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**The Role of Technology Assessment and Comparative Effectiveness Research
in Increasing Health Care Value in the U.S.**

Commentary and a Perspective from an Integrated Delivery System

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Introduction

In every discussion of health system reform in the U.S. today, at the municipal, state and federal level, there is a remarkable degree of agreement that “technology assessment” (undefined) offers at least part of the solution to the growing crises of affordability, access and inconsistent quality in healthcare in the U.S.

Who, in fact, could disagree that better information on the effectiveness, comparative effectiveness and relative value of competing technologies and interventions would improve quality, promote cost effective-decision making, and enable physicians and patients to make better decisions about the use of innovative technology? Yet, despite the apparent conceptual agreement among many stakeholders, there are substantial obstacles in our fragmented, pluralistic and individual-centric healthcare system which has limited progress towards an organized, coordinated and robust technology assessment apparatus approximating the functionality of the National Institute for Clinical Excellence (NICE).

There are substantial impediments – functional, structural and cultural, which limit the use of technology assessment today and which will need to be addressed in the context of health system reform if technology assessment is to realize its potential to deliver higher quality, higher value healthcare. Steve Pearson, in his very thorough and thoughtful paper, explores many of these in detail, and this commentary highlights several issues for further discussion.

The need for “interoperability” of many technology assessment schemes.

It is unlikely that the current diverse and independent public and private technology assessment schemes will be replaced in the U.S. by a centrally run and organized single authoritative body charged with conducting what makes sense in a centrally financed, tax-supported social insurance scheme like the UK. Yet there would be enormous value in the development of a platform for interoperability among technology assessment schemes: common language and definitions; common criteria for the evaluation of evidence; methodology and frameworks; and potentially an accreditation approach to technology assessment efforts which would enable users to “cross walk” assessments and understand the basis for different conclusions about the same technologies.

And, as discussed in Dr. Pearson’s paper, “speed to market” of assessments, language that is accessible to users without the sacrifice of rigor, and confidence in the methodology will all be essential.

The need for delivery system reform and engagement of physicians.

There is substantial evidence that, for both structural and cultural reasons, many physicians are not able or willing to use the comparative effectiveness and cost-effectiveness information that does exist today to inform clinical decision making. There are multiple examples of physician prescribing patterns, for example, which fly in the face of reason and value, and which represent billions of dollars of expenditures beyond what can be justified clinically, such as the use of Nexium in lieu of generic or OTC omeprazole, or the persistence of Lipitor as the most commonly prescribed statin in spite of the availability of two generic statins which could effectively treat a substantial proportion of hypercholesterolemia. While physicians in organized systems of care (eg. The VA, Group Health Cooperative, Kaiser Permanente, Geisinger Health System) are able to exploit these value opportunities, the fact remains that the majority of medical care in the U.S. is delivered in practices of four physicians or fewer. For technology assessment and comparative value assessment to have an impact on the expenditure growth rate, there needs to be a mechanism to integrate the information into practice and decision making throughout the delivery system. Credible, meaningful up to date and easily understood comparative effectiveness information, from a trusted source, available at the point of care, could have a powerful impact on treatment decisions. It will require 1) a systematic way to deliver the information, and to insure it is current; 2) providers and provider organizations which accept accountability for both the quality and value of health care services delivered, and 3) appropriately aligned incentives which make it easy and rewarding to do the right thing. These conditions exist in isolated pockets in the U.S., in large group practices and organized systems of care. The challenge is to create the circumstance through delivery system reform to make this the reality of the many, not the few.

The role of industry.

There is a critical need to clarify and codify the role of drug, device and equipment manufacturers in organized systems of technology assessment (TA) and comparative effectiveness research (CER). In discussions of stakeholder engagement there is great ambivalence about the role of industry. While

manufacturers are clearly key stakeholders, and need clarity about the framework and criteria by which their technology will be judged, they are stakeholders with a business model which is potentially in conflict with assuring maximum health and economic benefit for consumers. Achieving the highest profit margin and greatest market share for an innovative technology makes sense for the shareholders of a publicly held technology company, while at the same time, that profitability may be coming at the expense of the affordability of health insurance coverage.

Industry has been active and successful at thwarting the use of formularies through state and federal legislative and regulatory efforts. They have organized and financed consumer advocacy groups to lobby state and federal legislators to preserve access to every innovative technology and all FDA approved drugs and devices, and have maintained publicly that all new technology should be presumed to be effective until proven otherwise. Industry spends millions of dollars a year investing in physician “KOL’s” (key opinion leaders) to promote their products, and in 2006 alone sponsored more than 250,000 promotional events involving physicians, a four fold increase from 1998.

Creating an appropriate role for industry without creating opportunity to neutralize or undermine the work of technology assessment and comparative effectiveness research is a struggle today, and will be in the future.

