Travel time from home to hospital and adverse perinatal outcomes in women at term in the Netherlands

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Objective To study the effect of travel time, at the start or during labour, from home to hospital on mortality and adverse outcomes in pregnant women at term in primary and secondary care.

Design Population-based cohort study from 2000 up to and including 2006.

Setting The Netherlands Perinatal Registry.

Population A total of 751 926 singleton term hospital births.

Methods We assessed the impact of travel time by car, calculated from the postal code of the woman’s residence to the 99 maternity units, on neonatal outcome. Logistic regression modelling with adjustments for gestational age, maternal age, parity, ethnicity, socio-economic status, urbanisation, tertiary care centres and volume of the hospital was used.

Main outcome measures Mortality (intrapartum, and early and late neonatal mortality) and adverse neonatal outcomes (mortality, Apgar <4 and/or admission to a neonatal intensive care unit).

Results The mortality was 1.5 per 1000 births, and adverse outcomes occurred in 6.0 per 1000 births. There was a positive relationship between longer travel time (≥20 minutes) and total mortality (OR 1.17, 95% CI 1.002–1.36), neonatal mortality within 24 hours (OR 1.51, 95% CI 1.13–2.02) and with adverse outcomes (OR 1.27, 95% CI 1.17–1.38). In addition to travel time, both delivery at 37 weeks of gestation (OR 2.23, 95% CI 1.81–2.73) or 41 weeks of gestation (OR 1.52, 95% CI 1.29–1.80) increased the risk of mortality.

Conclusions A travel time from home to hospital of 20 minutes or more by car is associated with an increased risk of mortality and adverse outcomes in women at term in the Netherlands. These findings should be considered in plans for the centralisation of obstetric care.

Keywords Access to care, ethnicity, gestational age, health facilities, perinatal mortality, rural.

Introduction

A positive relationship between longer travel time from home to hospital and mortality has been found in life-threatening situations like emergency/trauma care and cardiology.1–6 Obstetrics is another setting in which travel time to hospital may potentially affect the outcome. Access to maternity care is often limited in rural areas and travel time is longer. Very few studies have been performed on this issue.7,8 None of them found a significant influence of travel time on perinatal mortality. This could be different in the Netherlands where most women start labour at home, even in the case of a planned hospital delivery. If geographic access to care is not equally distributed within the country, and travel time is longer in critical circumstances such as a delivery, this might lead to hypoxaemia/asphyxia, and eventually to intrapartum and neonatal death.9

The Netherlands has a two-stage maternity healthcare system (primary and secondary care). At the first prenatal visit pregnant women are considered as high risk if they have a complicated obstetric or general medical history, otherwise they are considered to be low risk. Primary care for low-risk women, including care during delivery at home...
or in an outpatient clinic, is conducted by independent midwives.\textsuperscript{10} If the low-risk status changes to high-risk during pregnancy or delivery, the woman is referred to secondary care (obstetrician) on the basis of a multidisciplinary guideline.\textsuperscript{10,11} This is in contrast to other countries where women deliver in hospital under secondary care, and travel to the hospital when early signs of labour are present, whereas home births are rare.\textsuperscript{12,13} In the Netherlands low-risk women choosing the outpatient clinic as their preferred place of delivery stay at home until the signs of labour are obvious to the midwife, and then travel to the hospital by car. Women selected as high risk at the start of labour, who have their delivery planned in hospital under the supervision of an obstetrician, travel to hospital by car in the early stage of labour. Ambulances are only used for maternal/child pregnancy-related diagnoses in the case of an emergency.

It is known that women referred to the hospital during labour had an increased risk of perinatal mortality compared with women who remained at low risk during labour and delivered at home or in an outpatient clinic.\textsuperscript{14} Recently, we reported that the perinatal mortality from 22 weeks of gestation onwards was elevated in the rural northern region in the Netherlands compared with the urbanised western regions.\textsuperscript{15} Regional differences in perinatal mortality were larger for women at term who changed status from low risk to high risk during labour: 4.0\% in the northern region versus 2.6\% in the western region. Because these regional differences could not be explained by demographic or socio-economic factors, it was hypothesised that travel time could have an influence on perinatal mortality, especially when women changed risk status during labour. We studied the relationship of travel time from home to the hospital with intrapartum/neonatal mortality, and with adverse outcome for women at term in primary and secondary care in the Netherlands. We adjusted the travel time for potential confounding factors such as the rurality of the areas and hospital volume.

