Managing alleged performance problems — are we ready?

'Success on any major scale requires you to accept responsibility... in the final analysis, the one quality that all successful people have... is the ability to take on responsibility.'

Michael Korda

POOR performance is perhaps the most pressing problem facing the medical profession; the combination of high profile failures of care and criminal activity has meant that every doctor is potentially under scrutiny.[1-3] One common element in all these cases was a failure by a person, or persons, to act when they knew something was going wrong. Often a lone voice was ignored or worse, shunned.[4] The medical profession has apparently failed in its responsibility to protect patients from poorly performing doctors. What can be done?

At a recent conference held in London the whole tangled mess of managing alleged poor performance was considered. If there was one message that came loud and clear from the speakers it was that nobody has yet got the issues sorted out; a mixed reassurance for those present. What else did the delegates learn?

No doctor, except a malign few, rises in the morning and thinks; 'I'll do a bad job today'. British general practice has much to celebrate, perceived by outside observers to be among the best in the world.[5,6] General practitioners (GPs) are working hard, so is it fair to ask them to shoulder the added, and difficult burden, of managing poor performance? Yes — otherwise as professionals we will have failed. Only by accepting responsibility will some of the relentless criticism stop and we can begin to *succeed* again.

Although this problem is worldwide, the United Kingdom (UK) seems to be most fraught with difficulties. With the apparent tardiness of the profession to put its house in order (for example, with delays in revalidation), the UK government has acted by introducing the National Clinical Assessment Authority (NCAA) for England.[7] The NCAA will offer advice and provide assessments on doctors, although it will not actually intervene to improve performance. Their capacity for assessments is limited and the NCAA sees local performance procedures as crucial.[8] It is local organisations then that will do most of the work, and with the demise of health authorities, the burden shifts to primary care organisations.[9] Following the publication of the School of Health and Related Research (ScHARR) report on managing alleged performance problems, a number of health authorities set up new performance groups or panels, while a few refined their existing ones.[10] While some authorities developed particular expertise, for others the implementation was patchy. It is uncertain whether every primary care organisation will have the capability, let alone capacity, to manage alleged performance problems. Further, local medical committees, many of which have experts in performance problems, appear in some cases to be sidelined.

Being identified as a doctor who might be performing poorly is a serious matter — for most it is the nadir of their career, and for some it is the final and tragic breaking point.[11] Therefore, any system that is used to manage alleged performance problems should be cognisant of the effects it may have on those being investigated.

Considering the stages of managing alleged performance problems, it is the assessment process that is most talked about. It must be fair and comprehensive and must always assess the doctors within the context of the system in which they work. Many failures of care are not due to one person but a whole series of problems within the system in which they work. Poor performance often has a complex aetiology that needs untangling carefully. Part of the assessment process should include an occupational health assessment. It is appalling that it is only now that an occupational health service is being introduced for GPs. From the experience of the GMC performance assessment system, it is clear that many doctors who underperform are ill, and these illnesses are not always the expected problems of depression or substance abuse. For some it is undisclosed cancer or chest pain from uncontrolled angina that limits their ability to perform. What kind of system is it that allows this to happen?

While assessment is better understood, interventions to improve performance are more difficult. There are often many issues that need addressing and it is not always clear if they work; the assessment process may just be the performance equivalent of opening Pandora's box. Further, the issue of resourcing interventions is far from clear. If a surgery needs renovating but the primary care organisation has no funds, then who is responsible for the continuing poor performance? From the legal perspective of the 1999 Health Act it is clear that primary care organisations have a statutory duty to deliver a 'quality service'.[12] If the problem is in part thought to be due to a large list size then given that the current contract encourages this perverse behaviour, who compensates the doctor, or indeed, should the doctor be compensated, if he or she reduces the list size? When practices are supported in this manner, how will the primary care organisations ensure equity for other practices?

The legal system does not help the process as it does not distinguish between systemic and individual failure; on the contrary, it seeks to find someone to blame (and this pervades our society as a whole). But if we as a profession want to encourage a systematic and supportive approach then we must accept responsibility — we have, as one of our duties of a doctor, a duty of candour.[13]

Part of the responsibility could be laid at the feet of medical colleges who have colluded in not dealing with the problems of poor performance.[14] By setting standards, and providing educational opportunities that address high fliers, they tacitly assumed that this would bring the poor performance tail along with it. It has now become clear that this simply does not work. Recognising this, the RCGP, for its

part, has done three important things: first, by defining both acceptable and unacceptable General Medical Practice for GPs we now have a clear idea of what we should and — more importantly — should not be doing;[15] second, by producing a toolkit for the management of alleged performance problems, the RCGP has indicated a positive approach;[16] and lastly, with the use of Quality Team Development programme by primary care organisations all across the country, which — although not designed for the purpose — is successfully engaging and seeing improvements in practices about whom there were concerns.[17] Perhaps we are beginning to accept responsibility. Maybe we will succeed.

