Open Access: free full text available online
For the full versions of these articles see bmj.com

Effect of point of care testing for C reactive protein and training in communication skills on antibiotic use in lower respiratory tract infections: cluster randomised trial

Jochen W L Cals,[1] Christopher C Butler,[2] Rogier M Hopstaken,[1,3] Kerenza Hood,[2,4] Geert-Jan Dinant[1]

EDITORIAL by Hay and Jüttner

[1]Department of General Practice, CAPHRI School for Public Health and Primary Care, Maastricht University Medical Centre, PO Box 616, 6200 MD Maastricht, Netherlands
[2]Department of Primary Care and Public Health, School of Medicine, Cardiff University, Wales
[3]Foundation of Primary Health Care Centres Eindhoven, Netherlands
[4]South East Wales Trials Unit, School of Medicine, Cardiff University, Wales
Correspondence to: J W L Cals
j.cals@hag.unimaas.nl

Cite this as: *BMJ* 2009;338:b1374
doi:10.1136/bmj.b1374

This article is an abridged version of a paper that was published on bmj.com. Cite this article as: *BMJ* 2009;338:b1374

ABSTRACT

Objective To assess the effect of general practitioner testing for C reactive protein (disease approach) and receiving training in enhanced communication skills (illness approach) on antibiotic prescribing for lower respiratory tract infection.

Design Pragmatic, 2×2 factorial, cluster randomised controlled trial.

Setting 20 general practices in the Netherlands.

Participants 40 general practitioners from 20 practices recruited 431 patients with lower respiratory tract infection.

Main outcome measures The primary outcome was antibiotic prescribing at the index consultation. Secondary outcomes were antibiotic prescribing during 28 days' follow-up, reconsultation, clinical recovery, and patients' satisfaction and enablement.

Interventions General practitioners' use of C reactive protein point of care testing and training in enhanced communication skills separately and combined, and usual care.

Results General practitioners in the C reactive protein test group prescribed antibiotics to 31% of patients compared with 53% in the no test group (P=0.02). General practitioners trained in enhanced communication skills prescribed antibiotics to 27% of patients compared with 54% in the no training group (P<0.01). Both interventions showed a statistically significant effect on antibiotic prescribing at any point during the 28 days' follow-up. Clinicians in the combined intervention group prescribed antibiotics to 23% of patients (interaction term was non-significant). Patients' recovery and satisfaction were similar in all study groups.

Conclusion Both general practitioners' use of point of care testing for C reactive protein and training in enhanced communication skills significantly reduced antibiotic prescribing for lower respiratory tract infection without compromising patients' recovery and satisfaction with care. A combination of the illness and disease focused approaches may be necessary to achieve the greatest reduction in antibiotic prescribing for this common condition in primary care.

Trial registration Current Controlled Trials ISRCTN85154857.

INTRODUCTION

Disease focused solutions address the limited value of history and physical examination in differentiating between pneumonia and self limiting acute bronchitis.[1-3] Diagnostic uncertainty increases the chances of inappropriate antibiotic prescribing.[4] C reactive protein is a promising biomarker for improving the assessment of lower respiratory tract infection in primary care: it performs better in predicting the diagnosis of pneumonia than clinical symptoms and signs in lower respiratory tract infection. It is also feasible and robust as a point of care test, making it the best available biomarker to enhance the diagnosis of lower respiratory tract infection in primary care.[2 3 5 6]

Illness focused solutions recognise the importance of non-medical influences on the decision to prescribe antibiotics, and emphasise eliciting and responding to patients' feelings, ideas, fears, and expectations about their illness experience.[7] General practitioners are often unable to satisfactorily deal with these influences to achieve evidence based prescribing decisions in time pressured consultations.[8-12] The resulting inappropriate prescribing of antibiotics reinforces misconceptions that impact on future help seeking and expectations for antibiotics.[13-15]

We evaluated the effect of general practitioners using a point of care test for C reactive protein and being trained in enhanced communication skills, separately and combined, on antibiotic prescribing for lower respiratory tract infection and on patient recovery.

METHODS

This study was a pragmatic, cluster randomised, factorial, controlled trial. A 2×2 factorial design was used to assess the effect of each intervention and to explore the effect of the interventions combined.[16] The four allocated groups were general practitioners' use of C reactive protein testing (1), training in enhanced communication skills (2), the interventions combined (3), and usual care (4). The groups were combined for analysis: factor A, C reactive protein test (cells 1 and 3) compared with no test (2 and 4) (controlling for effect of general practitioners' training in communication skills); and factor B, training in enhanced communication skills

(2 and 3) compared with no training (1 and 4) (controlling for effects of C reactive protein testing).

The primary outcome was antibiotic prescribing in the index consultation. Secondary outcomes were antibiotic prescribing during 28 days' follow-up, reconsultation, clinical recovery, and patients' satisfaction and enablement. We planned to recruit 20 general practices with two participating general practitioners per practice within a large suburban region of the Netherlands.

Practices were randomised into two groups of 10 practices per intervention, resulting in four trial arms (see bmj.com). The balancing factor used for randomisation was the amount of general practitioners' consultation time that the practice was contributing to the study. The randomisation was balanced for those with 1.5 or less full time equivalent or more than 1.5 full time equivalent.

Both interventions were targeted at the general practitioner level. The clinicians were given devices to test for C reactive protein (NycoCard II Reader; Axis-Shield, Norway) and guidance on how to use the test results within the consultation. General practitioners were given guidance on how to use the test results within the consultation during a 30 minute practice based training session delivered by the study team. The additional value of C reactive protein in ruling out serious infection was emphasised.[17] The communication skills intervention was built around 11 key tasks, with information exchange throughout based on the elicit-provide-elicit framework from counselling in behaviour change.[18] Key features of the training programme were the brevity of workshop based training, its context rich nature, and the innovative use of peer reviewing colleagues' transcripts of the consultations with simulated patients.[17 19] The Dutch guideline for managing acute cough, including diagnostic and therapeutic advice for lower respiratory tract infection, is distributed to all general practitioners in the Netherlands and informs usual care.[20]

General practitioners were asked to recruit sequential adults during the winters of 2005-6 and 2006-7 if they had a suspected lower respiratory tract infection with a cough lasting less than four weeks together with one focal and one systemic symptom.[17] Patients rated symptoms on a 7 point scale in a daily diary for 28 days. The diary also included a Likert scale question on satisfaction, and the patient enablement index.[21] Data on antibiotic prescribing and reconsultation for the 28 days of follow-up were obtained from the participants' medical records.

Data analysis

The primary analysis was intention to treat and assessed the predefined effects of the two interventions on antibiotic prescribing at the index consultation, incorporating an interaction effect, which we included to test and correct for a synergistic or antagonistic relation between the two interventions. Analysis was done using a three level logistic regression model to account and correct for variation at the level of the practice, general practitioner, and patient using a second order penalised quasi-likelihood approach. To correct for the effects on secondary outcomes we used a three level model, linear or logistic where appropriate. To explore simplification of the model we carried out analyses to investigate if the general practitioner level could be left out of the multilevel approach. Exploratory analyses investigating the influence of patients' and practitioners' characteristics on the main effects were carried out as sensitivity analyses. Results are presented as rates with corresponding P values.

Scores for each symptom item were added to create a total daily symptom score that ranged from 0% to 100%. A four level autoregressive moving average (1,1) model was fitted to the symptom scores (logged) to account for practice, general practitioner, patient, and repeated measurements over time using restrictive maximum likelihood. This modelled the correlation between repeated assessments within individual patients to allow for greater correlation between assessments that were closer in time. The effects of the interventions on recovery were studied by comparing the slopes of symptom scores over time in the groups.[22]

RESULTS

All 30 general practitioners received the allocated intervention, and 10 general practitioners were assigned to the usual care arm (see bmj.com). The

Effects of interventions on antibiotic prescribing at index consultation and antibiotic prescribing and reconsultation during 28 days' follow-up

Variables	Intervention groups		Control groups		P value†	Intracluster coefficient
	No of patients	Percentage (crude 95% CI*)	No of patients	Percentage (crude 95% CI*)		
C reactive protein test:	n=227		n=204			
Antibiotics at index consultation	70	30.8 (21.8 to 39.8)	108	52.9 (43.0 to 62.8)	0.02	0.12
Antibiotics at days 1 to 28	102	44.9 (35.2 to 54.6)	119	58.3 (48.5 to 68.1)	<0.01	0.12
Reconsultation within 28 days	79	34.8 (28.3 to 41.3)	62	30.4 (23.8 to 37.0)	0.50	0.01
Communication skills training:	n=201		n=230			
Antibiotics at index consultation	55	27.4 (25.6 to 36.6)	123	53.5 (43.8 to 63.2)	<0.01	0.12
Antibiotics at days 1 to 28	76	37.8 (28.1 to 47.5)	145	63 (53.6 to 72.4)	<0.001	0.12
Reconsultation within 28 days	56	27.9 (21.4 to 34.4)	85	37.0 (30.4 to 43.6)	0.14	0.01

*Calculated and inflated for clustering by using standard deviation inflated by variance inflation factor.[24]
†Calculated from second order penalised quasi-likelihood multilevel logistic regression model adjusted for variance at general practitioner and practice level (random intercept at practice and general practitioner level). Models included both interventions and interaction term of interventions. See web extra for corresponding β coefficients.

WHAT IS ALREADY KNOWN ON THIS TOPIC

Cough due to lower respiratory tract infection is one of the commonest reasons for prescribing antibiotics

Most such prescriptions in primary care do not benefit patients

Diagnostic uncertainty and patients' expectations and concerns are major drivers of unnecessary antibiotic prescribing

WHAT THIS STUDY ADDS

General practitioners' use of C reactive protein testing (disease focused approach) and training in communication skills (illness focused approach) both resulted in decreased antibiotic prescribing for lower respiratory tract infection in primary care

Patient recovery and satisfaction with care were not compromised

The two approaches combined resulted in the greatest reduction in antibiotic prescribing

characteristics of the general practitioners were similar across the groups and comparable to Dutch general practitioners (see bmj.com). In total, 431 patients with lower respiratory tract infection were recruited (factor A, 227 to the C reactive protein test group *v* 204 to the no test group, and factor B, 201 to the training in enhanced communication skills group *v* 230 to the no training group).

C reactive protein was measured in all 227 patients allocated to testing (results were <20 mg/l for 69%, 20-99 mg/l for 24%, and >100 mg/l for 7%). Compared with 19% of patients in the no training group, 66% in the training group recalled their doctors asking opinions on antibiotics, exploring worries, eliciting expectations, and providing information on the natural course and duration of lower respiratory tract infection.

General practitioners in the C reactive protein test group prescribed significantly fewer antibiotics than those in the no test group (31% *v* 53%, P=0.02; table). Similarly, general practitioners in the communication skills training group prescribed significantly fewer antibiotics than those in the no training group (27% *v* 54%, P<0.01). The two interventions showed no statistically significant interaction effect (P=0.78), although there was a trend for a synergistic effect.

The interventions showed no statistically significant difference in reconsultations. Prescribing during the 28 days after the index consultation was slightly lower for patients in the communication skills training group. After adjusting for clustering, however, this effect was not statistically significant. Antibiotic prescribing at any point during the 28 days' follow-up remained significantly lower in patients in the C reactive protein test group compared with those in the no test group (45% *v* 58%, P<0.01) as well as for patients in the communication skills training group compared with those in the no training group (38% *v* 63%, P<0.001). In total, 47 patients (10.9%) reconsulted more than once within the 28 days. This pattern was similar across the groups.

General practitioners using the test and also trained in communication skills prescribed antibiotics to 23% of participants compared with 67% in the usual care group (see bmj.com).

The interventions had no discernible effect on recovery. Baseline characteristics were similar between patients who completed the symptom scores (90%) and those who did not. Median patient reported time to recovery was 22 days (interquartile range 14-28).

Overall, satisfaction with the index consultation was high, with no statistically significant differences between groups. Fewer patients in the training group indicated that they would consult with similar symptoms in the future, but differences in future consulting intentions were not statistically significant between groups. The groups had similar scores for the patient enablement index (see bmj.com).

DISCUSSION

Both general practitioners' use of point of care testing for C reactive protein and training in enhanced communication skills had a clinically important effect on antibiotic prescribing at the index consultation for lower respiratory tract infection and antibiotic prescribing during the 28 days' follow-up period, without affecting clinical recovery or patients' satisfaction.

Strengths and limitations of the study

Factorial designs are efficient for assessing two interventions when they act independently of each other.[16] Our results did not show interaction effects between the C reactive protein test and the enhanced communication skills strategy—that is, the combined effect of the test and training was neither synergistic nor antagonistic. We nevertheless included interaction coefficients in all models to correct for possible undetected interactions.

The sustainability of the acquired communication skills may be questioned. We previously reported sustained competence in implementing these skills.[19] A sensitivity analysis of the results by winter period (2005-6 and 2006-7) showed that the observed effects on antibiotic prescribing were similar during both periods. Moreover, most patients seeing general practitioners who had been allocated to communication skills training recalled key topics being covered during the consultation. The enhanced communication skills may therefore have become embedded in the general practitioners' daily routine.[19] However, general practitioners may need time to gain confidence and experience in interpreting the results of the C reactive protein test in general, and in using the result to guide treatment in particular.

The higher than expected follow-up rate (100% ascertainment of the primary outcome, 90% ascertainment of patient reported outcomes) increased the study power. The target number of patients in the training arm was not achieved because three general practitioners went on maternity leave. Nevertheless, with over 200 patients in both groups we were able to evaluate the effect of training in enhanced communication skills.

A common potential weakness in randomised controlled trials using a cluster design is recruitment bias after randomisation, as differential numbers and types of patient may be enrolled after the intervention has

been allocated.[23-25] However, the baseline characteristics of the recruited patients were similar across the groups, and inclusion of known covariates in our models did not affect the observed effects.

