**TITLE (12; 12)**

**TITLE:**

**Workload impact of the Quality and Outcomes Framework for patients with diabetes:**

**RUNNING HEAD: an interrupted time series**

**KEYWORDS: Diabetes, Service Organisation, large database research**

**ABSTRACT (250; 248)**

**Objectives:** To assess the impact of the Quality and Outcomes Framework (QOF) on general practitioner (GP) consultation rates for patients with diabetes mellitus.

**Design:** Interrupted time-series using data from the Clinical Practice Research Datalink from 2000/2001 to 2014/2015.

**Setting:** 125 general practices in England.

**Participants:** 13,248,735 consultations for 37,065 patients with diabetes mellitus.

**Intervention:** The introduction of the QOF (01 April 2004).

**Main outcome measures:** Mean annual GP consultation rates per patient.

**Results:** Mean annual GP clinical consultation rates for patients with diabetes were 8.10 per patient in 2000/01, 6.91 in 2004/05 and 7.09 in 2014/15. Between 2000/01 and 2002/03 there was a downwards trend of -0.45 (95% CI -0.67 to -0.22) consultations per patient per year. The magnitude of the trend after introduction of the QOF increased by 0.46 (95% CI 0.23 to 0.69, p=0.001) consultations per patient per year giving a post-QOF trend increasing by 0.018 consultations per year. Combined GP and nurse clinical consultations trends

were relatively static throughout the study period. Introduction of the QOF was associated with an immediate stepped increase of 2.62 (95% CI 2.08, 3.16, P<0.001) ‘other’ encounters, and the magnitude of the pre-QOF trend increased by 0.57 (95% CI 0.34, 0.81, p<0.001) per year, resulting in a post-QOF trend increasing by 0.27 other encounters per year.

**Conclusions:** Introduction of the QOF was associated with a modest increase in clinical GP consultation rates and a substantial increase in other encounters for patients with diabetes mellitus, exacerbated by increases in diabetes prevalence.

**How this fits in (4 sentences)**

There are substantial concerns about general practitioner (GP) workload in England. The Quality and Outcomes Framework (QOF) was a ground-breaking financial incentive scheme introduced in 2004 for GPs in the UK that has had a modest impact on patient care but its impact on GP workload is not well understood. We show introduction of the QOF was associated with a modest increase in clinical GP consultation rates for patients with diabetes mellitus and a substantial increase in other GP encounters. When combined with increased prevalence of diabetes, this has contributed to a large increase in GP workload, and any refinements to the QOF need to carefully consider both impacts on patient quality of care and GP workload.

**WORD COUNT - 2750**

**INTRODUCTION - 335**

Nearly 2 in 5 (39%) of general practitioners (GPs) report considerable or high likelihood of quitting direct patient care in the next 5 years and increasing workloads is a leading contributor to GP stress.1 The Quality and Outcomes Framework (QOF) has been perceived by both professionals and patients to promote a more bureaucratic type of care, but the full impact of the QOF on GP workload is not well known.2 This ground-breaking pay for performance financial incentive scheme was introduced in 2004 as part of the new General Medical Services contract for GPs, linking approximately 25% of practice income to performance on a set of over 100 quality indicators.3 4 5

Studies of the QOF have found it has had a modest impact on clinical care. A systematic review6 found modest improvements in diabetes care,7 modest slowing of a previously underlying increase in emergency admissions,8 increase in consultations for people with severe mental illness,9 and no clear association between the QOF and mortality.10 Removal of indicators from the QOF in 2006 and 2011 found levels of performance were generally stable after removal of the incentives,11 however removal of further indicators in 2014 was associated with an immediate decline in documented quality of care.12

Improvements in patient care associated with the QOF may not have been achievable without increasing the frequency of general practice consultations, but few studies have directly examined this. A longitudinal study found that patients with serious mental illness had higher consultation rates than matched controls, and that the introduction of the QOF was associated with a modest increase in consultation rates for these patients.9

Diabetes was one of the original QOF conditions and has been consistently associated with a high number of points and therefore income. To our knowledge, the impact of the QOF on consultation rates for patients with diabetes has not been investigated previously. In this study, we aimed to assess the impact of the introduction of the QOF on GP consultation rates for patients with diabetes mellitus.

**METHODS - 789**

**Data**

The Clinical Practice Research Datalink (CPRD) is one of the largest longitudinal primary care databases in the world.13 We purposively sampled 125 practices from the CPRD database to be broadly nationally representative in terms of list size and area deprivation in the practice locality. 2,500 patients with one or more QOF conditions were randomly sampled from each practice (all patients were sampled from practices with fewer than 2,500 eligible patients). The variables were examined for integrity and miscoded data. We removed duplicate consultations of the same type, day, staff member and patient to avoid over-counting.

**Study Design**

We used an interrupted time-series (ITS) to assess trends in clinical consultation rates for patients with diabetes, with introduction of the QOF (on 01 April 2004) as the exposure. All entries to a patient’s electronic record are described by CPRD as a ‘consultation’. We defined a ‘clinical consultation’ as in-hours ‘direct contact between a clinician and a patient’ in keeping with previous studies,9 i.e. all face-to-face, telephone and home visit encounters. Out-of-hours and non-clinical consultation entries were defined as ‘other’ encounters (appendix table 1), a highly heterogenous group including third party consultations, mail from patients and hospital reports, included to give some insight into changes in overall general practice activity in keeping with previous studies.9

We chose the change in trend of annual GP clinical consultation rates as the primary outcome, and annual practice nurse clinical consultation rates, type of GP consultation (face-to-face, telephone and home visits), and ‘other’ encounters as secondary outcomes. Codes used to define ‘GP’ are given in appendix table 2.

