Letters

Taking folate in pregnancy and risk of maternal breast cancer

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Authors and publishers must not disclaim ethical responsibility

EDITOR—On 10 December 2004 a banner headline on the front page of a popular tabloid newspaper read: "Cancer danger of folic acid" on the basis of a paper by Charles et al on taking folate in pregnancy and risk of maternal breast cancer.[1 2] Although coverage in the broadsheets was more balanced, the overall message would inevitably cause concern to women taking folate to reduce the risk of fetal neural tube defect in a desired pregnancy.

CORDELIA MOLLOY/SPL

Despite the likelihood that the most likely explanation for the reported association is chance, as reported in the commentary to the paper,[2] numerous susceptible women will probably not take folate, and some of these may conceive fetuses with neural tube defects. In addition, what company or government will take responsibility for fortification of wheat and corn flour with folate, now that this question has been raised?

The authors themselves point out that the numbers are small and the confidence intervals large. The risk was also associated with a much larger dose of folate than is routinely used to reduce the risk of neural tube defects.

Those who write such papers and those who publish them cannot disclaim ethical responsibility for how the data are interpreted and must consider more carefully their ethical responsibilities in such situations.

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Competing interests: None declared.

1 Weldon J. Cancer danger of folic acid. *Daily Express* 2004 Dec 10:1.
2 Charles D, Ness AR, Campbell D, Davey Smith G, Hall MH. Taking folate in pregnancy and risk of maternal breast cancer [with commentary by GP Oakley and JS Mandel]. *BMJ* 2004;329:1375-76. (11 December.)

What's in a name?

EDITOR—In their interesting follow up of an old trial, Charles et al tell us that this randomised trial was of high quality and that the trial was double blind.[1] They also tell us that tablets were supplied in six colours, two of which contained folate in 0.2 mg and 5 mg daily doses. The tablets were kept in numbered drawers and distributed in sequence.

If the tablets had different colours for different treatments the trial wasn't double blind, as any trialists seeing the tablets would know the treatment. If treatments were given sequentially they were not random. Also, there was no allocation concealment, an important indicator of high quality, if treatments were given sequentially, as the treatment for the next subject would be known.

I would not criticise the authors because a trial carried out in the 1960s does not meet current standards, but we should use technical terms such as double blind and randomised to mean what it is agreed that they mean, not something else.

Another curiosity of their report is that there seem to be four times as many subjects receiving placebo as receiving either active treatment. I cannot get access to the original paper, but this seems a rather extravagant design, even for the 1960s. Were some of these "placebos" other treatments? If so, is it possible that these other treatments could reduce the risk of death, rather than folate increasing it?

There are 30 tests of significance here, including the confidence intervals. One is significant at the 0.05 level, $P = 0.02$. A simple Bonferroni correction would show that the P value for the composite hypothesis that folate increases risk of death is 30 times $0.02 = 0.6$. The authors do not tell us why of all the possible causes of death they picked breast cancer; they tell us they had no prespecified hypothesis that taking folate supplements in pregnancy would increase the risk of cancer. One wonders how many other causes they looked at and which have not been mentioned. Of course, the Bonferroni method is crude and the tests are not independent, but in the absence of any more appropriate analysis by the authors it is all the reader can do.

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1 Charles D, Ness AR, Campbell D, Davey Smith G, Hall MH. Taking folate in pregnancy and risk of maternal breast cancer [with commentary by GP Oakley and JS Mandel]. *BMJ* 2004;329:1375-76. (11 December.)

Authors' reply

EDITOR—We believe that we have behaved ethically. We emphasised the preliminary nature of our findings and submitted our paper as a research pointer. We worked with the press offices of our universities, the *BMJ*, and the Department of Health to promote responsible media coverage. The journalist working for the tabloid referred to by Stirrat did not speak to us.

Although we agree that media reporting of scientific articles might be improved, we do not think that suppression of research findings is justified. Greenland et al have argued empirical observations should be reported so that they can be used to develop and test theoretical understandings of disease aetiology.[1] It might be more appropriate to ask whether it is ethical not to conduct long term follow up of large randomised trials that produced immediate effects.

Participants in this trial were sequentially allocated to receive pills of different colours. Neither the investigator nor the subjects knew which colour was which. So, as folate does not produce any side effects that would lead the investigators to break the code, the treatment was concealed and this was a double blind trial. Although strictly speaking the allocation was not the same as random allocation, we used the term random because the process was essentially random. As Chalmers and Altman and Bland have pointed out,[2 3] sequential allocation should be unbiased providing concealment is adequate. As previously described there was no other treatment arm in this trial and the assignment ratios were as specified. This could be confirmed by reading the paper that we referenced.[4] We are happy to send Bland a copy of this paper, but we note from the website of the library at his institution, the University of York, that the journal is available there.

