"Results of eVALuate study of hysterectomy techniques: high rate of complications needs explanation."

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CITE THIS VERSION

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Random drug testing in schools fails screening criteria

Editor—Last month the prime minister, Tony Blair, lent his weight to random drug testing in schools in an interview for a downtown newspaper.1 He proposed a national programme be implemented soon, adhering to unspecified central directives. The Department of Health has 19 criteria for introducing new screening programmes.2 At least 18 of these 19 criteria are not met for widespread, wide spectrum drug urine analysis in schools. The remaining criterion is that the condition is an important health problem.

Drug use in young people is indeed associated with many health risks,3 but a single, positive urine test, for any illicit drug, is probably not meaningful in a clinical sense. Each schoolchild’s context of use (family history, social and emotional development) is crucial to interpreting any supposed “drug career.” Use by a homeless pregnant teenage runaway from local authority care with a history of deliberate self harm and high risk sex work to pay for her drugs may be very different from a single experimental use at home with adults during a family party.

Three failed criteria are especially pertinent to screening for school age drug use: (1) There should be an agreed policy on the further diagnostic investigation of people with a positive test result and on the choices available to them. (2) There should be an effective treatment or intervention for patients identified through early detection. (3) Clinical management of the condition and patient outcomes should be optimised by all healthcare providers before participation in a screening programme.

In three years of experience of school health provision for alcohol and drug problems and their related referral networks I do not know of one school that could satisfy these criteria, especially the underpinning policy of promoting informed choice for children and families.2

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Competing interests: None declared.

Follow up of hypertension by family practitioners

Editor—Properly conducted trials must inform those who produce guidelines on managing clinical conditions. Birtwhistle et al have contributed to this knowledge base for hypertension in family practice, but I am concerned about the generalisability of their trial.3

In choosing patients with “controlled” blood pressure they have selected from a pool of 13% (their figures) of hypertensive Canadians. Another problem is that hypertension is only one of several risk factors for cardiovascular disease. Frequency of visits is likely to be delineated by the presence of other cardiovascular risk factors and comorbidity and the need for their management. Frequency of review advice should therefore be based on absolute cardiovascular risk rather than the level of a single risk factor.

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Competing interests: None declared.

Select sample and absolute risk of cardiovascular disease

Editor—In a randomised equivalence trial over three years Birtwhistle et al tried to minimise care for essential hypertension if possible.1 Was it satisfactory to monitor blood pressures every six months rather than every three months?

The incomprehensible outcomes were three. The first was where blood pressure was measured, in doctors’ premises or patients’ homes by nurses. The second considered patients’ satisfaction. There is no criterion by which ordinary patients are in any position to know if they ought to be satisfied. The third was adherence to treatment, which is crucially fundamental to any outcome. Twenty per cent of the time patients may not take their pills (and presumably do not need them) but are considered properly treated.

If essential hypertension causes stroke or coronary thrombosis then care is all there is on offer. Death in this group of 600 might be quite rare over three years. We are told that 67 dropped out over three years but not how many died. Of each group, 296 are not enough to base the whole care of the middle aged on, and neither are three years. This “work” and its outcome are contrary to the axiomatic and the real test is whether any doctor would leave himself or herself unmonitored for six months.

Blood pressure is negligently controlled by minimum, rather than maximum, assessments of the observation. Patients need their own lifelong oversight on blood pressure readings. They may well look after it better than any doctor. The technique should be taught at school.

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Technique should be taught at school

Editor—The subjects of the study had hypertension in control at entry. We don’t think this affects the generalisability of the study in relation to patients with known hypertension who attend their doctor, since hypertension in about 20% of these patients was out of control at some time during the study. The study is not generalisable to all people with hypertension.

We agree with Nelson that a patient’s cardiovascular risk should be viewed in total. Sometimes patients need to be seen more often because of other risk factors such as


diabetes. The reality is that doctors see patients for “a blood pressure check,” and we showed that doing this every six months is equivalent to every three months. What else is discussed at the visit is being presented in another paper.

