





# How common is substandard obstetric care in adverse events of birth asphyxia, shoulder dystocia and postpartum hemorrhage? Findings from an external inspection of Norwegian maternity units

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## Abstract

**Introduction:** The Norwegian Board of Health Supervision inspects healthcare institutions to ensure safety and quality of health and welfare services. A planned inspection of 12 maternity units aimed to investigate the practice of obstetric care in the case of birth asphyxia, shoulder dystocia and severe postpartum hemorrhage.

**Material and methods:** The inspection was carried out at two large, four medium and six small maternity units in Norway in 2016 to investigate adverse events that occurred between 1 January and 31 December 2014. Six of them were selected as control units. The Norwegian Board of Health Supervision searched the Medical Birth Registry of Norway to identify adverse events in each of the categories and then requested access to the medical records for all patients identified. Information about guidelines, formal teaching and simulation training at each unit was obtained by sending a questionnaire to the obstetrician in charge of each maternity unit.

**Results:** The obstetric units inspected had 553 serious adverse events of birth asphyxia, shoulder dystocia or severe postpartum hemorrhage among 17 323 deliveries. Twenty-nine events were excluded from further analysis due to erroneous coding or missing data in the patients' medical records. We included 524 cases (3.0% of all deliveries) of adverse events in the final analysis. Medical errors caused by substandard care were present in 295 (56.2%) cases. There was no difference in the prevalence of substandard care among the maternity units according to their size. Surprisingly, we found significantly fewer cases with substandard care in the units which the supervisory authorities considered particularly risky before the inspection, compared with the control units. Seven of the 12 units had regular formal teaching and training arrangements for obstetric healthcare personnel as outlined in the national guidelines.

**Abbreviations:** CTG, cardiotocography; MBRN, Medical Birth Registry of Norway; NBHS, Norwegian Board of Health Supervision; PPH, postpartum hemorrhage.

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**Conclusions:** Prevalence of adverse events was 3% and similar in all maternity units irrespective of their size. A breach in the standard of care was observed in 56.2% of cases and almost half of the maternity units did not follow national recommendations regarding teaching and practical training of obstetric personnel, suggesting that they should focus on implementing guidelines and training their staff.

#### KEYWORDS

adverse events, asphyxia, failure of treatment, maternity units, postpartum hemorrhage, shoulder dystocia, supervision

## 1 | INTRODUCTION

In Norway, the supervision of health and welfare services is the responsibility of the Norwegian Board of Health Supervision (NBHS) and the County Governors ([www.helsetilsynet.no](http://www.helsetilsynet.no)). According to the Health Supervision Act, section 1, the purpose of supervision is to ensure safety and quality in the delivery of health and welfare services and to strengthen the population's trust in healthcare providers and the health and welfare services.<sup>1</sup> The supervisory activities are carried out either on the basis of a single adverse event or as a planned systems review. Governmental supervision corresponds to external inspection as described in the international literature.<sup>2</sup>

In 2004, a nationwide external inspection of 26 Norwegian maternity units was carried out. The results highlighted that there was room for improvement in both the clinical routines and the practical management of acute events, summoning of the obstetrician, clear understanding of roles and responsibilities, adequate documentation, and in the training of obstetric healthcare personnel.<sup>3</sup> Audits in Norway have shown that failure in obstetric care delivery is often due to inadequate or misinterpreted fetal monitoring, delay in summoning the obstetrician, lack of adherence to routines/guidelines, ineptitude, and delayed or traumatic delivery.<sup>4</sup> The supervisory authorities have found that a failure in organization and leadership is often the underlying cause.<sup>5,6</sup>

Several international studies have shown that adverse events occur in as much as 10% of patients admitted to hospital and about 40%-50% of these events could have been avoided.<sup>7,8</sup> Adverse events in the maternity units have been shown to occur in 3%-15% of admitted pregnant women.<sup>9,10</sup> In these studies, there is a discrepancy in the definition of the term "adverse event". Commonly, the term is used to define an injury caused by medical management resulting in measurable disability, not due to underlying illness. The injury may have a varied degree of severity ranging from less severe events such as prolonged hospital admissions, to more severe disability such as permanent handicap or even death.<sup>11</sup>

In Norway, obstetric units are required to have local guidelines for the management of acute complications. Based on an interpretation of legal requirements to implement sound professional practice, it is recommended that simulation training of acute events that may occur during births, should be practiced every 6 months.<sup>12</sup>

### Key message

Prevalence of adverse events due to birth asphyxia, shoulder dystocia or postpartum hemorrhage was 3%. Substandard care was observed in 56.2% of the events and half of the maternity units did not follow national recommendations regarding teaching and practical training.

