Recalibration in Validation Studies of Diabetes Risk Prediction Models: A Systematic Review

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Abstract: *Background*: Poor performance of risk prediction models in a new setting is common. Recalibration methods aim to improve the prediction performance of a model in a validation population, however the extent of its application in the validation of diabetes risk prediction models is not yet known.

Methods: We critically reviewed published validation studies of diabetes prediction models, selected from five recent comprehensive systematic reviews and database searches. Common recalibration techniques applied were described and the extent to which recalibration and impacts were reported analysed.

Results: Of the 236 validations identified, 22.9% (n = 54) undertook recalibration on existent models in the validation population. The publication of these studies was consistent from 2008. Only incident diabetes risk prediction models were validated, and the most commonly validated Framingham offspring simple clinical risk model was the most recalibrated of the models, in 4 studies (7.4%).

Conclusions: This review highlights the lack of attempt by validation studies to improve the performance of the existent models in new settings. Model validation is a fruitless exercise if the model is not recalibrated or updated to allow for greater accuracy. This halts the possible implementation of an existent model into routine clinical care. The use of recalibration procedures should be encouraged in all validation studies, to correct for the anticipated drop in model performance.

Keywords: Risk prediction, diabetes, update, recalibration, validation.

BACKGROUND

The use of risk prediction models in a validation population is expected to have an effect on the performance of the model (usually a drop in the performance) due to the differences between development and validation populations, particularly the variances in outcome frequency between the populations, case-mix and measurements used for the variables and outcome determination [1]. In an effort to improve the performance of a model in a new setting, updating strategies have been proposed [2, 3]. The updating strategies range from simple adjustment of models' parameters to more complex model alterations. Simple updating methods, termed re-calibration, describes the re-estimation of the model intercept (or baseline risk parameter) with or without re-estimation of the regression coefficients.

The recalibration of risk prediction models is encouraged, where the resulting updated model combines the prediction information that was captured in model development with the information of the new population. This lends to the concept that risk prediction models should be based on as many individuals' data as possible. Too often, existent models are externally validated and when performance is disappointing, a new prediction model is developed. This results in a large number of models available, which are all poorly externally validated [4]. For illustration, a systematic review by Noble and coworkers [5] found that between 1993 and 2011, over 145 models were developed to predict prevalent or incidents diabetes, of which only a few were externally validated. This is of concern, considering that use of accurate and validated risk models is increasingly advocated as a basis for risk screening in strategies to prevent the occurrence of diabetes among those at high risk, to promote early detection among those with prevalent undiagnosed diabetes, and tailoring the complexity and intensity of the management among those with diagnosed diabetes, to the risk of subsequent complications. Indeed, with diabetes mellitus growing to the epidemic proportions around the world, and considering the complexity of the interaction

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of factors contributing to diabetes occurrence and related complications, the ability of risk prediction models to incorporate a multitude of risk factors, accounting for this complexity, cements their importance in diabetes prevention and control strategies. Beyond the field of diabetes and non-communicable diseases in general, with the opening era of personalised healthcare, prediction models will be increasingly used to assist clinical decision making. Efforts to limit the number of prediction models through careful updating of existing models to work in various settings, have a potential to improve their uptake in routine practice.

A recent validation study applied simple updating methods to diabetes risk prediction models, and reported some improvement, although non-optimal, of models performance [6]. However, the extent of the application of recalibration strategies in the validation of diabetes risk prediction models is not yet known. In this paper, we critically review the level of reporting, method of choice and extent of use of recalibration methods in validation studies, through a systematic review of studies on the validation of incident and prevalent diabetes risk prediction models, in an attempt to make conclusions on the extent of recalibration in diabetes risk prediction research.

METHODOLOGY

Building on the five most comprehensive review articles on both incident and prevalent diabetes risk prediction models by Buijsse *et al.* (2011) [7], Collins *et al.* (2011) [8], Noble *et al.* (2011) [5], Thoopputra *et al.* (2012) [9], and Brown *et al.* (2012) [10], additional relevant articles were identified through a systematic literature review according to the PRISMA guidelines, where necessary [11]. We searched PubMed for all published studies aimed at validating diabetes risk prediction models using the following string search: ((“diabetes” OR “diabetes mellitus” OR “type 2 diabetes”) AND (“risk score” OR “prediction model” OR “predictive model” OR “predicting” OR “prediction rule” OR “risk assessment” OR “algorithm”) AND (“validation” OR ‘validate”)).

Studies were included if they validated risk scores, models or questionnaires and the outcome was prevalent undiagnosed or incident diabetes in adults (aged >18 years). Studies undertaking internal validation were excluded as model recalibration should not be required at this early stage. Additionally, studies aimed at validating guidelines in new populations were excluded. Models that were developed outside of the logistic, cox or Weibull development methods were excluded due to the inability to validate these models (e.g. classification tree analysis method). There was no restriction on the variables included in the models, both non-invasive and invasive models were included. Additionally, there was no restriction on sample size or country. The data extracted included country/setting, name of the models validated, whether the study aimed at validation alone or with development of a model and the presence of a discussion and action (or lack thereof) on the recalibration of models. We reviewed the included studies with the aim of providing the reader with a comprehensive list of validated models, instances and prevalence of model recalibration, as well as the possible increase in performance of the updated model.

