



Ethical Perspectives On Health Care Reform

COMPARATIVE EFFECTIVENESS RESEARCH

A Threat to Patient Autonomy?

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The Affordable Care Act of 2010 includes provisions to stimulate and fund comparative effectiveness research (CER), advocated as a critical component of health care reform. Critics are concerned that CER research ultimately will provide cover for those who wish to deny needed care to patients in order to cut costs. Former Arkansas Gov. Mike Huckabee has written that CER represents “the seeds from which poisonous death panels will grow.”¹

What are the actual ethical implications of comparative effectiveness research?

WHAT IS IT?

CER often is associated with evidence-based medicine. These terms, however, often are used inconsistently, leading Bryan R. Luce and colleagues at The International Working Group for HTA (health technology assessment) Advancement to propose a refined set of definitions and a conceptual scheme.² We generally accept their recommendations, but with one reservation we will note below.

Luce et al. begin by noting three questions that need to be asked about a medical intervention:

- Can it work? (efficacy)
- Does it work? (effectiveness)
- Is it worth it? (cost effectiveness)

The distinction between the first two questions calls attention to the fact that much medical research is conducted under conditions far removed from actual medical practice in the community. Subjects may be cared for in special facilities and very closely monitored, and they may have only the target disease and no other medical problems — unlike the multi-problem patients

who commonly occupy physicians’ offices.

A treatment that *can* work in such ideal conditions then has to show that it *does* work when transposed into real-life health care. A treatment that *does* work in the community may still end up being considerably more expensive than an alternative treatment that works equally well — thus it is less *cost effective*, the focus of the third question.

To answer these questions and make use of the answers in practice, Luce et al. continue, we generally have to proceed through three stages. Evidence must be generated through scientific trials. The evidence then has to be synthesized, since multiple trials of the same treatment under slightly different conditions may yield contradictory results. Finally, the synthesized evidence must be applied in the clinical setting to individual patients, taking into account both their unique health conditions and their personal preferences.

Luce et al. propose that we view CER as synthesizing existing evidence and generating new evidence to determine whether the treatment works.

But we dissent from that definition. CER is a narrower concept than their account suggests. Specifically, it seeks to evaluate (compare) “the impact of *different options* available for treating a given medical condition for a particular set of

patients.”³ Therefore, CER does not address the broad question of “Does it work?” but rather the narrower question, “Which works better?” We agree with Luce et al., however, that CER generates a body of evidence that evidence-based medicine can then use at the level of clinical decision-making.

Luce et al. next suggest that research aimed primarily at assessing cost effectiveness (to answer the “Is it worth it?” question) be called health technology assessment (HTA), a term that is widely used in Europe but out of fashion in the U.S. The physician using evidence-based medicine to aid decision-making with the individual patient will draw primarily on comparative effectiveness research to offer a treatment recommendation, but also needs to be aware of health technology assessment, as the burdens, including financial cost, of treatment need to be considered and discussed during informed consent. The policymaker deciding what treatments ought to be included as covered benefits under an insurance scheme may use data generated by both CER and HTA. Some have long argued that evidence-based medicine and clinical care ought not to take financial costs into account — in other words, that evidence-based medicine based on comparative effectiveness research should ignore the “Is it worth it?” question.^{4,5} We believe it is important for both clinicians and policymakers to consider the burdens, including financial costs, of effective interventions.

Burdens of treatment matter to patients. These include burdens of all kinds, including inconvenience, risk of side effects and indeed financial burden. Seniors who fell into “the doughnut hole” of Medicare drug reimbursement, for example, spoke of having to choose between paying rent, buying food and filling their prescription.⁶

Considering and discussing the burdens of treatment needs to be part of the informed consent process between physician and patient. Informed consent requires that information relevant to patient decision-making be disclosed to them. Thus physicians need to pay attention to financial costs.

