

Crossing the Great Divide: Adoption of New Technologies, Therapeutics and Diagnostics at Academic Medical Centers

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Authors' Note

Few endeavors are the work of a single individual or of a small group of individuals. This paper is no exception. The thoughts and approaches highlighted are the result of the work of the members of the Innovative Diagnostics Committee, the Medical Policy Committee and senior management of the Massachusetts General Hospital. It is to be noted that this paper was originally presented as part of the 2004 Symposium at the annual October meeting of the Society of Research Administrators International in Salt Lake City for which it was awarded Best Paper of the Year – Second Place.

Abstract

The role of new technology in healthcare continues to expand from both the clinical and financial perspectives. Despite the importance of innovation, most academic medical centers do not have a clearly defined process for technology assessment. Recognizing the importance of new drugs, diagnostics and procedures in the care of patients and in the financial well being of the institution, the Massachusetts General Hospital established the Innovative Diagnostics and Therapeutics Committee to provide consultation to senior leadership. The Committee is composed of senior management, along with selected members of the medical

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staff and others, and provides consultation on the appropriateness of new technology adoption. A case is presented that highlights the issues related to asymmetry of information and the Committee's role in placing an institutional perspective on adoption. Committee methodology is briefly described along with important lessons learned.

Key Words:

technology assessment, technology adoption, quality, safety, innovation, innovative therapy

"Technology is dominated by two types of people: those who understand what they do not manage, and those who manage what they do not understand." –Putt's Law

Introduction

At many academic medical centers, adoption of new technologies can be a chaotic and ill-defined process. Traditionally, stakeholder physicians have decided whether to use new medical technologies on the basis of their patients' best interests and wishes. Technologic advances in medicine have the capability to enhance diagnostic and therapeutic options, but in doing so will likely increase the cost of health care. In the era of cost-based charging for medical services, the direct costs of new technologies were not borne by physicians or academic institutions, but simply passed on to payers. Fiscal constraints in health care now increasingly force institutions to assess the absolute and comparative costs of what they do, and to balance these costs against their academic and community missions. If adequate means are not available for evaluating outcomes, diagnostic and therapeutic techniques may be used with

little outcome benefit and, in some cases, with high cost and harmful impact.

Today, what is best for an individual patient must be considered relative to what is best for other patients, the institution, and society at large. The competition between physicians' allegiance to their patients and the financial realities confronting society and institutions is increasingly apparent. This tension will likely be amplified by smaller and smaller operating margins in academic medical centers and is already affecting clinical research activities. The unwillingness or inability of premier clinical research facilities to accept technology tested locally may negatively impact the willingness of manufacturers to seek out these institutions as test sites.

A major barrier to a systematic institutional approach to the adoption of innovative technologies and therapeutic methods is what Folland (1997) terms "asymmetry of information." Folland defines "asymmetric information" as "situations in which the parties on the opposite sides of a transaction have different amounts of relevant information." Physicians often lack knowledge and understanding of the financial health of the academic institution and of the impact of new technology. Hospital administrators are usually not well versed in patient management issues or in the technologies themselves. This asymmetry of information leads many academic institutions to make decisions about new technologies in a relative vacuum. Politics, emotion, and the eminence of the physician stakeholder commonly replace an appropriate value-based assessment. Much of the tension around institutional adoption of new technology stems from this asymmetry of information.

Discussions concerning asymmetry of information in healthcare decision-

making have traditionally been confined to economists. We believe that this lack of discussion in academic medical centers is counterproductive. Effective technology assessment and adoption requires a balanced and thoughtful review process with information transparency, but such systematic approaches are unfortunately rare.

How then should academic medical institutions contend with new diagnostic or therapeutic technologies? One approach is perhaps best exemplified by a case report concerning new technologies designed to control patient body temperature.

Case Example

Clinicians involved in the care of patients who have suffered a form of acute brain injury called subarachnoid hemorrhage (SAH) have known for some time that fever is a prognostic indicator of a poor outcome. SAH involves the abrupt rupture of blood vessels in the brain, usually from a ruptured aneurysm, and bleeding into the space between the membrane covering the brain and the brain itself. Some 10 to 15% of patients suffering from SAH will die before reaching the hospital. The mortality rate in the first week of hospitalization approaches 40%.

