Reliability and benefit of diagnostic procedure for asthma in young children is unclear

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The Institute for Quality and Efficiency in Health Care (IQWiG) has investigated the reliability of diagnosing bronchial asthma in children aged between 2 and 5 years, and the benefit that the test results can have for these patients. IQWiG published its final report in August 2009. According to the report, the available studies do not reveal any diagnostic procedure to be particularly suitable. It also remains unclear whether the treatment given based on the test results can benefit the patients.

The Federal Joint Committee (G-BA) commissioned the Institute to carry out the research. Using IQWiG expertise, the committee seeks an answer to the question whether the existing DMP should be extended to children of preschool age. Until now, it has only been possible to enrol children from the age of 5 upwards on a DMP.

Diagnosis must be certain

Bronchial asthma frequently starts in early childhood, but it is very difficult to diagnose in this age group. Moreover, young children are often free of symptoms by the time they reach school age. On the one hand, the screening should ensure no asthma cases are overlooked, so that appropriate treatment can be given in good time. On the other hand, children that do not actually suffer from chronic asthma should not receive unnecessary treatment and thus be exposed to potential harm.

The certainty of the diagnosis is therefore of particular importance.

In the first report already completed, IQWiG investigated whether a reference standard could be derived from clinical practice guidelines, against which the diagnostic reliability of individual methods could be measured. The current optimum and most reliable method for diagnosing or excluding a disease is taken as a reference standard. As this type of test could not be identified, the Institute then investigated the accuracy of diagnostic procedures without using a reference standard.

No recommendation for diagnostic procedures can be derived from studies

In this second part of the commission, IQWiG investigated how suitable the procedures are in differentiating between those children who have symptoms but do not require long-term treatment and those children who develop chronic asthma. This ability to discriminate and predict is particularly important for those children who might have to be enrolled on a DMP.

After analysing a total of 7 studies available at that time, IQWiG came to the conclusion that the literature could not provide any recommendations for an individual method, or a combination of specific methods, that could be used as a criterion for enrolment on a DMP. The superiority of one test over any other could not be established.

This is firstly because there are only a few clinical comparisons dealing with the commission's research question. Secondly, the data contained in them have no validity, because the study and report quality displayed flaws. For example, there is a lack of data on the severity of disease in the patients examined, yet the degree of severity can have an influence on how reliably the test confirms the disease. The analysed studies

indicate that a diagnostic algorithm could be used, i.e. a certain sequence in which individual measures can be combined together.

"Linked evidence" method could not be applied

In order to assess the diagnostic procedures, IQWiG also evaluated their efficacy. The tests can only be described as efficacious if they result in a therapeutic benefit, i.e. the patients can benefit from treatment. However, as the search revealed, there are currently no diagnostic studies that could provide a direct answer to the question of test efficacy (Phase 4 diagnostic studies), because this would require a study design that investigates a treatment strategy consisting of a test and an intervention.

If information on diagnostic procedures and therapeutic measures is only available in separate studies (Phase 2 and 3 diagnostic studies, and therapy studies), it is possible to try to synthesize and link them to a certain extent. In this way, at least indirect findings on the clinical efficacy of diagnostic procedures can be obtained. However, this method of "linked evidence" involves certain methodological requirements. As IQWiG and its external experts established, the studies available to date on diagnosing asthma in children under 5 years of age do not contain these requirements. Thus, a reference standard was particularly lacking.

No robust conclusions concerning efficacy possible

Even a modified procedure which, based on the linked evidence criteria, attempts to link the studies without a reference test is not possible. This is in part because the asthma-specific selection criteria are not precisely described in the therapy studies. Furthermore, none of the therapy studies used a selection method whose diagnostic accuracy had already been proven by studies.

IQWiG has therefore concluded that the results from the diagnostic and therapy studies cannot actually be synthesized in terms of "linked evidence". No robust conclusions can be drawn concerning the accuracy of individual tests used in therapy studies nor on the clinical efficacy of interventions tested in Phase 2 and 3 diagnosis studies.

Report preparation stage

IQWiG published the preliminary results in two separate preliminary reports in June (Part 1) and in September (Part 2) 2008 and interested parties were invited to submit comments. When the comments stage ended, the two preliminary reports were revised and then compiled into a final report, which was sent to the contracting agency at the beginning of June 2009. Documentation of the written comments for both preliminary reports and the minutes of the hearing procedure are published in a separate document simultaneously with the final report. The report was produced in collaboration with external experts.

Research question comprehensively answered in three final reports

This final report completes the commission package. Using IQWiG expertise, the G-BA can now advise on whether or not the Asthma DMP should be extended to children under 5 years of age.

In the first part of the commission, IQWiG examined whether there was a generally recognized procedure for diagnosing asthma in children. However, the final report came to the conclusion that such a reference standard did not exist. In the second part of the commission, IQWiG therefore had to investigate the accuracy of diagnostic procedures without reference to a comparison test. The results were presented here in detail: firstly, it is not possible to recommend a specific test as a basis for registering on a DMP; secondly, it is not possible to draw robust conclusions on whether, based on the test, young children could then

receive treatment that would provide them with a benefit.

In the third part of the commission, IQWiG assessed the benefit of drug and non-drug interventions. As IQWiG has confirmed, it remains unclear whether 2 to 4-year-olds benefit from measures, which up till now have only been offered to children aged 5 upwards as part of the Asthma DMP, for suitable interventions for preschool children have not been adequately investigated. A few studies indicate that the drug, fluticasone propionate (ICS), approved for children aged 4 upwards, can lower the rate of acute exacerbations and increase the number of asthma-free days. However, it can also cause growth retardation.

An overview of the background, methods and further results of the final report on the reliability and benefit of diagnostic procedures is provided by an Executive Summary.

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