How much of orthodox medicine is evidence based?

Scientific heavyweights deplore the NHS money wasted on unproved and disproved treatments used by practitioners of complementary and alternative medicine (CAM), but Lewith, a CAM proponent (see previous letter), is cited elsewhere as saying that the BMJ reckons that 50% of the treatments used in general practice aren’t proved, and 5% are pretty harmful but still being used.¹

His data were taken from the BMJ Clinical Evidence website (http://clinical evidence.com/ceweb/about/knowledge.jsp, viewed 6 May 2007). A pie chart indicates that, of about 2500 treatments supported by good evidence, only 15% of treatments were rated as beneficial, 22% as likely to be beneficial, 7% part beneficial and part harmful, 5% unlikely to be beneficial, 4% likely to be ineffective or harmful, and in the remaining 47% the effect of the treatment was “unknown.” The text says, “The figures suggest that the research community has a large task ahead and that most decisions about treatments still rest on the individual judgements of clinicians and patients.” On 9 October 2007 the situation had changed—but not for the better. Treatments rated “beneficial” had decreased from 15% to 13%. The associated text is unchanged.

Acute low back pain is a common and well investigated condition. BMJ Best Treatments reports that back pain affects 70-85% of all adults, and each year almost half of us get back pain that lasts at least a day (http://besttreatments.bmj.com/btuk/conditions/1559.html). There are 18 treatments for acute low back pain which have been tested by randomised controlled trials (RCTs), of which two (11%) were graded “beneficial” and 13 (72%) “unknown.” The accompanying table shows all of the 18 treatments for acute low back pain and their rated effect. According to this table, a condition that is extremely common, and for which many treatments have been intensively researched, has an even higher than average proportion of treatments that are labelled “unknown” efficacy, or in other places “need further study.” There must be some mistake.

The solution to the mystery is that the label “unknown” does not mean, “We have no knowledge of the effect of this treatment because it has not been tested in an RCT.” Astonishingly, it means, “We have tested this treatment in several RCTs, but on balance there is currently no convincing evidence that it is effective for this condition.” So really the efficacy of these 13 treatments for acute back pain is not “unknown” but “not demonstrated.”

Lewith’s interpretation of the pie chart is highly misleading. The research community has been commendably diligent, but of course RCTs often fail to find that certain treatments are effective. Euphemisms such as “unknown” or “needs more study” for the inefficacy of such treatments may soothe the feelings of proponents of those treatments that have so far failed to show efficacy, but it does an injustice to the researchers who obtained these data, and misleads both practitioners and patients about the extent to which orthodox medicine is evidence based. It is particularly ironic that CAM therapies are over-represented in the “not shown to be effective” category, so if anyone should be concerned about lack of evidence it should be CAM practitioners rather than conventional medics.

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Competing interests: None declared.

1. Kemerow D. Wham, bang, thank you CAM. BMJ 2007;335:647. (29 September.)

PROPORTION OF COMMONLY USED TREATMENTS SUPPORTED BY GOOD EVIDENCE

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AMINOGLYCOSIDE OTOTOXICITY

Vestibular function is also vulnerable

We are concerned to correct a common misconception—namely, that ototoxicity is synonymous with deafness. Except for the rare cases of mitochondrial mutations discussed by Bitner-Glindzicz and Rahman, vestibular function is much more sensitive to aminoglycosides than hearing function.¹ Ninety per cent of patients with gentamicin associated vestibular loss will not be deaf.²

Most cases of aminoglycoside vestibulotoxicity with preserved hearing will not be diagnosed.³ The typical patient with aminoglycoside vestibular failure will have been in critical care often with renal failure. If not sedated, 20% experience spontaneous episodic vertigo² for a few days, with episodes lasting minutes to hours; an unexplained phenomenon as simultaneous, bilateral vestibular loss should not cause vertigo (since vertigo implies a right-left vestibular imbalance). The vertiginous episodes wane after a few days as the vestibular function is ablated. In all patients with aminoglycoside vestibulotoxicity, however, attempts to rehabilitate and mobilise are severely compromised due to gait imbalance and disabling oscillopsia on head movement. Occasionally, vestibular sedatives (for example, stemetil) are administered, which further compromises balance. Some patients are labelled as having had a cerebellar stroke.

The diagnosis of vestibulotoxicity must be considered in patients with a history of aminoglycoside administration who develop head movement induced oscillopsia and gait imbalance. The diagnosis is easily made clinically via the head impulse test⁴ and confirmed by caloric testing. Aminoglycoside vestibular failure, which is permanent, can have devastating consequences for a patient’s mobility and functional independence. Functional recovery, which is never complete, is slow (over years). Graded physical activity is important in aiding the recovery of gait and balance function.

