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Identification of gestational diabetes mellitus in European electronic healthcare databases: insights from the ConcePTION project

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ABSTRACT

Objective To develop and compare algorithms for identifying gestational diabetes mellitus (GDM) across European electronic healthcare databases and evaluate their impact on the estimated prevalence.

Design Multi-national cohort study using routinely collected electronic healthcare data

Setting National and regional databases in five European countries (Norway, Finland, Italy, Spain and France), in primary and/or secondary care.

Participants Pregnancy cohorts resulting in stillbirths or live births between 2009 and 2020, comprising 602 897 pregnancies in Norway, 507 904 in Finland, 374 009 in Italy, 193 495 in Spain and 116 762 in France.

Primary and secondary outcomes The primary outcome was the prevalence of GDM identified using six algorithms: (1) Only diagnosis; (2) Diagnosis or prescription; (3) Two diagnoses or prescriptions (*2DxRx*); (4) Diagnosis including unspecified diabetes in pregnancy or prescription (*DxRx broad*); (5) Diagnosis excluding pre-existing diabetes in pregnancy or prescription; (6) Registration of GDM in a birth registry (*BR*).

Results The strictest algorithm (*2DxRx*) resulted in the lowest GDM prevalence, while the broadest (*DxRx broad*) resulted in the highest, except in France where it was *BR*. In the Nordic countries, GDM prevalence varied only slightly by algorithm; greater variations were observed in other countries. The prevalence ranged from 3.5% (95% CI: 3.5% to 3.5%) to 4.6% (95% CI: 4.5% to 4.7%) in Norway; 12.1% (95% CI: 12.0% to 12.2%) to 15.8% (95% CI: 15.7% to 15.9%) in Finland, where prevalence was much higher than elsewhere. The prevalence ranged from 1.3% (95% CI: 1.3% to 1.3%) to 5.4% (95% CI: 5.3% to 5.5%) in Italy; 1.6% (95% CI: 1.5% to 1.7%) to 6.2% (95% CI: 6.1% to 6.3%) in Spain; and 1.7% (95% CI: 1.6% to 1.8%) to 5.8% (95% CI: 5.7% to 5.9%) in France.

Conclusions In this multinational study, GDM prevalence ranged from 1.3% to 15.8% depending on the algorithm and database. Nordic countries showed smaller differences in prevalence between algorithms, while the other countries showed larger variations, likely due to differences in coding practices, healthcare systems and database coverage.

STRENGTH AND LIMITATIONS OF THIS STUDY

⇒ A systematic component algorithm strategy to identify gestational diabetes mellitus (GDM) was applied in five European countries using harmonised data mapped to a common data model.
⇒ Multiple algorithms—based on diagnostic codes, prescriptions and specific birth registry variables—were used to estimate GDM prevalence, providing insights into how choices of algorithm components affect prevalence estimates.
⇒ This approach enabled consistent identification and comparison of GDM prevalence across heterogeneous electronic healthcare databases covering 1.8 million pregnancies.
⇒ Laboratory test results and procedure codes were not available in most databases, limiting the completeness of GDM identification.
⇒ The study was not a validation study, so algorithm performance could not be assessed using predictive values, sensitivity or specificity.

INTRODUCTION

Gestational diabetes mellitus (GDM) is a pregnancy complication associated with an increased risk of adverse outcomes in mother and infant.[1–3] In a systematic review and meta-analysis, the overall pooled GDM prevalence across 24 European countries was 10.9% (95% CI: 10.0% to 11.8%) during 2014–2019. The pooled GDM prevalence was highest in Eastern Europe (31.5%, 95% CI: 19.8% to 44.6%), intermediate in Southern Europe (12.3%, 95% CI: 10.9% to

13.9%) and Western Europe (10.7%, 95% CI: 9.5% to 12.0%) and lowest in Northern Europe (8.9%, 95% CI: 7.9% to 10.0%). However, there were considerable variations between countries within a region, particularly in Northern Europe, where the pooled GDM prevalence was 4.6% (95% CI: 3.8% to 5.5%) in Norway and 18.4% (95% CI: 16.7% to 20.2%) in Finland.[4] The variation in GDM prevalence is partly due to differences in disease occurrence as well as to other factors, such as use of different clinical definitions, diagnostic criteria and screening practices, variation in data sources and ascertainment methods for GDM.[5] Advancing maternal age, along with other factors such as obesity, family history of diabetes, prior GDM and certain ethnic backgrounds, is known risk factors for GDM. Differences in these risk factors may contribute to variation in prevalence across populations.[6]

Historically, diabetes first diagnosed during pregnancy has been classified as GDM, and up until 2013, the WHO defined GDM as glucose intolerance with onset or first recognition in pregnancy without distinguishing between diabetes arising during pregnancy and unrecognised pre-existing diabetes.[7] Since 2013, however, the WHO has made the distinction between diagnosis of diabetes mellitus in pregnancy and diagnosis of GDM, although diagnosis of GDM is based on fulfilment of the International Association of Diabetes and Pregnancy Study Group criteria anytime in pregnancy.[8] In contrast, the American Diabetes Association guideline from classifies GDM as 'diabetes diagnosed in second or third trimester of pregnancy that was not clearly overt diabetes prior to gestation',[9] thus clearly stating the diagnostic criteria are not derived from women in first trimester. However, this highlights the controversy regarding the applicability of a diagnosis of GDM during early pregnancy.[10] Consequently, the use of either a narrow or broader classification of GDM influences prevalence estimates. Regarding diagnostic criteria, the oral glucose tolerance test is considered the 'gold standard' for diagnosis of GDM, but the thresholds for blood glucose levels differ slightly across clinical guidelines, which may lead to minor differences in prevalence estimates.[6 11] Screening for GDM is increasingly being implemented throughout Europe, substantially influencing the temporal trends in prevalence and contributing to variation between countries due to differing approaches. Universal screening identifies more cases of GDM than risk-based screening or no screening, generating higher prevalence estimates.[12] This highlights the need to consider calendar time, screening practices as well as other healthcare factors and population characteristics when analysing variation in GDM prevalence.

