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Research paper

Convergence of HbA_{1c} values towards target in 272 primary care patients following nine years of target-driven care

EL Clarke
NIHR Academic Clinical Fellow, General Practice Trainee, Keele University, UK

JR Richardson
Foundation Year Trainee, Departments of Medicine/Clinical Biochemistry, Heart of England NHS Foundation Trust, Sutton Coldfield, UK

M Bhartia
Specialist Registrar in Diabetes and Endocrinology, University Hospital Coventry and Warwickshire NHS Trust, Coventry, UK

DM Kennedy
Consultant Clinical Biochemist, Department of Clinical Biochemistry

JJ Milles
Consultant in Diabetes and Endocrinology, Department of Medicine

S Ramachandran
Consultant Chemical Pathologist, Department of Clinical Biochemistry

Heart of England NHS Foundation Trust, Sutton Coldfield, UK

ABSTRACT

Background We wished to determine the effect of a target-driven incentivised programme on haemoglobin A_{1c} (HbA_{1c}) values in a UK diabetic population.

Methods An audit was carried out in 1999–2000, which included an estimation of glycaemic control in a randomly selected diabetic cohort from ten primary care practices in Sutton Coldfield, serving a population of 90 000 patients. Each practice was given a randomised list of patients and asked to complete detailed questionnaires on patients with confirmed diabetes. We collected data on 516 patients, 425 of whom had their HbA_{1c} measured in 1999–2000 (Audit 2000). A re-audit of HbA_{1c} was carried out in 2007–08 (Audit 2008) determining the changes in HbA_{1c} since the original audit. Of the original cohort, 272 patients had an audit of HbA_{1c} carried out in Audit 2008.

Results Overall, a small increase in median and mean HbA_{1c} values was observed. We estimated that the proportion of patients with HbA_{1c} achieving the lower Quality and Outcomes Framework HbA_{1c} target of < 7.5%; 173 of the 272 patients met this target in Audit 2000, whereas the number was 162 in Audit 2008. To understand the changes observed, patients were stratified as quintiles based on the HbA_{1c} in Audit 2000 and changes in HbA_{1c} after 8 years for each quintile were estimated. The mean changes for the different quintiles are: quintile 1 (HbA_{1c} < 6.1%), +1.49%; quintile 2 (HbA_{1c} 6.1–6.6%), +0.8%; quintile 3 (HbA_{1c} 6.7–7.3%), +0.3%; quintile 4 (HbA_{1c} 7.4–8.5%), –0.18%; and quintile 5 (HbA_{1c} > 8.5%), –1.55%.

Conclusion Our results suggest that, eight years on, patients with poor glycaemic control in 2000 saw an overall decrease in HbA_{1c} by 2008, with the reverse seen in patients with good control.

Keywords: audit, diabetes, HbA_{1c}, National Service Frameworks, Quality and Outcomes Framework, primary care

How this fits in with quality in primary care?

What do we know?
With an estimated 2.78 million people in the UK affected by diabetes and nearly 10% of the National Health Service budget being spent on diabetes care, any improvement in management will lead to significant benefits in healthcare and cost savings. The National Service Framework for diabetes in 2001, the introduction of the Quality and Outcomes Framework in 2004 and newer therapeutic agents have all had a huge impact on diabetes care. The drive behind the diabetes targets came from landmark studies such as Diabetes Control and Complications Trial and the United Kingdom Prospective Diabetes Study which reported lower complication rates in diabetic patients with improved glycaemic control.

What does this paper add?
We wanted to look at the impact of these changes on glycaemic control in a subset of patients in the West Midlands between 2000 and 2008. Those with poorer control in the initial audit showed the greatest improvement in HbA_{1c} in the second audit eight years later. Those with good control initially showed worse control in the second audit. In our population there was a non-significant increase in the mean HbA_{1c} between the two periods. This may reflect the natural progression of the disease. It is difficult to ascertain the extent to which newer agents and targets impacted on the HbA_{1c} over this period. Our results may highlight one of the negative impacts of performance-based payment, and contradict the standardisation of care intended by the introduction of the Quality and Outcomes Framework (QOF). A way forward could be that we need to look at trends rather than absolute values in QOF targets.

