LETTERS

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ASSISTED DYING

Where's the evidence for malign professionals, or carers?

Heath seems to be haunted with nightmarish visions of Drs Mengele and Shipman, together with fears that a "malign" future government may take advantage of dignity in dying and require one's death.[1] The reality is much less dramatic: in places that allow assisted dying, there have been no dramatic increases that would justify her fears. People request assisted dying in the face of intolerable pain and loss of autonomy caused by severe illness. Heath does not advance even anecdotal evidence of "complicit, self interested support from relatives, professionals, or carers."

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Competing interests: DG is a member of the steering committee, Healthcare Professionals for Assisted Dying.

1 Heath I. What's wrong with assisted dying. *BMJ* 2012;344:e3755. (29 May.)

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Legislation would protect against malign individuals

Heath's association of the names of Mengele and Shipman with doctors supportive of legislation for assisted dying is unwarranted.[1] The fundamental differences are centred in compassion and patient choice.

Heath's avowed reservations about assisted dying result from an expectation of the abuse of power, either by a relative or by the state should a "malign" government come to power. But it is more likely that malign individuals who coerce the "vulnerable" into seeking an assisted death will be identified proactively by the professional scrutiny that any legislation in this area will embody.

If a malign government were to come to power, as citizens, we would have far more to worry about than the abuse of assisted dying.

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1 Heath I. What's wrong with assisted dying. *BMJ* 2012;344:e3755. (29 May.)

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Consider suffering associated with lack of control over dying

Godwin's law states that whoever raises the holocaust in an ethical argument automatically loses, and Heath's article is a good case in point.[1] Most people who support the self determination of patients in the dying process are kind hearted and motivated by beneficence, unlike her unfortunate analogies.

If the avoidance of evil is Heath's prime motivation, as it seems to be, she would do better to consider more carefully the vast amount of suffering associated with lack of patients' control over the dying process. The spectre of "vulnerable" patients being coerced cannot justify all this avoidable suffering. If aware of the possibility of coercion, society can build in safeguards, here as elsewhere.

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1 Heath I. What's wrong with assisted dying. *BMJ* 2012;344:e3755. (29 May.)

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Legislation and debate needed

Heath asserts that "it will be impossible to draft a law robust enough to protect the vulnerable."[1] However, such legislation has been in place in the Netherlands, Belgium, and Oregon, USA, for at least 10 years, with no suggestion of coercion for the vulnerable and no rapid rise in numbers seeking assisted death. Lord Falconer's *Commission on Assisted Dying* published earlier this year provides a balanced legal framework on which we could move forward.

Legislation is needed not only to protect the vulnerable but also to protect professionals caring for patients. Amateur partners (acting with best intentions) who help their terminally ill loved ones to die are now unlikely to be prosecuted, but currently health professionals are not allowed even to discuss the matter.

Doctors are still not universally discussing their patients' wishes with regard to dying, and neither are they universally offering advanced directives for terminally ill patients. It is the lack of autonomy that patients fear at such a time.

Palliative care should be considered as complementary to assisted dying, not presented by our profession as the only choice available. In the Netherlands and Belgium these services are well developed yet the hospice movement continues to thrive.

Finally, Heath states, "I don't want assisted dying, but I also don't want a percutaneous endoscopic gastrostomy." That is her personal choice, but she should not deny patients their own choice of assisted dying if they consider their suffering has become unbearable.

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1 Heath I. What's wrong with assisted dying. *BMJ* 2012;344:e3755. (29 May.)

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Perfect art of allowing death with dignity

Heath eloquently outlines some of the difficulties that beset assisted dying.[1] In my experience, most families and carers would not coerce a person into considering the option of assisted dying and often go to great lengths to care for these people. These sacrifices made by carers are usually recognised and may lead to intense feelings of guilt, hopelessness, or even depression. This can create a potential moral obligation on the part of the patient to consider assisted dying as an option. The most vulnerable would be at greatest risk, and no legal framework could robustly prevent harm being caused.

The law would also need to guard vulnerable people against less well intentioned elements of society, especially when considering the potential financial consequences of long term care. Coercion in these cases may be impossible to detect.

