

The Clinical Evolution of a New Technology to Best Practice: A Registry Concept

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Advances in medical research inevitably bring new technologies to market. With both physicians and patients expecting better diagnostic and treatment tools for medical conditions, new technologies have become more prominent in medical practice. These technologies—such as diagnostic ductal lavage, proton beam radiation therapy, laparoscopic surgical procedures, positron emission tomography imaging devices, and stem cell medical therapies—are initially marketed as more promising cures—more effective, faster, less injurious, and easier to use, although they are not proven to be safe or effective. It is difficult for clinicians to keep up with the technology applications, expanding benefits, or developing complications. Consumers read about these new and promising technologies in the lay press, which seeks to advise on the latest and best in medicine. More than that the lay press (and now Web sites) are a marketing vehicle for new technology companies. Ultimately, the physician is left to determine when and which new technologies to integrate into their medical practice.

The Permanente Medical Groups collectively support an Interregional New Technology Committee (INTC) with the charge to assess the scientific evidence and make recommendations about the medical appropriateness of new technologies in the practice of Permanente Medicine (See *TPJ* Vol 5, No. 1). The categories of new technologies reviewed include: diagnostic tools, therapeutic devices, surgical instruments, and medical and surgical procedures. Pharmaceuticals are reviewed in a similar manner by the national Pharmacy and Therapeutics Committee.

We are first aware of new technologies as experimental and under investigation in federal Food and Drug Administration (FDA) studies. This is the first of several FDA approval phases, including phased clinical trials. As new technology evolves toward common use in medical practice, there are also governmental and health plan coverage decisions that affect their availability and affordability.

A new technology that is approved by the FDA as safe for use and is approved by the government for coverage doesn't, however, mean that the technology has long-term safety or safety across wide populations. FDA trials do not define how effective the technology is or necessarily compare it to other current technologies or alternative technologies. Even after randomized, controlled clinical trials (RCTs) have been completed, the question of the technology's ultimate effectiveness is not answered. It may be an effective new practice but may not be a best practice—widespread in use, safe in the short and long term, the range of side effects understood, clinically efficacious, and well integrated into the general clinical practice of medicine.

Permanente Medicine clinicians strive to practice within the “effective” to “best practices” phases of this evolution (Figure 1). Other practitioners may utilize new technologies early on before long-term safety and widespread effectiveness are achieved. They may also abandon proven agents in favor of the new agent. A pharmaceutical example is that the proven benefit of reducing post myocardial infarction readmissions by using standard beta-blockers is ignored when new agents are substituted. This pattern of using the newest agents creates a component of the variation in medical practice that is now being assailed by the Institute of Medicine¹ as resulting in not only high-cost medicine but also in potentially unsafe medicine and unnecessary medicine. Hospitals, physicians, and health plans may tout the latest in new technology as the best in the science of medicine—in part as a marketing strategy to gain market position and dominance. These assertions don't reliably predict the best in medical care.

The dilemma then is what to do in the interim between a “new” technology receiving approval for use and initial benefit coverage and that new technology becoming an “effective” technology in medical practice. In the early phase of evolution, a new technology is “potentially useful” (Figure 2), then it becomes “selectively useful,” then “generally beneficial,” and finally “valuable.” It is potentially useful

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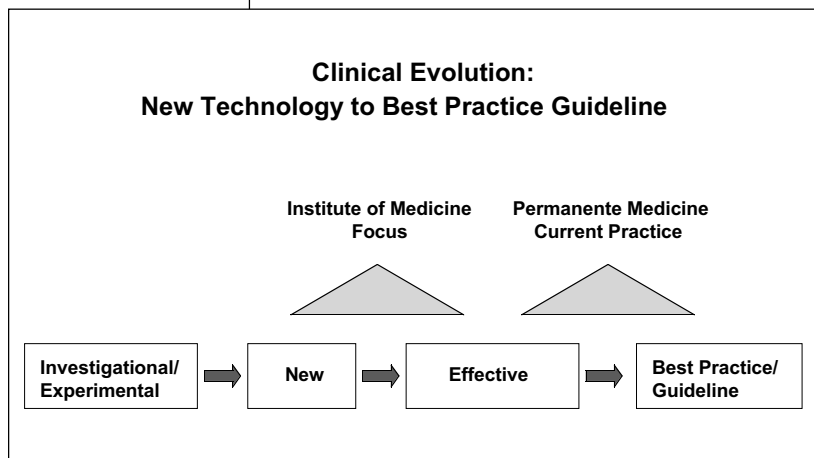


