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Grytten, J., Skau, I., Sørensen, R., & Eskild, A. (2018). Does the Use of Diagnostic Technology Reduce Fetal Mortality? *Health Services Research*, 53(6), 4437–4459. <https://doi.org/10.1111/1475-6773.12721>

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## Does the use of diagnostic technology reduce fetal mortality?

Jostein Grytten, Irene Skau, Rune Sørensen, Anne Eskild

### ABSTRACT

**Objective:** To examine the effect that the introduction of new diagnostic technology in obstetric care has had on fetal death.

**Data Source:** The Medical Birth Registry of Norway provided detailed medical information for approximately 1.2 million deliveries from 1967 to 1995. Information about diagnostic technology was collected directly from the maternity units, using a questionnaire.

**Study Design:** The data were analyzed using a hospital fixed-effects regression with fetal mortality as the outcome measure. The key independent variables were the introduction of ultrasound and electronic fetal monitoring at each maternity ward. Hospital specific trends and risk factors of the mother were included as control variables. The richness of the data allowed us to perform several robustness tests.

**Principal finding:** The introduction of ultrasound caused a significant drop in fetal mortality rate, while the introduction of electronic fetal monitoring had no effect on the rate. In the population as a whole, ultrasound contributed to a reduction of fetal deaths of nearly 20%. For post-term deliveries, the reduction was well over 50%.

**Conclusion:** The introduction of ultrasound made a major contribution to the decline in fetal mortality at the end of the last century.

## INTRODUCTION

We examined the effect that the introduction of new diagnostic technology in obstetric care has had on fetal death in Norway. Fetal death is a devastating outcome of pregnancy, and each year more than 3 million fetal deaths occur worldwide. The incidence varies between populations, from 4 to 40 deaths per 1000 births, but is most likely underestimated in developing countries (Stanton et al. 2006; Smith and Fretts 2007). Sixty per cent of all perinatal deaths are accounted for by stillbirths (Smith and Fretts 2007).

It is assumed that fetal deaths, at least to some extent, can be prevented by correct diagnosis of at-risk pregnancies. The most commonly used fetal diagnostic tools are ultrasound and electronic fetal monitoring (EFM). These are medium to high cost technologies (Leivo et al. 1996; Heintz et al. 2008; Schuler et al. 2010; Henderson et al. 2002). Somewhat surprisingly, to our knowledge, there are no studies in the economic literature where the benefits of these interventions have been assessed. In contrast, there is a large literature within economics where the benefits of medical interventions in neonatal care have been studied (for example see: Cutler and Meara 2000; Almond, Chay, and Lee 2005; Almond et al. 2010; Grytten et al. 2016).

Even within the medical literature, there are few well-designed studies in which the effect of ultrasound and EFM on fetal death have been examined. The studies that exist have their limitations. In particular, they have often been done on small and selected samples. The results may therefore be difficult to generalize to populations that are different from those in the study. For EFM, which is widely used in obstetric care, several studies indicate that its use has no effect on perinatal death (Neilson 2006; Thacker, Stroup, and Peterson 1995; Thacker, Stroup and Chang 2006). The limitations of the existing studies, and the lack of conclusive evidence about potential

effects, have led to debate, often controversial, within the medical profession about guidelines for the use of these technologies (Thacker 1985; Youngblood 1989; Neilson 1993; Parer and King 2000; Goddard 2001).

We examined our research question using a large and unique set of data that contains information about fetal deaths, and detailed medical information about nearly all births in Norway during the period 1967-1995. This is a period where there has been a significant decline in fetal deaths in most western countries, Norway included (Kalter 1991; Fretts et al. 1992; Erickson and Bjerkedal 1982; Haavaldsen et al. 2010). During the same period there has been a rapid increase in the use of ultrasound and EFM. To what extent has the use of these new diagnostic technologies contributed to the decline in the number of fetal deaths?

## TYPES OF INTERVENTION AND BACKGROUND LITERATURE

Within the field of medicine, clinical and experimental studies have been carried out in which the effects of the use of EFM on perinatal outcomes have been studied. The results from these studies have been summarized in Cochrane reviews (Neilson 2006; Thacker, Stroup and Chang 2006) and in an extensive review by Thacker, Stroup and Peterson (1995). The main conclusion from these reviews is that the clinical benefits of EFM are modest. For example, in most studies EFM has no effect on cord blood gases, Apgar score, referrals to neonatal units or infant mortality. One condition in which the use of EFM might have an effect is to reduce neonatal seizures. We have identified only one study in which fetal death has been an outcome measure (Leveno et al. 1986). In that study the use of EFM did not lead to a reduction in the number of fetal deaths.

