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RESEARCH

Risk of colorectal cancer seven years after flexible sigmoidoscopy screening: randomised controlled trial

Geir Hoff,[1,2] Tom Grotmol,[1] Eva Skovlund,[3] Michael Bretthauer,[1,4] for the Norwegian Colorectal Cancer Prevention Study Group

EDITORIAL by Imperiale

[1]Norwegian Colorectal Cancer Prevention (NORCCAP) Centre, Cancer Registry of Norway, Montebello, NO-0310 Oslo, Norway
[2]Department of Medicine, Telemark Hospital, NO-3710 Skien, Norway
[3]School of Pharmacy, University of Oslo, NO-0316 Oslo
[4]Department of Gastroenterology, Rikshospitalet University Hospital, NO-0027 Oslo
Correspondence to: G Hoff, Cancer Registry of Norway, P O Box 5313 Majorstuen, 0304 Oslo, Norway
hofg@online.no

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ABSTRACT

Objective To determine the risk of colorectal cancer after screening with flexible sigmoidoscopy.

Design Randomised controlled trial.

Setting Population based screening in two areas in Norway—city of Oslo and Telemark County (urban and mixed urban and rural populations).

Participants 55 736 men and women aged 55-64 years.

Intervention Once only flexible sigmoidoscopy screening with or without a single round of faecal occult blood testing (n=13 823) compared with no screening (n=41 913).

Main outcome measures Planned end points were cumulative incidence and mortality of colorectal cancer after 5, 10, and 15 years. This first report from the study presents cumulative incidence after 7 years of follow-up and hazard ratio for mortality after 6 years.

Results No difference was found in the 7 year cumulative incidence of colorectal cancer between the screening and control groups (134.5 *v* 131.9 cases per 100 000 person years). In intention to screen analysis, a trend towards reduced colorectal cancer mortality was found (hazard ratio 0.73, 95% confidence interval 0.47 to 1.13, P=0.16). For attenders compared with controls, a statistically significant reduction in mortality was apparent for both total colorectal cancer (hazard ratio 0.41, 0.21 to 0.82, P=0.011) and rectosigmoidal cancer (0.24, 0.08 to 0.76, P=0.016).

Conclusions A reduction in incidence of colorectal cancer with flexible sigmoidoscopy screening could not be shown after 7 years' follow-up. Mortality from colorectal cancer was not significantly reduced in the screening group but seemed to be lower for attenders, with a reduction of 59% for any location of colorectal cancer and 76% for rectosigmoidal cancer in per protocol analysis, an analysis prone to selection bias.

Trial registration Clinical trials NCT00119912.

INTRODUCTION

Symptoms of colorectal adenocarcinoma appear late in the course of the disease, and early surgery remains the only option for cure. For the past decade, screening for colorectal cancer with flexible endoscopes has been advocated in the United States.[1] Several European countries have recently launched colonoscopy screening programmes for the general population.[2 3]

Evidence shows that endoscopic screening may prevent colorectal cancer by detection and removal of premalignant, adenomatous polyps.[4-6] This effect might, however, have been overestimated, as the extent of spontaneous regression of adenomas is largely unknown and randomised trials on screening are lacking.[7] The NORwegian Colorectal CAncer Prevention (NORCCAP) trial 1 is a population based randomised controlled trial, comparing once only flexible sigmoidoscopy with no screening. The primary end point of the study is incidence of colorectal cancer at 5, 10, and 15 years of follow-up. This paper presents the first results from the NORCCAP trial 1 on the incidence of colorectal cancer after a minimum of six years and mortality from colorectal cancer after a minimum of five years of follow-up.

METHODS

Population and participants—All residents aged 55-64 years living in the city of Oslo and Telemark County, Norway, who were registered and alive in the national population registry by November 1998 (n=55 736), were eligible. Of these, 13 823 randomly selected people (men and women, 1:1) were invited to once only flexible sigmoidoscopy screening. Fifty per cent of those invited (6908 people) were asked to provide three consecutive stool samples, to investigate the effect on compliance of adding a supplementary screening modality. People randomised to the control group (n=41 913) were not offered any screening, and follow-up was registry based.

Screening intervention—Screening examinations were done at two centres and a rural satellite screening unit between January 1999 and December 2000. All lesions detected at the screening examinations were subjected to tissue sampling and histopathological diagnosis. For faecal occult blood testing, we used an immunochemical test. We defined a positive screening test as any polyp 10 mm or more in diameter, any histologically verified adenoma, carcinoma, or a positive occult blood test. We defined screen detected colorectal cancers as lesions found at flexible sigmoidoscopy or during work-up colonoscopy of screen positive participants. People who fitted any of the following criteria were not screened but were included in the intention to screen analyses: previous open colorectal surgery, ongoing cytotoxic

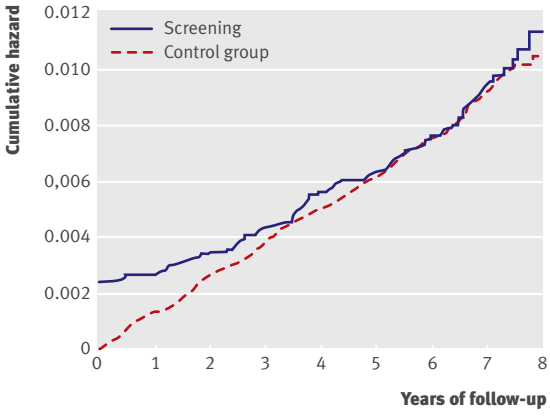

Fig 1 | Cumulative hazard for colorectal cancer in screening and control groups

treatment or radiotherapy for malignant disease, severe chronic cardiac or pulmonary disease, lifelong anticoagulant treatment, a coronary event during the previous three months, and cerebrovascular accident during the previous three months.

