

Validity of a selection of pregnancy complications in the Medical Birth Registry of Norway

Running headline: Validity of information in the MBRN

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Abstract

Introduction: The validity of information on pregnancy complications in the Medical Birth Registry of Norway (MBRN) is insufficiently studied. The objective was to examine the validity of information on gestational age, birthweight, medically initiated delivery and gestational hypertension in the MBRN.

Material and methods: We randomly sampled MBRN records among women who participated in the population-based HUNT Study in Nord-Trøndelag county and who gave birth during 1967-2012. We estimated the sensitivity, specificity and positive (PPV) and negative (NPV) predictive values of information in the MBRN, using hospital records as gold standard.

Results: Hospital records were available for 786 out of 797 sampled MBRN records. The PPVs of preterm (<37 weeks) and early preterm birth (<34 weeks) were approximately 90%, and the PPVs of low (<2500g) and high (>4500g) birthweight were 100%. For medically initiated delivery, the PPV was 28% during 1967-1985, but 80% during 1986-2012 and higher among preterm (76%) than among term births (51%). For gestational hypertension, the PPV was 68%, but 88% of women labeled with gestational hypertension in the MBRN had evidence of gestational hypertension or preeclampsia in hospital records.

Conclusions: The validity of information on gestational age and birthweight in the MBRN was very good. For medically initiated delivery, the validity was poor before 1985 and satisfactory thereafter. For gestational hypertension, lack of information in hospital records made the evaluation difficult, but our results suggest that most women labeled with gestational hypertension in the MBRN did have a hypertensive disorder of pregnancy.

Keywords: Validity, Medical Birth Registry of Norway, HUNT, pregnancy, preterm birth, gestational age, birthweight, medically initiated delivery, gestational hypertension

Abbreviations: HELLP syndrome, syndrome of hemolysis, elevated liver enzymes and low platelet count; HUNT Study, Nord-Trøndelag Health Study; MBRN, Medical Birth Registry of Norway; NPV, negative predictive value; PPV, positive predictive value

Key message:

- The MBRN has valid information on gestational age and birthweight, and on medically initiated delivery after mid-1980s.
- Most women with gestational hypertension in the MBRN have evidence of gestational hypertension or preeclampsia in the hospital records.

Introduction

The Medical Birth Registry of Norway (MBRN) is a population-based registry containing information on all pregnancies and deliveries in Norway since 1967. It is an important data source for epidemiologic studies due to its detailed information on pregnancy and perinatal health complications and the possibilities for linkage with other Norwegian health registries (1-3). The validity of such studies depends on the validity of the information in the MBRN. Two studies have examined the validity of MBRN diagnoses of preeclampsia (4, 5), but there is limited knowledge on the validity of information on other pregnancy characteristics including gestational hypertension, medical initiation of delivery, gestational age, and birthweight (1). The aim of this study was to examine the validity of this information using hospital records as gold standard. We performed the study within a population-based cohort (the HUNT Study) in Nord-Trøndelag county (6). The HUNT Study is a valuable cohort for epidemiologic studies of pregnancy complications (7-10) and knowledge of the validity of MBRN information is of particular importance within this cohort.

Material and methods

All births in Norway have since 1967 been compulsory recorded in the MBRN at the Norwegian Institute of Public Health. Midwives or physicians at the delivery units complete a standardized form for every birth. Data are recorded based on the information available at the delivery units, including antenatal forms and hospital records, and sent to the MBRN soon after delivery. In multiple pregnancies one form is completed for each child. Data includes demographic information, maternal diseases before and during pregnancy, complications during pregnancy and delivery, and information on birth defects and other perinatal health problems (2).

The birth notification form remained unchanged from 1967 to 1998 and pregnancy complications were reported in free text. In 1998, checkboxes were introduced, including separate checkboxes for mild, severe and early-onset preeclampsia, HELLP syndrome, eclampsia, gestational hypertension (without proteinuria), preexisting hypertension and preexisting chronic renal disease (11, 12). To estimate gestational age, the MBRN used the mother's self-reported first day of last menstrual period. In an alternative classification since 1998 (which we did not use in this study), the MBRN uses ultrasound-based due dates when available, and

otherwise the first day of the last menstrual period. Onset of labour is categorized as spontaneous (spontaneous onset of contractions), induced (any medical treatment or intervention, except from cesarean section, to start the labour), or cesarean section (carried out before start of established contractions), and in the present study, the two latter categories were classified as medically initiated delivery.

We selected pregnancies among women who participated in the HUNT Study, a population-based study in Nord-Trøndelag county, covering a broad range of health topics by means of questionnaires, clinical examination, and blood sampling (6). All residents in Nord-Trøndelag aged ≥ 20 years have been invited to participate in three surveys: HUNT1 (1984-1986), HUNT2 (1995-1997), and HUNT3 (2006-2008). In total, 77 212 people participated in HUNT1 (89% of the invited), 65 237 (69%) in HUNT2, and 50 807 (54%) in HUNT3. The participants gave consent to link data to other sources of health information (6). For the present study, we linked information from the HUNT Study, the MBRN and hospital records through the unique 11-digit identification number given to all Norwegian citizens. The study was approved by the regional committee for medical and health research ethics (REC Central, 2013/647).

