Ascertainment and verification of diabetes in the EPIC-NL study

I. Sluijs[1]*, D.L. van der A[2], J.W.J. Beulens[1], A.M.W. Spijkerman[3], M.M. Ros[2], D.E. Grobbee[1], Y.T. van der Schouw[1]

[1]University Medical Center Utrecht, Julius Center for Health Sciences and Primary Care, Utrecht, the Netherlands, [2]National Institute for Public Health and the Environment, Center for Nutrition and Health, Bilthoven, the Netherlands, [3]National Institute for Public Health and the Environment, Center for Prevention and Health Services Research, Bilthoven, the Netherlands, *corresponding author: tel.: +31 (0)88-756 81 95, fax: +31(0)88-756 80 99, e-mail: i.sluijs-2@umcutrecht.nl

ABSTRACT

Background: The objectives of this study were to describe in detail the ascertainment and verification of prevalent and incident diabetes in the Dutch contributor to the European Prospective Investigation into Cancer and Nutrition (EPIC-NL cohort) and to examine to what extent ascertained diabetes agreed with general practitioner (GP) and pharmacy records.
Methods: In total, 40,011 adults, aged 21 to 70 years at baseline, were included. Diabetes was ascertained via self-report, linkage to registers of hospital discharge diagnoses (HDD) and a urinary glucose strip test. Ascertained diabetes cases were verified against GP or pharmacist information using mailed questionnaires.
Results: At baseline, 795 (2.0%) diabetes cases were ascertained, and 1494 (3.7%) during a mean follow-up of ten years. The majority was ascertained via self-report only (56.7%), or self-report in combination with HDD (18.0%). After verification of ascertained diabetes cases, 1532 (66.9%) were defined as having diabetes, 495 (21.6%) as non-diabetic individuals, and 262 (11.5%) as uncertain. Of the 1538 cases ascertained by self-report, 1350 (positive predictive value: 87.8%) were confirmed by GP or pharmacist. Cases ascertained via self-report in combination with HDD were most often confirmed (334 (positive predictive value: 96.0%)). Conclusions: Two out of three ascertained diabetes cases were confirmed to have been diagnosed with diabetes by their GP or pharmacist. Diabetes cases ascertained via self-report in combination with HDD had the highest confirmation.

KEYWORDS

*A*scertainment, diabetes, hospital discharge diagnoses, self-report, verification

INTRODUCTION

Diabetes is an important cause of morbidity and mortality and its incidence is increasing worldwide.[1-4] In 2030 the prevalence of diabetes is expected to have increased by 57% compared with that in 2000.[4] Type 2 diabetes accounts for 90% of these cases.[5]

Accurate identification of diabetes cases in epidemiological studies is of great importance to obtain valid estimates of diabetes risk. In population-based studies, self-reported presence of disease is often used as part of disease ascertainment. Several studies compared self-reported diagnosis of diabetes with diagnosis according to the medical records or medical claims.[6-12] All studies presented high levels of agreement, with 73 to 95% of self-reported diabetes cases being confirmed and kappa values of agreement ranging from 72 to 92%. Alternative sources, such as hospital discharge data, can be used for ascertaining diabetes cases as well. Combining self-report data with alternative ascertainment sources might contribute to a higher identification of diabetes cases. However, still little is known about the validity of diabetes diagnoses from alternative sources such as hospital discharge registries.[13] Moreover, the validity of diabetes ascertained via a combination of self-report data and alternative sources is so far unknown.

In this article we describe in detail the ascertainment and verification of prevalent and incident diabetes cases in the Dutch cohort contributing to the European Prospective Investigation into Cancer and Nutrition (EPIC-NL). In this cohort of 40,011 Dutch adults with a mean age of 50 years, ascertainment of diabetes cases was based on several sources, including self-report, hospital discharge data, and a self-administered urinary glucose strip test. We present to what extent these different and combined

ascertainment sources for the diagnosis of diabetes agree with general practitioner (GP) medical and/or pharmacy records. Moreover, we investigated whether agreement differed by age.