\section*{Methods}

\subsection*{Data source}

For this study we used data from the perinatal registry of the Netherlands (PRN). The PRN is a database containing linked and validated data from the three professional registries of midwives, obstetricians and neonatologists. The PRN data are recorded at the individual level.\textsuperscript{16,17}

\subsection*{Study population}

The study population comprised all singleton births for the period 2000–2006, with a pregnancy duration between 37\textsuperscript{10} and 42\textsuperscript{10} weeks of gestation ($n = 1\ 091\ 496$). We excluded records with antepartum mortality ($n = 1731$), congenital disorders ($n = 23\ 560; 2.1\%$), records with invalid or missing postcodes of the women’s residence ($n = 3433; 0.3\%$), unknown or invalid hospital or outpatient codes ($n = 8338; 0.7\%$), unknown location of labour ($n = 7689; 0.6\%$) and women from the ‘Wadden’ islands ($n = 741; 0.1\%$), which are not connected by bridge to the mainland. Secondly, the home deliveries ($n = 291\ 676; 27.6\%$) were excluded. Hospitals who only participated for 1 or 2 years ($n = 2402; 0.2\%$) during this 7-year cohort were also excluded. This resulted in a final dataset that comprised 751\ 926 singleton term births without congenital anomalies and antepartum stillbirths delivered in one of the 99 (hospital and outpatient) clinics.

\subsection*{Definitions}

Travel time from home to the hospital was estimated using the time needed to travel by road between the postal code of the woman’s residence and the postal code of the hospital or outpatient clinic where the delivery took place. Travel time was calculated by using a geographic information system (GIS) package including a national drive time matrix taking into account the Dutch road network system, its features and its restrictions (highway or secondary road). Both travel time and travel distance by car were calculated. We focussed on travel time in minutes because the same travel distance may require different travel times, depending on the type of road and rurality.

The first outcome measure used was combined intrapartum and neonatal mortality. Intrapartum mortality was defined as death during labour before birth, and neonatal mortality was defined as deaths during the first 28 days of life. The second outcome measure was adverse outcome, which was a combined endpoint of mortality and/or 5-minute Apgar score below 4, and/or transfer of a newborn to a neonatal intensive care unit at birth.

\subsection*{Statistics}

Logistic regression was used to estimate the influence of travel time on mortality and adverse outcomes. First, the continuous variable travel time was plotted against the outcome mortality. Smoothing the binary values of mortality as a function of travel time by applying local weight regression was used to determine if and how to categorise the travel time variable. Based on this procedure the travel time was categorised in three classes: 0–14; 15–19; and 20 min or more.

Second, we described the women and hospital characteristics by travel time categories and tested this with the chi-square test. Third, we performed univariate logistic regression analyses on travel time and any possible confounding factors associated with the two outcome measures. In a multivariate analysis we then adjusted for the possible confounding factors of perinatal deaths or adverse
outcomes: maternal age, parity, ethnicity, socio-economic status (SES), gestational age and urbanisation.\textsuperscript{9,18}

We also adjusted for hospital type and volume. Maternal age was categorised into six classes. Parity was divided into nulliparous women (parity 0), second birth (parity 1) and third or later birth (parity 2+). The woman’s ethnicity/race was used as registered by the healthcare providers in seven-groups.\textsuperscript{19} The SES score per four-digit postal area, based on a combination of mean income level, the percentage of households with low income or without a paid job, was categorised in low- (25th percentile), mid- and high-SES groups (75th percentile). Gestational age was based on the date of the last menstrual period and/or crown-to-rump length measured by ultrasound during early pregnancy. In case of a difference of more than 7 days, the ultrasound age was preferred. Urbanisation was based on the number of households per four-digit postal area, and was categorised in urban (>2500 households), mid (500-2500 households) and rural (<500 households). The type of hospital was categorised as tertiary perinatal intensive care centres \((n = 10)\) versus other centres. The hospital volume (defined as hospital birth rate)\textsuperscript{20} was divided into six categories based on the total annual number of births from 22 weeks of gestation onwards, with identical cut-off points used in an earlier study.\textsuperscript{18}

Travel time and all possible confounding factors mentioned above were separately tested for interactions. The interaction model included, for instance, travel time and gestational age and a travel time by gestational age interaction term. The significance was tested with the Wald test. In addition to the logistic regression analyses in the overall study population, analyses were repeated for live births only.