Nord-Trøndelag county is served by two primary hospitals, Levanger and Namsos Hospitals (Nord-Trøndelag Hospital Trust). Both hospitals have maternity wards for low- and moderate-risk pregnancies, and their current annual number of births is approximately 1000 and 400-450, respectively. Women with high-risk pregnancy give birth at the nearest university hospital, St. Olavs Hospital, Trondheim University Hospital, which has approximately 4000 deliveries each year. The source population for this study was women giving birth during 1967-2012, who participated in the HUNT Study and lived in one of the municipalities that have Levanger Hospital as their primary hospital, and who gave birth at Levanger, Namsos or St. Olavs Hospital. Among these women, we randomly selected the following subsets of MBRN records based on information registered in the MBRN: 100 records with a diagnosis of gestational hypertension; 200 records in each of the following groups defined by gestational age at delivery: 16-33 weeks, 34-36, and ≥ 37 weeks of gestation; and 100 records with missing information on gestational age. This resulted in the selection of 797 unique records for inclusion in the validation study since three records were selected twice. For 645 records, the delivery had taken place at Levanger Hospital, for 144 records at St. Olavs Hospital, and for 8 records at Namsos Hospital.

Staff at the hospital archives presented the hospital records of the selected

women in random order to a medical student (F.N.M. or T.R.S., for Levanger and St. Olavs Hospitals) or a nurse (for Namsos Hospital) who was uninformed about which group each record was selected from. They used a standardized case record form to extract information recorded at the time of the selected pregnancy, including doctors' notes, partograms, and antenatal forms. When in doubt, they discussed with each other or conferred with an obstetrician (J.H.).

Nearly all hospital records contained a partogram that included information on gestational age at delivery, birthweight, and a description of the start of labour. For blood pressure and proteinuria, the available information differed over time. In the oldest records, blood pressure was often recorded only when the woman was hospitalized at start of labour, and the result of urine testing was recorded only if proteinuria was present. Therefore, we classified lacking information as negative findings. We used the information from hospital records to classify pregnancy complications as follows:

Preterm birth was defined as delivery <37 weeks, and early preterm birth was defined as delivery <34 weeks of gestation. We used the first day of last menstrual period and date of birth to calculate the gestational age, as this information was available throughout the study period.

The start of labour was indicated in the partograms, and onset of spontaneous painful contractions with a certain regularity, typically lasting 45 to 60 seconds and being three to four minutes apart, were considered as start of labour. Delivery was considered medically initiated if labour started with any form of induction, including medication, or amniotomy, or in the event of cesarean section without trial of labour. Spontaneous leakage of amniotic fluid was not considered as start of labour if present without uterine contractions that were sufficient to classify as ongoing labour. Prolonged latent phase, or "false labour", followed by induction was categorized as medically initiated delivery (13). Birthweight <2500 g was classified as low, and birthweight >4500 g was classified as high.

Gestational hypertension was defined as any recording of systolic blood pressure ≥ 140 mmHg, diastolic blood pressure ≥ 90 mmHg, use of antihypertensive medication or a physician diagnosis of hypertension after 20 weeks of gestation, excluding chronic hypertension (a physician diagnosis of hypertension or use of antihypertensive medication before 20 weeks of gestation) and preeclampsia. Preeclampsia was defined as a physician diagnosis of preeclampsia, eclampsia or

HELLP syndrome, or any recording of blood pressure $\geq 140/90$ mmHg after 20 weeks of gestation combined with proteinuria that did not spontaneously normalize during pregnancy and that could not be attributed to urinary tract infection or pre-pregnancy renal disease. Proteinuria was seldom quantified using 24-hour urine sampling, and we defined proteinuria as a protein concentration of ≥ 0.3 g/l or $\geq 1+$ on dipstick test. During most of the study period, one measurement of high blood pressure was regarded as sufficient when diagnosing gestational hypertension or preeclampsia, and we were not able to apply newer, stricter criteria that require at least two high blood pressure measurements (4, 14). Due to the incomplete longitudinal recording of blood pressure and proteinuria during pregnancy, we additionally applied four alternative definitions of gestational hypertension in the hospital records.

Statistical analysis

We estimated the sensitivity, specificity and predictive values of the diagnoses in the MBRN using the hospital records as gold standard. We estimated these measures both for the overall study period and, separately, for the periods 1967-1985 and 1986-2012. Statistical analyses were performed using the survey tabulate command in Stata for Windows (Version IC 13.1, StataCorp, College Station, Texas, USA) and weighted the MBRN records using probability weights that denote the inverse of the probability that the record was included because of the sampling design. This method means that our point estimates will not systematically differ from those observed if examining all the records, whereas the calculation of confidence intervals correctly accounts for the number of records we actually examined. The number of included MBRN records, the number of MBRN records that they represent, and the probability weights applied in the statistical analyses are given in Supplemental Table 1. For gestational age at delivery and birthweight, we also evaluated the agreement between the MBRN and hospital records by Bland-Altman plots, as recommended (15). We specifically examined the birthweights (as recorded in the MBRN) among births that were registered as preterm in the MBRN, but as term in the hospital records, to assess whether it was likely that these births could be preterm. In an additional analysis, we re-estimated the validity of preterm and early preterm birth after excluding births with unlikely combinations of gestational age and birthweight in the MBRN, as indicated by birthweight z-score (adjusted for gestational age and offspring sex (16)) of < -4.0 or

>4.0. The purpose of this analysis was to examine whether the PPV of preterm birth in the MBRN could be increased by applying the z-score criterion.

