

This is a repository copy of *Patient characteristics predicting failure to receive indicated care for type 2 diabetes*.

White Rose Research Online URL for this paper: http://eprints.whiterose.ac.uk/116473/

Version: Accepted Version

Article:

Mounce, LTA, Steel, N, Hardcastle, AC et al. (6 more authors) (2014) Patient characteristics predicting failure to receive indicated care for type 2 diabetes. Diabetes Research and Clinical Practice, 107 (2). pp. 247-258. ISSN 0168-8227

https://doi.org/10.1016/j.diabres.2014.11.009

© 2014, Elsevier Ireland Ltd. Licensed under the Creative Commons Attribution-NonCommercial-NoDerivatives 4.0 International http://creativecommons.org/licenses/by-nc-nd/4.0/

Reuse

Unless indicated otherwise, fulltext items are protected by copyright with all rights reserved. The copyright exception in section 29 of the Copyright, Designs and Patents Act 1988 allows the making of a single copy solely for the purpose of non-commercial research or private study within the limits of fair dealing. The publisher or other rights-holder may allow further reproduction and re-use of this version - refer to the White Rose Research Online record for this item. Where records identify the publisher as the copyright holder, users can verify any specific terms of use on the publisher's website.

Takedown

If you consider content in White Rose Research Online to be in breach of UK law, please notify us by emailing eprints@whiterose.ac.uk including the URL of the record and the reason for the withdrawal request.



eprints@whiterose.ac.uk https://eprints.whiterose.ac.uk/ Title page: Patient characteristics predicting failure to receive indicated care for type 2 diabetes

Short running title: Patient predictors of failure to receive diabetes care (54 characters)

LTA Mounce, PhD, Primary Care Research Group and School of Public Health and Epidemiology, University of Exeter Medical School

N Steel, PhD, Norwich Medical School, University of East Anglia

AC Hardcastle, PhD, Norwich Medical School, University of East Anglia

WE Henley, PhD, Health Statistics Research Group, University of Exeter Medical School

MO Bachmann, PhD, Norwich Medical School, University of East Anglia

JL Campbell, MD, Primary Care Research Group, University of Exeter Medical School

A Clark, PhD, Norwich Medical School, University of East Anglia

D Melzer, PhD, School of Public Health and Epidemiology, University of Exeter Medical School

SH Richards*, PhD, Primary Care Research Group, University of Exeter Medical School

*Corresponding author: Dr Suzanne H Richards, Primary Care Research Group, University of Exeter Medical School, Smeall Building, St Luke's Campus, Exeter, EX1 2LU. Telephone: +44 (0)1392 722742. Email: s.h.richards@exeter.ac.uk

Number of tables: 3, number of figures: 2

Structured Abstract

Aims

To determine which patient characteristics were associated with failure to receive indicated care for diabetes over time.

Methods

English Longitudinal Study of Ageing participants aged 50 or older with diabetes reported receipt of care described by four diabetes quality indicators (QIs) in 2008-9 and 2010-11. Annual checks for glycated haemoglobin (HbA1c), proteinuria and foot examination were assessed as a care bundle (n=907). A further QI (n=759) assessed whether participants with cardiac risk factors were offered ACE inhibitors or angiotensin II receptor blockers (ARBs). Logistic regression modelled associations between failure to receive indicated care in 2010-11 and participants' socio-demographic, lifestyle and health characteristics, diabetes self-management knowledge, health literacy, and previous QI achievement in 2008-9.

Results

A third of participants (2008-9=32.8%; 2010-11=32.2%) did not receive all annual checks in the care bundle. Nearly half of those eligible were not offered ACE inhibitors/ARBs (2008-9=44.6%; 2010-11=44.5%). Failure to receive a complete care bundle was associated with lower diabetes self-management knowledge (odds ratio (OR) 2.05), poorer cognitive performance (1.78), or having previously received incomplete care (3.32). Participants who were single (OR=2.16), had low health literacy (1.50) or had received incomplete care previously (6.94) were more likely to not be offered ACE inhibitors/ARBs. Increasing age (OR=0.76) or body mass index (OR=0.70) was associated with lower odds of failing to receive this aspect of care.

Conclusions

Quality improvement initiatives for diabetes might usefully target patients with previous receipt of incomplete care, poor knowledge of annual diabetes care processes, and poorer cognition and health literacy.

Word count: 248

Keywords

Quality of care, prediction, patient education.

1 INTRODUCTION

The increasing prevalence of type 2 diabetes is a global public health crisis that poses major care and economic challenges for both developed and developing countries[1]. While reversing the accompanying global obesity epidemic remains a central goal, ensuring that all patients receive good treatment for diabetes should substantially reduce adverse outcomes[2]. There is consensus that appropriate monitoring and care can significantly reduce complications arising from diabetes and associated morbidity and mortality[3-7]. Different approaches to standard setting and quality indicator development identify care processes that can be monitored through routine audit, and that have an evidence base linking them to improved patient health and wellbeing.

The United Kingdom (UK) has a long established 'free at the point of use' health care system, based around strong primary care services[8]. Since 2004 there has been a major drive to improve the quality of diabetes care through the introduction of the 'Quality and Outcomes Framework' (QOF), a payment for performance scheme in primary care[9], and before then through numerous local and national initiatives[10]. Quality has steadily improved, but there is still evidence of low achievement of QIs for diabetes care in the UK[11-14], with similar evidence in other healthcare systems[15, 16]. Achievement of bundles of indicators can be particularly low. For example, the UK's National Diabetes Audit reported data from 1,929,985 medical records from 2009-10, representing 81.1% of all people aged 17 or over with a diagnosis of diabetes reported in QOF[11]. This audit found that, although more than 95.4% of patients with Type 2 diabetes consulted their general practitioner at least once in the previous 12 months and despite achievement rates of individual indicators being high (e.g. glycated haemoglobin [HbA1c] check=92.6%, foot examination=85.2%, blood pressure recorded=95.4%)[11], only around half (52.9%) received all nine of the NICE quality-indicated care processes [17]. A recent study of nine Scottish practices, with a combined patient population of 56,948, assessed practice compliance to QOF-based care bundles - composite measures of related, condition-specific care process indicators - for a range of chronic conditions[12]. All-or-none achievement – the proportion of patients receiving all indicated care processes in a bundle – was lowest for diabetes mellitus (56.4%), compared to coronary heart disease (64.0%), chronic kidney disease (69.0%), stroke (74.1%) and chronic obstructive pulmonary disease (82.0%).