In multinational studies based on electronic health records across Europe, identification of GDM in routinely collected health data is complicated by heterogeneous databases including different healthcare settings for data collection and coding. Therefore, a transparent and systematic approach is necessary when developing algorithms to identify GDM in multinational studies, with possibilities to tailor them to the characteristics of a database. A systematic approach is the component algorithm strategy, which is based on designing a set of standardised algorithms for the outcome, called components, which are defined in each database. The individual component algorithms are then combined into composite algorithms using logic combinations. Subsequently, the impact of composite algorithms on the occurrence of the outcome is estimated, thus providing evidence for evaluation.[13–15] The aim of this study was to use a systematic approach to develop algorithms to identify GDM in five European sources of routinely collected health data and compare the influence of the different composite algorithms on the estimated prevalence of GDM within and across databases.

METHODS

Data sources and study population

For this study, we defined pregnancy cohorts distributed in five data sources across five European countries, including routinely collected health data at a national level for Norway and Finland and at a regional level for Emilia-Romagna in Italy, Valencian Region in Spain and Haute-Garonne in France, from 2009/2010 to 2018/2019/2020 depending on data availability. The data sources included information on maternal demographics, diagnoses recorded during inpatient or outpatient hospital visits and filled or dispensed prescription medication. Norway and Finland also included information on diagnoses recorded during primary care visits and specific information pertaining to the course of pregnancy and delivery from their birth registries (details of the data sources in online supplemental table S1). The data access providers (DAPs) extracted, transformed and loaded their local data into the ConcePTION common data model (CDM), described in detail elsewhere,[16] and the formatted data were stored and analysed locally in accordance with General Data Protection Regulation. To identify pregnancies, each DAP applied the ConcePTION pregnancy algorithm described in detail elsewhere.[17] In brief, the ConcePTION pregnancy algorithm identifies information on pregnancy markers from all locally available databases via four data streams. Afterwards, pregnancy records belonging to the same pregnancy episode are reconciled in a hierarchical manner where the most accurate information on pregnancy start date (the date of the first day of last menstrual period (LMP)), pregnancy end date (date of birth, miscarriage or termination) as well as type of pregnancy end (live or stillbirth, spontaneous or induced termination, ectopic pregnancy, unknown outcome of pregnancy or ongoing pregnancy (depending on availability in each DAP)) is retained according to a set of defined rules. Details on version and quality of pregnancy records for each DAP in online supplemental figure S1.

In this study, pregnancies with a gestational age of at least 20 completed weeks (depending on availability

in each DAP) resulting in stillbirth or live birth among women 15–49 years of age were eligible for inclusion in the study population. We conducted the study in accordance with the ethical standards of the Declaration of Helsinki and each DAP gained approval for data use from their relevant ethical and/or governance review boards (details in online supplemental table S2). The study was registered in the Heads of Medicines Agencies – European Medicines Agency (HMA-EMA) Catalogue of real-world data studies as part of a main study protocol with the European Union Post-Authorisation Safety Studies (EU PASS) number 43409.

Patient and public involvement

Although we support the involvement of patients and the public, there was no funding available for such activities in this study. Therefore, no patients were involved in setting the research question, designing, conducting or interpreting the study.

Development of algorithms to identify GDM

Systematic review of studies validating GDM algorithms

We conducted a systematic literature review to identify validation studies of algorithms identifying GDM in electronic health data, resulting in eight studies for data extraction. Details of the search strategy and results of the systematic review of validation studies of GDM algorithms in online supplemental materials (search terms in online supplemental table S3 and data extraction of validation studies in online supplemental table S4). In short, the extraction showed that most studies identified were from North America, including three from the USA[18–20] and four from Canada,[21–24] and only one study was from France in Europe.[25] Although most GDM algorithms based on International Classification of Disease (ICD) 9 or 10 codes had a high positive predictive value (above 70%), their performance in primarily North American settings was probably not directly transferable to a European setting, as the accuracy of diagnosis may vary across populations, time periods, healthcare systems, as well as how data is generated and coded. Nevertheless, useful knowledge was derived from these validation studies. The study by Andrade *et al* showed that many pregnant women with a diagnosis of GDM during pregnancy also had a diagnosis of pregestational diabetes in the 6-month period before and throughout pregnancy, suggesting that diabetes diagnosed in pregnancy may be termed and coded as GDM when it is not.[18] Therefore, to increase the accuracy of GDM identification in healthcare data, it is necessary to exclude the diagnosis of pregestational diabetes.

Case definition of GDM in the study

A shared definition of GDM was adopted for this study, defining GDM as diabetes diagnosed in the second or third trimester of pregnancy to clearly distinguish it from pregestational diabetes mellitus. According to this definition, the diagnosis of GDM in the first trimester represents undiagnosed pre-existing diabetes mellitus as GDM develops later during pregnancy. Therefore, the timing of recording in relation to gestational age is an important factor that needs to be considered in the development of GDM algorithms (for records of GDM without a specific date, the criterion of an exact time window was not achievable).

