

# Update of criteria for out-of-hospital births in Germany – how to deal with higher than low risks in obstetrics

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## ABSTRACT

After births at midwife-led birth centers, as well as home births, were included in the Social Security Statute Book (§134a SGB V), and thus became covered by the German national public health insurance, contract negotiations on flat rate costs followed. Consequently, the quality management section concerning allocation criteria for out-of-hospital births required an update, which needed to be as evidence based as possible.

Many countries have a catalog allowing choice in place of birth, but these are often not published in scientific journals and thus cannot be identified by usual research tools.

This article includes a link to an overview table with twelve columns, representing current practice in eleven countries (for Germany, two catalogs, from different settings, are included). These catalogs have been found through literature studies (often as links to the homepage of the ministry responsible) or by direct correspondence.

Obstetrics worldwide faces the same problems in terms of how to cope with higher than low risks. The overview table shows how very similar the solutions really are, and thus helps to define how responsibility can be shared effectively between midwives and obstetricians.

The specific regulations concerning quality management in the contract between self-employed midwives and the German Public Health Insurance will be updated on this basis.

## KEYWORDS

Out of hospital births, higher than low risks in pregnancy and intrapartum, responsibility between midwife and obstetrician, quality management, patient safety.

## Introduction

In Germany, public health insurance covers delivery in hospital, in a birth center or at home (§ 24f Social Security Statute Book, SGB V) <sup>[1]</sup>. Most women choose to give birth in hospital. Indeed, in 2018, 1.5% of births (11,956 out of 790,590) took place out of hospital; 115 birth centers and 18,425 self-employed midwives cared for these cases.

Since 2008, a contract <sup>[2]</sup> between the Statutory Health Insurance Funds Association and the midwives' associations, concerning birth centers, has regulated rights and duties on both sides, including flat rate costs. In 2014, the Ministry of Health asked both contracting parties to add quality requirements for the out-of-hospital setting, i.e., for antenatal care, home births and childbed care. This made an update of the list of exclusion criteria necessary; this list assigns higher than low risk obstetric situations to two categories: relative criteria demand consultant approval, whereas absolute criteria require transfer to hospital. We regard these regulations as an important contribution to quality assurance and patient safety, although they limit free choice over the place of birth to low-risk pregnancies only.

The present article describes how we managed the task of updating the criteria, striving in particular to respect midwives' demand for, as far as possible, evidence-based decision-making criteria.

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## Methods

A first attempt to identify exclusion criteria for home births was made through a systematic literature search in December 2014, which yielded four publications <sup>[3-6]</sup> referencing important guidelines or catalogs: the NICE Guideline "Intrapartum care: care of healthy women and their babies during childbirth" (2014) <sup>[7]</sup>; two catalogs with indications for discussion, consultation and transfer of care produced, respectively, by the Colleges of Midwives in Ontario (2000) and British Columbia (2015) <sup>[8,9]</sup>; and the Verloskundig Vademecum in the Netherlands, which was translated into English and published by Bleker in 2005 <sup>[10]</sup>.

Based on these documents, the first version of an overview table was drafted, containing four columns: the criteria for birth centers from the first German contract, the two Canadian contributions [marked with (O) for Ontario and (BC) for British Columbia], the Dutch position, and the NICE recommendations. Nevertheless, after thorough discussion, we concluded

that exclusion criteria cannot be derived from studies alone and that a consensus procedure needed to be implemented instead.

In 2018, a second working group was established, which decided to consult guidelines as well as regulations issued by the Federal Joint Committee (Gemeinsamer Bundesausschuss). Meanwhile, two more catalogs had been published and were added to the table: one, the catalog for a midwife-led delivery room (2007), was the result of a project by Osnabrück University of Applied Sciences <sup>[11]</sup> and the other was the Austrian catalog for midwives (2014) <sup>[12]</sup>. Finally, a publication by Halfdansson (2018) <sup>[13]</sup> cited various English-language catalogs in the references – from Ireland <sup>[14]</sup>, the American College of Nurse Midwives <sup>[15]</sup>, South Australia <sup>[16]</sup> and New Zealand <sup>[17]</sup> – and also mentioned ones from Iceland, Norway and Denmark (in their native languages). By correspondence with Berglind Halfdansson and Dr Ellen Blix, it proved possible to get English translations of the Icelandic and the Norwegian material for the table, thus resulting in a total of twelve columns.

It should be recorded, nevertheless, that we also tried to find catalogs from France, Italy, Spain and Sweden. The Haute Agence de Santé stated, that, in France, the Assurance Maladie regulations allow midwives to provide antenatal care only. In Italy and Spain, out-of-hospital births are not covered by public health insurance, while in Sweden, the system requires a strict risk assessment by the senior consultant obstetrician, who decides at 36 weeks of gestation whether or not birth may take place out of hospital.

