

# **A cluster randomised controlled trial of educational prompts in diabetes care: study protocol**

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## **Abstract**

*Background.* Laboratory services have a central role in supporting screening, diagnosis and management of patients and represent a significant expenditure for the UK National Health Service (NHS), of which around 25% can be attributed to general practice use. The increase in chronic disease management in primary care for conditions such as diabetes mellitus requires regular monitoring of patients' biochemical parameters. This process offers a route for improving the quality of care that patients receive by using test results as a vehicle for delivering educational messages as well as the test result itself.

*Aim.* To develop and evaluate the effectiveness of a quality improvement initiative to improve the care of patients with diabetes using test report reminders.

*Design.* 2x2 factorial design cluster randomised controlled trial.

*Participants.* General practices in Newcastle.

*Intervention.* Short educational messages added to paper and electronic general practice laboratory test reports of Haemoglobin A1c (HbA1c).

*Outcomes.* Number of HbA1c and cholesterol tests requested (standardised for practice size) and the general practice mean levels of HbA1c and cholesterol.

## Background

There is broad, international agreement over what constitutes high quality health care for people with diabetes.(1) In the UK, this is enshrined in a National Service Framework for people with diabetes, and a series of clinical practice guidelines from the National Institute for Health and Clinical Excellence. However, despite this increasing clarity on desirable care there is evidence of sub-optimal performance.(2)

It is well known that guidelines do not implement themselves and that active strategies are needed to enhance their uptake. Whilst there are a range of means for approaching this, one that has the potential advantages of feasibility and simplicity is the attachment of educational messages to the results of tests requested from general practice.

Laboratory services have a central role in supporting screening, diagnosis and management of patients and represent a significant expenditure for the NHS. Locally, the number of general practitioner (GP) requests is increasing by 5% each year, and such requests currently account for approximately 25% of all tests performed by the Newcastle Hospitals NHS Trust. In relation to diabetes, over a six month period from January 2004, GP requests accounted for 35% of all HbA1c requests processed and for 52% of all cholesterol (1557 and 5769 per month respectively). There are several factors which may have contributed to this increase in demand (for example, shifts in the delivery of healthcare to primary care, the impact of clinical guidelines and protocols). Across the UK, there has been a recent major increase in requests for several tests, including HbA1c and cholesterol, related to the introduction of the new GP contract.(3;4)

Available interventions to change test ordering behaviour have not been systematically tested in a NHS setting. There is one relevant systematic review of interventions to improve test ordering behaviour. A review of 49 studies concluded that audit and feedback of test requesting patterns, educational messages, changes of request form and guidelines were all effective in changing test ordering behaviour.(5) However, the studies reviewed were of variable methodological quality with only eight of 49 using randomisation. All but one of the studies were concerned with either *decreasing* the overall volume of tests ordered or *decreasing* the number of inappropriate tests ordered. There is less known on the effectiveness of the methods in *increasing* appropriate behaviour; the one study that looked at this was a trial of adding guidelines to patients' records conducted in a hospital setting. Subsequent to the review an NHS based study of investigation and treatment of iron deficiency anaemia found that a simple message on a haematology test result increased the appropriate prescription of oral iron but did not increase the appropriate investigation of patients.(6) Given the paucity of NHS information in this area it is important that any developments are conducted in a manner that both allows confidence in their results and provides generalisable information for the NHS.

### *Work that informs this proposal*

The Centre for Health Services Research runs a Clinical Effectiveness Research Programme that has completed, or collaborated on, a number of relevant studies.

ME, JG and NS demonstrated that educational reminder messages on X-ray reports returned to general practitioners reduced knee and lumbar spine X-ray requests by 20% (relative reduction).(7) They then examined the sustainability of the intervention using time series analysis, demonstrating that the effect was maintained throughout the 12 month intervention period.(8)

ME, JG & BC have collaborated on a study of enhanced educational audit and feedback and test report reminders on the number and appropriateness of GP laboratory test requests in Grampian, Scotland.(9) This quality improvement initiative was welcomed by GPs as a valuable channel of communication between laboratory services and primary care. Preliminary data suggest a more rational use of laboratory testing, thus promoting effective and efficient patient care and use of resources. However, the aim in this study was to decrease test ordering. It is not known whether these findings apply to other contexts, such as to increase appropriate tests ordering (rather than decrease inappropriate test ordering) and, specifically, to test ordering for diabetes by GPs in Newcastle.

We have conducted two studies that utilize routine data available from service settings: a randomised controlled trial of outreach visiting in primary care, evaluated using routinely available prescribing data (10); a time series evaluation of patterns of radiology referrals in primary care following the distribution of the Royal College of Radiologists Guidelines. This study used routinely available data from radiology departments.(11)

## **Aim**

To establish and evaluate a quality improvement initiative to improve the quality of care for patients with diabetes using test report messages.

## **Methods**

### *Participants*

All 39 general practices in Newcastle that mainly use the laboratory services of the Newcastle Hospitals Trust (Royal Victoria Infirmary, Newcastle General Hospital and Freeman Hospital), will be enrolled in the study. The planned interventions are being viewed as part of intended normal service development.

General practices in Newcastle will receive a postal invitation to participate in the study. This invitation, addressed to the Practice Manager, will include a study information sheet in the form of a covering letter and two copies of a consent form. The Manager will be asked to share these materials with members of the Practice team and provide signed consent if the Practice wishes to participate (signed either by the Senior Partner or the Practice Manager). This is an appropriate level for seeking consent given that the practices also represent the unit of randomisation. Practices wishing further details and clarification will be offered a practice visit to explain more about the study. A stamped addressed envelope will be provided to minimise inconvenience.