If the patient survives the event, a second critical juncture is reached some days later. Although the cause is unclear, some patients suffer an acute constriction of blood vessels (called vasospasm) in the vicinity of the original bleeding. The vasospasm can cause stroke and additional brain injury or death. Clinicians have seen a link between the development of vasospasm in patients and the presence of a fever. The presence of fever appears to be a predictor of poor outcomes in patients with SAH.

For many years, clinicians have sought to reduce or prevent fever in an effort to reduce the risk of vasospasm. Experimental animal models have demonstrated improved outcomes when cooling methods are employed. Various methods have been studied and are used clinically. Surface cooling methods have included alcohol wipes and cooling blankets. Research continues into the use of more sophisticated devices to achieve surface cooling. Inner core cooling methods have included the insertion of “refrigerating catheters” into large blood vessels. Although several surface and inner core devices have received approval for marketing by the Food and Drug Administration (FDA) on the basis of clinical research, no device has been shown to alter patient outcomes to date. The devices are expected to cost \$350-650 more per patient than cooling blankets. Is this a technology that should be adopted by academic medical centers?

The Physician’s Role

The physician’s role as the patient’s primary advocate is defined historically and by professional standards. The American Medical Association (2005) clearly defines this advocacy role in a policy statement. The policy also notes that physicians are not rationers of care, but “...will continue to utilize diagnostic and therapeutic measures and facilities in the best interest of the individual patient.” This clearly delineated role would appear, at face value, to be in potential conflict with institutional and administrative desires for cost containment.

It would be somewhat naïve to assume that the additional interests of the clinician researcher do not introduce yet another layer of complexity. Academic and financial conflicts are well documented in this regard. In this context, supplier-induced demand for a new technology may drive or be driven

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by the clinical and research interests of the physician stakeholder. (Taylor, 1995)

An Institutional Response

Academic medical centers have numerous constituencies, all of whom have parochial but reasonable expectations. The tripartite role of academic centers of clinical care, teaching and research are the traditional framework for the institutional expectations. Patients have reasonable expectations for appropriate clinical care while societal expectations also include teaching and research. Physicians reasonably expect to be able to manage patient diagnostic and therapeutic interventions without unnecessary infringements. Beginning in the late 1980's, however, a new stakeholder, third party payers, placed additional and seemingly contradictory demands on academic health centers. Cost containment has been the major concern for the majority of these payers. Academic medical centers now face a multitude of seemingly contradictory goals and objectives, fostered by the expectation that all of these activities will be conducted with appropriate fiscal responsibility in the face of increasingly constrained resources. This new paradigm has the potential for creating discord within the community and threatens the academic and social missions of academic medical centers.

That technology should bring value is not a new concept except perhaps in healthcare. The traditional value equation (Value = Quality/Cost) is transparent in most industries. Healthcare is remarkably different however. Healthcare value, like beauty or pornography, is in the eye of the beholder. Clinicians, patients, insurers and hospital administrators may have remarkably different views of exactly what value a new technology brings to the provision of care.

Recognizing that there is an asymmetric understanding of new technology, that the decision-making process is not transparent at most institutions, and that there is a growing need for a systematic approach to technology assessment and adoption, the Massachusetts General Hospital established the Innovative Diagnostics and Therapeutics Committee (IDT) in 1999. Although the hospital has for nearly thirty years had policies and procedures in place for bringing innovative diagnostic and therapeutic methods to the research domain for appropriate evaluation, no consistent or systematic process existed for informing and overseeing the actual adoption of these methods or new technologies into clinical practice. The creation of the IDT committee was intended to facilitate this process.

The IDT committee is charged with the responsibility of formally evaluating new diagnostic and therapeutic technologies for "quality, safety and efficiency." It is a permanent, standing subcommittee of the Medical Policy Committee and acts in a consultative role to senior management for technology adoption. The committee is also charged with ongoing monitoring of new technology use. Membership is detailed in Table 1. Senior level administrators as well as key stakeholders from the institutional review board (IRB), research administration, biomedical engineering, and medical staff are included. Legal counsel is available and the committee has a medical ethicist member.

