RESEARCH

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Specialty in the spotlight—the cardiology portal

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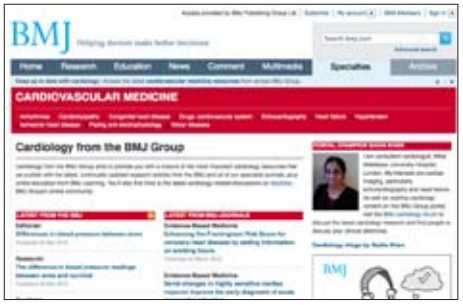

Should age be a factor in deciding who gets a heart transplant? How common is cardiac sarcoid? What are the causes of cardiac arrest in athletes? BMJ Group's new cardiology portal includes discussions from our online cardiology forum and the latest research, review articles and online learning modules. You can see abstracts on cardiology from all of our journal articles, including those from *Heart*. The cardiology portal is led by our cardiology champion, Sadia Khan, a consultant cardiologist at West Middlesex University Hospital, London. Her interests are cardiac imaging, particularly echocardiography and heart failure. Her regular blogs include topics such as "How many tests are enough?" and "What do you think of medical relatives?"

From Richard Lehman's blog

"Promoting exercise in sedentary patients is undoubtedly a worthwhile endeavour, but that does not mean we know how to do it effectively. A bit of exhortation now and again is unlikely to work, so the temptation is to refer patients elsewhere, and I have certainly written out lots of exercise prescriptions to local gyms. Unfortunately we don't really know if this tactic works either. This systematic review from the Cambridge primary care department reaches a rather downbeat conclusion."

http://www.bmj.com/content/344/bmj.e1389

SPL

RESEARCH ONLINE: For this and other new research articles see www.bmj.com/research

This linkage study between the National Joint Registry of England and Wales and hospital episode statistics showed no association between metal-on-metal hip replacements and increased incidence of cancer in the first seven years after hip replacement in a large representative sample. The one year incidence of cancer after total hip replacement is lower than that observed in the general population, say the authors, but they caution that the findings are observational and the follow-up was short.

White rice consumption and risk of type 2 diabetes: meta-analysis and systematic review

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EDITORIAL by Neal

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Cite this as: *BMJ* 2012;344:e1454
doi: 10.1136/bmj.e1454

This is a summary of a paper that was published on bmj.com as *BMJ* 2012;344:e1454

Response on bmj.com

"The magnitude of this study, analyzing cases in four countries and encompassing 352,000 people is impressive. But its methodology raises more questions than it answers."

Constance Hilliard, Nutritional Historian, University of North Texas

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Discuss this paper in *BMJ* Group's diabetes forum: http://bit.ly/HjiyRH

STUDY QUESTION

Are high levels of white rice consumption associated with risk of developing type 2 diabetes in both Asian (Chinese and Japanese) and Western populations and, if so, what is the dose-response relation?

SUMMARY ANSWER

Higher levels of white rice intake were more strongly associated with risk of type 2 diabetes in Asian populations than in Western populations, but when data from all populations were pooled together a linear dose-response relation was seen.

WHAT IS KNOWN AND WHAT THIS PAPER ADDS

Although multiple studies have examined white rice intake in relation to risk of diabetes, results are inconsistent due in part to the dramatic differences in baseline rice intake levels between Asian and Western populations. Pooled data provide quantitative evidence suggesting that high levels of white rice intake increase risk of type 2 diabetes, especially for Asian populations.

Selection criteria for studies

We searched Medline and Embase for prospective cohort studies examining the association between rice intake and risk of type 2 diabetes. We also manually searched references cited in selected articles. We selected prospective observational studies that excluded participants with prevalent diabetes at baseline and provided relevant estimates of study associations. In addition, we required that the loss to follow-up rate was below 20%.

Primary outcome(s)

The primary outcome was type 2 diabetes.

Main results and role of chance

The meta-analysis summarised data from four studies that included seven distinct prospective cohort analyses in Asian (Chinese and Japanese) and Western populations. The baseline consumption levels of white rice were much higher in Asian populations than in Western populations (average intake levels 3-4 *v* 1-2 servings/week). The pooled relative risk was 1.55 (95% confidence interval 1.20 to 2.01) comparing the highest with the lowest category of white rice intake in Asian populations, whereas the corresponding relative risk in Western populations was 1.12 (0.94 to 1.33) (P for interaction=0.038). When data from Asian and Western populations were pooled together, a linear dose-response relation was seen: for each serving per day increment of white rice intake, the relative risk of type 2 diabetes was 1.11 (1.08 to 1.14) (P for linear trend<0.001).

