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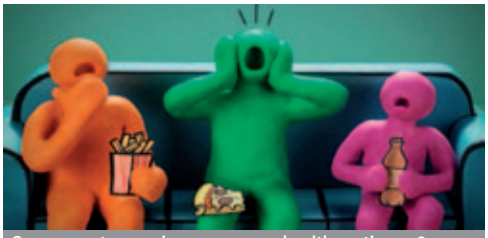

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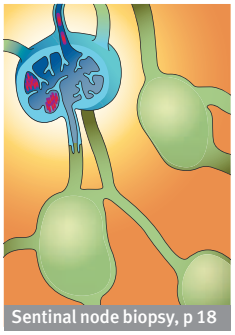

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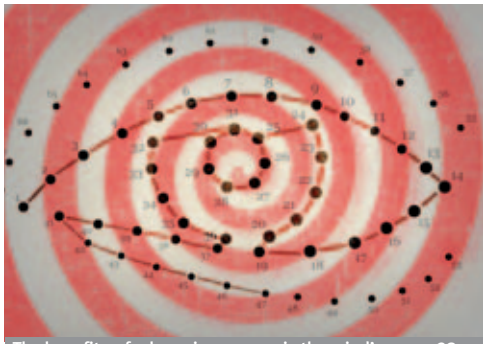
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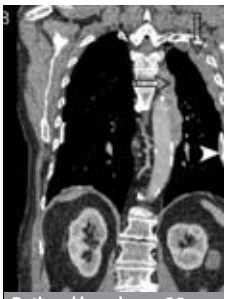
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ASER GARCÍA RADA

PICTURE OF THE WEEK

This cholera treatment facility at the Hôpital Immaculée Conception in Les Cayes, Haiti, is one of many that have sprung up in the country since the devastating earthquake of 12 January 2010, which killed some 300 000 people and displaced another 1.6 million. The disease, which was first reported in Haiti in October 2010, has claimed 7750 lives there.

RESPONSE OF THE WEEK

Since 1983 many general managers have been medically or clinically qualified. Since then, GPs have played key roles in commissioning, and medical directors have been universal. Why have they not challenged the obviously dysfunctional autocratic culture? The GMC has previously disciplined medically qualified managers who failed to protect the interests of patients. It must continue to do so. Existing voluntary management codes do require teeth but can only be effective if NHS management becomes truly independent of the Department of Health.

Sadly, my own contacts with victims lead me to conclude that the BMA is part of the problem. It treats each successive case as a unique and isolated employment issue. If it were to reflect on its experience and publish aggregated data, preferably in association with other representative organisations, we might get a little closer to an accurate diagnosis of the evidence based reasons for this deeply worrying problem.

David Michael Hands, visiting professor In health policy and management, University of Glamorgan, Pontypridd, UK, in response to "When managers rule" (*BMJ* 2012;345:e8239)

BMJ.COM POLL

Last week's poll asked: "Should everyone over 74 be screened for dementia?"

45.3% voted yes
(total 1467 votes cast)
BMJ 2012;345:e8588

This week's poll asks:

"Will expansion of the NHS abroad benefit UK patients?"

BMJ 2012;345:e8493

Vote now on bmj.com

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Gluten sensitivity: real or not?
Why Rudolph's nose is red: observational study
Inhaled corticosteroids: first do no harm
Everyone could enjoy the "survival advantage" of elite athletes
When managers rule

EDITOR'S CHOICE

Overtreatment? Only the trial data will tell

If you agree that all clinical trials should be published, sign the petition

Two *BMJ* campaigns coincide this week: for publication of all clinical trial results, and against overdiagnosis and overtreatment. Sentinel node biopsy is widely used to stage breast cancer and malignant melanoma. It carries a risk of lymphoedema and other complications, which increases if patients with positive sentinel nodes go on to have further lymph nodes removed in an effort to improve their survival. Evidence from several large trials has saved women with breast cancer from having axillary lymph node dissection if they have no clinical signs of axillary involvement: the trials found no significant difference in overall or disease free survival when axillary dissection was added to sentinel node biopsy.

But, as Ingrid Torjesen reports (p 18), patients in the UK, the US, and elsewhere with malignant melanoma routinely undergo sentinel node biopsy, followed by regional lymphadenectomy if the biopsy is positive, this despite guidance from the UK National Institute for Health and Clinical Excellence that there is no published evidence from randomised controlled trials that sentinel node biopsy improves survival.

What trial evidence there is comes from the Multicenter Selective Lymphadenectomy trial (MSLT-1). Five year follow-up data published in 2006 found no overall survival advantage in patients who had sentinel node biopsy compared with those who didn't. But controversy has arisen over the authors' claims of improved disease free survival. These claims are based on a lower rate of nodal recurrence in the biopsy group; critics say this is unsurprising, as the patients in the intervention group who are most at risk (those with a positive sentinel node) have had their regional nodes removed. The researchers promised further analyses after 10 years of follow-up and at an interim point. Had these been published as expected the controversy might have been resolved by now, but they have not yet been published. Meanwhile, sentinel node biopsy has become the standard of care in many countries. NICE says the procedure is justified only in clinical trials, but Torjesen has learnt that it is carried out in at least 19 trusts in England, only two of which are involved in ongoing trials. Is this another example of harmful overtreatment? Only the trial data will tell.

This is not the only case in which clinical trial data have been published late or not at all. Last week we reported on the long delay in publication of a trial of deworming and vitamin A that was completed in 2005 (*BMJ* 2013;346:e8558). This week in an editorial we reference a large trial of adenoidectomy that has only just reported after nearly a decade (p 8). The editorial calls for ethics committees, funders, and institutions to take responsibility for ensuring that the trials they approve, support, and host are published in full and in good time. Working with others, we are taking the campaign to patients and the public. If you agree that all clinical trials should be published, sign the petition at alltrials.net.

Fiona Godlee, editor, *BMJ* fgodlee@bmj.com

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