Educational outreach to promote screening for tuberculosis in primary care: a cluster randomised controlled trial

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Summary

Background **Tuberculosis is re-emerging as an important health problem in industrialised countries. Uncertainty surrounds the effect of public-health control options. We therefore aimed to assess a programme to promote screening for tuberculosis in a UK primary health care district.**

Methods **In a cluster randomised controlled trial, we randomised 50 of 52 (96%) eligible general practices in Hackney, London, UK, to receive an outreach programme that promoted screening for tuberculosis in people registering in primary care, or to continue with usual care. Screening was verbal, and proceeded to tuberculin skin testing, if appropriate. The primary outcome was the proportion of new cases of active tuberculosis identified in primary care. Analyses were done on an intention-to-treat basis. This study was registered at clinicaltrials.gov, number NCT00214708.**

Findings **Between June 1, 2002, and Oct 1, 2004, 44 986 and 48 984 patients registered with intervention and control practices, respectively. In intervention practices 57% (13 478 of 23 573) of people attending a registration health check were screened for tuberculosis compared with 0·4% (84 of 23 051) in control practices. Intervention practices showed increases in the diagnosis of active tuberculosis cases in primary care compared with control practices (66/141 [47%] *vs* 54/157 [34%], odds ratio (OR) 1·68, 95% CI 1·05–2·68, p=0·03). Intervention practices also had increases in diagnosis of latent tuberculosis (11/59 [19%] vs 5/68 [9%], OR 3·00, 0·98–9·20, p=0·055) and BCG coverage (mean BCG rate 26·8/1000 vs 3·8/1000, intervention rate ratio 9·52, 4·0–22·7, p<0·001).**

Interpretation **Our educational intervention for promotion of screening for tuberculosis in primary care improved identification of active and latent tuberculosis, and increased BCG coverage. Yield from screening was low, but was augmented by improved case-finding. Screening programmes in primary care should be considered as part of tuberculosis control initiatives in industrialised countries.**

Introduction

Many industrialised countries are witnessing a re-emergence of tuberculosis, notably in cities and in immigrant populations.[1–4] This trend matches the continuing rise in worldwide incidence of tuberculosis.[5] Much professional and public debate surrounds public-health policy in settings that have traditionally had low incidence. Screening is a common approach to tuberculosis control[2,6,7] endorsed by national guidelines,[8–10] but is of uncertain value, and has been criticised as ineffective and even unethical.[11–14] We know of no randomised trials that have addressed the effectiveness of screening in low-incidence settings. At present, policy is based on observational data and modelling.[6,8,13,15]

Our aim was therefore to measure the effectiveness of screening patients for tuberculosis when they registered with primary care practices in a UK primary care health district (City and Hackney Teaching Primary Care Trust).

Methods

Procedures and participants

We developed[16] a cluster randomised controlled trial of an outreach programme to promote screening for tuberculosis in primary care in Hackney, London, UK, a deprived, ethnically diverse borough with high numbers of residents born outside the UK, and a rising yearly incidence of tuberculosis, presently 66 cases per 100 000 people (15 per 100 000 people in the general population of England and Wales).[17] Our programme promoted verbal screening and tuberculin skin testing by practice nurses of new patients registering in primary care and raised clinician's awareness of tuberculosis during routine consultations.

We did a pragmatic cluster randomised controlled trial to measure the effectiveness of implemention of the screening programme in one health district (City and Hackney Teaching Primary Care Trust).

All but one of 53 general practices in the Hackney primary care trust were eligible, the ineligible practice was a pilot practice for this study.[16] We wrote to the remaining 52 practices, inviting them to join the study. Fifty practices (96%) agreed and the remaining two declined to participate. We chose a cluster randomisation design because our intervention was for groups of clinicians in practices. We randomised practices with a computer minimisation program (Minim Version 1.3), maintaining allocation concealment.[18] Minimisation criteria were number of partners in the general practice, employment of a practice nurse, approval for training of general practitioners, use of an EMIS practice computer system[19]

(which helped to support the screening software's reminder prompts), whether the surgery was registering new patients, rate of registration checks in new patients, and participation in a local scheme to promote registration of asylum seekers.

