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Diagnostic performance of the Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) equation at estimating glomerular filtration rate in adults with diabetes mellitus: a systematic review and meta-analysis protocol

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ABSTRACT

Introduction Timely detection leading to the implementation of reno-protective measures reduces the progression of diabetic kidney disease. Estimated glomerular filtration rate (eGFR) is a major surrogate of kidney function. The Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) Equation is a tool to estimate GFR. This protocol outlines a systematic-review, assessing the diagnostic accuracy of the CKD-EPI equation in adults with diabetes.

Methods and analysis MEDLINE, Embase, Cochrane Central Register of Controlled Trials and grey literature will be searched for publications in English, Farsi, Dutch and Chinese from 2009 (when CKD-EPI was first introduced) to January 2019. Bridging searches will be conducted to capture literature published from January 2019 until final review publication. The inclusion criteria will be (1) study participants with diabetes; (2) age ≥18 years; (3) creatinine-based CKD-EPI eGFR as index test; (4) measured GFR using the clearance/plasma disappearance of inulin, iohexol, iothalamate, diethylenetriamine-pentaacetic acid (DTPA) or chromium labelled ethylenediaminetetraacetic acid (Cr-EDTA) as reference test; (5) report of the diagnostic accuracy of the index test. Exclusion criteria will be participants with renal transplant, chronic use of corticosteroids, chronic inflammatory diseases, pregnancy, non-diabetes related kidney disease, thalassaemia, heart failure, pregnancy and potential kidney donors as well as critically ill patients. Screening, eligibility check, risk of bias assessment and data extraction will be carried out by two independent reviewers. Any discrepancies will be discussed, and third-party opinion will be sought. The risk of bias will be assessed using the Quality Assessment of Diagnostic Accuracy Studies–2 tool. A quantitative synthesis of the aggregated-data will be used if the included studies are homogenous.

Ethics and dissemination No ethics approval is required. The outcome will be published in a peer-reviewed journal. The results will help researchers and clinicians evaluate

Strengths and limitations of this study

► To the best of our knowledge, this will be the first systematic review to evaluate accuracy, precision and bias of the Chronic Kidney Disease Epidemiology Collaboration estimated glomerular filtration rate (eGFR) equation in people with diabetes.
► The frequency of utilising other statistical methods like interclass correlation coefficient which are more accurate in evaluating diagnostic accuracy of tests will be assessed.
► Methods of measuring GFR in different studies varies and this might affect the homogeneity of the data and limit the possibility of conducting quantitative analysis of the results.
► The definition of bias and precision could vary in different studies, hence, there may be limited scope to conduct a meta-analysis of the collected data.

the diagnostic accuracy of the creatinine-based CKD-EPI eGFR in adults with diabetes.
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INTRODUCTION
Target condition being diagnosed
Diabetic kidney disease, defined as having albuminuria or estimated glomerular filtration rate (GFR) $<60\,\text{mL/min}/1.73\,\text{m}^2$, affects approximately 40% of people with diabetes and is the most common cause of dialysis or renal transplantation worldwide.[1–4] Moreover, having diabetic kidney disease is associated with an increased risk of cardiovascular as well as all-cause mortality.[5 6] The development of irreversible chronic kidney disease (CKD) is characterised by a preceding phase of renal

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function decline in both type 1 and type 2 diabetes which is clinically silent, but potentially reversible. In some cases, there is a marked hyperfiltration phase before the reduction in kidney function begins. However, many people who are passing through this phase are undiagnosed due to underperformance of the current routine kidney function estimation tools.[7–9] Research shows that if diagnosed early, interventions could be implemented to halt the progression of kidney function decline, potentially resulting in an improved quality of life.[10–12]

Reference test(s)

GFR is considered the best overall index of normal and diseased kidney function. GFR can be measured using the clearance/plasma disappearance of exogenous filtration markers like inulin or radiotracer molecules such as technetium-99m diethylenetriamine-pentaacetic acid (^{99}mTc-DTPA), ^{125}I-iothalamate, or ^{51}Cr-EDTA which are neither secreted nor absorbed in the glomeruli. The methods used to assess measured GFR (mGFR) are expensive and require multiple serum sample collections from patients over approximately 4 hours. Hence mGFR is not considered to be a desirable screening test.