We made it clear that our findings were not prespecified and agree that the P values should be interpreted with caution.

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1 Greenland S, Gago-Dominguez M, Castelao JE. The value of risk-factor ("black-box") epidemiology. *Epidemiology* 2004;15:529-35.
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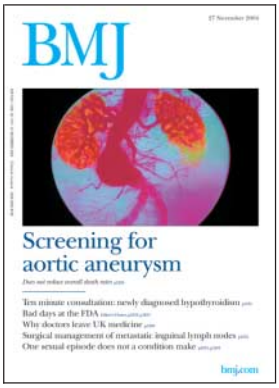
Screening for abdominal aortic aneurysm

Headline is misleading

EDITOR—The front cover of the *BMJ* of 27 November declared that screening for aortic aneurysm does not reduce overall death rates. This headline misrepresents the conclusions of the study itself,[1] let alone evidence from the UK multicentre aneurysm screening study of 68 000 men, which showed that screening halves aneurysm related deaths by reducing risk of rupture.[2]



The Australian trial studied 41 000 men aged 65-83, and the authors admit their target group was not suitable.[1] Half the men over 75 invited for screening did not attend and accounted for two thirds of deaths from aneurysm. Among those aged 65-74, not one patient died of aneurysm disease in 8641 men attending screening, compared with 11 deaths in non-attendees and 13 deaths in controls. The authors concluded that the chief reasons for their overall result seemed to have been their failure to identify and exclude men who were unlikely to attend, a substantial proportion being older than 75.

In Britain only suitable men aged 65-74 are invited by and scanned in general practitioners' surgeries. The Australians selected from electoral rolls and scanned people in specialised clinics. The Gloucestershire experience showed general practice based screening achieves 85% compliance,[3] compared with 63% in the Australian study. The lesson from Australia, acknowledged by the authors but not the headline, is that aneurysm screening programmes must be designed carefully and monitored rigorously to be effective. A recent survey from the Vascular Society shows national screening programmes for aortic aneurysm to be the highest priority for consultant vascular surgeons in the United Kingdom.

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1 Norman PE, Jamrozik K, Lawrence-Brown MM, Le MTQ, Spencer CA, Tuohy RJ, et al. Population based randomised controlled trial on impact of screening on mortality from abdominal aortic aneurysm. *BMJ* 2004;329:1259-62. (27 November.)
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3 Earnshaw JJ, Shaw E, Whyman MR, Poskitt KR, Heather BP. Screening for abdominal aortic aneurysms in men. *BMJ* 2004;328:1122-4.

Screening reduces deaths related to aneurysm

EDITOR—The Australian randomised trial of aortic aneurysm screening observed 18 deaths related to aneurysm in the group of men invited for screening and 25 in the control group.[1] The corresponding reduction in mortality was 39% (relative risk 0.61, 95% confidence interval 0.33 to 1.11), which the authors summarise as showing that screening did not reduce overall death rates. The authors have fallen into the common trap of interpreting a non-significant difference as evidence of no difference.

The stated conclusion is all the more surprising given the available evidence from other randomised trials (table). In each trial, the number of aneurysm related deaths in the men invited for screening is lower than in the control group, and so the relative risks are all below 1. The widths of the confidence intervals vary according to the size and power of the trial. The largest trial, the multicentre aneurysm screening study (MASS), shows a significant benefit.[2] So does the Danish trial, based on the published aneurysm related mortality in hospital.[3] The Chichester and Australian trials, were too small to show the difference convincingly.[4]

But it does not take a formal meta-analysis to deduce the high level of evidence, across the four trials, that screening reduces mortality related to aneurysm by the order of 40% (corresponding to a relative risk of 0.60). Speculation about possible reasons for the differences between the results of the trials is unhelpful, when what is more notable is their consistency.

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1 Norman PE, Jamrozik K, Lawrence-Brown MM, Le MTQ, Spencer CA, Tuohy RJ, et al. Population based randomised controlled trial on impact of screening on mortality from abdominal aortic aneurysm. *BMJ* 2004;329:1259-62. (27 November.)
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4 Vardulaki KA, Walker NM, Couto E, Day NE, Thompson SG, Ashton HA, et al. Late results concerning feasibility and compliance from a randomized trial of ultrasonographic screening for abdominal aortic aneurysm. *Br J Surg* 2002;89:861-4.