Figure 1

when first deemed safe enough for clinical use with FDA approval. But the questions remain: useful for whom, in what conditions, and for how long a term of use? When a technology evolves to “selectively useful,” the questions remain: how safe, and how widely effective? When evolution to “generally beneficial” occurs, there should be data to prove benefit through scientific evidence and expert opinion based on experience. Finally, when a technology becomes “valuable,” we can say that its safety is time-tested, that it is highly efficacious, and that it is well integrated into routine medical practice and into guidelines for both individual and population-based use.

Focusing on the period from when a technology is new until it is effective, what are the options for physicians? Use of the technology in practice could occur: only within the research protocols of clinical trials; in the widely variant use of physicians as they apply their individual criteria; or use, outside trials, could be restrained until evidence exists from RCTs, consecutive case series, or expert opinion.

I would propose another option: use of a new technology within a “registry.” The information collected could simultaneously begin to define a “new practice guideline” (Figure 3). This process would be similar to the Pharmacy and Therapeutics Committee permitting use of a new nonformulary drug. In Northwest Permanente Medical Group, with the benefit of the electronic medical record embedded in a regional clinical information system, a reminder automatically appears when the physician orders a nonformulary drug questioning the rationale for its use. The registry for a new technology would be used far less often, but all would benefit from an electronic reminder and electronic capture of patient and procedural information and outcome data. A registry (Figure 4) would request certain information: 1) statement of need, 2) practice/procedure description, 3) patient identification, 4) log of sequential use, 5) effects of use, 6) safety profile, 7) quality of life measurement. This documentation of clinical experience would build evidence for the specific region, and for other regions, in the ongoing assessment of safety and efficacy within our national Permanente Medicine practice and integrated delivery systems. Collection of data within a registry would also begin to build a new practice protocol, which could be updated and enhanced with increased clinical experience of the new technology.

This registry process would aid a department in better understanding its members’ use of the new

