

European Court of Human Rights

Attn: Mr Johan Callewaert
Deputy Grand Chamber Registrar
Council of Europe
67075 Strasbourg
France

Dubská and Krejzová v. the Czech Republic (nos. 28859/11 and 28473/12)

Expert statement

Introduction

This expert statement has been prepared for the purposes of the case of Dubská and Krejzová v. the Czech Republic, application nos. 28859/11 and 28473/12 upon the request of both applicants. As the merit of the case relates to the assessment of safety of a planned childbirth assisted by a qualified professional and its comparison with other models of childbirth healthcare, this expert statement is confined to a summary of valid methodologies for studying the safety of home birth, outcomes comparing planned home vs. planned hospital birth, women's experience of home birth, the cost of home birth, and ethical considerations with respect to the choice to give birth at home.

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Valid Methodologies for Studying Home Birth

The debate on the safety of home birth continues because the only study design that can prove or disprove that home birth is safe is a randomized controlled trial (RCT). To date there have been no large RCTs because women have not been willing to be assigned by chance to plan birth at home versus hospital. In the absence of large trials, the most credible studies are observational studies with strict adherence to aspects of design that ensure validity of findings. The following criteria are necessary to ensure that findings are valid, relevant and comparable among studies.

Known Birth Attendant

Firstly, the credentials of birth attendants must be known and consistent across study settings in order to be able to attribute differences in outcomes to the place of birth rather than the provider. In many studies to date, outcomes of births attended at home with midwives are compared to outcomes of births in hospital attended by physicians.

Planned Place of Birth

Secondly, exposure groups need to be formed on the basis of planned vs. actual place of birth because the information provided by the study needs to inform the decision-making process. Thus the salient information to the decision maker is the outcome associated with *planning* home vs. hospital birth regardless of whether the birth actually takes place at home or hospital. Arguments made on the basis of differences in outcomes according to whether the birth subsequently takes place in home or hospital or what the transfer rates are, are irrelevant to the fundamental question of rates of adverse outcomes associated with the decision to plan home birth. Comparison groups must inform the choice to be made: begin labour in home or hospital. Further, studies that document planned place of birth at the onset of labour exclude unplanned home births. Failure to exclude unplanned home births inevitably is associated with elevated rates of neonatal mortality.¹

Trained and Credentialed Birth Attendants

A third critical aspect of study design is to define the credentials of the home birth attendant. Thus the exposure of interest is not just planned home birth; it is planned home birth with a trained and credentialed birth attendant. No credible investigator suggests that studying home birth without specifying metrics for the training of the attendant would constitute a valid assessment. Studies which fail to restrict births to those in which the training of the birth attendant is known cannot be compared to other studies.²

Third Party Reporting

Fourth, with respect to ascertainment of outcomes, it is necessary that data is collected on a non-voluntary basis by a third party in order that births with adverse outcomes not be withheld, i.e. reporting bias.

Representative Data

Fifthly, it is essential that data represents populations, that is, with complete ascertainment of births in a given geographic area. This avoids selection bias, that is, that births would be entered into a data base preferentially according to some characteristic that could bias study findings, for example, urban vs. rural settings in which one or another exposure group were disproportionately represented.

Comparability of Risk Status

A sixth design requirement is that women across comparison groups are of equal risk status and that eligibility requirements for planned home birth are evidence-based and supported by professional practice standards.

