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RESEARCH

THIS WEEK'S RESEARCH QUESTIONS

1088 Does telling peer reviewers that their signed reviews of original research papers might be posted on bmj.com affect the quality of their reports?

1089 What is the long term risk of hypertension and renal impairment after acute gastroenteritis from drinking water contaminated with *E coli* O157:H7 and *Campylobacter*?

1090 Is the risk of suicide attempts increased in patients with severe acne, regardless of subsequent exposure to isotretinoin?

To what extent has HealthSpace, a personal electronic health record, been adopted in England and what explains its non-adoption and abandonment?



Personal electronic health records

In 2007 the NHS launched an online personal electronic health records system called HealthSpace, where patients could enter health data such as blood pressure readings, gain secure access to their summary care record, book outpatient appointments, and exchange email style electronic messages with their doctor. The aim was that the programme would lower NHS costs, produce better quality data, improve health literacy, and lead to greater patient empowerment.

However, Trisha Greenhalgh and colleagues have found that patients aren't interested in using HealthSpace and those who did sign up found it neither useful nor easy to use (p 1091). The 56 patients and carers who were asked about the programme reported that its functionality aligned poorly with their expectations and self management practices.

These findings are in line with those of a previous study by Professor Greenhalgh and colleagues, published in the *BMJ* in 2008, which found that around 60% of the 103 patients interviewed would not want a HealthSpace account and many were unsure of its purpose (*BMJ* 2008;336:1290; doi:10.1136/bmj.a114).

The authors conclude that "the risk that [personal electronic care records] will be abandoned or not adopted at all is substantial."

Opening up peer review

The traditional peer review system has many flaws, not least the fact that reviewers can delay or prevent the publication of a research study from behind a cloak of anonymity.

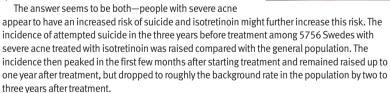
Over the years, the *BMJ* has undertaken several randomised controlled trials to find out the effect of disclosure of reviewers' identities on the quality of their reports.

The third study, published in this week's issue (p 1088), was "the most radical" says author Tony Delamothe, because it entailed telling reviewers that their signed reports would be appearing online alongside the papers reviewed when published on bmj.com. This foreknowledge did not reduce the quality of the peer review reports, although it did increase the time reviewers spent on a manuscript.

Next year the *BMJ* plans to adopt this approach as its new policy. And not just the reviewers' opinions will be publicly available, but all the documentation relating to the journal's review process: the authors' manuscript as originally received; our editorial committee's comments (if any); our statistician's comments (if any); and the authors' explanation of how they had changed their original manuscript in the light of these comments.

Acne, isotretinoin, and suicide

The severe acne drug isotretinoin has been linked with depression and suicide, and in the European Union the product comes with warnings about psychiatric adverse reactions. Anders Sundström and colleagues were concerned about the lack of a proved causal link, however, so looked back through 21 years' worth of health records to untangle whether the drug itself is responsible for the increased risk of attempted suicide, or whether people with severe acne may simply be at a higher risk regardless of exposure to isotretinoin (p 1090).



Writing in a linked editorial (p 1060), Parker Magin and John Sullivan suggest that "these findings could be interpreted to mean that acne confers an increased risk of attempting suicide (an increased risk that attenuates in the years after successful isotretinoin treatment)." They recommend that patients with acne of a severity for which isotretinoin is indicated, as well as those who are prescribed the drug, should be carefully monitored for depression and suicidal thoughts.





Is the BMJ the right journal for your research?

We give priority to articles reporting original, robust research studies that can improve decision making in medical practice, policy, or education, or in future research. But we receive many more research articles than we can publish, send fewer than half for external peer review, and currently accept only around 7%.

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Effect on peer review of telling reviewers that their signed reviews might be posted on the web: randomised controlled trial

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*SVR died in February 2005

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STUDY QUESTION Does telling peer reviewers that their signed reviews of original research papers might be posted on the *BMJ*'s website affect the quality of their reports?

SUMMARY ANSWER Reviewers' foreknowledge that their reviews might be available in the public domain on the BMJ's website did not significantly affect the quality of their reports.

WHAT IS KNOWN AND WHAT THIS PAPER ADDS Secrecy and lack of accountability are serious flaws of traditional peer review, but most scientific journals are reluctant to address these concerns. Telling peer reviewers that their signed review might appear online alongside the published paper does not affect the quality of their report, but it does increase the time they take to write it.

Participants and setting

This study comprised 541 authors of original research articles, 471 peer reviewers, and 12 editors working for a large international general medical journal based in the United Kingdom.