MATERIALS AND METHODS

Setting

EPIC-NL consists of the two Dutch contributions to the European Prospective Investigation into Cancer and Nutrition (EPIC),[14] i.e. Prospect-EPIC and MORGEN-EPIC. The individual cohorts of EPIC-NL were set up simultaneously in 1993-1997 and were merged according to standardised processes into one large Dutch EPIC cohort in 2007. Its design and baseline characteristics are described elsewhere.[15]

The Prospect-EPIC Study includes 17,357 women aged 49 to 70 years at baseline, participating in the national breast cancer screening program, and living in the city of Utrecht and its surroundings.[16] The MORGEN-EPIC cohort consists of 22,654 men and women aged 21 to 64 years selected from random samples of the Dutch population in three towns in the Netherlands (Amsterdam, Doetinchem, and Maastricht).[17,18] All participants signed informed consent before study inclusion. The study complies with the Declaration of Helsinki and was approved by the Institutional Board of the University Medical Center Utrecht (Prospect) and the Medical Ethical Committee of TNO Nutrition and Food Research (MORGEN).

Ascertainment of diabetes

Three sources of ascertaining diabetes were used in our study: self-report, hospital discharge diagnoses (HDD) and urinary glucose strip test (in the Prospect part of the cohort only). Details of all three sources are given below.

Self-report

At baseline, all individuals who agreed to participate received a self-administered general questionnaire containing questions on demographic characteristics, presence of chronic diseases, and risk factors for chronic diseases.[19] Response rates for this questionnaire were 45% for MORGEN (Amsterdam 33%, Maastricht 45%, Doetinchem 68%) and 35% for Prospect. The baseline questionnaire contained three questions on diabetes. Participants were asked if they had been diagnosed with diabetes previously, and if yes, additional questions on the year of diagnosis and type of treatment were asked.

To detect changes in health status and exposure, two follow-up questionnaires were sent to all surviving participants within regular intervals of three to five years. Response rates for these questionnaires were 64% for the first and 57% for the second questionnaire for the

Amsterdam-Maastricht part of MORGEN and 75 and 78%, respectively, for the Doetinchem part of the cohort. Response rates for Prospect were 78% for the first and 73% for the second questionnaire. These questionnaires included a question about whether diabetes was diagnosed since the last questionnaire, and if so, which physician (GP or specialist in internal medicine) (MORGEN) or which hospital (Prospect) was involved in treatment. Furthermore, information on year of diagnosis and medication use was collected.

Hospital discharge diagnoses

Diagnoses of diabetes were also obtained from the Dutch Center for Health Care Information, which is responsible for a standardised computerised register of hospital discharge diagnoses. Admission files were filed continuously from all general and university hospitals in the Netherlands from 1990. Data on sex, date of birth, dates of admission and discharge were recorded whenever a patient was discharged from the hospital. One mandatory principal diagnosis and up to nine optional additional diagnoses were reported. All diagnoses were coded according to the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9). The database was linked to the EPIC-NL cohort on the basis of date of birth, sex, postal code, and GP with a validated probabilistic method.[20] Follow-up was complete until 1 January 2006. Participants who had a principal or additional diagnosis of diabetes at discharge (ICD codes 250) were ascertained as diabetes cases in our cohort.