Barnes notes that our outcomes are not the ones he would have chosen. We agree that outcomes such as stroke and death are the ultimate measures of success, but for this type of study large numbers of patients would need to be followed up over many years. The outcomes we used provide some approximation to these definitive outcomes. Given our results, we think that visiting the doctor every six months is satisfactory for the types of patients we studied.

Blood pressure measurement is a different matter, and having patients take control and measure their own blood pressure between visits may be desirable.

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Results of eVAluate study of hysterectomy techniques

**Conversion to open surgery should not be regarded as major complication**

Editor—Although Garry et al looked closely at outcomes for different surgical techniques in hysterectomy, I am concerned about the criteria they use to classify major complications.1

It is routine practice, at least in laparoscopic cholecystectomy, to seek patients’ consent for conversion to an open procedure. This is recognised as prudent if persisting with the laparoscopic approach would add risk. To classify a strategy that encourages caution as a major complication therefore runs the risk of dissuading surgeons from converting appropriately and in a timely manner. In addition, it may open the way for complaints and litigation should a laparotomy be required.

It is widely accepted in laparoscopic gastrointestinal surgery that, although conversion rates should be kept as low as possible and audited appropriately, conversion to an open procedure in itself is not a major complication. The particular problem encountered may arise from the disease process or from an iatrogenic injury. The cause of conversion, not the conversion itself, may be the major complication.

I note that none of the authors are gastrointestinal surgeons, and I believe that they were badly advised during their trial discussions.

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Competing interests: None declared.


Laparoscopic hysterectomy may yet have a bright future

Editor—Garry et al showed that laparoscopic hysterectomy was associated with a higher rate of major complications than was abdominal hysterectomy.1 Can two techniques be compared, however, when one has been used for 100 years and the other for only a few months?

We found that in a group of surgeons performing laparoscopic surgery for more than 10 years the learning curve for laparoscopic hysterectomy is much greater than 25 cases, particularly when studying infrequent major complications.

Comparing patients operated on between 1989 and 1995 with those operated on between 1996 and 1999, we found that the incidence of conversion to laparotomy decreased from 4.7% (53 cases out of 695) to 1.4% (13 cases out of 952), the incidence of major complications from 5.6% to 1.3%, and the operating time from 115 minutes to 90 minutes. The percentage of laparoscopic hysterectomy among non-vaginal hysterectomies, however, increased from 68% to 94.4%.
Consequently we think that
- It was too early to design such a trial
- The main conclusion of the study cannot be accepted
- The increased complication rate would be valid if the study was repeated today by teams who have been using laparoscopic hysterectomy for more than five years.

As this trial confirmed all the advantages of laparoscopy over laparotomy, and the complication rate decreases significantly when the learning curve has been completed, we conclude that this study is actually the first to show the bright future of laparoscopic hysterectomy.

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Competing interests: None declared.

1 Garry R, Fourni et al conducted two parallel randomised studies to evaluate the effects of laparoscopic hysterectomy compared with abdominal and vaginal hysterectomy. The major bias of their method led them to the wrong conclusion.

Secondly, the experience of the 43 gynaecologists most certainly differed from centre to centre. The rate of complications is not analysed according to the gynaecologists' experience.

Thirdly, the learning curve greatly exceeds 25 cases. In our series of 1600 laparoscopic hysterectomies, the rate of major complications was 0.6% after laparoscopic subtotal hysterectomy and 2% after laparoscopic hysterectomy. All but two of the complications occurred from 1990 to 1995 (laparoscopic subtotal hysterectomy, n = 295; laparoscopic hysterectomy, 135).5 Later the rate of major complications was exactly the same as that observed after abdominal hysterectomy.

Four different laparoscopic surgical approaches (laparoscopic hysterectomy, laparoscopic vaginal hysterectomy, laparoscopic subtotal hysterectomy, total laparoscopic hysterectomy) were used. This constitutes a serious bias. Differences in the rate of complications, depending on technique, have been described, especially during the learning curve (table). This should be pointed out in the paper.