Implications

The broad approach exemplified by the interventions evaluated in this trial may enhance management of a wider range of patients than just those with lower respiratory tract infection. Both approaches could be used for most common infections in primary care. Moreover, the combined effect of the interventions stresses the importance of a shared approach. Crucially, combining the disease and illness approach implies that decisions on antibiotic prescribing should focus on targeting the drug to the patient while balancing benefits and possible harms of treatment to those with potential societal benefits from restrictive prescribing.[26] C reactive protein may contribute to safely withholding antibiotics from most people with low C reactive protein values who most probably would not benefit from antibiotic treatment, while enhanced communication may increase patients' understanding of prescribing decisions without the feeling of being dismissed with unsatisfactory explanations.

Although the Netherlands has one of the lowest overall prescribing rates for antibiotics worldwide, prescribing for lower respiratory tract infection remains high, with rates similar to other European countries and the United States. As most patients in our study did not undergo chest radiography we do not know the number who had community acquired pneumonia. The characteristics of the patients, however, seem comparable to previous studies on lower respiratory tract infection, in which about 11% of patients had community acquired pneumonia.[2]

The antibiotic prescribing rate of 67% for our usual care group is comparable to other studies in the Netherlands and elsewhere.[27-29] Given that 370 000 prescriptions for antibiotics are issued in 550 000 consultations for lower respiratory tract infection (based on 44 adults consulting for lower respiratory tract infection per 1000 adults per year[30 31]) in the Netherlands each year, up to 240 000 prescriptions may be avoided annually if our findings were to be replicated on a national scale. Reducing antibiotic prescribing in primary care may decrease levels of antibiotic resistance nationally and internationally, but it may also have substantial effects locally.

Conclusions

Both interventions were effective on their own. Prescribing fewer antibiotics in the intervention groups did not result in poorer patient outcomes. Both interventions required training clinicians in new skills and have potential applicability in primary care beyond the condition we studied.

We thank Susanne Hanssen, Paula Rinkens, and Ger Driessen (Maastricht) for their support with data collection and the logistics of the study; Mark Kelly (Cardiff) for his assistance with the analysis of the clinical recovery model; and the participating general practitioners and patients.

Contributors: See bmj.com.

Funding: This trial was funded by the Netherlands Organisation for Health Research and Development (grant 945-04010). JWLC is supported by a grant from the Netherlands Organisation for Health Research and Development as a MD-medical research trainee. KH is funded by the Wales Office for Research and Development. The funders had no role in the design and conduct of the study; collection, management, analysis, and interpretation of the data; and preparation, review, or approval of the manuscript.

Competing interests: None declared.

Ethical approval: This study was approved by the ethics committee of Catherina Hospital in Eindhoven, the Netherlands.

1 Fischer T, Fischer S, Kochen MM, Hummers Pradier E. Influence of patient symptoms and physical findings on general practitioners' treatment of respiratory tract infections: a direct observation study. *BMC Fam Pract* 2005;6:6.
2 Hopstaken RM, Muris JWM, Knottnerus JA, Kester ADM, Rinkens PELM, Dinant GJ. Contributions of symptoms, signs, erythrocyte sedimentation rate and C-reactive protein to a diagnosis of pneumonia in acute lower respiratory tract infection. *Br J Gen Pract* 2003;53:358-64.
3 Melbye H, Straume B, Aasebo U, Brox J. The diagnosis of adult pneumonia in general practice. The diagnostic value of history, physical examination and some blood tests. *Scand J Prim Health Care* 1988;6:111-7.
4 McIsaac WJ, Butler CC. Does clinical error contribute to unnecessary antibiotic use? *Med Decis Making* 2000;20:33-8.
5 Van der Meer V, Neven AK, Broek PJvd, Assendelft WJJ. Diagnostic value of C reactive protein in infections of the lower respiratory tract: systematic review. *BMJ* 2005;331:26-9.
6 Dahler Eriksen BS, Lassen JF, Petersen PH, Lund ED, Lauritzen T, Brandslund I. Evaluation of a near-patient test for C-reactive protein used in daily routine in primary healthcare by use of difference plots. *Clin Chem* 1997;43:2064-75.
7 Butler CC, Kinnersley P, Prout H, Rollnick S, Edwards A, Elwyn G. Antibiotics and shared decision-making in primary care. *J Antimicrob Chemother* 2001;48:435-40.
8 Davey P, Pagliari C, Hayes A. The patient's role in the spread and control of bacterial resistance to antibiotics. *Clin Microbiol Infect* 2002;8(suppl 2):43-68.
9 Avorn J, Solomon DH. Cultural and economic factors that (mis)shape antibiotic use: the nonpharmacologic basis of therapeutics. *Ann Intern Med* 2000;133:128-35.
10 Altiner A, Knauf A, Moebes J, Sielk M, Wilm S. Acute cough: a qualitative analysis of how GPs manage the consultation when patients explicitly or implicitly expect antibiotic prescriptions. *Fam Pract* 2004;21:500-6.
11 Butler CC, Rollnick S, Pill R, Maggs Rapport F, Stott N. Understanding the culture of prescribing: qualitative study of general practitioners' and patients' perceptions of antibiotics for sore throats. *BMJ* 1998;317:637-42.
12 Coenen S, Michiels B, Renard D, Denekens J, Van Royen P. Antibiotic prescribing for acute cough: the effect of perceived patient demand. *Br J Gen Pract* 2006;56:183-90.
13 Little P, Dorward M, Warner G, Stephens K, Senior J, Moore M. Importance of patient pressure and perceived pressure and perceived medical need for investigations, referral, and prescribing in primary care: nested observational study. *BMJ* 2004;328:444-6.
14 Little P, Gould C, Williamson I, Warner G, Gantley M, Kinmonth AL. Reattendance and complications in a randomised trial of prescribing strategies for sore throat: the medicalising effect of prescribing antibiotics. *BMJ* 1997;315:350-2.
15 Cals JWL, Boumans D, Lardinois RJM, Gonzales R, Hopstaken RM, Butler CC, et al. Public beliefs on antibiotics and respiratory tract infections: an internet-based questionnaire study. *Br J Gen Pract* 2007;57:942-7.
16 Montgomery A, Peters T, Little P. Design, analysis and presentation of factorial randomised controlled trials. *BMC Med Res Method* 2003;3:26.
17 Cals JW, Hopstaken RM, Butler CC, Hood K, Severens JL, Dinant GJ. Improving management of patients with acute cough by C-reactive protein point of care testing and communication training (IMPAC3T): study protocol of a cluster randomised controlled trial. *BMC Fam Pract* 2007;8:15.
18 Rollnick S, Kinnersley P, Butler C. Context-bound communication skills training: development of a new method. *Med Educ* 2002;36:377-83.
19 Cals JW, Scheppers NA, Hopstaken RM, Hood K, Dinant GJ, Goettsch H, et al. Evidence based management of acute bronchitis; sustained competence of enhanced communication skills acquisition in general practice. *Patient Educ Couns* 2007;68:270-8.
20 Verheij TJM, Salomé PL, Bindels PJ, Chavannes AW, Ponsioen BP, Sachs APE, et al. NHG-Standaard Acuut hoesten. [Dutch College of

General Practitioners guidelines on acute cough]. *Huisarts Wet* 2003;46:496-506.
21 Howie JG, Heaney DJ, Maxwell M, Walker JJ. A comparison of a patient enablement instrument (PEI) against two established satisfaction scales as an outcome measure of primary care consultations. *Fam Pract* 1998;15:165-71.
22 Box GEP, Jenkins GM, Reinsel GC. *Time series analysis: forecasting and control*. 3rd ed. Englewood Cliffs, NJ: Prentice Hall, 1994.
23 Puffer S, Torgerson D, Watson J. Evidence for risk of bias in cluster randomised trials: review of recent trials published in three general medical journals. *BMJ* 2003;327:785-9.
24 Donner A, Klar N. *Design and analysis of cluster randomization trials in health research*. London: Arnold, 2000.
25 Hahn S, Puffer S, Torgerson DJ, Watson J. Methodological bias in cluster randomised trials. *BMC Med Res Methodol* 2005;5:10.
26 Cosby JL, Francis N, Butler CC. The role of evidence in the decline of antibiotic use for common respiratory infections in primary care. *Lancet Infect Dis* 2007;7:749-56.
27 Gonzales R, Steiner JF, Sande MA. Antibiotic prescribing for adults with colds, upper respiratory tract infections, and bronchitis by ambulatory care physicians *JAMA* 1997;278:901-4.
28 Kuyvenhoven MM, Verheij TJ, de Melker RA, van der Velden J. Antimicrobial agents in lower respiratory tract infections in Dutch general practice. *Br J Gen Pract* 2000;50:133-4.
29 Macfarlane J, Lewis SA, Macfarlane R, Holmes W. Contemporary use of antibiotics in 1089 adults presenting with acute lower respiratory tract illness in general practice in the UK: implications for developing management guidelines. *Respir Med* 1997;91:427-34.
30 Macfarlane J, Holmes W, Gard P, Macfarlane R, Rose D, Weston V, et al. Prospective study of the incidence, aetiology and outcome of adult lower respiratory tract illness in the community. *Thorax* 2001;56:109-14.
31 Hak E, Rovers MM, Kuyvenhoven MM, Schellevis FG, Verheij TJ. Incidence of GP-diagnosed respiratory tract infections according to age, gender and high-risk co-morbidity: the second dutch national survey of general practice. *Fam Pract* 2006;23:291-4.

Accepted: 16 January 2009

Participation in life situations of 8-12 year old children with cerebral palsy: cross sectional European study

Jérôme Fauconnier,[1] Heather O Dickinson,[2] Eva Beckung,[3] Marco Marcelli,[4] Vicki McManus,[5] Susan I Michelsen,[6] Jackie Parkes,[7] Kathryn N Parkinson,[2] Ute Thyen,[8] Catherine Arnaud,[9] Allan Colver[2]

EDITORIAL by Rosenbaum

[1]Université Joseph Fournier, DIM-Pôle Santé Publique Equipe ThEMAS, CHU de Grenoble BP 217, 38043 Grenoble Cedex 9, France
[2]Institute of Health and Society, Newcastle University, Newcastle upon Tyne NE1 7RU
[3]Göteborg University, Queen Silvia Children's Hospital, S-41685 Gothenburg, Sweden
[4]Azienda Sanitaria Locale Viterbo, Viale Trento 18 H, 01100 Viterbo, Italy
[5]Enable Ireland, Lavanagh Centre, Ballintemple, Cork, Republic of Ireland
[6]National Institute of Public Health, University of Southern Denmark, Oster Farimagsgade 5A, 1399 Copenhagen, Denmark
[7]School of Nursing and Midwifery, Queen's University Belfast, Belfast BT9 5BN
[8]Klinik für Kinder und Jugendmedizin, Universitätsklinikum Schleswig-Holstein, Ratzeburger Allee 160, 23538 Lübeck, Germany
[9]Institut National de la Santé et de la Recherche Médicale, Université Paul Sabatier, Faculté de Médecine, 37 allées J Guesde, 31073 Toulouse, France
Correspondence to: A Colver
allan.colver@ncl.ac.uk

Cite this as: *BMJ* 2009;338:b1458
doi:10.1136/bmj.b1458

ABSTRACT

Objectives To evaluate how involvement in life situations (participation) in children with cerebral palsy varies with type and severity of impairment and to investigate geographical variation in participation.

Design Cross sectional study. Trained interviewers visited parents of children with cerebral palsy; multilevel multivariable regression related participation to impairments, pain, and sociodemographic characteristics.

Setting Eight European regions with population registers of children with cerebral palsy; one further region recruited children from multiple sources.

Participants 1174 children aged 8-12 with cerebral palsy randomly selected from the population registers, 743 (63%) joined in the study; the further region recruited 75 children.

Main outcome measure Children's participation assessed by the Life-H questionnaire covering 10 main areas of daily life. Scoring ignored adaptations or assistance required for participation.

Results Children with pain and those with more severely impaired walking, fine motor skills, communication, and intellectual abilities had lower participation across most domains. Type of cerebral palsy and problems with feeding and vision were associated with lower participation for specific domains, but the sociodemographic factors examined were not. Impairment and pain accounted for up to a sixth of the variation in participation. Participation on all domains varied substantially between regions: children in east Denmark had consistently higher participation than children in other regions. For most participation domains, about a third of the unexplained variation could be ascribed to variation between regions and about two thirds to variation between individuals.

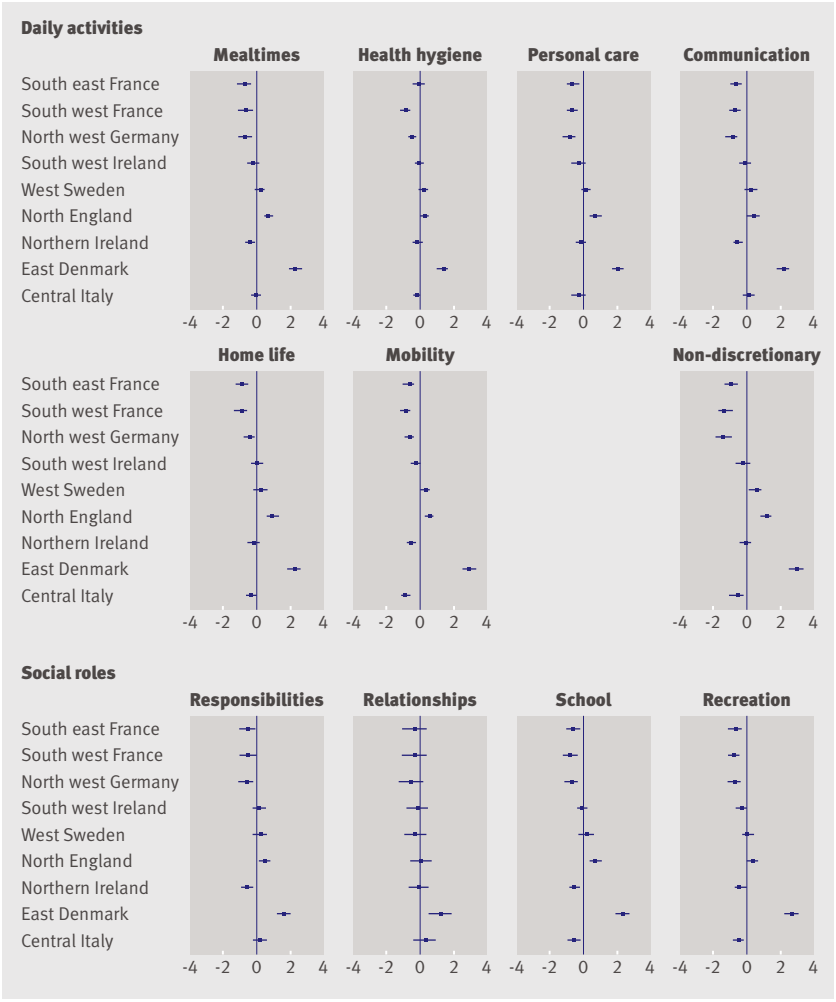
Conclusions Participation in children with cerebral palsy should be assessed in clinical practice to guide intervention and assess its effect. Pain should be carefully assessed. Some European countries facilitate participation better than others, implying some countries could make better provision. Legislation and regulation should be directed to ensuring this happens.