Results

Among 797 MBRN records selected for evaluation, hospital records were available for 786 (99%), which were included in the statistical analyses. Among them, information was available on gestational age at delivery for 643 (82%) records, on initiation of delivery for 779 (99%) records, and on birthweight for 764 (97%) records. Characteristics of the selected pregnancies were similar to all pregnancies among women who participated in the HUNT Study (Table 1). The crude numbers of true positive, false positive, false negative and true negative MBRN records are given in Supplemental Table 2.

Table 2 shows validity estimates for preterm (delivery <37 weeks) and early preterm birth (delivery <34 weeks) in the MBRN, based on the first day of last menstrual period. The overall sensitivity, specificity and NPVs were excellent, approximately 99% for both diagnoses, while the PPVs for the entire time period were lower at 90-93%. Among the 26 births that were registered as preterm in the MBRN, but as term in the hospital records, the median (inter-quartile range (IQR)) birthweight was 3265 g (3030-3910 g), which was quite similar to the birthweight of term infants (median 3580 g, IQR 3190-3920 g), but substantially higher than that of preterm infants (median 2080 g, IQR 1320-2690 g). Disagreements in gestational age between the MBRN and hospital records did not systematically differ by gestational age, but some pregnancies had a markedly shorter gestational age recorded in the MBRN than in the hospital records. These pregnancies often had unlikely combinations of gestational age and birthweight in the MBRN (indicated by birthweight z score <-4.0), but not in the hospital records (Figure S1). After exclusion of MBRN records with unlikely combinations of gestational age and birthweight (z-score <-4.0 or >4.0), the PPVs of preterm and early preterm birth increased to approximately 95% (Table 2). In an additional analysis, we used delivery <32 weeks as definition of early preterm birth, but the results were similar to the main analysis (Supplemental Table 3).

Table 3 shows validity estimates for medical initiation of delivery recorded in the MBRN. The overall estimates for term and preterm births combined were 81%

sensitivity, 88% specificity, 54% PPV and 96% NPV. The PPV was very low, 28%, in the first time period (1967-1985), but increased to 80% in the last time period (1986-2012). The PPV was higher among preterm (76%) than term births (51%). Among preterm births in the last time period, the PPV was satisfactorily high at 86%.

The offspring classified as having low (<2500 g; n=242) and high (>4500 g; n=27) birthweight, respectively, were identical in the MBRN and in the hospital records. Thus, all validity estimates for low and high birthweight were 100%. Disagreements in birthweight between the MBRN and hospital records did not systematically differ by birthweight (Figure S2).

Table 4 shows validity estimates for gestational hypertension in the MBRN using five different diagnostic criteria for gestational hypertension based on available information in the hospital records. In general we found a very low sensitivity (4-13%) and high specificity (99-100%). The values were nearly the same for both time periods. The overall PPV for gestational hypertension was 68%, but 88% of women with a diagnosis of gestational hypertension in the MBRN had evidence of either gestational hypertension or preeclampsia in hospital records. The PPV decreased to 52% when the diagnostic criteria were restricted to gestational hypertension that was noted before the hospital admission for labour and did not spontaneously normalize during pregnancy. However, when these diagnostic criteria were expanded to also include hypertension combined with a record of proteinuria (i.e. preeclampsia), the PPV increased to 74%.

Discussion

The preterm and early preterm birth recordings in the MBRN showed very good validity when compared to hospital records, with overall diagnostic test values above 90% for the PPV and approaching 100% for the other test criteria. Also, the validity of low and high birthweight in the MBRN was excellent, with diagnostic test values of 100%. The percentage of confirmed medical initiation of delivery was lower, with an overall PPV of 54%, but the PPV was more satisfactory among preterm births and after mid-1980s. For gestational hypertension, the overall PPV was 68%, but only in 52% of the cases, the hospital records contained evidence of gestational hypertension that was noted prior to the hospital admission for labour and did not spontaneously normalize during pregnancy. Nonetheless, 88% of women labeled with gestational

hypertension in the MBRN had evidence of either gestational hypertension or preeclampsia in hospital records.

This study is population-based and covers the population within a defined geographic area, including births on local hospitals as well as more complicated births at the university hospital. Another strength of our study is that for almost all the selected MBRN records, the corresponding hospital record was identified and received. The hospital staff that provided us with the different records in random order was unaware of the respective diagnosis in the MBRN. The people extracting information from the hospital records were also uninformed about which group each record was selected from, but true blinding of the MBRN diagnosis was not always achieved, as copies of the MBRN form were sometimes kept in the hospital records.