The use of ultrasound was introduced a few years later than EFM. The clinical benefits are: more accurate gestational age assessment, detection of multiple fetuses and fetal malpresentations (for example breech), and diagnosis of placenta praevia (Bricker, Neilson, and Dowswell 2015). The use of ultrasound is meant to be particularly useful for identifying pregnancies that have gone beyond term (Savitz et al. 2002). In these pregnancies there is an increased risk of fetal death, which partly arises from asphyxia and/or birth injury (Hilder, Costeloe and Thilaganathan 1998; Doherty and Norwitz 2008; Olesen, Westergaard, and Olsen 2003). In twin pregnancies, the risk of perinatal death is five times greater than for single pregnancies (Botting, Davies, and Macfarlane 1987). The use of ultrasound improves early detection of twin fetuses (Saari-Kemppainen et al. 1990). Placenta praevia occurs in about 0.5% of all pregnancies, and is associated with considerable risks for both the fetus and the mother (Crane et al. 1999). The best method for locating the position of the placenta is the use of ultrasound.

Numerous studies have been carried out in which the benefits of using ultrasound as a screening tool for fetal assessment have been assessed. The results have been summarized in several Cochrane reviews (Bricker, Neilson, and Dowswell 2008; Bricker, Medley, and Pratt 2015; Neilson 1998; Whitworth et al. 2010) and in an extensive review by Haws et al. (2009). These reviews encompass more than 100 studies. A consistent finding is that using ultrasound as a screening tool has no effect, or only a very small effect, on perinatal mortality and morbidity. However, in most studies there is a lack of statistical power due to small sample sizes. This has led Whitworth et al. (2010) to conclude that “a much larger number of participants would be required to demonstrate that better gestational dating and earlier detection of multiple pregnancy result in improved outcomes for babies”. In his review, Haws et al.

(2009) came to the same conclusion: “Much larger numbers of participants would be required to accurately measure this outcome” (fetal outcome).

One effect that routine ultrasound examination may have is to increase the number of terminations of fetuses with congenital abnormalities. This has been examined in two large randomized controlled trials: the Helsinki trial and the RADIUS trial. The main finding from the Helsinki trial was that routine ultrasound examination led to an increase in the number of terminations of fetuses with congenital abnormalities (Saari-Kemppainen et al. 1990). This finding was not supported in the RADIUS trial from the USA (Crane et al. 1994; Ewigman et al. 1993)<sup>1</sup>.

There are several descriptive studies in which the rate of termination of fetuses with congenital abnormalities have been reported (Dolk, Loane, and Garne 2010; Svensson et al. 2014; Barisic et al. 2001; Garne et al. 2005). Most of these studies were performed during a time period when routine ultrasound examination had already been introduced - from the 1990s and onwards. In the large study of European Surveillance of Congenital Anomalies (2003-2007), the prevalence of congenital abnormalities was estimated to be 2.39% of all livebirths, fetal deaths and terminated pregnancies (Dolk, Loane, and Garne 2010). Of these, 80% were livebirths, 2% were fetal deaths and 18% were terminated pregnancies. Fairly similar results have been reported from other studies (Svensson et al. 2014; Barisic et al. 2001; Garne et al. 2005).

## MATERIAL AND METHODS

### *The institutional setting for maternity services in Norway*

In Norway, all health services, maternity care included, are financed through taxes. Government policy is that everyone is entitled to free health care at the point of delivery and equal access given equal need (Ministry of Health 2002). Antenatal health care is offered to all women free of charge. Almost 100% of pregnant women follow the programme from early pregnancy. From week 9 in the pregnancy until the expected date of delivery, mothers have seven antenatal clinical examinations with a midwife and/or a doctor (Norwegian Directorate of Health and Social Affairs 2005). During pregnancy weeks 17-18, all women have an ultrasound examination to determine gestational age, and to detect multiple fetuses and the localization of the placenta. These ultrasound examinations were gradually introduced as part of antenatal care from the late 1980s and the beginning of the 1990s.

Nearly all deliveries take place in hospitals. Only 0.3% of all deliveries take place at home (Blix, Øian, and Kumle 2008). Hospitals are publically owned and financed, with obstetricians who receive a fixed salary. For further details about the organization of hospital services in Norway see: Grytten et al. 2014.

### *The source of the data*

The analyses were carried out on data from the Medical Birth Registry of Norway (MBRN) for the period 1967 to 1995 ([www.fhi.no](http://www.fhi.no)). All maternity units are required to report all births to MBRN (Irgens 2000). Data from MBRN were merged with two data registers. The first register contains information about immigrant background for all first generation immigrants (Statistics Norway 2015). The second register, the



Norwegian Standard Classification of Education (Statistics Norway 2000), contains information about the highest education for all Norwegians.

Information about use of diagnostic technology was collected using a questionnaire that was sent to all senior consultants in every maternity unit in all the hospitals in the country. We asked them to provide the following information: “Enter as accurately as possible the five-year interval your hospital introduced the use of ultrasound and electronic fetal monitoring”. The response options were the following: the first interval was 1967-1969, then each 5-year interval from 1970 to 2004. We restricted the analysis to the period 1967-1995, as all maternity units had introduced ultrasound and EFM by the early 1990s. The survey was carried out by the Norwegian Medical Association’s Research Institute in 2008. The response rate was high. 44 of 46 senior consultants replied. During the period covered by our study, some maternity units have been closed down, so that it was not possible to send a questionnaire to them. Therefore, the analyses could only be done for maternity units that had existed for the whole period 1967-2008.

