



APOGEE/SPL

THIS WEEK'S RESEARCH QUESTIONS

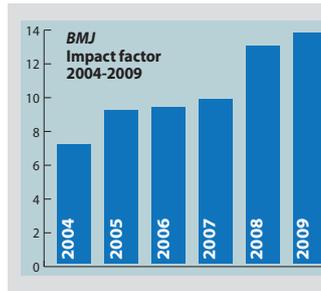
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- 1401** Do family care givers of patients with advanced lung cancer have patterns of wellbeing and distress typical of the patient as the illness progresses?

Summary care records

Trisha Greenhalgh and colleagues' complex case study of the adoption and effect of NHS summary care records in England shows that these electronic outlines of patients' histories have not lived up to policy makers' expectations (p 1399). Summarising this study about summaries isn't easy, so—as Professor Greenhalgh notes in a *BMJ* podcast (<http://bmj.com/podcasts>)—the full report is appropriately entitled “The devil's in the detail.” It's being published online by the Department of Health and will be a key plank of the government's impending review of NHS information technology.

Responding to our accompanying Head to Head debate (p 1390), Peter Singleton defended the scheme: “There are more than enough confused patients turning up who cannot remember what pills they are on to make the summary care record worthwhile in itself, but only where the information is actually needed” (www.bmj.com/cgi/eletters/340/jun16_4/c3020).

But the *Daily Mail* urged patients to opt out of the initiative, focusing on the finding that “as many as 85% of those who have received letters giving them the chance to opt out of the scheme simply throw them away unopened” (www.dailymail.co.uk/health/article-1287263/Millions-patients-dark-medical-records-online.html). This statement seemed to go down well with the newspaper's online readers, ever wary of the “nanny state,” although Timelord replied: “Surely this cannot be true; the envelope clearly states on the front ‘Important information about NHS health care records enclosed—please read.’ So anyone throwing it away unopened is a little silly or downright stupid.”



BMJ impact factor The 2009 impact factor for the *BMJ* is 13.66, up from 12.83 and 9.72 in 2008 and 2007.

doc2doc journal club Discuss the link between oral hygiene and cardiovascular disease, and other *BMJ* research, in the journal club on doc2doc, *BMJ* Group's global online clinical community. <http://bit.ly/aU175G>.

Patterns of wellbeing and distress among carers of patients with lung cancer

Secondary analyses of qualitative research are yielding some interesting findings. Earlier this year, for example, the *BMJ* published a systematic and thematic review of qualitative research on patients' and carers' views of decision making in chronic kidney disease (*BMJ* 2010;340:c112).

Now Scott Murray and colleagues report a secondary analysis of serial qualitative interviews with patients who have lung cancer and their families (p 1401). They find that distress among carers tends to follow a predictable pattern, so support could be planned in a targeted way. The authors acknowledge, however, that many care givers are resilient and appreciate the opportunity to care, and that many do not suffer clinically significant distress or complicated grief.



DAVID HANCOCK/JALAMY



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Mobile phones and childhood cancer In this case-control study, Paul Elliot and colleagues found no association between risk of early childhood cancers and estimates of mothers' exposure to mobile phone base stations during pregnancy (doi:10.1136/bmj.c3077). The findings were based on data in Great Britain's cancer registry and national birth register from between 1999 and 2001, with four individually matched controls for each of the 1397 cases of cancer in children aged 0-4.

In an accompanying editorial (doi:10.1136/bmj.c3015), John Bithell discusses the possibility that the study could have missed a true effect—but he says that as far as we know to date, anxiety about the health risks of living near a mast is unjustified.

CME

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Primary total hip arthroplasty versus hemiarthroplasty for displaced intracapsular hip fractures in older patients: systematic review

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EDITORIAL by Madsen

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Cite this as: *BMJ* 2010;340:c2332
doi: 10.1136/bmj.c2332

This is a summary of a paper that was published on *bmj.com* as *BMJ* 2010;340:c2332

STUDY QUESTION

Do patients aged over 60 treated with total hip arthroplasty for displaced fractures of the femoral neck have a lower risk of local and systemic complications and better functional outcomes than those treated with hemiarthroplasty?

SUMMARY ANSWER

In older patients with femoral neck fractures, single stage total hip arthroplasty is associated with a lower risk of reoperation and better function but a higher risk of dislocation and general complications compared with hemiarthroplasty.