One limitation of the study is that older records in general contained less clinical information, and this limitation was most obvious when we attempted to classify gestational hypertension and preeclampsia. Old records had a tendency to document only positive test results, and only a simple partogram was used to register clinical data of interest. Consequently we had to classify lacking information as negative findings, which may have led us to underestimate the true occurrence of hypertension and proteinuria. Standardized partograms and antenatal forms were introduced in the 1980s (10), and this appears to have improved quality of information. From this time onwards, we could usually follow the blood pressure and urine tests throughout the pregnancy, as these measures were systematically registered in the antenatal form and a copy of this form was kept in the hospital record. Nonetheless, in cases where the registered information in MBRN was not in agreement with the hospital records, we had to consider the imperfect nature of our gold standard. For example, most women with evidence of hypertension in the hospital records did not have gestational hypertension recorded in the MBRN. It is possible that the hospital records did not completely document normotensive blood pressures, and that more information was available to those coding the MBRN form, such as spontaneous resolution of high blood pressure during pregnancy.

When studying associations between pregnancy complications and other outcomes, the PPV of the diagnoses in MBRN is of primary interest, as it gives us the proportion having true disease among people with a diagnosis in MBRN. Although the validity of preterm and early preterm birth was satisfactory in our study, the PPV was lower than the other measures. This may indicate that some births classified with

short gestational age in MBRN actually were term births. The observed birthweights for these particular cases, being similar to those of term infants, lend support to this suggestion. Our analyses suggest that in studies where a high PPV for preterm birth is required, this may be achieved by excluding MBRN records with unlikely combinations of gestational age and birthweight; this exclusion raised PPVs for preterm birth from 93% to 95% and early preterm birth from 90% to 94%.

For medical initiation of delivery, the PPV was low prior to the mid-1980s. Our results suggest that most births classified as medically initiated in the MBRN in this period in reality had a spontaneous start of labour. Even in the first time period, the partograms in the hospital records usually included a precise and thorough description of the start and course of labour. Therefore we could, almost in every record, evaluate the start of labour and decide whether it was spontaneous or induced, and whether a cesarean section had been done without trial of labour. Therefore, the hospital records appeared to be a satisfactory gold standard for classifying the initiation of delivery. In the MBRN form used from 1967 to 1998, the question concerning induced labour was: “Was the birth provoked?”. The lack of specificity in that question may have contributed to misclassification of medical augmentation of labour as medical initiation of labour in the MBRN, resulting in its low PPV compared to the hospital records. We found support for such misclassification in the later time period, when the partogram included checkboxes for spontaneous and induced start of labour: there appeared to be instances in which the checkbox for ‘induced start of labour’ was endorsed, but the hospital record indicated that medical intervention was used only to accelerate labour after a spontaneous onset. Although the MBRN form was unchanged until 1998, a change in coding practice appears to have occurred earlier, as reflected by our observed increase in the PPV for medically initiated delivery after the mid-1980s.

We found a very low sensitivity for gestational hypertension in the MBRN, and the high prevalence of elevated blood pressure recordings in the hospital records suggests that our gold standard, the hospital records, erroneously labeled many women as hypertensive. Due to the lack of systematic recording of blood pressure measurements in the hospital records, we often could not determine whether a high blood pressure measurement spontaneously normalized or not. When re-estimating the PPV using alternative diagnostic criteria for gestational hypertension, we found that the PPV increased considerably when hypertension combined with proteinuria

was included in the definition of gestational hypertension. This suggests that most women labeled with gestational hypertension in the MBRN had a hypertensive disorder in pregnancy, but that some of them may have had preeclampsia rather than gestational hypertension.

The MBRN records were randomly selected from the HUNT study cohort, a large population-based cohort of women, and pregnancy characteristics of the selected MBRN records were similar to those of all MBRN records of women who participated in the HUNT Study. This suggests that our selected pregnancies are representative for pregnancies in Nord-Trøndelag county. The generalizability of our results to other areas in Norway depends on how the personnel at the different hospitals apply diagnostic criteria and carry out the coding procedures. We cannot assure that these properties are identical across hospitals and time periods, but we assume patterns are likely to be similar throughout Norway. As this type of data has also been collected in other Nordic countries (1, 3), we assume that our results may be relevant for corresponding data in the Nordic region.

In conclusion, the validity of information on gestational age and birthweight in the MBRN was very good. For medical initiation of delivery, the validity was satisfactory after the mid-1980s. For gestational hypertension, lack of information in hospital records made the evaluation difficult, but our results suggest that most women labeled with gestational hypertension in the MBRN did have a hypertensive disorder of pregnancy.

