OBSERVATIONAL EVIDENCE FOR DETERMINING DRUG SAFETY

Too high a pedestal

Freemantle and Ir are wrong to say that only properly randomised trials can provide truly reliable evidence on adverse events, just as these are the only source of convincing data on drug efficacy. Harms due to drugs differ from benefits in several ways: they are multifarious and affect fewer individuals, some of whom may have particular susceptibilities. Harms often cannot be identified in advance. In some cases these features militate against the practicable use of randomised trials.

If observational studies show no evidence of harms, randomised trials are certainly necessary. They are always desirable, and some adverse effects can be elicited reliably only in this way. However, there are examples of anecdotal reports that provide definitive evidence of both harms and benefits, making randomised trials unnecessary. There are also examples of adverse effects that have only emerged from observational studies, having failed to be elicited by randomised studies.

If an observational study suggests a serious adverse effect, it would be hard to justify studying it in a randomised trial. If the benefit to harm balance is unknown, and may be unfavourable, erring on the side of caution is justified. Should we ignore evidence of an adverse effect, rare but with a high mortality, in preference to the evidence from trials, which are randomised trials unnecessary? Picking signal from noise. BMJ 2007;334:349-51.

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Incapacity, work, and benefits

Incapacity benefit should not be seen as a payment for being unable to carry out any work at all owing to illness. Instead it is seen by most claimants as a form of income support and as a gateway benefit to other state support such as housing and council tax benefits. This package can typically amount to over £700 each month. It is easy to claim and requires only a medical certificate to allow payment by direct bank transfer. No further evidence is initially required, and recipients do not need to sign on at regular intervals. There are powerful incentives to continuing the claim as benefit levels increase after one year, and returning to paid work may entail a drop in income or at best a small increase as all benefits are lost.

It is extremely difficult for a general practitioner to refuse a sick note request for incapacity benefit and to be impartial when giving advice. Certificates for incapacity benefit are not statements of incapacity for all work but really just confirmation that the patient has consulted a doctor and requested a certificate. In my experience more than 90% of claimants are able to do some type of work, and in fact many do so unofficially.

From this, the single most important way to help recipients of incapacity benefits and new claimants is to take GPs out of the requirement to provide long term certification, and payment should not be dependent on them. A GP may be asked to provide an initial certificate to a patient, so that he or she can access the system, but payment should be made only after assessment by an independent doctor and confirmation that the claimant is unable to work in any way at all.

The patient should then be assessed regularly before further payments are made. Assessments should be functional, and if some type of work is possible then further help and advice about finding work can be given. Other considerations are secondary but may be important. I have concerns about benefits increasing after 12 months as this may contribute to long term claims. The linkage to other benefits may also need to be addressed to reduce the “poverty trap.” But fundamentally the most important measure is to remove the link between GP certification and benefit payments.

1 White C. Report calls for shake up in management of sick notes. BMJ 2008;336:631. (22 March.)

HELICOBACTER PYLORI TEST AND TREAT VERSUS PROTON PUMP INHIBITOR

Role of H pylori in dyspepsia

The main conclusion to be drawn from the study reported by Delaney et al is that no benefit at 12 month follow-up of dyspeptic patients is to be derived from eradication of Helicobacter pylori combined with a four week course of a proton pump inhibitor compared with a four week course of proton pump inhibitor alone.

The message is surely that cases of persistent dyspepsia need investigation. Almost certainly, several of these patients would have duodenal ulcers. With this in mind, it would be very interesting to know what the findings were in the group of 99 patients who had eradication treatment for H pylori, and particularly the 57 patients in whom the eradication was confirmed, as almost certainly some of these would have duodenal ulceration and should have benefited from the eradication therapy. This information is not available.

Another message is that this study suggests that H pylori infection is not a causal factor in dyspepsia. In a different context, this is consistent with the view that H pylori is not a causal factor in duodenal ulceration but is a secondary infection, causing delay in healing.

REPORT CALLS FOR SHAKE UP IN MANAGEMENT OF SICK NOTES

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and chronicity. Eradication of the infection leads to healing.1,2

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Competing interests: None declared.


2 Hobsley M, Tovey FJ. Helicobacter pylori: the primary cause of duodenal ulceration or a secondary infection? World J Gastroenterol 2001;7:149-51.