We divided time into 15 annual ‘bins’ corresponding with the financial years 2000/01 – 2014/15 in keeping with previous studies7 9. All time points were included except for 01 April 2003 – 31 March 2004 which was treated as a ‘preparatory year’ and excluded in line with previous studies, as information about the QOF was publicly available during that time which may have influenced consultation rates.6 9 14 We used separate models for each primary and secondary outcome.

There are no pre-defined limits to the number of datapoints needed for an ITS as the power depends not only on the number of datapoints, but also their distributions pre- and post- the intervention, variability within the data, strength of effect and confounding effects. 15 However, ITS with 12-18 data points should be interpreted with some caution,16 and as such we also analysed the primary outcome at quarterly intervals.

**Participants**

There were 37,065 patients with diabetes in the sample after the selection process. We identified patients with diabetes mellitus using a broader list of diagnostic Read codes than that captured by QOF registers specified in appendix table 3. Once diagnosed, the condition was assumed to be permanent in keeping with other studies.9 This study aimed to include all GP clinical consultation data post diagnosis for patients with diabetes (regardless of indication), including those registered for a short period of time or those nearing the end of their life, as these comprise an important part of GP workload.

We defined a patient as ‘active’ in a bin and their consultation data collected if: i) they were registered with the practice and diagnosed with diabetes prior to the end of that bin; ii) did not transfer out or die until after the start of that bin; iii) the practice had their last collection date after the end of that bin; and iv) the practice data was at research standard. All other consultation data were excluded.

**Patient Demographics**

Patient age was approximated to the nearest year for anonymity. Age range, mean, standard deviation, median, interquartile range and gender distribution for each year is given.

**Statistical methods**

We calculated annual consultation rates as the number of consultations divided by the number of active patient days in each bin, multiplied by 365 (366 for leap years). Quarterly analysis was calculated as consultation rates per patient day. To test the null hypothesis that consultation rates did not change following the introduction of the QOF, we used an ITS analysis using segmented linear regression analyses to assess relationships between consultation rates and time with dummy variables for the introduction of the QOF. A Durbin-Watson statistic was calculated for each of the regression analyses to test for serial autocorrelation of the error terms in the regression model.17 18 Values can range from 0 to 4 and values close to 2 indicate no first order auto-correlation.17 A Prais-Winsten statistic was used for Durbin-Watson statistics outside of the 1.5 – 2.5 range; Prais-Winsten uses a generalised least-squares method to estimate the parameters in a linear regression model in which the errors are assumed to follow a first-order autoregressive process.19

Data were analysed using Stata V. 15 and α level of 5%.

**RESULTS – 1146 – 202 – 332 = 612**

There were 37,065 patients with a diagnosis of diabetes and a total of 13,248,745 consultations included in the sample during the study period; 6,119 consultations without a date were excluded.

**Patient demographics**

The age range was 0-105 years-old, and mean age increased from 63.3 in 2000/01 to 64.5 in 2014/15 (Table 1). The proportion of males increased from 54.5% in 2000/01 to 56.9% in 2014/15, and the number of active patients with diabetes mellitus increased from 5,028 in 2000/1 to 15,056 in 2014/15.

Table 1. Demographics of the sample each year (sd = standard deviation, iqr = interquartile range)

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Year** | **Age Range**  | **Mean** **Age (sd)** | **Median age** **(iqr)** | **Number of ‘active’ patients with diabetes** | **Male (%)** | **Female (%)** |
| **2000/01** | (0-102) | 63.3 (15.7) | 66 (54-74) | 5080 | 2764 (54.4) | 2316 (45.6) |
| **2001/02** | (2-103) | 63.5 (15.4) | 66 (55-75) | 6616 | 3607 (54.5) | 3009 (45.5) |
| **2002/03** | (3-100) | 63.6 (15.4) | 66 (55-75) | 8255 | 4515 (54.7) | 3740 (45.3) |
| **2003/04** | (0-101) | 63.7 (15.4) | 66 (55-75) | 9909 | 5472 (55.2) | 4437 (44.8) |
| **2004/05** | (1-99) | 63.7 (15.4) | 66 (55-75) | 11197 | 6207 (55.4) | 4990 (44.6) |
| **2005/06** | (1-105) | 63.8 (15.4) | 66 (55-75) | 12971 | 7172 (55.3) | 5799 (44.7) |
| **2006/07** | (2-106) | 63.7 (15.4) | 66 (55-75) | 14069 | 7769 (55.2) | 6300 (44.8) |
| **2007/08** | (2-104) | 63.8 (15.4) | 65 (55-75) | 14885 | 8281 (55.6) | 6604 (44.4) |
| **2008/09** | (1-101) | 63.9 (15.3) | 65 (55-75) | 15833 | 8874 (56.0) | 6959 (44.0) |
| **2009/10** | (1-102) | 63.9 (15.4) | 65 (55-75) | 17029 | 9596 (56.4) | 7433 (43.6) |
| **2010/11** | (2-103) | 63.9 (15.4) | 65 (55-75) | 18266 | 10335 (56.6) | 7931 (43.4) |
| **2011/12** | (2-104) | 64.0 (15.5) | 66 (55-75) | 19367 | 10994 (56.8) | 8373 (43.2) |
| **2012/13** | (3-105) | 64.2 (15.5) | 66 (55-75) | 20698 | 11713 (56.6) | 8985 (43.4) |
| **2013/14** | (3-104) | 64.5 (15.4) | 66 (55-75) | 18363 | 10528 (57.3) | 7835 (42.7) |
| **2014/15** | (0 - 102) | 64.5 (15.4) | 66 (55-75) | 15056 | 8574 (56.9) | 6482 (43.1) |

**Consultation rates in 2000/01**

There were observed values of 11.06 clinical consultations from the data, of which 8.10 were with physicians, 2.96 with nurses. There were 4.22 ‘other’ encounters (Table 2).

