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Supporting the management of type 2 diabetes with pharmacist-led reviews: an observational analysis

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Transparency declaration: As Lead Author and the manuscript's guarantor, I 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 have been explained.

Contributorship statement: This manuscript describes original work which is not under consideration by any other journal. All designated as authors of this manuscript meet the ICMJE criteria for authorship. All authors have approved the manuscript and this submission. As Lead Author (TL) I confirm there are no related papers by any of the authors already published or under consideration for publication. As guarantor, TL conceived the study. AB and JGD managed the data collection and presentation, whilst TL and NN monitored the conduct of the study and provided clinical interpretation and analysis of the results.

Study funding/potential competing interests: This research did not receive any funding. It was conducted as a retrospective analysis of a pharmacist-led clinic programme which was funded by NHS Slough CCG and delivered in partnership with Interface Clinical Services Ltd, an independent clinical services provider.

Ethics committee approval: This research took the form of a retrospective clinical audit for which ethical approval was not required. No patient-identifiable data was recorded during this retrospective clinical audit.

Data sharing statement: No additional data available.

Clinical trial registration: This research took the form of a retrospective clinical audit, not a clinical trial.

Abstract

Objective: To describe and then assess the impact of a pharmacist-led patient review programme on the management of diabetes.

Design: Observational analysis

Setting: GP practices within NHS Slough Clinical Commissioning Group (CCG).

Participants: 5,910 patients with type 2 diabetes.

Interventions: 5,910 patients were reviewed to identify opportunities to put in place any of the 9 key care processes recommended by the National Institute for Health and Care Excellence (NICE) that any of the patients were either missing or overdue, to optimise medication where required, and to make other interventions such as providing lifestyle advice where appropriate.

Main outcome measures: Change in proportion of patients receiving the NICE-recommended 9 key care processes and change in proportion of patients whose glycated haemoglobin (HbA1c), blood pressure (BP) or total cholesterol (TC) readings were over target before, during and after the intervention period.

Results: The proportion of patients receiving all of the NICE-recommended 9 key care processes increased from 46% at project outset in April 2013 to 58% upon completion in April 2014. The percentage of patients having HbA1c, BP, and TC readings and the percentage whose HbA1c, BP, and TC readings achieved target also increased. Quality Outcomes Framework (QOF) data for the CCG showed the percentage of diabetic patients achieving target HbA1c, BP, and TC readings increased from April 2013 to April 2014but then diminished in the year after the project completed.

Conclusions: The programme combined the strategic drive and project facilitation skills of the CCG, the practices' knowledge of their patients and the clinical and IT system expertise of an experienced pharmacist team. Focusing on key care processes and the treatment optimisation opportunities that this revealed appears to have enhanced diabetes control during programme delivery period, but longer improvement might have been better if the programme was ongoing rather than fixed term.

Article summary – strengths and limitations

- An example of effective multi-disciplinary team working, this project was able to deliver improved focus on T2D management in NHS Slough CCG by combining the strategic drive and project facilitation skills of the CCG, the practices' drive to deliver ever higher standards of service to their patients and the clinical and IT system expertise of an experienced pharmacist team.
- This project represents a good example of the aspirations of the joint working initiatives created by the Royal College of General Physicians and the Royal Pharmaceutical Society in order to identify areas where GPs and pharmacists can work together to improve the quality of patient care.
- The key limitation when evaluating the outcomes of this project is that it represented just one element of the overall package of care received by the patients. However, within the outcomes reported, the 21% increase in the number of patients receiving all nine of the NICE-recommended nine key care processes (from 48% to 58% of patients) can be more clearly attributed to the project, as the lists of missing care processes per each patient were generated by the pharmacists and then systematically worked through by the practices.
- Whilst a clinical programme such as this carries associated financial costs, it is widely accepted that the financial costs of managing poorly controlled T2D patients (and the associated complications) far exceed the costs of managing well controlled T2D patients.

Introduction

Type 2 diabetes (T2D) is a complex condition to manage. When T2D is not well managed, it is associated with considerable morbidity and serious complications including heart disease, stroke, diabetic retinopathy, kidney disease and amputation – over time leading to disability and premature mortality[1]. In addition to the clinical burden of T2D care, there are also substantial financial costs associated with it[1]. Since 1996 the number of people diagnosed with diabetes in the UK has increased from 1.4 million to 2.9 million and by 2025 it is estimated that there will be 5 million people with diabetes[2]. To add to the growing burden of diabetes, an estimated 850,000 people in the UK are currently living with undiagnosed T2D and in diagnosed patients, by the time of diagnosis, approximately 50% of T2D patients show signs of complications[2]. Around £10 billion (or 10%) of the NHS budget is spent on diabetes. The total cost (direct care and indirect costs) associated with diabetes in the UK currently stands at £23.7 billion and is predicted to rise to £39.8 billion by 2035/6[2].

The prevalence of (diagnosed) T2D in NHS Slough Clinical Commissioning Group (CCG) is higher than the national average and is increasing. According to the National Diabetes Audit 2012/13 which was published during the project year only a minority (40.0 %) of T2D patients in NHS Slough CCG achieved all treatment targets recommended by the National Institute for Health and Clinical Excellence (NICE)[3] and this was consistent with the national picture. With too few patients achieving all treatment targets the need for improvement was key to delivering better patient care. The diabetes outcomes versus expenditure (DOVE) tool allows a CCG-level assessment of performance in the relationship between expenditure on diabetes prescribing and clinical outcomes[4]. It shows the relative position of a selected CCG in comparison to other CCGs. At the outset of the project, the DOVE tool showed NHS Slough CCG to have below-average diabetes prescribing spend and also below-average patient outcomes. At practice level, analysis of patient outcomes showed significant variation in the proportion of T2D patients achieving the NICE-recommended BP, TC and HbA1c targets. In addition to this there was also marked variation in the prescribing rates of different anti-diabetic drugs and insulin within the area.

Given the local picture regarding the quality of T2D management and the future projections of a substantial increase in T2D prevalence, NHS Slough CCG identified the improved management of T2D as a key strategic priority[5]. Recently published studies demonstrate that safety of prescribing and the quality of long term care can be improved through pharmacist and IT support[6,7]. Based on this and with a need to deliver improvements in patient outcomes, educate prescribers and reduce practice by practice variations, NHS Slough CCG identified a role for a clinical pharmacist team. Firstly, the pharmacists would support practices in increasing the proportion of patients receiving the NICE-recommended 9 key care processes by identifying missing care processes per patient and working with the practices to agree an action plan to put the missing care processes in place. Secondly, the pharmacists would review all patients whose key care processes relating to the monitoring of HbA1c, BP and TC showed the patient to be over target on one or more measure and as such to be defined as “poorly controlled”. All such patients were further reviewed by the pharmacist team, with recommendations for optimisation of patient care made to the GP project leads at each practice. GP-approved recommendations would then either be actioned by the pharmacist or GP, depending on the nature of the intervention required and also the practice preference regarding implementation of recommendations. In delivering the service outlined above, the pharmacist team also assisted the practices in improving the use of Read Codes within the delivery of T2D care.

