LIFE AND DEATH **Iona Heath**

# Do not sit on the bed

Rules that mostly diminish rather than enhance the joys of life have no place in hospitals, where joy is too often in short supply

Still trying to come to terms with the widespread banning of flowers from hospital wards (*BMJ* 2009;339:b5406), I learnt recently from senior nursing colleagues that sitting on a patient's bed, by either visitors or clinicians, is now also prohibited, apparently in the interests of infection control. A quick internet search of "sitting on the bed" and "infection control" produces a huge list of leaflets from a variety of hospital trusts across the country, from Northumberland to Cornwall, each reinforcing the prohibition. My immediate reaction is to thank all my lucky stars that I have been able to spend my career in general practice, where flowers are still welcome and sitting on the patient's bed positively encouraged.

Doctors should never be discouraged from sitting, because patients consistently estimate that they have been given more time when the doctor sits down rather than stands. Standing makes the conversation seem hurried even when it is not; and, in the hospital setting, sitting on the chair does not seem to work nearly as well, because the levels are somehow all wrong. Some of the most intimate and effective interactions between doctor and patient that I have either witnessed or experienced have occurred while the doctor has been sitting on the patient's bed. Such interactions are precious and should be made easier rather than more difficult.

This ban on sitting on the bed seems to be imposed without exception even for patients who are known to be dying. How and why has this happened? Infection control is clearly a subset of "health and safety" but needs to guard against taking on too much of its rhetoric and public face, which is increasingly characterised by its lack of humanity, common sense, and even humour. I can find no mention of either flowers or sitting on beds in the "epic2" national guidelines on preventing healthcare associated infections in hospitals in England, so the default presumption must be that there is no hard evidence for either of these demeaning prohibitions. There seems to be something very strange going on. Is it all in the interests of being seen to be doing something very noticeable about the worrying levels of hospital based infections, however ineffective and otherwise disruptive? Is this some sort of virtual cleanliness—an illusion of activity with no substance? What is the framework of pressures and constraints under which infection control staff have to work?

Too many patients report that the technological care in hospital is excellent but that the human dimension of care is often lacking. There is much talk about bringing care closer to home in the design of health services, and this is intended to keep patients away from hospitals as much as possible, which will always be a good thing because they are both expensive and dangerous places. But providing hospital treatments at home and even arranging outpatient functions in local clinics are likely to prove at least as expensive as existing services. The ever increasing subspecialisation of expertise, with a progressive narrowing of the range of skills and with performance being related to the numbers of procedures performed across this narrow range, means that the trend to centralisation seems set to continue despite the good intention of trying to reverse it. And whatever the eventual outcome of this policy paradox, many people still need the levels of care and skill and technological intervention that only hospitals can provide—and so perhaps we need to be looking at bringing care closer to home in a different sense, by bringing back elements of home into hospitals and by enforcing rules only when clear evidence exists to justify the erosion of any sense of homeliness that results.

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Home means familiarity of both surroundings and people. Patients could be encouraged to bring tokens of home into hospital rather than actively discouraged. In his great poem "The Building," Philip Larkin describes a hospital as being "curiously neutral" with "homes and names suddenly in abeyance." What can we do to make this less true? In the same poem Larkin found hospital flowers "wasteful, weak, propitiatory," but I am certain that he would not have thought their prohibition an advance. Familiar faces are an essential element of home, and yet continuity of the familiar is less and less evident on hospital wards as staff are distributed on the basis of maximising efficiency at the expense of any other virtue. One of my patients lost the will to live over a long bank holiday weekend, when each new shift brought new faces, each of whom required him to recount his frightening story all over again. Such an experience is the very opposite of home and is dehumanising not only for patients but also for staff.

So can we not campaign for home within hospital and encourage flowers and sitting on the bed and every other informality, unless there is robust evidence to deter us? "Do not sit on the bed" and "No flowers" are injunctions that are all too similar to "Do not walk on the grass" and "No ball games" rules that mostly diminish the joys of life rather than enhance them, and such rules, unless absolutely necessary, have no place in hospitals, where joy is too often in short supply.

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MEDICINE AND THE MEDIA

# Prostate screening: is the tide turning against the test?

After his *New York Times* article created a stir, the discoverer of prostate specific antigen tells **Nigel Hawkes** that the Food and Drug Administration should never have approved the PSA screening test


**Free PSA tests on offer at a health centre in Florida—but is the medical community turning against this screening?**

The UK Prostate Cancer Charity recently lamented the ignorance of British men about "a simple blood test" for prostate cancer. Seven out of 10 men, it found in a survey, were unaware of the prostate specific antigen (PSA) test and of their right to ask for one. It described this state of ignorance as "completely unacceptable."

At about the same time the man who discovered PSA, Richard Ablin, was offering the *New York Times* an opinion piece about the use to which his discovery has been put. The article, published on 10 March,[1] caused quite a stir in the United States, where the PSA test is seen by many as a birthright up there alongside life, liberty, and the pursuit of happiness.