Table 2. Observed annual consultation rates per patient with general practitioners (GPs) and nurses for patients with diabetes

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Year** | **Total GP clinical** | **GP Face to face** | **GP Telephone** | **Home visit** | **Other encounters** | **Total nurse clinical** | **Total clinical (GP plus nurse)**  | **Nurse proportion of total clinical (%)** |
| **2000/01** | 8.10 | 7.20 | 0.51 | 0.39 | 4.22 | 2.96 | 11.06 | 26.8 |
| **2001/02** | 7.92 | 7.18 | 0.39 | 0.35 | 3.77 | 3.30 | 11.22 | 29.4 |
| **2002/03** | 7.21 | 6.57 | 0.33 | 0.32 | 3.62 | 3.60 | 10.81 | 33.3 |
| **2003/04** | 7.03 | 6.38 | 0.32 | 0.32 | 4.70 | 3.81 | 10.84 | 35.1 |
| **2004/05** | 6.91 | 6.19 | 0.38 | 0.34 | 5.98 | 4.06 | 10.97 | 37.0 |
| **2005/06** | 7.12 | 6.44 | 0.37 | 0.31 | 6.41 | 4.19 | 11.32 | 37.0 |
| **2006/07** | 7.01 | 6.31 | 0.42 | 0.28 | 6.90 | 4.22 | 11.23 | 37.6 |
| **2007/08** | 6.74 | 5.96 | 0.47 | 0.31 | 6.97 | 4.11 | 10.85 | 37.9 |
| **2008/09** | 6.72 | 5.92 | 0.49 | 0.31 | 7.46 | 4.04 | 10.76 | 37.5 |
| **2009/10** | 6.96 | 6.13 | 0.54 | 0.29 | 7.58 | 4.09 | 11.05 | 37.0 |
| **2010/11** | 6.98 | 6.19 | 0.53 | 0.26 | 7.70 | 3.91 | 10.89 | 35.9 |
| **2011/12** | 7.02 | 6.22 | 0.54 | 0.26 | 8.00 | 3.86 | 10.88 | 35.5 |
| **2012/13** | 7.05 | 6.26 | 0.53 | 0.26 | 8.26 | 3.75 | 10.80 | 34.7 |
| **2013/14** | 7.15 | 6.23 | 0.66 | 0.26 | 8.84 | 3.80 | 10.95 | 34.7 |
| **2014/15** | 7.09 | 6.12 | 0.71 | 0.26 | 8.79 | 3.83 | 10.92 | 35.1 |

From the model, patients with diabetes had a mean 11.15 (95% CI 10.32, 11.70) clinical consultations per year with their practice in 2000/01, including 8.19 (95% CI 7.47 to 8.91) with physicians and 2.96 (95% CI 2.57 to 3.36) with nurses (Table 2). There were 4.17 (95% CI 3.45 to 4.90) ‘other’ GP encounters per year.

**Impact of the QOF on consultation rates**

GP clinical consultation rates fell by nearly half a consultation (-0.45, 95% CI -0.67 to -0.22) per year in the pre-QOF period (Table 3, Figure 1). When the QOF was introduced, there was an immediate non-significant rise of 0.017 (95% CI -0.52 to 0.55, p=0.95) GP clinical consultations per year. The magnitude of the underlying trend increased by nearly half a consultation (0.46, 95% CI 0.23, 0.69 p=0.001) per year, giving a post-QOF trend increasing by 0.018 consultations per year. These trends are supported by the quarterly analysis (Table 3).

INSERT FIGURE 1 HERE

**Type of clinical GP consultation**

Introduction of the QOF had a statistically significant impact on the previous declining trend for face-to-face, telephone and home visit consultation rates (Tables 2 - 3). The post-QOF trend of face-to-face and home visit consultations declined after the introduction of the QOF by 0.005 and 0.007 consultations per year respectively whilst telephone consultations increased by 0.03 per year.

**Nurse consultations**

Nurse consultations increased by 0.32 (95% CI 0.20 to 0.45, Prais-Winsten adjustment) consultations per patient per year prior to the QOF. Immediately after the introduction of the QOF there was a stepped change of 0.31 (95% CI 0.009 to 0.61, p=0.045, Prais-Winsten adjustment), and the magnitude of the trend changed by -0.36 (95% CI -0.49 to -0.24, p<0.001, Prais-Winsten adjustment) consultations per year, giving a post-QOF trend falling by 0.042 consultations per patient per year.

Taking GP and nurse clinical consultations together, trends remained relatively static throughout the study period. Prior to the QOF, combined GP and nurse consultations fell by -0.12 (95% -0.38 to 0.14, p=0.331) per patient per year. After introduction of the QOF, there was a non-significant stepped change of 0.33 (95% CI -0.29 to 0.95, p=0.265) combined consultations and an increase in trend of 0.096 (95% CI -0.17, 0.36, p=0.442) per year, giving a post-QOF trend falling by 0.025 consultations per patient per year. The proportion of nurse consultations increased from 26.8% in 2000/01 to 37.0% in 2004/05 and declined to 35.1% in 2014/15 (appendix table 1).

