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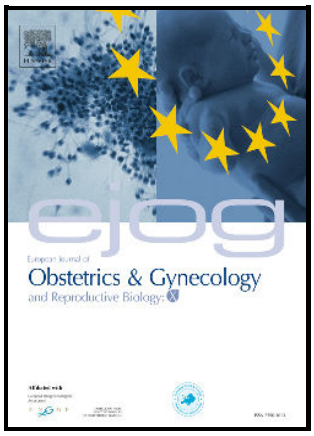

Ludovic Baauw, Ageeth N Rosman, Thomas H van den Akker

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Lessons learned in cases of late preterm mortality in the Netherlands: results from nationwide perinatal audits, a mixed method study

Ludovic Baauw, MSc[1]

Ageeth N Rosman, PhD[2,3]

Thomas H van den Akker, MD PhD[1,4]

1. Department of Obstetrics and Gynaecology, Leiden University Medical Centre, Leiden, Netherlands
2. Department of Healthcare studies, Center of Innovations of Care, Rotterdam University of Applied Sciences, Rochussenstraat 180 3015 EK Rotterdam, the Netherlands
3. Perined, Mercatorlaan 1200 3528 BK Utrecht, the Netherlands
4. Athena Institute, VU University, Amsterdam, Netherlands

Corresponding author: Ageeth Rosman: arosman@perined.nl

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Introduction

Late preterm infants have increased risks of adverse events such as respiratory insufficiency, hypoglycaemia, jaundice and impaired cognitive development, and have higher mortality rates compared to neonates born at term. [1, 2] Late preterm mortality is defined as a neonate that died in the first 28 days after a birth between 32+0 weeks up to and including 36+6 weeks gestational age, or intrapartum demise between these gestational ages.[3] In the Netherlands, the late preterm mortality rate varied between 16.9 and 18.7 per 1000 births over the years 2014-2017.[4-7]

A high perinatal mortality rate may imply compromised quality of maternity and perinatal care and warrants critical review.[8] The perinatal mortality rate in 2019 in the Netherlands was 4.4‰. In the European ranking, according to the latest European Perinatal Health Report, the Netherlands takes the 14th position of 23 participating countries. A Cochrane meta-analysis previously suggested that such critical review, in the form of audit, combined with feedback, has the potential to reduce severe pregnancy outcomes.[9]

Therefore, a system of systematically organizing perinatal audits was introduced in the Netherlands in 2010.[10,11,12] In the early years (2010-2016), audit focused on perinatal mortality and morbidity in general.[13,14] The years thereafter, audits were theme-based. Late preterm mortality was selected as a theme for nationwide audit for 2017-2019.[11] It was hypothesized that perinatal audit of late preterm deaths could contribute to relevant lessons for maternity care and clinical practice.

Materials and Methods

Study design

Mixed-method study compiling locally identified improvable care factors around late preterm deaths over the years 2017-2019.

Setting

In The Netherlands, maternity care is three-tiered comprised primary, secondary and tertiary level. At the primary level, community midwives provide care in low-risk pregnancies and assistance during births at home, in free-standing birth clinics or birth units within hospitals. At secondary and tertiary levels, hospital midwives and medical doctors provide care to women with medium or high-risk pregnancies and during hospital birth. All levels collaborate in local 'perinatal cooperation groups' (PCG), (figure 1 Definition local perinatal cooperation groups).

[Insert Figure 1- Definition local perinatal cooperation groups]

The Dutch perinatal audit system is based around these PCGs, comprising of a hospital with a maternity unit and community-based practices within its catchment area.[12] At audit meetings, cases are evaluated for presence of improvable care factors and their relation to the occurrence of late preterm mortality, which was decided during these meetings and classified as 'none/unlikely', 'possible', '(very) likely', 'unknown' or 'no consensus'.[15] The most likely cause of death was determined by using the Wigglesworth/Hey and Modified ReCoDe classifications.[16-18]

The perinatal audit is registered by Perined, the national birth registry for midwives, obstetricians and paediatricians, which contains 96% of all pregnancies and birth outcomes in

the country.[19] Audit outcomes were disseminated to the field regarding the prevention of late preterm mortality.

