Comparative Effectiveness: Can We Get Better Health Value for the Dollars We Spend?
Alliance for Health Reform
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ED HOWARD, J.D.: I'm Ed Howard with the Alliance for Health Reform. I want to welcome you to this briefing on behalf of Senator Jay Rockefeller, our honorary Chairman, Senator Susan Collins, our honorary Vice Chairman – Co-Chairman, excuse me, and our board of directors to this briefing on how best to get more value for our very large investment in healthcare spending in this country. The tool we're looking at today for doing that is called Comparative Effectiveness Analysis. It doesn't exactly trip of the tongue, but it's a term with a lot of promise to help improve the uneven performance of our healthcare system.

Today, when the Food and Drug Administration okays a new drug, it in effect certifies that the new drug is better than nothing. Even if it isn't as effective as something, that's already on the market and costs 10 times as much, it's better than nothing. And generally, that policy applies not just to drugs, but to other clinical interventions and equipment as well. It's comparative effectiveness analysis that attempts to get us beyond that point.

Out partner in today's briefing is the Robert Wood Johnson Foundation. It's America's largest philanthropy devoted to health and health care and it's a leader in pursuing comparative effectiveness work, which when you think about it,

it isn't very surprising given that the foundation CEO Dr. Risa Lavizzo-Mourey is in fact herself one of the country's most respected health researchers.

If comparative effectiveness is right with promise, it's also fraught with concerns. And a lot of them have to do with the appropriate role of government in this activity. What kind entity ought to be doing this research or commissioning it? Who ought to set the agenda? Who ought to pay the price? What ought the price tag be? How should the results be used? That is, more specifically, should it be tied and how closely to payment policies? So, there's an awful lot for us to discuss today.

Let me make my usual logistical observations. You'll be able to see a Webcast of this session as of Tuesday morning and maybe sooner on Kaisernetwork.org. You'll also be able to see a transcript a few days after that. There'll be copies of the materials in your packets available on the Kaiser Network Website and on the Alliance's. In fact, those are already there. That's Allhealth.org. Those of you who can do Podcasts, you can Podcast this one in a few days.

You're going to have a chance to ask a lot of questions. There are green question cards in your packets for that purpose. There are microphones both in front and in back

for you to ask them orally. So, be prepared to be an active participant in this discussion.

Let me turn now to our panel. Let me first ask you to turn your pagers and your telephones to vibrate or off or whatever you need to do. We don't want to hear whatever it was that new ring you downloaded last week is. We want to hear from our speakers who are in fact an extremely capable and distinguished lot today. There is more information than I have time to give to you about them in your materials.

And we're going to start with Dr. Carolyn Clancy who's entering her sixth year as Director of the Agency for Health Care Research and Quality AHRQ. Dr. Clancy has a distinguished career that includes a number of prestigious academic and research positions. Her agency not only conducts and funds a whole range of quality-related research, but was given explicit authority and a little bit of money in the Medicare Modernization Act to conduct comparative effectiveness analysis.

I want to say by the way, Carolyn joins us even though her advisory council was meeting today. So, we're going to change the usual protocol a little bit. After her remarks, we'll take a few questions specifically directed for her, if you have them before she has to leaves us, and then we'll hear

from our other panelists. Carolyn thanks for making time in a very busy day to join us today.

CAROLYN CLANCY, M.D.: Is this on? That sounds better. Yes. Thank you very much, Ed and good afternoon everyone. I'm really thrilled to be here with my other three colleagues. And normally, I don't approve of this prima donna or sort of I have to come and run, but today, my advisory council is in town, which in this instance means a rock fell.

So, I'm very pleased to have an opportunity to tell you about the work that we've been doing in comparative effectiveness research. Our authority derives from the Medicare Modernization Act as you said. And the specific language directs us to improve the quality effectiveness and efficiency of healthcare delivered through Medicare, Medicaid and SCHIP. So, our focus is on what's known now ensuring that programs benefit from past investments in research. Many of you have probably heard that it often takes us quite a long time to translate findings from research into practice and to identify what research gaps are critical to fill. Our focus is explicitly on clinical effectiveness, not on cost effectiveness.

So, the key program attributes that we have strived and our funding started in fiscal year 2005. First, to make sure that we're building an infrastructure not only to conduct the work but also an infrastructure that will support the rapid uptake and use of this

information, so the clinicians and patients can have good information when they're making very important decisions.

This obviously builds on our connections and partnerships with providers, consumers, health plans and so forth. If there's one thing that we want the work to be, it has to be unbiased, and it has to be responsive to the needs of those who are receiving care, delivering it, leading health care organizations, and paying for it.

To that end, we have a group of stakeholders who have been invaluable to us as we have launched and continually refined this program. And we know that the work has to be trusted or it won't be credible. And to that end, we do a great deal including a very strong focus on transparency.

So we actively seek input on setting priorities for this work. We seek specific public input from nomination for topics or research, comments on how specific questions are framed, as well as comments on draft reports. In fact, some of these reports are actually covered by electronic newsletters and so forth. And we think that is great because if everyone can see it and understand the work, then there will not be black box. People won't feel like someone had a database and did something and magically came out with an answer that doesn't make sense at all because if they do feel that way then the work won't be perceived as credible.

Now we've been fortunate that we could actually build off and leverage our existing research infrastructure, so the evidence-

based practice centers are located across North America and we turned to them to synthesize existing research. In anytime we do that, we, of course, are doing a very active search to see if the Cochrane collaboration or other well-known and prestigious groups have already done something similar because we don't want to waste a single federal dollar if someone else has already a similar sort of research that we can build on.

In addition to that, the Centers for Education and Research and Therapeutics have been up and running for about nine years. The two new components are the DecIDE Network, which is a network of research, contractors, including University of Chicago, the HMO Research Network, about 13 different partners who have access to substantial databases with clinical electronic information and they help us close some of the research gaps. And the Eisenberg Center is a new center named for our former director at the University of Oregon that helps us develop important prototypes for a variety of audiences.

So the program outputs metaphorically here. The research reports are really, really long. Probably a terrific cure for insomnia, but they're extremely explicit in every single step of the process. So that people – we take transparency very, very seriously here.

The Systematic Review is this short guide for clinicians is what's labeled systematic review. And then we

have Consumer Guides. Now, how you present the same information to consumers and to clinicians is quite different. And for many products, what we were talking about is actually helping individuals assess and balance for themselves the balance of benefits and potential harms or side effects. Getting this right for people with varying degrees of health literacy is an important challenge. I should have said at the outset two important things.

First, our priorities are set by condition because the issue isn't is Drug A better than Drug B or Device C better than Device D, but what makes the most sense giving this particular clinical condition. That's the kind of decision that clinicians and patients have to make all the time. The second is that anytime a manufacturer is potentially affected by our review, they are notified at the very outset. If they've got additional data or information we can take advantage of, we are thrilled to do that.

So just to give you a sense, we're very, very excited that Medscape now uses this as the basis for continuing education for clinicians. We're also excited that the consumers union uses it in many of their reports, The National Business Group on Health and most of these reports have been published at the same time that we posted online in the Annals Of Internal Medicine, which right after the New England Journal

and JAMA is I think one of the most widely distributed clinical journals.

So at a very high level, what have we learned? I think there's been some concern that the ultimate outcome could be perceived by someone as a giant thumbs up or giant thumbs down on a particular service. And in fact, we find that that's rarely the case. In fact, we think the reports actually help refine and it will help clinicians and health care organizations refine the process of identifying more rapidly which patients are most likely to benefit from particular services, so that access to effective treatments is actually maximized. We also are humbled or amazed by how much we don't know about common and ubiquitous treatments and we've understood that we need to anticipate questions that decision makers will be asking years in advance.

Now, this year 2008, we are really excited that our investment doubles from $15 million to $30 million. That means that the number of comparative effectiveness reviews and technical briefs will double. A new series of technical reports will establish a foundation to guide the evaluation of gene-based diagnostic test performance. And the number of products designed to help patient and clinicians make informed decisions will increase. In addition to that, we're making some key investments to begin to expand the capacity to do this

kind of work. We need to be thinking right now, how do we recruit the best and the brightest to make careers in this kind of work because as a result of biomedical innovation, there's a tremendous need for this kind of work.