The real debate should be about the nature and level of intervention afforded to people with serious conditions. End of life care in dementia is in its infancy and is riddled with

moral dilemmas that are still to be resolved. We should be concentrating on perfecting the art of allowing patients to die with dignity.

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Competing interests: None declared.

1 Heath I. What's wrong with assisted dying. *BMJ* 2012;344:e3755. (29 May.)

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● EDITORIAL, p 10, OBSERVATIONS, p32, PERSONAL VIEW, p 35

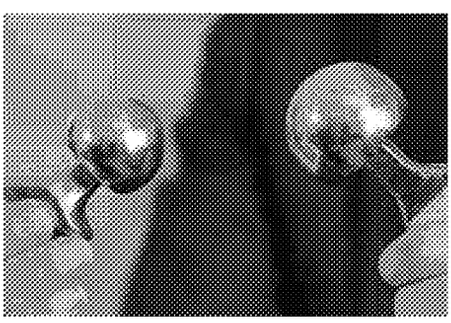
METAL-ON-METAL HIP IMPLANTS

UK quality assurance of blood metal ions after hip implants

In 2010 the Medicines and Healthcare Products Regulatory Agency (MHRA) issued a medical device alert recommending measurement of cobalt and chromium concentrations in blood from patients experiencing discomfort or pain associated with metal-on-metal hip prostheses.[1 2] This followed concerns relating to possible adverse effects of metal released from the implants. A second alert updated the advice and provided recommendations for managing patients with and without symptoms in four groups based on the type of hip replacement.[3] Accurate measurements of cobalt and chromium are imperative for implementing these alerts, both requiring that samples be sent to laboratories participating in the UK National External Quality Assessment Scheme for trace elements (TEQAS), which is accredited by Clinical Pathology Accreditation (UK).

Each month two blood specimens selected from six different pools were sent to scheme participants for analysis. During the year from April 2011 to March 2012 each of the pools was analysed on four different occasions. The pools were prepared by spiking equine blood with the metals to match patient samples and to calculate recovery of the added cobalt and chromium.

Cobalt concentrations ranged from 10 µg/L to 60 µg/L and chromium from 10 µg/L to 35 µg/L. The mean recovery for the analysis of all 20 specimens was 96.4% (SD 2.23, coefficient of variation 2.3%) for cobalt and 96.1% (3.19, 3.3%) for chromium. The excellent agreement between the amounts in the specimens and the mean values indicates that the results reported are accurate. The agreement between the pools distributed on different occasions shows that results are also reproducible.



These results should reassure surgeons and patients that the laboratories measuring cobalt and chromium concentrations are producing results that are fit for purpose.

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Competing interests: None declared.

1 Medicines and Healthcare Products Regulatory Agency (MHRA). Medical device alert: all metal-on-metal (MoM) hip replacements (MDA/2010/033). www.mhra.gov.uk/Publications/Safetywarnings/MedicalDeviceAlerts/CON079157.
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VARENICLINE'S ADVERSE EVENTS

Flaws in analysis lead to misleading conclusions

The meta-analysis by Prochaska and Hilton has several methodological limitations in data analysis and interpretation, which lead to misleading conclusions.[1] Despite the removal of cardiovascular events from the trials and a statistical approach that has limited power to detect a significant effect, there is an excess risk of cardiovascular events with varenicline in all five measures reported.

The risk difference model Prochaska and Hilton used is statistically underpowered at low event rates and biases the estimates towards the null.[2] This flawed approach is not recommended by the Cochrane Handbook, which states that the Peto odds ratio method was found to be "the least biased and most powerful method" and that risk difference analytical methods "tended to show conservative confidence interval coverage and low statistical power when risks of events were low."[3]

They analyse data by treatment level and exclude events occurring in randomised patients. By contrast, we adhered to intention to treat analysis according to the regulations and established and generally accepted scientific principles of the US Food and Drug Administration.[4] The higher dropout rate in the placebo group is irrelevant when the intention to treat principle is adhered to.

Their study does not have the optimal information size to detect a significant result. They conflate the lack of significance in an underpowered meta-analysis as clinically insignificant.