Several countries have national guidelines describing the management of various conditions during pregnancy and birth, for instance Denmark ([www.dsog.dk](http://www.dsog.dk)), the UK (<https://www.nice.org.uk/>), the US (<https://www.acog.org/>) and Norway.<sup>13</sup> Every single obstetric care unit in Norway is responsible for the adoption and implementation of updated guidelines into local practice, as well as the dissemination of current knowledge to all midwives and obstetricians working in the unit. Adherence to such guidelines should also be monitored.<sup>12</sup> Local guidelines are often similar to, or slightly modified from, the national guidelines.

The aim of this study was to investigate whether the adverse events with asphyxia, shoulder dystocia and severe postpartum hemorrhage (PPH) in 12 Norwegian maternity units were handled in accordance with established practice (adherence to national guidelines or evidence-based practice). Furthermore, we wanted to obtain information about the availability and implementation of local guidelines, and the training of obstetric healthcare personnel (ie obstetricians, doctors under speciality training and midwives) within these three important categories of acute obstetric practice.

We hypothesized that small maternity units would have more frequent breaches in established practice compared with larger units, and that medical errors would be seen more often in the units that the supervisory authorities considered particularly risky.

## 2 | MATERIAL AND METHODS

The NBHS has, by the authority of its supervisory mandate, completed inspection of 12 obstetric care units looking at three categories of serious adverse obstetric events. The study period was

limited to include reported cases occurring between 1 January and 31 December 2014. Six of the units were chosen because the supervisory authorities had suspected that the obstetric care delivered at these units was potentially at high risk and that there were indications that their routines and practices should be surveyed. This risk assessment was based on experience from previous inspections. Another six units were chosen randomly by a draw for comparison. In total, we evaluated six maternity units with <1000 births per year (small), four units with 1000-1999 births per year (medium) and two units with ≥2000 births per year (large).

The three categories of serious adverse events were chosen according to the following criteria:

- Birth asphyxia: singleton birth during which the baby died in utero after admission, during birth, during the first 6 days after birth, or an infant with an Apgar score of <7 after 5 minutes and also transferred to the neonatal intensive care unit.
- Shoulder dystocia: vaginal singleton birth with difficult delivery of the shoulder and admission to neonatal intensive care unit or infant with confirmed brachial plexus injury.
- Severe PPH: vaginal singleton birth during which the mother bled more than 1500 mL within 24 hours of birth and/or received blood transfusion.

On 6 July 2016, the NBHS requested information from the Medical Birth Registry of Norway (MBRN) regarding the number of adverse events in these three categories reported by each selected maternity unit during the study period, based on the criteria described above.

Births occurring before 36 weeks of gestation and infants with malformations were not included in the study.

On 30 November 2016, the NBHS requested the obstetricians in charge of each maternity unit to provide further information by answering a questionnaire. Closed questions (yes/no) were utilized concerning the units' internal guidelines, teaching and practical training activities, and certification of health personnel (File S1). NBHS also requested copies of medical records of the cases, along with the journal entries by midwives and obstetricians regarding births, as well as cardiotocography (CTG) recordings and discharge summaries. In addition, NBHS requested the institutions' local guidelines on the management of threatening birth asphyxia, shoulder dystocia and PPH.

All 12 obstetric units responded to the inquiry. Eleven obstetric units responded by 6 January 2017. The last unit replied on 2 June 2017, after a reminder.