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Competing interests: None declared.

1 Bitner-Glindzicz M, Rahman S. Ototoxicity caused by aminoglycosides. BMJ 2007;335:784-5. (20 October.)

How practical is this genetic screening test?

Bitner-Glindzicz and Rahman highlight an important side effect associated with aminoglycoside administration and a possible screening method to reduce this potential risk.⁵ They do not, however, point out the lack of clinical practicality of the genetic test.

In a recent case of acute mastoiditis complicated by a lateral sinus thrombosis it was decided to start administering intravenous gentamicin after mastoidectomy. It was suggested that this genetic screening test be performed before administration. On contacting the genetics department, we were informed that the test could not be performed at our own hospital and would be referred elsewhere for analysis. We were also informed that a result would take two to three days. Gentamicin was therefore started before obtaining the result of the genetic test on the basis of the clinical severity of the case.

Although this form of screening could reduce the rates of ototoxicity secondary to aminoglycoside administration, its widespread use is limited by its practicality. Aminoglycoside treatment is started most commonly in the acute setting, where withholding treatment for two or three days for the results of a genetic screening test would not be in the best interests of the patient.

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Competing interests: None declared.

1 Bitner-Glindzicz M, Rahman S. Ototoxicity caused by aminoglycosides. BMJ 2007;335:784-5. (20 October.)

Evidence should not be the only consideration: patients’ and clinicians’ views matter too

Health systems need to use resources to their maximum effect. This naturally leads them towards evidence based medicine—interventions that have been shown in well conducted (randomised) studies to be most effective should usually be prioritised over those where high quality evidence is lacking.

Problems arise where systems have to juggle alternative choices where the evidence is lacking or weak, or the benefits/harms trade off is marginal. The figures quoted by Garrow (previous letter) from BMJ Clinical Evidence are correct, but they provide an overly pessimistic picture of the state of evidence for orthodox medicine, since interventions in complementary and alternative medicine (CAM) and other non-orthodox treatments are included and are over-represented in the “unknown” category. Contrary to Garrow’s implications however, where multiple well conducted studies have shown no effect BMJ Clinical Evidence would categorise these interventions as “unlikely to be beneficial” rather than “unknown effectiveness”. None the less, the general point is correct that many orthodox and complementary interventions are in common use despite uncertainty about their effectiveness.

I cannot completely agree with Colquhoun in his denunciation of homeopathy.¹ A principle of evidence based practice is that the evidence should be only one influence on clinical decision making, alongside the expertise and perspectives of both patients and clinicians. However uncomfortable for health system planners, an evidence based service should reflect expressed patient preference.

One solution would be for CAM practitioners to involve the “stuck” patients in N of 1 trials. As the highest level of evidence this might be a desirable, appropriate, and ultimately informative approach in selected situations.

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Competing interests: DIT is editorial director for the BMJ Knowledge department, which produces evidence based products for clinicians and the public.

1 Colquhoun D. What to do about CAM? BMJ 2007;335:736. (13 October.)
Viability is probably irrelevant

Arguments to lower the gestational age limit at which abortion may be performed are based almost entirely on the idea of fetal viability—the gestational age at which, if the fetus were born prematurely, it would have a reasonable chance of survival. The viability argument can be a convenient one for both sides of the debate, but it does not hold up to rational analysis. Suppose that, by some medical breakthrough, we were able to support spontaneously miscarried pregnancies, even at very early gestational ages—perhaps by suspending them in some life-sustaining fluid, in which they could fully develop as they would in the uterus. Would this be compelling evidence that we should abolish abortion altogether? Conversely, suppose some new virus epidemic sweeps through the nation, becoming endemic in all hospitals and special care baby units in which premature babies are cared for. The virus infects and kills all babies born before 32 weeks, as their lungs are not mature enough to recover from the insult caused. Would this be a compelling argument to increase the gestational age limit on abortion?

Both sides of the debate need to realise that viability is probably irrelevant.

Richard J Lyus

Colorectal Cancer

Missing elements of modern management

Ballinger and Anggiansah’s review of the management of colorectal cancer made little or no mention of important aspects of current treatment. They did not mention the role of laparoscopic large bowel resection for colorectal cancers, which has become increasingly widely used in the United Kingdom and abroad and is now recommended as an alternative to open surgery by the National Institute for Health and Clinical Excellence (NICE). A recent study has shown that laparoscopic surgery allows rapid mobilisation of the patient, an earlier return of bowel function, lower complication rates and a much earlier discharge from hospital (4 days v 11 days). Secondly, liver resection, for unilobar or bilobar colorectal tumour metastases, has revolutionised treatment of the condition yet only merits one sentence. Up to 50% of patients with colorectal cancers develop liver metastases after diagnosis. Chemotherapy has been shown to extend median survival. However, without liver resection, five year survivors are extremely rare. Some units are achieving a five year survival of 46% with low mortality (2.1%) and morbidity. The use of neoadjuvant chemotherapy before liver resection, avoidance of perioperative blood transfusion, and meticulous surgical technique may all have contributed to this success story.