We screened new patients according to our previously reported method,[16] and complied with local guidelines adapted from national recommendations.[20,21] We first did verbal screening (eliciting BCG status, tuberculosis symptoms, migration history, and contact with cases of tuberculosis) to establish risk of tuberculosis, then did tuberculin skin testing with the Heaf method,[22] chest radiography, or referral, if appropriate. Our guidelines included algorithms to promote consistent decision-making and referral (webappendix).

Drawing on evidence for the effectiveness of educational outreach on clinician behaviour change[23] and our experience of trials testing interventions to change clinician behaviour in this setting,[24–26] we chose a multifaceted approach of practice-based education sessions, computerised screening reminder prompts, screening equipment, and financial incentives to encourage uptake of the screening intervention (panel).

Panel: Implementation of screening

Practice visits

A tuberculosis specialist nurse and a local academic GP (CG) made one educational outreach visit to each intervention practice to promote tuberculosis screening and raise awareness of tuberculosis as a local public health concern, and distributed copies of local tuberculosis screening guidelines with algorithms (webappendix).

Computer prompts

We incorporated prompts into the template for the practice computer system used for registration health check consultations to remind clinicians to ask the screening questions stipulated in the guidelines. These prompts comprised READ* coded items, such that a searchable code was entered in response to a positive answer to a screening question.

Equipment

We provided equipment for tuberculin skin testing: Heaf heads and guns, and tuberculin.

Support

We arranged telephone support by a tuberculosis specialist nurse for advice and to receive referrals.

Financial incentive

A financial incentive of £7 (10·2 Euros; US$12·9) was paid to the practice for every tuberculin skin test.

*READ codes are a coded thesaurus of clinical terms that enable clinicians to make effective use of computer systems. The codes facilitate the access of information within patient records to enable reporting, auditing, research, automation of repetitive tasks, electronic communication and decision support. The READ code is named after James Read who was a GP.

The educational visits to practices lasted an hour, were attended by the general practitioners and practice nurses, and used the social influence model of behaviour change.[23] At this visit, the two educators discussed recommendations from local tuberculosis screening guidelines, taught tuberculin skin testing using the Heaf method, and imported screening prompts into the practice computer system, and demonstrated their use. We discussed screening at health checks for newly registering patients and promoted awareness during routine consultations. The tuberculosis specialist nurse telephoned practices a week later to reinforce the education and deal with any difficulties in skin testing. The nurse continued to contact practices throughout the study to provide supplies for tuberculosis testing, and to provide encouragement.

See Online for webappendix

Control practices received no contact and continued with usual care. Several were doing some tuberculin skin testing before the study and continued to do so.

All study practices were provided with laminated information sheets describing the study for receptionists to show to new patients. These were available in the most common languages spoken by local residents (English, Turkish, Bengali, French, and Somali), and described the allocation of their practice to screening (intervention) or non-screening (control) groups. The research ethics committee approved an opt-out process, with valid implied consent in place of written informed consent. Patients in intervention practices could choose not to be screened, and patients in control practices could choose to be screened.

The primary outcome measure was the proportion of all cases of active tuberculosis identified in primary care. Secondary outcomes were the proportion of cases of latent tuberculosis identified in primary care, and the numbers of people aged 5 years and older receiving BCG immunisation, percentage of new registrations screened for tuberculosis, and numbers of tuberculin skin tests undertaken.

We identified all people notified with active tuberculosis registered with participating practices during the study (June 1, 2002, to Oct 1, 2004). De-notified cases were excluded. We obtained written consent from these patients to photocopy their primary care and secondary care medical records. Consent was obtained either during attendance at the local tuberculosis outpatients clinic, or in a few cases at home visits. Before copying the medical records, we removed the practice identity, including names of general practitioners, practice name, and its address from all medical records by covering these details with opaque tape. We photocopied records from 5 years before the date of tuberculosis diagnosis. Patients' electronic records were copied from practice computers with similar anonymity.