INTRODUCTION

In the past decade, concepts of disability and disadvantage for children with impairments have become clearer, largely due to the World Health Organization's International Classification of Functioning, Disability and Health (ICF).[1] Since its publication, interest has focused less on actual impairments and more on the impact of the impairments on the personal and social life of the individual. The classification defines "participation" as involvement in life situations; it is understood to be a consequence of a dynamic interaction between a person and environmental factors rather than a direct consequence of illness. Disabled children experience difficulty in participating across a wide range of domains.[2,3] These include non-discretionary aspects of daily life, such as eating, sleeping, and toileting.

The classification is consistent with the social model of disability,[4] which regards disability as a consequence of the failure of the environment to be adjusted sufficiently to meet the needs of the individual.[5,6] The social model predicts that participation will vary between countries.

Cerebral palsy is the commonest cause of severe motor impairment in childhood, with a rate of about



Mean level (with 95% confidence intervals) of children's participation in each region, adjusted for impairment and pain. Higher scores indicate higher participation. Mean adjusted participation is zero and each unit is 1 SD of residual variation between children

2.5 per 1000 live births.[7] Affected children have various types and severities of impairments and so might be regarded as typical of a wide range of disabled children.

Many studies of participation in affected children are unsatisfactory because of inadequate sample size,[8] non-representative convenience samples,[9 10] use of instruments that do not capture the modern concept of participation,[11 12] or neglect of social dimensions of participation.[13 14]

In a large representative sample of children with cerebral palsy we evaluated how participation varied with type and level of impairment and with pain and assessed the geographical variation predicted by the social model of disability.

METHODS

The study is part of a wider project, SPARCLE (www.ncl.ac.uk/sparcle).[15] Eligible children were those born from 31 July 1991 to 1 April 1997 and on population registers of children with cerebral palsy in eight regions of six European countries: south east France, south west France, south west Ireland, west Sweden, north of England, Northern Ireland, east Denmark, and central Italy. There were 1884 such children. We randomly sampled 1174 eligible families, of whom 743 (63%) took part. We were unable to trace 12% of families sampled; of those traced, 73% agreed to take part, 3% were not approached, and 24% declined to take part.[16] A further region in north west Germany recruited 75 children from multiple sources. Thus the sample comprised 818 children. Research associates visited children at home in 2004-5 to administer questionnaires to parents and children, if possible when the children were aged 8-12.

Participation was assessed with the Life-H questionnaire, which has been validated for use in disabled children.[8] It comprises 62 items grouped into 11 domains covering both daily activities and social roles. Our main analysis ignored questions about use of aids and adaptations for participation. Parents reported the frequency and severity of their child's pain in the previous week and provided sociodemographic information, and information about their child's impairments (gross motor function,[17] fine motor skills,[12] intellectual ability, vision, hearing, seizures, feeding, communication), school type, and siblings. Data on type of cerebral palsy were available from the registers.

Statistical methods

The statistical methods are described in detail in appendix 1 on bmj.com. We coded responses to 15 non-discretionary items—regarded as essential to a child's daily life—as binary variables (with or without difficulty) and responses to the other 47 items as ordinal variables (performed without difficulty, performed with difficulty, not performed because too difficult, missing if not performed for other reasons).

We analysed each domain separately. We also analysed all non-discretionary items grouped together. We estimated each factor (that is, the child's level of participation on each domain) and related it to covariates—sociodemographic characteristics, impairment, and pain—in a single, unified, multilevel model that allowed for clustering of children within regions.

Frequency and severity of pain were highly correlated (Spearman's rank correlation coefficient=0.83) so we included only frequency in the model. For each type of impairment, we present odds ratios comparing the participation of children with a specific severity of impairment with the participation of the least impaired children. We noted the change in log likelihood as an indicator of the variation in participation explained by the covariates. We estimated the significance of heterogeneity between regions. We report the proportion of the residual variance that is between regions.

RESULTS

The parents of 818 children were interviewed. A summary of the type and severity of the children's

This article is an abridged version of a paper that was published on bmj.com. Cite this article as: *BMJ* 2009;338:b1458

impairments and parental reports of their child's pain are available on bmj.com.

All items of Life-H, except one about school participation, had response rates of over 97%. In univariate analyses, all impairments except hearing and type of cerebral palsy were significantly associated with lower participation on all domains (P<0.01).

Tables 1 and 2 summarise the final multivariable models. On most domains, except relationships, lower participation was associated with impairment of motor function (walking ability or fine motor skills, or both). Additionally, lower participation was associated with intellectual impairment, communication difficulties, and pain on most domains. Other specific

Table 1 | Multilevel, multivariable regression models, relating participation for each Life-H domain in daily activities to type and level of impairment and pain of 799 children with cerebral palsy. Figures are odds ratios* (95% confidence intervals) unless stated otherwise

	Mealtimes	Health hygiene	Personal care	Communication	Home life	Mobility
% Change in log likelihood due to impairment and pain	16%	9%	7%	14%	16%	8%
P for heterogeneity between regions	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
Variance between regions as % of total residual variance	51%	51%	27%	33%	36%	63%
Gross motor function						
I Walks and climbs stairs, without limitation	1.0	1.0	1.0	NS	1.0	1.0
II Walks inside	1.4 (1.0 to 2.1)	2.3 (1.7 to 3.2)	3.1 (2.1 to 4.6)	NS	3.4 (2.2 to 5.3)	4.0 (2.9 to 5.5)
III Walks with assistive devices	1.9 (1.2 to 2.8)	3.7 (2.7 to 5.2)	5.4 (3.6 to 8.3)	NS	14.8 (9.0 to 24)	5.5 (3.9 to 7.8)
IV Unable to walk, limited self-mobility	2.4 (1.5 to 3.9)	5.3 (3.7 to 7.6)	7.9 (4.8 to 13)	NS	17.6 (10 to 31)	5.2 (3.5 to 7.6)
V Unable to walk, severely limited self mobility	3.6 (2.0 to 6.5)	7.8 (5.1 to 12)	9.1 (4.7 to 18)	NS	20.5 (10 to 41)	7.6 (4.8 to 12)
Fine motor skills						
I Without limitation	1.0	NS	1.0	1.0	1.0	NS
II Both hands limited in fine skills	3.4 (2.3 to 4.8)	NS	3.4 (2.4 to 4.9)	1.9 (1.3 to 2.7)	2.0 (1.3 to 2.9)	NS
III Needs help with tasks	3.2 (2.1 to 4.8)	NS	4.0 (2.6 to 6.2)	2.1 (1.4 to 3.1)	2.6 (1.7 to 4.1)	NS
IV Needs help and adapted equipment	3.5 (2.0 to 6.2)	NS	4.6 (2.5 to 8.5)	2.2 (1.3 to 3.7)	4.3 (2.3 to 8.1)	NS
V Needs total human assistance	5.0 (2.6 to 9.7)	NS	3.1 (1.5 to 6.3)	2.9 (1.7 to 5.0)	4.1 (2.0 to 8.4)	NS
Intellectual impairment						
>70	1.0	NA	1.0	1.0	1.0	1.0
50-70	1.7 (1.2 to 2.3)	NA	1.5 (1.0 to 2.0)	4.3 (3.1 to 5.9)	1.7 (1.1 to 2.4)	1.7 (1.3 to 2.3)
<50	4.8 (3.4 to 6.7)	NA	2.3 (1.6 to 3.3)	14.2 (9.5 to 21)	2.9 (1.9 to 4.5)	1.7 (1.2 to 2.4)
Communication						
Normal speech	NS	1.0	NS	1.0	1.0	1.0
Difficult but uses speech	NS	2.3 (1.7 to 3.1)	NS	5.2 (3.6 to 7.5)	1.8 (1.2 to 2.7)	1.8 (1.3 to 2.5)
Uses non-speech for formal communication	NS	1.4 (1.0 to 2.0)	NS	8.8 (5.4 to 14)	1.1 (0.7 to 1.9)	0.9 (0.6 to 1.4)
No formal communication	NS	2.1 (1.5 to 3.1)	NS	31.4 (17 to 57)	2.6 (1.4 to 4.8)	1.8 (1.1 to 3.0)
Type of cerebral palsy						
Spastic unilateral	NS	NS	NS	1.0	1.0	NS
Spastic bilateral	NS	NS	NS	1.2 (0.9 to 1.5)	1.9 (1.4 to 2.7)	NS
Dyskinetic	NS	NS	NS	1.5 (1.0 to 2.4)	2.0 (1.2 to 3.4)	NS
Ataxic	NS	NS	NS	4.1 (2.2 to 7.7)	2.0 (1.0 to 4.1)	NS
Feeding						
No problems	1.0	NS	NS	NS	NS	NS
Orally with difficulty	1.8 (1.3 to 2.6)	NS	NS	NS	NS	NS
Partial or complete feeding by tube	3.5 (2.0 to 6.3)	NS	NS	NS	NS	NS
Vision						
Has useful vision	NS	NS	NS	1.0	NS	NS
No useful vision	NS	NS	NS	2.8 (1.7 to 4.6)	NS	NS
Parental report of frequency of child pain in previous four weeks						
None of the time	NS	1.0	1.0	NS	1.0	1.0
Once or twice or a few times	NS	1.4 (1.1 to 1.8)	1.5 (1.2 to 2.1)	NS	1.8 (1.3 to 2.4)	1.5 (1.2 to 2.0)
More often	NS	2.3 (1.7 to 3.1)	2.6 (1.8 to 3.7)	NS	2.4 (1.6 to 3.5)	1.9 (1.4 to 2.6)

NS=factors not significantly associated with participation on specific domains. Additionally, none of the sociodemographic factors considered (child's age and sex, number of siblings and whether they were disabled, type of parental employment, level of parental educational qualifications, whether family lived in an urban or rural area) was significantly associated with participation on any domain.
*Odds ratios from latent regression ordinal item response models (see bmj.com). Odds ratios >1 indicate greater difficulty in participation in children in that category.

Table 2 | **Multilevel, multivariable regression models, relating participation for each Life-H domain in social roles and non-discretionary to type and level of impairment and pain of children with cerebral palsy. Figures are odds ratios* (95% confidence intervals) unless stated otherwise**

	Responsibilities (n=798)	Relationships (n=798)	School (n=795)	Recreation (n=799)	Non-discretionary (n=799)
% Change in log likelihood due to impairment and pain	13%	5%	4%	8%	4%
P for heterogeneity between regions	<0.001	0.009	<0.001	<0.001	<0.001
Variance between regions as % of total residual variance	15%	5%	34%	35%	38%
Gross motor function					
I Walks and climbs stairs, without limitation	NS	NS	1.0	1.0	1.0
II Walks inside	NS	NS	2.3 (1.6 to 3.4)	2.5 (1.7 to 3.7)	3.4 (2.3 to 5.1)
III Walks with assistive devices	NS	NS	3.0 (2.0 to 4.4)	3.6 (2.3 to 5.5)	6.4 (4.1 to 10)
IV Unable to walk, limited self mobility	NS	NS	3.3 (2.1 to 5.3)	2.5 (1.5 to 4.2)	9.6 (5.5 to 17)
V Unable to walk, severely limited self mobility			3.5 (2.1 to 5.8)	2.6 (1.3 to 5.1)	9.6 (4.5 to 20)
Fine motor skills					
I Without limitation	1.0	NS	NS	1.0	1.0
II Both hands limited in fine skills	2.4 (1.6 to 3.6)	NS	NS	1.9 (1.3 to 2.7)	2.5 (1.7 to 3.7)
III Needs help with tasks	2.6 (1.6 to 4.2)	NS	NS	2.8 (1.8 to 4.4)	3.3 (2.1 to 5.2)
IV Needs help and adapted equipment	1.9 (1.0 to 3.6)	NS	NS	2.7 (1.4 to 5.1)	4.0 (2.0 to 8.2)
V Needs total human assistance	3.1 (1.5 to 6.3)	NS	NS	4.0 (1.9 to 8.5)	2.7 (1.2 to 6.3)
Intellectual impairment					
>70	1.0	1.0	1.0	1.0	NS
50-70	6.3 (4.2 to 9.4)	1.9 (0.8 to 4.2)	1.6 (1.1 to 2.2)	2.3 (1.6 to 3.2)	NS
<50	26.2 (15 to 44)	4.6 (1.7 to 12)	2.3 (1.5 to 3.5)	5.6 (3.6 to 8.7)	NS
Communication					
Normal speech	1.0	1.0	1.0	1.0	1.0
Difficulty but uses speech	2.5 (1.5 to 3.9)	3.3 (1.3 to 8.2)	2.0 (1.4 to 3.0)	1.8 (1.2 to 2.7)	3.0 (2.0 to 4.6)
Uses non-speech for formal communication	4.4 (2.3 to 8.2)	2.4 (0.8 to 6.9)	1.4 (0.8 to 2.3)	1.3 (0.8 to 2.2)	1.6 (1.0 to 2.8)
No formal communication	16.0 (7.4 to 35)	7.9 (2.6 to 24)	2.9 (1.6 to 5.4)	2.7 (1.5 to 5.1)	2.4 (1.3 to 4.4)
Vision					
Has useful vision	1.0	NS	NS	1.0	NS
No useful vision	5.2 (2.5 to 11)	NS	NS	3.0 (1.8 to 5.1)	NS
Parental report of frequency of child pain in previous four weeks					
None of the time	NS	1.0	NS	1.0	1.0
Once or twice or a few times	NS	1.8 (0.9 to 3.6)	NS	1.6 (1.2 to 2.2)	1.6 (1.1 to 2.2)
More often	NS	5.2 (2.2 to 12)	NS	2.5 (1.7 to 3.6)	2.7 (1.8 to 4.1)