Creation of component and composite algorithms to identify GDM

We applied the component algorithm strategy, and a set of standardised algorithms for GDM was designed. A component algorithm includes three standard parts: (1) the healthcare setting of the data collection (eg, specialist or primary care), (2) the data domain included in the algorithm (eg, diagnoses, prescription medication, laboratory test results, medical procedure or data source specific variables) and (3) set of concepts that defines the list of codes used to identify the outcome in the data source (eg, diagnostic codes, Anatomical Therapeutic Chemical (ATC) classification codes, procedure codes or additional concepts).[15] For this study, information from three data domains was used for the creation of the algorithm's components including (1) diagnoses, (2) prescription medication and (3) data source specific variables from birth registries. Next, the concept sets were created for each of three data domains including (1) a list of medical concepts that can be defined as GDM as well as a list of medical concepts that can be defined as (pregestational) diabetes mellitus along with their diagnostic codes in different coding systems (ICD-10, ICD-10-ES and International Classification of Primary Care-2), (2) a list of medication concepts that can serve as a proxy for GDM or (pregestational) diabetes mellitus along with their ATC codes (see online supplemental table S5 for details) and (3) a list of additional concepts specific to each data source that can be defined as GDM (online supplemental table S6 for details). This resulted in eight component algorithms listed in online supplemental table S7.

The individual component algorithms were then combined into composite algorithms using logic combinations of AND, OR and AND NOT that resulted in the creation of six different composite algorithms to identify GDM (table 1). Since the use of diagnostic codes to distinguish between GDM and diabetes mellitus is not sufficient, we used the following combination: a diagnosis of GDM in second or third trimester AND NO diagnosis of GDM in first trimester AND NO diagnosis of pregestational diabetes from 6 months prior to pregnancy through first trimester to be classified as GDM. As for medication codes, antidiabetic prescriptions can be used as a proxy to identify additional cases of GDM or diabetes mellitus (treated with medication), particularly in healthcare databases that do not capture primary care visits. However, since the indication for the prescription is usually not available, differentiation between GDM and diabetes mellitus is solely based on the timing of medication records in relation to the pregnancy. In our study, any antidiabetic medication in the second and third

Table 1 Composite algorithms to identify GDM based on combinations of components of diagnosis, prescription and specific variables of GDM

	Components							
	1	2	3	4	5	6	7	8
Description of composite algorithm	**Diagnosis of GDM in primary or secondary care**	**Diagnosis of unspecified diabetes during pregnancy in secondary care**	**Filled outpatient antidiabetic medication for GDM**	**Registration of GDM in birth registry**	**Diagnosis of early GDM (unrecognised pre-existing diabetes) in primary or secondary care**	**Diagnosis of diabetes mellitus in primary or secondary care**	**Diagnosis of pre-existing diabetes mellitus during pregnancy in secondary care**	**Filled outpatient antidiabetic medication for diabetes mellitus**
Only diagnosis (Dx)	≥1				AND NOT	AND NOT		
Diagnosis OR prescriptions (DxRx)	≥1		OR ≥1		AND NOT	AND NOT		AND NOT
Two diagnosis OR two prescriptions (2Dx2Rx)	≥2		OR≥2		AND NOT	AND NOT		AND NOT
Diagnosis including unspecified diabetes during pregnancy OR prescriptions (DxRx broad)	≥1	OR≥1	OR≥1		AND NOT	AND NOT		AND NOT
Diagnosis excluding pre-existing diabetes during pregnancy OR prescription (DxRx narrow)	≥1		OR≥1		AND NOT	AND NOT	AND NOT	AND NOT
Registration of GDM in birth registry (BR)				≥1				

'≥1' and '≥2' indicate the number of diagnosis or prescription records required to meet the algorithm criteria. Component definitions are detailed in online supplemental table S7 and code lists in online supplemental table S5 and S6.
GDM, gestational diabetes mellitus.

trimester AND NO antidiabetic medication in 6 months prior to pregnancy and throughout the first trimester are used as proxy variables for GDM. Some healthcare databases include other variables indicating a diagnosis of GDM, such as a registration of GDM in the Norwegian and Finnish birth registries, but do not include date of diagnosis.

Statistical analysis

The prevalence rates with 95% CIs were estimated for the different algorithms with the numerator changing according to the algorithm type and the denominator remaining constant. In additional analyses, the prevalences were stratified according to maternal age (divided into three categories 15–24, 25–34 and 35–49) and calendar year of pregnancy start (divided into three categories 2009–2012, 2013–2016 and 2017–2020). Stratification by maternal age and calendar year was undertaken to account for known demographic and temporal trends in GDM prevalence, which may influence observed differences across populations and time periods.

Differences in prevalence were considered significant when the 95% CIs did not overlap. R V.4.4.0 (R Foundation for Statistical Computing, Vienna, Austria) was used for all analyses, with centrally programmed study scripts distributed to the DAPs via a repository on Github.com.[26] The DAPs ran the scripts locally on their ConcePTION CDM-formatted data and shared aggregated results via the secure remote Digital Research Environment.

RESULTS

For the nationwide data sources, a total of 602 897 births from Norway and 507 904 births from Finland were included in the study. For the regional data sources, a total of 374 009 births from Emilia-Romagna in Italy, 193 495 births from the Valencian Region in Spain and 116 762 births from Haute-Garonne in France were included in the study (online supplemental figure S2). The demographic characteristics of the pregnancy cohorts identified in the five databases are presented in table 2. Overall, the distribution of pregnancies according to calendar years and maternal age was very similar across the data sources with a few exceptions: in the Nordic countries, the maternal age was younger, whereas the maternal age was older in the Southern European countries.

