Accuracy of ultrasound screening in pregnancy: Effects of examiner and device quality unclear

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Only indications of positive associations; no studies on the German health care setting available

International studies indicate that there is an association between examiner qualifications and device quality on the one hand, and detection rates of ultrasound screening tests in pregnancy on the other. However, it is unclear which minimum preconditions must be fulfilled in order to achieve sufficiently high detection rates for major foetal abnormalities.

The question also remains unanswered as to whether the association described in other health care systems also exists in the specific organisational setting (multi-level concept) of the German system, as relevant studies are lacking. This is the conclusion of a report by the German Institute for Quality and Efficiency in Health Care (IQWiG), Cologne, which was published in June 2008 and for which an English-language summary is now available.

Screening is organised very differently on an international level

In Germany, ultrasound tests are an established procedure in health care during pregnancy. Among other things, their aim is the early detection of foetal abnormalities. In this context, the most correct evaluation possible is essential, as parents should be informed about any individual risk of

severe deformity or chromosomal abnormality if they so wish. However, false positive diagnoses, which place a considerable burden upon parents, must be avoided as far as possible. Quite different concepts exist on an international level as to how to organise ultrasound screening tests in pregnancy. This applies to both the frequency and timing of the tests, as well as to the requirements for examiners and devices.

In Germany, three regular ultrasound tests are planned (one in each trimester). The German programme is organised in a decentralised manner, i.e., the tests are not only performed in specialised centres. The basic screening tests (level 1) are usually performed by office-based obstetricians. If abnormalities are detected, these are reviewed in level 2, i.e., in specialised practices with long-term experience or in general hospitals with certified examiners. If a finding requires further clarification or if specific treatment is needed for the mother or child, level 3 facilities, mainly university clinics, are available.

German Federal Joint Committee revises maternity guidelines

In order to be able to review the German ultrasound screening procedures (which have been established for over 10 years and are embedded in the maternity guidelines) and to adapt them to the current state of knowledge, the Federal Joint Committee (G-BA) first commissioned IQWiG to assess the detection rates for major foetal abnormalities with regard to examiner qualifications and device quality. This report therefore deals exclusively with test accuracy. Issues concerning parental information, consent, and medical counselling, which are also of major relevance in this type of screening, are investigated in a separate report, which the G-BA commissioned on 15 May 2008.

Test accuracy varies strongly

A total of 60 studies eligible for analysis were found in the literature search. These studies repeatedly indicated that examiners and devices were important factors in the outcome quality of screening. However, test accuracy between studies varied strongly; the causes of this variation were not clear. In addition, all of these studies originated from abroad and mainly referred to the health care levels 2 and 3 noted above. It is therefore questionable whether the results are transferable to the German setting, where the initial screening test takes place mainly on level 1. On this basis, the question cannot be answered as to which minimum standards need to be fulfilled by examiners and technical equipment in order to achieve sufficiently high detection rates. Relevant studies on the German - or at least a comparable - screening programme are completely lacking.

In view of this deficit, IQWiG suggests conducting studies in Germany. Only in this way can the quality of the German multi-level concept be represented. In order to follow the development of screened children and compare their development with screening results, these studies should also be linked to perinatal registers yet to be established in Germany.

Procedure of report production

The preliminary results (preliminary report) were published for discussion on the IQWiG website in November 2007. Unclear aspects of the 12 comments submitted on the preliminary report were discussed with the authors of the comments in an oral debate. The preliminary report was subsequently revised and the final report sent to the contracting agency (Federal Joint Committee) in April 2008. The meeting minutes of the debate, as well as the written comments, will be published in a separate document at the same time as the final report.

External experts from Europe (UK, Switzerland, Belgium), Israel, and Egypt were involved in the preparation of the report. Their names are listed in the final report.

Source: Institute for Quality and Efficiency in Health Care