W J Fawcett

Competing interests: None declared.

GP Contract

It’s payback time

Heath seems to have lined up beside the journalists, politicians, and health economists who, after none too subtle signalling from the government, have queued up to give general practitioners in general (and the new contract in particular) a good kicking. The Quality and Outcomes Framework (QOF) has meant that, for the first time, large areas of evidence based care have been provided across communities by practices at funding levels well below those charged in the payment-by-results tariff of other NHS organisations. General practitioners accepted this challenge on the basis that if they failed to deliver they would not get the funding—a challenge never before accepted by any other type of NHS organisation.

Continuity of care is closely related to whether practices have personal lists, how they deal with same day and future appointment requests, and whether the doctors are full time or part time. Whether the contract is with the practice or the individual doctor makes little difference.

There are now more employment options and opportunities for flexible working. Staff numbers and pay are increasing, according to accountants’ organisations and the Department of Health.

Criticism of the new out of hours arrangements is mostly directed at general practitioners, although these services are the responsibility of trust managers, who have deliberately chosen not to employ more doctors in out of hours work and avoided all criticism by the media and government. It is difficult not to conclude that politicians are manipulating media comment to force general practitioners...
HEALTH IN AN UNEQUAL WORLD

What about the needs of health workers in developing countries?

In their randomised trial showing reduced in-hospital mortality after improved management of children under 5 years with malaria, Bai et al concede that “we cannot distinguish between the effect of supervising the implementation of the guidelines and the effect of the financial incentive in reducing mortality.” But this crucial point was lost in the abstract—and in others’ interpretations:

- The box summarising what the study adds—“In poor countries, small financial incentives can contribute to a dramatic decrease in in-hospital mortality”—was omitted.
- The latest headlines on bmj.com on 2 November 2007—“Financial incentives may hold key to cutting child malaria deaths”
- Editor’s choice—“Mortality from malaria on the children’s ward, once people’s poverty was tackled head on, was just 5% in the intervention group and 10% for controls”
- The accompanying editorial—“The extra pay was enough to enable staff to work efficiently.”

There was no mention of how the unequal hospital environment created by the study may itself have contributed to the results. It would have been useful to hear from the nurses and doctors themselves. How did it feel to be in the control group, to receive no extra money, and to have to continue moonlighting to pay for food and rent, while colleagues (working in a similar children’s ward in the same building) enjoyed a monthly bonus ($50 and $160 a month for nurses and doctors respectively)? The bonus is described by authors and commentators as small, but small is relative. We are not told the basic salaries of nurses and doctors in the study, but in Guinea-Bissau, where this study took place, a chief nurse with 18 years’ service reports that she earns less than $100 a month.

For further discussion on the needs of health workers in developing countries, join HIFA2015 (Healthcare Information For All by 2015) and CHILD2015 global email discussion groups.

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ALCOHOL INDUSTRY

Review was limited

Farrell provides a limited view of the potential to intervene to reduce alcohol related harms. In reviewing Drinking in Context his premise is that public health approaches to alcohol rely exclusively on reducing total consumption. Drinking in Context was written to show the inadequacy of population level approaches. These alone will not tackle the individual, community, and social impacts of drinking alcohol. The book aims to highlight a wide range of opportunities for reducing alcohol related harms that do not require waiting for government action on tax and availability (indeed, barely an option for non-commercial alcohol which accounts for half of global consumption). Arguing solely for population level approaches also inhibits creative and needed local responses: municipalities cannot wait for governments to act, and much can be done now to reduce the impact of drinking and start the long process of cultural change.

To condemn the National Institute for Health and Clinical Excellence (NICE) as ageist when it limits access to donepezil is hardly a hardship. The tremendous wall of vendor sponsored randomised controlled trials that are not sponsored by the vendors show there is no benefit whatsoever to this drug.

In particular, neither carers nor patients can tell any difference between donepezil and placebo. The tremendous wall of vendor sponsored randomised clinical trials that are not sponsored by the vendors show there is no benefit whatsoever to this drug.

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Omitting donepezil is hardly a hardship

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Competing interests: None declared.

1 Guillard A. NICE guidelines create ethical dilemmas in care of elderly people, says report. BMJ 2007;335:791. (20 October.)