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References

1. Gissler M, Louhiala P, Hemminki E. Nordic Medical Birth Registers in epidemiological research. *Eur J Epidemiol*. 1997 Feb;13(2):169-75.
2. Irgens LM. The Medical Birth Registry of Norway. Epidemiological research and surveillance throughout 30 years. *Acta Obstet Gyn Scan*. 2000 Jun;79(6):435-9.
3. Langhoff-Roos J, Krebs L, Klungsoyr K, Bjarnadottir RI, Kallen K, Tapper AM, et al. The Nordic medical birth registers--a potential goldmine for clinical research. *Acta Obstet Gynecol Scand*. 2014 Feb;93(2):132-7.
4. Thomsen LC, Klungsoyr K, Roten LT, Tappert C, Araya E, Baerheim G, et al. Validity of the diagnosis of pre-eclampsia in the Medical Birth Registry of Norway. *Acta Obstet Gynecol Scand*. 2013 Aug;92(8):943-50.
5. Klungsoyr K, Harmon QE, Skard LB, Simonsen I, Austvoll ET, Alsaker ER, et al. Validity of Pre-Eclampsia Registration in the Medical Birth Registry of Norway for Women Participating in the Norwegian Mother and Child Cohort Study, 1999-2010. *Paediatr Perinat Epidemiol*. 2014 Sep;28(5):362-71.
6. Krokstad S, Langhammer A, Hveem K, Holmen TL, Midthjell K, Stene TR, et al. Cohort Profile: the HUNT Study, Norway. *Int J Epidemiol*. 2013 Aug;42(4):968-77.
7. Magnussen EB, Vatten LJ, Lund-Nilsen TI, Salvesen KA, Davey Smith G, Romundstad PR. Prepregnancy cardiovascular risk factors as predictors of pre-eclampsia: population based cohort study. *Brit Med J*. 2007 Nov 10;335(7627):978-81.
8. Magnussen EB, Vatten LJ, Myklestad K, Salvesen KA, Romundstad PR. Cardiovascular risk factors prior to conception and the length of pregnancy: population-based cohort study. *Am J Obstet Gynecol*. 2011 Jun;204(6):526 e1-8.
9. Myklestad K, Vatten LJ, Magnussen EB, Salvesen KA, Davey Smith G, Romundstad PR. Offspring birth weight and cardiovascular risk in parents: a population-based HUNT 2 study. *Am J Epidemiol*. 2012 Mar 15;175(6):546-55.
10. Romundstad PR, Magnussen EB, Davey Smith G, Vatten LJ. Hypertension in Pregnancy and Later Cardiovascular Risk Common Antecedents? *Circulation*. 2010 Aug 10;122(6):579-84.

11. Irgens LM. [Medical birth registry--an essential resource in perinatal medical research]. Tidsskr Nor Laegeforen. 2002 Oct 30;122(26):2546-9.
12. Nasjonalt folkehelseinstitutt Afh, Divisjon for Epidemiologi. Veileder til utfylling av melding til Medisinsk Fødselsregister. Elektronisk fødselsmelding versjon 1.0. Oslo 2014. Available from:
<http://www.fhi.no/dokumenter/bfe4bf779f.pdf>.
13. Department of Reproductive Health and Research W. WHO Care in Normal Birth - a practical guide. Geneva 1996. Available from:
http://whqlibdoc.who.int/hq/1996/WHO_FRH_MSM_96.24.pdf?ua=1.
14. Hypertension in pregnancy. Report of the American College of Obstetricians and Gynecologists' Task Force on Hypertension in Pregnancy. Obstet Gynecol. 2013 Nov;122(5):1122-31.
15. Bland JM, Altman DG. Comparing methods of measurement: why plotting difference against standard method is misleading. Lancet. 1995 Oct 21;346(8982):1085-7.
16. Skjaerven R, Gjessing HK, Bakketeig LS. Birthweight by gestational age in Norway. Acta Obstet Gynecol Scand. 2000 Jun;79(6):440-9.

Table 1. Pregnancy characteristics among all 71 500 Medical Birth Registry of Norway (MBRN) records from deliveries in 1967-2012 among women who participated in the HUNT Study, and among the 797 MBRN records that were selected for validation.

Characteristics as recorded in the MBRN	All MBRN records (n=71 500)	MBRN records in the validation study (n=797) ^a
Mean maternal age at delivery, years	27	27
Para 0, %	37	39
Year of delivery, %		
1967-1985	53	51
1986-2012	47	49
Mean offspring birthweight, g	3513	3503
Medically initiated delivery, %	19	21
Gestational age at delivery, %		
16-33 weeks	2	2
34-36 weeks	4	4
≥37 weeks	94	93
Preeclampsia, %	3	2
Gestational hypertension, %	2	2

^aMBRN records were weighted to account for differences in sampling probability.

Table 2. Validity of preterm (delivery 16-36 weeks of gestation) and early preterm (delivery 16-33 weeks) birth recorded in the Medical Birth Registry of Norway (MBRN), comparing information in the MBRN to hospital records among 643 MBRN records^a of women residing in Nord-Trøndelag county and giving birth between 1967 and 2012.