Now, I'm showing you here a picture of a journal called Medical Care, which many of you may not be familiar with, but it's a journal that's very, very well-known for its methodological rigor. And we take the issue of continuing to improve and innovate in the methods used to do this work very, very seriously. The reason for that is we are approaching a time when data are going to be ubiquitous. That's because if investments and multiple levels of interest in the use of health IT to improve care, but at the same time that means that we have to be very, very confident that studies done, observational or quasi-experimental studies done using these data are rigorous and robust, and that we can trust the results.

So, we have continued to emphasize throughout the program the need to keep innovating in methods. So, this is just a picture of one of the journal supplements that post that. And these are available free of charge. And these too were reviewed by a very, very broad audience.

Now, the big question, I think that many of us are contemplating is, so, how do we get from high quality research

to high value in healthcare? Ed introduced this discussion by saying that this is now seen as an answer. So, what I'm going to give is a sense of how we're thinking about this issue.

What's clear is that we need to be thinking now about how the information from the work we're supporting is actually made ready to use and easy to use by clinicians and patients in real time. So, that means that we're increasingly talking with product developers, those who develop electronic health records and as a way of figuring out how can they embed the findings from this work in clinical decisions support and so forth. To that end, I think we're very blessed to be able to work with the Office of the National Coordinator as well as the resources we've gotten from the Congress to support evaluation and promotion of health IT to improve safety and quality.

Now, the second bullet here speaks to distributed leadership, and what I mean by that is there has to be a very clear alignment and we use a variety of strategies to promote this alignment between the needs of those who are paying for healthcare, leading healthcare organizations, and so forth, and the priorities for the work that we're supporting. Clearly, within HHS, we have a lot of opportunities to make sure that the work that we're supporting is aligned with the priorities for Medicare, Medicaid, and SCHIP. But it's equally important for the private sector. Ultimately, we see that there's a

terrific opportunity for this work to provide important feedback to much earlier phases of biomedical research, in other words that the delivery system itself becomes a platform for discovery.

There's a lot excitement right now about the use of patient registries, for us, it's a key part of what the work that CMS is doing for coverage with evidence development. It's of enormous interest to many clinician professional organizations as they strive to come up with strategies to improve the care that they're providing. And we see that we're going to be taking great advantage of that as well. It's also a very, very important strategy to identify the particular needs of relatively unusual conditions or relatively unusual treatments, so, to that end, about a year and a half ago, we published an online guide to developing patient registries which benefited from input from people across the country.

So, let me just close by saying, I think that this is a very important opportunity from us. I want to thank those of you in the Congress who had anything to do with this and say that we think that it's incredibly important that transparency in both the production and the use of this information is going to be critical to make sure that this work actually helps us get to high value healthcare. So, with that, I will thank you for your attention and I would be happy to take any questions.

ED HOWARD, J.D.: Great. Thank you, Carolyn. I think we will preclude the use of written question at this stage. If you have a question for Dr. Clancy, I would urge you to come to one of the microphones.

Let me start off if I can, while we're waiting for that to happen, Carolyn, and just ask if this may be a little too early, but can you identify one or two of the findings from your work in this area that have been of most interest to clinicians or the other folks most interested in them?

CAROLYN CLANCY, M.D.: Well, let me just give you one from the very first report that we published, which was on gastroesophageal reflux disease, known to clinicians as GERD and to the rest of the world as heartburn. [Laughter] This turns out to be not surprisingly for anyone who's ever watched TV, even if it's educational programming, a very, very important problem for the Medicare population. A lot of resources used a lot of discomfort time off and problems caused by this issue.

There are basically two lines of treatments. One is two types of drugs, two classes of medications; and the other is surgery. And what our report found was that one class of drugs was clearly superior to the other and we found that the mainstream or classic surgical techniques and the superior class of drugs were roughly equivalent. We were very clear to point out that there were newer surgical techniques coming online in the form of laparoscopic

techniques and said that we simply didn't have enough information to synthesize so we weren't going to make it up or guess or make a judgment, but said that updates of this report would focus on newer techniques.

And we also made it clear to people that if you went in and had a classic or traditional surgical procedure and thought that you could throw your pills away, that you might be actually misguided. Abut two-thirds of people end up needing to take some medication, not as much as before surgery. So, what we're giving people is the facts and saying "Here it is in a way that you can understand it and you and your clinician need to make a decision."

ED HOWARD, J.D.: Yes, and for you would identify yourself and state your question.

KRISTIN BASIL: I'm Kristin Basil [misspelled?], Senate Committee. Carolyn, you talk about transparency being very important which we would agree with of course. I wonder if you can a little bit about the steps that you take within AHRQ to make sure that your methodology and the research you're doing is transparent. I wouldn't mind having David Nexon comment on whether he thinks that's adequate?

CAROLYN CLANCY, M.D.: Sure. And let me just start off by saying I have no idea if David will be positive or negative, but we welcome feedback and suggestions in terms of how we can improve that.

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So, if you think about this setting as starting with setting priorities, we have benefited enormously from feedback, both from the public programs, obviously, CMS programs and also from the private sector. We've had a number of listening sessions and we have an ongoing way to collect that information on our website. But priorities that 10 or 12 conditions where we focused our work for the first couple of years are very, very high level. Beyond that, we're also looking for feedback on specific topics and specific questions.

One of the challenges clinicians face is actually trying to take clinical research and in some way translate it to the patient and this specific question in front of them. There's often a big gap there. So, to that end, we want a lot of input on how those questions are framed. The work is then commissioned to one of our evidence based practice centers or one of the DEcIDE Networks. And then the draft report is put out for public comment. Any of you who are interested in these details, the Website is Effectivehealthcare.ahrq.gov and you can sign up to get notifications at one topics or update on when there are other opportunities to comment and so forth. And as I noted earlier, these draft reports are often reported on in newsletters and so forth.

Now, we solicit explicit review as well, particularly on the statistical side because many of these methods that are using very large databases actually do raise very important statistical questions, so we want to make sure that we have the best people

reviewing that. And sometimes in response to comments the people submit to us, we then go out and get more reviews. So, that's a high level view of how it works.

KRISTIN BASIL: Can I just ask a quick follow up questions and then let David go. I guess my question was more focused on the methodology at the time the research is being undertaken?

CAROLYN CLANCY, M.D.: Sure.

KRISTIN BASIL: Because some of the criticisms that we've heard is that, being able to comment after the fact doesn't necessary help as much potentially as being able to comment on the methodology ahead of time, so that the research that's done is done in a way that is methodologically better or more correct or whatever. Now, we've also heard concerns that when you then – especially with you guys – when you then sub it out that a lot of times, people have good comments, maybe transparency at your level, but the subs don't necessarily, so if you could just and then I'll shut up. [Laughter]

CAROLYN CLANCY, M.D.: No. If you think about that, we've got 13 partners in the DEcIDE Network and I think either 12 or 13 evidence based practice centers. I'm probably embarrassing a colleague not knowing the precise number here. To some extent, making sure that their work is consistent and that there's some synergy and consistency across all those partners is very important. So, we actually have a coordinating center that helps us do this. The coordinating center also is the group that helps us identify

where other centers have done similar work and so forth. So, to some extent, framing the questions, we have identified as the most important part of this because we've got this coordinating center and we're often looking back and using the public comment as a way to improve our processes, we think that's a good way.

If people have alternative suggestions, we're all ears in terms of how we might do a better job doing this. I will say that some people have asked, "Can the public comments be public?", and we're actually exploring how we might do that. Nice does this in the UK. I think they do it after a certain time period and we're trying to figure out the feasibility of doing that. But again, we think that the more people can actually see what's happening, so I'm not sure if I'm answering your question exactly, but maybe David can help.

ED HOWARD, J.D.: David?

DAVID NEXON: Probably not.

ED HOWARD, J.D.: We can't hear you. Yes, and lean in pretty close.

DAVID NEXON: Okay. Obviously, in general, we've very pleased with the functioning of AHRQ under Carolyn's leadership. We think the quality of their work is good and there is certainly been an openness to discussing issues with industries, so we're very pleased with that. In terms of whether the formal processes are those that we think are the

right ones, I really have to defer to other people within our organization. I'd be happy to get you back some more specific information, Kristin.

KRISTIN BASIL: Thanks.

ED HOWARD, J.D.: Your last chance to ask a question.

