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ORIGINAL RESEARCH ARTICLE

Maternal Recall of Prescription Medication Use During Pregnancy Using a Paper-Based Questionnaire

A Validation Study in The Netherlands

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Abstract

Background In case-control studies that assess associations between medication use and birth defects, detailed information on type of medication and timing of use is essential to prevent misclassification. However, data on the accuracy of recall of medication use during pregnancy are scarce.

Objective The aim of this study was to validate a self-administered questionnaire to assess prescription medication use in the 3 months before and during pregnancy.

Methods This validation study was embedded in Eurocat Northern Netherlands, a population-based birth defects registry that covers 10 % of all births in The Netherlands. The questionnaire was validated among 560 mothers of infants with major birth defects registered from 1 January 2009 through 30 June 2010 by comparing it with a reference standard consisting of pharmacy data which were checked for compliance by maternal interviews. Sensitivity and specificity were calculated to quantify validity for any prescription medication use, groups of medications and individual medications. In addition, we determined whether maternal characteristics influenced disagreement between the questionnaire and the reference standard using logistic regression analyses.

Results The sensitivity for any prescription medication use was 0.57, ranging between 0.07 (dermatological corticosteroids) and 0.83 (antihypertensives) for medication groups, and between 0.00 (naproxen) and 0.73 (salbutamol) for individual medications. Overall, specificity was high (0.93–1.00). Smoking during pregnancy and completing the questionnaire >2 years after delivery were associated with increased disagreement between the questionnaire for prescription medication use and the reference standard.

Conclusions The validity of the self-administered questionnaire for prescription medication use during pregnancy was moderate to poor for most medications and disagreement differed by some maternal characteristics. As many epidemiological studies use similar questionnaires to assess medication use these studies may need additional data sources such as pharmacy records or prescription databases for medication use next to self-reported methods. Also, previous knowledge on the effect of questionnaire design should be taken into account.

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1 Background

Prescription medication use is common during pregnancy, with prevalence estimates ranging from 44 % to 79 % in several European countries [1–3]. Although it has firmly been established that some medications, including thalidomide and isotretinoin, are capable of producing birth defects, the human teratogenic risks are undetermined for 91 % of pharmacological treatments approved for marketing in the US since 1980 [4]. This is due to a number of reasons. For ethical considerations, pregnant women are

often excluded from pre-marketing clinical trials. In addition, results obtained from animal studies are not always predictive for a teratogenic effect in humans because of differences in factors such as anatomy, physiology, placentation and embryonic development between laboratory animals and humans [5]. Prenatal medication exposure has also been associated with adverse long-term outcomes, including increased risks of childhood asthma [6] and attention-deficit hyperactivity disorder [7], but few studies have been conducted on this topic. Nevertheless, medication use is occasionally unavoidable in the treatment of women during pregnancy, for instance among women with epilepsy, diabetes or severe hypertension. Therefore, epidemiological studies that assess associations between medication use and birth defects and other developmental outcomes are needed [8].

Since specific birth defects occur with a very low prevalence, studies on the teratogenicity of medication are mostly conducted using a case-control design, in which reliable data on medication intake are difficult to obtain [9, 10]. In many studies in perinatal and paediatric epidemiology, prenatal medication exposure information was obtained through maternal self-report using questionnaires or interviews, but data on the validity of these methods are scarce. Previous validation studies indicate that the amount of data obtained depends on the type of medication of interest [9] and on the specificity of the questions asked, with structured questions about indications and specific medication names being more successful in gathering reports of use than open-ended questions [11]. In general, however, mothers tend to underreport medication use during pregnancy [9, 12, 13]. In contrast, prescription and medical records or databases, which are commonly used as a reference standard (i.e. the measurement instrument that definitely determines whether the subject used medication or not), may overestimate prescription medication use as noncompliance may be particularly frequent among pregnant women [14]. As a result, previous studies may have underestimated the validity of self-reported modes of data collection. In addition, mothers may be more likely to recall medication use nowadays as many women use the Internet to retrieve pregnancy-related health information [15]. Over 50 % of pregnant women who sought information online used the Internet to search for information about a treatment prescribed [16]. This may lead to an increased awareness of the potential teratogenic risks of medication use.

As detailed information on the type of medication and the timing of use is essential in case-control studies on the teratogenicity of prenatal medication exposure to prevent misclassification [17], we validated a self-administered questionnaire to assess prescription medication use just before and during pregnancy. This questionnaire is part of a larger questionnaire being used in an ongoing study and similar sets of questions are incorporated into the questionnaires of many other large epidemiological studies as well. In this study, which is by far the largest validation study conducted up to now, we compared this questionnaire to pharmacy data which were checked for compliance by maternal interviews. This is a better reference standard than those used in previous studies, as pharmacy records or databases alone, the commonly used reference standard, may overestimate prescription medication use. We also determined whether maternal and pregnancy characteristics influenced disagreement between questionnaire data on prescription medication use during pregnancy and the reference standard, an issue that has not been studied before.

2 Methods

2.1 Study Population

This validation study was embedded in Eurocat Northern Netherlands (Eurocat-NNL), a population-based birth defects registry that was established in 1981. The registry covers the provinces of Groningen, Friesland and Drenthe, with approximately 18,000 births annually (10 % of all births in The Netherlands). Infants and fetuses with major structural birth defects, monogenetic syndromes and chromosomal anomalies are eligible for registration if the mother lived in the registry area at the time of delivery. Infants and fetuses with only minor anomalies are excluded. As there is no lower age limit, induced abortions and miscarriages of fetuses with birth defects are included, but children with birth defects have to be notified to Eurocat-NNL before 16 years of age. Notification is voluntary and registry staff are actively involved in the search for eligible cases using multiple sources, including hospital registry databases, pathology reports and cytogenetic reports. Parents have to give consent for registration, for which the positive response rate is 80 %. Cases registered from 1 January 2009 through 30 June 2010 ($n = 1105$) were included in this validation study.

