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Withdrawing life sustaining treatment and euthanasia debate

Euthanasia may be ethical, but it is not legal

EDITOR—Street and Henderson invite debate about an accepted medical practice (withdrawing life sustaining treatment under the influence of paralysing agents) that is approved by an authoritative ethical advisory committee and yet is of questionable legality.¹ It should be no surprise that a course of action that is ethically justifiable may be illegal, for the law of England on care at the end of life is both morally and intellectually misshapen.²

In their commentary Inwald and Vandyck submit that the advice of the ethical committee is not compatible with the common law of England, and that to cause respiratory muscle paralysis in a patient without providing ventilatory support is a form of euthanasia. I agree with their view, but I am not confident that their proposed solution of discontinuing the administration of the paralysing drug shortly before the abrupt discontinuation of ventilation, omitting to allow the drug to be eliminated or reversed, would be accepted by a court.

Edwards tries to reconcile the practice of ventilator withdrawal under pharmacological paralysis with the legal doctrine of

double effect, but she misses or avoids the point that we cannot claim that muscle relaxants are drugs necessary to alleviate suffering and primarily used for such palliation. Their lethal pharmacological effect on unventilated patients is therefore not secondary, and the practice constitutes euthanasia. Outside of its narrow legal standing, double effect is not universally accepted as a morally relevant concept.^{3,4} In both these commentaries the only submitted justification for not waiting the hour or two it would take to clear the drug from the system (if it has been administered in a therapeutic dose) is to claim that the delay harms the patient who is lingering on a ventilator. Given that patients given curare ought normally to be sedated or anaesthetised during pharmacological paralysis, this alleged suffering cannot be given much weight. Moreover, Lord Goff specifically rejected the compassionate avoidance of lingering as a defence against mercy killing.²

Although we can construct a strong case for the moral acceptability of euthanasia in such circumstances, it is unlikely that a court could be persuaded that the practice is legal according to England's current law. Edwards unsubstantiated statement that atracurium does not have problematic residual effects ought to be corrected.⁵

Tom Woodcock *consultant, critical care directorate*
Southampton University Hospitals NHS Trust,
Southampton General Hospital, Southampton
SO16 6YD
woodcock@intonet.co.uk

1 Street K, Henderson J, Inwald D, Vandyck W, Greig-Midlane H, Edwards SJL. Ethical debate: the distinction between withdrawing life sustaining treatment under the influence of paralysing agents and euthanasia. *BMJ* 2001;323:388-91. (18 August.)

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3 Harris J. *Violence and responsibility*. London: Routledge and Kegan Paul, 1980.

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Doctrine of double effect should be discarded

EDITOR—The debate about the moral culpability or otherwise of withholding life prolonging treatment in a child aged 2 years with meningococcal sepsis where the effects of neuromuscular blocking agents will undoubtedly hasten death perpetuates the irrationality of the doctrine of double effect.¹

The doctrine of double effect maintains that doctors are responsible for the intended

effects of their actions but not for the unintended but foreseen side effects of the same actions. The doctrine thus seems to absolve doctors of responsibility in any situation where a reasonably foreseeable and preventable side effect intervenes to the detriment of the patient.

To suggest that leading specialists in paediatric intensive care could not be fully aware that extubation in the presence of neuromuscular blockade will not lead to a rapid death is absurd. To suggest furthermore that by somehow intending to avoid imposing treatment that is not in the patient's best interests those doctors are not morally responsible for the other effect of the action—namely, death—is akin to suggesting that doctors who administer treatment with more than one potential effect are only responsible for one of those effects. I would be reluctant to attend a physician or surgeon who was so readily able to divest themselves of such responsibility.

In the scenario presented by Street et al, it has been decided that on the basis of likely resultant quality of life, and the likely futility and burdensome nature of continued treatment, death is a better outcome than continued existence for the child. The medical profession, with the support of the law and the community, should recognise this and strive for the same degree of excellence in attaining death that it aims for in maintaining life. Death in the presence of neuromuscular blockade achieves that end better than if paralysing agents are reversed before extubation.

Paul Biegler *emergency physician*
Sandringham Hospital, Sandringham, Victoria
3191, Australia
pbiegler@netlink.com.au

1 Street K, Henderson J, Inwald D, Vandyck W, Greig-Midlane H, Edwards SJL. Ethical debate: the distinction between withdrawing life sustaining treatment under the influence of paralysing agents and euthanasia. *BMJ* 2001;323:388-91. (18 August.)

Double effect is different from euthanasia

EDITOR—Readers will not be surprised to learn that the topic of paralysing agents and euthanasia was discussed lengthily by both the working group and the ethics advisory committee of the Royal College of Paediatrics and Child Health before inclusion into their framework.¹ There is always a fine line with the principle of double effect that demands integrity from the caregiver.

The final wording by Inwald and Vandyck, that it is not necessary to withdraw the paralysing agent before the respiratory support is withdrawn, entails a misconception that the corollary is to continue the

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paralysing agent after respiratory support is withdrawn.² The phrasing used more simply indicated that the agent should be withdrawn at the same time that the respiratory support is withdrawn—it would be euthanasia otherwise, which the working group unanimously rejected, as is stated quite clearly in the first sentence of this section in the framework. The working group accepted that the effects of the paralysing agent would continue after withdrawal from the ventilator, but withdrawal of the medicine before this point—if it were indeed required for optimal ventilation—would not be in the child's best interests. Life saving treatment is withdrawn at the point when the ventilator is switched off or the child is extubated. The paralysing agent until this point has also been a life saving treatment allowing successful ventilation.

