Trends in the incidence of diagnosed diabetes: a multicountry analysis of aggregate data from 22 million diagnoses in high-income and middle-income settings

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Summary

Background Diabetes prevalence is increasing in most places in the world, but prevalence is affected by both risk of developing diabetes and survival of those with diabetes. Diabetes incidence is a better metric to understand the trends in population risk of diabetes. Using a multicountry analysis, we aimed to ascertain whether the incidence of clinically diagnosed diabetes has changed over time.

Methods In this multicountry data analysis, we assembled aggregated data describing trends in diagnosed total or type 2 diabetes incidence from 24 population-based data sources in 21 countries or jurisdictions. Data were from administrative sources, health insurance records, registries, and a health survey. We modelled incidence rates with Poisson regression, using age and calendar time (1995–2018) as variables, describing the effects with restricted cubic splines with six knots for age and calendar time.

Findings Our data included about 22 million diabetes diagnoses from 5 billion person-years of follow-up. Data were from 19 high-income and two middle-income countries or jurisdictions. 23 data sources had data from 2010 onwards, among which 19 had a downward or stable trend, with an annual estimated change in incidence ranging from –1·1% to –10·8%. Among the four data sources with an increasing trend from 2010 onwards, the annual estimated change ranged from 0·9% to 5·6%. The findings were robust to sensitivity analyses excluding data sources in which the data quality was lower and were consistent in analyses stratified by different diabetes definitions.

Interpretation The incidence of diagnosed diabetes is stabilising or declining in many high-income countries. The reasons for the declines in the incidence of diagnosed diabetes warrant further investigation with appropriate data sources.

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Introduction

The prevalence of diabetes has risen substantially over the past few decades.[1,2] Monitoring of the total burden of diabetes has focused mainly on describing diabetes prevalence,[1–3] with the rise being interpreted as reflecting increasing risk in the population. However, prevalence is a crude and potentially misleading metric of the trajectory of an epidemic, since increasing prevalence of a disease might be due to increasing incidence rates (ie, the rate at which new cases develop), improved survival, or simply incidence exceeding mortality. Furthermore, prevalence is not a reliable metric to study changes in population risk for diabetes. Such changes would be detected earlier and more reliably by examining trends in incidence rates over time.

Findings from some studies have suggested that diabetes incidence might be falling despite rising or stable prevalence,[4,5] but data are not consistent.[6] Our previous systematic review showed that among 15 studies reporting diabetes incidence data in the period from 2006 to 2014, 22 (67%) of the 33 populations had stable or decreasing diabetes incidence rates.[7] This systematic review was limited by differences between the studies with respect to reported time periods, diabetes definitions, the scarcity of age-specific data, and an inability to ascertain whether changes to screening practice could be driving these trends. In the current study, we aimed to assemble summary data on clinically diagnosed diabetes incidence from registries, administrative data, health insurance data, and health surveys to characterise the recent direction of the diabetes epidemic among a set of mostly high-income countries with such data available. Furthermore, we did exploratory

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Research in context

Evidence before this study

We previously published a systematic review of studies reporting trends of diagnosed diabetes incidence in adults from January, 1980, to December, 2017. In this systematic review, we showed that, in most countries for which data were available, the incidence of diagnosed diabetes increased from the 1990s to the mid-2000s, but was stable or declined in the period from 2006 to 2014 in two-thirds of populations. However, data were reported across different time periods, used different diabetes definitions, and age-specific data were scarce. Furthermore, we could not ascertain whether changes to screening practice could be driving these trends. We completed an informal literature search in MEDLINE using the same search terms as for the systematic review to find studies published in English between Jan 1, 2018, and Aug 28, 2020. This identified nine further studies, which similarly showed a downward trend in incidence in the majority of studies in recent years.

Added value of this study

Using systematically collected, aggregated data by age group, sex, and calendar year from 24 population-based data sources (in 21 mostly high-income countries or jurisdictions), we showed that the incidence of diagnosed total or type 2 diabetes has been falling or stable since approximately 2010 onwards in both men and women in many of these countries. Changes in diabetes screening and diagnostic tests seemed unlikely to account for all of the decrease in the incidence of diagnosed diabetes in the datasets with available screening data.

Implications of all the available evidence

The causes for the decline in the incidence of diagnosed diabetes are uncertain but might include prevention activities.

analyses with the aim of determining whether changes in diagnosed diabetes incidence were associated with changes in diabetes screening and diagnosis using available data from two data sources.

Methods

Data sources and procedures

For this multicountry, aggregate data analysis, data sources measuring diabetes incidence were identified from our systematic review of incidence[7] and from sources known to the authors. Data sources were required to: have ongoing enrolment of new members (or regular recruitment of new independent cohorts); record new-onset (incident) diabetes; record sex-specific and age-specific data; and include at least 5000 people in the population at risk of developing diabetes in each calendar year. We identified 24 data sources (including registries, administrative data, health insurance data, and health surveys) that had individual-level information on diagnosed diabetes incidence. Each data source provided detailed aggregate reports for each individual calendar year on diagnosed diabetes incidence (total or type 2 diabetes) by sex and by 5-year age group over the time period from 1995 to 2018 (or a subset thereof). We also collected information on definitions of diabetes in each data source and on use of HbA_{1c} for diabetes diagnosis in each relevant country. The protocol and the standardised data collection tool can be found in the appendix (pp 1–7)

The outcome of interest was the incidence rate of clinically diagnosed diabetes. The means by which diabetes diagnosis was ascertained varied among the data sources, and included blood glucose concentration, HbA_{1c}, linkage to medication or reimbursement registries, clinical diagnosis by health-care professionals, administrative data (International Classification of Diseases, version 9 [ICD-9] or version 10 [ICD-10], codes), self-report, or algorithms based on several of these elements. A detailed description of how each data source defined diabetes is shown in the appendix (pp 8–9). Data sources provided the data by sex, 5-year age bands (from <20 years to >85 years), and single calendar year. Counts (incident cases) and amount of risk time among people without diabetes were also provided.