**‘Other’ consultations**

Patients had 4.17 ‘other’ encounters with GPs in 2000/01 such as out of hours consultations, non-consultation administrative entries and test results (appendix table 1). Trends in ‘other’ encounters fell by -0.30 per patient per year prior to the QOF (95% CI -0.53 to -0.071). Immediately after the introduction of the QOF there was a stepped increase of 2.62 (95% CI 2.08, 3.16, P<0.001) encounters, and the trend increased by 0.57 (95% CI 0.34, 0.81, p<0.001) per year, resulting in a post-QOF trend increasing by 0.274 per patient per year (table 2).

Table 3. Interrupted time series analysis by type of consultation

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Dependent variable (consultation type)**  |  | **Coefficient**  | **p value** | **95% CI (lower limit)** | **95% CI (upper limit)** | **Durbin-Watson** |
| Total GP clinical (annual) | Change in rate per year 2000-2003 | -0.445 | 0.001 | -0.673 | -0.217 | 1.62 |
| Step change in 2004  | 0.017 | 0.945 | -0.519 | 0.553 |
| Change in trend in 2004 | 0.463 | 0.001 | 0.232 | 0.693 |
| Post-QOF trend | 0.018 |  |  |  |
| Face-to-face | Change in rate per year 2000-2003 | -0.315 | 0.022 | -0.575 | -0.055 | 1.62 |
| Step change in 2004  | -0.144 | 0.610 | -0.754 | 0.466 |
| Change in trend in 2004 | 0.310 | 0.025 | 0.048 | 0.572 |
| Post-QOF trend | -0.005 |  |  |  |
| Telephone | Change in rate per year 2000-2003 | -0.090 | 0.004 | -0.145 | -0.035 | 1.56 |
| Step change in 2004  | 0.102 | 0.108 | -0.026 | 0.230 |
| Change in trend in 2004 | 0.120 | 0.001 | 0.065 | 0.175 |
| Post-QOF trend | 0.030 |  |  |  |
| Home visit | Change in rate per year 2000-2003 | -0.035 | 0.007 | -0.058 | -0.012 | 1.61 |
| Step change in 2004  | 0.046 | 0.085 | -0.008 | 0.100 |
| Change in trend in 2004 | 0.028 | 0.024 | 0.004 | 0.051 |
| Post-QOF trend | -0.007 |  |  |  |
| Other | Change in rate per year 2000-2003 | -0.300 | 0.015 | -0.529 | -0.071 | 2.13 |
| Step change in 2004  | 2.621 | <0.001 | 2.083 | 3.159 |
| Change in trend in 2004 | 0.574 | <0.001 | 0.343 | 0.806 |
| Post-QOF trend | 0.274 |  |  |  |
| Nurse | Change in rate per year 2000-2003 | 0.321 | <0.001 | 0.195 | 0.447 | 1.43 |
| Step change in 2004  | 0.321 | 0.036 | 0.025 | 0.616 |
| Change in trend in 2004 | -0.364 | <0.001 | -0.491 | -0.237 |
| Post-QOF trend | -0.043 |  |  |  |
| Nurse (Prais-Winsten adjustment) | Change in rate per year 2000-2003 | 0.321 | <0.001 | 0.196 | 0.446 | 1.59 |
| Step change in 2004  | 0.311 | 0.045 | 0.009 | 0.612 |
| Change in trend in 2004 | -0.363 | <0.001 | -0.489 | -0.236 |
| Post-QOF trend | -0.042 |  |  |  |
| GP and nurse clinical consultations | Change in rate per year 2000-2003 | -0.121 | 0.331 | -0.384 | 0.143 | 2.09 |
| Step change in 2004  | 0.328 | 0.265 | -0.291 | 0.947 |
| Change in trend in 2004 | 0.096 | 0.442 | -0.171 | 0.362 |
| Post-QOF trend | -0.025 |  |  |  |
| Total GP clinical (quarterly consultation rates per patient day) | Change in rate per year 2000-2003 | -0.00029 | <0.001 | -0.00042 | -0.00016 | 1.72 |
| Step change in 2004 | 0.00028 | 0.698 | -0.00116 | 0.00178 |
| Change in trend in 2004 | 0.00031 | <0.001 | 0.00017 | 0.00044 |
| Post-QOF trend | 0.00003 |  |  |  |

**DISCUSSION - 1014**

**Statement of principal findings**

Patients with a diagnosis of diabetes were having 8.10 clinical consultations per year with their GP in 2000/01, 6.91 in 2004/05 and 7.09 in 2014/15. From 2000/01 to 2002/03 these consultation rates were decreasing at a rate of -0.45 per patient per year. After the introduction of the QOF, the slope of the trend changed by 0.46 consultations per patient per year and post-QOF annual GP consultation rates increased by 0.018 per year. The QOF was associated with statistically significant changes in the trends for all types of GP consultation. The biggest change was for ‘other’ encounters, with a step-change increase of 2.6 encounters immediately after the introduction of the QOF, the magnitude of the pre-QOF trend increasing by 0.57 giving a post-QOF trend increasing by 0.27 per patient per year.

In contrast, nurse clinical consultations were increasing prior to the introduction of the QOF, had a stepped increase when the QOF was introduced, but have subsequently fallen. This decrease in nurse consultations offset the increase in GP consultations, so that overall rates remained relatively static throughout the study period.