Although the BMA suggests that withdrawing respiratory support in these circumstances could be interpreted as intended killing, the working group considered this illogical.³ Although it has yet to be tested in law, it is useful to have Edwards coming to a similar conclusion.² Critical to all of this is the perspective of the parents. There will always be guilt with the grief when they have been party to a decision about the withdrawal of life saving medical treatment. As members of the health care team our job is, firstly, to be honest from beginning to end, not just with the parents, but also with ourselves and, secondly, to support the parents through these events.

Neil McIntosh *professor of child life and health*
University of Edinburgh, Edinburgh EH9 1UW
neil.mcintosh@ed.ac.uk

- 1 Royal College of Paediatrics and Child Health. Withholding or withdrawing life saving treatment in children: a framework for practice. London: RCPCH, 1997.
- 2 Street K, Henderson J, Inwald D, Vandyck W, Greig-Midlane H, Edwards SJL. Ethical debate: the distinction between withdrawing life sustaining treatment under the influence of paralysing agents and euthanasia. *BMJ* 2001;323:388-91. (18 August.)
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Role of paralysis during withdrawal of care needs clarifying, not polarising

EDITOR—By taking the simplistic view that muscle relaxants at the end of life accelerate death, Inwald and Vandyck have reached an inappropriately absolute stance on euthanasia and unlawfulness.¹ Their suggestion that both current practice and guidelines cross the threshold for these criteria not only engenders uncertainty among the professional groups responsible for intensive care, but it leads to mistrust among patient's relatives, if not investigations by the General Medical Council, coroner, or police.

Muscle relaxants should be prescribed only after failure of analgesic and sedative regimens to optimise ventilatory support or reduce oxygen consumption. If used appropriately in the first instance, relaxants should alter the manifestations of death rather than the cause or timing. Severe disruption of lung architecture, refractory myocardial failure, overwhelming brain injury, and gross

metabolic disturbance are the usual causes of rapid death, as exemplified by the case in point. In conjunction with the degree of support before withdrawal, which can be manipulated, these pathologies dictate the timing of death, regardless of the administration of muscle relaxants.

The associated analgesic and sedative regimens, by their impact on ventilatory drive and cardiovascular performance, are also relevant to the timing of death after withdrawal of support for either system, in the timescale hypothetically determined by relaxants alone. It could indeed be argued that struggling preterminal respiratory effort, rather than providing effective gas exchange, will accelerate hypoxia and death, generating the paradox of relaxants delaying the timing of death.

Although sparing the family the distress of witnessing that struggle may be viewed as unfashionably paternalistic by those not responsible for care of this nature, the former arguments predicate against defining this process as euthanasia. If, however, owing to the idiosyncrasies of a particular case, paralysis were to be the main determinant of timing of death, the residual effects of a discontinued infusion would be identical with those of a continued infusion, rendering the distinction as to lawfulness between the two approaches illogical.

I can also foresee the scenario whereby discontinuing relaxants before withdrawal of support, but not reversing the residual effect, could be considered unlawful, contrary to the authors' stance. In distinction to the above pathologies with the potential to cause rapid death, if the child had sustained a significant brain injury but retained ventilatory drive with little or no associated lung or cardiovascular impairment, the immediate cause of death would be muscle paralysis.

Decision making about futility and techniques of withdrawal is difficult and subject to differing opinion. Not every decision or action may be defensible, warranting both guidelines and the scrutiny the review intended. It is unfortunate, however, that Inwald and Vandyck, in taking a polarised view of just one aspect of care, have potentially generated difficulties in an already problematic area rather than creating a helpful template defensible from a medical, ethical, and legal perspective.

M D D Bell *consultant in intensive care*
General Infirmary, Leeds LS1 3EX
dom@wybells.freeserve.co.uk

- 1 Street K, Henderson J, Inwald D, Vandyck W, Greig-Midlane H, Edwards SJL. Ethical debate: the distinction between withdrawing life sustaining treatment under the influence of paralysing agents and euthanasia. *BMJ* 2001;323:388-91. (18 August.)

Neuromuscular blockade must be used with adequate sedation and analgesia

EDITOR—The debate on the withdrawal of life sustaining treatment under the influence of neuromuscular blockade was interesting.¹ The end result of death was inevitable in this scenario, and the intent of this course of management was to relieve suffering. I was

surprised that there was not more emphasis placed on the use of sedative and analgesic agents to ensure lack of awareness and comfort in the period after extubation.

If one of the main aims of the continuation of the paralysing agents were to allow the patient a serene and dignified death, would it not be more appropriate to make use of the pharmacological actions of the numerous available sedatives and analgesics to achieve this? Paralysing agents in current use have no sedative or analgesic actions, although they may mimic this effect from the bedside. The continuation of paralysing agents may leave a doubt about awareness. The knowledge that these agents are no longer active, and the patient seems calm because of comfort and lack of awareness rather than neuromuscular blockade, must provide reassurance to family and staff alike.

It is standard practice in anaesthesia to ensure that muscle relaxants are given in conjunction with sufficient doses of analgesic and sedative drugs to ensure that the patient is unaware of paralysis and other stimuli. Our primary duty of care is to the patient, and we must ensure that there is no patient awareness at this time. By ensuring adequate sedation and analgesia, with or without the use of neuromuscular blockade, our duty to remove suffering is fulfilled. When we achieve these aims, we automatically fulfil our secondary duty to relatives and carers who should be allowed the memory of a calm, comfortable death, free of suffering.