2.2 Ascertainment of Prescription Medication Use

After consent for registration is received by Eurocat-NNL, an extensive questionnaire is sent to the parents. Through this questionnaire, information is collected on potential risk factors for birth defects, such as demographic factors, pregnancy and medical histories, lifestyle factors, including smoking, consumption of alcohol and use of folic acid supplements, and occupational exposures, but not on medication use. For this validation study, an existing questionnaire on prescription medication use during

pregnancy was added to the regular Eurocat-NNL questionnaire (see supplementary appendix [Online Resource 1]). Following a general screening question about prescription medication use ("Did you use any medications in the three months before or during pregnancy that were prescribed to you by a medical doctor?", followed by an example of a prescription medication and a reference to look at the indication-oriented questions), women who responded positively were asked whether they used prescription medication for 11 specific indications/pharmacological groups, and whether they used other prescription medications (Table 1). If medication use for a specific indication was reported, women were asked to specify the medication using an open-ended question and to give information on the timing of use (in the 3 months before pregnancy, gestational months 1–2, months 3–4 and/or months 5–9). The questionnaire on prescription medication use was developed using examples from previous studies that assessed prescription medication use through paper-based questionnaires. It was evaluated for content validity as part of a larger questionnaire on risk factors for birth defects among 15 mothers. A reminder was sent when the questionnaire was not returned within 2 months.

In addition to questionnaire data, information on prescription medication use was collected using the standard procedures implemented in Eurocat-NNL in 1997 [19]. In the regular Eurocat-NNL questionnaire, consent is asked to obtain pharmacy records for the time period starting 3 months before pregnancy until the time of delivery. In The Netherlands, almost everyone is registered with a single pharmacy and all pharmacies use computerized dispensing records. Therefore, medication records are virtually complete [20]. After the data on the medications dispensed in the requested period were received from the pharmacist, a telephone interview with the mother was conducted in which we asked whether she used the medications that were on the pharmacist's list and when and how often she used these. The majority of interviews took place more than 1 month after completion of the questionnaire. All medications that were actually used in the 3 months before pregnancy until delivery are registered in the Eurocat-NNL database as detailed as possible: name of medication, amount dispensed, daily dose and time period of use.

All medications were coded using the Anatomical Therapeutic Chemical (ATC) classification system [18]. Only prescription medications were included as pharmacy records do not contain data on distribution of over-the-counter medication. In addition, use of anaesthetics (ATC code N01), vaccinations (J05, J06 and J07), oral contraceptives (G03A) and folic acid supplements (B03BB01) were excluded from this study, because the first two are not dispensed by pharmacies and the latter may not be prescribed by a medical doctor or were not considered as medication by the respondent. Also, the Eurocat-NNL database is known to have incomplete data on these medications. We ordered the prescription medication used in the 3 months before or during pregnancy into three mutually exclusive categories, as reported by Bakker et al. [2]: medication for chronic conditions, medication for occasional and short-time use, and pregnancy-related medication (Table 1). Medications for chronic conditions were not necessarily taken on a chronic basis but may have been used on an as-needed basis only.

Table 1 Indication/pharmacological groups included in the questionnaire and their classification according to Anatomical Therapeutic Chemical nomenclature [18]

Indication/pharmacological group	Classification (ATC code)	Category[a]
Iron preparations	Iron preparations (B03A)	Pregnancy-related
Medication for nausea	Antiemetics (A03FA01, A04A, N05BA04, R06AD, R06AE)	Pregnancy-related
Sleep medication or sedatives	Hypnotics and sedatives (N05C)	Occasional/short-time use
Medication for anxiety or depression	Antidepressants, anxiolytics, and antipsychotics (N05A [excluding N05AB04], N05B, N06A)	Chronic use
Medication for asthma or chronic bronchitis	Antiasthmatics (R03)	Chronic use
Medication for epilepsy	Antiepileptics (N03A)	Chronic use
Medication for high blood pressure	Antihypertensives (C02, C07, C08, C09)	Chronic use
Medication for diabetes (including insulin)	Drug used in diabetes (A10)	Chronic use
Antibiotics	Antibiotics (D01, D06A, G01, J01, J02)	Occasional/short-time use
Prescribed pain medication	Anti-inflammatory/pain medication (M01, N02)	Chronic use
Prescribed anti-inflammatory medication	Anti-inflammatory/pain medication (M01, N02)	Chronic use
Other prescription medication		

ATC Anatomical Therapeutic Chemical

[a] Mutually exclusive categories as reported by Bakker et al. [2]

Table 2 Calculation of measures to estimate validity in test research

	Reference standard	
	Positive (truly exposed)[a]	Negative (truly unexposed)[b]
Questionnaire positive	TP	FP
Questionnaire negative	FN	TN

FN false-negative, *FP* false-positive, *TN* true-negative, *TP* true-positive

[a] Sensitivity = proportion of women who reported prescription medication use among those who were really exposed = TP/(TP + FN)

[b] Specificity = proportion of women who did not report prescription medication use among those who were really unexposed = TN/(TN + FP)

2.3 Statistical Analysis

We defined prescription medication use according to the Eurocat-NNL database (pharmacy records in combination with maternal interviews) as our reference standard. To determine the validity of the self-administered questionnaire, sensitivity (proportion of women who reported prescription medication use among those who were really exposed) and specificity (proportion of women who did not report prescription medication use among those who were really unexposed) with 95 % CIs were calculated (Table 2). These measures were calculated for any prescription medication use, for the three pre-defined medication categories and for individual medications or groups of medications if there were at least ten exposures according to the reference standard. As almost all birth defects originate in the first 4 months of pregnancy, while other neonatal outcomes are probably more dependent upon late pregnancy exposure, we determined the validity for these two time periods separately as well. Because the screening question made it easy to skip the indication-specific questions, we performed a sensitivity analysis in which we excluded all women who falsely denied prescription medication use in the screening question. In addition, as some women reported in the questionnaire that they used, for instance, an antidepressant, but did not specify the name of the medication, we classified all women who reported only medication groups as being exposed to the most frequently used subgroup or individual medication in that group according to the reference standard.