WHAT IS KNOWN AND WHAT THIS PAPER ADDS

Displaced femoral neck fractures are common surgical conditions and arthroplasty has been shown to produce better results than internal fixation. It is unclear whether fractured hips should be replaced by total hip arthroplasty or hemiarthroplasty in the emergency setting. A comprehensive review of the entire body of comparative evidence was carried out to compare important clinical outcomes between the two types of endoprostheses.

Selection criteria for studies

Two reviewers independently searched Medline, Embase, the Cochrane register of controlled trials, and publishers' databases for randomised controlled trials, quasirandomised trials, and cohort studies that compared total hip arthroplasty with hemiarthroplasty for displaced femoral neck fractures in adults aged more than 60. We excluded uncontrolled case series and registry data.

Primary outcomes

We used random effects models to pool the relative risks and risk differences of the binary end points reoperation, dislocation, deep infection, general complications, and one year mortality. Weighted mean differences were calculated for the Harris hip score. We assessed heterogeneity by the I^2 statistic, with values more than 50% suggesting substantial variability between studies. We explored subgroup effects according to the key characteristics of patients and studies using the test for interaction proposed by Altman and Bland, and the ratio of relative risks.

Main results and the role of chance

Overall, 202 of 3821 references were scrutinised in full. Fifteen were eligible for inclusion: four randomised trials ($n=421$), three quasirandomised studies ($n=355$), and eight cohort studies ($n=1114$). Baseline profiles in non-randomised studies were sufficiently balanced for meta-analysis. Total hip arthroplasty was associated with a lower risk of reoperation compared with hemiarthroplasty (relative risk 0.57, 95% confidence interval 0.34 to 0.96, risk difference 4.4%, 95% confidence interval 0.2% to 8.5%). Heterogeneity was low for this end point ($I^2=27%$). Total hip arthroplasty also showed consistently better ratings in the Harris hip score (weighted mean difference 5.4, 95% confidence interval 2.7 to 8.2) after follow-up periods ranging from 12 to 48 months. However, total hip arthroplasty was also associated with a slightly higher risk of dislocation (relative risk 1.48, 95% confidence interval 0.89 to 2.46) and general complications (1.14, 0.87 to 1.48). The risk of deep infections and one year mortality did not differ.

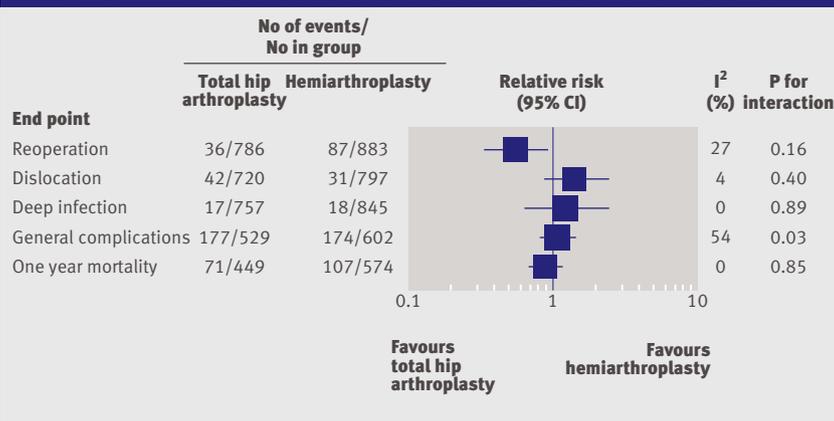
Bias, confounding, and other reasons for caution

The major finding of a lower risk of reoperation was mainly driven by investigations without concealed treatment allocation (relative risk ratio 2.59, 95% confidence interval 0.83 to 8.07, test for interaction $P=0.10$). Other variables such as mobility before fracture and cementation of stems in the hemiarthroplasty control group interfered with effect estimates. Functional outcomes could only be traced from a few studies, and the weighted mean of 5.4 may be below the minimally important difference of the Harris hip score. Also, the description of patient characteristics in non-randomised studies was poor, and results are prone to residual confounding.

Funding

All authors are independent of funders except CH who is an employee of DePuy International, a manufacturer of orthopaedic devices.