Such all-or-none measurement of a care bundle offers a number of important advantages over using individual indicators[18]. Firstly, this method better reflects the interests of patients who wish to receive complete care. Second, this approach fosters a 'system perspective' where the aim is to deliver a full package of care processes to each eligible individual. Third, all-or-none achievement is likely to be a more sensitive method for assessing improvements in quality: Achievement rates of individual indicators are often high and therefore subject to ceiling effects, whereas all-or-none achievement rates will be lower and thus provide more room for improvement and goal setting, arguably making them a more meaningful measure of variation in delivery of care[12].

Understanding what drives variation in the receipt of diabetes care is vital in informing quality improvement strategies. The National Diabetes Audit described above found that all-or-none achievement of a nine-indicator care bundle was not related to social deprivation, gender or length of time with diabetes, but that younger age and non-white ethnicity were associated with not receiving all care processes[11]. Patients of a younger age, living in rural areas or who had a mental illness were found to be less likely to receive all items in a care bundle of HbA1c, cholesterol and eye tests, in a study analysing 757,928 medical records in Ontario, Canada, between 2006 and 2008[16]. Kontopantelis et al.[13] investigated the quality of care recorded in the medical records of 23,930 patients with diabetes registered with general practices in England using a composite measure of 17 QOF-based diabetes indicators, and found that receipt of care varied significantly with patients' age, gender, years of previous care and number of comorbid conditions.

This study aimed to explore the extent to which a broad range of baseline patient factors predicted subsequent failure to receive elements of indicated care for type 2 diabetes, using data from the English Longitudinal Study of Ageing (ELSA). ELSA data includes participants' self-reported

6

socio-demographic, lifestyle, psychosocial and health characteristics, as well as receipt of processes of care for diabetes, adapted for survey use in the UK from the Assessing Care of Vulnerable Elders (ACOVE) quality indicators[19-21].

2 SUBJECTS, MATERIALS AND METHODS

ELSA is a longitudinal cohort study of adults aged 50 and over living in private households in England. Beginning in 2002-3, participants were followed up with two-yearly 'waves' of data collection. The original cohort was drawn from households that had previously responded to the Health Survey for England (HSE) in either 1998, 1999 or 2001[22]. Replenishment cohorts were added in 2006-7 (sampled from HSE 2001-2004)[23] and 2008-9 (sampled from HSE 2006)[24] to correct for the original sample ageing and loss to follow-up. ELSA is intended to be representative of older people living independently in England. Data collection took place via face-to-face interviews in participants' homes, with additional information collected during a nurse visit in 2008-9[24]. Proxy respondents were interviewed in place of individuals with cognitive impairment. In depth accounts of the sampling and data collection methods have been published previously[22-24]. We explored responses from two consecutive waves of ELSA; 2008-9 (baseline) and 2010-11. We excluded proxy respondents. Participants' interviews were at least one year apart (mean= 2.02 years, SD=0.18).

2.1 Quality indicators

At both waves, four QIs developed for older people with diabetes were derived from information reported by eligible participants. No further QIs for diabetes were available at both time points. These four QIs were originally developed in the United States for the ACOVE project at RAND, based on systematic reviews of evidence of improved outcomes and expert clinical opinion[25]. The indicators were designed to assess the minimum acceptable standard of care and focus on healthcare processes, rather than health outcomes, as processes are under the control of the healthcare system

and are not subject to the array of other factors that influence health outcomes[26]. Using a modified RAND/UCLA appropriateness method[27], an expert panel of clinicians found these indicators to reflect current good practice in the UK, be valid for adults aged 50 and over, and suitable for self-report questionnaires[21]. Questions on quality of care were piloted in ELSA to ensure that they could be successfully implemented. Supplementary Table S1 shows how the ELSA indicators compare to related QOF indicators.

Glycated haemoglobin (HbA1c) - IF a person aged 50 or older has diabetes, THEN their glycated haemoglobin or fructosamine level should be measured at least annually.

Proteinuria - IF a diabetic person aged 50 or older does not have established renal disease and is not receiving an ACE inhibitor or angiotensin II receptor blocker, THEN they should receive an annual test for proteinuria.

Foot examination - ALL diabetic persons aged 50 or older should have an annual examination of their feet.

Angiotensin converting enzyme (ACE) inhibitor/angiotensin II receptor blocker (ARB) - IF a diabetic person aged 50 or older has one additional cardiac risk factor (i.e. smoker, hypertension, hypercholesterolemia, or renal insufficiency/microalbuminuria), THEN they should be offered an ACE inhibitor or receptor blocker.

Non-achievement of QIs was investigated by dividing the number of participants who did not receive the indicated care by the total number eligible for that care, expressed as a percentage. The processes for identifying the numerators and denominators for the QIs are displayed in Figures 1 and 2. We combined indicators for HbA1c, proteinuria and foot examination into a care bundle relating to annual monitoring checks. The care bundle was defined as not achieved for eligible participants who did not receive at least one of the three components. In addition to the benefits of all-or-none achievement discussed earlier, this method is best suited to process measures[18] and care bundles have the added advantage of providing more reliable scores from smaller samples than

individual indicators[28]. The fourth indicator assesses whether participants with diabetes and at least one further cardiac risk factor have been offered an ACE inhibitor/ARB. This QI was not added to the care bundle because not all patients with diabetes were eligible for it and, unlike the bundle components, is not an annual care process. Therefore, we analysed it separately.

2.2 Patient characteristics

Baseline patient characteristics that were potential predictors of subsequent receipt of care were identified by a multidisciplinary panel consisting of academics, clinicians and public and patient representatives, based on clinical relevance and presence in ELSA. The covariates used in modelling, were assessed in 2008-9 wherever possible.

Demographics

Participants' age split into three bands (50-64, 65-74 and 75 years of age or older), sex and National Statistics Socio-Economic Classification (NS-SEC), with three categories of occupation (managerial/professional, intermediate and routine/manual). NS-SEC was not available in 2008-9 so was assessed in 2010-11.

Health characteristics

Participants level of eyesight (excellent/good vs. fair/poor/blind), hearing (excellent/good vs fair/poor) and chronic pain (none/mild vs. moderate/severe).

Previous care - Whether or not the indicated care was achieved at the previous assessment in ELSA (2008-9) for eligible participants. New cases since the last assessment were treated as a separate category.