RESULTS

Overview of Included Studies

Following the sifting process, a total of 94 articles were included (Figure **1**). These articles included 70 models and 236 validations were conducted. Figure **2** depicts the distributions of risk prediction model validation. Included published studies undertook the validation of existent diabetes risk prediction model/s, where validation refers to the process of evaluating the performance of a model. Studies were focussed on external validation which goes beyond the assessment of model performance in all or a portion of the developmental datasets by assessing the performance in an independent dataset. The validation of a model can be grouped by a hierarchy proposed by Justice *et al.* (1999) [12], according to the reproducibility and historic, geographic, methodologic, spectrum and follow-up period transportability (Text Box **1**). Additionally, one paper can report on the validation of more than one model. Many studies undertook the validation of a model(s) as an added section to the development of a model in their population group (48.8%). Details of the included studies are provided in Table **1**; published between 1997 and 2014, but most appeared in 2005-2011. Articles reporting recalibration of existent models only appeared from 2008 onwards with the most appearing in 2010. The number and combination of predictors was variable, with age, sex, body mass index and waist circumference being the most commonly used variables. The study setting was highly heterogeneous; models were validated in 31 countries across 5 continents (only 1 from Africa). Models predicting incident diabetes were more

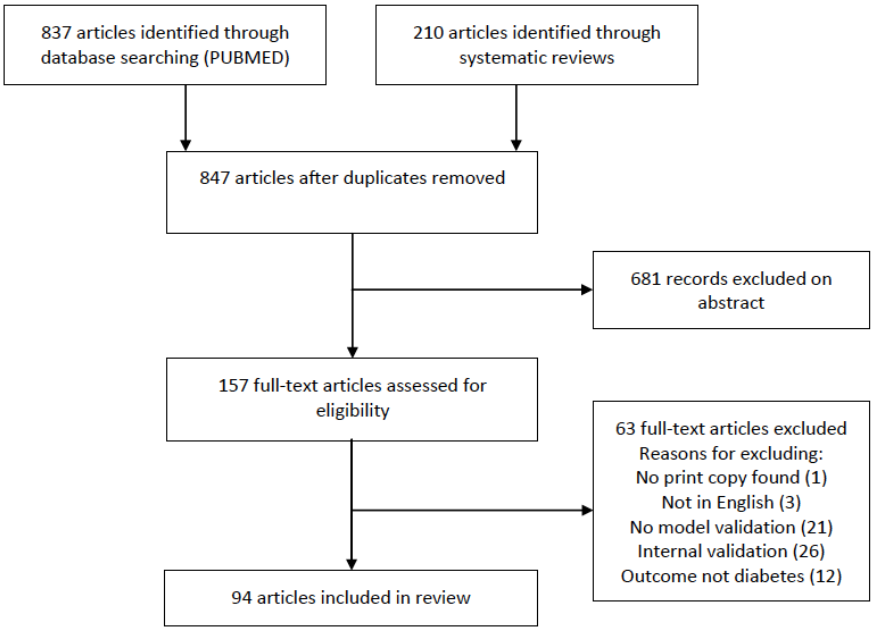

Figure 1: Flow diagram of selected studies.

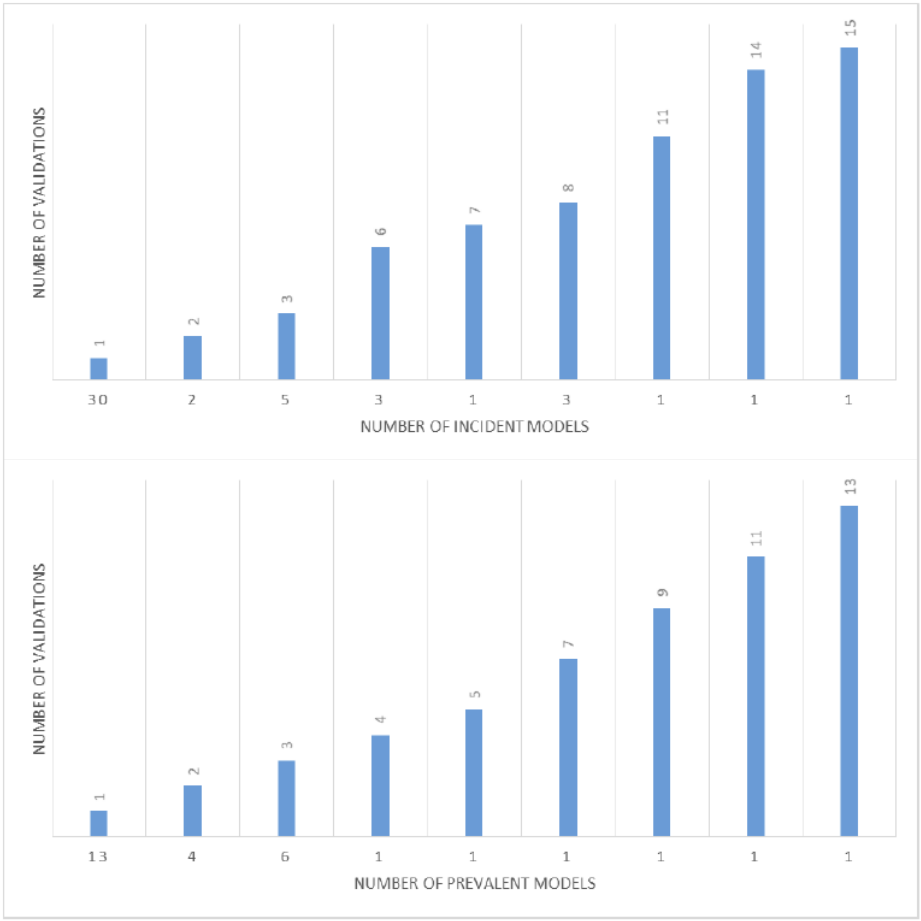

Figure 2: Bar diagram illustrating of frequency of incident (top) and prevalent (bottom) models validation.