NS=factors not significantly associated with participation on specific domains. Additionally, no sociodemographic factor considered (child's age and sex, number of siblings and whether they were disabled, type of parental employment, level of parental educational qualifications, whether the family lived in an urban or rural area) was significantly associated with participation on any domain.
*Odds ratios from latent regression ordinal item response models, except for non-discretionary which are from latent regression Rasch model (see bmj.com). Odds ratios >1 indicate greater difficulty in participation in children in that category.

impairments were associated with lower participation on specific domains. Odds ratios comparing difficulty in participation among children with the most and least severe impairment of walking ability ranged from 2.6 (95% confidence interval 1.3 to 5.1) for recreation (table 2) to 20.5 (10 to 41) for home life (table 1). Odds ratios among children who experienced pain fairly often and those with no pain ranged from 1.9 (1.4 to 2.6) for mobility (table 1) to 5.2 (2.2 to 12) for relationships (table 2). Impairment and pain, however, accounted for only 4% (for the school domain, table 2) to 16% (for mealtimes and home life, table 1) of change in log likelihood (equivalent to deviance).

For the non-discretionary items, participation was associated with pain and impairments of walking ability, fine motor skills, and communication with a clear trend of lower participation being associated with greater impairment of walking ability and more pain. Impaired walking ability was the most important impairment in reducing participation: the odds ratio comparing difficulty in participation among children with the most and least severe impairment of walking ability was 9.6 (4.5 to 20) (table 2). Nevertheless, impairment and pain accounted for only 4% of the deviance.

None of the sociodemographic factors considered was significantly associated with participation. After adjustment for the child's impairment, the type of school attended was not associated with participation.

Participation—non-discretionary and on all domains except relationships—showed significant variation between regions (P<0.001) (tables 1 and 2). The figure shows the mean level of the children's

participation in each region, after adjustment for impairment and pain. The average level of participation of children in east Denmark was much higher than that of children in other regions on all domains except relationships, generally by 1-2 SD. Children in north of England and west Sweden also had consistently high levels of participation on all domains except relationships and home life. For all domains except relationships, the variation in participation between regions was substantial compared with the overall variation in participation (tables 1 and 2): it accounted for about a third of the total variation for personal care, communication, home life, school, recreation, and non-discretionary participation and was even higher for mobility (63%), mealtimes, and health hygiene (51%).

DISCUSSION

Among children with cerebral palsy, impairment of walking ability, fine motor skills, intellectual ability, communication, and parental report of pain were significantly associated with lower participation on most domains, whereas sociodemographic factors were not. Impairment and pain explained up to a sixth of the variation in participation. After adjustment for impairment and pain, children's participation varied substantially between regions, with children in Denmark having, on average, much higher participation than children in other countries on all domains except relationships. For most domains, about a third of the unexplained variation in participation could be ascribed to variation between regions and about two thirds to variation between individuals.

Measuring participation

We based our analysis on the responses to each item in Life-H without modifying them if the child needed help to participate. This resulted in the magnitude of the effect of impairment on participation being much smaller, compared with conventional scoring of Life-H (see bmj.com). This would explain why previous studies that included aids and adaptations in the scoring system found between 55% and 70% of the variation in participation was explained by impairment.[18 19] Allowing aids, adaptations, and help to influence the participation score makes the implicit assumption that participation with environmental help is inferior to that without such help, and inevitably overestimates the strength of the relation between impairment and participation.

Frequency of participation might allow more appropriate comparison of discretionary participation between disabled children and children in the general population and should be considered in future studies.

Strengths and limitations of the study

We included a large representative sample of children with cerebral palsy in nine European regions, eight of which had population based registers. We included all children regardless of their impairments, carried out robust statistical analyses of participation in relation to a wide range of impairments, pain, and sociodemographic factors; and assessed geographical variation.

Just over a third of the families of children with cerebral palsy who were sampled did not participate in the study. The participation of non-responders might have been systematically different from that of responders, so some bias could be present.

We considered alternative explanations for the differences that we found between regions. Different researchers visited the families in each region, which might have introduced systematic differences into parents' responses. We minimised this risk by training the researchers together at dedicated workshops. Language differences seem an unlikely explanation of the regional differences as children in north England had consistently higher participation than Irish children, despite their common language. Regions might differ in the type of participation to which they aspire for their children; however, non-discretionary participation—which is unlikely to be culturally determined—showed similar regional heterogeneity to discretionary participation.

Comparison with other studies

The results of some studies that also used multivariable models differ from ours. The large number of children in our study, randomly sampled from population registers, gives weight to our findings. We considered a wider range of impairments than many studies. Because impairments are highly correlated with each other, studies that assessed fewer impairments might identify different dominant associations. The strong associations between severity of motor impairment

WHAT IS ALREADY KNOWN ON THIS TOPIC

Participation, defined as involvement in life situations, is important for all children

Disabled children have reduced participation, partly because of their intrinsic impairments

The social model of disability proposes that participation of disabled people depends not only on their impairments but also on the social, physical, and attitudinal environment in which they live

WHAT THIS STUDY ADDS

After adjustment for severity of impairment, pain is strongly associated with lower participation in children with cerebral palsy and should therefore be carefully assessed

Participation varies substantially across nine European regions, as predicted by the social model of disability

National regulation and legislation should be directed to ensuring all countries adapt environments to optimise the participation of disabled children, building on the experience of those countries that make best provision

and intellectual impairment and lower participation confirm results of other studies.[12 20-22]

The differences that we found between regions might be partly explained by the different policies and legislation in the different countries. Advocacy groups for disabled people have worked with policy makers in Denmark to ensure that every sector implements the principle of equal access. Denmark and Sweden have national resources for providing information to families of disabled children about assistive technology. In terms of financial assistance to poor families, Denmark is ahead of other countries, with UK and Ireland following and Italy well behind.

We did not examine the contribution of familial factors, which might partly account for the unexplained variation in participation between individuals, but a recent Canadian study did so. It found that child impairment, child behaviour and personality, and family recreational styles predicted about a third of the variation of leisure and recreational participation.[23]

Implications for research and practice

Assessment of participation should enable the child and family to identify areas of life in which they want greater participation and so influence the choice of medical, therapeutic, and environmental interventions. Our study makes clearer the association of pain with lower participation. Clinicians should ask about children's pain. Children with cerebral palsy might have always lived with pain and might assume this to be normal. Psychological factors play an important part in most chronic pain, and the importance of interventions such as cognitive behavioural therapy has been emphasised for older children with cerebral palsy.[24]

Analysis of the causes of the geographical heterogeneity should provide evidence for changes to regulation and legislation, and so respond to the duty to provide accessibility under Article 9 of the UN Convention on the Rights of Persons with Disabilities.[25] The best way to characterise and measure participation must continue to be debated.[2] New instruments need to be developed that incorporate frequency and quality of participation.

We thank the families who participated in SPARCLE and the study's research associates—Kerry Anderson, Barbara Caravale, Malin Carlsson, Eva Lise Eriksen, Delphine Fenieys, Bettina Gehring, Louise Gibson, Heidi Kiecksee, Ann Madden, and Ondine Pez—for their enthusiasm and dedication to contacting families and collecting high quality data.

Contributors: See bmj.com.

Funding: The study was funded by the European Union Research Framework 5 Programme, grant number QLG5-CT-2002-00636. The German region joined later, funded by Bundesministerium für Gesundheit/German Ministry of Health (GRR-58640-2/14) and Stiftung für das Behinderte Kind/Foundation for the Disabled Child. The funders had no role in the study design; collection, analysis and interpretation of data; writing of the report; or decision to submit for publication.

Competing interests: None declared.

Ethical approval: This study was approved by ethics committees in each country. All parents gave written consent. All children with sufficient cognitive capacity gave written consent or communicated consent if unable to write.

1 World Health Organization. *International classification of functioning, disability and health*. Geneva: WHO, 2001.
2 McConachie H, Colver AF, Forsyth RJ, Jarvis SN, Parkinson KN. Participation of disabled children: how should it be characterised and measured? *Disabil Rehabil* 2006;28:1157-64.
3 Coster W, Khetani MA. Measuring participation of children with disabilities: Issues and challenges. *Disabil Rehabil* 2007;30:639-48.
4 Oliver M. *The politics of disablement*. London: Macmillan, 1990.
5 Majnemer A, Mazer B. New directions in the outcome evaluation of children with cerebral palsy. *Semin Pediatr Neurol* 2004;11:11-7.
6 Fougeyrollas P, Noreau L, Bergeron H, Cloutier R, Dion SA, St-Michel G. Social consequences of long term impairments and disabilities: conceptual approach and assessment of handicap. *Int J Rehabil Res* 1998;21:127-41.
7 Prevalence and characteristics of children with cerebral palsy in Europe. *Dev Med Child Neurol* 2002;44:633-40.
8 Noreau L, Lepage C, Boissiere L, Picard R, Fougeyrollas P, Mathieu J, et al. Measuring participation in children with disabilities using the assessment of life habits. *Dev Med Child Neurol* 2007;49:666-71.
9 Kerr C, McDowell B, McDonough S. The relationship between gross motor function and participation restriction in children with cerebral palsy: an exploratory analysis. *Child Care Health Dev* 2007;33:22-7.
10 Law M, King G, King S, Kertoy M, Hurley P, Rosenbaum P, et al. Patterns of participation in recreational and leisure activities among children with complex physical disabilities. *Dev Med Child Neurol* 2006;48:337-42.
11 Samson-Fang L, Fung E, Stallings VA, Conaway M, Worley G, Rosenbaum P, et al. Relationship of nutritional status to health and societal participation in children with cerebral palsy. *J Pediatr* 2002;141:637-43.
12 Beckung E, Hagberg G. Neuroimpairments, activity limitations, and participation restrictions in children with cerebral palsy. *Dev Med Child Neurol* 2002;44:309-16.
13 Maher CA, Williams MT, Olds T, Lane AE. Physical and sedentary activity in adolescents with cerebral palsy. *Dev Med Child Neurol* 2007;49:450-7.
14 Schenker R, Coster W, Parush S. Participation and activity performance of students with cerebral palsy within the school environment. *Disabil Rehabil* 2005;27:539-52.
15 Colver A. Study protocol: SPARCLE—a multi-centre European study of the relationship of environment to participation and quality of life of children with cerebral palsy. *BMC Public Health* 2006;6:105.
16 Dickinson H, Parkinson K, McManus V, Arnaud C, Beckung E, Fauconnier J, et al. Assessment of data quality in a multi-centre cross-sectional study of participation and quality of life of children with cerebral palsy. *BMC Public Health* 2006;6:273.
17 Palisano R, Rosenbaum P, Walter S, Russell D, Wood E, Galuppi B. Development and reliability of a system to classify gross motor function in children with cerebral palsy. *Dev Med Child Neurol* 1997;39:214-23.
18 Van Meeteren J, Roebroeck ME, Celen E, Donkervoort M, Stam HJ. Functional activities of the upper extremity of young adults with cerebral palsy: a limiting factor for participation? *Disabil Rehabil* 2008;30:387-95.
19 Forsyth R, Colver A, Alvanides S, Woolley M, Lowe M. Participation of young severely disabled children is influenced by their intrinsic impairments and environment. *Dev Med Child Neurol* 2007;49:345-9.
20 Voorman JM, Dallmeijer AJ, Schuengel C, Knol DL, Lankhorst GJ, Becher JG. Activities and participation of 9 to13-year-old children with cerebral palsy. *Clin Rehabil* 2006;20:937-48.
21 Hammal D, Jarvis S, Colver A. Participation of children with cerebral palsy is influenced by where they live. *Dev Med Child Neurol* 2004;46:292-8.
22 Morris C, Kurinczuk JJ, Fitzpatrick R, Rosenbaum PL. Do the abilities of children with cerebral palsy explain their activities and participation? *Dev Med Child Neurol* 2006;48:954-61.
23 King G, Law M, Hanna S, King S, Hurley P, Rosenbaum P, et al. Predictors of the leisure and recreation participation of children with physical disabilities: a structural equation modeling analysis. *Child Health Care* 2006;35:209-34.
24 Engel JM, Schwartz L, Jensen MP, Johnson DR. Pain in cerebral palsy: the relation of coping strategies to adjustment. *Pain* 2000;88:225-30.
25 United Nations. *Convention on the rights of persons with disabilities. Resolution 60/232. Adopted 13 December 2006*. New York:United Nations, 2006.