Long-standing illness - Participants were asked "*Do you have any* long-standing illness, disability or infirmity? By long-standing I mean anything that has troubled you over a period of time or that

is likely to affect you over a period of time." Participants who responded "yes" to this question were then asked *"Does this illness or disability limit activities in any way?"* We used three categories; none, long-standing illness and limiting long-standing illness.

Activities of Daily Living (ADLs) – Participants self-reported difficulties with basic ADLs (dressing, walking across a room, bathing, eating, getting in/out of bed, using the toilet). Participants were classified as having difficulties with none/one or more than one of the activities.

Instrumental ADLs – Participants self-reported difficulties with instrumental ADLs (orientation, preparing meals, shopping, using the telephone, taking medications, housekeeping, money management). Participants were classified as having difficulties with none/one or more than one of these activities.

Cognitive performance – A composite score was computed from participants' score on tests of prospective memory, attention, processing speed, verbal fluency, orientation, immediate word recall, delayed word recall and numeracy. These test scores were standardised and summed to form a cognitive performance scale. This scale was then standardised and the bottom 10% of scores were classified as 'low performance'. This method has been used previously with ELSA data[29].

Health literacy – Participants were given a fictitious medicine label to read (size A4). Whilst being able to refer to this label, participants were then asked four questions, such as *"list one condition for which you might take this tablet"*. Participants who made no errors were classified as having high health literacy and those who made one or more errors as having low health literacy.

Time since diagnosis – At each wave of ELSA from 2004-5 onwards, participants had the opportunity to report a diagnosis of diabetes. The number of previous waves from 2010-11 to the wave at which participants reported a diagnosis of diabetes was used to infer a measure of time since diagnosis. This formed a scale of 0 ELSA waves (reported in 2010-11) to 3 ELSA waves (reported in 2004-5).

Body Mass Index (BMI) – The height and weight of participants was measured during the nurse visits in 2008-9. Participants BMI was calculated from this data and was classified as underweight (<18.5), normal weight (18.5-25), overweight (25-30) or obese (30 or more). Only around 0.3% of participants eligible for the QIs were found to be underweight (Table 1), so this category was combined with normal weight prior to modelling.

Depression – Depressive symptoms (8 items) were self-reported using the Center for Epidemiological Studies Depression (CES-D) scale[30]. In accordance with the scale design, participants reporting four or more symptoms were classified as depressed.

Lifestyle factors

Participants self-reported their frequency of alcohol consumption (1-2 days/week or less, 3-4 days/week or more), smoking status (never smoked, smoked in past, currently smokes) and whether or not they usually eat five portions of fruit and/or vegetables per day. Reported levels of work activity, as well as frequency and intensity of leisure time activities, were used to derive a measure of physical activity (moderate/high, sedentary/low), using an established method[31].

Diabetes self-management knowledge – Participants were asked "*How much do you think you know about managing your diabetes*?" Participants were classified as high if they responded 'Just about everything-/ most of what you need to know' and low if they responded 'some-/ a little-/ almost none of what you need to know'.

Psychosocial factors

Participants reported their marital status (married/ in partnership, not married/ in partnership) and whether or not they lived alone.

Social detachment – A measure of social detachment was derived using the method described in the ELSA 2010-11 report[31]. Social detachment is a multi-dimensional construct covering four domains: civic participation, leisure activities, cultural engagement and social networks. Those classified as detached on 3 or more of these domains were classified as socially detached.

Quality of life – The ELSA interview included the Control Autonomy Self-realisation and Pleasure (CASP-19) scale of quality of life[32], consisting of 19 items covering the four domains from which the instrument's name is derived. Participants overall scale score was transformed into tertiles (high, medium, low) of equal response frequency.

Locus of control – Participants rated the extent to which they agreed with the statement "*what* happens in life is often determined by factors beyond [his/her] control" on a 6-point Likert scale. Those who strongly-slightly agreed were classified as having an 'external' locus of control and those who strongly-slightly disagreed as having an 'internal' locus of control.

2.3 Data analysis

We report the non-achievement rate for each QI and the care bundle in 2008-9 and 2010-11, adjusting for differential non-response at the respective wave using the cross-sectional weights provided with ELSA[23, 24].

To maximise the sample sizes available for regression analyses, missing values in covariates were coded as an extra category (continuous covariates were first transformed into tertiles). The frequencies of all covariates' categories were then checked. Categories were combined if there were <10% of responses in a category. If combining categories was not suitable, then we excluded them on the basis of poor data quality. A short-list was then drawn up a priori, selecting covariates deemed to be the most clinically relevant where several covariates were related. Supplementary

Table S2 describes all the covariates considered for modelling and the reason they were excluded from the shortlist if not selected.

We constructed two regression models predicting non-achievement in 2010-11; one for the care bundle and the other for the ACE inhibitor/ARB QI. Univariable logistic regression analyses were first performed for each short-listed covariate. We treated all categorical covariates as dummy/indicator variables. Covariates found significant at p<0.1 in the univariable regressions, for either outcome, were then included in a forced entry logistic regression for both outcomes. We conducted sensitivity analyses to look for trends across ordinal covariates (e.g. age group – 'missing data' categories were excluded), to further explore the effect of 'previous care' and to investigate how excluding participants with low cognitive performance in 2010-11 affected the models. All regression analyses were adjusted for age, gender and differential non-response in 2010-11 and were performed using Stata SE version 12.1.

3 RESULTS

3.1 Samples

8,222 ELSA participants responded in 2008-9 and 2010-11. Of these, 746 (9.1%) reported in 2008-9 that a doctor had told them that they had diabetes, with 165 incident cases reported in 2010-11 (n=911, 11.1%). 907/911 (99.6%) were eligible for at least one QI for the diabetes care bundle and 759/911 (83.3%) for the ACE inhibitor/ARB QI in 2010-11. The numbers included at each stage of deriving the QIs are displayed in Figs. 1 and 2. The characteristics of the samples are displayed in Table 1. The sample with diabetes comprised more males than the overall ELSA population, had more participants aged 75 or older, were more likely to be from the lowest socio-economic classification and to have no educational qualifications. The mean age in years of the 8,222 ELSA participants, the care bundle sample and the ACE inhibitor/ARB sample respectively were 65.6

(SD=9.3), 67.8 (SD=9.2) and 67.8 (SD=9.1) in 2008-9, and 67.7 (SD=9.4), 69.9 (SD=9.5) and 69.9 (SD=9.4) in 2010-11. It should be noted, however, that ELSA collapsed all ages over 90 as an age of 90 in order to maintain confidentiality, hence the use of a categorical age variable in analyses.