The numbers on the X-axis indicate the number of models for each frequency, and the number at the tip of each bar indicate the frequency of model validation. The top 3 validated incident diabetes models are: 15 times – Framingham offspring simple clinical diabetes model; 14 times – San Antonio clinical risk model; 11 times – Cambridge diabetes risk score. The top 3 validated prevalent diabetes models: 13 times – Full prevalent FINDRISC risk model; 11 times – Rotterdam risk predicative model 1; 9 times – Cambridge diabetes risk model.

Text box 1: A Hierarchy of External Validation of Predictive Systems – Adapted from Justice *et al.* [12]

Level of validation	Cumulative generalizability evaluated
0: Internal validation	Reproducibility
1: Prospective validation	Level 0 + historic transportability
2: Independent validation	Level 1 + geographic transportability, methodologic transportability, spectrum transportability
3: Multisite validation	Level 2 at multiple sites
4: Multiple independent validation	Level 3 by multiple investigators
5: Multiple independent validations with life-table analyses	Level 4 + follow-up period transportability

commonly validated (62.7%) when compared to prevalent diabetes risk prediction. The development, recalibration and use of incident and prevalent risk prediction models vary and will therefore be discussed separately.

Incident Diabetes Risk Prediction Models

The most commonly validated model was the Framingham offspring simple clinical risk model [13] (10.1%) followed by the San Antonio clinical risk model [14] (9.5%). Validations were ranked according to the levels of transportability. There was no evidence of level 4 or 5 diabetes risk prediction validation. The most common form of validation (level 2) tested the models' geographic, methodologic and spectrum transportability in addition to the reproducibility and historic transportability (62.8%). This included models which were validated in the same country as their development but a different city or cohort to development, as well as validation of a model for a different outcome.

Prevalent Diabetes Risk Prediction Models

The Finnish diabetes full risk model was the most frequently validated prevalent diabetes risk prediction model (14.8%) [15, 16], followed by the Rotterdam predictive model 1 (12.5%). As with incident risk models, hierarchy level 2 was the most common level of validation (81.8%), with no level 4 or 5 validation.

Recalibration Methods

Multiple updating methods exist [2, 3, 17-19], varying in the complexity and the number of parameters that are adjusted or re-estimated. The term 'recalibration' is used to describe basic techniques to fit a predictive model to a new setting. The development of the model dictates the recalibration methods available. The mathematical model chosen for development may follow logistic regression, cox or Weibull principles. The intercept, or equivalent, of risk models is determined by the prevalence of the outcome in the population in which the model was developed and the updating of this intercept aims to solve the discrepancy between the mean predicted risk and mean observed risk resulting in better calibration. To be noted, recalibration, through either method, does not change the discriminatory ability of the risk prediction model as the relative ranking of the predicted probabilities remain the same [20].

Logistic regressions are the most commonly used for risk prediction research. Recalibration methods, described by Steyerberg [1] and Janssen *et al.* [3], aim to update the intercept of logistic models to better account for the prevalence in the validation population. The intercept can be updated by fitting a logistic regression model with a linear predictor as the only covariate in the updating set or by calculating a correction factor that is based on the mean predicted risk and observed outcome frequency in the validation population. When the outcome frequency is not particularly low or high, the correction factor will equal the calibration intercept. The final correction factor is simply added to the intercept of the original model. This is considered the most basic form of logistic model updating. An additional method, termed logistic calibration, fits a logistic regression model with a linear predictor as the only covariate in the updating set [3]. The calibration slope is used to recalibrate (multiply by) the original regression coefficients. The closer the calibration slope is to 1, the less adjustment the original regression coefficients required. The intercept is also updated by adding the calibration intercept to the intercept of the original prediction model.

Survival models available for risk prediction research depend on the distribution assumptions that can be made. Weibull models are generalised

Table 1: Characteristics of Validation/Updating Studies of Diabetes Prediction Models

Author	Year	Location of study	Model/s	Incident or prevalent model	Validation with development	Level of validation	Recalibration	Increase in calibration	Alteration to model (if any)
Abbasi *et al* [30]	2012	Netherlands	KORA base model (model 1) – logistic [31]	Incident	No	2	Yes	No	Addition of WC following recalibration
			KORA clinical model (model 2) – logistic [31]					Yes	Exclusion of HbA1c and uric acid; Addition of WC following recalibration
			KORA clinical model (model 3) – logistic [31]					Yes	Exclusion of HbA1c and OGTT; Addition of WC following recalibration
Abbasi *et al* [32]	2012	Netherlands	DETECT-2 model – logistic [33]	Incident	No	3	Yes	Yes	
			BRHS simple clinical model – logistic [34]						
			BRHS fasting biomarker model – logistic [34]						
			BRHS non-fasting biomarker model – logistic [34]						
			KORA base model (model 1) – logistic [31]						
			KORA clinical model (model 2) – logistic [31]						
			AUSDRISK – logistic [35]						Self-reported prevalent cases of diabetes excluded - history of high blood glucose variable unavailable, therefore set to zero
			DPoRT – weibull [27]						
			Tromso – cox [36]						
			ARIC basic model – weibull [37]						
			ARIC enhanced model – weibull [37]						
			QDScore – cox [38]						Z score combination of education levels and occupation status as proxy for social economic status