Data collection

For 2017-2019, four themes for audit were selected: uterine rupture, neonatal hyperbilirubinemia, term asphyxia and late preterm mortality.[11] Late premature mortality was chosen since in 2015, out of 163,893 singleton pregnancies, 181 late preterm children were reported to have died during pregnancy, during birth, or in the first 28 days after birth.[11] Excluding antepartum deaths, it was estimated that around 80 cases per year would be suitable for audit. [4]

For audit meetings, comprehensive case information was gathered and a combined, chronological report (CR) of the case compiled. Delivered care was compared to guidelines, standards or -where guidance was unavailable- 'normal daily practice' as determined by the panel. Improvable care factors were collected and archived at the national level in a database at Perined (Perinatal Audit Database, PAA).

Data outcomes

The chronological reports contained maternal, birth and neonatal baseline characteristics used for descriptive analyses only (table 1). Regarding late preterm mortality, neonatal characteristics included gender, birthweight, birth percentiles according to Hoftiezer[19], APGAR scores, neonatal cord pH, congenital malformations, time of death, cause of death, postpartum neonatal intensive care unit (NICU) admittance and postpartum mortality. These

parameters were chosen to obtain insight into the circumstances under which late preterm mortality occurred.

Improvable factors regarding guidelines, standards and local protocols or daily clinical care were considered important outcomes of audit meetings.

Data analysis

Based on guidelines provided by Perined, improvable care factors were classified by participants of the local perinatal audits into two main categories and 12 subcategories (figure 2: improvable factors).

[insert Figure 2. Improvable factors in main and subcategories]

Normal professional and daily practice was regarded as standard care that every patient may be expected to receive as defined by the relevant professional cadres.

Analysis of audit outcomes collected in the Perined database was performed by the primary researcher (LB) and checked by the secondary researcher (AR), who is the national audit coordinator and an experienced midwife-researcher. Improvable care factors were analysed in-depth using corresponding chronological reports. Analysis of categories was performed using structured methodology around the questions: what happened, who was involved, what made that it could happen and was the improvable factor in line with these 'what, who, what' questions.

For each (sub-)category, an overview was presented to a panel of expert professionals including several obstetrician-gynaecologists (n=3), one paediatrician, one midwife working in primary care and several coordinators of local perinatal audit teams, who were also hospital midwives (n=3). These overviews were then discussed in order to validate the outcomes and strengthen recommendations. The final result of this discussion was an overview of improvable care factors present in late preterm deaths and corresponding recommendations for quality of care improvement.

Statistical analysis

Quantitative data were collected into frequency tables, for descriptive analysis only. No comparison between groups was done in line with the design of the national Perinatal Audit: not every case with adverse outcomes is audited, prohibiting nationwide population-based analyses.

Ethics

Under Dutch law, for this study no Institutional Review Board approval was needed since no human or non-human experimentation took place. However, patient informed consent for discussing the case in a perinatal audit was asked by involved obstetricians and obtained at the hospital where birth took place. Anonymisation took place by allocating unique identification numbers. This study complied with privacy guidelines as established by Perined.[21]

Results

Local perinatal audit groups have to audit at least four cases a year, selected out of the national themes. Every three years a Perined committee, in consultation with professionals in the field, identifies new audit themes. The PCG's have an option to select cases from different themes, and the objective of the national perinatal audit has never been to be inclusive of all cases within each theme. Of 69 files retrieved from the nationwide database, 42 were excluded on the basis of in- and exclusion criteria. Main reasons for exclusion were intra-uterine foetal death (n=21) and twin birth (n=13). In case of twin entry, data for one child were doubled in the PAA output due to software limitations. This meant that twin entries could not be analysed appropriately. Therefore, we excluded twin births from further analysis. In total, 27 cases were included (figure 3: flow chart inclusions).

[Insert figure 3:flow chart inclusions]

Characteristics

Baseline characteristics are shown in table 1. Mean age of women at moment of birth was 32 years (range 26-44), mean gestational age at birth 35.1 weeks (32.0-36.5). Risk status at antenatal care intake was 'low-risk' for most women (70.4%). At birth, risk status shifted to medium (55.6%) or high (18.5%) risk[21].

Of all children born, 13 were male (48.0% of all births), mean birthweight was 2320 grams (range: 1425-3130). Four children weighed below the third percentile (Hoftiezer et al.[19]).