We have data for approximately 1.2 million deliveries (live born and still born) distributed among 44 maternity units. Throughout the period 1967-1995, there were about 1.5 million births in Norway. Previous analyses have shown that our sample is representative of the whole population of mothers who gave birth in Norway 1967-1995 (Grytten, Skau, and Sørensen 2011).

#### *Specification of the main model*

We defined two dummy variables for the two technologies. For each of the two variables, the value of the variable was 0 for each 5-year interval before it was

introduced, and 1 from the 5-year interval in which it was introduced, and subsequently. Our core regression model is then defined as:

$$\begin{aligned}
Y_{ijt} = & \alpha + \beta_1 \text{Ultrasound}_{jp} + \beta_2 \text{EFM}_{jp} + \sum_c \gamma_c \cdot \text{Control}_{ijt}^c \\
& + \sum_j \delta_j \cdot \text{Hospital}_j + \phi \cdot t + \sum_j \eta_j \cdot \text{Hospital}_j \cdot t \\
& + u_{ijt}
\end{aligned} \tag{1}$$

where  $Y_{ijt}$  is a binary variable indicating a stillborn baby  $i$  delivered at hospital  $j$  in year  $t$  (from 1967 to 1995) in period  $p$  (five-year interval). Stillborn is defined as a baby born with no signs of life at or after 28 completed weeks of gestation (WHO 2017; The Lancet 2016). The different types of technology may have different effects, according to length of gestation. In particular, this may be the case for the use of ultrasound, which is meant to be particularly useful for detecting prolonged pregnancies. Therefore, separate regressions were run for the following lengths of gestation: less than 37 completed weeks (pre-term), from 37 completed weeks to less than 42 completed weeks (term) and 42 completed weeks or more (post-term) (WHO 2006, 2016).

In order to take account of potentially confounding effects, Equation (1) includes several controls: First, the equation includes fixed hospital effects. This was done in order to control for all time-invariant heterogeneity between hospitals, for example differences in the quality of obstetric care. Second, the equation includes the birth year, which controls for common and stabilizing trends that could affect the number of fetal deaths, for example better living standards and public health measures such as

improved nutrition. To take into account that the time trend could have different effects for infants born in the different hospitals, hospital specific trends were also included using a set of interaction terms,  $Hospital_j \cdot t$ . Third, Equation (1) includes controls for several risk factors of the mother. These are variables that are well described in the literature, and that have been shown to be correlated with fetal death (for reviews see: Flenady et al. 2011; Gardosi et al. 2013; The Stillbirth Collaborative Research Network Writing Group 2011).

Risk factors of the mother that reduce the chance of survival of the fetus are: whether she had previously had a fetus that had died, whether she had previously had a Cesarean delivery, whether she was younger (<25 years old) or older (>35 years old) when she gave birth, whether the pregnancy was her first (null parity), and whether she had a chronic disease or not. The mothers were classified as having a chronic disease if they had one or more of the following diseases: asthma, diabetes, epilepsy, heart disease, chronic hypertension, chronic kidney failure, rheumatoid arthritis. The number of fetal deaths are fewer for mothers with a high level of education than for mothers with a low level of education, and for European immigrant mothers than for non-European immigrant mothers. We do not report the regression coefficients for the control variables, as they had the same signs and were of similar size as previously reported in the literature (Flenady et al. 2011; Gardosi et al. 2013; The Stillbirth Collaborative Research Network Writing Group 2011).

We clustered the standard errors at the hospital level to account for positive serial correlation and within hospital correlation (Cameron and Miller 2015).

### *Analyses of congenital abnormalities*

With the introduction of routine ultrasound examination during pregnancy in weeks 17-18, fetuses with serious congenital abnormalities are detected that would not have been detected previously. Some of these pregnancies are terminated. This means that the number of children with a high risk of being stillborn is reduced. This might bias the results of our study in that the beneficial effect of the introduction of ultrasound is overestimated.

We were able to test whether the introduction of ultrasound led to a decrease in the prevalence of infants with congenital abnormalities. This would be the case if there had been an increase in the number of elective terminations during the study period 1967-1995. We re-estimated Equation (1) with a new binary dependent variable. This variable was given the value 1 for infants (stillborn and liveborn) who were diagnosed at birth as having a congenital abnormality<sup>2</sup>; 0 otherwise.

## RESULTS

### *Descriptive statistics*

During the period 1967-1995, in the population as a whole, there has been a marked decline in the proportion of fetal deaths: from 1.3% to 0.04% (Figure 1). The decline was particularly large for post-term deliveries: from 0.9% to 0.2%. For the whole period, the highest proportion of fetal deaths was for pre-term deliveries.

Figure 1 here

By the second half of the 1970s, 30 of the 44 maternity units had EFM (Appendix 1). This increased to 41 units by the first half of the 1980s. Ultrasound was introduced during a short time span from the second half of the 1970s to the first half of the 1980s. By the end of the 1980s, 43 of the 44 maternity units had ultrasound.