The Safety of Home Birth

Studies that have met these rigorous requirements for study design and data collection have been published in the Netherlands, Canada, and the UK. The seminal study by Dr. A. de Jonge et al. in 2009, of 529, 688 births in the Netherlands compared national registration data to identify planned home vs hospital births attended by regulated midwives.³ Women were at term gestation with a singleton fetus and without medical or obstetric risk factors before labour. Rates of perinatal death (stillbirth or death

at 0-7 days) were 0.06% in the planned home birth group and 0.07% in the planned hospital group. A 2009 study of *all* planned hospital births attended by registered midwives in the Province of British Columbia, Canada compared to *all* planned hospital births meeting the College of Midwives criteria of planned hospital births attended by the *same* midwives reported no differences in rates of adverse maternal and fetal outcomes with significantly more interventions in the planned hospital birth.⁴ Rates of perinatal death in the planned home birth group were 0 and in the planned hospital birth – 0.3%. These differences were not statistically significant. A similar 2009 study in the province of Ontario, Canada, also using provincial registries, and the same exposure groups, reported neonatal mortality rates of 0.1% for both the planned home and hospital births.⁵ Stillbirth rates were 0 and 0.1% for home and hospital births respectively. These studies, which meet the highest standards of methodology for home birth research in the world today, have remarkably similar results. This is particularly noteworthy given the transport challenges Canadians face in terms of climate and geography.

These studies were followed in 2011 by the Birthplace in England study of 64,358 low risk women with a singleton pregnancy at term.⁶ Ninety-seven percent of all planned home births attended by National Health Service midwives during the study period were included. In this study the stillbirth rate among nulliparous women was 0.01% in the obstetric unit, 0.09% in the home birth group, 0.03% in the freestanding midwifery unit and 0.01% in the alongside midwifery led units. These rates were 0.02%, 0.01% 0.05% and zero among multiparous women. These differences were not statistically significant. Early neonatal death within 7 days among nulliparas were 0.04% in the obstetric unit, 0.04% in the planned home group, 0.05% in the freestanding midwifery units and 0.01% in the alongside midwifery units. These numbers were 0.01%, 0.03%, 0.03%, and 0.1% among multiparas. Based on these criteria, the UK National Institute for Health and Care Excellence (NICE) guidelines recommend that low risk women be supported in their choice of planned place of birth⁷.

From the Netherlands, De Jonge and colleagues published a study in 2014 comparing neonatal mortality among low risk planned home and hospital births attended by regulated midwives using data from national perinatal databases.⁸ In this adequately powered study including 743, 070 births, no differences were found in intrapartum or neonatal death, at 7 or 28 days after birth among either nulliparous or parous women. This study supported the findings of an earlier 2011 Dutch study of intrapartum and early neonatal death among 679,952 low risk pregnancies.⁹ Rates of intrapartum death and early neonatal death (0-7 days) were 0.09 % in the planned home birth group and 0.10% in the planned hospital group. Differences were not statistically significant in models adjusted for maternal age, ethnicity, and neighbourhood. A 2015 study of 83,289 women living in the catchment area of Amsterdam academic hospitals compared intrapartum and neonatal mortality according to planned place of birth among women without pregnancy complications at term in 2005-8 in midwifery-led primary care.¹⁰ Rates of intrapartum mortality were 0.15% for the planned home birth group and 0.23% for the planned hospital birth. Early neonatal death rates (0-7 days) were 0.57% and 0.33% respectively. These differences were not statistically significant and were consistent with rates previously reported from Canada and the UK.

The American literature is noticeably bereft of studies meeting the requirements of known planned place of birth, documented caregiver credentials, and comparable risk status across comparison groups.

This is a result in part due to their reliance on birth certificate data which in most states does not contain these elements. A recent synthesis of 24 studies evaluating the validity and reliability of birth certificate data in the US concluded that birth certificates are not valid sources of information on tobacco and alcohol use, prenatal care, maternal risk, pregnancy complications, or labor and delivery.¹¹ Accuracy of documentation varies by type of caregiver,¹² introducing an obvious systematic bias in studies with type of caregiver as an exposure of interest. Furthermore, the type of caregiver reported at birth has been shown to be inaccurate.¹³ Grünebaum et al. highlighted this problem in their paper reporting on Apgar scoring in out-of-hospital settings. They indicated that there was an *inexplicable* bias of high 5 minute Apgar scores in out of hospital births. Since this study was also not able to ascertain the planned vs. unplanned status of the birth it cannot be stated that the Apgar score was even assigned by a birth attendant. Apgar scores may have been assigned on arrival at hospital after an unplanned home birth, potentially at a time when the baby's condition was significantly changed. Even the most unsophisticated student of health research methods would refrain from drawing conclusions where the intended place of birth, and the qualifications of the caregiver (midwives are categorized as certified midwives or "other" midwives) are unknown. Further, the authors state that assignment of Apgar scores is done by one individual. Outside of the US this is not true. Births in Canada, for example, are attended by two midwives or a credentialed second attendant, usually a registered nurse. In Holland a certified second attendant is usually present as well.