Accepted: 21 January 2009

Sociodemographic variations in the contribution of secondary drug prevention to stroke survival at middle and older ages: cohort study

Rosalind Raine,[1] Wun Wong,[1] Gareth Ambler,[2] Sarah Hardoon,[3] Irene Petersen,[3] Richard Morris,[3] Mel Bartley,[1] David Blane[4]

[1]Department of Epidemiology and Public Health, University College London, London WC1E 6BT
[2]Department of Statistical Science, University College London and University College London/Hospital Biomedical Research Unit
[3]Department of Primary Care and Population Health, Royal Free and University Medical School, London
[4]Department of Primary Care and Social Medicine, Imperial College London

Correspondence to: R Raine
r.raine@ucl.ac.uk

Cite this as: *BMJ* 2009;338:b1279
doi:10.1136/bmj.b1279

ABSTRACT

Objectives To determine the extent to which secondary drug prevention for patients with stroke in routine primary care varies by sex, age, and socioeconomic circumstances, and to quantify the effect of secondary drug prevention on one year mortality by sociodemographic group.

Design Cohort study using individual patient data from the health improvement network primary care database.

Setting England.

Participants 12 830 patients aged 50 or more years from 113 general practices who had a stroke between 1995 and 2005 and who survived the first 30 days after the stroke.

Main outcome measures Multivariable associations between odds of receiving secondary prevention after a stroke, and sex, age group, and socioeconomic circumstances; hazard ratios for all cause mortality from 31 days after the stroke and within the first year among patients receiving treatment and by social group; and probabilities of one year mortality for social factors of interest and treatment.

Results Only 25.6% of men and 20.8% of women received secondary prevention. Receipt of secondary prevention did not vary by socioeconomic circumstances or by sex. Older patients were, however, substantially less likely to receive treatment. The adjusted odds ratio for 80-89 year olds compared with 50-59 year olds was 0.53 (95% confidence interval 0.41 to 0.69). This was because older people were less likely to receive lipid lowering drugs—for example, the adjusted odds ratio for 80-89 year olds compared with 50-59 year olds was 0.44 (95% confidence interval 0.33 to 0.59). Secondary prevention was associated with a 50% reduction in mortality risk (adjusted hazard ratio 0.50, 95% confidence interval 0.42 to 59). On average, mortality within the first year was 5.7% for patients receiving treatment compared with 1.1% for patients not receiving treatment. There was little evidence that the effect of treatment differed between the social groups examined.

Conclusion Under-treatment among older people with stroke in routine primary care cannot be justified given the lack of evidence on variations in effectiveness of treatment by age.

This article is an abridged version of a paper that was published on bmj.com. Cite this article as: *BMJ* 2009;338:b1279

INTRODUCTION

Stroke is the second most common cause of death after coronary heart disease in developed countries,[1] and 80% of cases occur in over 64s.[2] It shares many of the risk factors with coronary heart disease yet it is associated with a slower rate of decline in mortality.[3] It is therefore plausible that the balance between the contribution of health care compared with behavioural interventions to health outcomes may be different for stroke compared with coronary heart disease.

We analysed the contribution of secondary drug prevention to stroke survival among adults aged 50 or more between 1995 and 2005 using a national primary care dataset for England. We determined the extent to which secondary prevention for stroke varies by sex, age, and socioeconomic circumstances; whether the association between secondary prevention and one year mortality after stroke varies between social groups; and the effect of secondary prevention on one year mortality by sociodemographic group.

METHODS

We examined individual patient data from primary care using the health improvement network database,[4] which comprises data on 1.99 million patients from 253 general practices across England. Unlike the general practice research database,[5] the health improvement network database includes an indicator of deprivation (Townsend index) associated with patients' postcodes.[6] Scores for the ward of residence of each patient are ranked and divided into fifths (1 least deprived, 5 most deprived).

We identified practices that had contributed data for at least five years between 1995 and 2005. We included data only from practices that consistently recorded at least one medical record, one additional health data record, and at least two prescriptions on average for each patient a year. We also restricted our sample to practices with acceptable mortality throughout the 11 year study period.[7]

We confined our analyses to patients aged 50 or more with a diagnosis of incident stroke recorded between 1995 and 2005. UK clinical guidelines for the secondary prevention of stroke in primary care recommend drug combinations for ischaemic and haemorrhagic stroke[8]: patients with high blood pressure should receive antihypertensives. In addition, patients with ischaemic stroke and total cholesterol levels greater than 3.5 mmol/l should be given antithrombotics and lipid lowering drugs. Recent evidence suggests that the benefits of reducing blood pressure and cholesterol levels are irrespective of their baseline levels.[9 10] Furthermore, 70% of men and 84% of women over 50 have high total

cholesterol levels (>5 mmol/l),[11] so most patients with ischaemic stroke would be eligible to receive lipid lowering drugs and antihypertensives. As these data were available only for the latter part of the study we assumed that all patients with ischaemic stroke were eligible to receive antihypertensives and lipid lowering drugs, and then we restricted the sample to patients eligible to receive antihypertensives, according to the guidelines. We defined secondary drug prevention as being prescribed either antihypertensives plus lipid lowering drugs plus antithrombotics or antihypertensives plus lipid lowering drugs. We assumed that prescriptions provided between 0 and 90 days from the date of the stroke diagnosis were prescribed for the event.

As lipid lowering drugs are contraindicated in patients with liver disease, we carried out sensitivity analyses after adjustment for liver disease at any time before stroke until 90 days from the date of diagnosis.

Patients' smoking status was defined according to their closest record to the date of stroke. We created a binary smoking variable: current smoker at stroke date (including former smoker after stroke) and not current smoker (including non-smoker and former smoker before stroke).

We used registration data to identify patients who died (all causes). Our discussion of mortality within the first year assumes that the patient survived the first 30 days. Patient time was calculated from the 31 days after the date of the first record of the stroke to the date of death, the date that the patient left practice, the last data collection from the practice, or end of the study period, whichever came first.

Statistical analysis

To investigate univariable and multivariable associations between the odds of receiving secondary drug prevention and sex, age group, and deprivation fifth, we undertook logistic regression with standard errors adjusted for clustering by general practice. A lower than expected proportion of patients were smokers suggesting some misclassification, therefore we excluded the variable "smoking status" in the main analyses but included it in secondary analyses. To further examine the association between patient characteristics and treatment we developed three further regression models with the outcome variable secondary prevention replaced by lipid lowering drugs, antihypertensives, and antithrombotics (all yes or no). We also investigated whether the associations for use of lipid lowering drugs changed over time by fitting models with a dichotomous time variable (1995-9, 2000-5) and the relevant interaction terms.

We applied the Cox proportional hazard model to investigate univariable and multivariable associations between one year mortality and sex, age group, deprivation fifth, and secondary prevention, adjusted for clustering by general practice. We created and tested interaction terms between treatment and the other covariates to investigate potential differential treatment associations. The Wald test was used to test for statistical significance. We checked the proportional hazards assumption using Schoenfeld residuals. We used Stata 9.2 for all analyses.

We evaluated the probabilities of mortality within the first year for those social factors of interest (adjusting for the other social factors) and treatment. We repeated the analyses having restricted the sample to patients with blood pressure records and who were eligible to receive antihypertensives.

Sensitivity analyses were done by increasing the prescription period to 365 days to account for patients with long hospital stays. We repeated the analyses

Odds ratio for association between secondary drug prevention and sex, Townsend fifth, and age

Variable	No of patients	No (%) of patients receiving secondary drug prevention*	Univariable model		Multivariable model†	
			Odds ratio (95% CI)	P value‡	Odds ratio (95% CI)	P value‡
Men	6228	1594 (25.6)	1	<0.001	1	0.07
Women	6602	1372 (20.8)	0.76 (0.70 to 0.84)		0.90 (0.80 to 1.01)	
Townsend fifth:						
First (least deprived)	3159	748 (23.7)	1	0.36	1	0.44
Second	2829	677 (23.9)	1.01 (0.86 to 1.19)		1.04 (0.88 to 1.23)	
Third	2719	590 (21.7)	0.89 (0.75 to 1.06)		0.92 (0.78 to 1.10)	
Fourth	2432	546 (22.5)	0.93 (0.74 to 1.17)		0.94 (0.73 to 1.21)	
Fifth (most deprived)	1691	405 (24.0)	1.02 (0.78 to 1.32)		1.01 (0.76 to 1.34)	
Age group:						
50-59	1639	432 (26.4)	1	<0.001	1	<0.001
60-69	2749	820 (29.8)	1.19 (1.00 to 1.42)		1.19 (1.00 to 1.42)	
70-79	4319	1155 (26.7)	1.02 (0.85 to 1.22)		1.03 (0.86 to 1.24)	
80-89	3387	528 (15.6)	0.52 (0.40 to 0.66)		0.53 (0.41 to 0.69)	
≥90	736	31 (4.2)	0.12 (0.08 to 0.19)		0.13 (0.08 to 0.21)	

Standard errors adjusted for clustering (113 practices); n=12 830.
*Secondary drug prevention prescribed within 0-90 days of incident stroke.
†Each risk factor (sex, Townsend fifth, age group) adjusted for other factors.
‡Wald test.

adjusted for liver disease. When we examined the association between patient characteristics and drug treatment, only the model for lipid lowering drugs was adjusted for liver disease.

RESULTS

In total, 12 830 patients from 113 practices across England were included in the study (see bmj.com): 11 202 (87.3%) had unspecified stroke, 1019 (7.9%) ischaemic stroke, 351 (2.7%) intracerebral haemorrhage, and 258 (2%) subarachnoid haemorrhage. Because of the high proportion of strokes classed as unspecified the analyses assume that all patients were eligible to receive antihypertensives and lipid lowering drugs. The results of these analyses are in the tables on bmj.com. In addition we have provided results that were limited to the 6820 (53.2%) patients eligible to receive antihypertensives When analyses were adjusted for smoking status, the 11 791 (91.9%) patients with a record for smoking status were included, of whom 1989 (16.9%) were current smokers. Overall, 221 (1.7%) patients had a record of liver disease.

Variation in secondary prevention by sex, age group, and deprivation

In univariable analyses (table) men were more likely to receive secondary prevention than women (25.6% *v* 20.8%). The odds of receiving secondary prevention decreased for the over 80s (26.4% of patients aged 50-59 received treatment versus 15.6% of patients aged 80-89 and 4.2% aged ≥90). The proportions of patients receiving treatment in each Townsend fifth were similar, ranging from 21.7% to 24.0%.

The differences in the proportions receiving treatment between the age groups persisted in multivariable analyses. In particular, the odds for receiving treatment decreased for the over 80s. After adjustment for age and deprivation, weak evidence showed an association between sex and treatment (0.90, 0.80 to 1.01, P=0.07) and no evidence of variation between Townsend fifths. Findings were not changed by adjusting for smoking status or liver disease, or restricting the analysis to patients eligible to receive antihypertensives.

Overall, 32% of men and 25.7% of women received lipid lowering drugs, just over 60% of both sexes received antihypertensives, and 62.3% of men and 60.4% of women received antithrombotics. The odds of being prescribed individual drugs varied by age group. There was also some evidence of variation by sex (see bmj.com). Thus the evidence of a lower probability of receiving lipid lowering drugs for the over 80s was strong. Compared with patients aged 50-59 the odds for patients aged 80-89 receiving treatment was 0.44 (95% confidence interval 0.33 to 0.59) and for those aged 90 or more was 0.12 (0.08 to 0.19). These results were not affected by adjustment for liver disease.

Between 1995 and 1999 the differences between older and younger people in the odds of receiving lipid lowering treatment were large but between 2000 and 2005 had narrowed, although older people were still less likely to receive lipid lowering drugs (odds ratio for patients aged ≥80 0.36, 0.28 to 0.46). The odds of being prescribed antithrombotics, however, increased with increasing age: compared with patients aged 50-59 the odds of patients aged 80-89 receiving antithrombotics was 2.92 (2.09 to 4.09). The odds of being prescribed antihypertensives was also generally higher for older ages; patients aged 70-79 had the highest chance of receiving such drugs (1.76, 1.46 to 2.11).

Evidence suggested that women were less likely to receive lipid lowering drugs (0.88, 0.79 to 0.99) and antithrombotics (0.85, 0.75 to 0.96). The probability of receiving antihypertensives did not differ between the sexes. Finally, there was no evidence of a difference in the probability of receiving any of the three categories of drugs by deprivation fifth. When analyses were restricted to patients eligible to receive antihypertensives, patients in the most deprived fifth were more likely to receive antihypertensives (1.43, 1.03 to 1.98).

Secondary drug prevention and risk of mortality within first year

In total, 10.4% of men and 12.5% of women died between 31 and 365 days after stroke (see bmj.com). Univariable analyses showed that risk of mortality within the first year was associated with secondary drug prevention, age group, deprivation, and sex. The risk of mortality was lower in those who received secondary drug prevention (hazard ratio 0.38, 95% confidence interval 0.31 to 0.46), younger patients, and men. There was some evidence of an association with Townsend fifth (P=0.06).

The multivariable analysis showed similar associations for receipt of secondary drug prevention (0.50, 0.42 to 0.59), and with age and deprivation. Thus compared with 50-59 year olds, the risk of mortality increased with each decade: the hazard ratio among 60-69 year olds was 1.66 (1.24 to 2.23) and among 80-89 year olds was 5.63 (4.03 to 7.86). There was some evidence for different survival experiences by Townsend fifth. Compared with patients in the least deprived fifth, those in the most deprived fifth had an increased risk of mortality (1.29, 1.07 to 1.55). However, the adjusted risk of mortality by sex showed that women had a lower risk of mortality than men (0.86, 0.77 to 0.96). This was due to the presence of a larger proportion of women (40.8%) than men (23.0%) aged 80 or more with stroke. The findings were not altered after adjustment for liver disease or smoking status, restriction of analyses to patients eligible to receive antihypertensives, or expansion of the treatment period.

Effect of secondary drug prevention on risk of mortality within first year by age and sex

Model based estimates of dying within one year suggested that, on average, patients receiving treatment had a 5.7% probability of death compared with 11.1% of patients not receiving treatment. These values changed little by sex and across Townsend fifths.

