

## General practitioners say that evidence based information is changing practice

EDITOR—As the publishers of the BMJ's *Clinical Evidence* we have more than a passing interest in the extent to which the provision of evidenced based information changes clinical practice. In this context, the results of an evaluation of *Clinical Evidence* commissioned by us assumed some importance.

A total of 5960 general practitioners in England were contacted by Stingray Research, an independent market research company, and asked to provide some broad perceptions about the role of evidence in their day to day practice and to pass judgment on *Clinical Evidence*. The response rate was 838/5960 (14.1%).

Some findings were not surprising. Seventy five per cent of general practitioner respondents reported that their patients were likely to show interest in the latest research findings. Ninety seven per cent of the general practitioners had used an information resource to find the latest evidence, and 45% expected to do so at least once every fortnight. Subject matter ranged across the broad spectrum of disease. *Clinical Evidence* was used mainly around clinical consultations—before, during, and after. However, other uses, such as education and teaching, and assisting the development of practice guidelines, were also reported by 77% and 52% of respondents, respectively.

The most crucial findings related to the proportion of doctors, 75%, who reported that they had changed their practice as a result of using *Clinical Evidence*. Two thirds of these had done so in the previous six months. Change of practice in response to *Clinical Evidence* was most likely in younger doctors, but was also reported by 56% of respondents aged over 55.

Quotes from respondents underlined the message; that provision of evidence from an independent, trusted source supported them in developing their practice and improved the quality of their consultations.

There are limitations to this evaluation. We don't know what the non-respondents thought, for example. However, the evidence seems to imply that there is a substantial body of clinicians of all ages—in this case English general practitioners, but we know that similar results have been found among Italian<sup>1</sup> and US doctors—who are motivated to use evidence based sources to improve their care for patients.

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1 Formoso G, Moja L, Nonino F, Dri P, Addis A, Martini N, et al. Clinical evidence: a useful tool for promoting evidence-based practice? *BMC Health Services Research* 2003;3:24 doi:10.1186/1472-6963-3-24.

## Truth and evidence based medicine: spin is everything

EDITOR—Abbasi quotes Richard Smith saying, "Journals are in the debate business, not the truth business."<sup>1</sup> Evidence based medicine (EBM), on the other hand, is supposed to glean facts and is clearly in the truth business. It is disturbing when these truths become debatable. We would like to use your columns to debate the truth business.

We recently completed a small randomised controlled trial of surfactant in premature newborn infants of 27-30 weeks' gestation in India. We found that surfactant did not improve survival. This study apparently contradicted a Cochrane review that says that the meta-analysis supports a decrease in the risk of neonatal mortality (typical relative risk 0.60, 95% confidence interval 0.44 to 0.83; typical risk difference -0.07, -0.12 to -0.03).<sup>2</sup>

On examination of the details of the Cochrane report we found that the meta-analysis did not actually find better survival in those receiving surfactant (relative risk 0.70, 0.47 to 1.06, for survival up to discharge). Further meta-analysis found better survival when looking at death within 30 days of birth. This was sufficient "evidence" for the reviewer's conclusion, that there "was a decreased risk of mortality."

How many parents would consider survival for 30 days a crucial end point if their baby did not survive to go home? "What is truth?" Pontius Pilate once asked.<sup>3</sup> It seems that evidence based medicine reports are not averse to a bit of spin.

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1 Abbasi K. Lifeline. *Lancet* 2004;364:675.

2 Soll RF. Prophylactic natural surfactant extract for preventing morbidity and mortality in preterm infants (Cochrane Review). In: *Cochrane Library*. Issue 3. Chichester: John Wiley, 2004. (*Cochrane Database Syst Rev* 2000(2):CD000511.)

3 *Holy Bible*. John 18, 38. (New international version.)

## Compulsory registration of clinical trials

### Publicly funded national register of trials would be best in the United Kingdom

EDITOR—We support the statement of the International Committee of Medical Journal Editors on trial registration discussed by Abbasi,<sup>1,2</sup> but we reiterate that currently no register satisfies all requirements.