*Effects of the use of technologies on fetal deaths and on congenital abnormalities*

For the population as a whole, the use of ultrasound had a negative and significant effect on fetal death (Table 1). In two different model specifications, with and without hospital specific trends included in Equation (1), the size of the regression coefficient was in the range -0.0013 to -0.0014. This figure was slightly larger in a specification where the control variables were not included. During the period 1967-1995, the proportion of fetal deaths was 0.00688 (Table 1). Evaluated at this proportion, our results imply that the use of ultrasound has contributed to a reduction in fetal deaths of nearly 20%. Estimated on the whole population, the regression coefficients for the use of EFM, were far from being statistically significant at conventional levels in any of the model specifications.

For pre-term deliveries, the use of ultrasound had no effect on fetal death (Table 1). The use of EFM had a statistically significant effect at the 10 per cent level in the model specification with hospital specific effects and control variables included. However, the sign of the regression coefficient was incorrect. For term and post-term deliveries, the use of EFM had no effect on fetal death.

For the use of ultrasound, the regression coefficient was largest for post-term deliveries (Table 1). In a model where control variables, hospital specific effects and hospital specific linear trends were included, the use of ultrasound reduced the

probability of fetal death by 0.0021. In post-term deliveries, the proportion of fetal deaths was 0.00368 (Table 1). Evaluated at this proportion, our results imply that the use of ultrasound has contributed to a reduction in fetal deaths of more than 50%.

The regression coefficients for term deliveries were half the size as those for post-term deliveries. The sizes of the coefficients were in the range -0.0009 to -0.0010 in different specifications ( $p < 0.05$ ). In term deliveries, the proportion of fetal deaths was 0.00365 (Table 1). Evaluated at this proportion, our results imply that the use of ultrasound has contributed to a reduction in fetal deaths of nearly 30%.

In the analyses with congenital abnormalities as the dependent variable, the regression coefficients for ultrasound and EFM were small, and far from being statistically significant at conventional levels. This was the case for all lengths of gestation (Appendix 2).

### *Supplementary analyses*

#### *Leads and lags*

An advantage with our data is that it was possible to check whether the significant coefficients for ultrasound were biased due to unobservable variables. This was done by redefining Equation (1) to capture pre- and post-intervention effects. We defined the following variables: The contemporaneous effect was defined as 1 in the five-year period when ultrasound was introduced and 0 in all other periods. The lead dummy variable was equal to 1 in the (five-year) period preceding the introduction of ultrasound, and 0 otherwise. The lagged dummy was equal to 1 in the first period after the introduction (=5 years after) and later.

In these regressions, we did not expect the lead variable to have any effect on our outcome. This is supported by our results (Table 2). The estimates for the lead variable were not statistically significant at conventional levels. This was the case for the whole population, and for the two subsamples of term and post-term deliveries. These results are in clear contrast to the effects of the lag variable. The coefficients for the lag variable were of a reasonable size, they had the correct sign (negative), and they were statistically significant at conventional levels.

The estimates for the variable measuring the contemporaneous effect were negative and statistically significant at conventional levels. Interestingly, the coefficients for the lag variable were larger in absolute values than the coefficients for the variable measuring the introductory period; i.e. there were some delayed effects. This may be because it takes some time for the health personnel to be familiar with when and how to use ultrasound.

#### *Alternative trend specifications and fewer periods*

Equation (1) was specified with a linear time trend. We re-estimated Equation (1) with quadratic and cubic time trends. The results from this estimation (Table 3) were fairly similar to the results from our main analyses as presented in Table 1.

Our main analyses were performed using data from a period of more than 20 years. The 44 hospitals were then included in the estimation with *at least* one pre- and one post-intervention period (5-year interval). Naturally, some hospitals had more than one pre- and/or post-intervention period. It is reasonable to assume that the more years included in our analyses, the more vulnerable are our estimates of bias, due to unobservable variables. We took this into account by re-estimating Equation (1) on samples with fewer periods.

In the first sample, each type of technology was included with three periods: pre-intervention, intervention and post-intervention (altogether 15 years). In the second sample, each type of technology was included with two periods only: pre-intervention and intervention (altogether 10 years). The analyses were done for each type of technology separately, but with control variables, hospital specific effects and hospital specific linear trends included. For the use of ultrasound, the regression coefficients were negative and of the same size as the regression coefficients from the main analyses reported in Table 1. For the use of EFM, the regression coefficients had the incorrect sign (positive), and they were far from being statistically significant at conventional levels.

*Do the effects of the use of the technology persist after birth?*

This hypothesis was tested by estimating Equation (1) where  $Y_{ijt}$  was redefined to be a binary variable indicating fetal death and infant mortality. The effects of the use of ultrasound were negative and significant, both in models with and without hospital specific trends (Table 4). This implies that liveborn babies would also survive the first year after birth.