The quality of the data sources was assessed by use of a modified Newcastle–Ottawa scale designed to assess the risk of bias in cohort studies.[8] This modified scale included items that assess representativeness of the study population, sample size at each timepoint, the method of assessing diabetes status, whether gestational diabetes could be excluded, and the number of data points (years) reported. The maximum score that could be allocated was 8. Risk of bias was classified as high (total score between 0 and 4), medium (score 5 or 6), or low (score 7 or 8; appendix p 11).

This study was approved by the Human Research Ethics Committee of Alfred Health.

Statistical analysis

We modelled incidence rates using age and calendar time as quantitative variables. We used Poisson likelihood for multiplicative models with events as outcome and log person-years as offset. We fitted age–period–cohort models[9] using cubic splines. Knots for the splines were placed at evenly spaced quantiles of the marginal distribution of the event times for each of the three variables in the model (age, period [calendar time], and cohort [period minus age]). For each data source and sex, we plotted the estimated incidence rates by age for a select set of dates 4 years apart, spanning the observation period, as well as incidence rates by period for five selected ages (40, 50, 60, 70, and 80 years). The estimated rates from the age–period models were used to compute

age-standardised and sex-standardised rates via direct standardisation (to the 2010 EU standard population) by calendar time for each data source, to provide an overview of general trends. We also fitted a set of age–period models with smooth age effects but a linear spline effect of calendar time with a single knot (join point), located at 2009, 2010, 2011, and 2012 for each data source. 95% CIs were computed as Wald CIs (back transformed from log rates ± 1·96 SE). In sensitivity analyses, we stratified findings by diabetes definition and by type of data source, restricted findings to data sources reporting exclusively type 2 diabetes, and excluded data sources with a quality score in the bottom quartile. Data were reanalysed after excluding women younger than 50 years to remove the possibility that the capture of gestational diabetes could be driving the patterns of incidence. Detailed statistical models are described in the appendix (pp 15–17).

To explore the potential effect of the use of HbA_{1c} as a diagnostic test on trends in diagnosed diabetes incidence and to investigate whether changes in screening rates have affected these trends, we collected detailed screening data from two data sources that were able to provide such data (Maccabi Healthcare Services in Israel and a dataset from Ontario, Canada [a subset of national Canadian data]). From these two data sources, we obtained the proportion of the population having blood glucose and HbA_{1c} tests among the population free of diagnosed diabetes in each year. We also obtained the yield of diabetes cases for each year from these two data sources, calculated as the number of newly diagnosed cases per 1000 blood glucose tests.

Stata software (version 15.1) was used for data management, and R software (version 3.6.3) was used for statistical analyses and graphics.

Role of the funding source

The US Centers for Disease Control and Prevention is the employer of two authors (MEP and LJA). MEP was involved in study design, data collection, data interpretation, and editing of the report. LJA was involved in data collection, data interpretation, and editing of the report. Diabetes Australia and the Victoria State Government Operational Infrastructure Support Program had no role in study design, data collection, data analysis, data interpretation, or writing of the report.

Results

24 datasets from 21 countries or jurisdictions, with 22 million new cases of diagnosed diabetes from 5 billion person-years, were available for analysis (table 1; appendix p 10). Four of the data sources were from Asian populations (Hong Kong, Singapore, South Korea, and Taiwan). 19 high-income, two middle-income (Russia and Ukraine), and no low-income countries or jurisdictions had datasets included in the analysis. 13 of 24 data sources were derived from whole populations in the relevant countries or jurisdictions. A further three data sources were nationally representative samples.

Various data sources were included: 12 (50%) of 24 were administrative sources, five (21%) were health insurance data sources, six (25%) were registries, and one (4%) was a health survey. Diabetes was defined by clinical diagnosis in ten (42%) data sources, an algorithm in ten (42%), diabetes medication use in three (13%), and by self-report of a health-care provider diagnosis in one (4%). 13 (54%) datasets reported incidence specifically for type 2 diabetes, with the remainder reporting incidence of all types of diabetes combined (table 1). Study quality scores ranged from 3·0 to 8·0, with a median of 6·0 (IQR 4·5–7·0; appendix pp 12–14).