**Strengths and weaknesses of the study**

This is the first longitudinal study that we are aware of that gives estimates for GP consultation rates for patients with diabetes mellitus and how it has changed over time. One of the main strengths of this study is it uses routinely collected consultation data from individual patient records drawn from a nationally representative sample of practices, capturing real-life practice.

However, there are a number of limitations. First, this is an observational study and we cannot be certain that changes in consultation rates are fully attributable to the introduction of the QOF. It was not possible to include a control group as the QOF was introduced at a national level and there are no comparable national systems with available data to act as a control. However, ITS is the best quasi-experimental design for evaluating longitudinal effects of interventions in the absence of a control group.17

Second, this study shows changes in trends in consultation rates per patient with diabetes. Prevalence of diabetes mellitus since the QOF was introduced has increased by 90.7% from 3.34% in 2004/05 to 6.37% in 2014/15,20 so workload impacts at a practice level will be much higher. Changes in clinical diagnostic criteria such as use of glycated haemoglobin (HbA1c) recommended by the World Health Organisation in 201121 and people with diabetes being detected at an earlier stage than in the past22 may alter the sample over time. Our code list for diabetes may vary slightly from those used in other studies and may result in some selection bias.

Third, this study does not capture changes in other parts of care such as community appointments with diabetes specialist nurses or hospital care. All consultations regardless of indication were included rather than those specifically coded for diabetes due to concerns of coding accuracy for patients presenting with multiple conditions, so our consultation rates are for patients with diabetes rather than specifically for diabetes care.

Fourth, the biggest change we report was for ‘other’ encounters, which need to be interpreted with caution as this is a heterogeneous group of encounters (appendix table 1). CPRD only captures computerised parts of the clinical record, and it is likely there was heterogeneity among practices around which parts of the record were computerised and when. However, the ‘other’ category does give an indication of the increasing electronic and administrative workload faced by GPs.

**Comparison with existing literature**

This study supports previous literature that total general practice workload has increased by 16% from 2007 to 2014.23 Previous literature has also shown practice nurses accounted for 30.6 – 32.2% of consultations for patients with diabetes from 2002 to 2011.22 A study investigating the impact of the QOF on consultations rates, comparing patients with serious mental illness to matched controls, found similar trends to those in our study. Annual face-to-face consultation rates in the control group decreased by -0.05 per patient per year in the pre-QOF period and increased by 0.01 per patient per year post-QOF. For patients with serious mental illness, annual consultation rates declined by -0.04 per patient per year pre-QOF and increased by 0.19 consultations per patient per year post-QOF.9

**Implications of the study for practice and research**

We have provided evidence that introduction of the QOF was associated with a modest increase in clinical consultations with GPs at an individual patient level and more substantial increase in other encounters for GPs. However, at a practice level, this combined with increases in diabetes prevalence means a large increase in workload. For example, NHS Digital reported mean practice list size in 2014 as 6944 24; based on our observed consultation rates, a static practice of 6944 patients with prevalence of 3.34% diabetes in 2004/05 and 6.37% in 2014/15 20 would have provided 1602 GP clinical consultations for patients with diabetes in 2004/05 and nearly double this number at 3137 per year in 2014/15. Similarly, GPs provided 1411 other encounters for patients with diabetes in a practice of 6944 patients in 2004/05 compared to 4087 other encounters in 2014/15. Our study is likely to have underestimated the total practice burden of work imposed by the QOF as administrative work by other members of the team recording the data needed for QOF payments is not captured.

Increases in consultation rates are not necessarily undesirable, as improvements in clinical outcomes are likely to have been influenced by clinical activity. However, any further refinement and development of the QOF system expected after the recent NHS England review of the QOF25 needs to carefully consider both impact on patient quality of care and GP workload.

The QOF has been discontinued in Scotland, with its quality improvement function being replaced by a system of GP peer-support clusters.26 GPs in Scotland are divided on whether stopping the QOF had eased workload; when surveyed 40% thought workload had not improved, 33% thought it had, 27% were unsure.27 This demonstrates the importance of carefully considering the implications on workload of introducing, and of removing, quality improvement initiatives.28

**FUNDING**

This study was not directly funded.

The National Institute for Health Research funded Claire Gilbert’s Academic Clinical Fellowship salary whilst this work was conducted.

**ETHICAL APPROVAL**

The dataset in this study was approved by the independent scientific advisory committee (ISAC) for Clinical Practice Research Datalink research (reference number: 14\_104R). All data was provided in anonymised form and provided by consenting practices. No further ethics approval was required for the analysis of the data. The interpretation and conclusions contained in this study are those of the authors alone.

**COMPETING INTERESTS**

All authors declare: no support from any organisation for the submitted work; no financial relationships with any organisations that might have an interest in the submitted work in the previous three years, no other relationships or activities that could appear to have influenced the submitted work. Claire Gilbert’s Salary was paid for by the National Institute for Health Research (NIHR) as an Academic Clinical Fellow in General Practice but the NIHR had no involvement in this study"

**ACKNOWLEDGEMENTS**

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**DATA SHARING**

The dataset was derived from the Clinical Practice Research Database and cannot be shared owing to licensing restrictions.