3.2 Non-achievement of quality indicators

The indicators for HbA1c, proteinuria and foot examination had similar rates of non-achievement (weighted 2010-11 range= 17.4%-22.8%). At least one of these checks was not received in 288/907 cases in 2010-11 (weighted rate=32.7%, 95% confidence interval [CI] 29.6-35.8). The ACE inhibitor/ARB indicator had higher non-achievement (weighted 2010-11 score=44.5%). The non-achievement rates of the individual QIs and the care bundle in 2010-11 varied little from non-achievement in 2008-9 (Table 2).

3.3 Modelling subsequent non-achievement

Fifteen covariates were selected and entered into forced-entry models for both outcomes (Table 3). All univariable effects are provided in Supplementary Table S3. 902/907 of those eligible for the care bundle and 757/759 of the ACE inhibitor/ARB QI sample contributed to the analyses. These discrepancies were due to small numbers of missing values that were not transformed into an extra category for respective covariates because doing so would have resulted in small numbers in the respective cell (<1% of the sample).

For both models, the key predictor of non-achievement in 2010-11 was previous non-achievement two years earlier, which more than trebled the odds of subsequent non-achievement of the care bundle (odds ratio [OR]=3.32, 95% CI 2.28-4.84, p<0.001) and increased the odds nearly sevenfold for non-achievement of the indicator for ACE inhibitors/ARBs (OR=6.94, 95% CI 4.54-10.61, p<0.001) (Table 3). Participants classified as cognitively impaired had a 78% increased likelihood of non-achievement of the care bundle (OR=1.78, 95% CI 1.09-2.89, p=0.021). Those who did not feel they knew 'most-' or 'everything that they need to know' about managing their diabetes had double the odds of not receiving all their annual checks in the bundle (OR=2.05, 95% CI 1.29–3.26,

p=0.002), but not significantly raised odds of failure to achieve the ACE inhibitor/ARB QI (OR=1.32, 95% CI 0.78-2.25, p=0.305).

Participants with low health literacy had 50% higher odds for non-achievement of the ACE inhibitor/ARB indicator compared to those with high health literacy (OR=1.50, 95% CI 1.01-2.24, p=0.046), with no significant difference apparent for the care bundle. The odds of non-achievement of the ACE inhibitor/ARB indicator were decreased in the oldest age group (OR=0.56, 95% CI 0.33-0.96, p=0.034) and for participants categorised as obese (OR=0.48, 95% CI 0.26-0.89, p=0.019), but were increased over twofold for participants who were not married or in a civil partnership (OR=2.16, 95% CI 1.39-3.37, p=0.001).

3.4 Sensitivity analyses

Linear trends on ordinal covariates (age group, socio-economic classification, long-standing illness and BMI category) were tested by entering each of these as individual variables, rather than dummy variables, with the 'missing data' category excluded where applicable. Every other covariate remained unchanged (Table 3). Sensitivity analyses were performed excluding the 'previous care' covariate, as finding that the strongest predictor of not receiving care was historical non-receipt does not advance our understanding of wider factors associated with not receiving care. Participants with routine/manual socio-economic status had 50% increased odds of non-achievement of the care bundle relative to those in the managerial/professional group (OR=1.5, 95% CI 1.02-2.21, p=0.039). For the ACE inhibitor/ARB QI, the difference between underweight/normal weight and overweight reached significance (OR=0.50, 95% CI 0.27-0.92, p=0.025). Supplementary Table S4 displays the ORs and 95% CI without 'previous care'.

A further sensitivity analysis re-ran the forced entry logistic regressions whilst excluding participants with low cognitive performance in 2010-11 (Supplementary Table S5), as it is possible that these participants may have reduced ability to recall whether the indicated aspects of care were

delivered. In these analyses, cognitive performance in 2008-9 was no longer a significant predictor of failure to receive care for either the care bundle (n=781) or the ACE inhibitor/ARB QI (n=662) models. The effect of low health literacy was diminished to the point that it was only marginally significant in the ACE inhibitor/ARB model (OR=1.48, 95% CI 0.96 - 2.28, p=0.077), as were the trend tests for age and BMI category in this model, and NS-SEC in care bundle model. However, the ORs and 95% CI for these covariates were very similar to the models using the full sample, indicating that these changes in significance may be due to the loss of power caused by the reduced sample sizes. No further covariates changed from significance to non-significance or vice versa.

4 DISCUSSION

We explored patient-reported non-receipt of quality-indicated diabetes healthcare in a large cohort study of people aged 50 and over in England. One or more of the annual monitoring checks were not received in nearly a third of eligible patients in 2008-9 and 2010-11, and nearly half of eligible patients were not offered an ACE inhibitor or ARB. We investigated a broad range of patient characteristics and showed that non-achievement tended to endure for the same patients, and that the patients lacking diabetes self-management knowledge or having mild cognitive impairment were more likely to not get routine checks. In our extensively-controlled analyses, some covariates highlighted by work on patient records were conspicuous by their absence in both models, such as comorbidities (as assessed by long-standing illness), socio-economic status and length of time with the condition.

Being the first longitudinal (as opposed to repeated cross-sectional) study of QI achievement in the given population (as far as we know), there are no directly comparable previous reports. Our findings for individual QIs are consistent with figures reported for 2009-10 in the recent National Diabetes Audit[11], examining all available clinical records in the UK, which found non-achievement rates of 7.4%, 26.3% and 14.8% for HbA1c checks, renal risk checks and foot

examinations respectively, although the rates in the group aged 50 and over that we studied were not separately reported. It is difficult to compare the achievement of our care bundle with other research due to substantial variability within the literature in the specific indicated care included, the number of components, the healthcare context of the population studied and the guidance from which QIs are taken. Despite the recent reports of shortfalls in quality of care for diabetes discussed previously, there is evidence that modest improvements in achievement of indicated care have been made in the UK since the introduction of the QOF payment for performance scheme in 2004[11, 13, 33-35]. For example, Kontopantellis et al.[13] longitudinally analysed the achievement of a 17-item composite measure of diabetes care from three years before the introduction of QOF to three years afterwards, using data extracted from the medical records of 23,930 patients with diabetes. Quality of diabetes care improved over-and-above the pre-incentive trend by 14.2% in the first year of the scheme, which reduced to 7.3% above trend by the third year. However, our sample showed little variation across two years.

