GerOSS (German Obstetric Surveillance System)

A Project to Improve the Treatment of Obstetric Rare Diseases and Complications Using a Web Based Documentation and Information Platform

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Summary
Background: Severe and very rare obstetric complications (e.g. eclampsia, postpartum haemorrhage or uterine rupture), typically culminate in a chaotic, uncontrollable sequence of events. Outcome for mother and child depends on whether doctors and midwives are able to quickly take correct decisions and initiate optimal treatment.

Objectives: GerOSS (German Obstetric Surveillance System) aims at generating deeper insight into relevant risk factors to improve diagnosis and treatment of severe complications during pregnancy and delivery. As such it is primarily conceived as a system for quality improvement and less as a register. Another focus is the provision of an information and communication platform for dissemination of these insights. Finally, incidences of selected rare obstetric events may be derived.

Methods: These rare events are monitored for two to five years in Lower Saxony, Bavaria and Berlin. Quantitative analyses of aggregate data are complemented with in depth case based anonymised evaluations by experts. The temporal sequence of measures taken as well as the management of care is inspected. Participants receive a feedback of comments on the synopsis of individual cases. Aggregate data results are published and made available through the GerOSS platform. A scientific advisory committee ensures the link with the professional scientific bodies. A comparison within INOSS (International Network of Obstetric Survey Systems) allows additional insights into the treatment of obstetric rare diseases and complications. More reliable estimates of the incidence of such events can be computed and compared within a larger database.

Results: Following the implementation in three federal states in Germany in 2010, participation in GerOSS-Project has increased to 100% of all hospitals with a delivery unit in Lower Saxony, 30% in Bavaria and 80% in Berlin. Feasibility of the project is shown by successful implementation of GerOSS. Quantitative analyses enable construction of risk profiles (e.g. for the prevalence of hysterectomies and uterine ruptures) such that tailored treatment algorithms may be derived. Age, body mass index and previous caesarean section are common risk factors when complications occur. Respective recommendations have not always been adhered to in the diagnosis and therapy of such cases. The presentation of initial GerOSS results has paved the path for first changes in obstetric care.

Conclusions: The envisaged expansion of GerOSS to an interactive platform will allow dissemination of insights such that optimal obstetric care and transferal among all involved medical facilities may see future enhancements via the internet or even through smartphone applications.

1. Introduction
GerOSS (German Obstetric Surveillance System) is primarily composed as a system to improve treatment of extremely severe and very rare complications of pregnancy and delivery (e.g. eclampsia, HELLP syndrome (Haemolysis Elevated liver enzymes, low platelet count) or uterine rupture) typically culminating in a chaotic, uncontrollable sequence of events [1, 2] using a web based documentation and information platform. The outcome for mother and child depends on whether doctors and midwives are able to quickly take correct decisions and initiate optimal treatment [3]. Headlines such as “Delayed motherhood – pregnant over 40?” in a weekly public magazine reflect
social changes in family planning [4]. Additionally we observe altered eating habits resulting in obesity as a risk factor as well as the incidence of accompanying diseases (such as eclampsia, HELLP or cardiovascular problems) [5, 6]. These and other changes such as a continual rise in caesarean section rate present current challenges to obstetrics [7]. For selected high risk areas of medical care, especially for events with an incidence of 3 to 5 per 10,000 deliveries thus additional support for the staff is required to enable safe treatment of patients under high risk conditions while maintaining high levels of medical care. Valuable insights into the future treatment may be gained from an analysis of such events within the GerOSS project and also in comparison with the recent results from INOSS (International Network of Obstetric Survey Systems) [9].

2. Objectives

- Optimization of management of care through in depth individual case analyses (e.g. root cause analysis, process analysis) conducted by experts (obstetricians, midwives, intensive care specialists, paediatricians etc.) and the development or refinement of optimal strategies for care and recommendations [10]
- Development of preventive strategies (“early warning system”) for rare but difficult to control events. The aim is a timely control and monitoring of “at risk” cases from pregnancy to delivery
- Provision of an information and communication platform for the dissemination of insights gained from statistical analysis of documented events (aggregate and case based) as well as interactive self-learning modules and algorithms for appropriate actions to be taken in the form of smartphone APPs
- Derivation of incidences for selected obstetric rare events

3. Methods

3.1 General Concept, Organization and Pilot Phase

GerOSS was independently founded in 2010 by concerned obstetricians primarily as a concept for supporting their own efforts in improving obstetric care. Thus the opportunity for establishing a novel approach complementary to the existing mandatory quality assurance programs involving ongoing collection of standardized basic data for a defined subset of all hospital based interventions in accordance with German legislation [11, 12] was seized. GerOSS, by contrast, gathers differentiated information however only on extremely rare and severe events during pregnancy and delivery and terminates data collection for each event once sufficient data have been compiled. Thus the emphasis is on gaining rapid insight to options for improvement of obstetric care resulting in measures to be adopted at clinic level while covering a broad range of rare and complicated events. Conclusions are drawn from analyses of statistically sufficient number of events augmented with in depth inspection of individual case reports by clinical experts.