For the use of ultrasound, the estimates of the regression coefficients reported in Table 4 were slightly larger than the estimates reported in Table 1. This could indicate an additional gain in survival after birth. This was tested by running separate regressions where  $Y_{ijt}$  was redefined to be a binary variable indicating infant mortality only. The regression coefficients were small, and were far from being statistically significant at conventional levels (Table 4). Therefore, we cannot conclude that the use of ultrasound has an additional effect on survival during the first year after birth.



For the use of EFM, the regression coefficients were negative, but far from being statistically significant at conventional levels (Table 4). These findings support our previous result that EFM has no effect on fetal death. In addition, they show that EFM has no effect on survival after birth.

## DISCUSSION

EFM and ultrasound are commonly used in obstetrics. For example, in the United States in the early 1990s, nearly three of four pregnancies were monitored by EFM (Thacker, Stroup, and Chang 2006). Within the medical literature there is a lack of evidence to show that the use of these technologies has clinical effects. For the use of EFM, our results support the evidence from the medical literature. For the use of ultrasound, we found beneficial effects. This result is contradictory to that found in most studies.

Most studies within medicine where the effects of the use of these technologies have been examined, are randomized controlled trials and clinical field studies. One limitation of these studies is that the number of participants is too low to detect differences in outcome. For example, numerous studies have less than a few thousand participants. There are only a few studies with more than 10 000 participants (for a summary of studies see: Bricker, Neilson, and Dowswell 2008; Bricker, Medley, and Pratt 2015; Neilson 1998; Whitworth et al. 2010). Large sample sizes are needed, because the prevalence of the outcome variable (fetal death) is low. Our set of data is large. It encompasses nearly the whole population from a period where there was a marked decrease in fetal deaths. Thus, our analyses should have the potential to detect real differences in outcome, if there were any. Therefore, it is unlikely that the

lack of significant effects for the use of EFM can be explained by lack of statistical power.

Our results have implications for technology evaluation within obstetric care. For example, the use of EFM can be reduced, without that leading to an increase in fetal deaths. This in itself will lead to cost savings in obstetric care. There is a fairly strong association between the use of EFM and the number of Cesarean deliveries (Thacker et al. 2006; Placek et al. 1984; Haverkamp et al. 1979). Therefore, with less use of EFM, the number of Cesarean deliveries is likely to be reduced. Fewer Cesarean deliveries will then lead to further cost savings. Ultrasound reduces the number of fetal deaths. The evidence from the literature on health technology assessment indicates that the benefits of the lives saved largely outweigh the costs of saving these lives (Cutler and Meara 2000; Cutler, Meara, and Richards-Shubik 2012).

The effect of ultrasound in reducing the number of fetal deaths was most pronounced for post-term deliveries. This indicates that an important way in which ultrasound reduces fetal death is by enabling more accurate assessment of gestational age. It is also likely that the use of ultrasound for detecting multiple fetuses and for diagnosing placenta praevia has contributed to the decrease in the number of fetal deaths. We were not able to investigate this specifically, because the prevalence of these conditions was too low. Most fetal deaths occur for pre-term deliveries. For these fetuses ultrasound had no effect in reducing the number of deaths. This may be because these fetuses were not viable, for example due to malformation or abnormal growth.

We did not find that the introduction of ultrasound led to a decrease in the prevalence of infants with congenital malformations (Appendix 2). One likely explanation for this result is that a large proportion of fetuses with congenital

abnormalities – about 50% in several studies – is not detected by routine ultrasound screening (Rosendahl and Kivinen 1989; Crane et al. 1994; Levi et al. 1991; Saari-Kemppainen et al. 1990; Grandjean et al. 1998a)<sup>3</sup>. If they are detected, not all mothers decide to terminate the pregnancy. In Norway, for mothers who decide to terminate the pregnancy, the criteria for being given permission to have an abortion after week 12 of the pregnancy are strict: “There has to be a great risk that the child will suffer from a serious disease as a result of a genetic problem or problems encountered during the pregnancy” (Ministry of Health and Care Services 2017). The criteria in Norway were the same during the whole study period, and they are strict compared to other European countries (Ministry of Health and Social Affairs 1995; NordForsk 2014; Boyd et al. 2008; Garne et al. 2005; Library of Congress 2015). National figures are available on the number of elective terminations due to congenital abnormalities from 1979 and onwards (Norwegian Institute of Public Health 2016). During the period 1979-1990, 329 terminations were carried out, a mean of 27 per year. This constitutes less than 10% of all fetal deaths per year. These figures are so small that it is unlikely that the lack of data on elective terminations in our study has led to any significant bias in our results.

Our study had some advantages that improve the credibility of the results. First, the study was carried out on a population in which neither the pregnant mother nor the obstetrician had economic incentives that could influence whether the mother received care or not, or which type of diagnostic technology was used. Second, in the analyses we had extensive controls for risk factors<sup>3</sup> of the pregnant mother. After inclusion of all these control variables, it is unlikely that the results were biased due to unobservable risk factors that were correlated with the timing for when the technologies were introduced. Third, we used hospital fixed effects and hospital

specific trends in the estimations. The hospital specific trends would pick up non-observable characteristics that could vary within hospitals over time. Fourth, we carried out analyses with different trend specifications, and with leads and lags. The results from these analyses did not weaken our main results.