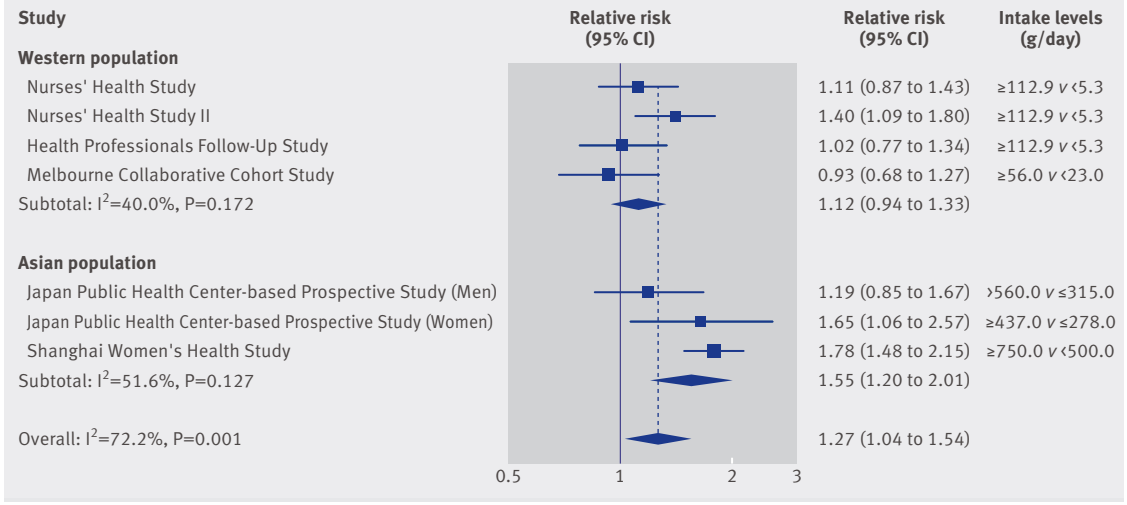
Bias, confounding, and other reasons for caution

The role of uncontrolled or residual confounding that cannot be excluded in observational studies may also bias the results of our meta-analysis in either direction. In addition, measurement errors in assessments of rice intake in individual studies may lead to an attenuation of true associations. Furthermore, although all individual studies excluded baseline cases of prevalent diabetes, some undiagnosed cases may still be included in the analysis and could bias the results toward the null.

Study funding/potential competing interests

QS was supported by a career development award K99HL098459 from the National Heart, Lung, and Blood Institute, USA.

Pooled random effects relative risk of type 2 diabetes comparing high with low white rice consumption levels



Effect of the human papillomavirus (HPV) quadrivalent vaccine in a subgroup of women with cervical and vulvar disease: retrospective pooled analysis of trial data

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Cite this as: *BMJ* 2012;344:e1401
doi: 10.1136/bmj.e1401

This is a summary of a paper that was published on bmj.com as *BMJ* 2012;344:e1401

STUDY QUESTION Does the quadrivalent HPV vaccine decrease the risk of developing subsequent disease in patients after treatment for HPV related disease?

SUMMARY ANSWER Previously vaccinated women who had surgical treatment for HPV related disease showed a significant reduction of subsequent HPV related disease, including high grade disease, compared with women who had not been vaccinated.

WHAT IS KNOWN AND WHAT THIS PAPER ADDS HPV vaccination does not reduce progression of ongoing HPV infections at the time of vaccination, but its effect on subsequent disease after treatment is unknown. This study found vaccination with quadrivalent HPV vaccine was associated with a reduction of subsequent HPV related disease in women who were diagnosed and treated for cervical and vulvar or vaginal disease.

Participants and setting

In two international, double blind, placebo controlled, randomised efficacy trials of quadrivalent HPV vaccine (FUTURE I and FUTURE II trials) in health centres in 24 countries and territories around the world, 17 622 women aged 15–26 years underwent 1:1 randomisation to vaccine or placebo. This analysis identified a subset of 2054 who subsequently received cervical surgery or were diagnosed with genital warts, vulvar intraepithelial neoplasia, or vaginal intraepithelial neoplasia.