Study entry—The date of entry into the study for the screening group was the date of the screening appointment. Individual entry dates within the same time period were randomly allocated for the control group.

Outcomes—The primary end point is incidence of colorectal cancer to be reported after 5, 10, and 15 years of follow-up on an intention to screen basis. Further end points are mortality from and incidence of colorectal cancer within the reach of the flexible sigmoidoscope for screening attenders.

Follow-up—In Norway, reporting of data on any incident cancer to the cancer registry of Norway and on any cause of death to the Norwegian cause of death registry is compulsory. We retrieved all incident cases of colorectal cancer from the cancer registry. The end of follow-up for incidence of colorectal cancer was 31 December 2006. Information on cause specific death came from the Norwegian cause of death registry. The end of follow-up for cause specific death was 31 December 2005. Assessment of both the cause of death and colorectal cancer staging was blinded to the group status of participants.

Statistical methods—We present results as cumulative incidence rates. We illustrate time to colorectal cancer by estimating the cumulative hazard function. We analysed mortality from colorectal cancer and total mortality by using Cox proportional hazards model. We estimated cumulative hazard rates in the screening and control groups. We censored all time to event data at the end of the follow-up period and at emigration. For analyses of incidence of colorectal cancer and estimates of cumulative hazard we censored data at death and at diagnosis of colorectal malignancy other than adenocarcinoma.

RESULTS

Altogether, 753 cases of colorectal cancer or death occurred before the study entry date. This left 13 653 people in the screening group and 41 092 in the control group. Censoring owing to emigration occurred for 1196 people, and 21 people were censored as a result of colorectal malignancy other than colorectal carcinoma. In the screening group, 459 people were excluded from examination.

The two groups were similar in the distribution of age (mean 59 years) and sex (50% female in both groups). Of the 13 653 people eligible, 8846 had a screening examination, giving an attendance rate of 64.8%. At screening, a neoplastic lesion was found in 19% (1685/8846) of people screened, and 5.0% (440/8846) of attenders had high risk adenoma (≥10 mm in diameter, high grade dysplasia or villous components) or invasive cancer.[8]

Median follow-up was seven (range six to eight) years for incident colorectal cancer and six (range five to seven) years for mortality from colorectal cancer. We found no difference in the cumulative hazard of colorectal cancer between the screening group and the control group (intention to screen analysis; 134.5 *v* 131.9 cases per 100 000 person years) (fig 1). The accumulated number of colorectal cancers after six to eight years of follow-up was 123 in the screening group, including 33 screen detected tumours, and 362 in the control group. In the two screening groups, 54 accumulated colorectal cancers occurred in the flexible sigmoidoscopy group (7.9 per 1000) and 69 (10.1 per 1000) in the group invited to combined flexible sigmoidoscopy and faecal occult blood testing. When we restricted the cumulative hazard plot to attenders and rectosigmoidal cancers only, the line crosses that of the control group, suggesting an imminent effect of polypectomy for left sided colorectal cancer in those attending for screening (fig 2). The cumulative incidence of rectosigmoidal cancer was 35 cases in 8846 attenders (58 per 100 000 person years) and 217 in 41 092 controls (79 per 100 000 person years) (P=0.103). Of 90 post-screen incident colorectal cancers in the screening group, 37 appeared among 6915 people invited for flexible sigmoidoscopy only (5.4 per 1000) compared with 53 in 6908 people invited for combined flexible sigmoidoscopy and faecal occult blood testing (7.7 per 1000).

A total of 24 of 13 653 people in the screening group and 99 of 41 092 in the control group died from colorectal cancer during follow-up. In the screening group

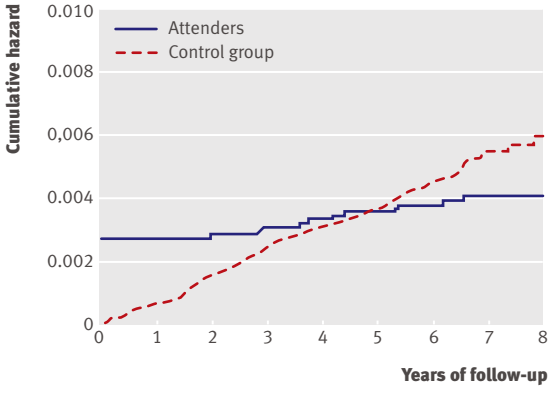

Fig 2 | Cumulative hazard for rectosigmoidal cancer among attenders compared with control group

WHAT IS ALREADY KNOWN ON THIS TOPIC

Screening for colorectal cancer by endoscopy (flexible sigmoidoscopy and colonoscopy) has been advocated and implemented in several countries without previous randomised trials

Screening for faecal occult blood is a poor method for detection of colorectal cancer precursor lesions (adenomas) compared with endoscopy

Quantification of the effects of endoscopic screening has not been investigated through randomised trials

WHAT THIS STUDY ADDS

A non-significant reduction in mortality from colorectal cancer after six years of follow-up was seen in intention to screen analysis

The accumulated incidence rates of colorectal cancer were similar in the screening and the control groups, suggesting that seven years' follow-up may be too early to see any reduction in incidence

The risk of mortality from colorectal cancer for attenders was less than half that seen in controls; it was smaller for rectosigmoidal cancer than for all colorectal cancers

as a whole, total mortality was reduced by 27% (hazard ratio 0.73, 95% confidence interval 0.47 to 1.13, P=0.16) for colorectal cancer and by 37% (0.63, 0.34 to 1.18, P=0.15) for rectosigmoidal cancer compared with the control group. For those actually screened, total mortality was reduced by 59% (hazard ratio 0.41, 0.21 to 0.82, P=0.011) for colorectal cancer and by 76% (0.24, 0.08 to 0.76, P=0.016) for rectosigmoidal cancer; this corresponded to three and 57 deaths from rectosigmoidal cancer. All cause mortality was similar in the screening group and the control group (hazard ratio 1.02, 0.98 to 1.07, P=0.28).