Moreover, physicians have an ethical obligation to exercise due care in the stewardship of

scarce societal health resources, alongside their ethical obligation to advocate for the interests of individual patients.^{7,8} We agree with Eddy that when physicians or health systems allocate resources unwisely or wastefully, it is ultimately individual patients, not some nameless “society,” who are denied needed care.⁹

It might seem a tempting division of moral labor to insist that policymakers need to take costs into account, but that individual clinicians may never “ration at the bedside.” However theoretically attractive, this proposal is both unrealistic and unwise. It is unrealistic because clinical decisions involve a complex interplay of benefit, harm and cost considerations. Telling physicians to exclude cost from consideration is likely to drive rationing underground and hide it from ethical scrutiny.

The proposal is unwise because physicians can make finer-grained rationing decisions than any

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policymaker, based on patients’ unique clinical characteristics. As we will discuss in more detail below, this includes advocating strongly for the occasional patient who is highly likely to benefit from an intervention that is often not cost-effective. “Bedside rationing,” done the right way, is therefore actually in patients’ interests.¹⁰

There are two ways that the evidence gleaned from CER (as well as from other sorts of research) may fail to address an individual patient’s situation when the practitioner applies evidence-based medicine methods to that patient’s case. Most obviously, the patient’s personal preferences may run counter to what the evidence would otherwise recommend. For example, a patient told that surgery for his coronary artery disease has a greater likelihood of extending his life than simple medical management may still choose to avoid surgery.

A less obvious disconnect reflects the fact that any clinical trial ultimately provides an average result across a given population of patients. The

clinical trial patients almost never exactly match an individual patient's situation. Even if one could do a study on subjects *exactly like one's patient* in all relevant ways (assuming we could even determine what those are), we would still know only a result that represents an average of everyone in the trial. We would not know exactly what would happen when this treatment is administered to a specific individual. This inherent limitation of clinical research means it is always possible that applying the results of CER to any individual patient's case might lead to that patient being denied potentially useful care.

If relying on the outcomes of CER risks denying potentially useful care to patients, what are its benefits?

Advocates respond that comparative effectiveness research is valuable, indeed necessary, to clinical practice because the vast majority of clinical trials being conducted today either fail to answer the "Does it work?" question, or else they only generate evidence and then fail to synthesize it. The end users of the evidence — the physician

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and patient — want to know what test or what treatment is *best* for the patient. Many clinical trials are conducted under circumstances and with study designs that are ill-suited to answer this ultimate question. There are several reasons for this failure:

- Training and interests of clinical investigators
- Lack of resources and support for complex, longer-term trials
- Commercial interests

Investigators may do limited trials under ideal conditions that address surrogate endpoints rather than outcomes of most interest to patients

and physicians because that's what they have been trained to do, know how to do, know how to get funding for and are rewarded for within academic circles. It is generally much easier to fund a short-term study that addresses questions of limited practical concern than it is to find funding for a longer-term or more complex study that would tell us what really matters most to physicians and patients. (Consider for example the United Kingdom Prospective Diabetes Study, which provided much useful information about the management of Type II diabetes, but which took a decade to complete.)¹¹

Finally, the vast majority of clinical trials studying drugs or devices are today funded by the manufacturers. Commonly, the Food and Drug Administration will approve new drugs in the U.S. based only on evidence that the drug is superior to placebo ("Can it work?"), without requiring any evidence that the new drug works better than any existing drug or compared to non-drug therapy. Thus, for-profit companies are naturally less interested in conducting comparative studies that would generate the evidence

that would most help physicians advise their patients about the relative effectiveness of available interventions. Their goal is to get their products quickly onto the market by overcoming regulatory hurdles and then to maximize product sales. Years of "regulatory capture" (the tendency of government regulatory agencies to become inexorably influenced by the regulated

industry) have led these agencies to lower the bar for market approval.¹²

Commercial interests have been among the strongest critics of CER and especially of health technology assessment.¹³ Asking hard questions about which treatment actually works better than the alternatives, and also considering comparative costs, would be contrary to the interests of many firms with a large financial stake.¹⁴ By contrast, research that could be used to limit patients' covered benefits could be of great financial value to private insurance companies, and indirectly to the U.S. taxpayer, as more care is funded through government programs. Thus financial interests potentially intrude on both sides of the "Why CER?" question.

