnostic gap

However, about a fifth to a quarter of cases of CCHD are not recognized in the U1 or U2 examinations. This diagnostic gap is supposed to be closed by additional pulse oximetry, where the oxygen saturation of the child's blood, as well as the pulse rate, are measured via the skin.

Healthy newborns do not suffer disadvantages from this non-invasive examination. However, a conspicuous finding in pulse oximetry screening can also be a sign of other diseases such as lung disease. Their diagnosis at this [early stage](#) can possibly lead to unnecessary examinations and treatments.

Intervention study supports hypothesis

The benefit assessment now completed included a total of 6 studies, 1 comparative [intervention study](#) and 5 studies on the assessment of diagnostic accuracy. These test accuracy studies were eligible for the assessment, as it can be assumed that early diagnosis and treatment of CCHD can prevent complications and deaths.

The intervention study compared routine clinical examinations of newborns with and without add-on pulse oximetry screening. The proportion of newborns in which CCHD was determined was slightly higher in the intervention group than in the control group (0.13% vs. 0.10%). Severe preoperative acidosis (hyperacidity of the blood) as a further sign of oxygen deprivation occurred far less often than in the control group.

The results support the hypothesis that additional pulse oximetry screening reduces disease-related morbidity in newborns with CCHD. However, as the study was not randomized and confounders cannot be excluded, no benefit of the intervention can be derived from this study alone.

Test accuracy studies confirm benefit

The 5 studies on diagnostic accuracy consistently show that pulse oximetry screening can detect additional newborns with CCHD whose findings were inconspicuous in the routine clinical examination. To find an additional child with CCHD, between 421 and 7100 asymptomatic newborns in the studies had to undergo pulse oximetry screening. Assuming that an earlier intervention offers advantages in CCHD, from these results IQWiG infers a hint of a benefit of pulse oximetry screening as an add-on test to routine examinations.

Due to large differences between the studies the results cannot be evaluated conjointly in a meta-analysis. In addition, clear recommendations for a screening strategy (when to screen, where to measure, and which threshold values to use) are not possible on this basis.

Risk of over-diagnosis and over-treatment

The test accuracy studies showed a wide range of results: A quarter to three-quarters of newborns with conspicuous findings in [pulse](#) oximetry screening did not actually suffer from CCHD. These cases were either false-positive findings or non-critical [heart defects](#) or other diseases for which the benefit or harm of earlier diagnosis and treatment is unclear. Prior to such a screening parents should always be informed that false-positive test results are possible.

Process of report production

IQWiG published the preliminary results in the form of the preliminary report in November 2014 and interested parties were invited to submit comments. At the end of the commenting procedure, the preliminary report was revised and sent as a final report to the commissioning agency in March 2015. The written comments submitted were published in a separate document at the same time as the final report. The report was produced in collaboration with external experts.

More information: [www.iqwig.de/download/S13-01_K...
ht_Pulsoxymetrie.pdf](http://www.iqwig.de/download/S13-01_K...ht_Pulsoxymetrie.pdf)

Provided by Institute for Quality and Efficiency in Health Care

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