Logistic regression analysis was used to evaluate whether selected maternal and pregnancy characteristics, including maternal age at delivery, level of education, gravidity, fertility problems prior to the index pregnancy, use of folic acid in the periconceptional period, smoking or alcohol consumption during pregnancy, place of birth, vital status at birth, type of birth defect, timing of diagnosis and the time from delivery to completion of the questionnaire, influenced disagreement between the questionnaire data and the reference standard. These data were all available from the standard Eurocat-NNL questionnaire. The regression analyses were adjusted for smoking status during pregnancy and time from delivery to completion of the questionnaire whenever applicable, because these factors were associated with disagreement in the univariate analyses. All statistical analyses were performed using SPSS Version 16.0 for Windows (SPSS Inc., Chicago, IL, USA).

3 Results

Of the 1105 case mothers initially registered in Eurocat-NNL, 24 (2 %) were ineligible because they lived outside the study area at the time of delivery or their children were diagnosed with a birth defect ineligible for registration. In case of twin pregnancies in which both infants were affected with a birth defect ($n = 3$), the mother was included in this validation study only once. A total of 777 completed questionnaires on prescription medication use were returned within the study period, yielding a response rate of 72 %. Of these 777 cases, 13 mothers (2 %) did not give permission to obtain pharmacy records, and for 42 women (5 %) pharmacy records were unavailable. On 1 August 2010, pharmacy records were not yet obtained and/or maternal interviews were not yet conducted for 162 cases (21 %). Therefore, 560 women were included in this validation study. The median time between birth of the index child and completion of the questionnaire was 1.2 years (range 0.1–15.3 years).

Prescription medication use was reported by 233 (42 %) women in the questionnaire, whereas 389 (69 %) women used prescription medication in the 3 months before and during pregnancy according to the reference standard. A total of 129 different individual medications or medication groups were reported in the questionnaire and 221 in the reference standard. In Table 3, the sensitivity and specificity are shown for the medication categories, medication groups and selected individual medications. The sensitivity of the questionnaire for any prescription medication use was 0.57 (95 % CI 0.52–0.62). After ordering the medications into the three pre-defined categories, the sensitivity decreased to 0.47 (95 % CI 0.40–0.55) for medication for chronic conditions, with large numbers of false-negatives for anti-inflammatory/pain medication and corticosteroids in dermatological preparations. Sensitivity was only 0.34 (95 % CI 0.29–0.40) for medication for occasional and short-time use, and 0.51 (95% CI 0.43–0.58) for pregnancy-related medication, among which antiemetics and iron preparations were reported relatively well, with sensitivities of 0.62 (95 % CI

Table 3 Validity comparisons of prescription medication use during the 3 months before and during pregnancy among mothers of infants with birth defects

Medication group[a]	No. of subjects				Validity	
	TP	FP	FN	TN	Sensitivity (95 % CI)	Specificity (95 % CI)
Any prescription medication	221	12	168	159	0.57 (0.52–0.62)	0.93 (0.89–0.97)
Medication for chronic conditions	84	11	94	371	0.47 (0.40–0.55)	0.97 (0.95–0.99)
Antiasthmatics	23	3	6	528	0.79 (0.65–0.94)	0.99 (0.99–1.00)
Salbutamol	11	3	4	542	0.73 (0.51–0.96)	0.99 (0.99–1.00)
Antidepressants, anxiolytics, and antipsychotics	11	2	17	530	0.39 (0.21–0.57)	1.00 (0.99–1.00)
SSRIs	5	1	9	545	0.36 (0.11–0.61)	1.00 (0.99–1.00)
Antihypertensive medication	20	1	4	535	0.83 (0.68–0.98)	1.00 (0.99–1.00)
Methyldopa	3	0	7	550	0.30 (0.02–0.58)	1.00
Anti-inflammatory/pain medication	16	12	39	493	0.29 (0.17–0.41)	0.98 (0.96–0.99)
NSAIDs	8	8	32	512	0.20 (0.08–0.32)	0.98 (0.97–1.00)
Diclofenac	3	3	13	541	0.19 (0.00–0.38)	0.99 (0.99–1.00)
Ibuprofen	2	1	10	547	0.17 (0.00–0.38)	1.00 (0.99–1.00)
Naproxen	0	1	10	549	0.00	1.00 (0.99–1.00)
Antithrombotics	4	2	7	547	0.36 (0.08–0.65)	1.00 (0.99–1.00)
Corticosteroids, dermatological preparations	4	0	55	501	0.07 (0.00–0.13)	1.00
Medication for occasional and short-time use	95	8	183	274	0.34 (0.29–0.40)	0.97 (0.95–0.99)
Antibiotics, antifungals, and anti-infectives	76	7	143	334	0.35 (0.28–0.41)	0.98 (0.96–0.99)
Antifungals for dermatological use	3	1	29	527	0.09 (0.00–0.19)	1.00 (0.99–1.00)
Gynaecological anti-infectives	12	3	89	456	0.12 (0.06–0.18)	0.99 (0.99–1.00)
Antibacterials for systemic use	41	7	110	402	0.27 (0.20–0.34)	0.99 (0.97–1.00)
Amoxicillin	17	0	57	486	0.23 (0.13–0.33)	1.00
Amoxicillin and enzyme inhibitor	2	0	14	544	0.13 (0.00–0.29)	1.00
Doxycyclin	1	1	11	547	0.08 (0.00–0.24)	1.00 (0.99–1.00)
Nitrofurantoin	8	0	33	519	0.20 (0.07–0.32)	1.00
Trimethoprim	1	0	11	548	0.08 (0.00–0.24)	1.00
Ear, eye, nose and throat preparations	12	1	54	493	0.18 (0.09–0.27)	1.00 (0.99–1.00)
Pregnancy-related medication	86	16	84	374	0.51 (0.43–0.58)	0.96 (0.94–0.98)
Antacids	6	3	17	534	0.26 (0.08–0.44)	0.99 (0.99–1.00)
Omeprazole	3	0	8	549	0.27 (0.01–0.54)	1.00
Antiemetics	23	4	14	519	0.62 (0.47–0.78)	0.99 (0.98–1.00)
Meclozine, combinations	7	0	13	540	0.35 (0.14–0.56)	1.00
Medication used in fertility treatment	10	2	28	520	0.26 (0.12–0.40)	1.00 (0.99–1.00)
Chorionic gonadotrophin	2	2	20	536	0.09 (0.00–0.21)	1.00 (0.99–1.00)
Clomiphene citrate	5	1	7	547	0.42 (0.14–0.70)	1.00 (0.99–1.00)
Follitropin alfa	1	1	11	547	0.08 (0.00–0.24)	1.00 (0.99–1.00)
Iron preparations	51	12	43	454	0.54 (0.44–0.64)	0.97 (0.96–0.99)
Ferrous fumarate	9	1	60	490	0.13 (0.05–0.21)	1.00 (0.99–1.00)
Ferrous sulphate	2	1	19	538	0.10 (0.00–0.22)	1.00 (0.99–1.00)