Design, size, and duration

With retrospective analysis of trial data, we followed these women after their first HPV related disease for subsequent disease outcomes. The trials lasted less than four years (mean of 3.6 years).

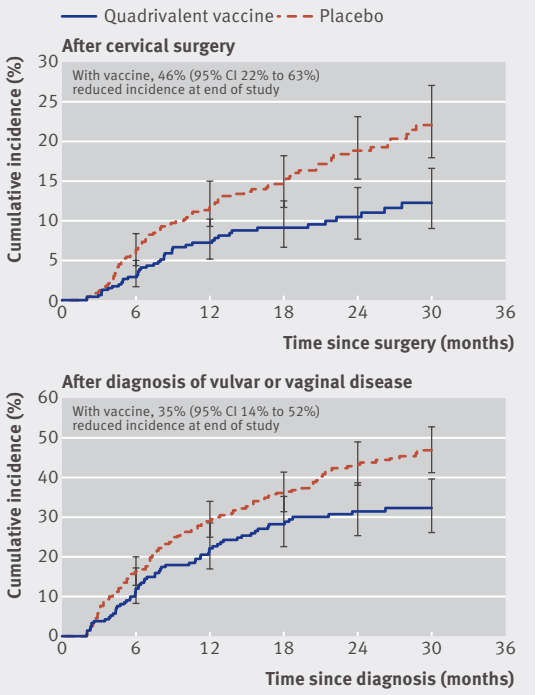
Primary outcome(s), risks, exposures:

We evaluated the incidence of subsequent disease from 60 days after treatment or diagnosis of the first HPV related disease. The women received three doses of quadrivalent HPV vaccine or placebo at day 1, month 2, and month 6 of the primary trials.

Main results and the role of chance

A total of 587 vaccine and 763 placebo recipients underwent cervical surgery after randomisation. The incidence of any subsequent HPV related disease after surgery was 6.6 and 12.2 per 100 person years at risk in vaccine and placebo recipients, respectively (46.2% reduction (95% CI 22.5% to 63.2%) with vaccination). Vaccination was associated with a reduced risk of any subsequent high grade disease of the cervix (cervical intraepithelial neoplasia grade II or III) of 64.9% (20.1% to 86.3%). A total of 229 vaccine recipients and 475 placebo recipients were diagnosed with genital warts or vulvar or vaginal intraepithelial neoplasia; the incidence of any subsequent disease after diagnosis was 20.1 and 31.0 per 100 person years at risk in vaccine and placebo recipients, respectively (35.2% (13.8% to 51.8%) reduction).

Time to detection of any HPV related disease* after cervical surgery or diagnosis of vulvar or vaginal disease



* Cervical intraepithelial grade I or worse, genital warts, vulvar intraepithelial neoplasia grade I or worse, or vaginal intraepithelial neoplasia grade I or worse. Case counting began 60 days after surgery or diagnosis

Bias, confounding, and other reasons for caution

The trials were not designed or powered to evaluate the effects of vaccination after treatment. Women with a prior history of HPV related disease were excluded from enrolment in the primary trials. Hence we cannot directly measure the vaccine's impact in women who have undergone treatment before vaccination, since all women in this study were vaccinated before treatment.

Generalisability to other populations

The generalisability of our findings was enhanced by enrolling women from both developed and developing nations and by using standard management algorithms.

Discontinuation of hormone replacement therapy after myocardial infarction and short term risk of adverse cardiovascular events: nationwide cohort study

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Cite this as: *BMJ* 2012;344:e1802
doi: 10.1136/bmj.e1802

This is a summary of a paper that was published on bmj.com as *BMJ* 2012;344:e1802

STUDY QUESTION

Do women who continue hormone replacement therapy (HRT) after myocardial infarction, in spite of guidelines recommending discontinuation, have an increased risk of reinfarction or death?

SUMMARY ANSWER

No certain conclusions can be drawn regarding increased or decreased risk of adverse cardiovascular events with continuing hormone replacement therapy after myocardial infarction.