Incidence in each data source, which was standardised to the 2010 EU standard population, varied over the time period included in the analysis (1995–2018). From about 2010 onwards, among the 23 data sources that reported at least 1 year of data after 2009, 19 showed a downward or flat trend in diabetes incidence (figure 1). Sex-specific findings were broadly similar (appendix pp 29–30). Among the remaining four data sources, Lithuania and Singapore showed continuously increasing incidence across all the available years; Israel (Maccabi Healthcare Services) showed a small rise in some of the most recent years, having fallen in earlier years; and for the data from Kaiser Permanente Northwest in the USA, the incidence of diagnosed diabetes increased from the start of reporting (1995) to 2000 and then decreased until 2006, followed by increasing incidence until the end of the reporting period (2016). In sensitivity analyses, we stratified findings by diabetes definition (appendix pp 31–34) and by type of data source (appendix pp 35–38). We also restricted findings to data sources reporting exclusively type 2 diabetes (appendix p 39) and excluded data sources with a quality score in the bottom quartile (appendix p 40). In these sensitivity analyses, patterns of incidence trends did not vary substantially from the main analyses, with the vast majority of data showing declining or stable incidence trends after 2010. In a sensitivity analysis that excluded women younger than 50 years, there was no detectable difference in trends (data not shown). The age-standardised and sex-standardised estimates by year and data source are shown in the appendix (pp 17–19).

Several populations had a change in the trajectory of incidence at or around 2010 (figure 1). Thus, incidence trends were compared for every population before and after the years around 2010 (using join points at 2009, 2010, 2011, and 2012). Figure 2 shows the annual estimated change in incidence before and after each of these years for each population. A significant downward trend in incidence was seen in 19 (79%) of 24, 19 (83%) of 23, 18 (82%) of 22, and 17 (81%) of 21 populations after the 2009, 2010, 2011, and 2012 cutoff points, respectively (appendix pp 20–27). 23 data sources had data from 2010 onwards, among which 19 had a downward or stable trend, with an annual estimated change in incidence ranging from –1·1% to –10·8%. Among the four data sources with an increasing trend from 2010 onwards, the annual

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See **Online** for appendix

	Origin of data	Type of data	Years analysed for incidence	Age range (years)	Person-years (1000s)	Number of incident diabetes cases	Diabetes definition	Diabetes type
Australia	National Diabetes Services Scheme	Registry	2002–15	0–89	286 819	859 604	Clinical diagnosis	Type 2 diabetes
Canada	Canadian Chronic Disease Surveillance System*	Administrative	2000–15	≥1	489 132	3 035 440	Algorithm	All diabetes
Denmark	National Patient Register, prescription database, health insurance database, diabetes quality database, and eye screening database	Registry	1996–2016	≥0	111 005	351 127	Algorithm	Type 2 diabetes
France	National Health Data System	Administrative	2012–17	≥0	368 629	1 508 809	Antidiabetes medications	All diabetes
Hong Kong	Hong Kong Hospital Authority	Administrative	2005–16	≥0	79 742	497 636	Algorithm	All diabetes
Hungary	National Institute of Health Insurance Fund Management database	Administrative	2009–16	≥0	73 425	295 532	Antidiabetes medications	Type 2 diabetes
Israel	Clalit Health Services	Health insurance	2004–16	≥0	51 296	357 225	Algorithm	All diabetes
Israel	Maccabi Healthcare Services	Health insurance	2001–15	≥0	25 548	114 173	Algorithm	Type 2 diabetes
Lombardy, Italy	Administrative health databases	Administrative	2002–12	≥0	97 951	618 891	Algorithm	All diabetes
Latvia	Latvian Diabetes Registry	Registry	1999–2016	≥0	38 252	120 753	Clinical diagnosis (ICD-10)	Type 2 diabetes
Lithuania	National Compulsory Health Insurance Fund Information System	Administrative	2003–16	≥0	42 479	108 279	Clinical diagnosis (ICD-10)	All diabetes
Netherlands	NIVEL Primary Care Database	Administrative	2011–16	≥0	7306	32 484	Clinical diagnosis (ICPC-1)	All diabetes
Norway	Norwegian Patient Registry, Primary Care Database and Norwegian Prescription Database	Administrative	2009–14	≥0	29 971	97 325	Clinical diagnosis (ICD-10, ICPC-2)	Type 2 diabetes
Russia	National Diabetes Register of the Russian Federation	Registry	2000–18	≥0	2 737 313	4 841 628	Algorithm	Type 2 diabetes
Scotland, UK	SCI–Diabetes database	Registry	2004–15	≥0	60 120	214 548	Clinical diagnosis (Read codes)	Type 2 diabetes
Singapore	National administrative data (Ministry of Health of Singapore)	Administrative	2012–16	≥0	17 978	126 365	Clinical diagnosis (ICD-10)	All diabetes
South Korea	National Health Insurance Service–National Sample Cohort	Health insurance	2006–15	≥0	9206	50 515	Antidiabetes medications	All diabetes
Spain	Information System for the Development of Research in Primary Care	Administrative	2007–16	≥0	53 326	250 987	Clinical diagnosis (ICD-10)	Type 2 diabetes
Taiwan	National Health Insurance Research Database (LHID 2000)	Health insurance	2002–11	≥0	8845	58 333	Algorithm	Type 2 diabetes
UK	THIN database	Administrative	2000–13	≥0	113 856	205 498	Clinical diagnosis (physician)	Type 2 diabetes
Ukraine	System of Diabetes Mellitus Care in Ukraine (Volyn Oblast)	Registry	2005–10	≥0	6057	10 503	Clinical diagnosis (physician)	Type 2 diabetes
USA	KPNW (integrated managed care consortium)	Health insurance	1995–2016	≥0	9479	54 070	Algorithm	Type 2 diabetes
USA	Medicare (claims data for beneficiaries)	Administrative	2001–15	≥68	230 852	8 206 913	Algorithm	All diabetes
USA	NHIS	Survey	1995–2015	20–84	534	5672	Self-report	All diabetes