DISCUSSION

Is it too early to see an effect in intention to screen analyses?

The flat incidence curve for rectosigmoidal cancer in attenders (fig 2) illustrates that attendance for flexible sigmoidoscopy screening is associated with a reduced risk of post-screening rectosigmoidal cancer, whether this is due to self selection of people at low risk, a high screening detection rate for established cancers, or a genuine effect of polypectomy in preventing cancer. Attenders in the NORCCAP trial 1 had a modestly lower risk profile compared with the control group.[9] Thus, a major "healthy screenee" effect does not seem to be occurring in this study.

We found a trend towards reduced mortality from colorectal cancer for both total colorectal cancer mortality (27% reduction) and rectosigmoidal cancer mortality (37%), but this was not statistically significant in intention to screen analysis. Corresponding reductions in mortality among attenders were 59% and 76%, both statistically significant compared with the control group. However, one should bear in mind the inherent risk of selection bias in looking at attenders only.

Two possibilities could explain the limited effect of screening in this study: either the method is not effective in reducing incidence of colorectal cancer or the lag period for the development of cancer from precursor lesions is longer than is commonly assumed. The second possibility is more likely, as Cuzick and associates pointed out.[10] Contamination of the control group with colonoscopy is not a likely explanation for our findings, as no organised screening for colorectal cancer occurs in Norway.

How to evaluate with a high proportion of prevalent, screen detected cancers

Prevalent (screen detected) colorectal cancers will dilute any incidence reducing effect of polypectomy. Selectively excluding prevalent screen detected colorectal cancers from the analysis would give an apparently highly significant effect of screening with flexible sigmoidoscopy in reducing the incidence of rectosigmoidal cancer for people who attend, but this leads to severe bias. As the similar group of prevalent cancer cases cannot be identified and excluded from the control group, this type of analysis would overestimate the screening effect.

Previous case-control and observational studies, as well as a small scale randomised trial, have indicated that endoscopic screening may reduce the incidence of colorectal cancer by 50-90%.[4-6 11] Our results indicate that screening with flexible sigmoidoscopy may detect close to 50% of neoplastic lesions already malignant or destined to turn malignant. This is consistent with estimates from Danish and Canadian studies.[12 13] Some differences exist in diagnostic yield between ongoing studies of screening with flexible sigmoidoscopy. The pick-up rates for both any neoplasia (19%) and advanced neoplasia (5%) in our study were comparable to or higher than those in the ongoing British (12% and 5%) and Italian (12% and 3.4%) flexible sigmoidoscopy screening trials.[8 14 15] It will be interesting to follow these studies with their differences in baseline pick-up rates and polyp size dependent thresholds for a work-up colonoscopy.

Our results indicate that screening with flexible sigmoidoscopy may not reduce the overall incidence of colorectal cancer to the extent and within the timeframe expected at a population level, but it seems to be promising for reducing the incidence of rectosigmoidal cancer among attenders. The results also indicate a need to look into alternative screening modalities. Screening with colonoscopy has not yet been subjected to adequately designed randomised trials. Our findings on polypectomy for prevention of colorectal cancer may not automatically be extrapolated from the rectosigmoidal segment and flexible sigmoidoscopy to the entire colon and colonoscopy, as the risk profiles and natural course may be quite different for proximal and distal colorectal cancers.

Conclusions

The effect of screening with flexible sigmoidoscopy and polypectomy on reducing the incidence of colorectal cancer may be lower and will certainly occur later than anticipated. A large proportion of screen detected colorectal cancers makes it uncertain whether the observed flattening of the incidence curve during the first years after screening is a genuine preventive effect on colorectal cancer by removal of adenomas. The findings,

however, suggest an incidence reducing effect on distal colorectal cancer, matched by a 76% reduction in mortality for people attending screening.

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Effect of the quality and outcomes framework on diabetes care in the United Kingdom: retrospective cohort study

Melanie J Calvert,[1] Aparna Shankar,[2] Richard J McManus,[1] Helen Lester,[3] Nick Freemantle[1]

[1]Department of Primary Care and General Practice, University of Birmingham, Edgbaston, Birmingham B15 2TT
[2]Department of Epidemiology and Public Health, University College London
[3]National Primary Care Research and Development Centre, University of Manchester
Correspondence to: M Calvert
m.calvert@bham.ac.uk

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ABSTRACT

Objectives To examine the management of diabetes between 2001 and 2007 in the United Kingdom and to assess whether changes in the quality of care reflect existing temporal trends or are a direct result of the implementation of the quality and outcomes framework.
Design Retrospective cohort study.
Setting 147 general practices (annual list size over 1 million) across the UK.
Patients People with type 1 or type 2 diabetes.
Main outcome measures Annual prevalence of diabetes and attainment of process and clinical outcomes over the three years before and the three years after the introduction of the quality and outcomes framework.
Results Significant improvements in process and intermediate outcome measures were observed during the six year period, with consecutive annual improvements observed before the introduction of incentives. However, the current diagnostic case definition for the quality and outcomes framework does not capture up to two thirds of people with type 1 diabetes and a third of people with type 2 diabetes. After the introduction of the quality and outcomes framework, existing trends of improvement in glycaemic control, cholesterol levels, and blood pressure were attenuated, particularly in people with diabetes who did not meet the case definition of the quality and outcomes framework. The introduction of the quality and outcomes framework did not lead to improvement in the management of patients with type 1 diabetes, nor to a reduction in the number of patients with type 2 diabetes who had HbA_{1c} levels greater than 10%. Introduction of the quality and outcomes framework may have increased the number of patients with type 2 diabetes with HbA_{1c} levels of ≤7.5%;

odds ratio 1.05 (95% confidence interval 1.01 to 1.09; P=0.02).

