Medicine As It Should Be: A Cultural Shift

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“Chekov once observed that a good writer helps us to feel not just life As it Is, but life As it should be. The movement for evidence-based medicine offers something similar—enlightenment coupled with views of a promise land.”—Sir Liam Donaldson, 1997.

One could surmise that the necessity to practice evidence-based medicine is implied even in a modern version of the Hippocratic Oath: “I will continue with diligence to keep abreast of advances in medicine.” The oath of Maimonides invokes prayer to “Grant me the strength, time and opportunity always to correct what I have acquired, always to extend its domain; for knowledge is immense and the spirit of man can extend indefinitely to enrich itself daily with new requirements. Today he can discover his errors of yesterday and tomorrow he can obtain a new light of what he thinks himself sure of today.” These oaths are also the basis of continuing medical education, a process by which the continuum of medical learning is reinforced, to the benefit of physician and patient alike.

Repeatedly, there is a call for clinicians to practice evidence-based medicine and to ensure the quality of the care that is delivered. This call is voiced by multiple stakeholders in the health care enterprise, including professional societies, government, insurers, and the advocacy community, among others, driven in large measure by the unrelenting increase in health care expenditures and by uncertainty as to whether the benefits outweigh the costs. The American health care “system” is such a formidable entanglement of disconnected and often incoherent infrastructure that it has been a challenge to address quality of care on a cohesive platform. Individual professional societies, insurers, and health care networks selectively have attempted to address quality of practice, particularly in recent times, through efforts that include the development of pathways, guidelines, and quality measurement constructs. The past is littered with innumerable guideline documents, most of which fail to advance adherence to evidence-based practice, principally because they have not been embedded in practice models, have limited availability, and have not been maintained as a continuum to incorporate rapid advances in medical knowledge. In addition, many guidelines do not encompass precision tools that reflect the many nuances of individual patient care, which reflect the art and science of complex medical practice. Indeed, it is the interaction between the individual clinician and patient that can complicate compliance with evidence-based strategies of care. These complexities often include level of expertise; resource availability, including presence of appropriate subspecialists; time constraints; access to care; reimbursement for care; patient comorbidities; and patient expectations and beliefs.

Furthermore, even when clinicians fully comprehend a body of evidence, at times they do not invoke the evidence in caring for at least some individual patients for reasons not fully elucidated, but perhaps linked to individual clinician and/or patient characteristics.

In the May issue of *Journal of Oncology Practice*, Massarweh et al¹ discuss the observation that one third of elderly Medicare beneficiary patients with hepatocellular cancer had a diagnostic biopsy, representing an overuse of the procedure. This is in contrast to current guideline recommendations, in which biopsy is required for only a subset of patients to confirm the diagnosis. The authors also point out that many more patients received a biopsy when a guideline-nonconforming diagnostic sequence was followed. Possible reasons for nonconcordance include quality and/or interpretation of imaging, misconception about the disease, or reluctance to use imaging alone. The risk of unnecessary biopsies is of added concern because they can result in tumor dissemination and needle track seeding. Unfortunately, these results are not surprising given what has been previously reported about guideline adherence in general. For example, Harlan et al^{2,3} evaluated patients with newly diagnosed cancer, including 11 different malignancies, to determine whether there was an association between insurance status and receipt of guideline therapy. Not only was adherence to guideline treatment recommendations lower than expected, it was even lower for patients with Medicaid or Medicare.

Acceptance of and adherence to oncology practice guidelines are vehicles to enhance continuing medical education by providing up-to-date clinical information and more consistency in care delivery to promote better and more uniform outcomes, and by helping to avoid both under- and overuse of care, thus promoting more cost-effective resource use. Some would also argue that wide-scale promotion of guidelines could result in the most cost containing effort that would be feasible in our disjointed care delivery and reimbursement system. There are, however, many challenges that impede the more global application of evidence-based medicine and measurement of quality and improved outcomes. The merger of practice guidelines into the electronic medical record and routine care of individual patients is of great interest and could supply the data needed to evaluate compliance, quality, and outcomes. However, given the paucity of centers with a fully operational electronic medical record and the multitude of different electronic systems, a linkage strategy cannot be fully implemented at this time. In the context of the overall health care enterprise, there are addi-

tional challenges that affect the “big picture” of oncology care delivery in the United States, including:

1. Projected workforce shortages have the potential to limit access to care and integration of essential oncology services.
2. Continued rising cost of care and an aging population, with potential adverse effects on delivery of essential oncology services, innovation, and access to care.
3. Increasing demands for acquisition of data that demonstrate quality of care and effects on the practice workload and budget.
4. Lack of an appropriate information technology infrastructure.
5. A rapidly changing practice environment, including integration of oncology services into the hospital setting, loss of community-based practices, and corporate acquisition of networks of practices.