WHAT IS KNOWN AND WHAT THIS PAPER ADDS

Current guidelines recommend women to discontinue HRT when they have a myocardial infarction, even though randomised trials have not found that it increases cardiovascular risk in women with coronary heart disease. Women who follow these guidelines do not have a lower risk of cardiovascular events than continued users of HRT.

Participants and setting

We included all Danish women aged 40 years or over who survived 30 days after a myocardial infarction and were prescribed HRT at the time of the myocardial infarction in the period 1997 to 2008.

Design, size, and duration

This study was a nationwide register based cohort study based on information from registers of hospital admissions, drug prescriptions, and demographics. We included 3322 women in the study and assessed their use of HRT overall and different categories of HRT. The main outcomes were reinfarction, cardiovascular death, and all cause death in the first year after admission to hospital for myocardial infarction.

Main results and the role of chance

The unadjusted incidence rates of reinfarction were 90.9 per 1000 person years in women discontinuing overall HRT and 112.9 per 1000 person years in women continuing overall HRT. The corresponding rates of cardiovascular mortality were 91.9 and 74.2 per 1000 person years, and those for all cause mortality were 156.3 and 119.2 per 1000 person years. The table shows the adjusted hazard ratios of discontinuation, including results for the different categories of HRT.

Bias, confounding, and other reasons for caution

We cannot rule out the possibility that unmeasured confounders, such as smoking and obesity, and possibly a "healthy user" effect may have biased the results.

Generalisability to other populations

The study used data from complete nationwide registers in Denmark, which reduced selection bias, but whether the results can be generalised to other populations, such as women with no known coronary heart disease, is unclear. The Danish population is mainly white.

Study funding/potential competing interests

D-MB was supported by the Danish Heart Foundation and the Lundbeck Foundation. CT-P has received consultant fees from Sanofi, Neurosearch, Cardiome, and Merck.

Hazard ratios (95% CI) for discontinuing hormone replacement therapy, with continuing as reference

Hormone replacement therapy	Reinfarction	Cardiovascular death	All cause death
Overall	0.90 (0.68 to 1.19)	1.21 (0.90 to 1.62)	1.22 (0.97 to 1.53)
Systemic oestrogen	0.56 (0.28 to 1.11)	1.39 (0.73 to 2.66)	1.17 (0.70 to 1.94)
Systemic oestrogen and progestogen	0.30 (0.09 to 0.96)	0.94 (0.37 to 2.39)	0.96 (0.53 to 1.75)
Vaginal oestrogen	0.54 (0.34 to 0.86)	1.15 (0.78 to 1.72)	1.31 (0.95 to 1.83)
Other hormone replacement therapy	0.11 (0.01 to 2.20)	0.60 (0.03 to 11.8)	1.00 (0.24 to 4.28)

Multivariable Cox proportional hazards analysis adjusted for age group, year of myocardial infarction, comorbidity, concomitant drugs, and income.

Trends in cause specific mortality across occupations in Japanese men of working age during period of economic stagnation, 1980-2005: retrospective cohort study

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Cite this as: *BMJ* 2012;344:e1191
doi: 10.1136/bmj.e1191

This is a summary of a paper that was published on bmj.com as *BMJ* 2012;344:e1191

Response on bmj.com

"Although not mentioned by the authors, smoking appears to be the most important health-related behaviour that explain the dramatic rise in the mortality in the particular period among the professional/management class workers by the following reasons."

Takeharu Koga, Internist, Asakura Medical Association Hospital, Japan

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STUDY QUESTION

How did temporal trends in occupation specific all cause and cause specific mortality in men aged 30-59 change from 1980 to 2005 in Japan?

SUMMARY ANSWER

Occupational patterns in cause specific mortality changed dramatically in Japan during the period of its economic stagnation and resulted in the reversal of occupational patterns in mortality that have been well established in Western countries. The significant negative effect on the health of management and professional workers rather than clerks and blue collar workers could be because of increased job demands and more stressful work environments and could have eliminated or even reversed the health inequality across occupations that had existed previously.

WHAT IS KNOWN AND WHAT THIS PAPER ADDS

Economic stagnation can be responsible for changes in working environments and employment systems, making the lives of working age people stressful. Risk of mortality in management workers in Japan, which was previously the lowest, largely increased after 1995, whereas in other non-professional workers mortality steadily decreased between 1980 and 2005. Economic crises might not simply negatively affect health equality but might have a complex impact on various subpopulations regardless of their socioeconomic status.