The algorithm 2DxRx (requiring two diagnostic codes for GDM or two prescriptions of antidiabetic medication), which is the strictest algorithm, resulted in the lowest GDM prevalence in all countries. The algorithm DxRx broad (requiring a diagnostic code for GDM or diagnosis of unspecified diabetes in pregnancy or a prescription of antidiabetic medication), which is the broadest algorithm, resulted in the highest GDM prevalence in all countries except for France where it was the algorithm BR (requiring a registration of GDM in a birth registry) (table 3). However, in the Nordic countries, the difference in the GDM prevalence varied only slightly (less than 25%) between the strictest algorithm and the broadest algorithm. In Norway, the GDM prevalence varied from 3.5% (95% CI: 3.5% to 3.5%) to 4.4% (95% CI: 4.5% to 4.7%). In Finland, the GDM prevalence, which was considerably higher than all other countries, varied from 12.1% (95% CI: 12.0% to 12.2%) to 15.8% (95% CI: 15.7% to 15.9%). In the Nordic countries, the algorithm BR generated a GDM prevalence of 3.9% (95% CI: 3.9% to 3.9%) in Norway, and 14.1% (95% CI: 14.0% to 14.2%) in Finland, which was midway between those generated by the stricter and the broader algorithms. In contrast, there was considerable variation in the GDM prevalence between the strictest and the broadest algorithms for the other countries. Prevalences differed by a factor of three when the algorithm 2DxRx was compared with the algorithm DxRx broad and the algorithm BR for France. The GDM prevalences varied from 1.3% (95% CI: 1.3% to 1.3%) to 5.4% (95% CI: 5.3% to 5.5%) in Emilia-Romagna in Italy, from 1.6% (95% CI: 1.5% to 1.7%) to

Table 2 Characteristics of the pregnancy cohorts distributed in the five data sources

	Norway No. (%)	Finland No. (%)	Italy, Emilia-Romagna No. (%)	Spain, Valencian Region No. (%)	France, Haute-Garonne No. (%)
Total number of pregnancies	602 897 (100)	507 904 (100)	374 009 (100)	193 495 (100)	116 762 (100)
Calendar year of pregnancy start					
2009–2012	223 705 (37.1)	237 033 (46.7)	146 254 (39.1)	NA	42 630 (36.5)
2013–2016	217 649 (36.1)	215 815 (42.5)	131 478 (35.2)	118 514 (61.2)	43 658 (37.4)
2017–2020	161 543 (26.8)	55 056 (10.8)	96 277 (25.7)	74 981 (38.8)	30 474 (26.1)
Maternal age at pregnancy start					
15–24	98 988 (16.4)	99 377 (19.6)	37 428 (10.0)	22 253 (11.5)	18 268 (15.6)
25–34	402 253 (66.7)	323 712 (63.7)	215 930 (57.7)	109 122 (56.4)	79 645 (68.2)
35–49	101 656 (16.9)	84 815 (16.7)	120 651 (32.3)	62 120 (32.1)	18 849 (16.1)

NA, not assessed.

Table 3 Prevalence of GDM according to the six different composite algorithms for each data source

Data sources (total number of pregnancies)	Composite algorithms					
	Only diagnosis (*Dx*)	Diagnosis OR prescriptions (*DxRx*)	Two diagnosis OR two prescriptions (*2Dx2Rx*)	Diagnosis including unspecified diabetes during pregnancy OR prescriptions (*DxRx broad*)	Diagnosis excluding pre-existing diabetes during pregnancy OR prescription (*DxRx narrow*)	Registration of GDM in birth registry (*BR*)
Norway (N=602 897)						
Pregnancies identified, No.	26 077	26 623	21 337	27 781	23 145	23 354
Prevalence per 100 (95% CI)	4.3 (4.2 to 4.4)	4.4 (4.3 to 4.5)	3.5 (3.5 to 3.5)	4.6 (4.5 to 4.7)	3.8 (3.8 to 3.8)	3.9 (3.9 to 3.9)
Finland (N=507 904)						
Pregnancies identified, No.	72 686	73 247	61 407	80 160	70 852	71 471
Prevalence per 100 (95% CI)	14.3 (14.2 to 14.4)	14.4 (14.3 to 14.5)	12.1 (12.0 to 12.2)	15.8 (15.7 to 15.9)	13.9 (13.8 to 14.0)	14.1 (14.0 to 14.2)
Italy, Emilia-Romagna (N=374 009)						
Pregnancies identified, No.	16 709	20 104	4877	20 104	17 503	NA
Prevalence per 100 (95% CI)	4.5 (4.4 to 4.6)	5.4 (5.3 to 5.5)	1.3 (1.3 to 1.3)	5.4 (5.3 to 5.5)	4.7 (4.6 to 4.8)	NA
Spain, Valencian Region (N=193 495)						
Pregnancies identified, No.	10 471	12 043	3039	12 079	11 355	NA
Prevalence per 100 (95% CI)	5.4 (5.3 to 5.5)	6.2 (6.1 to 6.3)	1.6 (1.5 to 1.7)	6.2 (6.1 to 6.3)	5.9 (5.8 to 6.0)	NA
France, Haute-Garonne (N=116 762)						
Pregnancies identified, No.	3745	5672	2013	5672	5570	6735
Prevalence per 100 (95% CI)	3.2 (3.1 to 3.3)	4.9 (4.8 to 5.0)	1.7 (1.6 to 1.8)	4.9 (4.8 to 5.0)	4.8 (4.7 to 4.9)	5.8 (5.7 to 5.9)

GDM, gestational diabetes mellitus; NA, not assessed.

