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FROM THE DESK OF THE PRESIDENT

Synte-gration: A Knowledge-based Approach to the Practice of Medicine

Syn-te-gra-tion represents a combining of the words synthesis and integration to capture a more complex concept than either word alone. Synthesis is also synonymous with fusion, a process by which individual parts combine to form a qualitatively different whole. In the literature, synthesis is the word most frequently used to describe the process of evidence-based medicine (EBM), usually in connection with the meta-analysis of various types of randomized studies. The word integration can also be defined as the process of bringing together separate parts into a whole. However, integration is also defined as an *unrestricted and equal association among parts*, a harmonious functioning whole. These distinctions allow each word to bring a unique contribution to the word synte-gration. While I cannot make claim to the first use of the word synte-gration, I find its application appealing in the circumstance physicians find themselves today regarding EBM and randomized clinical trials in surgery.

The position of some authors is that EBM and “traditional” clinical medicine make bad bed-fellows in terms of solutions to many complex patient care issues, and clinical medicine must look to EBM to create a new path in medical and surgical decision-making. Another of the problematic issues is that EBM language can give the appearance of seeing itself as a *new* medicine and, rather than be assimilated into “traditional” clinical practice, clinical medicine must *become* EBM. On reading various texts of EBM, one can sense a co-optation by EBM of various long-established practice standards of clinical medicine, a *déjà vu*, if you will, of what one already knows presented as owned and operated by EBM. It is one reason some authors *do* claim that EBM is not as new at the level of ideas some of their texts suggest. Both medical journals and public media have represented EBM and clinical medicine as entities unto themselves, with one overlapping area in common – patients

who are caught in the middle.

In traditional terms, medicine has been defined as an art based in science, a reference to the complex blend of different skills physicians require. EBM is a movement to redefine medicine in terms of, not so much science, as the scientific method — where method is elevated to criterion and the summit goal is to achieve an unprecedented number of databases of “current best evidence” to inform clinical practice. How EBM positions clinical expertise is vital, then, for the debate is not only about *how* we decide *what* treatment and *when* to intervene, it is also about *who* decides. Advocates have defined EBM as being the integration of the best research evidence with clinical expertise and patient values and that it is the clinical expert who decides whether external evidence is appropriate for a patient.¹

So, why do we have flash fires occurring in both the medical and public media over EBM? In part, because despite the prominent inclusion of clinical expertise at its front lines, in reality, EBM is redefining, or reassigning, clinical expertise to a narrower role, reducing it relative to therapeutic management. Prominent mention of the importance of clinical expertise to EBM by advocates tends to shield EBM from criticism. Just strolling the Internet, however, provides a startling comment that EBM has successfully relegated the voice of the medical expert to the least valid form of evidence. Within a regarded and currently published EBM text, even seeking advice from a colleague more expert than yourself is a form of blind acceptance and reduction to a “trainee level” of conduct.¹ Ironically, or interestingly, the warning by EBM of accepting expert advice without knowing the expert’s “source” is the mirror image of concerned physicians that EBM could become a blindly accepted knowledge base of medicine. Both these images are viewed by EBM advocates as misunderstandings. I think experts should be the judge of that!

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to capture the moral high ground, giving the impression that it is a brand new concept that must sweep through and clean the house of "opinion-based medicine." The platform is one that encourages polarization.

One of the "hottest" debates surrounds the use of randomized surgical clinical trials and meta-analysis of surgical studies as the foundation for clinical decision-making. Sleight called *common sense* the "ultimate meta system" in an article on the logical limitations of randomized clinical trials (RCTs).² Spine care specialists may be a group vulnerable to what is perceived by some as the inflexibility of EBM and may need to apply liberal and frequent doses of common sense from our practice experience. How do we improve technologies for spine treatment advances without stepping outside the box of conclusions "fused" from a synthesis of studies framed as "the best available evidence"? Eventually, someone must implant that first new device or risk that different idea or stay the course as "the course" matures to provide patient benefits.

A criticism of EBM meta-analysis has also been occasionally leveled at national registries, both of which can take a 35,000 foot view of events that can obscure important clinical detail, for example, when national databanks inappropriately analyze the relationship between two surgical procedures – laminectomy and fusion for back pain – two different procedures that are performed for different reasons.⁴ From the "clinical street level," surgeons can see the absolute differences as we examine and manage patients individually. Most recently, some EBM advocates have aggressively attached their views to criticize surgical implants, to present an uninformed condemnation of cervical fusion following discectomy, and to question spinal fusion surgery and associated techniques as operative treatment for degenerative conditions.⁴ These views take such a narrow perspective of progress in surgical research and individualized treatment, it is alarming.