	Sensitivity, %		Specificity, %		Positive predictive value (PPV), %		Negative predictive value (NPV), %	
	Estimate	95% CI	Estimate	95% CI	Estimate	95% CI	Estimate	95 %CI
Total study population (n=643)								
Preterm birth								
Overall	99.6	97.4-100	99.5	99.3-99.7	92.7	89.4-95.0	99.98	99.8-100
1967-1985	100	NE ^b	99.4	98.9-99.6	90.0	84.2-93.9	100	NE ^b
1986-2012	99.3	95.1-99.9	99.7	99.3-99.8	95.2	91.0-97.5	99.95	99.7-100
Early preterm birth								
Overall	99.0	93.3-99.9	99.8	99.6-99.9	90.4	85.2-93.9	99.98	99.8-100
1967-1985	100	NE ^b	99.8	99.6-99.9	93.7	86.6-97.2	100	NE ^b
1986-2012	97.9	86.7-99.7	99.7	99.4-99.8	86.9	78.3-92.5	99.95	99.7-100
Among records with offspring birthweight z score ≥ -4.0 and ≤ 4.0 (n=604) ^c								
Preterm birth								
Overall	99.6	97.2-99.9	99.7	99.5-99.8	94.8	91.5-96.9	99.98	99.8-100
1967-1985	100	NE ^b	99.5	99.1-99.7	91.7	85.6-95.4	100	NE ^b
1986-2012	99.3	94.8-99.9	99.9	99.6-99.95	97.6	93.7-99.1	99.95	99.7-99.99
Early preterm birth								
Overall	98.9	92.5-99.8	99.9	99.8-99.9	94.3	89.5-97.0	99.98	99.8-100
1967-1985	100	NE ^b	99.95	99.8-99.99	97.6	90.9-99.4	100	NE ^b
1986-2012	97.6	84.6-99.7	99.8	99.6-99.9	90.7	81.6-95.5	99.95	99.7-99.99

^a MBRN records were weighted to account for differences in sampling probability.

^bNo estimate available

^cFrom this analysis, we excluded 19 records with birthweight z score < -4.0 or > 4.0 , and 20 records where birthweight z score could not be calculated due to missing information.

Table 3. Validity of medical initiation of delivery recorded in the Medical Birth Registry of Norway (MBRN), comparing information in the MBRN to hospital records among 779 MBRN records^a of women residing in Nord-Trøndelag county and giving birth between 1967 and 2012. Delivery was considered medically initiated if labour was induced by medication or amniotomy, or in the event of cesarean section without trial of labour.

	Sensitivity, %		Specificity, %		Positive predictive value (PPV), %		Negative predictive value (NPV), %	
	Estimate	95% CI	Estimate	95% CI	Estimate	95% CI	Estimate	95% CI
Term and preterm births								
Overall	81	67-90	88	83-92	54	41-66	96	93-98
1967-1985	63	37-83	83	75-89	28	15-47	96	90-98
1986-2012	90	76-96	95	88-98	80	61-91	97	94-99
Term births								
Overall	83	64-93	88	83-92	51	36-65	97	93-99
1967-1985	63	31-86	83	74-89	25	11-46	96	89-99
1986-2012	94	67-99	95	87-98	79	56-92	99	91-100
Preterm births								
Overall	69	60-76	89	84-92	76	67-83	85	80-88
1967-1985	56	40-70	89	82-93	57	41-72	88	82-92
1986-2012	75	65-83	89	81-94	86	76-92	80	71-87

^a MBRN records were weighted to account for differences in sampling probability.

Table 4. Validity of gestational hypertension recorded in the Medical Birth Registry of Norway (MBRN), comparing information in the MBRN to hospital records among 786 MBRN records^a of women residing in Nord-Trøndelag county and giving birth between 1967 and 2012.

Type of hypertensive disorder according to information in the hospital records	Sensitivity, %		Specificity, %		Positive predictive value (PPV), %		Negative predictive value (NPV), %	
	Estimate	95% CI	Estimate	95% CI	Estimate	95% CI	Estimate	95% CI
Gestational hypertension ^b								
Overall	4	3-5	99.2	98.8-99.4	68	59-76	68	62-74
1967-1985	4	3-5	98.7	97.9-99.2	72	61-81	53	44-61
1986-2012	4	2-7	99.5	99.1-99.7	58	40-74	84	76-89
Gestational hypertension or preeclampsia ^c								
Overall	4	3-6	99.7	99.4-99.8	88	81-93	64	58-70
1967-1985	4	3-6	99.3	98.7-99.7	87	78-93	49	40-57
1986-2012	5	3-7	99.9	99.6-100	90	74-97	80	72-86
Any hypertension ^d								
Overall	4	3-6	99.8	99.7-99.9	95	88-98	63	57-69
1967-1985	4	3-6	99.6	99.1-99.8	92	84-97	49	40-57
1986-2012	5	3-7	100	NE ^e	100	NE ^e	78	70-84
Gestational hypertension that was noted before the hospital admission for labour and did not spontaneously normalize during pregnancy ^f								
Overall	13	8-21	99.1	98.8-99.3	52	43-61	94	90-96
1967-1985	14	7-24	98.8	98.2-99.1	54	43-65	91	85-95
1986-2012	13	5-29	99.4	99.0-99.7	45	29-63	97	93-99
Preeclampsia, or gestational hypertension that was noted before the hospital admission for labour and did not spontaneously normalize during pregnancy								
Overall	12	8-17	99.5	99.2-99.6	74	65-81	90	86-93
1967-1985	12	7-20	99.1	98.6-99.4	70	59-79	87	80-92
1986-2012	11	6-21	99.8	99.6-99.9	84	67-93	93	88-96

^aMBRN records were weighted to account for differences in sampling probability.