There are two limitations of the study: First, we lack data on elective terminations. This might have led to a small, but probably not significant bias in our results. Second, we lack data on the exact year in which each of the diagnostic technologies was introduced. This might have led to some bias in our results. However, our supplementary analyses with leads and lags, and with fewer periods, indicates that if there is a bias, it is not large.

In conclusion, our study showed that the introduction of ultrasound during the 1970s and 1980s made a significant contribution to the decline in the number of fetal deaths in Norway. The introduction of EFM made no contribution. These results are important, as they provide insight into the effectiveness of the use of diagnostic technology in preventing stillbirths.

## ACKNOWLEDGEMENTS

We wish to thank Linda Grytten for language correction and the Medical Birth Registry and Statistics Norway for providing data. This study had financial support from the South-Eastern Norway Health Authority; research grant number 2709002.

## CONFLICT OF INTEREST

The authors have no conflict of interest.

## NOTES

1. Two other trials have investigated the effects that routine ultrasound examination has on perinatal outcomes (Waldenström et al. 1988; Bakketeig et al. 1984). In these two trials, the rate of termination of fetuses with congenital abnormalities is not reported.

2. Includes the following abnormalities: anencephalus, spina bifida, encephalocele, hydrocephalus, microtia, transposition of the great vessels, hypoplastic left heart, cleft palate without cleft lip, cleft lip with or without cleft palate, esophageal atresia, ano-rectal atresia, hypospadias, renal agenesis, limb reduction defects, diaphragmatic hernia, omphalocele, gastroschisis and Down's syndrome.

3. The detection rate varies according to the type of organ in which the congenital abnormality occurs (DeVore 1998; Skupski 1998; Valentin and Marsál 1998; Grandjean et al. 1998b). The detection rate is high for anencephalus (94%) and low for transposition of the great arteries (27%) (Garne et al. 2005).

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Table 1: The effects of the use of ultrasound and electronic fetal monitoring on fetal death. Regression coefficients with standard errors clustered at the hospital level in brackets. 1967-1995

Type of technology	Whole population <sup>1</sup>			Gestational age period					
				Pre-term <sup>2</sup>		Term <sup>3</sup>		Post-term <sup>4</sup>	
Ultrasound	-0.0014 ** (0.0004)	-0.0013 ** (0.0004)	-0.0016 ** (0.0005)	-0.0007 (0.0030)	0.0010 (0.0034)	-0.0009 ** (0.0003)	-0.0010 ** (0.0003)	-0.0019 ** (0.0005)	-0.0021 ** (0.0006)
Electronic fetal monitoring	0.00001 (0.0005)	-0.0002 (0.0005)	-0.0003 (0.0005)	0.0086 * (0.0045)	0.0040 (0.0047)	-0.0003 (0.0003)	-0.00020 (0.0003)	-0.0003 (0.0006)	0.00001 (0.0007)
Control variables included	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes
Linear trend (year)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Hospital fixed effects	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Hospital fixed effects x linear trend	No	Yes	Yes	No	Yes	No	Yes	No	Yes
Number of fetal deaths	8 024	8 024	8 263	4 007	4 007	3 386	3 386	631	631
Total <sup>5</sup>	1 166 613	1 166 613	1 199 475	69 365	69 365	926 041	926 041	171 207	171 207

\* p<0.10, \*\* p<0.05

<sup>1</sup> 28 completed weeks or more of gestation

<sup>2</sup> From 28 completed weeks to less than 37 completed weeks of gestation

<sup>3</sup> From 37 completed weeks to less than 42 completed weeks of gestation

<sup>4</sup> 42 completed weeks or more of gestation

<sup>5</sup> Includes number of live born infants and number of fetal deaths



Table 2: Lead and lag effects for the use of ultrasound on fetal death. Control variables included in all analyses. Regression coefficients with standard errors clustered at the hospital level in brackets. 1967-1995

Variables	Whole population <sup>1</sup>		Gestational age period			
			Term <sup>2</sup>		Post-term <sup>3</sup>	
Lead	-0.0007 (0.0005)	-0.0008 (0.0008)	-0.0006 (0.0004)	-0.0003 (0.0004)	-0.0005 (0.0008)	-0.0012 (0.0014)
Introductory period (contemporaneous effect)	-0.0018 ** (0.0006)	-0.0016 * (0.0009)	-0.0012 ** (0.0004)	-0.0008 ** (0.0004)	-0.0020 ** (0.0008)	-0.0032 ** (0.0015)
Lag	-0.0026 ** (0.0008)	-0.0023 ** (0.0012)	-0.0016 ** (0.0006)	-0.0011 ** (0.0005)	-0.0026 ** (0.0011)	-0.0041 ** (0.0018)
Linear trend (year)	Yes	Yes	Yes	Yes	Yes	Yes
Hospital fixed effects	Yes	Yes	Yes	Yes	Yes	Yes
Hospital fixed effects x linear trend	No	Yes	No	Yes	No	Yes
Number of fetal deaths	8 024	8 024	3 386	3 386	631	631
Total <sup>4</sup>	1 166 613	1 166 613	926 041	926 041	171 207	171 207