A CRISIS OF CONFIDENCE

Failing to explain basics can only undermine confidence

The General Medical Council’s guidance says that most people understand and accept that information must be shared within the healthcare team in order to provide their care, a part of the guidance that Sokol conveniently overlooks.1,2

Sokol suggests that patients will know this from observing practice in hospitals, and watching medical dramas on television; to ask doctors to provide leaflets explaining how information will be used, or to explain face to face, would be too tedious and time consuming for doctors.

Most young people’s expectation is that doctors will share their information with parents, social services, the police, and others. Many older people’s formative experience of health care is that of the singlehanded general practitioner, whose notes serve only as personal aide mémoire. And a substantial number of Western health care (or less than accurate perceptions of health care) media) about the uses to which their personal data of a colleague may be motivated in other instances by curiosity or even malice. Healthcare personnel are especially vulnerable to confidentiality breaches owing to their profile in the workplace and the ease of inappropriate browsing by others in the organisation. Legislation, guidance, local rules and the General Medical Council’s Good Medical Practice are not enough. Each day a healthcare professional logs on for the first time, a reminder should appear that they should only access data or images of a patient when they can, if challenged, justify their role in the patient’s care and the need for such access. It should be made clear that such access is monitored; inappropriate access will be investigated, and, if justified, disciplinary action will follow.

Access to records and images of healthcare staff should be externally audited. Such a strategy is necessary to ensure healthcare staff do not delay seeking diagnosis and treatment for illness because of fear of job security through current potentially porous and unmonitored access to their data. Such delay could compromise patients’ safety as well as the wellbeing of healthcare personnel.

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Competing interests: None declared.

1 Sokol DK. A crisis of confidence. BMJ 2008;336:639. (22 March.)

DO WE NEGLECT PATIENTS WITH MULTIPLE HEALTH PROBLEMS?

Doctors do their best not to

Doctors used to be criticised for talking about “the appendix in bed.” The criticism was of the reduction of a human being to a single symptom or condition. Yet at a time when the NHS is talking ever more about “patient centredness”1 it adopts payments systems that reduce patients who have many problems and illnesses to “the patient with a right shoulder problem.” It leads to the absurdity in hospital clinics well captured by Anwar et al.2 In primary care it leads to referrals that go, “Thanks for dealing with his left knee. Please will you next sort his right knee out.”

The attempt by health economists and management to reduce medical care of human beings to bite sized chunks that can be completed, counted, and billed will lead to some odd consequences. At a time when doctors are moving away from seeing all illness as acute finite problems, and towards the appreciation of complexity,3 continuity, and comorbidity4 of patients we have a management system laid across us that goes back to the old model of fixed, finite events in otherwise normal people.

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Competing interests: PGP is a GP whose practice receives income via a directed enhanced service for practice based commissioning.


Vulnerability of healthcare staff

Sokol’s experience of his own scan being reviewed by a “friend working in a different part of the hospital” is not unique.1 Although such activity may in the author’s case have been well intentioned, access to electronic healthcare data of a colleague may be motivated in other instances by curiosity or even malice. Healthcare personnel are especially vulnerable to confidentiality breaches owing to their profile in the workplace and the ease of inappropriate browsing by others in the organisation. Legislation, guidance, local rules and the General Medical Council’s Good Medical Practice are not enough. Each day a healthcare professional logs on for the first time, a reminder should appear that they should only access data or images of a patient when they can, if challenged, justify their role in the patient’s care and the need for such access. It should be made clear that such access is monitored; inappropriate access will be investigated, and, if justified, disciplinary action will follow.

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DOCTORS WARN OF PREMATURE MOVE TO POLYCLINICS

Joined-up thinking?

There are many potential problems with polyclinics (or Darzi’s karzies, as I like to think of them), but the most obvious is the effect they could have on the environment.1 My practice operates two village surgeries, and I estimate that at least 50% of our consultations are with patients who have walked to surgery. A polyclinic combining local practices would be based about 15 km away. As we can see about 300 patients a week, this means an extra 150 car journeys of 30 km or more, which adds up to roughly 4500 km worth of CO₂ per week. Replicate this around the country, and you have a figure that would make a nonsense of the government’s plans to reduce emissions.

Equally irritating is the fact that, whenever they are asked, patients express a clear preference for local surgeries staffed by familiar faces who understand their hinterland. The government seems hellbent on delivering the opposite—soulless bucket shops where the patient is seen as a series of ticks on a computer protocol. Naturally, the preferred provider of these delightful institutions is “anybody but the NHS.” Makes you understand how revolutions start.

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Competing interests: None declared.

1 O’Dowd A. Doctors warn of premature move to polyclinics. BMJ 2008;336:635. (22 March.)