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# **Relationship between provider volume and outcomes in the care of preterm infants and neonates with very low birth weight<sup>1</sup>**

## **Executive Summary**

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<sup>1</sup> Translation of the executive summary of the final report “Zusammenhang zwischen Leistungsmenge und Ergebnis bei der Versorgung von Früh- und Neugeborenen mit sehr geringem Geburtsgewicht.” (Version 1.0; Status: 14.08.2008). Please note: This translation is provided as a service by IQWiG to English-language readers. However, solely the German original text is absolutely authoritative and legally binding.

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### **Executive summary**

#### **Background**

Against the background of the planned consultation on the new version of the Federal Joint Committee's resolution on minimum provider volumes for preterm infants and neonates with a birth weight < 1500g (very low birth weight, VLBW), the Institute for Quality and Efficiency in Health Care (IQWiG) was commissioned to assess the current literature.

#### **Research questions**

The main aim of this assessment was to describe the relationship between the number (volume) of treated preterm infants and neonates with VLBW and the quality of outcomes on the basis of the published scientific evidence. The assessment was to consider the transferability of results to the current health care setting in Germany. In addition, it was to be investigated to what extent published data allowed reliable conclusions on potential threshold values.

#### **Methods**

The study population to be investigated comprised preterm infants and neonates with a birth weight < 1500g or a maturity grade of  $\leq 32$  completed gestational weeks. The primary outcome for this report was mortality; further patient-relevant outcomes, such as morbidity, were secondary outcomes. Intervention and observational studies were regarded as relevant for the investigation of the research question posed. For studies investigating the relationship between provider volume and the quality of outcomes, appropriate risk adjustment was required in order to reduce potential bias resulting from different patient populations (case mix) between hospitals with high and low case numbers. Therefore, only those studies were included that considered further risk factors, in addition to gestational age and gender. The report included studies published from 1992 onwards, and in which solely data from 1990 onwards were analysed. Due to the required transferability to the current health care setting in Germany, studies from the following countries were considered: Germany, Benelux states, Denmark, Finland, France, Greece, Great Britain, Ireland, Italy, Norway, Austria, Portugal, Sweden, Switzerland, Spain, USA, Canada, Australia, and New Zealand.

The search for relevant studies was conducted in the bibliographic databases EMBASE, MEDLINE, CENTRAL, BIOSIS, CINAHL, and The Cochrane Library (CDSR, DARE, HTA). The reference lists of all included publications and excluded publications available in full text, as well as the reference lists of relevant secondary publications, were searched by hand for further potentially relevant studies. In addition, a request for information was sent to the Vermont Oxford Network (VON).

Characteristics and results of the studies included were summarized in evidence tables. In addition, an assessment of the bias potential of studies was performed.

## **Results**

A total of 12 publications on 10 observational studies were identified that fulfilled the inclusion and exclusion criteria. Eight studies investigated the primary outcome mortality; all in all, no completely consistent picture emerged. However, the overall data indicated a statistical relationship between provider volume and the quality of outcomes in VLBW infants in the sense that an increase in provider volume improved the quality of outcomes. No significant relationship between provider volume and the quality of outcomes was shown in 3 of the 8 studies (of which 2 showed a high bias potential). In contrast, 4 studies (all with a low bias potential) showed a statistical relationship between provider volume and the quality of outcomes. A further study with a high bias potential did not allow a statement of significance concerning the relationship between provider volume and mortality. In particular, the studies including German health care data showed a significant statistical relationship between provider volume and the quality of outcomes.

Only 4 publications investigated the relationship between provider volume and various morbidity variables. Overall, the data available were scarce, so that a conclusive substantial assessment could not be conducted here.

## **Conclusion**

A total of 12 publications on 10 studies were identified and assessed to investigate the relationship between provider volume and the quality of outcomes in the care of preterm VLBW infants. As the studies included were exclusively observational studies, no causal relationships can be inferred from the results. None of the studies were designed to determine explicit threshold values for minimum provider volumes; due to the existing data situation, statements on specific threshold values have no sound scientific basis.

With regard to a statistical relationship between provider volume and the quality of outcomes in the care of preterm VLBW infants, the results of the publications included do not show a completely uniform and clear picture. However, for the primary outcome mortality, overall the data provide clear indications of a statistical relationship, which shows that an increase in provider volume is associated with a trend towards risk reduction (under consideration of the study and publication quality as well the population basis of the data). Data on morbidity were scarce and unclear, and do not allow a conclusive assessment with regard to a relationship between provider volume and the quality of outcomes.

Provider volume is to be regarded as a surrogate factor. Other factors, such as obstetric conditions, transportation of mother and child, the average daily hospital occupancy rate, the number of experienced obstetricians/neonatologists and specifically trained nurses in the daytime, night time, and at weekends, as well as unknown factors not yet studied, could have effects on the outcomes investigated.

In the case of the introduction of a regulation on minimum provider volumes in the care of preterm VLBW infants, the Institute recommends an accompanying evaluation suited to record the effects of this intervention in an adequate fashion.

**Key words:** Preterm infants, brain haemorrhage, intensive care, minimum provider volume, mortality, morbidity, neonatology, very low birth weight (VLBW)