**TRANSPARENCY DECLARATION**

I (Claire Gilbert, manuscript guarantor) affirm that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

**APPENDIX**

Appendix table 1. Consultation type by CPRD consultation codes

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Consultation type** | **Code** | **Consultation type (defined by CPRD)** | **Consultation type** | **Code** | **Consultation type (defined by CPRD)** |
| Face-to-face | 1 | Clinic | ‘Other’ | 22 | Third party consultation |
| 9 | Surgery consultation | 23 | Hospital admission |
| 18 | Emergency consultation | 25 | Day case report |
| 36 | Co-op Surgery consultation | 26 | GOS18 report |
| Telephone | 10 | Telephone call from a patient | 29 | NHS Direct Report |
| 21 | Telephone call to a patient | 32 | Twilight Visit |
| 35 | Co-op telephone advice | 33 | Triage |
| 55 | Telephone consultation | 34 | Walk-in Centre |
| Visit | 3 | Follow-up/routine visit | 38 | Minor Injury service |
| 11 | Acute visit | 39 | Medicine Management |
| 24 | Children’s home visit | 40  | Community clinic |
| 27 | Home visit | 41  | Community Nursing Note |
| 28 | Hotel visit | 42 | Community Nursing Report |
| 30 | Nursing home visit | 43 | Data Transferred from other system |
| 31 | Residential home visit | 44 | Health Authority Entry |
| 37 | Co-op home visit  | 45 | Health Visitor Note |
| ‘Other’ encounters | 2 | Night visit, Deputising service | 46 | Health Visitor Report |
| 4 | Night visit, local rota | 47 | Hospital Inpatient Report |
| 5 | Mail from patient | 48  | Initial Post Discharge Review |
| 6  | Night visit, patient | 49  | Laboratory Request |
| 7  | Out of hours, practice | 50 | Night visit |
| 8 | Out of hours, non practice | 51 | Radiology request |
| 12 | Discharge details | 52 | Radiology result |
| 13 | Letter from outpatients | 53 | Referral letter |
| 14 | Repeat Issue | 54 | Social Services Report |
| 15 | Other | 56 | Template Entry |
| 16  | Results recording | 57 | GP to GP communication transaction |
| 17 | Mail to patient | 58  | Non-consultation medication data |
| 19 | Administration | 59 | Non-consultation data |
| 20 | Casualty attendance | 60 | ePharmacy data |

Appendix table 2. Roles as coded by the Clinical Practice Research Datalink (CPRD) and their associated Health and Social Care Information Codes. 1 = physician, 2 = other clinical role, 3 = other non-clinical role, 4 = attached staff, 5 = locum.

‘GP’ = CPRD codes 1-8, 10, 47, 50, 60; ‘Practice Nurse’ = CPRD codes 11, 61, 62.

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Code** | **Description** | **Category (HSCIC)** | **Code** | **Description** | **Category (HSCIC)** | **Code** | **Description** | **Category (HSCIC)** |
| 0 | Data Not Entered | 0 | 25 | Receptionist | 3 | 51 | Phlebotomist | 4 |
| 1 | Senior Partner | 1 | 26 | Physiotherapist | 2 | 52 | Other Medical & Dental | 2 |
| 2 | Partner | 1 | 27 | Chiropodist | 2 | 53 | Other Students | 2 |
| 3 | Assistant | 1 | 28 | Dentist | 2 | 54 | Other Nursing & Midwifery | 2 |
| 4 | Associate | 1 | 29 | Dietician | 4 | 55 | Other Allied Health Professionals | 2 |
| 5 | Non-commercial local rota of less than 10 GPs | 1 | 30 | Counsellor | 4 | 56 | Other Professional Scientific & Technical | 3 |
| 6 | Commercial Deputising service | 1 | 31 | Osteopath | 2 | 57 | Other Healthcare Scientists | 2 |
| 7 | Locum | 5 | 32 | Maintenance staff | 3 | 58 | Other Additional Clinical Services | 2 |
| 8 | GP Registrar | 1 | 33 | Other Health Care Professional | 2 | 59 | Other Admin & Clerical | 3 |
| 9 | Consultant | 1 | 34 | Hospital Nurse | 2 | 60 | Clinical Practitioner Access Role | 1 |
| 10 | Sole Practitioner | 1 | 35 | Community Medical Officer | 4 | 61 | Nurse Access Role | 2 |
| 11 | Practice Nurse | 2 | 36 | School Nurse | 2 | 62 | Nurse Manager Access Role | 2 |
| 12 | Health Visitor | 4 | 37 | Health Education Officer | 2 | 63 | Health Professional Access Role | 2 |
| 13 | Community Nurse | 4 | 38 | Contact Tracing Nurse | 2 | 64 | Healthcare Student Access Role | 2 |
| 14 | Midwife | 4 | 39 | Stomatherapist | 2 | 65 | Biomedical Scientist Access Role | 2 |
| 15 | Community Psychiatric Nurse | 4 | 40 | Computer Manager | 3 | 66 | Clinical Coder Access Role | 3 |
| 16 | Social Worker | 4 | 41 | Interpreter/Link Worker | 3 | 67 | Optometrist | 2 |
| 17 | Pharmacist | 2 | 42 | Chiropractor | 2 | 68 | Radiographer | 2 |
| 18 | Dispenser | 3 | 43 | Acupuncturist | 2 |  |  |  |
| 19 | Non-qualified Dispenser | 3 | 44 | Homeopath | 2 |  |  |  |
| 20 | Practice Manager | 3 | 45 | Mental Handicap Nurse | 2 |  |  |  |
| 21 | Fund Manager | 3 | 46 | Carer | 2 |  |  |  |
| 22 | Business Manager | 3 | 47 | Salaried Partner | 1 |  |  |  |
| 23 | Administrator | 3 | 48 | Occupational Therapist | 2 |  |  |  |
| 24 | Secretary | 3 | 49 | Speech Therapist | 2 |  |  |  |
| 25 | Receptionist | 3 | 50 | GP Retainer | 1 |  |  |  |