Methods

Led by a senior pharmacist and a team of 3 clinical pharmacists, the programme was delivered between April 2013 and April 2014. To ensure a high level of continuity within the work delivered, each of the 13 GP practices participating in the programme was assigned to 1 of the 3 clinical pharmacists, who worked with the same GP practices throughout the year.

The programme consisted of 3 phases. The first phase of the project involved data collection, analysis and work-stream prioritisation. The aim of this phase was to benchmark current achievements within T2D management (and co-morbidities), to engage with practice teams and to allow the pharmacists to prioritise patient cohorts for review in line with relevant NICE and local guidance. Key activities included:

- Identification of patients who were missing any of the NICE-recommended 9 key care processes
- Referral of patients to receive any missing or outdated care processes
- Identification of patients for further review due to over-target HbA1c, BP and TC levels
- Analysis of treatment interventions in relation to local and NICE guidance
- Analysis and presentation of findings to the practices, along with recommended actions per individual patient where opportunities to optimise care were identified
- Educational sessions for practice personnel in optimising T2D management

To ensure consistency, all pharmacists undertook the same searches on the clinical systems within the GP practices throughout the programme. The NICE-recommended 9 key care processes searches were completed and results/achievements were recorded 3 times during the year.

Following the analysis of practice performance in relation to the NICE-recommended 9 key care processes in the financial year prior to project commencement in April 2013, the findings were discussed with key personnel within each GP practice. A tailored strategy to increase the percentage of patients receiving all of the NICE-recommended 9 key care processes was designed and agreed with each practice.

The second phase of the programme was designed to increase the value and effectiveness of prescribing within T2D and associated co-morbidities, as well as to maximise adherence to NICE and local guidance. Key activities within this phase included:

- Prioritising patients for review according to their HbA1c, BP and TC levels
- Reviewing patient records to ensure prescribing was aligned with NICE guidance CG66 and CG87 for T2D and associated co-morbidities, was within licensed indications, and reflected the level of clinical need

It had been agreed prior to initiation of the clinical programme that any patients requiring adjustments to insulin would be reviewed and managed by the practices themselves rather than by the pharmacist team. The pharmacists compiled a list of insulin-using patients during the patient group analysis at each practice and then presented the lists to each practice for review.

The clinical data from phase 1 enabled the pharmacists to risk profile the patients and identify those who required medicines optimisation or other optimisation of their care. The patient cohorts identified for a more detailed review were those patients exceeding any of the agreed targets of HbA1c 7.5% or 59 mmol/mol, BP 150/90 mm/Hg or BP 140/80 mm/Hg (as required, at the request of practices or based on individual BP targets) and TC of 5mmol/l.

The result of the searches and patient reviews enabled the pharmacists to make recommendations based on a full clinical review of test results, current therapy and co-morbidities. The recommendations were discussed with the GP project lead at the practice, who then decided the most appropriate course of action to take with each patient. Recommendations made included, but were not limited to drug initiations, dose changes, drug discontinuations and interventions regarding adherence to and persistence with treatment.

Each practice decided how different recommendations should be actioned. Recommendations were actioned proactively using a mix of clinic consultations, telephone consultations, and letters to patients. In some instances, the GP project leads at the practices opted to action recommendations reactively at a later date.

During phase 3 of the programme each GP practice received 2 follow-up visits to evaluate the impact of interventions made during phases 1 and 2. The aim of these visits was to assess the extent to which agreed recommendations had been implemented, to identify further opportunities for improvement through re-audit, and to maintain practice engagement in the project. The visits took place 6 and 12 months after project initiation.

Results

During phase 1 the pharmacist team identified 3,211 patients missing at least 1 of the NICE-recommended 9 key care processes. A plan was agreed with each practice to ensure that the missing care processes were completed with each patient wherever possible.

Overall, the number of patients receiving all of the NICE-recommended 9 key care processes was increased from 46% at the beginning of the project to 58% at the end of the project (Figure 1). This despite the impact of a 3.65% increase (from 5,910 to 6,134 patients) in the number of patients diagnosed with T2D between the project start and end i.e. April 2013 and April 2014.

Figure 1: NICE-recommended 9 key care processes: achievement before and after project delivery