\* p<0.10, \*\* p<0.05

<sup>1</sup> 28 completed weeks or more of gestation

<sup>2</sup> From 37 completed weeks to less than 42 completed weeks of gestation

<sup>3</sup> 42 completed weeks or more of gestation

<sup>4</sup> Includes number of live born infants and number of fetal deaths

Table 3: The effects of the use of ultrasound and electronic fetal monitoring on fetal death. Alternative trend specifications and fewer periods. Control variables included in all analyses. Regression coefficients with standard errors clustered at the hospital level in brackets. Whole population

Type of technology	Quadratic time trends	Cubic time trends	Three 5-year periods	Two 5-year periods
Ultrasound	-0.0013 ** (0.0004)	-0.0013 ** (0.0004)	-0.0012 ** (0.0004)	-0.0008 (0.0006)
Number of fetal deaths	8 024	8 024	4 159	3 080
Total <sup>1</sup>	1 166 613	1 166 613	563 382	367 217
Electronic fetal monitoring	-0.0002 (0.0005)	-0.0002 (0.0005)	0.0007 (0.0005)	0.0004 (0.0005)
Number of fetal deaths	8 024	8 024	4 302	3 054
Total <sup>1</sup>	1 166 613	1 166 613	551 133	345 926

\*\* p<0.05

<sup>1</sup> Includes number of live born infants and number of fetal deaths

Table 4: The effects of the use of ultrasound and electronic fetal monitoring on fetal death and infant mortality. Control variables included in all analyses. Regression coefficients with standard errors clustered at the hospital level in brackets. Whole population 1967-1995

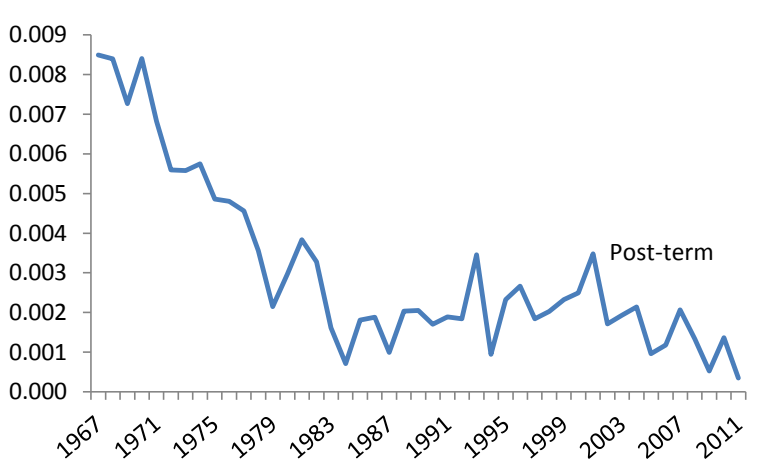
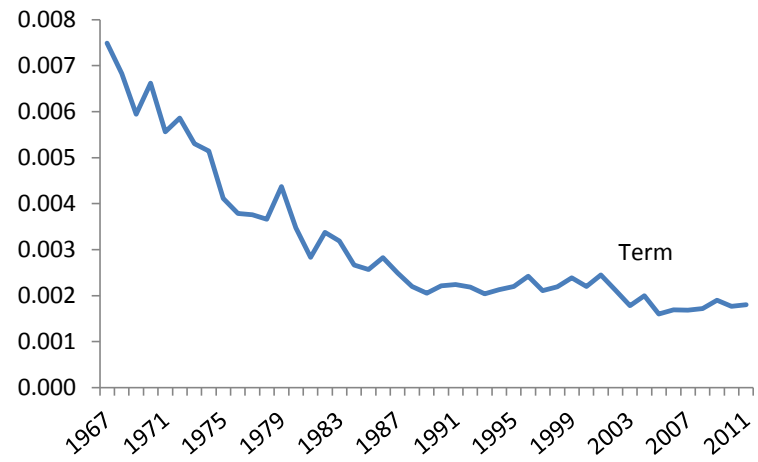
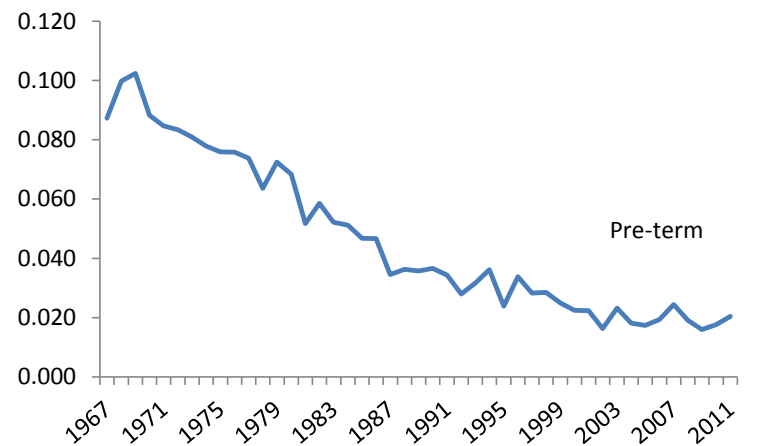
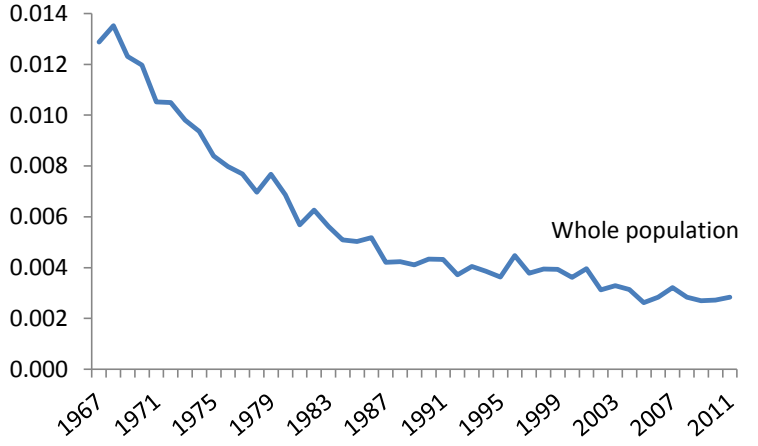
Type of technology	Whole population <sup>1</sup>		Population of all live born infants <sup>2</sup>	
Ultrasound	-0.0019 ** (0.0006)	-0.0021 ** (0.0006)	-0.0002 (0.0004)	-0.0006 (0.0005)
Electronic fetal monitoring	-0.0005 (0.0007)	-0.0005 (0.0006)	0.00001 (0.0005)	-0.0003 (0.0004)
Linear trend (year)	Yes	Yes	Yes	Yes
Hospital fixed effects	Yes	Yes	Yes	Yes
Hospital fixed effects x linear trend	No	Yes	No	Yes
Number of deaths	16 419	16 419	8 391	8 391
Total	1 166 613	1 166 613	1 158 367	1 158 367