Appendix table 3. Read Codes for defining 'diabetes mellitus'

|  |  |  |
| --- | --- | --- |
| **medcode** | **readcode** | **readterm** |
| 711 | C10..00 | Diabetes mellitus |
| 18278 | C109J00 | Insulin treated Type 2 diabetes mellitus |
| 36633 | C109K00 | Hyperosmolar non-ketotic state in type 2 diabetes mellitus |
| 43453 | C10C.00 | Diabetes mellitus autosomal dominant |
| 36695 | C10D.00 | Diabetes mellitus autosomal dominant type 2 |
| 1549 | C10E.00 | Type 1 diabetes mellitus |
| 12455 | C10E.11 | Type I diabetes mellitus |
| 51261 | C10E.12 | Insulin dependent diabetes mellitus |
| 47582 | C10E000 | Type 1 diabetes mellitus with renal complications |
| 102946 | C10E012 | Insulin-dependent diabetes mellitus with renal complications |
| 47649 | C10E100 | Type 1 diabetes mellitus with ophthalmic complications |
| 99311 | C10E111 | Type I diabetes mellitus with ophthalmic complications |
| 98071 | C10E112 | Insulin-dependent diabetes mellitus with ophthalmic comps |
| 42831 | C10E200 | Type 1 diabetes mellitus with neurological complications |
| 101735 | C10E212 | Insulin-dependent diabetes mellitus with neurological comps |
| 47650 | C10E300 | Type 1 diabetes mellitus with multiple complications |
| 91942 | C10E311 | Type I diabetes mellitus with multiple complications |
| 45276 | C10E312 | Insulin dependent diabetes mellitus with multiple complicat |
| 43921 | C10E400 | Unstable type 1 diabetes mellitus |
| 49949 | C10E411 | Unstable type I diabetes mellitus |
| 54600 | C10E412 | Unstable insulin dependent diabetes mellitus |
| 18683 | C10E500 | Type 1 diabetes mellitus with ulcer |
| 93878 | C10E511 | Type I diabetes mellitus with ulcer |
| 98704 | C10E512 | Insulin dependent diabetes mellitus with ulcer |
| 69993 | C10E600 | Type 1 diabetes mellitus with gangrene |
| 102112 | C10E611 | Type I diabetes mellitus with gangrene |
| 18387 | C10E700 | Type 1 diabetes mellitus with retinopathy |
| 95343 | C10E711 | Type I diabetes mellitus with retinopathy |
| 93875 | C10E712 | Insulin dependent diabetes mellitus with retinopathy |
| 35288 | C10E800 | Type 1 diabetes mellitus - poor control |
| 72702 | C10E812 | Insulin dependent diabetes mellitus - poor control |
| 40682 | C10E900 | Type 1 diabetes mellitus maturity onset |
| 96235 | C10E911 | Type I diabetes mellitus maturity onset |
| 97849 | C10E912 | Insulin dependent diabetes maturity onset |
| 69676 | C10EA00 | Type 1 diabetes mellitus without complication |
| 62613 | C10EA11 | Type I diabetes mellitus without complication |
| 99719 | C10EA12 | Insulin-dependent diabetes without complication |
| 68105 | C10EB00 | Type 1 diabetes mellitus with mononeuropathy |
| 46301 | C10EC00 | Type 1 diabetes mellitus with polyneuropathy |
| 91943 | C10EC11 | Type I diabetes mellitus with polyneuropathy |
| 101311 | C10EC12 | Insulin dependent diabetes mellitus with polyneuropathy |
| 10418 | C10ED00 | Type 1 diabetes mellitus with nephropathy |

|  |  |  |
| --- | --- | --- |
| **medcode** | **readcode** | **readterm** |
| 102163 | C10ED12 | Insulin dependent diabetes mellitus with nephropathy |
| 39070 | C10EE00 | Type 1 diabetes mellitus with hypoglycaemic coma |
| 99716 | C10EE12 | Insulin dependent diabetes mellitus with hypoglycaemic coma |
| 49554 | C10EF00 | Type 1 diabetes mellitus with diabetic cataract |
| 100770 | C10EF12 | Insulin dependent diabetes mellitus with diabetic cataract |
| 93468 | C10EG00 | Type 1 diabetes mellitus with peripheral angiopathy |
| 18642 | C10EH00 | Type 1 diabetes mellitus with arthropathy |
| 54008 | C10EJ00 | Type 1 diabetes mellitus with neuropathic arthropathy |
| 30323 | C10EK00 | Type 1 diabetes mellitus with persistent proteinuria |
| 30294 | C10EL00 | Type 1 diabetes mellitus with persistent microalbuminuria |
| 102620 | C10EL11 | Type I diabetes mellitus with persistent microalbuminuria |
| 10692 | C10EM00 | Type 1 diabetes mellitus with ketoacidosis |
| 62209 | C10EM11 | Type I diabetes mellitus with ketoacidosis |
| 40837 | C10EN00 | Type 1 diabetes mellitus with ketoacidotic coma |
| 66145 | C10EN11 | Type I diabetes mellitus with ketoacidotic coma |
| 22871 | C10EP00 | Type 1 diabetes mellitus with exudative maculopathy |
| 97894 | C10EP11 | Type I diabetes mellitus with exudative maculopathy |
| 55239 | C10EQ00 | Type 1 diabetes mellitus with gastroparesis |
| 95636 | C10ER00 | Latent autoimmune diabetes mellitus in adult |
| 758 | C10F.00 | Type 2 diabetes mellitus |
| 22884 | C10F.11 | Type II diabetes mellitus |
| 18777 | C10F000 | Type 2 diabetes mellitus with renal complications |
| 57278 | C10F011 | Type II diabetes mellitus with renal complications |
| 47321 | C10F100 | Type 2 diabetes mellitus with ophthalmic complications |
| 100964 | C10F111 | Type II diabetes mellitus with ophthalmic complications |
| 34268 | C10F200 | Type 2 diabetes mellitus with neurological complications |
| 98616 | C10F211 | Type II diabetes mellitus with neurological complications |
| 65267 | C10F300 | Type 2 diabetes mellitus with multiple complications |
| 43227 | C10F311 | Type II diabetes mellitus with multiple complications |
| 49074 | C10F400 | Type 2 diabetes mellitus with ulcer |
| 91646 | C10F411 | Type II diabetes mellitus with ulcer |
| 12736 | C10F500 | Type 2 diabetes mellitus with gangrene |
| 104323 | C10F511 | Type II diabetes mellitus with gangrene |
| 18496 | C10F600 | Type 2 diabetes mellitus with retinopathy |
| 49655 | C10F611 | Type II diabetes mellitus with retinopathy |
| 25627 | C10F700 | Type 2 diabetes mellitus - poor control |
| 47315 | C10F711 | Type II diabetes mellitus - poor control |
| 54773 | C10F800 | Reaven's syndrome |
| 39481 | C10F811 | Metabolic syndrome X |
| 47954 | C10F900 | Type 2 diabetes mellitus without complication |
| 53392 | C10F911 | Type II diabetes mellitus without complication |
| 62674 | C10FA00 | Type 2 diabetes mellitus with mononeuropathy |