The results were registered in a database designed for this study. For each obstetric adverse event, the maternity unit, type of event and method of delivery were registered. We registered whether there was a breach in the surveillance, diagnostics, professional interaction, use of medications or surgical intervention, and whether there was a delay or lack of intervention during management. In addition, failure in documentation was registered. Two study authors (L.T.J., P.Ø.) with specialist obstetric competence evaluated whether the obstetric care was adequate in accordance with clinical practice

based on Norwegian national and local obstetric guidelines.<sup>12,13</sup> This evaluation was carried out independently. In case of discrepancy, a final decision was made after discussion. The cases with incorrectly coded diagnosis or missing clinical information needed to extract data were excluded. The cases recorded to have more than one category of events were assigned to the category that had the greatest significance for the outcome.

Data analysis was performed using SPSS version 18.0. Data are presented as n (%). The odds ratios (OR) were calculated with the 95% confidence interval (CI) using the Chi-square test. A *P* value of <.05 was considered significant.

## 2.1 | Ethical approval

The study was carried out as a regulatory audit and thus as a part of the annual working plan of NBHS. The legal basis for evaluating the data is the Health Supervision Act; the Health Research Act does not affect this project. A request was forwarded to the Regional Committee for Medical and Health Research Ethics (REK) and the conclusion was that the project was not obliged by law to obtain a separate ethical approval (reference 2016/1500B). All data were treated and stored in accordance with relevant public administration legislation and the NBHS internal guidelines.

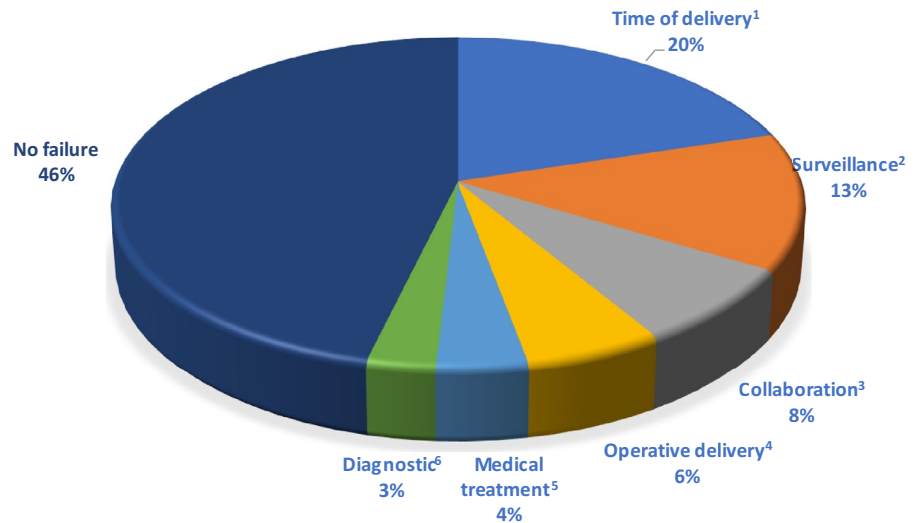
## 3 | RESULTS

The 12 obstetric units that were inspected had registered 553 serious adverse events among 17 323 deliveries. In 10 cases the diagnosis was incorrectly registered and in 11 cases the clinical information available in the medical records was substantially inadequate to extract relevant data. These were not included in the analysis. In eight cases, the adverse events were registered in more than one category. These cases were assigned to the category with the greatest significance for the outcome. A total of 524 cases with adverse events (prevalence 3.0%) were included in the final analysis: 103 cases (19.7%) with asphyxia, 60 cases (11.4%) with shoulder dystocia or brachial plexus injury and 361 cases (68.9%) with severe PPH.