Conclusions The management of people with diabetes has improved since the late 1990s, but the impact of the quality and outcomes framework on care is not straightforward; upper thresholds may need to be removed or targets made more challenging if people are to benefit. Many patients in whom care may be suboptimal may not be captured in the quality and outcomes framework assessment.

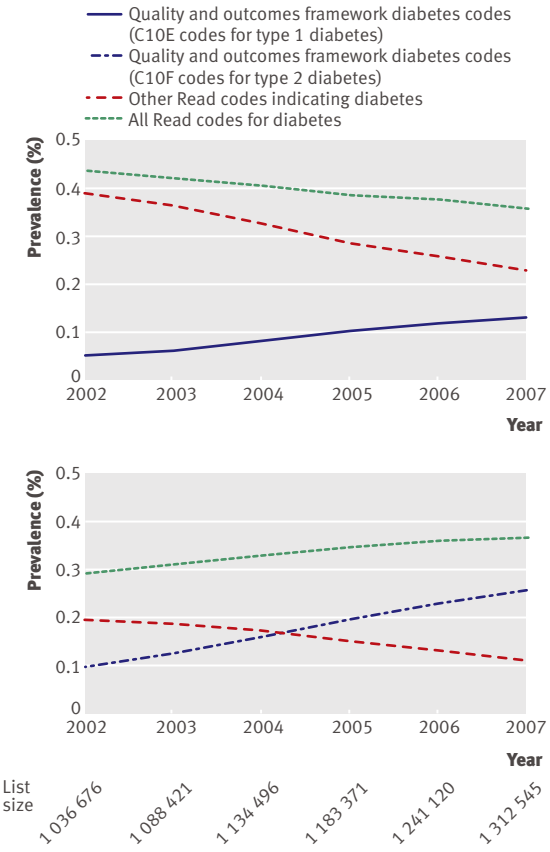
INTRODUCTION

In April 2004 the quality and outcomes framework was introduced in the United Kingdom.[1] This scheme offers general practitioners financial rewards for achieving a series of process outcomes (what is done in giving and receiving care) and intermediate outcomes (changes in health that affect subsequent health outcomes) that should improve the quality of patient care. Data on people with diabetes are identified in the quality and outcomes framework using Read codes, a system for coding clinical data.[2] When the quality and outcomes framework was introduced, people with diabetes were identified from the presence of any diabetes Read code (C10 and any codes below). In April 2006 the definition for diabetes was changed to a narrower set of codes; type 1 diabetes mellitus (C10E hierarchy) and type 2 diabetes mellitus (C10F hierarchy).[3] Interpretation of the change in the quality and outcomes framework indicators has proved difficult because of this change.[3 4] Even use of the less specific C10 codes may exclude some people with diabetes from evaluation through the quality and outcomes framework.

Owing to the limitations of previous studies, it remains unclear to what extent the introduction of incentives has impacted on existing temporal trends.[5] We examined the prevalence of diabetes and the proportion of people meeting targets for diabetes management annually three years before and three years after the introduction of the quality and outcomes framework (April 2002 to March 2007). We also assessed the impact of the scheme on glycaemic control, cholesterol levels, and blood pressure in people with type 1 and type 2 diabetes.

METHODS

We obtained data from the doctors' independent network (DIN)-LINK database.[6 7] The age-sex structure of the database has been shown to be similar to the UK average, but with over-representation of practices in the south of England and higher socioeconomic groups.[8] We identified people with a diagnosis of diabetes from practices with data over a 10 year period (1 April 1997 to 31 March 2007) if they had a Read code for diabetes or one or more prescriptions for oral antidiabetic drugs, insulin, or glucose testing kits. People were classified as having type 1 diabetes if they were prescribed insulin (or insulin device), lacked a Read code for type 2 diabetes, or had any prescription for an oral antidiabetic drug. The remaining people were classified as having type 2 diabetes.



Prevalence of type 1 and type 2 diabetes across study period

To interpret the effect of the change in diagnostic case definition from April 2006, we also identified the first occurrence of codes in the C10E and C10F hierarchies for people during the study period.[3] We estimated the prevalence of diabetes annually on 31 March from 2002-7.

We carried out analyses on attainment of diabetes and smoking outcomes using data between 1 January 2001 and 31 March 2007, as annual targets in the quality and outcomes framework are assessed over 15 months.[9] For our principal analyses we considered all people with diabetes. In the primary analyses we excluded diabetes exception reporting codes (9h4 hierarchy) with no reason for exception given.

We assessed the relation between attainment of glycaemic targets (HbA_{1c} levels ≤7.5% and ≤10%) and year of assessment, introduction of the quality and outcomes framework, and evidence of the new coding definitions, using mixed models with a logit link and binomial error and a random effect term describing the effect of practice with a Gaussian error structure using the SAS nlmixed procedure. Four models were produced: HbA_{1c} level ≤7.5% or ≤10% in people with type 1 and type 2 diabetes. For patients with multiple HbA_{1c} assessments recorded during each year we used the latest assessment before the quality and outcomes framework reference date. We assessed linear and

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non-linear functional forms (natural logarithm and exponential functions) for year. To allow for a sudden shift in the rate of change as a result of the introduction of the quality and outcomes framework in addition to annual changes we used an additional variable to indicate whether the framework was being implemented.