While patients who felt they lacked knowledge around managing their diabetes were less likely to achieve the care bundle, this was not found for the ACE inhibitor/ARB QI, which was instead predicted by low health literacy. This dissimilarity may reflect the qualitative differences in indicated healthcare, with the care bundle relating to diabetes monitoring checks and the other QI relating to taking medications due to cardiovascular complications. Both these covariates, however, may be amenable to improvement through patient education. On-going, structured patient education and training is already a core component of diabetes guidance[7, 17]. Although education is recommended, the content and format are not fixed and there is considerable flexibility in how such education is delivered. Recent, definitive trials have sought to test the effectiveness of multifactorial self-management and education programmes for diabetes[34] and long-term conditions[36, 37]; with only modest benefits or no differences in key outcomes reported. A recent overview of systematic reviews on improvement strategies for intermediate outcomes and delivery of processes of care for diabetes found 21 high quality systematic reviews on the effect of various patient

education interventions. All 21 reported effects on different intermediate outcomes (e.g. HbA1c control), but none reported process measures. Further research should explore whether providing patients/carers with a simple checklist detailing the core annual diabetes care processes improves receipt of care.

4.1 Strengths and limitations

This study was able to model a large number of in-depth baseline patient characteristics on subsequent non-achievement of process of care indicators. The longitudinal nature of the design gives stronger support for the causal influence of these patient characteristics than would be possible with a cross-sectional cohort. Additionally, our models were well-controlled, due to the number and range of covariates included, enabling greater confidence that the unique effects of covariates were captured.

All diagnoses and quality of care measures were self-reported at interview, which may be a less reliable source than medical records. The QIs included in ELSA had all been selected on the basis of feasibility of collecting accurate self-reported data. During development of ACOVE indicators, validation work found that for diagnoses of some chronic conditions and process of care measures such as drugs, concordance between self-reports and medical records was good, and self-reports tend to score the same or higher than medical records[38, 39]. This would have caused us to overestimate the level of quality received rather than underestimate it, although it remains possible that self-reports underestimated quality. Medical records may also suffer from poor record-keeping which can influence pass rates of studies documenting QIs pass rates. That our diabetes indicators were broadly comparable to the pass rates reported for equivalent QIs from national audit data[11], provides partial validation of the self-reported data. We were not able to ascertain whether ACE inhibitors/ARBs were not offered to eligible participants due to contra-indications.

4.2 Conclusions

The quality of diabetes care in the UK is improving[11, 17], and financial incentives rewarding providers to achieve individual QIs may have contributed in part[40]. Our findings add weight to the growing body of evidence supporting the move towards setting standards based on bundle achievement. Providers should critically reflect on why not all components of the core bundle of processes are being implemented annually. Incentives might also encourage auditing the care of those who did not achieve indicators in previous years, and those reporting less knowledge on how to self-manage their diabetes.

5 FUNDING

This article presents independent research commissioned by the National Institute for Health Research (NIHR) under the Health Services Research programme. The views expressed in this publication are those of the authors and not necessarily those of the NHS, the NIHR or the Department of Health. The funders had no role in the study design, data collection, data analysis, data interpretation, writing of the report, or decision to submit the article for publication.

6 CONFLICTS OF INTEREST

None declared.

7 ACKNOWLEDGEMENTS

Dave Stott and Amander Wellings, representatives of Public and Patient Involvement in Research

(PPIRes), brought a helpful lay perspective to this research, including identification of covariates to

examine and specific comments on earlier versions of this paper.

REFERENCES

1. Hu FB. Globalization of Diabetes: The role of diet, lifestyle, and genes. Diabetes Care. 2011;34(6):1249-57.

2. Swinburn BA, Sacks G, Hall KD, McPherson K, Finegood DT, Moodie ML, et al. The global obesity pandemic: shaped by global drivers and local environments. The Lancet. 2011;378(9793):804-14.

3. American Diabetes Association. Implications of the United Kingdom Prospective Diabetes Study. Diabetes Care. 2002;25(suppl 1):s28-s32.

4. Holman RR, Paul SK, Bethel MA, Matthews DR, Neil HAW. 10-Year Follow-up of Intensive Glucose Control in Type 2 Diabetes. New England Journal of Medicine. 2008;359(15):1577-89.

5. Pyörälä K, Pedersen TR, Kjekshus J, Faergeman O, Olsson AG, Thorgeirsson G, et al. Cholesterol Lowering With Simvastatin Improves Prognosis of Diabetic Patients With Coronary Heart Disease: A subgroup analysis of the Scandinavian Simvastatin Survival Study (4S). Diabetes Care. 1997;20(4):614-20.

6. UK Prospective Diabetes Study Group. Tight blood pressure control and risk of macrovascular and microvascular complications in type 2 diabetes: UKPDS 38. BMJ. 1998;317(7160):703-13.

7. National Institute for Clinical Excellence. The management of type 2 diabetes. London: National Institute for Clinical Excellence; 2009.

8. Kringos D, Boerma W, Bourgueil Y, Cartier T, Dedeu T, Hasvold T, et al. The strength of primary care in Europe: an international comparative study. British Journal of General Practice. 2013 November 1, 2013;63(616):e742-e50.

9. NHS Confederation BMA. The New General Medical Services Contract. London: The NHS Confederation; 2003.

10. Pierce MB, Zaninotto P, Steel N, Mindell J. Undiagnosed diabetes - data from the English longitudinal study of ageing. Diabetic Medicine. 2009;26(7):679-85.

11. The NHS Information Centre. The National Diabetes Audit 2009-10. Leeds: NHS Information Centre; 2011.

12. de Wet C, McKay J, Bowie P. Combining QOF data with the care bundle approach may provide a more meaningful measure of quality in general practice. BMC Health Services Research. 2012;12(1):351.

13. Kontopantelis E, Reeves D, Valderas JM, Campbell S, Doran T. Recorded quality of primary care for patients with diabetes in England before and after the introduction of a financial incentive scheme: a longitudinal observational study. BMJ Quality & Safety. 2013 January 1, 2013;22(1):53-64.

14. Steel N, Bachmann M, Maisey S, Shekelle P, Breeze E, Marmot M, et al. Self reported receipt of care consistent with 32 quality indicators: national population survey of adults aged 50 or more in England. BMJ. 2008;337:a957.