Introduction

The prevalence of diabetes in the UK in 2009 was estimated to be 4.26%, accounting for 2.78 million individuals.[1] This has resulted in almost 10% of the NHS budget being spent on diabetes care and suggests that any improvement in diabetes care could lead to significant benefit in healthcare.[2]

Evidence from the Diabetes Control and Complications Trial (DCCT) and United Kingdom Prospective Diabetes Study (UKPDS), which reported associations between better glycaemic control and lower complication rates in patients with both type 1 diabetes mellitus (T1DM) and type 2 diabetes mellitus (T2DM), exerted pressure for major changes to diabetes healthcare.[3,4] In 2001, the National Service Framework (NSF) for Diabetes was published, with 12 standards to improve and standardise care.[5] At the time, primary care was organised and administered by local primary care groups (PCGs), most of which subsequently merged to become larger primary care trusts (PCTs). While anticipating the publication of the NSF in 2001, a local implementation team was formed in Sutton Coldfield that included healthcare professionals across both primary and secondary care. Prior to planning services and recommending the necessary changes, it was decided that an assessment of the then level of care provided within the PCG should be carried out. To meet this objective, an audit was designed and carried out in 2000 (Audit 2000) to determine the prevalence of macro- and microvascular complications, as well as risk factors such as glycaemic control, blood lipids values, renal function and blood pressure, in a randomly selected diabetic cohort within the locality.

After the NSF, the care of patients with diabetes became incentivised by the Quality and Outcomes Framework (QOF) in 2004, a voluntary target-driven remuneration structure within primary care, which was widely adopted. It linked income to achievement in ten chronic disease areas including diabetes.[6] The QOF for diabetes included 18 clinical indicators. Points accrued from meeting these targets translated into additional income. The initial indicators included haemoglobin A_{1c} (HbA_{1c}) $\leq$ 7.4% and $\leq$ 10%. In 2006, the lower HbA_{1c} target was altered minimally to $\leq$ 7.5%.[7] The indicators were altered in 2009 with HbA_{1c} payment thresholds changed to 7, 8 and 9%.[8]

Since 2000, there have been newer therapeutic agents such as meglitinides, thiazolidinediones, incretins and rimonabant (until it was withdrawn in 2008), and newer insulin preparations. These agents made it easier to address poor glycaemic control by targeting the underlying mechanisms and offering better flexibility in treatment regimes. Eight years after the initial audit, we wished to determine whether the HbA_{1c} of the patients studied in Audit 2000 had naturally progressed, as observed in the UKPDS, or whether the target-driven incentivisation programme had altered this trend.

Methods

Good Hope Hospital, part of the Heart of England Foundation NHS Trust, serves a population of around 440 000 in north-east Birmingham and south-east Staffordshire, encompassing five PCGs in 2000, being subsequently condensed into two and a half PCTs. The 2001 census estimated that ethnic minorities accounted for 5.7% of the Sutton Coldfield population.[9]

We audited the Sutton PCG which consisted of 12 practices and served a population of 90 000, with about 2000 of these patients having been diagnosed with diabetes (Audit 2000). Ten of the 12 practices took part in Audit 2000. A questionnaire was designed to collect the following information: patient demography; treatment (diet, oral hypoglycaemic agents, insulin, ACE inhibitors, aspirin and lipid-lowering medication); glycaemic control; blood pressure control; smoking status; total cholesterol; and the presence of complications related to diabetes, i.e. coronary heart disease, renal disease, retinopathy and erectile dysfunction.

Each practice was handed a randomised list of possible patients with diabetes (HbA_{1c} measurements carried out during the previous three years; 1599 patients) and asked to complete questionnaires on as many patients as possible with confirmed diabetes, keeping strictly to the list order over the following eight weeks. This process using randomised lists eliminated sample bias. Questionnaire-based data were collected on 516 patients, i.e. 32.3% of all patients with diabetes. The average age of patients with diabetes in Audit 2000 was 66.2 years (SD 12.8). Details of HbA_{1c}, lipids and other biochemistry carried out on each individual between April 1999 and March 2000 were obtained via the Telepath™ pathology database; 425 of these patients had their HbA_{1c} measured. The data are presented in Table 1.

A follow-up audit of HbA_{1c} measurements in the patient group during the 12-month period 01/04/2007 to 31/03/2008 was carried out, eight years after the initial audit (Audit 2008). HbA_{1c} data were available for 272 of the 425 patients with HbA_{1c} data in Audit 2000. These details were then entered into the original spread sheet and statistical analyses were carried out.

Table 1 Data obtained from questionnaires and pathology database for 516 patients with diabetes audited in 1999–2000

		No. patients (total no. recorded)	%
Mean age; years (SD)	66.2 (12.8)	516 (516)	100
Male		295 (516)	57.2
Current smoker		58 (481)	12.1
Ex-smoker		119 (481)	24.7
Never smoked		304 (481)	63.2
Aspirin		153 (358)	42.7
ACE inhibitors		114 (332)	34.3
Lipid lowering		75 (354)	22.2
Diet only		126 (512)	24.6
Diet/oral hypoglycaemic agents (OHA)		291 (512)	56.8
Diet/insulin ± OHA		95 (512)	18.6
Complications			
Retinopathy		63 (357)	17.6
Proteinuria		9 (206)	4.4
Coronary heart disease		82 (368)	22.3
Mean HbA_{1c} (%)	7.3	425 (516)	82.3
Total cholesterol (mmol/l)	5.3	286 (516)	55.4
BP (mmHg)	144/79	513 (516)	99.4

A paired *t*-test was performed to determine the significance of changes in HbA_{1c} in the 272 patients over the eight years. Linear regression analyses were carried out to establish factors that were associated with changes in HbA_{1c}.