Index test(s)

Estimating GFR with endogenous filtration markers like creatinine has been proposed as a feasible and less invasive methods for evaluating kidney function.[13 14] The Modification of Diet in Renal Disease (MDRD) Study equation has gained widespread acceptance. The estimated GFR (eGFR) using this equation is reported by most clinical laboratories when measurement of serum creatinine is ordered.[15] The MDRD Study equation was developed in people with CKD, and as such its major limitations are imprecision and systematic underestimation of mGFR (bias) at higher levels of renal function.[16] In an attempt to overcome some of the limitations of the MDRD equation, the Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) equation was developed.[17] In particular, it has been reported to reduce bias compared with the MDRD equation for GFR >60 mL/min/1.73 m^2 in various study populations.[18 19] However, the diagnostic performance of the CKD-EPI equation per se in people with diabetes, especially those with eGFR above 60 or at the hyperfiltrating stage has been an issue of controversy. While some studies demonstrated a high bias and low precision and accuracy for the current equation,[20–23] other studies argued that the equation's diagnostic performance is adequate in people with diabetes.[24 25] Some studies have shown occurrence of a considerable misclassification of CKD stage when using the CKD-EPI equation in people with diabetes while others found a low misclassification rate.[23 26] These controversial results and conclusion with regards to whether the creatinine-based CKD-EPI equation is appropriate to be used in people with diabetes, necessitates a systematic review of the current literature to possibly reach a consensus.

Objectives

We aim to systematically review the diagnostic performance of the creatinine-based CKD-EPI equation in people with diabetes looking at the equation's accuracy, precision and bias, compared with the gold standard tests of measuring GFR, in depicting (1) the kidney function at a single time point and (2) change in GFR during time. The results of this systematic review might help in reaching a consensus regarding the diagnostic performance of the creatinine-based CKD-EPI equation in people with diabetes and taking a further step to modify this equation in this specific population if indicated.

METHODS AND ANALYSIS
Eligibility criteria

The systematic review intends to evaluate the diagnostic performance of CKD-EPI creatinine-based eGFR formula in estimating (1) GFR at a specific timepoint or (2) GFR change during time in adults with type 1 or type 2 diabetes. Studies in English, Farsi, Dutch and Chinese since 2009 (when the CKD-EPI equation was introduced) will be obtained using electronic databases, trial registers and grey literature. The inclusion criteria are defined as: (1) study participants with type 1 or type 2 diabetes, (2) study participants aged ≥18, (3) using creatinine based CKD-EPI GFR estimation equation as the index test, (4) mGFR using the clearance/plasma disappearance of inulin, iohexol, ^{125}I-iothalamate, ^{99}mTc-DTPA or ^{51}Cr-EDTA as the reference test and (5) report of at least one of the diagnostic accuracy specifiers (ie, bias, accuracy and precision) of the creatinine-based CKD-EPI. Studies conducted on participants with renal transplant, chronic use of corticosteroids, chronic inflammatory diseases and non-diabetes related kidney disease, thalassaemia, heart failure, pregnancy and potential kidney donors as well as critically ill patients will be excluded.

Information sources

We will search MEDLINE (Ovid interface, 2009 onwards), Embase (Ovid interface, 2009 onwards) and the Cochrane Central Register of Controlled Trials (CENTRAL) (Wiley interface, 2009 onwards). Our search strategy will be developed using Medical Subject Headings (MeSH) and text words related to diabetes mellitus, CKD, eGFR using CKD-EPI Equation and mGFR. The electronic database search will be supplemented by searching the grey literature via trial registries, Google Advanced Search and by contacting authors where insufficient data are available. The literature search will not be limited by language; however, a date limit of 2009 onwards will be applied as this is when the CKD-EPI equation was developed. To ensure literature saturation, we will scan the reference lists of included studies or relevant reviews identified.

Search strategy

MEDLINE, Embase and CENTRAL will be searched from 2009 to January 2019 with no language limits applied.

The specific search strategies will be created by a Clinical Librarian with expertise in systematic review searching. The MEDLINE strategy will be developed with input from the review team, then peer reviewed by a second librarian, not otherwise associated with the review, using the PRESS standard. A draft MEDLINE search strategy is included below. After the MEDLINE strategy is finalised, it will be adapted to the syntax and subject headings of the other databases. As well, the International Clinical Trials Registry Platform Search Portal and ClinicalTrials.gov will be searched for ongoing or recently completed trials, and PROSPERO will be searched for ongoing or recently completed systematic reviews. As relevant studies are identified, reviewers will check for additional relevant cited and citing articles. A bridging search will be conducted prior to publication of the review to ensure inclusion of any relevant studies published since January 2019.