In addition to including 21 guidelines from the Association of the Scientific Medical Societies in Germany (Arbeitsgemeinschaft der Wissenschaftlichen Medizinischen Fachgesellschaften e.V., AWMF), we conducted evidence-based research in order to reach consensus with the midwives' associations on eight topics. For most of these, a literature research in PubMed and Cochrane was performed. The number of publications finally analyzed is here indicated in brackets after each topic (all documents can be provided by MDS on demand).

- Uncertain date/overdue (3);
- pre- and perinatal infections (course, topic addressed at a congress in February 2019);
- intrapartum fever (3);
- definition and assessment of anemia in pregnancy (17);
- probability of recurrence of placental abruption (6), post-partum hemorrhage (2), shoulder dystocia (4) and HELLP syndrome (9);
- failure of engagement of the fetal head despite labor/slow progress (21);
- obesity (1, the NICE guideline 2019) <sup>[18]</sup>;
- premature rupture of membranes (1, the Cochrane review 2017) <sup>[19]</sup>.

## Results

All the catalogs quoted in the table show coping strategies from countries that do provide out-of-hospital births covered by public health insurance. The table uses traffic light colors to indicate:

- situations the midwife will cope with alone, shown in green
- situations to be discussed with a medical doctor, shown in yellow and
- situations that require obstetric care, in orange.

In Austria and New Zealand there is a fourth (red) category for emergency cases; and in the Netherlands a light red option, which allows the self-employed midwife to accompany the woman to hospital in order to finish a birth there, although it had been initiated in a birth center or at home. The NICE guideline only contains two categories (green or orange), with an “individual assessment” for assignment, which often also involves consultation.

The table, with its 243 rows, is organized in four sections:

- I. general history (pink frame)
- II. pregnancy-specific history (blue frame)
- III. delivery (grey frame) and
- IV. post-partum care (lilac frame).

The evaluation is made by following the colors along a row. This way, it can be ascertained, at a glance, how many catalogs comment on a given situation at all, and whether they place it in the same or different categories.

Table 1 provides an overview on risk management according to the identified catalogs, and it can be reached via this link: <https://www.mds-ev.de/geburtshilfe.html>.

On the homepage of Medizinischer Dienst des Spitzenverbandes Bund der Krankenkassen (MDS). The table can there be found both in German and in English together with some explanatory remarks.

This overview table was agreed upon on November 14<sup>th</sup>, 2019 and has since served, in contract negotiations, as an instrument for quality assurance in obstetric care. Assignment according to absolute and relative criteria is relevant for remuneration of self-employed midwives, as out-of-hospital births are not paid for if the contractual conditions concerning quality management are not met. An absolute criterion demands transfer into obstetric care, a relative criterion demands consultant approval.

The application of criteria refers to article 42 in the Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications <sup>[20]</sup> as well as to the German legislation concerning midwives, which both state, that the midwife is allowed to handle normal pregnancy and normal delivery, but is obliged to consult an obstetrician or transfer the woman into hospital as soon as she perceives pathology.

The resulting catalog of criteria so far only covers sections I to III and will be part of the contract with the midwives' associations. It is intended that the transfer indications shown in section IV will also be added as soon as possible.

## Discussion

The influence of the choice of birthplace on obstetric outcome is an issue that has already long been discussed. A few publications (e.g. Scarf 2018) <sup>[21]</sup> collected data from several countries for the purpose of addressing this issue, aiming mainly to compare maternal and fetal outcomes according to setting.

This paper concentrates on the underlying criteria of cooperation between midwives and obstetricians and, in the overview table, shows the coping strategies adopted in eleven different countries and in one additional German setting (the midwife-led delivery room). The table includes 243 findings from pregnancy and the perinatal period. The system of highlighting responsibilities in traffic light colors was a useful means of demonstrating risk allocation. Looking along the full length of a row often reveals the same color, which means that there is unanimous assessment of obstetric risk.

Naturally, this risk classification cannot be taken as strict scientific evidence; rather, it shows a “swarm intelligence” kind of practical evidence.

Nevertheless, the overview table helped us to find a consensus in negotiation of many problems and is an important contribution for international exchanges, comparison of results and further development of obstetric care within different social security systems.

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**Table 1** Overview of how to cope with risks from identified catalogs. Cave: there will only be a link to this table in the article, as it consists of twelve columns and 243 rows!

The link <https://www.mds-ev.de/geburtshilfe.html> connects you with the homepage of Medizinischer Dienst des Spitzenverbandes Bund der Krankenkassen (MDS), where you will find the table (both in German and English).

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**Conflict of Interest Statement:** The author works for the German Public Health Insurance according to the regulations of Social Security Statute Book V.