Urinary glucose strip test

Among prospect participants only, a urinary glucose strip test (Clinistix, Bayer Diagnostics, Tarrytown, NY, USA) was sent out with the first follow-up questionnaire. The lower threshold for detection of glucose with this test was 5.5 mmol/l. Participants were asked to report in the questionnaire whether the strip had turned purple after waiting ten seconds, indicating glucosuria. Participants who reported having a positive test were ascertained as diabetes cases in our cohort and advised to contact their GP.
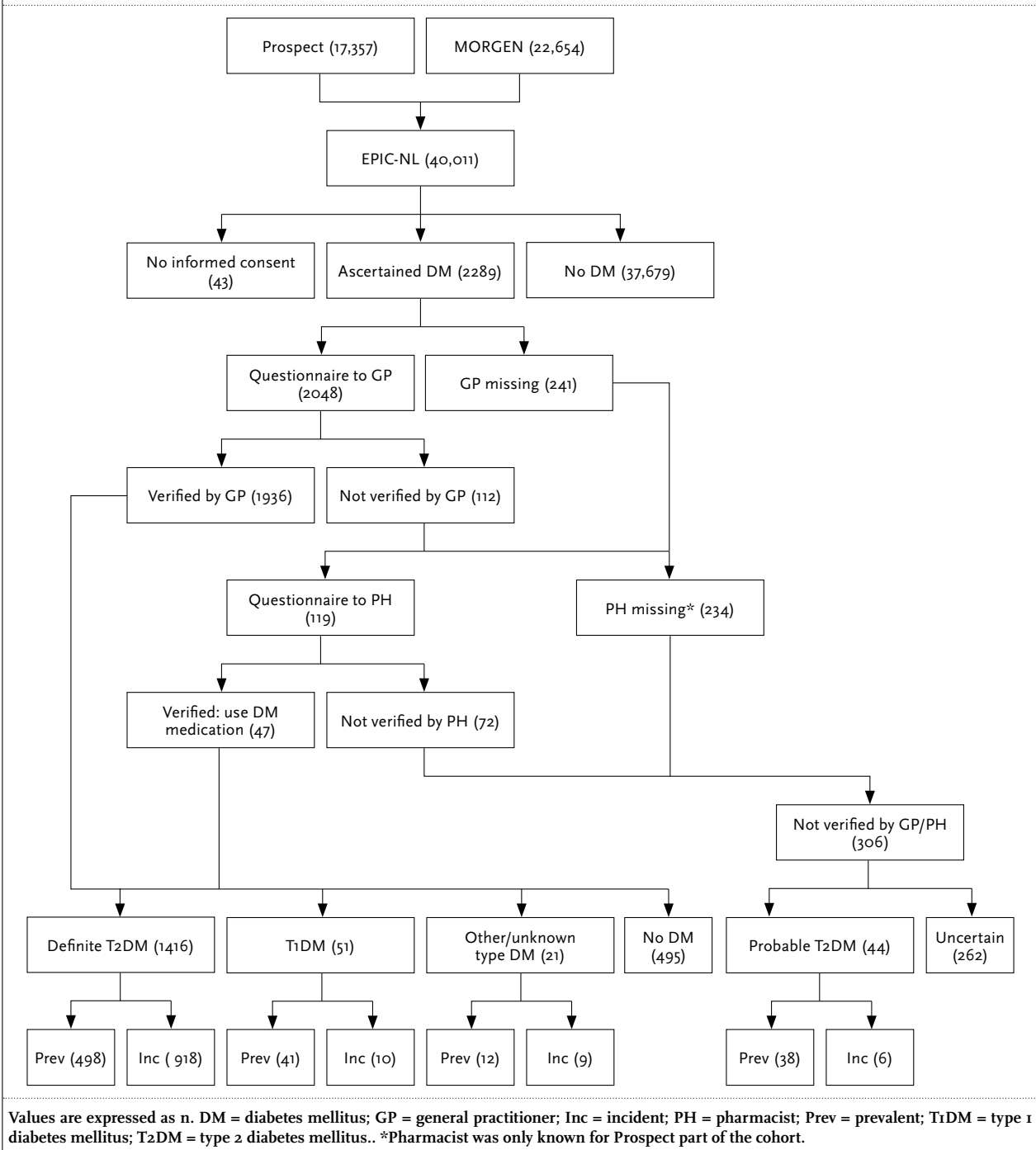
Verification of diabetes

The verification process of ascertained diabetes cases is visualised in *figure 1*. Verification was carried out by means of GP or pharmacist information. We only verified diabetes in patients who gave signed informed consent for obtaining follow-up information.

GP information

In the Netherlands, general practice is the optimal source for providing information on the patients' health and illness as virtually all non-institutionalised Dutch citizens are registered with a GP practice. In the Dutch healthcare system the GP is the gatekeeper and controls access to

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Figure 1. *Ascertainment and verification of diabetes cases in the EPIC-NL cohort*

Values are expressed as n. DM = diabetes mellitus; GP = general practitioner; Inc = incident; PH = pharmacist; Prev = prevalent; T1DM = type 1 diabetes mellitus; T2DM = type 2 diabetes mellitus.. *Pharmacist was only known for Prospect part of the cohort.

specialised medical care. The GP has a complete overview of the medical status of the patient. All potential incident and prevalent diabetes cases, ascertained through the three previously described methods, were validated against GP information obtained via mailed questionnaires.

Information on name and address of the participants' GPs was obtained from the baseline questionnaire. Extensive efforts were made to obtain accurate current GP contact details. For Prospect and the Doetinchem part of the MORGEN cohort, information on participants' GPs

was updated in the follow-up questionnaires. For the Amsterdam and Maastricht part of the MORGEN cohort, updates were inquired in the first follow-up questionnaire only. Addresses were checked and, if necessary, updates were made using various data sources, such as online medical address books and internet sites.