SUMMARY OF META-ANALYSES OF BINARY MEASURES AFTER TOTAL HIP ARTHROPLASTY AND HEMIARTHOPLASTY FOR DISPLACED INTRACAPSULAR HIP FRACTURES



Bevacizumab for neovascular age related macular degeneration (ABC Trial): multicentre randomised double masked study

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Cite this as: *BMJ* 2010;**340**:c2459
doi: 10.1136/bmj.c2459

This is a summary of a paper that was published on bmj.com as *BMJ* 2010;**340**:c2459

Response on bmj.com
“Although intravitreal bevacizumab injection seems encouraging in terms of provisionally treating visual loss associated with neovascular age related macular degeneration, it might cause retinal pigment epithelial or photoreceptor injury, or both, that in turn could aggravate the overall disease process and ultimate outcome..”

Mohammad H Nowroozzadeh, ophthalmologist, Poostchi Ophthalmology Research Center, Shiraz, Iran

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STUDY QUESTION

Are intravitreal bevacizumab injections better than standard care at improving vision in patients with neovascular age related macular degeneration (AMD)?

SUMMARY ANSWER

Bevacizumab 1.25 mg intravitreal injections given as part of a six weekly variable retreatment regimen are superior to standard care (pegaptanib sodium, verteporfin photodynamic therapy, sham) at improving vision in eyes affected by neovascular AMD.

WHAT IS KNOWN AND WHAT THIS PAPER ADDS

Bevacizumab has become one of the most widely used agents for the treatment of neovascular AMD worldwide, despite being unlicensed for this indication. This study provides the first level 1 evidence supporting the use of intravitreal bevacizumab every six weeks, resulting in a reduction of hospital visits by a third over conventional monthly dosing while maintaining improvement in vision.

Design

This was a prospective, double blinded, multicentre randomised controlled trial.

Participants and setting

Overall 131 patients were randomised to two intervention groups, 65 eyes of 65 patients to bevacizumab 1.25 mg intravitreal and 66 eyes of 66 patients to standard care (pegaptanib sodium, verteporfin, or sham). Participants were aged at least 50, and the mean age was 81. The study took place in three ophthalmology centres in the United Kingdom.

Primary outcomes

The primary outcome was the proportion of patients gaining 15 or more letters of visual acuity at one year (54 weeks).

Main results and the role of chance

At the end of the 54 week follow-up period, 21 (32%) patients in the bevacizumab group gained 15 or more letters of visual acuity from baseline compared with two (3%) in the standard care group ($P < 0.001$), estimated adjusted odds ratio 18.1 (95% confidence interval 3.61 to 91.24), number needed to treat 4 (3 to 6)). Mean visual acuity increased by 7.0 letters in the bevacizumab group, with a median of seven injections, and decreased by 9.4 letters in the standard care group ($P < 0.001$). The initial improvement at week 18 (6.6 letters) was sustained to week 54. Among 65 patients treated with bevacizumab, there were no cases of endophthalmitis or serious uveitis related to the intervention.

Harms

There was no evidence of increased ocular adverse events in the bevacizumab group. In this elderly cohort, one patient in the bevacizumab group died.

Bias, confounding, and other reasons for caution

Our study was a double blinded randomised controlled trial with patients' characteristics at baseline evenly distributed, so the likelihood of bias is minimal. As with other studies dealing with this class of drug for this indication it is underpowered to evaluate the possibility of rare cardiovascular side effects.

Generalisability to other populations

Our results are likely to be generalisable to patients with neovascular AMD. In addition, the pragmatic trial design with variable dosing and study visits every six weeks reduces the number of hospital visits for affected elderly patients by a third compared with conventional monthly dosing.

Study funding/potential competing interests

This study was funded by the special trustees of Moorfields Eye Hospital. We also received financial support from the Department of Health through an award made by the National Institute for Health Research to Moorfields Eye Hospital NHS Foundation Trust and UCL Institute of Ophthalmology for a Specialist Biomedical Research Centre for Ophthalmology. Additional local support was obtained from the National Eye Research Centre, Bristol. Several of the authors have received industry sponsorship (see bmj.com for further details).

Trial registration number

Current controlled trials ISRCTN83325075.

KEY PRIMARY AND SECONDARY OUTCOMES IN PATIENTS WITH NEOVASCULAR AMD

Change in letters read on chart	Standard therapy (n=66)	Bevacizumab (n=65)	Difference (95% CI), P value	Adjusted odds ratio* (95% CI)
Gain of ≥ 15	3% (2)	32% (21)	29 (17 to 41), < 0.001	18.1 (3.6 to 91.2)
Gain of ≥ 10	8% (5)	46% (30)	39 (25 to 52), < 0.001	10.8 (3.6 to 32.0)
Loss of < 15	67% (44)	91% (59)	24 (11 to 38), < 0.001	4.7 (1.7 to 13.0)

*Adjusted for age, sex, baseline visual acuity.