We prespecified the definition of a case identified in primary care at the start of the study and applied these independently to the medical records by two researchers blinded to practice allocation with arbitration of any differences (webtable 1) by a third researcher who was

See Online for webtable 1

Practice characteristic	Intervention practices (n=25)	Control practices (n=25)
Number of doctors		
1	7	6
2	8	7
3 or more	10	12
Proportion of patients registering in previous 2 years who attended registration checks*		
0–33%	3	4
34–66%	7	5
67–100%	13	14
Practices registering new patients at trial outset (open lists)*		
Yes	17	19
No	8	6
Practice nurse*		
Yes	24	24
No	1	1
Approved for training doctors*		
Yes	7	4
No	18	21
EMIS computer system*		
Yes	18	19
No	7	6
List size*		
≤3500	10	9
≤7000	9	10
>7000	6	6
Proportion of time list open to new registrations	63%	58%
Total number of patients	121 291	116 780
Porportion of white patients†	51·6%	50·0%
Proportion of black patients†	31·6%	30·9%
Proportion of south Asian patients†	7·6%	9·1%
Number of new immigrants registering during study per practice (mean)	248	272
Mean percentage rank of multiple deprivation	13·3%	11·0%

*Minimisation factor. †Ethnic origin categories from UK census data (white British, white Irish, white other; black African, black Caribbean, black other; south Asian).

Table 1: **Characteristics (including minimisation factors) of participating practices**

	Screening practices (n=25)	Control practices (n=25)
Total number of new patients	44 986	48984
Number of new patients per practice*	1546 (244–3864)	1573 (0–4790)
Mean age (years)	29	26
Proportion of new patients who were male	21143 (47%)	22 533 (46%)
Proportion of new patients who were white†	20 244 (45%)	20 573 (42%)
Proportion ofnew patients who were black†	9897 (22%)	11 756 (24%)
Proportion of new patients who were south Asian†	4049 (9%)	4898 (10%)
Mean number of immigrant new patients per practice	248	272

*Median (range). †Ethnic origin categories from UK census data (white British, white Irish, white other; black African, black Caribbean, black other; south Asian).

Table 2: **Characteristics of new patients registering in screening and control practices**

blinded to allocation. Identification route, patient demographics, and clinical data were entered blind into the study database. East London and City Health Authority, London, UK supplied patients' country of origin and, if appropriate, date of entry into the UK. They also provided patient registration history including precise dates of registration with practices.

We identified all people registered with study practices who were diagnosed with latent tuberculosis and treated at Homerton University Hospital (the sole provider of preventive treatment for tuberculosis in Hackney). Patients' route of referral to secondary care was obtained from the hospital's latent-tuberculosis database by the respiratory consultant, who was also blinded to practice allocation. The route of referral was coded (webpanel) and entered blind onto our database.

At the end of the trial we did electronic searches of the practice's computer systems to elicit the number of new patients registering in the trial period, new registration health checks, patients screened for tuberculosis, tuberculin skin tests done, and BCG immunisations in patients aged 5 years and older. We contacted all practices every 6 weeks to find out if each practice was currently registering new patients or had closed their list. Data for BCG coverage in patients aged 5 years and older was available from 43 of 50 participating practices (22 intervention and 21 control practices).

To allow payment for tuberculin skin testing during the trial, we also undertook four audits of testing activity in intervention practices. Data were extracted by electronic searches of the READ (panel) coded data listed in the prompts imported into the registration health check template.

Approval for the study was given by East London and the City Research Ethics Committee.

Statistical analysis

In the year before the study, 150 patients with active tuberculosis were identified in Hackney. 55% (83) of these were referred by general practitioners for investigation or were diagnosed in general practice. We assumed that the detection rate in the control practices would remain the same, and that extra cases identified in primary care in the intervention group during the study would have been detected elsewhere in the same period without the intervention. We allowed an inflation factor of 1·2 (assuming an intracluster correlation coefficient of 0·05) for the effect of clustering. To detect a clinically important increase of 20% (from 55% to 75%) in the diagnosis of new tuberculosis cases in primary care with 80% power at the 5% significance level we needed a total of 280 active tuberculosis cases in the study practices during the study period. Allowing for practice closures during the study, we aimed to recruit for 25 months.