RESULTS

Overall, 147 of the 300 practices contributing to the DIN-LINK database had usable data over the study period, of which 34 (23%) provided pharmacy dispensing services. The mean list size on 31 March 2007 was 8929 (SD 4147). During the six years of the study period (2002-7) the prevalence of type 1 diabetes remained stable whereas that of type 2 diabetes increased (figure).

Improvements in all diabetes indicators were observed (see bmj.com). The proportion of people with type 1 diabetes attaining process targets (except testing for microalbuminuria) was greater than 70% in 2007. The proportion of people with type 2 diabetes attaining these targets was higher.

The proportion of people attaining intermediate outcomes also improved over time but was lower than that for process targets. The proportion of people attaining targets for glycaemic control, cholesterol level, and blood pressure showed attenuation of annual trends in improvement after the introduction of the quality and outcomes framework (see bmj.com). This effect appeared greater for those attaining glycaemic control.

Model results (table) showed significant annual increases in the proportion of people attaining HbA_{1c} targets. Attainment was significantly higher in those people with a quality and outcomes framework diagnostic Read code (except people with type 1 diabetes and an HbA_{1c} target ≤10%). Introduction of the quality and outcomes framework was only significantly associated with an increase in the proportion of people attaining HbA_{1c} target ≤7.5% in people with type 2 diabetes, and this effect was relatively small.

Of 3811 people with type 1 diabetes in the most recent (2007) cohort, 1228 had a C10E code and would be assessed in the quality and outcomes framework. Of the remainder, none had a Read code indicating type 2 diabetes and all had a prescription for insulin but no oral antidiabetic drug before the reference date. Exploratory analyses indicated that people with a C10E code were younger than those without a C10E code (mean 40.6 *v* 50.4 years; P<0.001). They were also more likely to be men (61.4% *v* 55.3%, P<0.001). Of 42 032 people with type 2 diabetes in the cohort, 29 674 had a C10F code. Of the remainder, 8994 (72.8%) had either a prescription for an oral agent and insulin (insulin device) before the reference date or a Read code indicating diabetic treatment. Overall, 2460 people (19.9%) had either the broader diabetes Read codes (C10 hierarchy) or the codes indicating screening for, or complications associated with, diabetes. Of the remaining people, 904 (7.3%) had codes indicating assessment or care of diabetes. People with a C10F code were older than those without a C10F code (mean 66.1 *v* 63.5 years; P<0.001). They were also more likely to be men (55.2% *v* 51.8%, P<0.001) and to belong to a higher socioeconomic class (66.8% *v* 58.3%; P<0.001).

DISCUSSION

Significant improvements were seen in all of the quality and outcomes framework clinical indicators over time for diabetes care in the UK. People with type 2 diabetes generally underwent more testing for diabetes related complications than people with type 1 diabetes. This might reflect a higher proportion of people with type 1 diabetes receiving specialist care that may not be as well recorded in primary care records.[10] By the end of the study, attainment of process measures was high. Whether this was a direct result of the quality and outcomes framework or reflects existing trends in improvement of care over time in response to other driving factors remains unclear.[5]

Relation between glycaemic control with time, introduction of quality and outcomes framework, and meeting diagnostic case definition of quality and outcomes framework

	HbA_{1c} target ≤7.5%		HbA_{1c} target ≤10%	
Variables	Odds ratio (95% CI)	P value	Odds ratio (95% CI)	P value
Type 1 diabetes:				
Year	1.02 (1.01 to 1.04)†	0.003	1.06 (1.03 to 1.08)	<0.001
Quality and outcomes framework	*	*	*	*
Presence of C10E Read code	1.41 (1.24 to 1.59)	<0.001	0.72 (0.64 to 0.80)	<0.001
Year and presence of C10E Read code	0.97 (0.90 to 1.0)†	0.04	*	*
Type 2 diabetes:				
Year	1.06 (1.05 to 1.08)	<0.001	+2.51 (2.13 to 2.95)	0.001
Quality and outcomes framework	1.05 (1.01 to 1.09)	0.02	*	*
Presence of C10F Read code	1.67 (1.64 to 1.71)	<0.001	1.68 (1.61 to 1.75)	<0.001

Years were coded in model as −3 to 2 to indicate their relation to introduction of quality and outcomes framework unless otherwise stated.
*Variable not included in final model as non-significant (P>0.05).
†Year with an exponential transformation.
+Year with log transformation (rescaled years as 1 to 6). Although this rescaled log transformed model had best model fit as judged by Akaike's information criterion, this metric is difficult to interpret practically.

WHAT IS ALREADY KNOWN ON THIS TOPIC

Since the introduction of the quality and outcomes framework in the United Kingdom, a series of studies has suggested an improvement in the management of people with diabetes in primary care

It remains unclear to what extent the introduction of incentives has had an impact on existing temporal trends

WHAT THIS STUDY ADDS

Significant improvements in diabetes care were observed from 2002-7, although this does not seem to be a direct result of the quality and outcomes framework

Many people in whom care may be suboptimal do not seem to be captured in the quality and outcomes framework assessment owing to the current diagnostic case definition

Significant improvements in intermediate outcomes were observed, with successive improvements before the introduction of the quality and outcomes framework. This could be due to awareness among general practitioners of its impending introduction or the influence of clinical governance initiatives. After the introduction of the quality and outcomes framework, the trends appear to be attenuated. One study observed a modest acceleration in the improvement of care between 2003 and 2005 compared with 1998 to 2003, which the authors suggested might have been associated with the introduction of pay for performance.[5] In our study, outcomes improved between 2002 and 2005, with attenuation in improvement between 2005 and 2007. This attenuation could reflect the increasing difficulty of target attainment in poorly controlled people,[11] or reflect the lack of further incentive after attainment of the upper payment thresholds (ceiling effect).