Undeterred, Grünebaum et al. utilized birth certificate data from 2010-2012 to study risk factors among women planning birth at home.¹⁴ This study, demonstrated that certified nurse midwives (CNM) and "other" midwives were delivering high risk women at home, including vaginal breech deliveries, and twin gestations. These factors would be outside the scope of practice of midwives in Canada, the UK or the Netherlands. Again, the qualifications of "other" midwives are unknown and it is possible that a significant number of these are untrained attendants who call themselves midwives.¹⁴ It may also be true (but can't be verified) that some of these births were unplanned at home and potentially unattended and that birth certificates were signed by receiving caregivers at hospitals. Another recent study utilizing birth certificate data for 27 states in the US found that planned home births were associated with increased neonatal complications, but were similarly unable to distinguish between births that were attended by regulated vs. non-regulated midwives.¹⁵

A study of neonatal mortality in relation to birth setting in the US, 2006-9, again by Grünebaum et al, used birth certificates linked to infant death certificates; this study compared births attended by physicians and midwives in the hospital versus free standing birth centres and home births.¹⁶ This data did not permit ascertainment of planned place of birth, nor were they able to distinguish between regulated and unregulated midwives. Unplanned home births are well known to be associated with adverse outcomes because they sometimes occur in emergency situations such as precipitate preterm birth in which the mother was unable to get to hospital quickly enough to give birth there. Furthermore, in the US there are a number of different systems of credentialing midwives, including certified nurse midwifery, certified midwifery, certified professional midwifery, and licensed midwifery, and the credentialing process differs by state. Birth certificates do not distinguish between these categories of credentialed midwives or lay midwives who have been trained through apprenticeship models. This

shortcoming makes the findings of these American studies uninterpretable. Other countries such as the Netherlands, Canada, the UK, New Zealand, Germany, and France have unified standards for credentialing midwives after standardized formal training programs.

Continuing on, the study of Apgar score of 0 at 5 minutes and neonatal seizures in relation to birth setting by Grünebaum and colleagues reports an increased risk of these outcomes in out-of-hospital settings, based on birth certificate data.¹⁷ In addition to the inability to determine the qualifications of midwives attending home births, the authors note another significant limitation of birth certificate data accessed through the US Centres for Disease Control; they are unable to distinguish hospital births that resulted from transfer from home birth settings. This negates the critical evaluative component of known place of planned birth. It should be of concern that these studies with major design flaws were without exception published in the American Journal of Obstetrics and Gynecology. This was also the journal that published the now infamous meta-analysis by Wax et al.¹⁸

The statistical analysis upon which Wax's conclusions were based contained numerical errors, inclusion of outdated studies, mischaracterization of cited works, and non-standard definitions of mortality.¹⁹ In addition, the software tool used for nearly two thirds of the calculations contained errors that resulted in at least one spuriously statistically significant result. Despite the publication of statements and commentaries querying the reliability of the findings, and the published errata,²⁰ this faulty study formed the evidentiary basis for the American college of Obstetricians and Gynecologists Committee Opinion.²¹ The article by Pang et al. from the US in which provided more than half of the neonatal deaths for the meta-analysis contained an unknown number of unplanned homebirths, which the authors themselves acknowledged.²² The de Jonge study, which contributed more than 95% of the births used in the analysis, was excluded from the calculation of neonatal deaths. Its inclusion would have reversed the finding on neonatal mortality to indicate that the rate was reduced in planned home compared to births.³