At the time of the Audit 2000, general biochemistry including lipids was measured using the Vitros 950 automated dry-slide system (Ortho Clinical Diagnostics Ltd, High Wycombe, UK). Between April 1996 and July 2004, HbA_{1c} was measured by ion-exchange chromatography using the HA-8140 HPLC system (Menarini Diagnostics, Wokingham, UK). The interassay coefficient of variation (CV) was < 3%. In July 2004, the HbA_{1c} method was changed to an alternative ion-exchange HPLC system, TOSOH G7 (TOSOH Bioscience Ltd, Redditch, UK). Interassay CV for this method is < 3.5%. Comparison data between the HPLC methods (both DCCT standardised) showed excellent correlation (TOSOH = 0.9753 × Menarini + 0.1783, $r = 0.9939$, $P < 0.001$, $n = 220$).

Results

Audit 2000

Some of the details of the 516 patients studied are recorded in Table 1. The proportion of patients with each practice whose details were entered in Audit 2000 varied from 12.7 to 94.7% of the total number of patients with diabetes registered with that practice.

Audit 2008

Table 2 gives the HbA_{1c} measurements in the 272 patients who were re-audited in 2007–08. There was a small, non-significant increase in mean HbA_{1c} values over the eight years between the two audits ($P = 0.057$, paired *t*-test). In order to study factors associated with this change in HbA_{1c}, linear regression was performed with change in HbA_{1c} as the dependent variable and age, the individual practices (factorised) and HbA_{1c} values from the Audit 2000 as the independent variables. Only the HbA_{1c} value in 1999–2000 (Audit 2000) was associated with the change in HbA_{1c} [coefficient (95% CI): –0.72 (–0.81 to –0.63), $P < 0.001$, $r^2 = 0.46$].

In view of the negative coefficient, we further examined the pattern of this association. We stratified the patients into quintiles based on the HbA_{1c} values in Audit 2000. The change in HbA_{1c} between the two audits was estimated for each quintile and the mean value is presented in Figure 1. An interesting pattern was observed, as suggested by the negative coefficient; there was an inverse relationship between the HbA_{1c} values in Audit 2000 and the results eight years later.

We also estimated the number of patients with HbA_{1c} at or below the subsequent lower QOF HbA_{1c} target of 7.5% in 1999–2000 and compared it with the corresponding data in 2007–08. It can be seen from Table 3 that 173 of the 272 patients had an HbA_{1c} value $\leq$ 7.5% in 1999–2000 and this number was 162 in 2007–08. Table 3 also shows the data stratified into quintiles based on the HbA_{1c} in 1999–2000. The pattern was as expected from that observed in Figure 1, with patients who had higher HbA_{1c} values in 1999–2000 showing greater improvement.

Discussion

In 1993, the DCCT showed that patients with T1DM undergoing intensive glycaemic control had lower progression of microvascular complications compared with patients receiving standard therapy.[3] A meta-analysis by Ray *et al* of five randomised controlled trials, including UKPDS, Prospective Pioglitazone Clinical Trial in Macrovascular Events (PROactive), Action to Control Cardiovascular Risk in Diabetes (ACCORD) and Action in Diabetes and Vascular Disease (ADVANCE) trials of 33 000 patients, showed that intensive blood-glucose reduction led to a 17% decrease in non-fatal myocardial infarction and a 15% decrease in coronary heart disease when compared with standard care, but there was no significant effect on stroke or all-cause mortality.[10] The mean HbA_{1c} concentration was 0.9% lower for participants given intensive treatment than for those given standard treatment. Despite the limitations of meta-analyses

Table 2 Comparison of the HbA_{1c} distribution in the 272 patients who had HbA_{1c} levels measured during Audit 2000 and Audit 2008

	Mean	Median	25th percentile	75th percentile
HbA_{1c} (%) in Audit 2008	7.5	7.2	6.6	8.1
HbA_{1c} (%) in Audit 2000	7.3	7	6.2	8.1