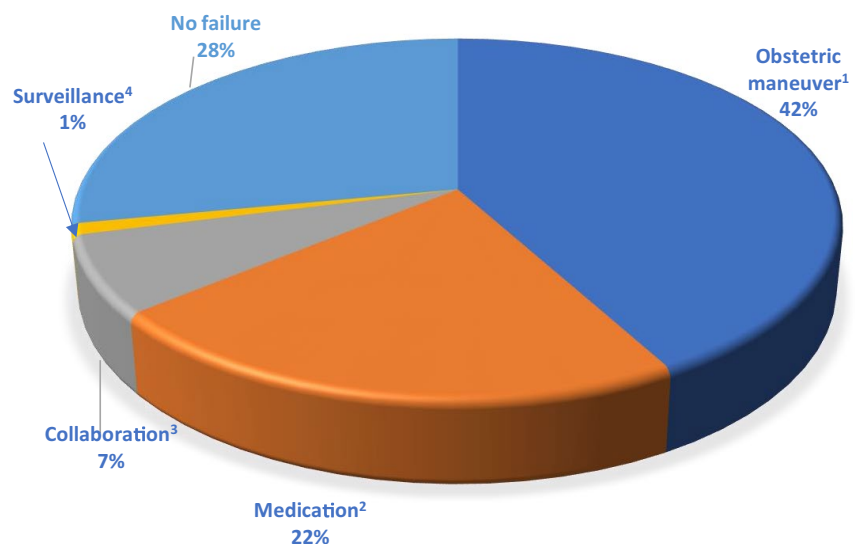
### 3.1 | Clinical practice

Under the category of asphyxia, 57 mothers (55.3%) were delivered by cesarean section, vacuum or forceps. Our assessment was that a breach in the standard of care was of crucial importance for the negative outcome in 56 (54.3%) events. In 18 cases (17.4%) we considered both substandard care and inadequate documentation to be present. Figure 1 shows the number of events in which there was a breach in the standard of care. A major part was due to delayed delivery, caused either by a delay in the decision for operative delivery or an increased decision-to-delivery time. Failure in monitoring was due to lack of monitoring when indicated, or misinterpretation of the

**FIGURE 1** Reasons for substandard care in 12 Norwegian maternity units in 2014, where the neonate died or had an Apgar score <7 after 5 minutes and was transferred to the neonatal care unit (n = 103). <sup>1</sup>Delayed delivery. <sup>2</sup>Lack of or misinterpreted fetal monitoring. <sup>3</sup>Failure in collaboration between midwife and physician. <sup>4</sup>Failure in operative delivery. <sup>5</sup>Incorrect medication. <sup>6</sup>Lack of clinical examination



**FIGURE 2** Proportion of births with substandard care and their causes in 12 Norwegian maternity units in 2014, in cases with shoulder dystocia or brachial plexus injury to the neonate (n = 60). <sup>1</sup>Inadequate technique used to deliver shoulders. <sup>2</sup>Oxytocin not discontinued. <sup>3</sup>Physician not called. <sup>4</sup>Inadequate fetal surveillance



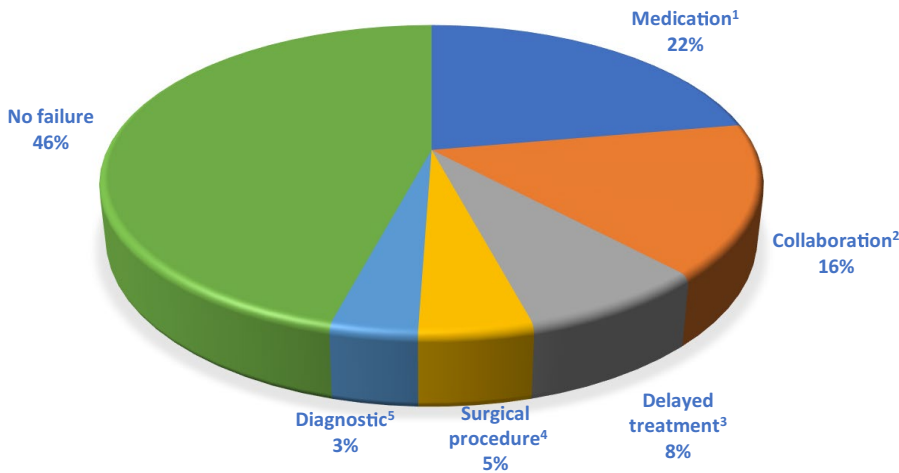
CTG and/or fetal electrocardiogram ST-analysis (STAN) registration. Failure in operative vaginal delivery was mainly due to extraction time of more than 20 minutes using vacuum, and use of traction only to advance the fetal head further down in the pelvis instead of performing the full extraction (vacuum cup or forceps blades removed before the infant was born), when CTG showed signs of severe fetal asphyxia. Incorrect medication consisted mainly of inappropriate use of oxytocin infusion, leading to hyperstimulation.