			DESIR clinical risk model – logistic [39]						
			DESIR clinical and biological risk model – logistic [39]						
			Framingham offspring simple clinical categorical model 1 – logistic [13]						
			Framingham offspring simple clinical categorical model 2 – logistic [13]						
			Framingham offspring simple clinical categorical model 3 – logistic [13]						
			EPIC-Norfolk – logistic [40]						
			German diabetes risk score – cox [41]						
			Finnish diabetes risk score concise – logistic [15]						Self-reported prevalent cases of diabetes excluded - history of high blood glucose variable unavailable, therefore set to zero
			Finnish diabetes risk score full – logistic [15]						Self-reported prevalent cases of diabetes excluded - history of high blood glucose variable unavailable, therefore set to zero
			San Antonio risk clinical model – logistic [42]						
			PROCAM risk model – logistic [43]						
			San Antonio reduced model – logistic [44]						
Adbul-Ghani *et al* [45]	2009	Finland	San Antonio risk clinical model – logistic [42]	Incident	No	2	No	/	Addition of 1-hour plasma glucose
			California scoring model – logistic [46]						
			Finnish diabetes risk score– logistic [15] (concise/full model not stated)						
Adhikari *et al* [47]	2010	India	Indian diabetes risk score – logistic [48]	Prevalent	No	2	No	/	Incident to prevalent
Akyil *et al* [49]	2014	Turkey	Finnish diabetes risk score full – logistic [15, 16]	Prevalent	No	2	No	/	/

Al Khalaf *et al* [50]	2010	Kuwait	American Diabetes Association risk assessment questionnaire [51]	Prevalent	Yes	2	No	/	/
			Rotterdam predictive model 1 – logistic [52]						
			Cambridge diabetes risk score – logistic [53]						
			Finnish diabetes risk score full – logistic [15, 16]						
			Danish risk score – logistic [54]						
			Indian diabetes risk score – logistic [48]						
			Thai simple risk model – logistic [55]						
			Omani risk score – logistic [56]						
Al-Lawati *et al* [56]	2007	Oman	Rotterdam predictive model 1 – logistic [52]	Prevalent	Yes	2	No	/	/
			Thai simple risk model – logistic [55]						
			Finnish diabetes risk score full – logistic [15, 16]						
			Danish risk score – logistic [54]						
Alssema *et al* [33]	2011	Netherlands, Denmark, Sweden, UK, Australia, Mauritius	Finnish diabetes risk score concise – logistic [15]	Incident	No	3	Yes	Yes	History of high blood glucose swopped for gestational diabetes
Alssema *et al* [57]	2012	Netherlands	Finnish diabetes risk score concise – logistic [15]	Incident	Yes	2	No	/	/
Baan *et al* [52]	1999	Netherlands	Rotterdam predictive model 1 – logistic [52]	Prevalent	Yes	1	No	/	/
			Rotterdam predictive model 2 – logistic [52]						
Balkau *et al* [39]	2008	France	San Antonio risk clinical model – logistic [42]	Incident	Yes	2	No	/	/
			Finnish diabetes risk score full – logistic [15]						
			DESIR clinical risk model – logistic [39]			1			
			DESIR clinical and biological risk model – logistic [39]						
			DESIR clinical, biological and genetic risk model – logistic [39]						

Bang *et al* [58]	2009	USA	Rotterdam predictive model 1 – logistic [52] American Diabetes Association risk assessment questionnaire [51]	Prevalent	Yes	2	No	/	/
Bergmann *et al* [59]	2007	Germany	Finnish diabetes risk score concise – logistic [15]	Incident	No	2	No	/	/
			Finnish diabetes risk score concise – logistic [15, 16]	Prevalent					
Bhadoria *et al* [60]	2014	India	Indian diabetes risk score – logistic [48]	Prevalent	No	2	No	/	/
Bozorgmanesh *et al* [61]	2010	Iran	ARIC enhanced model – Weibull [37]	Incident	No	2	No	/	/
Bozorgmanesh *et al* [62]	2010	Iran	San Antonio risk clinical model – logistic [42]	Incident	No	2	Yes	No	Addition of OGTT
			San Antonio reduced model – logistic [44]				No	/	
Bozorgmanesh *et al* [24]	2011	Iran	Framingham offspring simple clinical model – logistic [13]	Incident	Yes	2	Yes	Yes	/
Chaturvedi *et al* [63]	2008	India	Urban Asian Indian risk score – logistic [63]	Prevalent	Yes	1	No	/	/
Cameron *et al* [64]	2007	Mauritius	San Antonio risk clinical model – logistic [42]	Incident	No	2	No	/	/
Cameron *et al* [65]	2008	Australia	Finnish diabetes risk score full – logistic [15]	Incident	No	2	No	/	History of high blood glucose excluded
			San Antonio risk clinical model – logistic [42]						Family history only included parental history
Chen *et al* [35]	2010	Australia	AUSDRISK – logistic [35]	Incident	Yes	1	No	/	/
Chien *et al* [66]	2009	Taiwan	Framingham offspring simple clinical model – logistic [13]	Incident	Yes	2	No	/	/
			San Antonio risk clinical model – logistic [42]						
			Cambridge diabetes risk score – logistic [53]						
			PROCAM risk model – logistic [43]						
Collins *et al* [8]	2011	United Kingdom	QD Score – cox [38]	Incident	No	2	No	/	Continuous Townsend score replaced by categorical proxy
Farran *et al* [67]	2013	Kuwait	US screening score – logistic [58]	Incident	Yes	2	No	/	/
Franciosi *et al* [68]	2005	Italy	Finnish diabetes risk score full – logistic [15, 16]	Prevalent	No	2	No	/	/