WHAT IS ALREADY KNOWN ON THIS TOPIC

Recent research on the contribution of medical care to population health has focused on the reduction in mortality from coronary heart disease

The contribution of medical care for other major conditions, including stroke, has, however, not been quantified

WHAT THIS STUDY ADDS

Patients aged over 80 are less likely to receive secondary drug prevention after stroke than younger patients

Evidence suggested that women were less likely to receive treatment than men but that socioeconomic status was not associated with differences in treatment

Under-treatment of older people cannot be justified in terms of variations in effectiveness because older people are at least as likely to benefit from treatment as younger people

Younger patients, because of their lower mortality rate, exhibited little absolute difference in mortality (2% of treated patients compared with 3.9% of untreated patients among 50-59 year olds), whereas older patients exhibited a larger absolute difference (10.5% of treated patients compared with 20% of untreated patients among 80-89 year olds).

DISCUSSION

In this national study of nearly 13 000 patients aged 50 years or more from 113 practices in primary care, we found low rates of receipt of secondary drug prevention: 25.6% of men and 20.8% of women. We also found evidence of an association of reduced treatment with older age, with the odds of 80-89 year olds receiving secondary prevention nearly half that of 50-59 year olds. This was because older people were less likely to receive lipid lowering drugs. This variation in treatment is important because secondary drug prevention in patients who survived the first 30 days after a stroke was associated with a 50% reduction in the hazard of dying during the first year. This reduction had different implications for different age groups as a result of the underlying increased rates of mortality for older people. The effect of treatment did not seem to differ between the social groups examined.

We did find some evidence for different survival by Townsend fifth and sex that could not be explained by differences in treatment. The most deprived patients had lower one year survival than their most advantaged counterparts, and women had a higher likelihood of one year survival than men.

Strengths and limitations of the study

We measured the relation between receipt of recommended drug treatments and one year mortality within primary care. The size of the beneficial effect of such treatments in routine clinical practice has not been previously shown. Meta-analyses of randomised controlled trials have established the effect of individual drugs for secondary prevention.[12-14] However, treatment effects in routine clinical practice tend to be lower than in randomised trials (N Bennett and R Hooker, personal communication, 1996) and it cannot be assumed that all interventions have independent effects.[15] By using the health improvement network dataset, we were able to establish the effect on one year survival of treatment in routine clinical practice and whether this varied by age, sex, and deprivation. All patients registered with a practice were included so selection bias should not be a problem.

Our study shares limitations of research using routinely collected data on patients. This includes non-standardised coding of date of diagnosis for incident stroke and non-standardised and incomplete coding of stroke subtype, comorbidity, management, and cause of death. Although we were able to examine the appropriateness of antihypertensive treatment, incomplete coding of stroke subtype and a lack of data on lipid levels meant that we were unable to assess patterns of prescribing by stroke type. Inaccurate and missing data on blood pressure levels may also explain the results of our subgroup analyses for antihypertensive treatment. The proportion of patients who smoked was lower than expected (16.9% compared with 60% in other studies).[16,17] This may be due to misclassification. The results after adjustment for smoking status are, however, plausible; given the association of smoking with deprivation.[18] Although data on cause of death were incomplete, data on all cause mortality were available. Such data are commonly used because research has shown that the most common cause of death in the year after stroke was the index stroke (64%).[19]

Several other methodological issues need to be taken into account. Firstly, to limit overlap between treatment and outcome periods (0-90 days and 31-365 days, respectively), we used the 90 day cut-off point for prescriptions in our main analysis. This minimised the possibility of immortal time bias or survival bias, which can lead to overestimation of treatment effect.[20] The remaining 60 day overlap between the treatment and outcome periods could nevertheless have led to some overestimation of treatment effects. Secondly, we used a well established method of assigning deprivation based on area of residence. Thirdly, we confined our survival analyses to one year after stroke. We used the Cox proportional hazards model, which assumes that the proportional effect of any variable on risk of mortality does not change over time. This assumption is not likely to hold over more than one year since the effect of treatment is maximal in the short term. This limitation is justified because the risk of death is greatest in the first year after stroke. Finally, we cannot assume that prescribing secondary drug prevention during the first year after stroke is maintained long term.

Comparison with other studies

We found low rates of prescribing of effective secondary prevention in patients after stroke. A study of nearly 45 000 Canadian patients with stroke reported low rates of aspirin use (38.1% in men and 35.6% in women).[21] In another Canadian study of over 390 000 patients aged 66 years or more and with a

history of cardiovascular disease only 19.1% were prescribed statins.[22]

A large study of prescribing lipid lowering drugs in primary care for coronary heart disease found a reduced likelihood of receiving such drugs with increasing age (as in our study) and in women.[23]

Our results are in line with previous research, which has documented better one year survival in older women than in elderly men.[21,24,25] Other research has also found lower survival among socially disadvantaged groups.[1,26] The mechanisms through which socioeconomic circumstances affect stroke outcomes are unclear. A high prevalence of risk factors for stroke in disadvantaged groups has been widely reported.[1] However estimates vary as to how much of the difference in stroke outcome by deprivation can be accounted for by variations in prevalence of risk factors.

Implications and conclusions

It is reassuring that this national study of patients after stroke did not find that deprived patients were less likely to receive treatment than their more affluent counterparts. Indeed, we report increased use of antiplatelets among older and more deprived patients. This is likely to be explained in part by the over the counter availability of aspirin for people who are not eligible for free prescriptions but can afford to pay.

The low treatment rates for lipid lowering therapies among elderly people may in part be explained because the first national clinical guidelines for stroke were not published until half way through the study period. Also, doctors who care for patients with multiple comorbidities may focus on these rather than on secondary prevention. However neither explanation accounts for the under-use of lipid lowering drugs only, which suggests that this may be due to the pressure on budgets in primary care. Alternatively, variations in the use of evidence based therapies may be appropriate if they are secondary to variations in effectiveness, cost effectiveness, or the likelihood of adverse consequences and of adherence to treatment. These factors may explain under-use in elderly people.[27] However, the relative survival benefits associated with lipid lowering drugs have been shown among elderly patients.[22] Doctors may also be reluctant to prescribe therapies to patients thought unlikely to adhere to treatment. However we found an increased likelihood of being prescribed antihypertensives and antiplatelets with increasing age, so concerns about adherence to lipid lowering drugs alone are an unlikely explanation. Finally, lipid lowering drugs for secondary prevention in elderly people have been shown to be cost effective.[28] Thus the evidence suggests that concerns about the trade-off between benefits and risks in elderly people may be exaggerated and that one year survival benefit is not modified by age. Therefore under-treatment of older people cannot be justified, unless it is explained by informed patient choice.

We thank the Longevity Steering Group for their valuable advice, comments, and support for this research, particularly John Bunker (University College London), Richard Wilkinson (University of Nottingham), Joseph Lu and Richard Humble (Legal and General), and Richard Willets (Willets Consulting); Martin Brown and Kate Walters (University College London) for their expert clinical input; and Mary Thompson (EPIC), Louise Marston (University College London), Andrew Hutchings (London School of Hygiene and Tropical Medicine), and Charlotte Ashton (Wandworth Primary Care Trust) for their advice.

Contributors: See bmj.com.

Funding: RR is partly funded by a National Institute for Health Research public health career scientist award and by the National Institute for Health Research University College London Hospital/University College London Comprehensive Biomedical Research Centre. WW is funded by Legal and General Group. The research was funded in part by the actuarial profession (Institute of Actuaries in England and Wales and the Faculty of Actuaries in Scotland). The authors' work was independent of the funders.

Competing interests: None declared.

Ethical approval: This study was approved by the London research ethics committee, National Research Ethics Service (07/MRE02/19).

1 Cox AM, McKevitt C, Rudd AG, Wolfe CDA. Socioeconomic status and stroke. *Lancet Neurology* 2006;5:181-8.
2 Carroll K, Murad S, Eliahoo J, Majeed A. Stroke incidence and risk factors in a population-based prospective cohort study. *Health Stat Q* 2001;12:18-26.
3 Willets RC, Gallop AP, Leandro PA, Lu JLC, Macdonald AS, Miller KA, et al. Longevity in the 21st century. *Br Actuar J* 2004;10:685-832.
4 Bourke A, Dattani H, Robinson M. Feasibility study and methodology to create a quality-evaluated database of primary care data. *Inform Prim Care* 2004;12:171-7.
5 Davies AR, Smeeth L, Grundy EM. Contribution of changes in incidence and mortality to trends in the prevalence of coronary heart disease in the UK: 1996-2005. *Eur Heart J* 2007;28:2142-7.
6 Townsend P, Phillimore P, Beattie A. *Inequalities in health in the northern region*. Newcastle upon Tyne: Northern Regional Health Authority and University of Bristol, 1986.
7 Maguire A, Blak BT, Thompson M. The importance of defining periods of complete mortality reporting for research using automated data from primary care. *Pharmacoepidemiol Drug Saf* 2009;18:76-83.
8 Intercollegiate Working Party for Stroke. *National clinical guidelines for stroke*, 2nd ed. London: Royal College of Physicians of London, 2004.
9 PROGRESS Collaborative Group. Randomised trial of a perindopril-based blood-pressure-lowering regimen among 6105 individuals with previous stroke or transient ischaemic attack. *Lancet* 2001;358:1033-41.
10 Shepherd J. Who should receive a statin these days? Lessons from recent clinical trials. *J Intern Med* 2006;260:305-19.
11 Banks J, Breeze E, Lessof C, Nazroo J, eds. *Retirement, health and relationships of the older population in England: the 2004 English Longitudinal Study of Ageing*. London: Institute for Fiscal Studies, 2006.
12 Afilalo J, Duque G, Steele R, Jukema JW, de Craen AJM, Eisenberg MJ. Statins for secondary prevention in elderly patients. *J Am Coll Cardiol* 2008;51:37-45.
13 Antithrombotic Trialists' Collaboration. Collaborative meta-analysis of randomised trials of antiplatelet therapy for prevention of death, myocardial infarction, and stroke in high risk patients. *BMJ* 2002;324:71-86.
14 Gueyffier F, Boissel J-P, Boutitie F, Pocock S, Coope J, Cutler J, et al. The INDANA Project Collaborators. Effect of antihypertensive treatment in patients having already suffered from stroke. *Stroke* 1997;28:2557-62.
15 Rothwell PM. Making the most of secondary prevention. Editorial. *Stroke* 2007;38:1726.
16 Hajat C, Dundas R, Stewart J, Lawrence E, Rudd A, Howard R, et al. Cerebrovascular risk factors and stroke subtypes. *Stroke* 2001;32:37-42.
17 Di Carlo A, Lamassa M, Baldereschi M, Pracucci G, Basile AM, Wolfe CD, et al. Sex differences in the clinical presentation, resource use, and 3-month outcome of acute stroke in Europe: data from a multicenter multinational hospital-based registry. *Stroke* 2003;34:1114-9.
18 Lyratzopoulos G, Heller RF, McElduff P, Hanily M, Lewis P. Deprivation and trends in blood pressure, cholesterol, body mass index and smoking among participants of a UK primary care-based cardiovascular risk factor screening programme: both narrowing and widening in cardiovascular risk factor inequalities. *Heart* 2006;92:1198-206.

19 Hankey GJ, Jamrozik K, Broadhurst RJ, Forbes S, Burvill PW, Anderson CS, et al. Five-year survival after first-ever stroke and related prognostic factors in the Perth Community Stroke Study. *Stroke* 2000;31:2080-6.
20 Zhou Z, Rahme E, Abrahamowicz M, Pilote L. Survival bias associated with time-to-treatment initiation in drug effectiveness evaluation: a comparison of methods. *Am J Epidemiol* 2005;162:1016-23.
21 Holroyd-Leduc JM, Kapral MK, Austin PC, Tu JV. Sex differences and similarities in the management and outcome of stroke patients. *Stroke* 2000;31:1833-7.
22 Ko D, Mamdani M, Alter D. Lipid lowering therapy with stains in high risk elderly patients: the treatment paradox. *JAMA* 2004:21:1864-70.
23 DeWilde S, Carey IM, Bremner SA, Richards N, Hilton SR, Cook DG. Evolution of statin prescribing 1994-2001: a case of agism but not of sexism? *Heart* 2003;89:417-21.
24 Jiang Y, Sheikh K, Bullock C. Is there a sex or race difference in stroke mortality? *J Stroke Cerebrovasc Dis* 2006;15:179-86.
25 Griffiths C, Brock A. Twentieth century mortality trends in England and Wales. *Health Stat Q* 2003;18:5-17.
26 Arrich J, Lalouschek W, Mullner M. Influence of socioeconomic status on mortality after stroke: retrospective cohort study. *Stroke* 2005;36:310-4.
27 Alter DA, Manuel DG, Gunraj N, Anderson G, Naylor CD, Laupacis A. Age, risk-benefit trade-offs, and the projected effects of evidence-based therapies. *Am J Med* 2004;116:540-5.
28 Ward S, Lloyd Jones M, Pandor A, Holmes M, Ara R, Ryan A, et al. A systematic review and economic evaluation of statins for the prevention of coronary events. *Health Technol Assess* 2007;11:1-160,iii-iv.