We expected the background prevalence of tuberculosis to rise during the study because of a projected increase in the medical registration of refugees and asylum seekers

	Screening practices (n=25)	Control practices (n=23*)	Adjusted odds ratio or intervention rate ratio (95% CI)
Total number of new patients	44 986	48 984	
Number attending registration health check	23 573 (52%)	23 051 (47%)	
Number screened for tuberculosis	13 478 (57%)	84 (0·4%)	
Number of tuberculin skin tests	1996 (8·5%)	84 (0·4%)	20·6 (8·5–50·0)
Cases of active tuberculosis identified in primary care	66/141 (47%)	54/157 (34%)	1·68 (1·05–2·68)†; 1·61(1·08–2·39)‡
Cases of latent tuberculosis identified in primary care	11/58 (19%)	5/68 (9%)	3·00 (0·98–9·20)†; 3·45 (1·51–7·87)‡
BCG coverage in people aged 5 years and older¶	26·8 per 1000	3·8 per 1000	9·52 (4·0–22·7)‡

Intra cluster correlation: active cases=–0·0313; latent cases=–0·055. *In two instances, two control practices merged during the study, thus the total number of control practices for analysis changed from 25 to 23. †Without adjustment for clustering. ‡With adjustment for clustering. ¶Data available from 22 screening and 21 control practices.

Table 3: **Screening activity, identification of active and latent tuberculosis, and BCG coverage**

encouraged by the local development scheme run by East London and the City Health Authority and therefore that this calculation would be conservative. For analysis of active tuberculosis cases (primary outcome), and latent tuberculosis cases, we did intention-to-treat analyses using generalised estimation equations with a logit link to account for clustering. We assumed that true intracluster correlation coefficients could not be negative and therefore any negative coefficients were due to sampling error; if they were negative, we reported analyses both unadjusted and adjusted for clustering.

For unadjusted analyses we assumed that the intracluster correlation coefficient was zero. For analysis of numbers of tuberculin skin tests and BCG coverage, we used Poisson regression. To allow for clustering, each practice was incorporated as a random effect. Since our intervention was mainly for increasing screening in people newly registering with primary-care practices, we controlled for the numbers newly registering at each practice in the study period by including these data as an exposure in the model. We used Stata version 8·2 for the analysis. Data extraction was blinded, but clinicians and patients were potentially aware of allocation. This study was registered at clinicaltrials.gov, number NCT00214708.

Role of the funding source

The sponsor of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report. The corresponding author had full access to all the data and had final responsibility for the decision to submit for publication.

Results

Characteristics of the 50 participating practices and their existing populations were well balanced after randomisation at the start of the study (table 1). Characteristics of the populations registering during the study were also well matched (table 2). The figure shows the study flow diagram. All intervention practices took part in the educational visits and all but three began actively screening for tuberculosis. Verbal screening was documented in electronic medical records for 13 478 of 23 573 patients attending health checks in intervention practices, of whom 1996 received a tuberculin skin test (table 3). Intervention practices did a median of 67 tuberculin skin tests (range 0–427) compared with one (0–30) per control group practice (incident rate ratio 20·6 [95% CI 8·5–50·0]).