Participants and setting

All men aged 30-59 in Japan.

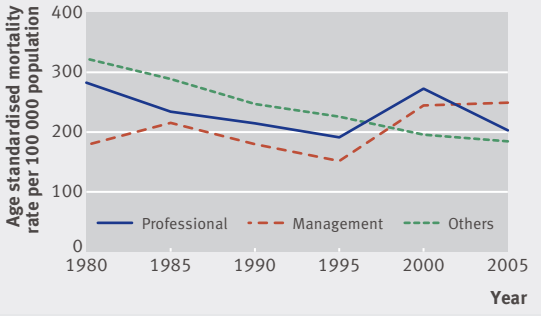
Design, size, and duration

Retrospective cohort study with data from the national census and death certificates from 1980 to 2005.

Main results and the role of chance

Age standardised mortality rates for all causes and the four leading causes of death (cancers, ischaemic heart disease, cerebrovascular disease, and unintentional injuries) steadily decreased from 1980 to 2005. Mortality from cancer showed the largest reduction (−42%) followed by mortality from cerebrovascular disease (−33%). The exception was suicide, for which the rates in 2005 were increased by 21.2 per 100 000 compared with 1990. Management workers showed the highest increase in the rate for suicide from 1980 to 2005 (271%), whereas the rate for suicide among sales, clerical, and production/labour workers did not rise even in the most recent period (after 1995).

Temporal trends and comparisons of mortality rates for all causes of death in Japanese men aged 30-59, 1980-2005



Over the study period age standardised mortality rates for all causes substantially declined for all occupations and unemployed people, except for management and professional workers, for whom rates began to rise in the late 1990s. Before 2000 the management and professional workers experienced significantly lower mortality rates across all six causes of death. After 2000 this situation was reversed for all cause and all cancer mortality, and the mortality rate for suicide and cerebrovascular disease equalised that seen in non-management and professional workers.

Bias, confounding, and other reasons for caution

Potential information bias or misclassifications in occupational categories and lack of further information prevented us from examining the detailed mechanisms underlying the changes in mortality. Numerator-denominator bias attributable to the use of different sources to gather information on the number of deaths and occupations must also be considered. Because of the small number of data points available, we could not test a wider range of model choices without a high risk of spurious statistical results. There were also only six time points, so the findings might be sensitive to boundary effects in the model.

Generalisability to other populations

This study was done only in Japan. It is unclear if the results are generalisable to other countries.

Study funding/potential competing interests

This study was funded by the Ministry of Education, Culture, Sports, Science, and Technology (Grant-in-Aid for Scientific Research (B) No 22390130 and Grant-in-Aid for Scientific Research on Innovative Areas No 22119504) and the Ministry of Health, Labour and Welfare (H23-seisaku-shitei-033).

The difference in blood pressure readings between arms and survival: primary care cohort study

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EDITORIAL by Kim

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Cite this as: *BMJ* 2012;344:e1327
doi: 10.1136/bmj.e1327

This is a summary of a paper that was published on bmj.com as *BMJ* 2012;344:e1327

Response on bmj.com

"Another limitation of this study stems from the lack of specific data on arm measurements for women vs men, which renders a sex bias in any conclusions since we cannot and should not assume that study results are supported for women unless the data are stratified by sex to assess any gender differences."
Jodi Godfrey, Managing Editor, Advancing Women's Health Initiative, New Jersey
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doc2doc

Do you take blood pressure in both arms?
http://bit.ly/z9nKlc

STUDY QUESTION Does a difference in blood pressure between arms predict increased cardiovascular or all cause mortality?

SUMMARY ANSWER Interarm differences in blood pressure predict an increased risk of cardiovascular events, cardiovascular mortality, and all cause mortality over 10 years in people with hypertension in primary care.

WHAT IS KNOWN AND WHAT THIS PAPER ADDS Interarm differences in systolic blood pressure have been associated with increased mortality in secondary care populations with high vascular risk. Evidence from a primary care cohort with hypertension shows that interarm differences in systolic blood pressure of >10 mm Hg or >15 mm Hg are associated with an increased risk of cardiovascular and all cause mortality over 10 years.