The conclusion reached by Garry et al is not admissible because of considerable bias. The high complication rates are probably due more to the inexperienced surgeons in laparoscopic hysterectomy than to the technique of laparoscopic hysterectomy itself.

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1 Garry R, Fourni et al conducted two parallel randomised trials, one comparing laparoscopic with abdominal hysterectomy, the other comparing laparoscopic with vaginal hysterectomy. BMJ 2004;328:129-36. (17 January)

High rate of complications needs explanation

Editor—Garry et al conducted two parallel randomised studies to evaluate the effects of laparoscopic hysterectomy compared with abdominal and vaginal hysterectomy.1 The major bias of their method led them to the wrong conclusion.

Firstly, 43 gynaecologists from 30 centres took part. The mean number of laparoscopic hysterectomies (n = 584) per gynaecologist was 13 over four years.

Secondly, the experience of the 43 gynaecologists most certainly differed from centre to centre. The rate of complications is not analysed according to the gynaecologists' experience.

Thirdly, the learning curve greatly exceeds 25 cases.2 In our series of 1600 laparoscopic hysterectomies, the rate of major complications was 0.6% after laparoscopic subtotal hysterectomy and 2% after laparoscopic hysterectomy. All but two of the complications occurred from 1990 to 1995 (laparoscopic subtotal hysterectomy, n = 295; laparoscopic hysterectomy, 135).3 Later the rate of major complications was exactly the same as that observed after abdominal hysterectomy.

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Authors’ reply

Editor—Given the pre-eminent role of gynaecologists in developing both operative laparoscopy and randomised trials, we were astonished that we might need a gastro-intestinal surgeon in our team. Many of our team were, however, intuitively sympathetic with Atkinson’s concern that preoperative conversion should not be considered a major complication. To exclude patients who did not receive the planned treatment would alter the complication rates and represent a post-randomisation selection bias in favour of laparoscopic hysterectomy. We therefore classified such cases as failures of the approach and thus major complications. Like Atkinson, we consider conversion to laparotomy sometimes to be prudent and the best option.

Saunders has overlooked one of the virtues of randomisation. We could not insist on a single standard anaesthetic and analgesic regimen. We could, however, ensure that in each centre the same regimen was used for both arms of each trial. As the randomisation process was rigorous, the effect of confounding variables such as the anaesthetic used should be equally distributed in each group and any effect on results essentially eliminated. We are confident in the integrity of the data showing that laparoscopic hysterectomy is associated with less pain than abdominal hysterectomy.

Canis et al and Donnez et al think that we undertook the study too early in our collective experience. However, the learning curve of Canis et al was 600 cases, and Donnez et al evaluated their results only after 1000 cases. Their definitive results represent the best in the world and are the gold standard to strive for. Our primary aim was not to collect the results of such “super surgeons” but to determine the role of laparoscopic hysterectomy in routine practice.

We asked, “Are the advantages of laparoscopic surgery so great that all gynaecologists should be encouraged to undertake this approach?” The answer seems to be no, or at least not yet. The benefits of laparoscopic hysterectomy over the abdominal approach are real but are of practical value only if they can be achieved with an acceptable complication rate. Canis et al and Donnez et al show that this can be achieved, but to meet the best results may require the development of many centres of laparoscopic excellence similar to theirs.

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Competing interests: None declared.

ABC of eyes: Injury to the eye

Eye padding is not recommended for corneal abrasions

Editor—The evidence based literature does not concur with the recommendation by Khaw et al in the ABC of eyes that corneal abrasions be padded.4 The topical use of non-steroidal anti-inflammatory drugs is preferred.

Eye is incredibly painful, the pain often recurring at night after the patient has left the doctor’s surgery. Is there evidence that the use of two 0.5 ml vials of local anaesthetic eye drops self administered at home, if necessary, is toxic to the cornea?

Little evidence recommends routine use of topical antibiotics for corneal abrasions,
Letters

especially after removal of a foreign body. Would it not be better to prescribe hydroxypropyl methylcellulose/dextran-70 solution or topical non-steroidal anti-inflammatory drugs, using topical antibiotics only as needed, until the necessary trials answering this common problem are done?