Table 1. Committee Membership

Chief Medical Officer
Medical Ethicist
Legal Council (ex officio)
Senior Hospital Management
Chief Financial Officer
Patient Care Services/Chief Nurse Executive
Research Administration
Biomedical Engineering
Laboratory Medicine
Medical Staff
Institutional Review Board
Institute for Health Policy
Center for Integration of Medicine and Innovative Technology

A key element in the committee's ability to identify and assess new and emerging technologies and therapeutics is the presence of members from the hospital's research community. Membership of two IRB chairs is intended to provide the committee with a "view over the horizon" into emerging technologies. This perspective allows the committee to identify technologies early, and in many cases during clinical trials. It also allows new and existing technologies to be compared to emerging technologies of the near future. The committee seeks an assessment of the clinical attributes and administrative impact of the technology. Of note, the clinical assessment must also detail the social, political, and ethical impacts of the proposed new technology.

Committee methodology

The committee methodology includes active and lead participation by the clinical stakeholders. Members of the hospital's Decision Support and Quality Management Unit staff the committee, and provide analytic support for technology stakeholders.

These members, with a committee co-chair, support clinician stakeholders in preparation for presentations to the IDT. The stakeholder is the actual presenter. Technologies discussed to date have included laboratory tests, new interventional cardiology techniques, drugs and surgical procedures.

The IDT review process involves a standardized assessment of the institutional impact of the proposed new technology. The assessment is conducted with the active involvement of the clinical stakeholder and involves a community-based assessment that crosses departmental and institutional boundaries. A brief description of the domains of interest is noted below:

Clinical Assessment

Is it safe and effective?

The initial task in determining safety and efficacy is the development of standardized definitions for the technology under consideration. While improvement in patient outcomes is the desired definition of effectiveness, surrogate measures may

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be used out of necessity. Most devices are examined during clinical research without intent to determine changes in patient outcome. As a result, the true value of the technology is indeterminate. In the case of patient cooling technology, the devices are safe when used appropriately. Their effectiveness, however, is a matter of debate. In most cases, new technologies are approved for marketing by the FDA solely on the basis of safety and effectiveness in achieving a specific clinical effect. For example, in the case of cooling devices, the FDA assessment is based on one primary measure: the ability to safely reduce body temperature. Accordingly, many new technologies may be FDA-approved and introduced into clinical practices long before their ability to improve patient outcome is established. If effectiveness is defined as the ability to alter body temperature, cooling devices meet the requirement. If, however, effectiveness is defined in terms of reducing patient morbidity or mortality, the devices have not been demonstrated to be effective. The designs of clinical studies submitted to support FDA approval are often inadequate to demonstrate clinical effectiveness by the latter definition, thereby necessitating a more detailed outcome assessment prior to wide-scale adoption.

Is it an improvement over existing technology?

A critical element in the institutional decision to adopt new technology is a comparative assessment. New technologies must provide better value compared to existing technologies or procedures. Unfortunately, information on comparative effectiveness is not always available early in the adoption phase of a new technology. When comparative effectiveness and safety cannot be determined, clinical equipoise must be assumed, and further clinical

studies are likely to be necessary to provide sufficient information for this assessment.

Is there an urgent need for the technology?

The degree to which a new technology is embraced is in part related to the clinical need. For example, the value of a new technology in the treatment of a previously untreated illness may be high even if the safety is relatively low or costs are high.

Has the technology received regulatory approval?

As mentioned previously, adoption of a new technology by the marketplace at large usually occurs only after regulatory approval, and such adoption may occur prior to full assessment of clinical effectiveness. Academic medical centers engaged in clinical research are in a unique position of “adoption” prior to marketing approval as a result of participation in clinical trials. Because of this unique position, academic centers should conduct a technology assessment prior to actual market approval. Linkage with the IRB allows the IDT Committee to see technologies just over the “marketplace horizon” and prior to the traditional adoption phase. An important consideration in the acceptance of new technology, even in the clinical research phase, is the institutional acceptance of protocol constraints.