\*\* p<0.05

<sup>1</sup> Dependent variable: fetal death and infant mortality

<sup>2</sup> Dependent variable: infant mortality

Figure 1. The proportion of fetal deaths, according to year and gestational age period. 1967-2011



Appendix 1: Percentage of deliveries (n=1 199 475) and number of hospitals according to type of technology and time period of implementation

Time period	Ultrasound		Electronic fetal monitoring	
	Percentage of deliveries	Number of hospitals	Percentage of deliveries	Number of hospitals
<=1970	0	0	0	0
1971-1975	16	3	31	7
1976-1980	74	23	83	30
1981-1985	96	38	96	41
1986-1990	99	43	100	44
1991-1995	100	44	100	44

Appendix 2: The relationship between the use of ultrasound and electronic fetal monitoring and the prevalence of infants<sup>1</sup> with congenital abnormalities<sup>2</sup> 1967-1995. Control variables included in all analyses. Regression coefficients with standard errors clustered at the hospital level in brackets

Type of technology	Whole population <sup>3</sup>		Gestational age period					
			Pre-term <sup>4</sup>		Term <sup>5</sup>		Post-term <sup>6</sup>	
Ultrasound	0.0035 (0.0024)	0.0022 (0.0025)	0.0001 (0.0038)	-0.0020 (0.0035)	0.0037 (0.0023)	0.0031 (0.0020)	0.0022 (0.0025)	0.0007 (0.0029)
Electronic fetal monitoring	-0.0005 (0.0022)	0.0014 (0.0025)	0.0034 (0.0044)	0.0070 (0.0046)	-0.0011 (0.0020)	0.0008 (0.0020)	0.00001 (0.0025)	0.0022 (0.0030)
Linear trend (year)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Hospital fixed effects	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Hospital fixed effects x linear trend	No	Yes	No	Yes	No	Yes	No	Yes
Number of infants with congenital abnormalities	32 410	32 410	3 084	3 084	24 622	24 622	4 704	4 704
Total number of infants <sup>1</sup>	1 166 613	1 166 613	69 365	69 365	926 041	926 041	171 207	171 207

<sup>1</sup>Includes all infants - both stillborn and liveborn.

<sup>2</sup>Includes the following abnormalities: anencephalus, spina bifida, encephalocele, hydrocephalus, microtia, transposition of the great vessels, hypoplastic left heart, cleft palate without cleft lip, cleft lip with or without cleft palate, esophageal atresia, ano-rectal atresia, hypospadias, renal agenesis, limb reduction defects, diafragmatic hernia, omphalocele, gastroschisis and Downs syndrome.

<sup>3</sup> 28 completed weeks or more of gestation

<sup>4</sup> From 28 completed weeks to less than 37 completed weeks of gestation

<sup>5</sup> From 37 completed weeks to less than 42 completed weeks of gestation

<sup>6</sup> 42 completed weeks or more of gestation