The UK National Register of Cancer Clinical Trials meets the criteria in that it is freely available, managed by a not for profit organisation, and stores all required data items. It is, however, restricted to UK randomised cancer trials. Setting national and disease boundaries has enabled an in-depth approach whereby we are confident that we have captured most publicly funded trials. Passively providing a database for registration does not work. Trials need to be actively sought and managed. A high proportion of our registrations are effected by our register manager seeking permissions and abstracting information from protocols; thereafter, we actively seek updated accrual and publication information. To move beyond this, while maintaining comprehensiveness, undoubtedly requires an element of compulsion.

The database of the International Standard Randomised Controlled Trial Number Register and the utility of a unique numbering system has undoubtedly progressed the registration argument. However, it has not solved the problem: registration is voluntary, and for some organisations, even a modest cost of number purchase is a disincentive.

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We are also aware that those conducting trials are increasingly burdened by administration, and many feel they are already “registering” their trials in many different places. So far the response to registration has been piecemeal, and we need a coordinated approach, both nationally and internationally. We believe that in the United Kingdom, the best approach would be to build a publicly funded national register of trials, using a similar model to [clinicaltrials.gov](http://clinicaltrials.gov), but which operates across all interventions and areas of health care. Backed by legislation or obligation of governance that all trials conducted in the UK should be entered in this particular register, this could lead to the first ever fully comprehensive register of trials. Perhaps the recently created UK Clinical Research Collaboration will rise to the challenge of pursuing this.

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2 Abbasi K. Compulsory registration of clinical trials. *BMJ* 2004;329:637-8. (18 September.)

### Maybe European research should be protected

EDITOR—The merits of transparency of clinical research from the ethics point of view are not to be disputed. The request of the International Committee of Medical Editors for a publicly accessible registry seems exaggerated in its present form, and we agree with Abbasi's points.<sup>1 2</sup>

A further, more serious, development is the fact that, in practice, a monopoly is created—namely, the unavoidable use of the US based registry [www.clinicaltrials.gov](http://www.clinicaltrials.gov). We emphasise this point because a monopoly already exists with direct and substantial impact on European clinical trials.

The standardised international terminology that is required by the now implemented European Directive 2001/20/EC is clearly the terminology of MedDRA (Medical Dictionary for Regulatory Activities). It can be obtained only from a single source and must be purchased on the basis of an annual subscription.

The maintenance and support service organisation for MedDRA is Northrop Grumman, one of the Pentagon's prime weapon contractors. A mouse click takes the researcher directly to the newest deals in centric warfare as the website for the database is the official Northrop Grumman website ([www.northropgrumman.com](http://www.northropgrumman.com)).

Obviously we have to live with the fact that Europe is supporting a US based monopolist mainly involved in weapons supply. We consider this a most irritating and impossible situation. Shouldn't Europeans consider steps to protect their academic researchers from exposure to

increasing bureaucratic burden and database monopolies?

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1 De Angelis C, Drazen JM, Frizelle FA, Haug C, Hoey J, Horton R, et al. Clinical trial registration: a statement from the International Committee of Medical Journal Editors. *N Engl J Med* 2004;351:1250-1.

2 Abbasi K. Compulsory registration of clinical trials. *BMJ* 2004;329:637-8. (18 September.)

### Under-reporting is not an option

EDITOR—Abbasi discussed the compulsory registration of clinical trials.<sup>1</sup> MedicoLegal Investigations is one of the leading bodies concerned with investigating misconduct and fraud in relation to clinical trials, both in the United Kingdom—where currently most of our cases have been—and overseas. The company is a not for profit company financed primarily by subscriptions from numerous (but not all) pharmaceutical companies that share our objective of safeguarding patients through maintaining and enhancing the quality and reputation of clinical research in the United Kingdom and elsewhere.