Technically this is achieved through an internet based system for reporting and documenting of rare obstetric events. From the outset provisions were made to extend the project on a modular basis (every event corresponds to a module). This primarily concerns the portfolio of currently documented events. Each reporting cycle spans two to at most five years for documentation of selected complications of pregnancy and during delivery. For some of these (pulmonary and amniotic fluid embolism, transfusion of six or more units of blood plasma and oesophageal atresia) merely the event itself is reported for calculating incidences whilst for others comprehensive data is documented (uterine rupture, peripartum hysterectomy (PPH), eclampsia, placenta accreta, increta and percreta). At the end of each cycle the data are analysed and results and insights gained are presented and disseminated. Once obstetric management at clinic level has been reviewed the respective module is considered as completed giving room for the next module in line. Principally GerOSS does allow for follow up of individual cases matched by a trust centre as well as on a cohort basis after an interval of two to three years has lapsed such that compliance to altered regimes may be assessed. So far none of the present modules has been envisaged for this purpose. The GerOSS data base is primarily conceived for quality improvement rather than as a register. Any further use of this data for instance the calculation of incidences then requires special measures in organization and documentation.

A scientific advisory committee (SAC) of members from all participating regional constituencies (the federal states Lower Saxony, Bavaria and Berlin) ensures inclusion of the professional bodies such as the German society for obstetrics and gynaecology. The SAC decides on the general focus and future development of GerOSS, the current set of events to be monitored, their respective study periods as well as the extension to other federal states. In addition the SAC members evaluate statistical analyses and resulting publications. An important task for the SAC is the development of suitable strategies for dissemination of results and insights gained through presentation at annual general meetings of the professional societies, publication in corresponding journals but also directly on the website (www.geross.de) [13]. The SAC assigns working groups to define the obstetric events and accordingly to specify the data items for documentation. The working groups also evaluate individual case histories and participate in the presentation and publication of study results. The study centre is responsible for providing the required data management (plausibility and completeness checks and general administration).

The definitions of events also embrace inclusion and exclusion criteria. For instance, only those PPH are included, that meet the following conditions: supracervical or complete excision of the uterus in connection with delivery or puerperium up to 42 days from birth.

Since its beginning GerOSS has cooperated closely with UKOSS (United Kingdom Obstetric Surveillance System) [14] who began in 2005. The basic design was copied and lessons learnt from several years of UKOSS experience proved valuable. Additional help was offered by the German ESPED (Erhebungseinheit für Seltene Pädiatrische Erkrankungen) [15] section of a similar international collaboration in the field of rare paediatric diseases which
started in 1992. In addition to this GerOSS is affiliated to the International Network of Obstetric Survey Systems (INOSS) set up in 2010. All INOSS member states aim to publish analyses from pooled data and to jointly develop intervention and prevention strategies for the future which necessitates the definition of a minimum common dataset. All definitions for new events are harmonized across INOSS members currently comprising Australia/New Zealand (AMOSS), Belgium (BOSS), Denmark, Finland, Norway and Sweden (NOSS), Bavaria, Berlin and Lower Saxony in Germany (GerOSS), France, United Kingdom (UKOSS), Italy (ITOSS), Netherlands (NETHOSS) and Catalonia in Spain (CatOSS).