Alasdair Waite *specialist registrar in anaesthesia*
Department of Anaesthesia, Royal Hospital for Sick Children, Edinburgh EH9 1LF
alasdairwaite@yahoo.com

- 1 Street K, Henderson J, Inwald D, Vandyck W, Greig-Midlane H, Edwards SJL. Ethical debate: the distinction between withdrawing life sustaining treatment under the influence of paralysing agents and euthanasia. *BMJ* 2001;323:388-91. (18 August.)

Cannabinoids in pain management

Study was bound to conclude that cannabinoids had limited efficacy

EDITOR—Campbell et al's paper on whether cannabinoids are effective and safe in the management of pain purports to be qualitative and systematic,¹ but it is neither. Because it focused on two clinically questionable synthetic cannabinoids and oral delta-9-tetrahydrocannabinol (THC) without providing any focus on the synergistic components of herbal cannabis, and examined only certain facets of the broad topic of pain, it ensured that a conclusion of limited efficacy was reached. That is not news.

What is surprising, in contrast, is that the authors chose to broaden the alleged impact of their limited investigation to relegate the use of cannabis and cannabinoids to a back seat in future analgesic applications. This contention is not supported by their limited data.

I see nothing published about pioneering British doctors and their clinical successes with cannabis extracts in a myriad of painful conditions between 1840 and 1940.²⁻⁴ I see virtually nothing of modern scientific studies showing the multifactorial benefits of cannabis on a range of neurotransmitter systems, which I have reviewed.⁵ No mention is made of bureaucratic and political obstructions to clinical research into cannabis; one cannot show results when the requisite studies are not permitted. Thus until recently we have been left with an overwhelming (but ignored) body of anecdotal evidence from patients and their doctors.

What is truly newsworthy here is that the *BMJ* has ignored peer review and editorial standards in a scandalous manner. The popular media have seized the opportunity, and in the process valuable laboratory and clinical research, and their funding, in analgesia and pain control have been severely compromised. Great shame accrues to the journal as a result. Instead of probity we have propaganda.

Ethan Russo clinical assistant professor, University of Washington School of Medicine
Montana Neurobehavioral Specialists, 900 North Orange Street, Missoula, MT 59802, USA
erusso@blackfoot.net

Competing interests: Professor Russo has been a scientific adviser to GW Pharmaceuticals (a manufacturer of cannabis-based medicine extracts), which has reimbursed expenses for travel with regard to visits and clinical research. He is also the editor in chief of *Journal of Cannabis Therapeutics*.

- 1 Campbell FA, Tramèr MR, Carroll D, Reynolds DJM, Moore RA, McQuay HJ. Are cannabinoids an effective and safe option in the management of pain? A qualitative systematic review. *BMJ* 2001;323:13-6. (7 July.)
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Few well controlled trials of cannabis exist for systematic review

EDITOR—Campbell et al gave themselves an impossible task with their systematic review.¹ Anyone who has reviewed the scientific literature on the medical uses of cannabis rapidly finds that there is a dearth of well controlled clinical trials.² A meta-analysis of the use of cannabis in treating pain is therefore likely to find little of substance to comment on.

Unfortunately, this did not deter the authors from coming to a series of emphatic but ill founded conclusions. I hope that these will not be taken as the last word on the topic: large and well controlled clinical trials are about to start in the United Kingdom³ and a wealth of animal data support a role for cannabinoids in pain modulation.⁴

Leslie Iversen visiting professor
Department of Pharmacology, University of Oxford, Oxford OX3 9DU
les.iversen@pharm.ox.ac.uk

Competing interests: None declared.

- 1 Campbell FA, Tramèr MR, Carroll D, Reynolds DJM, Moore RA, McQuay HJ. Are cannabinoids an effective and safe option in the management of pain? A qualitative systematic review. *BMJ* 2001;323:13-6. (7 July.)
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Spasticity is not the same as pain

EDITOR—The systematic review on cannabinoids in the treatment of pain¹ referenced a paper that I coauthored on the efficacy of a cannabinoid (delta-9-tetrahydrocannabinol (THC)) in spasticity.² My confusion in reading the review was the implication that that paper had anything to do with pain.

Spasticity and pain are distinctly different entities. Although pain may accompany symptoms of spasticity such as flexor or tonic spasms, the assessments of spasticity do not usually include the types of measure seen with analgesics. Our results have been confirmed by other researchers, and antispastic activity has been documented for marijuana,³ THC,⁴ and nabilone.⁵

More importantly, all studies that have been published have shown an antispastic effect for the cannabinoids. Currently, considerable research effort is under way to evaluate cannabinoids in multiple sclerosis. This effort is undermined when review articles are cited in the media as evidence that cannabinoids are either ineffective or unsafe.

Denis J Petro neurologist
Arlington, VA 22209, USA
djpmsmd@aol.com

Competing interests: None declared.

- 1 Campbell FA, Tramèr MR, Carroll D, Reynolds DJM, Moore RA, McQuay HJ. Are cannabinoids an effective and safe option in the management of pain? A qualitative systematic review. *BMJ* 2001;323:13-6. (7 July.)
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Cannabinoid receptor agonists will soon find their place in modern medicine

EDITOR—I am unsure whether the methods applied in the systematic reviews by Campbell et al and Tramèr et al are able to answer the questions of today's interest.^{1 2} If you pool the data from older studies of pain you will miss most of the interesting information, particularly differences in efficacy for different painful conditions, differences between the cannabinoids, and interindividual differences with regard to side effects.