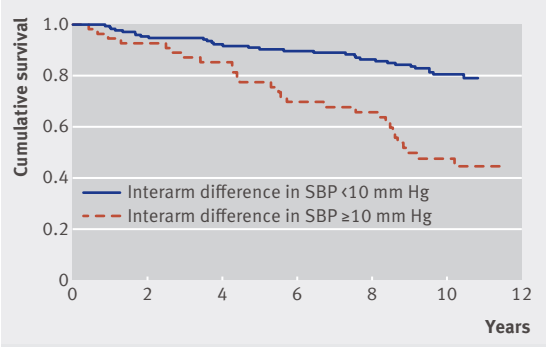
Participants and setting

230 people from the Mid Devon Medical Practice with hypertension, and without disease, injury, or surgery affecting one arm.

Design, size, and duration

We undertook a prospective cohort study. Sequential pairs of blood pressure readings were made at three successive visits using a standard mercury sphygmomanometer. Data on deaths and non-fatal cerebrovascular and cardiovascular events were collected prospectively. We used Kaplan-Meier survival plots to compare times to death or non-fatal events for interarm differences in blood pressure. Hazard ratios were calculated using a Cox's proportional hazards regression model, with adjustment for Framingham risk score, mean blood pressure, diabetes, and pre-existing vascular disease. We used likelihood ratio testing to assess the reduction in goodness of fit arising from omission of interarm differences from adjusted models.

Kaplan-Meier plot for all cause mortality in 230 people with hypertension according to interarm difference in systolic blood pressure



Main results and the role of chance

Overall, 55 (24%) patients had mean interarm differences in systolic blood pressure of ≥10 mm Hg and 21 (9%) >15 mm Hg, and 14 (6%) had differences in diastolic blood pressure of ≥10 mm Hg. Median follow-up was 9.8 years, with 59 fatal events. The fully adjusted hazard ratio for all cause mortality associated with interarm differences in systolic pressure was 3.6 (95% confidence interval 2.0 to 6.5) for ≥10 mm Hg and 3.1 (1.6 to 6.0) for ≥15 mm Hg and for cardiovascular deaths was 4.2 (1.7 to 10.3) and 2.7 (1.0 to 7.7), corresponding to a 5% or 6% increase in hazard of death per 1 mm Hg increment in interarm difference. Hazard ratio for fatal and non-fatal events with interarm differences in diastolic blood pressure of >10 mm Hg was 3.3 (1.6 to 6.8), corresponding to a 9% increase per 1 mm Hg increment in interarm difference. For interarm differences in systolic blood pressure, likelihood ratio tests showed significant reductions in the goodness of fit on removal of the interarm difference term from the models, indicating that incorporating interarm difference improved the predictability of the models. This was also shown for interarm differences in diastolic blood pressure of >10 mm Hg with non-fatal events and combined events and deaths.

Bias, confounding, and other reasons for caution

The prevalence of interarm differences in blood pressure is lower with simultaneous than sequential measurement methods; however, sampling this cohort with a simultaneous measurement technique produced similar prevalence rates. One investigator (CEC) gathered the data, but events were recorded prospectively so lack of blinding is unlikely to have biased the outcomes reported. Adjusted analyses were done to minimise confounding.

Generalisability to other populations

This is a small study from one rural general practice. The prevalence of people with hypertension in this study was comparable to UK figures at the time of recruitment, therefore these findings can be generalised to other primary care settings, although lack of representation of ethnic minority groups in Devon is a limitation.

Study funding/potential competing interests

CEC was supported by the Scientific Foundation Board of the Royal College of General Practitioners (grant No SFB-2009-06), the South West GP Trust, and the NIHR Peninsula Collaboration for Leadership in Applied Health Research and Care.

Patient safety, satisfaction, and quality of hospital care: cross sectional surveys of nurses and patients in 12 countries in Europe and the United States

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Cite this as: *BMJ* 2012;344:e1717
doi: 10.1136/bmj.e1717

*The authors are listed in the full paper on bmj.com

This is a summary of a paper that was published on bmj.com as *BMJ* 2012;344:e1717

STUDY QUESTION

In view of the potential conflict between cost containment in hospitals and improvements in quality and safety, how should the hospital nurse workforce be organised to achieve good patient and nurse outcomes, in a context of finite resources?