^bSystolic blood pressure ≥ 140 mmHg, diastolic blood pressure ≥ 90 mmHg, use of antihypertensive medication or a physician diagnosis of hypertension after 20 weeks of gestation, excluding chronic hypertension (a physician diagnosis of hypertension or use of antihypertensive medication before 20 weeks of gestation) and preeclampsia (a physician diagnosis of preeclampsia, eclampsia or HELLP syndrome, or blood pressure $\geq 140/90$ mmHg after 20 weeks of gestation combined with proteinuria (≥ 0.3 g/l or $\geq 1+$ on dipstick test) that did not spontaneously normalize during pregnancy and that could not be attributed to urinary tract infection or pre-pregnancy renal disease).

^cA physician diagnosis of hypertension, preeclampsia, eclampsia or HELLP syndrome, or systolic blood pressure ≥ 140 mmHg, diastolic blood pressure ≥ 90 mmHg or use of antihypertensive medication after 20 weeks of gestation, excluding chronic hypertension (a physician diagnosis of hypertension or use of antihypertensive medication before 20 weeks of gestation) that was not superimposed with preeclampsia.

^dA physician diagnosis of hypertension, preeclampsia, eclampsia or HELLP syndrome, or systolic blood pressure ≥ 140 mmHg, diastolic blood pressure ≥ 90 mmHg or use of antihypertensive medication at any time during pregnancy.

^eNo estimate available

^fAs for gestational hypertension, but excluding hypertension (if untreated or not diagnosed by a physician) that spontaneously normalized (to systolic blood pressure < 140 mmHg and diastolic blood pressure < 90 mmHg) during pregnancy or was only evident by blood pressure measurement performed during the hospital admission for labour.

Supplemental Table 1. The number of MBRN records selected for the study, the number of MBRN records that they represent, and the probability weights applied in the statistical analyses.

Pregnancy characteristics according to information in the MBRN		No. of MBRN records selected for this study	Total no. of MBRN records among women who participated in the HUNT Study	Probability weights
Gestational hypertension	Gestational age at delivery			
Yes	Any	111 ^a	1261	1261 / 111 = 11.36
No	16-33 weeks	194	1575	1575 / 194 = 8.12
No	34-36 weeks	194	2666	2666 / 194 = 13.74
No	≥37 weeks	198	62 314	62 314 / 198 = 314.72
No	Information missing	100	3662	3662 / 100 = 36.62
Sum		797	71 478 ^b	

^a Originally, 100 MBRN records were selected on the basis of gestational hypertension, but the diagnosis of gestational hypertension was also reported in 11 MBRN records originally selected on the basis of gestational age at delivery.

^b There were a total of 71 500 MBRN records among women who participated in the HUNT Study, but 22 MBRN records with gestational age at delivery <16 weeks were not represented in this study.

Supplemental Table 2. The crude (i.e. without weighting) number of true positive, false positive, false negative and true negative MBRN records for each outcome, using information in hospital records as the gold standard.

Outcome	True positives	False positives	False negatives	True negatives	Sum
Preterm birth					
Overall	334	26	1	282	643
1967-1985	159	16	0	160	335
1986-2012	175	10	1	122	308
Early preterm birth					
Overall	166	18	1	458	643
1967-1985	88	6	0	241	335
1986-2012	78	12	1	217	308
Medically initiated delivery					
Term and preterm births, overall	152	68	60	499	779
Term and preterm births, 1967-1985	46	45	32	279	402
Term and preterm births, 1986-2012	106	23	28	220	377
Term births, overall	44	33	12	207	296
Term births, 1967-1985	17	24	10	120	171
Term births, 1986-2012	27	9	2	87	125
Preterm births, overall	92	28	43	214	377
Preterm births, 1967-1985	24	17	21	133	195
Preterm births, 1986-2012	68	11	22	81	182
Low birthweight					
Overall	242	0	0	522	764
1967-1985	128	0	0	264	392
1986-2012	114	0	0	258	372
High birthweight					
Overall	27	0	0	737	764
1967-1985	9	0	0	383	392
1986-2012	18	0	0	354	372
Gestational hypertension					
Overall	75	35	209	467	786
1967-1985	57	22	139	184	402
1986-2012	18	13	70	283	384

Supplemental Table 3. Validity of early preterm birth recorded in the Medical Birth Registry of Norway (MBRN), defined as delivery 16-31 weeks of gestation, comparing information in the MBRN to hospital records among 643 MBRN records^a of women residing in Nord-Trøndelag county and giving birth between 1967 and 2012.