Authors' reply

See correction, p 596

EDITOR—We reported the study in a transparent fashion and were deliberately cautious in our conclusions. Australia and the United Kingdom are very different with regard to arrangements for primary care, which did not permit us to undertake a preliminary assessment of the eligibility of men for screening before we randomised them and issued half invitations to attend for the ultrasound examination. As such an assessment was possible in the British trials, direct comparison of response fractions between the studies undertaken in the two countries is not valid. In the Australian trial, the response to invitations was on a par with that for mammography screening, and there is good, population based evidence that the latter programme has had a clinically important impact on the presentation of breast cancer.[1]

The MASS trial indicates that screening should be introduced in the United Kingdom. Our results should not undermine this. One of the reasons our discussion focused on differences between our trial and MASS was that the effectiveness of screening may vary according to healthcare setting. Our contention is that, having been generated in an importantly different setting, the Australian results can be used to support the case for establishment of carefully designed screening programmes.

We agree with Thompson et al that the totality of the available level 2 evidence is the minimum basis on which national policies on screening for abdominal aortic aneurysm should be set. This body of evidence sets a standard against which the often heard calls to establish screening programmes for other conditions should be judged.

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Most recent published results from the randomised trials of abdominal aortic aneurysm screening in men

Trial	Age range at recruitment (duration of follow up) (years)	No of participants		No of aneurysm related deaths		Relative risk (95% CI)
		Invited	Control	Invited	Control	
Australian[1]	65-83 (5)	19 352	19 352	18	25	0.61 (0.33 to 1.11)
MASS, UK[2]	65-74 (4)	33 839	33 961	65	113	0.58 (0.42 to 0.78)
Denmark[3]	65-73 (5)	6 339	6 319	6	19	0.32 (0.11 to 0.59)
Chichester, UK[4]	65-80 (10)	3 000	3 058	24	31	0.79 (0.53 to 1.40)

1 Jamrozik K, Byrne MJ, Dewar JM, Harvey JM, Ingram DM, Parsons RW. The impact of mammographic screening on breast cancer in Western Australia. *Med J Aust* 2000;172:203-6.

Democratisation of scientific advice

Secrecy and democracy don't mix

EDITOR—Bal et al struggle to show that "concealing information from public scrutiny" is a necessary condition for "democratic function" but fail.[1] The fault in their argument is the assumption that an advisory committee should alone decide how the question is framed, how different types of evidence should be privileged, and how the "performance" should be presented. Similar debates have been vigorously pursued in the health impact assessment community.

Dissention in the scientific community is not a problem that should be hidden from an ignorant public but a fundamental mechanism in the advancement of knowledge. It is true that knowledge of temporary or continued dissention will be used naively or even mischievously and so confuse issues, but that is no excuse for hiding the process by which conclusions are reached.

Scientific reasoning is a powerful tool for improving public decision making, but it is not sufficient. Account has to be taken of lay knowledge. Experiential evidence, which covers far more than experience of disease, is one part of this. "Irrational" concerns (better described as differently rational) and values also have to be taken into account as do all the messy considerations of political possibility. That scientists should seek to avoid the complexity of wicked problems by retreating into secrecy is understandable, but benign paternalism is no answer to mature democratic making of public policy.

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Competing interests: None declared.

1 Bal R, Bijker WE, Hendriks R. Democratisation of scientific advice. *BMJ* 2004;329:1339-1341. (4 December.)

Authors advocate getting dressed for public performance, not nakedness is bad

EDITOR—Rather than arguing that nakedness is bad like Abbasi,[1] in our article on the democratisation of science we urge transparency advocates to be specific about the body parts that should be displayed publicly.[2]

As scientific advisory councils find themselves at the intersections of science and society, they necessarily transgress the boundaries of science. This makes them vulnerable to the politicisation of their work. Sound scientific advice is urgently needed in a time where our societies are overwhelmed with new technologies. Therefore, we think that science advisory boards do well in taking utmost care in shaping their relations with policy actors and the citizenry.

The experience of the Health Council of the Netherlands in dealing with scientific elements (colliding knowledge claims, etc), can be inspiring to develop methods and procedures to allow societal elements into the advisory process.[3] Transparency about one's arguments, allowing your readership to join you in (or dissent from) a line of reasoning, is one of these fragile new procedures that enables the council to be both scientific and useful to policy and public debate.