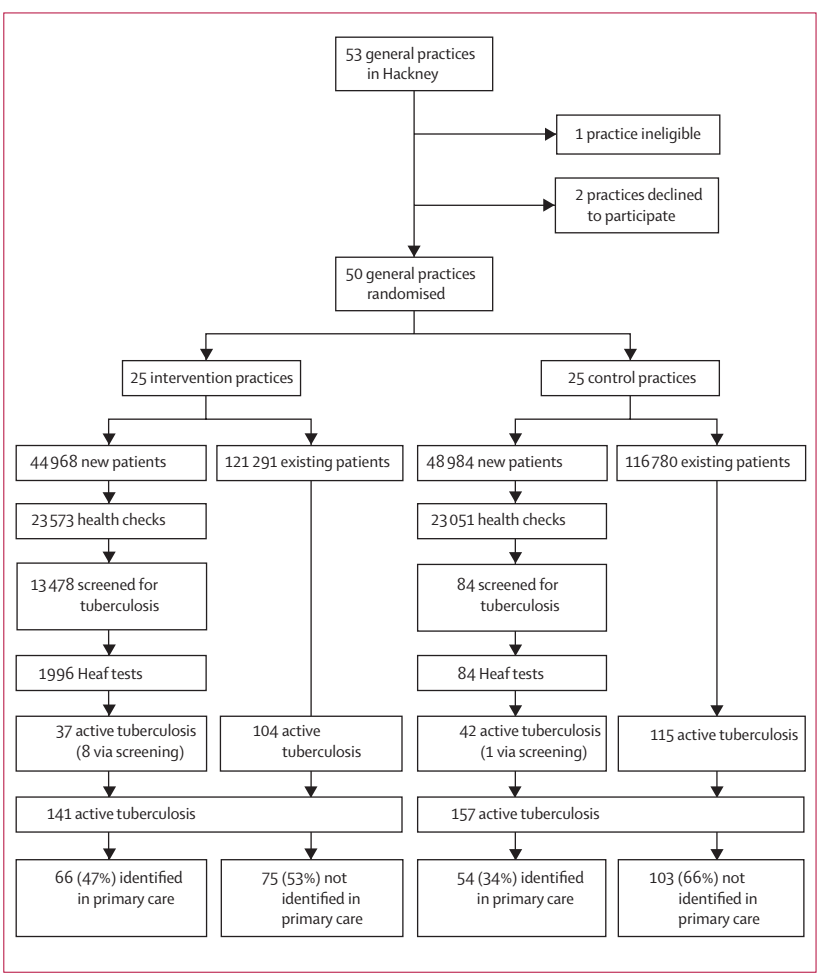

Figure: **Trial profile**

364 cases of active tuberculosis in Hackney were diagnosed during the trial period. Of these, 298 cases were registered with the 50 study practices: 141 with intervention and 157 with control practices (webtable 2).

See Online for webtable 2

The proportion of cases of active tuberculosis identified in primary care during the study was higher in intervention practices than control (66/141 [47%] *vs* 54/157 [34%] odds ratio (OR) 1·68, 95% CI 1·05–2·68 without adjustment for clustering; 1·61, 1·08–2·39 adjusting for clustering [table 3, figure]). Of the 141 patients diagnosed with active tuberculosis in intervention practices, 37 had registered as new patients during the study and were eligible for a registration health check. Of these, 19 (51%) attended for a registration health check. Screening at the health checks identified eight cases of active tuberculosis in these patients, with a yield of 0·06% (one in 1684). The remaining benefit accrued from improved case-finding for existing patients in intervention practices. Control practices had negligible screening rates but did identify one patient with active tuberculosis (figure). The rate of diagnosis of active tuberculosis in intervention practices was similar in new and existing patients (0·82 per 1000 and 0·86 per 1000, respectively [figure]).

We identified 184 cases of latent tuberculosis in Hackney. Of these, 59 were registered with intervention and 68 with control practices (webtable 2). Most cases were identified at hospital new entrant or contact tracing clinics. Although none were identified by screening in registration health checks, intervention practices referred a higher proportion of people with latent tuberculosis than did control practices (11/58 [19%] *vs* 5/68 [9%] OR 3·00, 95%CI 0·98–9·20 without adjustment for clustering; 3·45, 1·51–7·87 adjusting for clustering). Mean BCG coverage for people aged 5 years and older was seven-fold higher in intervention practices compared with control practices (table 3).

Discussion

We have shown that an educational outreach programme for promotion of screening for tuberculosis in an inner city primary-care health district improves both diagnostic and preventive activity, increasing the proportion of active and latent tuberculosis cases identified in primary care, and raising BCG coverage almost seven times. Benefits were modest, but our study was a pragmatic trial, testing general population screening in often under-resourced practices, covering 93% of the local primary-care population. Most practices implemented screening into routine practice, which suggests that our multifaceted implementation programme was successful. Screening at health checks identified more than a third of the extra cases of active tuberculosis diagnosed in primary care, with the remaining benefit accruing from case-finding during routine consultations, suggesting that our intervention was mediated by two effects: promotion of screening and raising clinicians' awareness of tuberculosis.

Our study has high internal and external validity. We used a pragmatic design with participation of almost all practices in the health district. Strengths included allocation concealment during randomisation, completeness of notified case ascertainment from medical records, blinded outcome data extraction, blinded entry and analysis of data, and intention-to-treat analysis. Cluster randomisation of practices proved a feasible design; a trial testing tuberculosis screening that randomised individual patients would present substantial design and logistical difficulties. Our study was limited by having power to measure changes in the proportion of cases identified, rather than changes in identification rate. Measurement of this change would have needed a much larger sample size than was feasible in this study.

Screening for tuberculosis is effective in the high incidence setting of rural South Africa.[27] Observational data for effectiveness of screening in low-incidence countries, at port of entry,[28] in prisons,[29] at hospital new-entrant clinics, and in the homeless[16] are difficult to interpret because there are no unscreened groups for comparison.