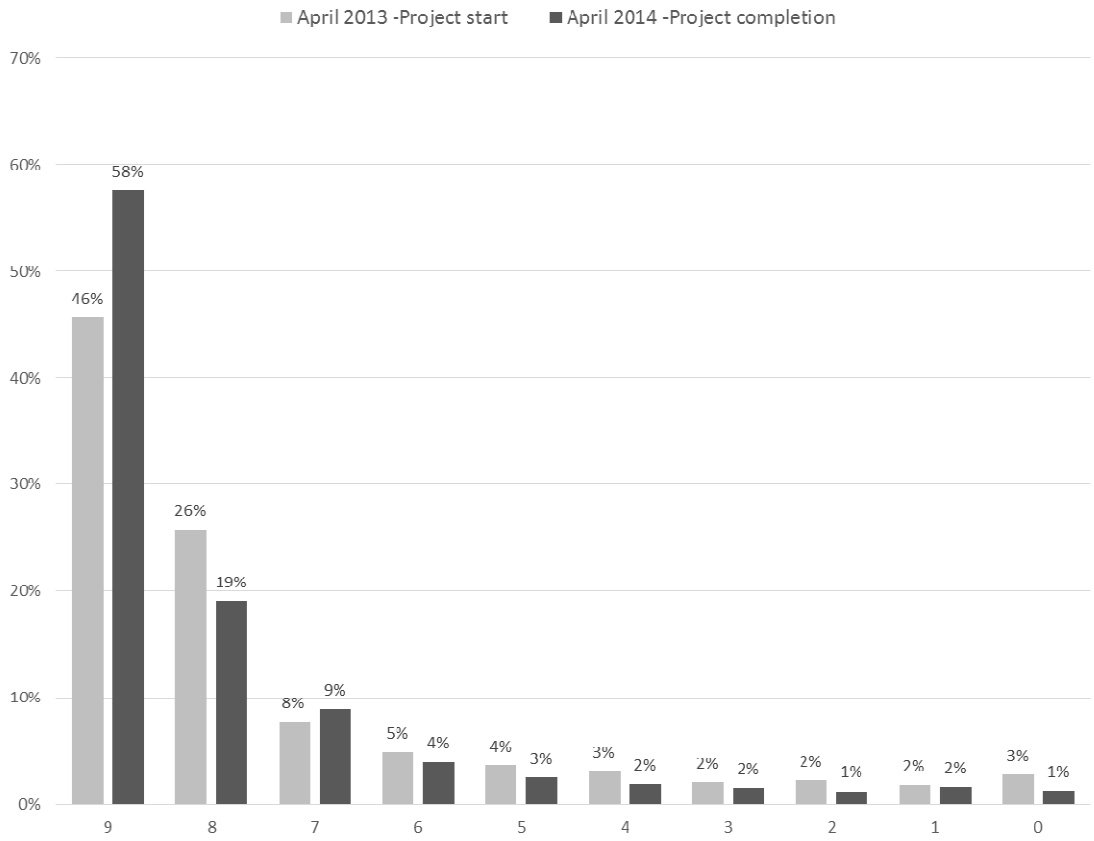
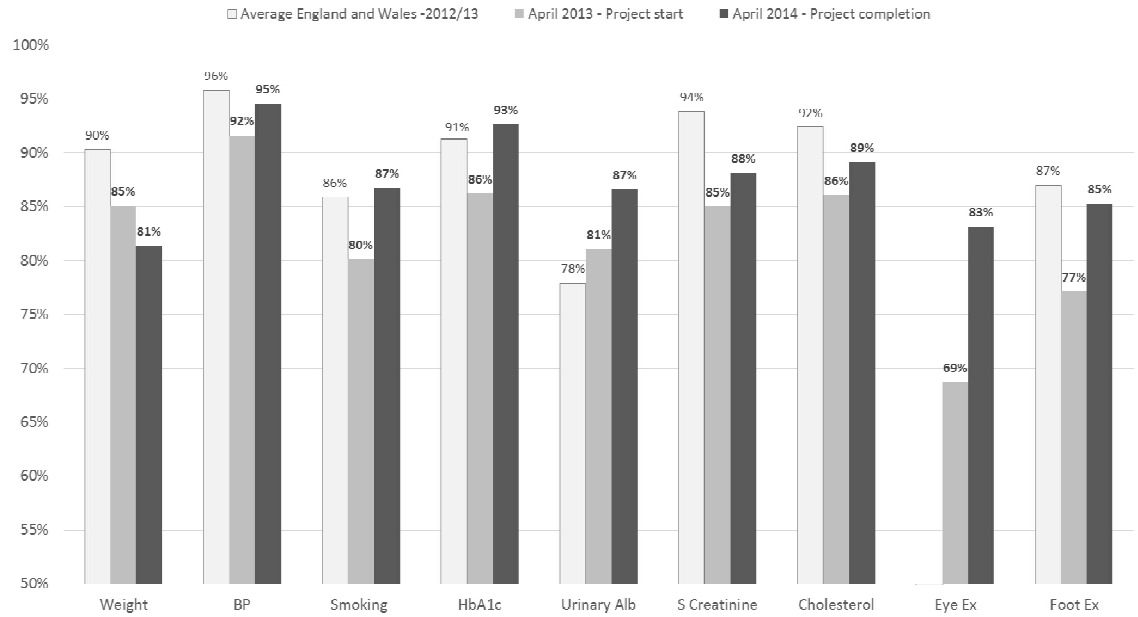


Figure 2 below shows that in April 2013 at the project outset, the percentage of patients completing 7 of the 9 care processes (weight, BP, smoking status, HbA1c, serum creatinine, TC and foot examination) was below the England and Wales average and above average for the percentage of patients with urinary albumin assessment. Comparative data relating to eye examinations was not available. In April 2014, after the clinical programme was completed, the percentage of patients who had received 8 of the 9 care processes had improved in comparison to the previous year. In all except for the assessment of weight (BMI), there was an increase in the proportion of patients recorded as receiving each individual care process from project start to project completion (Figure 2).

Figure 2: Achievement of the NICE-recommended 9 key care processes before and after project delivery and against the 2012/13 average for England and Wales[3]



During phase 1 of the project, a total of 2,984 of the 5,910 patients were found by the pharmacist team to be at risk of poor T2D control as defined by their latest HbA1c, BP or TC readings being over target. However, many of the readings were over a year old, and where this was the case, the pharmacists worked with the practices to try to arrange updated test results. This was often achieved but at times not until late into the project, meaning that there were fewer actions or recommendations that the pharmacist could make for such patients within the project timeframe. Such patients had to be flagged for more detailed review by the practice on completion of out of date care processes.

The pharmacists were able to undertake a more detailed review of the notes of each patient whose latest over-target HbA1c, BP or TC readings were less than a year old. Recommendations were made to the GP project leads at the practices as to how treatment could be optimised for each such patient. In addition to ensuring that these patients had more of the NICE-recommended 9 key care processes put in place as previously described, there were 1,035 patients for whom opportunities to optimise medication were recommended to the GP project leads.

The table below shows the number and proportion of patients whose latest HbA1c, BP or TC reading s were over target at the start versus the end of the project. It can be seen that by the end of the project, a greater proportion of the population had an HbA1c, BP and/or TC reading in their record, and a lower percentage of the readings were over target.

Table 1: Number and percentage of patients with HbA1c, BP or TC readings and project start vs. end

Care process	Phase 1 - project start – T2D population of 5,910. April 2013.				Phase 3 - project end – T2D population of 6,134. April 2014.			
	Patients with a reading	% of population	Latest reading over target	% of readings over target	Patients with a reading	% of population	Latest reading over target	% of readings over target
HbA1c	5,467	92.50%	1,937	35%	5,932	96.71%	1,765	30%
BP	5,617	95.04%	1,680	30%	6,043	98.52%	1,455	24%
TC	5,127	86.75%	1,125	22%	5,820	94.88%	1,019	18%

The way that the project was designed meant that only those patients with an over-target HbA1c, BP or TC reading taken within 12 months of project commencement were able to receive the most detailed review from the pharmacist team. Table 2 below shows the number of patients with an over-target HbA1c, BP or TC reading taken within 12 months of project commencement, who then had a further reading taken after they had been extensively reviewed by the pharmacist in collaboration with the project lead GP at each practice.

Table 2: Number of patients with up to date, over-target HbA1c, BP or TC readings at project outset, whose readings were repeated after project phase 1

Care process	Over target reading taken within the year preceding project commencement	Over target when reading repeated after pharmacist review	Change
HbA1c > 59 mmol/mol	940	659	-29.9%
BP >140/80mmHg	639	454	-29.0%
TC >5mmol/l	595	324	-45.5%

Table 2 shows that where patients underwent a detailed review by the pharmacist in collaboration with the practice team, between 29-45.5% of their markers of poor control at the project outset had improved to the point of achieving target by the end of the project, yet Table 1 shows that the overall numbers of patients whose latest reading was still over target at the end of the project had not reduced by the same proportions. There were 3 main reasons for this:

- Because of the progressive nature of T2D when poorly managed, many patients whose T2D was well controlled target at the project outset had become poorly controlled during the year of project delivery
- Many patients had outdated readings at the project outset which indicated good T2D control but which were updated during the course of project delivery and on occasion revealed that control had diminished
- The T2D population under review increased from 5,910 to 6,134 during the project year, bringing with it a proportion of patients with over-target readings

Table 3 below contains data relating to the percentage of all diabetic patients across NHS Slough CCG whose HbA1c, BP and TC were over target in the financial year ending prior to project delivery commencing (April 2013), at the financial year end which coincided with the completion of project delivery (April 2014) and at the financial year end 1 year after project delivery had completed (April 2015). This data was reported by practices via the Quality Outcomes Framework (QOF) reporting process[8].