Gao *et al* [69]	2010	China	Qingdao diabetes risk score – logistic [69]	Prevalent	Yes	1	No	/	/
			Rotterdam predictive model 1 – logistic [52]			2			
			Cambridge diabetes risk score – logistic [53]						
			Finnish diabetes risk score full – logistic [15, 16]						
			Danish risk score – logistic [54]						
			Asian Indian diabetes risk score – logistic [70]						
			Thai simple risk model – logistic [55]						
			DESIR clinical risk model – logistic [39]						
Ginde *et al* [71]	2007	USA	American Diabetes Association risk assessment questionnaire [51]	Prevalent	No	2	No	/	/
Glümer *et al* [54]	2004	Denmark	Danish risk score – logistic [54]	Prevalent	Yes	1	No	/	/
Glümer *et al* [72]	2005	Australia / Denmark	Danish risk score – logistic [54]	Prevalent	No	2	No	/	Physical activity excluded
Glümer *et al* [73]	2006	Global	Rotterdam predictive model 1 – logistic [52]	Prevalent	No	3	No	/	/
Gray *et al* [74]	2010	UK	Leicester Risk assessment score – logistic [74]	Prevalent	Yes	1	No	/	/
Gray et al [75]	2012	UK	Leicester practice risk score – logistic [75]	Prevalent	Yes	1	No	/	/
Gray *et al* [76]	2014	South Asians in UK	Leicester Risk assessment score – logistic [74]	Prevalent	No	2	No	/	/
			Leicester practice risk score – logistic [75]						
Griffin *et al* [53]	2000	UK	Cambridge diabetes risk score – logistic [53]	Incident	Yes	1	No	/	/
Guasch-Ferré *et al* [77]	2012	Spain	PREDIMED personal model – cox [77]	Incident	Yes	1	No	/	/
			Finnish diabetes risk score full – logistic [15]			2			
			German diabetes risk score – cox [41]						
Guerrero-Romero *et al* [78]	2010	Mexico	Mexican diabetes model – cox [78]	Incident	Yes	1	No	/	/
Hanley *et al* [79]	2004	USA	San Antonio risk clinical model – logistic [42]	Incident	Yes	2	No	/	/

Hartwig *et al* [25]	2013	Germany	German diabetes risk score – cox [41]	Incident	No	2	Yes	NS	Addition of HbA1c, blood glucose, triglycerides, HDL, alanine aminotransferase and gammaglutamyltransferase
He *et al* [80]	2012	China	DESIR clinical risk model – logistic [39]	Incident	No	2	No	/	/
			Finnish diabetes risk score concise – logistic [15]						
			Framingham offspring simple clinical model – logistic [13]						
			Thai simple risk model – logistic [55]						
			Taiwan scoring concise model – cox [66]						
			San Antonio risk clinical model – logistic [42]						
			PROCAM risk model – logistic [43]						
			California scoring model – logistic [46]	Prevalent	No	2	No	/	/
			Cambridge diabetes risk score – logistic [53]						
			Omani risk score – logistic [56]						
			Asian Indian diabetes risk score – logistic [70]						
			Urban Asian Indian risk score – logistic [63]						
Heizana *et al* [81]	2013	Japan	TOPICS diabetes categorical screening score –cox [81]	Prevalent	Yes	1	No	/	Prevalent to incident
			TOPICS diabetes continuous screening score –cox [81]						/
			Rotterdam predictive model 1 – logistic [52]			2			
			Danish risk score – logistic [54]						
			Omani risk score – logistic [56]						
			US screening score – logistic [58]						
			Asian Indian diabetes risk score – logistic [70]						
			Qingdao diabetes risk score – logistic [69]						
			Leicester Risk assessment score – logistic [74]						
			Screening tool in ADDITION-Leicester – logistic [75]						

Heldgaard & Griffin [82]	2006	Denmark	Cambridge diabetes risk score – logistic [53]	Prevalent	No	2	No	/	/
Hippisley-Cox *et al* [38]	2009	UK	QDScore – cox [38]	Incident	Yes	1	No	/	/
			Cambridge diabetes risk score – logistic [53]			2			
Hippisley-Cox *et al* [26]	2014	UK	QDScore – cox [38]	Incident	No	1	Yes	NS	/
Kahn *et al* [37]	2009	USA	Framingham offspring simple clinical model – logistic [13]	Incident	Yes	2	No	/	/
			DESIR clinical risk model – logistic [39]						
Kanaya *et al* [46]	2005	USA	California scoring model – logistic [46]	Incident	Yes	1	No	/	/
Keesukphan *et al* [83]	2007	Thailand	Thailand diabetes risk model – logistic [83]	Incident	Yes	1	No	/	/
Kengne *et al* [6]	2014	Europe	ARIC clinical only model – logistic [84]	Incident	No	3	Yes	Yes	
			ARIC enhanced model – weibull [37]					No	
			AUSDRISK – logistic [35]					Yes	Blood pressure medication replaced by proxy 'any hypertension'
			Cambridge diabetes risk score – logistic [53]					No	Family history of diabetes excluded Blood pressure medication replaced by proxy 'any hypertension'
			DESIR clinical risk model– logistic [39]					Yes	
			DPoRT – weibull [27]					No	
			Finnish diabetes risk score concise – logistic [15]					Yes	Blood pressure medication replaced by proxy 'any hypertension'
			Finnish diabetes risk score full – logistic [15]					Yes	Categorical daily intake of fruit, vegetables or berries replaced by continuous proxy Blood pressure medication replaced by proxy 'any hypertension'
			Framingham offspring complex clinical model 1 – logistic [13]					Yes	