Administrative assessment

What are the social, ethical and political impacts of the technology??

New technology is no longer adopted in a vacuum. Resources consumed as a result of a new technology are not available for other clinical needs. Resources consumed include money, intensive care unit beds, nursing and other profession time, training and access to care. For example, a new

technology that does not alter outcome but prolongs hospitalization may result in cancellation or postponement of care to others. This can have serious and unintended consequences, especially if key resources such as operating room time, intensive care unit beds and nursing personnel are required for care. Technology applied in futile care may injure the patient, the patient's family, and society at large when applied in a constrained environment. Patient cooling technology may require additional manpower, needlessly consuming scarce nursing resources. In a constrained environment, institutional perspectives must be considered even in circumstances where the technology does alter outcome. How many resources can be devoted to serve a small sub-population of the community to the detriment of others?

How much does it cost?

Prior to the introduction of prospective reimbursement, the cost of new technology was not a major consideration in its adoption. Cost considerations include direct costs of acquisition and operation as well as additional personnel and training costs, and impact on capacity management. The contribution to institutional margins must also be determined.

Will it affect personnel mix?

Shortages exist for several types of healthcare providers, including nurses, physical therapists, pharmacists, and others. New technology can relieve or exacerbate these personnel shortages.

Does the technology provide "value?"

Demonstration of total costs and quality is required for the true value of a new technology to be determined. The value equation must be applied from the context of all legitimate stakeholders. Clearly the

patient perspective should dominate the discussion. Additional considerations in the demonstration of the value of a new technology must also include an evaluation of how it relates to the strategic interests and mission of the academic medical center and the risk management and legal liability implications.

Committee Recommendations

The IDT committee is consultative to senior management. As a consequence, recommendations, not decisions, are offered concerning the adoption of new technology. The committee may recommend: 1) adoption without provisions; 2) adoption for compassionate use only; 3) provisional adoption (limited number of cases; 4) adoption with clear eligibility criteria and treatment limits; 5) approve for research use only, or 6) do not adopt.

Conclusions

A number of lessons have been learned since the inception of the committee. Perhaps the most important lesson is the role of the stakeholder. Traditionally, much of the technology review process has remained hidden from the view of clinical stakeholders. But the committee determined early in its existence that a critical element of success was the involvement of the clinical stakeholder. Involvement of the stakeholder in framing of the clinical argument for the technology requires a complete review of the literature and objective assessment, not by the staff assisting the stakeholder, but by the stakeholder him- or herself. This process of critical review has lead many stakeholders to reconsider the value of a new technology and allowed them to recommend a far more limited adoption process than they originally intended. In at least one

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instance a stakeholder became convinced the technology was not optimal and that newer devices in earlier stages of clinical investigation were worth waiting for. The stakeholder involvement in the clinical assessment and presentation permits the members of the committee the opportunity to seek clarification when necessary allowing for a better understanding of the clinical value.

Direct participation in the administrative assessment of the technology has allowed the clinical stakeholder to see the full scope of institutional issues that extend beyond the bedside and the direct application of the technology. Staff education, resource consumption, bed allocation and its impact on other critical clinical services provided are not the traditional areas of interest for clinical stakeholders. Financial analyses expose the stakeholder to the new technology's true costs to the institution. In essence, the problem of asymmetry of information appears to be addressed in part by this extensive pre-meeting analytic process

Technology assessment and adoption practices of academic medical centers will likely evolve from the current somewhat chaotic process to a more formalized one. Research directed toward development of medical products, including drugs, biologics and devices, will be impacted by this shift in the decision-making process. Evaluation of innovative diagnostic methods and medical and surgical procedures may be similarly impacted. Value assessment will by necessity increasingly drive and support rational adoption of new technologies by institutions and the medical community. Research administrators involved in clinical research should assess the ability of their institution to conduct high quality value analysis as well as traditional efficacy assessment. By doing so, many of the

potential pitfalls encountered in this process can be avoided as we cross the boundary between innovation and practice in a rational and efficient manner for the benefit of all.

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