Women's Experience of Home Birth

The international literature reports consistent factors associated with a woman's decision for home birth. They include a desire to have more control over the birth process, increased comfort in a familiar environment, more involvement from partners and family, enhanced opportunity for mobility, and avoidance of medical interventions.²³ Recent Canadian studies support these findings. A qualitative study of 500 women reported that women who had begun their labour at home believed that they could contribute actively in decision-making during their births, involve the whole family, and be in control of their environment and in the labour process. A qualitative study from Ontario and British Columbia²³ interviewing 35 women who had had or were planning a home birth reported that women felt that they would have more choice for pain management and other ways or coping in labour, including physical activity, uninhibited ability to eat and drink, the ability to control the room temperature, lighting and other aspects of the environment, including use of music, unlimited numbers of support persons and the choice to have water birth. They valued privacy in the home environment, and felt that they would be more relaxed, which in turn would facilitate the labour process. Benefits for

the baby were also mentioned, including unmedicated birth, skin-to-skin contact and co-sleeping.²⁴ Planning home birth was also an explicit means of avoiding perceived discomforts and dangers of hospital including avoiding the drive to hospital while in labour and prevention of acquiring infections in hospital.

A sense of control during labour, as an important component of satisfaction with the childbirth experience,²⁵ has been compared among women planning home or hospital births. A Canadian study reported significantly higher scores on a standardized scale of labour agency. Women who had planned a home birth more often experienced a sense of being with others who cared, of actively striving, of having a sense of perspective on what was happening, and of having a sense of success. Women who planned hospital birth more often felt powerless, awkward, incapable, fearful, confined, and anxious. The hospital group more often reported not knowing what to expect from one moment to the next and of not being in control. In a Dutch study of 2112 women²⁶, using the same scale,²⁷ there was no difference in feelings of control among women requiring transfer during labour from home to hospital compared to women requiring transfer of care to a physician in hospital. Sense of control was decreased when transfer of care occurred in both groups. This sense of loss of control can be mitigated by midwives handing over care in person and remaining involved in care during the hospital stay.²⁸ Rates of transfer to hospital during planned home birth vary widely among settings, and a range of 7.4-16.5% was reported in a 2007 review of 38 studies.²⁹ Rates of transfer in the Netherlands have been rising and are reported to be 26.2% for indications arising during the intrapartum period in 2004.³⁰ The rate of transfer for the Hutton study in Canada was 8.06% (data not published, courtesy of author, Dr. Hutton, Oct 31, 2015). More recently studies of women's satisfaction in Europe using the Mackey Childbirth Satisfaction Scale³¹ similarly reported higher scores for birth satisfaction among women planning home vs. hospital care.³²

The Cost of Home Birth

The largest economic analysis of home birth to date was conducted in the UK.³³ A cost-effectiveness analysis was undertaken according to planned place of birth among 64,531 births. A cost effective analysis weights the cost of providing care against the cost of managing adverse outcomes that are a consequence of care. This study concluded that planned home birth was the most cost effective option for multiparous women at low risk of complications, and for nulliparous women, was likely to be the most cost effective but was associated with an increase in the primary outcome. The primary outcome referred to here was a composite outcome comprised of vastly differing conditions in terms of impact; from a fractured clavicle with virtually no long term sequelae to perinatal mortality. Rates of stillbirth and neonatal death were not different among comparison groups as listed under *Safety of Home Birth*, above. This study was limited by voluntary participation of hospitals, birth centres, and midwives, with high but not complete ascertainment of eligible births, estimation of cost data from finance departments and secondary sources rather than actual cost data, and a limited time horizon extending only to the period immediately after labour and delivery.