			KORA base model (model 1) – logistic [31]					Yes	
			German diabetes risk score – cox [41]					Yes	
			QDScore – cox [38]					Yes	Continuous Townsend score replaced by categorical education proxy
Ko *et al* [85]	2010	China	Southern Chinese diabetes risk model – logistic [85]	Incident	Yes	1	No	/	/
Ku and Kegels [86]	2013	Philippines	Finnish diabetes risk score full – logistic [15, 16]	Prevalent	No	2	No	/	Removal of variables
Lee *et al* [87]	2012	Korea	Korean diabetes prediction score – logistic [87]	Prevalent	Yes	1	No	/	/
			Qingdao diabetes risk score – logistic [69]			2			
			Thai simple risk model – logistic [55]						
			Rotterdam predictive model 1 – logistic [52]						
			US screening score – logistic [58]						
Li *et al* [88]	2007	Germany	Framingham offspring simple clinical model – logistic [13]	Incident	No	2	No	/	/
Li *et al* [89]	2009	Germany	Finnish diabetes risk score full – logistic [15, 16]	Prevalent	No	2	No	/	Removal of variables
Li *et al* [90]	2011	Taiwan	American Diabetes Association risk tool [91]	Incident	No	2	No	/	Addition of family history of hyperlipidaemia, education levels, TV hours, history of cardiovascular disease and hypertriglyceride
Lin *et al* [92]	2009	Taiwan	ARIC clinical only model – logistic [84]	Incident	No	2	No	/	/
			Asian Indian diabetes risk score – logistic [70]						
			Cambridge diabetes risk score – logistic [53]						
			Danish risk score – logistic [54]						
			DESIR clinical risk model – logistic [39]						
			Finnish diabetes risk score concise – logistic [15]						

			Rotterdam predictive model – logistic [52] (model 1/2 not stated)						
			Omani risk score – logistic [56]						
			QDScore – cox [38]						
			Thai simple risk model – logistic [55]						
Lindstrom *et al* [15]	2003	Finland	Finnish diabetes risk score concise – logistic [15]	Incident	Yes	1	No	/	/
			Finnish diabetes risk score full – logistic [15]						
Luo et al [93]	2014	China	Chinese risk assessment model – logistic [93]	Incident	Yes	1	No	/	/
Lui et al [94]	2011	China	Chinese diabetes risk model 1 – logistic [94]	Prevalent	Yes	1	No	/	/
			Chinese diabetes risk model 2 – logistic [94]						
			Chinese diabetes risk model 3 – logistic [94]						
Lyssenko *et al* [95]	2008	Sweden and Finland	Framingham offspring simple clinical model – logistic [13]	Incident	Yes	2	No	/	/
Lyssenko *et al* [96]	2012	Denmark	PreDX diabetes risk score – logistic [97]	Incident	No	2	No	/	/
			San Antonio risk clinical model – logistic [42]						
			Framingham offspring simple clinical model – logistic [13]						
Mainous *et al* [98]	2007	USA	ARIC clinical only model – logistic [84]	Incident	No	2	No	/	/
Makrilakis *et al* [99]	2010	Greece	Finnish diabetes risk score full – logistic [15, 16]	Prevalent	No	2	No	/	/
Mann *et al* [14]	2010	USA	Framingham offspring simple clinical model – logistic [13]	Incident	No	2	Yes	Yes	/
			San Antonio risk clinical model – logistic [42]						
			ARIC clinical only model – logistic [84]						
McNeely *et al* [100]	2003	USA	San Antonio risk clinical model – logistic [42]	Incident	No	2	No	/	Addition of multiple variables
Mühlenbruch *et al*	2014	Germany	German diabetes risk score – cox [41]	Incident	No	2	No	/	Sibling history of diabetes

[101]									not available and all individuals assigned 0.5 Minor variable changes
Nicols *et al* [28]	2008	USA	Framingham offspring personal model – logistic [13]	Incident	No	2	Yes	N/S	/
			Framingham offspring simple clinical model – logistic [13]					Yes	/
			Framingham offspring complex clinical model 1 – logistic [13]					N/S	/
			Framingham offspring complex clinical model 2 – logistic [13]					N/S	
			Framingham offspring complex clinical model 3 – logistic [13]					N/S	
Park *et al* [102]	2002	UK	Cambridge diabetes risk score – logistic [53]	Prevalent	Yes	1	No	/	/
			Rotterdam predictive model 1 – logistic [52]			2			
Phillips *et al* [103]	2013	Ireland	DESIR clinical risk model – logistic [39]	Incident	No	2	No	/	/
			Cambridge diabetes risk score – logistic [53]						
			ARIC clinical only model – logistic [84]						
			ARIC enhanced model – weibull [37]						
			Finnish diabetes risk score full – logistic [15]						
			German diabetes risk score – cox [41]						
			Framingham offspring simple clinical model – logistic [13]						
Rahman *et al* [104]	2008	UK	Cambridge diabetes risk score – logistic [53]	Incident	Yes	2	No	/	Prevalent to incident
Ramachandran *et al* [70]	2005	India	Cambridge diabetes risk score – logistic [53]	Prevalent	Yes	2	No	/	/
Rathmann *et al* [105]	2005	Germany	Cambridge diabetes risk score – logistic [53]	Prevalent	No	2	No	/	/
			Rotterdam predictive model 1 – logistic [52]						
			San Antonio risk clinical model – logistic [42]						