Most likely causes of death were perinatal asphyxia (n=7, 25.9% of all births), unexpected or unanticipated congenital malformations (n=5, 18.5%), neonatal infection (n=4, 14.8%) and placental abruption (n=4, 14.8%). Of all neonates, 21 (77.8%) were admitted to the neonatal intensive care unit (NICU) after birth.. During NICU admission, 19 children (70%) died, of whom a classification of causes of death was not available in the perinatal registry of Perined. However, in 16/19 we were able to trace the cause of death from the perinatal audit database, which falls also under the responsibility of Perined. Commonest causes of deaths were perinatal asphyxia (n=5, 26.3%), necrotizing enterocolitis (n=3; 15.7%), early onset sepsis (GBS-sepsis; n=3; 15.7%), intracranial hemorrhage (n=2;10.3%) or a not further specified cause or unknown (n=5; 26.3%).

[Insert Table 1 : Baseline characteristics]

Improvable Care Factors

A total of 52 improvable care factors regarding standard care were retrieved and divided in subcategories (table 2). It is to be noted that not all improvable care factors were formulated unequivocally. A small number of improvable care factors consisted of only few words (n=2) hampering classification. These were not included. Categories selected for further analysis were: suboptimal CTG (cardiotocography) surveillance, organization and communication problems. Suboptimal CTG surveillance was selected, since it was determined as in nine cases having a very likely relation with the outcome. The other two categories were selected due to the high number of improvable care factors these contained.

[insert Table 2: Categories of improvable factors and relation with outcome.]

CTG surveillance

CTG surveillance, unclarity about responsibility for surveillance and inadequate CTG assessment were frequently mentioned. The process of CTG surveillance involved all events associated with actual monitoring and evaluation of tracings, and documentation thereof.

Responsibility referred to designation of healthcare professionals for ongoing CTG registrations was sometimes unclear. Clear assignment of such responsibility is of importance when more than one person is involved in CTG surveillance. When multiple CTGs are registered and shown on central screens using digital technology, it is conceivable that healthcare professionals wrongly expect colleagues to be responsible. In these circumstances, suboptimal or abnormal CTGs may be missed and adequate treatment delayed.

"Foetal emergency was missed, CTG surveillance suboptimal. In retrospect, tachycardia was present at an earlier moment in the case, there was no adequate documentation. As a result, no action was taken. This resulted in an emergency C-section and subsequent NICU admittance, where a poor prognosis was considered and it was ultimately decided to abstain from further treatment."

In this case, the CTG was not documented to be assessed in accordance with FIGO guidelines[23], which is the standard in the Netherlands. Absence of documentation about CTG

assessments was shown to be a major improvable care factor. In only 29% of cases, CTG assessments were correctly described.

Organization of care

Unclear or complicated procedures, unclear task assignments and uncertainty regarding local working agreements were improvable care factors. Unclear or complicated procedures obstruct smooth management. Problems regarding organization of care may delay treatment:

“Ordering 0-negative blood at the moment is too complex, it takes too long and the procedure is unclear.”

Unclear task assignments played an important role:

“During neonatal resuscitation, the contents of the emergency cart were incomplete. This caused the procedure to take longer than needed.”

In this case, the improvable care factor relates to all domains mentioned above. The organization of care needed to ensure a fully stocked cart failed.

Communication

Incomplete and unstructured transfer of care and uncertainty regarding local working agreements concerning communication were causes of improvable care factors. Incomplete and unstructured transfer of care were described as problematic for internal communication

within hospital as well as external communication between caregivers at different levels including general primary care:

"The general practitioner called for a consult regarding maternal jaundice during pregnancy. We should have asked for more information on the patient and have her assessed in hospital"

The failure of adequate information transfers in this case had the potential for severe consequences. Neonatal hyperbilirubinemia can lead to neurological deficits and even mortality.[24] The abovementioned case resulted in Intensive Care admission of both woman and neonate.

Uncertainty regarding local working agreements occurs when agreements are unclear. One improvable care factor was the unclear agreement regarding transfers from neonatologists/paediatricians back to primary care midwives. It was noted that transfer of care between childcare professionals in hospital and outside of hospital needed attention.

Discussion

Suboptimal CTG surveillance, organizational problems and communication breakdowns came up as important categories to improve care in cases of late preterm deaths in the Netherlands. The most common problems concerned uncertainty at the work place regarding local procedures and unclear allocation of tasks and responsibilities.