	Sensitivity, %		Specificity, %		Positive predictive value (PPV), %		Negative predictive value (NPV), %	
	Estimate	95% CI	Estimate	95% CI	Estimate	95% CI	Estimate	95 %CI
Total study population (n=643)								
Overall	96.1	89.8-98.6	99.9	99.8-99.9	92.8	86.7-96.2	99.9	99.8-99.98
1967-1985	98.4	89.3-99.8	99.8	99.6-99.9	89.7	79.9-95.0	99.97	99.8-100
1986-2012	93.6	81.5-98.0	99.95	99.8-99.99	96.5	86.8-99.1	99.9	99.7-99.97
Among records with offspring birthweight z score ≥ -4.0 and ≤ 4.0 (n=604) ^c								
Overall	95.4	88.1-98.3	99.96	99.9-99.99	97.0	91.1-99.0	99.9	99.8-99.98
1967-1985	98.2	88.3-99.8	99.9	99.8-99.97	94.8	85.1-98.3	99.97	99.8-100
1986-2012	92.0	77.3-97.5	100	NE ^b	100	NE ^b	99.9	99.7-99.97

^a MBRN records were weighted to account for differences in sampling probability.

^bNo estimate available

^cFrom this analysis, we excluded 19 records with birthweight z score < -4.0 or > 4.0 , and 20 records where birthweight z score could not be calculated due to missing information.

Figure S1. Differences between the MBRN-recorded and hospital-recorded gestational age at delivery versus means of MBRN-recorded and hospital-recorded gestational age at delivery, among 643 MBRN records of women residing in Nord-Trøndelag county and giving birth between 1967 and 2012. The size of each circle indicates the number of observations. Individual records suspected of having erroneous information, as indicated by unlikely combinations of gestational age and birthweight ($|\text{birthweight z score}| > 4.0$), are marked with X (unlikely combination recorded in the MBRN), square (unlikely combination in hospital records) or diamond (unlikely combination in both MBRN and hospital records).

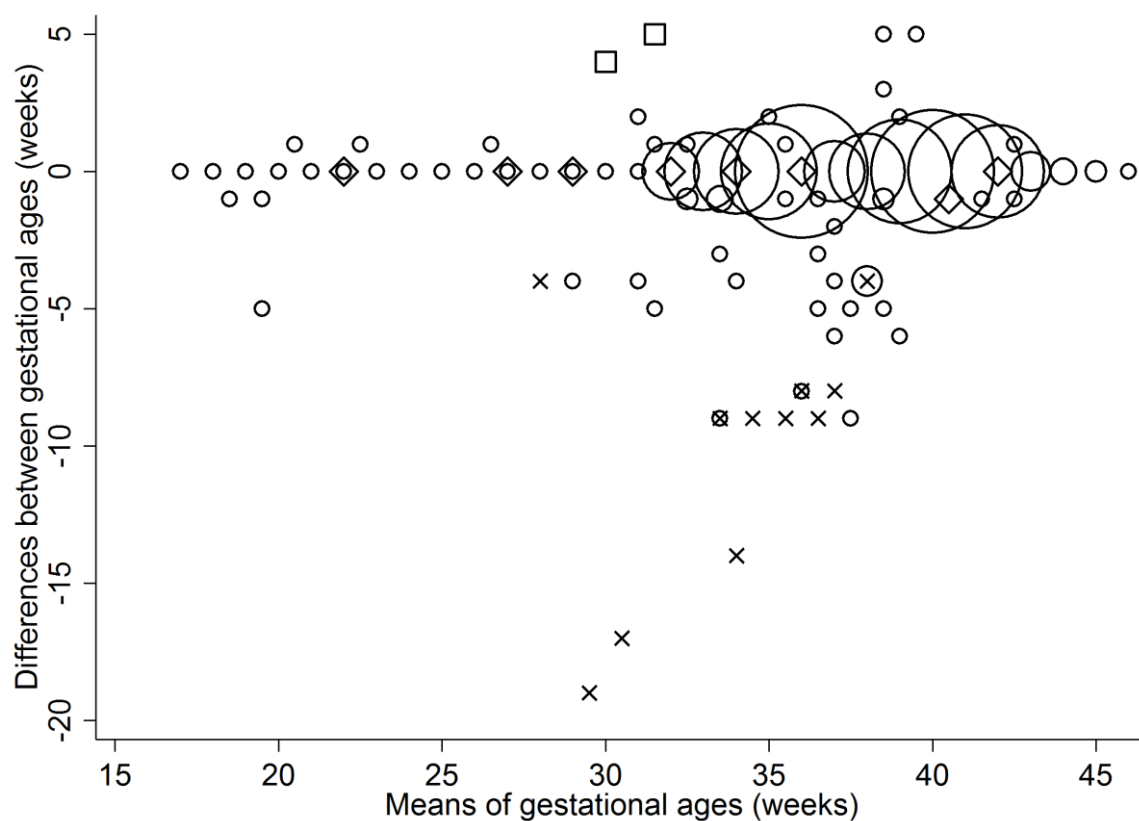


Figure S2. Differences versus means of birthweights recorded in the MBRN and in hospital records, among 764 MBRN records of women residing in Nord-Trøndelag county and giving birth between 1967 and 2012. Records suspected of having erroneous information, as indicated by unlikely combinations of gestational age and birthweight ($|\text{birthweight z score}| > 4.0$), are marked with X (unlikely combination recorded in the MBRN), square (unlikely combination in hospital records) or diamond (unlikely combination in both MBRN and hospital records).

