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CONCISE COMMUNICATION

Broad versus narrow clinical practice guidelines: avoiding rules for the high risk 1%

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Clinical practice guidelines are intended to help practitioners and patients select the diagnostic and therapeutic approaches that are best supported by the evidence. Guidelines are particularly useful in the context of evolving research, as they free practitioners from the burden of personally evaluating the often overwhelming corpus of knowledge [1, 2]. When high-level evidence is unavailable, guidelines rely on expert consensus to resolve uncertainty.

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Despite their utility, guideline documents usually explicitly disavow the intent to establish a standard of care [3, 4]. This is not a manifestation of false modesty, but a recognition that no guidelines, no matter how comprehensive and carefully crafted, cannot foresee every circumstance. Patients may differ in terms of their genetic predisposition, susceptibility to disease, and co-morbidities; disease processes may vary in their manifestations, and may include overlap with other diseases or syndromes; at the time of diagnosis, the disease process may be incipient or advanced, along a spectrum of disease severity or stage; prior treatments may have rendered infeasible otherwise appropriate treatment options; patients competent to participate in their care may decline certain options; or resource availability or local expertise may suggest the primacy of particular, non-standard diagnostic or therapeutic interventions.

In some cases, it may not be possible for guidelines to provide relevant recommendations. For instance, evidence regarding a particular clinical circumstance may be lacking; research on disease management in socially or economically diverse populations may be insufficient; or certain drugs or therapies may be too new to judge reliably [5].

Given these inherent limitations of clinical practice guidelines, it has been suggested that guidelines should be concise and not longer than a few pages [6]. Beyond providing general recommendations as well as some more detailed guidance when is necessary and supported by evidence, guidelines should defer to the clinical wisdom of the experienced physician.

One question that remains unsettled is what proportion of cases of a disease or condition should be covered by clinical practice guidelines. The National Comprehensive Cancer Network has suggested that its cancer guidelines apply to 95% of cases. Other organizations have been less specific about clarifying the breadth of their guidelines.

Theoretically, guidelines can be stratified by severity of disease, or even by stage. However, in general, guidelines are created for a disease or condition, not a specific manifestation or severity level. The same is true for cancer guidelines.

There are reasons why more specific cancer guidelines are not practical [7, 8]. While it is difficult to develop guidelines that apply consistently to the broad majority of patients with a particular type of cancer, it is even more challenging to refine these guidelines for individual subsets of patients. First, evidence for management of very specific patient subpopulations is necessarily sparse. This dearth of evidence becomes progressively more of a barrier as the specificity of the cancer subgroup increases. Second, there are very many specific subsets of cancer patients for which guidelines could be developed. If only a few such categories are addressed, the guidelines will not collectively be comprehensive. Alternatively, if many variants are separately addressed, the guidelines will be so cumbersome and long as to be of little use. Third, defining the bounds of subsets of cancer patients is fraught. Major divisions, such as local versus metastatic disease, or AJCC stages, are generally accepted. However, more fine categories are necessarily created by the guideline makers. This is problematic, since the purpose of practice guidelines is not to create nomenclature and categories, but to explain how patients in generally accepted categories should be managed. Fourth, guidelines for small subsets of cancer patients will necessarily be applicable to only a few patients. The effort and expense required to develop and update such specific guidelines may not be commensurate with the degree of benefit accruing to the small group to which they apply. Health care resources are a precious commodity, and may be better deployed in other ways to help patients. Fifth, since one important function of guidelines is to convince regulators and payers of the need to permit and reimburse medically necessary procedures, excessively narrow guidelines for a small subset can backfire. The very specificity of such guidelines implies that diagnostic or treatment procedures not envisioned in the guidelines are inappropriate and should not be paid for by insurers. The producers of extremely detailed guidelines cannot simultaneously credibly argue that interventions not explicitly endorsed by their guidelines should also be allowed because the guidelines are general in scope, with many clinical circumstances excluded.

Clinical practice guidelines for the 1% of most severe cases are, thus, not helpful to the patients they wish to describe. Rather, guidelines are useful when they are broadly

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applicable, and do not address only particular severity levels or new categories of their own creation. Specifically, ideal guidelines apply to most but not all patients with a disease or condition. 5–10% of the least affected and most affected patients, respectively, may be excluded from the guidelines. Extreme cases at either end of the severity spectrum will need to be treated differently than the large majority between these poles. Including in the guidelines written estimates of the proportion and type of patients not covered will be helpful to all users, including providers, patients, payers, and regulators. Such delineation of the scope of the guidelines will also allow for a brief, cohesive document in which discussion of every therapeutic approach is not qualified with exceptions and disclaimers.

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