KAREN SANDERS: Hi, my name is Karen Sanders. I'm with the American Psychiatric Association. And we actually tried to comment on some of the drug reviews, but one of the biggest problems we have is the short window of time. There's 300-paged drug review and you have two weeks to do that. So, it really becomes difficult for an organization like ourselves to be able to take it seriously. So I wonder if you could comment on that.

CAROLYN CLANCY, M.D.: My only comment would be to say, I'm really glad to hear it and I will take that back. I think on occasion, people have asked us if they could have more time and we've been responsive to that. I've had personal friends basically say, "I have to tell you, I don't even have an industrial printer to print off a very long report," and I am very, very sympathetic to that, so I want to thank you for brining it up and we'll continue to be on the alert for that.

ED HOWARD, J.D.: Carolyn, let me just ask one question that illustrates how ill-informed I am on this. The activity that you've described all represents synthesis of existing

information as opposed to new research. Is that a correct assumption?

CAROLYN CLANCY, M.D.: No, it's both synthesis of existing information and I will say quite a part from today's discussion, there are scientists who believed that every clinical trial ever done or major clinical study ought to be preceded by a systematic review so that we take advantage of work that's been done in the past. You may recall some of you seeing an article in The Post a couple of years ago that made the case that some researches have looked back and realized that we knew enough about the importance of sleeping on your back or having infants sleep on their backs to prevent sudden infant death syndrome back in the 70's. The Back to Sleep Campaign was ultimately motivated by much more recent studies, but the fact that we have failed to look back, was an important opportunity missed. So, yes, synthesis is a big part of it. But we also use this decide network in order to address and close research gaps.

ED HOWARD, J.D.: Okay. Our panelists may want to engage Dr. Clancy before we let her escape back to her council. Very good. Carolyn, thank you so much for doing this.

CAROLYN CLANCY, M.D.: Thank you.

ED HOWARD, J.D.: I really appreciate it and we'll look forward to the further developments.

CAROLYN CLANCY, M.D.: Thank you very much. [Applause]

ED HOWARD, J.D.: We have three very distinguished panelists with which to conduct the rest of this program. We're going to start with Wilhelmine Miller, who's an Associate Research Professor at George Washington's School of Public Health and Health Services. Before coming to GW in 2006, Prof. Miller was a Senior Program Officer at the Institute of Medicine where she directed a major project to advise federal agencies on the use of cost effectiveness data to evaluate various federal regulations. She's now a member of the IOM's Committee on Reviewing Evidence to Identify Highly Effective Clinical Services which does not have a good acronym. But it does have a great report called "Knowing What Works in Healthcare". That's in English. I like that.

And that appears we have a couple of short iterations of that report in your materials. That project, by the way, flows from a request and support from the Robert Wood Johnson Foundation, so we are circular in this activity in that regard. Wilhelmine, thank you for being with us to talk about some of the work in the IOM, and its related activity.

WILHELMINE MILLER: Thank you, Ed. I'm pleased to present the recommendations of the IOM Committee that produced "Knowing What Works in Healthcare". I won't repeat our excruciatingly long title. The 16-member committee worked over an 18-month period under the leadership of Barbara McNeil, Chair of the Department of Health Policy at Harvard University Medical School and Hal Sox, Editor of

the Annals of Internal Medicine at the American College of Physicians. Jill Eden was the Study Director at IOM and she and her staff made this report possible and of the quality it is in all respects. So, I want to be sure to thank her.

The Robert Wood Johnson Foundation commissioned this report in recognition that American healthcare and medical practice suffer from a lack of solid credible and readily usable information about the effectiveness of many health care services, technologies and treatment patterns. The foundation charged the committee to recommend an approach to identifying highly effective clinical services, a process to evaluate evidence about clinical effectiveness and in organizational framework for using evidence reports to make recommendations.

That charge to the committee was limited in the following respects: First, considerations of cost specifically the use of cost effectiveness analysis was tabled by the foundation, which stated its intention to delve into this area subsequent to the conduct of the IOM Committee's work. Second, the organizational low cost of any new program that the committee might propose was set aside as not necessary for the committee itself to consider. And finally, the committee was not asked to recommend specific funding levels for either the individual studies that would inform clinical effectiveness research or the program that it might ultimately device.

So, this schematics sets out the order of development and the relationship between individual studies that can inform judgments of clinical effectiveness the highest level box, the body of evidence which includes everything from randomized clinical trials to observational studies, case reports, information from registries, and studies-based on administrative claims data. All of that is the body of evidence.

Secondly, come systematic reviews of the body of evidence of effectiveness. This is when you take all the individual pieces of information judge their relative strengths, their limitations, the questions they actually answer and try to get some consistency with that.

And then finally, the variety and sources of policies that can make use of systematic reviews of clinical effectiveness information, so these policy applications range from practice guidelines that are addressed to clinicians, patients and consumers to performance measures for quality assessment or payment purposes and to coverage decisions that public and private payers might make.

The IOM report recommendations address the activities represented by the last two boxes approaches to reviewing and synthesizing primary evidence and the development of policies and specifically practice guidelines that are based on systematic reviews of clinical effectiveness.

So, what are some of the strengths of our national approach to technology assessment and effectiveness research? First, the actual methods for systematic reviews are quite developed. Thanks as Dr. Clancy showed us two investments that are AHRQ has made in methodology development and to the work of other organizations that have gone on over the past 20 to 30 years such as the U.S. Preventive Services Task Force and international collaborative efforts such as the Cochrane collaborations, which is based on parallel work on technology assessment and effectiveness research that is in large part based in Canada and Great Britain, but certainly has extended throughout the world.

Secondly, we do have a network in the U.S. of professional skilled in systematic reviews. They are engaged at academic centers or at bi-commercial firms that are sponsored by pairs to review technology and evaluate the clinical research. Out system is pluralistic, it’s close to the ground and as you’ll see in a couple of slides, our system can be quick to address emerging technologies, although maybe not always as consistently or efficiently as we might like.

We do have some excellent models for transparent, rigorous guideline development. For example, the American College of Cardiology and the American Heart Association, the American Academy of Clinical Oncologists, they are all kinds of professional

organizations that have been very open scientific in their approach to developing guidelines.

And finally, there are very influential users of guidelines, NCQA, which has developed PETA standards based on best practices, information and payers such as Medicare, Medicaid, Blue Cross Blue Shield.

So, some of the problems with the status quo, there's extensive duplication of efforts by insurers and private groups, which are often focusing their reviews narrowly on new technologies and unlike AHRQ, I would say, to AHRQ's credit, not so always focused on comparing emerging practices to existing practices. There are potential and real conflicts interest in assessing evidence and promulgating guidelines. A systematic reviews and guidelines themselves sometimes lack scientific rigor. It's a relatively new discipline and it's financially under-supported and so the field itself is working on upgrading its own standards.

And finally, it's difficult for users to often see the connections between the evidence generated on the research, literature and clinical recommendations. Clinical recommendation and guideline processes are neither systematic nor consistent across sponsors and they're not transparent.

So, the next couple of slides reproduce a table from the report that illustrates the duplication of efforts by health plans and technology assessment firms for a sample of 20 screening,

diagnostic, disease management and treatment services over the course of one year. And again, you see four health plans here – United Health Care, Kaiser Permanente, Aetna, WellPoint which generously shared with the committee some of the information about the specific services that they had their own internal or commissioned technology assessment work done. And three private technology assessment firms – Haze Incorporated, The Blue Cross Blue Shield Technology Evaluation Center and ECRY [misspelled?].

Of the 20 services sampled across these domains of services, 14 were found to be evaluated by all seven groups in one year. Seventeen were evaluated by five of the seven groups and AHRQ evaluated five of them. So this is just to show that a lot of effort is going on particularly with respect to emerging technologies to determine what health plans should do in response to the availability of a new kind of service about which not everyone knows a lot.

So on to the committee's recommendations. First the committee recommends that Congress direct the Secretary of the Health and Human Services to create a single entity with authority over arching responsibility, sustained resources, and the adequate capacity to ensure that credible, unbiased information about clinical effectiveness is produced. The program should set priorities for fund and manage systematic reviews of clinical effectiveness. It should develop a common language and standards for reporting on for conducting systematic reviews and reporting on recommendations,

provide a forum for addressing conflicting guidelines and recommendations and making annual report to Congress.