Separate analyses were applied for type of hospital and for the three different levels of care provision provided by the Dutch obstetric healthcare system: complete primary care; changing risk status during labour and secondary care at birth; complete secondary care. Odds ratios (ORs) and corresponding 95% confidence intervals (95% CIs) were used to describe the association between the predictor variables and the outcome variable in the overall population and in subgroups.

All statistical analyses were performed using \textsc{sas} for Windows \textsc{xp} v9.2 (SAS Institute Inc. Cary, NC, USA). Smoothing was obtained by the locally weighted scatter plot smoothing (LOWESS) technique in the \textit{r} statistical environment for Windows v2.9.0 (\textsc{r} Foundation for Statistical Computing, http://www.R-project.org). The DriveTime Matrix Netherlands was combined with ArcGIS.

### Results

During the period 2000–2006 there were 1125 intrapartum and neonatal deaths in 751 926 births (1.5 per 1000 births) and 4543 adverse outcomes (6.0 per 1000 births). The median travel time was 13.0 minutes and the median travel distance was 7.0 km.

Figure 1A, B shows the impact of travel time on mortality and on adverse outcomes, respectively. The vertical bars indicate the frequency of the travel time variable. Most women (74.2%) had a travel time of <20 minutes. After a travel time of at least 20 minutes, a positive association was found towards increased mortality. As shown in Figure 1, only a few women travelled more than 30 minutes to the hospital.

In Table 1 the characteristics of the women and the hospitals are shown by travel time categories. The women who travelled 20 minutes or more were slightly older, were often multiparous, were more often white, had a higher SES and...
were living in more rural areas. In addition, they delivered more often in both low- and high-volume hospitals and in tertiary-level perinatal centres.

Table 2 shows that 193,745 women who travelled 20 minutes or more had a significantly higher risk of intrapartum and early and late neonatal mortality \( (n = 336) \) (unadjusted OR 1.22, 95% CI 1.07–1.39). After adjustment for possible confounding factors the effect remained significant (adjusted OR 1.17, 95% CI 1.002–1.36). The overall \( P \) value for travel time for total mortality was 0.037. For adverse outcomes \( (n = 1267) \) the effects were also significant (adjusted OR 1.27, 95% CI 1.17–1.38). Both models fitted to the data (Hosmer–Lemeshow goodness-of-fit tests provided non-significant results).

In addition, when travel time was not categorised but used as a continuous determinant, the adjusted OR per minute increase of travel time was 1.01, 95% CI 1.00–1.01. Separate analyses showed that the effect of travel time on intrapartum mortality \( (n = 544) \) was not significant (OR 1.03, 95% CI 0.8–1.3). This is in contrast to the significant effect of travel time on neonatal mortality within 24 hours of birth \( (n = 255) \). Analyses of the live born infants (Table 3) showed that women who travelled 20 minutes or more had a significantly higher risk of neonatal mortality within 24 hours (adjusted OR 1.51, 95% CI 1.13–2.02). The effect of travel time was also visible in early neonatal mortality (0–7 days, \( n = 523 \) ) (adjusted OR 1.37, 95% CI 1.12–1.67), and not in the late neonatal mortality between 8 and 27 days after birth (Table 3). Outcomes were similar if travel distance in km was used instead of travel time in minutes.

Besides travel time, important risk factors for mortality were delivery at 37 weeks of gestation \( (OR 2.2, 95\% CI 1.8–2.7) \), delivery at 41 weeks of gestation \( (OR 1.5, 95\% CI 1.3–1.8) \), nulliparity, South Asian ethnicity \( (OR 1.8, 95\% CI 1.2–2.7) \), Turkish/Moroccan ethnicity \( (OR 1.5, 95\% CI 1.2–1.8) \), increased maternal age, and delivery in a tertiary care perinatal centre (Table 2). These risk factors were similar for the adverse outcomes. In addition, African ethnicity and delivery at 38 weeks of gestation were also important for adverse outcomes.