Table 3: QOF data for NHS Slough CCG[8]

NHS Slough CCG			
T2D patients over recommended target	**Financial year end April 2013 (project commenced)**	**Financial year end April 2014 (project completed)**	**Financial year end April 2015 (1 year post project completion**
HbA1c >59mmol/mol	34.18%	27.41%	31.21%
BP >140/80mmHg	22.98%	15.03%	15.34%
TC >5mmol/l	20.14%	16.80%	18.87%

The table above shows that the percentage of patients whose HbA1c, BP and TC readings were over target were at their lowest levels upon completion of the project before increasing again in the year after project delivery had completed.

Limitations and discussion

The key limitation when evaluating the outcomes of this project is that it represented just one element of the overall package of care received by the patients between April 2013 and April 2014. It is therefore difficult to say exactly how many of the patients whose HbA1c, BP or TC levels came back into target range as a direct result of the problems identified and the interventions delivered within this project. What is known is that a proportion of those patients who were well controlled at the project outset, or who appeared after the project outset, failed to achieve at least one of the HbA1c, BP or TC targets during the year of project delivery because whilst Tables 1 and 3 show a reduction in the proportion of poorly controlled patients across the CCG as a whole during the project delivery year, the reductions are not on the scale of those observed in the most extensively reviewed cohort of patients which were tracked in Table 2.

An analysis of QOF data relating to time periods before, during and after project delivery was undertaken and is shown in Table 3. Within the overall NHS Slough CCG population, the proportion of patients above the recommended targets for HbA1c, BP and TC were lower for all 3 parameters at the point of project completion than they had been in the QOF year preceding project delivery. The likelihood that this improvement was at least partially attributable to the project was perhaps further reinforced by the fact that the percentage of patients exceeding each of the 3 parameters once again increased in the year following project completion, perhaps suggesting that a rolling programme would be more beneficial than a fixed term project, and the importance of building a strong educational legacy with the practices so that they can continue to deliver a similar programme. The 21% increase in the number of patients receiving all nine of the NICE-recommended nine key care processes (from 48% to 58% of patients) can be more clearly attributed to the project, as the lists of missing care processes per each patient were generated by the pharmacists and then systematically worked through by the practices.

However difficult it is to isolate the impact of this project, it did succeed in identifying and focusing attention and resource on the majority of the poorly controlled T2D patients within NHS Slough CCG between April 2013 and April 2014. Missing care processes were sought for those patients, who were also recommended for priority review by their practices with a host of treatment optimisation recommendations suggested by the pharmacists. Going forward, NHS Slough CCG is targeting further improvements in T2D control, and the learning and outcomes from this project strengthen the argument to repeat the project in some way. Further consideration would also be given as to how practices might be able to routinely incorporate more of the patient identification, monitoring and tracking into their day to day activities in order to derive more of a legacy effect if the service cannot be provided each and every year.

As an example of effective multi-disciplinary team working, this project was able to deliver improved focus on T2D management in NHS Slough CCG by combining the strategic drive and project facilitation skills of the CCG, the practices' drive to deliver ever higher standards of service to their patients and the clinical and IT system expertise of an experienced pharmacist team. It represents a good example of the aspirations of the joint working initiatives created by the Royal College of General Physicians and the Royal Pharmaceutical Society in order to identify areas where GPs and pharmacists can work together to improve the quality of patient care[6].

Whilst a clinical programme such as this carries associated financial costs, it is widely accepted that the financial costs of managing poorly controlled T2D patients (and the associated complications) far exceed the costs of managing well controlled T2D patients[1]. Therefore a relatively modest investment in a clinical programme such as this should be help to ensure that the NICE-recommended key care processes are in place, monitored and acted upon in order to reduce morbidity, mortality and cost in the mid-term whilst improving practice and CCG performance against the Quality Outcomes Framework[8].

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STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No	Recommendation
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract **Yes - title and abstract describes our work as a "observational analysis".**
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found. **Yes –abstract on page 2.**
Introduction		
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported **Yes - introduction on page 3**
Objectives	3	State specific objectives, including any prespecified hypotheses **Yes –abstract on page 2 and methods section on page 4.**
Methods		
Study design	4	Present key elements of study design early in the paper **Yes - title on page 1 and abstract on page 2.**
Setting	5	Describe the setting, locations, and relevant dates , including periods of recruitment, exposure, follow-up, and data collection **Provided in abstract section and throughout the paper where required.**
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up **Presented in abstract and methods sections – all patients with type 2 diabetes.** *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable. **Outcomes in abstract and results sections and discussion of limitations in discussion section.**
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). **Presented in methods and results sections.** Describe comparability of assessment methods if there is more than one group.
Bias	9	Describe any efforts to address potential sources of bias. **Same methodology used at each participating practice. Limitations of results highlighted in discussion section**
Study size	10	Explain how the study size was arrived at. **Methods section page 4.**
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why. **Results section pages 6-8.**
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding **N/A.**
		(*b*) Describe any methods used to examine subgroups and interactions **N/A.**

(*c*) Explain how missing data were addressed **N/A.**

(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed. **N/A.**
Case-control study—If applicable, explain how matching of cases and controls was addressed
Cross-sectional study—If applicable, describe analytical methods taking account of sampling strategy

(*e*) Describe any sensitivity analyses **N/A.**

Continued on next page

Results		
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed. **Results section pages 6-8.**
		(b) Give reasons for non-participation at each stage. **Results section pages 6-8.**
		(c) Consider use of a flow diagram. **N/A.**
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders. **Results section pages 6-8.**
		(b) Indicate number of participants with missing data for each variable of interest. **Results section pages 6-8.**
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount). **Methods section on page 4.**
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time. **Results section pages 6-8.**
		Case-control study—Report numbers in each exposure category, or summary measures of exposure
		Cross-sectional study—Report numbers of outcome events or summary measures
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included. **Unadjusted results in results section pages 6-8. Discussion of limitations on page 9.**
		(*b*) Report category boundaries when continuous variables were categorized. **N/A.**
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period **N/A.**
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses. **All results in results section pages 6-8.**
Discussion		
Key results	18	Summarise key results with reference to study objectives. **Abstract on page 2.**
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias. **Discussion of limitations page 9.**
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence. **Discussion on page 9.**
Generalisability	21	Discuss the generalisability (external validity) of the study results. **Discussion on page 9.**
Other information		
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based. **Page 1.**

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

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Supporting the management of type 2 diabetes with pharmacist-led reviews

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Transparency declaration: As Lead Author and the manuscript's guarantor, I 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 have been explained.