FN false-negative, *FP* false-positive, *NSAID* non-steroidal anti-inflammatory drug, *SSRI* selective serotonin reuptake inhibitor, *TN* true-negative, *TP* true-positive

[a] Only medication groups with at least ten true exposures are shown

0.47–0.78) and 0.54 (95 % CI 0.44–0.64), respectively. For all medication groups, the sensitivity ranged between 0.07 (dermatological corticosteroids) and 0.83 (antihypertensive medication), while it ranged between 0.00 (naproxen) and 0.73 (salbutamol) for the individual medications that had at least ten true exposures. Overall, specificity was high, ranging between 0.93 (any prescription medication) and 1.00 (30 individual medications or medication groups).

Table 4 Validity comparisons of prescription medication use during pregnancy among mothers of infants with birth defects, stratified by pregnancy months

Medication group	Pregnancy months 1–4			Pregnancy months 5–9		
	No. of truly exposed[a]	Sensitivity (95 % CI)[b]	Specificity (95 % CI)[b]	No. of truly exposed[a]	Sensitivity (95 % CI)[b]	Specificity (95 % CI)[b]
Any prescription medication	248	0.49 (0.43–0.55)	0.93 (0.90–0.96)	250	0.42 (0.36–0.49)	0.93 (0.90–0.96)
Medication for chronic conditions	91	0.51 (0.40–0.61)	0.96 (0.94–0.98)	77	0.51 (0.39–0.62)	0.97 (0.95–0.98)
Antiasthmatics	15	0.87 (0.69–1.00)	0.99 (0.98–1.00)	16	0.50 (0.26–0.74)	0.99 (0.98–1.00)
Antidepressants, anxiolytics, and antipsychotics	17	0.41 (0.18–0.65)	1.00 (0.99–1.00)	9	NA	NA
SSRIs	11	0.36 (0.08–0.65)	1.00 (0.99–1.00)	4	NA	NA
Antihypertensive medication	11	0.64 (0.35–0.92)	1.00 (0.99–1.00)	16	0.88 (0.71–1.00)	1.00 (0.99–1.00)
Anti-inflammatory/pain medication	18	0.39 (0.16–0.61)	0.99 (0.98–1.00)	3	NA	NA
NSAIDs	12	0.25 (0.01–0.49)	0.99 (0.99–1.00)	1	NA	NA
Corticosteroids, dermatological preparations	25	0.08 (0.00–0.19)	1.00 (0.99–1.00)	24	0.04 (0.00–0.12)	1.00 (0.99–1.00)
Medication for occasional and short-time use	151	0.29 (0.22–0.36)	0.99 (0.97–1.00)	147	0.24 (0.18–0.31)	0.98 (0.97–0.99)
Antibiotics, antifungals, and anti-infectives	105	0.30 (0.22–0.39)	0.99 (0.98–1.00)	111	0.25 (0.17–0.33)	0.99 (0.98–1.00)
Antifungals for dermatological use	13	0.08 (0.00–0.22)	1.00	18	0.06 (0.00–0.16)	1.00
Gynaecological anti-infectives	42	0.05 (0.00–0.11)	1.00 (0.99–1.00)	54	0.06 (0.00–0.12)	1.00
Antibacterials for systemic use	67	0.27 (0.16–0.37)	0.99 (0.98–1.00)	62	0.27 (0.16–0.39)	0.99 (0.98–1.00)
Amoxicillin	34	0.24 (0.09–0.38)	1.00	45	0.16 (0.05–0.26)	1.00 (0.99–1.00)
Nitrofurantoin	18	0.17 (0.00–0.34)	1.00	13	0.23 (0.00–0.46)	1.00
Ear, eye, nose and throat preparations	31	0.23 (0.08–0.37)	1.00	27	0.11 (0.00–0.23)	1.00 (0.99–1.00)
Pregnancy-related medication	80	0.45 (0.34–0.56)	0.97 (0.96–0.99)	99	0.35 (0.26–0.45)	0.97 (0.96–0.99)
Antacids	10	0.10 (0.00–0.29)	1.00 (0.99–1.00)	9	NA	NA
Antiemetics	28	0.61 (0.43–0.79)	0.99 (0.99–1.00)	4	NA	NA
Meclozine, combinations	15	0.27 (0.04–0.49)	1.00	0	NA	NA
Medication used in fertility treatment	24	0.04 (0.00–0.12)	1.00	0	NA	NA
Chorionic gonadotrophin	10	0.00	1.00 (0.99–1.00)	0	NA	NA
Iron preparations	29	0.66 (0.48–0.83)	0.99 (0.98–1.00)	80	0.41 (0.30–0.52)	0.99 (0.97–1.00)
Ferrous fumarate	23	0.13 (0.00–0.27)	1.00 (0.99–1.00)	58	0.14 (0.05–0.23)	1.00 (0.99–1.00)
Ferrous sulphate	3	NA	NA	19	0.05 (0.00–0.15)	1.00 (0.99–1.00)