### *Identification of patients with diabetes/choice of test*

As there is no current way that the laboratory can identify patients with diabetes we will use Haemoglobin A1c (HbA1c) test requests as a marker for patients with diabetes. From general practice almost all requests for HbA1c will relate to patients with diabetes.

### *Interventions*

The precise details of the intervention (wording and clinical content) will be defined by a multi-disciplinary group including representatives of primary care, secondary care, laboratory services and the research team. It will be congruent with the local diabetes guidelines.

Short educational messages will be added to paper and electronic general practice laboratory test reports of Haemoglobin A1c (HbA1c). These will give succinct educational information regarding appropriate patient management. The content of the messages will be evidence-based.

The messages will be of two types. The first message will relate to glycaemic control, will be conditional on the HbA1c level, and will give general advice about appropriate treatment and suggest a time interval for a further test. The second message (still on an HbA1c test result form) will give a non-specific message relating to the treatment of hypercholesterolaemia in patients with diabetes.

### *Outcomes*

The outcomes will be the number of HbA1c and cholesterol tests requested (standardised for practice size) and the general practice mean levels of HbA1c and cholesterol.

We hypothesise that in practices receiving the glycaemic messages, compared to those practices not, the number of HbA1c test requests will be higher and the mean HbA1c value

will be lower. Similarly for cholesterol messages the number of cholesterol tests will be higher and the mean cholesterol value will be lower.

### *Data collection*

Data on the number of the tests and the value will be extracted from the main laboratory computer information system for each referring general practice for a period of 12 months before (to provide baseline values) and 8 months after the study start date.

The identification of the cholesterol results will be done as a manual interrogation of the laboratory computer information system by the research associate.

We are aware of the potential for using general practice-level data now routinely collected for Quality Outcome Framework (a system for UK general practices designed to reward higher compliance with documented standards of care) as a means of monitoring and evaluating the impact of the intervention. We plan to explore the potential value of doing this, considering issues around feasibility, data quality, efficiency, and data protection.

### *Design*

The evaluation will be a 2x2 factorial design cluster randomised controlled trial with general practices as the unit of randomisation. It is important that the study uses a randomised design as there will inevitably be other initiatives relating to diabetes that will occur during the time of the study. It is only by using a randomised design that any observed effects can be confidently attributed to the interventions.

Practices, stratified by list size, will be randomly allocated to each intervention (glycaemic control educational messages and cholesterol control educational messages) independently. Randomisation will be conducted independently by a statistician using numbers randomly generated by computer. In the first randomisation, practices will be allocated to receive the glycaemic educational messages or control (no glycaemic educational messages). In the second randomisation, practices will be allocated to receive the cholesterol educational messages or control (no cholesterol educational messages). This will result in four groups:

- Practices receiving glycaemic and cholesterol educational messages
- Practices receiving only glycaemic educational messages
- Practices receiving only cholesterol educational messages
- Practices receiving no educational messages

This will allow comparisons of the separate and combined effects of the two educational message interventions.

### *Sample size*

The sample size is based upon the following assumptions: (1) The study will be carried out in a population of 39 practices with an average number of 62 patients per practice (patients with diabetes whose care is undertaken either by the general practice or shared between the general practice and hospital); (2) a significance level of 5%; (3) 80% power; (4) for binary outcomes (e.g. was test ordered?) the intraclass correlation coefficient (ICC) equals 0.2; and (5) for continuous outcomes (e.g. mean HbA1c) the ICC = 0.05.

Under these assumptions we will be able to detect: a 20% improvement (from 55% to 75%) in a binary outcome measure; and an effect size of 0.25 in a continuous outcome measure – this represent a change of 0.36 in mean HbA1c and 0.27 in mean cholesterol. These are based on estimated standard deviations of 1.45 and 1.07 respectively from a recent trial of a diabetes recall and management system for primary care - the Diabetes REcall And Management (DREAM) Trial (MP Eccles, personal communication).

### *Statistical analysis*

The study utilizes a 2 by 2 factorial design. The unit of analysis will correspond to the unit of randomisation - the general practice. The dependent variable will be the number of tests ordered. The number of HbA1c tests ordered and the number of cholesterol tests ordered will be analysed separately using negative binomial regression. To allow for differences due to practice size the log of the number of patients registered with the practice will be declared as an offset (effectively practice size is treated as an explanatory variable). The study design is predicated on there being no interaction between the two interventions. We will therefore fit only a main effects model to the data (an independent effect of each of the two interventions on the dependent variable). Results will be presented in the form of a 95% confidence interval for the relative rates of test ordering.

### **Ethical considerations**

Ethical approval for the study was obtained from the Newcastle and North Tyneside Research Ethics Committee. The collection of pseudo-anonymised patient identifiable data with consent was granted support for 12 months under Section 60 of the Health and Social Care Act 2001 by the NHS Patient Information Advisory Group. We intend to collect completely anonymised patient data subsequently so that this approval will no longer be required.

### **References**

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**Additional files provided with this submission:**

Additional file 1 : Test ordering diabetes protocol for Impl Sci CONSORT  
checklist.d : 48Kb

<http://www.implementationscience.com/imedia/2074542560106646/sup1.DOC>