Interactions with travel time were tested separately for maternal age, ethnicity, parity, SES, pregnancy duration, tertiary-level hospital, urbanisation, volume, and type of hospital and care path. The different interaction terms were not found to be statistically significant for any of the above described confounding factors. However, we still performed separate analyses for the type of hospital and levels of care.

### Table 1. Characteristics of women and hospitals by travel time categories

<table>
<thead>
<tr>
<th>Travel time in minutes</th>
<th>&lt;15 minutes</th>
<th>15–19 minutes</th>
<th>≥20 minutes</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>425,952</td>
<td>132,229</td>
<td>193,745</td>
</tr>
<tr>
<td>Nulliparous</td>
<td>218,204</td>
<td>65,094</td>
<td>91,610</td>
</tr>
<tr>
<td>Median age (year)</td>
<td>51.2%</td>
<td>49.2%</td>
<td>47.3%</td>
</tr>
<tr>
<td>Maternal</td>
<td>30.0</td>
<td>31.0</td>
<td>31.0</td>
</tr>
<tr>
<td>Rural area</td>
<td>10,257</td>
<td>1902</td>
<td>2,545</td>
</tr>
<tr>
<td>Caucasian ethnicity</td>
<td>204,577</td>
<td>1,138</td>
<td>175,219</td>
</tr>
<tr>
<td>age &lt; 20 years</td>
<td>11.4%</td>
<td>1.1%</td>
<td>1.3%</td>
</tr>
<tr>
<td>Caucasian ethnicity</td>
<td>304,377</td>
<td>113,814</td>
<td>175,219</td>
</tr>
<tr>
<td>Rural area</td>
<td>49.2%</td>
<td>86.1%</td>
<td>90.4%</td>
</tr>
<tr>
<td>Median age (year)</td>
<td>24,957</td>
<td>36,423</td>
<td>70,591</td>
</tr>
<tr>
<td>Delivery at 37 weeks of gestation</td>
<td>157,792</td>
<td>20,374</td>
<td>22,249</td>
</tr>
<tr>
<td>Mean birthweight (g)</td>
<td>37.0%</td>
<td>15.4%</td>
<td>11.5%</td>
</tr>
<tr>
<td>Delivery at 37 weeks of gestation</td>
<td>29,348</td>
<td>9282</td>
<td>14,412</td>
</tr>
</tbody>
</table>

**Type of hospitals**

The median travel time was higher for deliveries in tertiary care centres compared with deliveries in other hospitals (14.0 versus 13.0 minutes, respectively). Stratified analyses by type of hospital showed that the mortality risk for a travel time of 20 minutes or more was increased for both tertiary care centres and other care centres, although this result was no longer significant (OR 1.1, 95% CI 0.96–1.3 and OR 1.3, 95% CI 0.8–2.0, respectively).

**Levels of care**

Mortality and adverse outcome rates differed among the levels of care provision in the Dutch healthcare system (Table 4). Women who were indicated as low risk at the start of labour and delivered at an outpatient clinic had the lowest mortality rates of 0.5% (63/120,896) and lowest rates of adverse outcomes. If those women had a travel time of at least 20 minutes, the mortality rate was not increased (adjusted OR 0.8, 95% CI 0.4–1.7).

Twenty-five percent of low-risk women changed risk status to high risk during labour, and these women had an increased mortality rate of 1.9% (277/142,824) and an adverse outcome rate of 6.5% (1,845/29,777) (Table 4). When they had a travel time of at least 20 minutes they had a non-significantly higher risk of mortality (OR 1.25, 95% CI 0.9–1.7) and of adverse outcomes.

Women who were indicated as high risk before the start of labour and delivered in the hospital had a mortality rate...
of 1.6\% (785/488 206), and a travel time of 20 minutes or more increased the risk of mortality (OR 1.18, 95\% CI 1.0–1.4) and adverse outcomes (OR 1.19, 95\% CI 1.10–1.30).