Design

Reviewers were chosen for all consecutive research manuscripts selected by editors for external peer review between November 1999 and July 2000. Manuscripts were then randomly allocated using a random number generator either to have the reviewer's signed report made available on the *BMJ*'s website alongside the published paper (intervention group) or to have the report made available only to the author—the *BMJ*'s normal procedure (control group). Reviewers were contacted with details of the study, although not the study arm into which the paper had been allocated, and asked whether they were willing to review the paper. Allocation was revealed when the full paper was sent to the peer reviewer. The intervention was therefore the act of revealing to reviewers that their signed report might appear on the *BMJ*'s website.

EFFECT ON REVIEW QUALITY AND TIME TAKEN TO REVIEW OF FOREWARNING REVIEWERS THAT THEIR SIGNED REVIEWS MIGHT BE PUBLISHED ONLINE

	Intervention (mean (SD))	Control (mean (SD))	Difference (95% CI)
Editors' assessment of quality (mean total score out of five)	3.40 (0.73)	3.36 (0.69)	0.04 (-0.09 to 0.17)
n	225	246	
Authors' assessment of quality (mean total score out of five)	3.16 (0.77)	3.10 (0.80)	0.06 (-0.09 to 0.20)
n	213	240	
Reviewers' time taken (minutes)	182 (135.2)	157 (101.9)	25* (3.0 to 47.0)
n	219	237	
18 reviews did not have an author's evaluation. *P<0.05.			

Primary outcomes

The main outcome measure was the quality of the reviews, as independently rated on a scale of 1 to 5 by two editors and the corresponding author using the same validated instrument. Additional outcomes were the time taken to complete the review and the reviewer's recommendation regarding publication.

Main results and the role of chance

A total of 558 manuscripts were randomised, and 471 manuscripts remained after exclusions. Of the 1039 reviewers approached to take part in the study, 568 (55%) declined. Two editors' evaluations of the quality of the peer review were obtained for all 471 manuscripts, with the corresponding author's evaluation obtained for 453. There was no significant difference in review quality between the intervention group and the control group (mean difference for editors 0.04, 95% CI –0.09 to 0.17; for authors 0.06, 95% CI –0.09 to 0.20). Reviewers in the intervention group took significantly longer to review than did those in the control group (mean difference 25 minutes, 95% CI 3.0 to 47.0 minutes).

Bias, confounding, and other reasons for caution

Poor sensitivity of the tool used to measure review quality could explain our failure to find differences between the intervention and control groups, although the same tool has successfully detected differences in review quality in several randomised studies. Reviewers who knew that their report might be posted online spent longer on the task than those in the control group, so adopting open peer review might result in the process feeling even more arduous to reviewers than it currently does.

Another concern relates to the possible negative effects of open peer review on relationships among individuals working in the same field. However, no adverse events were reported to a confidential reporting system set up for reviewers and authors.

Generalisability to other populations

The *BMJ* is an international general medical journal with a very large pool of authors and reviewers who are geographically dispersed. Whether our findings would be replicated by smaller journals, and in smaller fields, is unknown but worthy of study.

Study funding and potential competing interests

SVR and TD were both employed by the *BMJ* at the time of the study. The other costs of the study were met by the *BMJ*. Because members of the *BMJ*'s editorial staff conducted this research, assessment and peer review were carried out entirely by external advisers.

Long term risk for hypertension, renal impairment, and cardiovascular disease after gastroenteritis from drinking water contaminated with *Escherichia coli* O157:H7: a prospective cohort study

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STUDY QUESTION What is the long term risk for hypertension and renal impairment after acute gastroenteritis from drinking water contaminated with *E coli* O157:H7 and *Campylobacter*?

SUMMARY ANSWER Participants who experienced acute gastroenteritis during the outbreak were 1.3 times more likely to develop hypertension and 3.4 times more likely to develop both microalbuminuria and impaired estimated glomerular filtration rate.

WHAT IS KNOWN AND WHAT THIS PAPER ADDS Exposure to *E coli* O157:H7 Shiga toxins can cause both renal and vascular injury potentially leading to haemolytic-uraemic syndrome, but the long term health effects of milder exposure in adults are largely unknown. Gastroenteritis from drinking water contaminated with *E coli* O157:H7 and *Campylobacter* was associated with an increased risk of hypertension and renal impairment in adults.

Participants and setting

We recruited residents from Walkerton, Ontario (Canada) after an outbreak in May 2000, when a municipal water system became contaminated with livestock faecal matter.