The popularity of the test, wrote Dr Ablin, has led to "a hugely expensive public health disaster." The test was hardly more effective, he said, than a coin toss. "PSA testing can't detect prostate cancer and, more important, it can't distinguish between the two types of prostate cancer—the one that will kill you and the one that won't . . . Men with low readings might still harbor dangerous cancers, while those with high readings might be completely healthy."

The drawbacks of the PSA test are hardly unknown and in the United Kingdom have led to a "hands-off" approach in which the test is available but not actively encouraged. The risks of false positives, followed by biopsies and unjustified prostatectomies, have convinced most UK experts that PSA screening of healthy men is not justified.

But the US position is very different. "PSA testing costs at least $3bn [£2bn; €2.2bn] a year, much of it paid by Medicare and the Veterans Administration," Dr Ablin said in an interview with the *BMJ*. "I've spent 35 years trying to explain the drawbacks to people, but the dogma of screening and the money generated throughout the industry overrides some guy who says we shouldn't be doing this."

Dr Ablin, a research professor of immunobiology and pathology at the University of Arizona College of Medicine in Tucson, runs swiftly through the drawbacks of PSA as a screening tool. "First, it's not cancer specific: PSA is present in the normal, benign, and malignant prostate. Second, prostate cancer is an age related disease. If you take men between 60 and 70, 65% or more have prostate cancer.

But is it a turtle—a slow moving cancer that is never going to kill you—or a rabbit that is going to jump out of its box and spread? "We don't know. The problem is an absence of specificity. There's no real level that tells us the cancer is dangerous. The line is drawn at 4 ng per ml, but 80% of men who have PSA in the range 4-10 have benign prostatic enlargement, and for men with values below 4 the data show that 40% of them have cancer."

At best, he argues, the data from a big study that did show a saving of lives from PSA screening found that 48 men would need to be treated to save one life.[2] "That's 47 men who, in all likelihood, can no longer function sexually or stay out of the bathroom for long."

Dr Ablin acknowledges that PSA testing can have benefits, in monitoring treatment or in measuring the "doubling time" of PSA by regular testing. "The problem we've had here is that men have a single test and then are moved forward to treatment. The urologist will say, 'Joe, I've got bad news and good news. The bad news is that you've got cancer, and the good news is that we're going to cut it out next week.'"

What's the motivation? "It seems to me that financial motives have spurred a tsunami of testing," he says. "There's an unbelievable industry behind this. Unfortunately we don't practise evidence based medicine here; we do things and later rationalise what we've done by saying we thought it was the best thing to do at the time."

His stance has not always been popular. "At one meeting somebody said, 'Why don't you shut up and sit down?'" But mostly he has been cheered by the responses to his *New York Times* article. "It's been unreal. I've had upwards of 200 emails, and the *Times* says that the article is the number one requested article. The majority of people have been favourable, though some have told me I'm an idiot.

"The feeling I'm getting is that it seems like people had this huge pressure to be screened, and the people who were telling them to do this were often celebrities. Now that somebody with authority in the field has come out and said what I said, there's a tremendous feeling of relief."

He sees some evidence of a shift in opinion, with the American Cancer Society urging a more cautious approach[3]—although, "shamefully," the American Urological Association still recommends screening, and the US National Cancer Institute is vague. In the UK the Prostate Cancer Charity holds a nuanced view, saying that what is wanted is "a systematic opportunity for all men to exercise an informed choice about the PSA test." It's hard to argue against informed choice (though much depends on the quality of the information), but Dr Ablin is adamant: "This test should never have been approved for screening by the US Food and Drug Administration.

"The medical community must confront reality and stop the inappropriate use of PSA screening. Doing so would save billions of dollars and rescue millions of men from unnecessary, debilitating treatments."

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MEDICINE AND THE MEDIA

# Generic drugs: protest group was not quite what it seemed

Last month the *Times* published a letter from doctors and patients' groups warning against generic drugs and supporting branded prescribing. But who was really behind the protest? **Margaret McCartney** investigates

Generics are good for us. That's the mantra that is taught to doctors again and again: they are cheaper for the NHS but just as effective for the patient. So it was surprising to find a letter, signed by several doctors, in the *Times* last month decrying generics and pleading for doctors' choice to prescribe branded drugs to be paramount. The letter, titled "Patient wellbeing at risk from substituted generic medicines," was also signed by patients' groups such as the Cure Parkinson's Trust and the British Liver Trust and carried the names of the media doctor Patricia Macnair, Stephen Kownacki, chairman of the Primary Care Dermatology Society, and Jean Mossman, former chief executive of Cancer BACUP (www.timesonline.co.uk/tol/comment/letters/article7037957.ece).

The letter was a response to the Department of Health's current consultation on prescribing, which proposes an automatic generic substitution scheme (*BMJ* 2010;340:c135, 8 Jan). The consultation aims to find acceptable ways to reduce prescribing of branded drugs in the NHS, such as by allowing pharmacists to substitute generics in certain classes of drugs, such as statins, even when a brand has been prescribed. This, the consultation suggests, would save money without compromising the safety of patients or effectiveness of the treatment. However, there is evidence that certain branded drugs, such as treatments for epilepsy, should not be changed, and the consultation does recognise that prescribers may need to state that they do not want a switch to a generic. This seems reasonable, and we could exclude some groups of drugs altogether from a substitution scheme. So what's the problem?