Adequately powered randomised controlled trials are needed because none of the trials evaluated cardiovascular events as a primary outcome or was powered to detect individual differences in cardiovascular outcomes between varenicline and placebo. The CATS study, a 52 week post-marketing study comparing varenicline, placebo, bupropion, and nicotine replacement therapy in around 8000 patients, should provide further information on the size of this risk.[5]

Clinicians need to consider the overall risks of varenicline noted in the prescribing information—serious cardiovascular risk and risks of suicide and depression[6]—and balance them against its benefits. The United States Veterans Administration does not recommend varenicline as first line treatment for smoking cessation.[7]

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Competing interests: None declared.

1 Prochaska JJ, Hilton JF. Risk of cardiovascular serious adverse events associated with varenicline use for tobacco cessation: systematic review and meta-analysis. *BMJ* 2012;344:e2856. (4 May.)
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Cite this as: *BMJ* 2012;344:e3873

Authors' reply

The principle in intention to treat analysis is that all trial participants be analysed as randomised and followed up to the study end point of interest. Both our meta-analysis and that of Singh et al analysed all participants as randomised.[1 2] For assessment of cardiovascular safety, we identified the period of treatment exposure plus 30 days as biologically relevant and followed up both arms for equal duration.[1] Indeed, the primary end

point of the CATS study is major cardiovascular events occurring during the treatment phase. Singh et al analysed safety using the efficacy follow-up period, which extended well after treatment and differed between study arms.[2] Consequently, the excess risk reported by them could be attributable to bias resulting from more extensive follow-up of the varenicline arm. The CATS trial, a four-group design, will have 2000 treated with varenicline, compared with 5431 individuals treated with varenicline in our meta-analysis.

Our use of treatment emergent events as the end point reduced the crude baseline event rate from 0.8%[2] to 0.5%.[1] Bradburn et al showed that the power of all summary statistics declines with this rate, including the Peto odds ratio.[3] However, inclusion of 12% more participants in our meta-analysis on the basis of the risk difference increased its relative power.[1] Both meta-analyses allocated participants 3:2 to varenicline, on average, whereas Bradburn et al examined balanced allocation.[1-3] Thus this citation does not confirm the claim that our risk difference based meta-analysis[1] was underpowered. The Cochrane Handbook[4] discourages use of the Peto odds ratio when studies have unequal allocation.[4]

A manifestation of low statistical power is a wide confidence interval. Bradburn et al showed that coverage of the risk difference increases towards 100% as event rates drop under 1%.[3] Furthermore, they reported that the risk difference method "also produces relatively unbiased estimates of treatment effects."[3] These findings increase the assurance that the true risk difference lies below the estimated upper confidence limit of 0.63%.[1] The risk difference based cumulative meta-analysis showed the excess risk estimate has changed negligibly with inclusion of the most recent 11 trials.[1]

We concur with Singh that treatment risks and benefits need to be weighed. Our four summary estimates were intended to provide transparent and comparative findings to inform decision making for tobacco dependence treatment.

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1 Prochaska JJ, Hilton JF. Risk of cardiovascular serious adverse events associated with varenicline use for tobacco cessation: systematic review and meta-analysis. *BMJ* 2012;344:e2856. (4 May.)
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4 Cochrane Handbook. www.cochrane-handbook.org/. Section 9.4.4.2.

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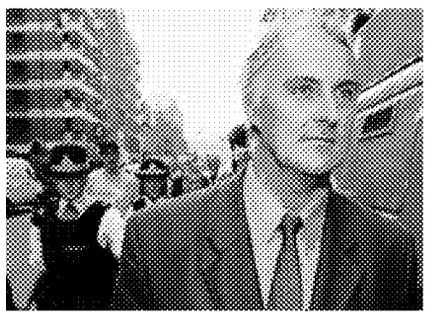
DAVID SOUTHALL CASE

Authorities should be held to account



MARTIN RICKETT/PA

Southall's wrecked career is a tragedy.[1] Unfortunately, all judicial systems (including General Medical Council (GMC) fitness to practise procedures) have their imperfections. When consultants employed by the NHS or university have to defend themselves in judicial proceedings on account of actions taken during work for the NHS or university, surely they should consider this part of the job. Doctors must recognise that the process of determining contentious issues often causes personal stress and should accept it as part of their role.