SUMMARY ANSWER

In hospitals with good work environments and reduced ratios of patients to nurses, patients and nurses reported improvements in care quality, increased safety grades, and improved patient and nurse satisfaction.

WHAT IS KNOWN AND WHAT THIS PAPER ADDS

Staff management accounts for a substantial portion of health expenditure and although good evidence is lacking, measures to contain costs could have negative consequences for quality of care. We found that hospitals with good work environments and better staffing of professional nurses had more satisfied patients and nurses, with evidence of better quality and safety of care.

Participants and setting

We surveyed 33 659 nurses and 11 318 patients in Europe, and 27 509 nurses and more than 120 000 patients in the United States. We surveyed nurses from 488 general acute care hospitals in 12 European countries and 617 general acute care hospitals in the US, and surveyed patients from a subset of 210 European hospitals and 430 US hospitals.

Design

Cross sectional surveys of patients and nurses.

Primary outcomes

Nurse outcomes were hospital staffing, work environments, burnout, dissatisfaction, intention to leave job in the next year, patient safety, and quality of care. Patient outcomes were satisfaction overall and with nursing care, and willingness to recommend hospitals.

Main results and the role of chance

Quality and safety problems were common in European and US hospitals, with considerable room for improvements in patient satisfaction. Some nurse and patient outcomes varied considerably across countries (table). Better work environments and lower patient to nurse ratios were associated with higher care quality and patient satisfaction. Nurses in European hospitals with better work environments were half as likely to report poor or fair quality of care in the ward (adjusted odds ratio 0.56, 95% confidence interval 0.51 to 0.61) and to give their hospitals poor or failing grades on patient safety (0.50, 0.44 to 0.56). Patients in European hospitals with better work environments were more likely to rate their hospital highly (1.16, 1.03 to 1.32) and to recommend their hospital (1.20, 1.05 to 1.37), whereas those in hospitals with higher patient to nurse ratios were less likely to rate them highly (0.94, 0.91 to 0.97) or recommend them (0.95, 0.91 to 0.98). Findings were similar in the US. Nurses and patients agreed on which hospitals provided good care.

Bias, confounding, and other reasons for caution

Cross sectional data cannot confirm causality. Although we used rigorous translation processes, language differences could have affected our survey results. Comparisons between the US and the countries in Europe should be made cautiously, since the sample of hospital nurses in the US was broader and patients were surveyed after discharge rather than before.

Generalisability to other populations

Our results accorded with a broad range of international literature showing that good hospital work environments and nurse staffing were associated with improved patient and nurse outcomes.

Study funding/potential competing interests

All authors have completed the Unified Competing Interest form at www.icmje.org/coi_disclosure.pdf (available on request from the corresponding author) and declare: funding from the European Union's Seventh Framework Programme and the National Institute of Nursing Research, National Institutes of Health; no financial relationships with any organisations that might have an interest in the submitted work in the previous three years; no other relationships or activities that could appear to have influenced the submitted work.

Variation in primary outcomes across study countries

Outcome	Best category	Middle category	Worst category
Nurses reporting poor or fair quality of care in ward (%)	Ireland (11), Norway (13), Finland (13)	Poland (26), Sweden (27)	Netherlands (35)Germany (35), Greece (47)
Nurses giving poor or failing safety grade to ward (%)	Switzerland (4), Norway (5)	Belgium (6), Germany (6), Netherlands (6), Spain (6), US (6)	Greece (17), Poland (18)
Nurses experiencing high burnout (%)	Netherlands (10), Switzerland (15)	Spain (29), Sweden (29)	England (42), Greece (78)
Nurses who intend to leave their job in the next year (%)	US (14), Netherlands (19)	Sweden (34), Germany (36)	Finland (49)Greece (49)
Patients rating their hospital highly (%)*	Ireland (61), Finland (61)	Poland (55), Germany (48)	Greece (42), Spain (35)
Mean staffing ratio of patients to professional registered nurse (n)	US (5.3), Norway (5.4)	Finland (8.3), England (8.6)	Spain (12.6), Germany (13.0)

*Patient surveys not conducted in England, Netherlands, Norway, or Sweden.

