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While few clinicians would doubt that there is some treatment efficacy and effectiveness for both older and newer agents, given that there is a vanishingly small amount of RCT data to establish these points, it must be clear that any attempt to move beyond this state of affairs to proper comparator studies between compounds raises the level of complexity of the evaluative exercise exponentially. It should also be clear that assessments of what treatments have been doing for the past 50 years have depended on clinical judgements, informed by visible factors such as return to work and feedback from patients, rather than judgements informed by clinical trial data. The megadose regimens of antipsychotics used during the 1980s illustrate the scope of factors other than clear benefits to patients to influence perceptions of outcomes. In addition to biases from theoretical preconceptions, a growing company outlay, currently estimated at approximately £8000 per doctor per annum in Western medical settings (Kirkpatrick, 2000), is unlikely to be without effect on how clinical outcomes are perceived and trial data interpreted.

We please ourselves with notions that a greater use of RCTs has ushered us into an era of evidence-based medicine. In fact, there is every reason to believe that far from stopping therapeutic bandwagons in their tracks, RCTs and the guidelines that stem from them have latterly become the fuel for new bandwagons. What should clinicians and budget holders do in the circumstances? There is little they can do. It might be possible to get a consensus for guidelines stating that high dose antipsychotics are not desirable. But does high dose include the 30 mg and more of olanzapine per day widely used at present or the combination of olanzapine with other antipsychotics in both oral and depot form? And what about the use of these agents for mania and for personality disorders? The government at present chides psychiatrists for shirking their duties in minimising risks to the public from patients with psychoses and personality disorders. Over and above the effects of any of the newer agents on schizophrenia processes, there lies the fact that these agents control behaviours. How will health care purchasers, providers and the government react, if, following the next attack and death in the community, the media latches on to the fact that the perpetrator was maintained on haloperidol 2.5 mg per day?

The current situation indeed, for two reasons, perhaps offers purchasers and patients the best they can hope for. First, companies are openly advocating lower doses of antipsychotics and monotherapy. Second, our ignorance of how these new agents actually mediate their effects means that, temporarily at least, clinical observations of patient benefits are probably more influential than theoretical preconceptions in tailoring appropriate treatments.

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"Nobody ever expects the Spanish Inquisition" (Python, 1991)†

Guidelines are systematically developed statements designed to help practitioners and patients make decisions about appropriate health care for specific circumstances (Jackson & Feder, 1998). 'Help' is an important word. Guidelines/guides, in most instances, may suggest a road to take in order to travel from A to B, and make explicit why those suggestions have been made. Provision of this information respects the traveller's ability to assimilate the information, and make decisions on applicability. The traveller is then not constrained by information but helped by it. At the end of the day, for clear reasons, a different road may be chosen.

Should guidelines be used unthinkingly to dictate practice, then the worst fears of both those with antipathy to evidence-based medicine (EBM), and those who support EBM are realised. Practitioners hostile to their perceived impressions of evidence-based practice will see inappropriately constructed or implemented guidelines as constraining of clinical freedom, often drawn up by those losing touch with 'real world' medicine and cries of 'dictation by numbers' will be heard throughout the land (Grahame-Smith, 1995). On the other hand, the accusation of 'dictation by numbers' – justified if guidelines are used as stipulations for practice – will also disturb those who wished EBM to be the "conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients" (Sackett *et al*, 1996).

Readers of guidelines should make up their own minds whether guidelines "made explicit identification of

†See editorial, pp. 281–282 and pp. 284–286, pp. 287–288, pp. 289–290 and pp. 290–291

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the major decisions, relevant to patients . . . and the possible consequences of these decisions" (Jackson & Feder, 1998). The same authors go on to describe the second component of successful guidelines, which "involves bringing together the relevant, valid evidence that clinicians need to make informed decisions at each of the key decision points" and the third as "the presentation of evidence and recommendations in a concise, accessible format" (Jackson & Feder, 1998).

UK psychiatrists can expect to hear a lot more about guidelines in the near future since, for example, the National Institute for Clinical Excellence (NICE) has been charged with either producing or giving its seal of approval to externally produced guidelines (Secretary of State for Health, 1998). Similarly, we await the publication of important evidence-based guidelines commissioned by the Royal College of Psychiatrists (2001), which may or may not form the basis of guidance issued by NICE.

The task of producing guidelines that are relevant, valid and useful to clinicians in making informed decisions will be, at best, challenging. Most of the randomised knowledge-base in psychiatry consists of trials, produced or funded by the pharmaceutical industry, and designed to meet licensing requirements, rather than the needs of UK clinicians. Difficulties begin when extrapolating these data to the real world, because patients whom we would recognise from our own practices would never make it into these trials owing to exhaustive exclusion criteria. Difficulties continue when we find that the success or otherwise of treatment has been judged using complex rating scales that are never used in the real world, and the results of which are difficult to interpret. The situation might be improved if trialists asked simple questions, such as whether patients feel any better, or recorded whether a drug kept patients out of hospital or in housing or out of trouble with the police. Finally, we are forced to make a leap of faith when judging the results of such research, when most studies of, for example, newer anti-schizophrenia drugs, lose between 30% and 50% of their participants over the 6-week duration of the research (Thornley & Adams, 1998; Adams & NHS Centre for Reviews and Disseminations, 1999). Trialists commonly assume that those who leave studies before completion remain stable. This may be true, but it seems unlikely, and the consequence, or validity, of this assumption is difficult, or impossible to test. This is especially the case when continuous measures (mostly scale-derived) are presented in preference to dichotomous (better/not better, yes/no) outcomes.

The research that might form the evidence-base of truly valid and relevant guidelines has yet to be conducted, and is unlikely to be conducted until real world evidence or clinical and cost-effectiveness (not just efficacy) is demanded by drug licensing bodies. Summarising evidence and transforming it into guidelines is a necessary but insufficient first step in influencing clinical practice (the ultimate aim of any guideline). Recent research suggests that well-constructed guidelines in the sphere of mental health are best ignored, even when accompanied by quite complex and well thought out implementation strategies (Thompson *et al*, 2000).

The nightmare of edicts from on high, making more of evidence than is justified, and being ignored, was cleverly parodied by the most august Nigel Molesworth writing in the *British Medical Journal* (Molesworth, 1998):

> "Some say all EBM-ers are arrogant, controvershal and seducitve. Others say they are parasites and alkemists. Also many hav beards (my observashun). This is called evidence. Others say: we do not lik all this meat analysis, giv us more bad old reviews the wors the better."

Molesworth continues,

> "EBM doctor then cry 'but you must follow guidlines' and non-EBM doctor pull out guidline written on parchmint, blow off dust and read out loud: 'This license the bearer to do what he or she likes, singed, Samule Peeps'." (Molesworth, 1998)

It would be a shame if guidelines produced from limited and largely irrelevant data were to cause clinicians to retreat to parchment-based medicine and away from the "conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients" (Sackett *et al*, 1996).

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