Scientific journals should publish dissenting voices, as this is important for the advancement of science (although journals also have their backstage processes, as McCabe says in her rapid response[4]). Science advisory boards, however, are to advise government on the state of the art. Debates in the committee further that goal, as this is useful in mobilising the expertise of committee members. Confidentiality of the committee process is essential for the production of such debates (public scrutiny during the process might deter openness among experts). Whereas it goes without saying that lasting dissent is not to be concealed, it seems unwise to bring temporary dissent into the open, as this would be easily taken up to politicise the advice and thus render it ineffective.

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Competing interests: None declared.

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Charcoal burning is also popular for suicide pacts made on the internet

EDITOR—Rajagopal's editorial discussed how strangers can initiate suicide pacts on the internet.[1] The two cited Japanese suicide pacts both used a new suicide method, charcoal burning. These widely publicised pacts were followed by four additional pacts and 13 deaths in two months, all of whom used charcoal burning. The new suicide method entails smouldering barbecue coal in a small and sealed environment, such as a bedroom, with the aim of producing a carbon monoxide chamber in a short time.[2–4]

In Hong Kong we had also observed that suicide pacts commonly used charcoal burning to institute death. In 2002 and 2003, 20 of the 22 suicide pacts (91%) used charcoal burning. Of all charcoal burning deaths during the same period, 7% were suicide pacts (unpublished review of coroners' case records for 2002-3, Coroner Court, Hong Kong SAR).

Several characteristics of charcoal burning make it desirable for people who want to commit suicide together. Unlike other methods of suicide, such as jumping and hanging, it can easily be shared. Besides, charcoal burning is often portrayed as non-disfiguring and painless. Hence, passive partners in suicide pacts could be more easily lured into the act.

The internet, apart from connecting otherwise isolated anomies in forming suicide pacts in Japan, has played an important part in spreading the new suicide method across societies. Charcoal burning and cyber suicide pacts are examples of how globalisation and new technology are creating new challenges for global health.

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1 Rajagopal S. Suicide pacts and the internet. *BMJ* 2004;329:1298-9. (4 December.)
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4 Chan KPM, Yip PSF, Au J, Lee DTS. Charcoal burning suicide in post-transition Hong Kong. *Br J Psychiatry* 2005;186:67-73.

Submission to multiple journals to reduce publication times

Idea needs further evaluation

EDITOR—Torgerson et al moot the idea of submission to multiple journals to reduce publication times, but their article raises more questions than it provides answers.[1]

Firstly, to how many journals would authors be allowed to submit their article, and who will decide the number of simultaneous submissions—the authors or the journal?

Secondly, in the event of simultaneous acceptance by many journals, who would decide that the accepted article should remain with which journal—the authors (who always want their article published in the best journal) or the journals themselves (which might fight for the article if it is really high quality)?

Thirdly, what would happen to low rated journals (which may not be getting the article in first place)?

Fourthly, if the article were rejected by all the journals to which it was submitted, should the authors be allowed to resubmit it

simultaneously to a couple of journals—again wasting the time of the whole scientific community apart from journal resources?

Multiple submission may not be an ideal way to deal with the problem of delay until all the issues related to are resolved. It needs further evaluation before being enforced. One of the ways to reduce the time for publication is that, if a journal is about to reject an article it should be responsible for suggesting to the authors to which journal (two or three, in order of preference) they should send their article next. The suggestion should arise from review of the article by panel of experts on the subject, who would know for which journal the submitted article is most suitable and where it is most likely to be accepted.

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1 Torgerson DJ, Adamson J, Cockayne S, Dumville J, Petherick E. Submission to multiple journals: a method of reducing time to publication? *BMJ* 2005;330:305-7. (5 February.)

Access to information might become truly universal

Editor—A multiple submissions system proposed by Torgerson et al would be workable if collective mentality were overhauled and changed drastically.[1] It would require (among other things) electronic online submissions across the board; membership of authors to a central association of authors (electronic database and annual membership subscription); an international association of medical journals with the central role of ensuring good communication between journals; and a general association of peer reviewers (preferably connected to the internet).

The membership fee might represent a serious problem for those authors who cannot afford it; but this problem is not entirely insurmountable as the collective pool of membership (including additional subsidies from states and drug companies?) might be able to absorb the costs (similar to insurance companies, etc). Furthermore, many reviewers would not necessarily abandon their voluntary work and would continue to work for the principle itself. Many other reviewers are authors themselves, and therefore their fees would return as membership fees.