ICD-10=International Classification of Diseases, version 10. ICPC-1=International Classification of Primary Care, first version. ICPC-2=International Classification of Primary Care, second version. KPNW=Kaiser Permanente Northwest. LHID 2000=Longitudinal Health Insurance Database, randomly sampled from the registered beneficiaries in the year 2000. NHIS=National Health Interview Survey. NIVEL=Netherlands Institute for Health Services Research. SCI=Scottish Care Information. THIN=The Health Improvement Network. *This Canadian data source excluded data from Yukon Territory and Saskatchewan. Furthermore, data from Nova Scotia excluded people aged 1–19 years.

Table 1: **Summary characteristics of the 24 data sources, by country or jurisdiction**

estimated change ranged from 0·9% to 5·6% (appendix pp 22–27). The distribution of studies was very similar when using any of the 4 years (2009, 2010, 2011, or 2012) as the cutoff point, and when stratified by sex (appendix pp 20–27). Age-specific and calendar year-specific data are shown for each population in the appendix (pp 42–65).

Table 2 is a summary of when the use of HbA_{1c} to diagnose diabetes was formally introduced in each country or jurisdiction for which data were available. The earliest formal introduction was in the USA, in 2010, with three other countries recommending its use before 2012. In France, Latvia, Lithuania, and Ukraine, there has been no formal recommendation to use HbA_{1c} for diagnosis; among these countries, France and Latvia have showed declines in incidence. Figures 3 and 4 present screening data by age and sex from Israel (Maccabi Healthcare

Services) and from an administrative diabetes dataset in Ontario, Canada. Among individuals without diagnosed diabetes, the rate of HbA_{1c} testing rose steadily over time. In the Maccabi Healthcare Services data, blood glucose testing rates increased or remained constant over time in all age groups, and, despite this, the number of new cases of diabetes identified decreased across the whole time period. The exception was among older males and females (ages 60–79 years and 80 years or older), for which the proportion of blood glucose tests undertaken decreased and diabetes incidence was stable (or slightly increased; figure 3). In the Canadian data, the proportion of the population undergoing blood glucose testing began to decline from around 2011–12 (in all age groups), but the incidence of diabetes declined from about 2005 (figure 4). Both analyses showed that the yield of diabetes cases per 1000 blood glucose tests remained relatively stable or fell over time.

Discussion

Using data on the incidence of diagnosed diabetes from 24 data sources, including 22 million diagnoses from 5 billion person-years in predominantly high-income countries, we have shown that diabetes incidence from 2010 onwards declined or was stable in all but four data sources (Israel [Maccabi Healthcare Services], Lithuania, Singapore, and the USA [Kaiser Permanente Northwest]). Furthermore, Ukraine showed increasing incidence across their whole reporting period until 2010. These data, which represent one of the largest data consortia ever analysed, are in contrast with previous studies that have assessed the pattern and direction of the diabetes epidemic and have shown increases in prevalence of diabetes over time. It is important to note that our findings mainly represent type 2 diabetes and mainly in high-income countries, since even though several data sources could not accurately define diabetes type, in general, the incidence of type 2 diabetes is several orders of magnitude greater than that of type 1 diabetes.[10]

The findings here are consistent with our recent systematic review of published incidence trends.[7] Furthermore, we showed that in two datasets (Israel [Maccabi Healthcare Services] and Ontario, Canada), it was unlikely that changes in screening and diagnostic practice fully account for the observed declines in the incidence of clinically diagnosed diabetes. The Global Burden of Disease group has also reported diabetes incidence across countries.[11] This study showed falling diabetes incidence in upper middle-income countries and rising incidence in high-income countries.[11] However, their estimates of incidence derive from modelling of prevalence and mortality statistics rather than from measuring incidence directly. Thus, they are not comparable with our data.

Several reasons could account for our observation of a slowing or declining diabetes incidence. The multifaceted type 2 diabetes prevention activities implemented across the world might have had some effects on behaviour.