Contributorship statement: This manuscript describes original work which is not under consideration by any other journal. All designated as authors of this manuscript meet the ICMJE criteria for authorship. All authors have approved the manuscript and this submission. As Lead Author (TL) I confirm there are no related papers by any of the authors already published or under consideration for publication. As guarantor, TL conceived the study. AB and JGD managed the data collection and presentation, whilst TL and NN monitored the conduct of the study and provided clinical interpretation and analysis of the results.

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Ethics committee approval: This research took the form of an observational analysis for which ethical approval was not required. No patient-identifiable data was recorded during this observational analysis.

Data sharing statement: No additional data available.

Clinical trial registration: This research took the form of an observational analysis, not a clinical trial.

Abstract

Objective: Describe and assess the impact of a pharmacist-led patient review programme on the management and control of type 2 diabetes (T2D).

Design: Uncontrolled prospective cohort study with before and after intervention data collection

Setting: General Practices within NHS Slough Clinical Commissioning Group (CCG).

Participants: 5,910 patients with T2D.

Interventions: Pharmacists reviewed 5,910 patients and worked with General Practice teams to schedule any of the 9 key care processes recommended by the National Institute for Health and Care Excellence (NICE) that the patients were lacking, to optimise medication and to make other interventions such as providing lifestyle advice.

Main outcome measures: Proportion of patients receiving the NICE-recommended 9 key care processes and proportion of patients whose glycated haemoglobin (HbA1c), blood pressure (BP) or total cholesterol (TC) readings were over target before and after the intervention period.

Results: The proportion of patients receiving all of the NICE-recommended 9 key care processes increased from 46% at project outset in April 2013 to 58% upon completion in April 2014 and the percentage of patients achieving HbA1c, BP, and TC targets all increased (65% to 70%, 70% to 76%, 78% to 82% respectively) Quality Outcomes Framework (QOF) data for Slough CCG showed the percentage of diabetic patients achieving target HbA1c, BP, and TC readings increased from April 2013 to April 2014 but then diminished in the year after project completion.

Conclusions: The pharmacist-led review increased the number of key care processes administered and improved diabetic control during the year of programme delivery. The improvement abated during the year after, suggesting that such programmes should be ongoing rather than fixed term. The programme combined the strategic drive and project facilitation skills of Slough CCG, the General Practice teams' knowledge of their patients and the clinical and information technology (IT) skills of an experienced pharmacist team.

Article summary – strengths and limitations

- An example of effective multi-disciplinary team working, this project was able to deliver improved focus on T2D management in NHS Slough CCG by combining the strategic drive and project facilitation skills of the CCG, the General Practice teams' drive to deliver ever higher standards of service to their patients and the clinical and IT system expertise of an experienced pharmacist team.
- This project represents a good example of the aspirations of the joint working initiatives created by the Royal College of General Physicians and the Royal Pharmaceutical Society in order to identify areas where GPs and pharmacists can work together to improve the quality of patient care.
- The key limitation when evaluating the outcomes of this project is that it represented just one element of the overall package of care received by the patients. However, within the outcomes reported, the increase in the number of patients receiving all nine of the NICE-recommended nine key care processes (from 48% to 58% of patients) can be more clearly attributed to the project, as the lists of missing care processes per each patient were generated by the pharmacists and then systematically worked through by the General Practice teams.
- Whilst a clinical programme such as this carries associated financial costs, it is widely accepted that the financial costs of managing poorly controlled T2D patients (and the associated complications) far exceed the costs of managing well controlled T2D patients.

Introduction

People in England can receive healthcare provided free at the point of delivery by the government-funded National Health Service (NHS). Patients register with a General Practitioner (GP) Practice which comprises of at least one GP and a wider team of healthcare professionals and administrative staff. Every GP Practice (Practice) in England is a member of one of more than 200 Clinical Commissioning Groups (CCGs). CCGs are clinically-led statutory bodies responsible for the planning and commissioning of healthcare services that meet the needs of the local population. Their success is measured by how much they improve health outcomes.

Type 2 diabetes (T2D) is a complex condition to manage. When T2D is not well managed, it is associated with considerable morbidity and serious complications including heart disease, stroke, diabetic retinopathy, kidney disease and amputation – over time leading to disability and premature mortality[1]. In addition to the clinical burden of T2D care, there are also substantial financial costs associated with it[1]. Since 1996 the number of people diagnosed with diabetes in the United Kingdom (UK) has increased from 1.4 million to 2.9 million, and by 2025 it is estimated that there will be 5 million people with diabetes in the UK[2]. To add to the growing burden of diabetes, an estimated 850,000 people in the UK are currently living with undiagnosed T2D and in diagnosed patients, by the time of diagnosis, approximately 50% of T2D patients show signs of complications[2]. Around £10 billion (or 10%) of the NHS budget is spent on diabetes. The total cost (direct care and indirect costs) associated with diabetes in the UK currently stands at £23.7 billion and is predicted to rise to £39.8 billion by 2035/6[2].

The prevalence of (diagnosed) T2D in NHS Slough Clinical Commissioning Group (CCG) is higher than the national average and is increasing. According to the National Diabetes Audit 2012/13, which was published during the project year, only a minority (40.0 %) of T2D patients in NHS Slough CCG achieved all treatment targets recommended by the National Institute for Health and Clinical Excellence (NICE)[3]. This was consistent with the national picture. With too few patients achieving all treatment targets, the need for improvement was key to delivering better patient care.

The 9 key care process that NICE recommends that each patient with diabetes should receive each year are:

1. Glycated haemoglobin (HbA1c) measurement, with a suggested target of 59mmol/mol
2. Blood pressure (BP) measurement, with a suggested target of 140/80mmHg
3. Cholesterol level measurement, with a suggested target for total cholesterol (TC) of 5mmol/l
4. Retinal screening
5. Foot checks
6. Urinary albumin testing
7. Serum creatinine testing
8. Weight check
9. Smoking status check

Given the local picture regarding the quality of T2D management and the future projections of a substantial increase in T2D prevalence, NHS Slough CCG identified the improved management of T2D as a key strategic priority[4]. Recently published studies demonstrate that pharmacist support can improve the safety of prescribing, improve the quality of care for long term conditions and reduce re-admissions rates through pharmacist support [5,6,7,8,9]. Within the UK there is currently a policy drive to use clinical pharmacists more effectively in Primary Care[6].