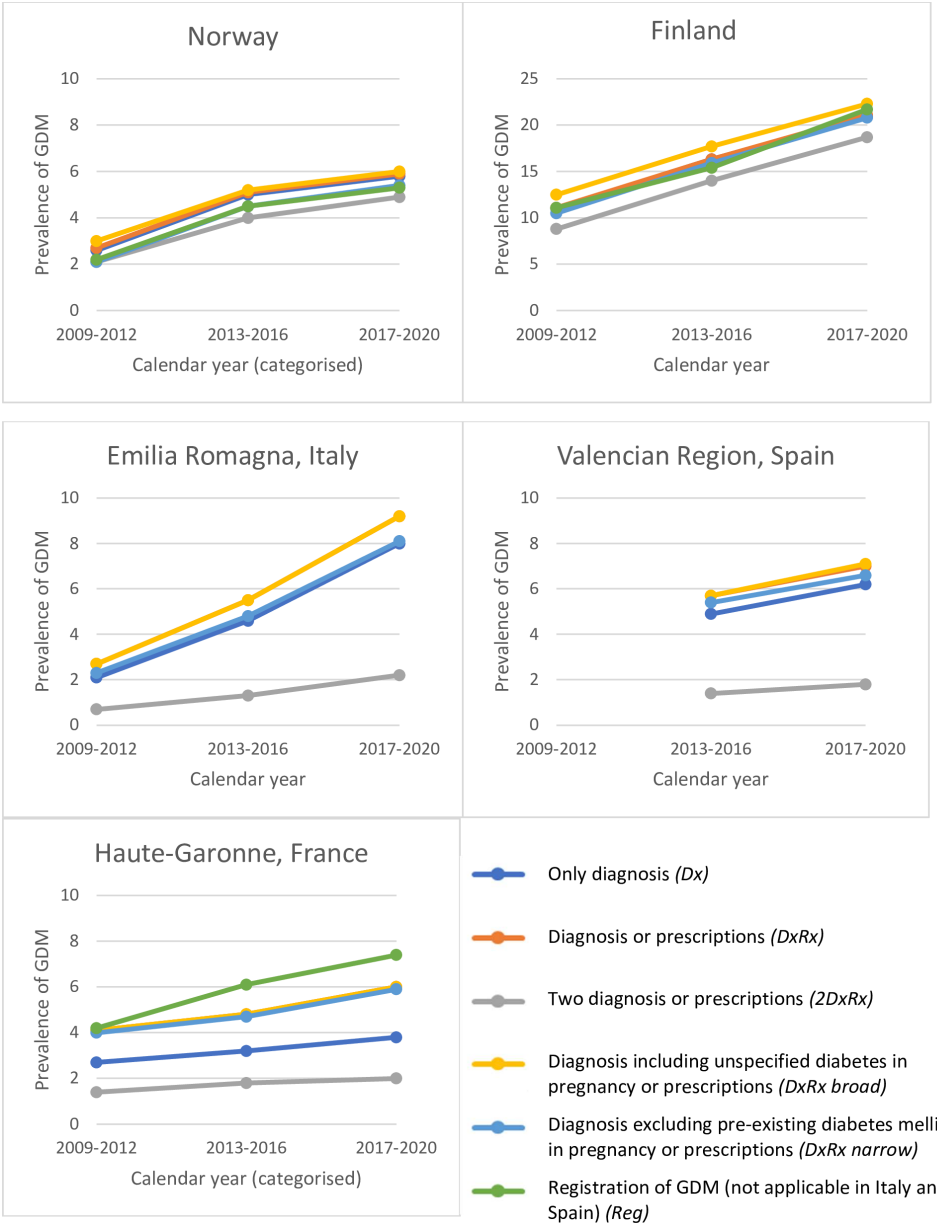

Figure 1 Prevalence of GDM stratified by calendar years at pregnancy start for each data source. Footnote: different scale on Y-axis for Finland. GDM, gestational diabetes mellitus.

6.2% (95% CI: 6.1% to 6.3%) in the Valencian Region in Spain and from 1.7% (95% CI: 1.6% to 1.8%) to 5.8% (95% CI: 5.7% to 5.9%) in Haute-Garonne in France.

For the prevalences stratified by calendar period, all algorithms yielded increasing GDM prevalence over time in all countries and showed the same pattern of the stricter algorithm 2*DxRx* and the broader algorithm *DxRx broad* (and the algorithm *BR* for France), resulting in the lowest and highest GDM prevalence over time (figure 1 and online supplemental table S8). In the Nordic countries, the prevalence roughly doubled over the period with the algorithm *DxRx*, whereas in Emilia-Romagna, the GDM prevalence increased even more over the period. For the prevalence stratified by maternal age, all algorithms yielded increasing GDM prevalence with increasing maternal age in all countries and showed the same pattern of the stricter algorithm *2DxRx* and the broader algorithm *DxRx* broad (and the algorithm BR for France) resulting in the lowest and highest GDM prevalence (figure 2 and online supplemental table S9). In Norway, the Valencian Region and Haute-Garonne, the GDM prevalence roughly tripled from the younger age group to the oldest age group with the algorithm *DxRx*. In Finland and in Emilia-Romagna, the GDM prevalence roughly doubled from the younger age group to the oldest age group with the algorithm *DxRx*.

DISCUSSION

This multinational study of approximately 1.8 million pregnancies evaluated six different algorithms to identify GDM in electronic healthcare databases in five European