A clinical effectiveness advisory board should oversee this program. The advisory board should be constituted to minimize bias due to conflict of interest and represent diverse public and private sector expertise and interests. And each area of activity, priority setting, evidence assessment, and guidelines development, the program should develop standards to minimize bias due to conflicts of interest. And I think you'll remember from Dr. Carolyn Clancy's slides, the importance of the openness of the priority setting process, the collection of input from all stakeholders and the like. So we think that in the AHRQ, effective health care program, there is a really good model for what a program like this should be doing.

So, a second advisory group should also be established by the program to set priorities for clinical effectiveness reviews. The priority and setting process should be open transparent and take nominations for priorities for clinical effectiveness studies from all stakeholders. The priorities, much like the priorities that the AHRQ effective health care program now has promulgated should reflect the potential for improving health across the lifespan, reduced the burden of disease and health disparities, eliminate undesirable variation in medical practice, and also consider economic factors such as the cost of treatment and the economic burden of the disease

addressed when it decides what are its priorities for clinical effectiveness reviews.

So, one of the most important contributions of a centrally coordinated comparative effectiveness review enterprise is to develop a common language for characterizing the strength of the evidence of effectiveness. Right now, scientifically rigorous and influential organizations have their own rating schemes which detract from their usability and understandability by clinicians and payers and consumers.

Second, the committee recognizes the need to support the development of the analytical capacity in the research workforce to conduct the effectiveness reviews. And I would also say that the increase in funding that AHRQ has experienced recently is certainly going to work to improve this capacity building effort in the research workforce.

Finally, groups that develop clinical guidelines or recommendations, and here the committee did not envision that the federal program or the centrally designed program would develop its own guidelines necessarily, but would essentially certify organizations such as professional groups who do develop guidelines to adhere to the standards set out by the program and be very public in their documentation of their adherence to these standards.

So, the committee envisions a wide audience and a range of consumers for clinical practice guidelines developed according to the

program's standards. These can be adopted by clinicians and other providers, public and private insurers, purchasers of health care, accrediting organizations for quality review and licensing performance measurement groups and patients and consumers. And that concludes my presentation. Thank you.

ED HOWARD, J.D.: Alright. Thank you very much, Wilhelmine.

We turn next to Karen Ignagni, who's President and CEO of America's Health Insurance Plans AHIP, which is the national trade association for just under 1,300 health insurance organizations. Karen has graced a number of alliance programs before. She has a rich and varied professional background including service right here on the Senate side on the staff. Karen's members have to decide in many cases which interventions to cover, which means they have one of the most direct stakes in comparative effectiveness analyses and not surprisingly, she and AHIP have thought a lot about this issue. We're please to have you share some of your thinking with us.

KAREN IGNAGNI, M.B.A.: Thank you, Ed. Good afternoon. If I could have the advancer or clicker, that would be great.

Good afternoon. It's a pleasure to be here and to be part of this important panel at a time that all of you are very close it seems, I don't mean to be presumptuous in saying that, but in advancing something that we think has tremendous possibilities. I was reflecting and listening to Wilhelmine's wonderful presentation

and present work that IOM has done. And listening to Carolyn, it struck me that there are a couple of observations that may contextually be useful as you think about this arena. The first is I think we contemplate the concept of comparative effectiveness at a time after the IOM first did its report on crossing the quality chasm. And essentially, and I know virtually everyone here has read, essentially what the IOM said was that the goal standard is right care, right time, right setting.

The disturbing and part of the IOM's analysis is that they said very clearly that we are far from that understanding what is the right care being able to diffuse it into practice and evaluating the appropriateness of settings. I think that one of the things that is most exciting about comparative effectiveness is that it offers promise to inform delivery in a way that we really haven't had that promise before.

Ed did a very good job and Wilhelmine as well, reflecting that there are a number of very important private sectors than indeed private activities out there evaluating technology, and by technology, I think we're all referring to drugs, devices, bios and therapies. So it's a rather broad meaning of the concept technology, but given the stakes now, the where we are on the precipice of change in terms of explosions of new technology, which is a marvelous thing for all of us as health care consumers. Now the question is, how do

we achieve those IOM objectives? And what in fact, can be applied strategically and functionally to move us down this continuum?

And if many of you are familiar, I know, with the work of Clayton Christiansen at Harvard, he's written about disruptive innovation. I think comparative effectiveness could be thought of as disruptive intervention. And the reason, I say that, I think it's a apt term because not only would it fill a gap that needs to be filled. We have a vacuum here of systematic kind of analysis that would be transparent in the public domain, et cetera.

But I do think it should be said that comparative effectiveness and even the discussion around it sets in motion a process that a number of important stakeholders are not sure about the consequences of. And therein, creates controversy, uncertainty, and a great deal of discussion with each and every one of you. And I think that that window or prism ought to inform our discussion not discourage it. And I want to try to come back to that point.

So I'd like to discuss there things today. First, from our perspective; why we need comparative effectiveness? Second, what it should do? How it should be structured? And a third, how it should be a part or thought of by all of you? Again, I don't mean to be presumptuous in saying this, but I know all of you are struggling with how do we get to a quality agenda nationally? So, how can we work together to do that? So, I wanted to put that in context a little too.

Okay, first, we have a marvelous opportunity in this country to evaluate the wonders of science. We all want innovation. We want to encourage innovation and the challenge of comparative effectiveness is doing it in a way that preserves innovation, preserves access, but also gets to that right care, right time, right setting. We have tremendous uncertainty now about safety and effectiveness. That's not to say that there aren't marvelous opportunities out there for practitioners, clinicians, and the delivery system to use technology, again, broadly stated.

But there's very little of the kind of robust research that is necessary as a practitioner to know what to do under what circumstances and yes, not simply from a safety perspective, from a quality perspective, but also from a cost perspective. I know that is tremendously controversial.

I recognize that the IOM has taken the cost issue off the table, but at a time when each and every one of you and your members, your bosses are looking very, very specifically at the rising cost of health care in the United States. Taking cost out of this discussion is equivalent to putting our heads in the sand. And for working families, for purchasers, and for government, we're going to have to figure out a way to confront that issue as well and I want to make some suggestions about it.

Carolyn Clancy talked the work they've done at AHRQ in terms of the setting consistency of methodology. That is key here

that if we're going to have reliable analysis, it has to be consistent. And we also, I wanted to share with you as you look at the third point, the growing concern which you hear well in all of your offices daily about the cost burden, the cost of care burden on families.

One of the major issues that are now working in a very exciting in terms of the partnerships that are going on between our community and the provider community is actually evaluating how to assess efficiency. So we are confronting in a payer community with practitioners and clinicians and a number of them are here today in the context of the AQA, which is an organization that I hope most of you are familiar with. If you're not, it's on the web, AQAalliance.org.

We are working with practitioner's side-by-side to evaluate quality and yes, begin to figure out together, not separately how to assess efficiency. We have to bring that same discussion in this arena and begin to have the same conversations with manufacturers and others. What problems can be addressed that clearly, I think the goal standard here is trusted source. And that informs how we want to think about establishing comparative effectiveness and I'll come to that in a moment. There is clearly insufficient information and practitioners, hands, consumers and purchasers and we have a difficulty now in hitting that IOM promise of a system that is more effective and efficient than it has been.

In terms of how this could be structured, our view is that it should be an independent body. And at the risk of sounding not politically correct, let me give you an example of why. More than 10 years ago, AHRQ began to develop best practices with respect to lower back pain. It created a tremendous backlash set of concerns on the part of practitioners and there was an effort to de-fund AHRQ and in fact, take AHRQ away as a result of that activity.

This needs to be an independent body insulated from the kind of back and forth political discussion. That is not to say that it should be on its own in a vacuum. It needs to have the direct participation of manufacturers, of consumers, of pairs, of scientists and the best and the brightest frankly. And we need to figure out a nomination process that would garner the individuals that would fit that bill. But that's why we think about largely based on that experience.

We could cite other experiences as well. You need an independent body, but we also need to make sure that it is an independent of the best and the brightest with a kind of opportunity for advice, consent and consensus that is necessary for this to move forward in a way that can be acceptable and take account of the concerns of all stakeholders.

If we don't develop and begin to think about the problems that could be confronted from the beginning, then we will never directly establish the right structure to hit the mark in the view of

the different stakeholders. We see it as public and private and we see it as having the ability to draw upon the work of AHRQ, of NIH, of the Institute of Medicine and a range of other entities that have done very important work also in the private sector. We see it functionally as setting priorities. We do not think that priority setting should be disembodied from this organization. It should set priorities. It should commission studies. It should validate results and one thing we have learned very definitely in the health plan community as we construct a different way of reimbursing clinicians is that a fundamental principle we found there applies here.