EBM has the potential to reorganize all of medical practice and training and become the basis for economic, government and health policy management decisions. We must pay assiduous attention now to what is put in place and to what we give our tacit and public approval. A knowledge-based, syntegegrated approach is based on concurrent

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THE INTEGRATION PROCESS

Recently, I asked the question "What are the critical resources and influencing experiences surgeons have had that cause us to suggest a specific treatment to an individual patient for a given diagnosis?" Historically, mentoring was probably the single most important factor guiding physicians' treatment plans. Today, a supervised and structured residency training curriculum has supplanted mentoring in the education of physicians – with the exception of the modern day fellowship.

A 2003 survey of Fellows of the Royal Australian Academy of Surgeons, designed to address the discussion of evidence-based surgery, emphasized just how important training is to practice – 71% (418) of a random selection of members stated their early surgical training as the "most highly ranked influence on (their) surgical practice."⁵ There is little to dissuade me that a similar survey of US surgeons would not produce an approximate result.

The formalization of residency training and board certification were quantum leaps in improving the overall quality of the practice of medicine. The board examination process ensured for each candidate that training resulted in sufficient retention of knowledge to qualify the candidate for board certification, a performance standard both we and patients could trust. To further improve the quality of medical care in orthopedics, the concept of recertification was introduced in the 1980s. The markers on the road to recertification are participation in continuing medical education (CME) courses and events which remain a major form of dissemination of current and emerg-

ing educational concepts, technologies and research.

Another major component of how we practice medicine is our personal clinical experience. On a day-to-day basis, this personal experience of applying, contrasting and comparing methods of diagnosis and treatment is profoundly important to the development of expertise for the practicing physician and to discover what works "in his hands."

In terms of more external sources of information, constant exposure to the scientific literature is a critical component in the education of clinicians. The ability to critically read and analyze the current literature is an important aspect of today's residency programs at journal clubs and is practiced repeatedly during residency rotation and similar academic settings. Whether there is enough evaluation and feedback to identify weaknesses in critical appraisal of the literature during residency/fellowship may be a question needing further thought. Unfortunately, the ability to and/or interest in continued critical reading of peer-reviewed scientific articles varies from clinician to clinician. The internet and proliferation of full text journal articles and databases, even books, as well as EBM dedicated resources continue to positively transform clinical practice. As members of the surgical community, it behooves us to consistently engage in and encourage the value of the literature in patient care and self-development.

These experiences are, in a practical sense, what has been guiding the reasoning and modern practice of medicine – reasoning practiced by the integration of all of the just mentioned factors: (a) mentoring, (b) clinical training during residency/fellowship, (c) preparation for board certification and recertification, (d) personal experience obtained during clinical practice, (e) CME courses and national meetings and (f) interpretation/appraisal of peer-reviewed scientific literature. The practice of medicine is the result of an

integration process, a system of ongoing, functioning, past and present component knowledge bases that continue to inform each other and from which we continually draw as we practice surgery (**Table 1**). Some physicians believe in this integrated process to positively shape practice so strongly that, for the sake of discussion, I will call them “integrationists” of medical culture or knowledge (**Figure 1a**). Traditional resources and clinical practice are typically not tapped by EBM as highly valued resources. This decrease in the number of acceptable resources from which clinical information should be acquired is another mechanism by which the role of clinical expertise in patient care is further reduced.

THE SYNTHESIS PROCESS

An overly simplistic view of EBM is that the total scope of the scientific literature serves to confuse and obfuscate the “truth.” This same view holds that conclusions from retrospective studies or nonrandomized prospective studies are no more than “pluralizing” personal experience, thereby prejudicing the conclusions with the human frailties of opinion, bias and selective memory.

“True” data in EBM is accomplished by prospective RCTs and a meta-analysis that synthesizes many such trials (**Table 2**). Although important, unfortunately, surgical RCTs offer particular obstacles, just two of which are that standardizing treatments is far more difficult and expensive, and that randomizing is potentially more complicated. Persons committed to this view of EBM for purposes of this brief discussion I’ll call “synthesists,” as they believe that the conclusions and data obtained by the prospective RCT are so powerful that the practice patterns arrived at by the “integrationists” are not valid in comparison (**Figure 1b**). Some of the synthesists’ persuasion efforts would even favor governmental intervention to limit/block health care expenditures for procedures not clearly validated by their perspective of EBM!

SYNTEGRATION

It is my hope that in identifying some of the flaws in both the synthesis and integration approaches, we raise the probability of bringing together the best that each has to offer using a syntegrated approach (**Figure 1c**). Integrationists who rely too heavily on the habits of

Table 1. Integration Process

The reasoning and modern practice of medicine results from physicians’ integration of critical resources and experiences such as:

- Clinical training and study during residency/Fellowship training
- Mentoring with senior physicians
- Preparation for board certification and recertification
- Personal experience obtained during clinical practice
- Knowledge obtained in CME courses and national meetings
- Personal interpretation & appraisal of the data in a variety of peer-reviewed scientific literature

Table 2. Synthesis Process

“True” data results from synthesis of:

- Prospective randomized clinical trials (RCTs, RCSTs)
- Meta-analyses
- Systematic reviews

their earlier training, enhanced dominantly by their continued personal experience, may not adequately “mine” the more critically important current information and data afforded by CME and the scientific literature, or even access their colleagues. Synthesists who rely exclusively on the “data” of EBM are more vulnerable to false conclusions if there are flaws in the studies they are choosing for practice decisions. These flaws frequently are to be found in the methodology of a study and may be quite complicated to uncover directly. The tendency is to overly trust the design and the statistically confirmed results. The integrationist, however, has a built-in check and balance tool in that he is more likely to be alerted to problems with the data because they will conflict with the data obtained by his integrative process. If the conclusion of a study interests us at all (could influence our practice), a steered review of the methodology must be done instead of passing responsibility for the quality of the study entirely to the author(s) or journal reviewers.