In our experience two primary causes underlie misconduct and fraud: laziness and greed. However, this tends to be at a personal level. At the corporate level, a desire to protect the image of a company or product, the wish to preserve or enhance a career, and the desire to maintain or enhance the share price also come into play. These factors may have encouraged companies to under-report the results of clinical research, potentially with a disregard for the impact on patients and clinical practice.

MedicoLegal Investigations has the goal of improving patients' safety; we believe that under-reporting cannot be justified in any circumstances. We therefore welcome the recently published statement of the International Committee of Medical Journal Editors, and the good publication practice guidelines.<sup>2 3</sup> To date, MedicoLegal Investigations has not been called on to investigate biased under-reporting of research, but we believe it is just a matter of time.

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1 Abbasi K. Compulsory registration of clinical trials. *BMJ* 2004;329:637-8. (18 September.)

2 De Angelis C, Drazen JM, Frizelle FA, Haug C, Hoey J, Horton R, et al. Clinical trial registration: a statement from the International Committee of Medical Journal Editors. *N Engl J Med* 2004;351:1250-1.

3 Wager E, Field EA, Grossman L. Good publication practice for pharmaceutical companies. *Curr Med Res Op* 2003;19:149-54.

### Pressures are growing to publish clinical trials

EDITOR—After the threat of a court case in New York, GlaxoSmithKline has announced that it will publish results of all its clinical trials on its website.<sup>1 2</sup> Eli Lilly recently made a similar announcement, including a commitment to publish all findings in peer reviewed journals.<sup>3</sup>

This will be welcome news to people such as Abrams and me, who have been (independently) campaigning for this for some time.<sup>4</sup> Last year, following several years of consultation, a group from within the pharmaceutical industry published guidelines on good publication practice for pharmaceutical companies.<sup>5</sup> One of the main recommendations was for companies to endeavour to publish the results of all clinical trials relating to their marketed products in peer reviewed journals.

We were careful to include the word “endeavour,” since, ultimately, journal editors decide what gets published. However, with the growth of electronic journals we believe it is usually possible to publish trials. We also focused on clinical trials (those involving patients, rather than preclinical, laboratory experiments) and on marketed products, since we believed that these have the greatest impact on patients and prescribers. Of course, we encourage companies to publish all their research but suggest that priority should be given to clinical trials of marketed products.

A few companies have publicly endorsed the guidelines on good publication practice, and we hope that others may follow. The *BMJ* has shown its support by including a link to the website from its instructions to authors. The moves by GlaxoSmithKline and Eli Lilly show that companies notice that the environment is changing, and I urge doctors, patients' groups, and anybody with an interest in ethical drug research and drug safety to encourage other companies to commit to publishing all their trial results.

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Competing interests: EW is one of the authors of the guidelines on good publication practice for pharmaceutical companies and runs courses on publication ethics.

1 GlaxoSmithKline. GlaxoSmithKline settles litigation with New York Attorney General's Office. Press release, 26 August 2004. [www.gsk.com/press-archive/press2004/press\\_08262004.pdf](http://www.gsk.com/press-archive/press2004/press_08262004.pdf) (accessed 31 Aug 2004).

2 Office of Attorney General, New York. Settlement sets new standard for release of drug information. [www.oag.state.ny.us/press/2004/aug/aug26a\\_04.html](http://www.oag.state.ny.us/press/2004/aug/aug26a_04.html) (accessed 31 Aug 2004).

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4 Abrams P. Access to every trial dataset is crucial. *BMJ* 2004;329:462-b. (21 August.)

5 Wager E, Field EA, Grossman L. Good publication practice for pharmaceutical companies. *Curr Med Res Op* 2003;19:149-54.

## Adenotonsillectomy in children with mild symptoms

### Watchful waiting may deny children opportunity for development

EDITOR—van Staaïj et al report a large study examining the effectiveness of adenotonsillectomy in children with mild symptoms of throat infection or adenotonsillar hypertrophy.<sup>1</sup> They conclude that adenotonsillectomy confers no major clinical benefits over watchful waiting.