Comparison to literature

Publications of outcomes of systematically organized perinatal audits are rare. A systematic review of Gutman et al (2022) revealed 20 articles from 2000 and onwards evaluating perinatal mortality audits.[22] Timely and adequate monitoring of foetal and maternal conditions were common improvable factors in cases of perinatal mortality. But also organization of care, the right care at the right moment were points of attention identified.[23] These results are in line with our findings.

Our findings are also similar to those in the United Kingdom, where in 2017, the Mothers and Babies: Reducing Risk through Audits (MBRRACE) report identified foetal monitoring and interprofessional communication problems as major improvable care factors.[23] Systematic training in CTG surveillance was recognized as important in improving perinatal care.[24,25]

Ravelli et al. (2020) published about a decreasing trend in preterm birth, perinatal mortality and disparities in the Netherlands. Within their interpretation and clinical implications they refer to the introduction of nationwide perinatal audits in the Netherlands. The authors stated that the audit resulted in the description of improvable factors in relation to death and recommended better care management, cooperation, documentation and guidelines, ready for implementation.[26] This is in line with our findings.

Strengths and Limitations

Nationwide assessment of late preterm mortality in perinatal audits was not done in the Netherlands before. Theme-specific feedback is expected to create a greater sense of responsibility and increased motivation to implement high quality improvement plans.

One of the differences we encountered was that studies in which late preterm mortality is described most often use gestational age of 34+0 up to and including 36+0 weeks.[3] Focus on a broader range of late preterm mortality provided the advantage that a larger group of infants could be included permitting more robust conclusions.

The perinatal audit sessions were performed by the PCG where the case took place. This may cause biases among individuals taking part in the audit and may influence the matters being discussed. Other audits, like MBRRACE-UK[26], use independent assessors, limiting chances of such biases. We believe that our national audit may overcome this problem by ensuring that all case information is available and a large group of perinatal healthcare professionals participate in audit.

It is certain that the study population is not reflective of all cases of late preterm mortality, given the fact that only a selected number of cases was audited. It is expected that some cases of late preterm mortality were not included for the reason that PCGs are not required to audit all cases that conform to audit inclusion criteria hampering discussion of all cases across all themes. The strength of our conclusions lies in our qualitative findings pertaining to the identified improvable care factors.

Recommendations

According to audit results from this study and earlier[27,28], there is a need for improvement of CTG surveillance and registration in late preterm births in The Netherlands. One way this

may be achieved is to add intrapartum CTG interpretation of (late-) preterm foetuses to the national guideline.[28] This is important since most guidelines available only provide information on monitoring in term pregnancies.[28] In addition, all healthcare professionals involved with CTG interpretation should be required to follow training in foetal monitoring and update their knowledge and skills regularly.[27]

Improvable care factors formulated during audit meetings were often inadequate. This undermines the quality of the perinatal audit and should be addressed. It is important that audit contributors feel a common responsibility for identifying and adequately formulating improvable care factors.

Based on the outcomes of the perinatal audits, lessons to learn for clinical care are: promoting knowledge on foetal monitoring/CTG surveillance, investing in communication skills and drills, and finally taking a critical look at protocols, working procedures and assigning tasks.

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Figure 1- Definition local perinatal cooperation groups

Perinatal Cooperation Groups (PCGs) – The Netherlands is divided into 80 PCGs which are requested by the Dutch Care Standard for Integral Perinatal Care to organize at least two audits per year. This is a document describing the desired level of perinatal care in The Netherlands. Additionally, audit participation will earn healthcare professionals accreditation points.

In case of doubt regarding the quality of care delivered by a certain PCG, the Dutch Health and Youth Care Inspectorate (IGJ) is authorized to request relevant audit data.

Figure 2. Improvable factors in main and subcategories

Improvable factors are first divided over 1) discrepancies of national guidelines used in obstetric and neonatal care and 2) discrepancies of what may be considered 'normal' professional and daily practice. Hence, improvable care factors within the category "discrepancies regarding what may be considered normal professional and daily practice" were further divided in subcategories, which were specified upfront by Perined: a) suboptimal cardiotocography (CTG) surveillance, b) inadequate diagnostics, c) inadequate documentation, d) failing alarm systems, e)patient no show, f) delay, g) inadequate investigation (post mortem/pathological), h) technical problem, i) organizational problem, j) inadequate supervision, k) communication problem, l) other, not earlier specified.