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Antibiotic treatment for cystitis

MANY readers of the study performed by Christiaens *et al*[1] will probably ask whether it was ethical to offer placebo for cystitis, a disorder that has been universally treated with antibiotic drugs for decades.

A revision to the Declaration of Helsinki,[2] although formulated by the World Medical Association (WMA) after the study was performed, can help us address this question. The revision, adopted in 2000, stated that a new treatment should be tested against the standard of care (and not against placebo). However a year later, the WMA clarified its guidance on placebo-controlled trials.[3] The use of placebo in a trial is deemed to be justified 'where for compelling and scientifically sound methodological reasons its use was necessary to determine the efficacy or safety of a prophylactic, diagnostic, or therapeutic method; or where a prophylactic, diagnostic, or therapeutic method was being investigated for a minor condition and the patients who received placebo would not be subject to any additional risk of serious or irreversible harm'.

Both conditions are fulfilled for cystitis. There are detriments associated even with a short course of antibiotics: patients might suffer from adverse effects; they pay (directly or indirectly) the cost of the medication; and they know that consumption of antibiotic drugs is probably driving resistance. To balance that, we do not know whether antibiotic treatment is efficacious in relieving complaints. It probably does not prevent short or long-term serious morbidity.

Adverse effects are an important consideration for a treatment that aims mainly to achieve control of symptoms. Many antibiotic drugs given for cystitis are associated with common and mild adverse events, but also with rare and severe ones. In the present study,[1] the minor side effects associated with nitrofurantoin were not different from the ones reported in the placebo group. Nitrofuratoin will rarely cause a severe complication (for example, pneumonitis, pulmonary fibrosis or hepatic failure).[4-6] The rate of hospital admissions related to complications of nitrofurantoin was estimated as six per 10 000 defined daily doses, but it was among the highest when compared with other drugs.[7] Patients should be aware of the risk (albeit small) for a serious complication, especially for a drug given mainly for symptomatic relief.

The cost of three days of treatment with an oral drug for cystitis is a minor consideration in most high-income countries.

Exposure to antibiotic drugs induces resistance to antibiotics in micro-organisms. In patients with bacterial infections, the odds for a resistant pathogen are greater if the patient has been treated with an antibiotic drug in the past 30 days.[8] For a healthy woman with a first episode (or a few episodes) of urinary tract infection this will probably not be an important consideration. The use of antibiotic drugs also increases the percentage of resistant micro-organisms in the population, but the levels of resistance to nitrofurantoin are almost steady over the years and resistant micro-organisms are rarely detected, even during long-term treatment.[4,6]

To balance the detriments, we should provide women with a measure of the benefits. To the best of our knowledge, cystitis in adult women has no serious sequelae, and antibiotic treatment of cystitis does not prevent short or long-term morbidity. Pyelonephritis following acute cystitis is a rare occurrence, but available data are poor.[4] Out of 88 patients with bacterial cystitis who agreed to postpone treatment for two days, none suffered from pyelonephritis.[9] Acute

pyelonephritis is seldom reported in studies as a sequel to failure of treatment of cystitis.[10]

Simple urinary tract infection and bacteriuria in healthy women probably do not lead to kidney damage.[4,11,12] Thus the main benefit of antibiotic treatment of cystitis is symptomatic relief. Till the present study, we could offer no assurance to our patients that antibiotic treatment will gain them relief of symptoms.

There are detriments associated with antibiotic treatment (some of them, albeit rare, are quite severe). We have no measure for the benefit afforded by the treatment, if at all. The women given placebo were not exposed to a risk of serious or irreversible harm. Therefore a well designed placebo-controlled trial of antibiotic treatment for cystitis in otherwise healthy women, using symptomatic relief as the main outcome, was ethically justifiable.