When all of these proceedings conclude with an acquittal or the absence of any case to answer it is surely wrong for the doctor to incur financial penalties. The profession should strongly support Southall in taking proceedings against the GMC to recover his probable financial loss, and the organisations of the profession—such as the BMA, his royal college and willing donors, and hopefully his defence organisation—should join in financing such proceedings. Of course, he may prefer to walk away from his nightmare, but I would hope that he would consider making such proceedings the apotheosis of his academic contribution to child protection by holding the authorities to account.

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Competing interests: MJG was a member of GMC fitness to practise panels, 2006-2009 and deputy chairman of the BMA Consultants Committee, 1997-2002.

1 Dyer C. David Southall: anatomy of a wrecked career. *BMJ* 2012;344:e3377. (16 May

Cite this as: *BMJ* 2012;344:e4024

PACA response

We endorse the excellent account of Southall's ordeal,[1] which describes "what steps have been taken to make sure no other doctor has to go through such an ordeal." Next month, the General Medical Council (GMC) issues guidance on how doctors should conduct themselves to safeguard children. However, it is the GMC that needs to change. We advise that:

- The GMC takes notice of previous inquiries by the doctor's employer and other agencies
- In child protection cases, the doctor's actions are analysed from the point of view of intended benefit to the child, perhaps by appointing an advocate for the child in the proceedings
- Any charge brought against a doctor at a full hearing should be sufficiently severe to warrant serious sanction. A suspicion of serious child abuse reported to the police, as in the Clark case, does not suggest impaired fitness to practise
- Members of fitness to practise panels hearing child protection cases should have training in its basic principles
- Experts are chosen more carefully: Professor David had defied a judicial order and Nicholson was not a bona fide expert
- The GMC should be wary of complainants' motives and have courage to resist unreasonable demands from politicians and the media.

The practice of child protection will suffer until the GMC shows that it wishes to do better.

Finally, other doctors have also suffered "prolonged suspension, traumatised personal lives, multiple GMC hearings, loss of income, career destruction and repeated vilification in the press."[1] In the UK, research and child protection work have experienced long term adverse consequences.[2-4]

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Competing interests: None declared.

1 Dyer C. David Southall: anatomy of a wrecked career. *BMJ* 2012;344:e3377. (16 May.)
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Cite this as: *BMJ* 2012;344:e4023

GMC was not "too lenient" with Southall

Although Dickson is to be applauded for his partial apology to David Southall, I wonder who advised him on his response that the GMC was "too lenient."[1]

In the Clark case, the Council for Healthcare Regulatory Excellence appealed the General Medical Council (GMC) decision, believing it to be too lenient. The court case proceeded on the basis that the panel decision was correct and leniency was judged against that background. Southall was unable to argue the merits of the case.

Subsequently, a differently constituted GMC panel considered his case, asking whether he had any continuing impairment to practise. This panel questioned many of the original panel's key findings. A criticism had been that he was precipitate in reporting his concerns. The 2008 panel explained this was wrong because there is a duty to raise child protection concerns, and they accepted the opinions of four expert witnesses, who felt that the events could have indicated non-accidental injury. On the criticism for not interviewing the Clarks, the 2008 panel heard from the experts, who said that this was not the accepted practice. There is little serious content in the rest of the criticisms, which included being guilty of failing to state in a report that he had not seen the medical records, which the recipients of the report knew; acting when barred by his trust from doing child abuse work, when he did so initially as a private citizen and subsequently with permission; and basing his concerns on a "mere hypothesis" stemming from his work on smothering, work that is widely regarded as seminal.

Therefore saying the GMC was found to be too lenient gives a less than full picture. No responsible person who has read the 2008 determination should suggest that the GMC had been too lenient on Southall.

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Competing interests: CW is a member of Professionals Against Child Abuse (PACA).