### Discussion

This study showed that a travel time of 20 minutes or more by car from home to hospital increased the risk of
The increase in mortality risk was especially clear within 24 hours of birth. Low-risk women at the start of labour and delivering in an outpatient clinic under primary care had the lowest mortality rates, and in this group no effect of travel time is observed. Notable was the high mortality risk of the women who changed risk status during labour. In general, besides travel time delivery at 37 or 41 weeks of gestation, and for women with South Asian ethnicity, the risk of mortality and adverse outcomes was increased.

Strengths and weaknesses
The strengths of this study included the use of a large linked database to investigate the association between travel time to the hospital and intrapartum/neonatal mortality, which is needed to detect differences in rare outcomes like neonatal mortality in term births. The rarity of outcomes potentially hampered the subgroup analysis by level of care. The PRN registry covers approximately 96% of all births in the Netherlands, and linkage procedures of the separate registries were validated. The travel time determinant and travel distance was calculated by using the road network calculation method, which is a far more realistic approximation of travel burden than a Euclidian (straight-line) calculation, especially in the case of physical barriers like rivers, canals and lakes.

There were also limitations. In the registry the causes of death and the time when women started travelling are not documented. The transportation is mostly by car, but the types of transport are not registered. National information on ambulance journeys showed that of all ambulance transports only 2% are used for pregnancy/labour emergencies. The estimation of travel time is based on travel under the best conditions. The real travel time was in many cases probably longer than we estimated.

The actual place of departure is unknown, but in the Netherlands it is daily practice that most women are on pregnancy leave and are at home around their due date. The information of traffic jams, rush hours, traffic congestion and housing situations for each individual case was unknown, and therefore could not be taken into account in the travel time calculation. As a consequence, the travel times are under estimated. We also did not have information on any further delay that may have occurred after women had successfully arrived in hospital.

Nearly all births in the Netherlands are included in the PRN registry; the missing 4% are mostly low-risk women taken care of by midwives or general practitioners, as 99% of the registry of obstetricians is complete. There is no evidence that non-participation is localised in one specific region, although general practitioners who are active in midwifery practice more often in rural areas. The risk associated with travel time can be associated with the risk profile of the woman or her child. This study therefore possibly suffers from confounding by indication: high-risk women have more chance of travelling to reach a tertiary-level hospital, although this is less obvious in women at term. After analysing deliveries in tertiary-level perinatal hospitals or other hospitals separately, the relationship between increased travel time and mortality/adverse outcome remained; however, because of low numbers, it was no longer significant in both groups. Neonatal hypoxaemia at birth (umbilical pH value and base excess) is not registered in the national registry. In this study we controlled for various confounding factors, although it is still possible that the effects of some important confounding factors that were not registered, for instance the body mass index of the women, were missed.

Previous research
Our study results are in line with a study performed in Japan that found that perinatal mortality was higher in
Table 4. Travel time, mortality and adverse outcomes in primary and secondary care

<table>
<thead>
<tr>
<th>Level of care at start of labour</th>
<th>Primary care</th>
<th>Primary care</th>
<th>Secondary care</th>
</tr>
</thead>
<tbody>
<tr>
<td>Place of birth</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Level of care at birth</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of births</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Percentage</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>OR 95% CI</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

| Mortality                       |              |              |               |
| Number of deaths                | 63           | 277          | 785           |
| Deaths per 1000 births          | 0.5          | 1.9          | 1.6           |

| Travel time crude               |              |              |               |
| <20 minutes                     | 1.00 reference| 1.00 reference| 1.00 reference|
| ≥20 minutes                     | 0.85 0.43–1.68| 1.35 1.04–1.75| 1.15 0.99–1.34|

| Travel time adjusted*           |              |              |               |
| <20 minutes                     | 1.00 reference| 1.00 reference| 1.00 reference|
| ≥20 minutes                     | 0.81 0.39–1.67| 1.25 0.94–1.66| 1.18 1.00–1.39|

| Adverse outcome                 |              |              |               |
| Number                          | 287          | 933          | 3323          |
| Per 1000 births                 | 2.4          | 6.5          | 6.6           |

| Travel time crude               |              |              |               |
| <20 minutes                     | 1.00 reference| 1.00 reference| 1.00 reference|
| ≥20 minutes                     | 1.04 0.78–1.41| 0.90 0.77–1.05| 1.11 1.03–1.19|

| Travel time adjusted*           |              |              |               |
| <20 minutes                     | 1.00 reference| 1.00 reference| 1.00 reference|
| ≥20 minutes                     | 0.96 0.69–1.33| 1.00 0.84–1.19| 1.19 1.10–1.30|