Discontinuation of antidepressants in people with dementia and neuropsychiatric symptoms (DESEP study): double blind, randomised, parallel group, placebo controlled trial

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Cite this as: *BMJ* 2012;344:e1566
doi: 10.1136/bmj.e1566

This is a summary of a paper that was published on bmj.com as *BMJ* 2012;344:e1566

STUDY QUESTION

What is the effect of discontinuing antidepressant treatment on depressive and neuropsychiatric symptoms in patients who have Alzheimer's disease with dementia or vascular dementia?

SUMMARY ANSWER

Patients with discontinued treatment had, after 25 weeks, a significant increase in depressive symptoms compared with those who continued with treatment.

WHAT IS KNOWN AND WHAT THIS PAPER ADDS

The evidence for pharmacological treatment of neuropsychiatric symptoms and depressive symptoms in patients with dementia is weak. Discontinuation of escitalopram, citalopram, sertraline, or paroxetine in patients with dementia increased their depressive symptoms significantly.

Differences in primary outcome between discontinuation and continuation study groups

Primary outcome	Difference (95% CI)	P
Cornell scale of depression in dementia		
Total score (all patients)	−2.89 (−4.76 to −1.02)	0.003
Total score (baseline value <9)	−3.36 (−5.23 to −1.48)	0.001
Total score (baseline value ≥9)	2.20 (−1.68 to 6.09)	0.251
Neuropsychiatric inventory		
Total score	−5.96 (−12.35 to 0.44)	0.068

Design

Double blind, randomised, parallel group, placebo controlled trial with 25 week intervention. Randomisation (1:1) was computer generated and done in blocks of four.

Participants and setting

Norwegian nursing home residents were recruited by 16 study centres in Norway from August 2008 to June 2010. We included patients with Alzheimer's disease or vascular dementia (or both) who had been prescribed escitalopram, citalopram, sertraline, or paroxetine for more than three months. Patients had at least one neuropsychiatric symptom, but did not have a depressive disorder. We excluded patients with severe somatic disease or terminal illness, or who were unable to take tablets or capsules as prescribed.

Primary outcome(s)

Patients' scores on the Cornell scale for depression in dementia and on the 10 item version of the neuropsychiatric inventory, after 25 weeks.

Main results and the role of chance

We allocated 63 patients to discontinue treatment, and 65 to continue with treatment. After 25 weeks, we recorded a significant difference in scores for the Cornell scale between groups, in favour of the continuation group (difference −2.89 (95% confidence interval −4.76 to −1.02), P=0.003;). We found a non-significant difference in the mean total score for the neuropsychiatric inventory at 25 weeks, also in favour of the continuation group (−5.96 (−12.35 to 0.44), P=0.068). A non-response analysis (>30% worsening on the Cornell scale) confirmed these results, because significantly more patients worsened in the discontinuation group than in the continuation group (32 (54%) *v* 17 (29%), P=0.006). Significantly more patients in the discontinuation group than those in the continuation group changed from a score of less than 14 points on the Cornell scale at baseline to a score of 14 points and higher after 25 weeks (P=0.008). Forty seven (37%) patients withdrew from the study early.

Harms

In the discontinuation group, eight (14%) patients had a change in their depressive symptoms from subclinical symptoms at baseline to a severe depressive disorder after 25 weeks.

Bias, confounding, and other reasons for caution

Although we excluded patients with a depressive disorder, the trial may have unintentionally included patients with a previous depressive disorder that had not been recorded. The increase in depressive symptoms recorded after discontinuation should be interpreted with caution in relation to the efficacy of antidepressants in the treatment of neuropsychiatric symptoms.

Generalisability to other populations

The study was done in Norwegian nursing homes, and some caution should be taken before generalising the results to patients who are not in institutions or patients from other cultures.

Study funding/potential competing interests

All authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure.pdf (available on request from the corresponding author) and declare: SB received study treatment free of charge from H Lundbeck A/S (escitalopram tablets and placebo), but with no obligations for publication; the study received funding support from the Innlandet Hospital Trust, the Research Council of Norway, and the South-Eastern Norway Regional Health Authority; no financial relationships with any organisations that might have an interest in the submitted work in the previous three years; no other relationships or activities that could appear to have influenced the submitted work.

Trial registration number

ClinicalTrial.gov NCT00594269, EudraCT 2006-002790-43.