Based on this and with a need to deliver improvements in patient outcomes, NHS Slough CCG commissioned the services of an experienced clinical pharmacist team. Each pharmacist would become part of the General Practice team at each site for the duration of the programme. Much of the published data on pharmacist intervention to improve the care for people with T2D is based upon pharmacists working in Community Pharmacies or clinics rather than being integrated into General Practice teams[10].

Methods

Led by a senior pharmacist and a team of 3 clinical pharmacists, the clinical programme was delivered between April 2013 and April 2014. To ensure a high level of continuity within the work delivered, each of the 13 GP practices participating in the programme was assigned to 1 of the 3 clinical pharmacists, who worked with the same GP Practices throughout the year. The programme consisted of three phases.

The first phase of the project involved data collection, analysis and work-stream prioritisation. The aim of this phase was to benchmark current achievements within T2D (and co-morbidities) management, to engage with General Practice teams and to allow the pharmacists to prioritise patient cohorts for review in line with relevant NICE and local guidance. Software was created to execute identical information searches on the clinical systems at each Practice at each phase of the project. Each practice gave permission for anonymised summary statistics from each phase of the project to be reported back to NHS Slough CCG. No patient identifiable data was removed from each Practice. Key activities at phase 1 of the project included:

- Identification of patients who were missing any of the NICE-recommended 9 key care processes
- Referral of patients to receive any missing or outdated care processes
- Identification of patients for further review where HbA1c, BP and TC targets not achieved
- Educational sessions for practice personnel in optimising T2D management and control

Following the analysis of practice performance in relation to the NICE-recommended 9 key care processes in the financial year prior to project commencement in April 2013, the findings were discussed with key personnel within each GP practice. A tailored strategy to increase the percentage of patients receiving all of the NICE-recommended 9 key care processes was designed and agreed with each Practice.

The second phase of the programme was designed to optimise treatment for those patients identified in phase 1 as having failed to achieve their HbA1c, BP and TC targets. The data from phase 1 combined with a detailed clinical review of each poorly controlled patient enabled the pharmacists to make recommendations to enhance treatment where appropriate. Recommendations for each individual patient were discussed at a multi-disciplinary team meeting including the GP who was project lead at each Practice, who then decided the most appropriate course of action to take with each patient. Recommendations made included but were not limited to drug initiations, dose changes, drug discontinuations, interventions regarding adherence to and persistence with treatment, lifestyle and diet advice, and referring to specialist care where complications were identified.

Each practice decided how different recommendations should be actioned. In some instances, the GP opted to action recommendations opportunistically when patients attended. However, recommendations were usually actioned proactively using a mix of clinic consultations, telephone consultations and letters to patients. Delivery of the agreed interventions was generally shared out between the General Practice team and the pharmacist.

During phase 3 of the programme each Practice received a follow-up visit from the pharmacist at 6 and 12 months post phase 2 in order to evaluate the impact of interventions made during phases 1 and 2. The aim of these visits was to assess the extent to which agreed recommendations had been implemented, to implement any outstanding actions, to identify further opportunities for improvement through re-audit, and to maintain practice engagement in the project.

Results

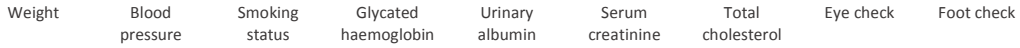
During phase 1 the pharmacist team identified 3,211 patients missing at least 1 of the NICE-recommended 9 key care processes. A plan was agreed with each practice to ensure that the missing care processes were completed with each patient wherever possible.

Figure 1 below shows that the proportion of patients receiving all of the NICE-recommended 9 key care processes was increased from 46% at the beginning of the project to 58% at the end of the project, and that the proportion of patients receiving less than 7 of the 9 key care processes reduced from 21% to 15%.

Figure 1: NICE-recommended 9 key care processes: achievement before and after project delivery

Figure 2 below shows that in April 2013 at the project outset, the percentage of patients completing 7 of the 9 care processes (weight, BP, smoking status, HbA1c, serum creatinine, TC and foot examination) was below the England and Wales average. Only the percentage of patients with urinary albumin assessment was above the England and Wales average. Comparative data relating to eye examinations was not available. In April 2014, after the clinical programme was completed, the percentage of patients who had received 8 of the 9 care processes had improved in comparison to the previous year. In all except for the assessment of weight, there was an increase in the proportion of patients recorded as receiving each individual care process from project start to project completion (Figure 2).

Figure 2: Achievement of the NICE-recommended 9 key care processes before and after project delivery and against the 2012/13 average for England and Wales[3]



During phase 1 of the project, a total of 2,984 of the 5,910 patients were found by the pharmacist team to be at risk of poor T2D control as defined by their latest HbA1c, BP or TC readings being over the NICE recommended target. However, some readings were over one year old, and where this was the case, the pharmacists worked with the Practices to try to arrange new tests. This was often achieved but at times not until late into the project, meaning that there were fewer actions or recommendations that the pharmacist could make for such patients within the project timeframe. Such patients had to be flagged for more detailed review by the Practice team on completion of out of date care processes.

The pharmacists were able to undertake a more detailed review of the notes of each patient whose latest over-target HbA1c, BP or TC readings were less than a year old. Recommendations were made to the GP as to how treatment could be optimised for each such patient. In addition to arranging for these patients to have any missing care processes put in place as previously described, there were 1,035 patients for whom opportunities to optimise medication were recommended to the GP.

The table below shows the number and proportion of patients whose latest HbA1c, BP or TC reading s were over target at the start versus the end of the project. It can be seen that by the end of the project, a greater proportion of the population had an HbA1c, BP and/or TC reading in their record, and a lower percentage of the readings were over target.

Table 1: Number and percentage of patients with HbA1c, BP or TC readings at project start and end

	Phase 1 - project start – T2D population of 5,910. April 2013.				Phase 3 - project end – T2D population of 6,134. April 2014.			
Care process	Patients with a reading	% of population	Latest reading over target	% of readings over target	Patients with a reading	% of population	Latest reading over target	% of readings over target
HbA1c	5,467	92.50%	1,937	35%	5,932	96.71%	1,765	30%
BP	5,617	95.04%	1,680	30%	6,043	98.52%	1,455	24%
TC	5,127	86.75%	1,125	22%	5,820	94.88%	1,019	18%

The way that the project was designed meant that only those patients with an over-target HbA1c, BP or TC reading taken within 12 months of project commencement were able to receive the most detailed review from the pharmacist team. Table 2 below shows the number of patients with an over-target HbA1c, BP or TC reading taken within 12 months of project commencement, who then had a further reading taken after they had been extensively reviewed by the pharmacist in collaboration with the GP at each practice.