Among 60 events of shoulder dystocia, half (n = 30) suffered (brachial) plexus injury. In 35 (58.3%) cases the birth was by operative vaginal delivery. We found a breach in the standard of obstetric care in 43 (71.6%) cases. In 17 (28.3%) cases we considered failure to be present in both care and documentation. The breach was predominately related to using the wrong technique to release the shoulders, often without trying rotational maneuvers. Furthermore, we found many cases in which oxytocin was not discontinued when shoulder dystocia occurred. In some cases, the physician was not summoned, despite indications for this (Figure 2).

Of the 361 cases with severe PPH, 116 (32.1%) had an operative vaginal delivery. Blood transfusions were given to 254 patients (70.3%). We considered that breach in the standard of care was the reason for the serious adverse outcome in 196 (54.2%) of the events. In 97 (26.8%) cases we considered that failure in both care and documentation was present. Figure 3 shows the numbers of deliveries with severe PPH where we found a breach in the standard of care. The breach consisted predominately of inadequate treatment with uterotonic medications, and delayed or lack of summoning of the physician (Figure 3).

In all three categories studied, medical errors caused by substandard care were present in 295 cases (56.2%). In 132 (25.1%) cases we considered failure to be present in both care and documentation.

Table 1 shows the distribution of events (asphyxia, shoulder dystocia, PPH) and the number of events with failure in treatment according to size of birth unit. No significant differences were found between the small, medium and large birth units.



**FIGURE 3** Proportion of births with failure in treatment and their causes in 12 Norwegian maternity units in 2014, complicated by serious postpartum hemorrhage (>1500 mL and/or blood transfusion) (n = 361). <sup>1</sup>Inadequate use of uterotonic medication. <sup>2</sup>Physician not called or summoned too late. <sup>3</sup>Delayed treatment in operating theater. <sup>4</sup>Inadequate surgical procedures. <sup>5</sup>Failure to correctly estimate blood loss

Table 2 shows the distribution of severe adverse events in institutions which the supervisory authorities had selected for closer surveillance and in the control group. The results show a significantly larger amount of adverse events due to a breach in the standard of care in the control group.

### 3.2 | Internal practice guidelines and teaching

All 12 maternity units responded that they had internal clinical practice guidelines describing which deliveries should be monitored by CTG, but for two of the units this was not evident in the written procedures (16.6%). Eleven units reported that they had internal practice guidelines regarding when an obstetrician should be summoned if CTG changes occurred; however, this was recorded in the written guidelines received from only five of the maternity units (41.6%).

Seven units (58.3%) responded that the midwives and doctors received education in fetal monitoring at least every 6 months. Certification for midwives were established in eight of the 12 units (66.6%) and for the doctors in seven units (58.3%). Ten (58.3%) units logged which midwives received training, and seven (58.3%) units logged the doctors' participation.

Written internal procedures for shoulder dystocia existed in all 12 obstetric units. Four (33.3%) units replied that the midwives received practical training every 6 months, and five (41.6%) units that the doctors received practical training. Which midwives and doctors actually performed practical training was registered in 11 (91.6%) and 10 (83.3%) units, respectively.

All 12 obstetric units had written procedures describing management of PPH. Teaching was established for the midwives in four (33.3%) units and for the doctors in five (41.6%). Nine (75%) units registered the participation.

## 4 | DISCUSSION

This study showed a prevalence of adverse events due to birth asphyxia, shoulder dystocia or severe PPH of 3.0%. Our review of

these adverse events showed a breach in the standard of care in 56.2% and failure in both care and documentation in 25% of cases. Almost half of the institutions did not follow national recommendations regarding teaching and practical training of their healthcare professionals.