Draft MEDLINE search: Ovid interface

1. Diabetes Mellitus, Type 1/or Diabetes Mellitus, Type 2/or Diabetes Mellitus/or Diabetic Nephropathies/or Diabetes Complications/or (chronic kidney disease or CKD or diabetic or diabetes or T2DM).mp.
2. (eGFR or estimating equation* or CKD-EPI or Chronic Kidney Disease Epidemiology Collaboration or cystatin* or (estimat* and (GFR or glomerular filtration))).mp.
3. (mGFR or (measure* adj5 (GFR or glomerular filtration))).mp.
4. 1 and 2 and 3.
5. Limit four to yr= '2009-Current'.

Study records

Using Covidence software, two independent reviewers will screen titles and abstracts. Any discrepancies will be resolved through discussion after completion of screening and third-party opinion will be sought. After attaining full texts of screened studies, eligible papers will be selected by two independent reviewers based on the inclusion/exclusion criteria. Discrepancies will be resolved with discussion at the end of this stage and where necessary, third reviewer's opinion will be sought. Full text of two to five of the included studies will be selected randomly to evaluate the pilot data extraction questionnaire. Any further information that is not considered in the pilot form will be added after being approved by the review team. Title, abstract and full text of the included studies will then be carefully read by two independent reviewers to extract the required data according to a predefined questionnaire (online supplementary appendix 1). Any existing discrepancies in data extraction will be discussed and where necessary, a third reviewer will be involved. If the included studies were sufficiently homogenous, meta-analysis of the aggregated data will be conducted. Calibration exercises will be performed at each level of the process.

The results of the systematic review will be reported based on the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement, and the results will be presented following the PRISMA flow diagram (figure 1).[27] The current systematic-review protocol has been written according to the PRISMA Protocols 2015 Statement.[28]

Data items

Using a data extraction form (online supplementary appendix 1), the following information from each study will be extracted:

1. The details of the included study with the first author as the study ID (the title, type of study, period of study, the year of publication, the country of origin).
2. The inclusion and exclusion criteria of the study.
3. Definition of diabetes.
4. Sample size (number of participants with type 1 or type 2 diabetes).
5. Demographic information (mean age, sex distribution, mean blood pressure, mean body mass index).
6. Index test, its calculation and whether it was corrected for body surface area.
7. Creatinine measurement method, calibration coefficient, traceability to isotope dilution mass spectrometry.
8. Persons executing and interpreting index tests.
9. Reference test (exogenous filtration marker used to measure GFR), its clearance or plasma disappearance, whether it was a single injection or continuous infusion. If a single injection was done, whether the reported mGFR had Brochner-Mortensen correction.
10. Persons executing and interpreting reference test.
11. Setting of data collection.
12. Time interval between the index and reference test and whether any interventions were carried between.
13. Mean of the eGFR derived from creatinine-based CKD-EPI equation.
14. Mean of the mGFR value.
15. The definition of bias, precision and accuracy.
16. The reported bias, precision and accuracy.
17. Bland-Altman plot and the limit of agreement.
18. Scatter plot of the mGFR versus eGFR and line of perfect concordance.
19. Any report of Lin's concordance correlation, intra-class correlation coefficient or reduced major axis regression analysis.
20. Any reports on change in mGFR and eGFR in time.
21. Results based on diabetes type (type 1 and type 2).
22. Results based on GFR category (GFR $<60\,\mathrm{mL/min/1.73\,m^2}$, GFR 60–$90\,\mathrm{mL/min/1.73\,m^2}$ and GFR $\geq 90\,\mathrm{mL/min/1.73\,m^2}$).