Table 2: Number of patients with up to date, over-target HbA1c, BP or TC readings at project outset, whose readings were repeated after project phase 1

Care process	Over target reading taken within the year preceding project commencement	Over target when reading repeated after pharmacist review	Change
HbA1c > 59 mmol/mol	940	659	-29.9%
BP >140/80mmHg	639	454	-29.0%
TC >5mmol/l	595	324	-45.5%

Table 3 below contains data relating to the percentage of all diabetic patients across NHS Slough CCG whose HbA1c, BP and TC were over target in the financial year ending prior to project delivery commencing (April 2013), at the financial year end which coincided with the completion of project delivery (April 2014) and at the financial year end 1 year after project delivery had completed (April 2015). This data was reported by practices via the Quality Outcomes Framework (QOF) reporting process[11].

Table 3: QOF data for NHS Slough CCG[11]

NHS Slough CCG			
T2D patients over recommended target	**Financial year end April 2013 (project commenced)**	**Financial year end April 2014 (project completed)**	**Financial year end April 2015 (1 year post project completion**
HbA1c >59mmol/mol	34.18%	27.41%	31.21%
BP >140/80mmHg	22.98%	15.03%	15.34%
TC >5mmol/l	20.14%	16.80%	18.87%

The table above shows that the percentage of patients whose HbA1c, BP and TC readings were over target were at their lowest levels upon completion of the project before increasing again in the year after project delivery had completed.

Limitations and discussion

This pharmacist led review program of patients with T2D showed an increase of the percentage of patients who had all of the 9 NICE-recommended 9 key care processes completed and a decrease in number of patients considered to be poorly controlled. This adds to the evidence for improvements in outcomes in T2D when pharmacists are involved[8,10].

The findings of this study are distinguishable from much of the data previously published because the pharmacists involved were integrated into already existing General Practice teams, which is the model currently being proposed by the Royal College of General Physicians and the Royal Pharmaceutical Society[5]. The pharmacists were acting as clinicians, making patient specific recommendations. They also used IT skills to interrogate electronic medical records to identify the individuals with T2DM who were at greatest risk of complications and target the work of different members of the General Practice team. This meant that resource was appropriately attributed to each patient based upon need and based upon the skills of each member of the team. Such an approach would be widely replicable because it does not require significant changes to patient pathways or the development of new providers but simply the inclusion of a new staff member with a different skill set into an already existing team.

The key limitation when evaluating the outcomes of this project is that it represented just one element of the overall package of care received by the patients between April 2013 and April 2014. It is therefore not possible to say exactly how many of the patients whose HbA1c, BP or TC levels came back into target range were as a direct result of the problem identification and the interventions delivered within this project, and how many would have come back into range if the project had not taken place. Potential confounding factors that were not controlled for include: local clinicians receiving training on the management of T2D from other sources; the marketing and subsequent prescribing of new treatments for T2D or improvements; or changes to other commissioned services for T2D locally.

What is known is that a proportion of those patients who were well controlled at the project outset, or who appeared after the project outset, failed to achieve at least one of the HbA1c, BP or TC targets during the year of project delivery, because whilst Tables 1 and 3 show a reduction in the proportion of poorly controlled patients across the CCG as a whole during the project delivery year, the reductions are not on the scale of those observed in the most extensively reviewed cohort of patients which were tracked in Table 2.

Table 2 shows that where patients underwent a detailed review by the pharmacist in collaboration with the Practice team, 29% to 45.5% of their markers of poor control at project outset improved to the point of achieving target by the end of the project, yet Table 1 shows that the overall numbers of patients whose latest reading was still over target at the end of the project had not reduced by the same proportions. There were 3 main reasons for this:

- Because of the progressive nature of T2D when poorly managed, many patients whose T2D was well controlled at the project outset had become poorly controlled during the year of project delivery
- Some patients had outdated readings at the project outset which indicated good T2D control but which were updated during the course of project delivery and on occasion revealed that control had diminished
- The T2D population under review increased from 5,910 to 6,134 during the project year, bringing with it a proportion of patients with over-target readings

An analysis of QOF data (a national database, independent of this study) relating to time periods before, during and after project delivery was undertaken and is shown in Table 3. Within the overall NHS Slough CCG population, the proportion of patients above the recommended targets for HbA1c, BP and TC were lower for all 3 parameters at the point of project completion than they had been in the QOF year preceding project delivery. The likelihood that this improvement was at least partially attributable to the project was perhaps further reinforced by the fact that the percentage of patients exceeding each of the 3 parameters once again increased in the year following project completion. This also suggests that a rolling programme would be

more beneficial than a fixed term project, and emphasises the importance of building a strong educational legacy with the Practices so that they can continue to deliver a similar programme.

The increase in the percentage of patients receiving all 9 of the NICE-recommended 9 key care processes (from 48% to 58% of patients) can be more clearly attributed to the project, as the lists of missing care processes per each patient were generated by the pharmacists and then systematically worked through by the practices.

However difficult it is to isolate the impact of this "real life" clinical programme, it did succeed in identifying and focusing attention and resource on the poorly controlled T2D patients within NHS Slough CCG between April 2013 and April 2014. Missing care processes were completed for those patients, who were also recommended for priority review by their practices with a host of treatment optimisation recommendations suggested by the pharmacists. Going forward, NHS Slough CCG is targeting further improvements in T2D control, and the learning and outcomes from this programme give confidence that improved outcomes could be achieved again, but that more consideration should be given as to how practices might be able to routinely incorporate more of the patient identification, monitoring and tracking into their day to day activities in order to derive more of a legacy effect if the service cannot be provided every year.

As an example of effective multi-disciplinary team working, this programme was able to deliver improved focus on T2D management in NHS Slough CCG by combining the strategic drive and project facilitation skills of the CCG, the practices' drive to deliver ever higher standards of service to their patients and the clinical and IT system expertise of an experienced pharmacist team. It represents a good example of the aspirations of the joint working initiatives created by the Royal College of General Physicians and the Royal Pharmaceutical Society to identify areas where GPs and pharmacists can work together to improve patient care[5].

Whilst a clinical programme such as this carries associated financial costs, it is widely accepted that the financial costs of managing poorly controlled T2D patients (and the associated complications) far exceed the costs of managing well controlled T2D patients[1]. Therefore a relatively modest investment in a clinical programme such as this may help to ensure that the NICE-recommended key care processes are completed, monitored and acted upon in order to reduce morbidity, mortality and healthcare costs, whilst also improving Practice and CCG performance against the Quality Outcomes Framework[12].