15. Wenger NS, Solomon DH, Roth CP, MacLean CH, Saliba D, Kamberg CJ, et al. The Quality of Medical Care Provided to Vulnerable Community-Dwelling Older Patients. Annals of Internal Medicine. 2003;139(9):740-7.

16. Kiran T, Victor JC, Kopp A, Shah BR, Glazier RH. The Relationship Between Financial Incentives and Quality of Diabetes Care in Ontario, Canada. Diabetes Care. 2012;35(5):1038-46.

17. National Institute for Clinical Excellence. Diabetes in adults quality standard. London: National Institute for Clinical Excellence; 2011.

18. Nolan T, Berwick D. All-or-none measurement raises the bar on performance. JAMA. 2006;295(10).

19. Shekelle P, Vijan S. Quality indicators for the care of diabetes mellitus in vulnerable elders. Journal of the American Geriatrics Society. 2007;55 Suppl 2:S312-7.

20. Shekelle PG, MacLean CH, Morton SC, Wenger NS. Assessing Care of Vulnerable Elders: Methods for Developing Quality Indicators. Annals of Internal Medicine. 2001;135(8_Part_2):647-52.

21. Steel N, Melzer D, Shekelle PG, Wenger NS, Forsyth D, McWilliams BC. Developing quality indicators for older adults: transfer from the USA to the UK is feasible. Quality and Safety in Health Care. 2004;13(4):260-4.

22. Taylor R, Conway L, Calderwood L, Lessof C, Cheshire H, Cox K, et al. Health, wealth and lifestyles of the older population in England: The 2002 English Longitudinal Study of Ageing: Technical Report. London: Institute of Fiscal Studies; 2007.

23. Scholes S, Medina J, Cheshire H, Cox K, Hacker E, Lessof C. Living in the 21st century: older people in England The 2006 English Longitudinal Study of Ageing: Technical Report. London: Institute of Fiscal Studies; 2009.

24. Cheshire H, Hussey D, Medina J, Pickering K, Wood N, Ward K, et al. Financial circumstances, health and well-being of the older population in England: The 2008 English Longitudinal Study of Ageing: Technical Report. London: Institue of Fiscal Studies; 2012.

25. Wenger NS, Shekelle PG. Assessing Care of Vulnerable Elders: ACOVE Project Overview. Annals of Internal Medicine. 2001;135(8 Pt2):642-6.

26. Mant J, Hicks N. Detecting differences in quality of care: the sensitivity of measures of process and outcome in treating acute myocardial infarction. BMJ. 1995 1995-09-23 08:00:00;311(7008):793-6.

27. Brook RH, Chassin MR, Fink A, Solomon DH, Kosecoff J, Park RE. A Method for the Detailed Assessment of the Appropriateness of Medical Technologies. International Journal of Technology Assessment in Health Care. 1986;2(01):53-63.

28. Kirk SA, Campbell SM, Kennell-Webb S, Reeves D, Roland MO, Marshall MN. Assessing the quality of care of multiple conditions in general practice: practical and methodological problems. Quality and Safety in Health Care. 2003 December 1, 2003;12(6):421-7.

29. Llewellyn DJ, Lang IA, Langa KM, Naughton F, Matthews FE. Exposure to secondhand smoke and cognitive impairment in non-smokers: national cross sectional study with cotinine measurement. BMJ. 2009 2009-02-12 00:00:338.

30. Radloff LS. The CES-D Scale: A Self-Report Depression Scale for Research in the General Population. Applied Psychological Measurement. 1977 June 1, 1977;1(3):385-401.

31. Banks J, Nazroo J, Steptoe A. The dynamics of ageing: Evidence from the English Longitudinal Study of Ageing 2002-10 (Wave 5). London: Institute of Fiscal Studies; 2012.

32. Hyde M, Wiggins RD, Higgs P, Blane DB. A measure of quality of life in early old age: the theory, development and properties of a needs satisfaction model (CASP-19). Aging and mental health. 2003;7(3):186-94.

33. Doran T, Fullwood C, Kontopantelis E, Reeves D. Effect of financial incentives on inequalities in the delivery of primary clinical care in England: analysis of clinical activity indicators for the quality and outcomes framework. The Lancet. 2008;372(9640):728-36.

34. Khunti K, Gadsby R, Millett C, Majeed A, Davies M. Quality of diabetes care in the UK: comparison of published quality-of-care reports with results of the Quality and Outcomes Framework for diabetes. Diabet Med. 2007;24(12):1436 - 41.

35. Oluwatowoju I, Abu E, Wild S, Byrne C. Improvements in glycaemic control and cholesterol concentrations associated with the Quality and Outcomes Framework: a regional 2-year audit of diabetes care in the UK. Diabet Med. 2010;27(3):354 - 9.

36. Kennedy A, Bower P, Reeves D, Blakeman T, Bowen R, Chew-Graham C, et al. Implementation of self management support for long term conditions in routine primary care settings: cluster randomised controlled trial. BMJ. 2013;346.

37. Rogers A, Kennedy A, Bower P, Gardner C, Gately C, Lee V, et al. The United Kingdom Expert Patients Programme: results and implications from a national evaluation. The Medical Journal of Australia. 2008;189(10):S21-S4.

38. Chang J, MacLean C, Roth C, Wenger N. A comparison of the quality of medical care measured by interview and medical record. Journal of General Internal Medicine. 2004;19(Suppl 1):s109-s10.

39. Tisnado DM, Adams JL, Liu H, Damberg CL, Chen W-P, Hu FA, et al. What is the concordance between the medical record and patient self-report as data sources for ambulatory care? Medical Care. 2006;44(2):132-40.

40. Gillam SJ, Siriwardena AN, Steel N. Pay-for-performance in the United Kingdom: impact of the quality and outcomes framework: a systematic review. Ann Fam Med. 2012 Sep-Oct;10(5):461-8.