Cannabinoids are weak analgesics compared with the opiates.³ The question of interest is not so much whether they are potent analgesics compared with codeine but, rather, which painful conditions they are

effective in. By stating that cannabinoids may have potential in neuropathic pains, particularly with spastic components, even Kalso hints at a need for such a differentiated assessment.⁴

The same is true for side effects. Levonantradol has not been brought on to the market, because it has a higher rate of side effects than tetrahydrocannabinol (THC). Today an interesting question might be, by which strategies could psychotropic side effects be reduced? Interindividual variation in side effects is high. Some patients may profit more because they tolerate relatively high doses without perceiving any unpleasant effects. Will we learn which patients have a favourable risk:benefit ratio?

With regard to antiemetic efficacy, I agree that modern serotonin receptor antagonists are effective to treat nausea and vomiting in cancer chemotherapy, but sometimes they fail and sometimes cannabinoids seem to be superior.⁵

The study by Maurer et al of 1990 cited by Campbell et al refers to another important aspect—the synergistic use of several pharmacological effects of cannabinoids, in this case the analgesic and antispastic effects in spinal cord injury. Results of research showing that cannabinoids reduce opioid induced emesis and act synergistically with opioids against pain point to a possible combination of analgesic and antiemetic effects of cannabinoids.

I believe that cannabinoid receptor agonists will find their place in modern medicine within the next few years. It will be interesting to see which indications they will be approved for and whether they will be limited to synthetic derivatives from drug companies engaged in cannabinoid research.

Franjo Grotenhermen doctor
nova-Institut, D-50354 Hürth, Germany
franjo.grotenhermen@nova-institut.de

Competing interests: The author is chairman of the International Association for Cannabis as Medicine, Cologne.

- 1 Campbell FA, Tramèr MR, Carroll D, Reynolds DJM, Moore RA, McQuay HJ. Are cannabinoids an effective and safe treatment option in the management of pain? A qualitative systematic review. *BMJ* 2001;323:13-6. (7 July.)
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Authors' reply

EDITOR—Systematic reviews tell us about research that has already been done. What we should learn from them is the research agenda for the future. For clinical trials of interventions we know that certain study architectures, particularly those that control selection bias and observer bias by randomisation and masking, go a long way to ensuring that those biases are minimised.

So why did we not include in our reviews, as Russo comments, “any focus on the synergistic components of herbal cannabis”? Because, despite including cannabis and marijuana in our search strategies, using various spellings, we found none. We did find information in the form of randomised controlled trials of tetrahydrocannabinol (THC) and synthetic cannabinoids. If there was good evidence on the efficacy and harm of herbal cannabis in the form of randomised controlled trials then we missed it. It is unlikely that such evidence exists.

If the *BMJ* ignored the peer review process it was not obvious to us. The route to publication was long and occasionally tortuous, with considerable argument with editors and peer reviewers. Like most authors, we believe that we could have been treated better, but the *BMJ* can be cleared of the slur that it shirked its responsibilities.

For acute pain, our attitude to any drug with dismal efficacy and a high rate of serious and potentially serious adverse events would be the same as it was for cannabis in these trials. We already have better drugs. For more difficult problems, such as painful spasms and neuropathic pain, none of us would want to overlook any possibility. For nausea and vomiting our attitude was similarly cautious. Where serious and common adverse events occur, this will limit the use of cannabinoids. Circumstances will sometimes dictate otherwise, as Grotenhermen points out.

We are surprised that these reviews were not done before fresh trials were funded. If they had been, the quality of the debate and of the decision making would have been higher. Large controlled studies are to be welcomed for some clinical problems, but their design should take into account the pitfalls of preceding trials lest the same mistakes are repeated. The ethics of starting a trial without doing a systematic review are questionable. The question that the trial seeks to solve is critical.

Previous trials do not answer important questions about relief of painful spasm. They do, however, suggest little future for existing cannabinoids in acute pain management and emesis.

Fiona A Campbell *consultant in anaesthetics and pain management*
Pain Management Centre, Queen's Medical Centre, Nottingham NG7 2UH
fiona.campbell@mail.qmcuk-tr.trent.nhs.co.uk

Andrew Moore *consultant biochemist*

Henry J McQuay *professor of pain relief*

Dawn Carroll *senior research nurse*

Pain Research, Nuffield Department of Anaesthetics, The Churchill, Oxford Radcliffe Hospital, Oxford OX3 7LJ

Martin R Tramèr *staff anaesthetist*

Division d'Anesthésiologie, Département APSIC, Hôpitaux Universitaires, CH-1211 Genève 14, Switzerland

D John M Reynolds *consultant clinical pharmacologist*

Department of Clinical Pharmacology, Radcliffe Infirmary, Oxford OX2 6HE

Competing interests: None declared.