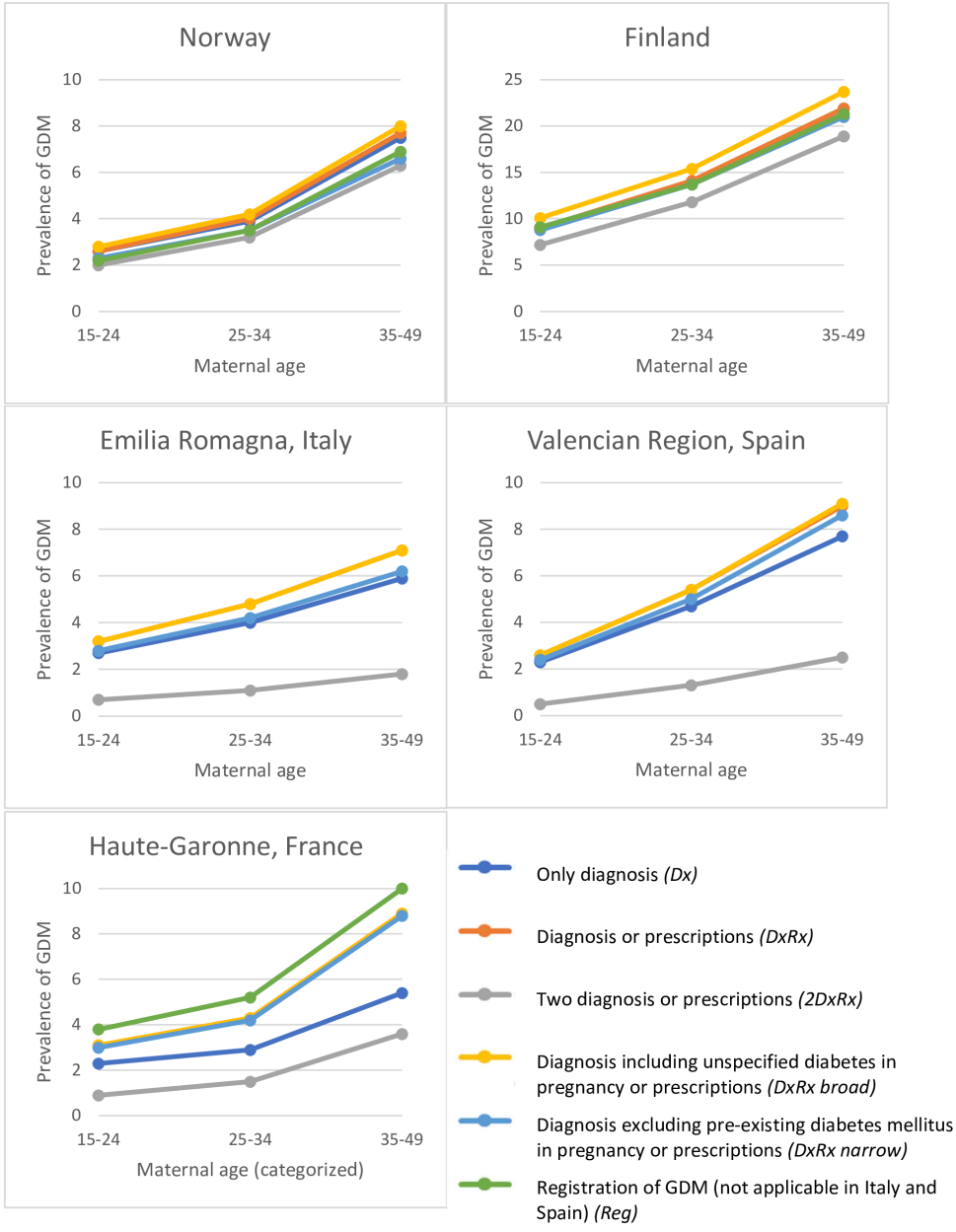

Figure 2 Prevalence of GDM stratified by maternal age at pregnancy start for each data source. Footnote: different scale on Y-axis for Finland. GDM, gestational diabetes mellitus.

countries including Norway, Finland, Italy, Spain and France. The GDM prevalence ranged from 1.3% to 15.8%, depending on the algorithm and data source used. For each of the six algorithms, there were minor but significant differences in the GDM prevalence between the countries, except for Finland, where a much higher GDM prevalence was observed. Within each of the countries, there were differences in GDM prevalence between the strictest and the broadest algorithms, but in the Nordic countries, these differences were small, whereas in the Southern and Western European countries, they were remarkably larger.

In a recent systematic review and meta-analysis of studies reporting GDM prevalence in Europe, the country-specific pooled GDM prevalence was 4.6% (95% CI: 3.8% to 5.5%) in Norway based on 19 studies, 18.4% (95% CI: 16.7% to 20.2%) in Finland based on 22 studies, 14.5% (95% CI: 11.1% to 18.1%) in Italy based on 32 studies, 15.0% (95% CI: 11.0% to 19.4%) in Spain based on 17 studies and 8.0% (95% CI: 5.9% to 10.4)% in France based on 16 studies.[4] Comparing to our results for Norway and Finland, the GDM prevalence derived from the six GDM algorithms is close to the pooled GDM prevalences reported for these countries. However, for Italy, Spain and France, the GDM prevalence derived from the six GDM algorithms was significantly lower than the pooled GDM prevalence reported for these countries in the meta-analysis. These differences may be due to most studies in the meta-analysis of Italy, Spain and France being based on different types of data sources than in our study. Our data sources from Emilia-Romagna, Valencian Region and Haute-Garonne did