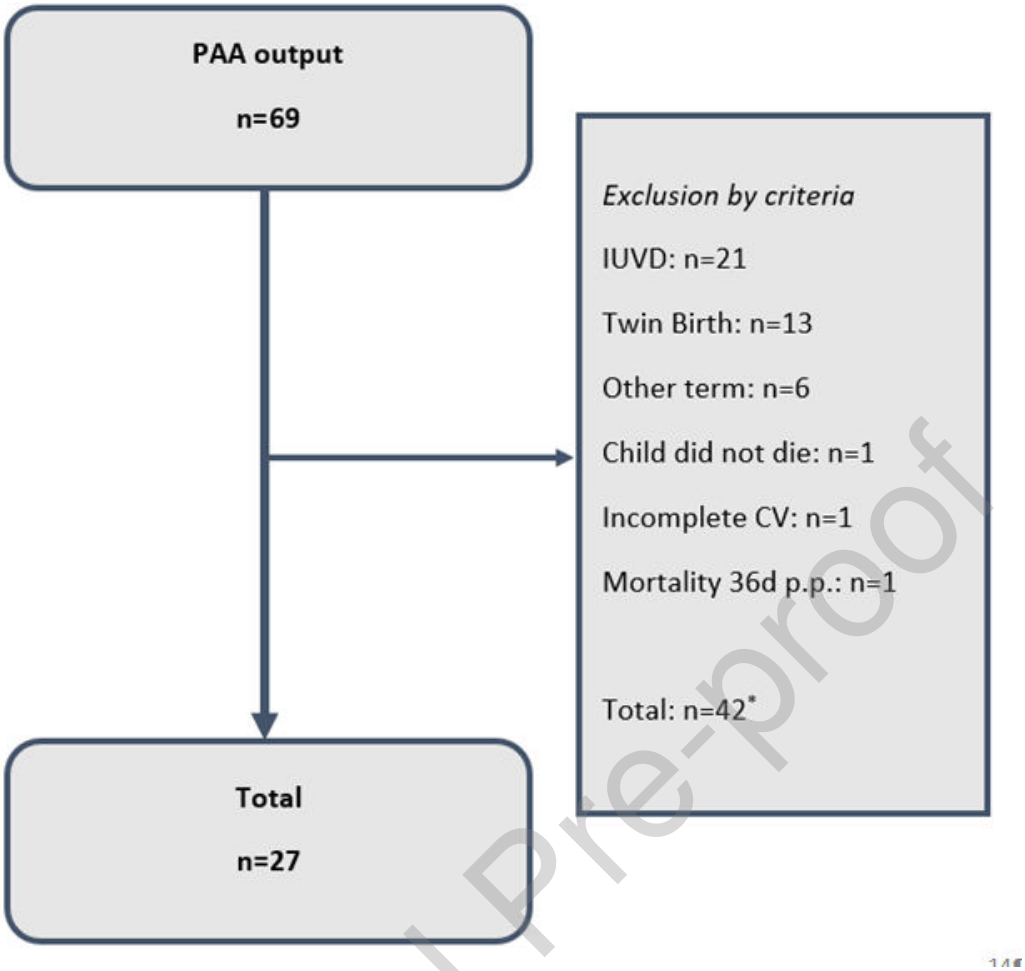

Figure 3. Flowchart, in and exclusion

*In one case, two exclusion criteria were met.

Table 1 Baseline characteristics

Maternal characteristics ~	
Mean gestational age in weeks (min-max)	35.1 (32.0-36.5)
Gravidity (mean, min-max)	3 (1-7)
Parity (mean, min-max)	1 (0-5)
Ethnicity (%)	

Caucasian	21 (77.8)
Mean age in years (min-max)	32 (26-44)
Mean Body Mass Index (BMI) (min-max)	25.1 (17.5-41.8)
Smoking behaviour (%)	
Did not smoke	20 (74.1)
Quit before/during current pregnancy	3 (11.1)
<10 cigarettes/day	1 (3.7)
Risk status at intake* (%)	
VIL A	19 (70.4)
VIL C	5 (18.5)
Academic care	1 (3.7)
Risk status at start of birth* (%)	
VIL A	5 (18.5)
VIL C	15 (55.6)
Academic care	5 (18.5)
Child mortality in medical history (yes; n)	2
Repeated mortality in medical history	1
Of which perinatal	1
Birth characteristics	
Mode of birth[#] (%)	
Spontaneous vaginal	5 (18.5)

