

# How far should guidelines be followed?

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## KEYWORDS

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Clinical guidelines irreparably characterize contemporary medicine. Referring to guidelines has become routine in both medical literature and daily clinical activity, with the risk of becoming the only—or at least the main—inspiring element of the physician's behaviour. This would lead to the mortification of clinical reasoning, a term that is synonymous with an individualized approach, focused on the single patient, and not on a population.

## What was medicine like before the era of guidelines?

'Guideline culture' is a direct result of evidence-based medicine (EBM), a phenomenon that has gradually spread since the 1990s and has progressively characterized the activities of almost all American and European scientific societies. According to Sackett's definition,<sup>1</sup> EBM consists in the conscious, judicious, and explicit use of the best evidence available to make decisions about the care of individual patients. This new culture is undoubtedly a response to the deregulated and self-referential climate of previous years, during which it was often the anecdotal and not critically validated opinion of individual opinion leaders, that strongly influenced the work of physicians amongst other things, this new cultural climate generated the explosion of randomized controlled clinical trials, that are theoretically capable of providing robust data. The large amount of data generated needed to be governed and filtered by experts, possibly recognized as such by the reference scientific societies, leading to the birth of diagnostic and therapeutic guidelines.

In fact, most guidelines of the major national and international scientific societies represent a (periodically updated) summary of the available literature, a powerful and clinically useful tool, that would otherwise be difficult to construct by the single physician.

There is no doubt that this idea of guidelines was an opportunity to break free from the 'regime' where behaviours were often dictated by the cultural power of those who held apical positions.

## To what extent are guidelines really a tool of evidence-based medicine?

It has been rightly noted that, when considering the main cardiovascular guidelines cumulatively (53 documents published between 1984 and 2008, with a total of 7196 recommendations), only 11% of recommendations have evidence level A, i.e. are generated by prospective randomized clinical trials, while 48% are associated with a level of evidence C (non-unanimous expert opinion).<sup>2</sup>

Following the initial phase of enthusiastic acceptance some of the following criticisms emerged:

- Clinical trials are not born magically or by divine will; in almost all cases they represent the convergence between a group of researchers and one or more companies producing drugs or devices. This may intrinsically limit the objective of clinical research and in any case makes it unlikely that trials will focus on rare diseases or economically 'uninteresting' treatments.
- Purely economic considerations are generally well represented within the guidelines. The risk is that they can be accepted, by non-impartial users, to cut healthcare costs at the expense of treatment.

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- There is a risk that guideline authors, sometimes identified within scientific societies with criteria of geographic-political representativeness, may in fact constitute a lobby that can reproduce the hierarchical and self-referential climate that was present prior to the era of EBM.

### Do we know the impact of the guidelines on health?

In cardiovascular medicine, especially with regards to the treatment of heart failure, atrial fibrillation, and acute coronary syndromes, both registries and the dedicated observational studies have shown a measurable mortality and morbidity benefit following the application of therapeutic recommendations.<sup>3-7</sup> The same level of certainty is not present for the recommendations relating to diagnostic algorithms, due to obvious methodological difficulties.

### Does following the guidelines protect us medico-legally?

The issue has been the subject of recent jurisprudential pronouncements in Italy. The topic is too extensive to be discussed here, however, some points should be noted:

- Guidelines were consecrated legally by the Balduzzi law (189/2012) that established that 'health professionals who had adhered to guidelines and good practices accredited by the scientific community, would be charged in criminal cases for mild fault'. The subsequent Gelli law (24/2017) largely modulates the content of the previous law. The implicit obligation of behaviour of the health personnel in relation to guidelines must be interpreted 'without prejudice to the specificities of the individual case'.
- All the most recent jurisprudence underlines how the observance of the guidelines should never be an automated approach, admitting wide possibilities of derogation in individual clinical cases. In fact, the uncritical observance of guidelines does not guarantee the absence of 'malpractice'.

### Diagnostic component vs. therapeutic component of guidelines

It is very difficult to force the diagnostic process of a disease into a series of practical behavioural recommendations. In fact, the diagnostic act itself has a 'creative' component that is difficult to describe by numbers or quantitatively in any way.<sup>8</sup> This is especially true for the first of the two moments of diagnosis, i.e. suspicion, while it is easier to define work-up in the search for the definitive diagnosis.

### Didactic and behavioural impact of guidelines on the medical community

Guidelines have a dual and discordant effect on the trainee doctor and more generally on anyone looking for a consolidation of their culture and experience. While on the one hand, the availability of guidelines is a formidable tool to summarize the available literature, on the other they risk limiting the autonomous processes of pathophysiological and clinical interpretation and more in general the whole clinical approach, that is individual to each patient.

The methodological premise present in all guidelines, that affirms the need for contextualized interpretation (i.e. referring to the specific patient setting), is in fact likely to be overlooked by the reader.

### Final considerations: lights and shadows of the guidelines

The conclusive considerations can be summarized in a shortlist of pros and cons.

#### Good reasons for not following guidelines

- (1) They apply to diseases rather than patients.
- (2) They are mainly generated by studies of relatively young patients with a low comorbidity burden.
- (3) They flatten individual reasoning and mortify the deductive component of diagnosis in the individual patient.
- (4) They attenuate scientific curiosity and the desire for research to the extent that they shift attention from the uncertain to the consolidated.
- (5) They are produced by a lobby of authors, often with strong links with pharmaceutical or biomedical companies.
- (6) They are more often expert opinions rather than recommendations based on solid EBM.

#### Good reasons to use the guidelines

- (1) They are an exceptional bibliographic update tool.
- (2) They offer a checklist of treatments to be considered in each patient.
- (3) They define the general lines of reasoning for diagnosis.
- (4) They define the general lines by which to make diagnostic and therapeutic decisions.
- (5) They favour a rational use of economic resources.
- (6) They offer a reasonable line of defence in the event of a malpractice charges.

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