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LETTERS

REGULATION'S THREAT TO RESEARCH

Can anyone beat my delays?

Stewart and colleagues report their problems in applying for research approval.[1] I easily trump their delay of one year.

For a randomised trial of general versus regional anaesthesia for hip fracture surgery, we first sought the approval of the Medicines and Healthcare products Regulatory Agency (MHRA). We applied in November 2004, and in October 2005 received a reply stating that MHRA approval was not necessary. Ethics approval was sought in October 2005 and granted in February 2007. The research and development application was made in February 2007 and approved in June 2007. The study started in June 2007. Total time for regulatory approval two years eight months.

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Competing interests: None declared.

1 Stewart PM, Stears A, Tomlinson JW, Brown MJ. Regulation—the real threat to clinical research. *BMJ* 2008;337:a1732. (16 October.)

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Time for patients to speak out?

For two studies with ethics approval on which I currently represent patient interests—both linking primary care or hospital records with cancer registry records—the Patient Information Advisory Group has taken six months and almost a year to enter them on its register of approved studies[1]; without such an entry cancer registries will not release their data. If the reviewers, grant awarding body, and local research ethics committee think that the study is important and methodologically sound, surely it is unethical to hold the research up in this way?

The pursuit of patient confidentiality, often by patient representatives, is almost obsessive and can be in no one's interests, particularly patients'. Allowing experienced researchers to access anonymised medical records has little potential for harm, but the default position, which the public has been conditioned into adopting, seems to be that any attempt to do so is a wicked infringement of personal rights. One study I am involved with explores the relation between a primary care diagnosis of iron deficiency anaemia and subsequent diagnosis of bowel cancer. Since non-response would introduce invalidating degrees of bias, this valuable study is only possible by analysing routinely held records. How can delaying such studies be in the public interest?

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Competing interests: None declared.

1 Stewart PM, Stears A, Tomlinson JW, Brown MJ. Regulation—the real threat to clinical research. *BMJ* 2008;337:a1732. (16 October.)

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Regulation has run amok

The situation Stewart and colleagues describe[1] is even more ludicrous in relation to health services research, where the study subjects are often healthcare practitioners or organisations and the methods of investigation are interviews or postal questionnaires.

Investigators undertaking health services research are subjected to the same regulatory systems as investigators undertaking clinical trials of treatments where there is genuine uncertainty about the risks to patients. We have examples such as a health services researcher required to have occupational health checks to undertake telephone interviews, and another where an ethics committee objected to qualitative case studies in a handful of patients on the grounds that the sample would not be statistically representative of the population. The former illustrates the system's inability to tailor regulatory procedures to the risks posed by the research. The latter illustrates the system's inability to judge the quality (and hence the ethics) of research that does not fit the conventional biomedical model.

The costs of dealing with this misguided bureaucracy are enormous as they absorb months of researchers' and administrators' time. Urgent action is needed to make regulatory systems fit for purpose.

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Competing interests: None declared.

1 Stewart PM, Stears A, Tomlinson JW, Brown MJ. Regulation—the real threat to clinical research. *BMJ* 2008;337:a1732. (16 October.)

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Barrier is impossible to leap

Getting approval for a simple questionnaire based study has taken me the best part of my four month rotation in breast and general surgery. The study's aim was to identify areas of weakness in the current breast cancer rapid access clinic and to improve services for patients and their partners. I am no closer to starting my study, and I transfer to the department of medicine in three weeks.

The whole experience has underlined to me how prohibitive, laborious, and bureaucratic attempting to conduct research has become.[1] If I ever proposed a study that is invasive or involves drugs, the proposal itself would take me the best part of my core training years.

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Competing interests: None declared.

1 Stewart PM, Stears A, Tomlinson JW, Brown MJ. Regulation—the real threat to clinical research. *BMJ* 2008;337:a1732. (16 October.)

Cite this as: *BMJ* 2008;337:a2917

Research is no longer attractive

My experiences include a six month delay following an ethics amendment in which we requested approval to take 10 blood samples from healthy subjects. Bearing in mind the whole study took one morning to complete, this seemed disproportionate. My last three grants

have taken more than a year from award to full approval, leading to the embarrassing situation of the first year's annual report in which our achievements are listed as "ethics and R&D approval obtained."

