

Comparative Effectiveness: What's at Stake for Consumers?

The Public Policy Institute and Consumers Union, with support from Divided We Fail, sponsored a Solutions Forum on October 9, 2008, to look at comparative effectiveness from a consumer perspective. AARP's president, Jennie Chin Hansen, and Consumers Union's chief executive officer, Jim Guest, spoke on the importance of comparative effectiveness as a foundation for evidence on what services work best in health care. Gail Shearer, director of Health Policy Analysis, amplified the Consumers Union perspective and moderated a panel of experts, who spoke to different consumer perspectives on the issue—from consumers as citizens, representatives at the decision-making table, members of different communities, and patients.

Comparative Effectiveness—Why It Is Important for Health Care Reform

Health policy experts point to investment in comparative effectiveness, the study of what works best in health care, as a critical component of a reformed health care delivery system. Jennie Chin Hansen started the forum by discussing AARP's key objectives—to achieve health and financial security for everyone. AARP members, like most Americans, look at health care from two perspectives—as a pocketbook issue because affordability is critical, and as a safety and quality issue. They are demanding solutions to the upward spiral in health care cost, which they correctly see as a threat to their financial security.

Many policy analysts have noted the lack of a scientific knowledge base to support many of the health care decisions that patients and clinicians now make. There is a good deal of consensus on the need for more research, including comparative effectiveness research that performs head-to-head

comparisons on what therapies work best for patients with a given health problem. Estimates vary widely on the proportion of medical care in the United States that is actually supported by evidence. Some place that figure at well below half. The lack of investment in comparative effectiveness is stunning. The Institute of Medicine has pointed out that, of the nation's more than \$2 trillion annual expenditure on health care, less than 0.1 percent is invested in assessing comparative effectiveness of prescription medications, healthy behaviors, and treatment interventions.

Promising efforts are under way to build the evidence base, but these efforts are not enough. They include the evidence-based practice centers at the federal Agency for Healthcare Research and Quality and state-level efforts such as Oregon's Drug Effectiveness Review Project. Private initiatives such as ECRI Institute and the Blue Cross Technology Evaluation Center also make important contributions. Many are calling for an independent entity to oversee the conduct of comparative effectiveness research. A key issue is governance. The

entity should be independent and free from economic and political influences while being transparent in its operations. The participation of all stakeholders, including consumers and patients, will be important.

What Consumers Union Has Done to Help People Understand What Works

Jim Guest of Consumers Union echoed the importance of investing in comparative effectiveness research. He reminded the audience that since 1936, when Consumers Union was formed, comparative effectiveness and evidence-based information has been a key focus of the organization, whether for buying a car, a toaster, a DVD, or a digital camera—giving subscribers and the public the information to make choices. Consumers Union also evaluates and rates drugs, using an unbiased scientific approach, and rates treatments. In a project with the *British Medical Journal*, Consumers Union takes the information that the *Journal* provides to doctors and turns it into plain English for consumers. This helps consumers understand which treatments for back pain, for example, are proven to be potentially effective, which ones have been proven to be ineffective, and which are in between. Consumers Union has also rated natural medicines, health maintenance organizations, hospitals, nursing homes, and a variety of other elements of the health care system.

Consumers are looking for useful information. Consumers Union makes it available through its magazine; there are more than 8 million subscribers to the different print products, and about 20 million people get the magazine from someone else. A Consumers Union health newsletter has been growing at double-digit rates for the last few years, which demonstrates that people are looking for information they can trust on

health care. Consumers Union also offers a drug reference guide and a program called Consumers Reports Best Buy Drugs. This program takes information from the Drug Effectiveness Review Project and adds price information. Best Buy Drugs can save people thousands of dollars, depending on their medical situation. And the Consumer Reports Health Ratings Center is a new initiative to give consumers objective sources of information around health care and related matters.

Consumers Union's focus groups and research reveal that people think their doctors are already using comparative effectiveness information. The organization is trying to let people know that they can expect more from their physicians, that they should not assume that all the health care they receive has been clinically proven, and that they should expect to ask questions and not be brushed off. Ideally, patients will get answers to their questions, improve the dialogue, and create a demand among both medical providers and patients for more comparative effectiveness information.

What Does Comparative Effectiveness Mean?

Gail Shearer of Consumers Union provided a framework concerning what comparative effectiveness really means for consumers. Comparative effectiveness research tends to go hand in hand with the term "evidence-based medicine." But the average consumer does not know what evidence-based medicine really means. To most consumers, it sounds like rationing. AARP and Consumers Union are combining their efforts to educate consumers about what comparative effectiveness research really means. Shannon Brownlee, the author, has a definition that is very helpful: the ability

to compare different kinds of treatments to find out which one works best for which patient.