In 2007 the monitoring and control of glycaemia still seemed suboptimal in some people, with over 10% of people having no record of an HbA_{1c} level or equivalent in the previous 15 months. Twenty six per cent of people with type 1 diabetes and 17% with type 2 diabetes had an HbA_{1c} level of more than 10%, and 41% of people with type 2 diabetes and 74% with type 1 diabetes had an HbA_{1c} level of more than 7.5%. The introduction of the quality and outcomes framework seems to be significantly associated with better glycaemic control in people with type 2 diabetes for the more stringent target (≤7.5%), although the quality and outcomes framework did not seem to significantly predict attainment of the higher target (≤10%), and attenuation in trends was observed for both targets.

Subgroup analyses of attainment of intermediate outcomes by patients with or without a Read code meeting the quality and outcomes framework case definition indicate that people included in the quality and outcomes framework denominator, and particularly those with type 2 diabetes, were more likely to attain the targets. Our finding that older people, men, and those from affluent backgrounds seem more likely to have a specific C10F code and therefore be assessed within the quality and outcomes framework is consistent with others' work and raises concerns that the scheme may not have been as efficient in reducing inequalities in diabetes care as hoped.[12 13] Detailed assessment of Read codes and prescriptions for patients that did not meet the current case definition for the quality and outcomes framework indicates that an important group of people that seem to have diabetes are no longer included within the quality and outcomes framework.

Strengths and limitations of the study

The mean prevalence in our study based on the quality and outcomes framework case definition was lower than reported nationally by Department of Health systems (2.7% *v* 3.7%),[14] although over 90% of practices included in the quality and outcomes framework reported a prevalence within our observed range. This may in part reflect the under-representation of practices in deprived areas, which tend to have higher proportions of people from ethnic minority groups and hence diabetes, in the database used in this study.[15-17] The practices included in the (DIN)-LINK database have a similar age-sex structure to that of the UK population but have been shown to over-represent practices in the south of England and higher socioeconomic groups.[8] Also, the practices included in this study were selected because they had high quality data for a 10 year period. These practices included a relatively high proportion of dispensing practices. Such practices might provide a different level of care, possibly higher, than those that do not meet such criteria. Furthermore, some patients seen in our practices might have increased uptake and possibly compliance with therapy because of accessibility to dispensing services.

Although the inclusion of people without C10 or the more specific C10E and C10F codes in the analysis might be criticised, other Read codes were more commonly in use before April 2006. As we aimed to assess the management of people with diabetes over time and the impact of the quality and outcomes framework, it was important to avoid spurious trends as a result of changes in diagnostic case definition.[4] We also included people with codes for exception reporting as these codes were not in use before April 2005.

Conclusions

The management of people with diabetes in the UK has improved since the late 1990s. The relation between incentives and attainment of targets may not, however, be as straightforward as thought. Pay for performance may have contributed to the improvement in diabetes care but the relative importance of the quality and outcomes framework to other national quality improvement strategies is unclear. The scheme fails to capture almost one third of people in whom care may be suboptimal and may lead to reduced levels of care for some groups of patients.

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Competing interests: MJC, AS, RJM, and NF have received funding for research, consulting, and travel from several companies that manufacture therapies for diabetes.

Ethical approval: This study went through our formal institutional review process and it was agreed that no further ethical review was required.

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CORRECTIONS AND CLARIFICATIONS

The week in numbers

In our "Week in numbers" box at the front of the print publication of 16 May (*BMJ* 2009;338) we wrongly stated "1.8 million: Number of prostate cancer cases in the UK (Research, p 1187)." In fact, the Research article stated, correctly, that "there are 1.8 million cases [of benign prostatic enlargement] in the United Kingdom"—which is a very different kettle of fish. We apologise for the mistake.

Polyclinics could be focus of care for offenders with mental health problems, author of report says

In this news story by Lynn Eaton about the report by Lord Bradley into the treatment of people with mental health problems or learning difficulties in the criminal justice system (*BMJ* 2009;338:b1841, print publication 9 May, p 1098), we stated wrongly that his report concluded that polyclinics could have an important role to play in their care. In fact, that remark was made to the *BMJ* correspondent by the author of the report in a discussion after the press conference. The error arose during the editing of the article.

Cauda equina syndrome: examination must be thorough

In the process of editing this letter by Angelos G Kolias and colleagues (*BMJ* 2009;338:b1724, print publication 2 May, p 1027), we lost some of the authors' original message—that anal tone should always be part of the examination when cauda equina compression is suspected. Thus, the first sentence should have been: "As well as neurological examination of the legs, anal tone and perianal and perineal sensation should be assessed in cases of suspected cauda equina syndrome."

TARTS at the dinner table

As a result of an editorial processing error, we inadvertently omitted an author from the authorship of this filler (*BMJ* 2009;338:b1179, print publication 9 May, p 1144). The full authorship details are: Martin Nuttall, Guy's Hospital, London; and Anna McDonald, Department of Paediatrics, Addenbrooke's Hospital, Cambridge.

Effect of guideline based computerised decision support on decision making of multidisciplinary teams: cluster randomised trial in cardiac rehabilitation

An editorial mistake led to an incorrect author's affiliation in this research paper by Rick Goud and colleagues (*BMJ* 2009;338:b1440, print publication 9 May, p 1132). Professor Gerben ter Riet's primary affiliation is the Department of General Practice, Academic Medical Centre, University of Amsterdam—rather than the Department of Medical Informatics as shown.