Outcomes and prioritisation

The primary outcome is to investigate bias, precision and accuracy of the creatinine-based CKD-EPI reported eGFR compared with the values measured by gold standard GFR measurement tools. If possible, the Bland-Altman graphs and 95% limits of agreement will be reviewed as well. As a secondary outcome, if possible, subgroup summarisation
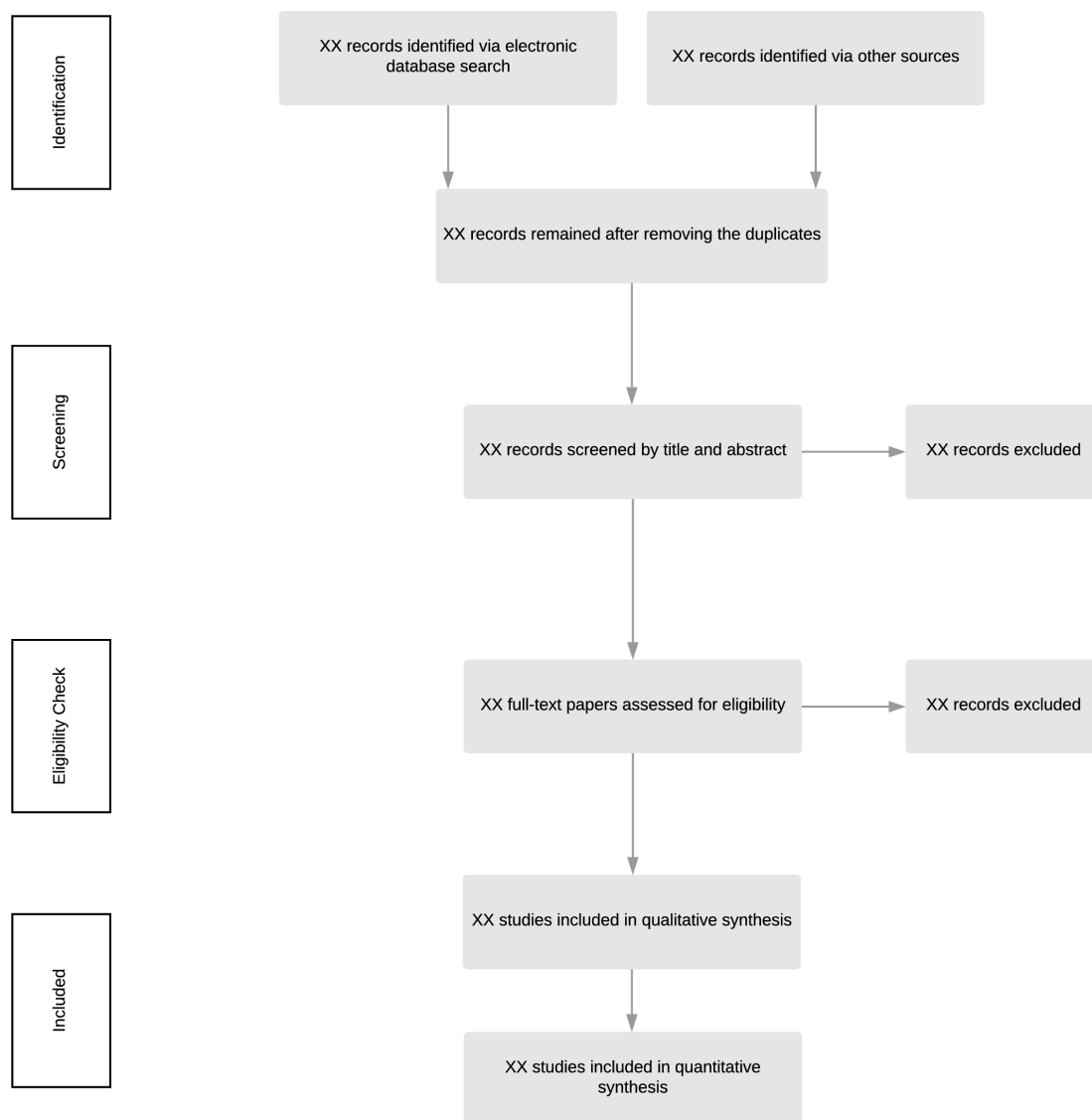
Figure 1 Preferred Reporting Items for Systematic Reviews and Meta-Analyses flow chart for reporting the process of selecting papers and number of papers in each phase.

and analysis of the diagnostic performance of the creatinine-based CKD-EPI equation based on participants diabetes type (type 1 and type two diabetes) and GFR category (GFR <60 mL/min/1.73 m^2, GFR 60–90 mL/min/1.73 m^2 and GFR ≥90 mL/min/1.73 m^2) will be conducted.

Risk of bias assessment

The Quality Assessment of Diagnostic Accuracy Studies (QUADAS)–2[29] will be used to assess the design and methods of the included papers and assess the risk of bias as well as applicability. QUADAS-2 tool has four domains (ie, patient selection, index test, reference standard and flow and timing) to evaluate the quality of the methods and the reporting of studies that validated the performance of the index test in the target population. the tool completion process has four stages namely (1) report the review question, (2) develop review-specific guidance, (3) review the published flow diagram for the primary study or construct a flow diagram if none is reported and (4) judge bias and applicability. In all four domains, the risk of bias is assessed (low, high, unclear). Assessment of applicability (low, high, unclear) takes place only in the first three domains. Two reviewers will independently conduct the quality assessment. Any disagreement will be solved by discussion and where required, third party consultation will be sought. The presence of potential biases within the studies will be reported descriptively.