|  |  |  |
| --- | --- | --- |
| **medcode** | **readcode** | **readterm** |
| 95351 | C10FA11 | Type II diabetes mellitus with mononeuropathy |
| 18425 | C10FB00 | Type 2 diabetes mellitus with polyneuropathy |
| 50527 | C10FB11 | Type II diabetes mellitus with polyneuropathy |
| 12640 | C10FC00 | Type 2 diabetes mellitus with nephropathy |
| 102201 | C10FC11 | Type II diabetes mellitus with nephropathy |
| 46917 | C10FD00 | Type 2 diabetes mellitus with hypoglycaemic coma |
| 98723 | C10FD11 | Type II diabetes mellitus with hypoglycaemic coma |
| 44982 | C10FE00 | Type 2 diabetes mellitus with diabetic cataract |
| 93727 | C10FE11 | Type II diabetes mellitus with diabetic cataract |
| 37806 | C10FF00 | Type 2 diabetes mellitus with peripheral angiopathy |
| 59253 | C10FG00 | Type 2 diabetes mellitus with arthropathy |
| 103902 | C10FG11 | Type II diabetes mellitus with arthropathy |
| 35385 | C10FH00 | Type 2 diabetes mellitus with neuropathic arthropathy |
| 1407 | C10FJ00 | Insulin treated Type 2 diabetes mellitus |
| 64668 | C10FJ11 | Insulin treated Type II diabetes mellitus |
| 34450 | C10FK00 | Hyperosmolar non-ketotic state in type 2 diabetes mellitus |
| 26054 | C10FL00 | Type 2 diabetes mellitus with persistent proteinuria |
| 60796 | C10FL11 | Type II diabetes mellitus with persistent proteinuria |
| 18390 | C10FM00 | Type 2 diabetes mellitus with persistent microalbuminuria |
| 85991 | C10FM11 | Type II diabetes mellitus with persistent microalbuminuria |
| 32627 | C10FN00 | Type 2 diabetes mellitus with ketoacidosis |
| 51756 | C10FP00 | Type 2 diabetes mellitus with ketoacidotic coma |
| 25591 | C10FQ00 | Type 2 diabetes mellitus with exudative maculopathy |
| 63690 | C10FR00 | Type 2 diabetes mellitus with gastroparesis |
| 95539 | C10FS00 | Maternally inherited diabetes mellitus |
| 51697 | C10G.00 | Secondary pancreatic diabetes mellitus |
| 96506 | C10G000 | Secondary pancreatic diabetes mellitus without complication |
| 61122 | C10H.00 | Diabetes mellitus induced by non-steroid drugs |
| 67212 | C10H000 | DM induced by non-steroid drugs without complication |
| 43857 | C10M.00 | Lipoatrophic diabetes mellitus |
| 22487 | C10N.00 | Secondary diabetes mellitus |
| 94383 | C10N000 | Secondary diabetes mellitus without complication |
| 93380 | C10N100 | Cystic fibrosis related diabetes mellitus |

**Primary outcome model**

GP clinical consultation rates per year = 8.633 – 0.445t + 0.017d + 0.463p + random error where

y-intercept = 8.633, t = time (2000/01 = 1, 2001/02 = 2 etc.), d = 0 for pre-QOF, 1 for post-QOF, p = time post QOF (2000/01 – 2002/03 = 0, 2004/05 = 1, 2005/06 = 2 etc.)

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 **FIGURES**

Figure 1. Annual GP clinical consultation rates per patient per year over time (Year, 2000 = 2000/2001, 2001 = 2001/2002 etc.) against predicted fitted values for patients with diabetes mellitus. Modelled estimates for 2003/04 and 2004/05 are shown based on the pre-QOF trend (pre\_QOF\_trend)



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