NA not applicable, *NSAID* non-steroidal anti-inflammatory drug, *SSRI* selective serotonin-reuptake inhibitor

[a] Truly exposed = true-positives + false-negatives

[b] Sensitivity and specificity were only calculated for medication groups with at least ten true exposures according to the reference standard

Table 5 Results of validity comparisons in the sensitivity analysis, excluding the false-negative reports on the screening question ($n = 168$)

Medication group[a]	Validity	
	Sensitivity (95 % CI)	Specificity (95 % CI)
Medication for chronic conditions	0.71 (0.63–0.79)	0.96 (0.94–0.98)
Antiasthmatics	0.92 (0.81–1.00)	0.99 (0.98–1.00)
Salbutamol	1.00	0.99 (0.98–1.00)
Antidepressants, anxiolytics, and antipsychotics	0.61 (0.39–0.84)	0.99 (0.99–1.00)
SSRIs	0.45 (0.16–0.75)	1.00 (0.99–1.00)
Antihypertensive medication	0.87 (0.73–1.00)	1.00 (0.99–1.00)
Methyldopa	0.30 (0.02–0.58)	1.00
Anti-inflammatory/pain medication	0.50 (0.33–0.67)	0.97 (0.95–0.99)
NSAIDs	0.36 (0.16–0.56)	0.98 (0.96–0.99)
Diclofenac	0.30 (0.02–0.58)	0.99 (0.98–1.00)
Corticosteroids, dermatological preparations	0.14 (0.01–0.26)	1.00
Medication for occasional and short-time use	0.59 (0.52–0.67)	0.97 (0.94–0.99)
Antibiotics, antifungals, and anti-infectives	0.59 (0.50–0.67)	0.97 (0.95–0.99)
Antifungals for dermatological use	0.15 (0.00–0.31)	1.00 (0.99–1.00)
Gynaecological anti-infectives	0.22 (0.11–0.33)	0.99 (0.98–1.00)
Antibacterials for systemic use	0.43 (0.33–0.53)	0.97 (0.94–0.99)
Amoxicillin	0.35 (0.22–0.49)	1.00
Amoxicillin and enzyme inhibitor	0.18 (0.00–0.41)	1.00
Nitrofurantoin	0.30 (0.12–0.47)	1.00
Ear, eye, nose and throat preparations	0.35 (0.19–0.51)	1.00 (0.99–1.00)
Pregnancy-related medication	0.75 (0.67–0.83)	0.94 (0.91–0.97)
Antacids	0.38 (0.14–0.61)	0.99 (0.98–1.00)
Antiemetics	0.85 (0.72–0.99)	0.99 (0.98–1.00)
Meclozine, combinations	0.44 (0.19–0.68)	1.00
Medication used in fertility treatment	0.40 (0.21–0.59)	0.99 (0.99–1.00)
Chorionic gonadotrophin	0.13 (0.00–0.31)	0.99 (0.99–1.00)
Iron preparations	0.74 (0.64–0.84)	0.96 (0.94–0.98)
Ferrous fumarate	0.17 (0.07–0.28)	1.00 (0.99–1.00)
Ferrous sulphate	0.17 (0.00–0.38)	1.00 (0.99–1.00)

NSAID non-steroidal anti-inflammatory drug, *SSRI* selective serotonin reuptake inhibitor

[a] Only medication groups with at least ten true exposures are shown

The sensitivity of the questionnaire for medication use in the first 4 months of pregnancy was comparable to or better than the sensitivity for medication use in the total period of 3 months before and during pregnancy (Table 4), except for any prescription medication use (0.49 vs 0.57), medication for occasional and short-time use (0.29 vs 0.34), antihypertensive medication (0.64 vs 0.83), antibiotics, antifungals and anti-infectives (0.30 vs 0.35), antacids (0.10 vs 0.26) and medication used in fertility treatment (0.04 vs 0.26). For medication use in pregnancy months 5–9, the sensitivity of the questionnaire was generally lower than for medication use in early pregnancy, notably for any prescription medication use (0.42 vs 0.49), pregnancy-related medication (0.35 vs 0.45), antiasthmatics (0.50 vs 0.87), amoxicillin (0.16 vs 0.24), ear, eye, nose and throat preparations (0.11 vs 0.23) and iron preparations (0.41 vs 0.66). However, the sensitivity for antihypertensive medications was higher in pregnancy months 5–9 (0.88) when compared with pregnancy months 1–4 (0.64). The specificities for both time periods were high (0.93–1.00) and generally comparable to or better than those in the complete pregnancy period.