A recently published Canadian economic analysis reported costs for the intrapartum period up to 8 weeks postpartum for mothers and one year of age for infants. This study has is the first to report economic indicators to one year of age, and thus reflects any “hidden” costs of home birth such as brain injury that are not diagnosed in the immediate postnatal period. Costs for all women planning home birth with a regulated midwife in the Province of British Columbia were compared with those of all women who met eligibility requirements for home birth and were planning to deliver in hospital with a registered midwife, and with a sample of women of similar low risk status planning birth in the hospital with a physician. Costs of physician service billings, midwifery fees, hospital in-patient costs, pharmaceuticals, home birth supplies, and emergency transport were included.

The hospitalization cost was derived by multiplying the In-Patient Resource Intensity Weight (P-RIW) by the Cost Per Weighted Case (CPWC) for the corresponding site and fiscal year. The RIW measures the intensity of resources used based on patient diagnosis, surgical procedure performed and the case mix group assigned to the individual patient. Case mix is an inpatient grouping methodology used in Canada to create discrete clusters of patients using clinical, administrative and resource consumption data. The case mix group takes into consideration the patient’s age, health status, and discharge status. The result is groups of patients that are clinically similar and/or homogeneous with respect to hospital resources used.³⁴ The Canadian Institute for Health Information (CIHI) defines RIWs for case mix groups. RIWs for individuals are available from the Discharge Abstract Database. To convert the RIWs into actual dollars, the RIW is multiplied by the CPWC. When the total expenditures for inpatient care in a particular acute care hospital for one year is divided by the total weighted cases of the same hospital during the same year, the result is the average cost of providing care to a patient with a weighted case value of 1.00. Thus, the CPWC is the cost of a stay with a weight of 1.00. The CPWC is different for each hospital each year. Province-wide CPWCs for the study period were obtained from the BC Ministry of Health. The CPWC value specific to each year and each hospital was applied when computing costs.³⁵

In the first 28 days postpartum, \$2,338 average cost savings per birth was reported among women planning home birth compared to hospital birth with a midwife and \$2,541 compared to hospital birth planned with a physician. These represent savings of 51.7% and 52.8% respectively. In longer term outcomes, similar reductions were observed, with cost savings per birth at \$1,683 compared to the planned hospital birth with a midwife, and \$1,100 compared to the physician group during the first eight weeks postpartum. These represent savings of 40.5% and 30.8%. During the first year of life, costs for infants of mothers planning home birth were reduced overall. Cost savings compared to planned hospital births with a midwife were \$810 and with a physician \$1,146. These represent savings of 51.3% and 48.7%. Costs were similarly reduced when findings were stratified by parity.

Ethical Considerations in Home Birth

The American College of Obstetricians and Gynecologists issued an Opinion on the topic of Maternal Decision making and Ethics in 2005.³⁶ In creating a framework for ethical decision-making, they note a historical premise of treating a fetus as a separate entity from the mother, legally, philosophically, and practically. The development of techniques for imaging, testing and treating fetuses has led to the

endorsement of the notion that fetuses are independent patients. They note that bioethical models such as that put forward by Dr Chervenak³⁷ have moral obligations for the fetus that are separate from their obligations to pregnant women. The ethics committee responds to this by presenting the opposing viewpoint, that such frameworks tend to distort, rather than illuminate ethical and policy debates.³⁸

In particular approaches such as these emphasize the divergent rather than shared interests of the pregnant woman and fetus, resulting in a view of the maternal-fetal relationships paradigmatically adversarial, when in fact in the vast majority of cases the interests of the pregnant woman and fetus actually converge. They explain their position further by stating that the doctrine of informed consent recognizes the right of individuals to weigh risks and benefits for themselves. Women almost always are best situated to understand the importance of risks and benefits in the context of their own values, circumstances and concerns. Furthermore, medical judgement in obstetrics itself has limitations in its ability to predict outcomes. In this document, the Committee on Ethics has argued that overriding a woman's autonomous choice, whatever its potential consequences is neither ethically nor legally justified. Fallibility – present to various degrees in all medical encounters – is sufficiently high in obstetric decision-making to warrant wariness in imposing legal coercion.