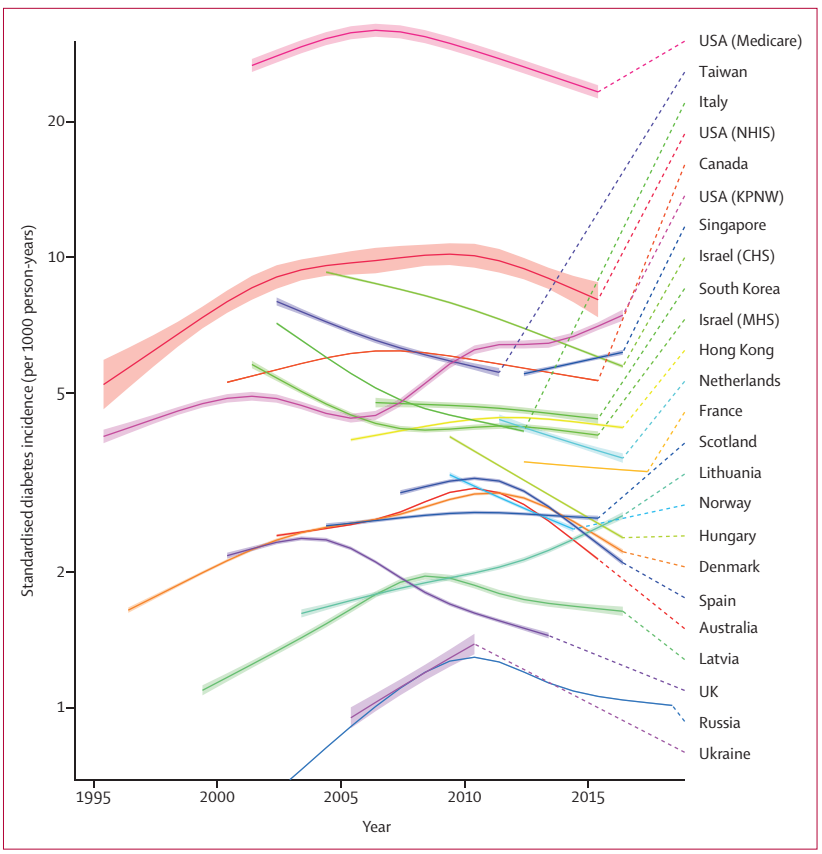

Figure 1: **Age-standardised and sex-standardised incidence rates of diagnosed diabetes per 1000 person-years (EU standard population 2010, with equal weights for men and women)**
Standardisation is based on annual age-specific incidence rates from age–period–cohort models fitted separately for each data source and sex. Shaded areas represent 95% CIs around incidence trends. CHS=Clalit Health Services. KPNW=Kaiser Permanente Northwest. MHS=Maccabi Healthcare Services. NHIS=National Health Interview Survey.

Such activities include those targeted at intensive lifestyle change in individuals at high risk of type 2 diabetes[12–15] and population-wide approaches including health awareness and education campaigns, modifications of the physical environment to facilitate physical activity, and taxation of select foods and beverages.[16] Investigators of studies from the USA have reported reductions in intake of sugar-sweetened beverages[17] and fat,[18] and declines in some unhealthy food purchases and small declines in overall energy intake.[19,20] Obesity prevalence has also decreased in some countries. In Scotland, where diabetes incidence has plateaued, there have been plateaus in obesity prevalence over the same time.[21] By contrast, in the USA, although earlier studies suggest that the rate of increase in obesity might be slowing,[22] more recent data show a small increase.[23] Collectively, these data provide some support for the notion that type 2 diabetes prevention activities might have led to sufficient behavioural and environmental changes to have an effect on the incidence of diagnosed diabetes.

Another explanation for the decreasing incidence from 2010 onwards is the introduction of HbA_{1c} for diabetes diagnosis. In 2009–10, WHO introduced HbA_{1c} as

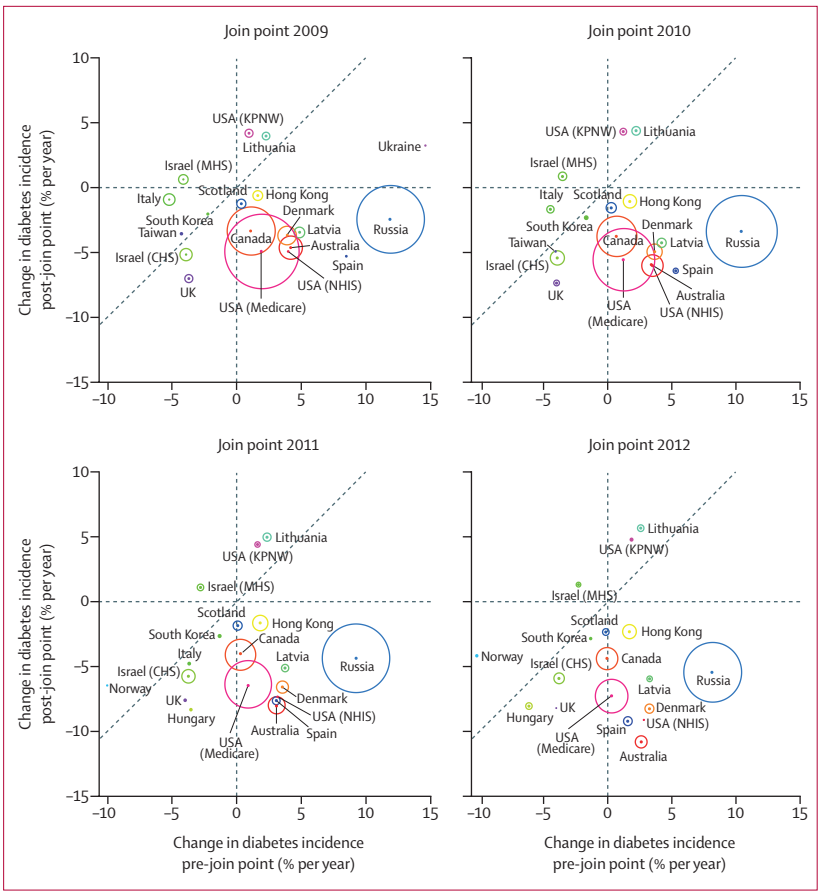

Figure 2: **Estimated changes in diagnosed diabetes incidence rates before and after the join points at the years 2009, 2010, 2011, and 2012**

The diagonal lines indicate equality of pre-join and post-join point changes in rates, in which there is no change in trend. Each coloured circle represents a data source; the area is proportional to the precision (inverse variance) of the sum of the estimated annual changes before and after the join point. Estimates are from a model with common slopes for men and women, controlling for sex. Model fit for the later time period is poor for Israel (MHS), leading to unreliable estimates of the annual trend in incidence in this time period. CHS=Clalit Health Services. KPNW=Kaiser Permanente Northwest. MHS=Maccabi Healthcare Services. NHIS=National Health Interview Survey.