not include diagnostic codes from primary care visits or outpatient hospital visits (except from emergency room visits for Emilia-Romagna), which may lead to the lower prevalence observed in our study. Although several of our algorithms included antidiabetic prescriptions as a proxy to capture GDM in primary care or outpatient hospital visits, most pregnant women control GDM with lifestyle modifications.[27 28] In Italy, the GDM prevalence only increased from 4.5% (95% CI: 4.4% to 4.6%) with the algorithm *Dx* to 5.4% (95% CI: 5.3% to 5.5%) with the algorithm *DxRx* and in Spain from 5.4% (95% CI 5.3% to 5.5%) to 6.2% (95% CI: 6.1% to 6.3%), although it increased slightly more in France from 3.2 (95% CI: 3.1 to 3.3) to 4.9 (95% CI 4.8 to 5.0). Therefore, adding this component to the GDM algorithms identified only a few additional cases of GDM, particularly for Spain and Italy. Furthermore, our study applied a narrow definition of GDM across all algorithms by only ascertaining records of GDM in second or third trimester of pregnancy, which may lead to a lower GDM prevalence. In addition, all our algorithms (except the algorithm *BR* in Norway, Finland and Haute-Garonne in France) required women not to have been diagnosed with pregestational diabetes in the 6 months before LMP to exclude potential false-positive cases of GDM where diabetes mellitus during pregnancy had been labelled as GDM.[18] However, this may result in lower GDM prevalence compared with studies that do not apply this exclusion criteria, for example, if observation time of the prepregnancy period is not available. Lastly, four of our algorithms (except the algorithm *Dx* and the algorithm *BR*) required women not to have a prescription for antidiabetic medication in the 6 months before LMP (ATC codes A10: Drug used in Diabetes). Although this component was intended as a proxy to capture (pregestational) diabetes mellitus in primary care or outpatient hospital visits, and thereby exclude potential false positive cases of GDM, it may be too restrictive. If the antidiabetic medication is prescribed off-label to women with non-diabetic diseases such as polycystic ovary syndrome (PCOS) or obesity, who are at increased risk of developing GDM, this may exclude potential true positive cases of GDM, resulting in lower prevalence. However, since our data only covers up to 2020, it can be assumed that among most women, antidiabetic prescriptions are used for treatment of diabetes in our study.

Screening practices for GDM varied across the five countries. Finland implemented universal screening in 2008 that is, before the start of our study cohort, which likely contributed to its considerably higher observed GDM prevalence compared with all other countries. A Finnish study showed that the GDM prevalence quickly increased following the introduction of the new screening recommendations from 7.3% in 2006–2008 to 11.3% in 2010–2012.[29] A similar comprehensive screening approach was first introduced in 2018 in Norway, that is, near the end of our study cohort, replacing the previous risk-factor based screening approach.[30 31] In France and Italy, there has been a risk-based screening approach for GDM throughout our study period.[32–34] These differences in screening practices explain some of the variation in GDM prevalence observed across countries.

In the Nordic countries, the differences in GDM prevalence between the strictest and the broadest algorithm were small, although the algorithm *BR* produced a GDM prevalence that was midway between those two. The registration of GDM in the birth registries is often considered the gold standard in Norway and Finland. A Norwegian study validating diabetes registration in the Medical Birth Registry in 1998 found a positive predictive value of 89% using medical records as reference standard.[35] A recent Finnish study linking laboratory results from oral glucose tolerance tests to pregnant women in the Medical Birth Registry in 2009 indicates high accuracy of the GDM registration. Among 1234 pregnant women with abnormal plasma glucose levels corresponding to GDM (according to the Finnish guidelines), all had a registration of GDM in the Medical Birth Registry.[36] In the Southern and Western European countries, the differences in GDM prevalence between the algorithms were remarkably larger due to the algorithm *2DxRx* producing a very low GDM prevalence indicating that only a few women have two diagnoses of GDM (or prescription of antidiabetic medications) during pregnancy. In Emilia-Romagna and Valencian Region, this may be due to their databases only including diagnostic codes from inpatient hospital visits (except from emergency room visits for Emilia-Romagna) and most women being only admitted to the hospital once in connection with their birth.

The main strengths of this study are the uniform data assessment procedures in regions with good geographical spread in Europe, covering approximately 1.8 million pregnancies. This study has several limitations that should be acknowledged. One significant limitation is the lack of access to additional data domains, such as laboratory test results and procedure codes, which could aid in identifying cases of GDM. In the ConcePTION CDM, laboratory results from oral glucose tolerance tests have been mapped to diagnosis of GDM but are only available in a few databases and with unknown completeness and therefore were not used for this study. In databases without GDM diagnoses from primary care visits, procedure codes for administration of an oral glucose tolerance test (without results) or procedure codes for diabetes management or counselling may be used as proxies to identify cases of GDM.[18] However, due to the inherently low specificity of these codes for GDM identification, such algorithm components were not used for this study.

Future research on GDM prevalence should focus on addressing the regional discrepancies observed in this study by harmonising diagnostic criteria and improving coding practices across healthcare systems. Standardising definitions and ensuring consistent data collection methods could help reduce variability and enhance the comparability of findings between countries. Additionally, further exploration of how different algorithms influence the identification and characterisation of GDM

cases is warranted, particularly in regions where differences between narrow and broad algorithms are substantial. Investigating the impact of these algorithms in GDM studies is essential for better understanding their implications in GDM research. Lastly, validation studies should be conducted to assess the performance and reliability of the GDM algorithms proposed in this study, ensuring their applicability and accuracy in diverse healthcare settings. Such efforts will contribute to more precise epidemiological insights and inform improved prevention and management strategies in Europe.

In this multinational study, GDM prevalence varied widely, ranging from 1.3% to 15.8% depending on the algorithm and data sources employed. In Norway and Finland, prevalence rates were consistent with those found in previous meta-analyses, while lower rates were observed in Italy, Spain and France. The differences between the strictest and the broadest GDM algorithms were relatively modest in the Nordic countries but notably larger in Southern and Western Europe. These regional discrepancies likely stem from variations in coding practices, healthcare system structures including diagnostic criteria and screening practices, and the completeness of database coverage. To optimise future studies of GDM, we recommend selecting algorithms based on the study's specific objectives, prioritising narrow algorithms when high specificity is essential and broader algorithms when high sensitivity is paramount.