Generic drugs are a threat to many parts of the industry. The European Court of Justice has recently said that drug switching incentive schemes, whereby general practices are paid to switch patients from more expensive to less expensive drug equivalents, often generics, are, in its opinion, illegal. This opinion is subject to appeal and needs to be ratified by the UK High Court, but the Association of the British Pharmaceutical Industry, which brought the case, is clearly sensing a squeeze on the branded drugs market.

Far from being a spontaneous protest from a group of patients and healthcare professionals, however, the *Times* letter was coordinated by Burson-Marsteller, a public relations company (which advertises itself, interestingly, as "evidence-based communications") that was employed in this task by Norgine, a relatively small drug company. It seems that Burson-Marsteller searched the literature, particularly free journals funded by pharmaceutical advertising, for articles written in support of prescribing of branded drugs. These authors were then invited to sign a letter protesting against generic substitution. It is, however, notable that Peter Martin, the chief operating officer of Norgine, despite being the major influence behind the campaign, did not add his name to the list of signatories. That seems to be a lack of transparency. Why didn't he add his name? "There was no conspiracy," he explains. "The frank truth, the honest truth, is that I thought that having a pharmaceutical company in there would sully the message somewhat. It shouldn't, but I thought it could."

Letters to the Editor

**Patient wellbeing at risk from substituted generic medicines**

Sir, We are concerned about the Department of Health's (DH) proposed introduction of the Automatic Generic Substitution scheme, whereby pharmacists could substitute a generic version of a medication, even if the doctor has written the prescription for a specific brand. This proposal could seriously jeopardise patient wellbeing.

There are many cases where generic prescribing is fully appropriate and helps to contain costs but there is clear evidence that, for some medicines, it may be dangerous to substitute a copy medicine for the one specifically prescribed for a particular patient.

Patient safety should be at the core of all prescribing decisions and the first priority in every case. Only the prescribing doctor or nurse knows the patient's medical history — substitutions should never be made without their consent and awareness.

The DH states that it favours limiting the scheme to selected medicines but recognises that there are risks involved. We believe that this could still compromise patient safety, and that the cost of implementation could outweigh any savings. Generic versions of an original branded medicine contain the same active ingredient, but they are not usually tested in patients before they are sold. They are tested in young, healthy volunteers to show that they are statistically "bio-equivalent" to the originator's brand but it has been shown clinically that the variability allowed means that some patients may receive a medicine that is less effective, or experience different side effects. This results in a disruption of the management of their chronic disease.

Switches in medications can also confuse patients, especially when medicines of different colours and shapes to the branded medicine, or even to other generic versions, are dispensed; particularly for elderly patients receiving multiple medications. These uncertainties can result in poorer disease control and management.

We stress that patients come first and urge the DH to respect the judgment of the prescriber.

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Executive Chairman, Primary Care Dermatology Society
ALISON ROGERS
Chief Executive, British Liver Trust
LEIGH SLOCOMBE
Chief Executive, Epilepsy Research UK
*Plus ten healthcare professionals. For a full list of signatories go to timesonline.co.uk/letters*

**Far from being a spontaneous protest from a group of patients and healthcare professionals, however, the *Times* letter was coordinated by Burson-Marsteller, a public relations company**

Norgine organised a paper to be written by a PhD writer from the PR company last year in response to the health department's proposals on pharmaceutical pricing, and it was this document that was used initially to gather support. Mr Martin believes that his company would be under direct threat as a result of increased use of generics. He offers the hypothetical example of testing Movicol (a macrogol), one of Norgine's products, for a new use, such as irritable bowel. "So we do a double blind trial, we register the trial, we do it by the book. And then, say our product works, we have a new indication on the licence. But we wouldn't do it. We would have no incentive." If a cheaper generic equivalent could be had, the risk is that Norgine would not recoup its expenses in setting up the trial.

David Candy has done research with Norgine on constipation in children. As a consultant paediatrician he believes that branded drugs have a role in this area. "We worked very carefully with Norgine," he says, "to get things right for patients. For example, we used chocolate flavouring, and the paediatric Movicol doesn't say 'for constipation' on the box, because children told us that they found it embarrassing, for example on sleepovers."

Certainly it is important that drugs are acceptable and palatable to patients, but this may also be seen as a failure of generic versions to compete properly. And while it is legitimate to be concerned that patients are happy with their drugs, it seems reasonable also to ask how much the drug industry is allowed to press for non-generics. The Cure Parkinson's Trust, the Primary Care Dermatology Society, and the British Liver Trust, for example, have all received funding from various drug companies. Some of the doctors who signed the letter have also advised drug companies or received research funding from them.

If freedom to prescribe less cost effective drugs is of such importance to grassroots doctors and patients, why did an anti-generics campaign have to be coordinated by a drug company at all?

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