Improving quality of mother-infant relationship and infant attachment in socioeconomically deprived community in South Africa: randomised controlled trial

In the print summary of this Research paper by Cooper and colleagues (*BMJ* 2009;338:b974, print publication 25 April, p 997) an editorial oversight led to the authors' final amendments not being incorporated. The "Design" section should have included the size of the intervention group (n=220) and should have specified that the authors used videotaped play observations to assess the quality of mother-child interactions at 6 and 12 months and infant attachment at 18 months post partum. The "Participants and setting" section should have specified that, of a consecutive series of 452 pregnant women, three refused to participate and 449 were recruited.

Diagnostic strategies used in primary care

In this article by C Heneghan and colleagues (*BMJ* 2009;338:b946, print publication 25 April, pp 1003-6), under the heading "Pattern recognition fit" in the section "Strategies in the refinement stage" (p 1004) we wrongly cited figure 2; it should have been figure 3.

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A comparison of fluoroquinolones versus other antibiotics for treating enteric fever: meta-analysis

Durrane Thaver,[1] Anita K M Zaidi,[1] Julia Critchley,[2] Asma Azmatullah,[1] Syed Ali Madni,[1] Zulfiqar A Bhutta[1]

EDITORIAL by Parry and Beeching

[1]Department of Paediatrics and Child Health, The Aga Khan University, PO Box 3500, Karachi 74800, Pakistan
[2]Institute of Health and Society, Newcastle University, Newcastle NE2 4HH
Correspondence to: A K M Zaidi
anita.zaidi@aku.edu

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STUDY QUESTION What is the extent and quality of evidence supporting the use of fluoroquinolones as first line agents over other antibiotics for treating typhoid and paratyphoid fever (enteric fever)?

SUMMARY ANSWER Clinical and microbiological failure rates in adults taking fluoroquinolones compared with chloramphenicol were not significantly different, but fluoroquinolones may reduce clinical relapses. Data were limited for other comparisons, particularly for children.

Selection criteria for studies

This meta-analysis was of randomised controlled trials identified from searches of the Cochrane Infectious Diseases Group specialised register, CENTRAL (issue 4, 2007), Medline (1966-2007), Embase (1974-2007), LILACS (1982-2007), selected conference proceedings, reference lists, and the ongoing trial register (in November 2007). We included randomised controlled trials comparing fluoroquinolones with chloramphenicol, cefixime, ceftriaxone, or azithromycin in culture-proved enteric fever in children and adults. Trials recruiting over 60% children were analysed separately from trials on adults.

Primary outcome(s)

We estimated odds ratios (95% confidence intervals) for clinical failure, microbiological failure, and relapse.

Main results and role of chance

Twenty trials were included. In trials on adults, fluoroquinolones were not significantly different from chloramphenicol for clinical failure (594 participants) (see table for odds ratios) or microbiological failure (n=378), but reduced clinical relapse (odds ratio 0.14 (95% CI 0.04 to 0.50), n=467). Azithromycin and fluoroquinolones seemed similar in two trials with insufficient numbers to detect any differences (n=152). Compared with ceftriaxone, fluoroquinolones reduced clinical failure (n=120) but not microbiological failure or relapse in small unblinded trials. Compared with cefixime, fluoroquinolones reduced clinical failure (n=238) and relapse (odds ratio 0.18 (0.03 to 0.91), n=218).

Only three of the 20 trials recruited children. In trials recruiting children infected with nalidixic acid resistant *Salmonella* serotypes Typhi and Paratyphi, older fluoroquinolones (ofloxacin) produced more clinical failures than azithromycin (n=125) (table), but there were no differences with newer fluoroquinolones (gatifloxacin, n=285). Fluoroquinolones and cefixime were not significantly different in one small trial (n=82).

Bias, confounding, and other reasons for caution

The included trials were small and often of limited methodological quality (assessed by method of randomisation, allocation concealment, blinding, and follow-up). Only 10 trials concealed allocation and only three were blinded, thus most of the included trials were susceptible to bias. Publication bias could not be ruled out entirely.

We identified few trials that recruited children, even though this age group has the highest burden of typhoid fever. Current recommendations for optimal treatment for enteric fever in children are not based on high quality evidence.

Study funding/potential competing interests

The study was supported by the Aga Khan University, Karachi, Pakistan, and by the Cochrane Infectious Diseases Group, UK, which is funded by the UK Department for International Development (DFID) for the benefit of developing countries.

SUMMARY OF EVIDENCE FOR EFFECTIVENESS OF FLUOROQUINOLONES VERSUS OTHER DRUGS IN TREATING ENTERIC FEVER

Antibiotics compared with fluoroquinolones	No of trials with allocation concealment	No of trials with blinding	Odds ratios (95% CI) for clinical failure with fluoroquinolone v other drug
Adults			
Chloramphenicol	2/10	3/10	0.65 (0.25 to 1.72), n=594
Azithromycin	2/2	0/2	3.32 (0.63 to 17.43), n=152
Ceftriaxone	2/3	0/3	0.08 (0.01 to 0.45), n=120
Cefixime	1/ 2	0/2	0.05 (0.01 to 0.24), n=238
Children			
Azithromycin*	1/1	0/1	2.67 (1.16 to 6.11), n=125
Azithromycin*†	1/1	0/1	0.96 (0.30 to 3.06), n=285
Cefixime	1/1	0/1	0.12 (0.01 to 1.02), n=82

**With high proportion of children infected with nalidixic acid resistant strains*
†Versus new generation fluoroquinolone (gatifloxacin)

BMJ pico: advice to authors

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To increase readership of research articles in the print *BMJ* and to give authors more control over the abridging, we are piloting a new way of abridging research articles for the print *BMJ*—publishing what is essentially an evidence abstract called BMJ pico. We hope that you will want to take part in this pilot if your research article is accepted. There is no need to prepare a BMJ pico in advance, however—please wait until we have offered to publish your article.