### 3.2 Technical and Organizational Solutions for Data Management and Data Protection

Initial recruitment of obstetric units from the aforementioned federal states was conducted with a paper based version of the datasets. From 2011 onwards a GerOSS specific web-based platform for data management was commissioned. To save costs this was constructed on the basis of an already existing application for disseminating of annual statistical reports for quality assurance in Bavarian hospitals. Core functionalities including a web-server structure, relational database management system (RDBMS), security mechanisms such as SSL encryption, input output tools in csv format as well as GerOSS specific features such as dialogue boxes for data entry and facilities for communication with hospital staff were added. After this stage complete participation was achieved in Lower Saxony in 2011, the year in which reporting and documentation was exclusively transferred to the http://www.geross.de. Reporting officers from each unit are given exclusive access to their specific data view via user-id and password. After initial login a new password must be assigned by the user. All registered reporters are requested by an automatically generated monthly email to either report a new event from the current catalogue of events if one occurred or to actively affirm the non-occurrence of any such event. Such a negative report is essential for the correct calculation of incidences. If a participating unit fails to respond to the regular reminders scanning for GerOSS events within the last month the study centre is alerted through a special status listing to initiate a direct phone call to the respective contact at the hospital. In the case of an obstetric event a complete documentation of all data items is required. In some federal states this also includes patient’s consent given. The remote data entry provides only basic data checks (largely to avoid compromising performance in a web based setting), thus reducing the administrative load on the project study centre to a certain degree. Plausibility checks are carried out on an item by item basis. Selected plausibility cross checks are conducted by the GerOSS administrator at the study centre and are directly resolved by means of email communication with the reporting officer on site at the obstetric unit. All completely documented records of GerOSS events are stored in anonymised form, neither name nor address of the patients is recorded. The identity of the reporting unit is required for plausibility checks and is removed after downloading the anonymised data from the web server onto the local study centre server. All identifying date and time references are transformed to intervals with respect to the date and time of admission to hospital prior to data export once all data queries have been resolved. Data export requires administrator status. The export function is executed at regular intervals by the study centre (Centre for Quality Management and Health Care, Chamber of Physicians, Hanover, Lower Saxony). This ensures currency of the database. Following data acquisition the information needs to be exported in csv format aggregated into summary tables and rendered readable for individual case based analyses. To achieve the former objective the csv files are processed with IBM SPSS statistics version 21 into aggregated data tables. Results from aggregate data analyses are made generally available through the GerOSS website. To achieve the second objective the csv files are imported to an ORACLE database version 11g from which structured individual case synopses are generated using the CRYSTAL REPORTS version 11 report generator. Working group experts inspect and evaluate these anonymized synopses providing salient comments bearing on current studies and guidelines or results from the GerOSS project itself (expert knowledge). Participating obstetric units receive their reports at regular intervals by email. After this stage it is no longer necessary to provide the complete GerOSS records on the website. Therefore all exported data are deleted from the GerOSS website (to economize on resources, reduce costs and last not least for data protection reasons).

### 4. Results

Statistics on participation and especially results suggesting possible options for quality improvement are of particular interest for GerOSS as they will help to increase the motivation of reporting contact officers in the hospitals. Such feedback serves as a “reward” and may thus encourage compliance with further rare event modules.

#### 4.1 Participation

Two hundred and forty-five obstetric units from Lower Saxony, Bavaria and Berlin are eligible to participate in GerOSS comprising approximately 180,000 births per annum thus reflecting about 30% of all births in Germany. 99% of units participated in Lower Saxony, 30% in Bavaria and 80% in Berlin. In GerOSS are 1035 cases reported and 910 of them are completely documented (as shown in ▶Table 1).

#### 4.2 International Comparisons

Comparisons with INOSS reveals an eclampsia incidence of 2.9 per 10,000 deliveries in Lower Saxony similar to 2.8 per 10,000 in the UK. Incidences ranged from 2.4 per 10,000 in Finland (FIN) to 6.2 in the Netherlands (NL) as shown in ▶Figure 1 [16].

#### 4.3 Clinical Results: Uterine Rupture

Analysis of the results for uterine rupture during pregnancy or delivery showed a higher proportion of maternal age 35 years or above (35%) than in the perinatal...
quality assurance register for Lower Saxony (NPE) (22.7%) which acts as a reference [17, 18]. 73.8% of pregnancies had only one previous pregnancy. 91.5% women had one or more previous caesarean section. This may be compared to a reference of 36.4% previous caesarean section rate. The association between previous caesarean and subsequent uterine rupture is known. GerOSS data reveal substantially higher caesarean section rates in obstetric histories than generally reported [19]. This may suggest a greater restriction to be exercised in indication of caesarean deliveries. This aspect was discussed at length especially during interdisciplinary in-house trainings of obstetricians, midwives and nurses with the view to identifying options for achieving an adequate caesarean section rate.

4.4 Clinical Results: Peripartum Hysterectomy

PPH constitutes the final resort in uncontrollable emergency situations, typically excessive post-partum blood loss. Current reported incidence ranges from 2.7 per 10,000 to 5.4 per 10,000 deliveries. The incidence of PPH is estimated at 5.2 per 10,000 for the region of Lower Saxony, where population based GerOSS data are available from 2011 onwards. A comparative INOSS analysis of data from 7 member states shows Lower Saxony ranked second (as shown in Figure 2). The overall incidence in this international study of 2,230,631 deliveries with 1005 cases of PPH was 4.5 per 10,000 (95% CI 4.2 to 4.8 per 10,000) [20].

A risk profile for the prevalence of hysterectomies in relation to birth complications may be described as follows. GerOSS data on 81 PPH cases from all three federal states between 2010 and 2013 shows 50.7% of pregnancies with maternal age 35 years or older (NPE 2012: 22.5%). Similarly a body mass index of 30 and higher is more prevalent (26.9%) than in the NPE reference database (16.6%). 34.0% of mothers are primiparous (NPE 2012: 47.9%). The leading hysterectomy indication is severe blood loss, for instance as a consequence of placental adhesion to part of the uterus or to other organs (placenta accreta, increta and percreta in 30%). Here too elevated maternal age is a risk factor. By contrast, disorders of placentation were identified only in 6% of pregnancies [18, 21]. Presentation of first results for possible risk profiles during conferences led to considerations of whether and how gynaecologists in practices outside the hospital might cooperate more closely with respective obstetrical units during pregnancy.