We, too, have been subject to inconsistent decisions[1]—for example, one ethics committee agreed to our subjects self administering growth hormone for 28 days at home while another declined allowing subjects to give even a single injection at home, when this was more convenient for the subject.

It is becoming increasingly difficult to attract to research, fellows and students who have become increasingly disheartened as their first experience of research turns into one of impenetrable administrative hurdles.

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Competing interests: None declared.

1 Stewart PM, Stears A, Tomlinson JW, Brown MJ. Regulation—the real threat to clinical research. *BMJ* 2008;337:a1732. (16 October.)

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A regulator writes

The National Research Ethics Service has several initiatives to address the problems raised by Stewart and colleagues.[1]

- The integrated research application system streamlines applications for all health research. It is a single electronic portal linked to different regulatory or funding bodies where information is entered only once. By early next year applications to the Medicines and Healthcare products Regulatory Agency (MHRA) will be possible through it
- For 10 years we have funded training days in research ethics where reviewer and researcher study together (those who learn together may better work together)
- We run and audit an email queries line to help researchers through the intricacies of regulation (queries@nres.npsa.nhs.uk)
- We ran a pilot study in 2008 to assess the feasibility of an expedited review process for research with "no material ethical issues," and a live pilot project will start early next year in south London
- We have worked with others to differentiate audit, service evaluation, and research to free work from unnecessary regulation.[2]

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Competing interests: HTD is seconded to the National Research Ethics Service as research ethics adviser.

1 Stewart PM, Stears A, Tomlinson JW, Brown MJ. Regulation – the real threat to clinical research *BMJ* 2008;337:a1732. (16 October.)
2 National Patient Safety Agency, National Research Ethics Service. Defining research. www.nres.npsa.nhs.uk/rec-community/guidance/#researchoraudit

Cite this as: *BMJ* 2008;337:a2920

A UK problem

The Executive Committee of the European Association for Clinical Pharmacology and Therapeutics (EACPT) recently discussed the problem of obtaining permission to undertake a clinical trial.[1] From those countries represented, the problem seemed to be predominantly an issue in the United Kingdom. Representatives of seven countries stated that clinical trials were nearly always fully approved in their country within 60 days of the application being made, and this included action by the regulatory body and any necessary approval by an ethics committee or hospital authority. This is in line with a recent paper comparing the time from application to approval of multicentre clinical trials in European countries, the United States, and Australia.[2]

Interestingly, the approval time in European countries following the EU clinical trials directive was longer than that in those countries that were not following it (75 *v* 59 days).

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On behalf of the EACPT Executive Committee

1 Stewart PM, Stears A, Tomlinson JW, Brown MJ. Regulation—the real threat to clinical research. *BMJ* 2008;337:a1732. (16 October.)
2 Heerspink HJL, Dobre D, Hillege HL, Grobbee DE, de Zeeuw D, et al. Does the European clinical trials directive really improve clinical trial approval time? *Br J Clin Pharmacol* 2008;66:546-50.

Cite this as: *BMJ* 2008;337:a2919

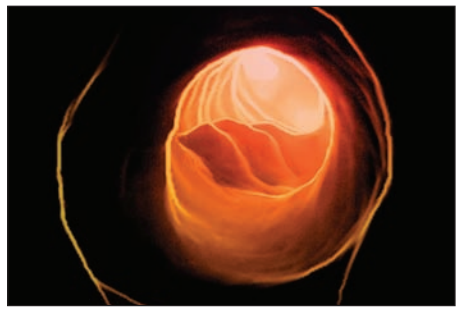
JUPITER STUDY

JUPITER may yet change practice

Donner-Banzhoff and Sönnichsen temper the hype following the publication of the JUPITER trial,[1] but other issues are also problematic:

- It is hard to find a good reason to stop the study early, given the low absolute benefit
- The mortality data show an even lower absolute reduction of 0.25% (number needed to treat (NNT) 400). Curiously, a short time before the study was interrupted the reduction was only around 0.1% (NNT=1000)
- The competing interests are staggering. For example, the first author and chair of the steering committee is a co-inventor of the high sensitivity C reactive protein test, which has been licensed to AstraZeneca.

JUPITER should simply be discarded as irrelevant and at best doubtful in its conclusions. In fact, it could be regarded as evidence that statins are probably much less effective than we want to believe. Indeed, in the CORONA trial rosuvastatin compared with placebo showed no benefit on clinical outcomes in high risk patients with heart failure.[2] Perhaps JUPITER will make



ZEPHYR/SPL

us consider carefully whether our patients really need statins.