Rehabilitation for chronic low back pain

Review was of little help in selecting treatment

EDITOR—We have misgivings about the conclusions drawn by Guzmán et al on multidisciplinary rehabilitation for chronic low back pain.¹ Low back pain problems are as heterogeneous as the wider category of chronic pain, and in disregarding systematic reviews and meta-analyses of multidisciplinary rehabilitation in chronic pain Guzmán et al have missed a large body of relevant evidence, including trials of cost effectiveness.^{2,3}

Standard quality criteria used for randomised controlled trials cannot be applied in an unmodified form to psychological treatments, which constitute important components of multidisciplinary rehabilitation. The impossibility of blinding patients and therapists need not lower standards. Several trials reviewed employed recognised methods for establishing treatment equivalence: patient rating of treatment credibility or expectations; manualised treatments; blind rating by experts of treatment excerpts; and close supervision of therapists. It is disappointing to see the Cochrane Back Review Group continuing to apply inappropriate criteria and thereby misjudging methodological quality of trials.

Variability in outcome arises from heterogeneity among patients, differences in treatment, and their interaction, not only from length of treatment. Content of treatment is far more important than the total time of the programme. Physical treatment alone, as Guzmán et al say, is a weak way to change behaviour, particularly in relation to work and use of health care. Patients who have become fearful of further pain and damage, and who are disabled as much by their fears and misapprehensions as by the pain itself,⁴ need psychologically based treatment, which is still in short supply.

The emphasis on return to work as the primary outcome is inappropriate when the population includes homemakers, as did several of the trials reviewed. Disability or function is a broader issue and includes the important, but neglected issue, of change in use of healthcare resources. An undue focus on return to work to define effectiveness leads to restricting access to treatment for non-workers, particularly among older patients.

Guzmán et al acknowledge that their conclusions may not apply in primary care, but patients are better defined by their level of disability than by the setting in which they are seen, and their treatment defined not by hours but by its adequacy to restore as near as possible normal function, whether in secondary prevention of recently injured workers or chronically disabled non-workers.⁵ This review offers clinicians little help in selecting the right level of treatment for patients with low back pain.

Cathy Price *consultant in pain management*
Southampton University Hospitals NHS Trust, Southampton SO14 0YG
cathyprice@freuk.com

Amanda C de C Williams *senior lecturer in clinical health psychology*

Guy's, King's and St Thomas's Medical School and INPUT Pain Management Programme, St Thomas's Hospital, London SE11 6SP

Chris J Main *professor in behavioural medicine*
Salford Behavioural Medicine Research Unit, Hope Hospital, Salford M6 8HD

1 Guzmán J, Esmail R, Karjalainen K, Malmivaara A, Irvin E, Bombardier C. Multidisciplinary rehabilitation for chronic low back pain: systematic review. *BMJ* 2001;322:1511-6 (23 June.)

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Authors' reply

EDITOR—Price et al misinterpreted the purpose of our systematic review, which was to summarise published randomised clinical trials of the effects of multidisciplinary biopsychosocial rehabilitation on clinically relevant outcomes in people with disabling chronic low back pain.¹ The review by van Tulder et al may better address their question of how to select appropriate psychologically based treatment for different patients with chronic pain.²

It is always possible to miss relevant evidence, but the quoted references seem more relevant to their question than to ours. We agree that blinding with psychological and multidisciplinary interventions might not be feasible, but it has been shown that when blinding is not done or is not feasible the results are more prone to bias.³ The treatment philosophy, components, and intensity and the therapist's skills are all important to the success of treatment. The trials of intensive functional restoration shared much more than treatment intensity, they had the same philosophy and very similar components (see bmj.com).^{1,4}

Return to work was not our primary outcome. Pain, function, employment status, quality of life, and global judgments were all relevant outcomes in our review. We agree that use of healthcare services is also important. We used severity and duration of disability for inclusion of studies, not their setting. We mentioned care settings to discuss the generalisability of our findings. We are not clear what is meant by “treatment should be defined not by hours but by its adequacy to restore function.” If it were already known which treatments are adequate to restore function in individual patients with chronic back pain, we would not be discussing the issue.² We agree that hours of treatment should not be the only criterion to define treatments.

We regret that our review does not answer the questions asked by Price et al, but we disagree that our review is of little help in selecting treatment for low back pain sufferers. It provides a succinct summary of the best available evidence on multidisciplinary biopsychosocial rehabilitation for chronic low back pain. It points out that clinicians considering referral to multidisciplinary treatment should check the content of the treatment and that an intensive programme with a functional restoration is the preferred approach, since it is supported by randomised controlled trials. It also informs clinicians that they can expect improvements in function and perhaps pain, but vocational outcomes might be variable.

Jaime Guzmán *research fellow*
Rosmin Esmail *Cochrane Collaboration coordinator*
 Institute for Work and Health, Toronto, Canada
 M4W 1E6

Kaija Karjalainen *research fellow*
Antti Malmivaara *assistant chief physician*
 Finnish Institute of Occupational Health, Helsinki,
 Finland 00250

Claire Bombardier *senior scientist*
 Institute for Work and Health, Toronto, Canada
 M4W 1E6

- Guzman J, Esmail R, Karjalainen K, Malmivaara A, Irvin E, Bombardier C. Multidisciplinary rehabilitation for chronic low back pain: systematic review. *BMJ* 2001;322:1511-6. (23 June)
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Scientific debate on animal model in research is needed

EDITOR—The editorial by Smith on animal research generated 23 responses on *bmj.com*, which are categorised in the table.^{1,2}

Five responses (and an additional letter by Botting) were published in the *BMJ*.³ Those selected fell into the category either of improvements to the current system, which supported the 3Rs (replacement, refinement, and reduction) approach (four letters), or of alternatives to animal research (one letter). All five letters adopted a conservative approach to the issue of animal research, and none challenged any of the points made in the editorial. Although some of the other letters may not have been suitable for publication, there seems to have been a selection bias.