Design, size, and duration

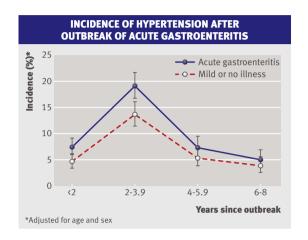
In this prospective cohort study (2002–8), we analysed 1977 adults with no pre-outbreak history of the outcome measures (acute gastroenteritis, hypertension, and renal impairment). We defined acute gastroenteritis as diarrhoea lasting >3 days, bloody diarrhoea, or >3 loose stools/day. We defined hypertension as blood pressure \geq 140/90 mm Hg and defined renal impairment as microalbuminuria or estimated glomerular filtration rate <60 ml/min/1.73 m².

Main results and the role of chance

Acute gastroenteritis was reported by 1067 (54%) of participants. Incident hypertension was detected in 697 participants (294 (32%) of group not exposed to acute gastroenteritis v 403 (38%) of exposed group). The adjusted hazard ratio for hypertension after acute gastroenteritis was 1.33 (95% CI 1.14 to 1.54). While 572 participants had at least one indicator of renal impairment (266 (29%) of unexposed v 306 (29%) of exposed), only 30 had both (8 (0.9%) of unexposed v 22 (2.1%) of exposed). The adjusted hazard ratio for the presence of either indicator of renal impairment was 1.15 (0.97 to 1.35) and was 3.41 (1.51 to 7.71) for the presence of both.

Bias, confounding, and other reasons for caution

Although adults who experienced acute gastroenteritis during the outbreak had more risk factors than those who were asymptomatic, we used several methods to control for con-



founding. In addition to excluding participants with a preoutbreak history of the outcome measures, we controlled for age, sex, smoking, obesity, diabetes, pre-outbreak healthcare surveillance, and family history of hypertension. A sharp peak in the incidence of hypertension that coincided with study enrolment and blood pressure monitoring (see figure) is likely due to the detection of previously undiagnosed hypertension. Excluding cases diagnosed at study entry produced stronger associations with exposure. We observed minimal bias from loss to follow-up on the association with hypertension; however, the unexposed group received significantly more assessments for renal impairment, which might attenuate this association because of differential information bias in favour of the unexposed.

Although *E coli* O157:H7 was the primary bacteria isolated in the contaminated drinking water, *Campylobacter*, a bacterium only rarely associated with renal sequelae, was also present. Although a mixed bacterial load would tend to attenuate the nephrotoxic effect of *E coli* O157:H7, the infectious dose of *E coli* O157:H7 (10 organisms) is much lower than that of *Campylobacter* (400-500 organisms); thus, the probability that a case of acute gastroenteritis was not due to *E coli* O157:H7 is small.

Generalisability to other populations

Given the silent, asymptomatic development of hypertension and renal impairment, annual blood pressure monitoring and periodic monitoring of renal function may be warranted for adults who experience acute gastroenteritis after exposure to *E coli* O157:H7.

Study funding/potential competing interests

All authors are independent of the study funders, the Ontario Ministry of Health and Long-term Care.

Association of suicide attempts with acne and treatment with isotretinoin: retrospective Swedish cohort study

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EDITORIAL by Magin and Sullivan

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STUDY QUESTION Is the risk of suicide attempts increased in patients with severe acne, regardless of subsequent exposure to isotretinoin?

SUMMARY ANSWER During three years preceding treatment with isotretinoin, the rates of attempted suicide were clearly rising; rates were highest within six months after the end of treatment, and two to three years thereafter the number of suicide attempts was close to the expected number.

WHAT IS KNOWN AND WHAT THIS PAPER ADDS Case reports and spontaneous reports of adverse drug reactions have suggested an association between isotretinoin and suicidal behaviour, but observational studies have had conflicting results. Severe acne is a risk factor for attempted suicide; an additional risk may be present during and up to one year after treatment with isotretinoin.

Participants and setting

We included patients prescribed isotretinoin for severe acne in Sweden, identified in a national named patient register held by the Medical Products Agency.

Design, size, and duration

This was a retrospective cohort study linking 5756 patients treated with isotretinoin (1980-9) to hospital discharge and cause of death registers (1980-2001). The patients were observed for 17 192 person years before, 2905 person years on, and 87 120 person years after treatment. We established the numbers of observed suicide attempts before, during, and after treatment and divided them by the expected number estimated from the sex, age, and calendar year specific rates in the general population, yielding standardised incidence ratios.