The study by Christiaens *et al*[1] raises another ethical concern. The participants in the trial were not provided with written information and were not asked to sign a written informed consent. Written information and signed informed consent are of utmost importance. They allow the research ethics committee to assure that full information is transmitted to the participant, and help the researcher to formulate, carefully and at leisure, any ethical problems and solutions related to the study. The participant is free to study the information in his or her own time, to ask for counsel, and keep a copy for future reference.

At the time the study was conducted, the research ethics committee did not ask for a written informed consent. The study did not violate practices of ethical research that were then in use. But it should serve as a reminder that written information and a signed informed consent are indispensable conditions for present research.

If the study passed the ethical threshold, what can we learn from it? Antibiotics do offer symptomatic relief. In the present study, 30 out of the 34 patients (88%) treated with nitrofurantoin for three days and available for follow-up were free of symptoms or improved seven days later, compared with 17 out of 33 patients (52%) given placebo ($P = 0.001$). In an intention to treat analysis, the percentages were 75% and 45% ($P = 0.006$). The number needed to treat is around three patients.

Cystitis can cause significant distress and symptomatic relief is important to patients.[13] It was therefore appropriate for the investigators to choose symptomatic relief — and not bacteriological cure — as the main outcome.

It is of interest to note that one patient in the placebo group (2.6%, 95% confidence interval [CI] = 0.07% to 13.8%) developed pyelonephritis, versus none in the treatment group — an approximate relative risk of 2.1 (95% CI = 0.2 to 22.8). The wide confidence intervals underline how little weight can be placed on a single occurrence.

The confidence that we can place in the results of the study is high, as the methodology of the study was robust. The allocation to groups was by a list of random numbers, and was concealed from the recruiting physicians. It was a double-blinded study. The fact that adverse effects were reported with the same frequency in the control and in the intervention group strengthens the claim that the blinding was adequate. The inclusion and exclusion criteria show that the study population is comparable with the general population of healthy women with cystitis.

The percentage of dropouts was high: 15% of the participants in the intervention group and 13% in the control group. However, whether we count all dropouts as failures (intention-to-treat analysis), or count them as successes, the difference between the treatment and the placebo group is significant. Even if we were to count all dropouts in the treatment group as failures, and all dropouts in the placebo group as successes, the rate of success in the treatment group would be higher. All the data needed to perform the calculations are provided in the article.

Should more placebo-controlled trials on treatment of cystitis be conducted? Probably not. However, information can be sought in observational studies. Two questions are worth addressing: How many women with untreated cystitis — or with cystitis that was treated with an antibiotic drug that did not match the susceptibility of the infecting bacteria — will suffer from pyelonephritis in the near future? What is the spontaneous cure rate of these women?

In summary, the study by Christiaens *et al* raised two important ethical issues. Are we justified in testing generally accepted practice by means of placebo-controlled trials? The answer is probably yes, if the balance of benefit and harm for the treatment is unknown and cannot be assessed by other means and if the participants in the placebo group are not subject to any additional risk of serious or irreversible harm. Written information and signed informed consent should be an integral part of any trial. The final justification for the trial is the information it provides. At a time when patients are more reluctant to take any treatment unnecessarily, it has provided valuable quantitative data on the probability of any woman with a urinary infection being helped by a short course of antibiotics.

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Boosting influenza immunisation for the over-65s

EVERY healthcare professional recognises influenza as a highly contagious acute viral disease of the respiratory tract affecting all ages, and in most years less than 15% of adults.[1] When influenza virus is known to be present in the community, laboratory tests confirm influenza virus in two-thirds of patients with signs and symptoms of the disease.[2] The respiratory complications includes viral pneumonitis, secondary bacterial pneumonia, and croup, as well as bronchiolitis in young children. Non-respiratory complications include Reye's syndrome, myocarditis, encephalitis and Guillain-Barré syndrome. The patients most at risk are those whose resistance is reduced by age or other underlying illness.