We are concerned that the conclusion may lead to a false sense of security about the safety of watchful waiting. The paper says that children with suspected obstructive sleep apnoea have been excluded because they scored more than 3.5 on Brouillette's obstructive sleep apnoea score.<sup>2</sup> A more recent publication from Brouillette et al has indicated that, although a score of greater than 3.5 is suggestive of obstructive sleep apnoea, a score of less than this does not distinguish obstructive sleep apnoea from primary snoring.<sup>3</sup>

Children with obstructive sleep apnoea are therefore unlikely to have been excluded from the cohort described in the paper by van Staaïj et al. Several authors have shown improvements in neurocognitive outcome in children with obstructive sleep apnoea after adenotonsillectomy,<sup>4,5</sup> and we are concerned that this important outcome measure was not included in or recognised as a limitation of the study by van Staaïj et al. The result of watchful waiting in children with adenotonsillar hypertrophy and obstructive sleep apnoea may deny these children potential for behavioural and neurocognitive improvement.

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- 1 Van Staaïj BK, Akker EH, Rovers MM, Hordijk GJ, Hoes AW, Schilder AG. Effectiveness of adenotonsillectomy in children with mild symptoms of throat infections or adenotonsillar hypertrophy: open, randomised controlled trial [with commentary by P Little]. *BMJ* 2004;329:651. (18 September.)
- 2 Brouillette R, Hanson D, David R, Klemka L, Szatkowski A, Fernbach S, et al. A diagnostic approach to suspected obstructive sleep apnoea in children. *J Pediatr* 1984;105:10-4.
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### Watchful waiting is appropriate

EDITOR—van Staaïj et al's large, open, multi-centre, randomised controlled trial of the effectiveness of tonsillectomy in children with mild symptoms was carried out in the Netherlands and all the patients randomised were sent and assessed as appropriate according to current medical practice.<sup>1</sup> The paper makes no mention of the fact that such practices vary from country to country.

In the United Kingdom most departments for ear, nose, and throat medicine would use the 1999 guidelines of the Scottish Intercollegiate Guidelines Network (SIGN) ([www.sign.ac.uk](http://www.sign.ac.uk)), which acknowledge that there is a paucity of high quality evidence for surgical intervention. Following the SIGN guidelines, however, would mean that many of the children in the randomised group would have been placed on a "watch and wait" policy. This seems to have been confirmed by the 34% in the watchful waiting group who underwent adenotonsillectomy.

Tonsillectomy itself is of benefit in preventing sore throats due to tonsillitis. Recurrent upper respiratory infection, the commonest cause of a fever in that age group, is not an indication for adenoidectomy, and therefore we are unsure how much information is added by the primary outcome of a fever alone. We agree with van Staaïj et al that watchful waiting in children with mild symptoms of throat infections or adenotonsillar hypertrophy is appropriate.

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- 1 Van Staaïj BK, Akker EH, Rovers MM, Hordijk GJ, Hoes AW, Schilder AG. Effectiveness of adenotonsillectomy in children with mild symptoms of throat infections or adenotonsillar hypertrophy: open, randomised controlled trial [with commentary by P Little]. *BMJ* 2004;329:651-4. (18 September.)

### Authors' reply

EDITOR—Although we excluded children with a Brouillette score of more than 3.5 from our trial, it is likely that some children with obstructive sleep apnoea participated.<sup>1</sup>

Of the 37 children in our trial with a Brouillette score between -1 and 3.5, indicating possible obstructive sleep apnoea, 18 were allocated to adenotonsillectomy and 19 to watchful waiting. At three months' follow up, parents reported obstructive symptoms during sleep in 0.9 v 11.8% of children, respectively. At 12 and 24 months, these percentages were 1.1% v 5.2% and 1.7% v 1.5%, indicating only a short term effect of surgery. In the absence of a long term effect on this outcome, an effect on behavioural and neurocognitive outcomes is unlikely.