That manufacturers and again, broadly stated that have drugs, device, bios, being evaluated and sometimes evaluated together across the spectrum. It's not simply going to be drug to drug, bio to bio, bio to device, or what-have-yous. It's going to be across the spectrum and it should be allowed to be across the spectrum, then it's very important for those entities to have an opportunity to assess the methodology, to provide input and to validate results.

So, we think that that's going to be an important feedback. And then, this would obviously involve disseminating results to the public and to clinicians, consumers, et cetera. It shouldn't be circumscribed too narrowly. It should be left to the board to look at the full span of activities in terms of devaluations. It should not be pre-decided about taking certain things off the table. Here,

I'm not talking about cost. I'm talking about the province of the research.

So to look across therapies, to drugs, drugs to devices, drugs to bios, the next slide talks about the opportunity to look at the issue of disparities for example in some of these studies. How do African-Americans with heart disease fair using certain devices, procedures, bios, et cetera. That's one example. Looking at effectiveness and value and yes, it should not dictate benefit, design, but the idea that we would have this robust research and not pay any attention to it. That makes no sense whatsoever in our view.

Finally, I think that as you think about a quality agenda, we've enumerated some issues here. I do think that we need a process to set a national research agenda to identify gaps. The IOM talked about that in their report. We think NIH could be particularly helpful here. There needs to be more effort to coordinate the dissemination of clinical best practices.

We think AHRQ could be very helpful here and disseminate that into practice much more quickly than we're doing right now. And we think that there should be a look at the approval of devices and whether or not it is adequate for the future. It works very differently than under at FDA for devices and it does in the area of pharmaceuticals as many of you know. And we think that given the wonderful opportunities you have now and in the future, that ought to be looked at again.

And then finally, there's been a great deal of work done on uniform performance measurement, data aggregation, dissemination. I'd be happy to talk about that if there are questions.

And finally, Ed, I know we're running out of time, but just quickly, I know you're all going to roll your eyes about malpractice reform. You're going to say it's too hard. Why is she bringing it up? It doesn't have to with the price of tomatoes. Here's why. If we want to get to best practice, we are talking about sorting through potential opportunities. And if you're a clinician, being expected to deliver best practice and yet the current system provides not only an incentive, but it basically requires you to do everything possible. Those two things are inconsistent. So, as you think about a quality agenda, I just wanted to make an argument once again for Congress to look again from the perspective of quality at the issue of malpractice reform. Thank you.

ED HOWARD, J.D.: Very interesting. Thank you, Karen. Finally, you're going to hear it now from David Nexon, who is the Senior Executive Vice President for Domestic Policy of the Advanced Medical Technology Association, AdvaMed. For more than 20 years before joining AdvaMed, David was the Democratic Health Policy Director for what are now the Centered Help Committee and Senior Health Advisor to Senator Ted Kennedy. It's AdvaMed's members who produce many of the products and technologies that might be subjected to comparative

effectiveness analysis. So, I guess you can say you've heard from some of the comparers and it's time to hear it from some of the potential comparees. David thanks for being here.

DAVID NEXON: Glad for that, Leonard. And thanks especially to the Alliance for Health Reform for putting on this seminar. Alliance for Health Reform for many, many years has been kind of a forefront of helping people sort through this policy debates and this is clearly a very important and timely topic and I thank you for doing this, Ed.

Let me say that speaking both for AdvaMed and as a longtime person interested in public health policy, I'd like to make five points very quickly then go back and talk about a few of them in more depth, but really it's going to be because if the time I'm chasing, it's going to be much hitting the high points and hope we can follow up on some of these stuff during the discussion. I should also say that we don't have any patient groups on this panel, but based on our discussions, we think that most patient groups probably share the viewpoint that I'm about to express.

First, I'd say that we strongly and I strongly favor more comparative effectiveness research. I think a heightened federal investment in this area is very welcomed overdue and very useful. Too often when patients and physicians are trying to decide about alternative courses of treatment for a

particular disease or condition they're flying blind and the more we can do to provide them helpful information, I think the better off our health system will be in the better individual patients are.

And as Carolyn and Karen pointed out, I think, dissemination of research files in some ways is important as doing the research in the first place because often we do the research, it takes a long time to filter down into clinical practice. Having said that however, I think there are some cautions about what we do with any new federal entity to conduct comparative effectiveness research.

The second point I'd like to make is the comparative effectiveness should be used to inform clinical decision-making. It should not be used to deny coverage for safe and effective treatments. And I'll talk about that more further in the discussion. There are many reasons for this, but the most important is that patients differ.

Comparative effectiveness research typically looks at the impact of a treatment on an average patient within a study population. It doesn't take into account the patient differences and usually in comorbidities, genetic irritability, race, ethnicity, even income levels can affect the effective treatment. And because it does that, because it fails to do that, making a blanket coverage denial based on a comparative

effectiveness studies if the two treatments are safe and effective, I think it's wrong. It's wrong for patients. It's wrong for doctors. It's wrong for our healthcare system.

The second point I would make is that using comparative effectiveness research is even for cost effectiveness is even more problematic. I don't think it's consistent with American values to say that we're going to give people the cheapest treatment, not the best treatment. We've always resisted that in the Medicare programs. We said it's not the right think for our senior citizens. I don't think we should be pursuing a research course that says that's the right course for our nation in the future.

The fourth point I'd like to make is that I don't think comparative effectiveness should be viewed primarily as a cost control tool. I do think that by improving clinical practice, it will have an impact on cost because I think better quality care in the long run ends up to lower costs. But there's no evidence really that doing the kind of a technology or a drug by drug kind of analysis does anything significant about the long term cost drivers in our system are really will have a significant effect in our $2 trillion healthcare endeavor.

I think there are ways where we can have a much more direct and effective influence on cost. And I think we ought to think about comparative effectiveness as something that may

influence cost over the long run, but it’s not really a cost control tool and shouldn’t be viewed that way.

And finally, just sort of one of the arching point and for this audience, I thin it particularly important to say this. I do think that when we look at all health policies, not just comparative effectives, one thing that we always ought to be thinking about is their impact on medical progress and on technological innovation. Since in the last 30 or 40 years, they cut the number of people who die of stroke by two-thirds; the death rate from stroke by two-thirds. We’ve doubled the survival rate from cancer.

In area of heart disease, we have 1 million people every year who would’ve died if we treated them by the technologies available in the 1960’s, but lived because of the medical progress we’ve made. And we’re now entering this era of the new century of the like sciences where the fundamental discoveries that we’ve made in terms of the characteristics of the cell or proteomics or genomics give us the opportunity to really make a much advance as much more than we’ve done in the last 30 or 40 years. So, it’s terribly important that if we consider policies, we think about, “Are we going to recharge or slow down?” when it might be otherwise be tremendous advances in public and individual health.

Let me now turn to the second issue I raised. The problems with making non-coverage decisions based on comparative effectiveness. Carolyn pointed out that these studies are rarely kind of definitive slam dunks rather they say, “Well, one thing appears a word better on most people and not as well on other people sometime”, although in most cases, they don’t do subgroup analysis because of the trouble of power in trials. They’re able to distinguish between who would work best and which is sort of the best information, but they’re rarely definitive. Definitive in the sense of saying that for each patient, we know that this treatment works better than this other treatment.

And so you don’t want to get into a situation where an insurance company bureaucrat or a government bureaucrat takes away that discretion from patients and physicians to decide what’s best for that individual patient sitting in front of them based on the best medical knowledge available. Nobody is average. Every one is different. And the treatment that works for people on average does not necessarily work for you or your mother or your child when they have a condition that needs to be addressed.

There are also significant differences and patient preferences that really are a separate issue from effectiveness. Some people would rather take a course of a

more risky surgery that can cure their disease completely. Others would rather have drug therapy which may not be as effective in curing the disease, but involves lower risk. Those are decisions that should be made my patients and doctors, not by insurance companies or by the Medicare or by government.

There's also a time dimension to this studies. I would take issue with Karen. I think that the new technologies, particularly in the area of devices are the last place that you ought to be doing comparative effectiveness research. And I'd be happy to expand on that further during the course of the discussion. I think that this comparative effectiveness used to deny coverage and lead to a cheapest as best approach to medicine. And I think that the results as I say are rarely conclusive not only for the individual patient, but even for the average patient. You know, you do one study and then you do another study and it's showing something different than the first one did.

