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Adherence to evidence-based guidelines is the key to improved health outcomes for general practice patients

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NO

'Clinical Practice Guidelines'—a Google search using this term netted 26 200 000 results in 0.43 seconds. Guidelines are as unmanageable as the research they were designed to summarise. Guidelines were intended to bring the best scientific evidence to bear on primary care practice—an upgrade from the Blue Book that we used to carry in case of knowledge emergencies as a house surgeon. Guidelines have now moved beyond this—the quality of family practitioners' care is increasingly measured by guideline adherence.

Is adherence to guidelines the best way to improve health outcomes? No—it may result in care that seems measurably better, but is meaningfully worse for health outcomes. There are three broad reasons for this—the quality of guidelines, the quality of the available research data that underpin them and their unfitness for purpose in a primary care setting.

The quality of guidelines

If guidelines stuck to the data and critical assessment of its gaps and uncertainties this might be useful—but back-filling the gaps in data with 'consensus' appears to be irresistible. In a study of 2700 recommendations in the American Heart Association / American Cardiology Association guidelines, only 10% were based on high-quality RCT evidence.[1] Half were simply consensus. The widespread levels of conflict of interest of group members with the manufacturers amplifies the concern.

The label 'level C evidence' does not undo the air of certainty of the written word on the page of a guideline. One example is HbA1c target levels for Type 2 diabetes, which are standards that increasingly doctors are exhorted to adhere to, and in some countries carry an income bonus. There is no good evidence for treating to any particular target HbA1c. Large well-designed studies have shown the harm and increased mortality associated with tight glucose control and the lack of meaningful benefit of tight control on outcomes that matter to patients. Yet guidelines continue to include these targets, and do so inconsistently: targets in recent Type 2 diabetes guidelines internationally vary between <6.5% (<47.5 mmol/mol) and 8% (<64 mmol/mol). Adhering to the targets specified in many guidelines for diabetes would kill more patients than were helped. Forcing HbA1c low also increases the risk of the patient suffering hypoglycaemia, which does have an association

with a long-term outcome that matters to patients: dementia. Similarly, large numbers of patients take aspirin and statins for primary prevention of cardiovascular disease, but recent research indicates that the risk–benefit ratio is not generally favourable for aspirin use in primary prevention, in particular in older patients, as well as there being increasing concerns about adverse effects. However, reversing guidelines is like reversing an ocean liner. Many guidelines are years out of date.

The quality of the evidence

The scientific base for guidelines has multiple weaknesses. Research is increasingly commercially constructed in a way that is likely to obscure the real effects of treatments. Half of efficacy and two-thirds of harm outcomes are incompletely reported.[2] Outcomes are biased in favour of the funding company's drug. Papers are often ghost-written, trial data are not available for public scrutiny, and publication decisions are commercial ones. Sixty percent of clinical trials remain unpublished and less than a third of published meta-analyses obtain the individual unpublished data.[3–5] The ineffective efforts of a Cochrane group to obtain Tamiflu data is just one example.

One study redid 42 meta-analyses, adding in unpublished trial data submitted by companies to the FDA. In the re-analysis, 46% showed lower efficacy of the drug, 7% showed identical efficacy, and 46% showed greater efficacy. The re-analysis showed more harm from the drug after inclusion of the unpublished trial data.

Virtually all 'evidence' is generated in populations highly selected to show maximum efficacy and minimum harms. Populations with comorbidities using multiple medications are usually excluded from the clinical trials, yet these are the populations in which we use them—increasing the potential for harm and reducing the potential for benefit. Adherence to guidelines based on this sea of uncertain evidence cannot be justified.

The misfit with primary care

The most compelling argument against adherence is the mismatch between the partialist-driven framework of guidelines and the generalist approach of primary care. One focuses on a single disease in many people, while the other focuses on a single person with many problems, including their particular set of values and priorities. The idea of guideline adherence cuts across the demonstrated benefit of patient-centred primary care. The attention paid in guidelines to the values of patient centredness espoused in evidence-based medicine is sparse and they provide inadequate quantitative data on risks and benefits to support informed treatment decisions.[6] The consensus on risk thresholds justifying treatment reflects physician values not patients'. Most patients would not think taking a statin justified at the kind of risk–benefit level currently offered.[7]

Box 1.

A 70-year-old woman with three chronic diseases and two risk factors, if guidelines were followed, would be prescribed 19 different doses of 12 different medicines at five different times of day. More importantly, there are 10 possibilities for significant drug interactions, either with other medicines or with other diseases. This prescriber would be rated as a good physician using single-disease measures, whereas the physician using wisdom and judgment in avoiding polypharmacy would be rated low on adherence. (Boyd JAMA 2006)

The idea of adherence to guidelines disempowers doctors and patients in the use of their observation of individual response and needs. Even at a simple pharmacological level, a single disease, non-patient-centred approach is perilous (Box 1).

Guideline adherence is based on therapeutic positivism, undermining the skill involved and value that should be placed on decisions not to give treatments, as well as the improved health outcomes. This is a specialist skill of primary care. Adverse drug events are the fourth leading cause of death in US hospitals. Polypharmacy is one of the biggest threats to healthy old age. The quality of primary care in coming decades is likely to be

defined not by what we do give, but by how well we make decisions not to give treatments.

Opportunities lost and opportunity costs

Procrustes was a figure in Greek mythology who had an iron bed in which he invited travellers to spend the night. If the guest was too short he would stretch them to fit. If they were too tall, Procrustes would amputate the excess length. Adherence to guidelines is a procrustean approach to good quality care. Variation in care does not necessarily mean poor care. It may represent good care in a complex context.

Single-disease guidelines have had their day. They are not fit for purpose for primary care and adherence can be outright harmful, as well as raising concerns about increasing inequity. They are also not the best we have. There are sophisticated and effective resources and programmes available that offer the kind of critical appraisal of the source research data that is of much more value to practitioners than a flowchart—and that make critical understanding of the evidence fun.[8,9] It's not possible to know when to follow and not follow guidelines without a fundamental understanding of the research data that does (and does not) underpin them. The worry is that critical reading and understanding of research will be replaced by reading guidelines.

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Theseus finally killed Procustes by making him fit his own bed: studies of the effect of adherence to guidelines usually only look at change in surrogate process measures and intermediate indicators, but in one analysis of five of the seven studies that looked at actual patient outcomes that matter, adherence to guidelines made absolutely no difference.[10] There is much better evidence about the benefits of strong primary care on health outcomes. We need to trust the evidence of our own eyes as our patients beta test treatments for the first time in the real world of multi-morbidity, unknown adverse effects and individual preferences. The combined knowledge of, and research by, family doctors and their patients in understanding the effects of these combinations of treatments, or of not taking treatments, has a lot more to offer patient outcomes than guideline adherence.

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