Data analysis

Heterogeneity will be judged visually by inspection of forest plots as well as using I^2 statistics defined as[30 31]:

$$I^2 = 100\% \times (\chi^2 \text{ statistic-1 degree of freedom})/\chi^2 \text{ statistic}$$

Summary of the proposed accuracy, precision and bias of the creatinine-base CKD-EPI eGFR as the index test compared with mGFR as the reference test will be reported. Bias will be defined as either mean or median of the difference between eGFR and mGFR (eGFR–mGFR).

Precision will be defined as either 1 SD or the IQR of the bias. Accuracy will be evaluated as the proportion of the eGFRs that are within a specific percentage (eg, 10% (P_{10})) of the mGFRs. Where possible, the values will be calculated if not reported and 95% CIs will be calculated when they are not reported in the articles. A bivariate random effect model will be used to derive summary estimates of precision, accuracy and bias, and their 95% CIs.

To equalise the participation of each study in the analysis, statistical weights based on the number of participants and measurements in each study will be calculated. In studies in which the number of measurements (m), exceeded the number of participants (n), each measurement will receive the weight n/m. Measurements in studies with equal or fewer identified measurements than participants will receive the weight 1.

Any GFR expressed in millilitres per minute will be converted to millilitres per minute per $1.73\,m^2$ assuming a body surface area of $1.73\,m^2$. This conversion does not affect bias and accuracy measures expressed in per cent. However, the Bland-Altman diagrams will be affected to some extent.

Besides reporting the creatinine measurement method, calibration coefficient and traceability to isotope dilution mass spectrometry, we will conduct a subgroup analysis in studies which have clearly stated that the creatinine is measured by a method standardised to a mass spectroscopy creatinine standard.

Where possible, validation statistics will be aggregated and stratified based on diabetes type (type 1 and type 2 diabetes) and GFR category. GFR categories will be inspected as defined by the Kidney Disease: Improving Global Outcomes CKD definition that is: G1 (GFR $\geq 90\,mL/min/1.73\,m^2$), G2 (GFR $60\text{–}90\,mL/min/1.73\,m^2$), G3a (GFR $45\text{–}60\,mL/min/1.73\,m^2$), G3b (GFR $30\text{–}45\,mL/min/1.73\,m^2$), G4 (GFR $15\text{–}30\,mL/min/1.73\,m^2$) and G5 (GFR $<15\,mL/min/1.73\,m^2$). Alternatively, if this categorisation is not used by all the included studies, a broader categorisation defined as GFR $<60\,mL/min/1.73\,m^2$, GFR $60\text{–}90\,mL/min/1.73\,m^2$ and GFR $\geq 90\,mL/min/1.73\,m^2$ will be used.

If the quantitative synthesis of data is not possible, an aggregated summary of creatinine-base CKD-EPI derived eGFR, mGFR (specifying the exogenous marker used), demographic data as well as bias, accuracy and precision of the creatinine-base CKD-EPI eGFR as the index test compared with mGFR as the reference test will be reported.

Meta-bias(es)

To assess papers for selective outcome reporting bias, we will use the Outcome Reporting Bias in Trials classification system.[32] To address the publication bias, research teams with available data on mGFR in people with diabetes will be contacted to check whether they had conducted studies with negative results which have not been published.

Confidence in cumulative evidence

The quality of evidence will be assessed using Grading of Recommendations Assessment, Development and Evaluation approach.[33]

Patient and public involvement

As this is a protocol for a systematic-review of the existing literature, reporting or planning for patients and public involvement is not applicable.

ETHICS AND DISSEMINATION

An outline of the protocol has been published in the PROSPERO International Prospective Register of Systematic Reviews in 2018. The results will summarise the studies that assessed the diagnostic performance of the creatinine-based CKD-EPI equation in people with diabetes. Where possible, a quantitative synthesis of the bias, precision and accuracy data will be provided and the outcomes using different algorithms will be discussed. Findings of the review will be presented at relevant scientific conferences and disseminated through publication in a peer-reviewed journal.

As a limitation, we will not be able to extract data from studies in other languages than English, Chinese, Farsi and Dutch.

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Correction: *Diagnostic performance of the Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) equation at estimating glomerular filtration rate in adults with diabetes mellitus: a systematic review and meta-analysis protocol*

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This article was previously published with incomplete author name.
The correct name for last author is Elif I Ekinci.

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