On the area of cost effectiveness, cost effectiveness is an academically very interesting issue. It's methodologically, extremely suspect as a way of doing individual decision-making. I've looked at it in some detail. I'd be happy to discuss it further, but what they try and do to do a cost effectiveness analysis is to put a value on a human

life and then assess the effectiveness of the treatment in terms of how many quality years of life it generates compared to the potentially doing another treatment or just in terms of some absolute standards. The value they put on the quality of years of life varies wildly depending on the researchers. Nice uses a figure of 40,000 or 60,000 generally. United States, we typically use 132,000. I can tell you right now, first of all, I don't know how you value your life or the life of you child or your parent, but I doubt that you'd want to say, "Well if it costs more than $100,000 for quality year of life to give him this treatment, I don't want him to get it. Just as soon have him die." 1. I don't think that's the view most Americans take. 2. The fact is that developing this number is more black magic than science and I'd be happy to talk about that further.

But beyond the sort of the methodological issues in it, I think it's just the wrong approach for Americans. I don't think that we believe people should be denied life-saving, life enhancing medical care based on the cost of that treatment. That's why we want to have everyone in the United States have health insurance. It's so that they can get access to the treatment they need even if they can't afford it individually.

Now the final point I'd like to make is that there are better ways to attack the cost problem than comparative

effectiveness researches. I indicated that there's no evidence at all that this kind of approach has a significant impact on cost. But what we do know and it's really becoming kind of the coin in the realm in political discourse and all the platforms of the presidential candidates. There are some ways that are very promising and allow us potentially to make a very major impact on the cost problems that inflict our country. And we know we have to get a handle on these healthcare cost as Karen pointed out.

The first thing we can do is take a serious look at our important federal intervention, investment and preemption. The cigarette company spends about $15 billion annually promoting products that kill people. I don't know what the total budget of the CDC is, but I doubt it's anywhere close to $15 billion. And certainly that's for one product. So we can certainly do a lot more in this regard.

Management of chronic care, our system for managing chronic care in the United States is a disgrace. It's so disorganized, so ineffective, so costly and so unrewarding for patients. We can do a lot better and as you know, chronic care is implicated and most of you know, I'm sure, an 80 percent to 85 percent of all healthcare cost. Isn't that a good place to start trying to get a handle on the cost problem?

There are other aspects of quality besides chronic care whether a tremendous opportunities to reduce cost while improving the quality of our healthcare system. We know that medical error, many of which are avoidable generate huge costs throughout the system. Hospital-acquired infections are a major cost driver which can be addressed by better management internally the hospital's better use of healthcare technology.

Efficiency. Our healthcare system is tremendously inefficient. We need to look at things like value-based purchasing to provide some incentives for efficiency, by which I mean both quality and lower cost in delivering care and the use of information technology are have this tremendous potential to bring down the cost of our system. We've got a 19th century healthcare system in terms of the information technology we use. It's been a tremendous driver of its productivity improving virtually every other industry in the United States.

And finally, innovation itself that it's development of new treatments and cures to my mind offers tremendous hope for reducing cost. You know, it's sort of common since that if you can prevent disease, detect it sooner, cure it quicker and more effectively, even bring cost down. We have wonderful opportunities to do this given the progress of science. Just laying the onset of all to take one example, just laying the

onset of Alzheimer's disease for five years and when there's a potential of having a cure within five to 10 years with some of the pharmaceuticals coming down the pipe would save us $50 billion a year is a sight. And there are many other examples like that. So, I've covered a lot of ground, why don't I stop and let it open for questions and comments.

ED HOWARD, J.D.: Excellent. Thank you, David. Let me remind you, you have green card you can use to write questions on. There are microphones that you can use to ask questions orally and there are blue evaluation forms as we get through the Q&A that we'd love to have you fill out to make these sessions even better than they are now. If you would identify yourself?

KATE SHERIFF: Sure, my name is Kate Sheriff [misspelled?]. I'm with the Department of Health and Human Services. And I guess I'm hearing on the panel some differences of opinion about whether a comparative effectiveness research is something that we can use to actually save costs in the medical system or whether it's just going to be something that's going to improve the quality of care. Furthermore, it sounds like there are some differences of opinion about whether we should use comparative effectiveness research just to be getting best practices out there and to be informing clinical decisions or whether it should be used in

making payment decisions in some way. And I guess, my question is, is there any research or numbers out there that would give us an idea of how much money we could potentially save both in the public sector and in the private sector from either of those ways of using comparative effectiveness research. Either just getting the best practices out there or actually using it to inform payment decisions. And I'm sure there's a lot of disagreement about that, but I'd be interested in hearing people's thoughts about kind of the potential for savings from this after if there's any.

ED HOWARD, J.D.: Karen? David? Wilhelmine?

WILHELMINE MILLER: Okay. Well, I just would call your attention to late last year the Congressional budget office did do a review of comparative effectiveness activity and I don't have the numbers at my fingertips and perhaps Karen or David can fill them in. But they did demonstrate that over several years, it would be a cost saving investment to invest in comparative effectiveness research both through the avenue that David mentioned which is higher quality care tends to be perhaps less wasteful and less expensive, but I don't believe the estimates excluded the possibility of it resulting in coverage determinations or payment limits.

KAREN IGNAGNI, M.B.A.: You want to go first?

DAVID NEXON: Go ahead.

KAREN IGNAGNI, M.B.A.: That's right and they also issued I think a very important report just about a month ago which supplemented that report you referred to Wilhelmine in the sense that they looked at the role of technology as a cost driver. And they found that 50 percent of the increase can be attributable to technology over a fairly long period. I think this is a very important research that CBO has done. One of the things, I wanted to use an example anticipating a question such as this. We know that the NIH National Eye Institute is conducting a head to head trial on two products both made by Genentechs for macular degeneration and that's AIDS-related macular degeneration. Avastin is one product and Lucentis is the other. Lucentis costs 50 times Avastin. So that's a very clear indication. It wouldn't mean that a health plan would, assuming they both have similar properties and can effectively perform the same function, doesn't that a health plan wouldn't cover them. We might put the more given the analysis and it hasn't yet been done. So, I am just hypothesizing now, but we might put it in a higher tier for example. This is the kind of research that is necessary done by a very objective third party which is why we're very much interested in comparative effectiveness being done robustly, objectively and with manufacturer input to make sure that we're getting as the matter of the public all the information we need. That's just one example. There are myriad examples that we can go through. So we're not making the point that it should be just

positive. We're making the point that to have a discussion that somehow we should create the best processes possible with the right kind of advice, consent from manufacturers, products, drugs, bios being evaluated, and then not look at it for determinations. It makes no sense to us.

ED HOWARD, J.D.: Okay. David?

DAVID NEXON: Well, let me add a couple of points. First, the only aspect I've seen that says how much you might potentially save in this --

ED HOWARD, J.D.: Can't hear it.

DAVID NEXON: I'm sorry. The only estimate I've seen that's sort of tries to put a number on how much you might save from this kind of activity and Karen's right that the CBO didn't distinguish from what savings that might be achieved from our improvement in clinical practice and from possibly using carry decisions as the CBO's. They found several billion dollar savings over 10-year period. It was a drop in the bucket in terms of our overall healthcare system. It's also the case that if you've read that report, there isn't any evidence at all to unleash that estimate is based.

So, I mean, you have to take it – they say you have to take it with a grain of salt. I do believe there are some savings to be gained by better clinical practice, but I don't think it's a solution to the cost problem in any significant or short term way.

With regard to the issue of whether we should use these findings and courage decisions, I think that they ought to be used in terms of the processes of care, you know, practice guidelines and that sort of thing, but I still believe very strongly that if treatments are safe and effective and I emphasize if they are safe and effective, they should be available to patients because there are so many individual variants in patient needs that a single solution isn't clinically right for in most cases for all patients and the insurance company or the government shouldn't be saying that you shouldn't have access to the things that's clinically best for you.

Now, sometimes, a comparative effectiveness and cost effectiveness study will in fact show that something is not safe and effective. Many products that are used have never passed through FDA's safe and effective screen because they are used off label. If a study is a good quality study, that's conclusive says that something is used that FDA has not approved for that purpose, is not safe and effective, of course in the insurance company. They have the ability to deny coverage for it.