Improving the information base about what services work will improve quality, safety, and costs. The Drug Effectiveness Review Project is a great success story: For example, most of the states that are members of the project did not put Vioxx on their preferred drug list. This decision probably saved thousands of lives and certainly thousands, if not millions, of dollars in medical expense. Another example can be seen in the October issue of *Health Services Research*, which shows the potential savings. Researchers at the University of Pittsburgh and Massachusetts General Hospital looked at the Best Buy Drug Program. They found potential savings of about \$2.7 billion if people who are taking a drug in one of four categories switched to a best-buy drug. That is about 8 percent of spending in those drug categories. Many individuals who are taking drugs in those categories can save between \$1,000 and \$2,000 a year by switching from what is probably a highly advertised drug to a best-buy drug that is equally effective, but costs much less.

Some of the pressing policy issues to be decided include how to engage stakeholders and ensure the long-term sustainability of a new entity that does comparative effectiveness research. The entity needs to be structured so it does not fail, stakeholders should be engaged, and the system should not build in conflicts of interest that would undermine the value of the research. Another key issue for policymakers is how to structure a new entity so the research does not increase health care disparities, but actually embarks on a path to reduce them.

Consumers Union is translating evidence-based medicine for consumers, an important role. On the Consumer Reports Health Web site, viewers can find research on translating evidence-based medicine about medical treatments. Consumers Union plans to expand its work on doctors and hospitals. Consumer Reports' Best Buy Drugs is based on data from the Drug Effectiveness Review Project, which about 14 states now use to select drugs for their Medicaid programs.

Consumers as Citizens

Marge Ginsburg, executive director of Sacramento Healthcare Decisions, talked about the role of citizens in contrast to the role of consumers. The role of citizens is to help define the underlying principles or values for how our society is going to provide health care, allocate shared health care resources, and influence providers and consumers. This citizen role, however, is not one that this country has fostered. If comparative effectiveness involves a value determination (finding the acceptable balance between the benefit of medical intervention and its cost), then it must incorporate citizens' views on the use of communal resources. Virtually all insurance products are based on the concept of shared risk and shared dollars.

Priorities change depending on which hat we wear, citizen or patient. The work Sacramento Healthcare Decisions has done suggests that citizens, given accurate, unbiased information, welcome the chance to weigh in on decisions about societal health care priorities. The big question is whether we as patients are willing to live with the limits that we establish prospectively as citizens. It will require greater openness about the reality of finite resources and consensus

on the obligations and limits of health care as a social good.

Sacramento Healthcare Decisions has engaged citizens in a variety of projects to explore priority setting in the face of finite resources. The intent of this work is to help policymakers understand how people make trade-offs and to convey the importance of citizen participation in these larger value-based questions. Two of its projects centered on comparative effectiveness and incorporated the concept of cost-effectiveness for making clinical or coverage decisions. While most of the project findings are qualitative, at the conclusion of the latest project, Sacramento Healthcare Decisions used a post-discussion written survey to ask participants if cost-effectiveness should be considered when the government makes decisions about insurance coverage. Eighty percent responded that it should be used in some or most situations. Fifteen percent responded that it should never be used, and 7 percent had some other response.

If the public is going to accept changes in health care policy and practice, then inclusiveness of their input and transparency of the process must be hallmarks of getting to a system we want and can afford.

Consumers as Stakeholders

Art Levin, director of the Center for Medical Consumers, addressed how consumers can be effective at the decision-making table. He supports the right and need for citizen experts to be fully enfranchised—not only to be at the health policy decision-making table, but when appropriate, to lead the discussion. Levin's most relevant experience is as the consumer representative on the Food and Drug Administration's (FDA) Drug Safety and Risk Management

Committee. This and other experiences have taught him that representation of citizen-consumer public interest is critical in all levels of health policy discussion and decision making. But it has to be meaningful representation, preferably more than one consumer, because there are lots of other people at the table in groups representing special interests.

Citizens and consumers should be selected as representatives on the basis of objective criteria, including an absolute prohibition of any material conflict of interest or inappropriate bias such as cooption by industry. It is not easy to be a consumer representative, especially in open public settings. Audiences can be very large and media coverage can be extensive. Many experts know each other by first name or by reputation, and do not know the consumer representative. It can take courage and passion to be a single consumer representative and to buck the trend set by other participants. Levin cast the only vote against Vioxx in the Drug Safety and Risk Management Advisory Committee; the chair of the advisory panel afterward said he told his friends that the only one who got it right was the consumer representative. So it is possible for consumer representatives to play a meaningful and important role in this process, even if the vote goes against them.