Accepted: 16 January 2009

Meeting information needs of patients with incurable progressive disease and their families in South Africa and Uganda: multicentre qualitative study

Lucy Selman,[1] Irene J Higginson,[1] Godfrey Agupio,[2] Natalya Dinat,[3] Julia Downing,[4] Liz Gwyther,[5] Thandi Mashao,[6] Keletso Mmoledi,[3] Anthony P Moll,[7] Lydia Mpanga Sebuyira,[8] Barbara Panajatovic,[9] Richard Harding[1]

[1]King's College London, Department of Palliative Care, Policy and Rehabilitation, King's College London, London SE5 9RJ
[2]Hospice Africa Uganda, PO Box 7757, Kampala, Uganda
[3]Witwatersrand Palliative Care, PO Box 212, Pimville, Soweto 1808, Johannesburg, Gauteng, South Africa
[4]African Palliative Care Association, PO Box 72518, Kampala
[5]Hospice Palliative Care Association of South Africa, PO Box 38785, Pinelands 7430, Cape Town, Western Cape, South Africa
[6]Palliative Medicine Unit, University of Cape Town, Observatory 7925, Cape Town
[7]Church of Scotland Hospital, P/Bag X502, Tugela Ferry 3010, KwaZulu Natal, South Africa
[8]Infectious Diseases Institute, Faculty of Medicine, Makerere University, PO Box 22418, Kampala
[9]Msunduzi Hospice, PO Box 220223, Pietermaritzburg 3208, KwaZulu Natal

Correspondence to: L Selman
lucy.selman@kcl.ac.uk

Cite this as: *BMJ* 2009;338:b1326
doi:10.1136/bmj.b1326

This article is an abridged version of a paper that was published on bmj.com. Cite this article as: *BMJ* 2009;338:b1326

ABSTRACT

Objectives To explore the information needs of patients with progressive, life limiting disease and their family caregivers in South Africa and Uganda and to inform clinical practice and policy in this emerging field.

Design Semistructured qualitative interview study.

Setting Four palliative care services in South Africa and one in Uganda, covering rural, urban, and peri-urban locations.

Participants 90 patients and 38 family caregivers enrolled in palliative care services; 28 patients had cancer, 61 had HIV infection (including 6 dual HIV/cancer diagnoses), and 1 had motor neurone disease.

Results Five themes emerged from the data. (1) Information sources: a lack of information from general healthcare providers meant that patients and caregivers had to draw on alternative sources of information. (2) Information needs: patients and caregivers reported needing more information in the key areas of the causes and progression of the disease, its symptoms and treatment, and financial/social support. (3) Impact of unmet needs: poor provision of information had a detrimental effect on patients' and caregivers' ability to cope. (4) Communication: negative experiences of communication with general healthcare staff were reported (misinformation, secrecy, insensitivity). (5) Barriers to effective provision of information: barriers related to symptoms, culture, time constraints in hospital, and paternalism in general health care.

Conclusions Lack of information was a major theme for both patients and carers, who had important unanswered questions relating to living with a progressive incurable disease. Evidence based recommendations for clinicians are presented, including the proactive provision of information tailored to individual patients and families.

INTRODUCTION

Palliative care is an essential component of public health services in sub-Saharan Africa, where in addition to the rising burden of HIV, cancer and other non-communicable diseases are becoming urgent public health concerns. Current provision of palliative care in the region is patchy, and coverage is poor.[1 2] Successful models of community based and home based palliative care have been described, but so have considerable challenges,[1] including lack of access to drugs, poor social conditions, criminality, high morbidity and mortality in health workers, and a lack of trained professionals.[3-6]

Meeting the information needs of patients with progressive, life limiting conditions and their families is a key concern of palliative care. A large body of evidence shows that lack of information on the causes, symptoms, treatment, and progression of disease adversely affects patients' and caregivers' abilities to cope with and manage serious illness and that good communication improves outcomes.[7-10] To date very little research has been done in this area in Africa, where illiteracy, poverty, and multiple deaths from AIDS within the same family are common.[1 11-13]

This qualitative study aimed to explore the information needs of patients and caregivers attending palliative care services in South Africa and Uganda.

METHODS

Design and setting—The study reported here is the qualitative component of a large, 30 month collaborative study. We used data from semistructured qualitative interviews with patients and caregivers enrolled at four non-profit palliative care services in South Africa and one in Uganda. We selected the participating sites

as established palliative care services representing a diverse range of service types.

Recruitment and sampling—Eligible patients and caregivers were approached at the five participating palliative care sites. We generated a purposive sample to a maximum target of 20 patients and 10 caregivers at each site. We included participants if they were adult patients or family caregivers and able to speak either English or one of six local languages fluently. The sampling frame took account of place of care (community/inpatient/outpatient), age, sex, location, and ethnic group.

Data collection—We drafted semistructured topic guides (see bmj.com). The research nurse based at each site did the interviews, either in the participant's home or at the site during a routine visit.

Analysis—One researcher coded each transcript, creating a coding frame of themes generated directly from the data and organised according to specific research questions. Through a constant comparison approach to analysis, sub-themes were generated and deviant cases highlighted within each theme, in order to describe the breadth of the data.[14] A second researcher reviewed a random sample of five transcripts from each service to ensure the internal consistency and independence of themes.[15] Inter-rater coding reliability was high.

RESULTS

Sample characteristics

We recruited 128 participants across the five sites (90 patients, 38 caregivers). Across the sample, 27 participants were from an urban location, 36 in a peri-urban location, and 65 in a rural location.

Qualitative findings

We coded qualitative interview data under 10 themes. Communication and information represented a central theme, referred to by 85 out of 90 patients in 143 passages of text. We broke down the data under this theme into the following sub-themes: sources of information, information needs, impact of unmet information needs, communication with general healthcare staff, and barriers to effective provision of information.

Information needs of patients: important topics

Causes and symptoms (n=29)

"They have not explained why my legs are so weak and painful, but in hospital they told me I am HIV positive . . . I don't think [the information] is enough, I still need to know what is wrong with my legs" (AIDS patient)

Progression, treatment, and management of disease (n=22)

"I would want to know maybe the first stage we are going to give this [and] then we shall review A, B, C, D . . . I need to know how many stages I am going to go through . . . That information should be there" (cancer patient)

Financial and social support (n=9)

"I also would like to know if the help got from [X] hospice will continue or after some time it will be stopped. Because I would need assistance like food, finance, building a house to help my children in future" (patient with AIDS and cancer)

Supporting others (n=2)

"Yes, there is something I would like to know: as I am HIV positive, how can I help the others that are HIV positive too?" (AIDS patient)

Sources of information

Patients and caregivers reported a range of sources of information about the disease and its management. Healthcare providers were a key source, reported by 30 patients and 12 carers. Non-governmental organisations such as support groups also played an important role for some patients, and the media was also mentioned, particularly by carers. Both patients and carers also talked about receiving information and support from friends, neighbours, and family members.

Such resourcefulness in accessing information was often necessitated by insufficient information from their healthcare services. A patient with cancer reported, "Sometimes you get a decent guy [hospital clinician], but then he's so stressed out that he hasn't got time to talk to you. Our knowledge of cancer was zero and we got most of our information through our daughter helping us out and through the internet."

Participants clearly recognised that healthcare staff needed to provide more information. However, one patient stated that she wanted to know as little as possible.

Where palliative care services had actively provided information and support, respondents expressed gratitude. The mother of a patient with AIDS said, "The information that you gave us, and the help you gave us, made my son get well. Oh, I love you, my children. If I see you coming up there on the road I just feel so happy."

Information needs

Patients and caregivers were asked if they would like additional information on any subjects. Nineteen patients and two carers reported that they did not need any additional information; however, 12 of these patients were not probed further for any unanswered questions. The box summarises patients' needs for information.

The topic on which caregivers most often reported needing more information was the patient's disease and its progression. Other information needs of caregivers concerned symptoms and their management and financial and social support

Nine patients and three caregivers reported not knowing which questions to ask staff or said that they were unable to judge if they had been given enough information. A patient with motor neurone disease exemplifies this: "They told me about my illness, though I don't know whether it was enough, as I am not familiar with the disease." This highlights patients' and caregivers' reliance on healthcare staff to start and guide conversations.

Impact of unmet information needs

Several interviews showed that being uninformed contributed to patients' and carers' worry. Patients

described the impact on their ability to plan for the future, for example: "Knowing medication is important . . . because it is costly to get medicine, so you need to plan for it way ahead" (cancer patient).

A lack of information seemed to reduce patients' ability to care for themselves, whereas being fully informed helped them to manage their conditions better, as reported by an HIV positive patient: "Yes, I was told everything at the clinic about HIV and AIDS, and I think I have used that to my advantage, because here I am now, still alive and getting stronger." Similarly, unmet needs for information affected the quality of care that some family members were able to provide.

Conversely, being well informed seemed to have a beneficial impact on some patients' ability to cope. A patient with colon cancer, for example, described how being informed contributed to a sense of inner peace. Another patient reported how access to information and open communication had helped her family to deal with the condition: "We discuss it, we talk about it. We are reading books about it. It has helped us" (patient with ovarian and breast cancer).

Communication with general healthcare staff

Respondents reported both positive and negative experiences of communication with healthcare staff in hospitals and clinics. Poor communication with generalist staff was a central theme across the sites, as illustrated by a patient with prostate cancer: "The information level is shocking, they [hospital staff] don't even want to give you PSA [prostate specific antigen] results, you know, we're not kids! And they think I don't know what they think—that you're going to die of fright if they tell you."

Four patients described the trauma of having bad news broken to them insensitively; for example, "I asked them if I was going to die. They told me that I won't die if I take my treatment I will be given. I was shocked and shattered by the news. I cried a lot and pleaded with the doctor to kill me, because I felt I was already dead. I was referred to hospital and I continued with my plea, but a fellow patient who talked me out of that thought helped me" (AIDS patient).

Across the sites, four patients and a caregiver described being misinformed by healthcare staff or test results not being shared with them. At one site, four patients described feeling mistreated, objectified, or spoken to without respect while in hospital. Caregivers across sites discussed feelings of being shut out by "secretive" staff. Three caregivers reported not being told the patient's diagnosis directly, but learning it from the medical notes or from being sent on a course.

Positive experiences of communication with healthcare staff were also reported. A patient with cancer described how her doctor helped her to break the diagnosis to her children, and two other patients reported a close relationship with staff. One patient described how open communication about prognosis, future care, and treatment options had helped her to come to terms with her condition: "Dr [X], the oncologist at [X hospital], told me all the dos and don'ts and said I could think about it . . . The doctor explained a lot, that every day there was something new and they could try all sorts of different things. She said that if I ran out of money she could arrange for me to be seen at the government hospital."

Barriers to effective information provision

Across four of the sites, eight patients and five caregivers stated that they had had enough information about their condition but on further probing revealed unmet needs for information. A 50 year old woman with cancer and AIDS illustrates this tendency.

Interviewer: "Has this information you have got from your doctor, and maybe other people, been enough for you?"

Respondent: "I feel I have got enough information about my illness."

I: "What would you like more information about?"

R: "I need more information about what cancer actually is, if it can be cured, and how soon. I would also like information on any social or financial support I could get either around [the hospice] or from organisations."

This tendency seems to indicate low expectations of health care, which might also be cultural.

Three patients reported confusion or memory loss that made comprehending and retaining information difficult. This may have been as a reaction to receiving bad news or difficult medical information, a manifestation of the disease's symptoms, or a side effect of treatment.

Staff related barriers were also described. A patient and a caregiver from one site reported that general healthcare staff were often too busy or stressed to communicate well: "The clinics are very busy and don't have the time for the questions. I wish I could get the information because one day she is going to be very sick and I won't know how to look after her" (caregiver of AIDS patient). Three patients found the language used by staff difficult to understand and criticised healthcare staff for adopting a paternalistic approach to provision of information.

DISCUSSION

This is the first study in Africa to try to understand experiences of communication and information giving among patients with incurable progressive disease and their informal caregivers. Most patients and caregivers lacked information and had unanswered questions about their conditions. This situation seemed to exist in spite of them drawing on a wide range of sources for information. Patients and caregivers often considered general medical services to be inadequate at providing accessible information, although they appreciated efforts made by their palliative care team to provide information.

Poor knowledge and provision of information adversely affected patients' and caregivers' ability to cope with their situation, directly affecting caregivers' ability to care for patients, as well as patients' ability to care for themselves and plan for the future. For both

WHAT IS ALREADY KNOWN ON THIS TOPIC

Research from developed countries shows that lack of information on causes, symptoms, treatment, and progression of diseases is associated with poor outcomes in patients and caregivers

Little research has been done on the information needs of patients with incurable progressive disease and their families in sub-Saharan Africa or on their experiences of communication with healthcare staff

Evidence is therefore lacking on how best to meet the information needs of these patients and their families at a service level

WHAT THIS STUDY ADDS

Patients and caregivers receiving palliative care in South Africa and Uganda are often uninformed about the patient's disease and its management, which impairs their ability to cope with the condition and plan for the future

Key areas of information need are causes and symptoms; progression, treatment, and management of disease; and financial and social support

groups, not having the information they needed was related to anxiety about the disease and the future.

Limitations of study

Data were collected by researchers with varying degrees of experience and with differing backgrounds. This resulted in some variability in the depth of the interviews across sites. The lead data analyst is European and has not lived in Africa, which could potentially lead to aspects of the data being misunderstood. We minimised this by regular consultation with the local African project team members. Differences in the socioeconomic, ethnic, and cultural backgrounds of interviewers and interviewees were inevitable and may have affected the responses given. However, "matching" interviewer and interviewee is not always possible and does not necessarily deliver better results.[16 17] Finally, within the sub-Saharan African population, the participants in this study are relatively unusual in that all were receiving palliative care. Most people dying with advanced illness in sub-Saharan Africa may have even less access to information and care than this sample.

Implications for clinicians and policy makers

Education, training, and support

All clinical staff should receive training in palliative care skills, including communication. Patients and caregivers experience high levels of worry and fear, so access to staff with counselling skills is imperative.[18] Liaison with professionals trained in palliative care is recommended to ensure that general healthcare staff receive the support they need in complex cases.

Information provision

Tailored to the individual—Specific needs for information vary between people. Communication should be individually tailored according to needs, preferences, and abilities, assessed at key points in the disease trajectory.[8] Information should be expressed in lay terms and take into account its psychological impact, as well as symptoms such as memory loss. Question prompt sheets and audio recordings of consultations improve recall.[19] In communities with high levels of illiteracy, pictorial educational materials and face to face teaching may be more effective.[20]

Reflexive and proactive—Some service users feel that they should seem grateful for the care they receive, even when their needs are not being met. Staff members need to consider how differences in cultural norms and perceptions of social power may affect their relationships with patients and caregivers.[21] To avoid needs for information going undetected, healthcare staff should question patients and caregivers proactively about their information needs and understanding.[22]

Open and honest—Communication with patients and caregivers should be open and honest. A recent systematic review found that hiding or distorting the truth does not engender hope but may instead increase patients' fear.[23] A minority of patients may prefer nondisclosure and find hope in avoiding the facts. In this case their autonomy should be respected, but their preferences should be assessed and re-negotiated throughout the disease trajectory.