Of the responses not selected for publication, eight fell under the category of scientific validity of the animal model. The most comprehensive of these, by Greek and Greek, argued that evolutionary theory undermines many of the assumptions on which the animal model relies and questioned the validity of the causal analogical models used in animal research. Although this was too long to print in its original form, a shortened version could have been

Categories of electronic responses to Smith's editorial on animal research¹

Scientific validity of animal model (n=8)	Ethical (n=6)	Improvements to current system (n=5)	Alternatives to animal research (n=2)	Off the subject (n=2)
Goodman (first letter)	Johnstone	Hau	Ramanathan	Fox
Greek and Greek	Zakarian	Meredith	Gray	Morrell (second letter)
Ferguson	Reik (second letter)	Reik (first letter)		
Green	Goodman (second letter)	Roberts		
Gajek	Morrell (first letter)	Hawkins		
Biel	Collins			
Partridge				
Yoe				

solicited for the *BMJ*. Green, Gajek, Biel, and Yoe also raised important questions about the scientific validity of the animal model, whereas Goodman, Ferguson, and Partridge defended the methodology. None of these letters was printed.

Smith is right: the current debate on animal research is far too simplistic. But he is wrong if he thinks that people who object to institutions such as Huntingdon Life Sciences do so purely on the basis of concern for animal welfare. Traditionally, the emphasis in the animal rights movement has been on cruelty to animals, and the objections to research on animals have been ethical. During the past few years, however, the focus has widened, and those conducting research using animals are now being challenged on scientific grounds. Furthermore, humans are arguably suffering as a result of animal research because the data derived from animal models cannot be reliably extrapolated to humans.

This paradigm shift is not surprising—the decline of public trust in the infallibility and neutrality of experts is well documented. The challenge to the scientific validity of the animal model needs to be taken seriously, as do concerns about the impact of animal research on humans. This issue must be debated thoughtfully and scientifically—not by throwing examples of drug disasters and medical advances to and fro. The Greeks are challenging the theory underpinning animal research. The *BMJ* would provide an excellent forum for this debate to take place.

Pandora Pound *freelance researcher*
 Radford Mill, Tisbury, Bath BA2 0QF
 radford.mill@ukonline.co.uk

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Collaboration with the Campbell Collaboration

tk;4Campbell principles are applied in West Midlands through public health research forum

EDITOR—We welcome the application of systematic reviews to the analysis of effective, healthy public policy.¹ In the West Midlands

we have applied Campbell principles through a public health research forum over the past two years. We have refined a shortlist of public policy interventions in education, criminal justice, and health fields through a series of in-depth reviews of evidence. We believe that these should be implemented systematically: if they were drugs it would be unethical not to use them.

Strong and consistent evidence was found for preschool interventions and family support for families with children at risk of school failure.² In Sandwell this has led to the implementation of a programme of training for nursery nurses and teachers, health visitors, and social workers funded through the Sandwell health action zone. Strong evidence was also found for a range of interventions for children with mild to moderate behavioural problems and their families. Cognitive behavioural therapies offer benefit in an expanding range of psychosocial and behavioural problems.

Interactive drug education programmes seem to offer strong benefits.³ A sound systematic review was identified for methadone based harm reduction regimens for opiate addiction,⁴ which lent support to the approach of some national policies in preventing drug related crime.

A small group of youth service and youth justice workers in the West Midlands is reviewing the evidence on interventions in young people's services. We have identified several interventions without clear evidence of benefit. The DARE (drug abuse resistance education) drugs education programme in the United States, although popular and widespread, has a much smaller size effect than interactive drug education programmes.⁵

The "Scared Straight" programme in the United States is another popular and politically attractive programme, in which high school students are shown life in prison in order to scare them out of a life of crime.⁵ Systematic reviews of the programme have shown adverse outcomes for the subjects. We have been alarmed to learn that a variant of this programme has been introduced into the United Kingdom, and we have asked the Home Office to discourage it from our schools (JM, personal communication).

Unanswered questions remain about many aspects of public policy, particularly in criminal justice and community safety—the effectiveness of closed circuit television (CCTV), street lighting, and police on the beat, and of boot camps versus adventure

camps. Many of these could be answered best through properly constructed randomised controlled trials.

John Middleton *director of public health*
John.Middleton@leghorn.demon.co.uk

Elizabeth Reeves *specialist registrar in public health*
Sandwell Health Authority, West Bromwich
B70 9LD

Richard Lilford *former director, research and development*

Frances Howie *programme manager, research and development*

West Midlands Regional Research and Development, Birmingham B16 9PA

Chris Hyde *senior lecturer in public health*
Institute of Public and Environmental Health,
University of Birmingham, Birmingham B15 2TT

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EPPI Centre reviews will aim to disseminate systematic reviews in education

EDITOR—Davies and Boruch draw the attention of *BMJ* readers to the Campbell Collaboration (<http://campbell.gse.upenn.edu>).¹ These readers will be well aware of the importance of systematic reviews in health,² particularly the reviews from the Cochrane Collaboration (www.cochrane.org).

Systematic reviews are less well accepted or even known about outside medicine, even though some of the early meta-analytic work was in education.³ The Campbell Collaboration and several initiatives based on the provision and dissemination of research evidence in social and public policy (www.esrc.ac.uk/EBPescrUKcentre.htm) suggest, however, that this situation is changing.