The prevalence of adverse events is similar to that reported internationally.<sup>9,10</sup> It is surprising that a breach in the standard of care occurred in more than half of the events identified. However, in another study involving cases with death or injuries in maternity care assessed by the Norwegian supervisory authorities, we showed that 48.3% of the reported cases involved serious errors in provision of healthcare.<sup>6</sup> An audit from UK on cases with adverse outcome during 2015, reported substandard care in 76%.<sup>14</sup> The same level of substandard care was shown in earlier studies.<sup>15</sup> In a Swedish study, there was substandard care during births in two-thirds of infants born with Apgar <7 at 5 minutes.<sup>16</sup> The main reason for substandard care was misinterpretation of CTG and not reacting to abnormal CTG in a timely manner. This is in accordance with our results.

Under the category shoulder dystocia or brachial plexus injury, we found a breach in the obstetric standard of care in 43 cases (72%). We assume that infants with brachial plexus injury often received exogenous downward traction of the head that was too hard, instead of using rotational maneuvers.<sup>17</sup> This is a well-known explanation for why such injury occurs, although it may not be the only reason.<sup>18</sup>

Despite the wide availability of evidence-based guidelines and practical courses, the incidence of PPH shows an increasing trend in developed countries.<sup>19</sup> A review on adherence to PPH guidelines found that 38% of women with ≥1500 mL blood loss received substandard care.<sup>20</sup> In our study, substandard care was identified in 54.2% of cases with severe PPH.

Several studies have shown that substandard care occurs in 60%–70% of adverse events.<sup>15,16</sup> Adverse events with death and serious injuries seem to have a higher level of substandard care, compared with events with less severe outcome. Clinician experts evaluating the standard of obstetric care after adverse events are often not blinded to neonatal outcome, which may lead to bias in the interpretation and classification of intrapartum CTG.<sup>21</sup>

**TABLE 1** Number of adverse events (birth asphyxia, shoulder dystocia, postpartum hemorrhage) and number of events with failure in treatment according to size of birth unit (small <1000 births per year, medium 1000-1999 birth per year, large ≥2000 births per year) in 12 Norwegian birth units in 2014

Type of maternity unit	Number of births at term	Number of adverse events	Number of adverse events per 1000 births	Number of adverse events with substandard care	Number of adverse events with substandard care per 1000 births
<1000 births per year	2927	72	24.59 (72/2927)	47	16.05 (47/2927)
1000-1999 births per year	5907	188	31.82 (188/5907)	88	14.89 (88/5907)
≥2000 births per year	8489	264	31.09 (264/8489)	160	18.84 (160/8489)

Note: Statistical analysis of events with substandard care:

OR (small vs medium): 1.079, 95% CI 0.76-1.54,  $P = .676$ .

OR (small vs large): 0.850, 95% CI 0.61-1.18,  $P = .330$ .

OR (medium vs large): 0.787, 95% CI 0.61-1.02,  $P = .074$ .

Our study shows that availability of guidelines alone is insufficient to ensure sound obstetric practice, and implementation can be challenging. However, it is an important administrative responsibility to ensure that health personnel have the qualifications required, are familiar with the guidelines and follow the recommendations. More time and funding should probably be spent on implementation of guidelines and training the staff to use them more effectively.<sup>6,22-24</sup>

To provide adequate care, obstetric healthcare personnel must possess both knowledge and practical skills. The experience from supervisory cases, trials and audits after serious adverse events is that failure in obstetric care is often related to failure in communication, interdisciplinary cooperation and teamwork.<sup>4-6,14,16</sup> Several studies have shown that the incidence of adverse events can be reduced and perinatal outcome improved when regular practical training is performed in the obstetric care units.<sup>17,25-27</sup> In our study, almost half of the institutions did not perform practical training in accordance with national requirements.<sup>12</sup> Until there is a proper emphasis on training, the proportion of substandard care is unlikely to decrease.