If we look at procedures which have never passed through an FDA screen, which would be through a surgical or medical procedures, of course the insurance companies should rely on good scientific evidence to make a coverage decision. If somehow, there's a slam dunk, it almost never happens and you find out from a subsequent study that the FDA made a mistake. And the study or product that

they thought was safe and effective turned out not to be, obviously that should be part of the decision-making. But when the products are safe and effective, I do not believe that the research should be allowed to be used to make blanket non-coverage decisions.

ED HOWARD, J.D.: By the way, we have some wonderful questions that you've put on cards. We also have a number of people lined up at the microphone, so, with about 20 minutes left for questions, if you have burning desire to have your question answered, I would advice you to repair to one of the microphones. So, with that, please identify yourself.

STUART GUTTERMAN: Hi, I am Stuart Gutterman at the Commonwealth Fund and on the issue of how much money might be saved by comparative effectiveness, the Commonwealth Fund actually put out a report in December called "Bending the Curve", where we looked at a set of options from improving value and the healthcare sector and one of the options involved comparative effectiveness mechanism combined with what we'll call "teeth" to be able to make sure that people had a strong financial incentive to act on that information when it was produced. And our estimate was that over 10 years, up to $368 billion could be saved by comparative effectiveness mechanism that had effective policies attached to it to actually inject that information into the decision-making process.

ED HOWARD, J.D.: Thank you. Thanks very much. You'll find that report on the Alliance website in the materials for the briefing on that subject that we did I think in January if I'm not mistaken.

Yes, go right ahead. And I'm sorry. Yes, there is someone there, but you go ahead and then we'll come to the other side.

LISA SUMMERS: Okay, I have two quick comments. My name is Lisa Summers and I'm with the National Partnership for Women and Families. And the partnership is part of a coalition called the Alliance for Better Healthcare, which includes a number of consumer groups and some of the disease specialty groups. I just wanted to make the comment that it's certainly my sense that there's a great deal of enthusiasm among the consumer groups for the comparative effectiveness and sort of really wanting to see that move forward with greater transparency et cetera.

And the second comment I wanted to make was in response to Karen's comment about liability reform. Certainly a progressive community, I think that's really nervous when people start talking about liability reform and everybody thinks you're talking immediately about caps on economic damages and total reform. I come from a background of obstetrics having practiced in academic health centers for a dozen years. And I think this discussion about comparative

effectiveness really underscores the fact that particularly in the field of obstetrics, you can have all the evidence on your side. Let me tell you, in this day in age, you don't go to court in a brain-damaged baby case unless you think you're going to win it. You can have all the evidence in the world and you can get a $16 million judgment against you because that's what the jury chooses to do.

So, I just can't underscore enough the importance I think of you comment, particularly in women's health and in obstetrics. We have a real crisis in obstetrics, so I was glad to hear you say that and I think that we can look beyond those conversations we've had to injury prevention funds and other sorts of reformed liabilities systems. So, thank you for that.

KAREN IGNAGNI, M.B.A.: Thank you. If I may, Ed, just a quick comment, I really appreciate your making that point. You guys do great work and we've partnered with you on a number of things so we very much appreciate that. And I think that one of the things I didn't say because I was watching that clock in front, is I think there can be new models that we haven't talked about. We've done a lot of thinking about this again with the physician community since we've been working so closely on the quality arena. And if you're interested, we'd be delighted to come to talk with you about more predictability in the system and more administrative processes versus legal processes making sure that patients are protected, but at the

same time allowing us to move forward in this context of best practice.

One other point that I think relates to Stuart's point, I should've remembered the Commonwealth Study and I'm sorry, Stuart, I didn't refer to it. It was very, very good. We, in the health plan community were very much involved 10 years in a discussion with many of you about so called patient protection. And during that time, we were using a number of tools and techniques to do utilization review. We were looking at guidelines, matching practice to guidelines, and there was an almost unanimous backlash from the professional community, but they didn't want to be evaluated and they didn't want to be evaluated by health plans pretty much the way David has suggested this might be the next round in terms of comparative effectiveness and how the data might be used.

Let me tell you, 10 years from then now, what's happening? We've represented tools, disease management, care coordination, et cetera, and we've taken account of the way the tools were operating. The purchasers are demanding. Now, public as well as private purchasers and now consumers purchasing on their own, they want us to look at imaging which is soaring, the numbers of imaging centers, and the numbers of things that are being done in the imaging arena and there are significant safety as well as cost concerns and so we're beginning to reintroduce that.

We're also reintroducing utilization review in terms of best practices aligned with reimbursement incentives to hit best practice according to clinical specialty societies, not according to health plans. So the idea here is that the health plans don't do the research, which is why we're very interested in the third party respected source that this can be subject to public scrutiny, comment and very transparent. Then when you have the information out there, our responsibility, in a very equally transparent way, would be to talk to the public about benefits decisions and how we would make them, how we would set them out to try to balance this access to everything that all consumers want with the cost containment that everybody needs and wants as well. These are hard issues. We had a lot of practice in addressing them and so, what we want to do is have a process where we can be as transparent about this issue as we are about now imaging best practice guidelines that are professional society guidelines. And so we will handle this in a very different way than we handled the discussion 10 years ago.

So, the comments about people with green eyeshades or insurance bureaucrats or government bureaucrats, they are very good people. Their chief medical officers making very robust decisions with scientists, with clinicians and physicians and

that's the process we intend to invite, not the processes that were discussed about.

DAVID NEXON: Let me comment on that. Certainly, I didn't mean impugn in any way the motivations of America's insurance companies. I've know Karen for a very long time. I respect her. I respect the many good people on that industry who are doing or trying to do the right thing. But the fact is, there is a profit motive driving the insurance companies as there is one driving our companies. And let me give you just an example of the kind of thing that can go wrong with misuse of comparative effectiveness research. There was recently a well-known study called, I'm sorry I'm forgetting the name. Called -

ED HOWARD, J.D.: It's less well known than [inaudible].

DAVID NEXON: Yes, it's well-known. It's the CATIE Trial, which was a Study of Psychotropic Medications for people with severe mental illness conducted by the NIH. It was a high quality study. The headline from the study was that the newer, more expensive didn't work any better than the older less costly ones. It turns out that wasn't really quite true. One of the newer drugs did work better in controlling the mental illness than the other ones did. But it had also undesirable side effects that patient and doctors had to balance. It was also the case that while the new ones on average did not work better than the older ones, that during the course of the 18-month study, two-thirds of the patients changed from one drug to

another because they found that the first drug that they were put on didn't work well for them because of their own individual reactions or the effectiveness kind of wore off overtime and they needed to do something new.

The conclusion – my conclusion from that study is basically all those drugs should've been covered and perhaps there may have been a practice guideline that says, if you had no additional information about the patient, you might try the less expensive drug first. But what happened was that government bureaucrats that is state Medicaid programs instituted of policies where they had a blanket denial of coverage for all the psychotropic medicines that were newer and more expensive. That's the kind of thing that this can be misused for. I think it's a real threat to America and medical care and into our ability as patients to get what's best for us.

And by the way, I do not believe that every patient wants everything. I think most American patients want the best care. They don't want everything. They don't want to be subjected to doing surgery that's uncomfortable, unnecessary and be a marginal benefit. But I do think they want the right to determine with their doctor what's best for them based on the best scientific evidence available.

ED HOWARD, J.D.: Thanks, David. Karen, let me just clarify something. When you were talking about malpractice reform, the idea is that the best practice knowledge would

somehow be incorporated into a safe haven standard of care. Is that the idea?

KAREN IGNAGNI, M.B.A.: Yes, exactly because right now the incentive and almost if you're practicing medicine today, you really have to do everything possible because you're quite rightly worried about being sued, and that's in direct contradiction with all the work at the IOM and all of the other researchers have done about the need for best practice. So, it's hard to get there from here without taking account of changing that system as well. But we recognize the controversy there, that's we try to do the some new thinking about ways to begin not just the Safe Harbors but to protect patients, so that patient groups could be assured that if something happened to them, they would be protected in the new system.

ED HOWARD, J.D.: Good. By the way, Lisa Swarsky [misspelled?] has sent up to us the CBO analysis on comparative effectiveness from December, I think it is. And there is a section in here that quotes the CBO cost estimates on the comparative effectiveness provisions that were actually passed by the House as part of the Champ Bill. And I commend that to you. Just make sure that the numbers correspond exactly to the comparative effectiveness parts.