Main results and the role of chance

One hundred and twenty-eight patients were admitted to

hospital for attempted suicide: 32 before treatment, 20 during and within one year after the end of treatment, and 76 thereafter. During the year preceding treatment, the standardised incidence ratio for attempted suicide was raised, but not significantly: 1.57 (95% confidence interval 0.86 to 2.63) for all attempts and 1.36 (0.65 to 2.50) counting only first attempts. Standardised incidence ratios during and up to six months after treatment were 1.78 (1.04 to 2.85) for all attempts and 1.93 (1.08 to 3.18) for first attempts. Three vears after the end of treatment, the observed number of attempts was close to the expected number-standardised incidence ratio 1.04 (0.74 to 1.43) for all attempts and 0.97 (0.64 to 1.40) for first attempts—and it remained so during follow-up. Twelve (38%) of 32 patients who made their first suicide attempt before treatment made a new attempt or committed suicide thereafter, compared with 10/14 (71%) who made their first suicide attempt within six months after treatment stopped (P=0.034).

Bias, confounding, and other reasons for caution

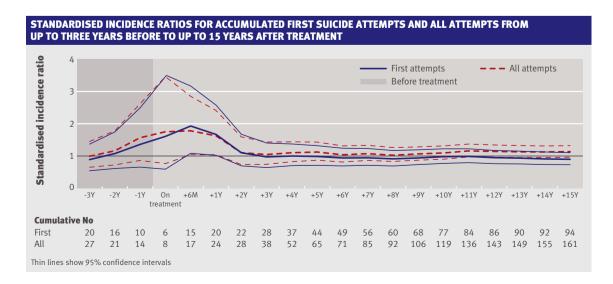
No information on potential confounders or other risk factors were available. However, for any unknown confounder(s) to explain our observations, such factors would have to be correlated with both severe acne and timing of treatment.

Generalisability to other populations

Our study was population based and included virtually all patients treated with isotretinoin in Sweden during a 10 year period. The results are likely to be generalisable to other similar sociocultural contexts.

Study funding/potential competing interests

JJ received funding for this study from the Swedish Research Council (project number K2009-61P-21304-04-4).



Adoption, non-adoption, and abandonment of a personal electronic health record: case study of HealthSpace

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STUDY QUESTION To what extent has HealthSpace (a personal electronic health record) been adopted in England and what explains its non-adoption and abandonment?

SUMMARY ANSWER Adoption has been limited for multiple reasons relating to concept, design, implementation, and context

WHAT IS KNOWN AND WHAT THIS PAPER ADDS Personal

electronic health records, managed by patients and linked in various ways with clinician led care, are being introduced in many health systems. Expectations for such records include patient empowerment and better continuity of care. Adoption of a personal electronic health record by patients in England in 2007-10 was low and benefits expected by policy makers were not realised over the period of the study.

Study design

Mixed method, multilevel case study.

Participants and setting

This study was carried out within the English National Health Service. We considered the basic HealthSpace technology (available nationally), and the advanced version, which could link to a centrally stored summary care record and support secure email-style messaging (available in a few localities).

Methods and data sources

We studied the policy making process, implementation by NHS organisations, and experiences of patients and carers.

Health Space

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Quantitative data comprised national statistics on invitations sent and HealthSpace accounts created. Qualitative data comprised interviews and ethnographic observation of 56 patients and carers (21 opened a basic HealthSpace account, 20 had diabetes but were not initially using HealthSpace, and 15 used advanced accounts to exchange messages with their general practitioner); 3000 pages of documents (policies, strategies, business plans, minutes of meetings, correspondence); observational field notes; and 160 interviews with policy makers, project managers, and clinical staff. Data analysis was informed by a sociotechnical approach, which considered macro and micro influences on both adoption and non-adoption of innovations, and by the principles of critical discourse analysis.

Main results

Between 2007 and October 2010, 172 950 people opened a basic HealthSpace account. An advanced account was opened by 0.13% of those invited (2913 people) compared with 5-10% of the population anticipated in the original business case. Overall, patients perceived HealthSpace as neither useful nor easy to use, and its functionality aligned poorly with their expectations and self management practices. Those who used email-style messaging were positive about its benefits but enthusiasm beyond three early adopter clinicians was low, and fewer than 100 of 30 000 patients expressed an interest. Policy makers' hopes that "deploying" HealthSpace would lead to empowered patients, personalised care, lower NHS costs, better data quality, and improved health literacy were not realised over the evaluation period.

Unless personal electronic health records align closely with people's attitudes, self management practices, identified information needs, and the wider care package (including organisational routines and incentive structures for clinicians), the risk that they will be abandoned or not adopted at all is substantial. Conceptualising such records dynamically (as components of a socio-technical network) rather than statically (as containers for data) and employing user centred design techniques might improve their chances of adoption and use. The findings raise questions about how eHealth programmes in England are developed and approved at policy level.

Generalisability to other populations and settings

Our findings suggest that whatever the setting there appear to be inherent problems with introducing self management technologies on a national scale using a technology-push implementation model.

Study funding/potential competing interests

The study was funded by the English Department of Health through the Connecting for Health Evaluation Programme.