Moreover, a watchful waiting strategy includes not only educating parents about the favorable natural course of obstructive symptoms, but also ensuring follow up if symptoms persist or increase; in those cases adenotonsillectomy should be reconsidered.

International practice varies with respect to adenotonsillectomy,<sup>2</sup> and some children selected for surgery in Dutch practice would be managed non-surgically in the United Kingdom. Although most UK departments for ear, nose, and throat medicine use 1999 guidelines of the Scottish Intercollegiate Guidelines Network (SIGN), the large variation in tonsillectomy rates across the health authorities shows that doctors still differ in their criteria for diagnosis of tonsillitis and indications for tonsillectomy and adenoidectomy.

The SIGN guidelines acknowledge that there is a paucity of high quality evidence for surgical intervention. Our trial adds to this evidence and shows that in children with mild symptoms of throat infections or adenotonsillar hypertrophy adenotonsillectomy offers no major clinical benefits over watchful waiting.

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- 1 Akker van den EH, Hoes AW, Burton MJ, Schilder AGM. Large international differences in (adeno)tonsillectomy rates. *Clin Otorhinolaryngol* 2004;29:161-4.
- 2 Capper R, Canter RJ. Is there agreement among general practitioners, paediatricians and otolaryngologists about the management of children with recurrent tonsillitis? *Clin Otolaryngol* 2001;26(5):371-8.

## Biopsy of potentially operable hepatic colorectal metastases is not useless but dangerous

EDITOR—We have followed with interest the debate about tumour seeding in the aftermath of fine needle aspiration cytology (FNAC) in patients with potentially resectable hepatic colorectal liver metastases.<sup>1</sup> The verdict of Metcalfe et al of "useless

and dangerous” seems to have provoked strong emotions among some of your readers, and we should like to contribute two observations.

Our staging protocol comprises liver specific magnetic resonance imaging, chest tomography, and the selective use of positron emission tomography, laparoscopy, or a “trial of time,” but excluding biopsy. Since 1986 we have undertaken more than 1000 liver resections for metastatic cancer without resort to preoperative biopsy or FNAC, with only seven false positives. In two patients, hepatic cysts were diagnosed at operation and resection was deferred, whereas liver resection was undertaken without complication in the other five (three haemangiomas and two cysts).

A recent analysis of 598 consecutive patients undergoing radical resection of colorectal liver metastases examined specifically the 90 patients in whom diagnostic biopsy had been performed before referral.<sup>2</sup> Histologically confirmed tumour seeding at the site of biopsy was confirmed in 17 patients (19%). This concurs with the findings of another two recent studies.<sup>3,4</sup> In every patient in our series, these deposits on the chest and abdominal wall were excised at the time of liver resection. Nevertheless, our analysis showed that survival after liver resection was substantially diminished compared with well matched patients in whom no biopsy or FNAC had been attempted.<sup>5</sup>

In our experience, the non-invasive evaluation of potentially resectable colorectal liver metastases is at least 99% specific. Furthermore, the violation of tissue planes by biopsy or FNAC compromises patients’ survival. We believe therefore that Metcalfe et al’s choice of title is apt. Consultation with a specialist hepatobiliary surgical team is recommended before a “tissue diagnosis” is attempted in such patients.

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- 1 Metcalfe MS, Bridgewater FHG, Mullin EF, Maddern GJ. Useless and dangerous—fine needle aspiration of hepatic colorectal metastases. *BMJ* 2004;328:507-8.
- 2 Jones OM, Rees M, John TG, Bygrave S, Plant G. Resectable colorectal liver metastases: to biopsy or not to biopsy? *Colorectal Dis* 2004;6:1-34.
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## Transradial angiography may deleteriously affect patency of radial artery grafts

EDITOR—The review by Archbold et al comprehensively outlines the many advantages of radial access.<sup>1</sup> However, it does not touch on the potential harmful effects that such an approach may have on the patency of radial artery grafts when patients later have coronary artery bypass grafts.