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Competing interests: None declared.

1 Donner-Banzhoff N, Sönnichsen A. Statins and primary prevention of cardiovascular events. *BMJ* 2008;337:a2576. (14 November.)
2 Kjekshus J, Apetrei E, Barrios V, Böhm M, Cleland JG, Cornel JH, et al; CORONA Group. Rosuvastatin in older patients with systolic heart failure. *N Engl J Med* 2007;357:2248-61.

Cite this as: *BMJ* 2008;337:a2921

QOFING WHINE

Don't be an ostrich

Spence's sceptical reaction to the quality and outcomes framework (QOF) will have hit home with many general practitioners.[1] Few of us spontaneously welcome the nagging computer prompts that interrupt our consultations, reduce our work to protocols and guidelines, and ignore the subtle, immeasurable aspects of the job. Nor do we like to acknowledge how easily our actions have been manipulated by cash incentives.

But wait, it's not about us: it's about our patients. The QOF reminds us to consider evidence based medicine for every patient, not just when we have the time or the inclination. I agree that applying clinical research findings to patients with complex cases is not straightforward, but that's where the skill comes in. We have to start somewhere, and we can improve QOF gradually as we see its real impact on our patients' lives.

So do we just squeeze in the extra work, get rich and grumpy? We don't have to. We could start by acknowledging that our work has quantitative and qualitative aspects. Letting QOF take care of the quantitative aspects frees us up to concentrate on the more thoughtful stuff. And QOF money can buy us time to do everything better: by increasing the length of consultations, or employing nurses to share chronic disease management, or arranging protected time to meet and plan how to improve the quality of our work and tackle the trickier, unQOFable things.

It's a question of your viewpoint. Look up and you'll see a patient.

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Competing interests: JH is GP QOF assessor for Oxfordshire Primary Care Trust, and was previously assessor for Norfolk Primary Care Trust.

1 Spence D. Lay your money down. *BMJ* 2008;337:a2619. (19 November.)

Cite this as: *BMJ* 2008;337:a2925

Soft and hard end points matter

Spence calls for hard end points such as cardiovascular mortality for the quality and outcomes framework (QOF).[1] Other correspondents suggest that important but less measurable aspects of care have declined since the new general practice contract.

Soft end points are important, but so are hard ones. In recent years UK life expectancy has steadily increased by around one year every five years,[2] cardiovascular mortality in men under 75 fell by 38% between 1998 and 2006,[3] and cancer survival has increased.[4] These changes are no doubt due to a combination of societal factors and improvements in both primary and secondary care. In general practice some aspects of clinical care have dramatically improved since 1998.[5]

Let us by all means debate the cause of the improvements and the unintended consequences of new initiatives. But let us not conduct the debate as if these major improvements in health were not real. They are likely to be attributable, at least in part, to changes in the way we deliver medical care.

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Competing interests: MR advised on the development of QOF in 2002 and 2003.

1 Spence D. Lay your money down. *BMJ* 2008;337:a2619. (19 November.)
2 Office for National Statistics. Life expectancy. www.statistics.gov.uk/cci/nugget.asp?id=168
3 Health Foundation. QQUIP (Quest for Quality and Improved Performance). Mortality from all Circulatory Disease. http://qquip.health.org.uk/qquip/index.aspx?chapterid=19486&contentid=21483&ContentTemplateID=2246
4 Office for National Statistics. Cancer survival 1999-2004. www.statistics.gov.uk/cci/nugget.asp?id=861
5 Campbell S, Reeves D, Kontopantelis E, Sibbald B, Roland M. Quality of primary care in England with the introduction of pay for performance. *N Engl J Med* 2007;357:181-90.

Cite this as: *BMJ* 2008;337:a2922

Accurate deprivation scores are needed

Linking the location of a general practice building to a deprivation score is not ideal.[1] As Ashworth and colleagues point out, we found in our study in Rotherham that deprivation scores based on the location of the practice building were a valid proxy for the "true" practice population deprivation score, but only in the sense that there was a high correlation between them.[2]

However, using the location of the practice building we underestimated the association between deprivation and mortality that we found using a score based on postcode data from the whole practice population. McLean et al showed a similar underestimation in a much larger study of Scottish practices.[3]

The negative association between deprivation and blood pressure monitoring in English general practice may be greater than Ashworth and colleagues were able to show. Thus we should be cautious before we conclude that inequalities in blood pressure monitoring and control in English general practice have disappeared.