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Competing interests: None declared.


ABC should incorporate evidence based medicine

Editor—In their ABC of eyes Khaw et al recommend three treatments for corneal abrasion, none of which seem to be supported by the literature. A meta-analysis of studies of eye patching for corneal abrasion found that it did not improve healing rate or reduce pain.1 The authors recommended against patching because of loss of binocular vision and possible increase in pain.

A meta-analysis of studies examining cycloplegics for corneal abrasion found only one study that met their criteria. Although this study was not masked and had other flaws, it did not show any benefit for cycloplegics. The authors concluded that cycloplegics cannot be recommended for use in patients with corneal abrasion.2 A similar paucity of evidence prevails regarding the use of topical antibiotics.

Although these three treatment modalities are classically taught, the article (and the upcoming book it is adapted from) should indicate the lack of supporting evidence for them.

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Competing interests: None declared.


Orbital injuries should not be considered in isolation

Editor—In their ABC of eyes Khaw et al discussed the management of orbital hard tissue injuries.1 Orbital fractures occur in isolation but are more commonly components of zygomatic complex or midface fractures.2

In our experience, a patient presenting with a subconjunctival haemorrhage, sclero-

Although we agree with the several studies which report that pads do not give benefit in smaller abrasions, this is not the clinical impression for large abrasions. Kaiser et al randomised 223 patients to either no patch or a patch.3 All received anti-biotics and mydriatics. In the large abrasions (>10mm2), the unpatched group took 4.2 (SD 0.45) days to heal compared with 3.45 (SD 0.82) days for the patched group (P<0.08). Therefore, for large corneal abrasions, patching is still appropriate.

Regarding cycloplegics, Carley and Carley found only one pertinent study, which they described as “flawed because of poor follow up and a number of confounding factors.” Some patients have marked relief of abrasion pain with the use of cycloplegics. Regarding topical antibiotics, secondary corneal infection is a rare but devastating consequence of a corneal abrasion. Therefore the use of antibiotics for abrasions is a very reasonable course of action. Non-steroidal anti-inflammatory drugs can reduce pain, but there have been some anecdotal reports of significant corneal problems.4 Although topical anaesthetics do give profound relief of pain, we do not recommend that patients receive these agents to self medicate as the risks of an anaesthetic cornea are great, including corneal perforation.

We agree that orbital fractures are best managed in conjunction with a department for maxillofacial surgery. Most patients with orbital and significant zygomatic fractures are referred to maxillofacial departments. It is important that they are also assessed in ophthalmic departments to exclude eye injury.

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Joy of rapid responses

Don’t take points raised in open and free discussion personally

Editor—Fazel describes her negative feelings about the rapid responses to her paper.1

No matter its limitations, the rapid response section of bmj.com is one of the most important and live mediums for open and free discussion among authors and readers. Authors, like everyone else, do not wish to be criticised for their work or conclusions, and their first response is to defend themselves. Often the concern raised by the reader is not answered in their replies. No one wants to be criticised, but we all make mistakes. A reasonable and unbiased critique—positive or negative—is important in enhancing scientific knowledge and developments and improving general well-being. Authors should not take such critiques personally and respond defensively.

Authors' replies in the paper journal are also often defensive and do not address the concern raised. Like rapid responses, they seem not to be reviewed by the editorial team to check whether the question raised by the reader has been answered.

In journals that do not have such an open system of responding, most letters to the editor are not accepted because of lack of space. Such journals fail an important element of enhancing scientific knowledge: appropriate discussion among readers and authors.

Most studies or randomised controlled trials are supported by the pharmaceutical industry with its own agenda. Articles are often written by medical authors hired by the industry and are stamped by someone well known, who is often the chief investigator but has no time to fully review the minor details of the publication. The review process may be just a short screen of the paper by the journal’s editors and a couple of reviewers. This does not guarantee that all mistakes in and deficiencies of the paper have been dealt with. In such instances, an open discussion and the opinions of readers in the same or different disciplines are important, even if the points made come from experience and are not evidence based or seem like neat hypotheses. Absence of evidence does not mean that the statement or explanation is incorrect.