Consumer attitudes toward technology

Consumers remain the key stakeholders in any effort to leverage technology assessment to optimize and increase health care value. There is a substantial body of evidence documenting consumer suspicion of cost effectiveness analysis as a thinly-disguised effort to limit access to expensive new technology, and of the belief that “new” means “improved” until proven otherwise. Compounding this is the chaotic state of health insurance coverage, the opaque nature of what is covered, (and how much is covered) in any given year, and the fact that insurance coverage rules for many who are continuously insured change on an annual basis. Three things will likely be needed to increase consumer receptivity to technology assessment and comparative effectiveness research, and for consumers to see this as value added and in their interest. 1) meaningful efforts to engage consumers and incorporate consumer values in a high integrity transparent process 2) enthusiastic support of TA and

CER by the physician community and 3) an effective social marketing effort to shift to an environment in which consumers are demanding evidence of benefit and value before agreeing to use a new drug or device or to participate in a clinical intervention. One piece of the social marketing effort could be to lay out clearly the tension between the performance of drug and health technology stocks in one's 401k, and the increasing cost of one's health insurance.

The challenges of incorporating cost effectiveness in technology assessment, and moving from comparative effectiveness to comparative value.

The limited use of explicit cost-effective analysis, and comparative value assessments, is a reflection not just of the lack of tools or the stomach to be able to apply cost-effective analysis (Pearson). It is also a reflection of the limited authority public and private plans and insurers have to do so. State and federal regulators have substantially constrained the explicit use of cost-effectiveness in decision making, and litigation has consistently reinforced the message that consumers and plaintiff's attorneys have strong concerns about its legitimacy as a basis for decision making.

Cost-effectiveness analysis is used successfully and generally without serious challenge when there are competing technologies of comparable quality and effectiveness. There is, however, almost no ability for private plans or insurers to determine that a drug device or intervention without a competing alternative is not cost-effective, and therefore not covered, based on price alone, no matter what the price tag. Is this likely to change in systems of health reform? If health system reform retains care and coverage provided through private health plans, rather than through a centralized tax supported and financed insurance scheme it is hard to envision consumers vesting the authority to say "no" based on price and "cost-effectiveness" or "cost-benefit" in a carrier or health plan, given the increasingly individualistic nature of health insurance, and the strong cultural bias toward continued access to innovative technology at any price.

The use of technology assessment and comparative effectiveness research to inform benefit design and coverage decisions.

There is tremendous appeal to the notion that robust TA/CER would ultimately inform benefit design and that we will move towards a world of evidence-based benefits packages. The National Business Group on Health, under the

leadership of Helen Darling, has had a working group on evidence-based benefits trying to address this issue for more than two years. The reality, at least at this point, is that benefit design is a very blunt instrument, and operates at a population or risk pool level. There are very few interventions, drugs or devices which meet the standard of “not a medically appropriate option” for anyone, and therefore, are candidates for exclusion at the level of benefit design. The more nuanced issue of coverage determination based on the characteristics of the patient and likelihood of clinical benefit is a much better candidate to benefit from improved TA and CER. This space, criteria-based utilization management (UM), has been the battle ground between insurers/health plans and physicians for many years, and better evidence about who will likely need or benefit from an intervention could go a long way towards diminishing this conflict. What has yet to be explored or tested is the role that full capture of clinical data in registries or, more likely, electronic medical records with sophisticated search capability, might have in enhancing or supplementing more formal TA and CER. Given the investments that are and continue to be made in these systems, it is an issue of great interest.

The challenge of high cost, marginal health benefit drugs and devices with scant evidence of benefit, or evidence of scant benefit.

Even in the most optimistic of forecasts, TA and CER will not provide timely answers to all questions about newly approved drugs, devices and interventions. Particularly challenging are extremely high cost interventions with limited evidence of benefit in circumstances with no alternatives. In most situations, at least for fully insured plans, non-coverage is not an option. Coverage-under-protocol, or coverage-with-evidence-development, can potentially offer at least the hope of collecting better information to inform future decisions about coverage. A closer linkage between evidence development through clinical trials and comparative effectiveness research, as described in Dr. Pearson’s paper, will help to ensure the right questions are being asked, and answers relevant to clinical practice are possible. For conditions with small affected population (e.g. mucopolysaccharidoses), however, those answers may be a long time in development. The pricing strategy of manufacturers for these drugs is not within the framework of this workshop.

The potential role for a federal entity to sponsor, coordinate and conduct TA and CER

The potential value of a federal effort to set standards for TA, and to conduct, sponsor or coordinate CER can not be overstated – to give legitimacy to the effort, to give power to the effort, and to be a vehicle for social marketing efforts to consumers and physicians, to enable more sophisticated and informed decisions about the appropriate use of technology – for whom, under what circumstances, and with what level of certainty about the outcome. There are many issues to resolve including, but not limited to: source of funding (public, or private-public partnership); level of funding (some estimate at 4-5 billion dollars per year); insulation from political pressure and industry influence; relationship to private or other public technology assessment efforts; eliminating/managing conflicts of interest in the most rigorous fashion possible; scale and scope of the effort. As Steve Pearson asserts in his paper, creation of such an entity will substantially enhance the impact of all other efforts to improve the quality, rigor and impact of TA and CER.