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Does the use of diagnostic technology reduce fetal mortality?

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Focus of the present work

- To evaluate clinical practice in maternity care
- To identify high value care care that can save lives:
 - to use a methodology that has the potential to provide causal estimates
 - to provide a scientific basis for the delivery of effective maternity care

Background – fetal deaths

- Each year more than 3 million fetal deaths occur worldwide
- The incidence varies: 4 to 40 deaths per 1000 deliveries
- Fetal deaths: 60% of all perinatal deaths
- From 1970 and onwards: significant decline in fetal deaths in most western countries, Norway included

Remarkable decline in fetal mortality (Norway)



Pre-term 28-36 completed weeks of gestation



Remarkable decline in fetal mortality (Norway)

Term







Is there a causal link?

Use of diagnostic technology/decline in fetal deaths

- Ultrasound and electronic fetal monitoring (EFM)
- Marked increase in the use of ultrasound and EFM 1970-1990
 - Less dependence on clinical signs, judgment, and interpretation of information from the mother for assessing whether the pregnancy/delivery is progressing without complications

Types of diagnostic technology

- Ultrasound
 - More accurate gestational age assessment
 - Detection of multiple fetuses and fetal malpresentations
 - Diagnosis of placenta praevia
- EFM
 - Monitoring of fetal heart rate and diagnosis of fetal distress, particularly in full term pregnancies and during delivery

Previous research

- Two types of study
 - Cross-sectional studies may suffer from bias due to unobserved heterogeneity
 - Clinical trials often questionable external validity
 Small samples and with selected groups of mothers
- Conclusion from Cochrane Reviews
 - "Much larger numbers of participants would be required to accurately measure this outcome" (fetal outcome) (Whitworth et al. 2010; Haws et al. 2009)
- Real life studies are lacking
 - No population studies of the contribution of the use of diagnostic technology to the decline in fetal deaths

Institutional setting – obstetric services in Norway

- Population: 5.2 million
 Number of deliveries per year: 60 000
- Women give birth in publically-owned and publically-funded hospitals (n=44)
- Mothers pay no fee, irrespective of the type of delivery
- Doctors receive a fixed salary
- No competition between hospitals for women giving birth
 - The capacity of maternity units is planned according to the expected number of births within the catchment area

Data and variables

- Medical Birth Registry of Norway
 - All deliveries 1967-1995 (about 1.2 million)
 - Outcome: Stillbirth before and during delivery
 - Control variables risk factors of the mother
 - Mother's age, highest education and immigrant background
 - Whether she had previously had a fetus that had died, or previously had a Cesarean delivery
 - Whether the pregnancy was her first (null parity)
 - Whether she had a chronic disease
- Norwegian Medical Association's Research Institute
 - Information about use of diagnostic technology (hospital level)

Data about the use of diagnostic technology

- Questionnaire sent to all senior consultants in every maternity unit. All replied.
 - Asked to provide the following information:
 - «Enter as accurately as possible the five-year interval your maternity unit introduced the use of ultrasound and EFM»
 - Response options:
 - First interval: 1967-1969
 - Subsequent intervals: 5-year intervals from 1970 and onwards

Type of diagnostic technology and time period of implementation (n=1.2 million)

_	Ultras	ound	EFM		
Time period	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	

Model specification Difference-in-difference estimation

$$Y_{ijt} = \alpha + \beta_1 Ultrasound_{jp} + \beta_2 EFM_{jp} + \sum_c \gamma_c \cdot Control_{ijt}^c + \sum_j \delta_j \cdot Hospital_j + \phi \cdot t + \sum_j \eta_j \cdot Hospital_j \cdot t + u_{ijt}$$

- Outcome: stillbirth before and during delivery
- Before/after design. Controls for all cross-sectional variation between maternity units that are stable over time
- t (=trend) controls for all non-measurable factors that might influence stillbirth over time (for example better nutrition and maternity care)
- Clustering at the hospital level (to take account of positive serial correlation)

The effects of the use of ultrasound and EFM on fetal death

Type of technology	Whole population	Pre-term	Term	Post-term
Ultrasound	-0.0013 * (0.0004)	0.0010 (0.0034)	-0.0010 * (0.0003)	-0.0021 * (0.0006)
EFM	-0.0002 (0.0005)	0.0040 (0.0047)	-0.00020 (0.0003)	0.00001 (0.0007)
Number of fetal deaths	8 263	4 007	3 386	631
Total ¹	1 199 475	69 365	926 041	171 207

* p<0.05

¹Includes number of live born infants and number of fetal deaths

Percentage reduction in the number of fetal deaths



Robustness tests – can we trust the results?

- Pre-intervention test (placebo test)
 - To detect bias due to a third unobserved variable
 - We pretend that the use of ultrasound was introduced earlier than it actually was introduced
 - Result of the test:
 - No effect no bias
 - Effect bias
- Terminated pregnancies
 - Routine ultrasound examination may have increased the number of terminations of fetuses with congenital abnormalities

Reduction of the number of fetuses with a high risk of being stillborn

Bias in our results – beneficial effect of ultrasound is overestimated

Pre-intervention test: Ultrasound introduced one period earlier than it actually was introduced

Period (five-year interval) of introduction	Whole population	Term	Post-term
Pre-intervention	-0.0008	-0.0003	-0.0012
(Lead)	(0.0008)	(0.0004)	(0.0014)
Introductory period	-0.0016 *	-0.0008 *	-0.0032 *
(Contemporaneous effect)	(0.0009)	(0.0004)	(0.0015)
Post-intervention	-0.0023 *	-0.0011 *	-0.0041 *
(Lag)	(0.0012)	(0.0005)	(0.0018)
Number of fetal deaths	8 024	3 386	631
Total ¹	1 166 613	926 041	171 207

* p<=0.05

¹ Includes number of live born infants and number of fetal deaths

Is there a link? The use of ultrasound/the prevalence of infants with congenital abnormalities

Type of technology	Whole population	Pre-term	Term	Post-term
Ultrasound	0.0022 (0.0025)	-0.0020 (0.0035)	0.0031 (0.0020)	0.0007 (0.0029)
Number of infants with congenital abnormalities ¹	32 410	3 084	24 622	4 704
Total number of infants ²	1 166 613	69 365	926 041	171 207

¹Includes 17 abnormalities

²Includes all infants - both stillborn and liveborn

Conclusions

- The introduction of ultrasound made a MAJOR contribution to the decline in fetal mortality at the end of the last century
 - The effect was most pronounced for post-term deliveries
- The introduction of EFM made NO contribution to the decline in fetal mortality
 - The use of EFM can be reduced, without that leading to an increase in the number of fetal deaths
- Our results cannot be explained by an increase in terminated pregnancies as a result of the introduction of ultrasound