1 Dickson N. Southall: the GMC responds. *BMJ* 2012;344:e3411. (24 May)

Cite this as: *BMJ* 2012;344:e4027

ACCESS TO ANONYMISED DATA

Risk for vulnerable patients

Our practice looked into allowing all patients to have access to their records via the internet when the facility became available about eight years ago. We didn't do it in the end because we couldn't find a way to prevent potential compromise to the confidentiality of vulnerable people, such as patients under 16 years, who, for some reason do not want their parents to know they have had a discussion with the GP.

In principle the proposed access to records is a good idea and can empower patients.[1] But it will cause me concern until ministers can explain how they will get around the unforeseen consequence of young people not wanting to access primary care services for advice about contraception or unwanted pregnancy, or even to disclose abuse, because they know their parents can read their confidential medical records online.

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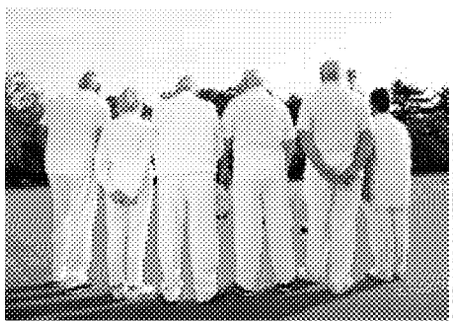
Competing interests: None declared.

1 Cross M. Anonymised data of all NHS treatments must be put in public domain by 2015, strategy says. *BMJ* 2012;344:e3648. (22 May.)

Cite this as: *BMJ* 2012;344:e4031



DIGITAL VISION/GETTY IMAGES

OLDER PEOPLE IN CLINICAL TRIALS

No more arbitrary upper age limits for clinical research

A multi-faceted approach is needed to end the systematic exclusion of older people from clinical research.[1] However, one simple measure could have a major impact—a zero tolerance policy from funders and ethics committees for arbitrary upper age limits. The use of such upper age limits is common, with 33% of papers published in four leading medical journals using explicit exclusions on the basis of age.[2] In many instances, researchers opt for an arbitrary upper age limit, without offering a scientific justification for why, for example, a 75 year old would be a suitable research participant but a 76 year old would not.

The Age and Ageing Specialty Group, supported by the National Institute for Health Research (NIHR) Clinical Research Network Coordinating Centre, has posted a statement on the NIHR public and researcher websites about equity in clinical research regarding the inclusion of older participants.[3] It aims to redress the imbalance of older people in clinical research, not only in the interests of equity, but because of the need to draw on the results of good quality research to inform best practice in the management of our growing older population. Other funders may wish to follow this lead if ageism in clinical research is not to flourish.

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Competing interests: METMcM is chair of the NIHR age and ageing specialty research group.

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Cite this as: *BMJ* 2012;344:e4046

SCREENING DEBATE

How we risk getting it wrong in cognitive screening too

McPherson asks how we got it wrong with breast screening.[1] Will we be asking a similar question of cognitive screening in 10 years' time? The discipline of public health epidemiology must be given due weight when considering cognitive screening in elderly people. Robust, repeated epidemiological findings worldwide show that more than half of elderly people with mild early memory loss do not progress to clinical dementia.[2] This group also needs consideration. A diagnosis of dementia is a life changing event: we cannot simply ignore the potential for false positive diagnoses. This is perhaps especially true for a vulnerable group like this whose voice has not been sought.

Fears have been expressed that screening based on the proposed *Diagnostic and Statistical Manual of Mental Disorders*, fifth edition, category of "minor neurocognitive disorder" may result in this group being classified as having early dementia.[3] Yet, seen from a clinical and epidemiological perspective, these patients do not have dementia—they have mild memory loss that is static (occasionally reversible), with no serious functional loss.

I support my colleagues in seeking a timely diagnosis of dementia and agree that this is a challenge that deserves serious thinking. But specialties such as mine must not ignore the wider real world sociology of ageing alongside robust epidemiological evidence. Furthermore, perhaps we need to consider lessons learnt through other early screening programmes.[4] Otherwise in 10 years' time we might be asking: how did we get it wrong with cognitive screening?

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Competing interests: None declared.

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Cite this as: *BMJ* 2012;344:e4043