			Finnish diabetes risk score full – logistic [15, 16]						
Riaz *et al* [106]	2012	Pakistan	RAPID model – logistic [106]	Incident	Yes	1	No	/	/
Rolka *et al* [107]	2001	USA	American Diabetes Association risk assessment questionnaire [51]	Prevalent	No	2	No	/	/
Rosella et al [27]	2010	Canada	DPoRT – weibull [27]	Incident	Yes	1	Yes	N/S	Recalibrated for ethnicity
Rowe *et al* [108]	2012	USA	PreDX diabetes risk score – logistic [97]	Incident	No	2	No	/	/
Ruige *et al* [109]	1997	Netherlands	American Diabetes Association risk assessment questionnaire [51]	Prevalent	Yes	2	No	/	/
			American Diabetes Association risk tool [91]						
Saaristo *et al* [16]	2005	Finland	Finnish diabetes risk score full – logistic [15, 16]	Prevalent	No	2	No	/	Incident to prevalent
Schmidt *et al* [110]	2012	Switzerland	ARIC basic model – weibull [37]	Incident	No	2	No	/	/
			ARIC enhanced model – weibull [37]						
			DESIR clinical risk model – logistic [39]						
			Cambridge diabetes risk score – logistic [53]						
			Finnish diabetes risk score full – logistic [15]						
			Framingham offspring simple clinical model – logistic [13]						
Schmidt *et al* [111]	2012	Switzerland	ARIC enhanced model – weibull [37]	Incident	No	2	No	/	Addition of genetic variables
Schulze *et al* [41]	2007	Germany	German diabetes risk score – cox [41]	Incident	Yes	3	No	/	/
Simmons *et al* [40]	2007	UK	Cambridge diabetes risk score – logistic [53]	Incident	Yes	2	No	/	Addition of a physical activity and diet
Spijkerman *et al* [112]	2004	Minorities in UK	Cambridge diabetes risk score – logistic [53]	Prevalent	No	2	No	/	/
Stern *et al* [113]	2004	Mexico	San Antonio risk clinical model – logistic [42]	Incident	No	2	No	/	Addition of metabolic syndrome
			Framingham offspring simple clinical model – logistic [13]						
Stern *et al* [114]	2008	USA	San Antonio risk clinical model – logistic [42]	Incident	No	2	No	/	/
			ARIC clinical only model – logistic [84]						

Sun *et al* [115]	2009	Taiwan	ARIC clinical model plus FBG – logistic [84] ARIC clinical model plus FBG and lipids – logistic [84]	Incident	Yes	2	No	/	/
Tabaebi *et al* [116]	2002	Egypt	Egyptian diabetes risk model – logistic [116]	Prevalent	Yes	1	No	/	/
Talmud *et al* [117]	2010	UK	Cambridge diabetes risk score – logistic [53] Framingham offspring simple clinical model – logistic [13]	Incident	Yes	2	No	/	Addition of genetic variables
Tankova *et al* [118]	2011	Bulgaria	Finnish diabetes risk score full – logistic [15, 16]	Prevalent	No	2	No	/	Incident to prevalent
Tuomilehto *et al* [119]	2010	Global	STOP-NIDDM risk score – cox [119]	Incident	Yes	2	No	/	/
Urdea *et al* [120]	2009	Denmark	PreDX diabetes risk score – logistic [97]	Incident	No	2	No	/	/
Wannamethee *et al* [121]	2005	UK	Framingham offspring simple clinical model – logistic [13]	Incident	No	2	No	/	Waist circumference replaced by BMI proxy
Witte *et al* [122]	2010	UK	Cambridge diabetes risk score – logistic [53] Rotterdam predictive model 1 – logistic [52] Rotterdam predictive model 2 – logistic [52] Finnish diabetes risk score full – logistic [15, 16] Danish risk score – logistic [54] Hoorn study risk model – logistic [109]	Prevalent	No	2	No	/	/
Xu *et al* [29]	2014	China	Framingham offspring simple clinical model – logistic [13]	Incident	Yes	2	Yes	Yes	/
Zhang *et al* [123]	2014	USA	Finnish diabetes risk score full – logistic [15, 16] US screening score – logistic [58]	Prevalent	No	2	No	/	/
Zhou *et al* [124]	2013	China	New Chinese Diabetes Risk Score - logistic [124]	Prevalent	Yes	2	No	/	/

exponential models with the inclusion of shape (survival rate), allowing for more flexibility on the types of data that the model can fit. The model has a hazard function which measures how likely the outcome/event will take place as a function of the length of observation [21]. While exponential distribution has a constant hazard function, the Weibull distribution hazard rate can increase or decrease in relation to time. The Weibull model is a popular method for parametric data. When distribution assumptions of the survival time (time until diagnosis) cannot be met, the Cox proportional hazard model can be used. Additionally, cox models are used when the risk factors have a multiplicative effect on the hazard function and can be extended for multiple regression situations [22]. Cox models do not have an intercept but rather an equivalent, the 'baseline survival function' or 'baseline risk'. This baseline information is almost never given by authors of published medical articles that report a cox model, however it can be recalculated [23]. Cox models are often referred to as semi-parametric, as the baseline hazard function is non-parametric, while the linear predictor in the cox model is fully parametric.