	Year that HbA_{1c} was recommended for diagnosis of diabetes
Australia	2015
Canada	2013
Denmark	2011
France	No recommendation
Hong Kong	2011
Hungary	2014
Israel	2013
Italy	2014
Latvia	No recommendation
Lithuania	No recommendation
Netherlands	2016
Norway	2012
Russia	2011
Scotland, UK	2017
Singapore	2019
South Korea	2015
Spain	2012
Taiwan	2012
UK	2012
Ukraine	No recommendation
USA	2010

Table 2: **Timing of the formal introduction of HbA_{1c} for diagnosis of diabetes, by country or jurisdiction with data sources included in the study**

an alternative method to diagnose diabetes.[24] There is evidence to suggest that HbA_{1c} detects fewer people with diabetes than does the oral glucose tolerance test (OGTT).[24,25] However, the OGTT is used infrequently in clinical practice, and fasting glucose, the most commonly used test to diagnose diabetes, produces a similar prevalence of diabetes as does HbA_{1c}.[24] Furthermore, unlike fasting glucose or the OGTT, HbA_{1c} can be done in the non-fasting state, which might increase the number of people who undergo diagnostic testing, leading to more cases diagnosed. To explore any potential effect of the introduction of HbA_{1c} for the diagnosis of diabetes on patterns of the incidence of clinically diagnosed diabetes, we obtained information on its introduction into clinical practice. Two countries (France and Latvia) from which data were analysed have not officially adopted screening or diagnosis of diabetes with HbA_{1c} and nevertheless saw a decline in incidence. In other countries and jurisdictions (eg, Australia, Canada, Hong Kong, Hungary, Israel, the Netherlands, Norway, Scotland, South Korea, Spain, Taiwan, and the UK), the implementation of HbA_{1c} for diagnosis occurred after the decline or stabilisation of incidence began. Nevertheless, it should be noted that HbA_{1c} might have been used in practice before it was officially recommended by a national organisation. Finally, we analysed the population-level use of HbA_{1c} in two data sources in exploratory analyses. Data from Israel showed that blood glucose testing rates did not decline (except for a small decline in people aged 60 years or older) over the time period after HbA_{1c} was introduced, with an overall increase in the number of people being screened for diabetes. Despite this increase in both blood glucose and HbA_{1c} testing in the population covered by the Maccabi Healthcare Services data source, diabetes incidence still decreased over most of the time period. Diabetes screening data from Ontario, Canada, clearly showed a shift from blood glucose testing to HbA_{1c} testing commencing in 2012, but the decline in diabetes incidence began in 2005. In both datasets, the yield (number of diagnosed cases per 1000 blood glucose tests) tended to decrease slightly over time. If screening were dropping off, it might be expected that yield would increase, as a smaller proportion of individuals tested would be expected to be asymptomatic. Thus, our exploratory analyses are not consistent with a conclusion that a change to HbA_{1c} as a diagnostic test or an overall reduction in population screening were major reasons for the decline in incidence of diabetes in these two populations. Our findings