Adoption and non-adoption of a shared electronic summary record in England: a mixed-method case study

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HEAD TO HEAD, p 1390

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Cite this as: *BMJ* 2010;340:c3111
doi: 10.1136/bmj.c3111

This is a summary of a paper that was published on *bmj.com* as *BMJ* 2010;340:c3111

Response on *bmj.com*

“The summary care record was based on an unresearched and unverified need. The two Greenhalgh reviews have shown the errors in this approach. The public by and large do not see the need for this and are concerned about security. That is if the information campaign has reached them at all—most of them are still unaware of its existence or proposed roll out.”

Roz Foad, information management and technology manager, Hertfordshire

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podcasts.bmj.com

▶ Listen to Trisha Greenhalgh talk about the study's findings at www.bmj.com/podcasts

STUDY QUESTION

To what extent have summary care records (internet-accessible electronic summaries of patients' medical details) been adopted in England, and what benefits have been associated with their use?

SUMMARY ANSWER

Summary care records have been adopted more slowly, and their benefits to date are less evident, than early policy documents anticipated. Reasons are complex and involve multiple interacting influences at individual, organisational, and environmental levels.

WHAT IS KNOWN AND WHAT THIS PAPER ADDS

Many people anticipate that nationally shared electronic records will improve quality, safety, and efficiency of health care. This study shows that, to date, efforts to introduce a shared electronic record in England have been characterised by high implementation workload, variable uptake, and limited benefits.

Participants and setting

English National Health Service 2007-10. The summary care record (SCR) was introduced as part of the National Programme for Information Technology. This official evaluation considered national policy and frontline implementation and use in three districts.

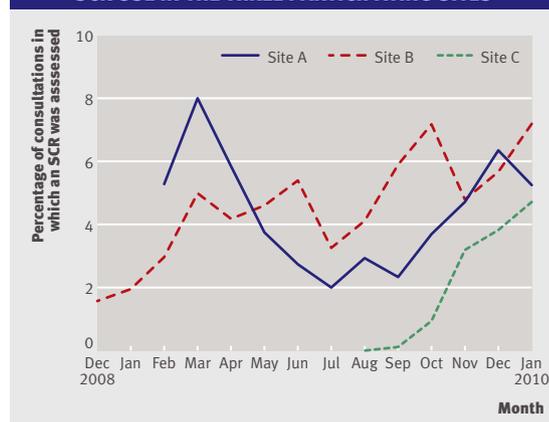
Methods and data sources

Qualitative data (140 interviews including policy makers, managers, clinicians, and software suppliers; 2000 pages of ethnographic field notes including observation of 214 clinical consultations; and 3000 pages of documents) were analysed thematically and interpretively to build a rich picture of national strategy, local implementation, and frontline use. Quantitative data (cumulative records created nationally plus a dataset of 416 325 encounters in participating primary care out-of-hours and walk-in centres) were analysed statistically.

Main results

Creating SCRs and supporting their adoption and use was a complex, technically challenging, and labour intensive process which occurred more slowly than planned. By early 2010, 1.5 million SCRs had been created. In participating primary care out-of-hours and walk-in centres, an SCR was accessed in 4% of all encounters and in 21% of encounters where one was available; these figures were rising in some but not all sites (figure). The main determinant of SCR use was the clinician: individual clinicians accessed available SCRs between 0 and 84% of the time. When accessed,

SCR USE IN THE THREE PARTICIPATING SITES



SCRs seemed to support better quality care and increase clinician confidence in some encounters. There was no direct evidence of improved safety, but findings were consistent with a rare but important positive impact on preventing medication errors. SCRs sometimes contained incomplete or inaccurate data, but we did not see any cases where this led to harm because clinicians drew judiciously on these data alongside other sources rather than regarding the SCR as the sole source of reliable data. SCR use was not associated with shorter consultations or reduction in onward referral.

Successful introduction of SCRs depended on interaction between multiple stakeholders from different institutional worlds with different values, priorities, and ways of working. Challenges had ethical and philosophical dimensions as well as operational and technical ones. The programme's fortunes seemed to turn on the ability of change agents to bridge the different institutional worlds of different stakeholders, align their conflicting logics, and mobilise implementation effort.

