

VIEWS & REVIEWS

PERSONAL VIEW

Guidelines can harm patients too

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The clinical entity of guideline fatigue syndrome has already been described in the BMJ: "a debilitating condition characterised by irritability and overwhelming lethargy in the presence of guidelines." My own chronic guideline fatigue syndrome underwent an acute exacerbation recently, with the arrival of another set of guidelines in my email inbox. On reviewing the level of evidence provided for the various recommendations being offered, I was struck by the fact that no relevant clinical trials had been carried out in the population of interest. Eleven out of 25 of the recommendations made were supported only by the lowest levels of published evidence (case reports and case series, or inference from studies not directly applicable to the relevant population). A further seven out of 25 were derived only from the expert opinion of members of the guidelines committee, in the absence of any guidance to be gleaned from the published literature.

Quite deliberately, I'm not naming the particular set of guidelines detailed above. I've no wish to single out the committee responsible, since these guidelines are typical: in large published datasets, it has been found that about half of practice guidelines are based on low level evidence or expert opinion.^{2 3}

Although guidelines have been with us for many decades, they have grown in popularity along with the concept of evidence based medicine. Guidelines committees are cast in the role of distilling evidence from the relevant literature to reduce it to a bullet pointed list or flow diagram, allowing busy practitioners to move on from practice based on mere anecdote and opinion. But half of the guidelines currently being published are based on little more than anecdote (case series, extrapolation from other populations) and opinion.

Guidelines, like other therapeutic interventions, should be considered in terms of balance between benefit and risk. The benefit of guidelines based on sound and compelling scientific evidence is large and demonstrable; but the risks associated with the dissemination of poorly founded guidelines must also be considered.

Because bad outcomes are usually rare and therefore difficult to capture in audit data, we increasingly find ourselves being assessed, not on our safety record, but on our compliance with published guidelines. Such compliance is easily measured: boxes are ticked, graphs are plotted, the public reassured, and a warm

glow of achievement shared, all in the absence of any demonstrated change in safety or benefit to patients.

If a patient is harmed, the guidelines are often our first point of reference, and they may serve to distract from potentially important lessons. If harm occurred despite punctilious adherence to guidelines, it is easy to be seduced into assuming that the bad outcome was therefore unavoidable. And if guidelines had not been followed it is likewise tempting to look no further for the cause of the adverse outcome.

Guidelines provide a means by which the opinion of a small group of like minded and highly motivated experts can drive the practice of an entire specialty in one direction. Guidelines decry one intervention and champion another. Some practitioners, expert and comfortable with the deprecated intervention, will nevertheless move away from that practice simply because the guidelines have pronounced against it. Others may continue to practise as they have always done but will stop recommending their approach to trainees. An area of medical practice therefore withers and dies, perhaps in the absence of any scientific evidence against it.

These changes are acceptable, even desirable, when there is robust scientific evidence to support one practice and to deprecate another. Guidelines issued with the support of good quality research are a means by which evidence based medicine gains traction in the world of everyday clinical practice. But guidelines issued without strong supporting evidence incur all the risks I've outlined without offering compensatory benefit to patients.

This is not to say that I dismiss the opinion of my expert colleagues: I am always glad to hear what others are thinking and doing. But there are means by which opinion and low quality evidence can be disseminated without incurring the risks associated with issuing a guideline: that's one function of the learned editorial, for instance.

But the lure of the guidelines committee is strong, especially when like minded individuals are drawn together. Guidelines have been requested; guidelines must therefore be issued. Has any guidelines committee ever come together, reviewed the evidence, and then disbanded after issuing a statement that the evidence is simply insufficient to justify any definitive statement on the topic under consideration? Until that becomes a regular

VIEWS & REVIEWS

occurrence, I fear that guideline fatigue syndrome will remain endemic in the medical community.

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