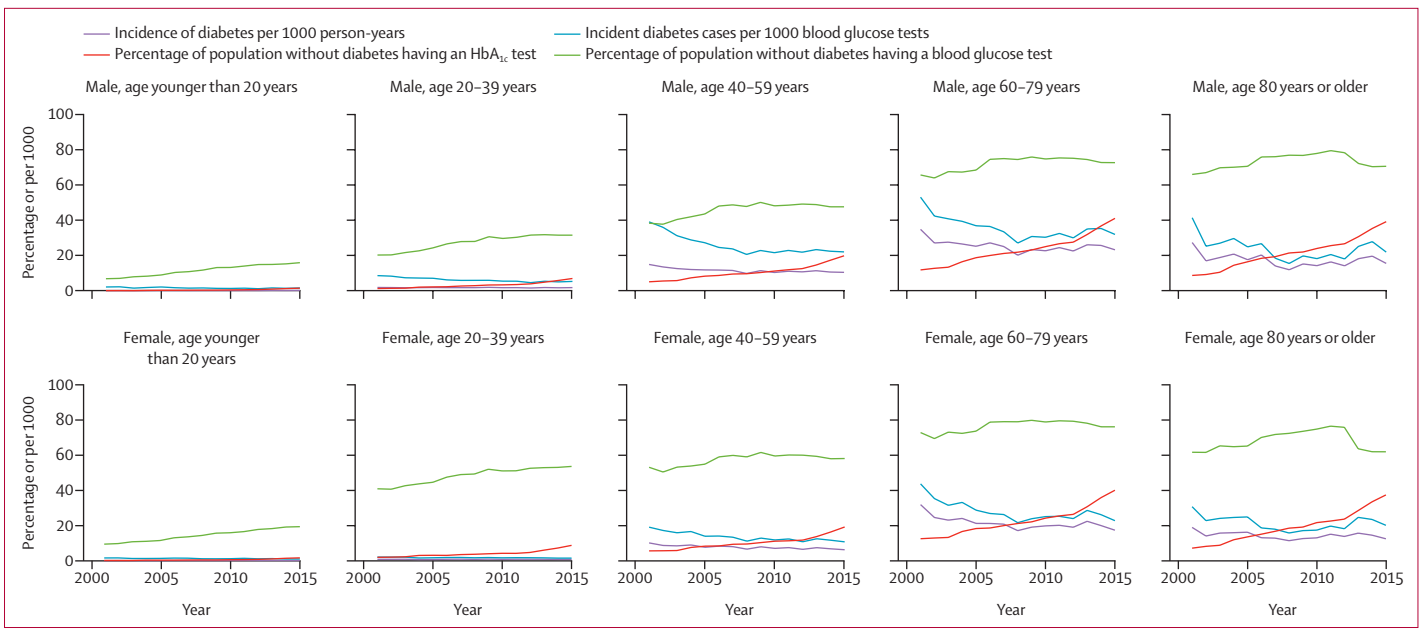

Figure 3: **Trends in the proportion of the population undergoing HbA_{1c} and blood glucose testing, along with diagnosed diabetes incidence, in data from Israel (Maccabi Healthcare Services)**
Incident cases are defined by an algorithm, incorporating blood tests, prescription of antidiabetic medications, and clinical diagnosis by clinical practitioners.

regarding the effect of screening on trends in diagnosed diabetes are also supported by work by Nichols and colleagues,[26] who reported that among 7 million people with health insurance in the USA, despite a shift towards HbA_{1c} as the diagnostic test in 2010, there was no change in the incidence of diabetes in 2010 or 2011.

In a review by Selvin and Ali,[27] it is proposed that declining or stable diagnosed diabetes incidence after the mid-2000s results from a reduction in the pool of undiagnosed diabetes through the intensification of diagnostic activities during the previous decade.[27] In support of this concept, the proportion of diabetes that is undiagnosed decreased in Germany (from 1997 to 2010)[28] and in Scotland (from 2010 to 2013).[29] However, in the USA, there has been no change in the ratio of diagnosed to undiagnosed diabetes at a time when incidence has fallen.[30] Unfortunately, in the absence of very large blood testing studies of the incidence of diabetes, it is very difficult to prove or disprove this hypothesis.

Another potential reason for the pattern in diagnosed diabetes incidence trends that we report is the lowering of the diabetes diagnostic threshold of fasting plasma glucose from 7·8 mmol/L to 7·0 mmol/L in 1997. An initial increase in incidence would be expected to follow this change, as a large pool of people instantaneously met the new threshold. Incidence might subsequently fall for a period of time, once the majority of these extra cases had been diagnosed. However, it is not likely that the change of diagnostic thresholds in 1997 would explain continuing and progressive falls in incidence 15 years later.

Our aim with this analysis was to identify large national population-based data sources measuring incidence over time. In two countries (Israel and the USA), this meant that we included multiple datasets from the same countries. Health care in Israel is covered by several subnational, non-overlapping health insurance companies among which Clalit Health Services and Maccabi Healthcare Services are the largest two. The membership of Clalit Health Services includes a high proportion of individuals of lower socioeconomic status and a relatively larger proportion of minority groups compared with the national population (27% *vs* 21%).[31] By contrast, the population covered by Maccabi Healthcare Services shares similar sociodemographic characteristics to the general Israeli population, except for income level, which is 15% higher among Maccabi Healthcare Services members than in the general population.[32] For the USA, the National Health Interview Survey is the only national source available, but is limited by relying on self-report of diabetes and by the relatively small sample size. Thus, the national US Medicare dataset (which includes individuals aged 68 years and older and some younger people with disabilities) was also included. We also included the Kaiser Permanente Northwest dataset from the USA, which has large numbers of members at all ages (on the order of several million), and in which diabetes status is not based on self-report.

The contrasting incidence trends among the US datasets warrants consideration. The standardised incidence rates in Kaiser Permanente Northwest drifted upward towards the end of the observation period, whereas the incidence data from the National Health Interview Survey and US Medicare data show decreasing diabetes incidence trends. Several differences between these data sources might account for the opposing patterns observed. First, the National Health Interview Survey data are nationally representative, whereas Kaiser Permanente Northwest