Another ground rule for effective consumer participation is for consumer representatives to be thoroughly committed, including being present at every meeting. They must do the homework and go to meetings well prepared. And they must be willing, to the degree permitted by the rules of the game—and it is important to follow the rules of the game—to talk to other folks, other advocates, and other citizens about

the topic of the meeting. Another critical concern is that consumer representatives not define themselves narrowly. Consumer representatives often bring medical and scientific expertise to the table as well as their advocacy experience.

Those who doubt the utility of having citizens, consumers, or patients involved in these deliberative processes about health care policy usually express two concerns. One is that the decisions to be made are too complex for the laity to understand. The second is that only those with impressive credentials, postgraduate education, professional education, and years of experience in scientific method, research, evidence synthesis, and clinical practice—a skill set far beyond that of many consumer representatives—can participate meaningfully in the process. That simply is not true. For example, the HIV/AIDS community became extremely well organized and outspoken when it became clear that the health care system, the research, and the treatment community were being terribly unresponsive to this epidemic. Many advocates and patients quickly developed a startling degree of scientific knowledge about the virus.

An important part of any comparative effectiveness bill might be to fund training for consumer and patient advocacy and compensate representatives for their time. This would address part of the unlevel playing field. Special interests are involved with their way already paid, but consumer representatives often participate on their own time. Industry representatives have huge support for their participation in the meeting and deliberative processes. Consumers don't. Consumers not only should be compensated for the meeting time, meals, and travel, but also need to be

able to call up other resources if they have questions about the integrity of a statement that is made, for example, about a study. For citizen-consumer participation to be meaningful, we have to remove the barriers. And the barriers include securing financing, accessing financing, and training and resourcing those people so they can be maximally effective in their role. (FDA, in the case of advisory committee meetings, does provide all panel members with a modest compensation for meeting time, along with travel, lodging, and other per diem expenses.)

Consumers as Parts of Diverse Communities

Perry Payne, a professor of health policy at George Washington University, conducts research on health disparities and on genetic information. He stated that communities should have input into the research process. Most researchers never have a chance to sit in front of the community that they are studying and meet with the types of people they are thinking about treating or for whom they are developing some kind of remedy. They should hear from those people. This is more important than having a consumer sit on a panel. Researchers should stand up in front of 100 people who have the disease they are studying or whose family members have that disease and talk about their research. Researchers and pharmaceutical companies should hear from the families; they should hear whether the work makes sense and whether the research is being done appropriately. They could ask what is missing, whether they are characterizing the community appropriately, and whether a better line of research is needed. These dialogues will provide strong community engagement from beginning to end.

At the beginning of the research process, someone has to establish priorities. That is where community input should start, including what diseases to study, what populations to include, and in what part of the country to conduct the research. This process will lead to more buy-in and in the end be more useful to consumers. These consumers are more likely to respond positively. Communities should be involved with priorities and funding at the outset.

Communities include those that experience health disparities, which exist throughout the nation. We will never get rid of health disparities, but we should move from disparities between healthy people and unhealthy people to disparities among healthy people. A diverse health care workforce can think more about the various types of communities and about how the results from comparative effectiveness research will play out in the delivery system. Some of the existing datasets used for comparative effectiveness research do not include diverse groups of people. Those datasets should be bolstered as we move forward.

Researchers should think about how they characterize themselves genetically, physiologically, and environmentally so that comparative effectiveness information can be useful for many types of people. This will allow them to use evidence in as personalized a way as possible. That does not mean that every type of person should be included in every study. But it does mean that researchers should think about how to characterize people in a way that helps clinicians and patients understand who this comparative effectiveness information really applies to.

How should comparative effectiveness information be communicated to payers, public and private? Some people are worried that if researchers say that one

drug that is 20 percent more effective than another and the costs are the same, a payer will decide to cover only the more effective drug. The problem is human variation—for some people the other drug might be more effective. For example, some people were doing fine with Vioxx. Perhaps providers can use genetic tests to identify the populations that can benefit more from certain drugs.

Another challenge is how to personalize this complex information for consumers. For example, how do you come up with some scale for the average consumer that simplifies the choices? Communication strategies may vary with communities, types of people, levels of education, and people in different age-groups. Language diversity is another challenge.

Comparative effectiveness is one part of the solution to address health disparities. But environmental issues, including how we have organized society, have an important role in health disparities. Comparative effectiveness can chip away at disparities, but it is not the solution to everything.