Consider these several examples. A recent prospective randomized trial showed no difference in the fusion rate or outcome between instrumented lumbar fusions and noninstrumented lumbar fusions.⁶ On face, the data can be assumed to be valid to synthesists because they came from a prospective RCT. However, my personal integration process produced a contradiction on reading the conclusion. A review of the methodology provides me with the answer. The criteria for evaluation of fusion was evidence of bridging trabecular bone. In my clinical practice, the all-inclusive

list of tools for assessing fusion are AP and lateral radiographs, flexion-extension views, CT scanning, bone scans, diagnostic infiltration of lidocaine into a suspicious area of pseudoarthrosis, and finally (if necessary), open surgical exploration of the fusion. The flaw of the study was that fusion was assessed solely on the basis of AP and lateral radiographs. The inadequacy of evaluative tools was clear to me as a surgeon, but might not be to an epidemiologist, internist or other nonoperative specialist reading the article. The instrumented group was at the additional disadvantage of having the visualization of the bridging bone partially obscured by the metal implants. At a minimum, flexion-extension radiographs should have been obtained and, I suspect, would have revealed a higher rate of pseudoarthrosis in the noninstrumented group. This study, however, has been frequently referenced by synthesists as “evidence” against using instrumentation in lumbar fusion surgery.

Another example in the EBM cervical literature is a randomized prospective study claiming “proof” that fusion following cervical discectomy for cervical radiculopathy is not necessary.⁷ Once again, my integration process sends up a red flag to the conclusion of this EBM study and creates a conflict. Fusion following a cervical discectomy is a treatment mainstay for the vast majority of cervical surgeons – for reasons of greater pain relief and avoidance of kyphotic disc space collapse. Can virtually all the residency and spine fellowship training be wrong? Clearly, this is a dilemma affecting both practice and



Figure 1a. For “integrationists,” the knowledge acquired in an ongoing integration process outweighs the data synthesis process of EBM.



Figure 1b. “Synthesists” value EBM more heavily than knowledge gained through the integrated approach.



Figure 1c. Balancing integration and synthesis to bring together the best of each in a knowledge-based “syntegrated” approach.

training!

The problem with the authors' conclusion, once again, lies within the methodology, but this time as part of the surgical technique. The study randomly divides the patient population into three groups. The first group is discectomy without fusion, the second discectomy with fusion (Smith-Robinson method) and the third discectomy with fusion plus plating (Caspar method). This seems on the surface to be reasonable. The flaw lies in the fact that in the nonfusion group the surgeon removed the disc and the end plate down to small points of bleeding bone. This allows bone to bone contact *and* allows access to the marrow elements to aid the fusion process. The surgeon, in effect, was *surgically performing a fusion* but without the use of an iliac crest bone graft (ICBG). The author stated that 90% of the “nonfused” patients went on to fusion. The correct interpretation of this paper is that the three groups were *all treated with attempts at fusion* but by different methods. This is a very different perspective of the study than one gains from reviewing the title of the paper and its conclusions. Perhaps the author had an unconscious negative bias to fusion which was reflected in labeling one group as nonfusion when they merely had a different, less effective method of fusion. It also remains to be seen if patients who consent to give up freedom of choice in a randomized surgical study are representative of the general population or a self-selected subset which we know contributes bias by that very fact.

SUMMARY

We must continue applying knowledge — integrated from clinical expertise and practice

— to therapeutic studies and outcomes that EBM has already “screened” and “synthesized” and “fused” — this in order to keep EBM in a state of constant course correction, and remembering all the while that statistics, randomization and systematic reviews are extremely valuable tools in our hands, but they cannot become the apogee of clinical medicine. They cannot become the master of what we do. If society or the medical and scientific communities begin to accept a downgraded, or narrowed role for clinical expertise in therapeutic management, we may find ourselves on a road with EBM as our Rome instead of patient care. If we bring all of our clinical expertise to properly position EBM, fully participating with the knowledge it brings, but always circumspect of its gifts, then we can achieve a knowledge-based, syntegrated approach to patient care, using all of the truly current best evidence.

The role of NASS in the development and publication of clinical guidelines that includes input from EBM and additional clinical resources for appraisal of areas of spine treatment is an important practical application of a “knowledge-based” approach to spine medicine.

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