After excluding the false-negative reports for any prescription medication use ($n = 168$), the sensitivity for almost all medication groups increased considerably (Table 5), but sensitivity remained below 0.50 for individual medications, with the exception of salbutamol (sensitivity 1.00). Only small or no decreases in specificity were observed. However, the large increase in sensitivity is partly biased as the number of false-negatives was artificially reduced in this sensitivity analysis, because some women who falsely denied prescription medication use in the screening question might also have denied use in the indication-specific questions if they had completed these. After reclassification of women who reported only medication groups instead of individual medications, the

Table 6 Adjusted odds ratios and 95 % CIs for the association between disagreement of the reference standard and the questionnaire and selected maternal characteristics ($n = 560$)

Characteristic	No. of subjects (%)	Any prescription medication aOR[a] (95 % CI)	Medication for chronic conditions aOR[a] (95 % CI)	Medication for short-time use aOR[a] (95 % CI)	Pregnancy-related medication aOR[a] (95 % CI)
Maternal age at delivery (years)					
<25	51 (9.1)	1.5 (0.8–2.9)	1.5 (0.7–3.3)	1.6 (0.9–3.1)	1.0 (0.4–2.4)
25–29	179 (32.0)	1.0 (0.7–1.6)	1.4 (0.8–2.3)	0.8 (0.5–1.2)	1.0 (0.6–1.8)
30–34	210 (37.5)	1.0[b]	1.0[b]	1.0[b]	1.0[b]
≥35	120 (21.4)	1.2 (0.8–2.0)	1.1 (0.6–2.0)	0.8 (0.5–1.3)	1.4 (0.8–2.5)
Low or intermediate level of education	333 (59.5)	1.0 (0.7–1.5)	1.1 (0.7–1.8)	1.1 (0.8–1.6)	1.2 (0.8–1.9)
First pregnancy	213 (38.0)	1.1 (0.8–1.6)	1.0 (0.7–1.6)	1.0 (0.7–1.5)	1.3 (0.8–2.0)
Fertility problems	87 (15.5)	1.2 (0.7–1.9)	0.7 (0.4–1.3)	1.1 (0.7–1.8)	3.5 (2.1–5.8)
Folic acid used					
Yes, in advised period	231 (41.3)	1.0[b]	1.0[b]	1.0[b]	1.0[b]
Yes, but not (completely) in advised period	235 (42.0)	0.8 (0.6–1.2)	1.0 (0.6–1.7)	1.1 (0.7–1.6)	0.7 (0.4–1.1)
No	90 (16.1)	1.1 (0.8–1.4)	1.2 (0.8–1.6)	1.1 (0.9–1.5)	1.1 (0.8–1.5)
Smoked during pregnancy	131 (23.4)	1.7 (1.1–2.6)	1.8 (1.1–2.8)	1.3 (0.9–2.0)	1.6 (1.0–2.6)
Alcohol consumption during pregnancy	99 (17.7)	1.0 (0.6–1.6)	0.8 (0.4–1.4)	0.6 (0.4–1.1)	0.7 (0.4–1.3)
Home birth	105 (18.8)	0.8 (0.5–1.3)	1.0 (0.6–1.7)	0.8 (0.5–1.2)	0.7 (0.4–1.2)
Vital status at birth					
Live-born	484 (86.4)	1.0[b]	1.0[b]	1.0[b]	1.0[b]
Miscarriage or stillbirth	15 (2.7)	1.7 (0.6–4.8)	2.4 (0.8–7.3)	2.6 (0.9–7.4)	0.4 (0.0–2.9)
Induced abortion	57 (10.2)	0.9 (0.6–1.2)	0.7 (0.5–1.2)	0.8 (0.6–1.1)	0.8 (0.5–1.2)
Chromosomal or monogenetic birth defect	148 (26.4)	0.9 (0.6–1.3)	1.4 (0.9–2.3)	0.9 (0.6–1.3)	0.8 (0.5–1.4)
Prenatal diagnosis of birth defect	131 (23.4)	1.2 (0.7–1.9)	1.0 (0.6–1.8)	0.8 (0.5–1.3)	0.8 (0.5–1.5)
Time between birth and completion of questionnaire					
≤6 months	92 (16.4)	1.0[b]	1.0[b]	1.0[b]	1.0[b]
>6 months and ≤1 year	144 (25.7)	0.7 (0.4–1.3)	1.3 (0.6–2.6)	0.5 (0.3–0.8)	1.3 (0.6–2.8)
>1 year and ≤2 years	143 (25.5)	0.8 (0.5–1.5)	1.1 (0.6–2.3)	0.9 (0.6–1.6)	1.4 (0.6–3.0)
>2 years and ≤5 years	94 (16.8)	1.6 (0.9–2.9)	1.4 (0.7–3.0)	1.3 (0.7–2.3)	2.0 (0.9–4.6)
>5 years	98 (15.5)	1.9 (1.0–3.5)	1.9 (0.9–4.0)	1.2 (0.6–2.2)	3.3 (1.5–7.4)

aOR adjusted OR, *OR* odds ratio

[a] Adjusted for smoking during pregnancy and time between birth and completion of the questionnaire. An increased OR denotes a higher level of disagreement between the reference standard and questionnaire data (i.e. worse maternal recall) compared with the reference category

[b] Reference group

sensitivity of the questionnaire for selective serotonin reuptake inhibitors (0.36), methyldopa (0.30), amoxicillin (0.23) and ferrous fumarate (0.13) increased significantly to 0.50, 0.90, 0.46 and 0.54, respectively. However, application of this assumption increased the number of false-positives, which slightly decreased specificity to 0.99 for selective serotonin reuptake inhibitors, 0.95 for amoxicillin and 0.96 for ferrous fumarate.