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Contributors HN and AL drafted the main study protocol, all coauthors provided input on it. DM-N drafted the GDM protocol and statistical analysis plan (SAP). All authors reviewed and commented on these documents. VH wrote the syntax analysis scripts based on the SAP with support from CLAN. HN and MHJvG liaised with the DAPs to run them. The first draft of the manuscript was written by DM-N. All authors commented on all versions of the manuscript. All authors contributed to the interpretation, discussed the results and approved the submitted manuscript. Norway: HN applied for the study data and obtained all required approvals for the Norwegian data in this study. HN, VMi and SH contributed to data curation and were responsible for the mapping of the Norwegian data onto the ConcePTION CDM. HN, DM-N, VMi and MHJvG contributed to data interpretation and benchmarking of the Norwegian data in the study and signed off on the aggregated Norwegian data that was uploaded to the DRE (safe server at UMCU). Finland: MLe applied for the study approval and obtained the Finnish data in this study. VM and MKL were responsible for the mapping of the Finnish data onto the ConcePTION CDM. VMa was responsible for data curation, running scripts on the Finnish data and debugging. MKL contributed to data interpretation and benchmarking of the Finnish data in the study. MKL reviewed the aggregated Finnish results and approved their upload to the DRE (safe server at UMCU). Italy: LC was responsible for data curation, running scripts on the Italian data and debugging. MM contributed to data interpretation and benchmarking of the Italian data in the study. AN and MM reviewed the aggregated Italian results and approved their upload to the DRE (safe server at UMCU). Spain (Valencian Region): CC-C, obtained all required approvals: the Spanish Medicines Agency (AEMPS) classification and the Clinical Research Ethics Committee approval; and applied for the study data to the Regional Commission (PROSIGA). LG-V contributes to the reception and adequacy of the data format. LB-B develops the mapping to the ConcePTION Common Data Model and executes the analysis scripts. During the script execution, LB-B and CC-C, implement the data quality according to the study methodology and manage some issues during the process. LG-V, CC-C, LB-B contribute to data interpretation and the benchmarking of the Valencian Region data and approved their upload to the DRE (safe server at UMC). CC-C guards for the custody of the local data into the institutional server. France: CD-M applied for the study approval and obtained the French data in this study. CD-M were responsible for the mapping of the French data onto the ConcePTION CDM. AC was responsible for data curation, running scripts on the French data and debugging. CD-M and MB contributed to data interpretation and benchmarking of the French data in the study. MB reviewed the aggregated French results and approved their upload to the DRE (safe server at UMCU). HN is the guarantor of this work and accepts full responsibility for the overall contents of the manuscript. While HN did not have full access to raw data in all countries, HN oversaw the study design, interpretation of results and preparation of the manuscript, and affirms that the report is an honest, accurate and transparent account of the study. Deceased Author: AL passed away in January 2025. She contributed significantly to the drafting of the main study protocol, interpretation of the results and provided comments on the manuscript during its development. Due to her passing, she was not involved in approving the final submitted version or any subsequent revisions. We respectfully acknowledge her contributions and dedicate this work to her memory.

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Competing interests DM-N is an employee of Novo Nordisk A/S. SL-L is an employee of Novartis and owns stocks. AG is an employee of Janssen Biologics B.V. and owns J&J company stocks. VH and CLAN are currently salaried employees at University Medical Center Utrecht, which receives institutional research funding from pharmaceutical companies and regulatory agencies, administered by University Medical Center Utrecht. All other coauthors have no competing interests to disclose.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Not applicable.

Ethics approval Norway: The study was approved by the Regional Committee for Research Ethics in South-East Norway (approval number 85224) and by the Data Protection Officer at the University of Oslo (approval number 519858). Data were handled and stored in accordance with the General Data Protection Regulation. Finland: Ethical approval is not required for register-based studies. Institutional Review Board at the Finnish Institute for Health and Welfare approved the study and waived the requirement for obtaining informed consent for the secondary use of health administrative data from study participants (THL/543/6.02.00/2021).

Data were handled and stored in accordance with the General Data Protection Regulation. Italy (Emilia Romagna Region): The study was approved by the local ethical committee (approval number 593/2023/Oss/UniFe). Data were handled and stored in accordance with the General Data Protection Regulation and in agreement with the Authority for Healthcare and Welfare, Emilia Romagna Regional Health Service, Bologna, Italy. We thank Elisa Ballardini and Aurora Puccini for their contributions to this work. Spain (Valencian Region): The study (code: IMI-IMN-2019-01) was classified as an Observational Post-authorisation Study 'Other designs' (EPA-OD) by Spanish Medicines Agency (AEMPS), available on: https://sede.aemps.gob.es; and approved by the Arnau de Vilanova Hospital's Clinical Research Ethics Committee on 29 January 2020, according to the Spanish regulations (approval number 1/2020). At regional level following the national Personal Data Protection and guaranteeing digital rights (Law 3/2018), the study was approved by the Commission of the Regional Government (PROSIGA) that has the right of giving RDRU Fisabio authorisation to process the data (references: SD2556; SD2577; SD2578; SD2579; SD2580; SD2581; SD2582). France: The EFEMERIS cohort was approved by the French Data Protection Authority on 7 April 2005 (authorization number 05-1140). This study was performed on anonymised patient data. The women included in the EFEMERIS database were informed of their inclusion and of the potential use of their anonymised data for research purposes. They could oppose the use of their data at any time. The women included in the EFEMERIS database know that their collected and anonymised data can be used for medical research purposes and can thus be published. The study was approved by the EFEMERIS steering group. Data were handled and stored in accordance with the General Data Protection Regulation. Informed consent was not obtained, as this study made secondary use of anonymised electronic healthcare data. All data analyses were performed locally on secured servers hosted by each data access partner in accordance with all applicable ethical approvals and GDPR regulations.

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Data availability statement All data relevant to the study are included in the article or uploaded as supplementary information. All relevant data are within the paper and its Supplemental material. Authors may not share additional data due to regulations which restrict access and distribution to those with ethical and legal permission to use the data. The study material is available to other researchers upon an application to relevant register holders.

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