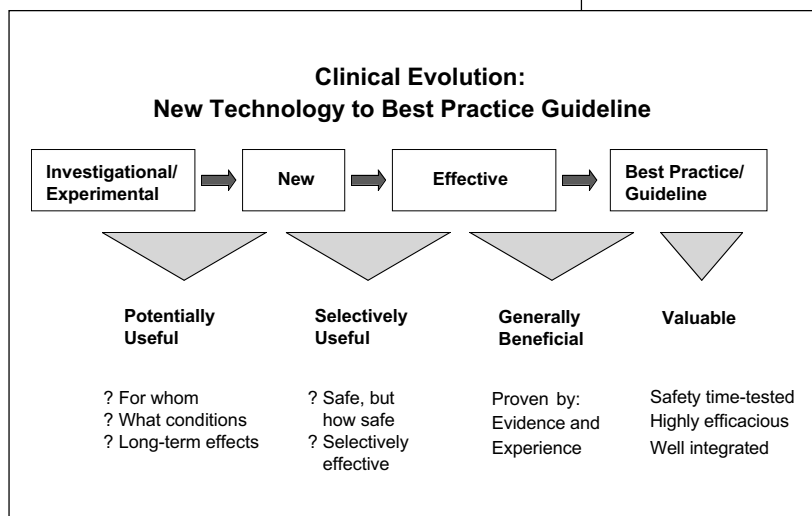


Figure 2

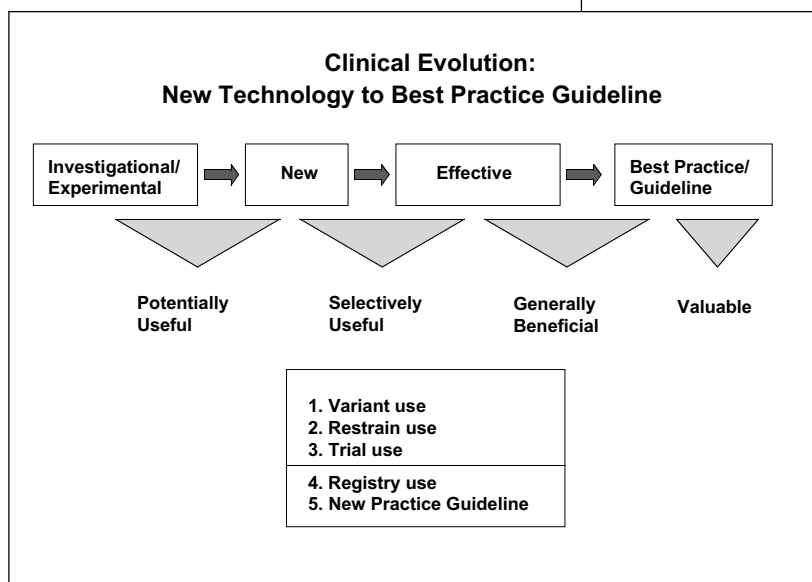


Figure 3

technology within its departmental practice. The department would be the owner of the registry, with the Regional New Technology Committee reviewing all registry practices at appropriate intervals to assess these new practices and update other departments. The Interregional New Technology Committee would be updated annually, or sooner based on important findings of the new practice, and would aid in the decision to reassess that new technology. Sharing practice findings among regions would accelerate national knowledge and experience (Figure 4).

In order to reduce the burden of documentation

of case use, the electronic medical record could provide a template for completion as part of the routine creation of a medical note for treatment. It could be customized so that the information required would be automatically extracted from the medical

note. Until the electronic record technology is available in every KP region, the registry information would have to be manually recorded at the expense of efficiency.

Several questions to be answered include: Would the new technology registry require a standardized set of data? Should registries be standardized across the KP regions? Who would provide analysis of the data? What area would fund the time, technical, and system support? Who would own the process? Who would manage the patient notification system?

Although new processing and evaluation may appear daunting, the benefit would be large if widespread variant use of an unsafe, or only marginally effective, new technology is avoided. Equally important, highly efficacious new technologies would be more quickly integrated into Permanente clinical practice with the outcome for patients being the safest, most effective, most affordable health care. ❖

Reference

1. Institute of Medicine, Committee on Quality of Health Care in America. Crossing the quality chasm: a new health system for the 21st century. Washington, DC: National Academy Press; 2001.

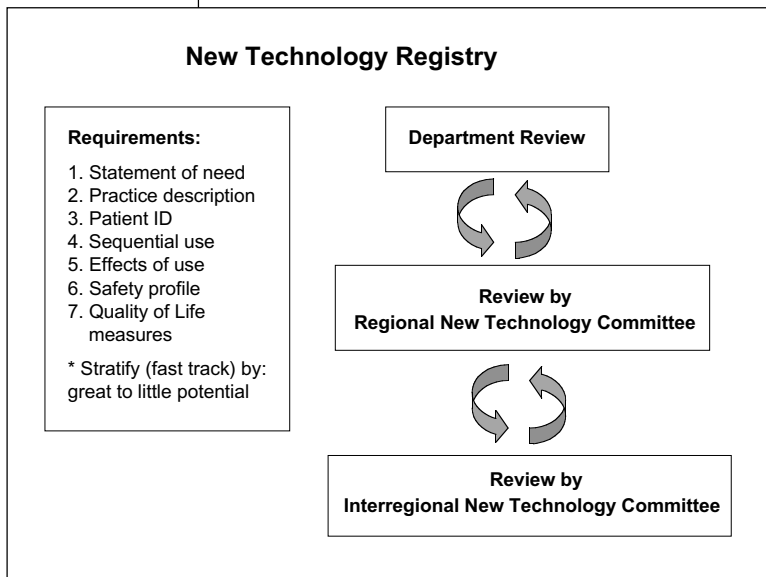


Figure 4

The Future

As for the future, your task is not to foresee it, but to enable it.
The Wisdom of the Sands, Antoine de Saint-Exupery, 1900-1944, French pilot, novelist and poet