5. Discussion

Doctors are hardly ever confronted with such rare and life threatening events during ordinary clinical practice. Some meet at most one such case in their entire career which rules out per se the opportunity to gain from experience. This state of affairs is the basis for development of the GerOSS internet platform for reporting and documentation of rare obstetric events. During the initial phase of GerOSS as from 2010 the main focus lay primarily on feasibility of the chosen concept for quality improvement. This implicates the entire organisational structure, minimum participation rates, technical solutions for IT tools and procedures for documentation and ultimately whether this project will guarantee sufficient data for initiation of quality assurance programs. For this different IT systems, especially to perform clinical trials, and associated management features were studied before [22]. Practicable application of such systems could be inspected in the great German Project “Competence Networks in Medicine” [23, 24]. Finally limi-

Table 1

<table>
<thead>
<tr>
<th>Completely documented</th>
<th>Lower Saxony</th>
<th>Bavaria</th>
<th>Berlin</th>
</tr>
</thead>
<tbody>
<tr>
<td>Uterine rupture</td>
<td>231</td>
<td>46</td>
<td>58</td>
</tr>
<tr>
<td>Peripartum hysterectomy</td>
<td>112</td>
<td>40</td>
<td>18</td>
</tr>
<tr>
<td>Eclampsia</td>
<td>70</td>
<td>15</td>
<td>17</td>
</tr>
<tr>
<td>Placenta accreta/increta/percreta</td>
<td>197</td>
<td>69</td>
<td>31</td>
</tr>
<tr>
<td>FMAIT (fetomaternal All immunothrombocytopenia)*</td>
<td>2</td>
<td>2</td>
<td>2</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Only reporting</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pulmonary embolism</td>
</tr>
<tr>
<td>Amniotic fluid embolism</td>
</tr>
<tr>
<td>Tranfusion 5+</td>
</tr>
<tr>
<td>Esophageal atresia</td>
</tr>
<tr>
<td>Total</td>
</tr>
</tbody>
</table>

*complete documented but only counted, not analysed due to very rare disease

Figure 1 Eclampsia incidence rates of INOSS countries
There are indications suggesting that analyses show that for severe complication of all cases recording of events is organized in two stages. At the first stage only the occurrence of the event as such is recorded and later complemented with the detailed information on all items. Thus checks on completeness are possible. This procedure also allows feasibility studies to check whether a proposed event is "too rare" and cannot be used for complete documentation and evaluation, because anonymity reasons.

Although the process of data checking and analysis has only just begun first tentative results are already showing a clear need for consequences to be drawn implying changes management and procedures to date which is the central goal of GerOSS. The successful implementation with discussions of first results and individual case histories during conferences as well as on site shows a clear demand for training and discussion within the hospitals for three reasons:

- There are indications suggesting that complications partly arise from unfocussed diagnostics in the presence of known risk patterns, such that measures to counteract critical situations are adopted not soon enough.
- Recommendations of the professional societies for management of delivery are not always heeded.
- Analyses show that for severe complications, such as extreme prematurity, permanent handicap or death are up to 5 to 10 times more frequent.

The GerOSS project allows collection of important information from an arbitrary number of institutions and thus to provide a larger database for quantitative analyses.

A special feature of this approach is the combination of aggregate based qualitative analysis with in depth inspection of individual case records through a panel of experts thus facilitating further conclusions and insights. Especially the handwritten comments or questions supplied by the experts upon each event synopsis are considered valuable. Medical staff in the reporting hospitals find here at short notice suggestions bearing directly on their particular case at issue which are more useful than extensive comparisons of all cases between hospitals which will be of limited used anyhow due to their low incidence.
6. Conclusions

GerOSS is the first project in Germany to enable analysis of rare and severe complications of pregnancy and delivery from a growing database as no local installation of software is required but instead enabling access for any number of users through a user-id and password. This allows unlimited distribution. The experience gained so far shows that design and management of the database as well as the rolling concept of reporting cycles for any number of events is feasible and accepted by its users. Future development of GerOSS will bridge the gap to modern information and communication platforms thus constituting the next step towards provision of effective support to participating units. Deficiencies or weaknesses in the management of these rare events can be identified to enable counteraction with suitable education and training measures. Easy access to these information and training materials is ensured by dissemination via the internet platform [25, 26], in future to be augmented by custom built smartphone APPs for specific management strategies.

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