Our results suggest that an educational outreach programme to promote screening for tuberculosis within primary care is moderately effective. When extrapolated across all study practices, the 13% increase in the proportion of patients with active tuberculosis identified in primary care (roughly an extra 39 patients identified in primary care) compares favourably with the 13 and 15 cases of active tuberculosis identified during the study via screening in the hospital clinic for new entrants and contact tracing, respectively. Increasing the numbers of cases of tuberculosis identified in primary care, especially at registration health checks, should reduce diagnostic delay compared with waiting for patients to present at emergency departments, and therefore lead to more prompt treatment with consequent improved outcome and reduced transmission of disease.

The similar rates of diagnosis of active disease in new and existing patients in intervention practices suggests that a simple mechanism for screening and case-finding in the general population in high-prevalence areas could be worthwhile. Sensitivity of screening at health checks was 42% (8/19) for active tuberculosis. This result might hint at poor sensitivity of the tuberculin skin test, or that some patients developed active disease only after screening.

Which component of our implementation programme contributed most to changing the behaviour of primary care clinicians is uncertain. Each component was chosen to address specific barriers to change, illustrating the benefit of a multifaceted strategy. However, practice-based education (academic detailing), has proven effective in a wide range of settings,[23,24] and practices probably would not have begun screening without free provision of tools (tuberculin and Heaf-testing equipment) and prompts to remind clinicians to ask screening questions. The financial incentive was small.

Surprisingly, intervention practices did not identify large numbers of cases of latent tuberculoss. This result might suggest a low-risk population screened compared with, for example, that of contact tracing, or the need to improve the coverage or targeting of tuberculin skin testing. Since reactivation of latent disease is an important cause of active tuberculosis in London, our result is disappointing.[30] Further studies should test more effective ways of detecting latent tuberculosis than ours, perhaps using serological immunodiagnostic tests.

A seven-fold increase in BCG coverage in people aged 5 years and older represents a striking improvement, since most interventions boost immunisation rates in primary care by 5–20%[31] Although BCG immunisation is most effective in neonates, older children and adults are still at risk of tuberculosis.[3,32] Immunisation also reinforces an important public-health message.

Our model of general population screening in primary care has both strengths and weaknesses. We have shown such screening to be acceptable to recipients[33] and inexpensive when done by nurses during health checks.[16] Our method addresses all groups at risk, such as homeless people, drug users, and immigrants; avoids the pitfalls of ethnic profiling; and provides an opportunity to deliver brief basic preventive education about tuberculosis to new patients. However, some people do not register in primary care, and those who attend health checks might be at lower risk of tuberculosis than those who do not attend.[34]

Substantial debate surrounds the choices of screening method (verbal screening, tuberculin skin testing, chest radiography, serological), site (country of departure, port of entry, primary care, community) and target population (general population, new entrants, homeless or incarcerated).[15,16,28,35,36] More evidence is needed to show effectiveness and cost-effectiveness in these contexts. Screening is likely to have an effect if done in a range of complementary settings.

Our study location shares features with other UK inner city areas and other European cities that have an increasing incidence of tuberculosis. These include socioeconomic deprivation, high percentages of foreign-born people, increased rates of antimycobacterial drug resistance and increased HIV prevalence.[2] These similarities suggest that our intervention should be useful. To date, screening for tuberculosis in primary care has not been thought to be a public-health measure. Our study suggests screening could have a clinically important effect, should have useful generalisability, and could be recommended as part of tuberculosis control initiatives in industrialised countries.

Contributors

CG had the idea for the study. The study was designed by GB, SE, GF, CG, SL, AM, MM, JR, PS, ST, and AZ. GB, PB, CG, SL, AM, JR, and PS acquired the data. Data analysis and interpretation was done by GB, SE, GF, CG, SL, AM, MM, JR, PS, ST, and AZ. CG and PS drafted the manuscript and all authors helped with revisions to the manuscript. Statistical analysis was done by SE and PS, and GB, SE, GF, CG, MM, JR, ST, and AZ obtained funding for the study. GB, CG, MM, JR, and PS gave administrative, technical and material support, and the study was supervised by GB, CG, and PS.

Conflict of interest statement

We declare that we have no conflict of interest.

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