Yes, sir?

MERRILL GOOZNER: Merrill Goozner with the Center for Science in the Public Interest. I want to return to the issue

of structure. One of the papers in the packet likened the comparative effectiveness agency to the Federal Reserve Board for Medicine and then at the same time, that paper actually called for stakeholder participation in the board and the design of the trials and/or these studies that would take place. My question really to stakeholders that are sitting on the panel, is your understanding of, as what you're calling for when you talk about transparency, are you talking about having comment and input should there be a clinical effectiveness institute set up somewhere or are you talking about actually having stakeholder input into the board, and then depending what your answer is that I would just simply point out that the Federal Reserve Board does not have any banks sitting on it given the function for it is given to perform why should stakeholders where there's clear financial interest in the output of this institute be allowed to have direct input into what goes on.

KAREN IGNAGNI, M.B.A.: We, I'm not sure what report you're referring to, but I don't believe it's ours. I don't think that we recommended a Federal Reserve model. We have recommended a public-private entity that would be independent and we have thought about a board with stakeholder representation because in large measure, looking back at where areas of controversy have erupted with respect to moving to improve the science, get our hands around best clinical

practice if folks particularly manufacturers, particularly others that tend to be very significantly affected by results aren't included from the beginning, we think that that may be a recipe for motivating individuals to, A, not have confidence in the entity, to dismantle the entity, and repeat at pass would be prologue. So to avoid that, we've thought about an independent objective entity with indeed stakeholder participation, so manufacturing participation, consumer participation, the best and the brightest researchers there and in terms of if people were to ask for recommendations from our community, the type of individual we would recommend would be a chief medical officer that has a significant amount of research experience. So, that's the window into our thinking about it.

ED HOWARD, J.D.: Participation but not control?

KAREN IGNAGNI, M.B.A.: No, of course not control. No, no, participation, right.

ED HOWARD, J.D.: David?

DAVID NEXON: Yes, I kind of second on what Karen said. We actually have not taken a position of public-private versus public, but we do think it should be. However it's organized, there should be representation for all stakeholders for the same reasons that Karen said and we're were thinking in the case of our industry, we have a lot of expertise to contribute about this technologies. We would probably have, as Karen did our chief medical guise represent or not, the business guise. We think the process should be

transparent with a full opportunity for comment, but we've not taken a position on the location of the agency.

ED HOWARD, J.D.: Wilhelmine?

WILHELMINE MILLER: Yes, I just like to go back to what I said on the presentation, while the IOM committee was not as to give advice on exactly the organizational structure or home of a central program. We did talk at length about the composition of a comparative effectiveness program and who needs to be at the table particularly on the priority setting advisory committee. The oversight board for a program to structure fund and oversee the conduct of comparative effectiveness studies through a hybrid model of local academically-based research centers and a central office that would identify the importance of particular topics for review and what is key in terms of the composition of specific expert panels brought together to determine how to develop a research question for a comparative review analysis and identify the priorities for those analyses as a whole.

The need to buffer the recommendations from industry's interests was made very clear and that there would be a prohibition from voting or that the decision made about individual studies or topics from anyone who had any kind of direct financial interest in the services at hand. So, a great deal of attention was paid to the issue of both balancing panels by brining in stakeholders that represented industry as

well as consumers as well as practitioners, but also insulating the decisions from direct financial conflict.

ED HOWARD, J.D.: Thank you. We have time for one more question, which I believe we have someone to ask. Let me as you as this last question is being if you would pull out those blue evaluation forms, start filling them out, so that we can figure out how best to improve these programs. And you've got the last word coming.

EMILY HOLUBOWICH: Great. Thank, Ed. My name is Emily Holubowich. I'm with Academy Health and the Alliance for Better Healthcare and our mission each year is to work with appropriators to try to increase the funding for AHRQ's effective healthcare program. I can tell you, it's a struggle at time in the current fiscal climate.

So my question relates to financing, which I think we haven't really talked about on the panel today for many reasons obviously, I think most people in this room would agree that comparative effectiveness research is a public good. And should be funded federally through appropriations, but the realities of the appropriations process both giving and competing priorities and also as Karen highlighted, the dangers of federal appropriations where an agency or program is vulnerable every year to the whims of appropriators.

What are your thoughts on the financing of this? Who should be paying for it? And do you have a sense of how much? This maybe a better question for Stu, but does any – is anyone aware of any studies that have shown the relation of the investment to the return that is if we invested more, would be get more back?

KAREN IGNAGNI, M.B.A.: We've done a lot of thinking about this, Emily and I appreciate the question. The most equitable way to do it and you're all grown now because there are no general revenues available for anything. I understand that, but that's the most equitable way to do it because it means that it comes from the public at large, all of us benefit from it.

The second way that has been looked at both in the House and the Senate, I believe, is looking at starting the funding with some dedicated funding from the Medicare trust fund. There are different models, PRO's are reimbursed from the trust fund et cetera. This is I think one can make an important quality argument for this, so that's one way. We have indicated that we believe that it should be a broad participation and are comfortable being asked to contribute and Blue Cross and Blue Shield association has indicated the same thing.

However, if you do it strictly based on government and then individuals who are directly insured and leave out those who are

insured in ERISA plans by employers, I think that you would be leaving probably about 140 million people.

So if we're going to have across the board sharing participation, financial participation, it should indeed be across the board. I think that the House and Senate has tried to walk through this issue very skillfully by thinking about government appropriations to start it, to build it and then beginning to think about what's next.

And I think the only other thing is to look at not a year-to-year appropriations, but to try to look at a five year appropriation so it truly could be built in the way that I think each of you would want it to be built to anticipate some of the issues that might come before the group and to anticipate the kinds of robust processes that would be necessary to address those issues satisfactorily across the board. So, I think there are a number of models and we're happy to be continuing to be engaged with each and every one of you about how to do it.

DAVID NEXON: We don't have a formal position on the financing. I just –

ED HOWARD, J.D.: You want to get closer to the mic, Dave.

DAVID NEXON: **S**orry. We don't have a formal position on the financing. Speaking for myself, I think it should most appropriately come out from public money. I don't think you want any

private sector gaining on due influence on the thing. And I think public money, you can maximize the transparency and accountability of the activity.

ED HOWARD, J.D.: Wilhelmine?

WILHELMINE MILLER: Yes, I would endorse both of those comments. I mean the IOM committee did make the strong argument that Emily made which is that this information is a public good that stands to benefit all Americans and therefore, public revenues are the appropriate way to finance it. That isn't a committee recommendation simply the statement that it is a public good.

I guess I'd also say that a long term appropriation or some consistency in guarantee of ongoing financing would be critical to the sustainability and the quality of the enterprise that we have outlined in the IOM report that is the uncertainty of funding for comparative effectiveness research and it's variability as one of the reasons why we don't have a stable and large and robust, a workforce and an infrastructure devoted to this activity. There's a wealth of information out there that needs to be assessed and crystallized that could be done by a program like this, but it will need a more sustained resources if that's to happen.

ED HOWARD, J.D.: Karen, you have a final word?

KAREN IGNAGNI, M.B.A.: Well, I just think Wilhelmine made just such an important point and I just want to put a plug in for

five years rather than three. It's going to take awhile to get this up and running and if you want to have it at the level achieving the kinds of expectations you have, I hope you look at five years rather than three.

ED HOWARD, J.D.: Okay. Well, as you fill out you blue evaluation forms, as I said redundantly, I want to apologize to those of you who wrote some very thoughtful questions on question cards that we couldn't get to. It is a multi-faceted issue. Karen's comments about the financing remind that there are a number of questions about the evolvement of Medicare in this issue either as a payer or a user of information or a generator. I can assure you, we're going to return to this issue as we go along. It's a very important part of the dialogue.

In the meantime, I want to thank the Robert Wood Johnson foundation once again for its support of this forum and for its general interest in this issue as evidenced by its support of the IOM project. I want to thank the Alliance staff. This was a very large and fast developing program. We're very happy it was popular.

We weren't expecting it to be this popular and it presented some logistical and technical as well as substantive challenges that our staff really rose up to meet. And finally,

I want to ask you to join me in thanking our panel for a very, very interesting and useful discussion. [Applause]

[END RECORDING]