Many practical details need to be sorted out, but if this new concept of simultaneous multiple submissions took off, the end result would be satisfactory—not only for all the parties involved but also for the patients, who would benefit much earlier from the results of medical advances. And, perhaps, the access to information would be truly universal.

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1 Torgerson DJ, Adamson J, Cockayne S, Dumville J, Petherick E. Submission to multiple journals: a method of reducing time to publication? *BMJ* 2005;330:305-7. (5 February.)

What about the readers?

Editor—None of the responses to the article by Torgerson et al has mentioned readers.[1 2] All have assumed the prime purpose of journals is to act as the final link in the research chain. As a former editor of a peer reviewed general clinical journal, I saw things differently: what I wanted to publish were useful messages, often wrapped up in scientific papers, for my readers to take home.

This simple desire was frustrated by many things—the most blatant being its distortion by the system of impact factors and the dependence on them (at least in the United Kingdom) of the research assessment exercise. Papers that would help my readers look after their patients better were therefore instead often sent to journals with far fewer appropriately targeted readers, simply because the impact factor was higher.

Researchers were, no doubt, satisfied with this, but it performed a disservice to readers and to patients. Multiple submission would serve only to make this worse as authors hurl themselves at a waterfall of journals with ever decreasing impact factors, regardless of their readership.

It might, of course, pressure journals that take far too long to process papers to perform more efficiently, but the opposite side of this coin is that no editor takes as kindly to a paper when he knows he is the sixth on the list as when he is first or second.

One solution to authors' grievances is for journals to make as great a use as possible of instant rejection—easy with electronic submission. Reviewers mostly work without reward, so it would be unfair to use them solely to help an author rewrite his paper for another journal. Peer reviewers are there to help editors reach decisions. Editors and journals are not there to provide a rewriting service for authors.

Perhaps the best international database would give the median times for each journal to conduct each part of the submissions and publication process. Authors who rate speed above appropriate readership would then know where to aim first.

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Competing interests: HM provides editorial services for the BMJ Publishing Group and is vice chair of the Committee On Publication Ethics.

1 Torgerson DJ, Adamson J, Cockayne S, Dumville J, Petherick E. Submission to multiple journals: a method of reducing time to publication? *BMJ* 2005;330:305-7. (5 February.)
2 Electronic responses. Submission to multiple journals. bmj.com 2005. http://bmj.bmjjournals.com/cgi/eletters/330/7486/305 (accessed 8 Feb 2005).

bmj.com

Summary of responses

Editor—Torgerson et al's idea of submission to multiple journals to reduce time to publication was mostly met with reservations.[1] But some unanimously favoured it to counteract the inefficiency of journals in dealing with submissions, increase competition, and instigate more academic coordination and cooperation.

Reservations included the increased workload of journal staff and reviewers. An "acceptable" author's fee might be a way to overcome this, or even a ranked system of fees to be paid to all journals being targeted for publication. Jutta Loeffler, a postdoc in New York, was concerned that all submissions would end up on the same reviewers' desks anyway. Another concern was that if an article were submitted to many journals it might be accepted by many—so what would happen to low impact journals?

Multiple submissions might then lead to "unethical pressures" and efforts to stall lower impact journals until a higher impact journal had responded. They might kill peer review by exerting too much pressure on too few reviewers. A real example of duplicate publication showed the problems of ownership. The value of research, and hence its publication, in today's world was raised. Does it equal money and prestige, or does it serve humanity?

Correspondents suggested how waiting times might be reduced. Journals should keep authors informed about how long they would have to wait for a decision and generally keep a dialogue open. Their replies should be clear and mainly based on reviewers' comments. If an article is targeted at the wrong journal, the journal should send it back without delay. Authors might inform the journal that, unless they hear from it in four to six weeks, they will try another journal. They should also be more rigorous about which journals they submit to—and not base their decision on impact factors. Saving the finer details of a publication's required style until after acceptance would also save time.

Most of those who were lukewarm about multiple submission were not, however, sanguine like Robert Rudolph, a dermatologist in Philadelphia, who wrote of his experience: "If the article was rejected by my journal of choice, I simply sighed, accepted my fate, and resubmitted it to another one for consideration. Then I had a drink."

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BMJ

Competing interests: None declared.

1 Electronic responses. Submission to multiple journals. bmj.com 2005. http://bmj.bmjjournals.com/cgi/eletters/330/7486/305 (accessed 3 Mar 2005).