In Table 6, the adjusted odds ratios (ORs) and 95% CIs are shown for the associations between maternal characteristics and disagreement between questionnaire and reference standard. Among younger women (<25 years of age), disagreement regarding medication for short-time use seemed to occur slightly more often than among women in the other age groups (adjusted OR 1.6; 95 % CI 0.9–3.1). Having had fertility problems before the index pregnancy decreased maternal recall of pregnancy-related medication (adjusted OR 3.5; 95 % CI 2.1–5.8), which was attributable to poor reporting of medication used in fertility treatment. Disagreement between questionnaire and reference standard was also increased among women who smoked during pregnancy compared with non-smokers for any prescription medication (adjusted OR 1.7; 95 % CI 1.1–2.6) and medication for chronic conditions (adjusted OR 1.8; 95 % CI 1.1–2.8) and seemed to be increased for medication for short-time use (adjusted OR 1.3; 95 % CI 0.9–2.0) and

pregnancy-related medication (adjusted OR 1.6; 95% CI 1.0–2.6) as well. Having had a miscarriage or stillbirth seemed to increase disagreement between questionnaire and reference standard for medication for chronic conditions (adjusted OR 2.4; 95 % CI 0.8–7.3) and for medication for short-time use (adjusted OR 2.6; 95% CI 0.9–7.4), but these results were based on small numbers. In addition, completing the questionnaire >2 years after delivery led to increased disagreement, in particular for any prescription medication and pregnancy-related medication. For this factor, the highest ORs were observed for completing the questionnaire >5 years after delivery compared with completing the questionnaire within 6 months after delivery for any prescription medication (adjusted OR 1.9; 95 % CI 1.0–3.5), medication for chronic conditions (adjusted OR 1.9; 95% CI 0.9–4.0), and pregnancy-related medication (adjusted OR 3.3; 95 % CI 1.5–7.4). The other maternal and pregnancy characteristics, including level of education, gravidity, use of folic acid, alcohol consumption during pregnancy, place of birth, type of birth defect and timing of diagnosis, were not associated with disagreement between the questionnaire and the reference standard.

4 Discussion

In case-control studies in prenatal and perinatal epidemiology, self-completed questionnaires and personal interviews are often the only source of prenatal medication exposure information. Our results showed that the validity of a paper-based questionnaire to assess prescription medication use in the 3 months before and during pregnancy, which is being used in a similar format in many epidemiological studies, was moderate to poor for the majority of medications. Even for the etiologically relevant time period for birth defects (first 4 months of pregnancy) and for late pregnancy, women considerably underreported prescription medication use. Most maternal and pregnancy characteristics were not associated with disagreement between the questionnaire and the reference standard, except for having had fertility problems or a miscarriage or stillbirth related to the index pregnancy, smoking during pregnancy and completing the questionnaire >2 years after delivery, which were all associated with increased disagreement.

The major strength of this validation study is the use of pharmacy data which were checked for compliance by maternal interviews as the reference standard. Compliance among pregnant women varies with the type of medication, with a high compliance for medication used in the treatment of chronic conditions (70–100 %) and a low compliance for local or short-time treatment (12–77 %) [14]. Therefore, pharmacy data alone may overestimate prenatal medication exposure and, if used as a reference in validation studies, may underestimate the validity of self-reported methods, especially for medication for occasional and short-time use. However, if women did not remember taking the medication or intentionally denied use during the interview, the reference standard could be prone to underreporting, which would have slightly inflated our sensitivity levels. Unfortunately, data on medication borrowing are not available for The Netherlands, but we may assume that this behavior is uncommon as almost all prescription medications are fully reimbursed in The Netherlands [20]. Although a home inventory would provide a superior measure of medication use [21], this method of data collection cannot be used in retrospective study designs.

Other strengths of this study include the high consent rate (98 %) to obtain pharmacy records, inclusion of pregnancies ending in a miscarriage or induced abortion, and availability of detailed data on demographic and other maternal and pregnancy characteristics. As a priori power analyses indicated that 400 women with complete information (i.e. data from the questionnaire and the reference standard) were sufficient to estimate sensitivity and specificity with satisfactory precision, we stopped data collection for this validation study on 1 August 2010. This yielded missing information on the reference standard for 162 women, who were therefore excluded from our analyses. As the women with missing data were a random sample of our complete study sample, these data may be regarded as 'missing completely at random', and handling the data in an available case approach thus gives unbiased results [22].

However, our study also has some limitations. Rockenbauer et al. [23] showed that recall bias may be an important issue in case-control studies on the teratogenicity of medication use. However, other researchers did not find differences in reporting of exposure variables including medication use by case and control mothers [24, 25]. Werler et al. [26] also found little evidence for recall bias, although three factors (use of birth control after conception, urinary tract or yeast infections and a history of infertility) were reported more accurately by cases than by controls. We could not verify this because only infants with birth defects could be included in our study as Eurocat-NNL does not enrol healthy controls. However, questions about recall bias may be irrelevant as our study showed that the validity of the questionnaire is already poor among cases and therefore has very limited value in case-control studies of pregnancy outcome. Secondly, because pharmacy records do not contain information on over-the-counter medication and medication used during hospital stay, only the validity of the questionnaire for outpatient prescription medication use could be evaluated. Thirdly, the general screening question

for prescription medication use as well as the relatively broad categories and open-ended questions used in our questionnaire may have resulted in a relatively high number of false-negatives due to their inherent non-specificity. However, such an approach is often still used in self-administered questionnaires. Finally, validity could not be determined reliably for the majority of individual medications due to the low prevalence of use, despite the relatively large study population.