The incorporation of diagnosis time in both of these models allows for them only to be used for the development of incident diabetes risk prediction models (as opposed to prevalent diabetes prediction). The choice of model is researcher dependent and each come with their own advantages, parametric models are more precise with smaller standard errors, while it is easier, and can prevent biases, not having to make assumptions of the underlying hazard function nature or shape with semi-parametric models. The recalibration of all survival analysis models use Kaplan-Meier to determine the average incidence rates and update the model to the validation population incidence rate [17]. Additionally available, the mean values of each variable within the model which were derived from the validation population is replaced by the mean values of the same variables from the validation population. These methods are described in more detail by D' Agostino (2001) [17]. Text box **2** details the components of the various models that are altered during recalibration.

Reporting of Recalibration

Of the 236 validations of diabetes risk prediction models in alternate populations, 54 (22.9%) reported the use of recalibration methods in an effort to increase performance of the existent models. The reporting of the recalibration method was clear, the only article to not report the method of recalibration was Bozorgmanesh *et al.* (2011) [24]. 42 of these studies (77.8%) reported an increase in model performance following the recalibration of the original model (seven studies did not report the original or recalibrated model performance [25-28]). Every recalibration was carried out on an incident diabetes risk prediction model, with most of them being logistic regression models (75.9%). Additionally, 68.5% of recalibrations were carried out in level 3 calibrations. There was no one model that was recalibrated significantly more often than others. The Framingham offspring simple clinical model was recalibrated four times (7.4%) [14, 24, 28, 29], while the DPoRT, concise Finnish, German, KORA base, KORA clinical, QDScore and San Antonio clinical diabetes risk models were recalibrated three times (5.6%).

DISCUSSION

The validation of existent models in a new population is highly encouraged, preventing the

Text box 2: Mathematical formula for key models illustrating change before and after recalibration – adapted from Janssen *et al.* [3] and Houwelingen [23]

Model	Formula	Components	Recalibration change
Logistic	$1/\{1 + EXP[-(ß_0 + ß_1 \times predictor_1 + \ldots + ßn \times predictor_n)]\}$	Intercept: $ß_0$ Variable coefficient: $ß_1$- ßn	Update intercept: $ß_0$ + correction factor
			Update intercept: $ß_0$ + correction factor Coefficient: linear predictor x $\beta_{calibration}$
Cox	$H_o(t)EXP(x\beta)$ where $x\beta = \beta_1(x_1 - M_{1 + \ldots +} \beta_n(x_n - M_n)$	Baseline hazard function: $H_0(t)$ Prognostic index: xβ Regression coefficient: β Mean of risk factor: M	Update incidence rate of validation cohort: $H_0(t)$
			Update mean value of variable in validation cohort: β
Weibull	$(\beta_0 + \beta_1 \ln(t))EXP(x\beta)$ where $x\beta = \beta_1(x_1 - M_{1 + \ldots +} \beta_n(x_n - M_n)$	Hazard function: $\beta_0 + \beta_1 \ln(t)$ Prognostic index: xβ Regression coefficient: β Mean of risk factor: M	Update incidence rate of validation cohort: β_0 of $(\beta_0 + \beta_1 \ln(t))$
			Update mean value of variable in validation cohort: β

availability of numerous models, where few have been externally validated. The common method of developing and validating models simultaneously in a database in which previous risk prediction research has not been, defeats this purpose. Ideally, should a database suitable for diabetes risk prediction research be available, models should first be validated in an attempt to find an existent model that can perform at an optimum discrimination and calibration. Should a model show systematic overestimation or underestimation of risk, and the performance be too low to allow for accurate prediction and successful implementation, recalibration techniques can be employed in an effort to increase the performance of the model.

The aim of this study was to determine the extent to which model recalibration was undertaken in validation of diabetes risk models. This review of available published literature on the validation of diabetes risk prediction models showed that although validation of existent models is occurring, the attempt to fit these models to the new setting is poor. Additionally, we wished to determine if this recalibration was successful in increasing model performance when incorporating information for the validation population. Most studies that undertook the recalibration of models were able to show that model performance can be increased with basic recalibration techniques. The new models retain their importance in a new setting, taking into account the underlying incidence of the outcome and the variable relative importance of each risk factor from the development to the validation population. This increase in performance though simple recalibration is important in the effort to encourage the updating of models during validation. The statistical effort in recalibrating a model is slight and the final product of a model better fitted to the population in question and increased model performance worth the added step.

Although we aimed to comprehensively review all published papers on development and validation of undiagnosed diabetes risk prediction models, it should be highlighted that we may have missed some published validation studies. However, the overall result would not be expected to differ significantly with the possible inclusion of more model validation studies.

CONCLUSION

Without recalibration in the validation of a diabetes risk prediction model, the ability of these models to generate an accurate point estimate of an individual's diabetes risk may be inadequate. The importance of generalizability and validation of current models is repeatedly emphasized in literature, however this is fruitless if extra efforts are not taken to fit the model as best as possible to the new setting. Unfortunately, only a relatively small number of validation studies have included recalibration in their methodologies. Additionally, no prevalent diabetes risk prediction models were recalibrated in an attempt to better fit the model to the validation population. An increased focus on the validation, and particularly recalibration, of existent models will improve the generalizability of the models and likely lead to greater application of diabetes risk prediction models in daily clinical practice. The question that remains is, when is a model ruled sufficiently validated and recalibration / updated? Future research should address this question and allow for the determination of how many validation studies, what type of adjustments need to be made and most importantly, what is optimum performance to justify the implementation of the risk prediction model into clinical practice.

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