They further note that coercive and punitive policies are potentially counterproductive in that they are likely to discourage prenatal care and successful treatment, adversely affect infant mortality rates, and undermine the physician – patient relationship. In the context of home birth, this opinion would apply to the potential for women to plan birth at home unattended, or with lay midwives. Indeed the prevention of such potentially disastrous occurrences was part of the motivation of legalizing regulated midwifery and home birth in Canada in 1994. In their recommendations ACOG concludes that efforts to use the legal system to protect the fetus by constraining women's decision-making or punishing them for their behaviour erode a woman's basic rights to privacy and bodily integrity and are neither legally nor morally justified.

In a 2013 publication, ethical considerations specific to home birth are discussed by an obstetrician and Professor of Bioethics from the University of Wisconsin.³⁹ After a review of the evidence on home birth, she argues that to ensure patient safety and respect their autonomy, obstetricians are obligated to refer women who desire home birth to the best providers who will offer it; continue respectful antenatal care when sought by those women choosing home birth; provide appropriate consultation to skilled home birth clinicians; and ensure that transfers to hospital are smooth and non-punitive.

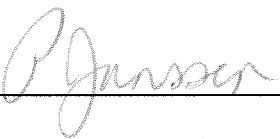
Raymond de Vries, a Professor in Bioethics from the University of Michigan Medical School and colleagues discusses how the science of birth has been used and misused in making ethical arguments about preferred place of birth.⁴⁰ Quoting the Cochrane review by Olson and Clausen,⁴¹ he states that increasingly better observational studies suggest that planned hospital birth is not any safer than planned home birth assisted by an experienced midwife with collaborative medical back up but may lead to more interventions and more complications. However, he reiterates, there is no strong evidence from randomised trials to favour either planned hospital birth or planned home birth for low risk pregnant women. In his discussion of the use and misuse of the science of birth, he draws particular attention to the work of Chervenak⁴² and their colleagues. He draws attention to their use of the Wax metaanalysis¹⁸ without comment of the critiques of the method or the sources of data used or not used, their use of anecdotal reporting, and omission of studies that might contradict their opinions, such

as the studies by de Jonge,³ Janssen,⁴ and Hutton⁵. Further, argues Devries, they dismiss evidence on the safety of home birth from the BirthPlace in England study⁶ by citing the Dutch Minister of Health's comments on the need to be able to provide intervention within 15 minutes of recognition of a concern during planned home birth⁴³ out of context. In fact the Dutch national policy governing hospitals and emergency care state that ambulances must be able to deliver a pregnant women to a hospital within 45 minutes of the time that the call was made.⁴⁴

Conclusion

In summary, the best available evidence on the safety of planned home birth for low risk women attended by regulated midwives compared to planned hospital birth consistently states that home birth has very low and similar risks for fetal or newborn adverse outcomes compared to planned hospital birth. American studies based on birth certificate data are not able to address this question accurately because of the limitations of the data. Home birth is valued by women as they report that enhanced comfort and control over their environment, including mobility and access to nourishment, promotes normal progress of labour. As well, they wish to minimize risk of infection which is higher in hospital settings. Among women requiring transfer to hospital, a sense of control is diminished, but is not less than women undertaking hospital birth. A cost effectiveness analysis from the UK reported that planned home birth was the most cost effective option for multiparous women compared to hospitals or birth centres and likely the most cost effective option for nulliparous women. The small increase in risk for nulliparous women was attributed to non-lethal birth trauma. A Canadian study from the Province of British Columbia reported savings of 30-50% for planned home vs. hospital birth for health costs of women to 8 weeks postpartum and the entire first year of life for the newborn. Ethical arguments put forward by the American College of Obstetricians and Gynecologists emphasize the shared interests of the pregnant women and fetus. Other noted bioethicists interpret this philosophical stance by arguing that obstetricians are obligated to ensure patient safety and respect autonomy by referring women who desire home birth to the best providers who will offer it and continue respectful antenatal care and appropriate consultation and transfer.

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