Although maternal recall is reliable for pregnancy-related events such as severe obstetric complications [27, 28], mode of delivery [28, 29], birth weight [28, 30, 31] and gestational age [28, 31, 32], maternal recall of medical interventions was found to be poor in previous studies [33, 34]. The results of our study are consistent with validation studies conducted in the 1980s and 1990s that showed that the validity of self-reported data on prescription medication use during pregnancy is also low [9, 12]. As expected [23, 35], the recall sensitivity of medication used in the treatment of chronic conditions and pregnancy-related medication was higher than the recall sensitivity of medication used for short-time use, with the notable exceptions of psychiatric medication (sensitivity 0.39), anti-inflammatory and pain medication (sensitivity 0.29), antithrombotics (sensitivity 0.36), dermatological corticosteroids (sensitivity 0.07), antacids (sensitivity 0.26) and medication used in fertility treatment (sensitivity 0.26). In particular, use of psychiatric medication may not only be poorly remembered, but may also be prone to social desirability bias. Although included in the medication for chronic conditions, anti-inflammatory and pain medication, as well as anxiolytics and antithrombotics, were frequently used on an as-needed basis instead of chronically, possibly leading to recall sensitivities similar to those for medication for short-time use. The poor reporting of dermatological corticosteroids might result from the fact that we did not specifically ask for the use of dermatological preparations in the questionnaire, which was also true for medication used in fertility treatment. Among the other pregnancy-related medication, antiemetics (sensitivity 0.62) and iron preparations (sensitivity 0.54) were relatively well reported, probably due to the impact of the pregnancy complication they were prescribed for. However, these levels of sensitivity of maternal self-report still limit the use of this method of data collection for epidemiological studies on pregnancy outcome.

In accordance with previous studies [27, 33], we found that time from delivery until completion of the questionnaire influenced disagreement between the questionnaire and the reference standard considerably, especially concerning pregnancy-related medication. To our knowledge, this is the first study that associated smoking during pregnancy with poorer maternal recall. Some other studies found associations between recall sensitivity of pregnancy or birth characteristics and maternal age [33], education [32, 36] and parity [28, 29, 32, 36], but others refuted these findings [26, 30, 33]. Therefore, it is still uncertain which maternal and pregnancy characteristics influence recall of pregnancy events. This issue should be the topic of future research as these associations may introduce differential misclassification. To prevent recall bias, some researchers advocate the use of malformed infants or infants with a genetic disorder instead of infants without birth defects as a comparison group [24, 37, 38]. Indeed, in our study disagreement for prescription medication use was comparable for mothers of infants with chromosomal or monogenetic birth defects and mothers of infants with non-genetic birth defects, although mothers of infants with genetic disorders appeared somewhat more likely to have disagreement for medication used for chronic conditions (adjusted OR 1.4; 95 % CI 0.9–2.3). Also, women who had a miscarriage or stillbirth instead of a live-born infant with a birth defect seemed to have increased disagreement for all medication groups except for pregnancy-related medication. This should be taken into account in studies that include fetal deaths. As women with a miscarriage or stillbirth generally have a shorter pregnancy duration than women with a live-born infant, they are less likely to have used pregnancy-related medication, particularly iron preparations. Therefore, the probability of becoming a false-negative is lower for this small group of women, which may explain the decreased OR for disagreement in this medication group.

In epidemiological research, valid measurement of all study variables is essential to prevent information bias [39]. When non-differential in nature, misclassification of a dichotomous variable resulting from underreporting (i.e. low sensitivity), as observed in this validation study, usually biases effect estimates towards the null value. As a result, associations between the exposure, in this case prescription medication use during pregnancy, and the outcome may be obscured and the exposure may unjustly be regarded as safe. Differential misclassification may lead to either underestimation or overestimation of the true effect. Sensitivity analyses in which the potential effects of exposure misclassification are quantified may provide a solution when variables are measured imperfectly, although measuring exposures without error is definitely preferable.

Retrospective studies of pregnancy outcome need additional sources of data next to self-reported methods to validly gather information on prescription medication use during pregnancy. Pharmacy records or prescription databases may be a good data source provided that compliance is verified. If questionnaires or interviews are being used, open-ended questions should be avoided [9, 11, 40, 41]. However, the sensitivity analysis in this validation study

shows that indication-oriented questions lead to incomplete ascertainment of prenatal medication exposure as well, which limits their use in epidemiological studies. In fact, medication-specific questions, which include the names of the individual medications, should be used in self-reported modes of data collection to increase sensitivity. As there are thousands of medications, however, paper-based questionnaires and interviews cannot list all individual medications that are being prescribed. Therefore, questions on medication use during pregnancy should be focused on medications of particular interest and/or on medications that are poorly reported, such as antidepressants, anti-inflammatory and pain medication, dermatological preparations and specific antibiotics. Alternatively, a combination of indication-oriented and medication-specific questions may be used in computerized questionnaires in which only relevant medications will be visible to the respondent. Whatever method of data collection is being used, interviews and questionnaires should be completed before or as shortly after delivery as possible to ensure better recall of prescription medication use during pregnancy.

5 Conclusions

The validity of the self-administered paper-based questionnaire for prescription medication use during pregnancy was moderate to poor for most medications. Furthermore, disagreement differed by some maternal characteristics, including smoking during pregnancy and completing the questionnaire >2 years after delivery. Epidemiological studies using similar questionnaires to assess medication use may need additional data sources such as pharmacy records or prescription databases next to self-reported methods. Also, previous knowledge on the effect of questionnaire design should be taken into account.

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