Documented—To ensure effective multidisciplinary care in resource stretched conditions, records should be kept of discussions between healthcare staff and patients and all relevant staff should have access to these.[24]

For both patient and caregiver—The data show that some carers are excluded from discussions with healthcare staff and that carers play a key role as information providers to the rest of the family and larger community. Services must work closely with families and caregivers, empowering them to provide the care the patient needs.[25]

Future research

Research is needed to explore patients' and caregivers' communication needs in more depth and in a wider variety of settings. Research is required into the needs for training and support of general healthcare staff and specialist palliative care staff to inform the development of health services in sub-Saharan Africa. Given the diversity of spoken languages and high levels of health illiteracy in the region, novel, non-written methods of providing information need to be developed.[26] Quantitative studies are also required to identify variables that predict specific information needs.

We are very grateful to all the patients and caregivers who participated, the service staff who helped with recruitment, and the Big Lottery Fund UK and Cicely Saunders International for funding this study. We thank Claire Gillespie and Penny Gwacela at South Coast Hospice, Patricia Ndlovu at Philanjalo Hospice, and Kabuye Deo and Lillian Mpeirwe at Hospice Africa Uganda for assisting with interviews, and Fliss Murtagh and Jonathan Koffman for comments on a previous draft.

Contributors: See bmj.com.

Funding: This study was sponsored by a grant from the Big Lottery UK through Cicely Saunders International. The authors declare their independence from the funders.

Competing interests: None declared.

Ethical approval: The study was reviewed and approved by the ethics review boards of the Universities of Cape Town, KwaZulu Natal, and

Witwatersrand; the Ugandan National Council for Science and Technology; Hospice Africa Uganda; and the Hospice Palliative Care Association of South Africa.

1 Harding R, Higginson IJ. Palliative care in sub-Saharan Africa. *Lancet* 2005;365:1971-7.
2 Clark D, Wright M, Hunt J, Lynch T. Hospice and palliative care development in Africa: a multi-method review of services and experiences. *J Pain Symptom Manage* 2007;33:698-710.
3 Foster S. Supply and use of essential drugs in sub-Saharan Africa: some issues and possible solutions. *Soc Sci Med* 1991;32:1201-18.
4 Soares L. Poor social conditions, criminality and urban violence: unmentioned barriers for effective cancer pain control at the end of life. *J Pain Symptom Manage* 2003;26:693-5.
5 Swartz L, Dick J. Managing chronic disease in less developed countries. *BMJ* 2002;325:914-5.
6 Harding R, Stewart K, Marconi K, O'Neill JF, Higginson IJ. Current HIV/AIDS end-of-life care in sub-Saharan Africa: a survey of models, services, challenges and priorities. *BMC Public Health* 2003;3:33.
7 Kutner JS, Steiner JF, Corbett KK, Jahnigen DW, Barton PL. Information needs in terminal illness. *Soc Sci Med* 1999;48:1341-52.
8 Parker SM, Clayton JM, Hancock K, Walder S, Butow PN, Carrick S, et al. A systematic review of prognostic/end-of-life communication with adults in the advanced stages of a life-limiting illness: patient/caregiver preferences for the content, style, and timing of information. *J Pain Symptom Manage* 2007;34:81-93.
9 Thorne SE, Bultz BD, Baile WF. Is there a cost to poor communication in cancer care? A critical review of the literature. *Psychooncology* 2005;14:875-84.
10 Mager WM, Andrykowski MA. Communication in the cancer 'bad news' consultation: patient perceptions and psychological adjustment. *Psychooncology* 2002;11:35-46.
11 Harding R, Powell RA, Downing J, Connor SR, Mwangi-Powell F, Defilippi K, et al. Generating an African palliative care evidence base: the context, need, challenges and strategies. *J Pain Symptom Manage* 2008;36:304-9.
12 Sepulveda C, Habiyambere V, Amandua J, Borok M, Kikule E, Mudanga B, et al. Quality care at the end of life in Africa. *BMJ* 2003;327:209-13.
13 Sukati NA, Mndebele SC, Makoa ET, Ramukumba TS, Makoae LN, Seboni NM, et al. HIV/AIDS symptom management in Southern Africa. *J Pain Symptom Manage* 2005;29:185-92.
14 Mays N, Pope C. Assessing quality in qualitative research. *BMJ* 2000;320:50-2.
15 Pope C, Ziebland S, Mays N. Analysing qualitative data. *BMJ* 2000;320:114-6.
16 Gunaratnam Y. *Researching 'race' and ethnicity: methods, knowledge and power*. London: Sage, 2003.
17 Graham J, Grewal I, Lewis J. *Ethics in social research: the views of research participants*. London: Government Social Research Unit, 2007.
18 Makoae LN, Seboni NM, Molosiwa K, Moleko M, Human S, Sukati NA, et al. The symptom experience of people living with HIV/AIDS in southern Africa. *J Assoc Nurses AIDS Care* 2005;16(3):22-32.
19 Clayton JM, Butow PN, Tattersall MHN, Devine RJ, Simpson JM, Aggarwal G, et al. Randomized controlled trial of a prompt list to help advanced cancer patients and their caregivers to ask questions about prognosis and end-of-life care. *J Clin Oncol* 2007;25:715-23.
20 Petersen I, Mason A, Bhana A, Bell CC, McKay M. Mediating social representations using a cartoon narrative in the context of HIV/AIDS—the AmaQhawe family project in South Africa. *J Health Psychol* 2006;11:197-208.
21 Van Den Berg M, Nasaba R, Nieuwmeyer SM. Communicating with patients and their families. In: Gwyther L, Merriman A, Mpanga Sebuyira L, Schietinger H, eds. *A clinical guide to supportive and palliative care for HIV/AIDS in Sub-Saharan Africa*. APCA, NHPCO, FHSSA, 2006:207-18 (available at www.fhssa.org/i4a/pages/Index.cfm?pageID=3359).
22 Williams MV. Recognizing and overcoming inadequate health literacy, a barrier to care. *Cleve Clin J Med* 2002;69:415-8.
23 Clayton JM, Hancock K, Parker S, Butow PN, Walder S, Carrick S, et al. Sustaining hope when communicating with terminally ill patients and their families: a systematic review. *Psychooncology* 2007;17:641-59.
24 Curtis JR. Patient-clinician communication. In: O'Neill JF, Selwyn PA, Schietinger H, eds. *A clinical guide to supportive and palliative care for HIV/AIDS*. USA: Health Resources and Services Administration, 2003.
25 Sepulveda C, Habiyambere V, Amandua J, Borok M, Kikule E, Mudanga B, et al. Quality care at the end of life in Africa. *BMJ* 2003;327:209-13.
26 Knapp P, Raynor DK, Jbar AH, Price SJ. Interpretation of medication pictograms by adults in the UK. *Ann Pharmacother* 2005;39:1227-33.

Accepted: 19 December 2008

A false alarm

John had an undiagnosed hypomanic state for several years. His undoubted intelligence had helped to mask his pressure of speech, grandiose ideas, and thought disorder. However, he could not hold a job down and, in the end, became homeless. While hypomanic, he was arrested by the police for a rather public misdemeanour. He escaped the criminal justice system but was admitted to a locked psychiatric ward, an experience he found humiliating and disturbing.

His symptoms were subsequently controlled with a combination of lithium and an antipsychotic drug, but these left him feeling slowed down and unmotivated. This was particularly troubling because he had managed to get back with his girlfriend and their son, and he wanted to be able to provide for them. He was anxious not to experience a relapse and wanted to avoid any further contact with the criminal justice system. Taking his medication was therefore not a problem, although he disliked the side effects and, understandably, wanted to reduce the dose he was taking. We therefore agreed to lower, very gradually, the dose of his antipsychotic and to meet regularly to pick up any early signs of relapse.

I met him in the outpatient department, soon after one dose reduction. He seemed well, but kept looking up over my shoulder as though distracted by auditory hallucinations. This was odd because he had been adamant all along that he had never heard voices. I said nothing at the time but asked his community psychiatric nurse to keep an eye out for this. He met John and saw nothing out of the ordinary.

A week later, I met John and again noticed that he was looking around in a distracted way. What was going on? Was this some strange withdrawal phenomenon I'd never encountered with antipsychotics ? After a few minutes, I asked him why he kept looking over my shoulder. "I'm keeping an eye on the time, doctor. I've got so much I need to talk about, and I know you're a busy man." I turned round and saw, on the wall, one of the few working clocks in the hospital. So, no psychotic symptoms, no relapse, and no need to increase his dose—just a desire to have the time to talk over the things that mattered to him.

Since then, I have taken to telling patients how much time we have together. And I always check for that clock on the wall.

Philip Timms consultant psychiatrist, START team, South London and Maudsley Trust, London
philip.timms@slam.nhs.uk

Patient permission obtained.
Cite this as: *BMJ* 2009;338:b1184

pico

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

Rick Goud,[1] Nicolette F de Keizer,[1] Gerben ter Riet,[1 2] Jeremy C Wyatt,[3] Arie Hasman,[1] Irene M Hellemans,[1] Niels Peek[1]

[1]Department of Medical Informatics, Academic Medical Centre, University of Amsterdam, Meibergdreef 15, 1100 DD, Amsterdam, Netherlands
[2]Horten Centre, University of Zurich, Zurich, Switzerland
[3]Health Informatics Centre, University of Dundee, Dundee DD2 4BF

Correspondence to: N Peek
n.b.peek@amc.uva.nl

Cite this as: *BMJ* 2009;338:b1440
doi: 10.1136/bmj.b1440

This is a summary of a paper that was published on bmj.com as *BMJ* 2009;338:b1440

STUDY QUESTION Can computerised decision support improve the concordance of multidisciplinary teams' decisions with recommendations in practice guidelines?

SUMMARY ANSWER In multidisciplinary cardiac rehabilitation teams motivated to adopt a computerised decision aid, the aid was effective in improving the concordance of teams' decisions with guideline based care plan recommendations.

Design

Cardiac rehabilitation centres were randomised to work with either the complete version of CARDSS (Cardiac Rehabilitation Decision Support System—an electronic patient record system with decision support functions) or a control version that offered no decision support. Centres were randomised with variable block sizes and stratified by centre type and volume. Allocation could not be influenced by, and was unknown to, investigators visiting the centres.

Participants and setting

The study included multidisciplinary cardiac rehabilitation teams from 21 centres in the Netherlands. Participating teams did the needs assessment procedure with CARDSS for at least six months for each patient receiving cardiac rehabilitation (after a cardiac event such as a myocardial infarction or a cardiac intervention such as heart surgery) seen during the trial (n=2787).

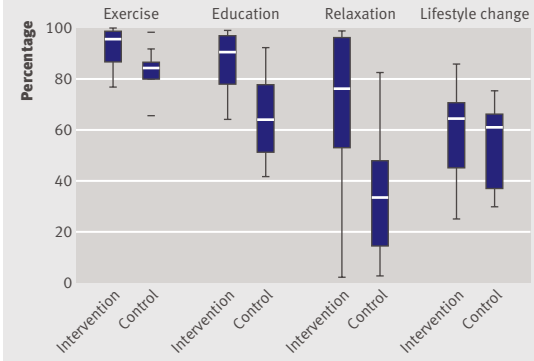
Primary outcome(s)

We assessed concordance with the recommendations of national guidelines for two traditional rehabilitation treatments, exercise and education, and for two novel rehabilitation treatments, relaxation and lifestyle change. We used generalised estimating equations to account for intra-cluster correlation and adjusted concordance rates for patients' age, sex, and indication for cardiac rehabilitation and for centre type and volume.

Main results and the role of chance

Computerised decision support increased concordance with guideline recommended decisions for exercise therapy by 7.9% (control 84.7%; adjusted difference 3.5%, 95% confidence interval 0.1% to 5.2%), for education therapy by 23.7% (control 63.9%; adjusted difference 23.7%, 15.5% to 29.4%), and for relaxation therapy by 25.5% (control 34.1%; adjusted difference 41.6%, 25.2% to 51.3%). The concordance for lifestyle change therapy increased by 3.3% (control 54.1%; adjusted difference 7.1%, –2.9% to 18.3%). Computerised decision support reduced decisions for both overtreatment and undertreatment.

CONCORDANCE OF CONTROL AND INTERVENTION CENTRES WITH GUIDELINE RECOMMENDED TREATMENT DECISIONS



Line inside box=median; box edges=quartiles; whiskers=extreme values; horizontal lines=outliers

Harms

None identified.

Bias, confounding, and other reasons for caution

We recruited entire multidisciplinary teams rather than individual professionals or patients, so the entire team had to be motivated. Concordance rates may have been influenced by the fact that some participating centres had insufficient facilities to offer the lifestyle change and relaxation therapies to all eligible patients. The study results may also be biased by attrition rate. Three control centres discontinued participation as they found that it was not worth the effort of implementing CARDSS without receiving decision support. We excluded three intervention clinics from the analyses as they failed to properly record their decisions in CARDSS. However, attrition did not seem to be related to concordance with guidelines.

Generalisability to other populations

The generalisability of our results may be restricted to settings where multidisciplinary teams are motivated to work with a computerised decision support system and where sufficient information technology support and facilities are available to implement that system.

Study funding/potential competing interests

The study was funded by ZonMW, the Netherlands Organisation for Health Research and Development, Health Care Efficiency Research Program 2004, subprogram Implementation, under project No 945-14-205. The funders had no role in study design, data analysis, or writing this report.

Trial registration number

Current Controlled Trials ISRCTN36656997.