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Competing interests: None declared.

1 Fazel M. Why I’m a reluctant rapid responder. BMJ 2004;328:413. (14 February.)

Letters

Readers read articles more closely when they can respond

Editor—Fazel is a reluctant rapid responder. I often read through whole articles on bmj.com because there is the opportunity to send a rapid response. If the rapid response facility were not there, I would read the abstract or conclusion and skip the rest.

To write a rapid response you have to read the whole article several times, digest it, and then draft the response. It is intrusive that rapid responses are like spinal cord reflexes. Because the response is rapid it may be emotional and not entirely scientific. It is, as described by Delamothe and Smith, a conversation.1 People may be offended, but surely not so much as to kill the rapid response facility altogether.

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Competing interests: None declared.


Rapid responses are useful…

Editor—Call them rapid responses, call them rapid responses, I’ve found them rapid responses useful.1 Mainly as part of a greater thing (the internet), but also as convenient storage for my data in areas of particular interest, and there’s definitely more humour than in the serious sections of the journal.

Emails to me requesting further information testify to the usefulness of my rapid responses, and justify the BMJ not paying me for them.

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Competing interests: None declared.

1 Fazel M. Why I’m a reluctant rapid responder. BMJ 2004;328:413. (14 February.)

…but perhaps not entirely effective

Editor—No matter whether rapid responders are overeducated professionals,1 it still takes hundreds of them to change a light bulb, including many to complain about how it’s done.

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Competing interests: None declared.

1 Fazel M. Why I’m a reluctant rapid responder. BMJ 2004;328:413. (14 February.)

Summary of responses

Editor—Fazel’s emotional appeal for less rudeness and greater respect from rapid responders on bmj.com sparked off numerous lively responses.2 They roughly divide into those who agree with him that the tone is unacceptable (even if the argument is sound), those who agree but think that readers can decide themselves what they want to read and believe, those who think she might be overreacting, and those who go off at a tangent completely, thus showing the utility of responses in stimulating debate in unforeseen ways. Some responses are funny, and most are gently sympathetic. The whole debate gives a good insight into what readers see as the function of rapid responses.

The offended faction includes Norwegian scientist Ulf Dahl, whose career experiences echo Fazel’s. “It is funny how some scientists lack the critical thinking that is necessary in their profession, when it comes to social behaviour,” he muses. Miles Witham from Dundee takes an equally dim view: “How do we expect people to stay in medicine when the atmosphere is often so poisonous?”

Alex Thain from Inverness wonders whether the lack of constructive feedback identifies a skill need but points out that open debate in an adult and mutually respectful way does not preclude humour. Italian correspondent Giovanni Prisone thinks that maybe respondents should not be so quite impulsive, to avoid offending.

No editorial censorship is necessary in the opinion of Ghalforan Syed, Akheel Syed, Wendy McLean, and Adam Jacobs, who all argue that readers are perfectly capable of making up their own minds and do not give equal weight to all they read.

Jay Illangaratne finds the criticism levelled at the article entirely justified and even suggests posting papers anonymously before publication to invite “open peer review.” Lalith Chandrakantha from Northampton, however, wonders whether the BMJ should ape the “general media” in giving equal importance to all opinions or whether it should be selective. In any case, most respondents make a strong plea for leaving the current policy for posting rapid responses unchanged.

Among those who are prepared to see the funny side are John Corish from St John’s in Newfoundland and Labrador, who asks Fazel to stop taking herself so seriously and suggests that rapid responses may help to make “eminently forgettable” articles linger in the memory for a few hours longer. Others point out that to publish inherently offensive, but perhaps not entirely effective, articles on bmj.com sparks off numerous lively responses. They roughly divide into those who agree with him that the tone is unacceptable (even if the argument is sound), those who agree but think that readers can decide themselves what they want to read and believe, those who think she might be overreacting, and those who go off at a tangent completely, thus showing the utility of rapid responses altogether.

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