In education, the Department for Education and Employment (now Department of Education and Skills) established the Evidence for Policy and Practice Information and Coordinating Centre (EPPI Centre) in 2000 at the Social Science Research Unit in the Institute of Education, London. The unit has a long history of systematic reviewing in social interventions⁴ and health and health promotion⁵ and is joint coordinator for the Cochrane health promotion and public health field.

The aim of the EPPI Centre (<http://eppi.ioe.ac.uk>) is to facilitate the production and dissemination of systematic reviews of research evidence to inform policy and practice in education. EPPI Centre reviews, like Campbell reviews, will consider research addressing a broad set of research questions including, for example, "what works?" and "what is the process?"

Influenced by the pioneering work at the Cochrane Collaboration, these reviews are being based around the establishment of education review groups, which include not

just academic researchers but also policy-makers, practitioners, and other actual and potential users of the research evidence. The groups are supported to take forward a programme of reviews in specific areas of education. There are currently groups in assessment and learning research, English teaching, gender and education, inclusive education, school leadership, and post-compulsory education, and a further four will probably be registered later. The reviews and the data underpinning them will be placed on the web for free access.

Members of the EPPI Centre collaborate with fellow reviewers in parallel organisations such as the Cochrane and Campbell Collaborations. Different disciplines have much to learn from each other, and we hope that this shared spirit of openness and collaboration will lead to better informed decisions for policy and practice.

Diana Elbourne *professor of evidence-informed policy and practice*
delbourne@ioe.ac.uk

Ann Oakley *professor of sociology and social policy*
David Gough *reader in social science*
Social Science Research Unit, Institute of Education, London WC1H 0NR

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Duchenne muscular dystrophy: relevant paper was not included

EDITOR—Dorling and Salt describe an evidence based approach to the assessment of a boy with locomotor developmental delay manifesting as late walking.¹ In their literature search they have missed a relevant paper.² This paper was probably not identified by their literature search as it is incorrectly indexed in Medline as a case report rather than a prospective cohort study. The fallibility of electronic databases is well known, and because of this previous authors have highlighted the need for expert help when performing a systematic review.³

The paper evaluates the community screening of a cohort of boys aged 18 months for late walking and Duchenne muscular dystrophy. Of the population of 25 299 boys, 19 986 (79%) were screened for late walking at 18 months, of whom 338 (1.7%) were not walking. Altogether 205 boys (75%) had creatine kinase concentrations measured on fingerprick blood testing, and two cases of Duchenne muscular dystrophy were identified. This programme provided further justification to screen boys who were late walking for Duchenne muscular dystrophy with a number needed to screen of only 100.

The issue of community screening for Duchenne muscular dystrophy is complex. Because the uptake of primary care developmental surveillance (which is not screening in its true sense) is not complete, some children who are not walking at 18 months will not be identified. Not all surveillance guidelines in primary care recommend referral for specialist assessment of all children who are late walking at 18 months. There are further complex issues relating to consent for the blood test. In addition, as 50% of boys with Duchenne muscular dystrophy are walking at 18 months, such a programme would at best identify half of the cases. Therefore such a community screening programme for Duchenne muscular dystrophy was not justifiable and the recommendation was for opportunistic screening of those late walking boys at 18 months who are identified.

We also disagree with Dorling and Salt that this information is not available in textbooks. Aicardi says in a standard text that, owing to the difficulty in early recognition, creatine kinase concentration should always be systematically determined in children who do not walk by 18 months of age.⁴

Dorling and Salt do, however, highlight the important issue of late diagnosis of Duchenne muscular dystrophy. Until screening of newborn infants is introduced on a wider scale we will need to rely on the early clinical recognition of the condition by general practitioners, paediatricians, and orthopaedic surgeons. This should also include wider recognition that in young boys with Duchenne muscular dystrophy language delay is often a more notable feature.⁵

Robert A Smith *consultant paediatrician*
Robert.A.Smith@excha.yhs-tr.northy.nhs.uk

Robert S Phillips *specialist registrar*
York District Hospital, York YO31 8HE

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Are randomised controlled trials in the *BMJ* different?

EDITOR—In the context of an evaluation of the CONSORT guidelines for the reporting of randomised controlled trials, we searched each issue published in 1998 of *Annals of Internal Medicine*, *BMJ*, *JAMA*, *Lancet*, and the *New England Journal of Medicine* for reports of randomised controlled trials.^{1 2} The hand search identified 290 articles. We excluded one quasi-randomised trial and nine reports whose focus was not on randomised comparisons. Our study sample thus consisted of 280 reports (table).

Characteristics of reports of controlled trials published in five general medicine journals in 1998

Characteristic of trial reports	<i>Annals of Internal Medicine</i> (n=20)	<i>BMJ</i> (n=48)	<i>JAMA</i> (n=47)	<i>Lancet</i> (n=82)	<i>New England Journal of Medicine</i> (n=83)
Parallel group trials	18 (90.0)	46 (95.8)	45 (95.7)	78 (95.1)	78 (93.9)
Randomised individuals	19 (95.0)	42 (87.5)	45 (95.7)	81 (98.8)	83 (100)
Tested pharmacological intervention	13 (65.0)	15 (31.3)	30 (63.8)	55 (67.1)	61 (73.5)
Median total sample size (range)	88 (35 to 1283)	214 (11 to 17 187)	197 (24 to 6605)	382 (15 to 19 193)	400 (20 to 10 948)

Differences were significant for unit of randomisation (individuals v other, P=0.003), type of intervention (drugs v other, P<0.001), and sample size (P=0.004). Probability from χ^2 and Kruskal-Wallis tests.