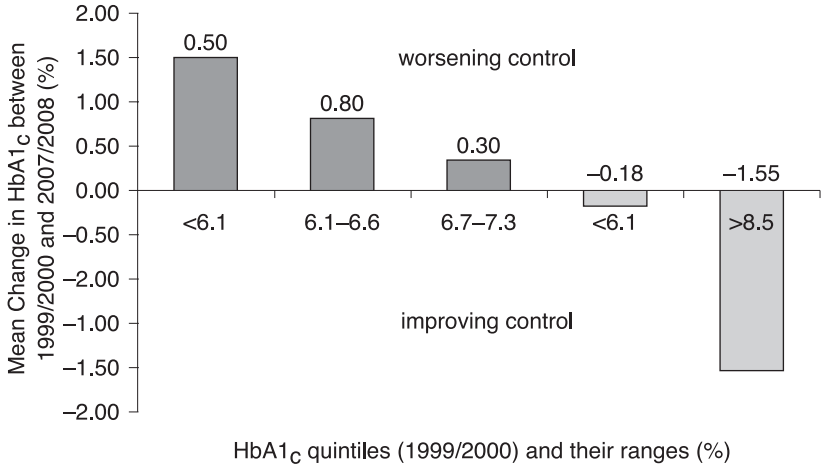

Figure 1 The mean change in HbA_{1c} between 1999/2000 and 2007/8 is presented with the 272 patients categorised into quintiles based on the HbA_{1c} levels in 1999/2000. This figure demonstrates worsening control and improved control. The numbers of patients in each quintile are found in Table 3.

Table 3 Number of patients (total 272) who had HbA_{1c} levels measured during Audit 2000 and Audit 2008, categorised into quintiles based on the HbA_{1c} results in 1999–2000, and the number (%) of patients meeting the 7.5% target in each quintile

No patients in each quintile (1999–2000)	No. of patients (%) with $HbA_{1c} \leq 7.5\%$	
	Audit 2000	Audit 2008
Quintile 1 ($HbA_{1c} < 6.1\%$, $n = 53$)	53 (100)	41 (77.36)
Quintile 2 (HbA_{1c} 6.1–6.6%, $n = 60$)	60 (100)	44 (73.33)
Quintile 3 (HbA_{1c} 6.7–7.3%, $n = 53$)	53 (100)	34 (64.15)
Quintile 4 (HbA_{1c} 7.4–8.5%, $n = 53$)	7 (13.2)	25 (47.17)
Quintile 5 ($HbA_{1c} > 8.5\%$, $n = 53$)	0 (0)	18 (33.96)
Total	173 (63.6)	162 (59.6)

this information is reassuring regarding intensive treatment to improve glycaemic control.

Our initial audit (Audit 2000) estimated the scale of the problem facing health providers in the local area planning the delivery of the diabetes NSF. The data were encouraging with regards to data recording, laboratory testing and treatment outcomes. The re-audit eight years later established the changes influenced by the NSF and QOF. The QOF targets changed minimally until 2009 with two threshold levels of HbA_{1c} (7.5 and 10%) determining incentivised payment. In 2009, the levels did change with targets of 7, 8 and 9%. Thus, it was important to re-audit prior to this change. Further, the results of the ACCORD and ADVANCE studies published in 2008 might also have influenced management.[11,12]

Overall, mean HbA_{1c} increased by 0.2% (non-significant) between the two audits. However, when stratifying the patients into quintiles and measuring the mean change in HbA_{1c} over eight years, an interesting pattern emerged. Patients with poor glycaemic control saw an overall decrease in HbA_{1c} by 2008, with the reverse seen in patients with good control. The results of our audit suggest that patients with worsening glycaemia, but still below the same QOF threshold, may not be given the same priority by the current system because there is no change in payment. This highlights one of the negative impacts of performance-based payment, and contradicts the standardisation of care intended by the introduction of QOF. A way forward might be that we need to look at trends rather than absolute values in QOF targets.

We must acknowledge the limitations of our study. Our data sample was not complete, although we sought to eliminate sample bias. Regression to the mean is a possibility. Our audit was carried out in an area that may not be representative of the country at large. It would be interesting if similar audits were repeated in other parts of the country. Despite the limitations of our audit it is important that patient-related outcomes be frequently evaluated followed by necessary changes to the healthcare delivery system.

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CONTRIBUTOR STATEMENT

The authors made the following contributions to this study: EL Clarke, data collection of Audit 2008 and preparation of manuscript; JR Richardson, data analysis of Audit 2008 and preparation of manuscript; M Bhartia, data analysis, data interpretation and preparation of manuscript; DM Kennedy, validation of HbA_{1c} and preparation of manuscript; JJ Milles, conception of audits and preparation of manuscript; and S Ramachandran, conception of audits, data collection of Audit 2000, data analysis, data interpretation and preparation of manuscript.

PEER REVIEW

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CONFLICTS OF INTEREST

None.

ADDRESS FOR CORRESPONDENCE

Dr S Ramachandran, Consultant Chemical Pathologist, Department of Clinical Biochemistry, Good Hope Hospital, Heart of England NHS Foundation Trust, Rectory Road, Sutton Coldfield B75 7RR, UK. Tel: +44 (0) 121 424 7246; fax: +44 (0)121 311 1800; email: sud.ramachandran@heartofengland.nhs.uk

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