ETHICAL DEFENSE OF CER IN HEALTH REFORM

In terms of commonly cited ethical principles, health care reform must address a tension among respect for autonomy, beneficence and justice. Physicians seek to offer, and most patients wish to have available, all medical treatments that hold some chance of improving the patient's health. In a world in which health care resources are limited, providing all possible care to one patient will mean that other patients must go without and that costs will escalate out of control. Current statistics suggest that between 18,000 and 44,000 Americans die each year as a direct result of lacking health insurance coverage.^{15,16} In short, we do not have the option of avoiding health care rationing; instead the question is what is the fairest and most humane way to ration.^{17,18,19}

We stated that physicians have dual ethical duties, primarily to advocate for the individual patient, but also to act as wise stewards of limited resources. This ethical claim suggests a general framework for the duties of both physicians and policymakers.

Individual physicians have a duty first and foremost to try to recommend for each patient whatever health care would provide the most benefit and the least harm. To carry out this duty, physicians obviously need good evidence as to the benefits and harms of various interventions—that is, sound evidence-based practice guidelines. (Let us for purposes of argument assume that all evidence derived from CER will eventually inform development of “guidelines,” without delving here into all of the debate over what good guidelines are, how many of the guidelines promulgated today meet those standards and so on.)

In applying the general practice guidelines to individual cases, physicians need to keep in mind the problem of individuals vs. populations and to be prepared to determine when the individual patient seems (based on clinical judgment) to count as an exception to the guideline recommendations. But at some point the duty of wise stewardship must be brought into the equation. When a patient demands a test or treatment that is contrary to the recommendation of the guidelines, and when the physician can find no good evidence that the guidelines do not apply well to the patient's case, then the physician's duty of advocacy eventually takes second place to the duty of stewardship. The patient has every right then to

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pursue an insurance appeals process, seek a second opinion or change physicians, but the physician's individual advocacy duty is not limitless.

Policymakers have ethical duties both to provide for a fair and transparent distribution of limited health resources and also to design systems that respect and facilitate individual physicians carrying out their own ethical responsibilities. This entails assuring that guidelines are developed through sound processes and that benefit coverage is based as much as possible on sound guidelines informed by appropriate CER and HTA. Policymakers also should assure that there is a fair appeals process when either physicians or patients claim exceptional need.

Finally, policymakers need to assure that the overall distribution of health resources is as fair as possible, especially taking into account minorities and other vulnerable populations whose needs have historically been neglected.²⁰ At least three lines of argument urge special attention to these vulnerable populations. First, justice requires that past unfair discrimination be rectified if possible. Second, sound principles of social justice require that economic inequalities be to the advantage of the least-well-off groups in society.²¹ Third, considerations of human capital demand that we invest in the health and education of vulnerable populations, lest their future contributions to the well-being of the entire society be compromised.

How difficult is the balancing act that we are asking our policymakers to fulfill?²² There is considerable reason to believe that the U.S. currently wastes a huge proportion of all the money spent on health care on non-beneficial or marginally beneficial treatments.^{23,24,25} Even by conservative estimates, if these funds could be redirected toward more beneficial treatments, then more than enough money would be saved to fund the medical care of all Americans who are now underserved by the system. If this overall economic analysis of the current U.S. system is on target,

then we have a very strong ethical obligation to develop whatever evidence-based tools are needed to allow both policymakers and physicians to accurately identify those interventions that now waste our resources. This would seem to argue

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for a considerable investment in CER and the associated HTA.