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Competing interests: None declared.

1 Ashworth M, Medina J, Morgan M. Effect of social deprivation on blood pressure monitoring and control in England: a survey of data from the quality and outcomes framework. *BMJ* 2008;337:a2030. (28 October.)
2 Strong M, Maheswaran R, Pearson T. A comparison of methods for calculating general practice level socioeconomic deprivation. *Int J Health Geographics* 2006;5:29.
3 McLean G, Guthrie B, Watt G, Gabbay M, O'Donnell CA. Practice postcode versus patient postcode: a comparison of data sources in England and Scotland. *Int J Health Geographics* 2008;7:37.

Cite this as: *BMJ* 2008;337:a2926

COPYING LETTERS TO PATIENTS

Copying patients in is not as simple as it seems

Richards advocates copying patients into all correspondence on the grounds of improving health literacy,[1] but a sizeable minority of people in the UK have general literacy problems and are unlikely to benefit.[2]

As currently written, many letters from hospitals are difficult for patients to understand. My colleagues and I have had to explain to alarmed and bewildered patients who have received copies of their correspondence the meaning of phrases such as "the benefits of IOL may be limited because of the presence of incurable dry AMD [translation at the bottom of the letter]." It is not difficult to see why patients with several chronic conditions may erroneously interpret such information in the worst possible way, or even as a terminal prognosis.

Some patients will not want confidential details of their medical history entrusted to the postal service, or the risk that they might be viewed by other family members. Patients would have to be informed about the potential for data loss once the letter leaves the NHS and should be asked to give consent. It cannot be routine. This of course will add to the length of any consultation.

Our practice sends and receives several hundred letters and investigation results every day. Who will pay even a conservative estimate of £0.50 (€0.60, $0.75) per item for copying patients into correspondence? Hospitals and practices will have to stop some services they currently provide to pay for it. How will we know if the intervention is cost effective? Access to an electronic record (for the computer literate) would reduce the cost but has its own drawbacks.[3]

IMAGE STATE/ALAMY

Before rushing to provide the service that Richards suggests, we must think it through, plan it properly to maximise its benefits to all patients, and decide whether the potential overall benefit is worth the cost.

IOL= intraocular lens replacement, AMD= age related macular degeneration.

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Competing interests: None declared.

1 Richards T. Copy them in. *BMJ* 2008;337:a2324. (4 November.)
2 Department for Education and Skills. *The skills for life survey. National needs and impact survey of literacy, numeracy and ICT skills*. London: Stationery Office, 2003.
3 McKinstry B. Vulnerable people have most to lose from online access. *BMJ* 2007;334:599.

Cite this as: *BMJ* 2008;337:a2687

Copying in or copping out?

I'm all in favour of health literate patients[1]—indeed, I see my role as helping patients to understand what is happening to them and detailing the options so they can then choose what they want.

But I don't copy my letters to them.

The purposes of clinic letters are to communicate with general practitioners and keep a legible record in the notes of what is happening and what might happen. It is written in medical speak, and it is fantasy to suggest that letters written like that will ever be meaningful, without further explanation, to most patients. So if I use those letters as a way of informing patients, I will need two letters—one for them, and one for the notes.

If I want my patients to know what is happening to them, it takes more than a letter. A motivated doctor who spends time in the clinic explaining things may well inform patients better than one who simply copies patients into all correspondence. And of course most of the research showing that copying in works will be done by enthusiasts who set out both to be informative in clinic and to copy letters.

I would be happy for patients to read their notes as they wait to see me so that they can easily and quickly ask about things they don't understand. Some departments in our hospital automatically copy letters, and sometimes patients ask me to translate them when they come to my clinic.

In the era of target driven medicine, doctors compulsorily copying patients into correspondence could easily become a surrogate measure of patient centred care. Like many easily countable targets, this one would be a simplistic cop out that tells us nothing about what we really want to know.

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Competing interests: None declared.

