Standard of Care Versus Standards of Care in Oncology: A Not So Subtle Distinction

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In medicine, in general, and cancer management, in particular, the term standard of care is often poorly defined. From use of this expression in the setting of a malpractice case to a pronouncement that justifies denial of health benefits by a third-party insurer, this three-word statement can have vastly different, often profound, and sometimes problematic as well as controversial

meanings. Does the term imply that: all patients in a specific clinical setting must be treated/managed in a particular manner; or only that the patient should be considered for treatment/management with the strategy? Who exactly should make this decision, the provider, the patient, or the entity paying the bills for the care?

Consider, for example, the common situation of the recently reported statistically significant results of a phase III trial in a particular setting that reveals a two-drug combination containing commercially available antineoplastic agents improves progression-free survival and overall survival, compared with single-agent therapy. If future patients with the condition satisfy the eligibility criteria, as defined for this trial, must treating physicians offer this strategy, only consider the approach (but not be required to present the option to the patient), or actually have any obligation to even contemplate employing this management?

These questions relate to the classic debate in biomedical ethics regarding the relative strengths of the moral arguments of physician-directed beneficence versus patient-centered autonomy. Should a patient, meeting the objective criteria of an evidence-based (phase III) trial which achieved a prospectively defined “positive” outcome be permitted the final determination of whether the level of observed “benefit” justifies the possible “risks”? Conversely, is it acceptable that this decision is made by the patient’s physician, or in many settings, those paying the cost of the patient’s care? Would calling something standard of care make it more likely that the patient would be offered the opportunity to receive the treatment?

Would the answers to these questions be different if the observed improvement in outcome was only in progression-free survival (but not overall survival), if the results had only (at this particular point in time) been presented at a national oncology meeting (eg, the annual American Society of Clinical Oncology [ASCO] meeting), or if all the individual drugs were not currently US Federal Drug Administration approved for this specific indication?

Who should decide the current standard of care, on what basis should that decision be made, by what process should a change (major or minor) in this determination be sanctioned, and how should this be orchestrated in the absence of data from randomized trials (eg, less common cancers or information from several well-designed and conducted phase II studies)? Should the standard of care be defined through the efforts of a nationally recognized not-for-profit organization (eg, American Cancer Society, ASCO, National Comprehensive Cancer Network), or is it permissible to describe the standard based on an individual practitioner’s review of evidence-based data published in the peer-reviewed literature?

Or, perhaps, we should recognize that attempting to define the standard of care in oncology is often a profoundly futile endeavor, due to the remarkable complexity of the disease processes (eg, stage, grade), individual patient (eg, preexisting comorbidity, prior therapy), and provider (eg, availability of technology in specific geographical settings) differences, and the rapidly changing science of cancer care (eg, development of novel strategies). In this environment, how can one really define a standard of care?

Rather, might it not be more reasonable to describe the various options as acceptable standards of care and suggest that patients meeting specific criteria should be given the choice of receiving a treatment within one of those standards?

Further, in any discussion of the quality of care being provided to individuals with malignant disease, society might demand that care falls within the acceptable standards, but not necessarily follow a single rigidly defined standard. A concept of standards of care might help reduce the disconcerting, but very real risk that a third-party payer will inappropriately employ the singular term standard as a method of cost containment (ie, pay for one approach; translated to the least expensive approach).

Finally, in the opinion of this commentator, while the fundamental question remains unanswered as to who should decide what falls within the category of standards of care, and whether it is the physician, patient, or third-party payer who will have the ultimate say as to the specific choice of disease management, recognition that this discussion rationally should focus on multiple reasonable options, rather than a single rarely changing standard, will begin to move this important, complex, and often highly contentious debate, in the right direction.

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