Arranging regular teaching and practical multiprofessional training may be useful in improving knowledge and retaining clinical skills. To ensure that everyone has this opportunity, participation should be documented. Our study shows that several obstetric units do not follow national recommendations concerning the management of threatening birth asphyxia, shoulder dystocia and PPH. A national audit performed in 2004 documented a shortcoming in the clinical routines in several maternity units and an inadequacy in the management of acute events in accordance with good practice. Our study shows that improvements have been made in terms of better guidelines. However, breaches of the standard of care are still common. This may imply that not all obstetric health personnel are familiar with the guidelines and their competence levels need to be improved.<sup>22,28,29</sup>

Obstetric healthcare personnel are required by Norwegian law to document relevant information regarding patients and their management (Health Personnel Act, sections 39 and 40). Our study demonstrated substantial shortcomings in documentation in 25.1% of cases with substandard care. In several cases, we found inadequate documentation regarding the course of adverse events, diagnosis and treatment. The clinical importance of good documentation in cases of complications and adverse events cannot be overemphasized. It is also of particular importance for governmental supervision when healthcare is evaluated.

The number of births per year defines the size of a maternity unit. Maternity units are defined as small when <1000 births per year occur, medium-sized when between 1000 and 1999 births occur, and large when units have >2000 births per year.<sup>30,31</sup> Large maternity units are responsible for a greater number of high-risk pregnancies. High-risk pregnancies carry a greater risk for complications and it is reasonable to assume that, by virtue of this, a greater number of adverse events with a serious outcome occur within large units. We did find that medium and large maternity units had more adverse events per 1000 deliveries than small units, but we did not find any significant differences regarding substandard care between the three levels of maternity units (Table 1). We have previously shown that the supervision



**TABLE 2** Number of adverse events (birth asphyxia, shoulder dystocia and severe postpartum hemorrhage) in 12 Norwegian maternity units in 2014, selected by the supervisory authorities for a closer surveillance (n = 6 units) and a randomly allocated control group (n = 6 units)

Type of maternity unit	Number of births at term	Number of adverse events	Number of adverse events per 1000 births	Number of adverse events with failure	Number of adverse events with failure per 1000 births
Six maternity units selected by the supervisory authorities	7720	215	27.84	113	14.63
Six maternity units selected as a control group	9603	309	32.17	185	19.26
P value			.1078 <sup>a</sup>	.0232 <sup>a</sup>	

<sup>a</sup>Chi-square test with Yates correlation.

authorities investigated more cases where mothers or infants suffered severe injury, in small and medium-sized units.<sup>6</sup> This is not necessarily contradictory to our current findings, as the current study looked at all adverse events within the three categories, as opposed to only those that led to a mandatory incident reported to the supervisory authorities.

We aimed to evaluate whether there were more adverse events in the maternity units considered to be at high risk by the supervisory authorities. Surprisingly, we found that a greater number of adverse events occurred in the control group. This demonstrates that governmental supervision needs to be present in all types of obstetric units, not only for those where a breach of routines, organization and healthcare delivery is suspected.

The strength of this study is that we are certain to have received information about all events within the three categories described, as this was controlled against the information recorded and reported to MBRN, providing good internal validity. Moreover, certain aspects of MBRN have been previously validated.<sup>32,33</sup> It is a legal requirement to submit a standard report on all births to MBRN. Miscoding is a possibility but in our study only 10 of 553 adverse events were miscoded in MBRN. However, the relatively small sample size of our study reduces its external validity. Another limitation is that a single person from each unit, namely the obstetrician in charge, responded to the questionnaire concerning clinical routines and teaching activities, which might reflect their subjective impression. However, some of the information was cross-checked using documents such as internal protocols and guidelines that were provided. Underlying causes of substandard care, such as system failures, organizational issues, staffing levels and other factors that might have affected an individual healthcare professional's decision, were not evaluated in this study.

## 5 | CONCLUSION

The prevalence of adverse events due to birth asphyxia, shoulder dystocia and severe PPH was 3% and was the same irrespective of the size of maternity units. A breach in the standard of care was observed in 56.2% of cases and almost half of the maternity

units did not follow national recommendations regarding teaching and practical training of obstetric personnel, suggesting that they should focus on implementing guidelines and training their staff.

## CONFLICT OF INTEREST

None.

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## SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section.

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