If indeed we could fund ideally all of health-care reform and considerably lower future health care costs by redirecting funding away from non-beneficial or marginally beneficial treatment, then an important political problem becomes obvious: All that money is now going into the pockets of providers and manufacturers who have a very strong financial interest in opposing those reforms. These powerful financial interests use arguments against health care reform, and specifically against CER and HTA, that are specious on close analysis but that politically can be highly effective. Examples of these claims include the use of “rationing” as a scare word (failing to distinguish between just and unjust rationing approaches), warnings against “the government getting between you and your physician” and, at the most extreme end, reference to government “death panels.” An accurate ethical analysis of the strengths and weaknesses of CER is more difficult in this highly politicized setting.

DOES CER THREATEN PATIENT AUTONOMY?

One common ethical concern raised (at least implicitly) about CER is that it will threaten both patient autonomy — the ability to secure needed treatment — and provider autonomy — the ability to advocate effectively on behalf of one’s patient. (As the rhetoric puts it, “the government getting between you and your doctor.”) Three responses are pertinent.

■ CER Can Aid Patient and Provider Au-

tonomy. Patients want to receive the care that is best for their condition and that avoids any unnecessary risks of harm. Physicians wish to be able to recommend such treatments to their patients with confidence. Today, both patient and physicians often lack the scientific evidence to accomplish these goals. CER is needed to fill the gaps.

Patient autonomy may also be aided by HTA that identifies the most cost-effective care. Patients may have a direct financial interest in cost containment — for example, when their insurance requires percentage co-pays. Indirectly, all patients have an interest in controlling costs so as to minimize future needs to increase their insurance premiums and the taxes that pay for Medicare and Medicaid.

■ CER Itself Does Not Threaten Patient Autonomy or Benefit. Properly understood, CER does nothing to restrict the access of any patient to any test or treatment. Problems that arise for patients are due to the uses to which a policymaker might put comparative effectiveness research — especially if the policymakers use it in ways that violate the general ethical guidelines sketched above, such as failing to allow for a fair appeals process. The possibility that CER may be misused does not negate its possible benefits. Opposition should be directed against the specific policies that misuse it to the patients’ detriment, not against comparative effectiveness research itself.

■ Some Interference with Autonomy Is Required by Justice. Simply because a policy based on CER denies access to some procedure a patient desires does not mean that the denial is ethically wrong. Autonomy is only one among several principles that govern health care ethics. The requirements of justice may conflict with and legitimately limit the exercise of autonomy. A patient awaiting an organ transplant, for instance, may autonomously choose to go to the front of the line, yet justice requires waiting in turn, even if he or she dies before receiving the desired organ. If the policy meets all specified ethical guidelines, then a denial of a patient’s access to a treatment may be defensible.

HOW CER PROMOTES JUSTICE

If CER is to be used to inform policies that ultimately ration health care, then the system of ra-

tioning must be fair and transparent. We define a fair rationing system, at least initially, as one that well-informed, healthy patients would willingly agree to accept should they or their loved ones fall ill.²⁶ We believe that any group of citizens, asked to participate in this variant of what philosopher John Rawls called an “original position” for selecting principles of justice, would readily agree that the first care to be excluded under a fair scheme is that demonstrated by solid scientific research to have no medical benefit.²⁷ The next to be excluded would be care that has some benefit, but that is notably less beneficial or more harmful compared to an alternative treatment for the same condition. Participants in this rationing discussion would also insist, as we have stressed, that there needs to be a fair and compassionate process for dealing with the exceptional patient who may receive comparatively greater benefit from this treatment due to idiosyncratic medical circumstances not well addressed by standardized guidelines. But if the guidelines are solidly grounded in evidence, the exceptional cases should be rare.

We have noted empirical evidence that if we were to effectively eliminate all the medical interventions now administered in the U.S. that fall under these two categories for agreed-upon exclusion, we could save considerable funds. The funds saved would be sufficient to reduce medical costs to an affordable level across society, allowing insurance coverage to be extended to all who now lack it. And all this could be done without denying anyone a medical treatment that is clearly and predictably beneficial — even if it is very costly. We would not, for example, have to resort to the rationing scheme proposed by Arizona Medicaid to trim costs by denying patients access to expensive but potentially life-saving organ transplants.²⁸ This set of outcomes would go far toward describing a truly just system of providing health care and containing costs in the U.S.