1 Richards T. Copy them in. *BMJ* 2008;337:a2324. (4 November.)

Cite this as: *BMJ* 2008;337:a2688

Try it and see

Generally, doctors who are sceptical about copying letters to patients seem not to have tried it, whereas those who send copies routinely are enthusiastic.[1] I had initial reservations, but for four years have sent copies of letters to patients, including my letters to general practitioners and for tertiary referrals. Asking patients if they would like copies adds minimal time to a consultation, and few decline (some ask for a close relative to receive the letter instead). The informal feedback from patients has been uniformly favourable, and they say it makes them feel more involved in their management.

None of my consultant colleagues who has tried copying letters to patients has subsequently stopped because of the theoretical problems, and most, like me, have become converts to the practice. Try it and see.

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Competing interests: None declared.

1 Richards T. Copy them in. *BMJ* 2008;337:a2324. (4 November.)

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NATIONAL OBESITY STRATEGY

There might be one big idea

There is indeed no single big idea that will solve the obesity crisis.[1] A cacophony of issues should be addressed through the ongoing, sustained, and coordinated implementation of support, education, and economic and regulatory messages.

Perhaps the one big idea underpinning much of public health is where and how to strike the balance between liberty and authority. Or put another way: How much personal freedom am I prepared to give up for an (political, economic, social) environment that makes it easier for me to be healthy? This is deeply political and hotly contested, and more light being shed on true social values in this matter will make the decision about what programmes to implement easier.

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Competing interests: None declared.

1 Hawkes N. National obesity strategy: what's the big idea? *BMJ* 2008;337:a2548. (18 November.)

Cite this as: *BMJ* 2008;337:a2927

BAILEY AND LOVE

Textbook response (1968)

I recently undertook a major cull of a lifetime's collection of books but spared my 1968 edition of the classic *Bailey and Love's Short Practice of Surgery*.[1] I treasure both the book and the memories it evokes.

Who could forget the surgeon's remark that the stool resulting from a stone in the common bile duct is "Pale, bulky and offensive—like Bailey and Love"?

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Competing interests: None declared.

1 Robertson K. Bailey and Love's Short Practice of Surgery. *BMJ* 2008;337:a2601. (18 November.)

Cite this as: *BMJ* 2008;337:a2929

FLU VACCINE IN OVER 65s

A proper RCT is needed

In discussing flu vaccine in the over 65s, Jordan and Hawker say that there is "knowledge that the vaccine is effective and cost effective."[1] They do not give a reference—hardly surprising in view of the many reservations and caveats they express about available studies.

Almost all of them are observational studies with their attendant risks of bias and exaggeration. Some make incredible claims for the vaccine—for example, a year round 50% reduction in all cause mortality.

An outstanding exception is the randomised double blind controlled trial (RCT) by Govaert et al, cited by Jordan and Hawker. However, no significant clinical or serological advantage of vaccination was observed in those over 70—the group targeted by the government. With the aim of covering 15 million patients, the cost must be staggering and the benefit minuscule, except for the purveyors of the vaccine.

Perhaps the most depressing aspect of this exercise in wishful thinking is the assertion that in countries where the vaccine is recommended it might be difficult to obtain ethics approval for randomised trials. This is a perfect example of defensive immunisation against criticism castigated by Popper.

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Competing interests: None declared.

1 Jordan RE, Hawker JI. Influenza vaccine in the over 65s. *BMJ* 2008;337:a2545. (18 November.)

Cite this as: *BMJ* 2008;337:a2924

10 MINUTES ON MEMORY PROBLEMS

Another 10 minute miracle

LWT/REX FEATURES

Amid the political and media onslaught against general practitioners, I always take heart from the high esteem in which we are held by the *BMJ*. What we are capable of in a 10 minute consultation never ceases to amaze. With "Memory problems in an older person" we achieve dizzying new heights.[1]

History and risk assessment together comprise 26 questions to be asked of a cognitively impaired pensioner and her daughter. Then an examination "paying particular attention to the cardiovascular and nervous systems" but with an implicit suggestion of a digital rectal examination among other embellishments. A formal cognitive assessment "can" then be fitted in (like other correspondents, I favour the six item cognitive impairment test (6-CIT)), with some form filling for the investigations. The referral letter at least waits for another occasion, perhaps when the results are back? Alleluia!

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Competing interests: JJM is a general practitioner who tries to achieve a half decent standard of care but struggles with time keeping.

1 Suresh K, Smalley D, Walker Z. Memory problems in an older person. *BMJ* 2008;337:a1170. (10 October.)

Cite this as: *BMJ* 2008;337:a2928