Influenza in older people is a major cause of hospitalisation and mortality during winter months. Even in a non-epidemic year, it is estimated that as many as 3000 to 4000 deaths in the United Kingdom are attributed to influenza. Over 80% of deaths occur among people over 65 years of age.[3]

Studies have shown that influenza immunisation produces a reduction of more than 50% of cases of respiratory illness, pneumonia, hospitalisation, and mortality. A UK study has shown that immunising patients against influenza can reduce mortality by about 40% and repeated annual vaccinations can reduce mortality by 75%.[4] One American study has shown that, for each season, among elderly patients receiving the vaccine, rates of admission to hospital for pneumonia and influenza were reduced by between 48% and 57%, and those for all acute and chronic respiratory conditions by between 27% and 39%. Mortality from all causes was reduced by between 39% and 54%. The direct cost savings attributable to influenza vaccination in this study averaged US $117 per patient for each of the 41 418 people immunised during the three years of the study.[5]

In the United States, influenza vaccine is now recommended for everyone aged 50 or over, regardless of the presence of chronic illness. There is increased prevalence of high-risk conditions among people in this age group. Those aged between 50 to 64 years who do not have high-risk conditions also benefit from vaccination through decreased rates of influenza, decreased absenteeism from work, and decreased need for medical visits and medication, including antibiotics. This is certainly the right policy for the UK.

The present UK national policy set by the Department of Health continues to be for annual immunisation of all people over the age of 65 years, and 'high-risk' patients for whom influenza is more likely to be a serious or complicated illness, regardless of age (patients with heart, respiratory, or renal disease, those with diabetes, asplenic patients, and the immunosuppressed).

We need to remember to target also those who can transmit influenza to those at risk and the over-65s. These include physicians, nurses, health visitors, personnel in both primary and secondary care, the emergency response workers, employees of nursing homes and other long-care facilities, carers, and others.

The over-65s influenza immunisation programme was introduced by the Department of Health in the winter of 2000/2001, when over 90% of health authorities achieved the set target of at least 60% coverage. This was increased to 65% in 2001/2002. It is possible that an advisory target of 70% of those aged over 65 years will be set for 2002/2003.

So, how can practices boost their influenza immunisation rates? This issue of the *BJGP* contains reports from three studies examining different methods for boosting immunisation rates. Arthur *et al* found that, although offering influenza vaccination as part of an over-75s health check, carried out by the practice nurse in the patient's home, had a moderate effect on increasing uptake of the vaccine, the improvement in uptake was more marked for those who do not routinely come forward for vaccination.[6] The value of this paper is its success in vaccinating more elderly than we would have normally been able to reach.

Hull *et al* targeted low-risk patients in East London practices aged between 65 and 74 years, who had not previously been in a recall system for influenza vaccination.[7] Their patient intervention group received a telephone call from the practice receptionist, offering an appointment at a nurse-run clinic. Such an intervention resulted in a 6% uptake boost.

Siriwardena *et al* targeted practices rather than patients.[8] All participating practices received audit and feedback. The intervention practices were offered and received an educational outreach visit lasting no longer than an hour and based on the principles of academic detailing. Improvements in influenza vaccination, although greater in the intervention group, did not reach statistical significance, while pneumococcal vaccination uptake did. This study also reminds us of the need to remember to vaccinate the groups at risk against pneumococcal infection, which are very similar to those for influenza but with the addition of patients with liver disease (I would add also patients with alcoholism).

In order that we try and find out ways of boosting our prac-

tice influenza immunisation rates, we need first to understand the barriers to immunisation from the patient's point of view (Box 1).

- Considering influenza as a mild disease
- Hoping one will not contract influenza
- Doubts about the effectiveness of the vaccine
- Fear of vaccine side effects
- Fear it will "give them 'flu" — in fact all vaccines can cause a "'flu-like illness" as a side effect
- Lack of campaign awareness
- Apathy
- Unable to attend — housebound, in nursing or residential homes
- Inconvenient timing of immunisation clinics
- Lack of posters in the practice
- Lack of information material for individual patients
- Lack of a sustained media campaign

Box 1. Barriers to a successful influenza campaign among the over-65s.

If improvement of our immunisation rate in the over-65s is what we are aiming for, then we shall have to accept that no single measure is enough to achieve this. The three papers published here all showed modest improvements in uptake, but such increases might be enhanced by an approach using a variety of methods and sustained over several years. The choice of methods will depend on the local resources available, together with information on which precise subgroups are to be targeted. Other methods include personal invitations, messages on repeat prescriptions, new patient checks, identifying and reminding non-attenders, opportunistic contacts, dedicated nurse-led clinics, use of publicity material (hard copy and electronic), and using both practice publicity materials and local media. There will also be opportunities for primary care organisations to coordinate local campaigns and disseminate good practice.

Immunisation of the over-65s is an important task of the primary care team, preventing morbidity and mortality from the complications of influenza. The final factor to help practices is to remind themselves of the real, but invisible benefits that their efforts achieve.

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