There is no guarantee that this idyllic possibility would be available forever. Globally, the two main drivers of medical cost increases are aging of the population and technological innovation.²⁹ These factors might combine in the future to create hard rationing choices, where the most clearly and predictably beneficial care is so expensive that we simply could not afford

it for everyone in our society. Highly individualized therapeutic approaches based on advanced genomic science, for example, might prove to be such a “break-the-bank” innovation.

But for at least the foreseeable future, a rationing scheme for U.S. health care need not be unduly onerous in order to achieve desired outcomes. This does not mean that such a scheme would be politically easy to implement, given the opposition of special interests.

So far we have seen that some of the frequently stated ethical reservations about CER are either based on misconceptions, or else can be mitigated by appropriate policies. We now turn to what we consider to be two more worrisome objections that ought particularly to concern policymakers.

QUALITY OF DATA

Comparative effectiveness research and evidence-based medicine guidelines relying on it can only be as good as the quality of the scientific research and data analysis on which they are based. Policymakers have a responsibility to do all they can to assure comparative effectiveness research is based on the best available evidence. In some cases, the best available evidence is not a randomized controlled trial, or at least not such trials performed on populations insufficiently similar to the current patient population or that ask a research question that does not directly address the current clinical concern.³⁰ This means CER advocates must avoid the temptation to engage in “decerebrate genuflection” at the altar of the randomized controlled trial.³¹

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One threat to the integrity of comparative effectiveness research is allowing commercial interests sufficient control of the evidence-gathering and evidence-analysis processes to “spin” the results in ways that favor the marketing of their products. The frequent representation of physicians with financial conflicts of interest on

guideline-writing panels is a particular cause of concern.³²

We believe it is unfortunate that of proposed models for administering CER, the final version of the health care reform law would implement a

All applications of comparative effectiveness research should be accompanied by a disparities impact statement, just like plans for industrial development ideally ought to be accompanied by environmental impact statements.

version allowing for a greater degree of influence by commercial interests. Moreover, it creates a new agency to oversee CER, rather than assigning the responsibility to the existing Agency for Healthcare Research and Quality, which has considerable experience with CER.³³

VULNERABLE POPULATIONS

Our second area of concern is actually a subset of the first. One way comparative effectiveness research can be based on inadequate data is if certain populations are disproportionately excluded from those enrolled in research trials. Groups subject to being overlooked in the main body of medical research include minorities, women, children and the elderly.^{34,35} When a person falls within several such groups, such as elderly African-American women, the risk that the data on which comparative effectiveness research must rely will be inapplicable to the patient's case increases exponentially.

Health disparities based on race or ethnicity present a particularly worrisome problem in health care justice. The causes for such disparities are complex and defy quick fixes.^{36,37} It has, however, been shown quite clearly that merely having excellent motives is no guarantee against perpetuating or exacerbating disparities.³⁸ Policymakers, therefore, cannot rely on usual processes and methods in assuring that CER is not used in ways that worsen existing health disparities. They must instead adopt approaches that address concerns about vulnerable populations

from the start, instead of allowing such concerns to be tacked on later as an afterthought. All applications of comparative effectiveness research should be accompanied by a "disparities impact statement," just like plans for industrial development ideally ought to be accompanied by environmental impact statements.

Properly used, CER can be a tool to promote both patient autonomy and justice, to aid physicians and other providers in their duties to advocate for their patients' interests and to inform both clinical practice and health policy. Some common objections to CER are based on misunderstandings. But the limitations of clinical trials on which comparative effectiveness research relies point to serious deficiencies that

should concern policymakers who use CER to guide health care cost containment efforts and to design health care systems that deliver the best possible care to patients.

We believe that these problems are manageable and that a robust comparative effectiveness research program should be a centerpiece of meaningful health care reform.

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