TABLES AND FIGURES WITH LEGENDS

Covariate	Whole sample n=8,222			Care bundle n=907		ACE inhibitor/ARB n=759	
	n 0, 22	%	n	%	n	%	
Gender							
Male	3,661	44.5	483	53.2	396	52.2	
Female	4,561	55.5	425	46.8	363	47.8	
A go hand	,						
Age band 50-64	4,250	51.7	369	40.7	306	40.3	
65-74	2,533	30.8	316	40.7 34.8	300 274	40.3 36.10	
75+	2,333 1,439	17.5	222	24.5	179	23.58	
	1,439	17.5		24.3	179	25.56	
Previous care			10.6	5 4 7	2.12	45.1	
Achieved	-	-	496	54.7	342	45.1	
Not achieved	-	-	225	24.8	240	31.6	
New case	-	-	175	19.3	144	19.0	
Missing	-	-	11	1.2	33	4.4	
NS-SEC							
Managerial / pro.	2,827	34.4	249	27.5	207	27.3	
Intermediate	2,085	25.4	208	22.9	173	22.8	
Routine	3,193	38.8	432	47.6	364	48.0	
Missing	117	1.4	18	2.0	15	2.0	
Eyesight							
Good to excellent	7,227	87.9	726	80.0	602	79.3	
Fair to blind	995	12.1	181	20.0	157	20.7	
	<i>))</i>	12.1	101	20.0	107	20.7	
Hearing	< <10	00.4					
Good to excellent	6,610	80.4	673	74.2	563	74.2	
Fair to poor	1,612	19.6	234	25.8	196	25.8	
Chronic pain							
None/mild	5,893	71.7	545	60.1	438	57.7	
Moderate/severe	2,278	27.7	354	39.0	315	41.5	
Has long-standing illness							
No	3,761	45.7	121	13.4	100	13.2	
Yes	1,725	21.0	318	35.0	253	33.3	
Yes - limiting	2,735	33.3	468	51.5	406	53.5	
-		0010		0110		0010	
Difficulties with basic ADL		02.2	702	062	651	050	
None/one	7,588	92.3	783	86.3	651	85.8	
Two or more	634	7.7	124	13.7	108	14.2	
Difficulties with instrument							
None/one	7,560	92.0	773	85.2	649	85.5	
Two or more	662	8.1	134	14.8	110	14.5	
Cognitive performance							
Top 90% of scorers	6,757	82.2	699	77.0	593	78.1	
Bottom 10% of scorers	634	7.7	115	12.7	96	12.7	
Missing	831	10.1	93	10.4	70	9.2	
•			-		-		
Health literacy	5 700	70.5	E 10	60.4	170	61.0	
High	5,798	70.5	548 278	60.4 20.7	470	61.9 20.0	
Low	2,069	25.2	278	30.7	227 62	29.9 8 2	
Missing	355	4.3	81	8.9	62	8.2	
Waves since diagnosis ¹							
0 (new case)	-	-	165	18.2	134	17.7	
1	-	-	216	23.8	176	23.2	
2	_	_	154	17.0	126	16.6	

Table 1: Descriptive characteristics of covariates in 2008/9 used in modelling subsequent non-achievement of care in 2010/11 by sample

3	-	-	371	40.9	371	40.9		
BMI categorisation								
Underweight ²	57	0.7	3	0.3	2	0.3		
Normal weight	1,804	21.9	87	9.6	68	9.0		
Overweight	2,949	35.9	263	29.0	218	28.7		
Obese	2,193	26.7	404	44.5	351	46.3		
Missing	1,219	14.8	150	16.5	120	15.8		
Alcohol consumption								
1-2 times/week or less	4,538	55.2	579	63.8	498	65.6		
3-4 times/week or more	2,670	32.5	178	19.6	148	19.5		
Missing	1,014	12.3	150	16.5	113	14.9		
Physical activity level								
Moderate/high	5,907	71.8	499	55.0	406	53.5		
Sedentary/low	2,314	28.1	407	44.8	353	46.5		
Smoking status								
Never	3,258	39.6	304	33.5	251	33.1		
In past	3,828	46.6	478	52.7	394	51.9		
Current smoker	1,108	13.5	123	13.6	113	14.9		
Diet								
Eats '5-a-day'	3,113	37.9	320	35.3	267	35.2		
Does not eat '5-a-day'	2,393	29.1	259	28.6	229	30.2		
Missing	2,716	33.0	328	36.2	263	34.7		
Knows mostly everything ab	out manag	ging diabetes						
Yes	-	-	604	66.6	505	66.5		
No	-	-	123	13.6	109	14.4		
Missing	-	-	180	19.9	145	19.1		
Married /civil partnership								
Yes	5,456	66.4	558	61.5	460	60.6		
No	2,765	33.6	348	38.4	299	39.4		
Social detachment								
Not detached	5,631	68.5	523	57.7	432	56.9		
Detached	961	11.7	142	15.7	125	16.5		
Missing	1,630	19.8	242	26.7	202	26.6		
Quality of life (CASP19)								
High	2,116	25.7	150	16.5	109	14.4		
Mid	2,534	30.8	252	27.8	216	28.5		
Low	2,351	28.6	328	36.2	295	38.9		
Missing	1,221	14.9	177	19.5	139	18.3		
Locus of control								
Internal	1,659	20.2	134	14.8	108	14.2		
External	5,545	67.4	618	68.1	532	70.1		
Missing	1,018	12.4	155	17.1	119	15.7		
CES-D depression								
Not depressed	6,970	84.8	708	78.1	579	76.3		
Depressed	1,132	13.8	179	19.7	163	21.5		
Missing	120	1.5	20	2.2	17	2.2		
Lives alone								
No	2,773	33.7	252	27.8	215	28.3		
Yes	5,140	62.5	618	68.1	512	67.5		
Missing	309	3.8	37	4.1	32	4.2		
701 11 1	1			1 2010 11	701			

The overall sample comprised participants in 2008-9 and 2010-11. The care bundle and ACE inhibitor/ARB QI samples reported a diagnosis of diabetes and were eligible for at least one QI. Forced-entry model n: care bundle= 903; ACE inhibitor/ARB QI= 757. The reference category of each covariate is listed first. Frequency of missing data is not reported if these account for <1% of cases. Previous care was assessed in 2008/9. ¹Time since diagnosis is measured in waves since the diagnosis was reported in ELSA and was entered into models as an ordinal variable. ²Due to the small number of participants categorised as

underweight, this category was combined with the normal weight category before use in modelling. ARB means angiotensin II receptor blocker. NS-SEC is the National Statistics Socio-Economic Classification.