Current interest in the use of radial arteries as the second conduit of choice after the internal mammary artery is rising. The negative effect of radial access on the patency rates of radial arteries used in coronary artery bypass grafting may be especially important in younger patients where greater longevity of the graft (above that of saphenous vein grafts) can be expected to bring long term benefit. Kamiya et al showed, in 22 patients who underwent transradial angiography before coronary artery bypass grafting, that angiographic patency of radial artery grafts was lower at one month after the procedure (77% v 90%,  $P = 0.017$ ).<sup>2</sup>

Furthermore, an ultrasonographic study by Nagai et al showed that, after transradial access for coronary angiography or angioplasty, 22% of radial arteries were diffusely stenosed, and 5% had no detectable flow at late (mean 95 days) follow up.<sup>3</sup> We have observed that most surgeons are hesitant to use the radial artery as a graft within a few days of transradial access due to presumed intimal damage.

We think that consideration should be given to the appropriateness of the transradial approach in acute patients in whom the likelihood of urgent coronary artery bypass grafting is high, in younger patients, and in patients in whom there may be a shortage of conduits.

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- 2 Kamiya H, Ushijima T, Kanamori T, Ikeda C, Nakagaki C, Ueyama K, et al. Use of the radial artery graft after transradial catheterization: is it suitable as a bypass conduit? *Ann Thorac Surg* 2003;76:1505-9.
- 3 Nagai S, Abe S, Sato T, Hozawa K, Yuki K, Hanashima K, et al. Ultrasonic assessment of vascular complications in coronary angiography and angioplasty after transradial approach. *Am J Cardiol* 1999;83:180-6.

## Email consultations in health care

### Set your auto reply to “no”

EDITOR—Car and Sheikh’s final conclusion, that making email communication more readily accepted as a part of routine medical practice should be a key objective of the UK NHS information technology strategy, may have unforeseen consequences for the NHS.<sup>1,2</sup> They point out that demand has been

mainly patient led, and their data, mostly from the United States, indicate that the demand is from wealthier, younger patients.

The United States has a different health system from the United Kingdom. What Americans want may not be what UK patients want. The two health systems also have different health policy goals. The policy goal of the NHS is generally accepted as equal access, based on need. Poor and elderly people are the most needy and the least likely to use the internet.<sup>1,3</sup> In each system, policy objectives often need to be traded off against each other.<sup>4</sup> Using email for communication may offer choice but probably at the expense of access.

Technological solutions are often hailed as the answer to old problems, but often the intended benefits are not as immediate or cheaper.<sup>5</sup> Full research into the impact of a new technology is needed before any steps are taken to adopt it as the norm. We expect this of any new medication or device, so why not a new mode of consultation? Maybe this might be added to the remit of the National Institute for Clinical Excellence? If not, where do we stop? At text messaging consultations, or maybe mobile phone video consultations?

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Competing interests: None declared.

- 1 Car J, Sheikh A. Email consultations in health care: 1—scope and effectiveness. *BMJ* 2004;329:435-8. (21 August.)
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### Patients need to be given a choice

EDITOR—I agree with Wong (previous letter) in response to Car and Sheikh that the healthcare systems in the United States and the United Kingdom are very different.<sup>1</sup> However, the needs of the patients are pretty much the same. The technology is available today, and it is inexpensive. The only way to measure its effectiveness is to pilot it.

The government’s E-Gif initiative has been forgotten in the current national programme for information technology (NPFIT) initiative. All government departments, including the NHS, are required to offer their services both electronically and using traditional methods. “Give the patient a choice.” Currently patients do not have a choice.

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Competing interests: JC is partner of ZixCorp Corporation, which has implemented secure encrypted email in over 80% of the healthcare industry in the United States.

- 1 Car J, Sheikh A. Email consultations in health care: 2—acceptability and safe application. *BMJ* 2004;329:439-42. (21 August.)