The number of trials published in 1998 ranged from 83 in the *New England Journal of Medicine* to 20 in *Annals of Internal Medicine*. Most trials were of parallel group design (265/280, 94.6%), with individuals as the randomisation unit (270/280, 96.4%). Most trials evaluated pharmacological interventions (174/280, 62.1%). Trials published in the *BMJ* differed from trials published in the other journals in two respects. Firstly, randomisation was more likely to be at an aggregate level—for example, practices in general practice—rather than at the individual level (odds ratio 9.86, 95% confidence interval 2.21 to 49.0, comparing *BMJ* reports with other reports). Secondly, trials were less likely to test drug interventions (0.35, 0.17 to 0.69).

Trials published in general medicine journals will to some extent reflect the agenda in clinical trial research, which has been shown to be at odds with the needs of consumers and planners of health services.^{3,4} Our results are in line with previous studies showing that drug interventions dominate the literature. For example, 380 (82.6%) of 460 trials of osteoarthritis of the knee evaluated drugs whereas the evidence on the effectiveness of other interventions was inadequate or absent.³ Commercial interests of the pharmaceutical industry, which funds many drug trials, vested interests of researchers, and lack of involvement of healthcare consumers may contribute to the dominance of drug trials. The low proportion of drug trials and the large proportion of cluster trials, many from health services research, indicate that the material in the *BMJ* may be less affected by the biases distorting the research agenda. Further research is required to refute or confirm this hypothesis.

Matthias Egger senior lecturer in clinical epidemiology
m.egger@bristol.ac.uk

Christopher Bartlett research associate
Medical Research Council Health Services Research Collaboration, Department of Social Medicine, Bristol BS8 2PR, United Kingdom

Peter Jüni specialist registrar
Department of Rheumatology and Clinical Immunology, Inselspital, CH-3010 Bern, Switzerland

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Harvesting organs from recently executed prisoners

Practice must be stopped

EDITOR—On 27 June 2001 Thomas Diffo, a New York transplant surgeon, Wang Guoqi, a Chinese doctor who had taken kidneys and skin from recently executed prisoners, and Harry Wu of the Laogai Association gave evidence to the committee on international relations of the United States House of Representatives in Washington, DC. They noted that in China, organs are taken from recently executed prisoners, to be transplanted into recipients from the United States, Taiwan, Malaysia, Japan, and other countries. The recipients pay \$17 000-40 000 each. It was not known whether the executed prisoners had given their consent.

In China prisoners can be executed for crimes such as rape, robbery, drug dealing, and black market activities, in addition to murder. It is extremely rare for those accused not to be found guilty. As soon as the prisoners are sentenced, blood samples are taken for grouping. The prisoners' appeals are hardly ever upheld. They find this out only when they are taken to be shot. Ambulances wait at the site of the executions, and the fresh organs from healthy young persons are harvested, to be transplanted into recipients from abroad.

The World Medical Association made declarations condemning these practices at Brussels in 1985 (on the grounds that this was commercial exploitation of human organs), at Madrid in 1987 (on the grounds that doctors should not participate and that it was not known if the executed prisoners had given consent to the use of their organs), and at Stockholm in 1994, when the BMA had rejoined the World Medical Association (on the same grounds as the 1987 declaration).

In Beijing, in 1998, Delon Humann, the secretary of the World Medical Association, Anders Milton, its chairman, and Dr T J Moon of the Korean Medical Association, reached an agreement with the Chinese Medical Association that these practices

were undesirable and that they would investigate them jointly, with a view to stopping them. Nevertheless, in 2000, the Chinese reneged on these undertakings and refused to cooperate. This lucrative and immoral trade continues unabated. One is entitled to ask whether any British patients have visited China to receive transplant from executed prisoners, and what the international medical community can do to stop these practices?

Harold Hillman director
Unity Laboratory of Applied Neurobiology,
Guildford, Surrey, GU1 2BX
hillmanh@breathemail.net

Opportunities to offer support to members from the China Medical Association have been limited

EDITOR—Hillman makes some important points on the use of the death penalty in China and its relation to the procurement of organs for transplantation.

When the China Medical Association rejoined the members of the World Medical Association at the general assembly, voting on that application was in the hope that membership of the World Medical Association would help the China Medical Association to oppose unethical practices and encourage the teaching of medical ethics and human rights. At an early meeting with the China Medical Association its leaders produced a statement with the World Medical Association, condemning harvesting of organs from executed prisoners. Other activities were planned; one of the first was to be a seminar on teaching human rights for doctors and medical students. The requirements of the World Medical Association—including freedom to set the agenda for the meeting and a guarantee that invited guests and speakers would get visas—were not met, and the meeting was cancelled.

Since rejoining the World Medical Association, members from the China Medical Association have rarely attended meetings, and the opportunities to offer them support have been limited. All members of the World Medical Association share Hillman's concern to effect change. We continue to hope that such contacts as we have with Chinese colleagues will encourage them to share our views, and to use our help in opposing this practice. Our human rights working group will continue to press this agenda.

Vivienne Nathanson head of professional resources and research group
British Medical Association, London WC1H 9JR



Rapid responses

Correspondence submitted electronically is available on our website