Quality indicator	<u>200</u>)8-9	<u>2010-11</u>			
	Failed/ Eligible	% (95% CI)	Failed/ Eligible	% (95% CI)		
HbA1c	130/692	20.0 (16.8-23.3)	154/861	17.4 (14.8-20.1)		
Proteinuria	58/273	22.7 (17.3-28.0)	76/349	22.8 (18.0-27.6)		
Foot examination	129/735	17.8 (14.8-20.8)	150/905	17.5 (14.8-20.2)		
Care bundle ¹	235/736	32.8 (29.2-36.4)	288/907	32.2 (29.1-35.5)		
ACE inhibitor / ARB QI	289/665	44.6 (40.6-48.6)	325/759	44.5 (40.7-48.3)		

Table 2. Non-achievement of quality indicators and the care bundle in 2008-9 and 2010-11.

ARB means angiotensin II receptor blocker. Percentages and CI are adjusted for differential non-response. ¹The care bundle was comprised of the glycated haemoglobin (HbA1c), proteinuria and foot examination QIs.

<u>Covariate</u>		Care bundle		ACE inhibitor/ARB		
	OR	95% CIs	р	OR	95% CIs	р
Gender						
Male	1.00	-	-	1.00	-	-
Female	1.10	0.74 - 1.65	0.635	1.10	0.72 - 1.67	0.674
Age group (trend)	1.14	0.93 - 1.48	0.170	0.76	0.59 – 0.99	0.043
50-64	1.00	-	-	1.00	-	-
65-74	1.26	0.85 - 1.87	0.241	0.90	0.60 - 1.36	0.626
75+	1.36	0.86 - 2.17	0.191	0.56	0.33 - 0.96	0.034
Previous care						
Achieved	1.00	-	-	1.00	-	-
Not achieved	3.32	2.28 - 4.84	< 0.001	6.94	4.54 - 10.61	< 0.00
New case	1.17	0.35 - 3.87	0.794	2.25	0.66 - 7.64	0.194
Missing	1.0	-	-	2.18	0.93 - 5.12	0.074
NS-SEC (trend)	1.23	1.01 - 1.50	0.042	1.17	0.94 - 1.45	0.100
Managerial/professional	1.00	-	-	1.00	-	-
Intermediate	0.87	0.54 - 1.40	0.571	1.13	0.67 - 1.90	0.64
Routine/manual	1.40	0.94 - 2.08	0.098	1.36	0.88 - 2.09	0.16
Missing	1.38	0.43 - 4.37	0.587	1.51	0.46 - 4.94	0.49
Eyesight						
Excellent/good	1.00	-	_	1.00	_	-
Fair/blind	0.95	0.63 - 1.45	0.826	1.00	0.64 - 1.60	0.95
Long-standing illness (trend)	0.93	0.73 – 1.18	0.547	1.03	0.79 – 1.34	0.83
No Yes	1.00 0.99	- 0.58 - 1.70	- 0.981	1.00 0.96	- 0.53 - 1.74	- 0.89
Yes - limiting	0.99	0.53 - 1.70	0.981 0.627	1.03	0.59 - 1.81	0.89
·	0.00	0.55 1.47	0.027	1.05	0.57 1.01	0.90
Cognitive performance	1.00			1.00		
Top 90% of scorers	1.00	-	-	1.00	-	-
Bottom 10% of scorers	1.78 1.58	1.09 - 2.89 0.92 - 2.70	0.021 0.095	1.61 1.04	0.88 - 2.93 0.52 - 2.07	0.12 0.91
Missing	1.38	0.92 - 2.70	0.093	1.04	0.32 - 2.07	0.91
Health literacy	1.00			1.00		
High	1.00	-	-	1.00	-	-
Low	1.07	0.74 - 1.53	0.729	1.50	1.01 - 2.24	0.04
Missing	0.92	0.50 - 1.69	0.783	2.39	1.18 - 4.86	0.01
Waves since diagnosis	1.04	0.83 - 1.30	0.714	1.00	0.79 - 1.26	0.96
Diabetes self-management know	ledge					
High	1.00	-	-	1.00	-	-
Low	2.05	1.29 - 3.26	0.002	1.32	0.78 - 2.25	0.30
Missing	3.45	1.17 - 10.15	0.025	2.47	0.79 - 7.76	0.12
BMI category (trend)	0.96	0.74 - 1.25	0.778	0.70	0.53 - 0.92	0.01
Under/normal weight	1.00	-	-	1.00	-	-
Overweight	1.05	0.58 - 1.89	0.881	0.71	0.37 - 1.36	0.30
Obese	0.97	0.54 - 1.72	0.907	0.48	0.26 - 0.89	0.01
Missing	0.86	0.44 - 1.69	0.657	0.63	0.30 - 1.30	0.21
Physical activity						
Moderate/high	1.00	-	-	1.00	-	-
Sedentary/low	1.22	0.86 - 1.74	0.274	1.14	0.78 - 1.66	0.50
Married/in civil partnership						
Yes	1.00	_	-	1.00	_	_
No	1.00	- 0.73 - 1.63	- 0.670	2.16	- 1.39 - 3.37	0.00
		0.75 - 1.05	0.070	2.10	1.57 - 5.57	0.00
CES-D depression classification				1.00		
No	1.00	-	- 0.702	1.00	-	-
Yes	0.92	0.61 - 1.40	0.702	0.97	0.61 - 1.53	0.89

Table 3. Effects of baseline characteristics on subsequent non-achievement of care in 2010-11: logistic regression models

Missing	0.68	0.24 - 1.92	0.464	3.00	0.84 - 10.69	0.090
Lives alone						
No	1.00	-	-	1.00	-	-
Yes	0.75	0.47 - 1.18	0.208	0.95	0.59 - 1.54	0.843
Missing	0.65	0.28 - 1.51	0.317	0.78	0.29 - 2.08	0.618
Log likelihood	-517.48			-424.71		
Wald χ^2	87.63			133.87		
р	0.000			0.000		
Pseudo R ²	0.106			0.198		
Ν	902			757		

All outcomes are adjusted for differential non-response in 2010-11. The reference category for each covariate is the first category listed and has an odds ratio (OR) of 1.00. An OR >1.00 represents increased odds of subsequent non-achievement of care, whereas an OR of <1.00 indicates reduced odds of this. Linear trends were investigated for appropriate covariates: the ORs and 95% CI for these are listed next to the respective covariate's name. Trend tests excluded the 'missing' category. 'Previous care' was assessed in 2008-9. ARB means angiotensin II receptor blocker. NS-SEC is National Statistics Socio-Economic Classification. CES-D is Center for Epidemiological Studies Depression scale.