GP questionnaire
The GP questionnaire contained 12 questions on diabetes. GPs were asked if diabetes had been diagnosed,

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and if so, in what year and which type (1, 2, other or unknown) of diabetes. Additional questions on how the diagnosis was established and on treatment during the first year after diagnosis and current treatment (diet, oral glucose lowering medication, insulin) were asked. Also, the GP was asked whether the patient suffered from long-term complications such as neuropathy and hypertension. GPs were requested to respond within four weeks upon receipt of the questionnaire. If no response was received within the set time limit, GPs were sent a reminder letter and were subsequently contacted by telephone if they did not respond to this second letter either. GPs received a financial compensation (€ 18, which is equal to a 20-minute consultation) for each returned questionnaire.

Pharmacist questionnaire

When the GP was unknown or the current GP was unwilling to participate, we used pharmacist information to verify the diagnosis of diabetes, via a mailed questionnaire. Pharmacists' data were only available for the Prospect cohort.

The pharmacist questionnaire contained eight questions concerning use of diabetes medication. The pharmacist was asked whether the participant had used any diabetes medication (i.e. oral glucose-lowering medication or insulin), currently and in the past. Also the year of initiation of diabetes medication was asked. The reminder procedure was the same as for the GPs. No financial compensation was given for returned questionnaires.

Definitions verified cases

All ascertained diabetes cases, confirmed to be diagnosed with diabetes by the GP, were classified as definite diabetes cases, and split by type of diabetes (1, 2, other or unknown). Ascertained patients for whom the GP did not confirm the diagnosis were defined as not having diabetes. Furthermore, since insulin and glucose-lowering medication are used exclusively for the treatment of diabetes and not for any other illness or disease, participants with confirmed use of diabetes medication by the pharmacist were verified as definite diabetes cases. However, participants who did not use any diabetes medication could not be classified as not having diabetes, because not all persons with type 2 diabetes require insulin or glucose-lowering medication. If information from both the GP and the pharmacist was absent, we classified participants as probable diabetes cases when two or more ascertainment sources indicated the participant had been diagnosed with diabetes. All probable cases were defined as type 2 diabetes cases. In further analyses, those with probable and definite diagnoses of type 2 diabetes were grouped together as type 2 diabetes cases. Cases ascertained through one ascertainment source

without any verification from the GP or pharmacists were classified as uncertain.

Data analysis

Median age, mean BMI, and distribution of sex and highest education at baseline (n (%)) were computed. Age was categorised in ten-year intervals, and the youngest two age groups were taken together, because of the relatively low number of cases in these groups. BMI was calculated as measured weight divided by measured height squared (kg/m^2). Education level was categorised into low (primary education or lower vocational education), middle (advanced elementary education or intermediate vocational education or higher general secondary education for three years or longer) and high (Bachelor or Master of Science degree). In addition, ascertainment and verification information on diabetes status were presented according to age. Finally, we determined the percentage of agreement between information on diabetes status from different ascertainment sources and verification via GP and pharmacist. As we only verified the diabetes cases, and not the non-cases, we only calculated the percentage of ascertained diabetes cases that were confirmed to have diabetes by their GP or pharmacist. This percentage can be interpreted as the positive predictive value (PV+) for having diabetes, with GP and pharmacist information being the reference standard. Kappa values of chance corrected agreement were calculated according to the following equation: [kappa = (observed agreement – expected agreement) / (1 – expected agreement)]. SPSS (version 14.0) for windows was used for the data analysis.

RESULTS

The study population had a median age of 51.4 years and a mean BMI of 25.7. One quarter were male, and 40% had a low education level (*table 1*).

In total, 2289 (5.7%) participants were ascertained as being diagnosed with diabetes, of which 795 (2.0%) were ascertained at baseline and 1494 (3.7%) during a mean follow-up of 10.1 (SD 1.9) years. Of all ascertained diabetes cases, more than half (56.7%) were ascertained via self-report only and 13.5% via linkage with HDD. One in ten was ascertained via the urinary glucose strip test. The remaining cases were ascertained through a combination of self-report and linkage with HDD (18.0%) and a minority via both self-report and the urinary glucose strip test (1.6%) or all three ascertainment sources (0.1%) (data not shown).