pico

Video decision support tool for advance care planning in dementia: randomised controlled trial

Angelo E Volandes,[1] Michael K Paasche-Orlow,[2] Michael J Barry,[1] Muriel R Gillick,[3] Kenneth L Minaker,[1] Yuchiao Chang,[1] E Francis Cook,[4] Elmer D Abbo,[5] Areej El-Jawahri,[1] Susan L Mitchell[6]

[1]General Medicine Unit, Department of Medicine, Massachusetts General Hospital, 50 Staniford Street, Boston, MA 02114, USA
[2]Department of Medicine, Boston University School of Medicine, 715 Albany Street, Boston, MA 02118, USA
[3]Department of Ambulatory Care and Prevention, Harvard Medical School/Harvard Pilgrim, 133 Brookline Ave, Boston, MA 02215, USA
[4]Department of Medicine, Brigham and Women's Hospital, 1620 Tremont Street, Boston, MA 02115, USA
[5]Department of Medicine, University of Chicago, 5801 South Ellis, Chicago, IL 60637, USA
[6]Hebrew SeniorLife, 1200 Centre Street, Boston, MA 02131, USA

Correspondence to: A E Volandes
avolandes@partners.org

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STUDY QUESTION Could a video decision support tool after a verbal description of advanced dementia improve end of life decision making for older patients, resulting in improved knowledge of the disease state and more stable preferences over time compared with just a verbal description?

SUMMARY ANSWER Older people who view a video depiction of a patient with advanced dementia after hearing a verbal description are more likely to opt for comfort as their goal of care, have more knowledge of the disease, and have more stable preferences over time compared with those who solely listen to a verbal description.

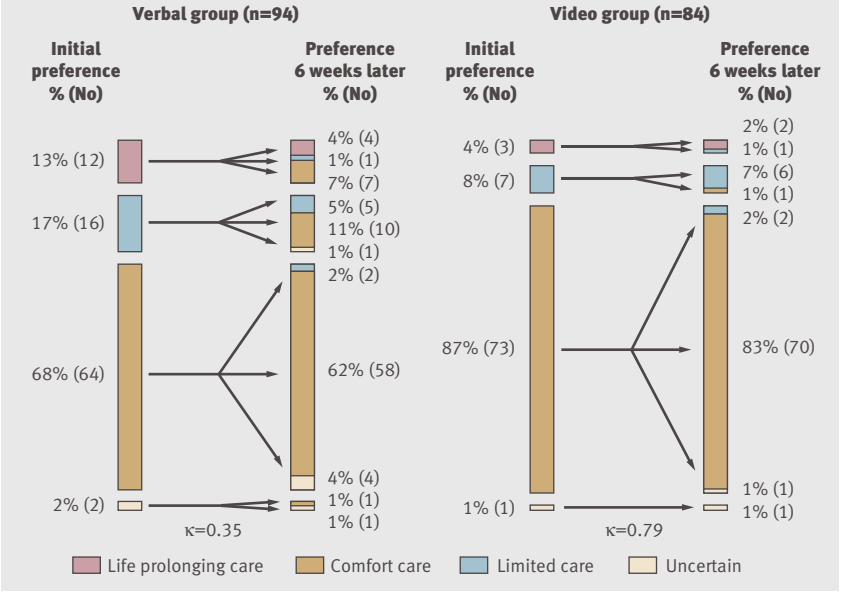
Design

This was an unblinded randomised controlled trial of participants who were randomised based on a computer generated scheme and then were called by telephone six weeks later. The video can be seen on bmj.com and at www.ACPdecisions.com.

Participants and setting

Participants were older people (≥65) living in the community who had previously scheduled appointments at one of four primary care clinics in Boston (two geriatric and two adult medicine) affiliated with three academic medical centres.

INITIAL PREFERENCES AND STABILITY OF PREFERENCES AFTER SIX WEEKS



Primary outcomes

End points were the preferred goal of care: life prolonging care (cardiopulmonary resuscitation, mechanical ventilation), limited care (admission to hospital but not cardiopulmonary resuscitation), or comfort care (symptom relief only); and the stability of preferences after six weeks.

Main results and the role of chance

Two hundred participants were randomised to verbal narrative (n=106) or video after verbal narrative (n=94). Among those receiving the verbal narrative, 68 (64%) chose comfort care, 20 (19%) chose limited care, 15 (14%) chose life prolonging care, and three (3%) were uncertain. In the video group, 81 (86%) chose comfort care, eight (9%) chose limited care, four (4%) chose life prolonging care, and one (1%) was uncertain (χ^2=13.0, df=3, P=0.003). In multivariable analysis, participants in the video group were more likely to prefer comfort care than those in the verbal group (adjusted odds ratio 3.9, 95% confidence interval 1.8 to 8.6). After six weeks, the proportion of participants changing their preferences was greater in the verbal group (P<0.001): in the verbal group 94/106 (89%) participants were interviewed and 27 (29%) changed preferences (κ=0.35); in the video group 84/94 (89%) participants were interviewed and five (6%) changed preferences (κ=0.79).

Harms

There were no adverse events reported.

Bias, confounding, and other reasons for caution

The research staff collecting data were not blinded to randomisation.

Generalisability to other populations

Our sample was primarily white and African-American and drawn from metropolitan Boston.

Study funding/potential competing interests

AEV was supported by a George Bennett Fellowship from the Foundation for Informed Medical Decision Making, a New Investigator Research Grant from the Alzheimer's Association, and a Center for Excellence Career Development Award from the Hartford Foundation. None of the foundations participated in the collection, analysis, or interpretation of the data or in preparation, review, or approval of the manuscript.