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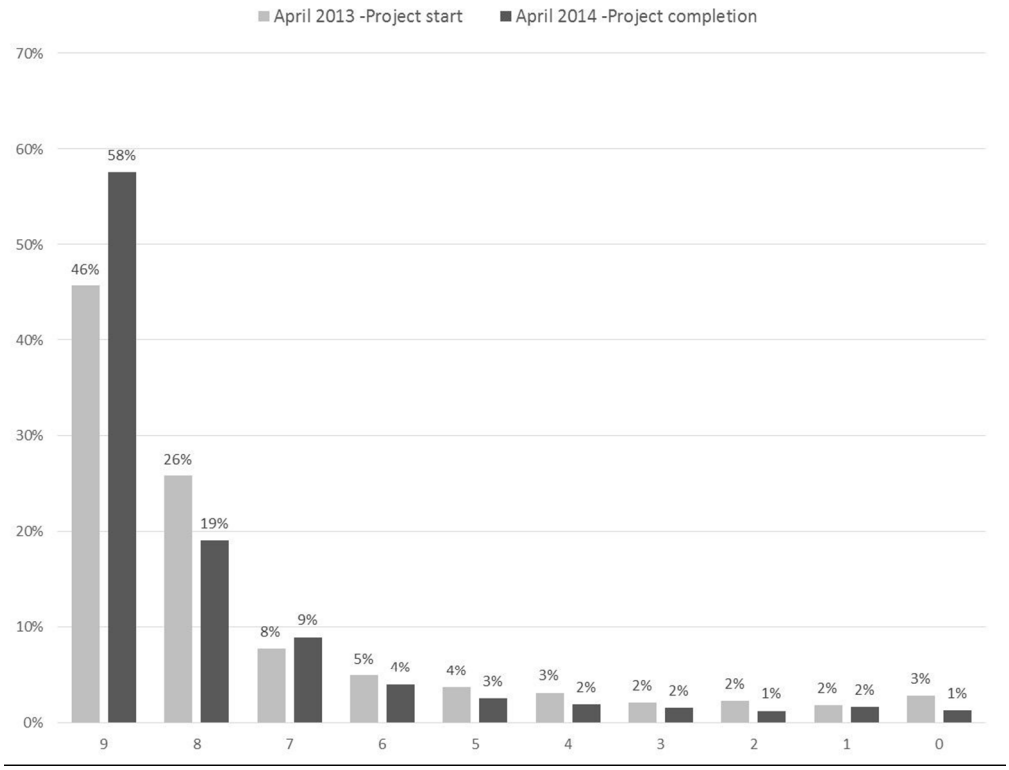

Figure 1: NICE-recommended 9 key care processes: achievement before and after project delivery

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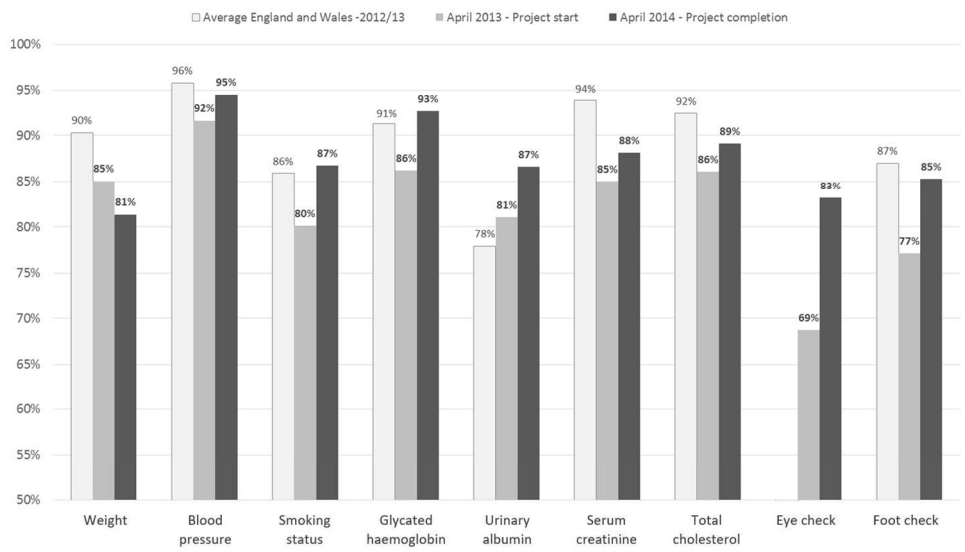

Figure 2: Achievement of the NICE-recommended 9 key care processes before and after project delivery and against the 2012/13 average for England and Wales

127x70mm (300 x 300 DPI)

STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No	Recommendation
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract **Yes - title and abstract describes our work as a "observational analysis".**
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found. **Yes –abstract on page 2.**
Introduction		
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported **Yes - introduction on page 3**
Objectives	3	State specific objectives, including any prespecified hypotheses **Yes –abstract on page 2 and methods section on page 4.**
Methods		
Study design	4	Present key elements of study design early in the paper **Yes - title on page 1 and abstract on page 2.**
Setting	5	Describe the setting, locations, and relevant dates , including periods of recruitment, exposure, follow-up, and data collection **Provided in abstract section and throughout the paper where required.**
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up **Presented in abstract and methods sections – all patients with type 2 diabetes.** *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable. **Outcomes in abstract and results sections and discussion of limitations in discussion section.**
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). **Presented in methods and results sections.** Describe comparability of assessment methods if there is more than one group.
Bias	9	Describe any efforts to address potential sources of bias. **Same methodology used at each participating practice. Limitations of results highlighted in discussion section**
Study size	10	Explain how the study size was arrived at. **Methods section page 4.**
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why. **Results section pages 6-8.**
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding **N/A.**
		(*b*) Describe any methods used to examine subgroups and interactions **N/A.**

(*c*) Explain how missing data were addressed **N/A.**

(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed. **N/A.**
Case-control study—If applicable, explain how matching of cases and controls was addressed
Cross-sectional study—If applicable, describe analytical methods taking account of sampling strategy

(*e*) Describe any sensitivity analyses **N/A.**

Continued on next page

Results		
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed. **Results section pages 6-8.**
		(b) Give reasons for non-participation at each stage. **Results section pages 6-8.**
		(c) Consider use of a flow diagram. **N/A.**
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders. **Results section pages 6-8.**
		(b) Indicate number of participants with missing data for each variable of interest. **Results section pages 6-8.**
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount). **Methods section on page 4.**
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time. **Results section pages 6-8.**
		Case-control study—Report numbers in each exposure category, or summary measures of exposure
		Cross-sectional study—Report numbers of outcome events or summary measures
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included. **Unadjusted results in results section pages 6-8. Discussion of limitations on page 9.**
		(*b*) Report category boundaries when continuous variables were categorized. **N/A.**
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period **N/A.**
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses. **All results in results section pages 6-8.**
Discussion		
Key results	18	Summarise key results with reference to study objectives. **Abstract on page 2.**
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias. **Discussion of limitations page 9.**
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence. **Discussion on page 9.**
Generalisability	21	Discuss the generalisability (external validity) of the study results. **Discussion on page 9.**
Other information		
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based. **Page 1.**

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.