*Adjusted for maternal age, parity, SES, ethnicity, urbanisation, gestational age, tertiary perinatal centres and hospital birth rate.

most rural municipalities compared with urban municipalities.24 Our study showed that even after adjustment for rural areas and low-volume hospitals, a woman’s travel time is of interest. Parker (n = 79 229) and Dummer (n = 287 993) performed research in Cumbria (UK), and found no association between an increased travel time to the nearest or second-nearest healthcare centre and stillbirth, nor infant mortality, which is in contrast with our findings.7,8 Differences in findings might be explained by the lower population size of the Cumbria region compared with our study.

Other obstetric outcome measures could also be influenced by a longer travel time. A study performed in the area of neonatology found that women who were living further than 25 miles away from the nearest neonatal intensive care unit (NICU) had a significantly increased odds of very low birthweight delivery at a non-NICU hospital (n = 24 094).25 The study showed that distance plays a role in receiving less adequate care, as delivery in a non-NICU hospital may result in increased morbidity and mortality of the child when specialised care is needed. Studies have also shown that delivery in rural areas is associated with delivering in low-volume hospitals. Low-volume hospital delivery in rural areas in Norway was shown to be associated with higher neonatal mortality.20 It is not new that early terms born at 37 weeks of gestation have increased risks of adverse outcomes.26

Implications and future research
The associations found in an observational study are not necessarily causal. Maybe other unmeasured factors in the care provision or in socio-economic/cultural perspective are underlying causal factors.27 Our research has several implications.

First, perinatal audits should include travel time to the hospital in their inquiries to determine if travel time to the healthcare centre is an aetiological factor, and to understand how travel time could have influenced the potential substandard care delivered to women.28,29

Second, to enable additional research on travel time in delivering women, when travelling during labour the departure and arrival time at the ward should be recorded, and whether emergency transportation was used.30 The finding of the elevated risks at 37 and 41 weeks of gestation needs further exploration, and may have implications for the place of delivery. In future research the reasons for urgent referral during labour should be studied in relation to travel time.31 Timely and appropriate risk selection is essen-
tial. If women are not referred in time and have to travel long distances then perinatal outcomes may worsen. Therefore if additional research identifies longer travel time as a substandard care factor, travel time could be used in the risk selection and assigned to the obstetric manual.\textsuperscript{10} The clinical implication of the study could be that home births should be reconsidered in low-risk women who are living a distance of 20 minutes travel time or more away from a hospital, especially when delivering at 37 or at 41 weeks of gestation.

Our study of the effect of longer travel time and adverse outcome is more generally applicable to other countries with a hospital-based maternity care system considering centralisation of care facilities, especially for rural areas.\textsuperscript{32,33}

In the Netherlands these findings also have implications for the choice of concentration of care facilities to be able to provide 24-hour acute obstetrical and neonatal services 7 days a week. If this concentration implies that travel time increases, the potential benefits of large-scale care might be jeopardized by the longer travel time both for low-risk women planning home delivery, as well as for women classified as high risk prior to the onset of labour.

**Conclusion**

In women delivering at term in the Netherlands there is a significant association between a longer travel time (20 minutes or more) from home to the hospital and mortality or adverse outcomes. Further research in this field is necessary to investigate the policy implications for the Dutch obstetrical care system.

**Disclosure of interests**
The authors have nothing to disclose with regard to potential conflicts of interest.

**Contribution to authorship**

Study concept and design: AR and KJ designed the study for MdG's master's thesis in Medical Informatics. The study was based on ideas for further research as described in the article on regional differences in perinatal mortality by Tromp et al. 2009.\textsuperscript{15} JE, GRvD and BWM were all involved in data collection. Drafting of the manuscript: MdG, AR, KJ and ME. Statistical analysis: AR and MdG were involved in the data analysis, and the locally weighted scatter plot smoothing technique was supervised by AAH. All authors contributed to the critical revision of the paper and approved the final version of the manuscript.

**Details of ethics approval**

No ethics approval was needed as the analyses were based on anonymous registry data.

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**References**