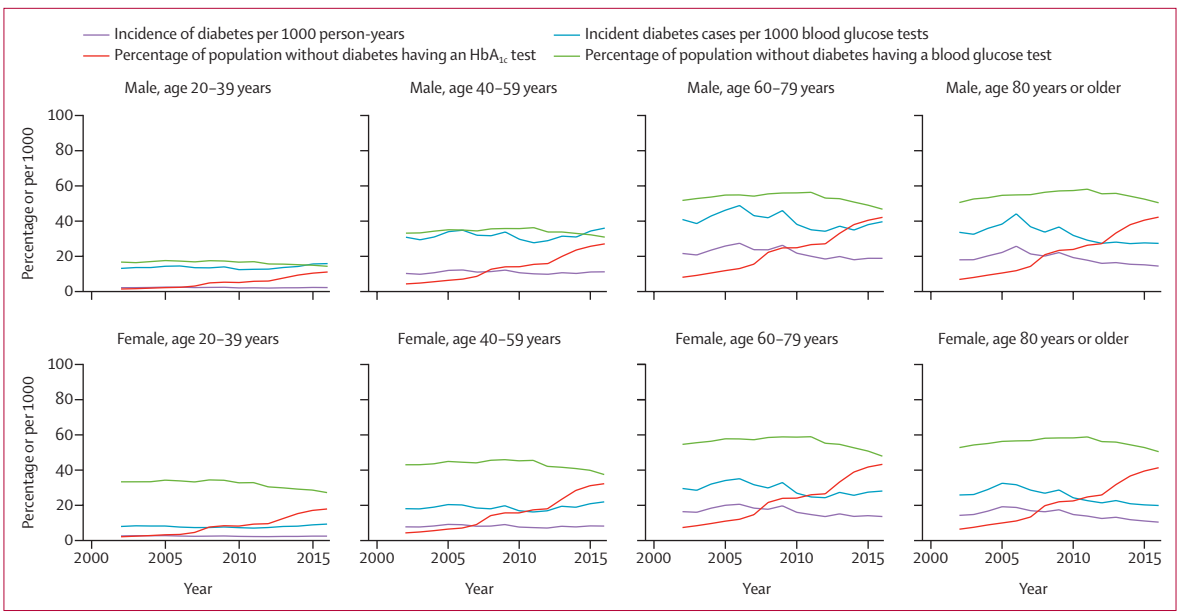

Figure 4: **Trends in the proportion of the population undergoing HbA_{1c} and blood glucose testing, along with diagnosed diabetes incidence, in data from Ontario, Canada (administrative diabetes database)**
Incidence data depicted here are from Ontario, rather than national Canadian incidence data. Incident cases are defined by an algorithm, incorporating at least one hospital admission or at least two physician claims with evidence of diabetes within 2 years.

only includes members of the Kaiser Permanente integrated managed care consortium in Oregon and southwest Washington. Second, ascertainment of diabetes used different methods of diabetes diagnosis (self-report in the National Health Interview Survey and an algorithm-based definition applied to clinical data in Kaiser Permanente Northwest). One possible reason for the increasing incidence in Kaiser Permanente Northwest is that in the Surveillance Prevention and Management of Diabetes Mellitus project, a registry of 11 integrated health-care delivery systems, of which Kaiser Permanente Northwest was a part, overall diabetes testing increased by 10% from 2006 to 2011 and almost all of the increase in testing was with HbA_{1c} (Nichols GA, unpublished).

The approach and design of this study, which involved multiple data sources and the use of a standardised data collection tool and prespecified protocol, are key strengths of our study. Another key strength is that the majority of the included data derive from whole-population, nationally representative data sources. We also obtained detailed information about each data source, allowing us to carefully assess the quality of the data. Furthermore, among the 24 data sources included, 13 (54%) have published reports validating their approach to diabetes diagnosis, with sensitivities and specificities of more than 85% in all but one data source, for which sensitivity was 75%. A further two (8%) data sources are registries of pharmacologically treated type 2 diabetes, which are likely to be highly specific for diabetes.

Several limitations must also be acknowledged. The data sources reported only on clinically diagnosed diabetes and so are subject to influences from changes in diagnostic behaviour and coding practices. Despite the large size of our data pool, many parts of the world, especially low-income and middle-income countries, were not represented and might have different trends in diabetes incidence. Furthermore, the definitions used to diagnose diabetes vary between and possibly within datasets. The data analyses used consistent diagnostic approaches over time within each dataset, but this approach does not exclude the possibility of changes in coding and clinical practice over time, which might affect the way in which such analyses perform. Our data are also limited in terms of the time period covered by some data sources, and by the absence of data on the proportion of the population being screened for diabetes. We were unable to explore reasons for the differences in incidence across data sources because we did not have access to risk factor data such as BMI. Finally, we used a modified version of the Newcastle–Ottawa scale to assess data quality, which has been used in an earlier publication on incidence trends[7] but has not undergone rigorous validation.

In conclusion, our analysis shows that in most of the (mainly high-income) countries for which data are available, the incidence of diabetes has been stable or falling in recent years. Although there was a measurable shift to diabetes screening with HbA_{1c}, this change is unlikely to be solely responsible for the declining diagnosed diabetes incidence trends. Preventive strategies and public health education and awareness campaigns and other factors might have contributed to declining trends.

Contributors
DJM, EWG, MEP, and JES conceived and developed the study and made contacts with contributing data sources. DJM, RMI, and LC oversaw the

practical gathering of data from the data sources. LC was responsible for creating and maintaining the database. BC and DJM designed and undertook the statistical analysis. TRH and LC applied the quality scales to the data from the centres. DJM wrote the report. All other authors curated data from centres into the standardised form. All authors contributed to data interpretation and critical evaluation; contributed to the editing of the report; and approved the final submitted version of the report. DJM, LC, and BC are guarantors of data and analysis integrity; they had full access to the database and verified the data.

Declaration of interests

We declare no competing interests.

Data sharing

Aggregated data may be available upon reasonable request to the corresponding author. Approvals must be obtained from all collaborators with a signed data access agreement.

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