Verification procedure

For 2048 (89.5%) of ascertained diabetes cases, we were able to send questionnaires to the GP. For 190 (8.3%) ascertained diabetes cases in the Prospect cohort we

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Table 1. *Baseline characteristics of the EPIC-NL cohort**

Age, median (range)	Years	51 (20-70)
Sex	Male	10,260 (25.6)
	Female	29,751 (74.4)
Education	High	8095 (20.4)
	Middle	15,761 (39.7)
	Low	15,844 (39.9)
BMI, mean (SD)	Kg/m²	25.7 (4.0)

*n=40,011; Values are expressed as n (%) unless indicated otherwise.

were unable to obtain validation information via the GP. Of 119 (62.6%) of these 190 individuals, current contact details were available for the pharmacists, and therefore questionnaires were sent to their pharmacists (*figure 1*). Total response rate for the GP and pharmacy questionnaires was 91.5% (94.5% for GP and 71.4% for pharmacy questionnaire). For 306 (13.3%) ascertained diabetes cases it was not possible to verify their diabetes status via GP or pharmacist. Of these individuals, 44 had two or more ascertainment sources indicating presence of diabetes. Consequently, these individuals were defined as probable type 2 diabetes cases (*figure 1*). Of all verified cases, 95.5% were verified by GP information, 2.3% by pharmacist information and 2.2% by multiple ascertainment information.

Verified diabetes status
After verification, 1460 (63.8%) individuals were defined as having type 2 diabetes (definite and probable), 51 (2.2%) as having type 1 diabetes and 21 (0.9%) as having another or unknown type of diabetes. In total, 495 (21.6%) of ascertained diabetes cases were not confirmed to have been diagnosed with diabetes and the remaining 262 (11.5%) were defined as potential, but not verified diabetes cases (*table 2, figure 1*). Prevalence and incidence of type 2 diabetes increased with age. Compared with younger persons, diagnoses of diabetes were more often confirmed in older persons and presence of diabetes was less often uncertain in older persons (*table 2*).
Of all ascertained prevalent cases, 104 (13.1%) switched to incident cases after verification, as the GP or pharmacist

reported the diagnosis date of diabetes to be after the inclusion date in the study. Of all incident cases, 68 (4.6%) switched to prevalent cases as the GP or pharmacist reported the diagnosis date of diabetes to be before the inclusion date in the study (data not shown).

Ascertainment sources
Cases ascertained via self-report only were often confirmed to have been diagnosed with diabetes by GP or pharmacist (PV+ 85.4%), whereas for cases obtained either by linkage with HDD or urinary glucose strip test, this was a minority (PV+ 39.6 and 22.0% respectively). We found a PV+ of 82.9% for diabetes ascertained via self-report in combination with the urinary glucose strip test, and a PV+ of 96% for diabetes ascertained via both self-report and HDD. The PV+ for diabetes ascertained by self-report (total) and HDD (total) was 87.8 and 73.9% respectively, whereas this was 31.3% for diabetes ascertained through the urinary glucose strip test (total) (*table 3*). The PV+ was higher for ascertained prevalent diabetes via self-report when they also reported receiving treatment with tablets or insulin (95.3%), as compared with those who reported only following a diet (61.5%) or receiving no treatment (67.6%) for their diabetes.

DISCUSSION

In the EPIC-NL cohort, two out of three of 2289 diabetes cases, ascertained via self-report, linkage with HDD and/or a urinary glucose strip test, were confirmed to have been diagnosed with diabetes by their GP or pharmacist. Diabetes ascertained via self-report only or in combination with linkage with HDD was confirmed relatively often.
Several limitations need to be discussed. First, we verified ascertained diabetes against GP information, which cannot be considered the golden standard. However, GPs have a complete overview of the medical status of patients and were therefore considered the best possible option for verification. Second, we did not establish the accuracy of self-reported absence of diabetes, which is equally important for clinical studies. Others reported 0.3 to 5% of self-reported non-diabetic individuals were verified as diabetes cases.[6,8,11,12]

Table 2. *Verified diabetes status, according to age at baseline among ascertained diabetes cases**

	Verified diabetes status					
Age (years)	Prevalent type 2 diabetes#	Incident type 2 diabetes#	Type 1 diabetes	Other / unknown type diabetes	No diabetes	Uncertain
20-39	8 (8.3)	19 (19.8)	11 (11.5)	1 (1.0)	31 (32.3)	26 (27.1)
40-49	42 (13.8)	133 (43.8)	13 (4.2)	6 (2.0)	69 (22.7)	41 (13.5)
50-59	257 (22.6)	467 (40.9)	19 (1.7)	10 (0.9)	260 (22.8)	126 (11.1)
60-70	229 (30.5)	305 (40.7)	8 (1.1)	4 (0.5)	135 (18.0)	69 (9.2)
Total	536 (23.4)	924 (40.4)	51 (2.2)	21 (0.9)	495 (21.6)	262 (11.5)

*n=2289. Values are expressed as n (%). #Definite and probable diabetes cases.