In addition, the integration of evidence-based medical practice and the use of guidelines will clearly highlight gaps in our knowledge base, which should become the focus of innovation and translational clinical research to best inform the use of new treatments, devices, diagnostics, and imaging techniques. The challenges mentioned above will further jeopardize the US cancer clinical trials enterprise and thus will require increasing attention if we are to fill gaps in evidence while continuing to promote innovations in oncology treatment to improve outcomes. Although many promote comparative effectiveness research as a method to improve evidence beyond clinical trials research, there are the challenges of lack of data infrastructure and the rapid advancement of technology in oncology, for example, that will mandate analyses based on molecular profiling to define appropriate subpopulations of patients most likely to benefit from a particular treatment approach.

Finally, there is the debate as to the level of scientific evidence that should drive decisions related to appropriate cancer care. These discussions also center around the appropriate end points for clinical trial interpretation and the need to look at new paradigms in clinical trial design that incorporate biologic observations. The two types of evidence-based guidelines most frequently discussed are:

1. Systematic review: an exhaustive review of a single issue that may address a single decision point and is a comprehensive review and analysis of the literature, often taking many months to complete.
2. Evidence-based/consensus guideline: a process map of integrated interventions over time that addresses coordination and continuum of care and for which there may be fewer (although pertinent) references for each decision. This process map can involve many hundreds of decisions for a given disease entity.

These two types of guidelines are not necessarily mutually exclusive, as the results of a systematic review would be appropriate to include in an evidence-based/consensus guideline. Regardless, each can inform decision making, reveal gaps in knowledge, inform future research endeavors, and

highlight quality measures to be used for practice assessment. Some of the particular advantages of an evidence-based/consensus guideline already have been mentioned. However, to emphasize, this approach addresses decisions across the spectrum of real-life clinical scenarios for a specific disease or symptom, not only to promote care based on high levels of evidence, but also to fill in gaps by consensus when clinical decisions must be made for patients on the basis of less than robust evidence.

To conclude, the success of a particular guideline process requires wide ranging applicability and acceptance. The National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines are the only guidelines to achieve success with world-wide distribution, acceptance, and use based on a strategy of comprehensiveness addressing nearly all cancer clinical scenarios. These guidelines are continually updated and available free of charge on the Internet (for full disclosure, I am the immediate past chair of the Board of Directors of NCCN, a panel chair, and member of multiple panels). As a result, several thousand decision pathways are incorporated with references and manuscript discussion, a number that cannot practically be addressed by systematic review of each element in the guidelines. The credibility of the guidelines is reinforced by a large number of multidisciplinary panel members representing diversity in geography and philosophy while maintaining a transparent process that is further enriched by institutional review as well as external review and input. The immediate availability on the Internet allows for a continual feedback loop. The lessons learned in establishing the NCCN guidelines and their international acceptance are based on a collection of organizational principles including:

1. Investment of millions of dollars by the membership.
2. A nonpolitical agenda within the member institution.
3. Dedication to the organization and mission.
4. A relatively small but quite diverse multidisciplinary group that is manageable and willing to provide continuous and knowledgeable service.
5. A knowledgeable and dedicated staff.
6. Stable leadership with the skill to keep to mission while embracing innovation, infrastructure, and staffing that enable a continuum of up-to-date guidelines that reflect real practice scenarios while integrating the variable evidence we have
7. Credibility of the members
8. Accountability
9. Transparency

By orchestrating a cultural shift that mandates more universal incorporation of evidence into medical practice and acceptance of such by both clinician and patient, we will come closer to a state of “medicine as it should be.”

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