Assisted birth vaginal	3 (11.1)
Secondary Caesarean section	12 (44.4)
Primary Caesarean section	6 (22.2)
Intervention to start birth (%)	
Balloon priming	2 (7.4)
Oxytocin induction	1 (3.7)
Primary Caesarean section	6 (22.2)
Indication for intervention to start birth (%)	
Acute life-threatening danger child	6 (22.2)
Not life-threatening danger child	3 (11.1)
Not life-threatening danger mother	1 (3.7)
Pain management (%)	
Morphinomimetics >3cm dilation	1 (3.7)
Spinal analgesia during Caesarean	13 (48.1)
General anaesthesia during Caesarean	3 (11.1)
Mean duration of ruptured membranes in hours, minutes (min-max)	42h93min (0h01min-519h 47min)
Duration of expulsion in hours, minutes (min-max)	0h 23min (0h01min-2h0min)
Colour of amniotic fluid (%)	
Clear	16 (59.3)
Meconium	5 (18.5)
Blood-tinged	3 (11.1)

Fetal position during birth (%)	
Cephalic	22 (81.5)
Breech	3 (11.1)
Neonatal characteristics	
Gender (%)	
Male	13 (48.1)
Mean birthweight in grams (min-max)	2320 (1425-3130)
Birth percentiles according to Hoftiezer (%)	
<=p3	4 (14.8)
p3 – p10	5 (18.5)
p10 – p95	16 (59.2)
>= p95	2 (7.4)
Median APGAR scores (min-max)	
After 1 minute	1 (0-9)
After 5 minutes	4 (0-10)
After 10 minutes	6 (0-10)
Mean umbilical cord blood gasses (min-max)	
Arterial pH	7.00 (6.73-7.24)
Venous pH	7.16 (6.70-7.32)
Arterial Base Excess	-15.39 (-30.00-, -2.80)
Venous Base Excess	-17.33 (-119-, -3.00)

Congenital malformations (%)	
Yes	6 (22.2)
Of which lethal	5 (83%)
No	16 (59.3)
Unknown	5 (18.5)
Moment of death/mortality (%)	
During childbirth	3 (11.1)
Neonatally (up to and including 28 days)	24 (88.9)
Most likely cause of death (%)	
Placental abruption	4 (14.8)
Perinatal asphyxia	7 (25.9)
Neonatal infection	4 (14.8)
Congenital malformation	5 (18.5)
Intracranial haemorrhage	1 (3.7)
Maternal illness (DM, HT) ^	1 (3.7)
Fetomaternal transfusion	1 (3.7)
Other factors	1 (3.7)
Not named	3 (11.1)
Pregnancy resulting from (%)	
Intra-uterine insemination (IUI)	1 (3.7)
Intracytoplasmic sperm injection (ICSI)	1 (3.7)
NICU-admittance (%)	
Yes	21 (77.8)

Died at NICU (%)	
Yes	19 (70.4)
No	7 (25.9)

~ Parameters where the outcome was zero, missing or unknown are not displayed

* VIL A= primary care; VIL B = care in consultation between obstetrician and midwife, VIL C = secondary care, VIL D = primary care in a secondary setting

Mode of birth: primary caesarean is defined as the mode of birth is planned during pregnancy. Secondary caesarean is defined as every caesarean applied during labour.

*Diabetes Mellitus, hypertension

Table 2. Categories of improvable factors and relation with outcome

Category (%)	
Suboptimal CTG surveillance	**3 (5.8)**
Inadequate diagnostics	2 (3.8)
Inadequate documentation	8 (15.4)
Failing alarm systems	2 (3.8)
Delay	2 (3.8)

Inadequate investigation (post mortem/pathological)	3 (5.8)
Technical problem	3 (5.8)
Organisational problem	**9 (17.3)**
Communication problem	**9 (17.3)**
Other	11 (21.2)
Total	52 (100)
Probable relation with outcome (%)	
Unknown	5 (9.6)
None/unlikely	38 (73.1)
Possible	7 (13.5)
(Very) likely	2 (3.8)
Total	52 (100)