Generalisability to other populations and settings

Large scale, centrally driven models for innovation in healthcare IT systems are—perhaps inevitably—associated with multiple competing perspectives, complex interdependencies, inherent tensions, and high implementation workload. Just because a particular technological innovation is national policy, its uptake and use at the clinical frontline should not be seen as a foregone conclusion.

Study funding/potential competing interests

The UK National Institute of Health Research funded the main evaluation, and the Medical Research Council funded background theoretical and methodological work. The authors reported no competing interests.

Toothbrushing, inflammation, and risk of cardiovascular disease: results from Scottish Health Survey

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EDITORIAL by Galgut

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Cite this as: *BMJ* 2010;340:c2451
doi: 10.1136/bmj.c2451

This is a summary of a paper that was published on bmj.com as *BMJ* 2010;340:c2451

STUDY QUESTION

Is self reported toothbrushing, as a proxy of oral hygiene, associated with incident cardiovascular disease and markers of inflammation and coagulation?

SUMMARY ANSWER

Less frequent toothbrushing is associated with higher levels of risk of cardiovascular disease risk and low grade inflammation.

WHAT IS KNOWN AND WHAT THIS PAPER ADDS

Poor oral hygiene is associated with periodontal disease, a common chronic inflammatory condition. This study confirms and further strengthens a known association between periodontal disease outcomes and the risk of cardiovascular disease. Inflammatory markers were also significantly associated with less frequent toothbrushing, and partly explained the association between oral hygiene and cardiovascular disease.

Participants and setting

11 869 men and women, mean age 50.0 (SD 11.0) who participated in the Scottish Health Survey, which draws a nationally representative sample of the general population living in households in Scotland. For the present analysis we combined data from the 1995, 1998, and 2003 surveys in adults aged 35 and older. These surveys were linked to a database of Scottish hospital admissions and deaths in patients with follow-up until December 2007.

Design

Repeated cross sectional national population based survey.

Primary outcomes

Risk of cardiovascular disease events or death and concentrations of inflammatory markers (C reactive protein and fibrinogen). The association between toothbrushing

behaviour and inflammatory markers (C reactive protein) and coagulation (fibrinogen) was also examined in a sub-sample of 4830 participants.

Main results and the role of chance

Oral health behaviours were generally good, with 71% (8481) of the sample reporting brushing their teeth twice a day. Participants who brushed their teeth less often were older, male, and of lower social status. There were a total of 555 cardiovascular disease events over an average of 8.1 (SD 3.4) years of follow-up; 170 were fatal. In about 74% (411) of cardiovascular disease events the principal diagnosis was coronary heart disease. Participants who reported less frequent toothbrushing (never/rarely brushed their teeth) had an increased risk of a cardiovascular disease event (multivariate adjusted hazard ratio 1.69, 95% confidence interval 1.25 to 2.30; $P < 0.001$) in the fully adjusted model. Less frequent toothbrushing was also associated with increased concentrations of both C reactive protein (β 0.04, 0.01 to 0.08) and fibrinogen (β 0.08, -0.01 to 0.18). These associations remained significant after multiple adjustments.

Bias, confounding, and other reasons for caution

Clinical data regarding the periodontal disease status of the participants might have strengthened our findings. Another limitation is the lack of follow-up data on toothbrushing behaviour.

Generalisability to other populations

As our data are from a nationally representative sample of the general Scottish population, the results are probably generalisable to the wider population of the United Kingdom and other similar populations.

Study funding/potential competing interests

This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

Response on bmj.com

“Tobacco is known to be one of the strongest risk factors for both cardiovascular disease and periodontal disease. So it would be interesting to know how many of the subjects of this study were smokers and how many were non-smokers.”

Desmond A Gale, retired general practitioner, Christ Church, Barbados

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TOOTHBRUSHING AND FATAL AND NON-FATAL CARDIOVASCULAR DISEASE (CVD) EVENTS

Toothbrushing	CVD events/total	Adjusted for age/sex	Hazard ratio (95% CI)	
			Model 1*	Model 2†
Total	555/11 869	—	—	—
Twice a day	308/8481	1.0 (reference)	1.0 (reference)	1.0 (reference)
Once a day	188/2850	1.4 (1.2 to 1.7)	1.3 (1.1 to 1.5)	1.3 (1.0 to 1.5)
<Once a day	59/538	2.3 (1.8 to 3.1)	1.8 (1.3 to 2.4)	1.69 (1.3 to 2.3)
P value for trend	—	0.001	0.001	0.001

*Adjusted for age, sex, socioeconomic group, smoking, physical activity, and visits to dentist.