Consumers as Patients

Jack Fowler, president of the Foundation for Informed Decision Making, addressed the importance of informed medical decision making that takes individual preferences into account. The foundation is committed to making patients as informed and involved as possible in the decisions that affect their health and well-being. The foundation is focused on collecting information, making it available, and getting it to consumers.

From an ethical perspective, patients should know the risks and benefits of treatments or tests that are proposed for them, and the alternatives, and should understand what each does for them compared with one another and

compared with doing nothing at all. This knowledge should be a standard part of expectations before a patient accepts medical treatment. And it would be hard to argue for ignorance, though current practice is testimony that ignorance is well tolerated.

A safety argument can be made for informed decision making. Let's say that patient A is the person with the bad knee, but patient B has the operation. When this happens, we call it a medical error. A medical error also occurs if people have a type of surgery that they would not want if they were informed and really understood what they were getting into. In both cases, we operated on the wrong patient.

Consider what would happen if the informed consent form for a surgical procedure were presented that said (after the list of the usual things), "I understand that my risk of a heart attack, stroke, or death will be no better after this stent is placed in my artery than if I simply manage my heart condition with medicine. And, in fact, I might get a little symptom relief, but in two or three years, my symptoms will be just about the same as if I had taken medicine alone." Although no informed consent forms actually read like this, isn't that how they should read?

Patients can make better medical decisions if they have input and are informed and involved. The evidence alone does not tell you what the decision ought to be. Consumers should apply their own set of values and weights to determine what care will best serve their interests. The doctor's job is to present the array of reasonable options. The costs and benefits, learned from comparative effectiveness studies, should factor into the equation. Patients can then add what they care about, their values, and their views of possible complications and side effects.

If doctors get the patient's input, they can make better decisions. Delegating the whole decision to the doctor is not the way to get the best decision. The doctor and the patient both play a role in getting it right. One of the disappointing realities is that decisions currently are not made in a way that is conducive to giving patients a say in what is done. Doctors are still the main source of information for people, and they do not routinely provide information on alternatives. Doctors rarely ask patients what they want. Too often, decision making is one-sided, that is, paternalistic, doctor-driven, not shared, and not informed.

Studies show that people exposed to decision aids are better informed than those receiving usual care. Informed consumers make decisions that are more consistent with their reported needs and concerns, and more consistent with the things they care about, than people receiving usual care. More often than not, when patients are informed, they also end up choosing the intervention—whether it is an operation, a test, or something else—less often than people in usual care.

In conclusion, informed decision making is ethical; it is the right thing to do. Second, there are safety issues about exposing people to risks and treatments that they would not choose if they had more information. Third, better medical decisions result from the input of patient values and concerns. When patients are informed and involved, they are more likely to receive the treatment that best serves their interests. Finally, when patients are given an informed say in their care, less intervention might result. And that could be a good thing for all of us.

How Can We Build Support for Comparative Effectiveness among the Public?

Mr. Fowler said that the argument that less care might be better than more is a hard one for people to grasp. A strength of the argument that patients should be informed and involved and have a big say in the care they receive is that having patients make their own decisions is a more politically palatable approach to reducing intervention than having others impose limitations on them. Mr. Levin pointed out that people are wary of a message that could be interpreted as insurance companies trying to cut back on care. Any entity that conducts comparative effectiveness research has to be organized in a way that convinces the public that this is operating for their interest. It should be a trusted source and resource. Making the case for comparative effectiveness is a huge job of social engineering, because in this country, all the effort is spent on getting people to consume more. The drug ads, the device ads, the marketing to physicians all say that more is better. We portray the willingness to absorb unnecessary, harmful, late-stage treatment as heroic. So we have to think about all of those subtle and not-so-subtle ways that we engineer people to think that more is always better. Ms. Ginsburg agreed that the public is bombarded with every possible message to consume more health care, devices, and drugs, and to use the hospital more often. If a group starts telling people that more is not better, are they going to believe it? When consumers look to people they trust, the first person they look to is their own physician. But this may not be the best source. We should get rid of fee-for-service medicine, ensure that all systems of delivery have the same motivations, and ensure that they are on the same wavelength and aiming toward the same goal, which is

high-quality medicine at an affordable price. Changing the relationships and how medicine is delivered is important as well.

Additional information on the panelists' organizations can be found at the addresses below:

Consumers Union
www.consumersunion.org

AARP
www.aarp.org

Sacramento Health Decisions
www.sachealthdecisions.org

Center for Medical Consumers
www.medicalconsumers.org

Foundation for Informed Decision Making
www.informedmedicaldecisions.org

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