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Table 3. *Verified diabetes status according to ascertainment source, among ascertained diabetes cases, verified by GP or pharmacist**

Ascertainment source	Verified diabetes status	
	Diabetes	**No diabetes**
Self-report only	984 (85.4)	168 (14.6)
HDD only	90 (39.6)	137 (60.4)
Glucosuria only	48 (22.0)	170 (78.0)
Self-report + HDD	334 (96.0)	14 (4.0)
Self-report + glucosuria	29 (82.9)	6 (17.1)
Self-report + HDD + glucosuria	3 (100)	0 (0)
Total, self-report[#]	1350 (87.8)	188 (12.2)
Total, HDD[$]	427 (73.9)	151 (26.1)
Total, glucosuria[&]	80 (31.3)	176 (68.7)

HDD = hospital discharge diagnoses; *n = 1983; values are expressed as n (%); [#]combination of self-report only and self-report + other ascertainment sources; [$]combination of HDD only and HDD + other ascertainment sources; [&]combination of glucosuria only and glucosuria + other ascertainment sources.

Furthermore, presence of diabetes may go undetected for up to 12 years.[21] Verifying non-diabetic individuals would thus include checking diagnoses with GPs and determining fasting glucose values for identification of undetected diabetes of 37,722 participants. This was not feasible in the framework of this study. As a consequence, we could not calculate sensitivities, specificities or kappa values. Yet, we estimated kappa values with percentages of non-diabetic individuals verified as diabetes cases found in literature (0.3 to 5%).[6,8,11,12] This resulted in kappa values of 53 to 83%. Third, we calculated PV+ from our study. As the PV+ is dependent on the diabetes prevalence in the population, we should be cautious in comparing with other studies and generalising our results. Fourth, participants for whom we were unable to verify their diabetes diagnoses were relatively young. These participants may have switched GPs more often because of a more flexible lifestyle. Other factors, such as cohort effects, may also be responsible. Unfortunately, the number of diabetes cases per separate cohort was too small to further examine this.

Another Dutch study that also verified self-reported diabetes against GP information found a PV+ of 73%, and a kappa value of 75%, among 899 hypertensive patients.[6] We observed a higher PV+ (87.7%). However, comparability is complicated by the hypertensive study population and small number of diabetes cases. Others also reported relatively high PV+ values (76 to 95%) when self-reported diabetes was verified against medical records, medical claims or an interview, in apparently healthy or disabled persons.[7-12,22] Kappa values ranged from 72 to 92%. One study reported lower PV+ values in younger persons,[9] which is in line with our study. This was, however, not confirmed elsewhere.[8]

PV+ for ascertainment of diabetes via HDD was relatively low (39.6% for HDD only, 73.8% for total HDD). Coding of HDD from discharge letters has been shown to be reliable,[23] and it is therefore unlikely that errors in coding largely explain this. Another possibility is that additional HDD of diabetes may be the result of temporarily elevated glucose levels, induced by stress caused by the principal disease. This was, however, not confirmed by our data as PV+ were apparently similar for additional and principal HDD of diabetes (data not shown). Another study found a PV+ of 72.3% for HDD-derived diabetes verified against drug treatment data,[13] in line with our findings.

It has often been reported that urinary glucose strip tests are of limited use for detection of diabetes.[24-29] We observed a rather low PV+ of 31.3% for diabetes ascertained via the urinary glucose strip test, which confirms these findings. The PV+ for diabetes ascertained via both urinary glucose strip test and self-report was comparable with the PV+ for self-report only. In contrast, the PV+ for diabetes ascertained via both linkage with HDD and self-report was 10% higher compared with self-report only. This implies the urinary glucose strip test had limited additional value above self-report, whereas linkage with HDD was of additional value for ascertainment of diabetes.

In conclusion, two-thirds of ascertained cases of diabetes in the EPIC-NL cohort were confirmed to have been diagnosed by their GP or pharmacist. Older participants were confirmed relatively often. Ascertainment of diabetes via self-report may give a valid indication of the presence of diabetes. This may be combined with ascertainment via linkage with HDD, to increase validity. However, single reliance on linkage with HDD or reliance on a self-administered urinary glucose strip test is not recommended for ascertainment of diabetes from this study.

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