†Additionally adjusted for BMI, family history of cardiovascular disease, hypertension (diagnosed by doctor or clinic blood pressure $>140/90$ mm Hg), diabetes diagnosed by doctor.

Archetypal trajectories of social, psychological, and spiritual wellbeing and distress in family care givers of patients with lung cancer: secondary analysis of serial qualitative interviews

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Cite this as: *BMJ* 2010;340:c2581
doi: 10.1136/bmj.c2581

This is a summary of a paper that was published on *bmj.com* as *BMJ* 2010;340:c2581

STUDY QUESTION

Do family care givers of patients with advanced lung cancer have patterns of social, psychological, and spiritual wellbeing and distress typical of the patients' trajectories as the illness progresses?

SUMMARY ANSWER

The experiences of family carers seem to mirror those of the patient.

WHAT IS KNOWN AND WHAT THIS PAPER ADDS

Characteristic trajectories of social, psychological, and spiritual wellbeing and distress for patients with progressive lung cancer have been described. We found that family carers share much of the illness experience of the patient. Psychological and spiritual distress were particularly dynamic and commonly experienced in parallel. Four key time points tended to be particularly problematic for both carers and patients: at diagnosis, at home after initial treatment, at recurrence, and during the terminal stage. Carers, like patients, may need support not only during the palliative phase and terminal stage, but from diagnosis.

Participants and setting

Nineteen patients with lung cancer and their 19 family carers in south east Scotland.

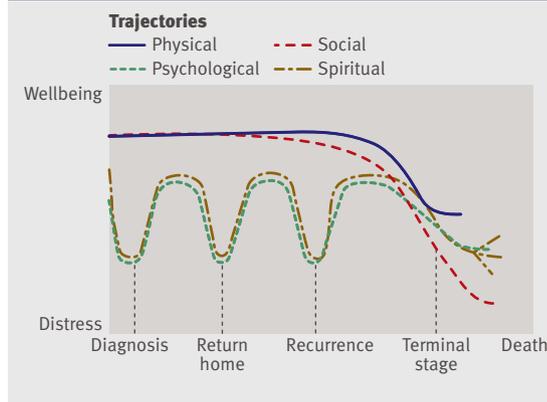
Design

Secondary analysis of 88 serial qualitative interviews (42 with patients, 46 with carers) carried out every three months up to 12 months, death, or bereavement. We identified references to distress in family carers, mapped these, and plotted the dimensions of distress typically noted by patients and carers as the illness progressed.

Main results

We found archetypal trajectories of social, psychological, and spiritual wellbeing in carers, as the multidimensional illness experience of the patients was reflected in their own lives, being most pronounced for psychological and spiritual distress. Some carers also experienced deterioration in physical health that impacted on their ability to care. As patients became progressively unwell, carers often felt less able to leave them, restricting their normal social contacts. As with patients, carers often felt they were on an emotional rollercoaster, experiencing peaks and troughs at the key transition times of stress in the cancer trajectory: at diagnosis, at home after initial treatment, at recurrence, and in the terminal stage. Spiritual distress was also com-

FLUCTUATIONS OF SPIRITUAL AND PSYCHOLOGICAL WELLBEING MAPPED WITH OTHER TRAJECTORIES OF WELLBEING IN FAMILY CARERS OF PATIENTS WITH LUNG CANCER



mon and dynamic, typically in step with psychological wellbeing.

Bias, confounding, and other reasons for caution

These data were generated from three previous studies by the same research team. Such reanalysis, especially by the same researchers, is considered good practice in qualitative research, but researchers not aware of typical trajectories in patients might not recognise them in family carers. There are also theoretical limitations in analysing data in this way when we were not pursuing purposeful sampling around carers' distress. There is a danger of stereotyping on the basis of archetypal trajectories. Distress in one dimension can increase distress in another, such as anxiety amplifying pain, and this may be true for carers as for patients. Other factors may affect carers' experiences, such as availability of services, education, information about the disease, and personal resilience. The predictive value at the level of the individual may be limited, but there are policy implications for providing appropriate and timely services from diagnosis.

Generalisability to other populations

These findings are likely to apply to carers of people affected by other cancers characterised by rapid decline. These findings need testing in further prospective studies of patient and carer interview dyads, setting out specifically to explore the carers' multidimensional dynamic experiences.

Study funding

The Chief Scientist's Office of the Scottish government funded the original studies. We have no competing interests.